Basic Guide of China New Food Additive Authorization for Australian Grape and Wine Incorporated

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Content

PART 1 Basic concepts of new food additives

1.1 New Food Additives Scope

In the following cases, food additive shall undergo new food additive authorization process before they are legally allowed to be used in foods circulated in China market.

a. The varieties of food additives that have not been listed in the Food Safety National Standards (GB 2760);
b. The varieties of food additives that have not been listed in the inventory announced by NHC;
c. The varieties of food additives with different application scope or amount of usage compared with current approved food additives.

1.2 Purpose of using food additives

Food additives shall serve one or more of the following purposes.

a. Maintain or improve the nutrient value of food.
b. As a necessary ingredient or composition of certain food for special dietary uses.
c. Improve the food quality, stability, and its sensory characteristics.
d. Make it convenient for food production, processing, packaging, transportation, or storage.

1.3 Requirement for the use of food additives

a. Food additives should be technically necessary and proven to be safe and reliable by risk assessment
b. Food spoilage should not be covered up.
c. Quality defects in the food or in its production process should not be covered up.
d. Do not use food additives for the purpose of adulteration and forgery.
e. The nutritional value of food should not be reduced.
f. Reduce the dosage in food as much as possible to achieve the expected effect.
g. Processing aids for food industry should be removed before the final product, except for those with permitted residues in final product.

1.4 Authorities in charge of registration of new food additives

中华人民共和国国家卫生健康委员会
National Health Commission of the People's Republic of China

Nation Health Commission of China（NHC）

NHC is responsible for the examination and approval of new varieties of food additives, and organize to formulate the specifications of technical evaluation and examination for new varieties of food additives.

CFSA 国家食品安全风险评估中心
China National Center for Food Safety Risk Assessment

China National Center for Food Safety Risk Assessment (CFSA)

CFSA Organizes technical review of new varieties of food additives, solicit opinions and

report the results of technical review (in charge of technical review)

Note: Regular food raw materials do not belong to the category of food additives, and are not subject to the regulation of food additives.

PART 2Application materials for new food additives

2.1 List of Declaration Materials

SN	Material items	Remark
1	Application form	-
1.1	Applicant information (name, address, post code, phone number and fax of contact person)	-
2	Common name, function, usage (amount and application scope)	-
2.1	Common name	-
2.2	Function	-
2.3	Proposed usage (amount and application scope)	-
3	Description of the necessity of using the food additive added in the food	-
3.1	Function mechanism	-
3.2	Comparative experiment report of effect on proposed foods with the food additives or not	-
3.3	Comparative experiment report of effect on designated foods with the food additives or other food additives with the same function	-
3.4	Other advantages: such as stability, cost to use, convenience etc.	-
4	Quality and specification requirements,	-

	production techniques and testing method as well as the method or instructions to test the additive in food	
5	Safety evaluation data, including raw materials or sources, chemical structure and physical properties, production techniques, toxicological safety evaluation data or testing reports and quality and specification testing report.	Applications for extension of scope are exempt from submission, unless correction is required in technical review.
6	Samples of label, instructions and food additive product	-
7	The supporting document of its production and use issued by other countries(region) or international organizations	-
8	The certificate to allow the production or sale of the food additive issued by the relevant department or organization of the exporting country (region)	It is a must for new varieties of food additives imported for the first time.
9	The supporting document of examination or accreditation of the manufacturer issued by the relevant institution or organization in the country (region) where the manufacturer is located	It is a must for new varieties of food additives imported for the first time.
10	The applicant entrusted shall submit the power of attorney	It is a must for entrusted application.
11	Sample of the additive（≥30gx3）	-

2.2 Language

The application dossiers must be written in Chinese.

2.3 Key Points

Point 1: Description of the necessity of using the food additive added in the food (No.3 in the list)

Scientific research literature, research reports, supporting documents provided by a third party, and research reports on the effect of experimental use can be used. The technical necessity materials should clarify:

1) Functional category and mechanism of food additives;
2) The effect comparison of adding it into the intended food or not (new varieties of spices are exempted);
3) The effect comparison of its use and the use of food additives within the same functional category (new flavour varieties are exempted);
4) Other necessary technical data.

