

新食品原料申请指南及新食品安全法的要点及解析

Registering New Raw Food Materials and Insights into the Food
Safety Law

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新食品原料注册申报及技术要点

Agenda

● 新食品原料基本概念 Definition of Novel Food

● 新食品原料注册申报流程 Application Procedure

● 新食品原料注册资料准备 Documents Preparation

● 批准情况及不批准原因分析 Approval Situations

● 新食品安全法要点及解析 Food Safety Law

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理解新食品原料

Understanding Novel Food

1. 食品属性：是可以吃的原料； Edible
2. 安全的； Safe
3. 新的； New in China
4. 举例：苹果的种子、叶子、种子的油；磷虾油； e.g.: seed of apple; leaf of apple, seed oil of apple; krill oil

新食品原料基本概念 Definition of Novel Food

新食品原料的意义

Significance of Novel Food

1. 作为普通食品原料； used as raw material for general food;
2. 作为保健食品的原料； used as raw material for health food (blue hat/cap);
3. 原料可以合法进口； raw material legally imported to China custom.

基本特征 Basic Characteristics

➤ 属性 Properties

根本属性是食品，与药品有严格的区分 (edible food, not drug)

➤ 食用安全性 Safety

对人体不产生任何急性、亚急性或慢性危害
(Safe for human consumption)

➤ 新的，之前非普通食品 New in China, no consumption history

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申报流程图 Application Flow
chart

确认该物质属于新食品原料 Novel Food Confirmation

准备风险评估资料 Documents Preparation for Safety Evaluation

准备全套申报资料 Preparation of all Application Documents

递交至卫计委卫生监督中心 Submission of Application to NHFPC

申报流程图 Application Flow chart (cont' d)

技术评审 Technical Evaluation

下发评审意见，补充修改直至通过评审 Address comments/
questions from
Expert Panel

征求社会意见 Public Hearing Period

正式公告 Formal Public
Announcement

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新食品原料注册资料准备 Documents Preparation

主要资料清单 Main Documents List

1. 物质来源 Source of the raw material
2. 工艺，质量标准 Processing Procedure and Spec.
3. 安全性资料，包括检验报告、风险评估报告 Safety Documents
4. 食用情况说明 Food or Supplement Consumption Statement
5. 对生产企业审查或认证的证明(进口产品) ISO or GMP of Manufacturer
6. 生产销售证明（进口产品） Free Sale Certificate
7. 申请表. Application Form



新食品原料注册资料准备 Documents Preparation

检验项目 Required Tests

1. 卫生学、成分检测; **Hygiene Test, CoA**

2. 毒理学评价 **Toxicity Tests**

(i.) 急毒; Ld 50

(ii.) 遗传三项: **Genetic Toxicology Tests**

a. Ames

b. Mice sperm abnormality test

c. Mammalian bone marrow cell chromosome aberration test

(iii.) 28天或90天喂养; **28 or 90 days feeding study**

(iv.) 致畸试验; **Teratogenicity study**



新食品原料注册资料准备 Documents Preparation

实验室资格 Certification of Labs

1. 国内实验室，需要有CMAF资格；
CMAF certification for domestic labs;
2. 国外实验室，需要有GLP资质；
GLP certification for overseas labs.



新食品原料注册资料准备 Documents Preparation

时间和费用 Timelines & Cost of Application

- ❖ **Time:** 如果所有试验资料都具备，从递交起一年左右；
Given satisfactory test reports and supporting documents, it takes around 1 year from submission;
- ❖ **Cost:** 主要是检测和风险评估的费用，约25-35万元。
Main cost drivers are testing fee and safety evaluation report, estimated cost around 250,000-350,000 CNY (40,000 to 60,000 USD).

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批准情况及不批准原因分析 Approval Situations

不批准原因 Non-Approval reasons

1 宣传疗效 **Medical efficacy claim**

切勿描述该物质的药理药效，尽管新食品原料可以有对健康对益处。

Important to note: Novel food raw materials can provide health benefits. However, the application of the raw material will not be approved if medical function claims are presented.



批准情况及不批准原因分析 Approval Situations

不批准举例 Example of rejection

D-甘露糖

过度宣传其可以治疗肺部急性炎症、尿道炎，简直就是药品，因此不能批准作为食品；尽管在国外可以作为膳食补充剂销售。

D-Mannose

Excessive claims for therapeutic effect on acute pulmonary inflammation and Urethritis, consequently not approved as food. Yet it has been allowed to sell in other countries as a food supplement.



