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China, Peoples Republic of

Agricultural Situation

Draft Standard for Imported Food

2009

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Report Highlights:
On May 6, the Ministry of Health published two draft regulations designed to implement certain aspects of the Food Safety Law related to imported products. These two regulations relate to imported foods that do not have Chinese safety standards and the licensing of new food related products. This GAIN report contains an UNOFFICIAL of translation of these draft regulations.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Beijing [CH1]
[CH]

Summary:

On May 6, the Ministry of Health published two draft regulations designed to implement certain aspects of the Food Safety Law (CH9019). These two regulations relate to imported foods that do not have Chinese safety standards and the licensing of new food product varieties.

The first regulation is "*Provisional Administrative Regulations on the Administrative Licensing of the Importation of Food without National Food Safety Standard* (draft)". It is listed as Annex 1 in the draft regulation. This applies to food types without previous established standards. The second part is "*Provisional Administrative Measures of Administrative Licensing of New Food Related Product Varieties* (draft)". It is listed as Annex 2 in the draft regulation. This relates to additives, packaging, and other food related products that have previously not been registered for use in China.

This regulation has been published for Chinese domestic comment. The due date for submission of comments to the Chinese Government was May 17. These regulations have not been reported to WTO. Other draft implementing regulations have been published as GAIN Report CH9040.

This GAIN report contains an UNOFFICIAL translation of the regulations.

BEGIN TRANSLATION

Letter Issued by the Ministry of Health for Collecting Opinions of "Provisional Administrative Regulations on the Administrative Licensing of the Importation of Food without National Food Safety Standard" (Draft for Comment) and "Provisional Administrative Measures of Administrative Licensing of New Food Related Product Varieties" (Draft for Comment)

To all the units concerned:

The Ministry of Health has drafted Provisional Administrative Regulations on the Administrative Licensing of the Importation of Food Without National Food Safety Standard (draft) and Provisional Administrative Measures of Administrative Licensing of New Food Related Product Varieties (draft) in cooperation with the application of the Food Safety Law in order to reinforce the administrations of importing food without national food safety standard and new food varieties. Public opinions are welcomed, so all the units and individuals concerned should provide feedback, comments and suggestions by May 17, 2009.

Fax: 086 – 10- 68792408

Email: food@moh.gov.cn

Appendices:

1. *Provisional Administrative Regulations on the Administrative Licensing of the Importation of Food Without National Food Safety Standard (Draft for Comment)*
2. *Provisional Administrative Measures of Administrative Licensing of New Food Related Product Varieties (Draft for Comment)*

May 6, 2009

Annex 1

Provisional Administrative Regulations on the Administrative Licensing of the Importation of Food without National Food Safety Standard (Draft for Comment)

Article 1 To enhance the administrative management over imported food products not registered with national food safety standards, for the sake of safeguarding public health, this *Regulation* is formulated in accordance with "Food Safety Law of PRC."

Article 2 Imported food products not registered with national food safety standards" (hereby abbreviated to *Imported Food*) refers to those food products manufactured and distributed in oversea countries. These products fall into no existing national food safety rules and standards.

As for the newly developed food materials, "*Provisional Administrative Measures of Administrative Licensing of New Food Related Product Varieties*" shall apply (Annex 2); For health care product, its raw material, trans-genetic product and foods that contains the residual of pesticide or animal drugs, the existing rules and regulations shall apply.

Article 3 The Ministry of Health of P.R.C. (hereafter abbreviated as the Ministry) shall be responsible for issuing administrative licenses and lay down relevant governing regulations for all imported food products.

Article 4 The inspection and auditing department of the Ministry is in charge of receiving all Imported Food declarations, committing evaluation opinion, processing product approvals, feedback auditing decisions, managing products archives and studying on feedback suggestions.

Article 5 The declaration, acceptation and auditing of Imported Food will be processed in accordance with the governing rules in the Measures for the Administration of Sanitary Administrative Licenses and Administrative Permission Procedure for Healthcare related products.

