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Guide to Compliance with the Japanese Positive List

by

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I. Executive Summary

Effective May 29, 2006, the Japanese authorities implemented new regulations for maximum residue limits ("MRLs") of approximately 800 agricultural chemicals in foods imported into Japan. These new MRLs, together with approximately 10,000 existing MRLS already established by the Japanese government, are known as the "positive list." All foods and food components must comply with the Japanese positive list or risk penalties ranging from delays at the border to an outright ban. While the responsibility for compliance rests with the importer of record, companies should implement their own compliance plans in order to avoid costly delays and satisfy themselves that the risk of noncompliance is low.

It is impractical to test a company's food products for the presence of all 10,800 chemicals on the positive list. Therefore, a company should create a compliance plan that:

1. Assesses the risk of noncompliance for each of its food products or components of food products that will be exported to Japan;
2. Obtains adequate assurances from its suppliers that materials sourced from these suppliers will comply; and
3. Clearly outlines when more costly compliance measures like pre-certification or pre-testing by the Japanese authorities are necessary.

II. Background

Due to its population of approximately 125,000,000 and limited area available for agriculture, Japan is a major importer of agricultural products.[1] Each year Japan imports over $30 billion or $34 million tons in agricultural products.[2] Of those, approximately one-third of those imports originate from the United States, the leading supplier of Japan's agricultural imports.[3] In order to ensure the safety of these imports, Japan has enacted three major food safety and standards laws: 1) The Food Safety Basic Law; 2) Japan Agricultural Standards Law; and 3) The Food Sanitation Law[4].

The Food Safety Basic Law creates the Food Safety Commission, a food related risk assessment body. It also creates the guidelines for developing a food safety scheme.[5] The Japan Agricultural Standards Law ("JAS") establishes standards and labeling regulations for agricultural and forestry products,[6] and the Food Sanitation Law establishes the role of the

[1] USDA, "Briefing Room-Japan," 3/20/08 (www.ers.usda.gov/briefing/Japan/).
[2] *Id.*
[3] *Id.*
[4] USDA Foreign Agricultural Service, GAIN Report JA6046, at 3 (Sept. 15, 2006).
[5] *Id.*
[6] Ministry of Agriculture, Forestry and Fisheries of Japan, "Overview of the Revised JAS Law", at 2 (February, 2007).

Japanese Ministry of Health, Labor and Welfare ("MHLW"), a food risk management agency, for ensuring the safety and sanitation of food.[7] Pursuant to Article XI, paragraph 1 of the Food Sanitation Law, the MHLW has the authority to create maximum residue limits in foods for pesticides, feed additives, and veterinary drugs, all of which are collectively referred to as "agricultural chemicals."[8]

III. The "Positive List"

Effective May 29, 2006, the MHLW implemented new regulations on the permissible MRLs of agricultural chemicals in food. In establishing these new regulations, the MHLW supplemented approximately 10,000 already existing official MRLs of agricultural chemicals with seven hundred and fifty eight "provisional" MRLs[9]. Together, these MRLs make up the Japanese "positive list."[10] All foods entering Japan are subject to regulation under the positive list system.[11] Foods containing residues exceeding the MRL levels identified on the positive list are prohibited from being sold or used as food in Japan because they violate the Food Sanitation Law.[12] Failure to comply with these MRLs could result in a product's being banned or the exporter incurring significant expense and time delays while trying to clear the product for importation.[13]

The positive list's regulatory scope is limited to the residual agricultural chemicals in food and does not add, remove or modify existing Japanese food additive regulations. Substances that are both food and feed additives will be subject to both the positive list regulatory scheme, as well as the standards under food additive regulations.

The positive list mechanism introduces four basic classifications of agricultural chemicals: 1) chemicals that are subject to specific residual limits; 2) chemicals that are known to pose no significant risk and are therefore not subject to any residual limitation; 3) prohibited agricultural chemicals that may not be detectable in foods in any amount; and 4) chemicals for which no item specific limit has been established and are therefore subject to a "uniform" limit. Any residues that are not included in the positive list are illegal.[14]

For the first classification, the MHLW sets specific but provisional MRLs on processed foods that did not have existing MRLs by taking into consideration, among other factors, Codex Alimentarius' MRLs for these products.[15] Food products for which the specific imported material is not given a residue limit are subjected to the requirements established for the product or commodity from which they were derived. In other words, processed foods without provisional MRLs rely on the MRLs of raw ingredients after converting the raw ingredients based on water content and accounting for concentration ratios. For example, if a finished product is five times concentrated, five times the MRLs of its raw commodity will apply.[16] The second classification is comprised of 65 exempt substances that are subject to change as new scientific information

