INSTITUTE FOR AGRICULTURE AND TRADE POLICY

# Three approaches to regulating agri-nanotechnology

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# Three approaches: an overview

- **Statement of policy interests**: IATP as co-petitioner in ICTA et al vs. EPA (2008): www.nanoaction.org

1. **Current and dominant approach**: voluntary regulator guidance to industry, voluntary submission of EHS data; industry determination of CBI and GRAS; commercialization without regulation
2. **Emerging approach**: mandatory submission of data towards risk assessment; negotiated CBI and GRAS determinations; commercialization with limited regulatory implementation (WTO "necessary")
3. **Public/environmental health approach**: mandatory submission per tiered risk (REACH: Wolf et al); regulator CBI and GRAS determination; commercialization after robust risk analysis and per regulatory capacity to implement and enforce rules

# Current and dominant approach: advantages and disadvantages

- Advantage: voluntary approach least burdensome to industry and investors (no "regulatory risk" to commercialization)
- Advantage: no pre-market safety assessment requirements enables strongest liability prevention strategy: ambiguity about legal responsibility for safety
- Disadvantage: voluntary materials stewardship programs has failed to produce data needed for risk analysis (U.S. EPA)
- Disadvantage: no data, no Risk Analysis (RA), no standards; no labeling; consumer distrust; possible loss of sales, at least for foods with Engineered Nano-Materials (ENMs)

# Emerging approach: advantages and disadvantages

- Advantage: Mandatory submission of data enables start of methods for *in situ* characterization and detection of ENMs, currently lacking (FAO/WHO Expert Meeting report, 36)
- Advantage: enables regulator knowledge of "biotransformation of nanoparticles after oral administration," currently lacking (FAO/WHO)
- Disadvantage: trade migration to jurisdictions without mandatory submission (UK government)
- Disadvantage: reduces industry CBI/GRAS control

# Public/environmental/occupational health approach: advantages/disadvantages

- Advantage (in addition to 'emerging approach'): Tiered risk approach to RA enables targeted data mandatory submission; more efficient use of regulatory resources and more robust RA
- Advantage: better risk communication and greater likelihood of consumer acceptance
- Disadvantage: asynchronous difficulties in implementing robust RA
- Disadvantage: threat of WTO challenge, e.g. REACH, labeling of nano-products

# Problems common to 3 approaches

- Nanotech challenges to present regulatory implementation and enforcement capacity problems, e.g. sampling methodology, import inspection and testing
- Cost/benefit analysis vs. risk analysis paradigm
- CBI vs. consumer/ user right to know
- International standards harmonization vs. standards enforcement (3rd party certification)
- Risk perception management vs. technology assessment

# Domestic regulatory capacity limits: e.g. U.S. Food and Drug Administration

(http://oig.hhs.gov/oei/reports/oei-02-08-00080.pdf)

