

# 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

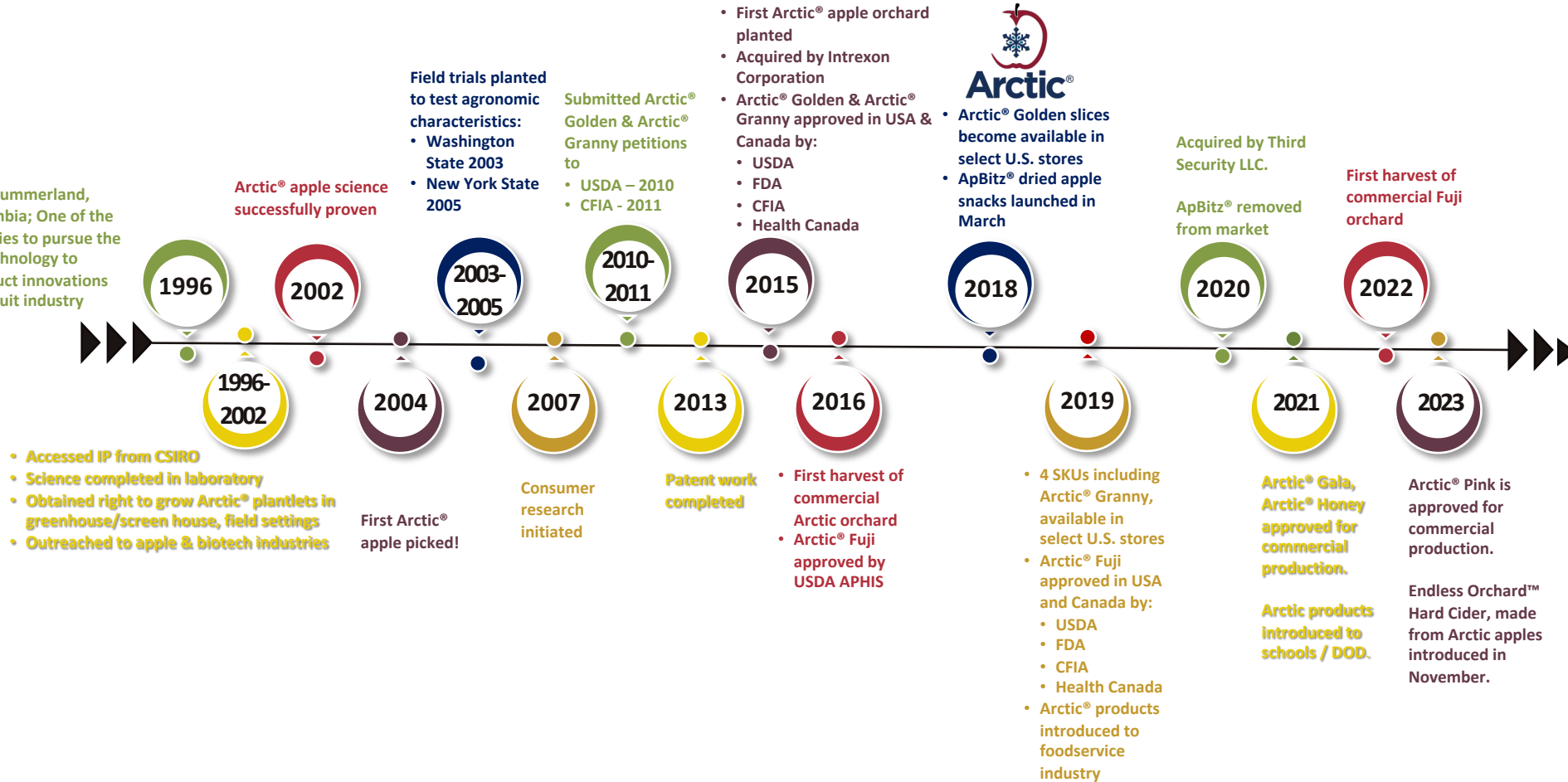




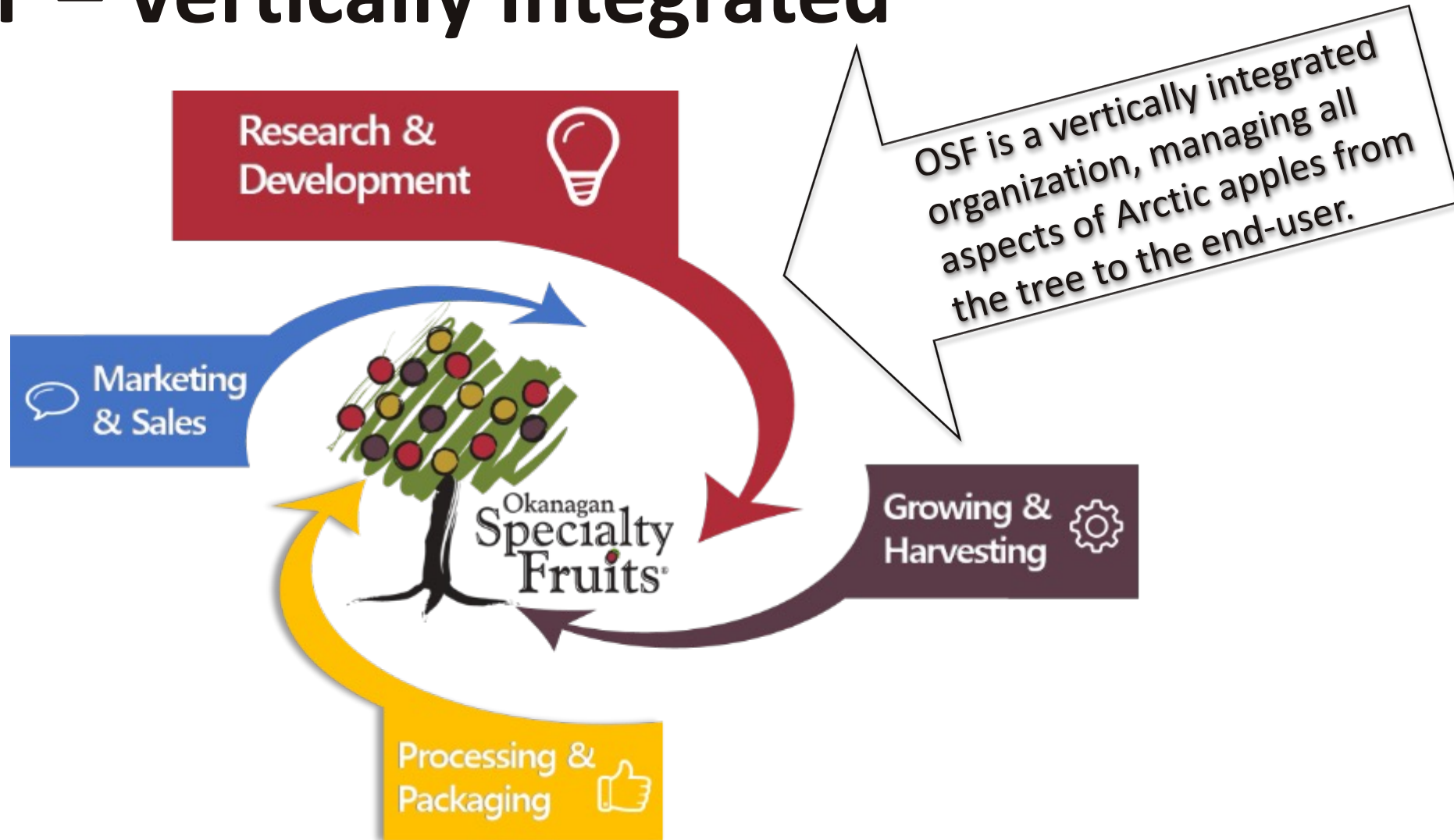
# Arctic® - >25 Years in the Making



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



# OSF – Vertically Integrated



# 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



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.

