



REGULATION OF BIOTECH PRODUCTS BY THE US GOVERNMENT

The U.S. Coordinated Framework

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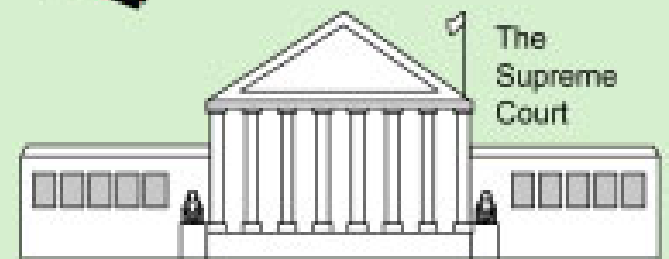
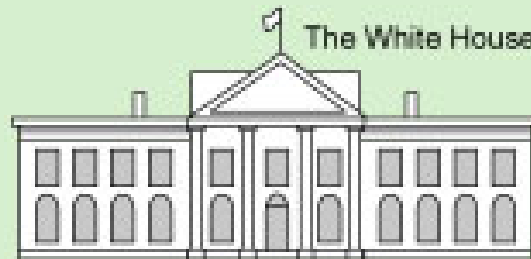
The Coordinated Framework for Regulation of Biotechnology

- Proposed by Office of Science and Technology Policy (OSTP)
- Published in the Federal Register in 1986
- Outlines basic federal policy for regulating products derived from biotechnology

