

# Overview of the U.S. Coordinated Framework

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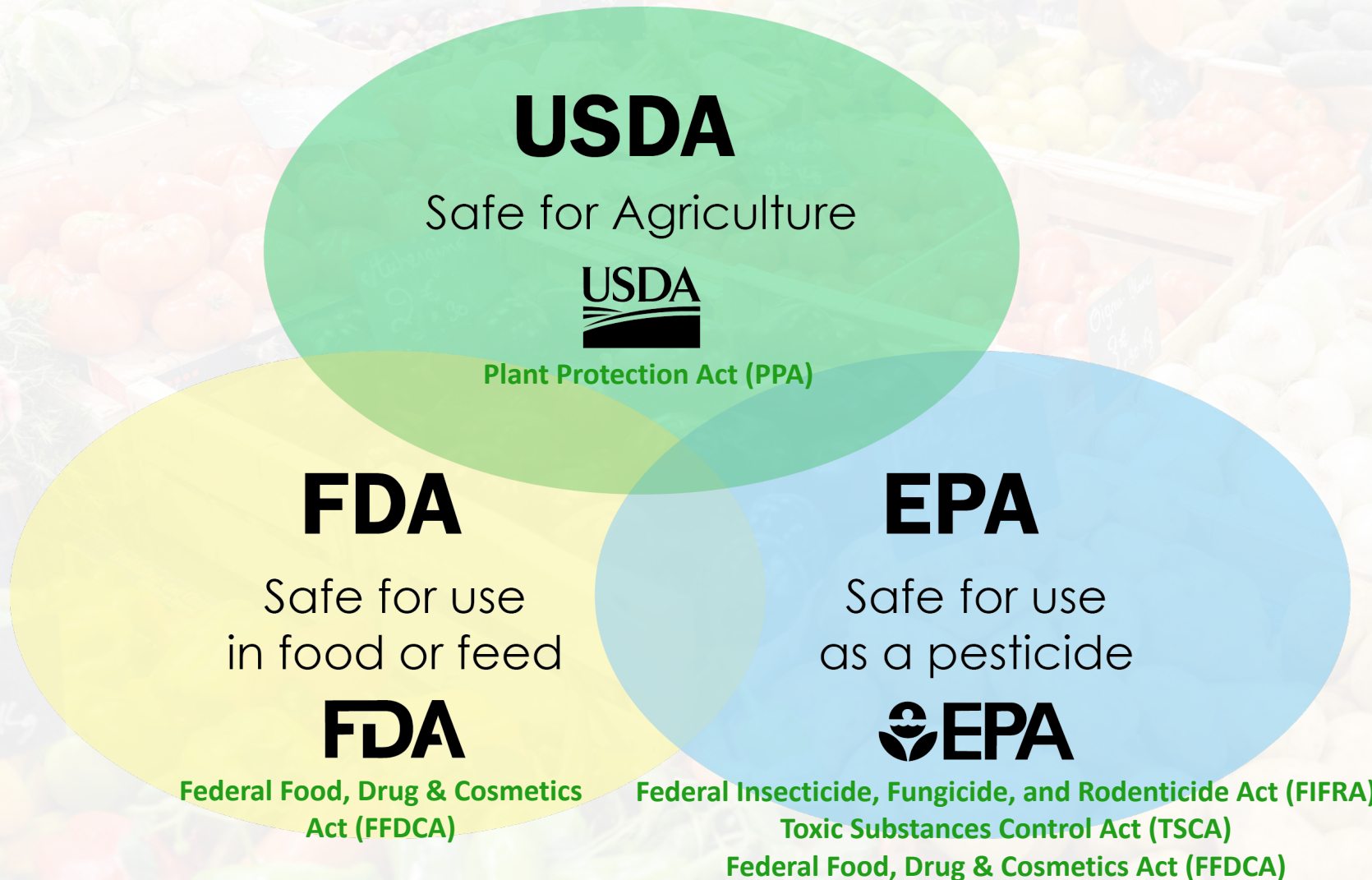
## ***Describes federal regulation for the products of biotechnology & how 3 federal agencies work together to achieve common goals***

- Based on formal policy (1986) & existing laws that detail statutory authority for each agency
  - Updates in 1992 & 2017 (***2016 National Strategy for Modernizing the Regulatory System for Biotechnology***)
  - 2 Recent Executive Orders
    - ❖ 2019 EO 13874
    - ❖ 2022 EO 14081
- Governed by the White House Office of Science & Technology Policy (OSTP)