批准情况及不批准原因分析 Approval Situations

不批准原因 Non-Approval reasons

2 药效明确，药性明显，不属食品 **Medicine character**

切勿描述该物质的药理药效，尽管新食品原料可以有对健康对益处。

Important to note: Novel food raw materials can provide health benefits. However, the application of the raw material will not be approved if medical function claims are presented.

批准情况及不批准原因分析 Approval Situations

不批准举例 Example of rejection

牛樟芝、灵芝

牛樟芝、灵芝，属于药用真菌，具有明确的药效，因此，不能够批准为普通食品。

Ganoderma lucidom

A kind of medical fungus which has obvious medical effects, cannot be approved as food. Same situation as for Camphor tree iris.

批准情况及不批准原因分析 Approval Situations

不批准原因 Analysis for no permission

3 食用依据不足 **Insufficient evidence of edibility**

i. 没有作为普通食品食用的历史；

No history as general food;

ii. 没有作为膳食补充剂食用的证明资料；

No history as food supplement;

iii. 在生产国不允许生产、销售，无上市证明文件。

No free sale certificate in manufacture county.

新资源食品申请案例分析 Application examples

✓ 黄莲花; Yellow Lotus Flower

✓ 人参; Ginseng

✓ 磷虾油; Krill Oil

新资源食品申请案例分析 Examples

黄莲花 Yellow Lotus Flower



因为黄莲是明确的中药，评审专家认为黄莲花依然是黄莲的延伸，还是属于药材，因此，不能申请为新食品原料。

Since yellow lotus is a typical Chinese medicine and the yellow lotus flower is a part of the yellow lotus, it cannot be approved as new food raw material.

新资源食品申请案例分析 Examples

人参 Ginseng



人参本是传统中药，但在国外，人参都属于食品，于是中国卫生部将人工种植的5年下的人参，批准为新食品原料。

Ginseng was Chinese medicine in the past, since Ginseng has been approved as general food in many other countries, Ministry of Health of China approved Ginseng as general food in China.

新资源食品申请案例分析 Examples

磷虾油 Krill oil



磷虾油是从南极磷虾中提取的油，在欧洲被批准为新资源食品，申请中国的新资源食品；中国部分专家认为其是普通食品，与中国的虾油一样；但磷虾油其实与中国的虾油有很大不同，经科学检测和分析，的确证明磷虾油与虾油不同，因此，中国卫生部将磷虾油批准为新食品原料。

Krill oil is extracted from Antarctic Krill. Earlier been approved as novel food in EU. After submitting to Chinese MoH for novel food application, some experts thought it was the same as Chinese shrimp oil and belonging to general food, not novel food. After proving krill oil is not the same as Chinese shrimp oil with various parameters, MoH approved krill oil as new food raw material.

新食品原料申请要点 Key points for application

- ✓ 前期论证； Well-documented argumentation before application
- ✓ 食品属性； Food, not medicine;
- ✓ 安全性； Safety;
- ✓ 食用历史，国外作为食品批准的情况。
Approval situation in other countries and its history as food.

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新食品安全法要点及解析--特殊食品 The Key Points and Analysis of Food Safety Law - Special Food

- 1 特殊医学用途配方食品—Special medical use formula food - Registration
- 2 婴幼儿配方食品, 婴幼儿配方乳粉—Infant formula foods, Infant formula milk powder
- 3 保健食品— Health Food



新食品安全法要点及解析--保健食品 The Key Points and Analysis of Food Safety Law - Health Food

- 注册： a. 使用保健食品原料目录以外原料的保健食品
b. 首次进口的保健食品（补充营养素、矿物质类产品除外）

Registration:

- a. using the material which is not in the Health food raw material list;
b. first time imported health food (except supplement with nutrients and minerals)

- 备案： a. 使用保健食品原料目录原料的保健食品（省局）
b. 首次进口的保健食品中属于补充维生素、矿物质等营养物质的（国家局）

- Filing: a. using the material which is in the Health food raw material list
b. first time imported health food as supplement nutrients and minerals

新食品安全法要点及解析--特殊食品 The Key Points and Analysis of Food Safety Law - Special Food

- 1 特殊医学用途配方食品—国务院食品药品监督管理部门注册
Special medical use formula food - Registration
- 2 婴幼儿配方食品—省、自治区、直辖市人民政府食品药品监督管理部门备案
Infant formula foods - Filing
- 3 婴幼儿配方乳粉—国务院食品药品监督管理部门注册
Infant formula milk powder - Registration



谢谢大家！

Thank you for your attention!