# BACKGROUND INFORMATION

## PART 1
## New Variety Evaluation

A typical diet for most people includes a variety of foods. Some of those foods are eaten in their original form (such as a whole apple or a banana), while other foods (such as apple pie or banana muffins) are a combination of ingredients. Food ingredients include spices, sweeteners, preservatives, and other substances that affect food characteristics such as taste, texture, and nutritional content. The ingredients in processed foods are required to be on the labels.

All foods, whether a whole food or a food ingredient, have a certain chemical identity, i.e., a characterizing composition that may include one or more of the following: amino acids, fatty acids, carbohydrates, vitamins, and minerals (to name a few). Some whole foods and ingredients may also have components that function as anti-nutrients (compounds that interfere with nutrient absorption) or natural toxins. Some components may also elicit allergenic responses in susceptible people. The levels of these food components provide the food's specific identity, i.e., what makes a banana a banana or a salmon a salmon, and what distinguishes corn oil from olive oil.

When a **new plant variety** is developed through genetic engineering (GE plant, GE variety), its composition is typically analyzed and compared with parental and commercial varieties. The levels of key components (nutrients, anti-nutrients, and toxins) are compared to assess any significant changes in those components. The safety and effects of any new or added substances are also assessed. Depending on the nature of the new substance(s) and with its history in other foods, the types of safety data will vary. The results of this comparison support whether or not food from the new variety has essentially the same safety profile and nutrient content as food from traditionally bred plants.

Accurate labeling helps people know more about the nutritional profile and ingredients in the food they eat. Consumers can use this information to ensure that they get enough of the nutrients they need and understand how to limit nutrients they want to minimize. They also can use food labels to identify and avoid food allergens such as peanuts, milk, wheat, and other ingredients that can cause allergic reactions in some people. If a food or ingredient is from a GE plant, it's the plant that has been genetically engineered, and not the ingredient per se. Many ingredients to date (like starches, sugars, and oils) derived from GE plants do not contain recombinant DNA, RNA, or protein and are chemically and functionally identical to their non-GE-derived counterparts. New labeling for some foods containing ingredients made through genetic engineering (bioengineering) becomes effective in 2020 with compliance mandated by 2022.

### What makes up a banana?

**INGREDIENTS:** WATER (75%), **SUGARS (12%)** (GLUCOSE (48%), FRUCTOSE (40%), SUCROSE (2%), MALTOSE (<1%)), STARCH (5%), FIBRE E460 (3%), **AMINO ACIDS (<1%)** (GLUTAMIC ACID (19%), ASPARTIC ACID (16%), HISTIDINE (11%), LEUCINE (7%), LYSINE (5%), PHENYLALANINE (4%), ARGININE (4%), VALINE (4%), ALANINE (4%), SERINE (4%), GLYCINE (3%), THREONINE (3%), ISOLEUCINE (3%), PROLINE (3%), TRYPTOPHAN (1%), CYSTINE (1%), TYROSINE (1%), METHIONINE (1%)), **FATTY ACIDS (1%)** (PALMITIC ACID (30%), OMEGA-6 FATTY ACID: LINOLEIC ACID (14%), OMEGA-3 FATTY ACID: LINOLENIC ACID (8%), OLEIC ACID (7%), PALMITOLEIC ACID (3%), STEARIC ACID (2%), LAURIC ACID (1%), MYRISTIC ACID (1%), CAPRIC ACID (<1%)), ASH (<1%), PHYTOSTEROLS, E515, OXALIC ACID, E300, E306 (TOCOPHEROL), PHYLLOQUINONE, THIAMIN, **COLOURS** (YELLOW-ORANGE E101 (RIBOFLAVIN), YELLOW-BROWN E160a), **FLAVOURS** (3-METHYLBUT-1-YL ETHANOATE, 2-METHYLBUTYL ETHANOATE, 2-METHYLPROPAN-1-OL, 3-METHYLBUTYL-1-OL, 2-HYDROXY-3-METHYLETHYL BUTANOATE, 3-METHYLBUTANAL, ETHYL HEXANOATE, ETHYL BUTANOATE, PENTYL ACETATE), 1510, NATURAL RIPENING AGENT (ETHENE GAS).

