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GMO Safety and Regulations

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A PATH FORWARD:

Calls for increased regulation do not account for the robust review already in place. The safety of GM food and crops is not in question in the scientific community. The current regulatory program ensures their safety both in the farm field and for consumers.

- Every major scientific body in the U.S. and around the world has reviewed independent research related to GM crops and food and has concluded they are as safe as food and crops developed from other methods in use today.
- New non-genetically engineered (GE) foods and crops are continually being added to the marketplace. None of these non-GE crops undergo safety testing and review prior to commercialization even though the potential exists for changes that could be harmful, while GE crops and foods must meet rigorous standards of safety.
- GM crops and foods are regulated at every stage of production from research planning through field-testing, food and environmental safety assessment, and after commercial use.
- GM crops and foods have been in use in the U.S. for 30 years with no evidence, despite allegations, that they cause any harm.
- GM foods contain the same nutritional attributes as like foods produced with non-GM crops (although some may contain added nutritional benefits such as vitamin enhancements.) Any GM food with a significantly different nutritional attributes will be rejected in the regulatory process.
- In decades of testing in the lab and in field trials, a transferred gene has never been known to produce a new allergen, toxin or anything functionally different from what was expected.

From Medicine to Food — Scientists Affirm the Safety of GM Technology

Since the initial development of genetic engineering more than three decades ago, there has been no scientific support for the perception among some consumers that GMOs are harmful. While no agricultural or food production method can be entirely free from risk, genetic modification (GM) is on par for safety as compared to other production methods.

Genetic engineering (GE), also called recombinant DNA (rDNA), is the underlying technology giving rise to Genetically Modified Organisms (GMOs). This process was first developed in the 1970s and used to make the first commercial GM product, human insulin, in the early 1980s. From the beginning, scientists questioned whether the GM process would result in hazardous substances. Several independent government studies in the 1980s concluded that the process of genetic engineering was not inherently hazardous (NAS, OECD).

Subsequently, additional professional scientific and medical organizations worldwide have conducted follow-up studies and reviews of existing studies as GM products have become more prevalent, not only in foods but also in medicines and industrial products, such as biofuels and detergents. All of these independent scientific analyses (British Royal Society, French Academies, etc.) support the original conclusions. Since the time that GM products were first commercialized in the 1980s, and despite allegations by some that they might pose health hazards, not a single case of harm can be attributed to GM technology. (NAS, 2004, AAAS, 2012)

In considering GMO safety, it's critical to differentiate between a specific GMO and the category consisting of all GMOs. A specific GMO could be a particular variety of corn or soybean that might conceivably produce a substance in the grain (e.g., an allergen) that could pose a health threat to a small subset of the population. In contrast, a categorical hazard—the production of a hypothetical harmful substance from all organisms undergoing the GM process—would arise from any GMO, not just certain specific ones.

We know that categorical hazards do not exist. Scientists have been studying a wide range of GMOs since the 1970s and have not identified any categorical hazards. If there is a hazard with a given GMO, it is limited to that specific GMO and not the entire spectrum of GMOs. This is why regulatory agencies review specific GMOs on a case-by-case basis. It is also why FDA and USDA decline food labels based on the process of genetic engineering, because of the process of how a food is irrelevant to food safety or nutrition.

Testing Is Extensive Prior to Commercial Release of a new GMO

When a GMO is being developed, a gene of interest (a piece of DNA carrying the genetic recipe for a specific protein imparting the desired trait) is inserted into the genome of the host species, usually in a crop such as corn or soybeans. There are several technical methods of inserting a new piece of DNA into the DNA genome, with the two most common being *Agrobacterium* and biolistic (aka "gene gun".)

Agrobacterium tumefaciens is a common bacterium and a naturally occurring genetic engineer. In nature, the bacteria live in soil and have the ability to transfer a portion of its bacterial DNA to a plant and have it inserted into the plant's DNA, making the bacterial DNA a permanent part of the plant's genome (*i.e.*, the total complement of DNA of that plant.) The genes carried on the bacterial DNA are "read" and "expressed" by the plant cell, resulting in the production of proteins new to the plant but beneficial to the Agrobacterium. In making GM crops, scientists trick the *Agrobacterium* by deleting its own bacterial genes and substituting genes of interest, that is, those genes creating a desired trait in the plant. The *Agrobacterium*, now carrying the genes of interest, naturally transfers those useful genes to plant cells in petri dishes, and the useful genes are naturally inserted into the plant genome and become a permanent part of the plant's genetic makeup.

The other method, using the biolistic 'gene gun', involves taking many copies of the gene of interest and coating them on tiny shotgun pellets, which are literally shot with a blast of air into the target plant cells in a petri dish. Again, the genes of interest are inserted into the genome of the plant cell and become a permanent part of the plant's genome.

In both cases, the engineering adds one or two additional genes to the 30,000 or so genes (depending on the species) already present in the genome. It's important to remember that the basic plant remains the same as before; genetic engineering merely adds a useful gene (or sometimes deletes a deleterious gene) to the complement of genes already present in the genome. Here's an illustrative analogy: inserting a desirable gene into a plant genome is like adding a useful app to your smartphone; the new app takes up a small bit of space and (usually) doesn't interfere with the other apps already present, but performs useful functions when called upon to do so.

Early testing of transformed (genetically engineered) cells takes place in the lab, while the recipient or host plant cells are still growing in petri dishes. Various tests are conducted to ensure that the cells have indeed taken up the transferred DNA and those successfully "transformed" cells are nurtured and grown into whole plants, which will flower and set seed, just as traditional plants of the same species. These seeds and their progeny are tested for many features, including food and environmental safety as well as the new trait of interest.

