Vulnerability Assessment

U.S. Food Defense Team

Vulnerability

A weakness in a processing, handling or storage facility or operation that would allow for **intentional contamination** of a food product

Vulnerability Assessment

- Process of identifying and prioritizing the weaknesses in a food operation

  weakness = vulnerability

- Used to identify specific points in the food supply chain where intentional contamination has the greatest potential to cause economic and public health harm

  specific points = critical process steps

Vulnerability Assessment
CARVER+Shock

Criticality = public health and economic impacts

Accessibility = physical access to the target

Recognizability = ease of identifying a target

Vulnerability = ease of adding sufficient contaminant

Effect = amount of direct loss

Recuperability = ability of the system to recover

+Shock = psychological effects

Why Use CARVER+Shock?

- Simplifies and standardizes the process
  - Breaks down “exposure” and “hazard” into characteristics that are easily defined and can be examined independently
  - Provides a measurable scale for each of the characteristics to facilitate quantitative assessment
- Examines public health, economic, and psychological consequences of an attack

How does vulnerability assessment help address food defense?

- Allows targeting of resources in the following areas:
  - Foods and agents of greatest concern
  - **Selection of mitigation strategies**
  - Research
    - Analytical methods (rapid and confirmatory)
    - Nature of disease (e.g., oral infective dose)
    - Food-agent compatibility
    - Food processing mitigation steps
    - Physical security mitigation steps

How does vulnerability assessment help address food defense?

- Allows targeting of outreach to stakeholders:
  - Guidance
  - Industry and regulator training
  - Preparedness exercises
  - Communication
- Emergency response preparedness
  - Sufficient laboratory capacity/capability
  - Sufficient medical mitigations
  - Effective disposal methods

Vulnerability Assessment in Action

- Break a food system into its unit operations (in other words create a process flow chart)
- Analyze each unit operation to identify targets most vulnerable to contamination = **“critical nodes”**
- Leads to the identification of mitigations to reduce the vulnerability at those nodes

Aggressor Profile

- Attackers could range from disgruntled employees to international terrorist organizations
  - Different capabilities and different goals
- Major assumption used by FSIS and FDA
  - Insider with the goal to cause mortality and economic harm to the company by adding acutely toxic agents to food products
  - That assumption does impact the scoring of the various parts of the supply chain and the scales for the attributes have been developed with that in mind

Industry Focus and Impact

- Learning from VA's done with the U.S. food industry:
  - For best prevention of intentional contamination focus mitigation efforts on reducing:
    - **VULNERABILITY**
    - **ACCESSIBILITY**

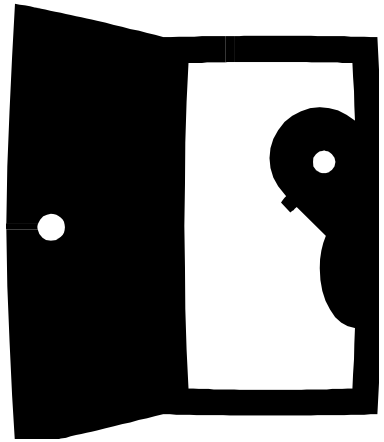
Accessibility

Measure of the ease with
which an attacker can
physically access
the intended target to
intentionally contaminate the food

Accessibility

- A target is **accessible** when an attacker can reach it to conduct the attack and leave undetected
- Accessible = **openness** of the target to the threat

OR



Accessibility Scale

CRITERIA	SCALE
Easily Accessible (e.g., target is outside building and no perimeter fence).	9 – 10
Accessible (e.g., target is inside building, but in unsecured part of facility).	7 – 8
Partially Accessible (e.g. inside building, but in a relatively unsecured, but busy, part of facility).	5 – 6
Hardly Accessible (e.g., inside building in a secured part of facility).	3 – 4
Not Accessible (e.g., there are physical barriers, alarms, and human observation to prevent reaching the target).	1 – 2

