Regulation of Agricultural Biotechnology in the United States:

The Coordinated Framework for the Regulation of Biotechnology

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Office of Food Additive Safety

October 14, 2015

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

The First Recombinant DNA Plant (1983)

MW Bevan, RB Flavell (1983) *Nature* **304**:184-7.

Photo:https://commons.wikimedia.org/wiki/File:Tabak_9290019.JPG#/media/File:Tabak_9290019.JPG

A chimaeric antibiotic resistance gene as a selectable marker for plant cell transformation

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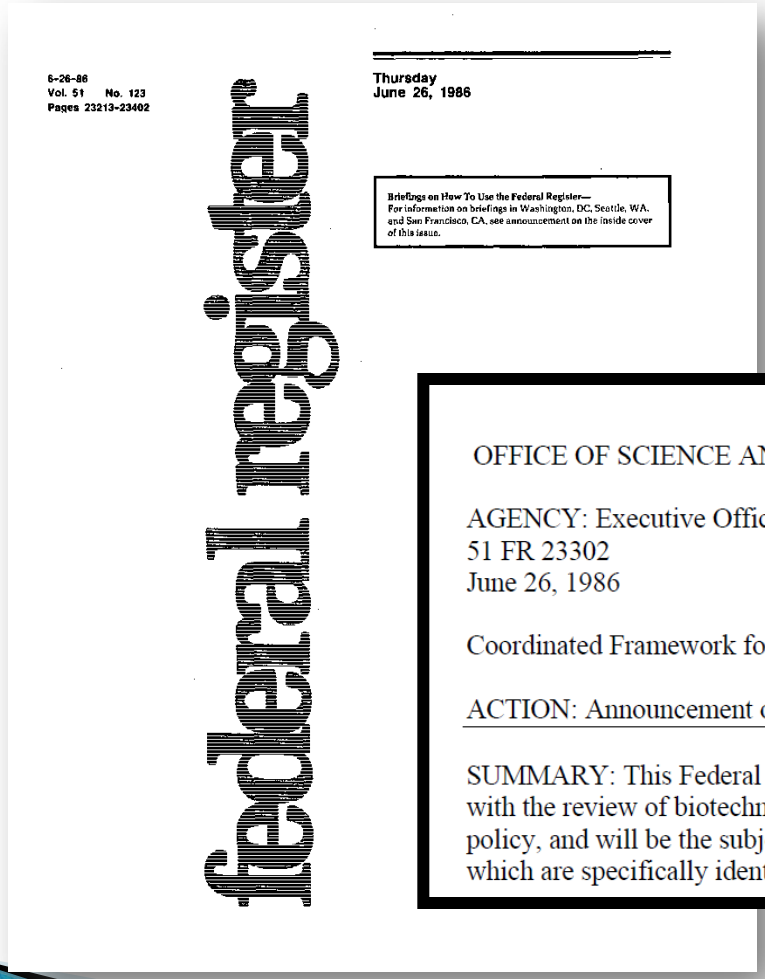
The T-DNA region of *Agrobacterium tumefaciens* tumour-inducing plasmids of the nopaline type[1] contains a gene coding for the enzyme nopaline synthase. This gene is expressed constitutively in host plant cells to which it is transferred during tumour induction[2]. We have exploited the regulatory elements of this gene to construct a chimaeric gene that confers antibiotic resistance on transformed plant cells. The chimaeric gene encodes the expected chimaeric transcripts in plant cells, and confers on transformed cells the ability to grow in the presence of normally lethal levels of the antibiotic G418 (ref. 3). Experi-

Coordinated Framework (1986)



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federal register

Thursday
June 26, 1986

Briefings on How To Use the Federal Register—
For information on briefings in Washington, DC, Seattle, WA, and San Francisco, CA, see announcement on the inside cover of this issue.

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

AGENCY: Executive Office of the President, Office of Science and Technology Policy.
51 FR 23302
June 26, 1986

Coordinated Framework for Regulation of Biotechnology

ACTION: Announcement of policy; notice for public comment.

SUMMARY: This Federal Register notice announces the policy of the federal agencies involved with the review of biotechnology research and products. As certain concepts are new to this policy, and will be the subject of rulemaking, the public is invited to comment on these aspects which are specifically identified herein.

