# U.S. Pesticide Regulatory Decisions and Channels of Trade Considerations for Implementation

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# EPA's Overall Goals for Pesticides:

- Effectively assess, manage and mitigate pesticide risks based on best available science, involving stakeholders and the public.
- After a pesticide is registered with EPA for the first time, subsequent reviews occur to ensure currently registered pesticides continue to meet safety standards defined by applicable federal statutes.

# U.S. Pesticide Regulatory Framework

| Federal Statute | Key Features |
|---|---|
| **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)** | •Provides for federal regulation of pesticide distribution, sale, and use.<br>•All pesticides distributed or sold in the U.S. must be registered (licensed) by U.S. EPA.<br>•Established risk/benefit standard for registering pesticide products; FIFRA risk mitigation must consider the benefits of pesticides to users.<br>•Grants U.S. EPA strong authority to obtain toxicity and exposure data from pesticide registrants.<br>•Grants U.S. EPA ability to regulate pesticide labels and packaging. |
| **Federal Food, Drug, and Cosmetic Act (FFDCA)** | •The law established quality standards for food, drugs, medical devices, and cosmetics manufactured and sold in the United States. The law also provided for federal oversight and enforcement of these standards.<br>•Grants U.S. EPA authority to establish pesticide tolerances for foods and feeds.<br>•Requires that FDA and USDA monitor and enforce tolerances.<br>•FFDCA is a risk-only statute; FFDCA mitigation does not consider pesticide benefits to users. |
| **Food Quality Protection Act (FQPA)** | •It amended both FIFRA and FFDCA and mandated a health-based standard for pesticides used in foods.<br>•Established a more health protective standard (certainty of no harm).<br>•Requires the consideration of aggregate pesticide exposure, cumulative effects of pesticides with common mode of toxicity and special sensitivity of infants and children to pesticides. |
| **Endangered Species Act (ESA)** | •Protects threatened and endangered fish, wildlife, and plants from extinction.<br>•Under Section 7(a)(2) of the ESA, Federal agencies must ensure that the “actions” they authorize will not result in jeopardy or adversely modify designated critical habitat for species listed as endangered or threatened by the U.S. Fish and Wildlife Service (FWS) and/or the National Marine Fisheries Service (NMFS).<br>•For the Office of Pesticide Programs, our “actions” are the registration and registration review decisions for pesticides. |

# Implications of FFDCA

- Benefits cannot be considered under FFDCA
  - Dietary Risk – food, water, and/or food plus water for a single pesticide and its breakdown products
  - Aggregate Risk – dietary plus residential risk for a single pesticide and its breakdown products
  - Cumulative Risk – risks from all pathways of dietary and nondietary exposures to more than one pesticide acting through a common mechanism of toxicity
- EPA will seek to mitigate risks through measures like rate reductions, geographical restrictions, soil restrictions, to try to retain use(s)
- If there is no acceptable risk management strategy to retain food or feed uses, tolerances may need to be revoked

# Tolerance Revocation

- FIFRA cancellation then tolerance revocation – more common
  - After specific uses or products are cancelled, EPA will then go through the process of revoking tolerances
- Tolerance revocation then FIFRA cancellation
  - EPA coordinates with FDA and/or USDA prior to revocation
  - FDA develops guidance for enforcement on how long legally treated commodities may be in the channels of trade
  - EPA will then proceed with cancellation of the registrations under FIFRA

# Considerations for Implementing Decisions

- When possible, EPA works to implement FQPA in a way that includes consideration for affected pesticide users having the time and resources needed for transition to different and effective pest management tools
- EPA does encounter situations where we've identified critical uses where commodity production could face disruption when a critical pesticide will be lost and there are no identified alternatives
- Continued critical uses could be available through regulatory options such as phase outs during a specified transition period
- If tolerance revocation must occur before FIFRA cancellation, these regulatory options might not be feasible

**For more information**

General tolerance information:
https://www.epa.gov/pesticide-tolerances
Tolerance revocation:
https://www.epa.gov/pesticide-tolerances/revoking-pesticide-tolerances
Pesticide cancellation
https://www.epa.gov/pesticide-tolerances/pesticide-cancellation-under-epas-own-initiative

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# Channels of Trade Considerations for Pesticide Residues in Foods

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# Channels of Trade Provision

- Section 408(l)(5) of the Federal Food, Drug, and Cosmetic Act (FFDCA):

If a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary 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 under the Federal Insecticide, Fungicide, and Rodenticide Act; and

(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 under a tolerance, exemption, food additive regulation, or other sanction then in effect under this Act;

# 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.

# Guidance to Industry

- In 2005, FDA published a Guidance to 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
- Under this approach, FDA determines showing dates, which are dates after which firms need to provide documentation to demonstrate that residues are the result of lawful applications.
- We intend to use the same enforcement approach for both domestic and imported food.

# How showing dates are calculated

- For pesticides that degrade to non-detectable (ND) levels in food during their availability in channels of trade, the showing dates are determined by how long it takes for the pesticide residues to degrade to ND levels, assuming the pesticides are applied on the last lawful application date.
- Example: Methyl parathion
  - Ambient temperature: degrades to ND in 9 months
  - Refrigeration: degrades to ND in 1 year
  - Showing date: 1 year after last lawful application

# How showing dates are calculated

For pesticides that remain 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: Strawberries and Stone Fruits/vinclozolin

- Showing date:  5 months after the last lawful application date

Example 2: Apples and Pears/chlorpyrifos

Growth: 5 months

Storage/distribution/sale: 13 months

Showing date:  18 months after the last lawful application date

# Enforcement strategy related to showing dates

Between tolerance expiration date 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.

*2022 Chlorpyrifos channels of trade guidance.

# Enforcement strategy related to showing dates

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.

# End of showing period

- For certain processed foods, i.e., frozen, dried, and canned foods, the end of showing period is generally 4 years from the time the treated crop is harvested.
  - After that, firms may still make a showing to demonstrate that the residue is present as a result of a lawful application of the pesticide within the channels of trade provision. However, based on the information available to us, we do not expect that most firms 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.

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