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Summary of Japan's New Positive List System for Regulation of Agricultural Chemical Residues

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Approved by:

Rachel Nelson
U.S. Embassy

Prepared by:

Tetsuo Hamamoto

Report Highlights:

Japan will implement new regulations on May 29, 2006 for residues of agricultural chemicals in food. Japan's Ministry of Health, Labor and Welfare (MHLW) established provisional Maximum Residue Levels (MRLs) for 758 agricultural chemicals, in addition to existing MRLs, and a uniform limit of 0.01 ppm for residues not on the list. After the implementation of the positive list regulation, foods containing residues exceeding the MRLs on the list, or 0.01 ppm in cases where there are no MRLs established, will be prohibited in Japan. With these new regulations, MHLW will not change its monitoring plan for imported foods, except that each sample will be tested for more residues. The same number of samples will be taken and there will be no new documentation or data requirements from MHLW after the implementation, however some importers are asking for additional information.

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Table of Contents

Executive Summary	3
Background	3
MHLW chemical residue policy until May 29, 2006	3
Introduction of positive list regulation	4
Time table	4
Regulation based on positive list MRLs	5
Maximum residue limits	5
Processed foods	5
Uniform limit	6
Exempted substances	6
Agricultural Chemicals that shall not be detected in any food	7
Request for establishment of new MRLs	7
Surveillance/testing program for pesticide residues in imported foods under the positive list regulation	7
General policy for monitoring and testing of imported foods	7
Actions to be taken when residues are found above the MRL	8
Agricultural chemical residue testing after introduction of the positive list regulation and additional requests from importers	8
The coordinates of relevant offices and online information	9

Note: This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service at the U.S. Embassy/Tokyo for exporters of U.S. agricultural products. While great care was taken in preparation of this report, information provided may not be completely accurate due to either changes in policies since its preparation, or because clear and consistent information about these policies was not available at the time of publication. U.S. Exporters are highly recommended to verify the relevant import requirements with their foreign customers, who normally have the most updated information on local requirements, prior to exportation. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

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Executive Summary

On May 29, 2006 Japan will implement new regulations on residues of agricultural chemicals, feed additives and veterinary drugs (hereinafter referred to as agricultural chemicals) in food. To implement the new regulation, Japan's Ministry of Health, Labor and Welfare (MHLW) announced the provisional MRLs for 758 agricultural chemicals on November 29, 2005, in addition to around 10,000 existing official MRLs. Those new provisional MRLs will remain "provisional" until they are reviewed. After a risk assessment of a provisional MRL is completed, an official MRL can be established. Together the existing MRIs and the provisional MRIs make up the "positive list". After the implementation date, foods containing residues exceeding the MRL levels on the positive list will be regarded as violations of the Food Sanitation Law and will be prohibited from being sold or used as food in Japan. MHLW established a uniform limit of 0.01 ppm, which will be the maximum allowable limit for combinations of chemicals and commodities that have no official or provisional MRLs. MHLW also listed 15 chemicals for which no residues may be detected because of high human health risks, and 65 substances used as agricultural chemicals for exemption from the regulation. MHLW established provisional MRLs on some processed foods besides raw commodities, mainly by adopting the Codex standards. For residues in processed foods without provisional MRLs, MHLW will use the provisional MRLs of raw ingredients after converting them based on water content and taking into consideration concentration ratios. With these new regulations, MHLW will not change its monitoring plan for imported foods, except that each sample will be tested for more residues. The same number of samples, however, will be taken and there will be no new documentation or data requirements from MHLW after the implementation.