Article 6 Distributing or utilizing Imported Food shall require the filing of an application before their first importing endeavor. They need to furnish the following information:

1. Administrative License Application Form for Imported Food Products (appendix 1).
2. Description of the origin of the concerned food products;
3. Statement of the reason and utilization of having such food products imported;
4. List of the main ingredient;
5. Statistic evaluation of the ingredients and the safety intake level;
6. Production process;
7. Quality standards and basis of establishment;
8. Sanitary quality inspection reports of three batch of such kind of food products;
9. Safety assessment materials;
10. Product tag and specification;
11. Supporting documents proving the fact that such imported food products are authorized for manufacturing and sale by the governing departments or institutions from the producing country (region) or exporting country (region). Or there exists any documentary materials proving the eating of such foods in historical records.

12. In case such food products are already registered with international organizations or other countries, provide the written description of the standards already practiced.
13. The smallest package of such products or 30g unit of product sample.

Food products eligible to be included into the umbrella of Food or Food Material Pollutant Safety Level Management Regulations, shall be exempted the necessity of such application.

Article 7 General Requirements of Submitted Files

1. For the first submission of national imported food permission, application materials shall be presented with one original and four duplicates;
2. With the exceptions of inspection reports and other official attestation documents, application profiles shall have the seal of the company on each page or an attached seal;
3. Printed in A4 format with obvious page marks and booked in required sequences;
4. Adoption of Chinese official counting unit;
5. All application archives shall be complete and well defined. All same categorized items shall be completed with adherence;
6. All foreign languages contained in the application archives shall be translated into standard Chinese. The corresponding Chinese translation shall be attached prior to the very page of the foreign archives. However, in the stipulated English or Latin ingredient appellations, people's names and foreign address shall not be included as the foreign languages that require translations.
7. All submitted profile shall be genuine, legal and valid. Duplicates directly from the originals is accepted only if it is sufficiently eligible and in perfect agreement with the originals.

Article 8 The manufacturing and distribution license issued by the governing departments or institutions from producing country (region) or exporting country (region) shall be presented in following manners:

1. Issued only by the governing government department or industrial associations. Duplicates are also accepted in case the absence of the original. However, all duplicates shall be endorsed by the issuing agency or confirmed by the Chinese embassy in the manufacturing country;
2. It is obligatory to clearly note the name of the product, manufacturer and license issuing agency. Add seal of the company or its legal representative (or its authorized legal person), signed and properly dated;
3. The name of the product and the manufacturer shall be exactly the same as those appeared in the application file;
4. In case one document annotates to a variety of products, these products shall be declared at the same time with at least one of these products vindicated by original documents. For the rest of the products, duplicates together with written explanation are also accepted. However, it is necessary to indicate from where these duplicates are made.
5. Supporting document shall be properly translated into standard Chinese when it is presented in a foreign language. The translated Chinese version shall be notarized in departments of Chinese government.

6. In case of the absence of the supporting documents, the Ministry of Health shall conduct on-site inspection onto the concerned product.

Article 9 Complementary documents shall be presented in the following manners:

1. One complete original sealed on each page and properly dated;
2. The concerned unit shall submit the due complementary materials within one year since the receipt of "Extension Notice of Administrative License Evaluation". Failure to submit the complementary materials will be viewed as an automatic termination of the declaration application.

Article 10 The evaluation department of the Ministry of Health shall decide, within 5 days since the receipt of the application materials, whether it will take the case or not.

Article 11 Within 60 days since the receipt of the application, the evaluation departments of the ministry shall organize a thorough investigation upon the application profiles received. For those profiles not yet completed in information, the concerned importer shall complete all missing information within one year. Failure to submit the complementary materials will be viewed as an automatic termination of the declaration application.

All received application materials and sample products will not be returned before any evaluation decisions are made.

Article 12 The Ministry of Health will dispatch experts from a variety of fields, such as food safety, toxins, nutrition, microbiology, craftsmanship and chemistry, to conduct assessment of the application materials submitted.

If the assessment proves that such product is subjected to the governance of similar industrial standards from relevant governing international organizations, other countries and China. The Ministry of Health will refer to the governing standards in for execution.