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

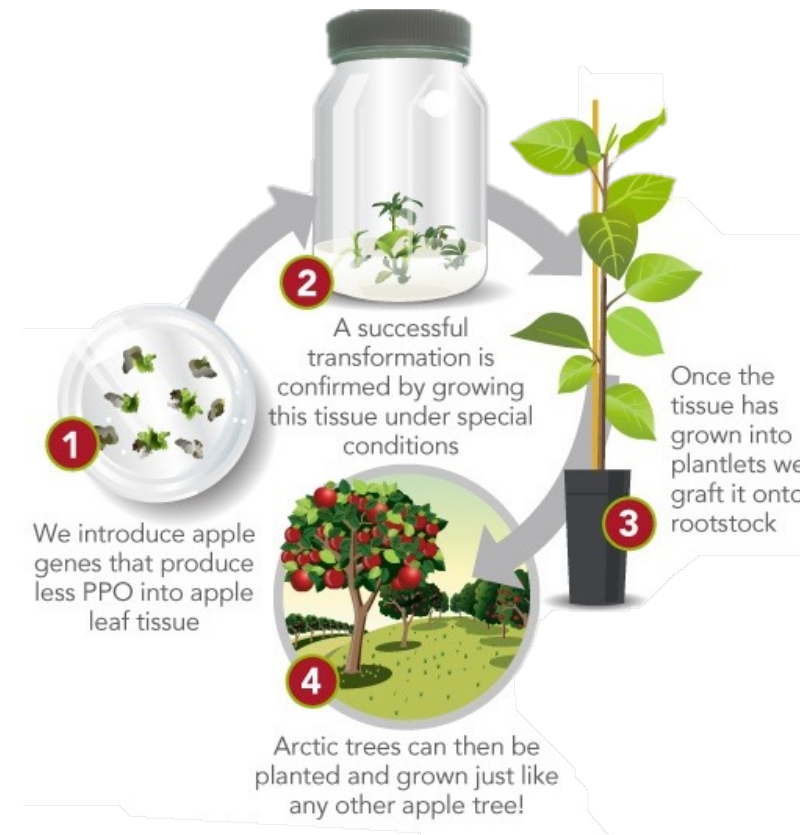


Arctic apple slices are sold in non-commercial and commercial food service industry.

Retailers use Arctic apples for meal kits or deli dishes.

# The Science Behind Arctic<sup>®</sup> Apples

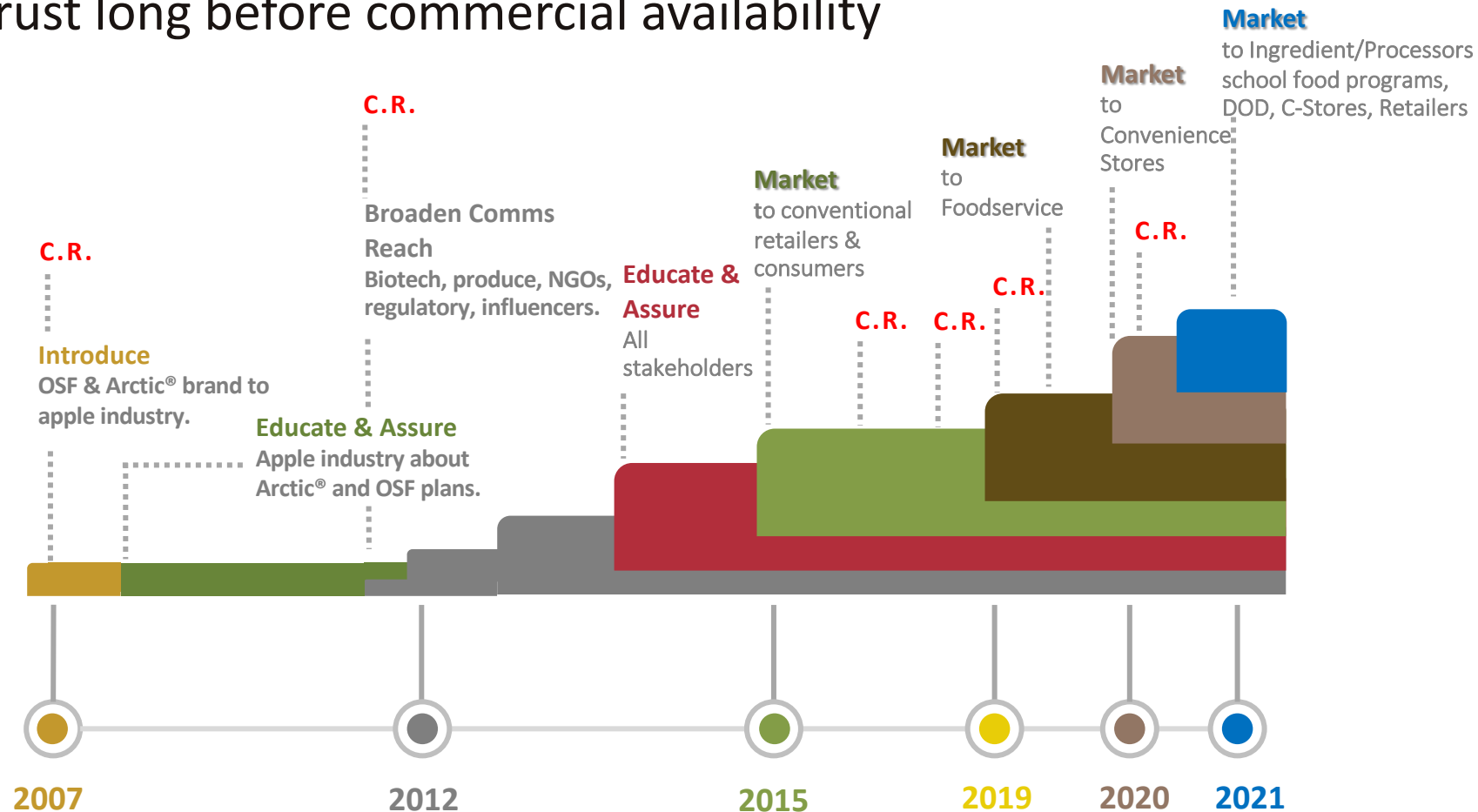
- Via RNAi technology, Arctic<sup>®</sup> apples have reduced levels of polyphenol oxidase (PPO)
  - PPO initiates browning in conventional counterparts
- PPO reduction can be applied to existing apple varieties & other produce
- Same composition & nutrition as conventional counterparts





