Risk Assessment or Assessment of The Risk in Fresh Produce, That's the Question

Thursday 12 May, 8.30-10.00

IAFP’s European Symposium on Food Safety 2016, Athens, Greece
Assessment of the Risk for Fresh Produce Primary Producers

Presenting the example of fresh produce assessment of the risk.

Dr Jim Monaghan,
Harper Adams University, UK
Overview

1. What fresh produce makes people sick?
2. Leafy salad production
3. Sources of risk in primary production
4. Requirements for risk assessment
5. Developing an evidence based approach
Commercial consequence of food safety issues!

EC support = 227 Million €
Produce associated with food borne illness *probably or definitely* linked to field contamination

<table>
<thead>
<tr>
<th>Leafy crops</th>
<th>The rest…</th>
</tr>
</thead>
<tbody>
<tr>
<td>• salad onions</td>
<td>• apple (juice)</td>
</tr>
<tr>
<td>• lettuce</td>
<td>• strawberries</td>
</tr>
<tr>
<td>• spinach</td>
<td>• raspberries</td>
</tr>
<tr>
<td>• rocket</td>
<td>• blueberries</td>
</tr>
<tr>
<td>• parsley</td>
<td>• carrots</td>
</tr>
<tr>
<td>• watercress</td>
<td>• cucumber</td>
</tr>
<tr>
<td>• coriander</td>
<td>• tomato</td>
</tr>
<tr>
<td>• basil</td>
<td>• melon</td>
</tr>
<tr>
<td>• cabbage (coleslaw)</td>
<td>• peas (mangetout)</td>
</tr>
</tbody>
</table>
The risk is small but can be serious when it goes wrong

Comparison of reported foodborne outbreaks of non-animal and animal origin 2007-2011 (EFSA, 2013)

<table>
<thead>
<tr>
<th></th>
<th>Outbreaks</th>
<th>Cases</th>
<th>Hospitalisation</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>All data</td>
<td>10%</td>
<td>26%</td>
<td>35%</td>
<td>46%</td>
</tr>
<tr>
<td>Excl. 2011 vtec O104 outbreak</td>
<td>10%</td>
<td>18%</td>
<td>8%</td>
<td>5%</td>
</tr>
</tbody>
</table>
Which crops are the greatest risk?

<table>
<thead>
<tr>
<th>Ranking position</th>
<th>Pathogen</th>
<th>FoNAO category</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td><em>Salmonella</em> spp.</td>
<td>Leafy greens eaten raw as salads</td>
</tr>
<tr>
<td></td>
<td><em>Salmonella</em> spp.</td>
<td>Bulb and stem vegetables</td>
</tr>
<tr>
<td></td>
<td><em>Salmonella</em> spp.</td>
<td>Tomatoes</td>
</tr>
<tr>
<td></td>
<td><em>Salmonella</em> spp.</td>
<td>Melons</td>
</tr>
<tr>
<td></td>
<td><em>Pathogenic E. coli</em></td>
<td>Fresh pods, legumes and grain</td>
</tr>
<tr>
<td>Second</td>
<td><em>Norovirus</em></td>
<td>Leafy greens eaten raw as salads</td>
</tr>
<tr>
<td>Third</td>
<td><em>Salmonella</em> spp.</td>
<td>Sprouted seeds</td>
</tr>
<tr>
<td></td>
<td><em>Shigella</em> spp.</td>
<td>Fresh pods, legumes or grain</td>
</tr>
<tr>
<td></td>
<td><em>Bacillus</em> spp.</td>
<td>Spices and dry powdered herbs</td>
</tr>
<tr>
<td></td>
<td><em>Norovirus</em></td>
<td>Bulb and stem vegetables</td>
</tr>
<tr>
<td></td>
<td><em>Norovirus</em></td>
<td>Raspberries</td>
</tr>
<tr>
<td></td>
<td><em>Salmonella</em> spp.</td>
<td>Raspberries</td>
</tr>
<tr>
<td></td>
<td><em>Salmonella</em> spp.</td>
<td>Spices and dry powdered herbs</td>
</tr>
<tr>
<td></td>
<td><em>Salmonella</em> spp.</td>
<td>Leafy greens mixed with other fresh FoNAO</td>
</tr>
<tr>
<td></td>
<td><em>Shigella</em> spp.</td>
<td>Fresh herbs</td>
</tr>
<tr>
<td></td>
<td><em>Pathogenic E. coli</em></td>
<td>Sprouted seeds</td>
</tr>
<tr>
<td></td>
<td><em>Yersinia</em> spp.</td>
<td>Carrots</td>
</tr>
<tr>
<td>Fourth</td>
<td><em>Norovirus</em></td>
<td>Tomatoes</td>
</tr>
<tr>
<td>Fifth</td>
<td><em>Norovirus</em></td>
<td>Carrots</td>
</tr>
<tr>
<td></td>
<td><em>Salmonella</em> spp.</td>
<td>Nuts and nut products</td>
</tr>
<tr>
<td></td>
<td><em>Shigella</em> spp.</td>
<td>Carrots</td>
</tr>
</tbody>
</table>

