

FDA's Pesticide Residue Monitoring Program Updates and Channels of Trade Guidance for Chlorpyrifos

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Agenda

- Overview of FDA's pesticide monitoring program
- Data from Fiscal Year 2019
- Channels of Trade guidance for chlorpyrifos

Pesticide Residue Monitoring Program



Threefold Approach:

1. Regulatory Monitoring

- Enforce tolerances

2. Special Assignments

- Specific commodity/pesticides/countries

3. Total Diet Study

- Estimate dietary exposure to contaminants and nutrients

Regulatory Monitoring



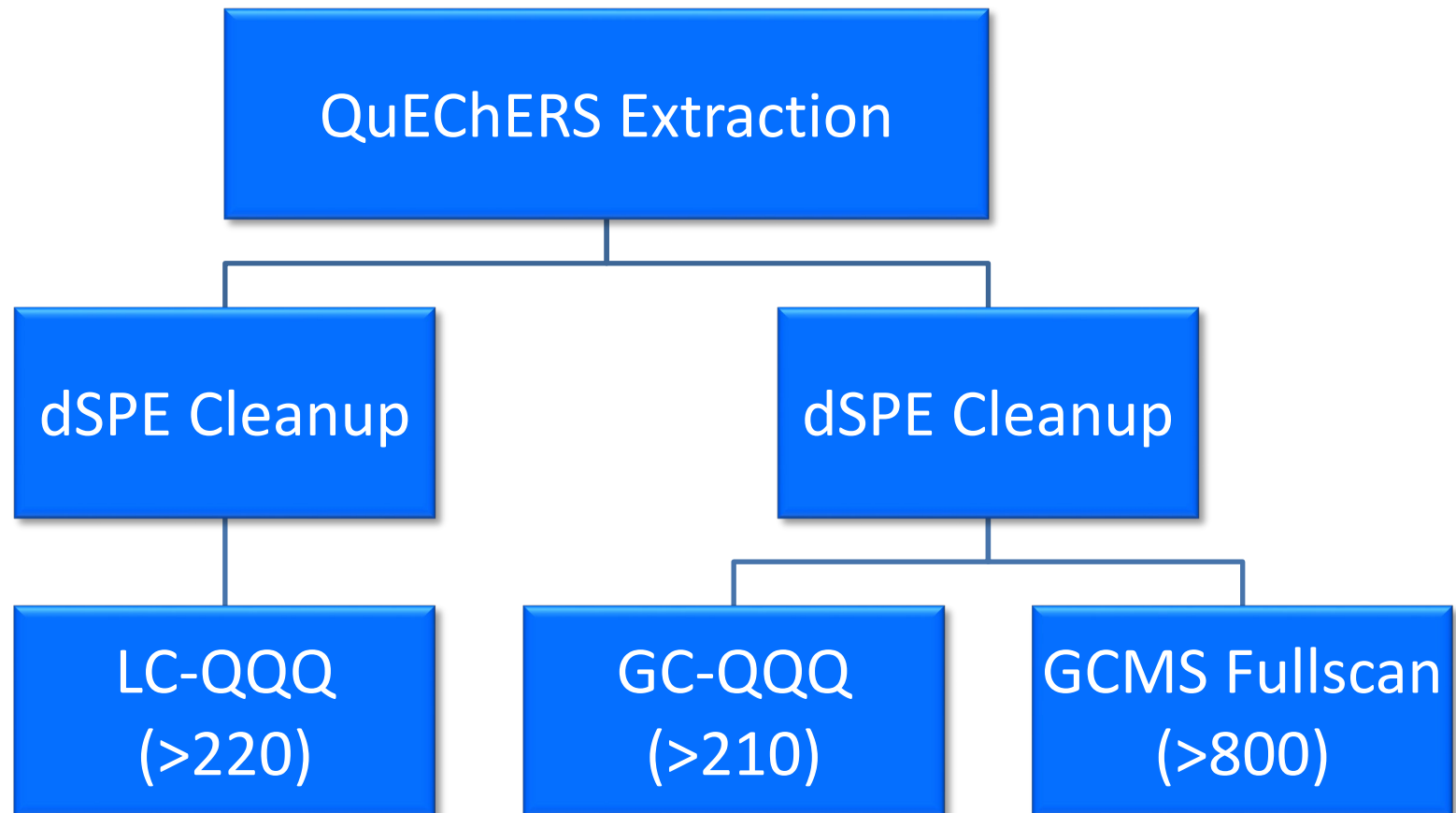
- Targeted sampling:
 - Violation history
 - State/USDA monitoring reports
 - Pesticide usage reports
 - Dietary significance
 - Foods consumed by infants & children
 - Foreign agencies reports
 - Volume in commerce
 - Toxicity & characteristics of pesticides
- Coordination with other agencies

Regulatory Monitoring

- **Domestic** – Interstate Commerce
 - close to the point of production (e.g., at grower or packing sheds)
- **Import** – Point of entry
- **Sample Types**
 - Raw agricultural commodities (unwashed, whole, unpeeled)
 - Processed foods (limited)
 - Animal food
- **Samples per year:** 4000-8000
- **Analytes:** ~800 pesticides per sample



Multi-residue Methods (MRMs)



Capable of simultaneously determining many different pesticide chemical residues and metabolites.

