What is a Genetically Modified Organism?

A genetically modified organism (GMO), also known as a transgenic organism, is any organism whose genetic material has been altered using genetic engineering techniques. (Wikipedia)

An organism or microorganism whose genetic material has been altered by means of genetic engineering. (Dictionary.com)

A genetically modified organism (GMO) is any organism the genetics of which have been altered through the use of modern biotechnology to create a novel combination of genetic material. (Monsanto Dictionary)

Organisms whose genetic material has been artificially manipulated in a laboratory through genetic engineering, or GE. This relatively new science creates unstable combinations of plant, animal, bacteria and viral genes that do not occur in nature or through traditional crossbreeding methods. (NONGMO Project)
APHIS regulates GMOs

- Release to environment
- Importation
- Interstate movement
- Doesn’t regulate already contained experiments
  - Field
  - Laboratory

Regulates under the Plant Protection Act:
- Authorizes the Secretary of Agriculture to “prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant or plant product.”

APHIS grants authorization in 3 ways

- Notification
- Permitting
- Determination of Nonregulated Status
Notification

- Lower risk plants
- Not classified as noxious weeds, or weeds in the release area
- Have to meet certain criteria
- Plant must be stably integrated
- Expression of genetic material must not result in plant disease

If notification denied, applicant can pursue a permit

Permit

- More restrictive; higher risk plants
- Applicant must submit information on:
  - Donor organism
  - Recipient organism
  - Expression of genetic material and biology of system used to produce the plant
- Loci of gene alteration
- Purpose
- Quantity to be produced
- Process to prevent release
- Intended destination
- Use and distribution
- Final disposition

If a permit is granted, APHIS designs conditions to ensure both the regulated plant remains controlled and the APHIS can maintain regulatory oversight.

Determination of Non-regulated Status

Plants have been tested and have shown to not pose a risk may be eligible for determination of non-regulated status

Petition must include:
- Detailed biological information
- Published and unpublished data
- Any other information from APHIS permit conditions
## GMO Deregulated Plants

<table>
<thead>
<tr>
<th>CROP</th>
<th>DEREGULATED</th>
<th>MODIFICATION</th>
<th>CROP</th>
<th>DEREGULATED</th>
<th>MODIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tomato</td>
<td>1992</td>
<td>Fruit ripening</td>
<td>Rice</td>
<td>1999</td>
<td>HT</td>
</tr>
<tr>
<td>Squash</td>
<td>1994</td>
<td>VR</td>
<td>Rice</td>
<td>1999</td>
<td>HT</td>
</tr>
<tr>
<td>Cotton</td>
<td>1994</td>
<td>HT</td>
<td>Tobacco</td>
<td>2002</td>
<td>Resistance</td>
</tr>
<tr>
<td>Soybean</td>
<td>1994</td>
<td>HT</td>
<td>Rice</td>
<td>2007</td>
<td>VR</td>
</tr>
<tr>
<td>Squash</td>
<td>1994</td>
<td>HT</td>
<td>Squash</td>
<td>2011</td>
<td>Fruit color</td>
</tr>
<tr>
<td>Potato</td>
<td>1995</td>
<td>PT</td>
<td>Alfalfa</td>
<td>2011</td>
<td>HT</td>
</tr>
<tr>
<td>Corn</td>
<td>1995</td>
<td>HT</td>
<td>Sugar</td>
<td>2012</td>
<td>HT</td>
</tr>
<tr>
<td>Papaya</td>
<td>1996</td>
<td>VR</td>
<td>Canola</td>
<td>2013</td>
<td>HT</td>
</tr>
<tr>
<td>Onion</td>
<td>1997</td>
<td>Male sterile</td>
<td>Apple</td>
<td>2015</td>
<td>Non-browning</td>
</tr>
<tr>
<td>Beet</td>
<td>1998</td>
<td>HT</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**VR= Virus Resistance**  **HT= Herbicide Trait**  **PT= Pests Trait**  **Source: USDA**

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**Figure 2**
Number of releases approved by APHIS: Top 10 crops (includes permits and notifications)

![Graph showing number of releases approved by APHIS for top 10 crops](source: USDA)

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**Figure 3**
Number of releases approved by APHIS by GE trait (includes permits and notifications)

![Pie chart showing GE traits and number of releases](source: USDA)
Why GM?