Vulnerability

Measure of the ease with which
a contaminant can be introduced
in **quantities sufficient**
to achieve the attacker's purpose
(*once the target has been accessed*)

Vulnerability

- Determined by the characteristics of the target
  - Volume appropriate to accommodate contaminant
  - Sufficient and uniform mixing after addition
  - Ability to work unobserved, e.g, poor supervision
  - Time available for introduction of agents
  - Downstream processing will not eliminate the contaminant
- It is also important to consider what interventions are already in place that might prevent an attack

Vulnerability Scale

CRITERIA	SCALE
Highly Vulnerable (e.g., product is openly exposed and there is lots of time to allow for easy introduction of contaminants without being seen).	9 – 10
Vulnerable (e.g., product has some open exposure and there is sufficient time to almost always allow for introduction of contaminants without being seen).	7 – 8
Somewhat Vulnerable (e.g., product has limited exposure points and limited times when contaminant can be added without being seen).	5 – 6
Barely Vulnerable (e.g., product has limited exposure points but is almost always under observation while in production).	3 – 4
Not Vulnerable (e.g., product is in sealed vessels/pipes with no practical exposure points or it is under full and controlled observation).	1 – 2

Volume

Measure of the amount of product that could be affected if a contaminant was successfully added at a particular point

Volume Scale

(What is the impact of a single contamination at this point?)

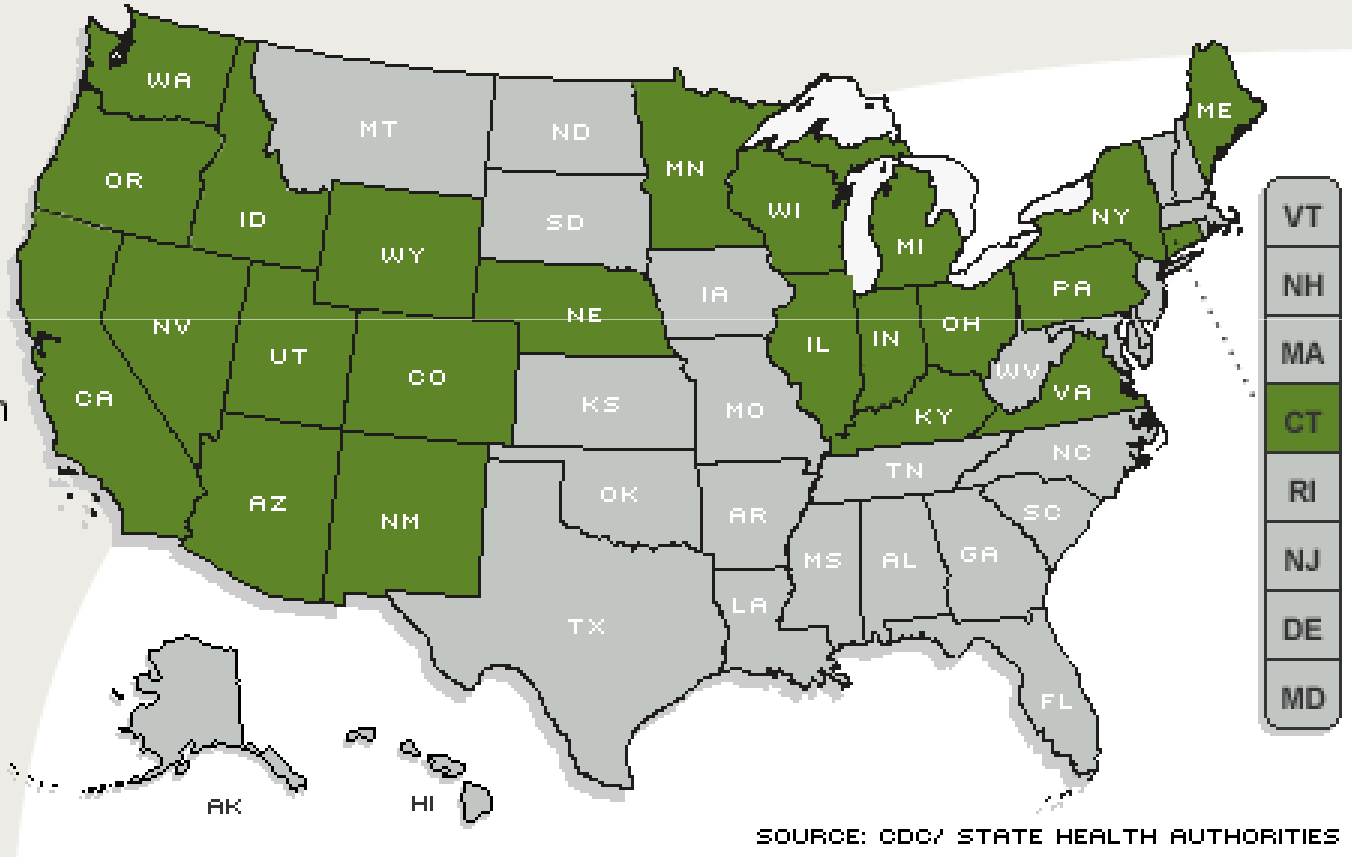
CRITERIA	SCALE
Very Large Volume Impact (e.g., a single instance of contamination at this point would contaminate multiple days of the production of this line).	9 – 10
Large Volume Impact (e.g., a single instance of contamination at this point would contaminate multiple shifts of the production of this line).	7 – 8
Medium Volume Impact (e.g., a single instance of contamination at this point would contaminate one shift or less of the production of this line).	5 – 6
Small Volume Impact (e.g., a single instance of contamination at this point would contaminate two hours or less of the production of this line).	3 – 4
Low Volume Impact (e.g., a single instance of contamination at this point would contaminate 30 minutes or less of the production of this line).	1 – 2