Selective Residue Methods (SRMs)

- Optimized to determine one or several specific pesticide chemical residues in foods.
- More resource intensive and therefore employed more judiciously.
 - To analyze pesticides that are not adequately extracted or detected using standard MRMs
 - To target specific pesticide/commodity combinations

Examples:

- Glyphosate SRM for glyphosate, glufosinate, and their metabolites
- Acid herbicides SRM for 30 selected acid herbicides

Limit of Quantitation

- FDA defines limit of quantitation (Lq) as the lowest level of residue that can be quantitated by a given method and whose identity can be confirmed in regulatory laboratories.
- When MRMs are used, a separate Lq applies to each residue determined by the method because each represents a different analytical situation.
- Section 105 of the [Pesticide Analytical Manual](#) states “For general purposes, results at or below 0.010 ppm are deemed to have an Lq of 0.010 ppm.”

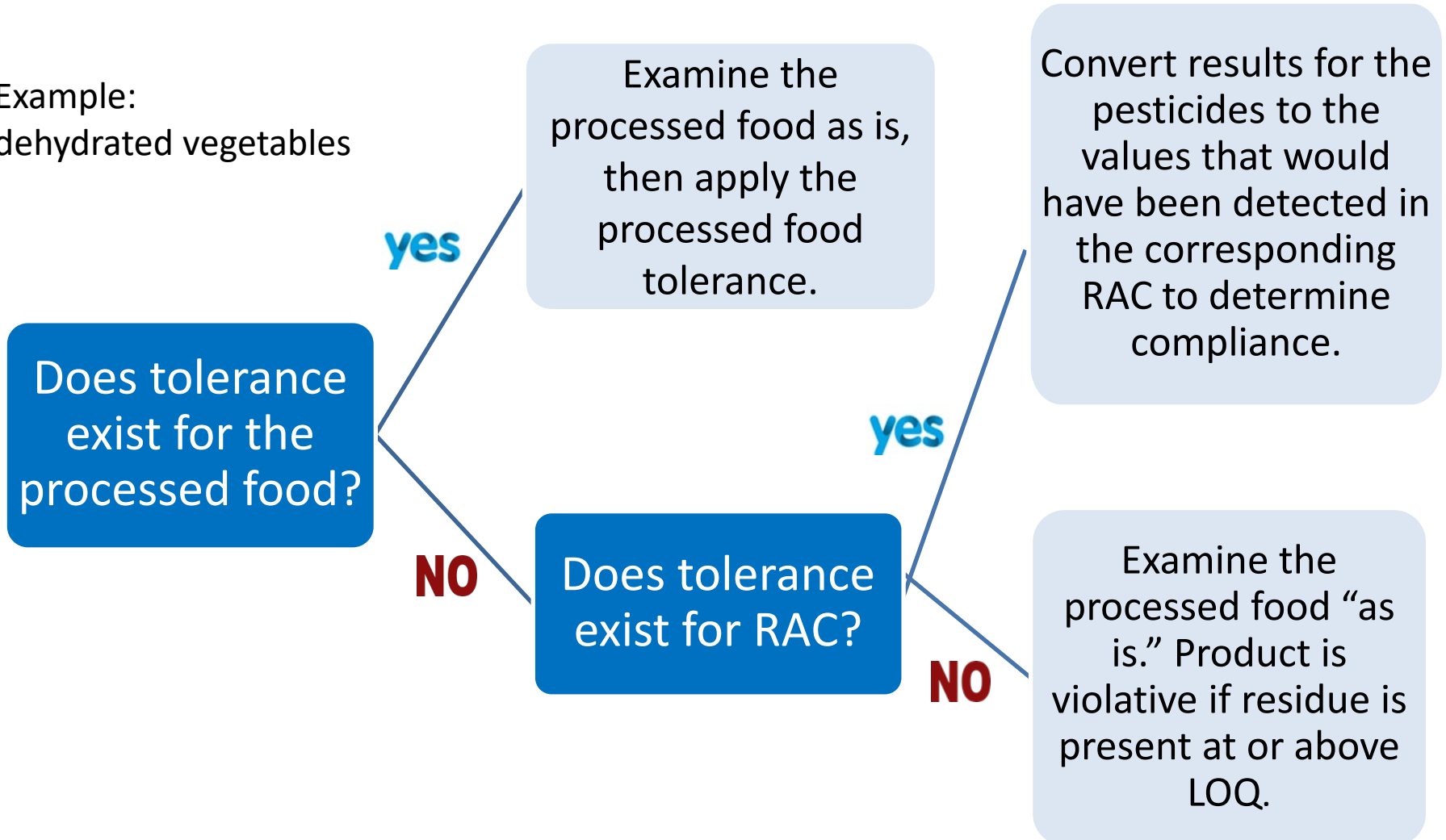
How does FDA enforce tolerances?

