

FOOD REGULATION ON AGROCHEMICALS FOR ENSURING QUALITY AND SAFETY OF FOOD SUPPLY IN JAPAN

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ABSTRACT

Agrochemical residue is a major food safety concern in Japan. Before, regulations on food safety were focused mainly on the end point of the food chain such as manufacturing. Because of this, more cases of chemical residue in food are being addressed in the later process of food production in which it should have been prevented earlier. Through thorough review and modification of previous legislations regarding food safety, the said issue was taken into consideration and directly dealt with. Good Agriculture Practice (GAP) and education of agrochemical handlers (e.g. farmers) on proper chemical use were some of the measures given to prevent residual incidence. New regulations on registration and usage of chemical substances as well as setting a new standard maximum residue limit (MRL) to foods were also considered. Lastly, strict importation and marketing policy of products that have undergone chemical treatment were also being enforced.

Key words: development of production capacity, regulation on agrochemicals, responsibility of private sector, education on agrochemicals, transparency and communication among sectors

INTRODUCTION

The globalization of food trade and the industrialization of food production have rapidly developed and grown two decades ago. Along with these revolutions, despite the efforts of every nation in maintaining product safety, food safety issues like food-borne infectious diseases and agrochemical residues have been experienced. The causes of these problems may not always be clearly identified so to address these issues, various kinds of measures throughout the entire food chain have to be considered. In doing so, not only private sectors but also the government should be involved.

As required in the agreement of World Trade Organization (WTO) in 1994, sanitary and phytosanitary measures must be based upon scientific evidences. These measures should be coordinated with international standards like the Codex Alimentarius, if applicable. When standardized food safety measures are developed, principle of risk

analysis is applied. Activities on risk assessment conducted independently based on scientific evidence and risk management are required.

Today more than 60% of Japanese diet comes from outside the country. Issues associated with imported products have been experienced. Agrochemical residues in fresh products are one of major concerns among Japanese consumers. In 2003, the Government of Japan conducted a survey on food safety concerns among 500 monitors who have knowledge on food safety. Even though there is awareness on food safety, the survey showed that over 60% of the monitors still had concerns on pesticide residue in imported food.

After some events involving food safety, including the first case of Bovine Spongiform Encephalopathy (BSE) in Japan, the Government of Japan decided to reform the regulations related to food safety. The result was a new regulation for agrochemical residue in food. The so-called "Positive List System" was enforced in June 2006.

Table 1. Survey on Food Safety Concerns by FSC in September 2003

Target: 455 Food Safety Monitors assigned by FSC Food Operators, Researchers, Medical Experts and Consumers	
Major Food Safety Concerns:	
Pesticides Residue	67.7%
Imported Food	66.4%
Food Additive	64.4%
Contaminant	60.7%
Microbiology	46.8%
Prion	42.6%

Source: The Food Safety Commission (FSC), Government of Japan

Food regulations on agrochemicals in particular risk analysis principle and “Positive List System” on food imports in Japan are presented.

RISK ANALYSIS

Codex Alimentarius, the FAO/WHO Food Standard Programme, recognized it as international standards for food referred in the WTO agreement, defines risk analysis related to food safety. It states that, “Risk Analysis: A process consisting of three components: risk assessment, risk management and risk communication” (the 16th edition of the Procedural Manual, Codex Alimentarius Commission). The Principle of risk analysis is applied in the Codex Alimentarius activities and is generally recognized as international principle for food safety approach. In 2007, the Codex Alimentarius Commission adopted “Working Principle for Risk Analysis for Food Safety for Application by Governments”.

In 2003, the Japanese Government implemented a new national rule for food safety called the Food Safety Basic Law. It outlines 1) principles on food safety administration, 2) establishment of Food Safety Commission (FSC), 3) Responsibilities of government, food producers and consumers, and 4) application of risk analysis in food safety administration. Due to the provisions of the Law, the Food Safety Commission was established in 2003. It serves as the unique body in Japan that conducts risk assessment based upon scientific evidence and is also independent from other government agency (Table 1).

The Ministry of Health, Labour and

Welfare (MHLW) and the Ministry of Agriculture, Forestry and Fishery (MAFF) serve as risk management bodies. The activities of these agencies are based upon rules such as Food Sanitation Law in MHLW and Agricultural Chemicals Regulation Law in MAFF. Both agencies establish standards and guidelines for food safety. MHLW conducts risk management during manufacture, retail, and consumption. Meanwhile, MAFF conducts risk management on agriculture, livestock and fishery. Both agencies have various branch offices for the enforcement of their regulations.

