

NAVIGATING FDA PRE-MARKET MEETINGS
“FOODS DERIVED FROM PLANTS PRODUCED USING GENOME EDITING”
A RESOURCE FOR DEVELOPERS
SEPTEMBER 2025

Abbreviations and terminology

Abbreviation	Definition
ASTA	American Seed Trade Association
CSFAN	Center for Food Safety and Applied Nutrition (former name of Human Foods Program)
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CVM	Center for Veterinary Medicine
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
GRAS	Generally Recognized as Safe
NPV	New Plant Varieties
NPV Policy	1992 Statement of Policy on New Plant Varieties
rDNA	Recombinant DNA
RFC	Request for comment
TALENS	Transcription Activator-Like Effector Nucleases
USDA	United States Department of Agriculture
VPC	Voluntary Premarket Consultation
VPM	Voluntary Premarket Meeting

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Section 1: Background. Summary Statement: This section offers a brief background on the FDA policy for evaluating food derived from genetically engineered plants and food derived from genome edited plants.

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Section 3: FDA Guidance Regarding Information Reviewed During VPM. Summary Statement: This section discusses what types of information may be presented during the VPM process.

Section 4: Practical Aspects of the VPM Process. Summary Statement: this section discusses communication, FDA actions and timelines regarding initiating and processing through the VPM process with FDA

ASTA disclaimer

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1. Background

1.1. The Coordinated Framework

In June 1986 the US Coordinated Framework for the Regulation of Biotechnology (the Coordinated Framework), was established laying out the various roles and responsibilities of three federal agencies, the Food and Drug Administration (FDA), the US Department of Agriculture (USDA) and the Environmental Protection Agency (EPA), in regulating and overseeing the products of “biotechnology”.

1.2. FDA’s 1992 Statement of Policy on New Plant Varieties (NPV)

The Food and Drug Administration (FDA) published in 1992 a Statement of Policy (referred to as “NPV Policy”) clarifying its oversight of human and animal foods (hereafter referred to as ‘food’) derived from new plant varieties (NPV) under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The US government decided that the NPV Policy was needed as the initial products of biotechnology, such as the FlavrSavr tomato, were nearing commercialization and the regulatory status of such foods needed clarification. https://archives.federalregister.gov/issue_slice/1992/5/29/22970-23005.pdf

The NPV Policy explained that the use of genetic modification techniques to develop new plant varieties is part of a continuum that includes traditional breeding methods and newer (at that time) methods like recombinant DNA (rDNA) techniques. FDA clarified that under the broad authority of the FFDCA¹, foods derived from genetically engineered plants generally are subject to the same requirements as other foods, and FDA would regulate such foods using “an approach identical in principle to that applied to foods developed by traditional plant breeding.” FDA stated that the main factors in assessing safety “should be the characteristics of the food product, rather than the fact that the new methods are used.” FDA noted that “unintended occurrences of unsafe levels of toxicants in foods” as a result of genetic modification could render the food injurious to health and thus adulterated under section 402(a)(1) of the FFDCA.

FDA also clarified that it considers transferred genetic material (DNA, RNA) itself to be “generally recognized as safe” (GRAS). Substances that are GRAS are not subject to premarket approval by FDA. With respect to intended expression product(s) present in foods from NPVs (typically proteins or substances produced by the action of protein enzymes, such as carbohydrates, and fats and oils), if the substance “is already present at generally comparable or greater levels in currently consumed foods, there is unlikely to be a safety question sufficient to call into question the presumed GRAS status of such naturally occurring substances and thus warrant formal premarket review and approval by FDA.” If the intended expression product “differs significantly in structure, function, or composition from substances found currently in food, such substance may not be GRAS and may require regulation as a food additive”, requiring premarket approval.

¹ The Federal Food, Drug and Cosmetic Act (FFDCA) is the umbrella legislation that FDA uses to regulate the manufacture, sale, and distribution of food, drugs, medical devices, cosmetics, and other products to ensure their safety and effectiveness. The legislation was initially passed in 1938 and has been amended numerous times.