**Raw Agricultural Commodity (RAC)
VS.
Processed Food**



Tolerance Compliance for Dehydrated Processed Food

Example:
dehydrated vegetables



FY 2019 Pesticide Residue Monitoring Report and Data

Pesticide Residue Monitoring Report and Data for FY 2019



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Pesticides

Pesticide Residue Monitoring
Program Questions and
Answers

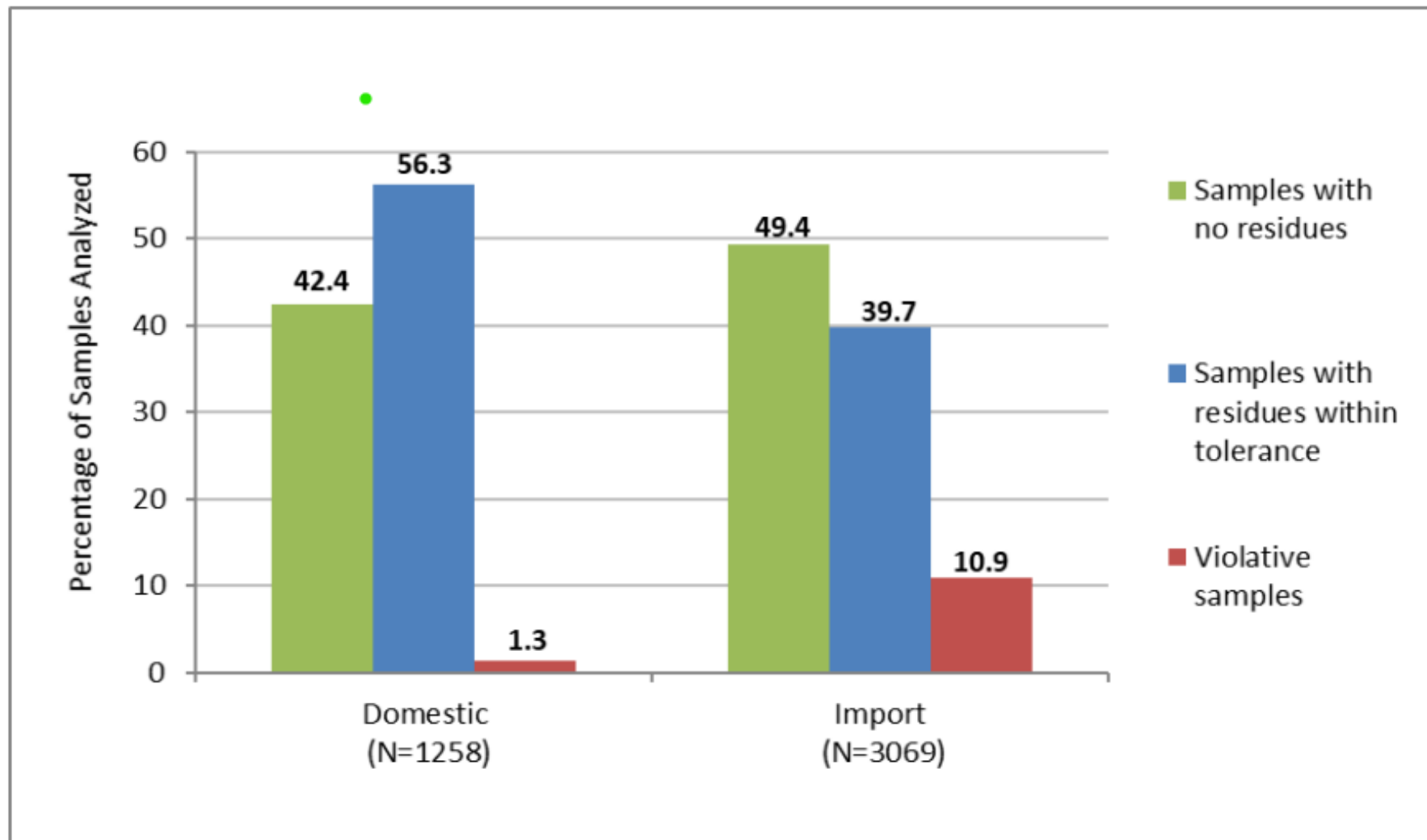
Welcome to the U.S. Food and Drug Administration (FDA) Pesticide Residue Monitoring Report and Data for Fiscal Year (FY) 2019. The report summarizes the results of FDA's pesticide monitoring program for FY 2019. Results in the report demonstrate that levels of pesticide residues in the U.S. food supply are well below established safety standards.