- Desirable Traits
  - With conventional breeding this can take up to 15 years
  - Abiotic/biotic stresses
  - Drought, temperature, salinity, insects and pathogens
- Genetic incompatibility
- Improve nutrient/nutritional content
  - Lysine rich corn, Golden Rice, Oilseed Rape vs. Canola
- Recombinant medicines and industrial products
  - Monoclonal antibodies, vaccines, plastics and biofuels

Source: USDA
Concerns?

Overall, risk to the environment or human health:

- Hybridize with non-GM plants through pollen (canola)
- Pests will become resistant (refuge in a bag)
- Conditions required to grow GM crops will interfere with wildlife habitat (biodiversity)
- Adverse effects on human health
  - Carcinogen, toxic, allergens

Source: Key et al. 2008

Hybridize with non-GM plants through pollen—Canola (B. napus)

- Pollen-mediated, intraspecies gene flow from canola to its wild relatives.
  - B. rapa L. (rapeseed), Raphanus raphanistrum L. (wild radish), Sinapis arvensis L. (wild mustard), and Erucastrum gallicum (common dogmustard)
- B. napus x B. rapa = ~7% in commercial fields and ~13.6% in the wild
- GE B. napus three wild varieties was shown to be low (<2 to $5 \times 10^{-5}$)
- Genes could move via wild volunteers
- Most outcrossing occurred in the first ten meters from the field
- Rate of outcrossing was influenced by factors relating to the field, plant, pollen, and environment influenced the rate

Pests will become resistant

Refuge in a bag

- Mandatory refuge requirements—planting sufficient acres of the non-Bt crop near the Bt crop—were needed to reduce the rate at which targeted insect pests evolved resistance
- Such refuges slow the rate at which Bt resistance evolves by allowing target insects that are susceptible to the Bt toxin to survive and reproduce
Conditions required to grow GM crops will interfere with wildlife habitat

- A lot of bird species returned to cotton fields as soon as GM cotton replaced conventional insecticides.
- Before GM cotton, birds were eating insecticide-laden insects and dying as a result.

Safe or no?

A project to develop genetically modified peas by adding a protein from beans that conferred resistance to weevils was abandoned after it was shown that the GM peas caused a lung allergy in mice.

**SCIENCE**

Safety testing of GM plants is effective by having identified allergenic potential before the product was released on the market.

**EMOTION**

All GM is unpredictable and if this caused allergic reaction then all GMOs probably due. The process is unpredictable and dangerous.
Unsafe

<table>
<thead>
<tr>
<th>Crop</th>
<th>Animal Species</th>
<th>Most Adverse Effect</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corn (MON 863)</td>
<td>Rats</td>
<td>Dose related weight variation, hepatorenal toxicity, increase triglycerides in females and diminished urine phosphorus in males.</td>
<td>Seralini et al. (2007)</td>
</tr>
<tr>
<td>Corn (NK 603, MON 810, &amp; MON 883)</td>
<td>Rats</td>
<td>Hepatorenal toxicity, other adverse effects were found in heart, spleen, adrenal glands, and hematopoietic system.</td>
<td>de Vendomois et al. (2008)</td>
</tr>
<tr>
<td>Rice expressing GmA lectin</td>
<td>Wistar rats</td>
<td>No adverse effects but a range of differences between groups (biological, clinical, pathological). Design of study was not able to conclude the safety of the diet.</td>
<td>Poulsen et al. (2007)</td>
</tr>
<tr>
<td>Soybean (CP4 EPSPS gene)</td>
<td>Mice</td>
<td>Several proteins belonging to hepatocyte metabolism, stress response, calcium signaling and mitochondria were differentially expressed.</td>
<td>Mathesius et al. (2009)</td>
</tr>
</tbody>
</table>

Source: Domingo et al. (2011)

Safe

- Corn: 12 out of 15 studies reported no adverse effects or nutritional differences
  - 90 days to 13 weeks
  - Rats, Chickens, and mice

- Rice: 3 out of 4 studies reported no adverse effects or nutritional differences
  - 90 days to 26 weeks
  - Rats

- Soybeans: 7 out of 9 studies reported no adverse effects or nutritional differences
  - 28 days to 104 weeks
  - Rats, mice, chickens,

Conclusion

- APHIS regulates GM pipeline.
- 3 phases: notification, permit, deregulation
- The US has had deregulated plants since 1992
- Corn typically has the most interest, followed by soybeans and cotton
- Speed up the breeding process or overcome incompatibility issues
- Traits should be conserved to avoid resistance issues
- Safe
- WHO declares that GM products currently on the market have all gone through risk assessment and passed.
- Majority of the scientific community deems GMO Crops safe
- On the market for 19 years
References


