

## Regulation of Transgenic Crops

- Institutional Biosafety Committee (IBC)
- APHIS – USDA – BRS (Biotech Regulatory Services)
- FDA
- EPA
- State Agencies
- International Agreements

---

---

---

---

---

---

---

---

## IBC

- Research Institutions must have IBC:
  - Monitors potentially hazardous biological research and ensures compliance with biosafety procedures
- Biosafety Levels from *NIH Guidelines for Research Involving Recombinant DNA Molecules* (April 2002):
  - BL1-P: Basic containment level
  - BL2-P: For agents of moderate potential hazard
  - BL3-P: For agents of serious potential hazard
  - BL4-P: work with extremely hazardous agents

---

---

---

---

---

---

---

---

## BL1-P Standard Practices

- Restricted access.
- All personnel entering the greenhouse are familiar with procedures for BL1-P greenhouse (performance standards/SOPs).
- A record shall be kept of experiments currently in progress in the greenhouse facility.
- Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility.
- Control program in place for pests.
- Precautions shall be taken to minimize escape of insects (e.g. pollinators) from the greenhouse facility.
- Experiments involving other organisms that require a containment level lower than BL1-P may be conducted in the greenhouse concurrently with experiments that require BL1-P containment, provided that all work is conducted in accordance with BL1-P greenhouse practices.

---

---

---

---

---

---

---

---

## BL1-P Greenhouse Design

- The greenhouse floor may be composed of gravel or other porous material. At a minimum, impervious (e.g., concrete) walkways are recommended.
- Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to contain or exclude pollen, microorganisms, or small flying animals (e.g., arthropods and birds); however, screens are recommended.

---

---

---

---

---

---

---

---

## BL2-P Standard Practices

Same as BL1-P, plus:

- Restricted access to individuals directly involved with the experiments when they are in progress.
- A record shall be kept of experimental plants, microorganisms, or small animals that are brought into or removed from the greenhouse facility.
- The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms
- Decontamination of run-off water is not necessarily required. If part of the greenhouse is composed of gravel or similar material, appropriate treatments should be made periodically to eliminate, or render inactive, any organisms potentially entrapped by the gravel.
- A sign shall be posted indicating that a restricted experiment is in progress. The sign shall indicate the following: (i) the name of the responsible individual, (ii) the plants in use, and (iii) any special requirements for using the area.

---

---

---

---

---

---

---

---

## BL2-P Standard Practices (cont.)

- If organisms are used that have a recognized potential for causing serious detrimental impacts on managed or natural ecosystems, their presence shall be indicated on a sign posted on the greenhouse access doors.
- If there is a risk to human health, a sign shall be posted incorporating the universal biosafety symbol.
- Materials containing experimental microorganisms, which are brought into or removed from the greenhouse facility in a viable or intact state, shall be transferred in a closed non-breakable container.
- A greenhouse practices manual shall be prepared or adopted. This manual shall: (i) advise personnel of the potential consequences if such practices are not followed, and (ii) outline contingency plans to be implemented in the event of the unintentional release of organisms.

---

---

---

---

---

---

---

---

## BL2-P Greenhouse Design

- A greenhouse floor composed of an impervious material. Concrete is recommended, but gravel or other porous material under benches is acceptable unless propagules of experimental organisms are readily disseminated through soil. Soil beds are acceptable unless propagules of experimental organisms are readily disseminated through soil.
- Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to exclude pollen or microorganisms; however, screens are required to exclude small flying animals (e.g., arthropods and birds).
- An autoclave shall be available for the treatment of contaminated greenhouse
- If intake fans are used, measures shall be taken to minimize the ingress of arthropods. Louvers or fans shall be constructed such that they can only be opened when the fan is in operation.

---

---

---

---

---

---

---

---

## BL2-P Other

- BL2-P greenhouse containment requirements may be satisfied by using a growth chamber or growth room within a building provided that the external physical structure limits access and escape of microorganisms and macroorganisms in a manner that satisfies the intent of the foregoing clauses.