1.3. FDA's Safety Assessment Principles and Consultation Process

In the 1992 NPV policy, FDA outlined principles for assessing the safety of foods derived from genetically engineered plants, publishing a series of six decision trees on various aspects of food composition and safety. As described in the previous section, FDA requires a premarket approval if the intended expression product is not GRAS for the intended use. If the intended expression product present in foods from transgenic NPVs is presumed to be GRAS, FDA does encourage developers to consult with the agency on the regulatory status of such foods and to identify and resolve safety, nutritional, or labeling questions before commercialization. During these voluntary “consultations” (sometimes referred to as voluntary premarket consultations, VPC, or consultation), FDA is not expected to conduct an exhaustive review of the submitted data and information but focuses on whether unresolved safety issues warrant action (meaning the food under intended uses may not be GRAS). Two branches at FDA are involved in such consultations: the Human Foods Program (formerly the Center for Food Safety and Applied Nutrition (CFSAN)) (human food) and the Center for Veterinary Medicine (CVM) (animal food). At the completion of a consultation with FDA, the developer receives a letter from FDA (jointly from CFSAN and CVM) stating that they “have no further questions at this time” and that it is the developers “continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements”.

Although the consultation process is voluntary, to date it is ASTA’s understanding that nearly all transgenic NPVs commercialized for food use have gone through the formal consultation process, with FDA having completed approximately 200 of these consultations. The majority of these consultations have been on widely grown transgenic row crops that were not modified to intentionally alter the nutritional characteristics of the crop. A list of products completing the consultation process can be found at: [New Plant Variety Consultations](#)

1.4. FDA and Genome Editing

In 2016, FDA began engaging with associations like ASTA and developers using genome editing tools (e.g. TALENS, Zinc-Finger Nucleases and CRISPR) to develop new plant varieties, signaling its plans to clarify the regulatory approach for foods derived from genome edited NPVs. In January 2017, FDA issued a request for comment (RFC) to gather input on the appropriate approach to evaluate foods derived from genome edited plants. In response to the RFC, FDA received more than 580 unique comments from a diversity of interests. Both ASTA and BIO provided feedback to FDA at that time on appropriate approaches the agency should consider in providing additional guidance to developers related to foods from genome edited plants^{2,3}.

Seven years in the making, FDA issued a final guidance document (hereinafter guidance or genome editing guidance) on “Foods Derived from Plants Produced Using Genome Editing” on February 22, 2024. The guidance reaffirmed that the principles of the 1992 NPV Policy apply to foods derived from

² ASTA - <https://www.regulations.gov/comment/FDA-2016-N-4389-0521>

³ BIO - <https://www.regulations.gov/comment/FDA-2016-N-4389-0537>

genome edited plants. Regarding the use of genome editing tools to generate genetic variation they stated that “food from these genome-edited varieties may have the same characteristics as foods from traditionally bred plants that have been safely consumed in the past.” Thus, FDA generally concurs that genome editing techniques per se pose no new safety concerns in the development of new varieties. FDA reiterated that developers, regardless of the breeding tools used to develop new varieties, must ensure that the products they offer for sale are safe and lawful.

In short, the guidance clarifies that developers may voluntarily inform FDA of the steps they have taken to ensure the safety of foods from any genome edited plant varieties. For foods derived from genome edited plants that have one or more of the specific characteristics identified in the guidance (described below), which may be more likely to raise food safety questions or regulatory considerations, FDA recommends that developers use the agency's existing voluntary premarket consultation process. For foods with none of the characteristics identified in the guidance, FDA recommends a new and simplified premarket engagement pathway – a voluntary premarket meeting (VPM) (Figure 1). While the FDA guidance was considered “final”, the agency invited input on the document. Industry did provide comments to FDA on the 2024 guidance, calling out both positive aspects and elements of concern⁴.

