

**Voluntary Report** – Voluntary - Public Distribution

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**Report Name:** Overview of Aflatoxin-related Import Regulations in Japan

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**Report Highlights:**

This report summarizes the legal basis for Japan's aflatoxin regulations for imported agricultural products. Aflatoxin regulations stem from different articles of Japan's Food Sanitation Act than those pertaining to agricultural chemicals.

## Regulatory Framework and Oversight for Aflatoxin-vulnerable Imports

Based on Japan's [Food Sanitation Act](#) (FSA), the Ministry of Health, Labour and Welfare (MHLW), Japan's competent authority for food safety, establishes and enforces aflatoxin regulations for domestic and imported food products.

According to Article 6<sup>1</sup> of the FSA, Japan prohibits imports of food products that do not comply with Japan's aflatoxin action limits.

Article 23 of the FSA directs the MHLW Minister to develop an annual national monitoring plan (hereafter "Imported Foods Monitoring Plan") for imported foods<sup>2</sup>, food additives, packages and containers.

FSA's Article 26 grants MHLW Minister the authority to conduct mandatory inspections, so called "inspection orders," when MHLW considers them necessary to prevent violations of the FSA. Consequently, the "[Imported Foods Monitoring Plan](#)" states "when a violation of the Act has been detected as a result of the monitoring inspection of aflatoxin, pathogenic microorganisms, etc., the imported food manufactured by the same manufacturer, processed by the same processor, or imported from the same exporting country will be immediately subjected to an inspection order." MHLW revises the monitoring plan on an annual basis and publishes the plan for the following Japanese fiscal year (April-March) in March.

According to FSA's Article 27, importers have to submit [import notifications](#) to one of [32 quarantine stations](#) for all food imports intended for commercial distribution in Japan. The import notifications inform MHLW officials whether incoming shipments contain aflatoxin-vulnerable products. Once quarantine officials verify information in the import notification, food imports are subject to the requirements set out in the "[Imported Foods Monitoring Plan](#)."

According to MHLW, aflatoxin-vulnerable products (for the list of affected commodity groups for all exporting countries, please consult [Appendix 1](#) of the Monitoring Plan) have been subject to inspection orders since 1996 due to a history of violating Japan's aflatoxin action limit (i.e. 10 parts per billion for tree nuts).

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<sup>1</sup> Article 11 prohibits import of foods that exceed Japan's maximum residue limits (MRLs) for agricultural chemicals.

<sup>2</sup> Article 24 of the FSA requires each prefectural governor to develop a prefectural annual monitoring plan for foods, food additives, packages and containers. These prefectural plans target products in the domestic distribution channels, including imported foods.

According to Japan’s “[Imported Foods Monitoring Plan](#)”, MHLW may lift an aflatoxin-related inspection order if the following conditions are satisfied:

- i. Root-cause investigation completed
- ii. Implementation of preventive measures based on investigation
- iii. Confirmation of effective implementation of preventive measure through bilateral discussions, on-site inspections, and/or cumulation of compliant inspection results.

Note: Japan’s approach to aflatoxin violations differs from its approach to violations of maximum residue limits (MRLs) for agricultural chemicals, where a single MRL violation results in the inspection frequency increasing to 30 percent (known as “enhanced monitoring”), rather than the immediate imposition of an inspection order. Moreover, the lifting of an aflatoxin inspection order is not associated with a specific time frame or number of cleared shipments, as is the case for MRL violations (for details, see [2020 Japan FAIRS](#)).

## **Aflatoxin-related Import Requirements**

Imports that are subject to an inspection order can be cleared by customs only after laboratory test results confirm compliance with Japanese aflatoxin action levels. [Schedule 5](#) of the Imported Foods Monitoring Plan and the "Testing Methods for Total Aflatoxin" ([Ministerial Notice No. 0816, Article 2 of the Food Safety Department, dated August 16, 2011](#), available in Japanese only) detail sampling and inspection methods, respectively, for aflatoxin testing (see [JA8061](#) for FAS/Tokyo’s summary of Japan’s aflatoxin testing protocol). FSA’s Article 25 and 26 precludes importers from questioning inspection results.

According to Article 54 of the FSA, importers are required to dispose or “take any other necessary measures to eliminate the food sanitation hazards” when test results indicate a violation. Although MHLW’s regulations do not identify “other necessary measures,” in practice, these measures are taken to mean shipment rejection and return to country of origin or diversion to third country. Still, the FSA does not preclude the possibility of reconditioning rejected imports. However, Article 40 of the [Japan’s Customs Act](#) permits activities such as “inspection, repacking, sorting or other normal handling operations” only within designated customs areas.

Article 9 and 17 of the FSA allow MHLW to announce a nation-wide ban on imports of a product after consulting with the Pharmaceutical Affairs and Food Sanitation Council if “considerable numbers” of the imported product do not comply with the FSA. Although the FSA does not specify what constitutes “considerable numbers,” the annual monitoring plan interprets it as violation rate “stands above approximately 5%” for a given product.

**Attachments:**

No Attachments.