Myths and Truths about the U.S. Regulatory System: FDA

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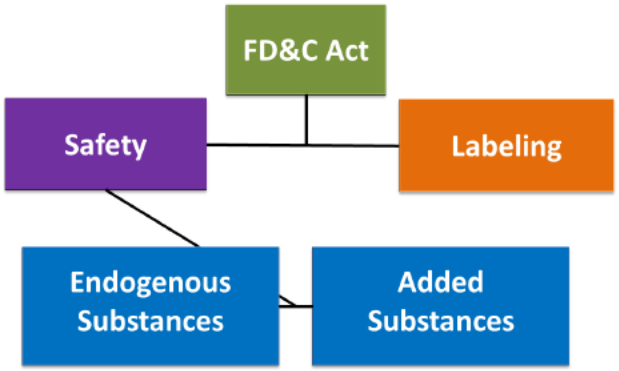
Recap

Statutory Authority: food

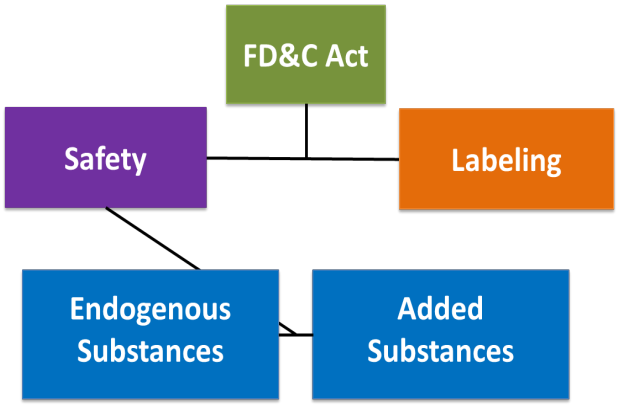


Safety Assessment

1. Molecular characterization
2. Safety of new protein(s)
3. Safety of other new component(s)
4. Composition

Consultation Process

Statutory authority: food



- FDA has broad authority to regulate food safety, with certain exceptions (USDA, EPA).
- FDA's authority applies to food produced using conventional methods and biotechnology.
- FDA has both pre-market and post-market authority.

Consultation Process

- FDA's consultation process is voluntary; compliance with the FD&C Act is mandatory.
- A consultation is the developer's opportunity to tell their safety and regulatory story.
- FDA's evaluation of the developer's narrative is similar to peer-review of a science manuscript.

Safety Assessment

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- Safety assessments are based on a combination of scientific principles, published literature, and experimental data.
- Safety assessments are case-by-case.

Resources for you

- **Websites**
  - www.fda.gov
  - www.fda.gov/GEplantfoods
  - www.fda.gov/bioconinventory
  - https://www.fda.gov/feedyourmind

- **Contact FDA Plant Biotech**
  - PlantBiotech@fda.hhs.gov


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