FSMA PSR and Sprout Safety: Industry impacts and resource opportunities

Carmen Wakeling
Kaiping Deng
Manny Wong
Robin Taylor

Produce Safety Educator’s Call #51
January 25, 2021
Instructions

• All participants are muted.
• There will be time for questions and discussion at the end of the meeting.
• This session will be recorded and the presentation will be shared via the listserv and on our website after the call.
Agenda

- Introductions
- Sprout Safety and Emerging Issues
- PSR requirements for sprout growers and available resources
- Sprout grower and educator panel discussion
Speaker Introductions

• Carmen Wakeling
  – CEO and Co-owner of Eatmore Sprouts and Greens Ltd, a certified organic farm producing sprouts, greens, and vegetables in British Columbia
  – President of the International Sprout Growers Association

• Kaiping Deng
  – Former co-lead and coordinator of the Sprout Safety Alliance
  – Currently with the FDA CFSAN Laboratory Proficiency and Evaluation team to work on microbial testing method validation
Welcome to the International Sprout Growers Association overview of the sprout industry

Safety and Emerging Issues: An ISGA Perspective

Presented virtually to the Produce Safety Association: By Carmen Wakeling: President ISGA

January 25, 2021
WHO OR WHAT IS THE ISGA? OUR NEW WEBSITE SAYS IT ALL....

WELCOME to the ISGA

Our mission is to promote global collaboration among professional sprout growers and suppliers, in order to promote the health benefits of sprouts, and to work with researchers and government agencies to assure the safe production of sprouted foods.

What brings you here?

We have so many resources, and they’re tailored based upon your needs. So how can we help you? To start, select what role you have in the wonderful world of Sprouts.
ACRONYMS: ALL INDUSTRIES HAVE THEM...HERE IS A SHORT LIST OF O URS RELEVANT FOR TODAY

- ISGA International Sprout Growers Association
- IFSH Institute for Food Safety and Health
- SSA Sprout Safety Alliance
- SSTF Sprout Safety Task Force
- FSMA Food Safety Modernization Act
- PSR Produce Safety Rule
- PSA Produce Safety Alliance
- FDA Food and Drug Administration
- CFIA Canadian Food Inspection Agency
- SFCRSafe Food for Canadians Regulations
Some basic information about ISGA:
Due to the pandemic our numbers were lower in 2020. 2021 is just beginning.

- ISGA has:
- 18 North American Members
- 1 Australia/Oceania members
- 1 South American members
- 3 Asian Members
Other sprout organizations that we are aware of:

- European Sprouted Seed Association (ESSA)
- The Bean Sprout Grower’s Association of Japan
- Sprouts & Microgreens Canada (A subcommittee of “Small Scale Food Processors Association” (SSFPA))
Relationship between ISGA and IFSH

- The ISGA has been a member of IFSH since IFSH’s inception.
- The IFSH team, along with producer representatives, have been very proactive in initiating and implementing many programs.
- We look forward to continuing this work.
- We are always looking for other opportunities to partner on research projects. If any of you have potential opportunities, please keep us in mind.

Relevant to the concept of continuous improvement it is important to understand the support our industry has received from alliances with other organizations.

We have worked closely with IFSH to evolve the Sprout Safety Task Force.

The results of this collaboration have been very important to our industry.
OVERVIEW OF SPROUT INDUSTRY 2020-2021

- More “North American Perspective”
- ISGA has an engaged board
- Due to the pandemic, we are working harder than ever to engage with all growers. As with many organizations, the more members are active and participatory the stronger the association and the work that can be achieved.
- We continue to reach out to sprout producers internationally. We want to participate in knowledge transfer. Both learning from others and sharing our knowledge.
- Unfortunately, we had 2 recalls for E.coli 0103 in 2020
CLEARING THINGS UP: DEFINING SPROUTS AND MICROGREENS

- **To be a sprout or a microgreen.....What is the difference?**
- A sprout is consumed with its roots attached. Sprouts are generally grown in water.
- A microgreen is consumed with its roots removed. Microgreens are generally grown in a substrate.
- Education for all stakeholders is needed.
Why do people love sprouts so?

- Sprouts could be a major part of a local sustainable year-round food source.

- Sprouts are available year-round.