Source: *Ingredients of an All-Natural Banana*, James Kennedy (VCE Chemistry teacher in Melbourne, Australia)

### Safety Evaluation of Food from New Plant Varieties

The Federal Food, Drug, and Cosmetic Act requires that food from plants for humans and animals meet the same food safety requirements regardless of their origin, whether they are made from a plant variety that was created through crossbreeding, chemical or irradiation-induced mutagenesis, or genetic engineering. As new plant varieties were developed using GE tools over the past decades, FDA worked with the plant breeders to evaluate the safety of food from these GE varieties. This evaluation includes data analysis based on a comparison of food from the new GE plant variety to food from traditionally bred plant varieties with a history of safe use. Any differences identified during this comparison are then evaluated for safety.

# BACKGROUND INFORMATION

### Plant Biotechnology Consultation Program

FDA established a consultation process in the 1990s to work cooperatively with plant developers to help them ensure that foods made from new varieties, including those developed by genetic engineering, are safe and lawful. The consultation process allows a developer who intends to commercialize a new plant variety developed using modern genetic modification methods to meet with FDA to identify and discuss relevant safety, nutritional, or other regulatory issues about food for humans and animals made from the new variety. Plant breeders conduct tests and gather science-based evidence to verify that food from the new variety is as safe to eat as food from traditionally-bred varieties, and then submit the data and information to FDA for evaluation. FDA evaluates the submission and responds to the developer by letter. Since 1994, FDA has evaluated more than 180 new GE plant varieties through this program. For a list of completed consultations, see FDA's **Biotechnology Consultations database**.

### Safety Evaluation of GE Plants

Developers of GE plants gather information and conduct scientific studies to generate data, which they use to evaluate foods and ingredients from new varieties for safety and nutrition. Their review of food from the new varieties includes an examination of the following factors:

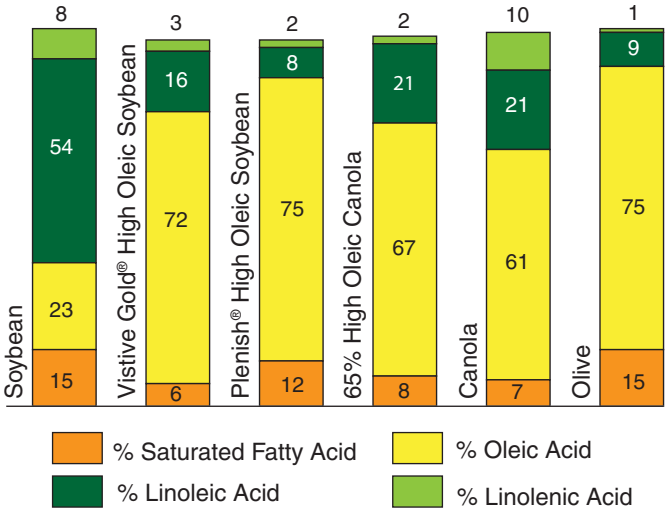
- **Identity**: Analyses to confirm the intended changes, including confirmation of the new or edited DNA, of new proteins produced from the DNA, and of other intended effects (traits).
- **Composition**: Whether key nutrients are within the expected ranges of values for the crop, whether endogenous (naturally occurring) toxins or antinutrients (compounds that interfere with the absorption of nutrients) are within acceptable levels
- **Safety and Regulatory Issues**: Potential for toxicity/allergenicity of new substances, and whether new substances require premarket review and approval by FDA by law. If the added substances are pesticides, they must be evaluated for food and environmental safety and authorized for use by the U.S. Environmental Protection Agency (EPA).

## Identity

Developers of new plant varieties, including new GE varieties, collect data to identify distinguishing attributes of the new traits in the plant and assess whether any new proteins or components present in the new variety are safe for humans or animals to eat.

When a substance produced in a new GE plant variety is one that is already present at a comparable level in currently consumed foods, a safety question about the new substance is unlikely. For example, high oleic acid soybean oil has higher levels of oleic acid compared to typical soybean oils, but the higher levels are similar to other food oils, such as canola and olive oil.

### Comparing Some Oils




Inform Magazine: High-oleic soybeans get the global green light, chart http://www.informmagazine-digital.org/informmagazine/april_2018/MobilePagedArticle.action?articleId=1367747#articleId1367747

When a substance produced in a new GE variety is one that is not present – or is present only at lower levels – in currently consumed foods, its safety in food must be evaluated.