[2019 Report \(PDF: 705 KB\)](#)

Content current as of:
10/20/2021

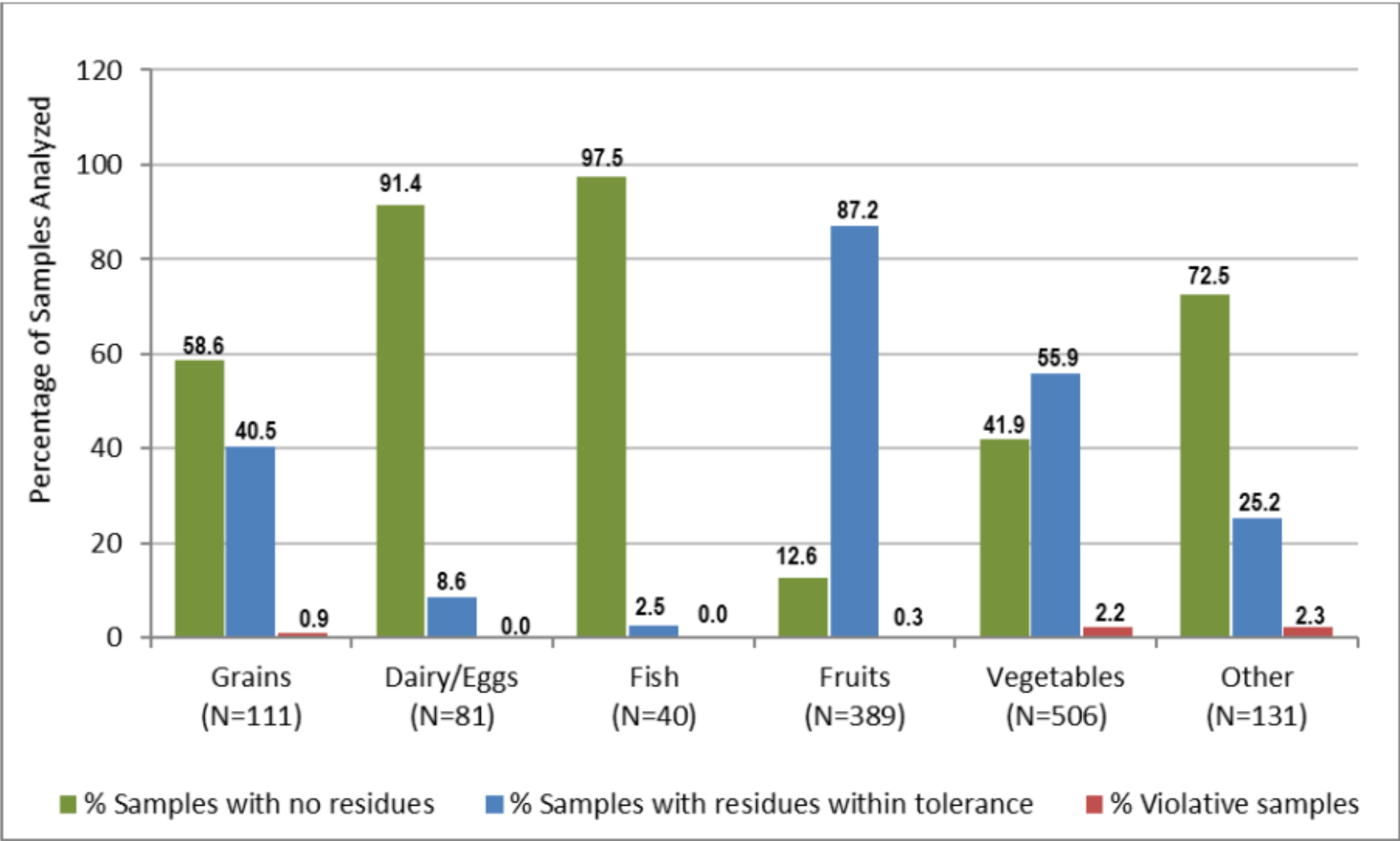
Regulated Product(s)
Food & Beverages

FY19 Data: Domestic vs. Import



Violations rate is consistent with recent years; for FY 2012-2018 the domestic violation rate ranged from 0.9-3.8% and the import violation rate ranged from 9.4 to 12.9%.