# Goals of Framework & Updates

- Increase public confidence in the U.S. regulatory system
- Prevent unnecessary barriers to future innovation & competitiveness
- Improve transparency, coordination, predictability
- Increase efficiency of the process
- Continue to protect health & environment

# 3 Federal Regulatory Agencies





## Plant Protection Act (PPA)

- Protection of Plant Health
- Safety of Veterinary Biologics



**Safe for use in food or  
feed**

## Federal Food Drug and Cosmetic Act (FFDCA)

- Safety of Food, Food Additives and Feed
- Safety of Veterinary and Human Drugs, and Human Biologics



**Safe for use as a pesticide  
(& the environment)**

## Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- Plant Incorporated Protectants (PIPs) as bio-pesticides

## Federal Food Drug and Cosmetic Act (FFDCA)

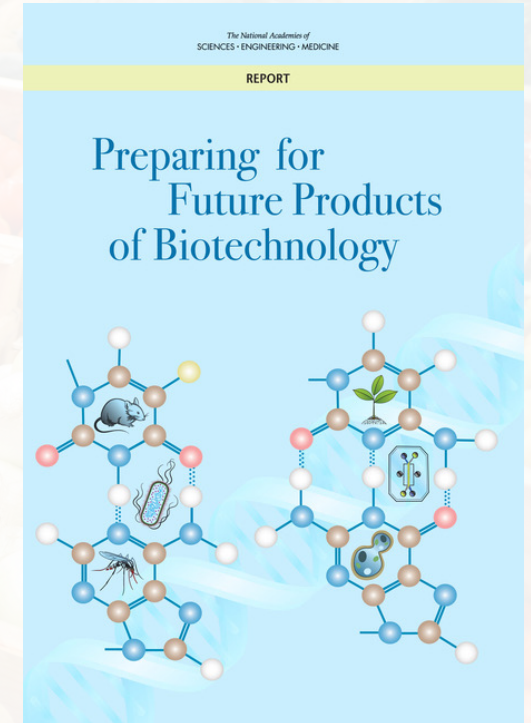
- Safe use of chemicals for food

## Toxic Substances Control Act (TSCA)

- Safe use of New Pesticides

# Modernization of Framework

- 1986 Coordinated Framework
  - End-product was regulated (not the process)
  - Science based & case-by-case basis
  - Lead Agency coordinated as needed with other relevant agencies
- 1992 Update
  - Reaffirmed: focus on end-product (not process)
  - Added: element of environment into which product was introduced
  - Clarified: federal oversight (scope of statutory authority) based on the risk posed by introduction (not particular process or technique)
- 2017 Update
  - Clarified: existing agency roles & responsibilities
  - Added: standardization mechanisms for agency communication & process for further updates
  - Added: long-term strategy and independent assessment for ensuring federal systems is prepared for future and new technologies; unified website
    - ❖ 2017 NASEM report: Preparing for Future Products of Biotechnology



