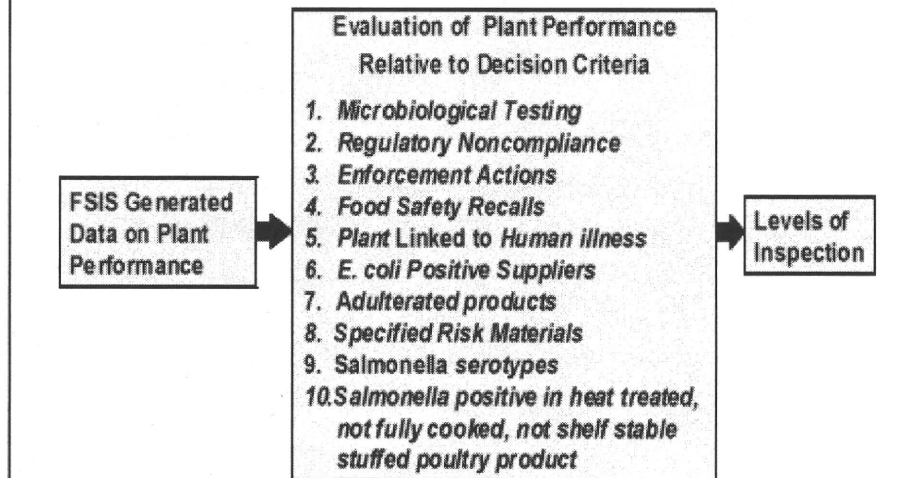


Rationale for Decision Criteria Selection

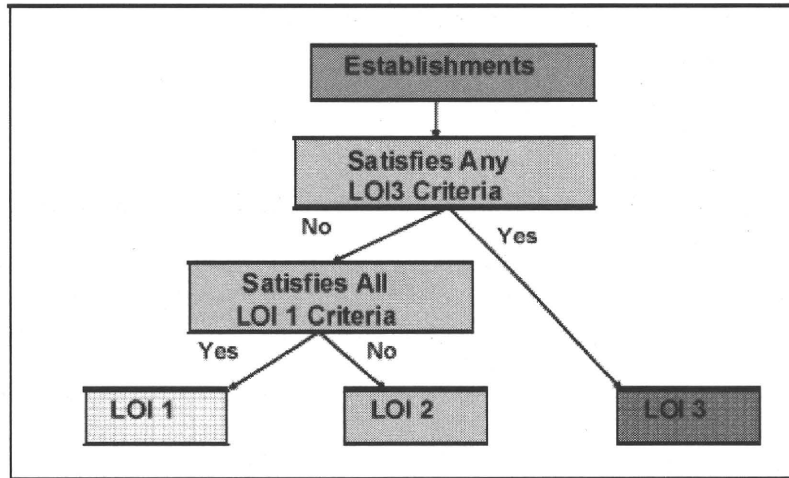
- The decision criteria identify establishments that:
 - Have a higher probability of causing human health impacts
 - Are not in compliance with federal HACCP laws and regulations
 - Are performing worse than their peers with respect to HACCP verification activities.

5

Decision Criteria Used to Place Establishments into Levels of Inspection



Decision Tree Used to Categorize Establishments into Levels of Inspection



7

Properties of Decision Criteria

- LOI 3 establishments have the highest potential to cause public health impacts
- LOI 1 establishments have low potential to cause public health impacts and are performing much better than their peers with respect to HACCP verification procedures
- LOI 2 establishments are in between

8



LOI Activities

- Establishments in LOI 3 will receive for cause FSA
- Establishments in LOI 1 and LOI 2 will receive routine FSAs over a 4 year period
- Establishments in LOI 3 and LOI 2 will receive a routine HAV once a month*
- Establishments in LOI 1 will receive a routine HAV once a quarter*

* Establishments with a prompt will receive a for cause HAV

9



Scientific Justification for Decision Criteria

- The decision criteria can be linked to public health impacts through existing quantitative risk assessments. For example
 - The FSIS *E. coli* risk assessment (2001) found that even one or two *E. coli* O157:H7 positives in raw ground beef increases the risk of illness and death from *E. coli* O157:H7, especially among children aged 0 to 5
 - The FSIS Lm risk assessment (2005) found that increased levels of Lm in RTE products at retail increases risk of illness and death from Lm
 - The Harvard Risk Assessments (2005, 2006) for Bovine Spongiform Encephalopathy show that removing SRMs from animals over 30 months of age almost completely eliminates human exposure and risk