---

---

---

---

---

---

---

---

## BL3-P Standard Practices

Same as BL2-P, plus:

- All experimental materials shall be sterilized in an autoclave or rendered biologically inactive by appropriate methods before disposal, except those that are to remain in a viable or intact state for experimental purposes; including water that comes in contact with experimental microorganisms or with material exposed to such microorganisms, and contaminated equipment and supplies.
- Experimental materials that are brought into or removed from the greenhouse facility in a viable or intact state shall be transferred to a non-breakable sealed secondary container. At the time of transfer, if the same plant species, host, or vector are present within the effective dissemination distance of propagules of the experimental organism, the surface of the secondary container shall be decontaminated. Decontamination may be accomplished by passage through a chemical disinfectant or fumigation chamber or by an alternative procedure that has demonstrated effective inactivation of the experimental organism.
- Disposable clothing (e.g., solid front or wrap-around gowns, scrub suits, or other appropriate clothing) shall be worn in the greenhouse if deemed necessary by the Greenhouse Director because of potential dissemination of the experimental microorganisms.
- Personnel are required to thoroughly wash their hands upon exiting the greenhouse.
- All procedures shall be performed carefully to minimize the creation of aerosols and excessive splashing of potting material/soil during watering, transplanting, and all experimental manipulations.

---

---

---

---

---

---

---

---

## BL3-P Greenhouse Design

- The greenhouse floor shall be composed of concrete or other impervious material with provision for collection and decontamination of liquid run-off.
- Windows shall be closed and sealed. All glazing shall be resistant to breakage (e.g., double-pane tempered glass or equivalent).
- The greenhouse shall be a closed self-contained structure with a continuous covering that is separated from areas that are open to unrestricted traffic flow. The minimum requirement for greenhouse entry shall be passage through two sets of self-closing locking doors.
- The greenhouse facility shall be surrounded by a security fence or protected by equivalent security measures.
- Internal walls, ceilings, and floors shall be resistant to penetration by liquids and chemicals to facilitate cleaning and decontamination of the area. All penetrations into these structures and surfaces (e.g., plumbing and utilities) shall be sealed.

---

---

---

---

---

---

---

---

## BL3-P Greenhouse Design (cont.)

- Bench tops and other work surfaces should have seamless surfaces that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
- The greenhouse contains a foot, elbow, or automatically operated sink, which is located near the exit door for hand washing.
- An autoclave shall be available for decontaminating materials within the greenhouse facility.
- An individual supply and exhaust air ventilation system shall be provided. The system maintains pressure differentials and directional airflow, as required, to assure inward (or zero) airflow from areas outside of the greenhouse.
- The exhaust air from the greenhouse facility shall be filtered through high efficiency particulate air-HEPA filters and discharged to the outside.
- Vacuum lines shall be protected with high efficiency particulate air/HEPA or equivalent filters and liquid disinfectant traps.

---

---

---

---

---

---

---

---

## BL4-P Standard Practices

Same as BL3-P, plus

- Personnel shall enter and exit the greenhouse facility only through the clothing change and shower rooms and shall shower each time they exit the greenhouse facility. Personnel shall use the airlocks to enter or exit the laboratory only in an emergency. In the event of an emergency, every reasonable effort should be made to prevent the possible transport of viable propagules from containment.
- A record shall be kept of all personnel entering and exiting the greenhouse facility, including the date and time of each entry.
- Water that comes in contact with experimental microorganisms or with material exposed to such microorganisms (e.g., run-off from watering plants) shall be collected and decontaminated before disposal.
- Standard microbiological procedures shall be followed for decontamination of equipment and materials. Spray or liquid waste or rinse water from containers used to apply the experimental microorganisms shall be decontaminated before disposal.

