



### ILSI Europe – IAFP webinar on 'Assessment of Microbial Risk for Fresh Produce'

All opinions and statements are those of the individual making the presentation and not necessarily the opinions or views of ILSI Europe or IAFP



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## Programme

- Welcome and Practical Announcements
   <u>Dr Belén Márquez García</u> (ILSI Europe, BE)
   <u>Prof. Marcel Zwietering</u> Moderator (Wageningen University, NL)
- Risk Assessment or Assessment of the Risk, That's the Question
   <u>Dr Jim Monaghan</u> (Harper Adams University, UK)
- Risk Assessment for Fresh Produce: Issues Faced While Putting "Formal MRA" into Industrial Practice in the Field

  <u>Dr Roy Betts</u> (Campden BRI, UK)
- Assessment of the Risk for Fresh Produce: Mitigating Risks in the Field <u>Prof. Michelle Danyluk</u> (University of Florida, US)
- Questions and Answers



### Programme

#### Welcome and Practical Announcements

Dr Belén Márquez García
 (bmarquezgarcia@ilsieurope.be)

 International Life Science Institute
 (ILSI Europe)





### ILSI Europe – Vision

We build multi-stakeholder science-based solutions for a sustainable and healthier world.



## ILSI Europe – Mission



We foster **collaboration** between relevant stakeholders.



We identify **existing and emerging challenges** in food, nutrition and health and facilitate proactive practical solutions.



We **communicate** and disseminate our scientific output widely.



Our way of working is designed to deliver science of the **highest quality and integrity**.

## Microbiological Food Safety Task Force Goals and Tools

Understanding potential detection, control and management procedures

Reviewing and summarising knowledge on pathogen behaviour and ecology and assessing their risk to consumers Developing tools to manage safety hazards and risks in food production systems Ultimate goal is to investigate microbial issues in foods that are related to public health risks

#### Tools:

- Peer-reviewed publications
- Workshops
- Webinars
- European projects

Publishing guidelines and working on an agreed terminology



## Microbiological Food Safety Task Force Topics and activities

### Industrial microbiological risk assessment

- Series of publications directed towards each food sector
- •Current focus: fresh produce
- •Manuscript published in Journal of Food Protection

Control options for viruses in food processing

- •Review and summarise control options and technologies
- Collect published prevalence data
- Evaluate data gaps
- •Paper submitted to International Journal of Food Microbiology

### Next Generation Sequencing

- Provide guidance on how to use NGS in microbiological food safety management
- •Identify limitations and challenges of NGS technologies
- •Report and peer-review publication in progress, expected end 2017

European project
EFFORT (Ecology from
Farm to Fork Of microbial
drug Resistance and
Transmission)

- European project: Framework 7
- Developed a review on ecology and transfer of resistance mechanisms
- •Involved in project dissemination and training
- Final conference in September 2018



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 To provide food safety professionals worldwide with a forum to exchange information on protecting the food supply



## IAFP Annual Meeting and IAFP European Symposium

Providing information on current and emerging food safety issues, the latest science, innovative solutions to new and recurring problems, and the opportunity to network with thousands of food safety professionals from around the globe.





#### Contact information for presenters

#### Moderator

Professor Marcel Zwietering (marcel.zwietering@wur.nl)
Wageningen University



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### Contact information for presenters

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Dr Jim Monaghan (jmonaghan@harper-adams.ac.uk)



Dr Roy Betts (roy.betts@campdenbri.co.uk)



Prof. Michelle Danyluk (mddanyluk@ufl.edu)







Dr Jim Monaghan
Principal Lecturer – Fresh
Produce
Harper Adams University
United Kingdom

Dr Jim Monaghan has worked in crop science for over 20 years. Following a biology degree at UCNW Bangor, he researched aspects of crop production at Harper Adams University (HAU) and John Innes Centre (PhD), Newcastle University, HRI-Efford and HRI-Wellesbourne, UK. Dr Monaghan then had a look at the real world for three years at Marks and Spencer as Salads Technologist, where he had responsibility for food safety, pesticide residue minimisation, and compliance with codes of practice for all salad products and salad ingredients in minimally processed foods, before heading back to HAU to develop teaching and research in the area of fresh produce production in 2005.

