Regulation for Registration of Food Additives (New Application)

I. Application for new food additives registration

1) For the registration of food additives, the applicant shall pay the application fees and submit completed application forms and all required dossiers.
    1. An application form of food additives registration.
    2. An original copy of the official document that supports the legitimacy of the original manufacturer.
       Instructions:
        i. The certificate that proves the legitimacy of the original manufacturer shall be the original copy issued by the authorities governing product sanitation or the issuance of certificates for legal manufacturers within 5 years. The content shall include name and address of the manufacturer, the business type, the product types, the sanitary status of the factory, the title of the authority that issues the certificate, and the signets or stamps of the official.
        ii. If a photocopy of the manufacturer certificate that does not specify the validity period is submitted, the date of issuance shall be within five years and notarized.
        iii. Domestic food additives are exempted.
    3. The original certificates of the manufacturer authorizing the distributor to sell the products or the certificates of the distributor commissioning the manufacturer to toll-manufacture the products.
       Instructions:
        i. The certificates shall be issued by the manufacturer or the distributor within a year.
        ii. This requirement can be exempted, if the manufacturer directly supplies to the applicant.
    4. The original certificate of the distributor authorizing the applicant to sell the products or the certificate of the

applicant commissioning the distributor to supply its with the product.

Instructions:

i. The certificates shall be the original copy issued by the applicant or the distributor within a year.

ii. This requirement can be exempted, if the manufacturer directly supplies to the applicant.

5. The original certificate of the manufacturer authorizing the applicant to sell the products or the certificate of the applicant commissioning the manufacturer to produce the product.

   Instructions:

   i. The certificates shall be the original copy issued by the manufacturer or the applicant within a year.

   ii. This requirement can be exempted, if the manufacturer supplies to the applicant through the distributor.

6. An original copy of the ingredient list.

   Instructions: The chemical names and the content of all the ingredients shall be specified on the ingredient list. For food additive combinations, the chemical names and the content of all ingredients contained shall be indicated.

7. The original copy of the Product Specification Sheet, Certificate of Analysis and the analysis methodology.

   Instructions:

   i. Identification, purity and quantitative tests shall be specified in the Product Specification Sheet, the analysis methodology and the Certificate of Analysis.

   ii. Besides self assessment, the domestic applicants can also commission the contract testing labs assigned by the Ministry of Health and Welfare for the Certificate of Contract Analysis.

8. The documents regarding types and materials of the inner and outer packaging of the products, labels and color photos of the packaging.

Instructions:

i. Labels include samples of the original and Chinese labels.
ii. Color photos of packaging shall be clear enough to read.
iii. Domestic products are exempted.

9. The proof of the source of ingredients.
   Instruction:
   i. For domestic ingredients, the food grade certificates of all the ingredients shall be submitted. In the case of the single food additive (except for the flavoring), the license number of the food additive shall be specified.
   ii. Imported ingredients are exempted.
10. An original Assurance Statements.
    Instruction: The applicant shall recognize that the product names are not identical to any other existing product names. If counterfeiting or insinuation are involved, the applicant shall bear any legal responsibilities should they incur and the Ministry of Health and Welfare shall cancel the registration license.
11. A copy of certificates or official documents of company registration or business registration and a copy of certificates or official documents of factory registration.
    Instructions:
    i. Importers shall submit certificates or official documents of company registration or business registration, in which importing food additives are specified.
    ii. Domestic companies shall submit certificates or official documents of company registration or business registration or a copy of certificates or official documents of factory registration, in which information regarding manufacture, processing, blending and modification of food additives.

12. A copy of the diploma of the sanitation staff or a copy of the certificate of the sanitation staff approved by the competent authority of the special municipality, counties (provincial cities).
    Instructions:
    i. The importers shall submit a copy of the diploma of the sanitation staff.
    ii. The domestic companies shall submit the certificate of the sanitation staff approved by the competent authority of the special municipality, counties (provincial cities).
13. Application fees.

II. After the application is submitted and approved according to the Act Governing Food Safety and Sanitation, a license with a validity of five years shall be issued.

III. If an applicant is requested to submit samples for verification after review of its application, sufficient samples for examination shall be submitted along with an examination fee to an analysis institution designated by the central competent health authority in accordance with the contents of the notice of said authority within two months of such notice. The application of an extension is allowed if needed. The extended deadline is one month after the expiry date of the original submission period. Results of the examination shall serve as reference for the above authority to rely on in granting approval. Failure to pay the examination fee or submit the samples within the prescribed period will result in the rejection of the application.

IV. For any post-approval change of information registered on the license, the application form, registration license, all required dossiers and application fees shall be submitted to the Ministry of Health and Welfare. For the reissuance of a new license copy, fees shall be charged. For the amendment application of

change in quality, submission of a sample shall be required, and an inspection fee shall be collected.