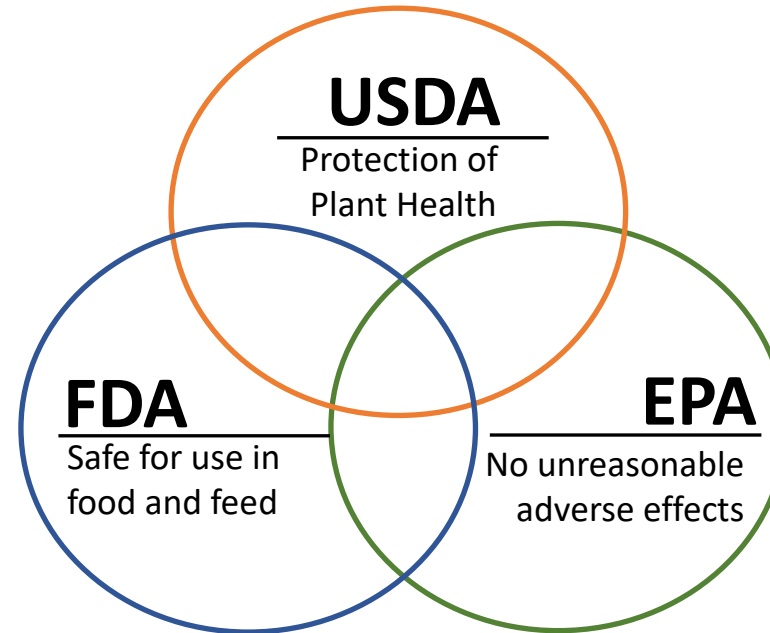




EPA's Role in the Coordinated Framework for Regulation of Biotechnology (C



EPA Regulates Pesticides under:

- Federal Insecticide Fungicide and Rodenticide Act (FIFRA) – regulates distribution, use and sale of pesticides, experimental use, reevaluation
- Federal Food Drug and Cosmetic Act (FFDCA) – establishes tolerances (maximum residue levels) for pesticides in/on food and feed

EPA may also regulate non-pesticidal genetically engineered microbes under the Toxic Substances Control Act (TSCA)



Biotechnology in Pesticides

Pesticide – any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant.

Pesticidal applications of biotechnology regulated by EPA:

- **Plant-incorporated protectants (PIPs)**
 - ❖ Defined as a **pesticidal substance** that is intended to be produced and used in a living plant, or in the produce thereof, and the **genetic material necessary for production of such a pesticidal substance**. It also includes any **inert ingredient contained in the plant or produce thereof**.
 - ❖ Can be transgenic or gene-edited (e.g., CRISPR)
 - ❖ e.g., DNA, RNA, protein (e.g. Bt Cry1Ab protein and *cry1Ab* gene)
 - ❖ e.g., selectable marker genes, CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase and *cp4 epsps* gene
- **Genetically engineered microbes**
 - ❖ Includes proteins or peptides produced by GE microbes (e.g., harpin)
- **RNAi – in PIPs or as exogenous “sprayable” products**
- **Genetically engineered (self-limiting) mosquitoes**



About PIPs

- Registered 130+ PIP products to date
 - Majority are *Bacillus thuringiensis* Cry protein-based for insect control
 - Mainly corn, cotton, and soybean
 - RNAi (DvSnf7) for corn rootworm
 - First RNAi approved for control of a macroorganism
 - Plant disease resistant PIPs
 - Viral coat proteins (papaya, plum)
 - Defensin proteins (citrus greening)
 - Resistance proteins (VNT1 in potato)
- Change of PIP landscape anticipated in near future
 - Increased product diversity (minor crops)
 - Greater involvement of smaller developers
- PIP Exemption Rule (effective 7/2023)
 - Covers PIPs that could have otherwise been created through conventional breeding.
 - Limited to native alleles; transgenes excluded



Photos: USDA-ARS; Keith Weller, Peggy Green, Scott Bauer