In addition to assuring that the DNA is successfully integrated into the host plant genome, tests assure that the inserted gene is actively "read" or "expressed" and that the appropriate protein is produced from the transferred gene recipe. In practice, a transferred gene either successfully produces the appropriate protein, or if unsuccessful, fails to produce anything functional.

Crucially, a transferred gene has never been known to produce a new allergen, toxin or anything functionally different from what was expected.

Years of Rigorous Testing Ensure GM Safety

Progeny testing continues into confined growth cabinets and, if all is well, then in greenhouses. At each generation, the testing becomes more elaborate. Any transgenic 'event' (the regulatory term for a single genetically transformed cell grown out into a whole plant, and all subsequent generations derived from the initial transformed cell) is tested and, if failing any test, the entire event line (*i.e.*, all the plants derived from the initial transformed cell) is culled.

Most event lines are culled due to features of the inserted gene, such as genetic instability, where the transferred gene is not permanently fixed in place in the host genome, or if the gene is not expressed sufficiently to produce enough protein to confer the desired trait. Other reasons for culling include changes from the original cultivar (a plant or group of plants selected for desirable characteristics) features, such as poor agronomic performance (especially decreased yield or delayed ripening), weak plants, or poor quality or nutritional results such as lower vitamin content than the parent variety grown under the same conditions.

By the time the transgenic plants graduate from confined indoor trials to reach open field trials, as regulated by the U.S. Department of Agriculture, there is already a huge collection of data relating to safety, stability and expression of the new trait. In field trials, the performance is compared with other plants of the same species to ensure the agronomic performance is at least as good as the parent. Such field trials are also grown in different regions where the commercial cultivars are grown to collect data on regional performance. Other tests assure the expression of the new trait functions sufficiently under field-grown conditions, because those are the conditions under which farmers will be growing them.

These tests can take several years to complete, and only then, if all the results are satisfactory, will the GM plant be considered for regulatory approval and eventual commercialization.

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Three U.S. Regulatory Agencies Assess GMO Safety

Crop and Food Safety are a Priority

In the U.S., three federal government agencies (USDA, EPA and FDA) are responsible for assuring the safety of GM crops and foods.

USDA

U.S. Department of Agriculture (USDA) reviews prospective new genetically engineered crops to assure environmental safety, especially focusing on whether the new plants will become plant pests (a.k.a. weeds). USDA considers the species under review, asking questions about the inherent weediness of the species, the prevalence of related species that show weediness, and the ease with which the cultivated varieties might outcross (introduction of unrelated genetic material into a breeding line) with those weedy relatives. USDA also regulates the import, interstate movement and open field trials of GE plants, called in regulatory terms "Regulated Articles."

EPA

U.S. Environmental Protection Agency (EPA) is mainly responsible for pesticides and pesticidal activities. For example, new GE crops that make new use of herbicides to control weeds or insecticides to protect against insect pests are fully investigated by EPA to assure the pesticidal use is safe and appropriate.

FDA

U.S. Food and Drug Administration (FDA) considers food and feed safety in an effort to recognize if health hazards are present as products or substances, such as toxic chemicals (e.g., cyanide) or biological pathogens (e.g. E. coli or Salmonella) in a food or feed consumed. In other words, methods or processes for making a given product are not inherently hazardous unless they result in a hazardous substance in the final product. Scientists at FDA focus on components of the food and feed derived from GE crops. In its investigations, FDA considers the nutrient composition of the new food and feed, looking at protein content, fiber, minerals, vitamins, amino acids and other substances in the food. FDA also focuses on allergens and toxins in the food, including pre-existing allergens and toxins as well as the possibility of introducing new allergens or toxins during the gene transfer. If any nutrient appears to be significantly higher or lower than what is seen in that species, the GE line is rejected.

In practice, the company or other developer collects such information for years prior to going to FDA, so they will already have culled any such variant lines. By the time FDA scientists see the proposed new GE variety, the data will almost invariably show no differences in nutritional composition, apart from the intended changes associated with the introduced trait. All GE crops and foods on the market have passed this FDA review.

New crops and foods are constantly being added to the marketplace, developed using an array of methods, including traditional crossing, ionizing radiation mutagenesis, organics and simple introductions from overseas. None of these non-GE crops undergo safety testing and review prior to commercialization even though the potential exists for changes that could be harmful, while GE crops and foods must meet rigorous standards of safety.

Assessing the Safety of GMOs - The Scientific Community Consensus

In addition to U.S. government agencies assessing the safety of GMOs, various professional, scientific, and medical bodies worldwide have also investigated the safety of GMOs. Those independent professional bodies usually appoint a blue-ribbon panel of a dozen or so experts in the relevant fields, including genetics, medicine, nutrition, agronomy, etc., and spend as long as two years on the investigation. A final report from the panel issues the findings.

All such studies to date have concluded, unsurprisingly, that no agriculture or food production method is risk free, whether GMO, conventional or organic, but on balance, GMOs are as safe, or safer, than other methods.

The Genetic Literacy Project notes that over 2,000 global studies affirm the food and environmental safety of GM. Below is a list of some of the leading scientific bodies that have affirmed the safety of GM foods and crops:

- **U.S. National Academies**
- **U.S. Institute of Medicine**
- **American Medical Association**
- **British Royal Society**
- **Royal Society of Medicine**
- **European Food Safety Authority**
- **EU Economic Commission**
- **World Health Organization**
- **American Association for the Advancement of Science**
- **American Dietetic Association**
- **International Seed Foundation**

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