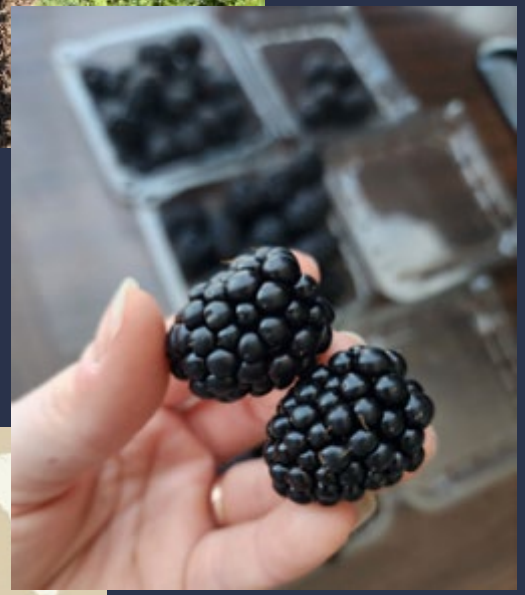
pairwise®

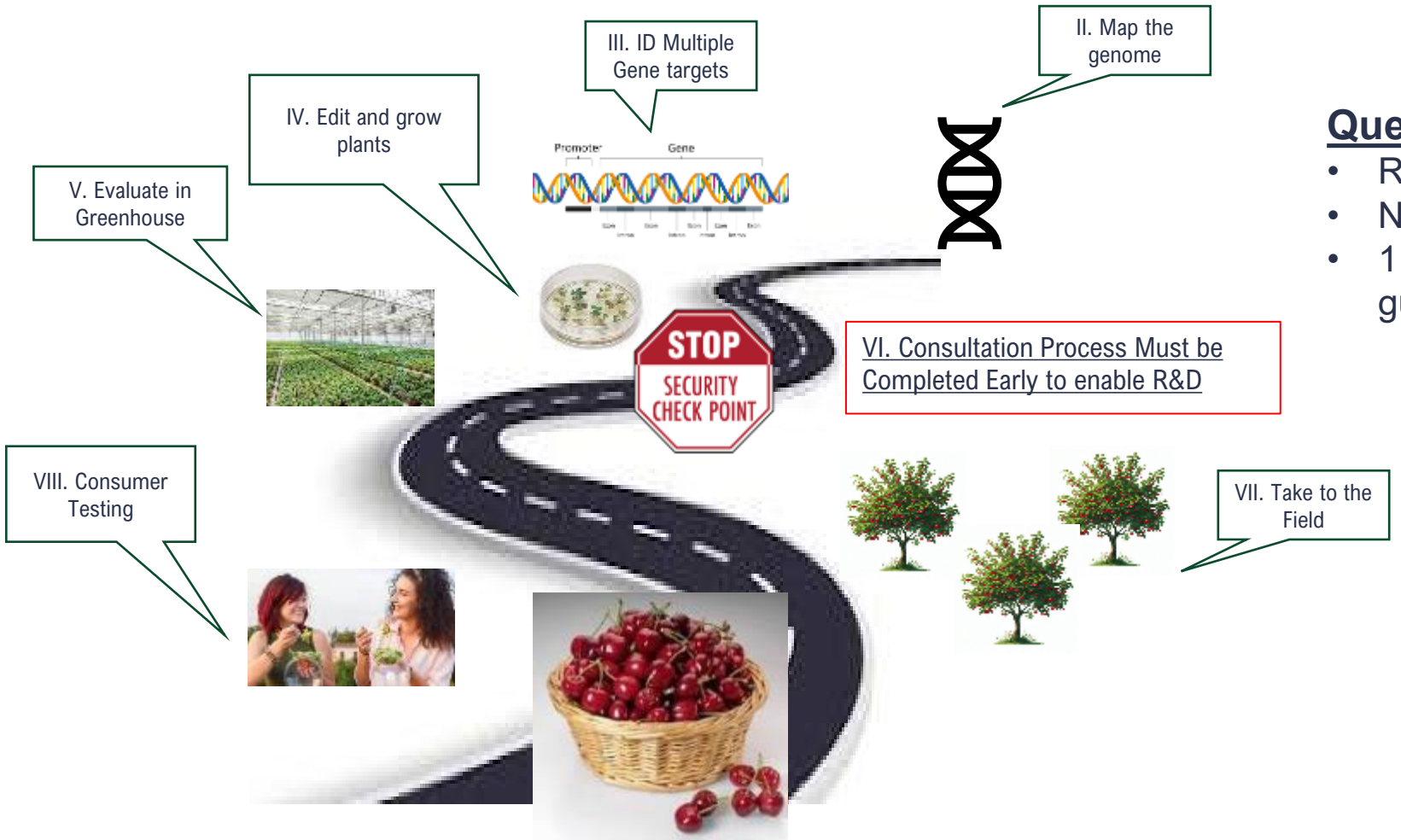
Go To Market Experience: Regulatory

Overview: Genome Editing Regulatory Experience

- 33 positive determinations to date that these products are equivalent to conventionally bred plants and not GMO
- Spanning:
  - 2 crops
  - 6 countries
  - 7 regulatory agencies
  - 20 gene targets
- Typical data requirements:
  - Plant, edit, lack of transgene
- Determination:
  - Equivalent to conventional
- Time to determination:
  - ~60 days (10 hrs. – 120 days)



Korea Discussion: More Complicated Approach



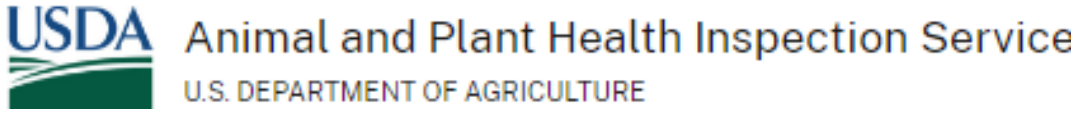
Questions

- Reference genome?
- Number of mismatches
- 1 edit/1 gene target/1 guide then iterate?