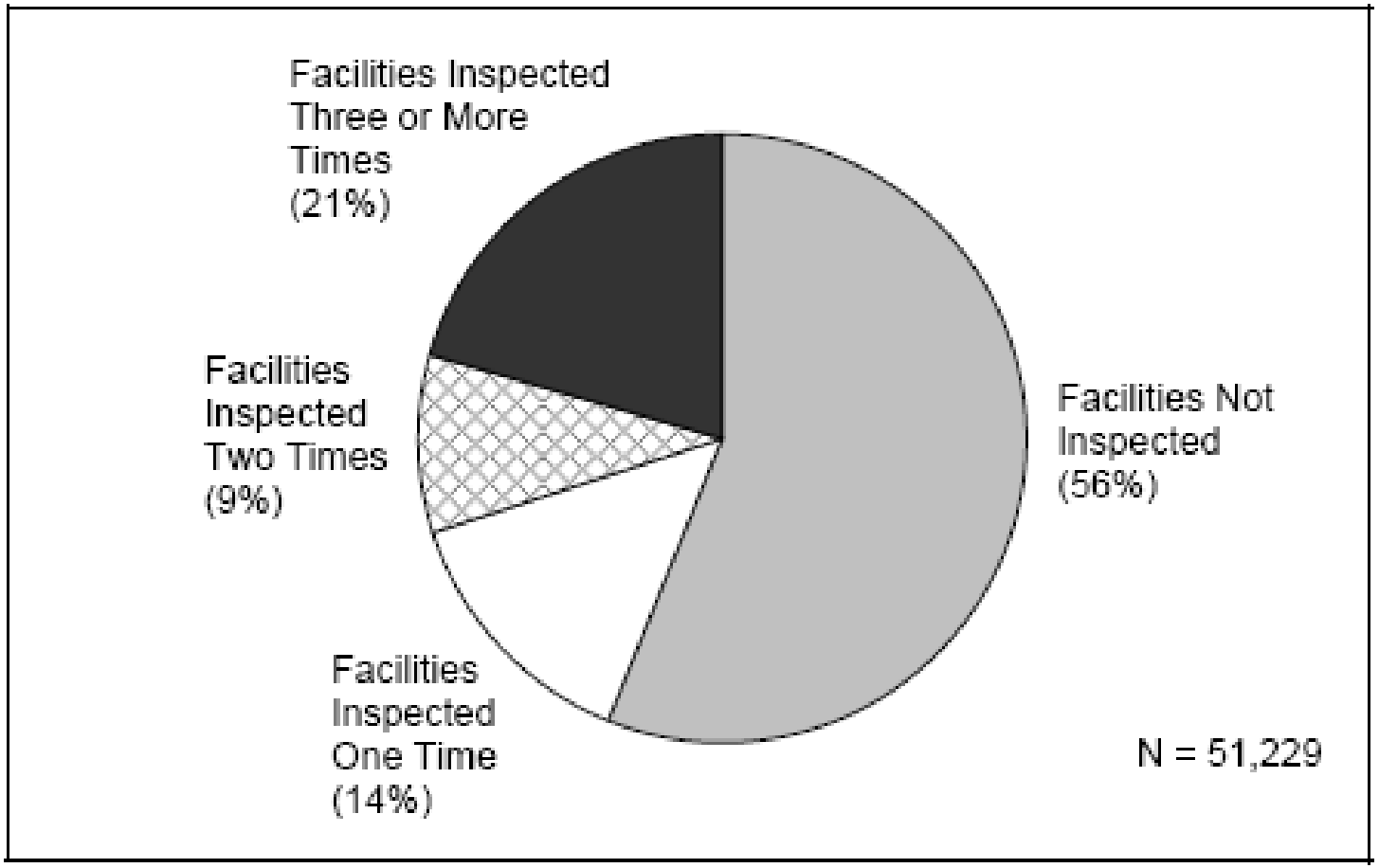
**Table 2: High-Risk Food Facilities Inspected by FDA, FYs 2004–2008**

| FY | Number of High-Risk Food Facilities | Number of High-Risk Food Facilities Inspected | Percentage of High-Risk Food Facilities Inspected |
|---|---|---|---|
| 2004 | 8,102 | 6,241 | 77% |
| 2005 | 8,330 | 5,547 | 67% |
| 2006 | 8,347 | 5,664 | 68% |
| 2007 | 8,568 | 5,535 | 65% |
| 2008 | 8,667 | 5,460 | 63% |

Source: OIG analysis of FDA data, 2009.

# Domestic regulatory capacity limits: e.g. U.S. Food and Drug Administration 2

**Figure 1: Number of Inspections per Food Facility Between FYs 2004 and 2008**




Source: OIG analysis of FDA data, 2009.

