Association of International Chemical Manufacturers
国 际 化 学 品 制 造 商 协 会

卫生部关于印发《食品相关产品新品种申报与受理规定》的通知

卫监督发〔2011〕49 号

Notice of Ministry of Health on “Chinese New Food-related Product petition”

MOH (2011) No.49

(Note: AICM’s non-official English translation, for your reference only)

各省、自治区、直辖市卫生厅局，新疆生产建设兵团卫生局，中国疾病预防控制中心、卫生部卫生监督中心：

Health Bureaus in various Provinces, Autonomous Regions and Municipalities, Health Bureau of Xinjiang Production and Construction Corps, the Chinese Center for Disease Control and Prevention, National Center for Health Inspection and Supervision:

为贯彻《食品安全法》及其实施条例，规范食品相关产品新品种行政许可工作，根据《食品相关产品新品种行政许可管理规定》，我部组织制定了《食品相关产品新品种申报与受理规定》。现印发给你们，请遵照执行,并将执行中的有关问题及时反馈我部。

For carrying out "Food Safety Law" and its implementing regulations and standardizing administrative licensing work of New Food-related Product Varieties, our ministry organizes to prepare “Chinese New Food-related Product petition” according to “Regulations on Administrative Licensing of New Food-related Product Varieties”. Now, it is issued to you. Please comply with it and timely feed back relevant problems generating in implementation to our ministry.

二○一一年五月二十三日

May 23, 2011

食品相关产品新品种申报与受理规定

Declaration and Acceptance Provision of New Food-related Product Varieties

第一条 为规范食品相关产品新品种的申报与受理工作，根据《食品相关产品新品种行政许可管理规定》，制定本规定。

Article 1 For standardizing declaration and acceptance work of New Food-related Product Varieties, prepare this provision according to “Regulations on Administrative Licensing of New Food-related Product Varieties”.

第二条 申请食品相关产品新品种的单位或个人(以下简称申请人) 应当向卫生部卫生监督中心提交申报资料原件 1 份、复印件 4 份、电子文件光盘 1 件以及必要的样品。同时，填写供公开征求意见的内容。

Article 2 Unit or individual applying for New Food-related Product Varieties (Hereinafter referred to as the applicant) should submit one original copy of application materials and four copies, one CD-ROM of electronic documents and necessary samples to National Center for Health Inspection and Supervision. At the same time, fill in the content for public consultation.

第三条 申报资料应当按照下列顺序排列，逐页标明页码，使用明显的区分标志，并装订成册。

Article 3 Application materials should be arranged in accordance with the following order. Mark page number page by page, use obvious division signs and bind the application materials in a volume.

(一) 申请表；

ⅰ. Application form;

(二) 理化特性；

ⅱ. Physical and Chemical Properties;

(三) 技术必要性、用途及使用条件；

ⅳ. Technical necessity, use purpose and use conditions;

(四) 生产工艺；

ⅳ. Production process;

(五) 质量规格要求、检验方法及检验报告；

ⅴ. Quality specifications, test methods and test reports;

(六) 毒理学安全性评估资料;

ⅵ. Toxicology safety assessment information

(七) 迁移量和/或残留量、估计膳食暴露量及其评估方法；

ⅶ. Migration and/or residue amount, estimated dietary exposure and its assessment method;

(八) 国内外允许使用情况的资料或证明文件；

ⅷ. Information or certificates of permission use at Home and abroad;

(九) 其他有助于评估的资料。

ⅸ. Other information beneficial to assessment

申请食品用消毒剂、洗涤剂新原料的，可以免于提交第七项资料。

As for application for new varieties of disinfectants and detergents used in food, it is feasible to avoid submission of material ⅶ.

申请食品包装材料、容器、工具、设备用新添加剂的，还应当提交使用范围、使用量等资料。

As for application for new additives used in food packaging materials, containers, tools and devices, some materials such as application range and application amount so on should be submitted.

受委托申请人还应当提交委托书。

Agency applicant should still submit the letter of authorization.

第四条 申请食品包装材料、容器、工具、设备用添加剂扩大使用范围或使用量的，应当提交本规定第三条的第一项、第三项、第六项、第七项及使用范围、使用量等资料。

Article 4 As for application for extension of application range or application amount of additives used in food packaging materials, containers, tools and devices,

some materials such as materials ⅰ, ⅳ, ⅵ, ⅶ in Article 3 of this provision and application range, application amount etc should be submitted.