10



Cut-points Used to Identify Plants Performing Worse Than Their Peers

- *Salmonella* cut points
 - A different cut point is used for each raw product category
 - Plants in *Salmonella* verification Category 3 are placed in LOI 3
 - Plants with a *Salmonella* positive rate less than one standard deviation above the mean *Salmonella* percent positive rate for each product it produces are placed in LOI 1
- W3NR cut points
 - Plants with a W3NR rate less than the mean W3NR rate of all plants are eligible to be placed in LOI 1
 - Plants with a W3NR rate between the mean W3NR rate for all plants and one standard deviation above the mean are placed in LOI 2
 - Plants with a W3NR rate greater than one standard deviation above the mean are placed in LOI 3

11



LOI Results as of Dec 31, 2008

LOI Category	Number Plants	% Plants
LOI 1	3650	70.9
LOI 2	1311	25.4
LOI 3	191	3.7

Plant Type	% LOI 1	% LOI 2	% LOI 3
Processing Only	74.5	22.6	2.9
Processing/Slaughter	54.8	38.4	6.8
Slaughter Only	65.6	27.8	6.6

12



Hazard Analysis Verification Objectives

- Verify Hazard Analysis addresses all relevant hazards for product/process/intended use
 - Ensure establishment has support for decisions made in Hazard Analysis
 - Ensure prerequisite programs are implemented as designed.
- * Inspectors will refer questions regarding Hazard Analysis design to supervisory channels.

13



Hazard Analysis Verification Prompts

Prompt	Data
Public Health NR	All W3NR citations excluding 416.4(d), 416.5(a), 416.15(b), 381.65(e)
Fecal Contamination NR	Citation of 381.65(e) or 310.18
Sanitation SOP NR	Citation of 416.14 or 416.12
Possible Supplier of 0157:H7 Positive Trim	Establishment entry into STEPS predecessor in PHIS.
Canning NR	Citation of 318.301 – 318.309

- Only one HAV will be directed within a 30 day period.
- A prompted HAV will replace a routine HAV in the same 30 day period.

14

Public Health Decision Criteria

Next Steps

- Revise report per NAS recommendations (e.g. terminology clarification)
- Conduct analyses to develop predictive relationships between criteria and future establishment behavior
- Use criteria for FSA scheduling in Summer 2009

- (6) Wagner, R. 2009. FDA' S Current Approach to Risk Based Domestic Inspection Planning.

FDA'S Current Approach to Risk Based Domestic Inspection Planning

Roberta F. Wagner, Director, Office of Compliance
Center for Food Safety and Applied Nutrition (CFSAN)
March 24, 2009

Topics to be Covered

- FY2002 High Risk Food Categories "Document"
- FY2007 Qualitative Risk Ranking of Food Product/Hazard Combinations
 - FY2008 Domestic Priorities List
- FY2008 Risk Ranking of Domestic Food Manufacturers
 - Component of the FY09 Domestic Inspection
- FY2009 Risk Ranking of Domestic Food Manufacturers (Part 2)
- Related Risk-based Initiatives
 - Research Triangle Institute (RTI)
 - CDC Attribution Data Collection

2

Domestic Inspection Prioritization Prior to 2008

Tools Provided to the ORA Field Organization to Assist with Domestic Firm Selection for Inspections

- **FY2002 High Risk Food Categories Document**
- **Compliance Programs**
- **CFSAN Program Priorities Lists**

3

FY2002 High Risk Food Categories “List”

- Document developed through elicitation of experts in CFSAN; those knowledgeable of hazards associated with specific food commodities
- Hazards and products identified separately
- Document circulated to ORA field staff as a resource for workplanning purposes
- Document defines "High Risk Foods", in part, as those that:
 - May contain hazards FDA believes present from their consumption a higher potential to cause harm
 - Contain bacterial or viral pathogens; biological toxins; allergenic substances; BSE infective material
 - Foods that have first priority for inspectional purposes

4

FY2002 High Risk Food Categories: HAZARDS

1. Bacterial Pathogens
2. Viral Pathogens
3. Biological Toxins
4. Parasites
5. Allergenic Substances
6. TSE Infective Materials
7. Infant Formula/Medical Foods

5

FY2002 High Risk Food Categories: FOODS

- Infant formulas, all processes and packaging
- Medical foods, all processes and packaging
- Seafood
- Produce
- Eggs
- Dairy
- Low acid canned foods/Acidified foods
- Ready to eat (RTE) foods
- Foods at risk for undeclared allergens
- Dietary supplements containing BSE infective materials