# BACKGROUND INFORMATION

## Composition

Developers of new plant varieties, including new GE varieties, collect data on the composition of the new variety by conducting field trials. Field trials for new GE varieties frequently include the new GE variety (test), along with a genetically comparable plant variety as a control and possibly one or more commercial varieties as reference varieties. Samples from the edible parts of the test, control, and reference varieties are collected, and the levels of key nutrients, anti-nutrients, and toxins are measured.

The results of the compositional analysis for the new GE variety are then compared with the results for the control and reference varieties. They may also be compared with plant composition data in science journals and public databases.

## Safety and Regulatory Issues

### Health and Safety

New substances present in food from the new plant varieties, such as those introduced by genetic engineering, are studied to determine whether they could be toxic or allergenic.

The composition of food from new plant varieties is also evaluated for meaningful changes in their nutritional values or increased levels of endogenous anti-nutrients or toxins. Plants are an important source of nutrients in the diet, so changes in their composition have the potential to impact the health of humans and animals.

Some plants that we eat also produce natural toxins that are usually defense molecules against environmental threats such as bacteria, fungi, insects, or predators. Two examples of natural toxins are glycoalkaloids in potatoes and psoralens in celery. These natural toxins are generally not present in domesticated food crops at levels high enough to affect human or animal health, but breeding may lead to changes in the levels of these substances.

Compositional changes are evaluated by dietary experts for their potential to impact the health of humans or animals. In some cases, the compositional change is specifically made to improve dietary intake status. For example, Golden Rice was developed to address vitamin A deficiency in south and southeast Asian countries where people typically consume a rice-based diet. However, if the level of a nutrient in the new plant variety is found to be too low or too high, this could lead to dietary deficiency or excess, respectively. Likewise, if the level of an anti-nutrient or toxin is found to be too high, this could cause harm. Either way, it is important to conduct the analysis in the context of the total diet. Scientists consider the role of food from the plant in the diet of humans and animals when performing this analysis. For example, they consider whether the food is an important source of particular vitamins and minerals in the context of the total diet.

### Long-Term Safety

Scientists with expertise assessing the long-term safety of food and food ingredients for humans and animals consider several factors when they evaluate food from new plant varieties, including new GE varieties. This includes information about the long-term safety of the food from traditionally bred crops and information about the food safety of the newly introduced traits. The plant's components (fiber, protein, fat, DNA, anti-nutrients, etc.) have typically been part of the human diet for thousands of years. Just like the plant's endogenous nucleic acids and proteins, the recombinant nucleic acids and proteins are degraded during digestion in the human or animal gastrointestinal tract into their building blocks. For all GE plant varieties evaluated to date through FDA's Plant Biotechnology Consultation Program, the long-term safety of food from the new GE variety is expected to be the same as that of food from comparable traditionally-bred and safely-consumed plant varieties.

Note: When FDA considers the safety of foods from a new plant variety, it considers uses of the plant in food for both humans and animals.

**DID YOU KNOW?**

Food packages are required by law to list certain nutrients in food using the Nutrition Facts label. Some other labels, such as "Country of Origin" are also required by law, but several other labels are only used for marketing, i.e., to appeal to certain consumers. Examples of marketing labels are "non-GMO" and "Kosher."

# BACKGROUND INFORMATION

## Developer's Safety Evaluation Steps

As a new plant variety is developed, the process includes several steps to compare various components in the new plant with the same components in the original parent (host) plant.

### Analyze Host/Parent Plant

Nutrients

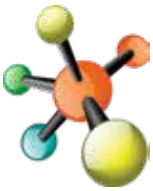
Naturally-occurring toxins (if any)

Naturally-occurring anti-nutrients (if any)

### Analyze New Plant Variety

| | | |
|---|---|---|
| Same nutrients? | Same amounts? | Safe amounts? |
| Same naturally-occurring toxins (if any)? | Same amounts? | Safe amounts? |
| Same naturally-occurring anti-nutrients (if any)? | Same amounts? | Safe amounts? |

### If there is New Protein in the Food Product…



Are new proteins from a toxic or allergenic source?