第五条 申请首次进口食品相关产品新品种的，除提交第三条规定的材料外，还应当提交以下材料：

Article 5 As for application for the first import of New Food-related Product Varieties, besides the materials specified in Article 3, it is necessary to submit following materials:

(一) 出口国(地区) 相关部门或者机构出具的允许该产品在本国(地区) 生产或者销售的证明材料；

ⅰ. Certificates which are issued by relevant authorities or institutes in exporting country (region) to permit produce or sell the product in the country (region);

(二) 生产企业所在国(地区) 有关机构或者组织出具的对生产企业审查或者认证的证明材料；

ⅱ. Certificates of review and certification on manufacturing enterprise issued by relevant authorities or organizations in the country (region) of manufacturing enterprise;

(三) 中文译文应当有中国公证机关的公证。

ⅳ. Chinese translation should be notarized by Chinese notarization authorities.

第六条 除官方证明文件外，申报资料原件应当逐页加盖申请人印章或骑缝章，电子文件光盘的封面应当加盖申请人印章；如为个人申请，还应当提供身份证件复印件。

Article 6 Except for official certificates, application materials should be sealed on each page or on the perforation with seal of the applicant. The cover of CD with electronic document should be stamped with seal of the applicant. In case of individual application, it is still necessary to provide a copy of identity document.

第七条 申请资料应当完整、清晰，同一项目的填写应当前后一致。

Article 7 Application materials should be complete and clear. For the same item, it should be consistent from start to finish.

第八条 申报资料中的外文应当译为规范的中文，文献资料可提供中文摘要，并将译文附在相应的外文资料前。

Article 8 Foreign language in application materials should be translated into standard Chinese. Literatures can provide Chinese abstract. Also, translations are attached before corresponding foreign literatures.

第九条 理化特性资料应当包括：

Article 9 Information of physical and chemical properties should include:

(一) 基本信息：化学名、通用名、化学结构、分子式、分子量、CAS 号等。

ⅰ. Basic information: chemical name, common name, chemical structure, molecular formula, molecular weight, CAS number, etc.

(二) 理化性质：熔点、沸点、分解温度、溶解性、生产或使用中可能分解或转化产生的产物、与食物成分可能发生相互作用情况等。

ⅱ. Physical and chemical properties: Melting point, boiling point, decomposition temperature, solubility, possible generated by possible decomposition or conversion in production or use, possible interaction with food ingredients, etc.

(三) 如申报物质属于不可分离的混合物，则提供主要成分的上述资料。

ⅳ. If application substance belongs to inseparable mixture, the above information of main ingredients should be provided.

第十条 技术必要性、用途及使用条件资料应当包括：

Article 10 Information of technical necessity, use purpose and use conditions should include:

(一) 技术必要性及用途资料：预期用途、使用范围、最大使用限量和达到功能所需要的最小量、使用技术效果。

ⅰ. Information of technical necessity and use purpose: intended use, application range, maximum use limitation, minimum necessary application amount for realizing functions and effects of application technology.

(二) 使用条件资料：使用时可能接触的食品种类(水性食品、油脂类食品、酸性食品、含乙醇食品等)，与食品接触的时间和温度；可否重复使用；食品容器和包装材料接触食品的面积/容积比等。

ⅱ. Information of use conditions: contactable food varieties (Water-based foods, fats and oils foods, acidic foods, foods with alcohol, etc.), time and temperature of food contact, judgment of reuse, area / volume ratio of food containers and packaging materials contacting with food contact, etc.

第十一条 生产工艺资料应当包括：原辅料、工艺流程图以及文字说明，各环节的技术参数等。

Article 11 Production process should include: raw materials, auxiliary materials, process flow diagrams and text description, the technical parameters of various processes, etc.

第十二条 质量规格要求包括纯度、杂质成分、含量等，以及相应的检验方法、检验报告。

Article 12 Quality specifications include purity, impurity ingredients, content, corresponding test methods, and test reports.