FDA: First through New Process

- Released new Guidance: Guidance for Industry: Foods Derived from Plants Produced Using Genome Editing (February 2024) (fda.gov)
- Pre-market meeting: presentation only; no submission
- Ground rules
  - Conclusion implications and options to withdraw
  - Lack of portal for sharing of materials
  - Website posting
  - Internal memo
- Time from initial meeting request to posting on site: ~5 months
  - ***Compared to recent Health Canada posting: 2 weeks***

USDA: Improving, but lags behind other systems



- Exemptions are processed efficiently (60 days), but have limited use
- Regulatory Status Reviews (RSRs)
  - Continue to take a long time…but have gotten a lot more done this year.
  - Step 1 vs Step 2
  - Multiplexing and analysis: molecular stack vs conventional stack vs retransformation
  - Completed one for mustards and one for berries, each with multiple edits
- Positive Trade/Phytosanitary support

Colombia: Building toward a model system

Dirección Técnica de Semillas
Subgerencia de Protección Vegetal
Instituto Colombiano Agropecuario – ICA
Oficinas Nacionales
Dirección: Avenida Carrera 20 # 83-20, Edificio NeoPoint 83 – Piso 8
Teléfono: 6017944492
www.ica.gov.co

- No in country company registration required as prerequisite to submit
- Market Access: **First export of blackberries to the United States in their history**
- Phytosanitary: tissue culture shipments
- 60 days to determination
- Multiple plasmids
- Species level
- Inclusion of other approvals

Mexico: Positive Engagement with Broader Stakeholders

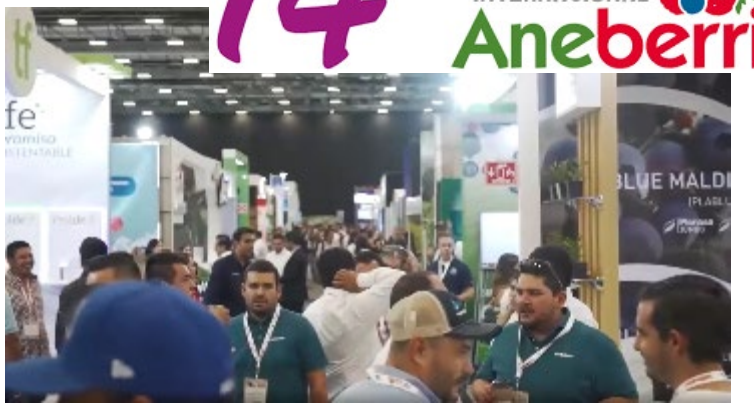
Background

- Annual meeting in Guadalajara - 2,200 people attended this year
- Nursery, Growers, Packer-shippers, retailers, service providers

Pairwise presented to Aneberries' Board

- Partnered with Simplot and PSI
- Current Minister of Agriculture and Regulator present
- Very high business interest
- Board voted to support the technology

Continued Conversations and Activities planned into 2025



Introducing a New Variety of Blackberry

A primocane fruiting variety with excellent taste and proven PSI base genetics

A **New, Primocane Fruiting Blackberry**

Flexibility: Very flexible cultivar that can be easily manipulated for year-round production in Mexico/Latin America

Floricane Crop: High yielding and fast time to fruiting

Production: 3 years of commercial production in California and Mexico with excellent yield and fruit quality

Specs

- **Appearance**: Good for 7-day hold
- **Firmness:** Good firmness in storage
- **Color:** Good deep color – low red drupelet reversion
- **Flavor:**
  - Great aromatics
  - 10% SS or more
  - 1% acidity
- **Size:** >7 g
- **Storage:** Store adequately for 14 days

The Pairwise Edited Blackberry Plants For Compact and Thornless

Thorny Blackberry

Edited Thornless Blackberry

Simplot's Genome Edited Strawberry Extends Fruiting Season

J.R. Simplot Company

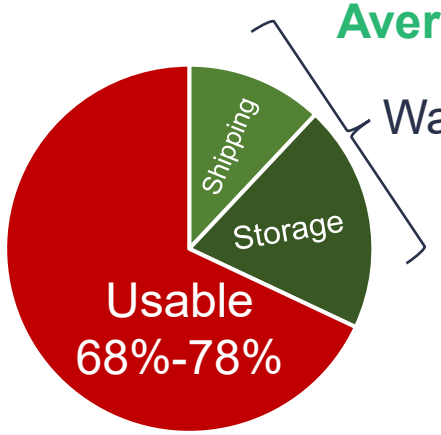
- ❑ **Family-owned**
- ❑ **International**
- ❑ **Food and Agriculture**

- 15,000 employees
- Production in 7 countries
- Exports to >60 countries

Simplot

- ❑ **Simplot used a strawberry variety with**:
  - Good flavor, color, and aroma
  - ***Long*** shelf life – approximately 15 days
  - Shipping waste can be reduced: ~2%
  - Storage waste can be reduced: ~ 5%
  - A short fruit-bearing window (typically 1 month)
  - Limited production from Dec to Feb

Average Strawberry



Waste (22% - 32%)

- ❑ **Genome editing provides a solution for fruiting duration**:
  - A natural mutation in cultivated and wild-strawberries causes a short season fruiting plant to become a long season fruiting plant
  - Allows strawberry production year-round
  - Commercialize in the United States in 2025

Edited Strawberry

Waste (≈ 7%)

Steady pace of submissions throughout Latin America will continue through 2025 for multiple traits

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THANK YOU