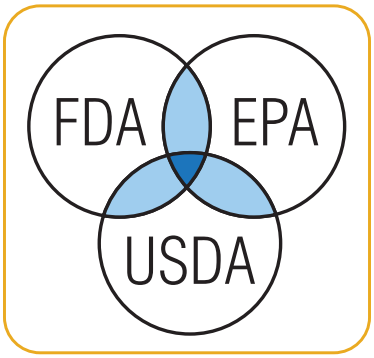
Are new proteins similar to known toxins?

Are new proteins similar to known allergens?

### Evaluate

Use the answers to questions above to decide whether food from the New Plant Variety is as safe and nutritious as food from the Host/Parent Plant or whether additional information is needed.

### Coordinated Biotechnology Regulation




Three federal agencies (FDA, USDA, and EPA) act under a coordinated regulatory framework to ensure the overall safety of GE new plant varieties:

- FDA regulates the safety of all food products for humans and animals in the United States other than meat, poultry, catfish and certain egg products, which are regulated by USDA.
- USDA, specifically the Animal and Plant Health Inspection Service (APHIS), is responsible for protecting agriculture from pests and diseases. They supervise field testing and monitor GE seed distribution until the GE plant variety is shown not to be harmful to agriculture and the environment.
- EPA regulates pesticides, including those that are produced in plants as a result of genetic engineering. To protect human and animal health, EPA assures that pesticidal substances expressed in GE plants are safe for consumption. EPA also regulates the environmental safety of the pesticidal substances.

To learn more about each agency's role, explore the resources below.

- Coordinated Framework: **https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home**
- FDA: *Food from New Plant Varieties* **www.fda.gov/Geplantfoods**
- USDA: *Regulation of Biotechnology* **https://www.aphis.usda.gov/aphis/ourfocus/biotechnology**
- EPA: *EPA's Regulation of Biotechnology for Use in Pest Management* **https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/epas-regulation-biotechnology-use-pest-management**

### GE Animals

GE animals can be developed for a variety of purposes including disease-resistance, improved nutritional composition (e.g. healthier fat or lower allergenicity), and greater productivity (faster growth with less feed). For example, AquAdvantage Salmon was genetically altered to grow more quickly, using a gene commonly found in another type of fish. This salmon is the first GE animal to be approved for human consumption.

# BACKGROUND INFORMATION

### Scientific Perspectives

The scientific consensus is that food from GE plant varieties available for consumers are safe, i.e., pose no greater health risks or environmental concerns than their non-GE counterparts.

Some of the scientific organizations that support this position are:

- FDA, USDA, and EPA
- National Research Council
- American Association for the Advancement of Science
- Council on Science and Public Health
- World Health Organization
- European Food Safety Authority

### Evolving Science

More technologies emerge as farmers and scientists address changing needs in food agriculture. One approach, genome editing, describes a relatively new set of techniques to make changes at specific locations in the DNA of a plant, animal, or other living organism. (See Module 2.) These technologies can be used to introduce, remove, or substitute one or more specific nucleotides at a specific site in the organism's genome. Examples of different genome editing techniques include clustered regularly interspaced short palindromic repeat associated nucleases (CRISPR), zinc-finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs), and oligonucleotide-directed mutagenesis (ODM). FDA completed its first voluntary food safety consultation on food derived from a plant produced using genome editing in February 2019. Regardless of how a plant is produced, food from the plant must be safe.

## Examples of Foods Made with GE Techniques

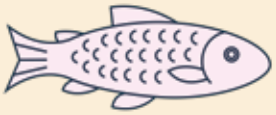
### Plant

- USDA Approves Genetically Modified Non-Browning Apple (Arctic® Apples) **www.youtube.com/watch?v=3LFmWhJu6Pw**

### AquAdvantage Salmon

- AquAdvantage Salmon is the first GE animal for consumption with an FDA-approved application. The company collected data for over 10 generations of the animal.

Read the FDA AquAdvantage Salmon Fact Sheet: **https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/aquadvantage-salmon-fact-sheet**



### Federal agency inventories of safety evaluations

(search by product, e.g., apple):

- FDA: **https://www.fda.gov/food/consultation-programs-food-new-plant-varieties/final-biotechnology-consultations**
- USDA: **https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status**
- EPA: **https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated**

**DID YOU KNOW?**

FDA and USDA use different words to characterize the regulatory processes by which a GE plant is evaluated and designated as safe. FDA uses a consultation process to evaluate whether food from a GE plant requires FDA's premarket approval for safe use. USDA uses a petition process to deregulate (remove from USDA's regulatory oversight) GE plants once it is determined they do not pose a plant pest risk.