---

---

---

---

---

---

---

---

## BL4-P Standard Practices (cont.)

- Supplies and materials shall be brought into the greenhouse facility through a double-door autoclave, fumigation chamber, or airlock that is appropriately decontaminated between each use. After securing the outer doors, personnel within the greenhouse facility shall retrieve the materials by opening the interior door of the autoclave, fumigation chamber, or airlock. These doors shall be secured after the materials are brought into the greenhouse facility.
- Street clothing shall be removed in the outer clothing change room. Complete laboratory clothing (may be disposable) including undergarments, pants, and shirts, jump suits, shoes, and hats shall be provided and worn by all personnel entering the greenhouse facility.
- Personnel shall remove laboratory clothing when exiting the greenhouse facility and before entering the shower area. This clothing shall be stored in a locker or hamper in the inner change room.
- All laboratory clothing shall be autoclaved before laundering.

---

---

---

---

---

---

---

---

---

---

## BL4-P Greenhouse Design

Same as BL3-P, plus

- The maximum containment greenhouse facility shall consist of a separate building or a clearly demarcated and isolated area within a building. The need to maintain negative pressure should be considered when constructing or renovating the greenhouse facility.
- Outer and inner change rooms, separated by a shower, shall be provided for personnel entering and exiting the greenhouse facility.
- A double-door autoclave, fumigation chamber, or ventilated airlock shall be provided for passage of all materials, supplies, or equipment that are not brought into the greenhouse facility through the change room.
- An individual supply and exhaust air ventilation system shall be provided. The system shall maintain pressure differentials and directional airflow as required to assure inward (or zero) airflow from areas outside of the greenhouse. Differential pressure transducers shall be used to sense pressure levels. If a system malfunctions, the transducers shall sound an alarm. A backup source of power should be considered. The supply and exhaust airflow shall be interlocked to assure inward (or zero) airflow at all times. The integrity of the greenhouse shall have an air leak rate (decay rate) not to exceed 7 percent per minute (logarithm of pressure against time) over a 20-minute period at 2 inches of water gauge pressure. Nominally, this is 0.05 inches of water gauge pressure loss in 1 minute at 2 inches water gauge pressure.

---

---

---

---

---

---

---

---

---

---

## BL4-P Greenhouse Design (cont.)

- Exhaust air from the greenhouse facility shall be filtered through high efficiency particulate air/HEPA filters and discharged to the outside and dispersed away from occupied buildings and air intakes. Filter chambers shall be designed to allow *in situ* decontamination before filters are removed and to facilitate certification testing after they are replaced. HEPA filters shall be provided to treat air supplied to the greenhouse facility. HEPA filters shall be certified annually.
- Sewer vents and other ventilation lines contain high efficiency particulate air/HEPA filters. HEPA filters shall be certified annually.
- Liquid effluent from sinks, floors, and autoclave chambers shall be decontaminated by heat or chemical treatment before being released from the maximum containment greenhouse facility. Liquid wastes from shower rooms and toilets may be decontaminated by heat or chemical treatment.
- If there is a central vacuum system, it shall not serve areas outside of the greenhouse facility. Liquid and gas services to the greenhouse facility shall be protected by devices that prevent back-flow.

---

---

---

---

---

---

---

---

---

---

**APHIS – USDA – BRS  
(Biotech Regulatory Services)**

**7CFR340 - Restrictions on the Introduction of Regulated Articles**

- No person shall introduce any regulated article unless the Administrator is:
  - Notified of the introduction in accordance with 340.3, or such introduction is authorized by permit in accordance with 340.4, or such introduction is conditionally exempt from permit requirements under 340.2(b); and
  - Such introduction is in conformity with all other applicable restrictions in this part.