第十三条 毒理学安全性评估资料应当符合下列要求：

Article 13 Toxicological safety assessment information should meet the following requirements:

(一) 申请食品相关产品新品种(食品用消毒剂、洗涤剂新原料除外) 应当依据其迁移量提供相应的毒理学资料：

ⅰ. Application for New Food-related Product Varieties (except for new varieties of disinfectants and detergents used in foods) should provide the corresponding toxicological information according to the migration amount.

1.迁移量小于等于 0.01mg/kg 的，应当提供结构活性分析资料以及其他安全性研究文献分析资料；

1. For migration amount less than or equal to 0.01mg/kg, structure-activity analysis information and other analysis information of safety research literature should be provided;

2.迁移量为 0.01mg-0.05mg/kg(含 0.05mg/kg)，应当提供三项致突变试验(Ames 试验、骨髓细胞微核试验、体外哺乳动物细胞染色体畸变试验或体外哺乳动物细胞基因突变畸变试验)；

2. For migration amount between 0.01mg and 0.05mg/kg (containing 0.05mg/kg) , three mutagenic tests should be provided (Ames test, micronucleus test of bone marrow cells, in vitro mammalian cell chromosome aberration test or in vitro mammalian cell gene mutation test);

3.迁移量为 0.05mg-5.0mg/kg(含 5.0mg/kg)，应当提供三项致突变试验(Ames 试验、骨髓细胞微核试验、体外哺乳动物细胞染色体畸变试验或体外哺乳动物细胞基因突变畸变试验)、大鼠 90 天经口亚慢性毒性试验资料；

3. For migration amount between 0.05mg and 5.0mg/kg (containing 5.0mg/kg), information of three mutagenic tests (Ames test, micronucleus test of bone marrow cells, in vitro mammalian cell chromosome aberration test or in vitro mammalian cell gene mutation test) and information of subchronic 90-day oral rat toxicity test should be provided;

4.迁移量为 5.0mg-60mg/kg，应当提供急性经口毒性、三项致突变试验(Ames 试验、骨髓细胞微核试验、体外哺乳动物细胞染色体畸变试验或体外哺乳动物细胞基因突变畸变试验)，大鼠 90 天经口亚慢性毒性，繁殖发育毒性(两代繁殖和致畸试验)，慢性经口毒性和致癌试验资料；

4. For migration amount between 5.0mg-60mg/kg, information of acute oral toxicity, three mutagenic tests (Ames test, micronucleus test of bone marrow cells, in vitro mammalian cell chromosome aberration test or in vitro mammalian cell gene mutation test), subchronic 90-day oral rat toxicity test, reproductive and developmental toxicity (two generations of reproduction and teratogenicity test), chronic oral toxicity and carcinogenicity should be provided;

5. 高分子聚合物(平均分子量大于 1000 道尔顿) 应当提供各单体的毒理学安全性评估资料。

5. For high molecular polymer (average molecular weight more than 1000 Dalton), toxicology safety evaluation information of various monomers should be provided.

(二) 申请食品用洗涤剂和消毒剂新原料的，应当按照《食品毒理学评价程序和方法》(GB/T15193) 提供毒理学资料。

ii. For application for new raw materials of disinfectants and detergents used in foods, toxicological information should be provided according to “Procedures for Toxicological Assessment of Food”.

(三) 毒理学试验资料原则上要求由各国(地区) 符合良好实验室操作规范(GLP)实验室或国内有资质的检验机构出具。

iv. In principle, toxicology test information should be issued by the laboratory consistent with Good Laboratory Practice (GLP) in various countries (regions) or domestic qualified inspection institutes.

第十四条 迁移量和/或残留量、估计膳食暴露量及其评估方法等资料应当包括：

Article 14 Information of Migration amount and/or residue amount, estimated dietary exposure and its assessment method should include:

(一) 根据预期用途和使用条件，提供向食品或食品模拟物中迁移试验数据资料、迁移试验检测方法资料或试验报告；

i. According to intended use purpose and use conditions, provide testing information of migration into food or food model, migration test methods or test reports;

(二) 在食品容器和包装材料中转化或未转化的各组分的残留量数据、残留物检测方法资料或试验报告；

ii. Residue amount data of various converted and non-converted components in food containers and packaging materials, residue test method information or test report;

(三) 人群估计膳食暴露量及其评估方法资料；

ⅳ. Estimated human dietary exposure and its assessment method

(四) 试验报告应当由各国具有相应试验条件的实验室或国内有资质的检验机构出具。

ⅳ. Test report should be issued by laboratories with corresponding testing conditions in various countries (regions) or domestic qualified inspection institutes.