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[7] USDA Foreign Agricultural Service, GAIN Report JA5040, at 3 (Aug. 1, 2005). The Food Sanitation Law is accessible on the Japan External Trade Organization website: **http://www.jetro.go.jp/en/market/regulations/**.
[8] USDA Foreign Agricultural Service, GAIN Report, JA7033, at 2 (May 24, 2007).
[9] USDA, GAIN Report JA6046, at 8.
[10] *Id.*
[11] Actual MRLs in positive list listed at **www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/index.html**.
[12] *Id.*
[13] USDA Foreign Agricultural Service, GAIN Report, JA7043, at 8 (Aug. 14, 2007).
[14] USDA Foreign Agricultural Service, GAIN Report JA6004, at 4 (February 6, 2006).
[15] *Id.* at 3.
[16] *Id.* at 6.

becomes available.[17] The third classification includes 15 chemicals for which residues are strictly prohibited and may not be detected in any level due to their association with high human health risks.[18] For the fourth classification---chemicals that have no official or provisional MRLs---the MHLW has established a uniform limit of 0.01 ppm.[19] If technology is not sufficient to detect chemicals at the 0.01 ppm limit, the appropriate MRL is then set at the lowest level at which they are detectable.[20] There are even more stringent requirements, set below the uniform limit for certain crops in place, for forty-seven additional agricultural chemicals. These provisional MRLs were established by using the lowest MRL acceptable in other crops with specific MRLS established for these chemicals.[21]

The positive list regulation is further complicated by the fact that each ingredient of a processed food without a provisional MRL must be compliant with the residual limits applicable to that ingredient, rather than requiring the processed food as a whole comply with a single general MRL requirement.[22] Thus, processed food products may not be imported into Japan unless each and every one of its component ingredients is compliant with the established limitations.

The positive list is evolving and ever changing, which also adds to its regulatory complexity. Over the next several years, risk assessments on approximately 150 chemicals per year will be performed by the Food Safety Commission on the “provisional” MRLs in order to establish “official” MRLs for these substances.[23] Such assessments will result in changes to published MRLs. For example, on May 21, 2007, the MHLW announced proposed changes to the MRLs for cyflumetofen, dimethomorph, flufenoxuron, dinotefuran, difloxacim, dramectin, and avoparcin.[24] Similarly, veterinary drugs once approved for use in Japan must be reassessed every six years, including a review by the MHLW on existing MRLs for these substances.[25] Additionally, the MHLW will set "new official MRLs as new agricultural chemicals and applications for approvals for pesticides are accepted in Japan."[26] These MRLS will be based on scientific data, the range and scope of the pesticide's use, including approval status in other countries, and manufacturer information.[27] Based on the ongoing activities by the Japanese authorities in response to ever-changing data and requests for establishment of MRLs not on the list, the positive list will need continuous monitoring as provisional MRLs are changed or new ones are established by the MHLW.

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[17] *Id.* (See Exhibit A).
[18] USDA Foreign Agricultural Service, GAIN Report JA6046, at 8 (April 3, 2006) (See Exhibit B).
[19] Based on analyses and information from Codex Alimentarius, JEFCA and regulatory agencies including the USFDA., *Id*., at 8.
[20] GAIN Report JA6004, at 6.
[21] Id. (See Exhibit C).
[22] USDA Foreign Agricultural Service, GAIN Report JA7043 at 8 (August 14, 2007).
[23] GAIN Report JA6046, at 8; GAIN Report JA6004, at 5.
[24] USDA Foreign Agricultural Service, GAIN Report, JA7033, at 2 (May 24, 2007).
[25] *Id*. at 15 (May 24, 2007).
[26] GAIN Report, JA6004, at 7; (For details regarding the establishment and/or revision of MRLs for pesticides see: **http://www.mhlw.go.jp/english/topics/foodsafety/residue/index.html**.).
[27] GAIN Report, JA6004, at 7; USDA Foreign Agricultural Service, GAIN Report, JA6030, at 2 (June 23, 2006). (See **www.mhlw.go.jp/english/topics/foodsafety/residue/index.html** for the MHLW publication "Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used Outside Japan") and new information regarding analytical methods can be found at **www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/dl/060526-1a.pdf**.

