Practical Trade Considerations of Arctic Apples

Session 3: International Regulations at a Glance

September 19, 2023
Important Notice

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More Apples in More Places
Arctic® - >25 Years in the Making

1996-2002
- Founded in Summerland, British Columbia; One of the first companies to pursue the use of biotechnology to deliver product innovations to the tree fruit industry
- Accessed IP from CSIRO
- Science completed in laboratory
- Obtained right to grow Arctic® plantlets in greenhouse/screen house, field settings
- Outreached to apple & biotech industries

2003-2005
- Field trials planted to test agronomic characteristics:
  - Washington State 2003
  - New York State 2005
- Submitted Arctic® Golden & Arctic® Granny petitions to:
  - USDA – 2010
  - CFIA - 2011

2004
- Arctic® apple science successfully proven

2007
- Consumer research initiated

2010-2011
- Patent work completed

2013
- First Arctic® apple orchard planted

2015
- Acquired by Intrexon Corporation
- Arctic® Golden & Arctic® Granny approved in USA & Canada by:
  - USDA
  - FDA
  - CFIA
  - Health Canada

2016
- 4 SKUs including Arctic® Granny, available in select U.S. stores
- Arctic® Fuji approved by USDA APHIS

2018
- First harvest of commercial Arctic orchard
- Arctic® Fuji approved in USA and Canada by:
  - USDA
  - FDA
  - CFIA
  - Health Canada

2019
- Arctic® products introduced to foodservice industry
- Arctic™ Gala, Arctic™ Honey approved for commercial production.

2020
- 4 SKUs including Arctic® Granny, available in select U.S. stores

2021
- Arctic® Fuji approved in USA and Canada by:
  - USDA
  - FDA
  - CFIA
  - Health Canada

2022
- Arctic® products introduced to foodservice industry

2023
- Arctic® Pink is approved for commercial production.
- Endless Orchard™ Hard Cider, made from Arctic apples introduced in November.

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OSF – Vertically Integrated

OSF is a vertically integrated organization, managing all aspects of Arctic apples from the tree to the end-user.
OSF: Where Technology and Innovation Meet

What Vertical Integration Means to OSF

OSF’s R&D team developed the science behind proprietary Arctic apples.

OSF grows 1.8 million Arctic apple trees in 1,250 acres of the company’s orchards in Washington state.

Arctic apples are also used to produce OSF’s cider brand Endless Orchard™.

Arctic apple slices are sold in non-commercial and commercial food service industry.

Retailers use Arctic apples for meal kits or deli dishes.

In July 2023, OSF opened a 110,000 square foot apple processing facility in Moses Lake, Washington. The facility stores, sorts, and processes Arctic apples exclusively from OSF orchards.
The Science Behind Arctic® Apples

• Via RNAi technology, Arctic® apples have reduced levels of polyphenol oxidase (PPO)
  • PPO initiates browning in conventional counterparts
• PPO reduction can be applied to existing apple varieties & other produce
• Same composition & nutrition as conventional counterparts
Marketing and Communication Path

Building trust long before commercial availability

- **2007**: Introduce OSF & Arctic® brand to apple industry.
- **2012**: Broaden Comms Reach. Biotech, produce, NGOs, regulatory, influencers.
- **2015**: Educate & Assure. Apple industry about Arctic® and OSF plans.
- **2019**: Educate & Assure. All stakeholders.
- **2020**: Market to conventional retailers & consumers.
- **2021**: Market to Ingredient/Processors, school food programs, DOD, C-Stores, Retailers.