Article 13 During the appraisal process, the representative of the applicant shall be present for answering the relevant technical problems on time according to the requirement of the Ministry of Health, but shall not take part in the appraisal.

Article 14 For any termination of the application, the importer may submit a written application for withdrawal of the submitted entrusted agency certificate and the certification of the production and sales in the producing country (or area) as well as the notary certificate.

Article 15 During the appraisal process, in case that the applied product can be subject to other laws and regulations stipulated by Article II, the applicant will be informed and the approval procedure will be terminated. It is recommended that the relevant application can be submitted in light of those administrative procedures.

Article 16 According to the appraisal of the experts and the relevant national laws and regulations, the Ministry of Health may, on its on discretion, make the final judgment.

The approved imported food may be announced with its name and qualification spec, etc. Furthermore, in accordance with the usage of the food, the relevant national security standard may be instituted.

For any noncompliance of the security demand, the license will not be issued with the reason supplied.

Article 17 In case of one of the following circumstances, the Ministry of Health may organize the relevant experts to re-appraise the imported food:

1) With the development of science and technology, any changes happen to the security feature of the imported food;

2) Any doubt occur to the security and quality spec of the imported food;

3) Supervision and inspection demand to the imported food.

For any disqualification of the re-appraisal, the Ministry of Health can announce its prohibition of production and use.

Article 18: These Regulations shall be interpreted by the Ministry of Health.

Article 19: These Regulations shall be implemented from the release date.

Appendix:

Application Form for *Administrative Licensing of the Importation of Food Without National Food Safety Standard*

Food Imported without National Food Safety Standard

Application Form for Administrative Permission

Chinese name of the food: _____

Made by the Ministry of Health of the Peoples' Republic of China

Instructions

1. This application form can be downloaded from the website of the Ministry of Health or the National Center for Health Inspection and Supervision:

http://www.jdzx.net.cn

2. This application form and all the declaration materials shall be printed.
3. The declaration item contained in this form shall be filled in completely and clearly with no erasing of information.
4. Please read carefully relevant regulations and rules on declaration and acceptance before filling in this form.

<table>
<tr><td rowspan="2">Name of the product</td><td colspan="2">Chinese name</td><td colspan="3"></td></tr>
<tr><td colspan="2">English name</td><td colspan="3"></td></tr>
<tr><td rowspan="4">The manufacturing enterprise</td><td rowspan="2">name</td><td>Chinese name</td><td colspan="3"></td></tr>
<tr><td>English name</td><td colspan="3"></td></tr>
<tr><td>address</td><td></td><td>Country (region)</td><td></td></tr>
<tr><td>Tel:</td><td></td><td>Contact person</td><td></td></tr>
<tr><td rowspan="3">Declaration unit</td><td>name</td><td colspan="3"></td></tr>
<tr><td>address</td><td colspan="3"></td></tr>
<tr><td>Contact person</td><td></td><td>Tel:</td><td></td></tr>
<tr><td colspan="5">Attestation
The declaration unit of the produce guarantees: the declaration items contained in the form as well as its attached materials are true, legal. The copied materials are identical to the original. And all the data contained in the attached materials are all those gained from the research and inspection. In the event of any unconformity, we are willing to bear corresponding legal responsibilities and all the results there from.

The declaration unit (seal) The legal representative (signature)
Year month day</td></tr>
</table>

The attached materials (please tick your choice with “v” in the “?”before the provided material)

- ☐ 1. The application form for a hygiene administrative permit of food imported without national food safety standard.
- ☐ 2. The source of the food
- ☐ 3. The purpose and function of the food
- ☐ 4. The main component
- ☐ 5. The evaluation materials concerning the application amount in the food as well as the acceptable intake
- ☐ 6. The production quality
- ☐ 7. The quality specification standard and its stipulation basis
- ☐ 8. The health quality inspection report of three-batched products
- ☐ 9. The safety evaluation materials
- ☐ 10. The label and instructions
- ☐ 11. The certificate on the permitted production or sale in the production country (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.
- ☐ 12. Relevant standards of international organizations or other countries
- ☐ 13. One unopened product sample or 30g.