IV. Testing for MRLs Established by the Positive List

Currently, the Food Sanitation Law requires that the MHLW create a monitoring test plan for each fiscal year.[28] In creating the plan, the MHLW's monitoring inspection system selects items subject to monitoring inspections based on the annual import total and each product's record of noncompliance in the past.[29] The monitoring inspection system's purpose is to collect data on the sanitation status of the many food items imported into Japan to avoid problems in the distribution of these items.[30] This annual monitoring plan includes the testing regime for samples, half of which are tested for agricultural chemical residues.[31]

Japan has three levels of at-the-border testing programs for imported foods: monitoring, testing-by-order, and a comprehensive ban.[32] Presently, quarantine offices and local government laboratories perform monitoring tests for pesticides and veterinary drug residues on imported foods.[33] After monitoring test results show a violation by a product, the Japanese authorities implement testing at the border for approximately 50% of the problem product from the same manufacturer.[34] At this stage, the MHLW bears the cost of testing.[35] If this increased monitoring reveals a second violation, testing-by-order is implemented for the problem product.[36] When testing-by-order is required, all imports of the problem product are held at the border for testing at the importer's expense.[37] Testing-by-order typically delays the product's entry into Japan by between one and three weeks.[38] The testing-by-order is lifted when appropriate measures have been implemented to prevent reoccurrence of the problem, and as a result, no foods in violation of the positive list are being exported.[39] The final level, a comprehensive ban, may be imposed on countries, regions or companies when the MHLW finds that the results of testing-by-order reveal a rate of violation of greater than 5%.[40] Thus, a failure to comply with the MRLs established by the positive list could result in significant expense and time delays and perhaps an outright ban by the Japanese authorities of the offending product.

V. Establishing a Compliance Plan

Ultimately, the responsibility for compliance with the Japanese positive list rests with the importer of the food products into Japan. Generally, companies use a local subsidiary or other third party as the importer of record. Accordingly, the responsibilities of the exporting company are secondary. Nevertheless, it is likely that importers will require the exporters/manufacturers to provide evidence or warranties regarding compliance with the positive list.[41] In order to satisfy the requests of or contractual obligations instituted by the company's importers or to

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[28] USDA Foreign Agricultural Service, GAIN Report, JA4005, at 3 (February 2, 2004).
[29] **www.mhlw.go.jp/english/topics/importedfoods/1-4.html** (Monitoring Inspection System); For example of monitoring plan see: Japanese Dep't of Food Safety, "Development of Imported Foods Monitoring and Guidance Plan for FY 2007, at 2, (March 23, 2007).
[30] **www.mhlw.go.jp/english/topics/importedfoods/1-4.html**.
[31] GAIN Report, JA6004, at 7.
[32] USDA, GAIN Report JA4005, at 2 (February 2, 2004).
[33] USDA, GAIN Report JA6025, at 2 (May 31, 2006); USDA, GAIN Report JA7043, at 8 (August 14, 2007).
[34] GAIN Report JA4005, at 4.
[35] *I.*, at 3.
[36] *Id.* at 2.
[37] *Id.*
[38] *Id.*
[39] *Id.* at 4.
[40] *Id.* at 2.
[41] See GAIN Report 6004, at 9.

assure the company of its compliance, companies should establish a compliance program with the Japanese positive list, keeping in mind the following points.

A. Risk Assessment

Companies need to perform a risk assessment of their products exported to Japan. This assessment should include knowledge of the origin of the ingredients used in the product as well as the likelihood of the presence of agricultural chemicals with MRLs on the positive list. If the materials are imported from other countries, the company should know the history of compliance by that country and whether agricultural chemicals banned under the positive list are legal there. If materials are purchased from third-party suppliers, the company should know the suppliers' history of compliance with the positive list and request certificates of compliance and test results. If the supplier refuses to provide certificates, the company should question the refusal and assess whether the refusal impacts the product's compliance with the positive list.

The assessment should also include the results of the company's examination of the current monitoring plan by the Japanese government and the compliance history of similar products exported by other countries. Companies should also review newly published or revised MRLS to determine whether new agricultural chemicals identified are likely to be found in their products and whether the allowable standards of agricultural chemicals likely present have changed. This risk assessment will help companies determine whether their products are compliant with Japanese law and, if not, what steps need to be taken to bring them into compliance before export.