General Principles

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

CONSTITUTION



LEGISLATIVE

EXECUTIVE

JUDICIAL

CONGRESS



PRESIDENT



VICE PRESIDENT



SUPREME COURT



HOUSE OF REPRESENTATIVES



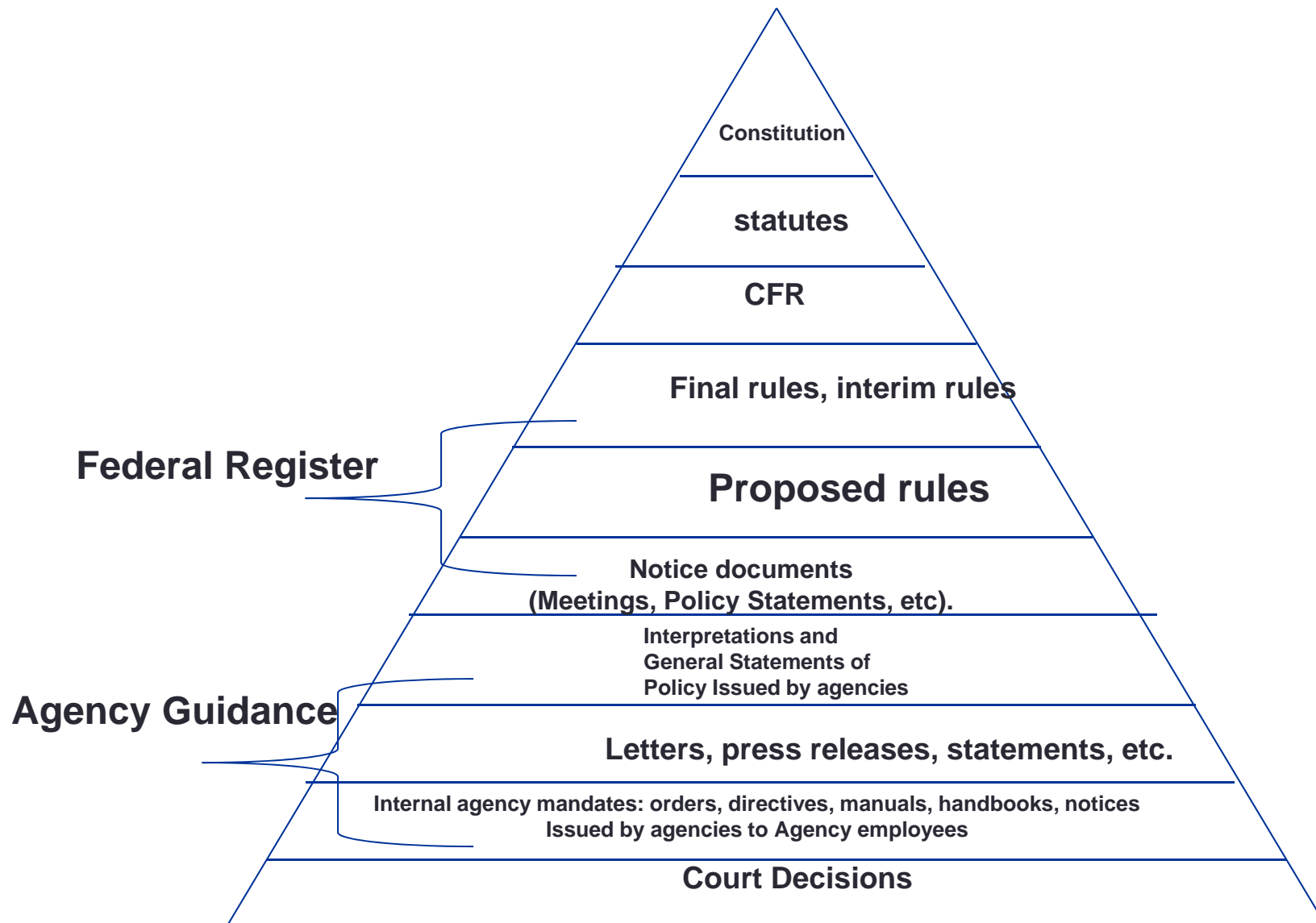
SENATE

Statutes versus Regulations

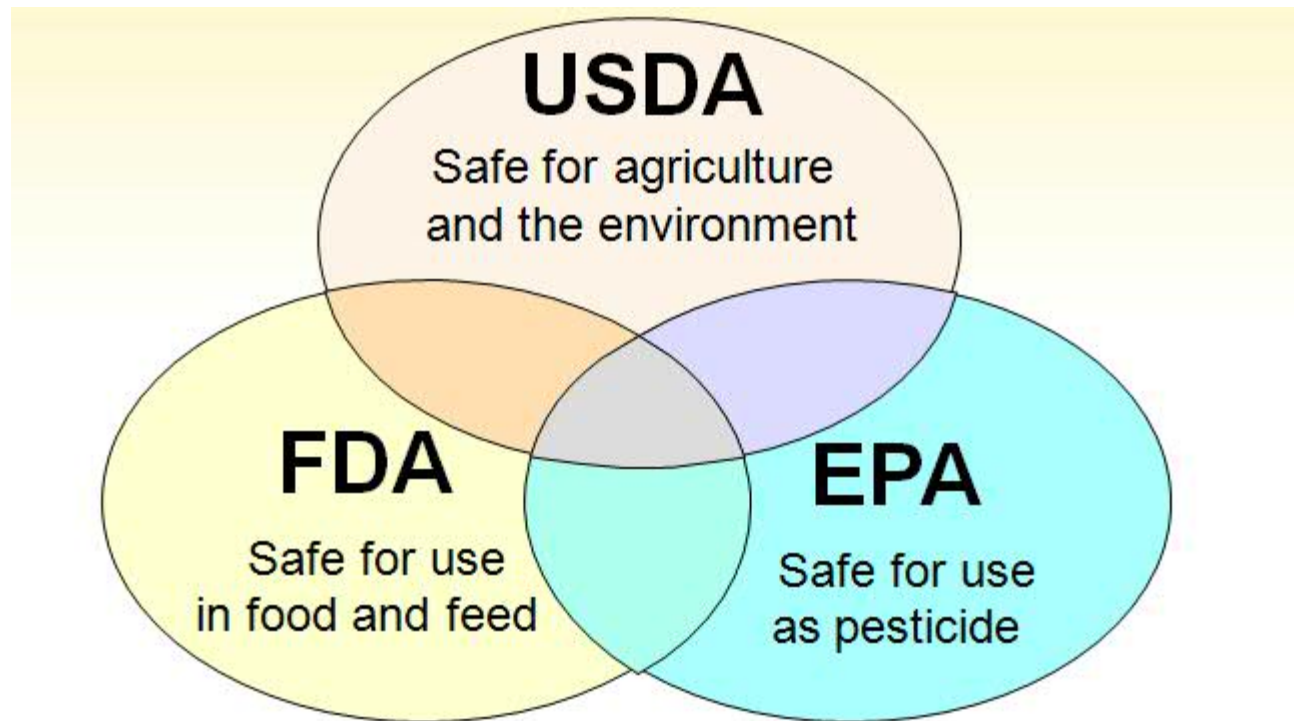
Statutes: THE LAW --- passed by Congress and signed by the President