---

---

---

---

---

---

---

---

**340.3 Notification for the introduction of certain regulated articles**

- APHIS may issue guidelines regarding scientific procedures, practices, or protocols which it has found acceptable in making various determinations under the regulations. A person may follow an APHIS guideline or follow different procedures, practices, or protocols. When different procedures, practices, or protocols are followed, a person may, but is not required to, discuss the matter in advance with APHIS to help ensure that the procedures, practices, or protocols to be followed will be acceptable to APHIS

---

---

---

---

---

---

---

---

**340.3 Notification for the introduction of certain regulated articles**

- Certain regulated articles may be introduced without a permit, provided that the introduction is in compliance with the requirements of this section. Any other introduction of regulated articles require a permit under 340.4

---

---

---

---

---

---

---

---

*Regulated articles eligible for introduction under the notification procedure*

Must meet 6 criteria:

- 1) The regulated article is any plant species that is not listed as a noxious weed in regulations at 7 CFR part 360 under the Federal Noxious Weed Act (7 U.S.C. 2809), and, when being considered for release into the environment, the regulated articles is not considered by the Administrator to be a weed in the area of release into the environment

---

---

---

---

---

---

---

---

- 2) The introduced genetic material is "stably integrated" in the plant genome
- 3) The function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease
- 4) The introduced genetic material does not:
  - 1) Cause the production of an infectious entity
  - 2) Encode substances that are known or likely to be toxic to nontarget organisms known or likely to feed or live on the plant species
  - 3) Encode products intended for pharmaceutical use

---

---

---

---

---

---

---

---

- 5) Plant virus-derived sequences must be:
  - 1) Noncoding regulatory sequences of known function
  - 2) Sense or antisense genetic constructs derived from viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species, and that do not encode a functional noncapsid gene product responsible for cell-to-cell movement of the virus
- 6) The plant has not been modified to contain the following genetic material from animal or human pathogens:
  - 1) Any nucleic acid sequence derived from an animal or human virus
  - 2) Coding sequences whose products are known or likely causal agents of disease in animals or humans.

---

---

---

---

---

---

---

---

Performance standards for introductions under the notification procedure

The following performance standards must be met for any introductions under the notification procedure:

- 1) If the plants or plant materials are shipped, they must be shipped in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment

---

---

---

---

---

---

---

---

- 2) When the introduction is an environmental release, the regulated article must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release
- 3) The plants and plant parts must be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use

---

---

---

---

---

---

---

---

4. There must be no viable vector agent associated with the regulated article
5. The field trial must be conducted such that:
  1. The regulated article will not persist in the environment
  2. No offspring can be produced that could persist in the environment.
6. Upon termination of the field test:
  1. No viable material shall remain which is likely to volunteer in subsequent seasons
  2. Volunteers shall be managed to prevent persistence in the environment

---

---

---

---

---

---

---

---

***Procedural requirements for notifying APHIS***

The notification shall include the following:

- 1) Name, title, address, telephone number, and signature of the responsible person
- 2) Information necessary to identify the regulated article(s), including:
  - 1) The scientific, common, or trade names, and phenotype of regulated article
  - 2) The designations for the genetic loci, the encoded proteins or functions, and donor organisms for all genes from which introduced genetic material was derived
  - 3) The method by which the recipient was transformed
- 3) The names and locations of the origination and destination facilities for movement or the field site location for the environmental release; and the size of the introduction
- 4) The date and, in the case of environmental release, the expected duration of the introduction (release)
- 5) A statement that certifies that introduction of the regulated article will be in accordance with the provisions of this section

---

---

---

---

---

---

---

---

***Procedural requirements for notifying APHIS***

Notification must be submitted to APHIS:

- 1) At least 10 days prior to the day of introduction, if the introduction is interstate movement
- 2) At least 30 days prior to the day of introduction, if the introduction is an importation
- 3) At least 30 days prior to the day of introduction, if the introduction is an environmental release

---

---

---

---

---

---

---

---

***Procedural requirements for notifying APHIS***

- Field test reports must be submitted to APHIS within 6 months after the termination of the field test :
  - Field test reports shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment
- Access shall be allowed for APHIS and State regulatory officials to inspect facilities and/or the field test site and any records necessary to evaluate compliance
- The Administrator shall be notified of any unusual occurrence within the time periods and in the manner specified in 340.4(f)(10)