## Recent Presidential Executive Orders

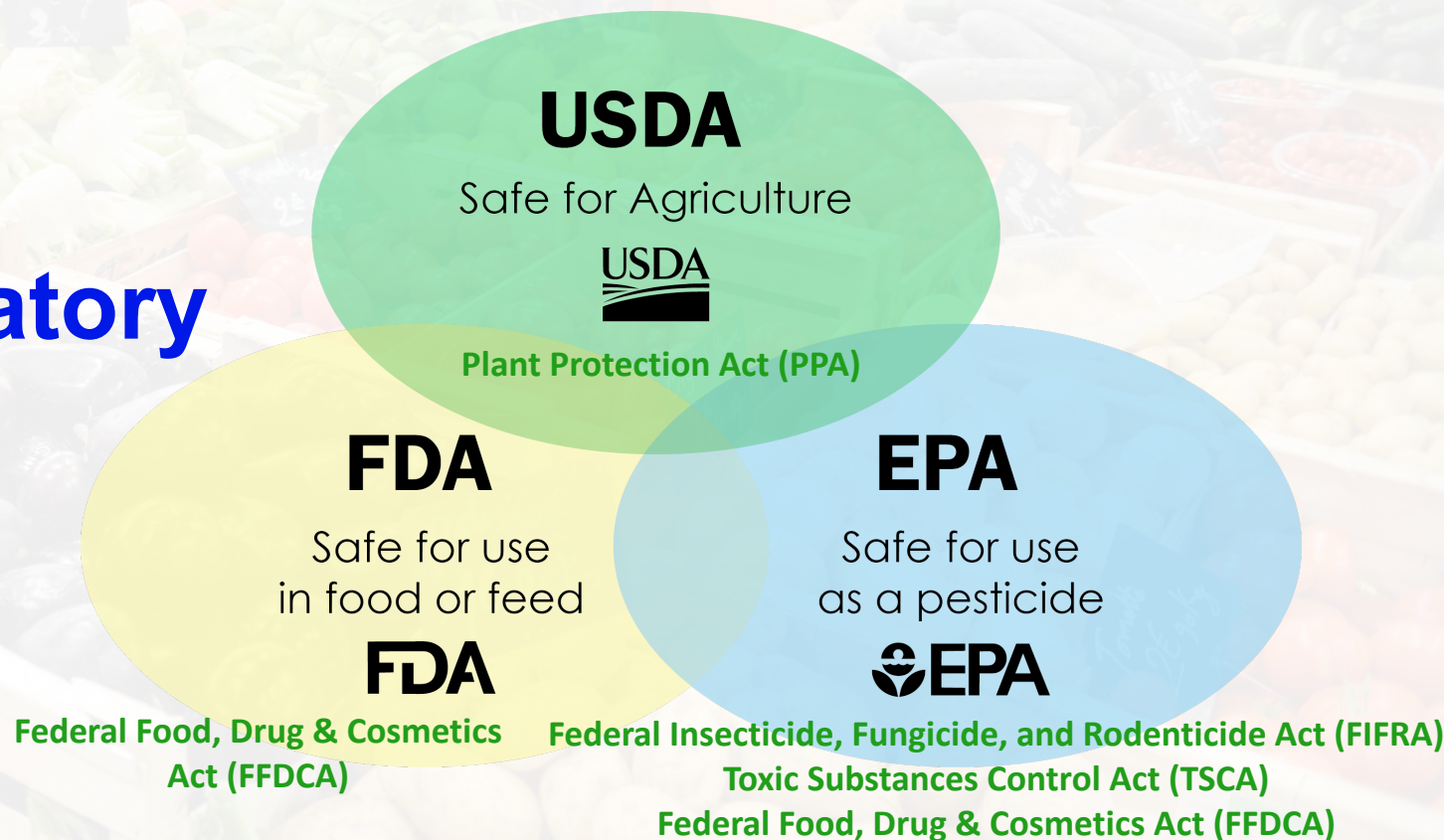
- 2019 EO 13874: *Modernizing the Regulatory Framework for Agricultural Biotechnology Products*
  - Recognizes that it is federal agencies' policy to protect public health & environment by adopting approaches for ag biotech products that are proportionate responses to the risks such products pose
    - ❖ Decisions based on scientific and technical evidence & consider economic factors as appropriate & consistent with statutory authority
    - ❖ Application reviews should be conducted in a timely, efficient manner, ensuring transparency, predictability and consistency with laws
    - ❖ Promotes trade & encourages trading partners to adopt science-and risk-based approaches
- 2022 EO 14081: *Advancing Biotechnology & Biomanufacturing Innovation for Sustainable, Safe, and Secure American Bioeconomy*
  - Renews efforts to improve clarity/efficiency of process
  - Increases coordination/communication between & among agencies
    - ❖ Directs agencies to identify any ambiguities, gaps, or uncertainties in current policy
    - ❖ Clarifies roles and responsibility of each agency
    - ❖ Improves Unified Website
    - ❖ Identifies deadlines for actionable items

# For more information

- Unified Website for Biotechnology Regulation  
<https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home/>
- NASEM report  
[https://usbiotechnologyregulation.mrp.usda.gov/NASEM\\_Study.pdf](https://usbiotechnologyregulation.mrp.usda.gov/NASEM_Study.pdf)
- EPA  
<https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra>
- FDA  
<https://www.fda.gov/safety/fdas-regulation-plant-and-animal-biotechnology-products>
- USDA-APHIS  
<https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>

# Thank you for your attention!

## More from the 3 Regulatory Agencies....



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[The Unified Website for Biotechnology Regulation](#)