

**REGULATORY FRAMEWORK AND PROCESSES FOR DEVELOPMENT AND
ADOPTION OF SANITARY AND PHYTOSANITARY MEASURES**

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Introduction

1. This paper sets out the principal of Japan's sanitary and phytosanitary regulatory framework and describes, in general, the processes for development and adoption of sanitary and phytosanitary measures by Japan.

2. There are two agencies with responsibilities in the SPS area:

(i) The Ministry of Health and Welfare (MHW) is responsible for administering regulations relating to food sanitation measures;

(ii) The Ministry of Agriculture, Forestry and Fisheries (MAFF) is responsible for administering regulations relating to animal quarantine measures and plant quarantine measures.

The following describes, in general, the process for developing and adopting sanitary and phytosanitary measures by MHW and MAFF.

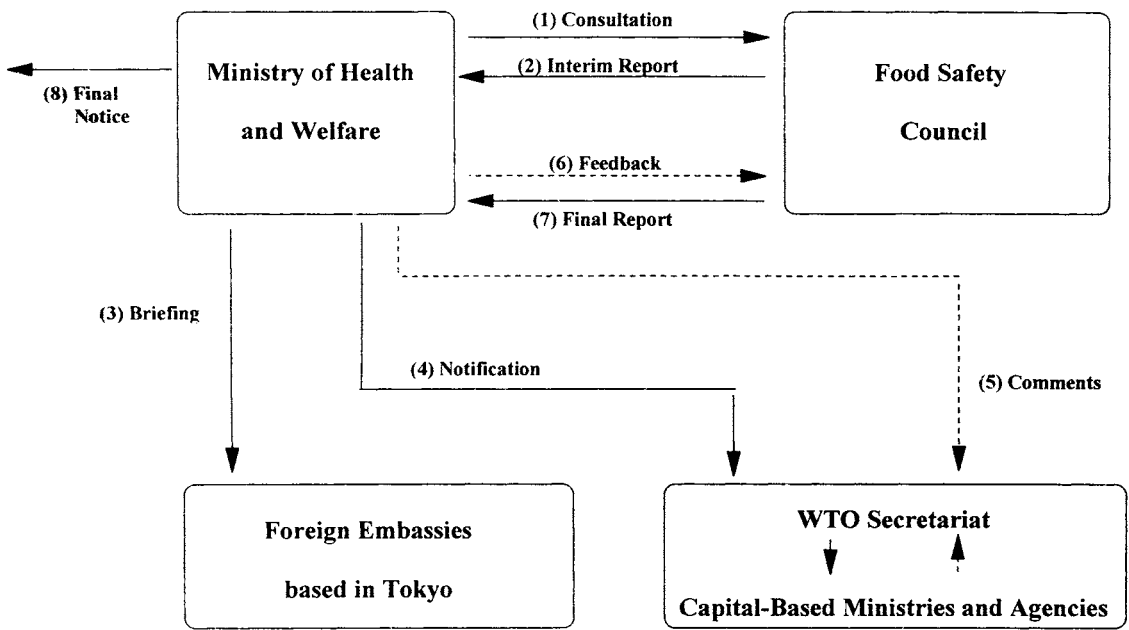
Setting Standards for Ensuring Food Safety

Example 1 - Maximum Residue Level of Pesticides

3. Article 7 of Japan's Food Sanitation Law stipulates that the Minister of Health and Welfare may establish, from the viewpoint of public health, standards and specifications for ingredients, contaminants, etc., and where they have been established, it shall be forbidden to manufacture, import, sell, etc., those foods which are not complying with them.

Standards on pesticide residue levels are established according to this Article.

Fig. 1 - Process of Setting Maximum Residue Standard of Pesticides



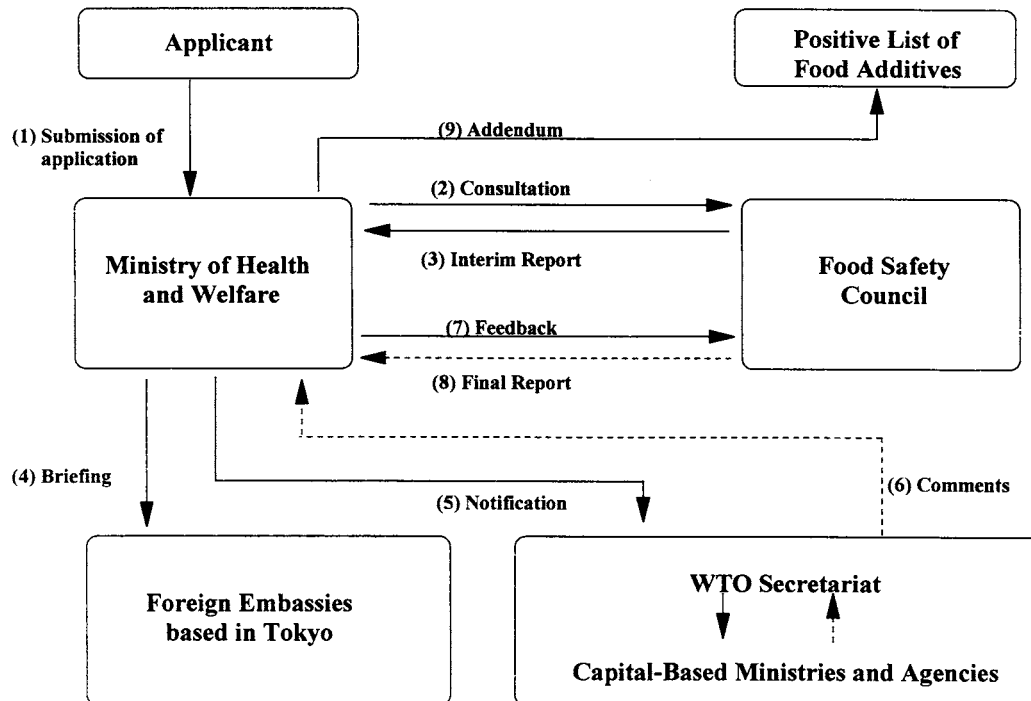
4. Basic Principles of Setting Maximum Residue Standard of Pesticides

