Public Announcement No. 2019-67 by the Ministry of Food and Drug Safety

Regulations on Substantiation of Claims in Labeling or Advertising of Foods

July 30, 2019

Ministry of Food and Drug Safety ("MFDS")

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Regulations on Substantiation of Claims in Labeling or Advertising of Foods

Article 1 (Purpose). This Announcement aims to substantiate claims in the labeling and advertising of foods and protect consumers from unfair labeling and advertising by establishing details such as the requirements for substantiating information and methods under Articles 9.1 through 9.7 of the *Act on Labeling and Advertising of Foods* and Articles 9.1 through 9.4 of the Enforcement Rules of the same Act.

Article 2 (Definition). For the purpose of these Regulations, the following definitions shall apply:

1. "Substantiating information" means a set of data prepared to prove that the claims in the labeling or advertising of foods, food additives, apparatus, containers, packaging, health functional foods, livestock products (hereinafter referred to as "Foods and Others") are true.
2. "Substantiating agency" means the organization performing the substantiation, such as testing and investigation institutions.
3. "Human Subject Study" means the testing of humans to verify whether the Foods and Others can help improve tissues and functions of the body, thereby proving the claims in the labeling or advertising of the Foods and Others.
4. "In vitro testing" means the measurement of results after treating test materials and reference materials in an artificial environment utilizing physical, chemical, electrical, sanitation-wise, formulation-wise, biological, or microbiological treatment.

Article 3 (General Requirements for Substantiating Information). ① The contents of substantiating information requested by the Minister of Food and Drug Safety shall be directly related to the claims in labeling or advertisement.

(An example of non-direct relationship) (1) The contents of the substantiating information are irrelevant to the claims in labeling or advertising of Foods and Others. (2) The contents of the substantiating information are partially related to the claims in labeling or advertising of Foods and Others;

② Substantiating information shall be documented using objective and scientific procedures and methods. In this case, the judgment criteria shall follow the provisions of Articles 4 through 6 hereof.

Article 4 (Requirements for Test Results). The requirements for test results related to substantiating claims in the labeling or advertising of Foods and Others under Article 9.1.1 of the *Enforcement Rules of* the *Act on Labeling and Advertising of Foods* (the "Rules") are as follows.

1. The testing agency shall be independent of the person who labels or advertises Foods and Others, and shall meet the requirements under Article 4.1.2 of the *Enforcement Decree of* the *Act on Fair Labeling and Advertising;* except for any of the following cases that are recognized by the Minister of Food and Drug Safety:

   A. There is no independent testing agency capable of substantiating claims in labeling or advertising;

   B. Testing by an independent testing agency is inappropriate to maintain trade secret that, if disclosed, could result in a significant infringement on the business activities; or

C. In other cases where the testing cost charged by an independent testing agency is too high in light of the claims to be substantiated, the effect of viewing and disclosing the substantiating information, and the scale of the business.

2. The testing agency shall have competent human and physical capabilities to perform the test and shall be one of the following:

A. A testing agency established under an individual statute;

B. A testing agency recognized as an "official testing agency" in the corresponding industry and sector under the *Framework Act on National Standards;* or

C. Other testing and research institutes recognized by the Minister of Food and Drug Safety that they possess specialized testing skills required in the applicable industry and sector.

3. The test procedures and methods for substantiating claims in labeling or advertising of Foods and Others shall be objective and reasonable as generally accepted by the academic or industrial circles in the field and shall meet the following requirements:

A. For generals testing, test procedures and methods shall be of those defined by CAC (Codex Alimentarius Commission, Association of Official Analytical Chemists (AOAC) or International Standard Organization (ISO);

B. For Human subject studies and in vitro testing, test procedures and methods shall be universally accepted by academia and industries or organizations such as International Council for Harmonization Good Clinical Practice (ICH GCP), World Health Organization Clinical Research Information Service (WHO

CRIS), and shall meet the requirements of Attached Table;

C. If there is no procedure or method for the development of new substances or new materials, test procedures and methods shall be objective and recognized by the Minister of Food and Drug Safety; and

D. Samples used in testing shall be those that are generally accepted by the government or the relevant academic circles for the industry and field concerned.

Article 5 (Requirements for Investigation Results) The requirements for investigation results to substantiate claims in labeling or advertising of Foods and Others under Article 9.1.1 of the Rules are as follows:

1. The investigation agency shall be independent of the person who labels or advertises Foods and Others, and capable of performing the investigation. The requirements concerning the independence of the investigation agency shall follow Article 4.1 hereof.
2. The investigation procedures and methods shall satisfy the following conditions:

A. The purpose of the investigation shall be appropriate, and samples shall be representative conforming to the purpose of the investigation (Appropriateness of the purpose of the survey and sample selection);

B. The results of the primary data must be accurately recorded and reported. (Appropriateness of the data management);

C. The sample selection, questioning, and questioning methods shall be consistent with the purpose of the investigation or with the statistical method. (Appropriateness of the questions);

D. The investigation shall be conducted fairly by a third party. (Objectivity of the investigating agency); and

E. Investigations or sample selection shall be conducted with the purpose of the investigation unknown to the investigators and investigatees. (Non-cognition of the investigation purposes).

Article 6 (Requirements for Expert's Opinions). The requirements for expert's opinions for substantiating claims in the labeling or advertising of Foods and Others under Article 9.1.2 of the Rules are as follows:

1. The judgment of experts and expert groups (organizations) shall be based on the universal standard in the field established by social norms.
2. The personal opinion of an expert shall be based on his/her field expertise, and the content shall be generally acceptable to other experts in the field; and the opinion must be made public, not private.
3. The opinion of an expert group (organizations) shall be generally acceptable to the experts in the field and must have followed the formal presentation procedures of the group (organizations).
4. Statistical data published by an expert group (organization) shall be generally accepted as objective and scientific by operators in the sector or field.