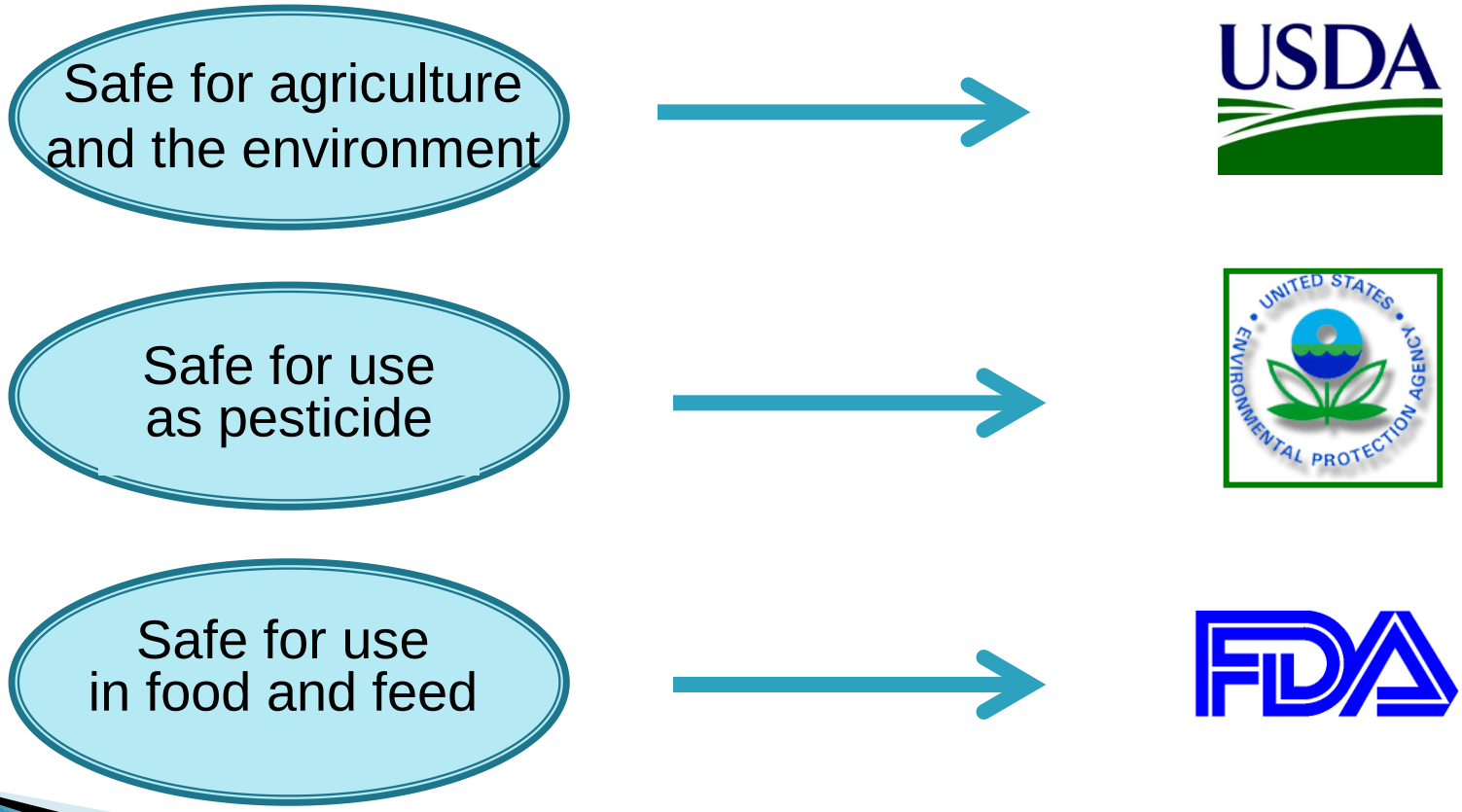
Coordinated Framework (1986)

Federal role in the safe use of biotechnology

- The safety risks of genetically engineered (GE) organisms are not fundamentally different from the risks posed by non-GE organisms with similar traits.
- The existing laws provide adequate authority.
- Regulation should be science-based and conducted on a case-by-case basis.

Regulation Under the Coordinated Framework

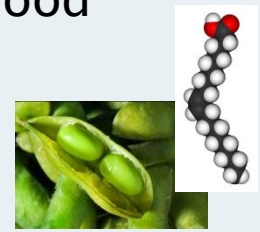
Federal role in the safe use of biotechnology



Regulation Under the Coordinated Framework

New Trait/Crop	Agency	Review
Insect resistance in food crop 	USDA EPA FDA	Agricultural and environmental safety Environmental, food/feed safety of pesticide Food/feed safety
Herbicide tolerance in food crop 	USDA EPA FDA	Agricultural and environmental safety New herbicide use Food/feed safety

Regulation Under the Coordinated Framework

New Trait/Crop	Agency	Review
Herbicide tolerance in an ornamental crop 	USDA EPA	Agricultural and environmental safety New herbicide use
Modified oil in food crop 	USDA FDA	Agricultural and environmental safety Food/feed safety
Modified flower color 	USDA	Agricultural and environmental safety

Regulation Under the Coordinated Framework

- **United States Department of Agriculture**

Plant Protection Act: protects against damage from plant pests and noxious weeds

- USDA regulates the introduction (importation, interstate movement, or environmental release) of certain GE organisms
  - if altered or produced through GE **and**
  - if there is a possibility it could be a plant pest

Regulation Under the Coordinated Framework

- **United States Department of Agriculture**

  - All regulated introductions of GE organisms must be authorized by USDA
    - permit or notification procedures
  - "Nonregulated" status by petition
    - the GE plant would no longer be subject to this regulation
    - two evaluations (1) plant pest risk assessment and (2) environmental assessment

