## Session III

# Import Tolerance Guidance

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# Import Tolerance Definition

- Tolerance in the absence of a U.S. registration.
- No statutory or regulatory distinction between an “import tolerance” and any other tolerance issued by EPA.
- Same FFDCA/FQPA standards apply to all tolerances.

# Purpose of Publishing Guidance on Import Tolerances

(scheduled for publication by the end of September)

- To put in writing EPA's current policy on import tolerance;
- To illustrate how FQPA requirements have affected import tolerances;
- To move toward developing NAFTA import tolerance policies that will maintain and enhance food safety while minimizing trade irritants and accommodating NAFTA issues; and

# Purpose of Publishing Guidance on Import Tolerances (cont.)

- To ask for comment on EPA's plan to require information about pesticides use and residues in imported commodities to establish or reassess tolerances when there is a domestic registration. (Only in limited circumstances.)

# Import Tolerance Data Requirements

- Product Chemistry Studies
- Toxicology Studies
- Residue Chemistry Studies

# Toxicology Data Requirements

- Only those studies used to determine health effects from the oral route would be required.
- Studies used to assess dermal toxicity or inhalation toxicity would not be required.

# Residue Chemistry Data Requirements

- Most studies required for a tolerance associated with a domestic registration would be required.
- Livestock and processing studies may not be required on a case-by-case basis.
- Guidance specific methodology for determining number and location of field trials.
- As the significance of an imported commodity in the U.S. diet increases, the required number of field trials increases.

# Example - Oranges

- 16 Field Trials are required for a tolerance associated with a U.S. registration
- Approximately 21% of all oranges products available for consumption in the U.S are imported.
- 12 Field Trials would be required for an import tolerance if the pesticide will be marketed everywhere but the U.S.

# If Codex MRL or Other International Standards Exist:

- Studies submitted to other regulatory bodies may be used; EPA will consider these reviews to the extent possible.
- FQPA requires EPA to provide a justification for deviating from Codex when setting tolerances.

# **Imported Food Commodities with Domestic Registrations:** New Approach Considered

- Currently, EPA assumes that residues in imported commodities will be the same as in domestically produced commodities (this assumption may under- or overestimate risk).

- In limited instances, EPA is intending to permit greater consideration of residues in/on imported food in establishing or maintaining tolerances for food uses registered in the U.S.

# **Imported Food Commodities with Domestic Registrations:** New Approach Considered (cont.)

- EPA expects that additional data on imported commodities will be necessary when:

  1) a high percentage of the commodity is imported (e.g., bananas);
  2) domestic residue data are not likely to be representative of grower conditions in other countries; or
  3) U.S. consumers could be exposed to significant residues in imported foods.

# Minimum Number of Field Trials

<75% of commodity in the U.S. is imported

| Required No. of Field Trials for a U.S. Registration | 0-10% crop imported | 10-35% crop imported | 35-75% crop imported |
|---|---|---|---|
| 20 | 5 | 16 | 20 |
| 16/15 | 5 | 12 | 16 |
| 12 | 3 | 8 | 12 |
| 9/8 | 3 | 5 | 8 |
| 6/5 | 3 | 5 | 8 |
| 3 | 2 | 3 | 3 |

# Imported Food Commodities with Domestic Registrations (cont.)

Basic screening information to be considered:

- What international tolerances or MRLs exist;
- Which countries export the commodity to the U.S.;
- Major seasonal variations in imports of the commodity;
- Percent of U.S. consumption which is imported;
- Percent of crop treated in the exporting countries; and
- Significance of the food in the U.S. diet.