Chlorpyrifos Update

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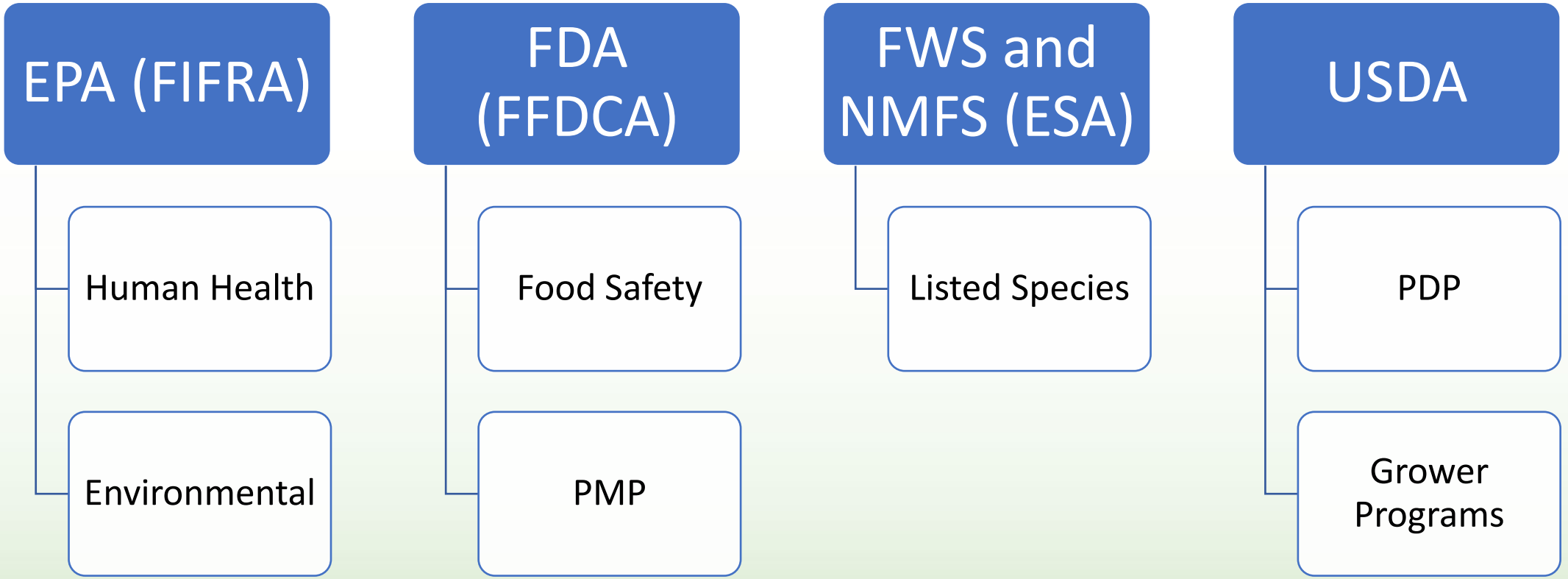
Pesticide Regulations in U.S



Chlorpyrifos: Epi Studies

- Columbia Center for Children's Environmental Health, Center for the Health Assessment of Mothers and Children of Salinas, and Mount Sinai School of Medicine, studies used as evidence of neurodevelopmental effects in infants and children following exposure
- CCCEH study must be understood in the context of the FQPA's requirement that EPA consider the "validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue"
  - Despite numerous requests, the researchers of the CCCEH study could not meet EPA's transparency needs nor agreed to the Agency's offers to anonymize the study data.
- EPA's Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel advised against using it as a basis for drawing a definitive link between chlorpyrifos and neurodevelopmental effects or using it to establish new toxicological points of departure
- CLA has commented on several flaws with the study over the years

Chlorpyrifos US Regulatory History

Background

- Since 2007 – series of lawsuits by activists for EPA to revoke food tolerances
- 2015 – President Obama requested EPA to initiate the process
- 2017 – President Trump reversed the rule
- 2021 – President Biden requested EPA to take action
- Lawsuits continued; banned in > 6 states

Current Status

- April 29, 2021: 9th Circuit Court of Appeals required EPA to either:
  - Revoke all food tolerances or modify tolerances with explanation of safety finding
  - Cancel registrations

EPA Next Steps

- Court Response - Issue final decision, expected ~August 2021
  - What crop uses survive?
  - Timeline for existing stocks?
  - Court decision only addresses food uses – what happens to non-crop uses?
- Chlorpyrifos PID
  - Safety Factor: 1x to 10x
  - Crop Uses

Science and Chlorpyrifos Regulatory Action

- New studies that do not show an adverse link between exposure and developmental outcomes not considered (Cartier et. al., 2016; Donauer et. al., 2016; Jusko et. al., 2019)
- Newly released data from in vitro developmental neurotoxicity assays developed by EPA's Office of Research and Development and the European Food Safety Authority support the conclusion that cholinesterase inhibition is the most sensitive toxicological endpoint for organophosphates chemicals (Masjosthusmann et al., 2020)
- The available toxicological databases for organophosphates are robust and include several high-quality guideline studies relevant to the evaluation of neurodevelopmental effects: rat multi-generation reproduction, rat and rabbit teratology, acute and sub-chronic neurotoxicity, comparative and age-related cholinesterase inhibition, and DNT studies. None of these studies have identified DNT effects below dose levels that cause cholinesterase inhibition.
- EPA should validate potential risks and revisit the literature review before cancelling any registrations or altering safety factor

What's Next:

- EPA is engaged with Registrants
  - Crop uses
  - Non-crop uses
  - Existing Stocks
- Registrants
  - Grower and commodity groups
  - States
- CLA
  - Continue to advocate for a science-based approach
  - Engage with stakeholders (Food and Beverage Companies)

CLA: Food and Beverage Committee

Vision: Be the recognized experts in management of existing and emerging issues affecting the global food and beverage industry regarding crop protection tools

Objectives

- Connecting the food and beverage industry with crop protection registrants
- Advocating for pesticide policies based on sound science
- Striving for mitigation of non-scientific barriers to global trade through establishment of import tolerances and MRL harmonization
- Educating stakeholders on safe use of pesticides and the safety assessment process used for pesticide registration in U.S

Thank you

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