B. General Importation Requirements

Assuming a company decides to export its products into Japan, it must ensure that both the company and the importer of record are in compliance with the overall Japanese import regulations, even beyond the positive list. The positive list scheme does not alter Japanese import requirements that officials be notified in advance regarding the importation of food through the submission of a "Notification Form of Food Importation" to the appropriate quarantine station at the port of import.[42] Currently, in order to obtain entry into Japan, the following import documents must be provided to the authorities, along with a sample of the product: 1) import notification (2 copies); 2) health certificate; 3) results of examination; and 4) documents showing the ingredients, additives, and manufacturing process (manufacturer's certification).[43] Following the submission of the notification, the product is examined to determine whether it complies with the Food Sanitation Laws.[44] The examination consists of the following determinations: 1) whether the imported food, etc. complies with the manufacturing standards established by the Food Sanitation Law; 2) whether additives used comply with these standards; 3) whether the product contains poisonous or hazardous substances; and 4) whether the manufacturer or country of origin has a history of sanitation problems.[45] Conformity to the Japanese Food Sanitation Law will be determined by the quarantine station.[46] If the exported products are in compliance with Japanese law, a "certificate of notification" will be sent to the

[42] GAIN Report, JA6046, at 11-12; Form located at **www.mhlw.go.jp/english/topics/importedfoods/1.html**.
[43] GAIN Report, JA6046, at 9, 12.
[44] *Id*.
[45] **www.mhlw.go.jp/english/topics/importedfoods/1.html**.
[46] *Id.*; GAIN Report, JA6046, at 12 (For a list of quarantine stations see: **www.mhlw.go.jp/english/topics/importedfoods/1-2.html**).

importer. If the cargo does not pass, the importer is notified and provided with the necessary measures that must be followed.[47]

In order to insure that there are no problems at the border, the MHLW suggests that companies desiring to export products to Japan deliver a small sample to the MHLW port inspectors prior to export, along with a certificate guaranteeing the product's compliance with Japanese regulations.[48] The MHLW will then inspect the samples to ensure that no importation problems exist before beginning the export process. Further, the MHLW strongly recommends that products not be exported until it has verified compliance.[49] Ultimately, products found in violation of the Food Sanitation Law are subject to re-exportation, destruction, or disposal.[50]

Companies needs to work out in advance with the importer who is responsible for creating the documents required by the Japanese authorities. This agreed-to relationship should be established contractually. Additionally, if the preparation of the import documents are dependent in large part on information coming from the company's suppliers, the company should also obtain certificates and/or other contractual representations from the supplier reinforcing the statements made in the importation documents.

C. The Pre-Test, Pre-Registration and Certification Options

Another option available to U.S. exporters is to have samples of products tested by any of the MHLW official or registered laboratories within the U.S.[51] Products imported from the United States do not need to be tested upon arrival to Japan if an analytical certificate from an MHLW-approved laboratory accompanies the shipment.[52] Obviously, the preliminary test route from an authorized MHLW lab can become very costly. Accordingly, in deciding whether to pretest, a company should consider several criteria, including recent developments in the monitoring plan implemented by the Japanese authorities, overall compliance with the positive list by third parties exporting the same product as the company, and the likelihood that the company's product will be in violation of the positive list. This final criteria can be assessed by a review of the history and origin of ingredients and raw commodities. Pre-testing should be reserved for products that have a higher risk of noncompliance with the positive list based on the information gathered.

Another option is to pre-register with the MHLW. The certification lasts for a certain period of time.[53] Once certified, the product may be imported into Japan by documentary inspection alone. One disadvantage of this method is that obtaining the certification is burdensome because the applicant must submit appropriate test data and other required documents. Additionally, the expense and burden of obtaining certification may not be worth the effort, given that most food products are subject to inspections only in limited cases. Thus, pre-registration may only be warranted when the product is likely to be inspected each time it passes through Japanese customs.

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[47] *Id.* (See Inspection Procedure Flow Chart attached hereto as Exhibit D).
[48] GAIN Report, JA7043, at 3.
[49] *Id.*, at 3.
[50] GAIN Report, JA6046, at 9.
[51] GAIN Report, JA6046, at 3. (List of US registered laboratories at: **http://www.mhlw.go.jp/topics/yun/yu/5/dl/a3.pdf**.)
[52] GAIN Report, JA6046, at 10.
[53] **www.mhlw.go.jp/english/topics/importedfoods/1-5.html** (Systems for Simplified and Expedited Systems as Import Procedures of Food and Related Items).