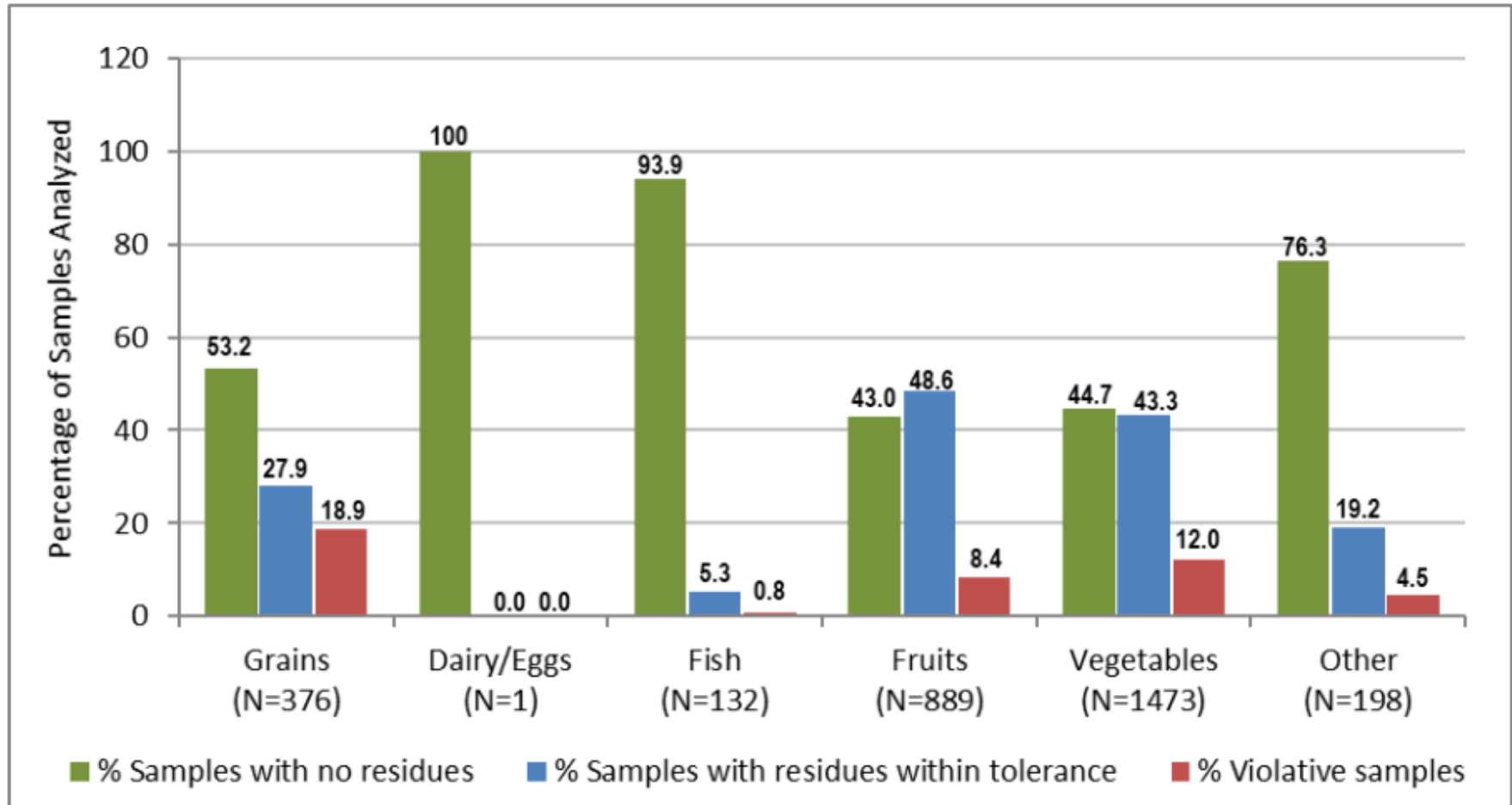
Domestic Samples by Commodity Group



N = Number of samples analyzed for commodity group

“Other” consisting largely of nuts, seeds, oils, honey, and spices,

Import Samples by Commodity Group



N = Number of samples analyzed for commodity group

The highest % of violation is found in imported grain, mainly due to rice. 61 (85.9%) of the grain product violations were rice and rice products.

