USDA United States Department of Agriculture
Foreign Agricultural Service

GAIN Global Agricultural Information Network

Voluntary Report – Voluntary - Public Distribution **Date:** May 12,2020

Report Number: JA2020-0098

Report Name: Most MRL Import Violations Due to Lack of Harmonization

Country: Japan

Post: Tokyo

Report Category: Sanitary/Phytosanitary/Food Safety

Prepared By: Tomohiro Kurai

Approved By: Mariya Rakhovskaya

Report Highlights:

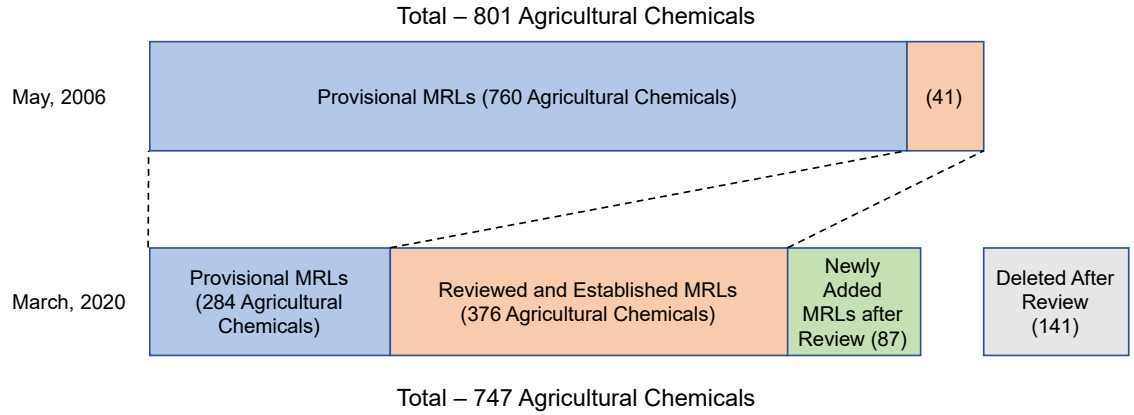
Of 117 violations reported in U.S. products since 2007, 75 percent of all non-compliance cases resulted from Japan's lack of specific maximum residue limits (MRLs) for compound-commodity combinations and subsequent adoption of a default uniform MRL of 0.01 parts per million. Japan implemented its positive list system for agricultural chemicals in May 2006.

General Information

In May 2006, Japan's food safety authority, the Ministry of Health, Labour and Welfare (MHLW), implemented a "positive list system" for agricultural chemical residues, feed additives and veterinary drugs (hereinafter referred to as agricultural chemicals) in food. Under this regulation, foods containing agricultural chemical residues not included in the "positive list" or those that exceed the maximum residue levels (MRLs) established via the "positive list" are classified as non-compliant with Japan's Food Sanitation Act.

Agricultural chemicals in the "positive list" fall into two categories: (i) permanent MRLs established following risk assessments by Japan's Food Safety Commission (FSC) and (ii) provisional MRLs (interim standards adopted in 2006) when FSC has not completed risk assessments. Upon implementation in May 2006, Japan's positive list had 801 agricultural chemicals, of which 760 had provisional MRLs. As of March 2, 2020, Japan's positive list contains 747 agricultural chemicals (due to some deletions and additions), of which 284 chemicals remain provisional (see Figure 1). Further details about Japan's positive list system can be found in MHLW's Introduction of the Positive List System for Agricultural Chemical Residues in Foods, and the complete list of Japan's MRLs for agricultural chemicals in foods is maintained by the Japan Food Chemistry Research Promotion Foundation (JFCRPF). For all other compound-commodity combinations, which do not have a specific MRL established, except for 20 substances stipulated to be "Not detected" in foods, the default uniform standard of 0.01 parts per million (ppm) is applied.

