Pesticide Residues in Food

GMA Science Forum
March 27, 2018

Michael McGuffin

President, American Herbal Products Association
mmcguffin@ahpa.org

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Overview

- Pesticide tolerances under FIFRA
- Prevalence of pesticide residues
- Pesticides under FSMA
- Ideas and suggestions

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Pesticide tolerances

- Set by regulation (FR notice); 40 CFR 180
- Significant fees apply ($627k-new active/food use; $264k-first food use; $66-additional foods)
- Per pesticide / per crop (general rule)
- Per crop group (option for some minor crops)
- Exemptions from tolerances also set
- If no tolerance or exemption, tolerance is zero (action at 0.01 ppm = 10 ppb)

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Residues in foods

FDA Pesticide Residue Monitoring Program for Fiscal Year 2015

- 5,989 samples: 5,572 human foods (4,737 import; 835 domestic) + 417 animal foods (202 imports; 215 domestic)
- Methods could detect 696 pesticides and industrial chemicals; residues of 207 actually found; 11 new in 2015 study.
- Many of the foods analyzed limited to 1 or 2 samples.
- *"…the levels of pesticide chemical residues measured by FDA in the U.S. food supply are generally in compliance with EPA pesticide tolerances."*

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Residues in foods

FDA Pesticide Residue Monitoring Program for Fiscal Year 2015

- *"…no pesticide chemical residues were found in 49.8% of the domestic and 56.8% of the imported human food samples…"*
- *"For human foods, the domestic violation rate was 1.8% and the import violation rate was 9.4%..."*
- *"The violation rates for FY 2015 are consistent with those from FY 2012 - 2014, i.e., 1.4 - 2.8 % for domestic samples and 11.1 – 12.6 % for import samples."*

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Residues in foods

FDA Pesticide Residue Monitoring Program for Fiscal Year 2015

- 27 imported human foods "may warrant special attention" if >20 samples **OR** >3 violations **AND** violation rate >10%
- Almost all minor crops: cabbage (27%), cilantro (27%), jackfruit (29%), mushrooms (27%); parsley (22%), peas (13%), quinoa (12%), rice (21%), wolfberry (40%); etc.
- The majority of the violations for these commodities are "no-tolerance violations" – that is, residue present for a pesticide for which there is no regulatory tolerance for the crop.
- *"… about 80% of them are < 0.1 ppm."*

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Residues in foods

USDA Pesticide Data Program, 2015

- Program ongoing since 1991
- 2015 sampling / testing carried out with the support of 10 states
- 10,187 samples (76.1% domestic; 23.0% imports; 0.9% unknown)
- Limited to 11 fruits (apples, cherries, grapefruit, grapes, nectarines, oranges, peaches, pears, strawberries, tomatoes, watermelon); 6 vegetables (cucumbers, green beans, lettuce, potatoes, spinach, sweet corn); and peanut butter.
- Minimum of 600 samples per commodity.
- Analysis after washing *"for 15-20 seconds with gently running cold water as a consumer would do."*

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Residues in foods

USDA Pesticide Data Program, 2015

- Residues exceeding established tolerance detected in only 54 samples (0.53%; 18 imported + 36 domestic).
- Residues with no established tolerance detected in 394 samples (3.9%; 129 imports; 259 domestic; 6 unknown).
- *"In most cases, these pesticides with no established tolerance were detected at very low levels."*
- *"Some pesticide residues may have resulted from unintentional spray drift in the field, planting of crops in fields previously treated with the pesticide, or transfer of pesticide residues of postharvest fungicides or growth regulators applied to other commodities stored in the same storage facilities."*

Environmental residues

- Hoferkamp L, Hermanson MH, and Muir DCG. 2010. Current use pesticides in Arctic media; 2000–2007. *Sci Total Envir* 408:2985-2994.
- Ruggirello RM et al. 2010. Current use and legacy pesticide deposition to ice caps on Svalbard, Norway. *J Geophys Res* 115(8): doi:10.1029/2010JD014005.
- Zhang X et al. 2013. Atmospheric deposition of current use pesticides in the Arctic: Snow core records from the Devon Island Ice Cap, Nunavut, Canada. *Environ Sci Processes Impacts* 15:2304-2311.
- Hung H et al. 2016. Temporal trends of Persistent Organic Pollutants (POPs) in arctic air: 20 years of monitoring under the Arctic Monitoring and Assessment Programme (AMAP). *Environ Pollution* 217:52-61.
- Morris AD et al. 2016. Current-use pesticides in seawater and their bioaccumulation in polar bear–ringed seal food chains of the Canadian Arctic. *Environ Tox Chem* 35(7):1695-1707.
- Moreno-González R and León VM. 2017. Presence and distribution of current-use pesticides in surface marine sediments from a Mediterranean coastal lagoon (SE Spain). *Environ Sci Pollut Res* 24:8033-8048.

Pesticides and FSMA

21 CFR 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

117.130: Hazard analysis

- (a)(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control.
- (b)(1) The hazard identification must consider … Known or reasonably foreseeable hazards that include … (ii) Chemical hazards, including … ***pesticide residues*** …
- (b)(2) Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons: … (ii) The hazard may be ***unintentionally introduced***

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Pesticides and FSMA

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: DRAFT Guidance, January 2018

- Foreign supplier verification activities "should be risk based and focus only on those hazards that are known or reasonably foreseeable."
- "For example, if you are purchasing cucumbers from a country, region, or grower with a history of pesticide residue violations for that food, we would expect you to address this potential adulteration and conduct verification activities to ensure that the cucumbers do not bear or contain pesticide chemical residues that cause the cucumbers to be adulterated. Conversely, if the cucumbers come from a country or region with no history of pesticide residue violations, we would not expect you to identify unsafe pesticide residues as a hazard that requires a control (unless new information came to light or questions about the use of pesticides or control of pesticide residues indicated an issue), and we would not expect you to conduct verification activities related to such a hazard."