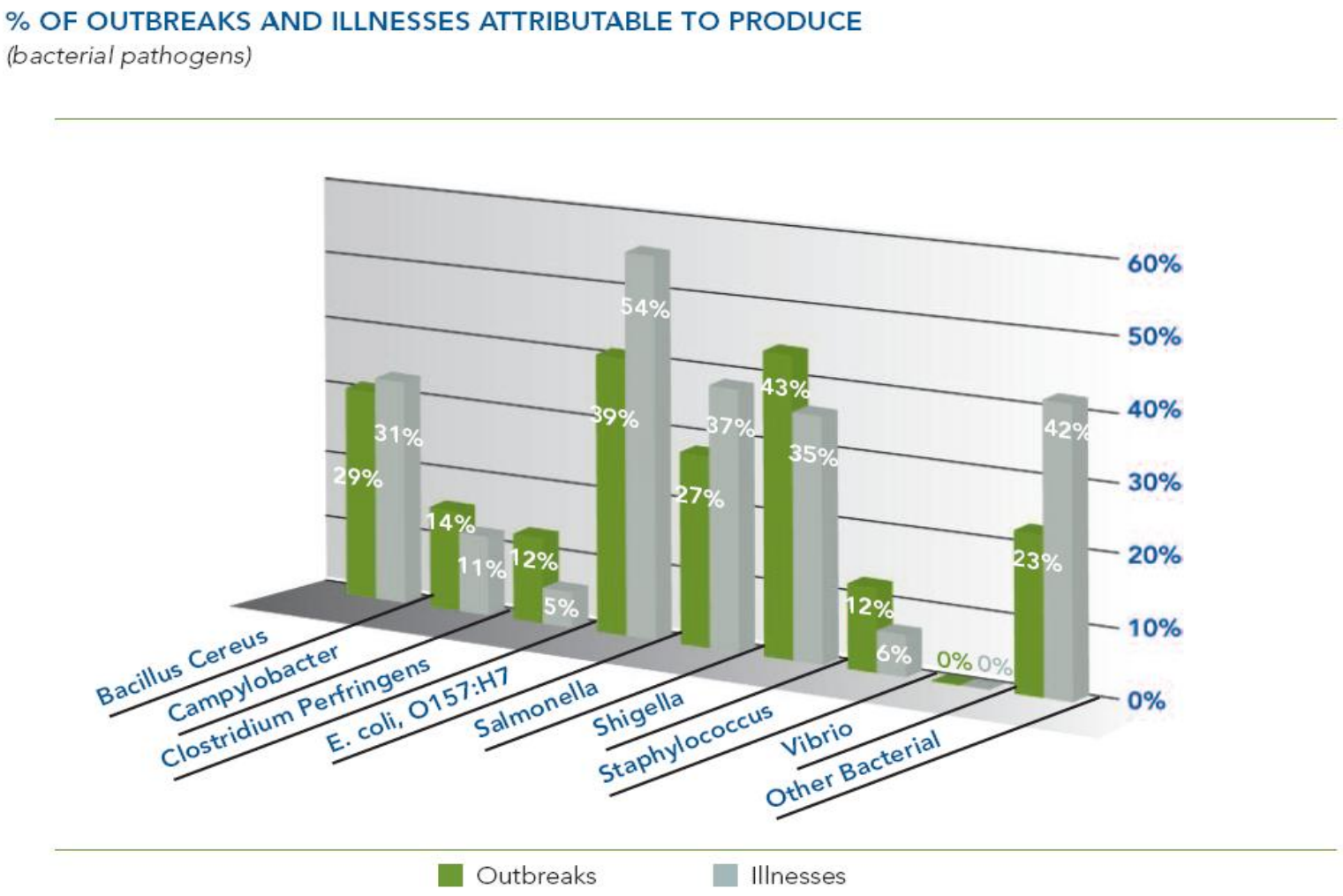
# Import regulatory capacity limits: e.g. U.S. Food and Drug Administration

- About 200 inspectors at about 300 ports of entry to re-inspect all products under FDA authority (B. England, former FDA administrator to Congress, 11/07) http://www.tradeobservatory.org/library.cfm?refID=102785
- "Appallingly low" rate of inspection and testing (*FDA Science and Mission at Risk*, 11/07)
- Difficulty of implementing equivalency agreements, e.g. U.S.-China with 3rd party certification of export facilities (http://www.tradeobservatory.org/library.cfm?refID=102837)
- Continue current practices or create nanotech product specific inspection and testing capacity?
- Challenge of paying for food safety, e.g. training and equipment for inspection and testing of agri-nano products

# Estimated annual costs of acute foodborne illness under FDA authority (3/10): a challenge for agri-nanotech (http://www.producesafetyproject.org)

- $152 billion/year: medical, productivity, lost life expectancy
- $96 billion due to "unknown [i.e. undetermined] agents" (weak traceability, recall capacity)
- Challenge: criteria for nanotech of targeting known vs. undetermined etiologies (FAO/WHO experts: no epidemiological studies for ENMs in food)
- Cost benefit analysis: e.g. U.S Office of Management and Budget model, priority of cost benefit over risk-based rules
- Jurisdictional challenge of applying nanotech solutions in farm to fork systems: e.g. Pathogens of animal origin contaminating produce

# Sample of animal pathogens in produce



# Some parting challenges

- Confusing RA with cost/benefit projections: e.g. "potential risks and benefits of a pesticide product must be assessed equivalently, so as to avoid any prejudicial impact that could thwart the promise and benefit this [nano]technology offers." (Linda Bergeson, Bureau of National Affairs, 5/17/10)
- GRAS determinations: distinguishing ENMs from natural nanoparticles in dietary exposure assessment
- Organizing technology and benefit assessments that are not risk perception management tools or just dialogues with industry
- Changing perception of regulation as a barrier to sustainable markets and investment