第十五条 国内外允许使用情况的资料或证明文件为国家政府机构、行业协会或者国际组织允许使用的证明文件。

Article 15 Information or certificate of permission use at Home and abroad is the certificates of national government institutes, industry associations or international organizations permitting use.

第十六条 出口国(地区) 相关部门或者机构出具的允许该产品在本国(地区) 生产或销售的证明文件应当符合下列要求:

Article 16 Certificates which are issued by relevant authorities or institutes in exporting country (region) to permit produce or sell the product in the country (region) should comply with the following requirements:

(一) 由出口国(地区) 政府主管部门、行业协会出具。无法提供原件的，可提供复印件，复印件须由文件出具单位或我国驻出口国使(领) 馆确认；

ⅰ. Certificates are issued by national government institutes and industry associations in exporting country (region). If the applicant can't submit the original copy, it is feasible to submit copies. The copies should be identified by certification issue unit or Chinese embassy (consulate) in the exporting country;

(二) 载明产品名称、生产企业名称、出具单位名称及出具日期；

ⅱ. Indicate product name, manufacturer name, name of issue unit and issue date;

(三) 有出具单位印章或法定代表人(授权人) 签名；

ⅳ. There is a seal of issue unit or a signature of the legal representative (authorizer) ;

(四) 所载明的产品名称和生产企业名称应当与所申请的内容完全一致；

ⅳ. Indicated product name and manufacturer name should be completely identical with application contents;

(五) 一份证明文件载明多个产品的，在首个产品申报时已提供证明文件原件后，该证明文件中其他产品申报可提供复印件，并提交书面说明，指明证明文件原件所在的申报产品；

ⅴ. In case that one copy of certificate indicates a number of products, after application of the first product submits the original copy of certificate, application of other products in the certificate may provides copies and submit written document that demonstrates the application product for original copy of certificate;

(六) 证明文件为外文的，应当译为规范的中文，中文译文应当由中国公证机关公证。

ⅵ. In case that certificate is of foreign language, it should be translated into standard Chinese, and Chinese translation should be notarized by Chinese notarization authorities.

第十七条 申报委托书应当符合下列要求：

Article 17 Application proxy should comply with the following requirements:

(一) 应当载明委托申报的产品名称、受委托单位名称、委托事项和委托日期，并加盖委托单位的公章或由法定代表人签名；

ⅰ. It should indicate product name of commission application, name of commissioned unit, commissioned matters and commission date. Also, it should be stamped with official seal of commission unit or signature of the legal representative;

(二) 一份申报委托书载明多个产品的，在首个产品申报时已提供证明文件原件后，该委托书中其他产品申报可提供复印件，并提交书面说明，指明委托书原件所在的申报产品；

ⅱ. In case that one copy of application proxy indicates a number of products, after application of the first product submits the original copy of certificate, application

of other products in the proxy may provides copies and submit written document that demonstrates the application product for original copy of proxy;

(三) 申报委托书应当经真实性公证；

ⅳ. Application proxy should be factually notarized;

(四) 申报委托书如为外文，应当译成规范的中文，中文译文应当经中国公证机关公证。

ⅳ. In case that Application proxy is of foreign language, it should be translated into standard Chinese, and Chinese translation should be notarized by Chinese notarization authorities.

第十八条 卫生部卫生监督中心接收申报资料后，应当当场或在 5 个工作日内作出是否受理的决定。对申报资料符合要求的，予以受理；对申报资料不齐全或不符合法定形式的，应当一次性书面告知申请人需要补正的全部内容。

Article 18 After National Center for Health Inspection and Supervision receives the application materials, the center should make a decision whether to accept on site or within 5 workdays. For application materials complying with requirements, he will make acceptance. For application materials which are incomplete or don't comply with legal form, he should once inform all necessary correction contents to the applicant in written form.