Dr Monaghan leads the Fresh Produce Research Centre at HAU which is focused on fresh produce production, particularly leafy vegetables. He also chaired the Technical Advisory Committee for Red Tractor Produce 2010-17.

## Risk Assessment or Assessment of the Risk, That's the Question

Dr Jim Monaghan

Harper Adams University, United Kingdom



#### Fresh produce – what is the challenge?

- Good for health
- Positive message about eating fresh produce
- But: foodborne illness outbreaks do occur

Geography	No. Outbreaks
Europe 2004-2012	197
USA 2004-2012	377

Foodborne Pathogens and Disease. January 2015, 12(1): 32-38

#### Bad Press

- NHS Choices UK 19/7/13: "Food Poisoning Warning over Fruit and Veg"
- Mail online (Daily Mail UK): Health section: "When fruit and vegetables are BAD for you: Getting your five-a-day is responsible for HALF of all food poisoning cases
- Daily Telegraph online 22/3/13: "Salad is more dangerous than beefburgers, leading food expert warns"



# Commercial consequence of food safety issues!



# What are the hazards linked to fresh produce production?





## Which crops and human pathogens are important to consider?

- Salmonella spp.
- Pathogenic *E.coli*
- Norovirus
- □ Shigella spp.





## So cook everything....

- Cooking kills bugs
- BUT consumers like to eat some products uncooked
- Production of crops that are eaten uncooked few or no 'true' CCPs.
- Growers are asked/told to manage food safety through 'Risk Assessments'

# Growers are asked/told to use 'risk assessments'

e.g. GlobalGap Annex AF1 defines 5 steps for RA as:

- 1. identify the hazards;
- 2. decide who/what might be harmed and how;
- 3. evaluate the risks and decide on precautions;
- record the work plan/findings (and implement them);
- 5. review the assessment and update if necessary. (www.globalgap.org)



# BUT is this a risk assessment as defined by Codex?

- Risk analysis = A process consisting of three components: risk management, <u>risk</u> <u>assessment</u>, and risk communication
- Risk assessment = A scientifically based process consisting of four steps:
- 1. hazard identification
- 2. hazard characterization
- 3. exposure assessment
- 4. risk characterization



Component	Process
1. <u>Hazard ID</u>	Generic risk of faecal contamination
2. Exposure assessment	Is it probable or possible that any microbial contamination on the product could lead to illness in a consumer?
3. Decide on precautions	What system/process needs to be put in place to reduce the risk of contaminated product?

Component	Process
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3. <u>Decide on</u> <u>precautions</u>	What system/process needs to be put in place to reduce the risk of contaminated product?

Component	Process
1. Hazard ID	Generic risk of faecal contamination
2. Exposure assessment	Is it probable or possible that any microbial contamination on the product could lead to illness in a consumer?
<ul><li>3. <u>Intervention assessment</u> AND</li><li>4. <u>Exposure assessment</u> <u>following intervention</u></li></ul>	What system/process needs to be put in place to reduce the risk of contaminated product?

## How can we use evidence to justify qualitative decisions?

- Reliance on best practice and expert <u>qualitative</u> opinion
- Environmental <u>quantitative</u> monitoring is minimal
   Tick box vs trending
- Academic papers are rarely suited to use by the industry
- Few direct scientific studies quantifying the effect of multiple interventions (hurdles?) in the field.
- Grower relevant EVIDENCE is needed for better RA.