As with the long-standing VPC process, engaging in VPM with FDA has the potential to provide developers with several benefits. Using the VPM process can help address transparency around product introductions⁵, supports confidence in development and evaluation processes by the value chain, could reduce regulatory uncertainty and provide a degree of international credibility given FDA’s standing globally.

⁴ ASTA-BIO Comment October, 2024 - <https://www.regulations.gov/comment/FDA-2019-D-4658-0030>

⁵ Also see: https://www.betterseed.org/wp-content/uploads/ASTA-Best-Practices-Information-Sharing-for-Products-of-Gene-Editing_final.pdf

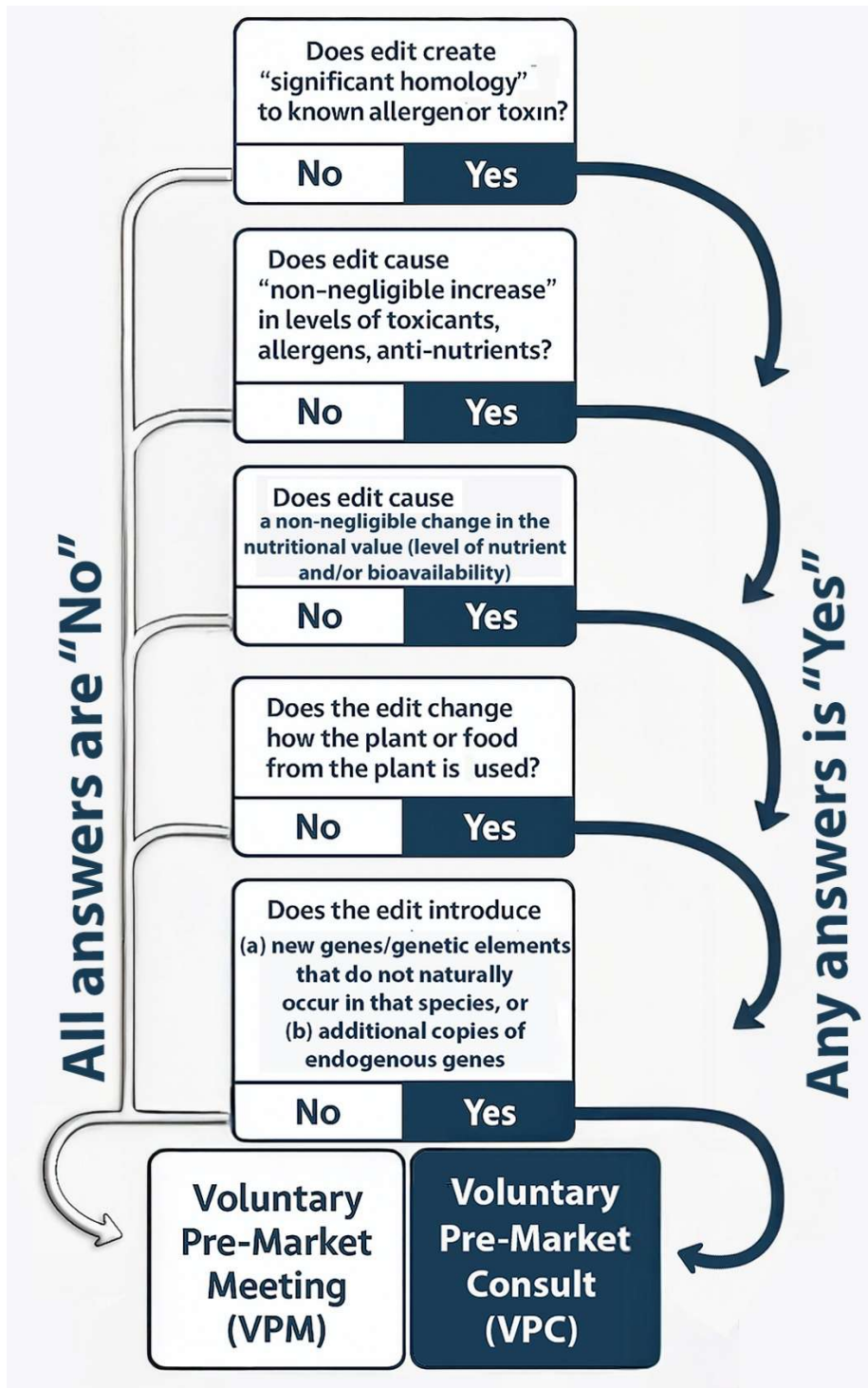


Figure 1. Genome editing modifications guiding FDA interaction path as outlined in 2024 FDA Guidance: Foods Derived from Plants Produced Using Genome Editing

2. Objective of Voluntary Premarket Meeting

As mentioned above, the guidance outlines two processes for a developer to voluntarily inform FDA about foods from their genome edited NPVs: voluntary premarket consultations (VPCs) and voluntary premarket meetings (VPMs). The objective of a VPM is a process to “*familiarize FDA with the types of foods from genome-edited plants entering the market and the steps developers have taken to ensure their safety and lawfulness*”. In the 2024 guidance FDA recommends developers to consider the voluntary premarket consultation process for genome edited NPVs with any of the following types of modifications:

1. Modifications of endogenous genes that create significant homology to a known allergen;
2. Modifications that cause a non-negligible increase in levels of potentially harmful components including toxicants, allergens, anti-nutrients and other components that can exhibit non-nutritive physiological effects on humans or animals;
3. Modifications that cause a non-negligible change in the nutritional value of the food;
4. Modifications that change how the plant or food from the plant is used;
5. Modifications that introduce a) new genes and/or genetic elements that do not naturally occur in that species; or b) additional copies of endogenous genes that are retained in the genome as a result of the editing process.

Importantly, FDA’s guidance documents, including FDA’s genome editing guidance, in general do not establish legally enforceable responsibilities. Instead, the information in its guidance documents regarding which information is potentially shared in the VPM should be viewed as recommendations and not requirements, “unless specific regulatory or statutory requirements are cited”.