Background

MHLW chemical residue policy until May 29, 2006

In Japan there are two major laws pertaining to food safety and standards; the Food Safety Basic Law and Food Sanitation Law. The Food Safety Basic Law sets the principles for developing a food safety regime and the role of the Food Safety Commission (FSC), a food related risk assessment body (for details, please see JA3029). The Food Sanitation Law ensures the safety and sanitation of foods by the Ministry of Health, Labor and Welfare (MHLW), a food risk management agency. The law prohibits the sale of foods containing poisonous or harmful substances. It also prescribes the standards for foods, additives, food apparatus and container packages, and certain toys. The law is available in English on the

Japan External Trade Organization (JETRO) website (<http://www.jetro.go.jp/en/market/regulations/>).

MHLW maintain a list of maximum residue levels (MRLs) for pesticides. As of November 2005, there were about 10,000 MRLs established for 250 pesticides and 33 veterinary drugs and feed additives on about 130 commodities. Each year, MHLW reviews a number of substances for the purposes of establishing MRLs.

Until May 29, 2006, MHLW will have a negative list system for pesticide and veterinary drug residues. That means that crops containing pesticides without MRLs may be distributed in Japan unless they are thought to pose a health hazard. To be regarded as such, residues on products without an MRL listed in the present list

must be safe, usually meaning that the residue levels are below either Codex or the exporting country standards - whichever is stricter. For a full list of existing MRLs, please refer to "Specifications and Standards for Foods, Food Additives, etc. Under The Food Sanitation Law" on the JETRO website: <http://www.jetro.go.jp/en/market/regulations/>. The website is updated once every year or two, as necessary. There is also a useful website for the list of food additives, residue chemical limits, and specifications for packaging and containers (<http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/eng.h-page>). MHLW has an English website that contains some food safety information (<http://www.mhlw.go.jp/english/topics/foodsafety/index.html>). The websites are also updated on an as needed basis.

Introduction of positive list regulation

As a response to a revision of the Food Sanitation Law on May 30, 2003, MHLW is in the process of changing the way it controls farm chemicals. Under the new legislation, MHLW is adopting a regulation similar to that used in the United States, featuring a "positive list" with maximum residue limits (MRL) for specific residues. Produce with pesticide with pesticide residues exceeding these MRL's or residues exceeding the default tolerance of the "uniform limit" (0.01 ppm) for those products for which there is no MRL, cannot be marketed in Japan and they will be rejected at the port after implementation of the new regulation. Since the release of the first draft of provisional pesticide maximum residue limits (provisional MRLs) by MHLW in the fall of 2003, there have been two revised drafts issued and the final provisional list was issued on November 29, 2005. All products sold in Japan, including imports, will have to comply with the currently established official MRLs or the provisional MRLs (*together, called the "positive list"*) beginning on May 29, 2006. Any residues not on the positive list will be illegal after May 29, 2006. MHLW will use the provisional MRLs until establishment of official MRLs based on full risk assessments for individual agricultural chemicals.

Time table

Below is the timetable for implementation of the positive list by MHLW.

May 30, 2003	Promulgation of revised Food Sanitation Law, requiring the establishment of a positive list
October 28, 2003	Announcement of the first draft of the provisional MRL list
August 20, 2004	Announcement of the second draft of the provisional MRL list

June 3, 2005	Announcement of the final draft of the provisional MRL list
November 29, 2005	Announcement of the final provisional MRL list
May 29, 2006	Implementation of the provisional MRLs
After 2006	Review and risk assessment of the provisional MRLs by the Food Safety Commission to establish official MRLs that replace the provisional ones

Applicability of the new positive list for imported foods

Raw commodities and fresh produce	Those on the market on or after May 29, 2006 (regardless of import date)
Processed foods	Those manufacturing/processing completed on or after May 29, 2006
Raw ingredients to be used in processed foods in Japan	Processed foods whose manufacturing/processing completed on or after May 29, 2006 (regardless of import date of raw ingredient)

Regulation based on positive list MRLs

Maximum residue limits

The 10,000 official MRLs currently established by MHLW will remain effective after the implementation of the positive list. The MRLs can be viewed in the JETRO website: <http://www.jetro.go.jp/en/market/regulations/>.

