



Voluntary Report - public distribution

Date: 7/30/2003

GAIN Report Number: JA3052

Japan

Sanitary/Phytosanitary/Food Safety

New Chemical and Pesticide Regulations

2003

Approved by:

Kevin Latner
U.S.Embassy

Prepared by:

Tetsuo Hamamoto

Report Highlights:

The government of Japan (GOJ) will change the way it controls farm chemicals. In the fall the GOJ will issue provisional pesticide maximum residue limits (MRL). After the 3-year transition period, imports must comply with MRL on this list or the final list, which will be based on risk assessments by the GOJ. During the 3-year transition period, for products without MRL in Japan, residue levels must be safe, usually meaning they must comply with the stricter of Codex or U.S. standards.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Tokyo [JA1]
[JA]

The government of Japan (GOJ) will change the way it controls farm chemicals. In the fall the GOJ will issue draft provisional pesticide maximum residue limits (MRL). The GOJ will also begin risk assessments to set MRL. At the end of the 3-year transition period, chemicals with risk assessments will have their MRL established on a final list. The MRL for chemicals without a risk assessments performed by the GOJ will remain on the provisional list. After the transition period, all products sold in Japan, including imports must comply with either the provisional or final MRL list. During the transition period, residues levels on products without an MRL must be safe. Usually this means the stricter of Codex or the exporting country standards. After the three-year transition period, MRL not on the provisional or final lists of chemicals will be illegal. The GOJ intends to replace the provisional MRL with final MRL based on full risk assessment for all farm chemicals, but has not determined an expiration date for the provisional list.

Principal Regulators: Ministry of Health, Labor and Welfare

The Ministry of Health, Labor and Welfare (MHLW) will transition from a negative list approach to a positive list approach for the regulation of pesticides, veterinary drugs, and feed additives. Implementation will be over a three-year transition period. In the past, residues from chemicals without MRL in Japan were permitted on U.S. exports if residue levels were considered as safe. MHLW has generally recognized safe residues levels as those established by Codex or, where there is no Codex standard, within the limits of U.S. regulations. This will continue during the transition period. During the transition period, the GOJ will also develop a list of permitted chemicals. This will be based on existing internal risk assessments, as well as those from Codex and other country risk assessments, including the U.S. Environmental Protection Agency (USEPA). After the transition period, only listed chemicals with MRL will be considered safe.

Transition Period Includes a Provisional List Based on Other's Risk Assessments

The GOJ will implement the new system over a three-year transition period. The first phase is to establish provisional maximum residue limit (MRL) based on Ministry of Agriculture, Forestry and Fisheries (MAFF) registrations for domestic uses, existing MHLW MRL, Codex MRL, and science-based MRL established by other countries. During the summer of 2003, an advisory committee will meet to develop an outline of how provisional MRL will be set. Japan intends to announce a draft list of provisional MRL for comments at the end of the summer 2003. The GOJ foresees a possible need for a subsequent revision and a second notification to the WTO. During the transition period, chemicals not on the positive list will be handled according to MHLW's traditional approach of referencing Codex or the exporting country MRL in order to determine whether the chemical is safe.

MHLW Willing to Amend the Provisional List During the Transition Period

During the transition period, MHLW indicated they would look favorably at U.S. requests for newly approved chemicals in the U.S. to be added to the provisional list. The transition period will conclude when MHLW establishes a final list. The final list will include those chemicals for which the GOJ has completed a risk assessment. MRL based on risk assessments done by Codex or foreign countries will remain on the provisional list. The provisional list will come into force after the transition period. The GOJ has not indicated a sunset on the provisional list.

GOJ Will Rely on USEPA Risk Assessments

MHLW indicated that it will rely on risk assessments provided by other agencies in developing the provisional list, including MAFF, Codex and foreign countries. The GOJ demonstrated

several possible scenarios where different risk assessment bodies could provide different MRL, leaving MHLW with a dilemma in deciding which MRL to adopt as a provisional MRL in Japan. MHLW suggested that the precedence for adopting MRLs, where they differ, would be the higher of MAFF and Codex, and then consensus standards in foreign countries. If the product is only approved in the U.S., the GOJ indicated it would positively consider accepting that MRL.

Determining a Final List of MRLs

The GOJ has not yet announced data requirements or risk assessment procedures for the establishment of permanent MRL for chemicals used in other countries. They intend to consult widely with other countries as well as expert advisory panels to determine the approach. Japan also indicated that they intend to develop a specific policy for the establishment of import MRL, so that residues of pesticides that are not registered for use in Japan can be evaluated and a MRL established.

Tolerance Discussed for Farm Chemicals Unapproved for a Particular Use and for Downstream Products

The GOJ indicated that it is evaluating an appropriate approach for identifying a default enforcement level, but that no decisions have been made. They also indicated that they have not yet decided on how they will handle MRL for processed foods.

Information Requests by GOJ

In response to information requests by MHLW, the U.S. has provided information regarding U.S. regulation of chemicals including an overview of EPA procedures for registering pesticides and establishing tolerances, including for downstream products, EPA's risk assessment procedures, including documents on probabilistic and Monte Carlo risk assessment approaches, FDA Pesticide Analytical Methods, the Pesticide Data Program, and an updated version of the U.S. ADI's and guidance on the establishment of import tolerances.