Violation Rate: Domestic vs. Import

	Domestic (%)	Import (%)
Grains	0.9	18.9
Fruits	0.3	8.4
Vegetables	2.2	12.0
Other	2.3	4.5

Violation Types

	Domestic	Import
# of Violative Samples	16	333
# of No Tolerance (NT)	13	308
# of Over Tolerance (OT)	4	68
# of NT and OT	1	43

Focused Sampling: Animal-Derived Foods Assignment



Commodity	Samples Analyzed N	Without Residues N (%)	Violative Samples N (%)
Total	153	136 (89.9)	2 (1.3)
Milk	38	38 (100)	0
Eggs	42	35 (83.3)	0
Honey	62	53 (85.5)	2 (3.2)
Bison	5	4(80)	0
Elk	2	No residues found	
Rabbit	2		
Venison	2		

Import Commodities That May Warrant Special Attention

The following criteria were applied to the data to select import commodities that may warrant special attention:

- commodities with at least 20 samples analyzed OR with a minimum of 3 violations, and
- a violation rate of 10% or higher

Import Commodities That May Warrant Special Attention



Commodity	Samples Analyzed	Violation Rate (%)
Taro, Dasheen*	9	77.8
Chana dal	7	42.9
Nectarine	7	42.9
Prickly pear*	10	40.0
Cilantro*	71	31.0
Spinach*	36	27.8
Dragon Fruit*	19	26.3
String beans*	24	25.0
Rice*	268	22.4
Dates	45	22.2
Figs	18	22.2
Radish*	46	21.7
Mushrooms and fungi*	47	21.3

Commodity	Samples Analyzed	Violation Rate (%)
Peas*	59	20.3
Mung beans	32	18.8
Kale	17	17.7
Carrots*	49	14.3
Celery*	21	14.3
Strawberries	41	12.2
Pepper, hot*	132	12.1
Raisins*	34	11.8
Pepper, sweet*	52	11.5
Yam/Sweet potato*	29	10.3
Pineapple	30	10.0

*Commodity was on the FY 2018 table of import commodities warranting special attention

Recent Scientific Publication



Food Additives & Contaminants: Part A



ISSN: (Print) (Online) Journal homepage: <https://www.tandfonline.com/loi/tfac20>

US Food and Drug Administration regulatory pesticide residue monitoring of human foods: 2009-2017

Chia-Pei Liang, Chris Sack, Sara McGrath, Yu Cao, Clinton J. Thompson & Lauren Posnick Robin

To cite this article: Chia-Pei Liang, Chris Sack, Sara McGrath, Yu Cao, Clinton J. Thompson & Lauren Posnick Robin (2021): US Food and Drug Administration regulatory pesticide residue monitoring of human foods: 2009-2017, Food Additives & Contaminants: Part A, DOI: [10.1080/19440049.2021.1934574](https://doi.org/10.1080/19440049.2021.1934574)

To link to this article: <https://doi.org/10.1080/19440049.2021.1934574>

Top 5 Frequently Detected Residues

Residue	Type of pesticide	Top five commodities in which pesticide was detected in ranked order by number of detections
Boscalid	Anilide fungicide	Strawberry, papaya, grape, tomato, blueberry
Imidacloprid	Neonicotinoid insecticide	Hot pepper, rice, sweet pepper, squash, tomato
Chlorpyrifos	Organophosphate insecticide, acaricide and miticide	Hot pepper, sweet pepper, rice, olive oil, cactus (nopales)
Carbendazim	Benzimidazole fungicide, metabolite of thiophanate-methyl	Hot pepper, rice, apple, strawberry, orange
Azoxystrobin	Strobilurin fungicide	Papaya, hot pepper, onion, sweet pepper, tomato

Channels of Trade Guidance

GUIDANCE DOCUMENT

Guidance for Industry: Questions and Answers Regarding Channels of Trade Policy for Human Food Commodities with Chlorpyrifos Residues

FEBRUARY 2022

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Docket Number: [FDA-2016-D-4484](#)

Issued by: Center for Food Safety and Applied Nutrition

Content current as of:
02/09/2022

Channels of Trade Provision



- Section 408(l)(5) of the FD&C Act:
 - addresses the situation where food, containing pesticide chemical residues from pesticide chemicals that were lawfully applied or used under FIFRA, is still in commerce after the pesticide chemical tolerance has been revoked, suspended, or modified.
- A firm needs to provide evidence showing that:
 - (A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful;
 - (B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food.

Channels of Trade Provision



- **Exception:**

If EPA has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

- We intend to use the same enforcement approach for both domestic and imported food.

Guidance for Industry



- In 2005, FDA published a [Guidance for Industry](#) explaining the general enforcement approach for foods containing residues of pesticide chemicals, for which tolerances have been revoked, suspended, or modified by EPA, pursuant to dietary risk considerations.
 - Pesticide specific guidance:
 - [Methyl parathion](#) in 2000
 - [Vinclozolin](#) in 2002
 - [Chlorpyrifos](#) in 2022
- Would not be used to cover pesticide tolerances revoked by the request of the registrant due to cessation of its production. EPA allows time for food that may bear such pesticide residues to clear the channels of trade before revocation of the tolerances.