However, if a company plans to import the same or a related item repeatedly into Japan, then the division should consider implementing either the Planned Import System or the Continuous Import of Same Items System.[54] Under the Planned Import System, an import plan may be submitted during the first import of the product into Japan. If the plan is satisfactory to the Japanese authorities, the requirement of an import notification submission is exempted for a certain period.[55] Under the Continuous Import of Same Items System, prior inspection results are attached to the import notification form at the initial import. If the document examination shows no problems, inspections are exempted for a certain time period.[56]

D. Contractual Options

As noted above, liability with respect to the Japanese authorities will fall to the importer in the event the company's product fails to comply with the positive list. Thus, it is anticipated that importers will want to contractually apportion the regulatory liabilities for failing to comply with Japanese law. Such contractual mechanisms will likely include representations and warranties about the quality of the product, as well as assurances of compliance with applicable Japanese regulations, and storage and handling requirements. If the company's importer requires such certification, then the representations and warranties of the company and its suppliers become particularly important in two respects. First, the company will need to have supporting documents for the representations and warranties it makes about its products' being imported into Japan. Second, to the extent any ingredients in the company's products comes from third parties, it will want to obtain representations and warranties from its suppliers to ensure that the finished product complies with the positive list and to further substantiate representations and warranties made by the company to the Japanese importer. The company should also engage in confirmatory testing itself, as well as require that suppliers demonstrate compliance with the positive list through their own confirmatory testing from time to time. However, since testing is expensive and time consuming, the company may initially want to only require a testing regime of its products for which the Japanese authorities are requiring testing by order since these products will have mandatory testing at the border.

If the supplier is unwilling or unable to provide such certificates or warranties, then the company needs to determine why and whether such failure to obtain certification from the supplier is an indication that the company's product won't comply with Japanese regulations, including the positive list. If the supplier's failure to provide certification is a red flag regarding compliance with the positive list, further evaluations must be conducted on the product ,and the Company may want to consider employing the options discussed above with respect to compliance with the positive list.

VI. Conclusion

Several considerations should be taken into account with a company's compliance plan, in order to assure the company's conformance to the Japanese positive list in an efficient and cost effective manner. Initially, companies should consider each of its food products or components of food products that will be exported to Japan and assess the risk of noncompliance with the positive list and all other import requirements. Next, companies should obtain adequate assurances from its suppliers that all materials will be compliant, and determine the best way to minimize risk that the materials are incompliant. Finally, companies should

[54] *Id.*
[55] *Id.*
[56] *Id.*

clearly outline the risk-management responsibilities of suppliers, be it certification from third party suppliers, confirmatory testing from a MHLW approved lab, pre-registration or certification of the product prior to entry, or implementation of the Planned Import System or the Continuous Import of Same Items System. If these steps are followed, importation of goods to Japan will become much more predictable and efficient, and the market for imported goods will potentially continue to expand.

EXHIBIT A

SUBSTANCES EXEMPT FROM THE JAPANESE POSITIVE LIST

Ascorbic acid	Biotin	Copper	Lactic acid
Alanine	Calciferol	Diatom earth	Lecithin
Allicin	Calcium	Folic acid	Leucine
Ammonium	β-Carotin	Glycine	Machine oil
β-Apo-caroteneethylster	Chlorella Extract	Glutamine	Magnesium
Arginine	Chlorine	Histidine	Menadione
Asparagine	Choline	Hydroxypropyl starch	Methionine
Astaxanthin	Cinnamaldehyde	Inositol	Marygold pigment
Azadirachtin	Citric acid	Iodine	Mineral oil
Barium	Coparamin	Iron	Niacin
Neem oil	Selenium		Tyrosine
Oleic acid	Serine		Urea
Pantothenic acid	Shiitake mushroom mycelia		Valine
Paprika color	Silicon		Wax
Paraffin	Sodium bicarbonate		Zinc
Potassium	Sulfur		
Propylene glycol	Sorbic acid		
Pyridoxine	Tartaric acid		
Retinol	Thiamine		
Riboflavin	Tocopherol		

USDA Foreign Agricultural Service, GAIN Report JA6004 (February 6, 2006), at 6- 7.

EXHIBIT B

CHEMICALS FOR WHICH NO RESIDUES MAY BE DETECTED

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

USDA Foreign Agricultural Service, GAIN Report JA6004 (February 6, 2006), at 7.

EXHIBIT C

AGRICULTURAL CHEMICALS WITH MRLS BELOW THE UNIFORM LIMIT

Abamectin (0.008 for A, 0.005 for L)
Altrenogest (0.003 for L)
Amoxicylin (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 isoinchomeronate (0.004 for L)
Doramectin (0.005 for L)
Emamecti 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)
Fentrothion (0.002 for L)
Fipronil (0.002 for A)
Flumethrin (0.005 for L)
Heptachlor (0.006 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)
Propoxycarbazone (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)

These figures are in ppms. A = Agricultural products; L= livestock products; and ND = no detection.

USDA Foreign Agricultural Service, GAIN Report JA6004 (February 6, 2006), at 6.

Exhibit D

INSPECTION PROCEDURE FLOW CHART