Risk communication is one component of risk analysis (Fig. 1). The Food Safety Basic Law is being followed by FSC and risk management agencies in conducting activities such as transparency of information on food safety and securing consumers opportunities to express their opinions. FSC, MHLW and MAFF organize various activities such as public meetings, public comments and monitor on consumer’s concerns on food safety.

FOOD CHAIN APPROACH

Food Chain Approach in food safety is internationally recognized today. This is an important concept so as to understand that to maintain safety of food, measures are required not only in some end point of the chain like manufacturing but also in some starting point like farm production. It is obvious that agrochemical residue in food is unmanageable at the point of consumption, but it can be managed at the point of production by using good agricultural practice (GAP).

The Food Safety Basic Law requires appropriate measures at every step in food

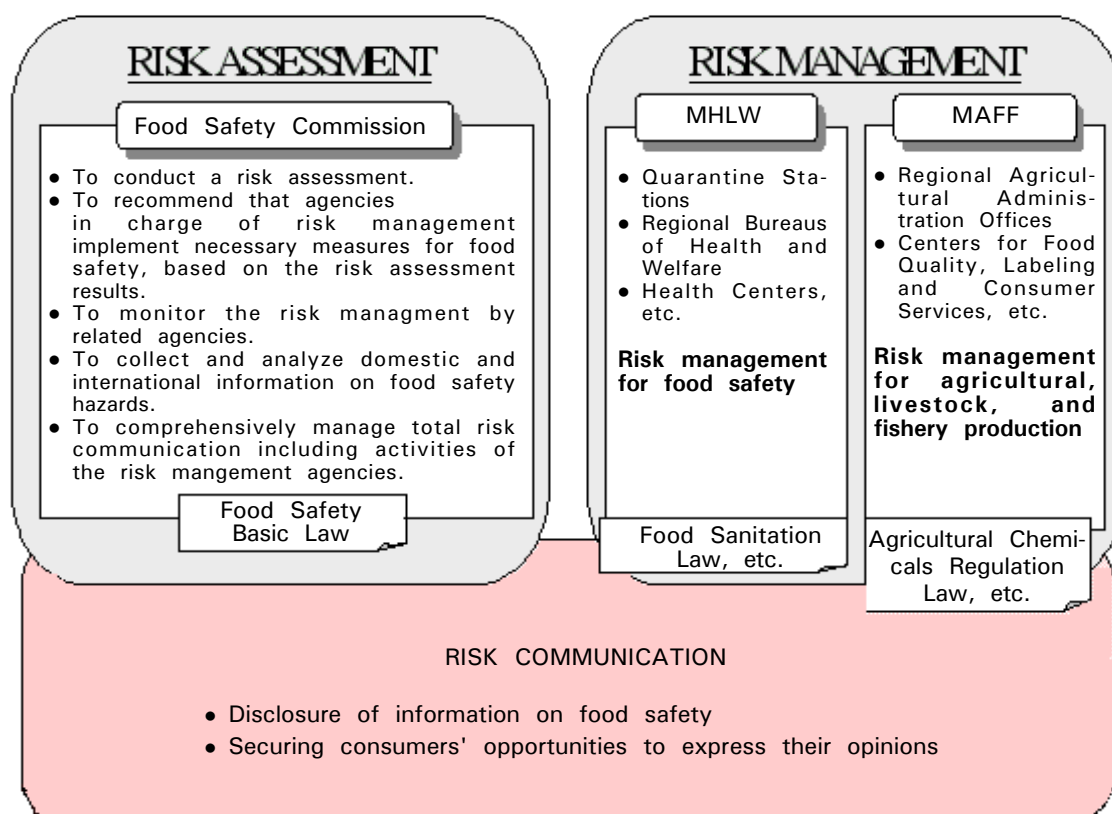


Fig. 1. New measures for Food Safety: risk analysis

chain from production to consumption and must be taken in terms of food safety which may be affected by various things at any stages of food chain. It is believed that food chain would not be limited domestically so parts in overseas should be covered.

In Japan, various legislations on food safety are currently enforced in food chain from farm to table (Fig. 2). For example, the Agrochemical Registration Law regulates marketing and use of agrochemicals in production. The Pharmaceutical Law regulates various aspects of veterinary drug used during production in Japan. The Food Sanitation Law regulates safety standard of food and license of food operators. Under these legislations, food safety should be protected.