FDA encourages developers to reach out with any questions, even when the appropriate regulatory pathway appears clear (i.e., either VPC or VPM). Direct communication with the agency is especially recommended to clarify any uncertainties. In particular, for those considering a VPC, engaging in early discussions with FDA can help define the scope and type of information to be provided. It is now expected that the considerations for genome edited NPVs would be similar to that as for NPVs developed through conventional breeding, with associated data or information needs focused on specific food safety or nutritional concerns. It is now expected that developers would not need to provide the extensive data package typically provided for consultations for transgenic NPVs.

Because the VPM process is a new option for developers of applicable genome edited NPVs to engage with FDA, this document intends to provide information to ASTA members / developers to facilitate navigating this process as experience is gained by both FDA and developers. It also includes information and suggestions for the types of information that can be presented to FDA as part of a VPM, based on the FDA’s guidance document and members’ experience. However, it should be noted that individual developers ultimately will decide if they wish to proceed through the VPC or VPM process with FDA and, if so, the information they share with FDA as part of any of these processes.

3. FDA Guidance Regarding Information Reviewed During VPM

3.1. Justification/Rationale

Developers wishing to elect the VPM path should be aware that FDA will expect a strong justification and rationale for use of the VPM path. The guidance states that when genome editing is used to make any of the modifications described in Section G.a. of the 2024 FDA Guidance, a VPC rather than a VPM is the recommended regulatory pathway. A strong justification for using the VPM path could address that edits made or targeted are not expected to result in any of the modifications identified in the guidance, and/or that the modifications are not likely to raise food safety questions or regulatory considerations; a developer may also review this information with FDA at the VPM. Developers should consider reviewing the information, descriptions, and examples provided in the guidance prior to initiating the VPM process.