Article 7 (Requirements for Academic literature) ① The requirements for academic literature for substantiating claims in the labeling or advertising of Foods and Others under Article 9.1.3 of the Rules are as follows:

1. Local academic literature shall be of those published in the Korea Citation Index

(KCI) or equivalent academic journals; and

2. Foreign academic literature shall be of those published in academic journals registered in the Science Citation Index (Expanded) (SCI(E)), Social Science Citation Index (SSCI) or other academic journals of equivalent level.

② Academic literature under Paragraph 1 shall be prepared according to the following procedures:

1. Conduct a qualitative literature review (systematic review);

2. All positive and negative contents of the related studies and their study designs shall be aggregated to conduct the review and draw conclusions; and

3. The entire processes implemented to come up with results shall be described, such as search conditions and adopted or non-adopted literature.

Article 8 (Advice on Substantiating Information). Where necessary to determine the objectivity and feasibility of substantiating information, the Minister of Food and Drug Safety may seek the advice of the advisory committee under Article 12 of *the Act on Labeling and Advertising of Foods*.

Article 9 (Review Period). Pursuant to the *Regulation on the Issue and Management of Directives and Established Rules,* these Regulations shall be reviewed for their reasonableness to take necessary measures, such as making improvement thereto, once every third anniversary (by June 30) starting from January 1, 2020.

Addenda <No. 2019-67, July 30, 2019>

This Notification shall enter into force on the date of its announcement.

[Attached Table] Standards for Human Subject Study and In Vitro Test Data

1. Human Subject Study Data

A. General Standards

1) Human subject studies shall be carried out and evaluated at a hospital, local or overseas university, or professional research institute related to Foods and Others under the guidance and supervision of those with the experience of at least five years in the field of human subject study involving Foods and Others;

2) Human subject studies shall be carried out in compliance with the ethical principles underlying the Helsinki Declaration;

3) Human subject studies shall be scientifically valid, and study data shall be documented clearly and in detail;

4) Medical treatment or determination of the subject during the human subject study shall be made under the responsibility of the physician or oriental medical doctor;

5) Human subject studies shall be conducted after obtaining the written consent to voluntary participation from all subjects (written consent form);

6) The consent form under Item 5) above shall include all information about the study (the purpose of the study, potential risks or inconvenience to the subject, compensation or treatment on offer if the subject is harmed, payment for participation in the study, etc.);

7) Safety of the Foods and Others for the human subject study must be secured;

8) Human subject studies shall be conducted in such a manner that they protect the rights, safety, and welfare of the subjects by reviewing and assessing

whether the reason for the subjects' participation in the human subject study is rational; and

9) Human subject studies shall have the established criteria for inclusion and exclusion for the study, and shall comply with such criteria when selecting and conducting the study.

B. Standards for Final Human Subject Study Report

1) Type or title of the study;

2) Identification of the test material by code or name;

3) Identification of the reference material by chemical name, etc. (if applicable);

4) Information on the sponsor and testing agency:

A) Name and address of the sponsor who requests the human subject study;

B) Name, location, and contact number of all testing facilities and test points concerned;

C) Name of the persons who conduct and supervise the test;

5) Dates (date of commencement and date of completion);

6) Quality Assurance Statement (including the type, date, phases, and result of the test);

7) Subjects:

A) Inclusion and exclusion criteria; and

B) The number of subjects and reason for the choice of such number.

8) Study methods:

A) Method of applying the test and reference (if any) materials;

B) The amount or concentration of intake, frequency of intake, time and range of intake, restrictions on use;

C) Equipment and reagents used;

D) The sequence and method of the test, examinations, observations, and statistical methods used; and

E) The correlation between the evaluation method and the test purposes, and evidence that identifies the correlation if the method is new.

9) Test result:

A) Summary of the test results;

B) Relevant information and data presented in the test plan;

C) Results including statistical significance determination and calculation processes; and

D) Evaluation of the results, considerations, and conclusions.

2. In Vitro Test Data

A. General Standards

In vitro testing shall be carried out in the method that is scientifically proven or pursuant to the standard worksheet established through validation.

(Example) If testing is carried out through document detailing procedures, performance methods, etc. for consistent execution under the standardized methods, it can be regarded as reasonable substantiating information.

B. Standards for Final In Vitro Test Report

1) Type or title of the test;

2) Identification of the test material by code or name;

3) Identification of the reference material by chemical name;

4) Information on the sponsor and testing agency:

A) Name and address of the sponsor who requests the test;

B) Name, location, and contact number of all testing facilities and test points

concerned;

C) Name of the supervisor of the test;

D) Name of the person who conducted the test and the phase of the test assigned to him/her; and

E) Name of the external expert who contributed to the preparation of the final report.

5) Dates (date of commencement and date of completion);

6) Quality Assurance Statement (including the type, date, phases, and result of the test);

7) Test materials and methods:

A) Test systems and reasons for the choice of those systems;

B) Characteristics of the test system (e.g., the type, system, supplier, quantity, and other necessary information);

C) Processing methods and reasons for the choice of those methods;

D) Processing capacities or concentrations, the number of processing cycles, processing or application periods;

E) Details of the test plan, including the sequence of the test and methods, examinations, observations, and statistical methods used; and

F) Equipment and reagents used.

8) Test result:

A) Summary of the test results;

B) Relevant information and data presented in the test plan;

C) Results including statistical significance determination and calculation processes; and

D) Evaluation of the results, considerations, and conclusions.