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Administrative Measures for National Food Safety Standards

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Food and Agricultural Import Regulations and Standards - Narrative

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Report Highlights:

The 2009 Food Safety Law charged the Ministry of Health with the unification of existing national food safety standards and creation of new ones. On October 20, 2010, Ministry of Health issued the Administrative Measures for National Food Safety Standards (MOH Decree No.77), which governs national food safety development and revision work. Since 2009, MOH has published over 300 new national food safety standards using these procedures.

This report provides an INFORMAL translation of the MOH Decree No.77 and an example of the Decree in action.

Executive Summary:

The 2009 Food Safety Law authorizes China's Ministry of Health to develop and revise national food safety standards. To provide guidance for this process, MOH formulated the Administrative Measures for National Food Safety Standards, which was published on MOH website as MOH Decree No.77. To demonstrate this process using an actual national food safety standard, following the full text of Decree No.77, we have provided a time line of actions which reflects this process in the revision and adoption of national food safety standard GB 2762-2012 – Maximum Levels of Contaminants in Foods.

General Information:**BEGIN TRANSLATION****Ministry of Health Decree No.77**

The Administrative Measures for National Food Safety Standards, which were adopted at the executive meeting of the Ministry of Health on September 20, 2010, are hereby promulgated and shall come into force on December 1, 2010.

Chen Zhu, Minister
October 20, 2010

Administrative Measures for National Food Safety Standards**Chapter I General Provisions****Article 1**

These Measures are formulated in accordance with the Food Safety Law of the People's Republic of China (hereinafter referred to as the Food Safety Law) and the Regulations on the Implementation thereof for the purpose of regulating development and revision of national food safety standards.

Article 2

Development of national food safety standards shall adhere to the principle of protecting public health and shall be based on results of food safety risk assessments, so as to be science-based , reasonable, open, transparent, safe and reliable.

Article 3

The Ministry of Health (MOH) shall be responsible for the development and revision of national food safety standards.

MOH will establish a National Food Safety Standards Review Committee (hereinafter referred to as the "Review Committee"), which shall be responsible for examining draft national food safety standards, and providing advisory opinions on the work on national food safety standards. The Review Committee will consist of specific sub-committees and a Secretariat.

Article 4

National food safety standards are developed and revised according to an overall plan, an annual plan, an annual standard project initiation, drafting, examination, approval, issuance, revision, and review.

Article 5

Citizens, legal representatives and other organizations are encouraged to participate in the development and revision of national food safety standards by initiating comments and suggestions.

Chapter II Overall Plan, Annual Plan, Standard Project Initiation

Article 6

MOH shall consult with other State Council members, including the Ministry of Agriculture (MOA), General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), State Administration of Industry and Commerce (SAIC), State Food and Drug Administration (SFDA), Ministry of Commerce (MOFCOM) and Ministry of Industry and Information Technology (MIIT) in formulating the overall plan for national food safety standards and implementation plans.

Article 7

The overall plan for national food safety standards and the implementation plans thereof shall specify short-term objectives for national food safety standard development, programs for implementing the overall plan and measures that guarantee implementation of the plan.

Article 8

MOH shall formulate annual plans for the development and revision of national food safety standards in accordance with the overall plan and the implementation plans; needs of the food safety work shall also be considered in this regard.

Article 9

Prior to (MOH) formulation of the annual plan food safety standard development and revision, Other ministries/administrations shall initiate project proposals to MOH for food safety standards they deemed necessary. The proposal shall contain the following information: important issues to be addressed, background and rationale for the project initiation, basis for food safety risk surveillance and assessment, and candidates for standard development; in addition, the project initiation proposals must be ranked according to their priorities.

Any citizen, legal person or organization may initiate a proposals for national food safety standard development.

Article 10

National food safety standards that are proposed for development shall fall within the scope provided in Article 20 of the *Food Safety Law*.

Article 11

The Review Committee shall, after considering the needs of national food safety standard work, study the project proposals, and advise MOH about the plans for development and revision of national food safety standards.

Article 12

MOH shall solicit public comments before announcing the overall national food safety plan, its implementation plan and the annual development/revision plan.