Figure 1. Comparison of Japan's Initial and Current MRL Positive Lists



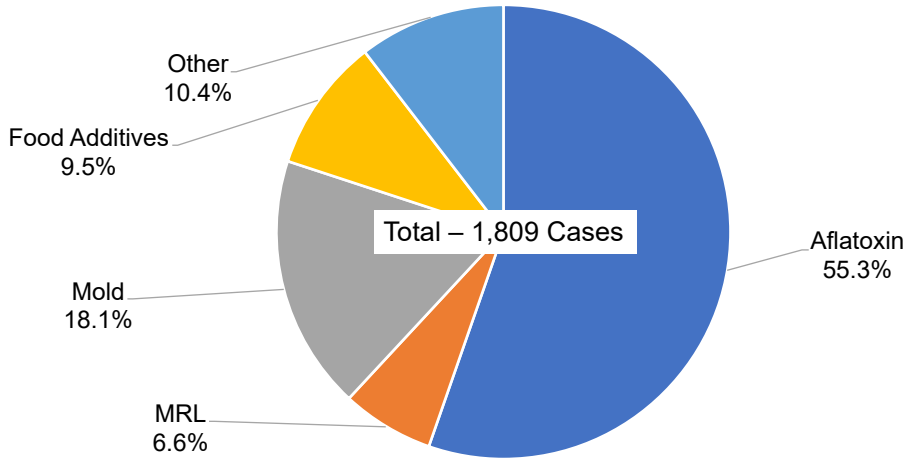
Source: MHLW
Note: Numbers in parenthesis indicate the numbers of agricultural chemicals in each category.

Every year, MHLW develops a "monitoring plan" for agricultural residues in imported products based on the record of violations from the previous Japanese fiscal year (JFY, April-March). The JFY 2020 monitoring plan was released on March 30, 2020 (in Japanese; JFY 2019 monitoring plan is the latest available monitoring plan in English). If MHLW's test findings of agricultural chemical residues in imported products exceed Japan's MRLs, then Japan designates all imports of the same product of the

same exporting country for "enhanced monitoring" *i.e,* the inspection rate increases to 30 percent. If there is a second case of non-compliance by a different operator for the same product and from the same exporting country while the enhanced monitoring regime is in place, then MHLW suspects systemic failure in the exporting country's process for that product and issues an "inspection order" (100 percent hold and test) for all imports of the same product from that country. An inspection order can involve substantial delays at port and additional costs for consignments (see JA2019-0216 for further details). MHLW publishes the list of violations with commodity, company and country names, and the list of imports subject to enhanced monitoring (see Schedules 2 and 3 of the "Monitoring Plan") and inspection orders on its Imported Food Safety site.

Between January 2007 and February 2020, there were 1,809 violations reported by MHLW for products imported from the United States. Of those 1,809 cases, only 6.6 percent or 118 cases were violations of agricultural chemical MRLs. By comparison, 55.3 percent were cases of non-compliance with Japan's maximum limit for aflatoxins. The remaining violations were due to mold detection (18.1 percent), non-compliance with food additive regulations (9.5 percent), and other causes (10.4 percent), such as absence of a phytosanitary certificate (Figure 2).

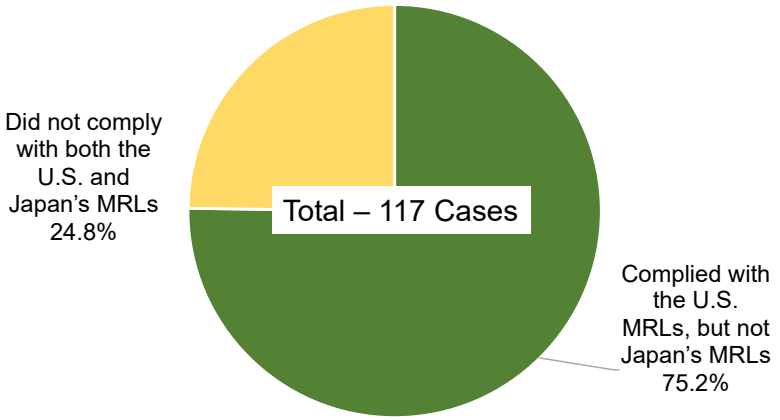
Figure 2. Types of Import Violations Reported in U.S. Agricultural Products that Entered Japan Since 2007