Pesticide residue standards are established on each pesticide for each agricultural product.

Any pesticide residue standard is established so that the amount of daily intake calculated from the annual National Nutrition Survey would not exceed the ADI of the pesticide.

Example 2 - Approval of Food Additives

5. Article 6 of Japan's revised Food Sanitation Law, which will be in effect in May 1996, stipulates that no food additive, except for natural flavouring agents and those additives which are also consumed as foods, shall be sold, manufactured, imported, used, etc., unless the Minister of Health and Welfare designates it as not hazardous to human health, based upon the opinion from the Food Safety Council (so-called *positive list system*).

Fig. 2 - Process of Approving Food Additives

6. Basic Principles of Approving Food Additives

- Safety of the food additive in the intended use method should be scientifically proven.
- Effectiveness of the food additive in terms of the following rationales should be scientifically proven:

- to preserve nutritional quality of foods;
- to provide necessary ingredients or constituents;
- to keep or stabilize quality of foods;
- to improve the organoleptic properties;
- to provide aids for manufacturing or storage.

Regulatory Framework and Processes for Development and Adoption of Animal Quarantine Measures

7. The Japanese export and import quarantine of animals and their products is operated under the Domestic Animal Infectious Diseases Control Law and the Rabies Prevention Law.

8. Animals and animal products are permitted to be imported after inspection on their arrival. They have to be accompanied by a Health Certificate issued by the Government authorities of the exporting country.

9. Certain animals and animal products are designated as quarantine items from the viewpoint of whether or not they may give rise to the possibility of spreading infectious animal diseases.

10. Imports of certain articles from certain areas are prohibited in order to prevent Foot and Mouth Disease, Rinderpest and African Swine Fever from entering Japan as the spreading of these diseases in Japan would seriously damage the nation's livestock industry. The designated areas and articles are publicized in the regulation.

11. Procedures used to lift the ban on prohibited areas and articles.

Prohibited areas

- (a) Confirmation of the "free status" in the exporting country (taking into account the OIE standards);
- (b) Evaluation of the livestock industry infrastructure and the animal health infrastructure in the exporting country;
- (c) Dispatch of a mission to the area;
- (d) Amendment of regulations;
- (e) Public notification by way of the official gazette.

Prohibited articles

- (a) Submission of the data regarding the processing method from the exporting country, and examination in Japan;
- (b) Dispatch of a mission to the area;
- (c) Amendment of regulations;
- (d) Public notification by way of the official gazette.

Introduction of a Quantitative Risk Assessment

12. A Quantitative Risk Assessment method is being developed in a three-year project as of this fiscal year. However, the concept of the risk assessment has been already used in decision-making concerning the lifting of bans on prohibited areas, articles and other measures.

Plant Quarantine in Japan

13. The Plant Quarantine system in Japan is based on the Plant Protection Law. Most plants and plant products (excluding highly processed plants) can be imported to Japan, subject to import inspection at entry points, by attaching the phytosanitary certificate from the authorities of the exporting country based on IPPC.

14. The import-prohibited items include:

- (a) plant pests and pathogens;
- (b) soil;
- (c) plants imported with soil; and
- (d) plants (mainly fruits and fruit vegetables) shipped from specific countries (or regions) where specific pests (14 different species and rice pests) occur, which have been assessed not yet to have occurred in Japan and which could cause serious damage to crops based on the pest risk analysis if they were allowed to enter.

These items have been notified to the general public in Japan and other countries, thus ensuring high transparency in Japan of the plant quarantine system.

15. Concerning import-prohibited vegetables and fruits, these can be approved for importation if the Minister of Agriculture, Forestry and Fisheries (MAFF) permits such importation on the basis of data and information from the authorities of the exporting country, in the following two cases:

- (a) the authorities of the exporting country where the relative pests and diseases occur can prove that a certain area of the country is free from such pests and diseases;
- (b) the authorities of the exporting country prove that such products can be imported to Japan without risk by employing certain phytosanitary measures including disinfection.

16. The following procedures are required for approving imports under the conditions mentioned above:

- (a) Presentation of data from the exporting country and a bilateral examination;
- (b) On-site confirmation in the exporting country;
- (c) Public hearing;
- (d) Amendment of the Ministerial ordinance and the regulations concerned;
- (e) Report in the official gazette.

17. For information, this plant quarantine system allows Japan to import many agricultural products amounting to 45 million tons (4,200 species) every year, and Japan is consequently one of the biggest importing countries of agricultural products.