Regulations: Implements the law --- written by the Agency and approved by the Executive Branch

Guidance: Agency interpretation of the Regulations for compliance



Shared Regulation of Biotech Products in Agriculture and the Environment



Regulation of Biotech Plant Products Under the Coordinated Framework

- **Department of Agriculture (USDA-APHIS)**
 - Plant Protection Act (PPA): Protecting against damage from plant pests and noxious weeds
- **Environmental Protection Agency (EPA)**
 - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA): Safe use of pesticides
 - Federal Food Drug and Cosmetic Act (FFDCA): Tolerance actions for pesticide residues on food and feed products
- **Food and Drug Administration (FDA)**
 - Federal Food, Drug and Cosmetics Act (FFDCA): Safe use of GE organisms in food and feed products

Regulatory Considerations

- The Statutes governing oversight of biotechnology have been in place for many years prior to transgenic techniques
- A product of biotechnology may be regulated by one or more than one Federal Agency
- Regulations are updated to keep pace with advancing technology
- Coordination and communication are key to effective regulation among agencies

Some examples of biotech products and which agencies would regulate them

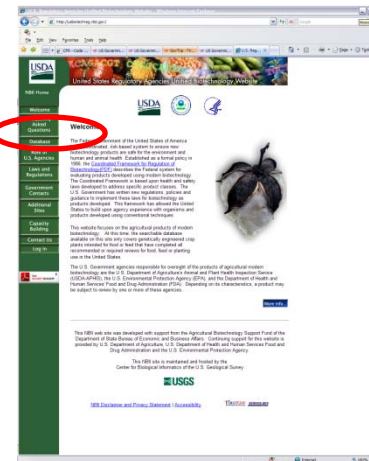
New Trait/Crop	Agency	Review
Insect resistance in food crop (Bt corn)	USDA EPA FDA	Agricultural and environmental safety Environmental, food/feed safety of pesticide Food/feed safety
Herbicide tolerance in food crop (glyphosate tolerant soybeans)	USDA EPA FDA	Agricultural and environmental safety New herbicide use Food/feed safety
Herbicide tolerance in ornamental crop (glufosinate tolerant azaleas)	USDA EPA	Agricultural and environmental safety New herbicide use
Modified oil in food crop (high oleic acid soybeans)	USDA FDA	Agricultural and environmental safety Food/feed safety
Modified flower color (blue poinsettias)	USDA	Agricultural and environmental safety

US Regulatory Agencies Unified Government Website 2003

- Three incentives
 - NSC Ag Biotech Working Group (August, 2001)
 - Transparency –
 - integration of agency websites
 - uniform system of identifying products to allow easy movement between databases
 - BioSafety Protocol (2000) – Biosafety Clearinghouse (2003)
 - Article 11.1 – Domestic decisions on LMOFFPs
 - Article 20 – Information Sharing
 - National Academy of Sciences – 2000
 - *Genetically Modified Pest-Protected Plants*
 - “To fulfill the intent of the coordinated framework, a database to link the agencies decisions should be developed to benefit a wide array of interested parties...”
 - Increase credibility of agencies