For foreign literature, submit it together with the Chinese translation of its abstract. For other foreign documents, please attach the Chinese translation of the full text.

Point 2: Toxicological safety evaluation data (No.5 in the list)

According to *GB 15193.1-2014 national food safety standard toxicological evaluation procedure for food safety*, different types of food additives need different toxicological evaluation data according to product source and safety characteristics.

Glossary reference

ADI: Allowable Daily Intake
CMA: China Metrology Accreditation
COE: Council of Europe
GLP: Good Laboratory Practice
FEMA: The Flavor and Extract Manufacturers Association of the United States
IOFI: International Organization of the Flavor Industry
WHO: World Health Organization

China recognizes toxicological test reports issued by CMA* and GLP* laboratories.

1) Flavorings

Toxicological tests required for application of new flavor varieties

Condition	Toxicological tests required	
ADI has been approved or developed by WHO.	Usually no need to test.	
Approved by at least two WHO, FEMA, COE and IOFI.		
Approved by only one international organization or incomplete information.	Acute oral toxicity test and combination of genetic toxicity test.	Require preliminary evaluation to decide whether further tests are needed.
No information available and not allowed to be used by international organizations.	Acute oral toxicity test, genetic toxicity test and 28-day oral toxicity test.	
The chemical structure formula and related data of single high-purity natural flavor extracted from edible parts of animals and plants do not indicate that it is unsafe.	Usually no need to test.	

2) Enzyme preparations

Toxicological tests required for application of new varieties of enzyme preparations

<table>
<tr><th>Condition</th><th colspan="2">Toxicological tests required</th></tr>
<tr><td>Produced by the edible parts of animals and plants with long-term safe edible history: with ADI has been published by WHO or no need to specify ADI, or approved by many countries.</td><td colspan="2">On the basis of providing relevant proof materials, generally no test is required.</td></tr>
<tr><td rowspan="2">Other sources, where the toxicological data are relatively complete: WHO has published ADI or does not need to specify ADI, or many countries have approved the use of it.</td><td>If the quality specification is consistent with the international quality specification, acute oral toxicity test and genetic toxicity test should be conducted.</td><td rowspan="3">According to the test results to determine whether further tests are needed.</td></tr>
<tr><td>If the quality specifications are inconsistent, 28 days oral toxicity test will be added.</td></tr>
<tr><td>Other sources, which are approved by one country: WHO does not publish ADI or toxicology data is incomplete.</td><td>Acute oral toxicity test, genetic toxicity test and 28 day oral toxicity test.</td></tr>
<tr><td>Other sources, all new varieties.</td><td colspan="2">Acute oral toxicity test, genetic toxicity test, 90 day oral toxicity test and teratogenicity test. Require preliminary evaluation to decide whether further tests are needed.</td></tr>
<tr><td>Genetically modified.</td><td colspan="2">In accordance with the relevant national provisions on genetic modification management.</td></tr>
</table>

3) Other food additives

Toxicological tests for application of new varieties of other food additives

<table>
<tr><th colspan="2">Condition</th><th colspan="2">Toxicological tests required</th></tr>
<tr><td colspan="2" rowspan="2">Toxicological data are relatively complete: WHO has published ADI or does not need to specify ADI, or many countries have approved its use.</td><td colspan="2">If the quality specification is consistent with the international quality specification, acute oral toxicity test and genetic toxicity test should be conducted.</td></tr>
<tr><td colspan="2">If the quality specifications are inconsistent, 28 days oral toxicity test will be added to determine whether other relevant tests are needed according to the test results.</td></tr>
<tr><td colspan="2">Approved by one country: WHO does not publish ADI or toxicology data is incomplete.</td><td>Acute oral toxicity test, genetic toxicity test, 28 day oral toxicity test and teratogenicity test.</td><td rowspan="3">Require preliminary evaluation to decide whether further tests are needed.</td></tr>
<tr><td rowspan="2">A single component, high purity additive made from animals, plants or microorganisms</td><td>New varieties</td><td>Acute oral toxicity test, genetic toxicity test, 90 day oral toxicity test and teratogenicity test.</td></tr>
<tr><td>Approved by a foreign country or international organization</td><td>Acute oral toxicity test, genetic toxicity test and 28 day oral toxicity test.</td></tr>
</table>