EFSA (2013)
Leafy Salads are an area of particular focus

- Soil grown
- Irrigated
- Short production cycle
- Short shelf life
- NOT COOKED
WHAT ARE THE RISKS?
Worker hygiene
Equipment
Livestock / wildlife
Potential vectors and routes of faecal contamination and the stages in production when the hazard may be present.

<table>
<thead>
<tr>
<th>Vector</th>
<th>Route of contamination</th>
<th>Growing</th>
<th>Harvest</th>
<th>Primary Processing</th>
<th>Storage and Transport</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Irrigation</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cooling systems</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wash water</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Flooding</td>
<td>(X)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soil</td>
<td>Manure based soil</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>amendments</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Livestock</td>
<td>Farmed livestock in</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>rotation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Incursion by farmed</td>
<td>(X)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>livestock</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wildlife/pests</td>
<td>(X)</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Surfaces</td>
<td>Workers</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Equipment</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

X = managed inputs; (X) = unmanaged inputs
RISK ASSESSMENT OR ASSESSMENT OF RISK?
Codex requires food to be safe

Baseline ‘guidance’ is from Codex Alimentarius

• *General Principles of Food Hygiene* – CAC/RCP 1-1969

• Code of hygienic practice for fresh fruit and vegetables – CAC/RCP 53-2003

• “*general framework of recommendations […] rather than providing detailed recommendations for specific agricultural practices…”*

1. It must be safe
Growers don’t ‘follow’ Codex guidelines directly

Implemented through:

• Quality Assurance Schemes (QAS)
• Good Agricultural Practice (GAP) programs
• Codes of Practice (COP)

• These **all** require Risk Assessments
QAS - 1st Generation

• EurepGAP – 1997
• Assured Produce – early 1990s
• Tesco Natures Choice - 1992
• M&S Field to Fork – 2004*

1. You need systems in place to make it safe
2. HACCP principles
3. Risk assess sources of microbial contamination
4. *Test water for E.coli
QAS – 2nd Generation

• GlobalGAP
• Red Tractor Fresh Produce
• Tesco Nurture
• M&S Field to Fork v2

1. You need systems to make things safe
2. HACCP principles
3. Risk assess sources of microbial contamination
4. Critical values for *E.coli* in water and indicators in composts
5. Guidance on RA methodology
QAS – 3rd Generation

• US FDA Food Safety Modernization Act
• McDonalds GAP
1. You need systems to make things safe
2. HACCP principles
3. Risk assess sources of microbial contamination
4. METRICS for water sources
5. Critical values for \textit{E.coli} in water and indicators in composts
6. Guidance on RA methodology
Codex defines Risk Assessment as

A scientifically based process consisting of:

• Hazard identification,
• Hazard characterization,
• Exposure assessment
• Risk characterization.
Primary producers do something different!

GlobalGAP Annex AF1 defines five 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
4. Record the workplan/findings and implement them
5. Review the assessment and update if necessary
Risk assessment or assessment of risk? The key debate at ILSI.

- **Hazard ID** is undertaken at a superficial level
  - Little consideration of different hazards
  - Generic faecal contamination
- **Exposure assessment** - qualitative assessment of the likelihood that contamination of a significant amount occurs during production.
Risk assessment or assessment of risk? The key debate at ILSI.

• Neither hazard characterisation nor risk characterisation are done at the grower level
  • these are tasks are at the food safety enforcement agency level (i.e. governmental).
What elephant?
Qualitative assessments are the foundations of grower ‘Assessment of Risks’

- **Hazard ID** = faecal contamination
- **Exposure assessment** - qualitative assessment of the likelihood that contamination of a significant amount occurs during production.
Are primary producers basing decisions on opinions and hopes?

How are primary producers JUSTIFYING assessments of risk?

1. Potential exposure of crop to contamination
2. Effectiveness of single interventions
3. Effectiveness of multiple interventions (Hurdles)
Can we develop an evidence based assessment of risk?