Other items needed to be added:

Annex 2

Provisional Administrative Measures of Administrative Licensing of New Food Related Product Varieties

(Draft for Comment)

Chapter I General Provisions

Article 1 For the purpose of strengthening administrative licensing management of new food-related product varieties, guaranteeing food safety, safeguarding public health and safety, these measures are hereby formulated.

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

1. *The materials or molding products used to food packaging materials, containers and food product*ion and management tools and equipment that directly contact foods without national food safety standards;
2. The *additives* not listed in hygienic standards for uses of additives in food containers and packaging materials (GB 9685);
3. The materials or molding products of food packaging materials, containers and food production and management tools and equipment that directly contact the food not listed in the List of Notice of the Ministry of Health;
4. The additives listed in the Hygienic standards for uses of additives in food containers and packaging materials (GB 9685.or in the List of Notice of the Ministry of Health, but requiring expansion of the use scope or increase of the use frequency.
5. New detergent materials used to the foods, tools and equipments for food production and business and food packaging materials and containers that may have food safety risks;
6. New disinfectant materials used to the foods, tools and equipments for food production and business and food packaging materials and containers that are not listed in the List of Disinfectant Raw Materials Used for Foods.

Article 3 The Ministry of Health shall be responsible for the administrative licensing of new food-related product varieties and the formulation of relevant regulations.

Article 4 The evaluation agency of the Ministry of Health shall be responsible for the declaration and acceptance, evaluation and product reporting and approval of the food-related product varieties and other relevant evaluation work.

Article 5 The evaluation agency of the Ministry of Health shall select appropriate experts to form an evaluation committee from the food evaluation expert bank, which will be responsible for technical examination work of safety evaluation materials of new food-related product varieties.

Article 6 The specific application and acceptance procedures of administrative licensing of new food-related product varieties shall refer to relevant provisions under *Measures for the Administration of Sanitary Administrative Licenses* and *Sanitary Administrative Licenses of Health-related Products*, etc.

Article 7 The administrative license of new food-related product varieties shall be carried out in strict accordance with the provisions of relevant state laws, regulations and standards and the principles of risk assessment.

Chapter II Application and Acceptance

Article 8 The units or individuals that produce and mange or use the new food-related product varieties within the licensing scope shall report to the Ministry of Health for examination and approval before the products come into the markets for the first time.

Article 9 When applying for the licensing of new food-related product varieties, the following materials shall be submitted to the evaluation agency of the Ministry of Health:

1. Administrative license application form of new food-related product varieties;
2. data of chemical properties (including chemical properties and constitutional formula, etc.);
3. usage and use conditions;
4. production processes;
5. enterprise standard;
6. toxicological information;
7. use conditions of other states and relevant supporting documents;
8. certificates for agency application; and
9. other documents for evaluation.

Article 10 For application for new food packaging material and container varieties and new food production and operation tools and equipment varieties, in addition to submitting the materials as stipulated in Article 9, the estimated dietary intake, migration amount and analytic method and other information should be submitted.

Article 11 For application for new varieties of food packaging material and container and food production and operation tool and equipment additives, in addition to submitting the materials as stipulated in Article 9, the documents of use scope and use amount and other data should be submitted.

Article 12 For application for new varieties of food disinfectants, in addition to submitting the materials as stipulated in Article 9, the data of disinfecting effect evaluation should be submitted.

Article 13 In addition to the materials set forth in Article IX, Article X, Article X or Article XII of the regulations, the importer who applies for the administrative licensing of new varieties of the imported food-related products shall also submit the following materials:

1. Documentary evidence on the permit of its production and distribution issued by the government of the producing country (region) or an institution ratified by the country (region);
2. Documentary evidence on the examination or ratification of the producer issued by the relevant institution or organization of the country (region) where the producing enterprise is located.