Guidance for Industry



- Does not apply to food regulated by USDA under the Poultry Products Inspection Act, the Federal Meat Inspection Act, and the Egg Products Inspection Act.
- Does not apply to animal food regulated by FDA.
- Questions regarding USDA-regulated products can be sent to USDA through askFSIS (<https://www.fsis.usda.gov/contact-us/askfsis>).
- Questions to CVM can be sent to AskCVM@fda.hhs.gov

Guidance for chlorpyrifos



- EPA issued a final rule on 8/30/2021 to revoke all pesticide tolerances for chlorpyrifos residues in food. The expiration date for the tolerances is 2/28/2022.
- On 2/9/2022, FDA published a guidance for industry to address the general enforcement approach for foods containing residues of chlorpyrifos after the tolerances expired.
- **Table 1** of the guidance lists showing dates, which are starting dates after which firms need to provide documentation to demonstrate that residues are the result of legal applications before 2/28/2022.

Commodities	Showing Date
Asparagus	September 1, 2022
Banana	
Beet, sugar, tops	
Cherry, sweet	
Cherry, tart	
Corn, sweet, kernel plus cob with husk removed	
Cranberry	
Cucumber	
Egg	
Fig	
Grape	
Nectarine	
Peach	
Pepper	
Peppermint, tops	
Plum, prune, fresh	
Pumpkin	
Radish	
Spearmint, tops	
Strawberry	
Turnip, tops	
Vegetable, brassica, leafy, group 5	
Vegetable, legume, group 6, except soybean [succulent legumes]	
Whole Milk	

Table 1

FDA

Commodities	Showing Date
Beet, sugar, roots	March 1, 2023
Fruit, citrus, group 10	
Kiwi	
Onion, bulb	
Rutabaga	
Sweet potato, roots	
Turnip, roots	Sep 1, 2023
Apple	
Pear	March 1, 2024
Almond	
Corn, field, grain	
Hazelnut	
Peanut	
Pecan	
Sorghum, grain, grain	
Soybean, seed	
Sunflower, seed	
Vegetable, legume, group 6, except soybean [dried legumes]	
Walnut	
Wheat, grain	

Table 1 does not include RACs intended for animal food use, or commodities under the jurisdiction of USDA, such as meat.

How showing dates are calculated

- Chlorpyrifos remains at detectable levels on crops during their entire storage and retail time period.
- The showing dates are estimated using the last lawful application date as a starting point, plus the time period required for crop growth, harvest, storage, distribution and sale.

Example 1: Sweet corn

Growth: 3 months

Storage/distribution/sale: 3 months

Showing date: 09/01/2022

Example 2: Apples and Pears

Growth: 5 months

Storage/distribution/sale: 13 months

Showing date: 18 months after the last lawful application date

Enforcement strategy related to showing dates



Stage 1: Between tolerance expiration date (2/28/2022) and showing dates:

- No documentation needed; we intend to consider that the pesticide residue found by FDA, that is within the former tolerance, is the result of lawful application.
- We anticipate that raw agricultural commodities (RACs) lawfully treated with the pesticide will not remain in the channels of trade as RACs after the showing dates.
 - Either sold to consumers or food processors.

Enforcement strategy related to showing dates

Stage 2: Showing date and beyond:

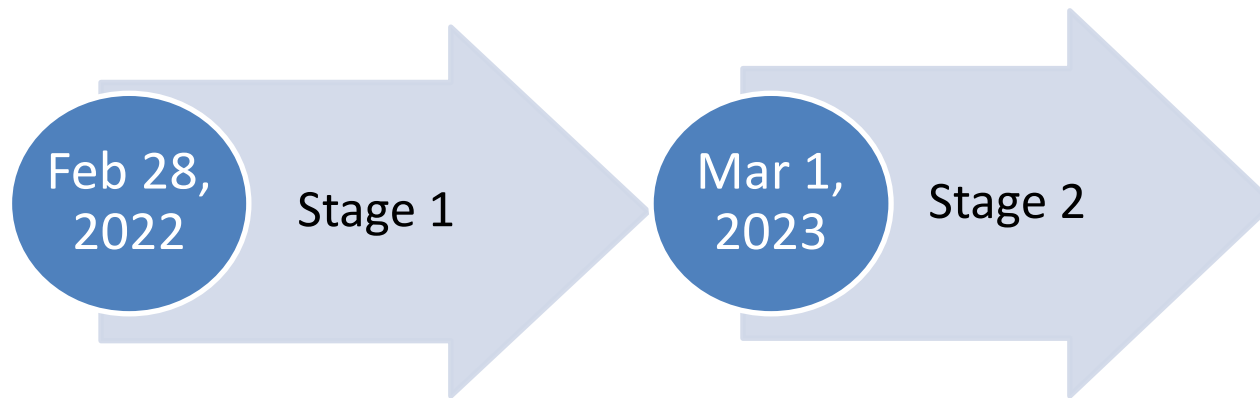
- Raw Agricultural Commodities (RACs):
Documentation is needed to prove residues are from lawful application under tolerances.
- Processed food: Documentation is needed to prove RACs are purchased by the showing dates for processing.