**C.R.** = Consumer Research Completed
Arctic Apples’ Value Propositions are Unmatched

- 28-day shelf life: longer shelf life than other pre-sliced, packaged apples
- Superior orchard-fresh flavor without the chemical aftertaste
  - Highest quality fruit in the slicing market due to specialized growing practices
  - Consistent and notable quality due to OSF’s ability to control all aspects of the process
- Less food waste throughout the supply chain
- Convenience. Pre-sliced apples save consumers time and operators appreciate the labor savings
Our Orchards ...
Processing ...
Packaging

2 oz.
**Perfect for your meal kits!**

5 oz.
**On-the-go size!**

20 oz. & 40 oz.
**Perfect for back room or value-added programs.**
Regulatory Approvals

Arctic® Apples Have Passed All Regulatory Approvals

Extensive field trials, over 15 years of data and studies, and multiple regulatory reviews have deemed Arctic® apples to be as safe and nutritious as conventional apple varieties.
## Regulatory Timelines – USA

<table>
<thead>
<tr>
<th>Agency</th>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>USDA</td>
<td>May 28, 2010</td>
<td>Submit <strong>GD743 and GS784 (Arctic Golden and Granny)</strong> petition document</td>
</tr>
<tr>
<td></td>
<td>April 11, 2011</td>
<td>Revised petition based on Technical Completeness additional data requests</td>
</tr>
<tr>
<td></td>
<td>Oct. 12, 2011</td>
<td>Revised petition based on Technical Completeness additional data requests</td>
</tr>
<tr>
<td></td>
<td>Feb 23, 2012</td>
<td>Revised petition based on Technical Completeness additional data requests</td>
</tr>
<tr>
<td></td>
<td>Feb 24, 2012</td>
<td>Technical Completeness Letter from USDA-APHIS-BRS</td>
</tr>
<tr>
<td></td>
<td>July 9, 2012</td>
<td>60-day Public Comment Period Started, extended 30 days, ran until Oct/2012</td>
</tr>
<tr>
<td></td>
<td>May 29, 2014</td>
<td>After 1,461 days, USDA issued their Determination of Non-Regulated Status of GD743 and GS784, however, this was not posted Feb 15, 2015</td>
</tr>
<tr>
<td></td>
<td>Dec. 23, 2015</td>
<td>Submitted <strong>NF872, Arctic Fuji</strong>, Petition document via Extension process</td>
</tr>
<tr>
<td></td>
<td>Sep 23, 2016</td>
<td>Determination of Non-Regulated Status for NF872 granted</td>
</tr>
<tr>
<td></td>
<td>June 1, 2019</td>
<td>Submitted <strong>PG451, Arctic Gala</strong>, Petition document via Extension process</td>
</tr>
<tr>
<td></td>
<td>Sep 22, 2021</td>
<td>Determination of Non-Regulated Status for NF872 granted</td>
</tr>
<tr>
<td></td>
<td>April 14, 2021</td>
<td>Submitted <strong>HCR835, Arctic Honey</strong>, under SECURE policy, exemption granted May 21, 2021</td>
</tr>
<tr>
<td></td>
<td>Feb 22, 2023</td>
<td>Submitted <strong>CPI1013, Arctic Pink</strong>, under SECURE policy, exemption granted April 20, 2023</td>
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<tr>
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<tr>
<td>FDA</td>
<td>May 30, 2011</td>
<td>Submit GD743 and GS784 (Arctic Golden and Granny) FDA Consultation Document</td>
</tr>
<tr>
<td></td>
<td>March 20, 2015</td>
<td>After a service period of 1,390- days, FDA issued a consultation response letter saying they had no more questions</td>
</tr>
<tr>
<td></td>
<td>March 30, 2016</td>
<td>Submitted NF872, Arctic Fuji, FDA Consultation Document</td>
</tr>
<tr>
<td></td>
<td>May 25, 2019</td>
<td>After 1,161 days, FDA issued a Consultation Response letter saying they have no more questions</td>
</tr>
<tr>
<td></td>
<td>April 29, 2022</td>
<td>Submitted PG451, Arctic Gala, FDA Consultation Document</td>
</tr>
<tr>
<td></td>
<td>To date</td>
<td>No response</td>
</tr>
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## Regulatory Timelines – Canada