Dr Roy Betts
Head of Microbiology
Campden BRI
United Kingdom

**Dr Roy Betts** is Head of Microbiology at Campden BRI, and independent international food research organisation based in the UK. Dr Betts manages a group of 45 Food Microbiologists, undertaking a range of industry focussed food research and testing projects for a worldwide client base. He originally managed a research team at Campden BRI that concentrated on the research, development and validation of microbiological test methods. After becoming Head of Department, his interests moved to the assessment of the microbiological quality and safety of foods, advising industry on techniques and procedures to produce and market high quality safe foods. Dr Betts has published widely in the area and is Scientific Advisor of ILSI Europe's Microbiological Food Safety Task Force, the UK Food and Drink Federation Food Hygiene Sub Committee and the UK Advisory Committee on the Microbiological Safety of Foods as well as British Standards Institute and ISO committees dealing with microbiological test methods.



#### Risk Assessment for Fresh Produce: Issues Faced While Putting "Formal MRA" into Industrial Practice in the Field

Dr Roy Betts
Campden BRI, Chipping Campden,
United Kingdom



## Objective of the ILSI Europe Group

#### To discuss/propose:

- A grower based RA approach
- Based on structured qualitative assessment
- Decisions to be based on evidence
- Documented & transparent
- Challengeable/defendable within the supply chain



### The Challenge

- Imagine being the primary producer of Fresh Produce (e.g. Leafy Greens)
- Your job is to plant & grow and harvest leafy greens to supply to a further processer (not in your control) who will process/supply them on.
- You are asked to do a microbiological risk assessment of your practices
- You have no specialist microbiological knowledge
- Minimal access to experts
- Limited previous information/data
- What do you do?



#### The Grower MRA

- A defined approach to doing an MRA
- Can be done at the field grower level
- Simple
- Effective
- Able to be documented



## Developing a Qualitative Risk Assessment for the Primary Producer – The Grower MRA

#### What can and cannot be done

#### Hazard Identification

Done at a basic level- identify the range of potential pathogens that may be present from available information sources.

#### Exposure Assessment

 Done qualitatively – an assessment that contamination of a significant amount occurs

#### Intervention assessment

 How likely is it that an individual intervention will reduce contamination

#### Exposure Assessment following intervention

 An assessment whether contamination of a significant amount occurs after single or multiple mitigation steps

#### Hazard Identification

- As in HACCP
- Very simple using available Literature sources
  - Salmonella, E.coli O157, Norovirus, Cyclospora
  - Contamination route: direct/indirect faecal contamination
- The generic hazard is faecal contamination
- No discrimination needed between microbial types
- Issues: irrigation water, harvest conditions, sanitation practices, worker hygiene, storage conditions.
- Identify production stages where faecal contamination could occur.



#### **Exposure Assessment**

- Any route of contamination is considered an issue;
- If there are multiple routes of contamination (hazards) develop a separate exposure assessment;
- Classify them: (can contamination occur at levels associated with illness).

Category	Definition
Negligible	so rare- not considered
Very Low	very rare but cannot be excluded
Low	rare but does occur
Medium	occurs regularly
High	occurs often
Very high	events occur almost certainly



### Intervention Assessment

- Assess the efficacy of any intervention
- Can be quantitative (if available)
  - e.g. Water filter removes 4 logs of an organism (with validation data)
- Or qualitative
  - e.g. Expert opinion
- Categorise efficacy
  - Effective (validated reduction)
  - Partially effective (non-validated, exposure risk may not be reduced to negligible levels)
- In any system single or multiple interventions may be present



## Assess Exposure Following Intervention

Simple consistent & transparent approach documenting likelihood of exposure following intervention

		Effectiveness of intervention		
		Effective	Partial	No intervention
Probability of significance contamination before intervention	Negligible	Acceptable	Acceptable	Acceptable
	Very low	Acceptable	Acceptable	Action Required
	Low	Acceptable	Acceptable	Action Required
	Medium	Acceptable	Action Required	Action Required
	High	Acceptable	Action Required	Action Required
	Very High	Acceptable	Action Required	Action Required