Location: <http://usbiotechreg.nbio.gov>

- Coordinate information from USDA-APHIS, EPA, and FDA
- Searchable database
- Provides information on genetically engineered crop plants intended for food or feed that have completed all recommended or required reviews for planting, food, or feed use in the United States
- URL will change next year due to belt tightening



The Searchable Database



the U.S. Database of Completed Regulatory Agency Reviews

ase contains information on genetically engineered crop plants intended for food or ave completed all recommended or required reviews for planting, food, or feed use in States. This database will be updated regularly. The overall content and scope of the may change in the future to ensure that the database continues to meet user needs.

Search

Common Name: None
 Alfalfa
 Beet

Scientific Name: None
 Agrostis stolonifera L.
 Beta vulgaris

Category: None
 Pest Resistance
 Insect Resistance

Applicant: None
 AgrEvo
 Agritope Inc.

Event: (Enter the event, or any part thereof)

Keyword(s): (Enter a keyword or a trait description or a tradename)

Sort Results by Uses

Database:
can search
by plant
type, trait
category,
name of
company,
event
number or
keyword

USDA EPA FDA

Search of the U.S. Database of Completed Regulatory Agency Reviews

Product Search Results ...

You searched for database entries: for Alfalfa product(s)
Number of Records Returned: 2

Record Number	Unique Identifier	Common Name(s) / Scientific Name(s)	Trait Category	Applicant(s)	Event(s)	Trait Description(s)	Reviewed Uses within the U.S.
144 <input type="button" value="More Info..."/>	MON-00163-7	Alfalfa Medicago sativa	Herbicide Tolerance	Monsanto Company	Event J163	Glyphosate tolerant; 5-Enolpyruvylshikimate-3-phosphate synthase (EPSPS), from Agrobacterium sp. strain CP4	Planting, food, and feed
150 <input type="button" value="More Info..."/>	MON-00101-8	Alfalfa Medicago sativa	Herbicide Tolerance	Monsanto Company	Event J101	Glyphosate tolerant; 5-Enolpyruvylshikimate-3-phosphate synthase (EPSPS), from Agrobacterium sp. strain CP4	Planting, food, and feed

Product uses are described in the database as: "food," "feed," or "planting". For each product, the database lists only those uses for which the product has completed all relevant procedures required or recommended by the regulatory agencies. Note that not all of the products in the database have completed reviews for all uses. For example, the database includes products that have completed reviews for food and/or feed uses, but have not completed reviews necessary for planting. In circumstances in which a use has been withdrawn by an agency, that use will no longer be listed.

"Food" use means that a product:

- Has completed an FDA review for consumption by humans; and
- If the product is a plant that contains a plant-incorporated protectant (PIP), the PIP has completed EPA reviews.

"Feed" use means that a product:

- Has completed an FDA review for consumption by animals; and
- If the product is a plant that contains a plant-incorporated protectant (PIP), the PIP has completed EPA reviews.

"Planting" use means that a product:

- Has completed USDA-APHIS review for cultivation in the United States; and

View all products

Sort Results by

http://usbiotechreg.nbio.gov/database_pub.html

U. S. Regulatory Agency Activity Summary

[Help...](#)

Product Information Summary:

Database Record Number:	146
Unique Identifier:	SYN-IR102-7
Reviewed Uses within the U.S.:	Planting, food, and feed
Product:	Cotton Gossypium hirsutum
Event:	COT102
Trait Category:	Lepidopteran Resistance
Trait Description:	Lepidopteran resistance; Vip3A from Bacillus thuringiensis strain AB88

Regulatory Agency Review Summary:



USDA Animal and Plant Health Inspection Service: 03-155-01p

Status: Granted petition for non-regulated status

Determination: http://www.aphis.usda.gov/brs/aphisdocs2/03_15501p_com.pdf



DHHS Food and Drug Administration: 94

Status: Consultation A

Response Letter: <http://www.fda.gov/Food/Biotechnology/Submissions/ucm155586.htm>