6

CFSAN Establishes "High Risk Workgroup" 2007

- *Workgroup tasked with updating the FY2002 High Risk Food Categories List*

CFSAN "High Risk Workgroup" Process

- Established worksheets to capture data from CFSAN program offices on product/hazard combinations of most concern relative to public health safety
- Performed qualitative risk ranking of product/hazard combinations based on data received from CFSAN program offices
 - Not all possible product/hazard combinations were considered; only those identified as a higher concern by CFSAN experts
- Created FY08 CFSAN Domestic Risk-Based Priorities List

What's New About the FY08 "High Risk" List ?

- **New title:** "CFSAN's Domestic Risk-based Priorities List"
- **New format:** Links product(s) with hazard(s)
- **New information:** Why a product/ hazard is on the list; conditions under which the hazard is likely to occur in the product
- **New process:** Risk ranking approach

9

Worksheet Questions

- What evidence links the hazard with the product?
- Where is the hazard introduced, prevented or eliminated in the farm-to-table continuum?
- What is the likely exposure to consumers from hazard/product?
- What are the consequences of exposure?
- What is the profile/compliance history of the industry associated with the product/hazard combination?
- What additional information should be taken into account when prioritizing the product/hazard combination?

10

Sources of Data (Examples)

- **Outbreak investigation reports**
- **Consumption surveys (e.g., NHANES)**
- **Surveillance data (e.g., CDC)**
- **Recall data**
- **Inspection reports (e.g., FACTS)**
- **Scientific journal publications**
- **Expert opinion**

11

Risk Defined

Risk is considered a function of:

- the **likelihood** of hazard in a product consumed/used to cause the health effect
- the **severity** of health effect

The focus is on public health outcomes

12

Relative Risk Ranking- Defined

- Relative risk relates the risk of one product to another (i.e., not absolute values)

- Relative risk ranking of product/hazard pairs

- Based on likelihood of hazard X severity of illnesses
- Risk binned into 3 categories: higher, medium, lower

		Likelihood		
		Unlikely (no illnesses)	Likely (some illnesses)	Very likely (many illnesses)
Severity	Moderate (mild)	lower	lower	medium
	Serious (incapacitating)	lower	medium	higher
	Severe (life-threatening)	medium	higher	higher

13

Examples: Outcome of Risk Ranking

Higher Category:

- Products: Produce (Lettuce, Leafy greens, Tomatoes, Cantaloupes, Green Onions, Herbs, Sprouts)
- Hazards: *E. coli* 0157:H7, *Salmonella* spp, Hepatitis A virus, Shigella, *Cyclospora cayentanensis*
 - Additional Information: Multiple hazards. Potential for fatal illness. Frequent outbreaks with widespread illnesses. Frequent consumption by all sections of the population
 - Conditions under which hazard is likely to occur: Hazards may be introduced by insanitary conditions at the farms, during product packing operations, or during fresh-cut processing operations
 - Anticipated Field Activities: Surveillance inspections of processors. On farm inspections as per CFSAN directed assignments in follow-up to foodborne outbreaks

Medium Category:

- Product/Hazard: Catfish (Farm-Raised)/Unapproved Use of Veterinary Drugs

Lower Category:

- Product/Hazard: Seafood Stuffing Products/*S. aureus* growth and toxin formation

Risk Ranking to Identify High Risk Domestic Food Manufacturers for FY09 Inspectional Coverage

• FOOD MANUFACTURERS IN FDA'S OFFICIAL ESTABLISHMENT INVENTORY EACH RECEIVED A RISK SCORE BASED ON THEIR ASSOCIATION WITH THE FOLLOWING RISK CATEGORIES (FY04, FY 05, FY 06 DATA USED):

- CLASS I RECALLS (CFSAN DATABASE)
- SERIOUS ADVERSE REACTIONS (CAERS)
- OUTBREAKS (CDC and CFSAN Data)

** ELEVATED SCORE IF HANDLE PRODUCT/HAZARD COMBINATION IDENTIFIED ON FY2008 DOMESTIC PRIORITIES LIST AS DETERMINED BY HIGH RISK FLAG ASSOCIATED WITH FIRM

15

Risk Ranking to Identify High Risk Domestic Food Manufacturers for FY09 Inspectional Coverage

