U.S. Food and Drug Administration
Pesticide Monitoring and Enforcement
LAPRW 2011

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U.S. Pesticide Regulation – Main Topics

- Roles of U.S. agencies
- FDA pesticide program key points, data, policies
- U.S. food imports
- Use of pesticide "intelligence"
- FDA enforcement
- What food exporters to the U.S. should know
- Links to FDA and U.S. pesticide information

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U.S. Pesticide Regulation

Three agencies working together!

- Environmental Protection Agency (EPA)
- U.S. Department of Agriculture (USDA)
- Food and Drug Administration (FDA)

Joint activities include collaboration on regulatory and policy issues, workplanning, and data sharing

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Environmental Protection Agency

- Registers pesticides, legal uses, and establishes tolerances
- Tolerances must ensure "A reasonable certainty of no harm from exposure". Considers aggregate exposures
- Required to periodically re-assess registration and residue tolerances with the goal of special protections for babies, infants, and children, and the use of safer pesticides
- Use of an unregistered or banned pesticide, or use of a registered pesticide on a food where the use is unapproved, is a violation of U.S. law. Residues of these will result in an adulterated food, including imports

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U.S. Department of Agriculture

- Enforces EPA residue tolerances for meat, poultry, and certain egg products
- Conducts the Pesticide Data Program (PDP) , a non-regulatory approach to acquire comprehensive residue data in foods primarily for EPA tolerance re-assessments. Several studies and thousands of analyses conducted annually through contracts with States in the U.S. (data are published on USDA's website)
- Implements the National Organic Program

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- Enforces residue tolerances on all foods not covered by USDA (fruit, vegetable, dairy, grain, seafood, etc.)
- Along with EPA, established guidance for enforcement of environmentally persistent, unavoidable residues in food from U.S. banned pesticides such as DDT, aldrin and dieldrin, heptachlor and heptachlor epoxide, etc. (FDA Compliance Policy Guide 7141.01)
- Conducts a Total Diet Study Program to provide incident and exposure estimates of pesticide residues, industrial chemicals, toxic and nutritional elements, and radionuclides (strontium 90 and gamma ray emitters (potassium 40, iodine 131, etc.). Four market-baskets of ~ 300 foods representing the U.S. diet are analyzed annually. Unusual findings often lead to regulatory follow-up.

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FDA's Regulatory Pesticide Program

Pesticide Program Keys

- Provide assurance that the FDA-regulated U.S. food supply is in compliance with MRLs
- Focuses on foods of dietary significance and children's foods, and appropriate residue coverage
- Not about chasing all potential violations, but will follow-up on bona fide reports of violations for minor foods
- Aggressive enforcement when violations detected
- Limited resources combined with size of food supply require strategic deployment

FDA's Regulatory Pesticide Program

Pesticide Program Keys (con't)

- FDA's program is regulatory, not production oriented; analyses have firm timeframes especially for perishables (can't really batch)
- Several hundred different commodities analyzed in any one year
- Violative residue findings require special internal identification and check analysis (over-tolerance) procedures before FDA will proceed with a regulatory action, including for imports

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FDA Regulatory Analyses

- FDA has 6 labs conducting regulatory analyses; half have already implemented LC-MS in its screening
- Using Quechers & PAM salt-out extractions coupled with GC with element selective and MS detection, and LC-MS, routine coverage expanded to ~ 500 residues including OH, OP, S, N, & O residues, carbamates, phenylureas (e.g., diuron), neonicitinoids (imidacloprid), and macrocyclic lactones (avermectin)
- Monitoring covers most metabolites and degradates, which under the FD&C Act are included with the parent pesticide for enforcement purposes
- LOQ for most residues is at least 10 ppb. Presently, the FDA enforcement level for a no tolerance residue finding is 10 ppb (levels below 10 ppb are not considered of regulatory significance)