Every sector along the food chain has responsibility to comply their products with food safety requirements of Japanese legislations. For instance, farmers should have knowledge about appropriate pesticide usage as regulated. It will protect themselves not only from direct exposure to pesticide but also from discrepancy in food safety and quality which

may occur from misuse of agrochemical. They may also be required to practice other food safety measures such as documentation and record keeping on agrochemical usage during production. It supports proof of actual practices in the production.

Food manufacturers are also required to supply products that comply with food safety standards. Food hygiene and sanitation must be in place and their processes must meet with requirements in regulation.

Responsibility and performance in food safety of private sectors is essential to protect consumers' food safety.

Japanese Government and local governments have resources to enforce the Food Sanitation Law. The Japanese organization of food safety administration is indicated in Fig. 3. The "Food Safety Inspector" who has technical background, as required by the law, is allocated in local branches of quarantine offices and health centers. Food safety inspectors conduct inspection on sites of food manufacturers and restaurants. They have legal authority to take

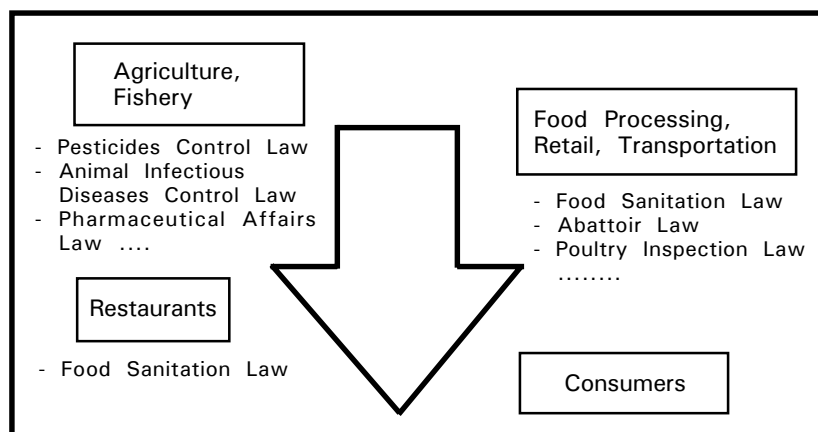


Fig. 2. Legislations related to Food Safety

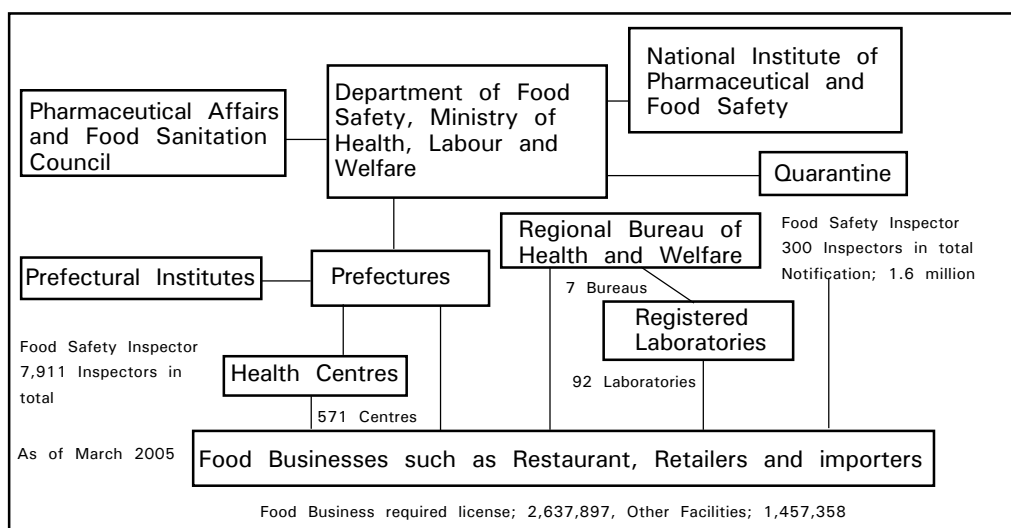


Fig. 3. Organization of Food Safety Administration

sample of food on market for laboratory test if necessary. There are several laboratories in central and local governments for testing food samples. These laboratories are required to meet quality assurance such as good laboratory practice (GLP). Some of them are accredited to ISO 17025 as international standard on laboratory quality assurance.

When food safety standards like Maximum Residue Limits (MRLs) for pesticide residue in food is to be established, MHLW asks its advisory body, the Pharmaceutical Affairs and Food Sanitation Council, for its advice. It is organized by experts from the academe and consumer sector. The deliberation of the body is open for public and their

comments can be raised during the discussion. When the proposal for new food safety standards is made, it is notified to member countries of World Trade Organization (WTO) as required.