# Marketing and Communication Path

Building trust long before commercial availability



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

## Market Channels

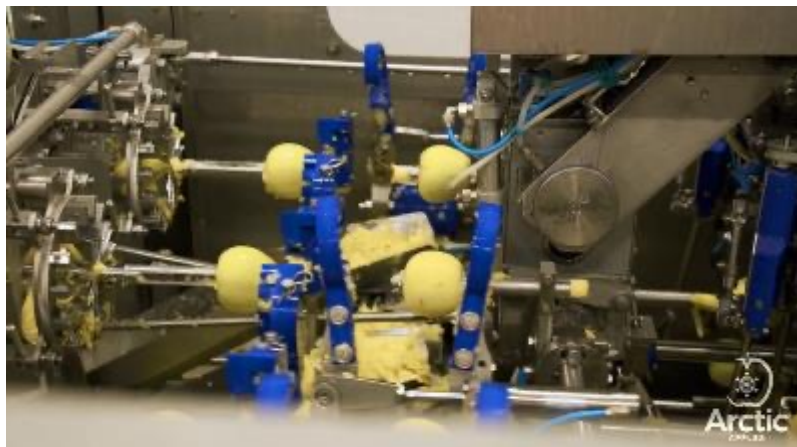


# Our Orchards ...





# Processing ...



alty Fruits. All rights res



# 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.

Conventional  
Apple





# Regulatory Timelines – USA

Agency	Date	Action
USDA	May 28, 2010	Submit GD743 and GS784 (Arctic Golden and Granny) petition document
	April 11, 2011	Revised petition based on Technical Completeness additional data requests
	Oct. 12, 2011	Revised petition based on Technical Completeness additional data reques
	Feb 23, 2012	Revised petition based on Technical Completeness additional data requests
	Feb 24, 2012	Technical Completeness Letter from USDA-APHIS-BRS
	July 9, 2012	60-day Public Comment Period Started, extended 30 days, ran until Oct/2012
	May 29, 2014	After 1,461 days, USDA issued their Determination of Non-Regulated Status of GD743 and GS784, however, this was not posted Feb 15, 2015
	Dec. 23, 2015	Submitted NF872, Arctic Fuji, Petition document via Extension process
	Sep 23, 2016	Determination of Non-Regulated Status for NF872 granted
	June 1, 2019	Submitted PG451, Arctic Gala, Petition document via Extension process
	Sep 22, 2021	Determination of Non-Regulated Status for NF872 granted
	April 14, 2021	Submitted HCR835, Arctic Honey, under SECURE policy, exemption granted May 21, 2021
	Feb 22, 2023	Submitted CPI1013, Arctic Pink, under SECURE policy, exemption granted April 20, 2023



# Regulatory Timelines – USA



Agency	Date	Action
FDA	May 30, 2011	Submit GD743 and GS784 (Arctic Golden and Granny) FDA Consultation Document
	March 20, 2015	After a service period of 1,390- days, FDA issued a consultation response letter saying they had no more questions
	March 30, 2016	Submitted NF872, Arctic Fuji, FDA Consultation Document
	May 25, 2019	After 1,161 days, FDA issued a Consultation Response letter saying they have no more questions
	April 29, 2022	Submitted PG451, Arctic Gala, FDA Consultation Document
	To date	No response





# Regulatory Timelines – Canada

Agency	Date	Action
CFIA PBO/ AFD	Dec. 7, 2011	Submitted GD743 and GS784 (Arctic Golden and Granny) Unconfined Environmental Release and Animal Feed approval application
	Mar. 20, 2015	CFIA No objection letter for Environmental Release and use in animal feed (867 days)
		* All subsequent retransformations with same species and vector don't need approval
		* New policy extends this to re-transformations and familiar-trait don't need approval





# Regulatory Timelines – Canada



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





# 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 buy-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!



**GLOBALG.A.P.**

All orchards Global G.A.P. Certified



BRC – GFSI  
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](http://www.arcticapples.com)

for company information and partnership opportunities, visit

[www.osfruits.com](http://www.osfruits.com).