**Three-Part, Science-Based Approach to Safety Evaluation of New Plant Varieties**

| Case-by-case approach | Comparative approach | Focus on new substances |
|---|---|---|
| Does the plant have a history of safe use? Is it typically used in human food? In animal food? What parts of the plant are eaten? Is it eaten fresh or is it processed? | Are the levels of important nutrients in food from the plant similar to the levels in food from varieties of the plant with a history of safe use? Are the levels of toxins and anti-nutrients the same or lower? If the levels are different, do the differences affect safety or nutrition? | Are there new substances in the plant? Will the new substances be present in food made from the new plant? If so, are the new substances toxins, antinutrients, or allergens? |

# BACKGROUND INFORMATION

## PART 2
## Food Labeling

The information listed on food labels serves different purposes. Some labeling is for safety and identity, and other labeling is for consumer interest/marketing (e.g., USDA's National Organic Program). Some information is required by law, and some is voluntary.

### FDA and Labeling of Food From GE Plants

FDA's mandatory labeling requirements that apply to food, including from GE plants, are the same requirements that apply to all other foods under FDA's authority. The law requires foods to be identified on their label by their common and usual name. The common and usual name of a food is a name that appropriately describes the basic nature of the food or its characterizing properties or ingredients. The composition and functional properties of many ingredients made from GE plants are comparable to non-GE-derived counterparts, so the GE plant-derived ingredients are often identified by the same common or usual name. However, in cases where the composition has been changed in a meaningful way, then food from the new plant variety, GE or non-GE, would have a new name that describes the change (e.g., high oleic acid soybean oil, pink pineapple).

### Mandatory Labeling of "Bioengineered (BE)" Food

In July 2016, Congress passed the National Bioengineered Food Disclosure Law, which directed USDA to establish standards for disclosing human foods that are or have ingredients that are bioengineered (BE). In December 2018, after gathering information and deliberating on what the standards should require, USDA announced the National Bioengineered Food Disclosure Standard (NBFDS or "the Standard"), which defines BE foods as those that contain detectable genetic material that has been modified through certain laboratory techniques and cannot be created through conventional breeding or found in nature. The Standard requires food manufacturers, importers, and certain retailers to disclose information about whether food offered for retail sale is BE or uses BE food ingredients. NBFDS is a marketing standard designed to provide consumers more information about their food. It does not address the health and safety of bioengineered foods, including any nutritional aspects of such foods.

The Standard requires food manufacturers, importers, and certain retailers to ensure that BE foods, and foods with BE ingredients, include a BE food disclosure. The disclosure may be made using one of several options: text, symbol, electronic or digital link, and/or text message. These disclosures are required by January 1, 2022.

Because the Standard defines BE foods as those that contain detectable modified genetic material, many highly refined foods will not require a BE food disclosure. Many highly refined foods are processed in a way that makes modified genetic material undetectable, which means these foods and ingredients are no longer considered BE foods. For example, sugar that is made from a BE sugar beet is usually processed to the point that modified genetic material is not detectable. As a result, sugar from a BE sugar beet would likely not require a BE food disclosure. However, the food manufacturer could voluntarily use the "Derived from bioengineering" disclosure shown below.

**NOTE:** Foods from genome edited plants usually do not require BE labeling, dependent on whether they fall within the definition of bioengineered foods as established in the Standard.

### BE Labels



For more information on USDA's BE Standard and labeling, see **www.ams.usda.gov/rules-regulations/be**.

### USDA's National Organic Program

What are USDA "certified organic" foods? USDA certified organic foods are grown and processed according to federal guidelines addressing, among many factors, soil quality, animal raising practices, pest and weed control, and use of additives. A product cannot be labeled "organic" unless it meets the criteria set forth by the National Organic Program (NOP), overseen by USDA's Agricultural Marketing Service, for organic food. According to the NOP criteria, the use of genetic engineering is prohibited.

The NOP is a marketing standard and not a safety standard. That is, the NOP is a standard required for labeling a product as USDA certified organic and does not imply that a food is more or less safe than its non-organic counterparts. In fact, USDA certified organic foods and non-organic foods must meet the same food safety standards.

For more information, see **https://www.ams.usda.gov/rules-regulations/organic/labeling**.