APPLICATION OF RISK ANALYSIS IN AGROCHEMICAL REGULATION

Agrochemicals must be registered to the Minister of Agriculture, Forestry and Fishery before manufacturing, processing or importing these products according to the requirements of the Agrochemical Registration Law. It also requires the Minister to publish standard use of registered agrochemical like target pest,

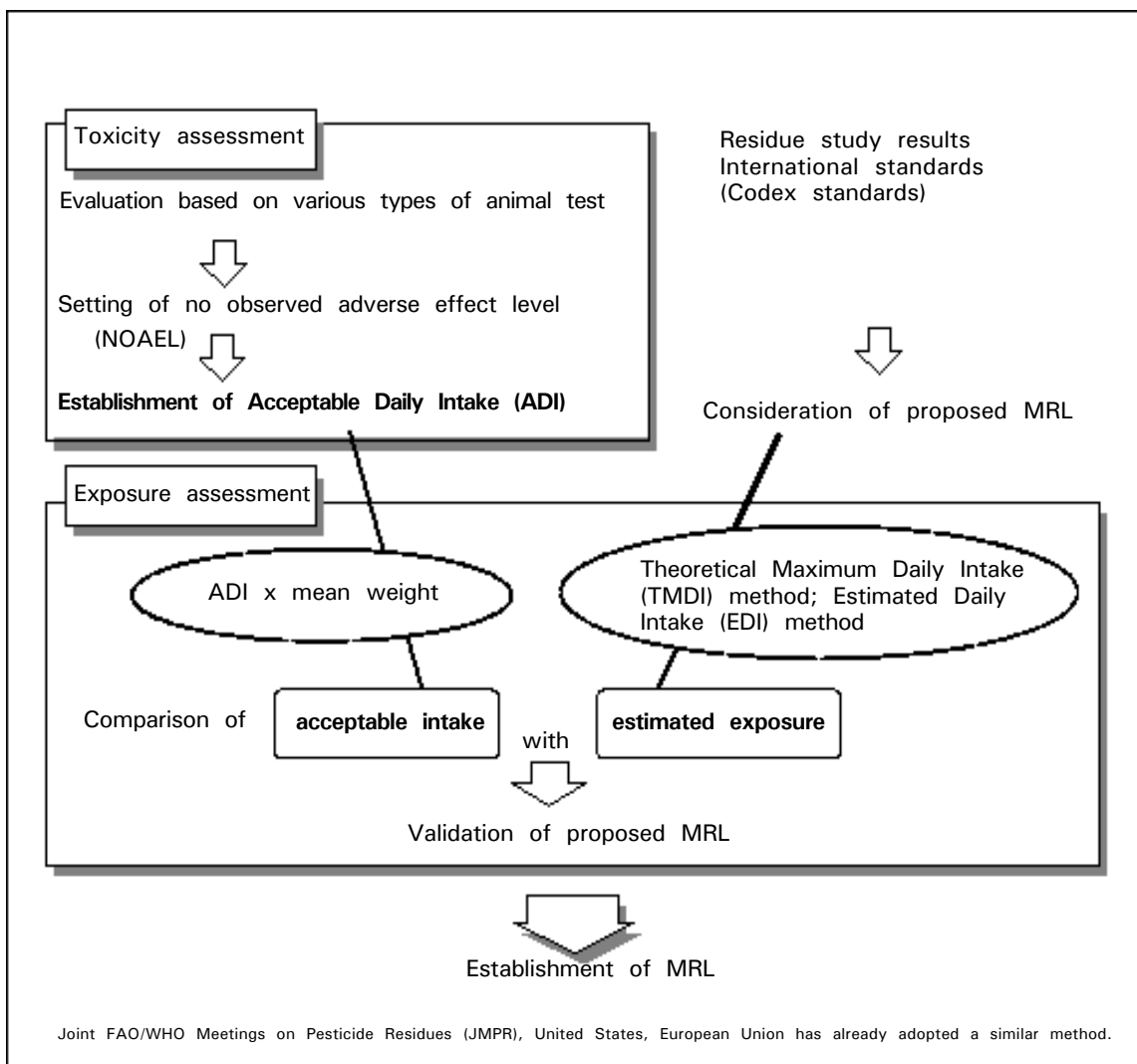


Fig. 4. Establishment of maximum residue limits for pesticides

timing and method on its application. Once it is published, farmers must follow when using agrochemical.

