

# Regulations Governing the Outsourcing of Health Food Product Registration

DOH Food No. 0960407549 Promulgated, October 24, 2007.

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Article 1 The Regulations is defined pursuant to Article 7 Paragraph 4 of the Health Food Control Act (hereafter referred as the HFCA).

Article 2 The outsourcing of the registration procedures defined in Article 7 Paragraph 1 of the HFCA instituted by a central competent authority to a related institution (facility), school, or organization (hereafter referred as the Appointed Body), should be processed in accordance with the provisions of the Regulations.

Article 3 The appointed body (facility) for the outsourced health food product registration procedure should possess the following qualifications:

1. At least three years of experience in handling food related accreditation/certification work or medical and pharmaceutical product related registration work;
2. At least three years of experience in conducting food sanitation and management related research which findings received the recognition from government agency; however, the appointed body should not act as the safety and efficacy assessment experiment plan implementer of an application case;
3. Possessing the fully-equipped work environment and established operating procedures and quality assurance plans suitable for the pursuit commissioned by the outsourcing body and a staff of professional assessors possessing adequate professional qualifications.

Article 4 The professional assessor referred in the preceding article should possess at least one year experience in health food or food product related registration

or accreditation/certification work and one of the following qualifications:

1. holding a bachelor's degree in a food nutrition related course from a domestic or foreign university or college recognized by the Ministry of Education;
2. passing a civil service junior examination or a professional practice or technician licensure examination and holding of a food product related licensure or eligibility certification;
3. having previous employment as civil servant with an Elementary Rank 5 or higher for a food sanitation related position at a health & sanitation authority.

Article 5 The appointed body is prohibited from outsourcing the procedure to the execution of another facility.

Article 6 The central competent authority is required to post information of the name, address, and line of business of the appointed body, the deadline of work appointment, and other related matters.

Article 7 The appointed body shall execute the appointed registration procedure according to the provisions of the health and food control related laws, the case application and processing deadlines of the central competent authority, and related documentation laws.

Article 8 Applicants should file applications for registration with the central competent authority and at the same time pay the pertaining assessment fee; thereafter, upon completion of the application acceptance procedure, the central competent authority shall forward cases to the appointed body for execution.

The appointed body shall execute the registration procedure in the same regard as the central competent authority; the applicant should cooperate with said body and accept its findings. All supplementary document or information requirements shall be directly issued by the appointed body.

Article 9 The appointed body shall employ the appropriate procedure and record the

registration procedure in order. Such records should bear the signatures of the related department personnel; moreover, a monthly report of which should be submitted to the central competent authority.

The appointed body shall keep such records in file for at least three years for future review purposes.

Article 10 The appointed body may request for relevant information from the central competent authority upon requirement of the registration procedure.

The appointed body should keep all information of documents and personal data received from the central competent authority and the applicant strictly confidential and implement excellent information control measures.

Article 11 The appointed body shall be accountable for any operation violations, document/information loss or disclosure, disclosure of confidential business operation information, or other infringement committed on the legal rights and interests of a third party occurring in the course of the registration procedure.

Article 12 The appointed body is prohibited from disclosing or publishing any registration procedure related information or news.

Article 13 The central competent authority may, upon requirement of circumstances, audit or assess the registration related operations of the appointed body, and upon requirement of circumstances, request the professional assessor(s) employed by the appointed body to undergo training; the appointed body is obliged to comply with said requirement and shall under no circumstances evade, obstruct, or refuse compliance.

Article 14 The central competent authority may, upon the expiration of the outsourcing period, continuously retain the service of the appointed bodies pursuant to the priority ranking based on their past implementation performance.

Article 15 In the event of a force majeure event or factor adequately affecting execution of the appointed task through no fault of the appointed body during the

appointment period, the appointed body should immediately advise the central competent authority of the matter and negotiate the institution of adjustments on the appointed task.

Article 16 Where the appointed body shall experience any factor that may cause the revocation of the contract or any cause for contract revocation defined in the Civil Law and related governing laws, and on the grounds of which the central competent authority has revoked the aforementioned appointment contract, the appointed body shall remain obliged to institute proper measures for the continued maintenance of the respective services.

Article 17 The Regulations shall take effect immediately upon enactment.