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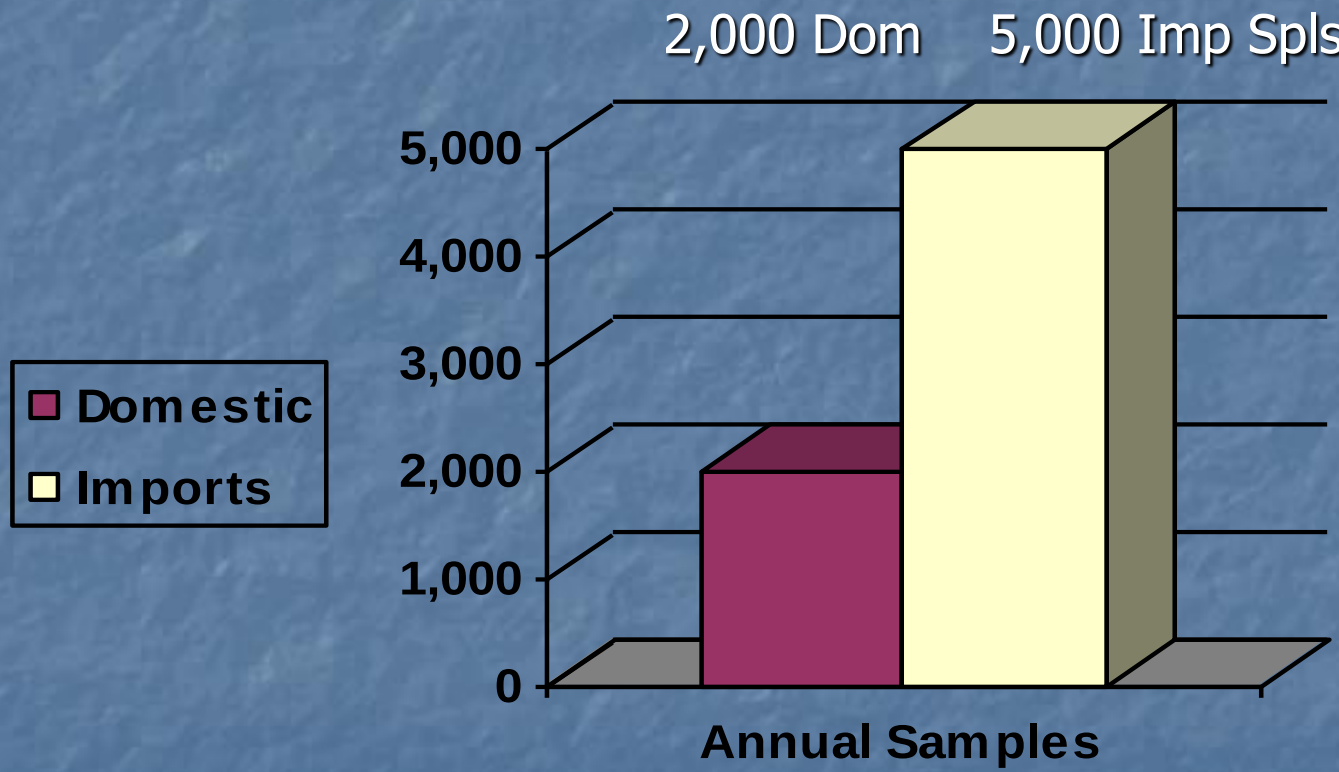
FDA's Pesticide Program Resources