- Sprout producers have come a long way in their knowledge and implementation of food safety.

- Sprouts are amazing because they are grown in controlled conditions in any climate.
Why do people want to eat sprouts and microgreens?

Sprouts and microgreens contribute to a diverse nutritional and flavour profile which can add interest, color and nutrition to every meal.

They can be grown anywhere and provide both vitamins and minerals along with fiber.

Sprouts are delicious and fun to grow and eat.
AN OVERVIEW OF SPROUT RECALLS AND ILLNESSES IN THE USA FROM 1996 TO 2020
USA TOTAL RECALLS: 1996-2020

<table>
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NOTE: 2016* two data points due to seed lot recall.

![Total Outbreaks 1996-2020](chart.png)
USA Sprouts Illnesses 1996-2020

### Sprouts Outbreaks 1996-2020

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**Note:** 2016* two data points due to seed lot recall.
SPROUTS ILLNESSES AND RECALLS TRENDS: 1996-2020

USA: Recalls and Illnesses 1996-2020
OF NOTE........FOR MICROGREEN PRODUCERS......

- I have personal experience with Listeria Monocytogenes and Microgreens......
- It became clear to me in September 2017 and spring of 2018 that the incoming soil mix we were receiving was sometimes contaminated with Listeria Monocytogenes.
- I found LM in several batches of incoming soil mix. Now we have a testing program that includes Listeria Species, Salmonella and STEC. I have found it important that the soil is dampened for at least 48 hours prior to testing. This helps LM come out of Viable but nonculturable (VBNC) state.
- I thought I was alone in this finding, but through our work with Sprouts & Microgreens Canada we discovered that there are others having the same experience.
- We would like to learn more about soil contamination in North America. This will be a project that we are looking for support with. It may be a very collaborative approach including soil producers, regulators and consumers of the products.
- I have lots of data to evaluate and some stories to tell....Right now industry stakeholders have a lot of concern about this issue, and we need help.
What has changed over the years?

Why have we seen reduction in sprout safety issues?
TIMELINES FOR IMPLEMENTATION OF MAJOR EVENTS FOR SPROUTING INDUSTRY

**USA**
- 1999: Draft Code of Practice for the Hygienic Production of Sprouted Seeds
- 2000: Code of Practice for the Hygienic Production of Sprouted Seeds
- 2016: USA: FDA’s guidance on sprout production: Initiated in 1999. Continued to be used till 2016
- 2016: USA: Produce Safety Rule: Initiated 2016. Sprout specific Sub part M

**Canada**
- 2020: ISGA Conventions have been happening for 30 years. 2020 is the first that we have had to cancel due to the Pandemic
- 2020: Sprouts and Microgreens Canada Established
- 2020: ISGA joined IFSH at time of IFSH inception
- 2020: Sprout Safety Task Force established
- 2020: Sprout Safety Alliance Established
- 2020: Curriculum Creation ongoing
- 2020: Audit Checklist developed

**Sprout Industry Production Best Practices**
- 2020: SSA Training initiated
- 2020: SSAudit Standard
- 2020: Implementation of FSMA including Subpart M

**Recommended testing program to be established**

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USA: FDA’s guidance on sprout production: Initiated in **1999**. Continued to be used till **2016**.

USA: Produce Safety Rule: Initiated **2016**. Sprout specific Sub part M

Draft Code of Practice for the Hygienic Production of Sprouted Seeds

Recommended testing program to be established

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Sprout Safety Alliance Established

Sprouts and Microgreens Canada Established

Curriculum Creation...ongoing

Audit Checklist developed

SS Audit Standard

SSA Training initiated

Implementation of FSMA including Subpart M

Sprout Industry Production Best Practices

Timelines of the sprout industry: important progress points: 1996 to 2020
WHAT DOES THIS DATA TELL US?

- What we can see is that since the late 90’s and early 2000’s we are making very good progress in reducing recalls and illnesses associated with sprouts.

- Our programs are working. The biggest challenge is getting the information to all involved parties.

- Improved food safety training for all growers in the USA is making an impact.

- With only one recall for sprouting seed in the last number of years it seems that sprout seed suppliers have improved their practices too.

- Spent Irrigation testing has made a substantial impact.

