

# **FDA Response: Canker- & HLB- Resistant Citrus**

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# Canker- & HLB- resistant Citrus – FDA Response



- **FDA’s role under the Federal Food, Drug, and Cosmetic Act (FD&C Act)**
  - The regulatory status of food is based on its objective characteristics.
    - This applies regardless of the development method used (genome editing, genetic engineering, or traditional breeding).
- **In this case, the objective characteristics of the orange fruit would be needed to ensure compliance with the FD&C Act.**
- **We encourage early engagement during research & development**
  - Helps focus safety assessment efforts to make them most efficient.
  - Can make regulatory path more predictable.



- **Canker- & HLB- resistance traits are PIPs (EPA's jurisdiction).**
  - FDA would focus on safety elements of the food other than those of the PIP
- **Genetic and Molecular Characteristics**
  - Description of the genetic change and how it was obtained.
  - Does food contain genetic elements that would not be PIPs?
  - Demonstrating genetic stability can help provide assurance that the safety assessment performed on an early generation will be durable across generations
    - We recognize there may be some need for flexibility when dealing with trees where long generation times are involved.



- **Have there been unintended changes that would be important to food safety?**
  - Often considered through compositional analysis but could also be addressed in other means
    - What analyses plant breeders typically perform to ensure safety of food from new varieties of this species.



# Contact information

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