The rationale for pursuing a VPM and not a VPC may also include other information relevant to FDA based on the agency's 1992 Statement of Policy (see Section 1.2).

3.2 VPM Scope

Developers should clearly define the intended uses of the product(s) presented at the VPM, i.e. if intended for human consumption, animal food, or both. Developers should also consider the breadth (scope) of what is discussed at the VPM meeting and efficiently use this meeting and FDA representatives' time, keeping in mind the main objective of a VPM is to inform FDA. For example, if products are marketed as multiple varieties or lines, and the same or similar characteristics are expected in additional or future lines, or even other crops, the developer should define the scope of the VPM accordingly. In other words, it may be useful to inform FDA about both the current and anticipated future products that share the same or similar characteristics. During the VPM, developers are encouraged to clearly articulate expectations regarding how the product(s) will be reflected in FDA's public website posting (described in 4.6). Being explicit about the type of input or clarification desired can help ensure that FDA's website posting aligns with the developer's intent.

3.3. Additional information

The following outline and associated text is based on members' experience and provides a framework for organizing the key elements that developers may want to address during a VPM with FDA. Developers typically present these elements in a PowerPoint format and are intended to inform the agency.

Importantly, to date developers have not been requested or required to generate new product-specific data to support their rationale. When applicable, developers may use a combination of scientific literature, hypothetical reasoning, comparative examples, historical precedent, and publicly available data.

1. Crop(s) and product(s) description information, including whether there is a hypothesis for changes relevant to human/animal safety

2. Development and breeding/selection practices (e.g. methodology to remove “foreign” DNA used during the editing process).
3. Modification(s) safety impact hypotheses:
 - a. Are there novel or harmful food/feed safety elements of the intended genetic variation(s) (protein, metabolism)?
 - i. Is there a hypothesis of the creation of novel compounds?
 - ii. Is there a hypothesis of an increase in known allergens/toxins/antinutrients?
 - iii. Is there a hypothesis of changes in key nutrients?

4. Practical Aspects of the VPM Process

It is important to note that as FDA, stakeholders, and developers gain more familiarity with this approach, the process and associated expectations may evolve. Developers should consider that this process is relatively flexible and consult FDA’s website or ASTA for the most up-to-date information.

4.1. Initiating the Process

The VPM process begins when a developer contacts FDA to request a VPM. Inquiries should be directed to the FDA via the designated email address: PlantBiotech@fda.hhs.gov. This initial contact should include a brief description of the product(s) and the developer’s intent to engage in a VPM.

4.2. FDA Assignment of Lead Contact

Upon receiving the request, FDA will assign a lead contact. This individual will serve as the primary liaison and will coordinate all necessary communications and meetings. The lead contact may initiate scheduling of preliminary calls to scope the VPM and determine the appropriate path forward.

4.3. Developer-FDA Interaction: Scoping Meeting and VPM

Developers should anticipate a series of interactions with FDA, likely including a virtual scoping meeting prior to the VPM. These preliminary discussions are designed to clarify the scope of the VPM and to ensure that both parties are aligned on expectations. While a scoping meeting does not always occur, they are typically conducted for unfamiliar crops, traits that may be relevant from a food/feed safety perspective, or if the developer is unfamiliar with the VPM process. In other cases, FDA may determine that a scoping meeting is unnecessary. This determination is made on a case-by-case basis, and the process remains fluid and adaptable.

FDA will likely request the developer’s presentation in advance of the scoping meeting to allow for internal review. It is essential that any Confidential Business Information (CBI) be removed from all materials sent, as FDA does not currently have a secure mechanism for receiving CBI in this context.

4.4. Expectations for Scoping Meetings

In preparation for the scoping meeting, developers may share a near-final version of their presentation and rationale for pursuing the VPM with FDA. During the meeting, FDA may provide verbal feedback and pose questions, which are expected to be addressed during the actual VPM. For this scoping meeting FDA will invite a small group of relevant personnel, tailored to the product's characteristics and/or regulatory considerations.