## Example

- Irrigation water –open water, no treatment
- Hazard ID:
  - Faecal contamination (*Salmonella*, STEC, *Norovirus*, etc.)
- Exposure Assessment:
  - Medium
  - Evidence
    - water testing programme (5 years)
    - 10- 850 cfu *E.coli*/100ml
    - Upper end shows faecal contamination occurs regularly
- Intervention Assessment
  - Categorise efficacy
    - Effective (validated reduction)
    - Partially effective (non-validated, exposure risk may not be reduced to negligible levels)

Category	Definition	
Negligible	so rare- not considered	
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### Intervention Assessment

- (1) Avoid leaf contact with Irrigation water
  - Use of drip tape
  - Evidence
    - Avoids contact with leaf (suggested GlobalGAP 2015)
    - Soil splash with contaminated soil can still happen (Monaghan & Hutchinson 2012)
  - Contamination could still occur
- (2) Stop irrigation 7 days before harvest
  - Evidence
    - Bacteria decline on leaves in warm dry conditions (Hutchinson et al., 2008)
    - Bacteria can persist in cooler conditions (Islam et al., 2004)
  - Contamination could still occur

		Effectiveness of intervention		
		Effective	Partial	No
				intervention
Probability of significance contamination before intervention	Negligible	Acceptable	Acceptable	Acceptable
	Very low	Acceptable	Acceptable	Action Required
	Low	Acceptable	Acceptable	Action Required
	Medium	Acceptable	Action Required	Action Required
	High	Acceptable	Action Required	Action Required
	Very High	Acceptable	Action Required	Action Required

### **Exposure Assessment After Intervention**

- Result 2 partial interventions
- How can this be assessed?
  - No Evidence of reduction in this case
- Ways forwards?
  - Monitor water/harvested crop for E.coli as hygiene criterion (EFSA 2014)?
  - Change water source/ put in an effective water treatment (e.g. UV)



### Risk Assessment or Assessment of Risk?

- Simple to use
- Allows use of own information
- Other information sources should be readily available
- Effective at documenting Hazards and Potential exposure
- Allows documentation of effect of interventions
- Provides evidence of a clear Assessment of Risks associated with primary produce.



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#### General Interest

#### Risk Assessment or Assessment of Risk? Developing an Evidence-Based Approach for Primary Producers of Leafy Vegetables To Assess and Manage Microbial Risks

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#### ABSTRACT

Over the last 10 years, some high-profile foodborne illness outbreaks have been linked to the consumption of leafy greens. Growers are required to complete microbiological risk assessments (RAs) for the production of leafy crops supplied either to retail or for further processing. These RAs are based primarily on qualitative judgements of hazard and risks at various stages in the production process but lack many of the steps defined for quantitative microbiological RAs by the Codex Alimentarius Commission. This article is based on the discussions of an industry expert group and proposes a grower RA approach based on a structured qualitative assessment, which requires all decisions to be based on evidence and a framework for describing the decision process that can be challenged and defended within the supply chain. In addition, this article highlights the need for evidence to be more easily available of a stiple to process and idea the the need to develop hygiene criteria to aid



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Dr Michelle Danyluk is an Associate Professor of Food Safety and Microbiology in the Department of Food Science and Human Nutrition, at the University of Florida. She is situated in the Citrus Research and Education Center, in Lake Alfred, Fl. Her current research and extension interests include microbial food safety and quality of fruit juices, fresh fruits, vegetables and nuts. Her primary research focuses on Salmonella in produce and nuts, along with the produce product and processing environments, its movement within these environments, and the subsequent implications for public health. Michelle's is a Lead Trainer/Instructor for FSMA's Produce Safety (PSR), Preventive Controls for Human Foods (PCR), and Foreign Supplier Verification Program (FSVP) Rule curricula; other extension programs include HACCP, GAPS and specialized food safety, or beverage processing programs. She serves as the PD for the USDA-funded Southern Training, Education, Extension, Outreach, and Technical Assistance Center to Enhance Produce Safety to prepare the produce industry for PSR and PCR compliance. For this grant, Danyluk oversees collaborators in 13 Southern US states, 1 territory and 3 nongovernment organizations.