Article 13

Should actual needs emerge in implementation, the plans for development and revision of national food safety standards may be adjusted.

Should significant incidents occur in food safety risk assessment or food safety supervision, MOH shall include such items as emergency supplemental project to the annual national food safety development/revision plan.

Chapter III Standard Drafting

Article 14

MOH shall, by bidding or assignment, select qualified entities to draft the national food safety standards.

Article 15

Research institutes, educational institutions, academic groups and industry associations are encouraged to collaborate on standard drafting.

Article 16

An entity undertaking standard drafting shall sign the national food safety standard development/revision agreement with the competent department at MOH.

Article 17

National food safety standards shall be developed based on risk assessment of food safety and edible agricultural products, the needs of China's social and economic development, as well as relevant international standards and international food safety risk assessment results.

Article 18

Drafters of national food safety standard shall conduct in-depth investigations and research to ensure the scientific basis and accuracy of the drafting work. After the draft is complete, (MOH) will, in writing, solicit comments from standard users, research institutes, colleges, industries, enterprises, consumers, experts and regulatory departments. An explanation of the standard development shall be provided along with the notice soliciting comment.

Article 19

The drafting entity shall complete the standard drafting and opinion solicitation within the time given in the agreement, and shall submit the materials to the Secretariat of the Review Committee (hereinafter referred to as the "Secretariat") for examination in a timely manner.

Chapter IV Examination

Article 20

The draft of a national food safety standard shall be examined according to procedure below:

1. Preliminary examination by the Secretariat;
2. Examination by the assembly of specific sub-committees under the Review Committee; and
3. Discussion by the assembly of directors of the Review Committee.

Article 21

The Secretariat's preliminary examination of the draft national food safety standard shall focus on integrity, standardization, and consistency of the draft standard with the assignment agreement.

Article 22

Standards that pass the Secretariat's preliminary examination shall be published on MOH's website for public comment. In general, MOH accepts public comments submitted within two months after publication of the draft standard.

Article 23

The Secretariat collects and delivers the collected comments to the drafting entity; the latter shall review the comments and make revisions; if the entity deems revision is unnecessary, it shall provide reasons for its decision.

Article 24

The specific sub-committees shall examine the scientific basis and practicality of the draft standards, with attendance of at least two-thirds of members of the sub-committee. The assembly shall reach consensus; when no consensus can be reached, the attendants shall vote after sufficient discussion. Only with a three-fourth vote of all attendants shall the draft standard pass sub-committee examination. The specific sub-committees shall prepare meeting minutes of discussions, major disputes and how the

disputes were solved.

If a draft standard fails to pass the sub-committee examination, the sub-committee, in writing, shall explain the reasons for rejection and provide opinions for improvement. The standard drafting entity shall submit the revised standard for examination again.

The Secretariat shall revise standards that pass the examination in principle but need to be improved. The sub-committee may, if deemed necessary, hold another assembly meeting to examine the revised standard or conduct examination by letter (draft sent by mail to the Secretariat for review).

Article 25

Standards that pass specific sub-committee examination shall be signed by the director of the sub-committee and then submitted to the Review Committee directors for examination.

Article 26

Draft standards approved by the Review Committee directors shall be reviewed by the Chief Technologist of the Review Committee for signature.

The Review Committee will issue a written explanation to the drafting entity if its draft standard fails to pass the review.

If the assembly decides to re-examine a standard after its revision, the Secretariat shall, according to suggestions made by the Review Committee directors, instruct the drafting entity to make revisions and resubmit the revised standard for reexamination.

Article 27

For draft standards that pass the review, the drafting entity shall submit all the materials necessary for approval within the time given by the Secretariat.

Article 28

The Secretariat shall review the submission, and submit to the MOH National Center for Health Inspection and Supervision.

Article 29

The National Center for Health Inspection and Supervision shall, in accordance with opinions of the specific sub-committees and the Review Committee directors, review contents and format of the submitted materials, and provide review opinions for the Secretariat.

Standards passing review shall be submitted by the National Center for Health Inspection and Supervision to MOH.