Sources: MHLW and FAS/Tokyo

Of the 117 cases of MRL violations, approximately 75 percent complied with U.S. MRLs, but not Japan's (Figure 3). Only 29 cases (2 cases per year on average) exceeded both U.S. and Japan's MRLs. Furthermore, out of 88 non-compliant cases where detected residue levels complied with the U.S. MRLs but not Japan's MRLs, 74 cases were reported on products for which Japan had not established specific MRLs for the relevant compound-commodity combinations and applied the default uniform MRL of 0.01 ppm. Of these 88 non-compliant cases since 2007, there have been no violations in U.S. agricultural exports when the commodity-chemical combination MRL for Japan was harmonized with either the United States or Codex standard, even when the Codex standard was below the U.S. MRL.

Figure 3. Breakdown of MRL Violations in U.S. Agricultural Exports by Compliance with U.S. Standards



Sources: MHLW and FAS/Tokyo

This finding indicates that Japan's lack of compound-commodity specific MRLs and the application of a default uniform MRL is the major cause of MRL violations in the U.S. agricultural exports. To minimize trade disruptions, the Japanese government has established processes for U.S. stakeholders to petition MHLW to adopt U.S. or Codex MRLs (see Appendix 1 for details). Japan's MRL harmonization with U.S. or Codex standards remains a key objective for FAS/Tokyo.

Appendix 1:
U.S. stakeholders can petition Japan to revise its MRL via the following three channels.

1. Food Safety Group (FSG)
   Approximately every other month, MHLW holds an FSG meeting for the Tokyo diplomatic community to share MHLW's proposed revisions to Japan's food safety standards, including MRLs, before submitting a notification on that sanitary-phytosanitary (SPS) measure to the World Trade Organization (WTO). Embassies, including the FAS section in Tokyo, typically can submit comments to FSG within a two-week comment period from the date of the FSG.

   The United States can only request adoption of a specific MRL if there is an established U.S. or Codex standard for the relevant compound-commodity combination. To request adoption of a U.S. MRL, the United States has to provide scientifically legitimate residue data for the compound-commodity combination *i.e.*, data collection complied with Good Agricultural Practice (GAP) and Good Laboratory Practice (GLP) regulations. A request to adopt a Codex standard does not require data submission as MHLW will obtain the necessary data from Codex directly. As the FSG process is managed solely by MHLW, the review process takes substantially less time as compared to the two other approaches described below.

2. WTO SPS Notification
   When no significant concerns are raised at the FSG, MHLW notifies the same proposed revision to the WTO. (Note: if MHLW revises the MRL(s) proposed at the FSG, MHLW withdraws the proposal and restarts the FSC review process.) Typically, Japan submits WTO notifications on chemicals covered by the FSG a few months after the end of the FSG comment period. If Japan proposes to lower an MRL, then it provides a two-month comment period. On the other hand, proposals to maintain or raise an MRL do not have a comment period and are immediately implemented. Nevertheless, even in the absence of a comment period, the United States can submit comments.

   Similarly to the FSG process, during the WTO comment period, the United States can ask Japan to adopt the U.S. MRLs for the subject compound-commodity combinations provided the United States (i) has established an MRL for that compound-commodity combination and (ii) provides Japan with a scientifically valid chemical residue data to support the MRL request. Alternatively, the United States can request Japan to adopt the Codex standard for that compound-commodity combination and no further data submission is required. As the Ministry of Foreign Affairs (MOFA), rather than MHLW, coordinate WTO/SPS notifications, interagency coordination between MOFA and MHLW tends to slow down the process.

3. Import Tolerance Application
   When the MRL for a compound-commodity combination of interest is not under MHLW's review as indicated through the FSG and WTO processes, U.S. stakeholders can request MHLW to harmonize Japan's MRL with the U.S. or Codex standards through an "import tolerance" application. For required information and "import tolerance" process, consult JFCRPF's Guideline

for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals used outside Japan. This is a lengthy process as it involves an FSC review and additional scientific data (*e.g.* toxicity and environmental data).

Attachments:

No Attachments.