Regulation Under the Coordinated Framework

- **Environmental Protection Agency**

<u>**Federal Insecticide, Fungicide and Rodenticide Act**</u>: no unreasonable adverse effects upon man or environment from the use of pesticides

- EPA regulates the distribution, sale, use, and testing of pesticides
  - any substance or mixture of substances intended for (1) preventing, destroying, repelling, or mitigating any pest, (2) use as a plant regulator, defoliant, or desiccant, (3) any nitrogen stabilizer
  - includes plant-incorporated protectants (PIPs)

Regulation under the Coordinated Framework

- **Environmental Protection Agency**
  - All pesticides must be registered by EPA
    - for PIPs: the protein and its genetic material
    - permit and registration processes

Federal Food Drug and Cosmetic Act: reasonable certainty of no harm from aggregate exposure of pesticide residues in or on food or feed

- safety of pesticide residue is determined by its toxicity profile
- requires a tolerance or exemption
- FDA enforces tolerance violations

Regulation Under the Coordinated Framework

- **Food and Drug Administration**

Federal Food Drug and Cosmetic Act (FD&C Act): protects the public health by requiring the safety and proper labeling of food

- FDA regulates foods and food ingredients introduced into or sold in interstate commerce
  - food means food or drink for man or other animals
  - food ingredients, whether directly added or food contact materials

Regulation Under the Coordinated Framework

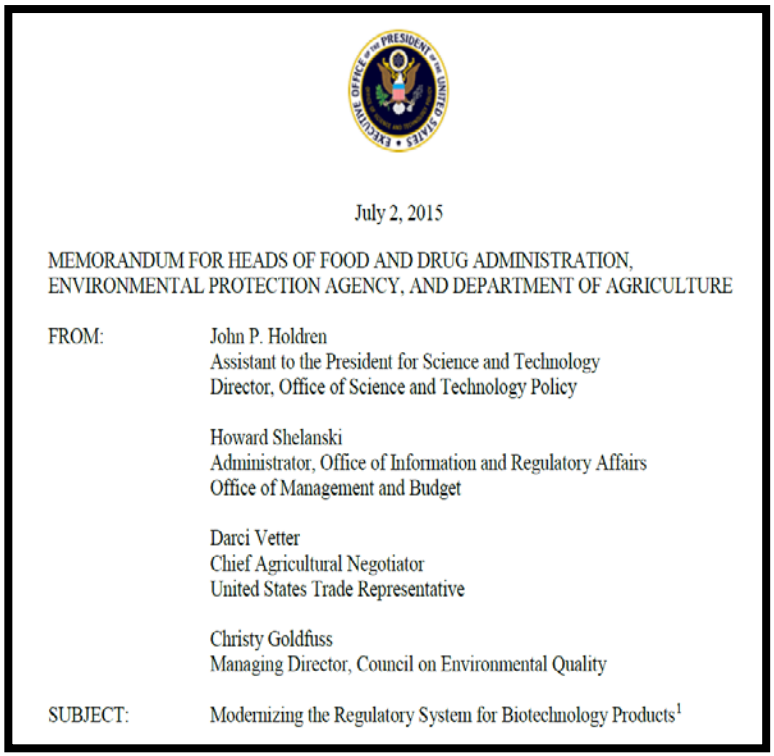
- **Food and Drug Administration**

  - The law applies equally to food from conventional plants and from GE plants
    - food must be safe
    - new substances in food require FDA review and approval, unless their use is generally recognized as safe, or "GRAS"
    - food labeling must be truthful and not misleading
  - Regulatory processes include petition, notification, and consultation

Coordination Under the Coordinated Framework

Updating the Coordinated Framework (2015)

https://www.whitehouse.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology



July 2, 2015

MEMORANDUM FOR HEADS OF FOOD AND DRUG ADMINISTRATION, ENVIRONMENTAL PROTECTION AGENCY, AND DEPARTMENT OF AGRICULTURE

FROM: John P. Holdren
Assistant to the President for Science and Technology
Director, Office of Science and Technology Policy

Howard Shelanski
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget

Darci Vetter
Chief Agricultural Negotiator
United States Trade Representative

Christy Goldfuss
Managing Director, Council on Environmental Quality

SUBJECT: Modernizing the Regulatory System for Biotechnology Products[1]

- public confidence
- transparency
- predictability
- coordination
- efficiency

of the biotechnology regulatory system

Updating the Coordinated Framework (2015)

- Improving transparency and ensuring continued safety in biotechnology
  - Update the Coordinated Framework by clarifying the roles and responsibilities of the EPA, USDA, and FDA
  - Develop a long term-strategy to ensure that the Federal regulatory system is well equipped to assess efficiently any risks associated with future products of biotechnology
  - Commission an outside, independent analysis of the future landscape of the products of biotechnology

For More Information

USDA

http:www.aphis.usda.gov/biotechnology/brs_main.shtml

EPA

http://www.epa.gov/pesticides/biopesticides/pips/index.htm

FDA

http://www.fda.gov/GEplantfoods