# Assessment of the Risk for Fresh Produce: Mitigating Risks in the Field

Prof. Michelle Danyluk University of Florida, United States

### Risk Assessment vs Assessment of Risk

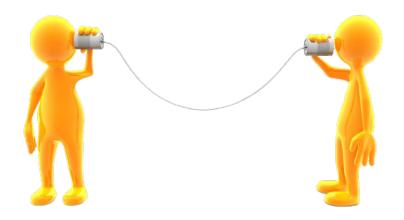








Photo: Tampa Bay Times



reginning to the end...quality and safety umber one.

ducts operates from a state of the art manufacturing facility boasting several uding cold-pack and thermal-pack products – operating at peak efficiency. Our main service business center and conference room suitable for client meetings with our

es offer full-service Research & Development Kitchens. Our expert culinary turing former restaurant and executive chefs, work direction with our customers and products to customer's exact flavor profiles and quality standards.

International Association for Food Protection.

n of and specialization in fresh, made to order, high-end, gourmet dips, spreads, a products allows Italian Rose to stand out in our market as the premier custom-

Italian Rose garlic Products, inc. handles several fresh produce ingredients and understands the need to have strong Food Safety and Quality Assurance department to ensure the constant supply of delicious safe products to the customers and consumers. With that in mind, since 2015, Italian Rose Food Safety and Quality Assurance Team is supervised by UF Food Science PhD Degree Recipient with specialization in Food Microbiology. We have HACCP certified and experienced technicians on board to monitor and verify our day to day activities.

Italian Rose safety and quality systems are designed around a HACCP and we are proud to have maintained SQF 7.2, Level 3 certification to be in compliance with the Global Food Safety Initiative. We have experienced and certified Preventive Control Qualified Individual (PCQI) on board to assist with the FDA Food Safety and Modernization Act requirements.

## Do a Risk Assessment?



YES

NO

The produce industry misuses the term "risk assessment" when they really mean "hazard analysis".

When true risk assessors hear the magic words "risk assessment" they get excited because they think there is going to be some actual risk assessment with numbers behind it. Not so in produce, it's just a hazard analysis that is almost always qualitative.

#### Michelle,

I know it is not a real risk assessment the way you and I know (the Don Schaffner way).

Consider the potential for known risk factors to be present and impact the safety of the produce. It's what we would call a hazard analysis (what hazards are reasonably likely to occur in the absence of control or monitoring), but without the HACCP plan. Because hazard analysis, risk analysis and risk assessment all have specific connotations and expectations, I usually say something that's not already taken, like hazard assessment. But others say risk assessment, not knowing that folks like Schaffner will hear something different than what's intended.

And I always have had a problem with the term risk assessment applied to a produce safety plan. But, I understand where this comes from and I still use it not to bring more confusion. In my last PSA course someone asked this question and I had to show them a few slides I had on Risk Analysis and the Risk Assessment part, gave a quick explanation of the terms and told them a few differences between "that risk assessment" and "our risk assessment."

I refer them to the audit they will be using and the specific guidelines there, the commodity specific risk assessment (e.g. leaf and cantaloupe) and the Produce Safety Rule requirements. It is broad and personalized.