---

---

---

---

---

---

---

---

### 340.4(f)(10)

- APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences:
  - Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article
  - In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms)

---

---

---

---

---

---

---

---

### 340.4 Permits for the introduction of a regulated article

- Permit for release into the environment
  - An application for the release into the environment of a regulated article shall be submitted at least 120 days in advance of the proposed release into the environment
  - The 120 day review period would be extended if preparation of an environmental impact statement in addition to an environmental assessment was necessary

---

---

---

---

---

---

---

---

### The permit application shall include the following:

- 1) Name, title, address, telephone number, and signature of the responsible person
- 2) All scientific, common, and trade names, and all designations necessary to identify the Donor organism(s); recipient organism(s); vector or vector agent(s); constituent of each regulated article which is a product; and, regulated article
- 3) Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article
- 4) A description of the means of movement (e.g., mail, common carrier, baggage, or handcarried (and by whom))
- 5) A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics)

---

---

---

---

---

---

---

---

- 6) A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article
- 7) Country and locality where the donor organism, recipient organism, vector or vector agent, and regulated article were collected, developed, and produced
- 8) A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design
- 9) The quantity of the regulated article to be introduced and proposed schedule and number of introductions

---

---

---

---

---

---

---

---

- 10) A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: Donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and regulated article
- 11) A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location; pilot project location; production, propagation, and manufacture location; proposed sale and distribution location)

---

---

---

---

---

---

---

---

- 12) A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations
- 13) A detailed description of any biological material (e.g., culture medium, or host material) accompanying the regulated article during movement
- 14) A detailed description of the proposed method of final disposition of the regulated article

---

---

---

---

---

---

---

---

## Movement Permits

- An application for the interstate movement or importation of a regulated article shall be submitted at least 60 days in advance of the first proposed interstate movement and at least 60 days prior to each importation
- No person shall move a regulated article unless the number of the permit appears on the outside of the shipping container
- The responsible person shipping a regulated article interstate shall keep records for one year demonstrating that the regulated article arrived at its intended destination

---

---

---

---

---

---

---

---

## Permit Conditions

A person who is issued a permit and his/her employees or agents shall comply any conditions which shall be listed on the permit as well as the following:

- 1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests
- 2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of plant pests

---

---

---

---

---

---

---

---

- 3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit
- 4) The regulated article shall be maintained only in areas and premises specified in the permit
- 5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article
- 6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation

---

---

---

---

---

---

---

---

7) The regulated article shall be subject to the application of measures determined by the Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article

8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the Administrator to be necessary to prevent the spread of plant pests

9) A person who has been issued a permit shall submit to APHIS a field test report within 6 months after the termination of the field test. A field test report shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment

---

---

---

---

---

---

---

---

10) APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences:

(i) Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article;

(ii) In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms)

---

---

---

---

---

---

---

---

11) A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:

(i) Import or offer the regulated article for entry only at a port of entry which is designated by an asterisk in 7 CFR 319.37-14(b);

(ii) Notify APHIS promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

(iii) Mark and identify the regulated article in accordance with 340.5

---

---

---

---

---

---

---

---

## Courtesy Permits

- The Administrator may issue a courtesy permit for the introduction of organisms modified through genetic engineering which are not subject to regulation under this part to facilitate movement when the movement might otherwise be impeded because of the similarity of the organism to other organisms regulated under this part
- Courtesy permits take 60 days

---

---

---

---

---

---

---

---

## 340.6 Petition for determination of nonregulated status

A person must present a full statement explaining the factual grounds why the organism should not be regulated under 7 CFR part 340

The petition shall include the following information:

- 1) Description of the biology of the nonmodified recipient plant and information necessary to identify the recipient plant in the narrowest taxonomic grouping applicable
- 2) Relevant experimental data and publications
- 3) A detailed description of the differences in genotype between the regulated article and the nonmodified recipient organism

