PRODUCE SAFETY & FSMA: UNPACKING THE PROPOSED RULE

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CSPI is a bi-national consumer advocacy organization founded in 1971 by Michael Jacobson, Ph.D. Focuses on nutrition, health, and food safety. Publishes the award-winning *Nutrition Action Healthletter*. Represents over 850,000 members in the United States and Canada. Accepts no government or industry funding.
Outbreaks erode confidence, and over time reinforce concerns about safety.

Consumers rarely differentiate between producers of similar produce items when responding to news of an outbreak.

Safety during production is a responsibility of the produce industry, but government oversight is vital to create a level-playing field that protects the whole industry.
IMpact of Outbreaks on Markets

- Lessons from the tomato warning of 2008
  - One-third of those who ate tomatoes before the warning stopped after hearing it
  - Almost half of respondents could not identify the affected tomatoes
  - 23% had not returned to eating tomatoes at the time of the interview

  Source: Rutgers Food Policy Institute 2009

- Spinach recall of 2006
  - 71% stopped buying spinach and 16% stopped buying lettuce

  Source: Food Marketing Institute 2007

Figure 1. Weekly retail purchases of spinach in bags

Source: FreshLook Marketing
WHO CONSUMERS HOLD RESPONSIBLE FOR SAFETY

- Ranking responsibility for ensuring safety
  - 41%: companies that wash and package produce
  - 41%: government food safety agencies
  - 36%: food growers/farmers

Sources: July 2008 Pew Food Safety Survey

- Government oversight strongly backed
  - 89% support more government authority to require safety measures
  - 90% support federal standards for produce growers

Sources: July 2009 Hart Research
CSPI’S FOOD SAFETY ATTRIBUTION DATA

CSPI maintains an outbreak database and publishes the annual report, *Outbreak Alert!*, a source of useful information for:

- Food safety risk rankings
- Government risk assessments and regulatory proceedings
- Industry hazard analysis
PRODUCE-RELATED OUTBREAKS & ILLNESSES

Produce Outbreaks

- Outbreaks N=696
- Illnesses N=25222

Graph showing the number of outbreaks and illnesses from 2001 to 2010.
PRODUCE V. OTHER FOODS
AVERAGE ILLNESSES PER OUTBREAK 2001-2010

Outbreaks (N=4,224)  Illnesses (N=106,592)
TOP HAZARDS IN PRODUCE

Pathogens in Produce, 2001-2010, Outbreaks=667

- Norovirus, 384
- Salmonella, 135
- Bacillus, 18
- Campylobacter, 16
- Clostridium, 23
- E. coli, 46
- Shigella, 11
- Staphylococcus, 12
- Calicivirus, 1
- Cyclospora, 9
- Giardia, 1
- Hepatitis A, 10
- Listeria, 1
- Shigella, 11
- Listeria, 1
- Bacillus, 18
- Campylobacter, 16
- Clostridium, 23
- E. coli, 46
- Norovirus, 384
- Salmonella, 135

Source: CSPI Outbreak Alert! Database
## HOW TO TARGET TESTING

### Riskiest Produce 2001-2010

<table>
<thead>
<tr>
<th>Produce</th>
<th>Outbreaks</th>
<th>Illnesses</th>
<th>Pathogen #1</th>
<th>Pathogen #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greens-based salad</td>
<td>221</td>
<td>5,373</td>
<td>Norovirus</td>
<td>E. coli</td>
</tr>
<tr>
<td>Lettuce</td>
<td>117</td>
<td>3,455</td>
<td>Norovirus</td>
<td>E. coli</td>
</tr>
<tr>
<td>Fruit salad and mixed fruits</td>
<td>51</td>
<td>1,911</td>
<td>Norovirus</td>
<td>E. Coli</td>
</tr>
<tr>
<td>Tomatoes</td>
<td>41</td>
<td>4,859</td>
<td>Salmonella</td>
<td>Norovirus</td>
</tr>
<tr>
<td>Salsa</td>
<td>41</td>
<td>1,539</td>
<td>Norovirus</td>
<td>Salmonella</td>
</tr>
<tr>
<td>Melon</td>
<td>29</td>
<td>1,593</td>
<td>Salmonella</td>
<td>Norovirus</td>
</tr>
<tr>
<td>Sprouts</td>
<td>29</td>
<td>872</td>
<td>Salmonella</td>
<td>E. coli</td>
</tr>
<tr>
<td>Chili Peppers</td>
<td>7</td>
<td>1,662</td>
<td>Salmonella</td>
<td>Clostridium</td>
</tr>
</tbody>
</table>