The provisional MRL list is available in Japanese at the MHLW website: (<http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/zanryu2/dl/051129-1c.pdf>). An English version of the list is expected to be available by MHLW in February 2006. When the English version is released we will issue a GAIN report like this, containing instructions on how to find the information. The list is arranged by chemical. The Japan Food Hygiene Association announced that it would publish the list, although in Japanese only, as a CD-ROM in February. The MRLs can be sorted by commodity using the CD-ROM. The CD-ROM can be purchased from the Association's website (<http://www.n-shokuei.jp/>) once it is released. However, it is readable only on the Japanese Windows Operation System (not compatible with English Windows OS).

MHLW will ask the Food Safety Commission (FSC) to review the provisional MRLs, starting from those considered a high priority. FSC plans to perform risk assessment of around 150 chemicals per year for five years to complete the review of all 758 provisional chemicals. The provisional MRLs will be replaced by official MRLs after the review and risk assessment by the FSC.

Processed foods

MHLW established provisional MRLs on processed foods for those that already have established Codex standards, including those for bottled water. For processed foods and chemicals with no provisional MRLs, MHLW will apply MRLs of raw ingredients after adjusting for things like water content, taking into consideration processing steps such as concentration. For example, if a juice is 8-times concentrated, 8-times the MRLs of its raw produce will apply.

Uniform limit

The Uniform limit is the maximum allowed level applied to agricultural chemical residues for which official or provisional MRLs are not established. The uniform limit is set at 0.01 ppm based on studies and information by Codex/JECFA/JMPR and other countries including USFDA.

For 95 chemicals for which thresholds of detection by their testing methods are above the uniform level, the detection threshold levels will be used instead of 0.01 ppm.

For 47 agricultural chemicals listed below for which MRLs below the uniform limit are established for some crops, the lowest level among those established for the agricultural chemicals in question is employed as provisional MRLs for those other than crops with specific MRLs.

Abamectin (0.008 for A, 0.005 for L), Altrenogest (0.003 for L), Amoxicilin (0.008 for L), Ampicillin (0.009 for L), Azoxystrobin (0.008 for L), Benzylpenicillin (0.004 for L), Betamethasone (0.0003 for L), Bilanafos (0.004 for A), Brotizolam (0.001 for L), Carazolol (0.001 for L), Clenbuterol (ND for L), Dexamethasone (ND for L), Diflufenican (0.002 for A), Diphenylamine (0.0004 for L), Dipropyl isoinchomerone (0.004 for L), Doramectin (0.005 for L), Emamectin benzoate (0.0005 for L), Endosulfan (0.004 for L), Endrin (ND for A, 0.005 for L), Ethoprophos (0.005 for A), Ethylene dibromide (EDB) (ND for A), Etyprostontromethamine (0.001 for L), Fenamiphos (0.005 for L), Fenpyroximate (0.005 for L), Fenthothion (0.002 for L), Fipronil (0.002 for A), Flumethrin (0.005 for L), Heptachlor (0.006 for L), Methidathion (0.001 for L), Metoclopramide (0.005 for L), Lindane (γ -BHC) (0.002 for A), Nafcillin (0.005 for L), Norgestomet (0.0001 for L), Prednisolone (0.0007 for L), Propoxycarbazon (0.004 for L), Sulfosulfuron (0.005 for L), Tefluthrin (0.001 for L), Terbufos (0.005 for A), Triazophos (ND for A), Tribuphos (0.002 for L), Trichlorfon (0.004 for L), Trifluralin (0.001 for L), Zeranol (0.002 for L),

Note: Figures in ppm, A for agricultural products, L for livestock products, and ND for no detection.

Exempted substances

The 65 substances listed below are designated as exempted from the positive list regulation, because they do not show any adverse effects to human health. The list may be revised as new scientific information becomes available.

