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Voluntary - Public

Date: 2/5/2019

GAIN Report Number: JA9004

Japan

Post: Tokyo

Guidance for Preparing Compliance Letters

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:

The Japan Ministry of Health, Labour and Welfare (MHLW) conducts random sampling of imports to maintain confidence that imports comply with Japanese food safety standards. When shipments violate those standards, MHLW enhances monitoring from 5 percent to 30 percent of shipments, or may hold product until tests verify compliance (referred to as an inspection order). Exporters may prepare a compliance letter that provides information on the causes of the violation and the countermeasures the company or industry implemented to prevent future violations. A compliance letter may provide MHLW with sufficient justification to lift heightened inspection sooner than the prescribed number of shipments or time.

Keyword: JA9004

General Information:

The Ministry of Health, Labour and Welfare (MHLW) is the regulatory agency for food safety in Japan, and is responsible for establishing and reviewing food safety standards, including maximum residue limits (MRL) of agricultural chemicals and the maximum level (ML) of mycotoxins such as aflatoxin. MHLW monitors both domestic and imported foods to ensure compliance with these food safety standards.

If an imported food violates a Japanese food safety regulation, MHLW enhances monitoring of the same commodity from the country of export from 5 to 30 percent. In addition, those involved in the violation (importer, shipper, or packer) are subject to an “inspection order”, in which port officials hold subsequent shipments until testing confirms their compliance with Japanese standards – an approach referred to as “hold and test”.

MHLW maintains enhanced monitoring for one year of compliant shipments or 60 consecutive compliant shipments (whichever comes first). If a second party should violate the same commodity/residue standard within one year, MHLW extends the inspection order to all shipments of that commodity from the exporting country. This action applies to all parties from the same country, regardless of compliance records.

MHLW maintains an inspection order for two years or 200 consecutive compliant shipments, whichever comes first. MHLW has determined that this number of compliant shipments provides statistically relevant data that Japan’s compliance processes are effective. Each subsequent violation before the conclusion of enhanced monitoring or an inspection order resets the duration and number of compliant shipments required (see [2017 FAIRS report](#)¹).

Inspection orders are costly. While MHLW covers the expense of enhanced monitoring, the parties subject to an inspection order incur the costs of testing, storage, and (in the case of another violation) disposal or return of the commodity. Inspection orders are especially costly for perishable commodities that lose quality and value while test results are pending.

In response to a violation of Japanese standards, MHLW issues a violation notice to the local Embassy. In the notice, MHLW requests that the violator(s) submit a “compliance letter” that outlines the conclusion of an investigation into the causes of the violation, and the countermeasures the violator (company or industry) has implemented to prevent the same type of violation in the future. A successful compliance letter provides MHLW with the information they require to justify a reduction in the duration or number of compliant shipments to conclude enhanced monitoring or an inspection order.

MHLW also monitors the frequency of violations for each commodity. Once the number of shipments that violate Japan’s standards exceed five percent of shipments in a year, Japanese law authorizes MHLW to impose a nationwide ban of that commodity. The submission of a compliance letter can reduce the number of compliant shipments necessary to remove enhanced

¹ See the 2018 FAIRS report in February 2019.

monitoring or an inspection order, and may prevent enhanced monitoring from progressing to a nation-wide ban.

This report provides an overview of the information MHLW has requested in the past when requesting a compliance letter. The letter should help MHLW understand the cause of the violation and provide a detailed explanation of the internal investigation conducted as a result of the violation. The letter should outline actions taken by the industry to avoid similar violations in the future. The provision of such information may provide MHLW with confidence that the industry is cognizant of the issue, and has taken action to prevent a recurrence.

Annex-1 of this report provides a limited list of the information that MHLW might look for in a compliance letter. However, MHLW considers each violation and request for compliance letters on a case-by-case basis and, therefore, compliance letters result in different outcomes. The list provided in Annex-1 is based on MHLW's questions and previously submitted compliance letters.

Annex -1: Limited list of information to include in a compliance letter to MHLW

Information that may be included in a compliance letter include:

1. The responsibilities/actions of the producer to comply with residue standards.

This section should explain to MHLW what measures the producer/packer/exporter employs to ensure compliance with Japan's standards. Standard operating procedures such as verifying Japan's standard, record-keeping, tracking fields intended for export, chemical application methods, pre-export chemical residue testing, or similar, would be appropriate details to include.

2. The responsibilities/actions of the regulatory authority (local and central).

This section should explain to MHLW the oversight role of the local or central government. Ideally, the local authority provides this section on official letterhead to the U.S. Embassy directly. The U.S. Embassy may support this information directly to MHLW based on details confirmed with the local authority.

3. The identified cause of the violation.

MHLW places considerable importance on a thorough investigation of the cause(s) of a violation and will respond more favorably based on the strength and breadth of the report. Because there was a violation, **MHLW does not look favorably on statements to the strength of the existing program.** The report should outline current procedures, and identify a shortcoming that contributed to the error.

4. The countermeasures adopted to prevent a recurrence of the violation.

Based on the identified shortcoming, this section should explain what steps have been implemented to prevent recurrences. If the violation was the result of human error, introducing employee training may be an appropriate remedy. If additional supply was procured from a third party, introducing a new verification procedure to confirm that product's compliance with Japan's standard would may be an option. The countermeasure should address the identified cause such that MHLW has reason to believe that the new procedure will ensure compliance with Japan's standards.

Messages that a compliance letter may include:

- State regret for the incident.
- Express continued commitment to abide by Japan's regulations.
- Identify the violating commodity, substance (e.g. agricultural chemical name), investigative findings, and date of reported findings.
- Provide information on the U.S. standard, Japanese standard, and the Codex standard for the substance (if available).
- Describe the results of an investigation and clearly state the cause of the violation.
- Describe the actions taken in response to identifying the cause of the violation.
- Provide records (e.g. spray records of sourced crops in the case of an MRL violation).
- Provide test results from pre-shipment monitoring (if available).
- Describe new procedures (e.g., an additional verification process) or training put in place to avoid similar violations in the future.
- Describe industry efforts to inform members of Japanese MRL standards and practices to ensure their compliance (e.g. Memorandum or Newsletter).
- Express interest in continued engagement with MHLW to address additional concerns.