FDA is developing high-throughput lab procedures to increase output

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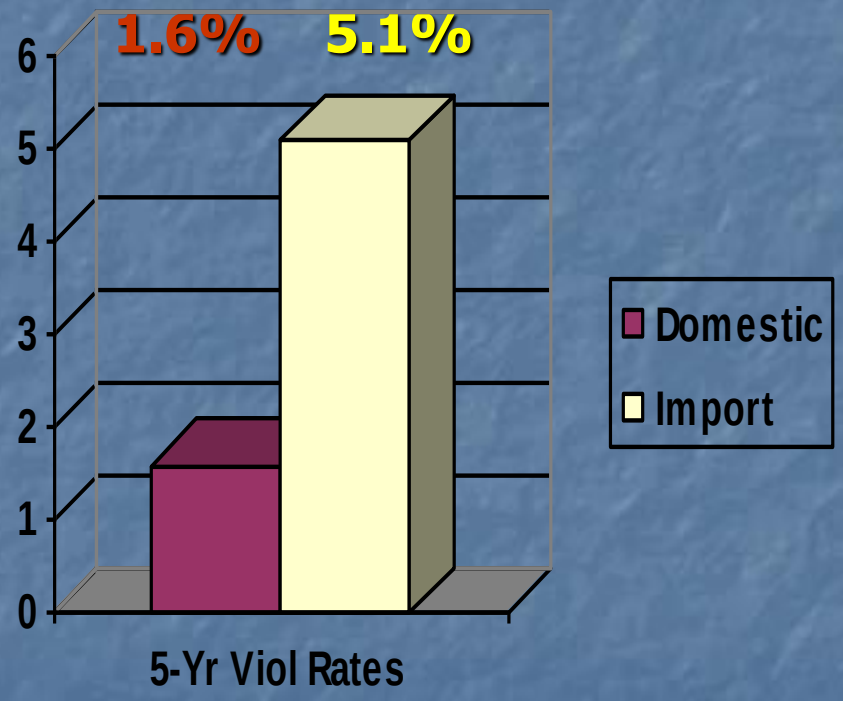
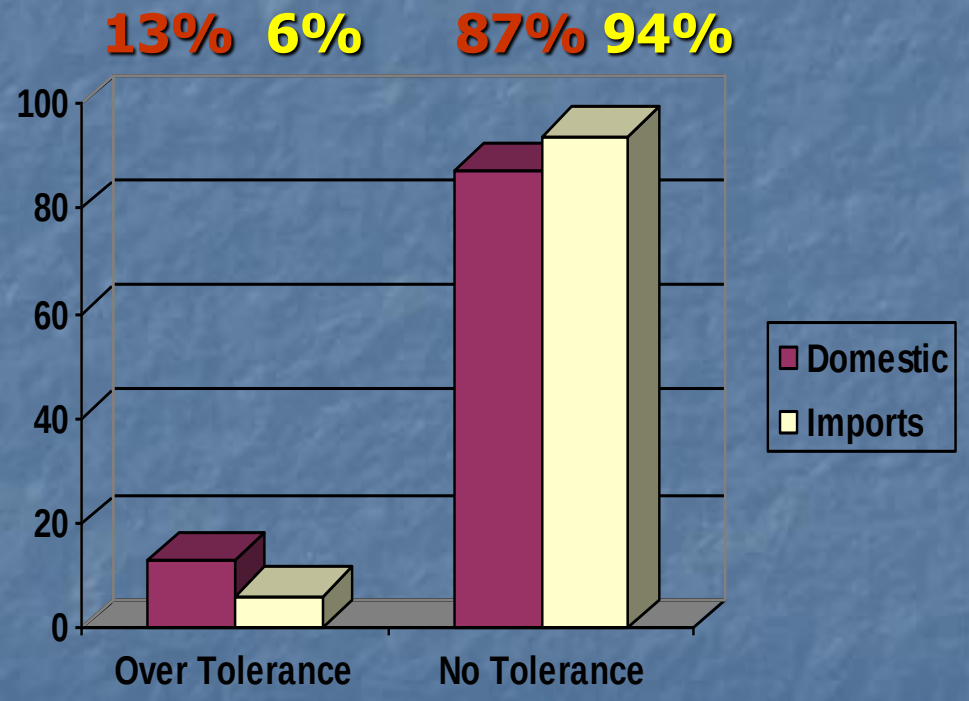
FDA Violation Rates & Nature of Violations

Viol Rate



Nature



Violations are overwhelmingly "No Tolerance"

Violation rate increasing with use of LC/MS

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FDA's Pesticide Program – Food Imports

FDA's program weighted towards imports – Why?