Stages in guidance related to showing dates: Stage 2 cont'd



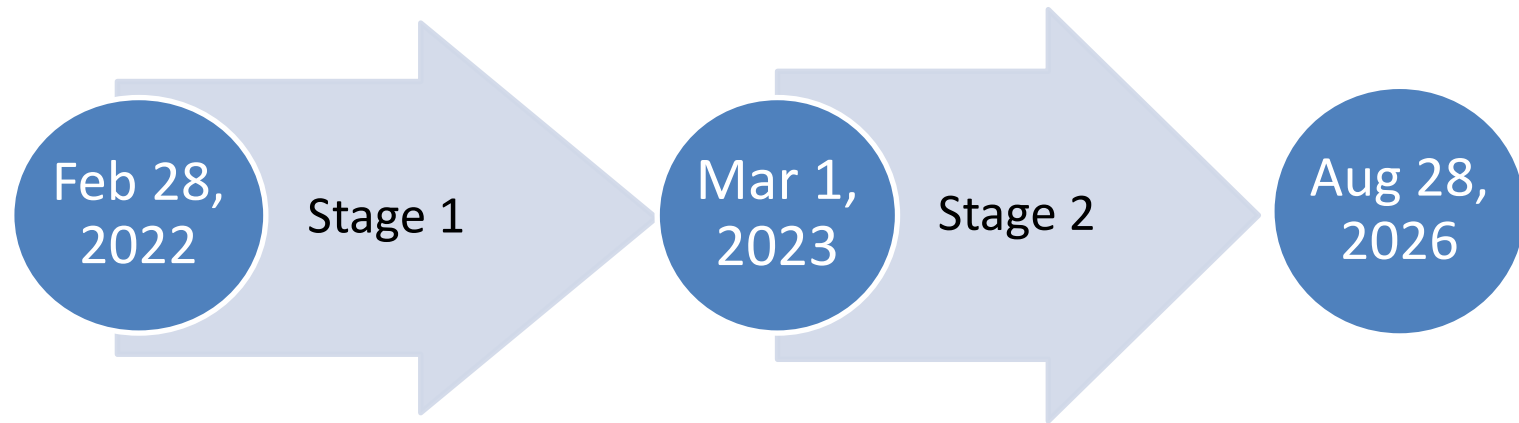
- The anticipated end date for considering showings is 4.5 years, based on an average growing time for crops of 6 months and an additional 4 years from the time the treated crop is harvested.
- After August 28, 2026, firms are still permitted to make a showing. However, based on the information available to us, we do not expect that most firms would be able to make such a showing after 4.5 years.

Example: Fresh Rutabagas



- Stage 1: If we find chlorpyrifos residues at or below 0.5 ppm, we generally do not intend to request a showing. We anticipate that fresh rutabaga would be either sold to consumers or processors by the end of stage 1.
- Stage 2: The firm responsible for the rutabagas would have the opportunity to show that the residues resulted from lawful application before February 28, 2022.

Example: Canned Rutabagas



- Stage 1: If we find chlorpyrifos residues at or below 0.5 ppm, we generally do not intend to request a showing.
- Stage 2: The firm responsible for the canned rutabagas would have the opportunity to show that the residues resulted from lawful application before February 28, 2022.
- Starting from August 28, 2026, we do not expect that the responsible firm would be able to make such a showing.

Examples of Documents to Show Applicability



- Dated invoices, bills of sale, airway bills, or customs entry forms to prove that a processor purchased raw agricultural materials from a grower on or before the showing date.
- A product's label bearing a packing code, in conjunction with documentation that relates that code to a batch record indicating a date on which the product was packed or processed, e.g., peeled, blanched, frozen.

Submit Comments

Submit Comments

Submit Comments Online

You can submit online or written comments on any guidance at any time (see 21 CFR 10.115(g)(5))

If unable to submit comments online, please mail written comments to:

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

All written comments should be identified with this document's docket number: FDA-2016-D-4484.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-channels-trade-policy-human-food-commodities>

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