<table>
<thead>
<tr>
<th>Agency</th>
<th>Date</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>CFIA PBO/AFD</td>
<td>Dec. 7, 2011</td>
<td>Submitted [GD743 and GS784 (Arctic Golden and Granny)] Unconfined Environmental Release and Animal Feed approval application</td>
</tr>
<tr>
<td></td>
<td>Mar. 20, 2015</td>
<td>CFIA No objection letter for Environmental Release and use in animal feed <em>(867 days)</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>* All subsequent retransformations with same species and vector don’t need approval</td>
</tr>
<tr>
<td></td>
<td></td>
<td>* New policy extends this to re-transformations and familiar-trait don’t need approval</td>
</tr>
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# Regulatory Timelines – Canada

<table>
<thead>
<tr>
<th>Agency</th>
<th>Date</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>Health Canada</td>
<td>Dec 7, 2011</td>
<td>Submit GD743 and GS784 (Arctic Golden and Granny) HC Novel Foods Application</td>
</tr>
<tr>
<td></td>
<td>March 19, 2014</td>
<td>HC Deficiency Letter</td>
</tr>
<tr>
<td></td>
<td>Oct. 15 2014</td>
<td>HC Deficiency Letter</td>
</tr>
<tr>
<td></td>
<td>March 20, 2015</td>
<td>Health Canada approval given after 707 days. Note Canada’s no-split-decision rule means all agencies grant their approval at the same time</td>
</tr>
<tr>
<td></td>
<td>May 6, 2016</td>
<td>Submitted NF872, Arctic Fuji, to HC for approval</td>
</tr>
<tr>
<td></td>
<td>Jan. 30, 2018</td>
<td>Health Canada granted approval for NF872, Arctic Fuji, after ~ 605 days.</td>
</tr>
<tr>
<td></td>
<td>Aug. 8, 2023</td>
<td>Pre-submission consultation completed for PG451, Arctic Gala. Given familiarity with the trait, approval should be granted within the mandate 120-day service period.</td>
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Regulatory Timelines – Mexico and Argentina

• Mexico
  • Submitted Application for food approval to COFEPRIS in January 2017
  • Slow movement and then changes in government policy made us decide to withdraw the application in January 2023 after little progress had been made.

• Argentina
  • Shipped GD743 and GS784 to Argentina to begin quarantine process in May 1, 2018
  • Gained virus free- quarantine approval October 5, 2021
  • Begin deregulation process in Q4/2023
Closing Comments

• Agency appreciate and developer benefit from pre-submission consultations. They are not always that quick or easy to organize.

• We never used any regulatory consultants, and the agencies preferred it this way.

• Next Generation Sequencing (NGS) has made the molecular characterization part of the data set much easier to deliver.

• Governments policies associated with Bioengineering are all headed the right direction but the lack of multi-agency by-in and slow pace is holding back product development.

• Weak transparency and poor communication coming from agencies leaves developers not knowing where things are at. This creates uncertainty, suppresses abilities to find funding and builds risk.

• New traits that agencies haven’t seen before continue to take a long time to gain approval. We should be better at this because this is where developers need to go to create products to combat climate change, improved sustainability and reduced waste.
Remember ...
still more Certifications are Required!

- SQF Certified
- BRC – GFSI Certified
- Global G.A.P. Certified
- BRC Certified
- HACCP Compliant
About Okanagan Specialty Fruits and Arctic® Apples

Okanagan Specialty Fruits (OSF) is a vertically integrated company specializing in the development, growing, processing and marketing of novel tree fruit varieties developed through bioengineering and other molecular tools. Based in Summerland, British Columbia, Canada, OSF was founded in 1996 and acquired by an affiliate of Third Security, LLC in 2020. OSF’s flagship product is its non-browning Arctic apples. Arctic apples provide a sustainable solution to reduce food waste and improve apple consumption. All Arctic apples are grown in Washington State.

For consumer information, visit www.arcticapples.com
for company information and partnership opportunities, visit www.osfruits.com.