**Practical RA**

- Hazard ID
- Exposure assessment
- Intervention assessment
- Exposure assessment following intervention

**Evidence**

- Generic risk of faecal contamination
- Monitoring of indicators; scientific reports; industry guidelines
- Scientific studies; industry guidelines
- Monitoring of indicators (*E.coli* – EFSA, 2014)?
Scenario – Risk Assessing an irrigation water source
Winter storage irrigation reservoir

- Open water source
- No water treatment

**Hazard ID**
Generic hazard is faecal contamination.
Potential Exposure assessment

Probability descriptors to classify likelihood that contamination can occur at levels associated with human illness.

<table>
<thead>
<tr>
<th>Probability category</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negligible</td>
<td>So rare that it does not merit to be considered</td>
</tr>
<tr>
<td>Very low</td>
<td>Very rare but cannot be excluded</td>
</tr>
<tr>
<td>Low</td>
<td>Rare, but does occur</td>
</tr>
<tr>
<td>Medium</td>
<td>Occurs regularly</td>
</tr>
<tr>
<td>High</td>
<td>Occurs very often</td>
</tr>
<tr>
<td>Very high</td>
<td>Events occur almost certainly</td>
</tr>
</tbody>
</table>

UK FSA, 2012 and adapted from EFSA 2006
Potential Exposure assessment = Medium

Evidence

- Water testing programme (5 years)
- 10-850 cfu \(E.\text{coli}/100\ \text{ml}\)
- <1000 cfu \(E.\text{coli}/100\ \text{ml}\) (GlobalGAP)
- Upper end of indicator levels showing that the faecal contamination of the water occurs regularly
Intervention assessment

Definition

• **Effective** = validated reduction to give a consistently negligible exposure risk.

• **Partially Effective** = non-validated reduction where it is possible that the exposure risk may not be reduced consistently to negligible levels.
Avoiding leaf contact by using drip tape to apply the irrigation

*Intervention assessment = Partial*

Evidence

- Avoiding contact with the leaf is a suggested intervention (GlobalGAP, 2015)
- Soil splash of contaminated soil can occur (Monaghan and Hutchison, 2012)
- **Contamination could still occur.**
Stopping irrigation 7 days before harvest

*Intervention assessment = Partial*

**Evidence**

- Bacteria rapidly decline on the leaves of lettuce in warm dry conditions (Hutchison et al, 2008).
- Bacteria can persist in cooler conditions (Islam et al, 2004a).
- **Contamination could still occur.**
## Exposure assessment following intervention

*Matrix of effectiveness of intervention x probability of significant contamination.*

<table>
<thead>
<tr>
<th>Probability of significant contamination</th>
<th>Effectiveness of intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Effective</td>
</tr>
<tr>
<td>Negligible</td>
<td>Acceptable</td>
</tr>
<tr>
<td>Very low</td>
<td>Acceptable</td>
</tr>
<tr>
<td>Low</td>
<td>Acceptable</td>
</tr>
<tr>
<td><strong>Medium</strong></td>
<td>Acceptable</td>
</tr>
<tr>
<td>High</td>
<td>Acceptable</td>
</tr>
<tr>
<td>Very High</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>
How to assess multiple partial interventions?

- Assumed synergy, or even a multiplicative interaction, between combinations of partial treatments, with different modes of action.
- Hurdle effect (Leistner, 2000).
- Multiple partial interventions are recommended (e.g. GlobalGAP, 2015).
- Few studies into the effect of a hurdle technology approach in leafy crop production.
Exposure assessment following intervention = Acceptable?

Evidence

• Partial reduction of risk x 2
• NO EVIDENCE of level of actual or relative reduction as conditions specific to growing location.
How do you know it is safe?

Evidence

• Partial reduction of risk x 2
• NO EVIDENCE of level of actual or relative reduction as conditions specific to growing location.
• Monitor water and harvested crop using E.coli as a hygiene criteria (EFSA,2014)?
• Change water source?
Evidence is hard for growers to access

• Evidence base = scientific literature, from databases such as those in the food industry, government agencies, and relevant international organizations and [...] opinions of experts (CAC, 2003)
  • Are smaller growers able to access and understand this information?
• Historic site specific microbiological sampling data.
Evidence is hard for growers to access

• Manufacturers or suppliers of equipment may provide evidence of effectiveness of processes such as water treatment.

• *E. coli* based hygiene criterion for leafy greens at pre-harvest, harvest or on farm post-harvest (EFSA, 2014)
Conclusion

1. Production of crops that are eaten uncooked has few or no ‘true’ CCPs.

2. Growers have to complete Risk Assessments (or Assessments of Risk) based on qualitative assessments

3. We propose an evidence based approach.

4. Evidence base is needed for primary producers.

5. Increased use of hygiene indicators?