- FDA has limited information of import spray history
- Estimated 15% of U.S. food supply is imported, including 20% of fresh vegetables, 50% fresh fruits, and 80% of seafood
- In 2010 there were 10 – 11 million import food entries into U.S. , and increasing

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U.S Food Imports

By Entry Count (FY 2010 FDA OASIS Data)

Canada 28%

Mexico 22%

Europe 19%

Asia less China 11%

China 9%

Central & South America less Mexico 5% (570K)

Rest of world 6%

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FDA Tools To Manage Imports

- Prior Notice – FDA mandatory advance notice of entries and their air, sea, or land entry points
- OASIS – FDA electronic system for tracking all import shipments by origin, commodity, and dispensation
- PREDICT – Import entry software that helps target FDA sampling and review using risk management principles and compliance histories

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Intelligence Applied To Import Monitoring

- U.S. Government purchased foreign pesticide usage data (dependent on funding; last data was 2007)
- Information from FDA foreign offices located in Chile, China, Costa Rica, Europe (3), India (2), and Mexico (e.g., isocarbophos in bean and pea products)
- Results of USDA's PDP and available state program data (particularly California)
- Other available reports of pesticide monitoring, such as that of the European Union

Intelligence Applied To Imports (con't)

- EPA is providing information to FDA on U.S. manufactured and exported, but never-registered pesticides, especially those that have foreign MRLs and may be used on children's foods
- Import data from USDA's Pesticide Data Program
- Results of recent FDA monitoring

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FDA Sanctions on Violative Import Entries

- Entry refused admission (exported or destroyed)
- Commodity and grower (or mfg) likely placed on FDA Import Alert for specific residue violation
- Future shipments are on Detention W/O Physical Examination (DWPE). Applies only to offending grower or mfg. Cannot extend sanctions to those in good standing. Products on DWPE permitted entry only if FDA provided acceptable lab analysis showing product is in compliance for the offending residue(s).

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FDA Detention W/O Physical Examination (DWPE)

- Removal of grower or manufacturer from DWPE requires a minimum of 5 consecutive in-compliance shipments and/or other evidence of correction
- Hundreds of commodity and growers or manufacturers currently on FDA Import Alert
- For country- or region- wide pesticide problems, geographical areas can also be placed on Import Alert

Exporters to the U.S. – What To Know?

- Be very familiar with U.S. MRLs, including crop groupings (about 30 crop groups exist; some tolerances may be for individual crops and others for the group)
- FDA testing is expanding residue coverage and using "intelligence" to better target samples
- Once on Import Alert, expensive to get off and subject to increased monitoring

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Exporters to the U.S. – What To Know?

- FDA goal is compliance with U.S. MRLs, not specifically regulatory actions or placing growers and manufacturers on Import Alert
- Based on foreign usage information, FDA may be targeting specific pesticides used abroad, such as benomyl and carbendazim (a pesticide & benomyl metabolite), and propineb. Carbendazim and propineb have no U.S. registration and all U.S. benomyl MRLs have expired
- Based on past violations, regional foods that may result in additional coverage include berries, fresh and dried hot peppers, leaf and stem vegetables (bok choy), pepinos, papaya, and squash

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U.S. Food Safety Modernization Act (FSMA)

(http://www.fda.gov/Food/FoodSafety/FSMA/default.htm)

- Signed into law 1/4/11
- Provides FDA with greater authorities for foreign inspections and food imports overall, including requiring the use of risk-based preventative controls
- Key for food contaminants – "Importers shall perform foreign supplier verification activities that imported food is not adulterated under section 402" (… of the FD & C Act). Section 402 includes pesticides
- FDA has 1 year to issue guidance to assist importers in developing foreign supplier program

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Links to FDA/U.S. Pesticide Information

fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/default.htm

epa.gov/gateway/learn/pestchemtox.html

usda.gov/wps/portal/usda/usdahome?navid=FOOD_SAFETY

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FDA's Regulatory Pesticide Program

Thank you!