Status quo: "bottom line"

Pesticide use/presence on any crop limited to:

- A pesticide exempt from tolerances
- Tolerance established for *that* pesticide on *that* crop
- Crop in a crop group with tolerance for *that* pesticide on *that* crop group
- FDA action level = 0.01 ppm (10 ppb)

Other factors:

- Environment pesticide presence well established
- Food pesticide residue is not overly common but also not rare; much more common on minor crops
- New FSMA rules define even "unintentionally introduced" pesticides as hazards that require control under cGMP

Practical rules: Status quo

Crop Groups

- 24 current crop groups
- Focus on “minor use” (less than 300,000 acres in U.S.)
- Tolerance set for a number of crops based on data from representative crop
- Significant current attention to revisions to crop groups (EPA; IR-4; Codex; NAFTA)

Practical rules: Status quo

Crop Groups

- Many minor use and herbal ingredients already included in several crop groups
  - CG1: Root and tuber vegetables: Burdock; chicory; ginger; ginseng; turmeric
    - Tolerances: 2,4-D; carbaryl; trifluralin; diquat; methomyl; etc.
  - CG3-07: Bulb vegetables: Fritillaria; garlic; wild leek
    - Tolerances: Endothal (indirect or inadvertent residue); glyphosate; pyriproxiphen; etc.
  - CG4: Leafy vegetables (non-brassica): Chrysanthemum; dandelion; sorrel; parsley
    - Tolerances: Captan; malathion; bensulide; several “indirect or inadvertent” residues; etc.
  - CG21: Edible fungi: Shiitake; reishi
    - No tolerances yet established

Practical rules: Status quo

Crop Group 19: Herbs and Spices

- 77 commodities currently listed
- Current tolerances: Ethylene oxide and propylene oxide (postharvest fumigants; 7-300 ppm respectively); glyphosate (0.2 ppm-herb subgroup / 7 ppm-spice subgroup); etc.
- Revision in process:
  - AHPA has requested addition of an additional ~200 commodities
  - AHPA's request submitted May 2013 – approaching 5 years
  - Reportedly EPA will propose two revised crop groups:
    - Herbs (300+)
    - Spices (100-150)

Practical rules: New ideas

Except environmental exposures from "pesticide" definitions

- A food is adulterated *"…if it bears or contains a pesticide chemical residue that is unsafe"* within the meaning of FFDCA. 21 U.S.C. 342 (a)(1).
- A pesticide is unsafe under FFDCA if present at a level more than an established tolerance or there is an tolerance exemption for the pesticide. 21 U.S.C. 346a (a).
- The Food Quality Protection Act of 1996 (FQPA) amended FIFRA and FFDCA; among other details, FQPA provided EPA with authority to except a substance from the definition of "pesticide chemical" or "pesticide chemical residue" if:
  - its occurrence … in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of the RAC or food;
  - EPA consults with FDA and determines that the substance more appropriately should be regulated under a different provision of food law.

  [21 U.S.C. 321 (q)(3)]

Practical rules: New ideas

Consideration of general tolerances

- Consider a mechanism to create default tolerances which would apply to “all other crops” whenever a pesticide is registered in the U.S. for use on one or more food crops or when an import tolerance has been established. The default tolerance for any food in the “all other crops” category should be calculated, based on the expected annual consumption of the food, to result in an exposure that is trivial compared to the exposures that EPA knows will result from the use of the pesticide as registered in the U.S.
- Consider establishment of a single tolerance level that would safely cover numerous pesticides on a wide variety of foods that form a trivial part of the diet. For example, EPA could issue a regulation that sets a tolerance of 0.1 ppm for all pesticides residues for all commodities in Crop Group 19 (herbs and spices). If the Agency had special risk concerns about some pesticides these substances could be specifically excluded from such regulation.

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Practical rules: New ideas

Greater harmonization

- Consider harmonizing with MRLs established by the Codex Alimentarius Commission. This approach is envisioned under FFDCA, where EPA is instructed in establishing a tolerance to *"…determine whether a maximum residue level for the pesticide chemical has been established"* by Codex, and, if a Codex MRL has been established for the pesticide and EPA does *not* propose to adopt the Codex level, to publish for public comment a *"notice explaining the reasons for departing from the Codex level."* 21 U.S.C. 346a (b)(4). The scientific evaluations to support these MRLs have already been conducted and should be available to EPA.
- Consider greater harmonization with MRLs and tolerances established by government agencies in other countries that also rely on scientifically sound processes to evaluate safety.

Practical rules: New ideas

Greater harmonization

- Consider the work of authoritative nongovernmental bodies that rely on sound scientific processes to evaluate pesticide safety.
  - NSF International: Chemical-Specific Maximum Allowable Levels for Pesticide Residues in Dietary Supplements
  - U.S. Pharmacopeia: General Chapter <561>, Articles of Botanical Origin

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THANK YOU!

Michael McGuffin

mmcguffin@ahpa.org

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