

Addressing MRL issues in Japan

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Addressing MRL issues in Japan:

- Introduction
- How does Japan handle MRL violations?
- Short-term strategies
- How should you respond to a violation?
- Longer-term Strategies /New Initiatives



Introduction

- 1.8 billion of trade to Japan
- Three horticultural products affected in FY2010
 - (Pistachios, Parsnip, Broccoli)
 - About \$52 million worth of trade
- While Incidence of U.S. MRL violations has slowed
 - Lack of harmonization in action levels
 - Japan's slow and cumbersome approval process
 - Unfamiliarity with changing MRLs
 - Food additive classification



How does Japan Handle MRL Violations

- First MRL violation:
 - MHLW enhances surveillance on shipper 100%, industry 30%
 - Enhanced surveillance lasts until 60 clean samples from shipper or two years of clean samples
- If there is a second MRL violation by same shipper:
 - No change in enhanced surveillance
- If there is a violation by other shippers:
 - Industry is subject to 100% surveillance
 - Enhanced surveillance lasts until 300 clean samples or two years
- However...



Short-term Strategies

Growers:

- Check Japanese MRLs regularly
- Impact goes beyond immediate financial losses
- Spread the word

Agro-chemical Companies:

- Consider a wide spectrum of crops
- Capitalize on EPA-MHLW data exchange
- Comment on MRL reviews



How should you respond to a violation?

- Elements of a Successful Compliance Plan
 - Promptness
 - Tone
 - What is your story?
 - Your company and shipping experience
 - What percentage of your crop is destined for Japan
 - How do you use the substance?
 - When was the substance registered for use in the U.S.?
 - What went wrong?
 - Cause of the violation (what, when, who, how)
 - Supportive Evidence

Successful Compliance Plan Continued...

- Action Plan (corrective measures)
 - What steps have you taken to remedy the current situation
 - What steps have you taken to ensure no further incidents in the future (using alternative substances with higher MRLs, pre-testing, others)
 - Supportive evidence is critical!!
- Respond to our Feedback
- Remember -No compliance plan is alike



Long-term Strategies

- Working with agro-chemical companies and registrants
- Encouraging active participation in domestic comment periods
- Working with CSCC/ Pilot Project
 - 46 MRL violations since 2006
 - 63% default tolerance violations
 - Need systematic approach



Long-term strategies

- Pilot Project Objectives
 - Develop list of MRL crop/pesticide combinations
 - Economically justifiable
 - Assessment of risk of MRL violations
 - Commercial life-expectancy of chemical
 - Willingness of registrants to submit an application
 - EPA support
 - Facilitating application for MRL establishment
 - Work with registrants
 - Work with EPA



Thank you

- Contact Information:

Office Of Agriculture Affairs/ FAS Japan

US. Embassy ,Tokyo Japan

email: agtokyo@fas.usda.gov

<http://www.usdajapan.org>