Summary Memo: <http://www.fda.gov/Food/Biotechnology/Submissions/ucm155617.htm>



Environmental Protection Agency:

Registration Number: 67979-9

Registration Status: Current

Expiration Date: 00:00:00

Assessment Summary: http://www.epa.gov/opppppd1/biopesticides/ingredients/factsheets/factsheet_006529.htm

Registration Label:

Labels can be updated by the registrant at any time, therefore this link might not reflect the most current information. Go to <http://www.epa.gov/pestiabl/pels/home> to search for the latest label by the registration number.

Comment: This is a combined product and the separate components can not be marketed individually without a specific registration for that crop.

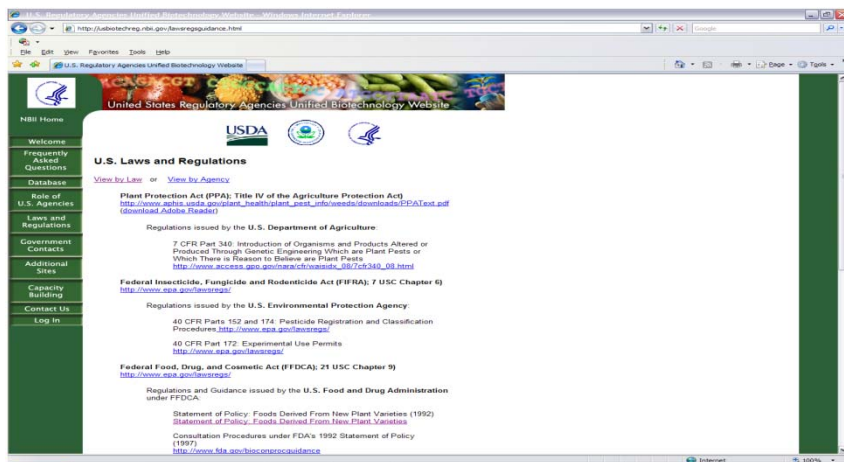
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More Information provides specific information and links to each agency's documents on their individual websites

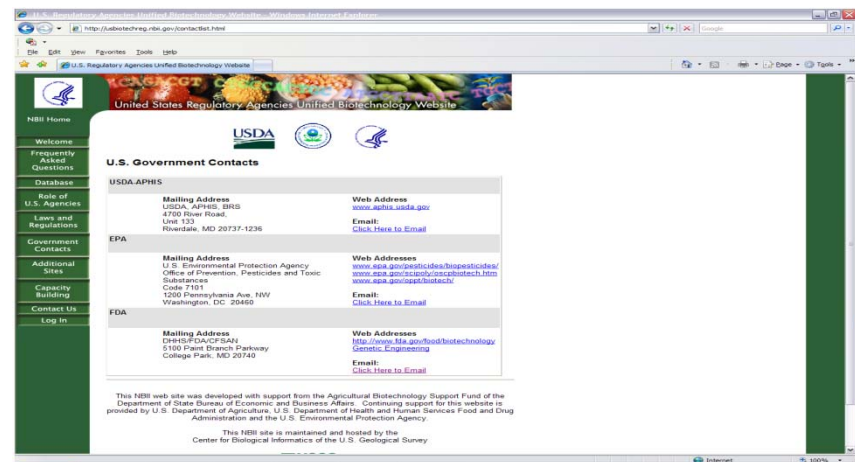
http://usbiotechreg.nbii.gov/DetailedRecord_pub.html?queryGUID=146