Following the scoping meeting, FDA will propose potential dates for the VPM and identify the internal FDA divisions that will participate. Once internal coordination is complete, FDA will send a meeting invitation to the developer.

Participation Expectations for Voluntary Premarket Meeting

The composition of FDA participants in the formal VPM will vary depending on the nature of the product(s) and will likely have more participants than the scoping meeting. In addition to staff from the Human Foods Program (formerly CFSAN), the VPM may include representatives from the Center for Veterinary Medicine (CVM) or other relevant offices with expertise pertinent to the product's characteristics. The VPM is typically scheduled for 90 minutes. During this time, similar to the scoping meeting, FDA may ask verbal questions related to the developer's presentation and rationale for pursuing a VPM rather than a consultation. Developers would typically respond to these questions in real time and to clarify any points raised by FDA in the meeting. While the meeting is structured, it is intended to be a collaborative and informative discussion and it is not a formal regulatory review. Developers are encouraged to ensure that their presentation is clear, concise, and focused on the scientific and regulatory aspects most relevant to FDA's FFDCa authority.

4.5. Timeline

If a scoping meeting is necessary, developers should anticipate that scheduling this initial meeting with FDA will generally take one to two weeks from the time of the initial request. Following the scoping meeting, developers should expect an additional two weeks to one month for FDA to schedule the formal VPM. After the VPM has taken place, early applicants have observed that it may take approximately three to six months for their product to be posted on FDA's website, which marks the formal conclusion of the VPM process. This timeframe may be longer for early VPMs as the agency continues to refine and adapt the process. It is important to recognize that timelines are inherently fluid and may shift depending on FDA's workload and the complexity of the product presented to FDA.

4.6. Conclusion of the VPM Process

At the conclusion of the VPM, FDA writes an internal memo to document that the VPM was conducted. The general expectation is that developers automatically receive a copy of this memo from FDA. If the memo is not automatically received from FDA after the VPM has concluded, developers may ask for a copy of this memo if they wish. Developers should be aware that they will not receive any

other formal acknowledgment from FDA confirming that the VPM process has been conducted. However, FDA may reach out to clarify or inform the language that will be in the public posting on the agency's website if this was not discussed during the VPM ([Premarket Meetings Regarding Food from Genome Edited Plants](#)). The public posting on the FDA's website serves as the final step in the VPM process and should be considered the official conclusion of the interaction.

Importantly, it is possible for a developer to complete the VPM process and receive feedback from FDA indicating that a VPC is recommended. This recommendation may be based on the nature of the product(s) and the issues discussed during the VPM. In such case, the developer could either decide to proceed with a VPC or decide that they will not further pursue this voluntary interaction with FDA.

5. Relevant supporting references (previous ASTA documents, select relevant publications)

- ASTA Guide: Evaluation of Genome Edited Plants (2019)
<https://www.betterseed.org/wp-content/uploads/ASTA-Guide-Char-Genome-Edited-Plants.pdf>
- [ASTA Best Practices](#): Seed Industry Information Sharing for Products of Gene Editing
- [Lemke et al \(2022\)](#) Assuring the Food Safety of Crops Developed through Breeding
- Kaiser et al (2020) [The role of conventional plant breeding in ensuring safe levels of naturally occurring toxins in food crops - ScienceDirect](#)
- [Slewinski and Turner-Hissong \(2025\)](#) Beautiful and delicious mutants: The origins, fates, and benefits of molecular sequence variation in plant evolution and breeding
- Food Standards Australia New Zealand (2025) Supporting document 1, Safety assessment: full technical report. P1055 – Definitions for gene technology and new breeding techniques. [Link](#)
- Health Canada (2022) Scientific opinion on the regulation of gene edited plant products within the context of Division 28 of the Food and Drug Regulations (Novel Foods) [Link](#)