U.S. Food and Drug Administration
Protecting and Promoting Public Health

2006: E. coli and spinach

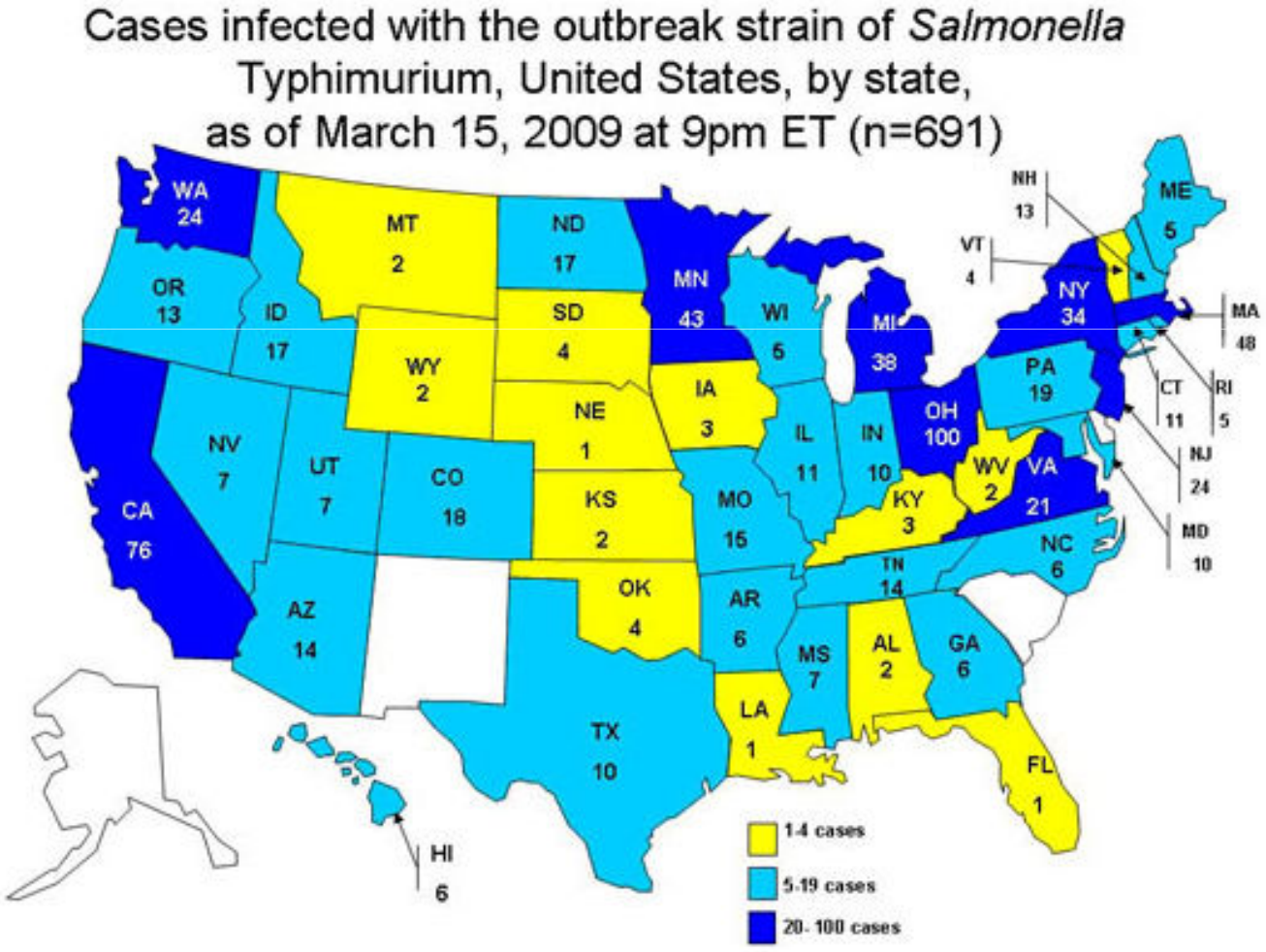
E. coli outbreak
The Food and Drug Administration is warning consumers not to eat any fresh spinach. The leafy vegetable has been linked to an E. coli outbreak that has sickened more than 140 people in 23 states and is blamed for the death of a woman in Wisconsin. The FDA urges consumers to throw out all fresh spinach because even a thorough washing won't get rid of the bug.

■ Confirmed E. coli cases.

