Guidance on Application for Non-traditional Food Ingredients

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I. Introduction

With the development of technology and the increasing international trade, more and more non-traditional food ingredients are available. In addition, compositions and properties of many traditional food have been changed due to non-traditional cultivation, reproduction or new processing technology. These are all categorized as non-traditional food ingredients, which are required to undergo safety assessment to make sure that they do not pose a health hazard. The safety assessment includes comprehensive data collection, risk assessment to check the safety of non-traditional food ingredients.

II. Purpose

This guidance is intended to regulate the definition, application procedures of non-traditional food ingredients, as well as the documents and application forms required for safety assessment, for the food enterprises to follow, in order to ensure food safety and development of the industry, and to facilitate the examination of the application for health authorities.

III. Definition of non-traditional food ingredients

The term "non-traditional food ingredients" in this guideline refers to:

1. Does not have a history of safe food use in Taiwan [1]; or, does have a history of food use but not used for human consumption to a significant degree, for example, only in a specific territory or among a particular group of people.
2. Traditional food materials that are produced with non-traditional breeding, planting methods or manufactured by novel processes that change the composition or properties of food. (Does not include food categories that are already regulated, such as genetically modified food or irradiated food.)

[1] The history of safe food uses shall be longer than 25 years.

IV. Procedure of safety assessment of non-traditional food ingredients

1. The Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare will first conduct a document examination to determine whether the application case falls into the category of non-traditional food ingredients referred to in this guidance before conducting a safety assessment.
2. The applicant shall fill in the questionnaire (Appendix 1), prepare the relevant documents, and submit them to the TFDA of the Ministry of Health and Welfare for examination. If the application item is determined to be a traditional food material, no safety assessment is required. Otherwise, the applicant is required to submit the application form and relevant documents (Appendix 2) for review according to the provisions of Section V, “Documents required in the application for safety assessment of non-traditional food ingredients” of the guidance. Detailed procedures are specified in Section VI, “Safety assessment of non-traditional food ingredients flowchart".

V. Documents required in the application for safety assessment of non-traditional food ingredients

Manufacturer or sellers of non-traditional food ingredients shall submit the following documents to the TFDA of the Ministry of Health and Welfare for the application of safety assessment. The application form is in the Appendix 2.

1. Information of the applicant
   (1) Name of the applicant and the company
   (2) Contact person, telephone number and address
   (3) Name of the ingredient applied
   (4) Information of manufacturer/processor
   (5) Purpose of application
   (6) Date of application
2. Basic information of the non-traditional food ingredient
   (1) Description of the appearance and physical characteristics of the raw material, name of the raw material (general Chinese and English names and scientific names), source, composition, properties and purpose of use.
   (2) Specifications of the ingredient applied, detailed description of the production process (including the use of enzymes, solvents or other materials used in processing), methods of quality control, stability in processing, and methods of storage.
   (3) Production by non-traditional breeding techniques or methods (including breeding methods, breeding processes, and detailed processes).
   (4) Part(s) of raw material used and proposed use for which types of food or products
   (5) The type of final product used in food (if the final product is the raw

material itself or its extract).

3. Consumption information of the non-traditional food ingredient
   (1) Proposed uses and use levels (consumption quantity under expected use conditions).
   (2) The estimated level and its maximum consumption level of general consumers and extreme consumers with the ingredient applied consumption amount.
   (3) The estimated level and its maximum consumption level for particular consumers who have special needs.
   (4) Suggestions for target consumers and excluded consumers.
   (5) History of use as food in Taiwan or other countries.
4. Toxicological information and other relevant information that may prove safety.
   (1) Non-traditional food ingredients that fall into the first definition in Section 3 of this guideline shall submit the following toxicity studies.
      i. Genotoxicity study
      ii. 90-day feeding toxicity study
      iii. Teratogenicity study
   (2) Non-traditional food ingredients that fall into the second definition in Section 3 of this guideline shall submit the following toxicity studies.
      i. Genotoxicity study
      ii. 28-day feeding toxicity study
   (3) If the non-traditional food ingredients falling into the first definition in Section 3 of this guidance, which are not approved for used as food in two or more countries in North America, Europe, New Zealand and Northeast Asia, the applicant shall submit the 90-day feeding toxicity study which at least one experimental animal (at least rats). The study shall be conducted and reported by laboratory with a good laboratory practice certification. If, upon examination, the available scientific information is considered not sufficient enough to prove its safety, the applicant shall submit a longer period animal toxicity study(for example, more than one year).
   (4) Other relevant studies that can prove safety, such as acute toxicity, chronic toxicity, reproductive and developmental toxicity, carcinogenicity, ADME(including absorption, distribution, metabolism and excretion), bioavailability, test of impact on other components; information on allergies, side effects, and pharmacological effects; comprehensive assessment reports by other countries or international organizations.
5. Labeling and instruction manual such as proposed uses, suggested for target consumers and excluded consumers, precaution and restriction of use.
6. Approval or rejection situation in other countries, in particular their relevant laws and regulations. Regulatory information in other countries.
7. Other necessary document.

VI. **Safety assessment of non-traditional food ingredients flowchart**