Article 14 General Requirements of Application Materials:

1. All Application materials should be real and legitimate.
2. Providing one original, four copies and one electronic copy. All copies shall be copied from the original and should be clear and completely consistent with the original;
3. All application materials shall be printed with A4 paper, shall be obvious marks

between every part of such materials and shall be bound up into a booklet arranged in the prescribed order:

4. All application materials should be complete and clear and the information filled in under a same item shall be consistent with each other.

5. In addition to the inspection reports and official documents, all application materials shall be affixed with the official seal of the reporting entity on each page or across the pages. If an individual applied for the administrative licensing, all application materials shall be affixed with applicant name and stamp or signature together with copies of identity documents;

6. All the application materials written in foreign languages shall be translated into standard Chinese, and the translated versions shall be attached prior to the corresponding original materials, except for the component names and foreign addresses that are required to be written in English or Latin and foreign references can be accompanied by their Chinese abstracts.

Article 15 If the supplementary application materials are required to be submitted, one original of the supplementary materials are required to provide and shall be affixed with the official seal (or signature of the applicant) of the reporting entity on each page with indication of the date of the supplementary materials.

Article 16 The evaluation agency of the Ministry of Health shall make the decision on whether to accept them immediately or within five working days after receiving the application materials of new varieties of food-related products.

Chapter III Approval and Annunciation

Article 17 The evaluation agency of the Ministry of Health shall organize a review committee composed of experts to carry out a technical review within 60 days after accepting the application for new varieties of food-related products. If the supplementary materials are required by the technical review, the application entity or individual shall submit the supplementary materials within one year; in case of no timely submittal of such supplementary materials, it will be taken as not notified.

Article 18 In the technical review process of new varieties of food-related products, the review committee shall decide to whether to carry out on-site review and a safety verification test according to the needs of the application. If a site review is required, the evaluation agency of the Ministry of Health shall organize the relevant experts to implement the review together with the relevant local departments. If a safety verification test is required, the statutory food safety inspection authority shall be responsible for the verification.

Article 19 The evaluation agency of the Ministry of Health shall be responsible for reporting the technical review opinions and the information to be announced on new varieties of food-related products suggested and approved by the Review Committee to the Ministry of Health.

The Ministry of Health will seek opinions from society for the new varieties of food-related products to be approved.

The evaluation agency of the Ministry of Health shall be responsible for consolidating and collating the opinions proposed by all walks of life in the society, organizing the Review Committee to research the opinions and reporting the research results to the Ministry of Health. For new varieties of food-related products that do not meet the food safety requirements, the evaluation agency of the Ministry of Health shall decide not to approve it and give reasons in writing.

Article 20 The Ministry of Health shall, according to the review opinions of the review organ, make a decision on whether to grant a license.

Article 21 The Ministry of Health shall publicize the approved new varieties of food-related products in list form.

Article 22 In case of any one of the following circumstances, the evaluation agency of the Ministry of Health shall organize the review committee composed of experts to re-evaluate the approved new varieties of food-related products:

1. changes to the awareness of the safety of the approved new varieties of food-related products with the development of science and technology;
2. There is some doubt to the safety and quality specifications of new varieties of food-related products;
3. Required by monitoring and testing of food-related products. If unqualified after re-evaluation and review, the Ministry of Health can prohibit the production and operation and use of the products.

Chapter IV Supplementary Provisions

Article 23 The terms under the Measures are defined as follows:

The materials used as food packaging materials, containers and food production and management tools and equipment refer to the main raw materials for food packaging materials, containers and food production and management tools and equipments, such as resin, ceramics and so on.

The molding products used to food packaging materials and containers refer to the products, utensils and films, etc., used for food packaging materials and containers.

The raw materials used to food detergents and disinfectants refer to the main raw materials of detergents and disinfectants produced for washing or disinfecting foods, tableware, the tools, equipments or food packaging materials and containers directly contacting the foods.

Article 24 If the raw materials listed in the *List of Food-based Disinfectant Raw Materials* are used to produce the disinfectants, the *Infectious Disease Prevention and Cure Law*, *Disinfection Management Approach* and relevant provisions of the Ministry of Health shall be implemented.