Residue limits of agrochemical in food are regulated under the Food Sanitation Law. The Minister of Health, Labour and Welfare publishes residue standard in official gazette and enforces it. Residue limit is normally stated as Maximum Residue Limit (MRL). According to the Law, it is a requirement that the food containing agrochemical residue higher than the residue standard shall not be marketed or imported.

The establishment of MRLs is described in Fig. 4. We apply safety value of substance, normally expressed as Acceptable Daily Intake (ADI), which is provided by risk assessment.

At the same time, results from residue studies are also applied. It is quite important to understand that MRLs are established based on the information on actual application of agrochemical.

THE SO-CALLED "POSITIVE LIST SYSTEM" ON AGROCHEMICAL RESIDUE IN FOOD

Japan has specified the introduction of a new system for agricultural chemical residues in the revised Food Sanitation Law. The system, positive list system, aims to prohibit the distribution of foods that contain agricultural chemicals such as pesticides, veterinary drugs and feed additives unless their MRLs are established under the Food Sanitation Law

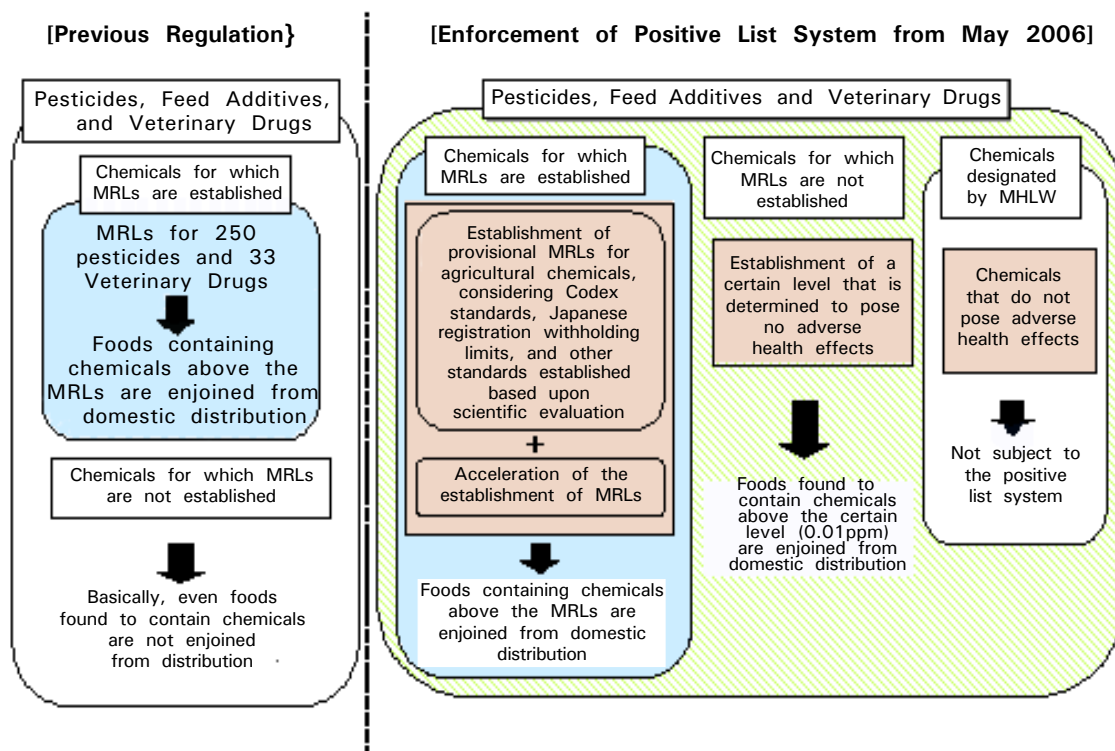


Fig. 5. Positive List System for Agricultural Chemical Residues

(Fig. 5 and Table 2). This system came into effect on May 29, 2006. A certain level of 0.01ppm is uniformly applied to chemicals for which MRLs are not established. Japan has developed provisional MRLs based upon Codex, registration withholding limits, and foreign MRLs as an interim measures to protect consumer health as well as to facilitate food distribution.

Japan has been working to develop provisional MRLs as an interim measure. The provisional MRLs are applied from the enforcement of the positive list system up to the time their formal MRLs will be established based on the regular procedure (Table 3). This measure is taken to prevent the possibility of the foods that have been allowed to be distributed would be unfairly treated after the introduction of the system because no MRLs were established. Provisional MRLs also targets chemicals which certain MRLs, such as Codex MRLs, have already been established based on sound science. These chemicals include pesticides that are permitted to use in Japan under the Agricultural Chemicals Regulation Law.