- We need to continue to have seed suppliers and producers work as partners. Quick communication is important. The faster we can catch issues the sooner we can address them.
E. Coli 0103 and How it Impacted Sprout Producers in 2019 and 2020

The two recent recalls in late 2019 and early 2020 with illnesses associated have been for Clover sprouts contaminated with E. coli 0103.

- E. coli 0103 is not being tested for at this time.

- Our industry needs support to find testing methods to stay ahead of emerging pathogens while being affordable.

- It would be very helpful for us to learn more about emerging pathogens and potential testing options.

- We would really appreciate any support we can get.

- It would be very helpful if the ISGA was kept informed by regulators of situations in real time so we can support our producers and partners more effectively. Recalls are hard, emotional and expensive.
WHAT RESEARCH IS NEEDED?
RESEARCH NEEDS……

- Listeria and other pathogens in growing medium
- How do we edit or remove warning labels from sprouts as a category?
- Continued work to improve epidemiological tracking
- Testing methods for emerging pathogens
- Continue to work on competitive exclusion concepts
- Improving growing methods: Seed treatments, pathogen reduction and innovation in growing equipment
- Complete temperature research
- Nutrition research for sprouts
  - Are there nutritional benefits to the human microbiome through a diet rich in sprouts?
- Education of producers, regulators and consumers about the difference between microgreens and sprouts
HOW DO WE GET ALL PLAYERS PARTICIPATING IN PROACTIVE FORWARD MOVEMENT?

- Grower to grower is a good start.
- Mentoring works. Competition can stand in the way of this.
- Training sessions: Language barriers, time and finances can all be challenges. Understanding the root cause of the resistance is helpful.
- Understanding responsibility associated with food production is essential.
- By helping each other we can build a more robust and transparent food safety system.
- Enforcement has a place if all else fails.
Let’s continue to collaborate to support the health of all humans. By working together, we can tackle much bigger issues than going it alone.

Our industry believes in the health benefits of the food we grow. That’s why we are so committed.

By making sprouts and microgreens the safest they can be we are able to support health. This food can be grown in communities across the planet.

Thank you for your time today.
REFERENCES

Questions?
PSR Requirements for Sprout Growers and Available Resources

Kaiping Deng

PSA Educator Call

1-25-2021
SSA Timeline

- SSA established
- Proposed PSR finalized
- SSA Training
- Curriculum Development
- Training pilot sessions conducted
- Curriculum 1st version finalized
- Curriculum 2nd version finalized
- Online Course finalized
- Draft Sprout Guidance finalized
- Virtual training started
- 2012
- 2013
- 2014
- 2015
- 2016
- 2017
- 2018
- 2019
- 2020
Requirements for Sprout Growers

Key requirements:
• Building and sanitation
• Environmental sampling for *Listeria*
• Beans and seeds inspection
• Seed treatment
• Spent sprout irrigation water sampling
• Recordkeeping
Bin-Grown Bean Sprouts

Mung bean sprouts

Source: FDA Inspector
Tray-Grown Green Sprouts
Rotary Drum-Grown Green Sprouts
Listeria Monitoring Requirements

Each sprout operation must test the growing, harvesting, packing and holding environment for *Listeria* spp. or *L. monocytogenes* to prevent the introduction of hazards into sprouts (§112.144(a))
Listeria Monitoring Requirements (cont.)

• Development and implementation of an environmental monitoring plan for *Listeria*

• Sampling during production

• Minimum acceptable frequency – monthly from food contact and non-food contact surfaces
  • For operations showing control of *Listeria* over time
Methods for *Listeria* Testing

• FDA reference methods:
  https://www.fda.gov/media/94358/download

  Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples
  October 2015, Version 1

• Scientifically valid methods equivalent to the FDA methods in accuracy, precision, and sensitivity- 3 methods were approved for *Listeria* testing
Seed Treatment

• Seed treatment requirement is not new to the sprout industry
• A scientifically valid treatment method
• A written seed treatment SOP –HIGHLY recommended
• Monitoring records for critical parameters in the SOP
Spent Sprout Irrigation Water Testing

• A written sampling plan for testing *E. coli* O157:H7 and *Salmonella*

• Aseptically sampling spent sprout irrigation water (or in-process sprouts) from **every batch of sprouts**