Article 25 The evaluation agency of the Ministry of Health shall implement the file management over approval materials of new varieties of food-related products, establish the approval database of new varieties of food-related products, and provide search and consulting services in accordance with the relevant provisions.

Article 26 The present measures shall be interpreted by the Ministry of Health. In case the past document issued by the Ministry of Health is inconsistent with the present measures, the present measures shall prevail.

Appendix:

1. Application Form of Administrative Licensing of New Food-related Product Variety

2. Specific Requirements on Application Materials of Administrative Licensing of New Food-related Product Variety

Appendix 1:

Application Form for Administrative Licensing of New Food Related Product Varieties

Chinese Name of Product_____

Printed and made by the Ministry of Health of People's Republic of China

Instructions

5. This application form can be downloaded from the website of the Ministry of Health or the National Center for Health Inspection and Supervision:

http: //www.jdzx.net.cn

6. This application form and all the declaration materials shall be printed.

7. The declaration item contained in this form shall be filled in completely and clearly with no erasing.

8. Please read carefully relevant regulations and rules on declaration and acceptance before filling in this form.

<table>
<tr><td rowspan="2">Name of the product</td><td>Chinese name</td><td colspan="3"></td></tr>
<tr><td>English name</td><td colspan="3"></td></tr>
<tr><td rowspan="4">The manufacturing enterprise</td><td rowspan="2">name</td><td>Chinese name</td><td colspan="2"></td></tr>
<tr><td>English name</td><td colspan="2"></td></tr>
<tr><td>address</td><td></td><td>Country (region)</td><td></td></tr>
<tr><td>Tel:</td><td></td><td>Contact person</td><td></td></tr>
<tr><td rowspan="3">Declaration unit</td><td>name</td><td colspan="3"></td></tr>
<tr><td>address</td><td colspan="3"></td></tr>
<tr><td>Contact person</td><td></td><td>Tel:</td><td></td></tr>
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The declaration unit of the produce guarantees: the declaration items contained in the form as well as its attached materials are true, legal. The copied materials are identical to the original. And all the data contained in the attached materials are all those gained from the research and inspection. In the event of any unconformity, we are willing to bear corresponding legal responsibilities and all the results therein.

The declaration unit (seal) legal representative (signature)
Year month day</td></tr>
</table>

The attached materials (please tick your choice with “v” in the “?”before the provided material) ☐ 1. The application form for a hygiene administrative permit of food imported without national food safety standard. ☐ 2. The resource of the food ☐ 3. The purpose and function of the food ☐ 4. The main component ☐ 5. The evaluation materials concerning the application amount in the food as well as the acceptable intake ☐ 6. The production quality ☐ 7. The quality specification standard and its stipulation basis ☐ 8. The health quality inspection report of three-batched products ☐ 9. The safety evaluation materials ☐ 10. The label and instructions ☐ 11. The certificate on the permitted production or sale in the production country (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. ☐ 12. Relevant standards of international organizations or other countries ☐ 13. One unopened product sample or 30g.
Other items needed to be added:

Appendix 2

Detailed requirements on application documents for *Administrative Licensing of New Food Related Product Varieties*

I. Data on chemical characteristics

Data of chemical structure: Chemical name, common name, chemical structure, molecular formula, molecular weight, CAS number, and so on.

Data of physical character: Melting point, boiling point, decomposition temperature, solubility, chemical reaction activity, products resulted from decomposition or conversion during manufacture or application, possible interaction with food ingredients.

If the substance applied is a mixture, the above-mentioned data on its main components should be provided.

II. Data of usage and service condition

Data of usage: The expected application, range of application, maximum level of application, minimum level to achieve the desired function, and technical result of application.

Data of service condition: Food types that it may contact during application (water-rich foods, oil or fat rich foods, acid foods, alcohol-containing foods, etc), time and temperature that it contact with foods directly, ratio of area/ volume of food containers and packaging materials contacting foods.

III. Data of manufacturing technique

Flow chart of manufacturing technique and describing words, technique parameter of each steps, and so on.