**Outbreaks N= 536**    **Illnesses N= 21,264**

Source: CSPI Outbreak Alert! Database
As requirements under FSMA languish, other entities have developed guidelines and standards. For example:

- Codex 2003 Code for Fresh Fruits and Vegetables
- Western Growers Guidelines for Lettuce and Leafy Greens
- AFDO Model Code for Produce Safety

Consumer-facing certification programs may follow, and may focus on more than only food safety: such as environmental sustainability and labor...
Food Safety Modernization Act will require SCIENCE-BASED MINIMUM STANDARDS, for:

- Soil amendments
- Hygiene
- Packaging
- Temperature controls
- Animals
- Water

After 2 long years of waiting...they’re here!
What is covered?
- Commodity specific based on outbreak data
- Commodity specific based on commodity characteristics
- Market channel approach
- Integrated approach: likelihood of contamination posed by agricultural practices applied to the crop, while exempting the lowest-risk produce

Integrated approach is most likely the best option... but we do have some concerns
- List is “exhaustive” and etched in regulatory stone
- List contains some items that we believe are inappropriate:
  - For example, kale, beets, and potatoes
Qualified Exemptions

- FDA should make clear that inspectors will check records to ensure that you are a qualified farm; a failure to have records creates a presumption that you are not qualified for an exemption.
- State law still applies: although some question as to which state law applies across state laws within the mileage range.
- Strong incentive to compliance, since causing problems = loss of exemption.

Labeling of Produce from Exempt Farms

- Recognizing that the statute requires a single label with name and business address of farm...
  - There may be an argument that there is a deficiency in the statute that FDA should correct, by requiring additional language on that single label to clarify for consumers that the produce was grown on a farm “Not Subject to Federal Food Safety Regulations”
**PLANS, RECORDS**

- **Written plan not required**
  - CSPI believes at the very least, farms should have a written hazard analysis
    - Shows that farms are considering hazards that directly confront their operation, whether those are unique within the farming community or common to all;
    - Provides a farm-specific roadmap for inspectors to follow when assessing what each farm is doing to comply

- **Alternatives (aka Exceptions that Could Swallow the Rule)**
  - FDA proposing to allow farms to create alternative compliance methods for certain things: for example, testing water, composting, application intervals.
  - While farms must theoretically have a scientific basis for the alternative... we’d like more than that:
    - Formal notice of intent
    - Periodic notice from agency of alternatives, success, etc.
    - Trigger for withdrawal of acceptability
Looking closely at requirements for testing
- Environmental testing: just for Listeria, or for other pathogens of concern?

“Standards Directed to Sprouts and Other High-Risk Products”
- Are sprouts the only commodity?

Monitoring for Compliance
- Without enforcement, these standards are meaningless.
- FDA needs to develop a robust program similar to the one proposed for manufactured food... may include working with state ag departments and others to ensure compliance.
CSPI’s position on farm worker issues writ large:
- Both a human rights and a food safety issue
- Intend to take the requirements for farm worker health and hygiene very seriously, including, for example:
  - Definition of “readily accessible” toilet facilities
  - Decision to exempt toilet provisions for employees working in-field for 3 hours or less
  - Additional issues that impact whether farm workers can be reasonably expected to carry out food safety oversight tasks during harvest.
  - Timelines for implementation of farm worker-related provisions...
OVERALL

- The rule looks good!