In October 2003, the MHLW proposed

the first draft of the provisional MRLs for the positive list system as well as requested comments on it. The provisional MRLs for 647 agricultural chemicals, including veterinary drugs, are proposed. Around 1,200 comments from domestic and foreign parties were received. On August 2004, the MHLW published the second draft of the provisional MRLs; and incorporated some comments from the first draft. This time they requested comments from the foreign governments, consumers and industry sectors. The MHLW submitted the proposed MRLs to the World Trade Organization (WTO) in accordance with the WTO SPS agreement on June 2005. On November 2005, the Japanese Government published the final version of provisional MRLs in Official Gazette for enforcement.

Since the agricultural chemicals such as pesticides and veterinary drugs are allowed to use during the production with authorization based upon the evaluation concerning human health and in some case the substances' appropriate application to meet the limit of residues in foods, the default level in the Japanese positive list system for agricultural chemicals applies cases like residue from

Table 2. Summary of the Positive List System for Agricultural Chemical Residue in Food

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- Residues in foods resulting from the use of Veterinary Drugs, Feed Additives and Pesticides.
 - Food in which residue of agricultural chemical exceeds a certain level, "Default Level", shall not be marketed. But the case that the MRL for the residue is established and the residue level does not exceed the MRL is exclusive.
 - The regulation applies to domestic and import foods.
 - The regulation is enforced from 29 May 2006.
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Table 3. Substances for which MRLs are currently established after the Government Notifications

- Newly Established include	15 substances as "Not Detected" 743 substances as "MRLs"	758 Substances
- Unchanged as existing MRLs		41 Substances
	Total	799 Substances

Note: The existing MRLs for the 758 substances for which MRLs were newly established this time were unchanged.

unauthorized substance or unauthorized application.

“Default Level” in Japanese Positive List System

The Pharmaceutical Affairs and Food Sanitation Council have discussed the default level for a risk management option on agricultural chemical residues in foods. It evaluates the toxicological thresholds of various substances and exposures through food consumption. During the discussion of the toxicological thresholds, the Council reviews the report on the forty-fourth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) concerning the safety evaluation of flavoring substances in 1995 and the 1995 food contact articles about the US Federal Registers on threshold of regulation for substances. These two documents conclude that the thresholds of human exposure to substance at less than 1.5µg/person/day would be reasonable to protect human health from substances in foods.

The council also reviews the ADIs set by the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) and the MHLW, as well as exposures to the substances. While the Council

has not reached any conclusion, 0.01 ppm as the default level in the Japanese positive list system for agricultural chemicals would not result human exposure to a substance exceeding 1.5µg/person/day.

The Commission of the European Communities proposed a regulation on MRLs of pesticides within plant and animal products in 2003. The regulation states that the products shall not contain any pesticides residue exceeding 0.01mg/kg active substances for products in which no specific MRL is set.

Import Tolerance

Petition for establishment and/or revision of MRLs by agrochemical producer Contribution from Foreign Government to Review process. As described in the previous section, MRL of an agrochemical is based upon residue data from laboratory trials on certain application of the substance. Since prevalence of plant diseases and pests are different in every part of the planet, application of a particular substance to a particular plant would be different. In addition, a substance newly registered in a country may be introduced. In some case, the MRLs in the Japanese Food

A Guideline on application for the establishment and revision of the Japanese MRL for the residues of agricultural chemicals used outside Japan.

Notification No. 0205001, 5th February 2004
 from Director-General, Department of Food Safety, MHLW

For further information:
<http://www.mhlw.go.jp/english/topics/foodsafety/dl/importguideline.pdf>

Fig. 6. A Guideline for "Import Tolerance"