• **Data Analysis**

- Statistical analysis to rank according to recall, outbreak, and adverse event report data from 2004, 2005 and 2006
- Apply a scoring algorithm from these rankings to individual food firms

16

Risk Ranking to Identify High Risk Domestic Food Manufacturers for FY09 Inspectional Coverage- Example

Firm X: Risk Ranking/Point Score = 10

Industry Codes	03	12	16	24	28	High Risk Marker	Totals
Outbreak		1		1	1		3
Adverse Event		1	1				2
Class 1 Recall		1	1	1	1		4
High Risk Marker						1	1

17

Risk Ranking to Identify High Risk Domestic Food Manufacturers for FY10 Inspectional Coverage

- Ranked firms according to association with class 1 recalls, outbreaks and adverse events using existing algorithm
- Elevated scores for firms never inspected
- Elevated scores for firms handling produce, seafood and edible nuts and oils
- Overlaid with Compliance History of firms
 - Firms with 4-5 year VA/OAI inspection history elevated to “high risk” firms

18

Future Data Sources for Risk Ranking of Domestic Food Manufacturers

- Include such things as the following:
 - Financial viability of the firm
 - Number of employees
 - Criminal activity associate with the firm

**** Contract in place to enhance FDA's
domestic official establishment data**

19

FY09 Domestic Inspection Workplanning Model

Category 1

Risk Based Performance Goal Inspections

* Firms identified through domestic food
manufacturer risk ranking exercises

Category 2

Intervention and Response Inspections/Investigations

* Next Slide

Category 3

Preventive Monitoring Inspections

*Low Risk Industry Blitzes

20

Category 2: Intervention and Response

- Reinspection of VAI/OAI Firms
- For Cause Inspections/Investigations
 - Outbreak Investigations
 - Inspections in Response to Natural Emergencies
 - Inspections/Investigations Directed in Response to Recalls
- Compliance Driven National or Local Inspection Assignments
 - Based on objectionable conditions/violations uncovered during routine inspections, sample analyses, information from States or other sources

21

Categories of Domestic Work

- Each of three categories of work has the same weight; it is of equal importance
- It is just as important to satisfy the high risk food inspection performance goal as it is to perform intervention and response activities and to perform baseline monitoring of low risk establishments

This is a culture shift.....

22

Risk Based Inspectional Strategies

- Concurrent with risk based workplanning initiatives, CFSAN and ORA are reviewing our inspectional strategies, and updating these where appropriate
 - Environmental sampling

23

CDC Attribution Data

- Working with CDC to attribute pathogens to specific foods and identify where in the production life cycle the foods become contaminated
 - Will use attribution data to drive risk decisions. Specifically, assist in further defining which food/pathogen pairs present the highest risk

24

Contract with RTI

- Comparative risk assessment of produce/ hazard pairs (qualitative)
- Leafy greens/ *E. coli* – quantitative risk assessment farm to fork
- Inventory and evaluation of methods/ tools for risk ranking and risk prioritization
- Comparative risk assessment of 50 commodities/ 20 hazards (quantitative) using the tool, iRISK (available at www.foodrisk.org)

25

(7) アンケート調査票

食品衛生監視員による食品衛生監視手法の高度化に関する研究
アンケート調査票

※本調査は、わが国における食品衛生監視の効果を、具体的な食品の製造加工プロセスに沿って整理することを目的としております。つきましては、日ご
る皆様が重視している点や、監視活動のポイントや、監視活動の内容についてご回答いただければ幸いです。

問1 以下に示した「鶏の唐揚げ」の製造・加工プロセス（別添1）および重要管理点（CCP）についてお答えください。

- (1) それぞれのCCPについて、普段どのような監視活動を行っていますか。下表の回答欄にご記入ください。特に実施していない場合は、空欄で結構です。
- (2) また、それらの監視活動について、その重要性を5段階評価（5が最重要）するとどれにあてはまりますか。主観で結構です、数字を○で囲んでください。
- (3) さらに、監視活動の際、どのような基準・指標で可否判断していますか。下表の回答欄にご記入ください。

製造加工プロセス	CCP	(1) 監視活動	(2) 評価	(3) 判断基準
① 原材料の受入れ 原材料	a. 2～3℃で冷蔵保存【鶏肉】		5 4 3 2 1	
	b. 原材料受入基準の設定・遵守 c. 受入検査の実施 d. 検査証明書の提出請求		5 4 3 2 1	