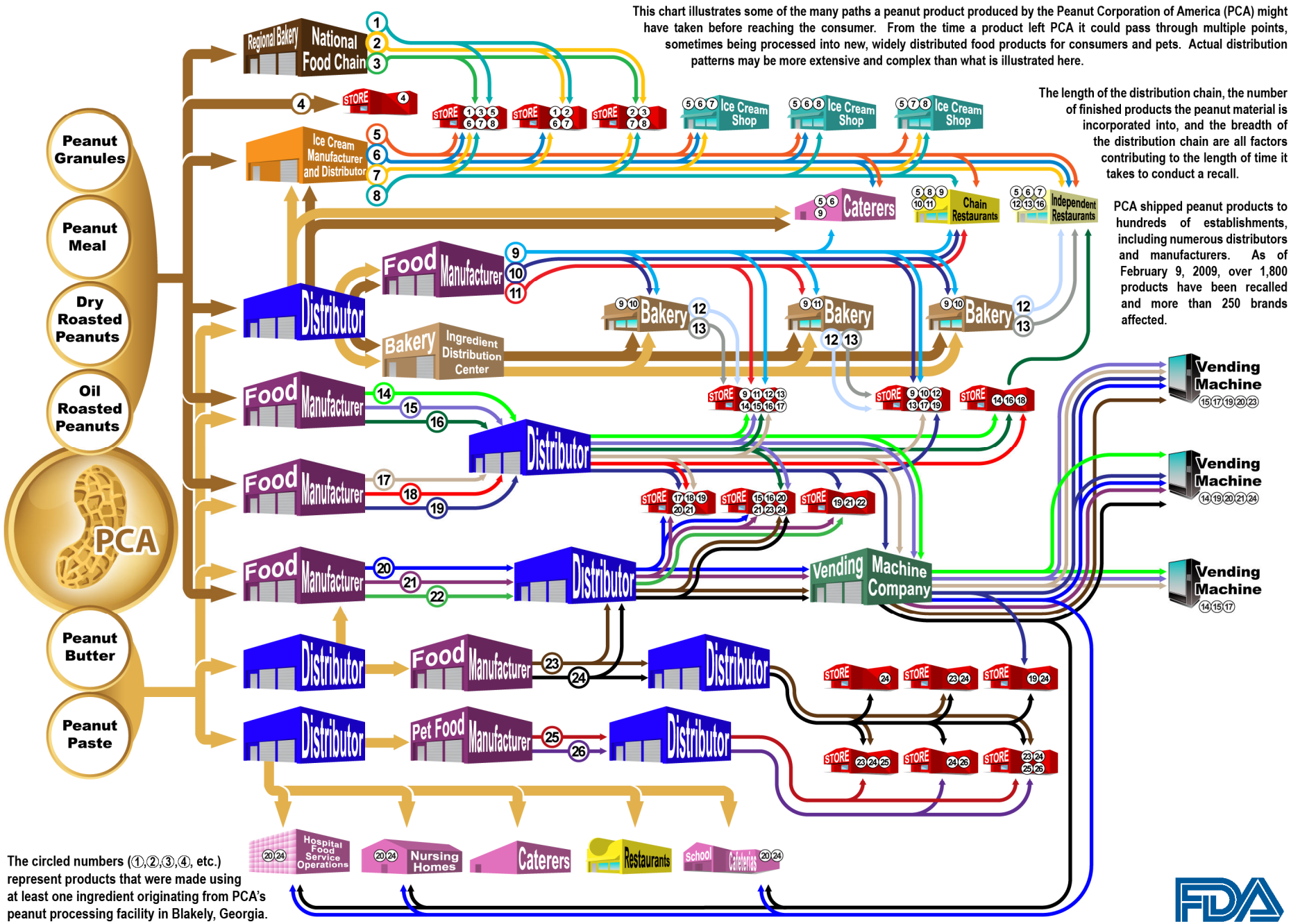


- Demonstrates vulnerability: efficient and widespread distribution

2009: Salmonella and peanuts



Simplified Peanut Product Distribution Pattern From Peanut Corporation of America (PCA) to Point of Sale



Factors that contribute to high VA scores

- Serving size - sufficient agent delivery
- Short shelf life
  - rapid turnaround at retail, rapid consumption
- Ability to disguise the contaminant
- High impact consumer = children, elderly
- Lack of processing/preparation steps to inactivate, reduce agent
- Uniform Mixing

Factors that cause high VA scores

- Large batch size
  - high number of contaminated servings, potential affected individuals
- Uniform mixing
  - efficient agent distribution into servings

Factors that cause high VA scores

- Easy access
  - Ability to reach process at high risk points
- Poorly supervised food production areas, processes
- Widely disseminated foods
  - Efficient food distribution = potential for mass casualties
  - Decreased chance of public health recognition, intervention

Vulnerability Assessment Software

- No cost, downloadable
- Includes agriculture and manufacturing modules
- Focus on
  - **V**ulnerability and **A**ccessibility

www.fda.gov/fooddefense

Where to start

- Select a person or team to be responsible
  - Answer the questions in the assessment to help determine which parts of the facility may be more vulnerable
  - Consider both potential internal and external threats
  - Keep results confidential so that they do not provide a roadmap for future attacks

Thank you

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