---

---

---

---

---

---

---

---

- 4) A detailed description of the phenotype of the regulated article. Describe known and potential differences from the unmodified recipient organism that would substantiate that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived, including but not limited to: Plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the regulated article on nontarget organisms, indirect plant pest effects on other agricultural products, transfer of genetic information to organisms with which it cannot interbreed, and any other information which the Administrator believes to be relevant to a determination. Any information known to the petitioner that indicates that a regulated article may pose a greater plant pest risk than the unmodified recipient organism shall also be included
- 5) Field test reports for all trials conducted under permit or notification procedures, involving the regulated article. Field test reports shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment

---

---

---

---

---

---

---

---

340.6 Petition for determination of nonregulated status

- After the filing of a completed petition, APHIS shall publish a notice in the Federal Register. This notice shall specify that comments will be accepted from the public on the filed petition during a 60 day period commencing with the date of the notice. During the comment period, any interested person may submit to the Administrator written comments, regarding the filed petition, which shall become part of the petition file

---

---

---

---

---

---

---

---

340.6 Petition for determination of nonregulated status

- The Administrator shall, based upon available information, furnish a response to each petitioner within 180 days of receipt of a completed petition

---

---

---

---

---

---

---

---

## FDA Regulation

- The FDA has authority under the Federal Food, Drug, and Cosmetics Act to determine the safety of foods or food ingredients
- FDA staff consult with the plant developer, review safety and nutritional data, and request additional data considered appropriate for each product
- Additional investigation may be required for transgenic crops if they involve:
  - known toxicants
  - altered nutrient levels
  - new substances
  - antibiotic resistance markers

---

---

---

---

---

---

---

---

## FDA Regulation

- At the end of the consultation and review process, FDA sends a letter to the developer stating that the agency is satisfied with the data regarding food safety of the product
- After a product is on the market, FDA has authority to order its removal if the food is deemed unsafe

---

---

---

---

---

---

---

---

## EPA Regulation

EPA regulates transgenic plants that are engineered for pest resistance  
To implement its oversight of transgenic crops, EPA:

- Examines data characterizing the plant-incorporated protectant, e.g., the biochemical nature of the product, its mode of action, and the time and tissues in which the product is expressed.
- Reviews environmental effects (both risks and benefits) of the proposed plant-incorporated protectant, including effects on non-target organisms and environmental fate.
- May require a "resistance management plan", measures to slow down development of resistance in the target pest.
- Determines whether the introduced gene or its product are toxic, typically based on toxicity testing in animals.
- Sets tolerance levels for pesticide residues, if there is evidence of toxicity. Because of lack of toxicity in plant-incorporated protectants evaluated to date, they have been exempt from this requirement.
- Regulates new uses of existing pesticides, such as use of herbicides together with herbicide-resistant transgenics.

---

---

---

---

---

---

---

---

## State Regulation

- In addition to federal regulation, some states require additional review and approval of transgenic crops at the state level. State agencies work together with APHIS to monitor transgenic field testing
- e.g. California and Minnesota

---

---

---

---

---

---

---

---

## International Agreements

International Biosafety Protocol to regulate international trade of genetically modified organisms (not yet ratified):

- International shipments that "may contain" transgenic food products must be so labeled. The exact nature of the genetic modification need not be specified, but the agreement calls for negotiations on more specific labeling requirements in the future. This labeling provision applies only to large-scale shipments, and does not affect labeling requirements on consumer products, which are determined by each country.
- Governments may use the so-called "precautionary principle" to bar import of a transgenic product even in the absence of conclusive evidence that the product is not safe. However, the protocol does not override other international agreements, including the WTO, which requires that import decisions be science-based.
- To assist countries in making import decisions, a database will be established to make available uniform information on transgenic crop varieties

---

---

---

---

---

---

---

---