#### HARMONIZED PRODUCE SAFETY STANDARD (HPSS)

#### CONTROL POINTS AND COMPLIANCE CRITERIA

V1.0\_MAY2014

VALID FROM: JUNE 2014
OBLIGATORY FROM: SEPTEMBER 2014



#### HARMONIZED PRODUCE SAFETY STANDARD (HPSS) Control Points and Compliance Criteria (CPCC)

N°	Control Point	Compliance Criteria	Level
2.2.2.1	An initial risk assessment shall be performed and documented that takes into consideration the historical testing results of the water source, the characteristics of the crop, the stage of the crop, and the method of application.	A review or new assessment shall be conducted seasonally and any time there is a change made to the system or a situation occurs that could introduce an opportunity to contaminate the system. The risk assessment shall address potential physical, chemical, and biological hazards and hazard control procedures for the water distribution system.	Major Must

"GlobalGAP is such a great audit, they have to do a risk assessment before they harvest"

- Anonymous IAFP member

"I don't care what the h@#\$ they call it, it makes a difference"

-Same Anonymous IAFP member



## GAP (Module 2) Guidelines

is it probable or possible that any microbial contamination on the product could lead to illness in a consumer?

Monaghan et al., 2017 JFP 80:725-233

2.03.07: Has a documented risk assessment been undertaken for the appropriate corrective actions to minimize identified hazards where

Total points 10: A risk assessment of the growing area must be performed include assessment of microbial, chemical and physical risks covering at I growing area, adjacent land, water sources (chemical hazards e.g. heavy microbial hazards e.g. pathogenic *E. coli*), fertilizers, crop protection chemical hazards e.g. pathogenic *E. coli*), fertilizers, crop protection chemical hazards e.g. pathogenic *E. coli*).





Photo: Tampa Bay Times



Photo: Tampa Bay Times



Photo: Tampa Bay Times

It is similar for the packinghouse. I recommend they look around the outside and think about what could contaminate the produce then do the same thing inside the packinghouse. I also suggest they bring someone else from outside to assess the potential risks then decide if changes are needed to prioritize which are more important.

Michelle that is a quick version of what we do during training. The one area that concerns me is what is a "risk". Many of us including me do not know how to prioritize risks that we cannot see. Looking at equipment or a field and make judgements is not too difficult, but what about potential pathogens on equipment? Is there a need to swap equipment, where, when, etc.







However, I will make it sweet and simple. When I work with growers, I would have them evaluate certain factors on their farm that could introduce hazards.

People, The environment, Equipment (food contact surfaces)

For example, we know that water can introduce microbiological hazards onto the farm. You would evaluate your water sources and determine if you might have a problem. Is it sourced from a well vs a pond? A well would be less risky than a pond. How do you apply the water? Is it with drip or overhead? Drip is less risky than overhead.

Another example could be adjacent land use. Do you have animals next to you? For example, you have a hobby horse farm next door. It is up on a hill and when it rains the water drains down into your field. Maybe you build a berm or ditch to reroute the water so it doesn't run into your field. But another farm has free roaming cattle. There is a fence between your farm and the cattle and it is on level land. After checking the fence regularly, the risk is fairly minimal.





"If I washed my hands every time you think I should wash my hands, all I'd do is stand at the sink washing my hands all day"

-Overheard at a

**PSA** 

**Grower Training** 



I tell them this is something they do every day. They look for hazards that might occur in the operation, that's the risk assessment, then they take they extra step of fixing the problem. I explain that when they do a formal risk assessment it's a good idea to take the operation step by step and write down possible hazards so can think through risk mitigation strategies and prioritize actions. Many times I give an example: A couple months ago I visited a small farm in MS, the 86 year old farmer had been cleaning the rafters in the packing area that morning. He told me that when he came in that morning he found bats above the packing area. This farmer had assessed the risk of bat drippings in the packing area, and decided to take action before starting packing that day.

What I mean is that the look at their practices and assess which ones may be increasing risks or done in a way that could be modified to reduce risks. How do they know which ones these are? This comes down to providing them information to help make that assessment. For example, after training sometimes growers will say "well I can do it your way or my way. It is 6 one-way and a half dozen the other so I'll do it your way if you think that's better."

