



<http://www.epa.gov/scipoly/biotech/pubs/framework.htm>

Last updated on April 22, 2010

Office of Science Coordination and Policy Biotechnology

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Regulatory Framework

In 1986, the United States government published the [Coordinated Framework for the Regulation of Biotechnology \(51 FR 23302\)](#). This policy statement detailed an approach for the regulation of products of modern biotechnology using existing statutes administered by the [U.S. Food and Drug Administration \(FDA\)](#) [EXIT Disclaimer](#), the [U.S. Department of Agriculture \(USDA\)](#) [EXIT Disclaimer](#), and EPA.

EPA administers three statutes that are used to regulate products of biotechnology:

- Under the [Federal Insecticide, Fungicide, and Rodenticide Act \(FIFRA\)](#) [EXIT Disclaimer](#), EPA regulates the domestic manufacture, sale, and use of all pesticides, including those derived through modern biotechnology.
- Under section 408 of the [Federal Food, Drug, and Cosmetic Act \(FFDCA\)](#) [EXIT Disclaimer](#), EPA ensures that any pesticide residue in or on a food product falls within a safe limit. Either a safe limit (known as a food tolerance) is set, or an exemption from the requirement of a tolerance is granted.
- TSCA provides authority over chemical substances and mixtures manufactured (including imported), processed, distributed in commerce, used, or disposed in the United States, including provisions to allow EPA to control unreasonable risks, and require testing, reporting, recordkeeping, and premanufacture notification. Genetically engineered microorganisms are considered "chemical substances" under TSCA [, unless excluded from the definition under TSCA section 3 (e.g., as pesticides, foods, drugs or cosmetics)].

FIFRA and section 408 of FFDCA are administered by the Office of Pesticide Programs (OPP), while TSCA is administered by the Office of Pollution, Prevention, and Toxics (OPPT).