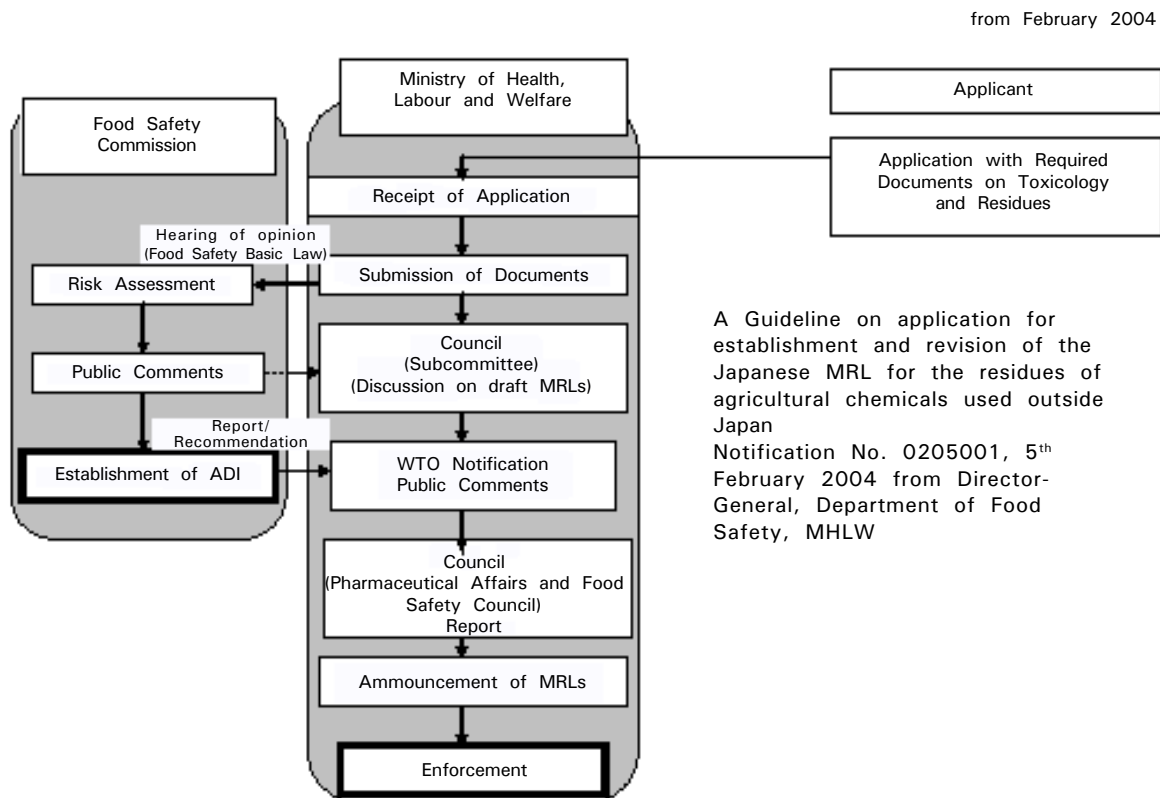


Fig. 7. Establishment of Import MRL/Tolerance

Sanitation Law may not be good enough for imported products due to the difference of agrochemical applications in Japan and in other countries. In this case, such product may not be introduced to Japan. Therefore, MHLW issued a guideline for "Import Tolerance" in 2004 (Fig. 6 and Fig. 7). It guides agrochemical producers on how to make petition for establishment or revision of Japanese MRLs in 2004. The requirement of documentation and information of an import tolerance application and the administration process for its establishment are same with the case of

domestic application.

Provisional MRLs, which are established when Japanese Positive List System starts, are under review process of the Food Safety Commission (FSC). Over 700 substances, for which provisional MRLs were established, are scheduled to be assessed for five years starting 2006. MHLW has been seeking for assistance from foreign authorities or agrochemical companies to provide information on the substances like toxicology and residue trials for FSC assessment.