Article 30

In special circumstances, MOH may adjust the public comment period for national food safety standards; the standards may be directly reviewed by the specific sub-committees and the Review Committee directors.

Article 31

Drafts of national food safety standards shall be notified to the World Trade Organization (WTO) in accordance with relevant provisions.

Chapter V Standard Approval and Issuance

Article 32

Standards that pass examination shall be issued by MOH in form of Ministry of Health public notices.

Article 33

National food safety standards shall be uploaded to the MOH website for public access within 20 working days of issuance, free of cost.

Article 34

The MOH is responsible for national food safety standard interpretation. The interpretations shall be published in the form of MOH documents, and shall have the same power as national food safety

standards.

Chapter VI Standard Revision and Review

Article 35

Should specific contents of a national food safety standard need to be revised after its issuance, MOH will issue a public notice of the revision of the standard.

Article 36

After national food safety standards are implemented, the Review Committee shall conduct review at an appropriate time, and put forward suggestions for whether the standard remains effective, will be revised or abolished. National food safety standards that need to be revised shall be included in a timely manner in the initiation plan for the revision of the annual plan for national food safety standard development/revision.

Article 37

MOH shall organize the Review Committee, provincial food safety authorities and relevant entities to track the implementation of national food safety standards.

Any citizen, legal person or organization may put forward comments or suggestions toward problems in implementation of national food safety standards.

Chapter VII Supplementary Provisions

Article 38

Funds for development and revision of national food safety standards shall be allocated by the central finance budget; the fund use shall be administered in accordance with relevant financial systems and administrative measures for special funds.

Article 39

National food safety standards issued are scientific and technological achievements, and shall be used for appraisal of professional and technical qualifications of the main drafter of the standards.

Article 40

Development and revision of standards for pesticides and veterinary drug residues in food shall be carried out by MOH and the Ministry of Agriculture together.

National food safety standards shall be coded based on consultations between MOH and the Standardization Administration and follow relevant provisions.

Article 41

Development and revision of local food safety standards may be governed analogically by these Measures.

Article 42

These Measures shall come into force on December 1, 2010.

Full text of the Administrative Measures can be found at: http://www.gov.cn/flfg/2010-11/10/content_1742131.htm

END OF TRANSLATION

An Example of National Food Safety Standard Development/Revision Procedure - Maximum Levels of Contaminants in Foods (GB 2762—2012)

Article in the Administrative Measures	Document Title	Date of Issuance	Content of the Document
Article 6. MOH formulates overall plan	Notice of the General Office of the State Council on Issuing the	February 6, 2009	Prioritize development/revision standards for pesticide and veterinary drug residue level in foods,

	Food Safety Rectification Plan [2009]		contaminants in food, pathogenic microorganism, mycotoxin limits and food additive using standard.
Article 8. MOH formulates annual plan for development and revision of national food safety standards	MOH and MOA Joint Notice concerning National Food Safety Standard Review and Consolidation Work in 2010	June 25, 2010	Give priority to revision of (national food safety) standard of contaminants in food, pesticide residue, veterinary drug residue, pathogenic microorganisms...
Article 22. Standard pass the Secretariat's preliminary examination and is published on MOH's website for public comment. Article 18. MOH provides an explanation of the standard development along with the notice soliciting comments.	MOH Public Notice Soliciting Public Comments on National Food Safety Standard-Contaminants in Food (with Explanation of Draft)	August 4, 2010	Full text of the Standard and explanation of draft for public comments; comment period: 60 days.
Article 31. Notify the WTO of the draft standards	WTO SPS Notification G/SPS/N/CHN 312 - National Food Safety Standard: Maximum Levels of Contaminants in Foods	August 12, 2010	Notifies the WTO of full text of the draft standard for trading partner comments; comment period is 60 days.
Article 32. Final standards issued by MOH in form of Ministry of Health public	MOH Public Notice [2012] No. 21 – National Food Safety Standard - Maximum Levels of Contaminants in Foods (GB 2762—2012)	November 13, 2012	Final version of the standard that reflects comments collected.