PART 3 Application Process and Time

The application process is as follows. Steps that highly influence project timing are technical necessity effect test, quality specification inspection, toxicological test and/or literature materials, the estimated time to complete file application is 8-12 months, and the estimated time to obtain application result is 12-24 months.

No.	Work stage	Description	Estimated time
1	Preparation	- Product R&D while apply for account & password in NHC (National Health Commission of the People's Republic of China) online system - Finish toxicology test & product test - Ready the dossiers	Various, depending on the product.
2	Submit materials	Online - the file shall be bound into a volume and put into online system. Offline - the materials shall be submitted to the administrative acceptance hall of (NHC).	15 working days
3	Notice of acceptance and correction	Administrative acceptance hall checks and accepts the materials. If a notice of supplementation issued by authority, the supplementary materials shall be submitted until successful acceptance.	The administrative time for acceptance is 5 working days. In case of correction, the period shall vary with the specific correction

			requirements.
4	Review progress	The evaluate center solicits opinions and do the technical assessment, and finally makes conclusion and suggestion on whether to approve or disapprove the application.	60 working days.
5	Obtaining the notice of review conclusion	NHC issues the Announcement of approval or the decision of disapproval.	20 working days.

PART 4 Project Costs

4.1 Testing Costs

Projects		Estimated cost (Lab with CMA certificate,2020)	Remarks
Toxicity test	Acute oral toxicity test	~1,600 USD	Please confirm which toxicity test items to do according to the requirements in Section 2.3.2
	Genetic toxicity test	~3,200 USD	
	Combination of genetic toxicity test	~9,600 USD	
	28-day Oral Toxicity Test	~24,000 USD	
	90-day Oral Toxicity Test	~36,800 USD	
	Teratogenicity Test	~48,000 USD	
Quality specification inspection	All items (in specification) test	1,600~4,800 USD	
	Verification of test methods	≥8,000 USD	If there is a test method but it is not applicable, it needs to be verified.
Other	Development of testing methods	≥16,000 USD	If there is no test method, it needs to be developed.

* Note: the above costs are for reference only, the specific costs fluctuate according to different products, please consult the testing laboratory for details.

4.2 Other Costs

Projects	Content	Estimated cost	Remarks
Translation	Translation of dossiers, including test reports and abstracts of literature (Estimates range from 30,000 to 100,000 Chinese characters)	1,000~3,000 USD	25-30 USD per thousand Chinese characters
Notarization	Notarization of production and sales certificate	~1,000 USD	
Application Agent	Dossier preparation, submit registration and follow up	15,000~30,000 USD	

* Note: the above costs are for reference only, the specific costs fluctuate according to different products, please consult the corresponding agencies for details.

Regulatory Reference

1) *Administrative measures for new varieties of food additives* (Order No. 73 of the Ministry of Health)

2) Notice on *Rules for application and acceptance of new varieties of food additives* (WJF [2010] No.49, Ministry of Health)

3) Notice on *Standardizing the license management of new varieties of food additives* (No. 29, 2011)

4) Notice of the general office of the Ministry of Health on entrusting to undertake the work of new variety license of food additives (WBJH [2012] No. 609)

5) Reply on quality specification requirements of new food additives (WJSH [2012] No.276)

6) Notice of the National Health and Family Planning Commission on Revising the *Relevant provisions on Administrative on examination and approval of new food raw materials* (GWSFF [2017] No.21)

7) Decision of the National Health and Family Planning Commission on Amending seven departmental rules including the *Administrative measures for the safety examination of new food raw materials* (Order No. 18 of the National Health and Family Planning Commission of the People's Republic of China)