第十九条 申请人应当按照技术审查意见，在 1 年内一次性提交完整补充资料原件 1 份，补充资料应当注明日期，逾期未提交的，视为终止申报。如因特殊原因延误的，应当提交书面申请。

Article 19 The applicant should once submit one original copy of complete supplement materials within one year according to technical review comments. In the supplement materials, date should be marked. If submission is overdue, application is regarded as termination. If submission is overdue due to special reasons, the applicant should submit a written application.

第二十条 终止申报或者未获批准的，申请人可以申请退回已提交的出口国(地区)相关部门或机构出具的允许生产和销售的证明文件、对生产企业审查或者认证的证明

材料、申报委托书(载明多个产品的证明文件原件除外)，其他申报资料一律不予退还，由审评机构存档备查。

Article 20 If application is terminated or ungratified, the applicant can apply withdrawal of submitted certificates issued by relevant authorities or institutes in exporting country (region) to permit produce or sell, Certificates of review and certification on manufacturing enterprise, application proxy (except for certificate indicating a number of products) . Other application materials can't be returned, and they are stored in assessment institutes for review.

附件：食品相关产品新品种行政许可申请表.doc

Appendix: Application Form for Administrative Licensing of Food-related New Varieties.doc

附件

Appendix

受理编号：卫食相关申字( )第 号

Acceptance No.: Wei Food-related Application ( ) No.

受理日期： 年 月 日

Acceptance time:

食品相关产品新品种

New Food-related Product Varieties

行政许可申请表

Application Form for Administrative License

产品中文名称：

Chinese Name of the Product

中华人民共和国卫生部制

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

填 表 说 明

Instruction to Application Form

一、本申请表应当在卫生部卫生监督中心网站在线填写。

网址：http：//www.jdzx.net.cn

Ⅰ. This application form should be filled in on the network of National Center for Health Inspection and Supervision.

URL: http：//www.jdzx.net.cn

二、本表申报内容及所有申报资料均须打印。

Ⅱ. Application contents in the table and all application materials should be printout.

三、本表申报内容应当完整、清楚,不得涂改。

Ⅲ. Application contents in the table should be complete and clear and shall not be altered.

四、填写此表前，请认真阅读有关法律法规及《食品相关产品新品种行政许可申报与受理规定》。

Ⅳ. Before filling in this table, please carefully read relevant laws and regulations and “Regulations on Administrative Licensing of New Food-related Product Varieties”.

五、国内申请人可不填写英文名称，个人申请无须加盖公章。

Ⅴ. It isn’t necessary for domestic applicant to fill in English name. It isn’t necessary for individual application to stamp official seal.

产品名称 Product Name	中文 Chinese	
	英文 English	
产品类别 Product type	□ 尚未列入食品安全国家标准或者卫生部公告允许使用的食品包装材料、容器及其添加剂 □ Food packaging materials, containers and their additives which are not included in the national food safety standards or which are allowed in Notice of the Ministry of Health. □ 扩大使用范围或者使用量的食品包装材料、容器及其添加剂 □ Food packaging materials, containers and their additives with extension of application range or application amount. □ 尚未列入食品用消毒剂、洗涤剂原料名单的新原料 □ New materials not listed in raw material list of disinfectants and detergents used in food.	

<table>
<tr><td></td><td colspan="5">□ 食品生产经营用工具、设备中直接接触食品的新材料、新添加剂
□ new materials and new additives directly contacting with food in tools and device for food production</td></tr>
<tr><td rowspan="4">申请人
Applicant</td><td rowspan="2">名称
Name</td><td>中文
Chinese</td><td colspan="3"></td></tr>
<tr><td>英文
English</td><td colspan="3"></td></tr>
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<tr><td colspan="2">联系人 Contact person</td><td></td><td>联系电话、传真
Contact telephone, fax</td><td></td></tr>
<tr><td rowspan="3">受委托申请人
Agency applicant</td><td colspan="2">名称
Name</td><td colspan="3"></td></tr>
<tr><td colspan="2">地址 Address</td><td colspan="3"></td></tr>
<tr><td colspan="2">联系人 Contact person</td><td></td><td>联系电话、传真
Contact telephone, fax</td><td></td></tr>
<tr><td colspan="6">保证书
Letter of guarantee
本产品申请人保证：本申请表中所申报的内容和所附资料均真实、合法，复印件和原件一致，所附资料中的数据均为研究和检测该产品得到的数据。如有不实之处，我愿负相应法律责任，并承担由此造成的一切后果。
The applicant of this product guarantee that application contents in this application form and attached materials are authentic and legal, copies are identical with original copy, and all data in attached materials are data obtained in research and test of this product. In case any inconsistency occurs, i would be responsible for all legal liabilities, and for any consequences involved.</td></tr>
</table>