Ascorbic acid, Alanine, Allicin, Ammonium, β -Apo-caroteneethylester, Arginine, Asparagine, Astaxanthin, Azadirachtin, Barium, Biotin, Calciferol, Calcium, β -Carotin, Chlorella extract, Chlorine, Choline, Cinnamaldehyde, Citric acid, Coparamin, Copper, Diatom earth, Folic acid, Glycine, Glutamine, Histidine, Hydroxypropyl starch, Inositol, Iodine, Iron, Lactic acid, Lecithin, Leucine, Machine oil, Magnesium, Menadione, Methionine, Marygold pigment, Mineral oil, Niacin, Neem oil, Oleic acid, Pantothenic acid, Paprika color, Paraffin, Potassium, Propylene glycol, Pyridoxine, Retinol, Riboflavin, Selenium, Serine, Shiitake mushroom

mycelia, Silicon, Sodium bicarbonate, Sulfur, Sorbic acid, Tartaric acid, Thiamine, Tocopherol, Tyrosine, Urea, Valine, Wax, Zinc

Agricultural Chemicals that shall not be detected in any food

The 15 agricultural chemicals listed below shall not be detected in any food based on their high risk to human health.

2,4,5-T, Amitrole, Captafol, Carbadox including QCA, Chloramphenicol, Chlorpromazine, Coumafos/Coumaphos, Cyhexatin and Azocyclotin, Daminozide, Diethylstilbestrol, Dimetridazole, Metronidazole, Nitrofurans, Propham, Ronidazole

Request for establishment of new MRLs

MHLW will establish new official MRLs as new chemicals and applications are approved in Japan. MHLW establishes MRLs on each pesticide mainly based on scientific data and information provided by its manufacturer. The information used to make this determination includes its range and scope of use, such as registered crops and approval status in other countries.

However, since MHLW will not be able to monitor and establish MRLs for all chemicals approved around the world, particularly for those not used in Japan, MHLW published the "Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used Outside Japan" as a general guidance for foreign entities to apply for new MRLs. The guideline is listed in the MHLW website: (<http://www.mhlw.go.jp/english/topics/foodsafety/residue/index.html>)

Relevant industry groups are encouraged to apply for a Japanese MRL when new MRLs, including those under the Section 18 emergency tolerances, are established in the U.S.

Surveillance/testing program for pesticide residues in imported foods under the positive list regulation

General policy for monitoring and testing of imported foods

Quarantine offices (for imported crops) and local laboratories in municipalities (for domestic crops) conduct monitoring tests for pesticides for which MRLs are established. The purpose of the monitoring tests is to check whether crops in the marketplace comply with established MRLs. Any product found to contain a substance in excess of an established MRL must not be marketed in Japan.

At ports, MHLW normally monitors between 3-10% of imports for antimicrobials, chemical residues, food additives, microorganisms, fungal toxins and unapproved genetically modified products. The annual monitoring plan announced for each fiscal year includes testing of samples for antimicrobials, residue chemicals, food additives, microorganisms, fungal toxins and unapproved genetically modified products. A half of the total samples are for testing chemical residues (agricultural chemicals and antimicrobials).

For imported foods, MHLW has different levels of testing and regulating schemes. First is the normal monitoring described above. Then if MHLW finds two or more violations or problems with a certain imported food, it imposes testing-by-order (which means 100% of that product is held at the port for testing, at the cost of the importer). Finally, if MHLW finds the problem

persists, it may implement a comprehensive ban of imports from the origin or the persistent problem.

MHLW has been conducting surveys of residues, including pesticides without MRLs, to obtain basic data for the establishment of MRLs. The monitoring test results typically show that less than 0.1% of the samples tested were above the established MRLs. The monitoring test plans and results are made available to the public on the MHLW Japanese website.

Details of testing programs for imports are summarized in the Gain Report JA4005.

Actions to be taken when residues are found above the MRL

Crops not meeting the standards and specifications of the Food Sanitation Law, including MRLs, were discarded, re-exported, reconditioned, or otherwise disposed of.