IV. Data of quality standard

Specification, purity, components and levels of impurity, and the explanation of basis for the standard.

V. Toxicological data

1. For application of new type of packaging materials and containers of foods, new types of utensils and apparatus used in manufacturing of foods, new types of food additives, and extended range of old food additives, relevant toxicological data should be provided according to the migration level of new species into foods:

   (1) For new types from which the migration level into foods is less than or equal to 0.01mg/kg, analytical data of structure, activity, and other literatures on safety should be provided.

   (2) For new types from which the migration level into foods is between 0.01 and 0.05mg/kg (including 0.05mg/kg), data of three tests for mutagenicity should be provided (i.e., Ames test, In vitro mammalian cells chromosome aberration test, and micronucleus test of bone marrow cells).

   (3) For new types from which the migration level into foods is between 0.05 and 5mg/kg (including 5mg/kg), the following data should be provided: three tests for mutagenicity (i.e., Ames test, In vitro mammalian cells chromosome aberration test, and micronucleus test of bone marrow cells) and 90 days sub-chronic toxicity test in rats.

   (4) For new types from which the migration level into foods is between 5 and 60mg/kg, the following data should be provided: acute oral toxicity, three tests for mutagenicity (i.e., Ames test, In vitro mammalian cells chromosome aberration test, and micronucleus test of bone marrow cells), 90 days sub-chronic toxicity test in rats, reproduction and development toxicity (two-generation and teratogenicity test), chronic oral toxicity and carcinogenic test.

   (5) If the new type is a polymeric material (weight-average molecular weight is more than 1000 Dalton), toxicological data of monomers for the polymer should be provided.

2. For application of new types of detergents and disinfectors, toxicological data should be provided in accordance with GB/T 15193, Procedures and methods for toxicological assessment of food.

VI. Approval in other countries and relevant documentary evidence

Documentary evidence for the approval by government agencies or industrial association of other countries or international organization.

VII. Documentary evidence for authorized procurement

1. The name of products commissioned for application, the name of agency on commission, and the commitment and date, with official seal of client or signature of its legal representative;

2. If more than one product is listed in one piece of documentary evidence for authorized procurement, they should be applied at the same time; the original document should be provided together with the application document of one of the products, and its copies could be provided with that of other products; a written explanation is necessary to interpret which the original document is submitted

together with;

3. If the documentary evidence is written in foreign language, it should be translated to standard Chinese and notarized by a government agent of China.

VIII. Migration test and residue data

According to usage and service condition of the new type, the data of migration test of new type into foods and the test methods should be provided.

Data of residue: Data of residue of ingredients converted or not converted in containers and packaging materials of foods, as well as the test methods.

IX. Data of evaluation of sterilization effect

Test report on sterilization effect of disinfector made from this substance.

X. Documentary evidence for manufacture and distribution issued by the government or authorized organization of country of production.

1. It should be issued by the administration or industrial association of country (region) of production. If the original document can not be provided, the copy is also valid only if it is verified by the issuing institution or diplomatic mission of China in the country (region) of production.
2. The following information is necessary: the name of product, the name of manufacturer, the name of issuing institution with official seal of or signature of its legal representative (or authorized person), and date.
3. The name of product and manufacturer recorded should be completely identical to that applied for; if it is manufactured by third party processing or other means, and the manufacturer recorded on the documentary evidence is not the same as that applied for, the requestor side should provide document to explain.
4. If more than one product is listed in one piece of documentary evidence, they should be applied at the same time; the original document should be provided together with the application document of one of the products, and its copies could be provided with that of other products; a written explanation is necessary to interpret which the original document is submitted together with;
5. If the documentary evidence is written in foreign language, it should be translated to standard Chinese and the Chinese translation should be notarized by notary department of China.

The above-mentioned documents should be provided in Chinese. Chinese abstract is necessary for the data provided by foreign institution (except for documentary evidence and that for authorized procurement).

Test data should be the test report or other special data provided by laboratories complying with Good Laboratory Practice (GLP) or inspection institutions approved by Ministry of Health of China.

END TRANSLATION