• Holding product unless pathogen results are negative

• Recordkeeping
Water Sampling from Rotary Drum

Single or multiple seed types could start at the same time in a common drum.
Water Sampling from Trays

Rack of connected trays start at the same time and water drips through
Resources

• SSA Training Manual
• SSA website
• SSA Online Course
• FDA Sprout Guidance – 2017 draft
• FDA Decision Trees
• Technical Assistance Network (SSA TAN)
SSA Training Manual

Training manual (free download):

https://d1vy0qa05cdjr5.cloudfront.net/c6f30ca0-84ae-4613-bec0-5439702d4b9e/FSPCA%20-%20Sprouts/SSA%20curriculum%20V2.3%20-%20For%20PRINT%20watermark%20optimized.pdf

In the Manual:

- Appendix 1- Acronyms and definitions
- Appendix 2- Produce Safety Rule
- Other appendices- Templates of SOPs and log sheets
SSA Websites

https://www.ifsh.iit.edu/ssa/resources

Resources

Educational Materials and Tools

SSA CURRICULUM

Safer Sprout Production for Produce Safety Rule Compliance

SSA Sample Documents in Word format

Sprout Safety Related References (Full Text)

SSA WEBINARS


SSA Courses

• SSA Online Course:
  - Managed by IFPTI LMS
  - 8-12 hours self-learning
  - Cost: $198

• SSA Blended Course
  - Part 1: Online Course
  - Part 2: Instructor-Led Course (8 hours)

• In-person SSA Course (2-days)
Sprout Guidance and Decision Trees

• FDA Guidance Documents
  - Draft Sprout Guidance -2017
  - Draft Seed Guidance -2019

• Decision Trees
  - Test Methods Requirements of *Salmonella* and *E. coli* O157:H7 in Spent Sprout Irrigation Water (or Sprouts)
  - Determining Coverage under Subpart M of the Produce Safety Rule
Welcome to the Sprout Safety Alliance Technical Assistance Network (TAN)

The Sprout Safety Alliance (SSA) was created to develop a training curriculum and outreach programs for stakeholders in the sprout production community to enhance the industry’s understanding and implementation of the requirements in the FDA Food Safety Modernization Act (FSMA) Produce Safety Rule, and best practices for improving sprout safety. Utilizing the resources on this webpage, you may submit a sprout safety related technical question to the SSA Food Safety Resource Team (FSRT) Members. For regulation and policy interpretation questions related to the Produce Safety Rule and sprout safety, please submit your inquiry to the FSMA TAN here.

For More Information

SSA website:  
http://www.iit.edu/ifsh/sprout_safety/

Contact the SSA:  
sproutalliance@iit.edu
Acknowledgement

Produce Safety Alliance (PSA)

International Sprout Growers Association (ISGA)

Food Safety and Preventive Control Alliance (FSPCA)
Panelist Introductions

• Manny Wong
  – Founder of Fullei Fresh, one of the largest sprout growers in the SE United States
  – Board member of the International Sprout Growers Association

• Robin Taylor
  – Owns and manages Sun Grown Organics in San Diego, CA, a sprout, wheatgrass, and microgreen farm
  – Vice President of the International Sprout Growers Association
Sprout Grower and Educator Panel Discussion

Please ask our panel any questions that you may have!
PSA Updates

• Upcoming PSA Remote Train-the-Trainer Courses
  – February 1-4, 2021 (Registration closed)
    • Last remote TTT pilot
  – March 15-18, 2021
  – April 26-29, 2021
  – June 7-10, 2021

• Sign up on the PSA website to be notified when registration opens for each course
  – [https://producesafetyalliance.cornell.edu/training/train-trainer-course/upcoming-train-trainer-courses/](https://producesafetyalliance.cornell.edu/training/train-trainer-course/upcoming-train-trainer-courses/)
Next Meeting

• Next meeting:
  – Monday, February 22, 2021 – 2pm Eastern
  – Topic: Remote Training Delivery Tips
  – Speaker: Dr. Connie Fisk, PSA Northwest Regional Extension Associate
The PSA Website
http://producesafetyalliance.cornell.edu/
En español: es.producesafetyalliance.cornell.edu

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Follow us on Instagram
Watch us on YouTube