

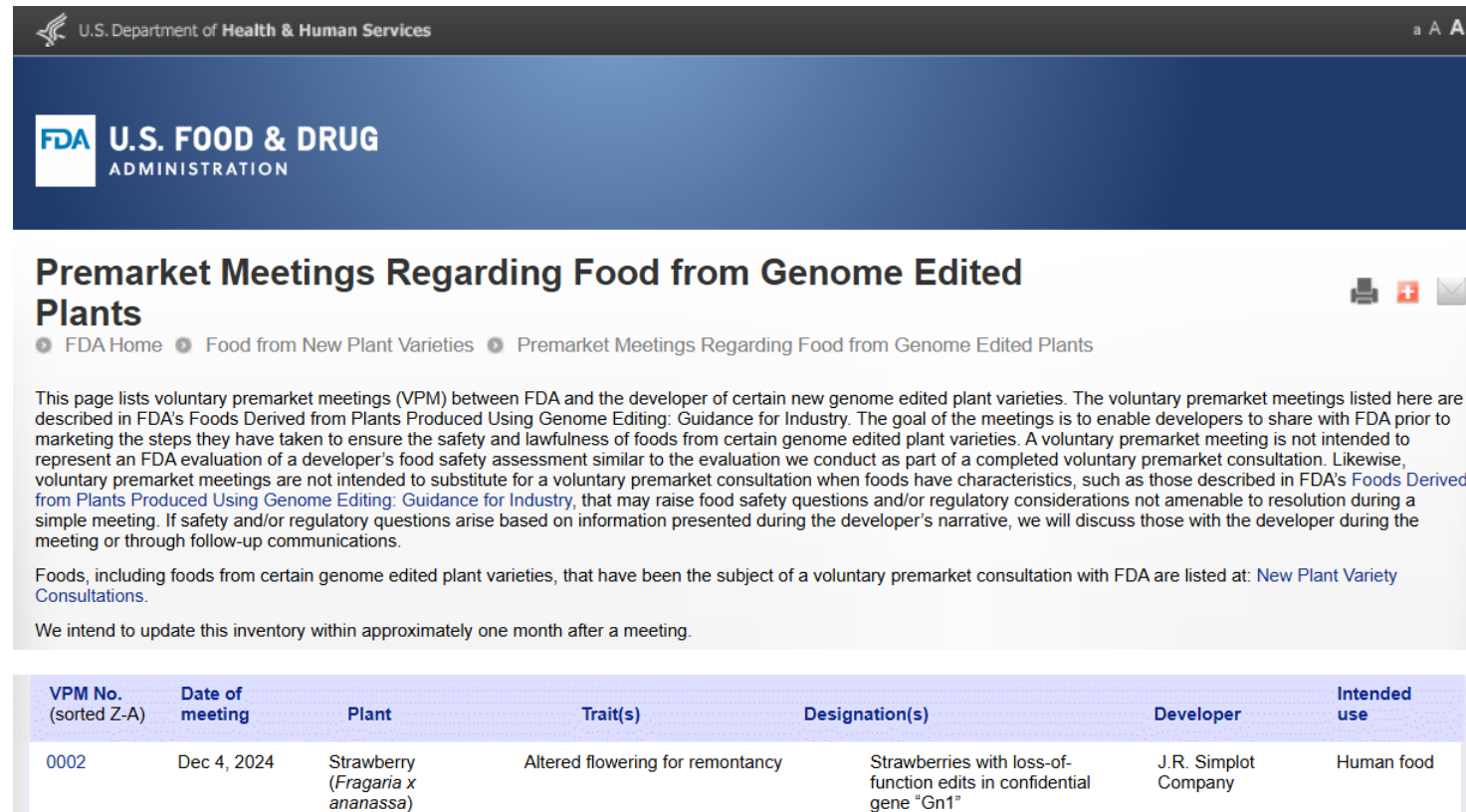


Voluntary Premarket Meeting (VPM) – Simplot Plant Science’s Genome Edited Strawberries with Altered Flowering for Remontancy

- Conducted pre-VPM meeting (10/25/24) with Simplot to ensure that the new, genome edited variety would be appropriate for a VPM, in accordance with FDA’s 2024 Genome Editing Guidance. VPM is not recommended if any of the following apply:
 - Creation of significant homology to a known allergen or a toxin
 - A non-negligible increase in levels of potentially harmful components, e.g., toxicants, anti-nutrients, in the plant
 - A non-negligible change in the nutritional value of the food
 - A change to how the plant, or human or animal food derived from the plant, is used
 - Introduction of either:
 - » New genes and/or genetic elements that do not naturally occur in that species; or
 - » Additional copies of endogenous genes that are retained in the genome once genome editing is complete.
- VPM (virtual; 1 hour) conducted on 12/04/24, attended by Simplot and FDA staff from HFP Innovative Foods (IFS) and CVM Division of Animal Food Ingredients (DAFI)
 - background: Simplot Plant Sciences, strawberry usage and biology
 - trait and mechanism of action
 - development
 - selection
 - food safety: molecular characterization, potential allergen and toxin homology, composition

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- Drafting of internal VPM summary memo; record of completed VPM added to inventory on public website



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Premarket Meetings Regarding Food from Genome Edited Plants

FDA Home • Food from New Plant Varieties • Premarket Meetings Regarding Food from Genome Edited Plants

This page lists voluntary premarket meetings (VPM) between FDA and the developer of certain new genome edited plant varieties. The voluntary premarket meetings listed here are described in FDA's [Foods Derived from Plants Produced Using Genome Editing: Guidance for Industry](#). The goal of the meetings is to enable developers to share with FDA prior to marketing the steps they have taken to ensure the safety and lawfulness of foods from certain genome edited plant varieties. A voluntary premarket meeting is not intended to represent an FDA evaluation of a developer's food safety assessment similar to the evaluation we conduct as part of a completed voluntary premarket consultation. Likewise, voluntary premarket meetings are not intended to substitute for a voluntary premarket consultation when foods have characteristics, such as those described in FDA's [Foods Derived from Plants Produced Using Genome Editing: Guidance for Industry](#), that may raise food safety questions and/or regulatory considerations not amenable to resolution during a simple meeting. If safety and/or regulatory questions arise based on information presented during the developer's narrative, we will discuss those with the developer during the meeting or through follow-up communications.

Foods, including foods from certain genome edited plant varieties, that have been the subject of a voluntary premarket consultation with FDA are listed at: [New Plant Variety Consultations](#).

We intend to update this inventory within approximately one month after a meeting.

VPM No. (sorted Z-A)	Date of meeting	Plant	Trait(s)	Designation(s)	Developer	Intended use
0002	Dec 4, 2024	Strawberry (<i>Fragaria x ananassa</i>)	Altered flowering for remontancy	Strawberries with loss-of-function edits in confidential gene "Gn1"	J.R. Simplot Company	Human food