Other Features on the Site

Laws and Regulations



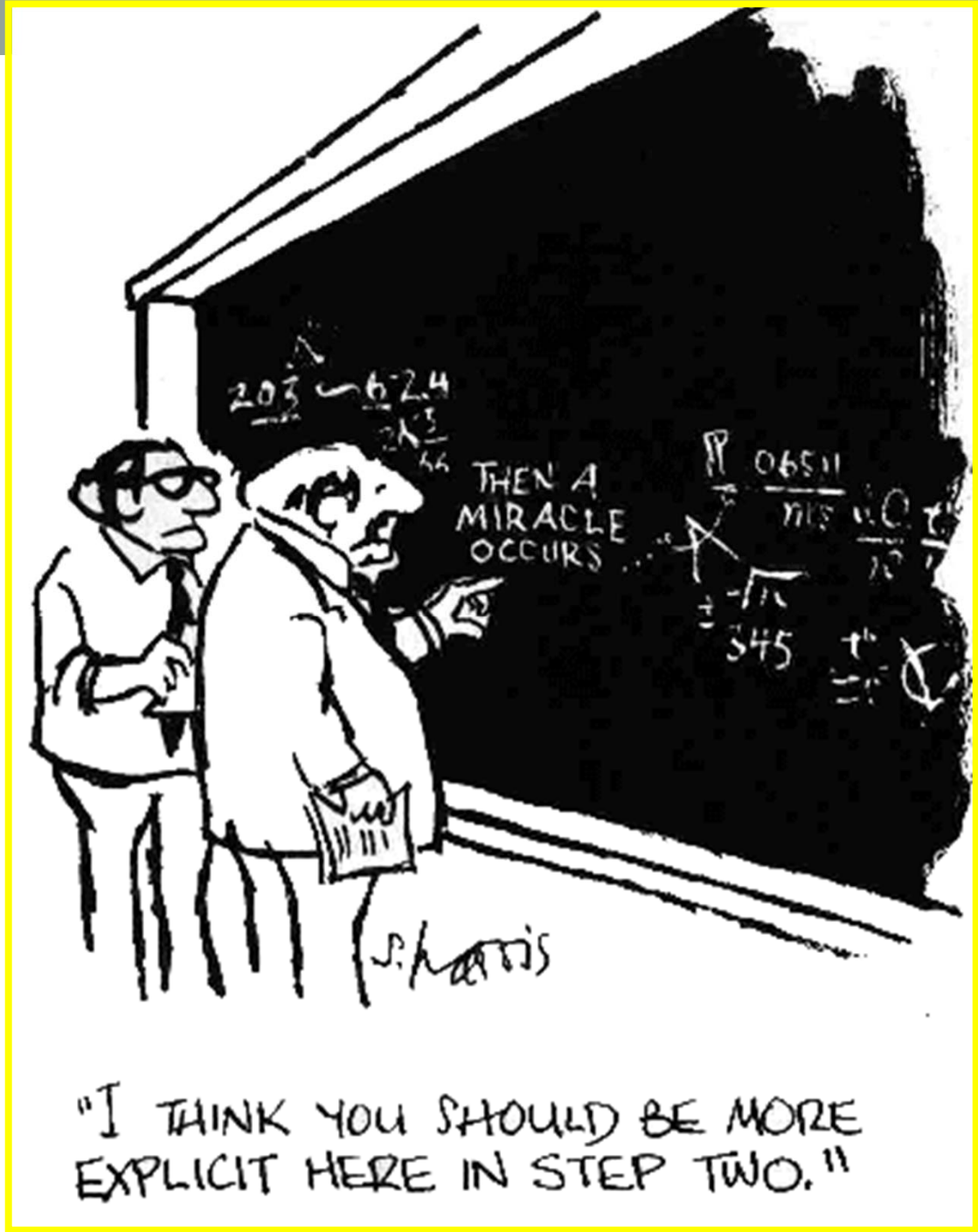
Links to Agency web pages, secure email to Agency contacts



<http://usbiotechreg.nbio.gov>

Also, links to:

- Frequently Asked Questions
- Role of agencies
- Other web sites of interest (e.g. Government, BIO)



"I THINK YOU SHOULD BE MORE EXPLICIT HERE IN STEP TWO."