I think of it as a peculiar hazard analysis that is applied to an operation where there is not an actual control measure. Therefore you focus In understanding not just the sources, but possible mechanisms for transfer of pathogens from these sources to the produce. When you know the mechanisms applied to each source, you can come up with ways to prevent these mechanisms from operating.



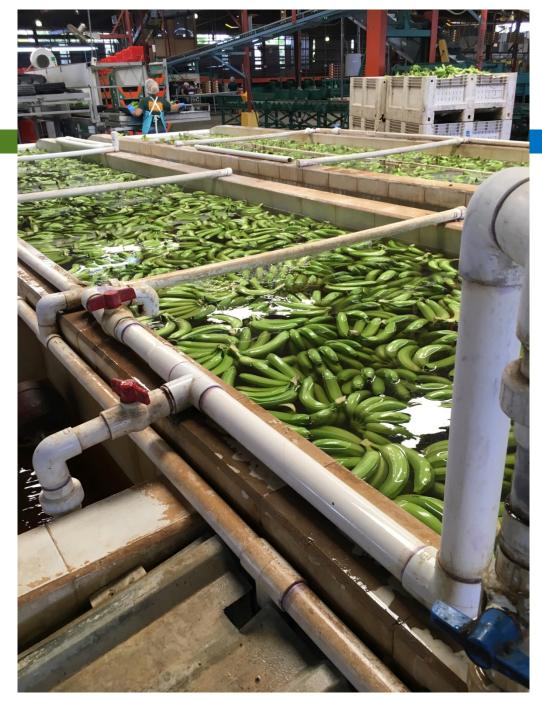




Usually when I think about telling a farmer to do a risk assessment, I try to get them to think about the hazards that exist in the farm operation (whatever part we are talking about, pre, harvest, post), and then prioritize those hazards that they identify based on the likelihood that they could happen and also the likelihood that they will cause contamination. So kind of prioritize those that are A) most likely to happen and B) most likely to contaminate the most produce. Like a 2x2 grid, likeliness Low and High, and Contamination (impact, volume, amount) Small and Large. Then from there a farmer could prioritize those that are MOST likely X LARGE Volumes of produce as the biggest possible risks.

So, something like, no lock on the box storage room may be a hazard, but it less likely to cause contamination than say, no sanitizer in the dump tank.









### Risk Assessment vs Assessment of Risk

- Risk Assessment is not defined in the Produce Safety Rule
- PSA Risk Assessment definition
  - A process to identify potential hazards on a farm and/or in a packinghouse as well as the likelihood the hazard will impact the safety of fruits and vegetables



### Risk Assessment vs Assessment of Risk

PSA Risk Assessment definition – A process to identify potential hazards on a farm and/or in a packinghouse as well as the likelihood the hazard will impact the safety of fruits and vegetables

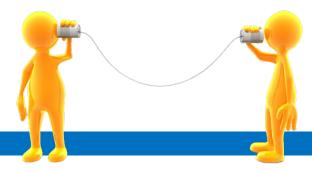
In order to help, do we all need to be on the same page in terms of what we mean, or what our expectations are when we say – do a risk assessment?

IS just understanding what someone else means enough?

Can we get there?



## Risk Assessment vs. Assessment of Risk



No one meaning or consensus when we talk about doing a risk assessment in the produce industry.

Better communication and understanding, or consistency about what all groups mean

Do we all need to be on the same page in terms of what we mean, or what our expectations are when we say – do a risk assessment?

IS just understanding what someone else means enough?

Can we get there?



## **Questions and Answers**

## Contact information for presenters

### Contact information for presenters

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### ILSI Europe – IAFP webinar on 'Assessment of Microbial Risk for Fresh Produce'

#### Thank you for watching!

If you would like to receive more information, please email Belén Márquez García at <a href="mailto:bmarquezgarcia@ilsieurope.be">bmarquezgarcia@ilsieurope.be</a> or take a look at our websites below

www.ilsi.eu www.foodprotection.org

Please, answer the survey that you will receive by email.