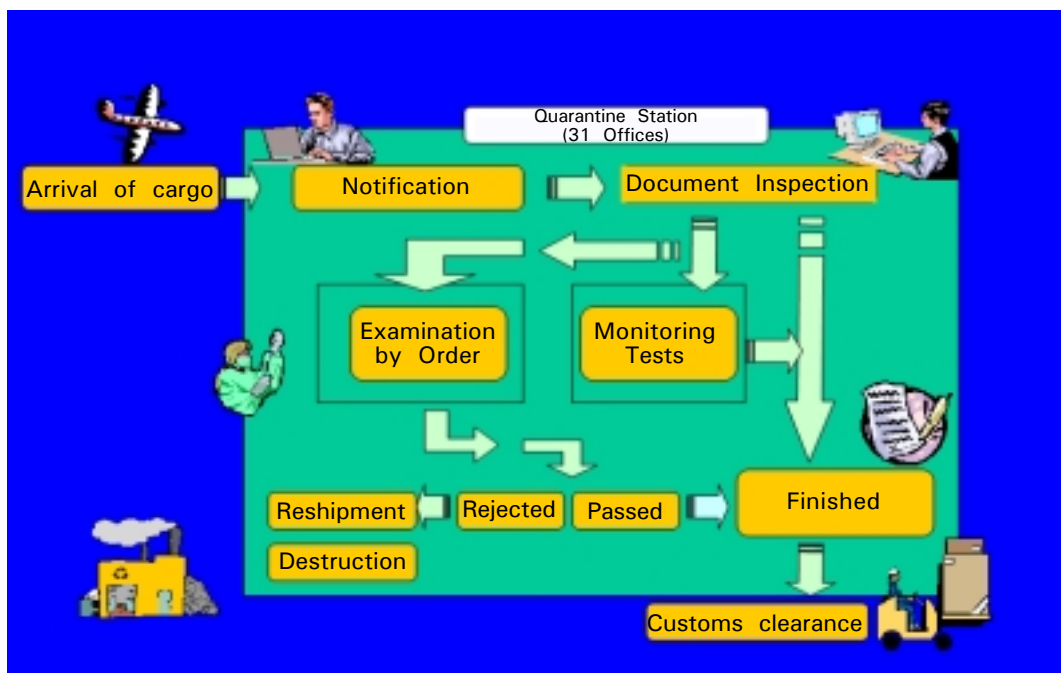


Fig. 8. Import Food Inspection at Port

FOOD SAFETY INSPECTION ON IMPORTED FOOD

According to the provision of the Food Sanitation Law, every shipment of food products imported in Japan is required to be notified to the Minister of Health, Labour and Welfare. For this purpose, 31 quarantine offices are located at major airports and seaports (Fig. 8). The figure below shows the procedures of import food inspection at a quarantine office. Every fiscal year, MHLW develops a plan for official inspection in accordance with the provision of the Food Sanitation Law. It includes monitoring on agrochemical residue in food.

Around 1.85 million notifications were received in 2006. It counted more than 31 million metric tons in volume. Quarantine office has conducted 80 thousand inspections including laboratory tests on agrochemical residues and 100 thousand examinations by order in which importers were legally required to provide evidence to the quarantine office about the compliance of their products on Japanese requirements. Among these inspections and examinations by order, 1,500 of noncompliance to the Japanese requirements including 455 in agrochemical residues and 246

in veterinary drug residues were found in 2006. Once noncompliance of the product was found in inspection by the quarantine office or by test order, the product is prohibited to be imported and marketed in Japan.

Non-compliance in agrochemical residue to Japanese food safety standard in the Food Sanitation Law would not always result to health issues. However, since non-compliance cases of residues counts more than other cases of food safety, agrochemical residue issue is the major concerns of food traders as well as the Japanese population.

More detailed information is available on the Internet. You may consult the MHLW homepage for import food inspection service at <http://www.mhlw.go.jp/english/topics/importedfoods/index.html>

The MHLW issues a databook on monitoring results on agrochemical residues in food every year. Quarantine offices and local government monitor residues in food and the result is reported to the MHLW. According to our databook, portion of food in which residue is found is not substantial.

CONCLUSION

It is recommended to take any necessary

measures for food safety throughout the entire food chain. When we deal with agrochemical residue in food, the only way to take necessary measures to manage agrochemical usage during production. There should be a protocol for appropriate use of agrochemical such as Good Agriculture Practice (GAP) and instruction for farmers or for others who apply agrochemical for production. Such protocol includes variety of products, concentration, frequency and duration after last application. The instruction can include a practice to protect farmers during application. To develop GAP expertise on agriculture, toxicology and biology are required.

Regulatory system to control agrochemical use during production is required. Agrochemicals registration, importation and/or marketing of them, as well as the use of the substances should be regulated. The substance, which has not been evaluated and authorized, should not be marketed and should be prohibited for use during production. These regulations should include requirements of food safety to control limits of residues in food. It is also required to have resources to enforce the regulation. Resources involve technical experts, laboratory service and legal service.

Having good regulatory system in country, it should be recognized that private

sectors from production up to retail and trade have responsibility to comply their products with the requirements. Activities like keeping production records that includes application of agrochemicals, and corrective measures if required as well as monitoring these activities should be performed. It must be aware that the product of another country must comply with the food safety requirement here in our country. Every effort for this objective should be primarily taken by the private sector.

Finally, transparency of the above mentioned activities is required. In particular, information on the registered agrochemicals including details of requirements in application of those chemicals during production should be provided to the personnel who apply for them. Appropriate labeling on agrochemicals may help provide information to the required personnel.

In addition, communication among sectors in production, retail, trade, laboratory service and government agency of Japan and other countries should be encouraged. In case there is a violation against residue requirement by a foreign country, communication between that particular country and Japan would be the only way to find the cause of the problem and resolve it.