When monitoring test results reveal a violation, the first consequence is usually that monitoring of the same product from the same country of origin is increased by a factor of 10, usually to 50%. If a second violation is found under the increased monitoring program, testing-by-order is triggered for the food product. Depending on the ability to trace back the product, the testing-by-order may apply to an exporting country, a region, or a specific producer or manufacturer. When a human health-related incident occurs or serious health hazard is strongly suspected from an imported food, one violation under the monitoring program can trigger testing-by-order. If MHLW finds the problem persists, it may implement a comprehensive ban of imports.

Testing-by-order is a mandatory testing program under which each shipment has to be held until the test result show that the product is not in violation. Tests under testing-by-order are performed at one of the designated domestic laboratories at the expense of the importer.

MHLW lifts the order of testing when it is confirmed that no violating foods are being exported due to appropriate measures that prevent the same incident from occurring again from the exporting country, region, manufacturer or processor.

A comprehensive ban may be considered by MHLW if "there are a considerable number of violations (over 5% violation ratio for the most recent 60 samples under the testing-by-order for imported foods) or human health hazard occurrence or situations that have a potential of adulterating foods (e.g., radioactive contamination from a nuclear plant accident). The ban will only be imposed after consultation with the exporting country, an investigation of production or manufacturing finds a potential hazard, and the relevant expert committee (the Pharmaceutical and Food Sanitation Committee) affirms the ban.

Agricultural chemical residue testing after introduction of the positive list regulation and additional requests from importers

There will be no changes in the annual monitoring and testing plan by MHLW after the implementation of the positive list regulation on May 29, 2006. Therefore, the frequency of sampling and the number of samples for chemical residue tests under the annual monitoring plan will not change. However, MHLW may test for more chemicals on each sample after the implementation of the positive list regulation. Again, this shall have no effect on the number of samples taken.

MHLW does not require new paper or audit trails to verify compliance of the new regulation either. MHLW thus does not require any documentation on the compliance on either raw commodities, fresh produce or processed foods.

There may be requests, however, from some importers in Japan for data or documentation to help them determine whether or not the imported products are in compliance with the new positive list regulation. This might include requests for information on pesticides used, test data for one or several shipments after the implementation of the new law in May, or written assurances that the products will comply fully with the new law. Some importers will be comforted by having such data or documentation in their hands. It is entirely a business decision whether or not to provide such information or data since it will not be required by Japanese law. In some occasions, it may be helpful to provide the information, or explain production and processing practices, in order to limit the scope of testing done by Japanese importers.

The coordinates of relevant offices and online information

The United States Department of Agriculture, Foreign Agricultural Service provides assistance to U.S. exporters and may be able to help identify relevant local contacts for additional information.

In Japan: Office of Agricultural Affairs
U.S. Embassy, Tokyo
Tel: 81-3-3224-5102
Fax: 81-3-3589-0793
Email: agtokyo@usda.gov

In the United States:
Food Safety and Technical Services Division
USDA-FAS
Washington, DC
Tel: (202) 720-1301
Fax: (202) 690-0677
Email: OFSTS@fas.usda.gov

Additional Information on food safety regulations in Japan including those on pesticide residues can be found at the following places:

The JETRO information website:
(<http://www.jetro.go.jp/en/market/regulations/http://www.jetro.go.jp/en/market/regulations/>)

The Japan Food Chemical Research Foundation website:
(<http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/eng.h-page>).
MHLW' English website that contains some food safety information:
(<http://www.mhlw.go.jp/english/index.html>)
(<http://www.mhlw.go.jp/english/topics/foodsafety/index.html>)

Responsible Division in the Japanese Ministry of Health, Labor, and Welfare:

Standards and Evaluation Division
Department of Food Safety
Ministry of Health, Labor and Welfare
1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8916
Japan
Fax: 81-3-3501-4868