申请人(单位公章) 法定代表人(签字) Applicant (official seal) Legal representative (signature) 年 月 日 Year Month Day
所附资料(请在所提供资料前的□内打“√”) Attached materials(Please mark "√" in □ in front of provided materials) □ 1.申请表 □ 1. Application form; □ 2.理化特性 □ 2.Physical and Chemical Properties; □ 3.技术必要性、用途及使用条件 □ 3. Technical necessity, use purpose and use conditions □ 4.生产工艺 □ 4.Production process □ 5.质量规格要求、检验方法及检验报告 □ 5. Quality specifications, test methods and test reports □ 6.毒理学安全性评估资料 □ 6.Toxicology safety assessment information □ 7.迁移量和/或残留量、估计膳食暴露量及其评估方法(申请用于食品的包装材料、容器、工具、设备新材料和添加剂的需提供) □ 7.Migration amount and / or residue amount, estimated dietary exposure and its assessment method (It is necessary for application for new materials and additives used in food packaging materials, containers, tools and devices) □ 8.国内外允许使用情况的资料或证明文件 □ 8. Information or certificates of permission use at home and abroad; □ 9.其他有助于评估的资料 □ 9. Other information beneficial to assessment

□ 10.使用范围、使用量等资料(申请用于食品的包装材料、容器、工具、设备用添加剂时需要提供)

□ 10. Materials of application range and application amount so on (It is necessary for application for new materials and additives used in food packaging materials, containers, tools and devices)

□ 11.申报委托书(委托申请时需要提供)

□ 11. Application proxy (it is necessary for commission application)

□ 12.样品(必要时提供)

□ 12. Samples (provided, if necessary)

进口食品相关产品新品种还需提供如下材料：

Application for new varieties of import food-related products should still provide the following materials:

□ 13.出口国(地区) 相关部门或者机构出具的允许该产品在本国(地区) 生产或销售的证明文件

□ 13. Certificates which are issued by relevant authorities or institutes in exporting country (region) to permit produce or sell the product in the country (region)

□ 14.生产企业所在国(地区) 有关机构或者组织出具的对生产企业审查或者认证的证明文件

□ 14. Certificates of review and certification on manufacturing enterprise issued by relevant authorities or organizations in the country (region) of manufacturing enterprise

申报资料的一般要求：

Application materials generally require:

1.提交申报资料原件 1 份、复印件 4 份、电子文件光盘 1 件；

1. Submit one original copy of application materials and four copies and one CD-ROM of electronic documents;

2.使用 A4 规格纸打印，逐页标明页码，使用明显的区分标志，按顺序并装订成册；

2. Application materials should be printed with A4 specification papers. Mark page number page by page, use obvious division signs and bind the application materials in a volume.

3.申报资料原件应当逐页加盖申请单位公章或骑缝章；如为个人申请，申报资料应当逐页加盖申请人印章或签字，并提供身份证件复印件(官方证明文件除外)；

3. Application materials should be stamped with official seal or check mark of the application unit. In case of individual application, application materials should be stamped with seal or signature of the applicant page by page, and copies of identity document should be provided (except for official certificates);

4.申请资料应当完整、清晰，复印件与原件完全一致，同一项目的填写前后完全一致；

4. Application materials should be complete and clear. For the same item, it should be consistent from start to finish.

5.申报资料中的外文应当译为规范的中文，文献资料可提供中文摘要，并将译文附在相应的外文资料前(成份名称、人名以及外国地址等除外)。

5. Foreign language in application materials should be translated into standard Chinese. Literatures can provide Chinese abstract. Also, translations are attached before corresponding foreign literatures (except for Ingredient name, person name and foreign address).

其他需要说明的问题：

Other issues which should be illuminated: