Lettuce, EHEC and Irrigation Water: Apply FDA-iRISK for Rapid Risk Assessment

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Food and Drug Administration

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Outline

- Purpose of Lettuce-EHEC risk assessment
  - Risk management questions
  - A case study applying the FDA-iRISK tool
- Results from the risk assessment
- Concluding thoughts

Purpose of Lettuce-EHEC Risk Assessment

- Support proposed produce regulation
- Estimate effectiveness of certain provisions of the proposed produce regulation
- Apply FDA-iRISK for rapid risk assessment

Food Safety Modernization Act

"I thank the President and members of Congress for recognizing that the burden that foodborne illness places on the American people is too great, and for taking this action."

Margaret A. Hamburg, M.D.,
Commissioner of Food and Drugs

FSMA enacted in 2011 requires FDA to develop regulations that set risk-based standards for produce safety.

Risk Management Questions

Develop lettuce/ enterohemorrhagic *E. coli* (EHEC)/ irrigation water scenarios to address

1. What is the probability of EHEC illness from fresh-cut lettuce as a result of irrigation water that contains varying levels of *E. coli* ?
2. What is the impact of changing practices so that all lettuce is grown in compliance with the irrigation water provisions of the proposed regulation?
3. ...

Application of FDA-iRISK Tool

- FDA-iRISK previously developed in collaboration with experts within and outside government
  - undergone external peer review
  - templates and library to draw from
  - suitable for addressing the risk management questions

Brief Introduction of FDA-iRISK: a Comparative Risk Assessment Tool

Available at http://irisk.foodrisk.org

Public version released October 4, 2012, via JIFSAN www.foodrisk.org

FDA-iRISK: Novel Capacities

- Quickly compare risk from many types of hazards (microbial and chemical)
  - various points in supply chain
  - different populations
- Enable relatively rapid quantitative risk assessments
  - Built-in mathematical architecture
- Express results using a variety of metrics
  - Illnesses (mean risk of illness, total number of cases)
  - Disability Adjusted Life Years (DALYs)

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FDA-iRISK 1.0

Home | Models | Reports | Sharing | Help

Home -> irisk@foodrisk.org's Models

Risk Models

Select a hazard, food, process model or risk scenario to work with on the tabs below, or add a new one.

Dose response models and hazard metrics are defined as part of hazards. Consumption models are included as part of foods. Process models modify hazard concentration in the food as the food is processed.

Computed risk scenarios combine information from previously-defined food, hazard, dose response, hazard metric, consumption and process model entries to compute a risk measure. Specified risk scenarios use provided data to compute the risk measure for a previously-defined food and hazard.

For a complete description, review the Quick Start Tutorial and User Guide on the Help page before beginning.

Show models for : irisk@foodrisk.org

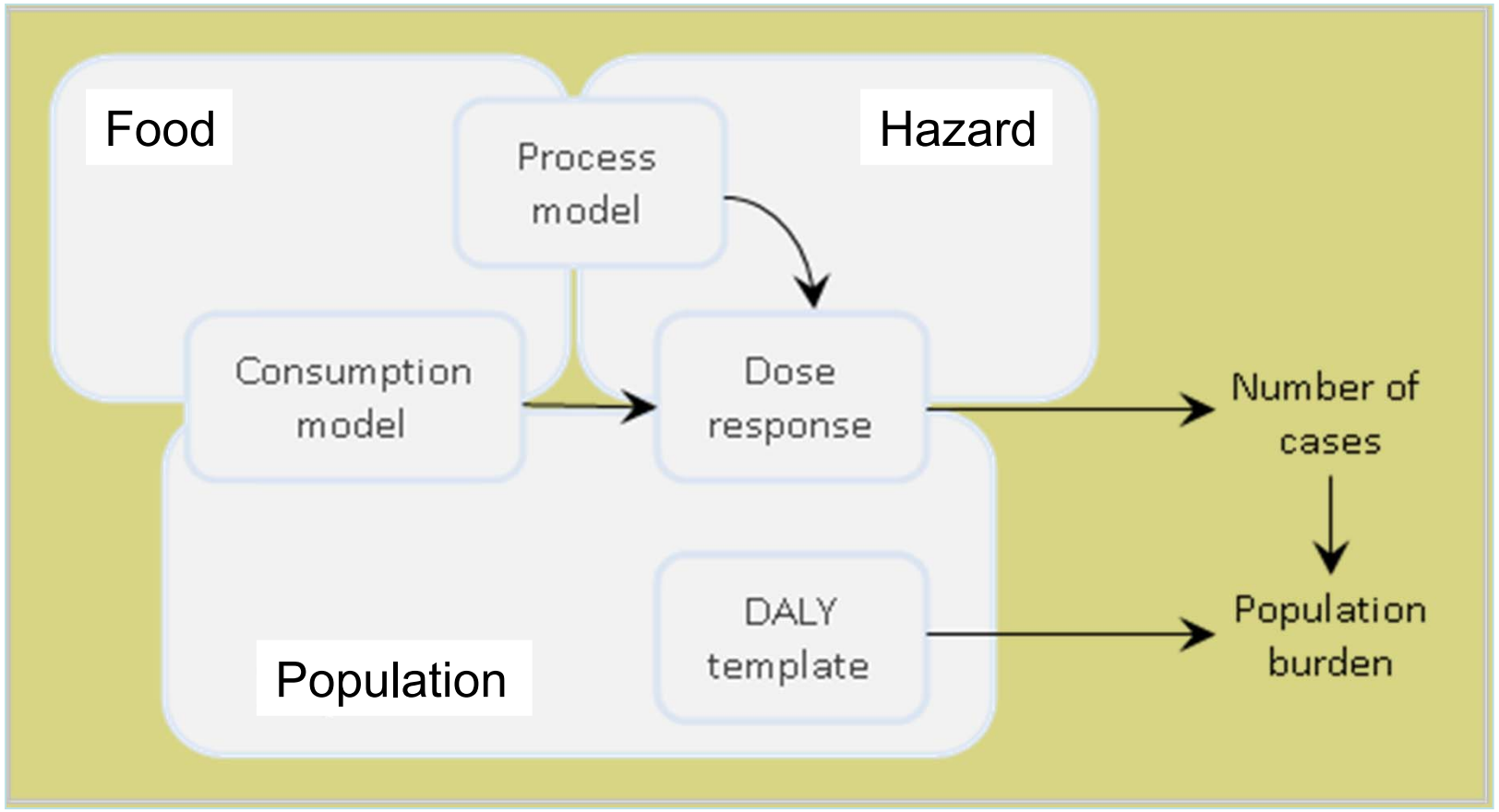
Hazards (4) | Foods (4) | Process Models (4) | Risk Scenarios (5)

Hazards

Select a hazard from the list below to view.

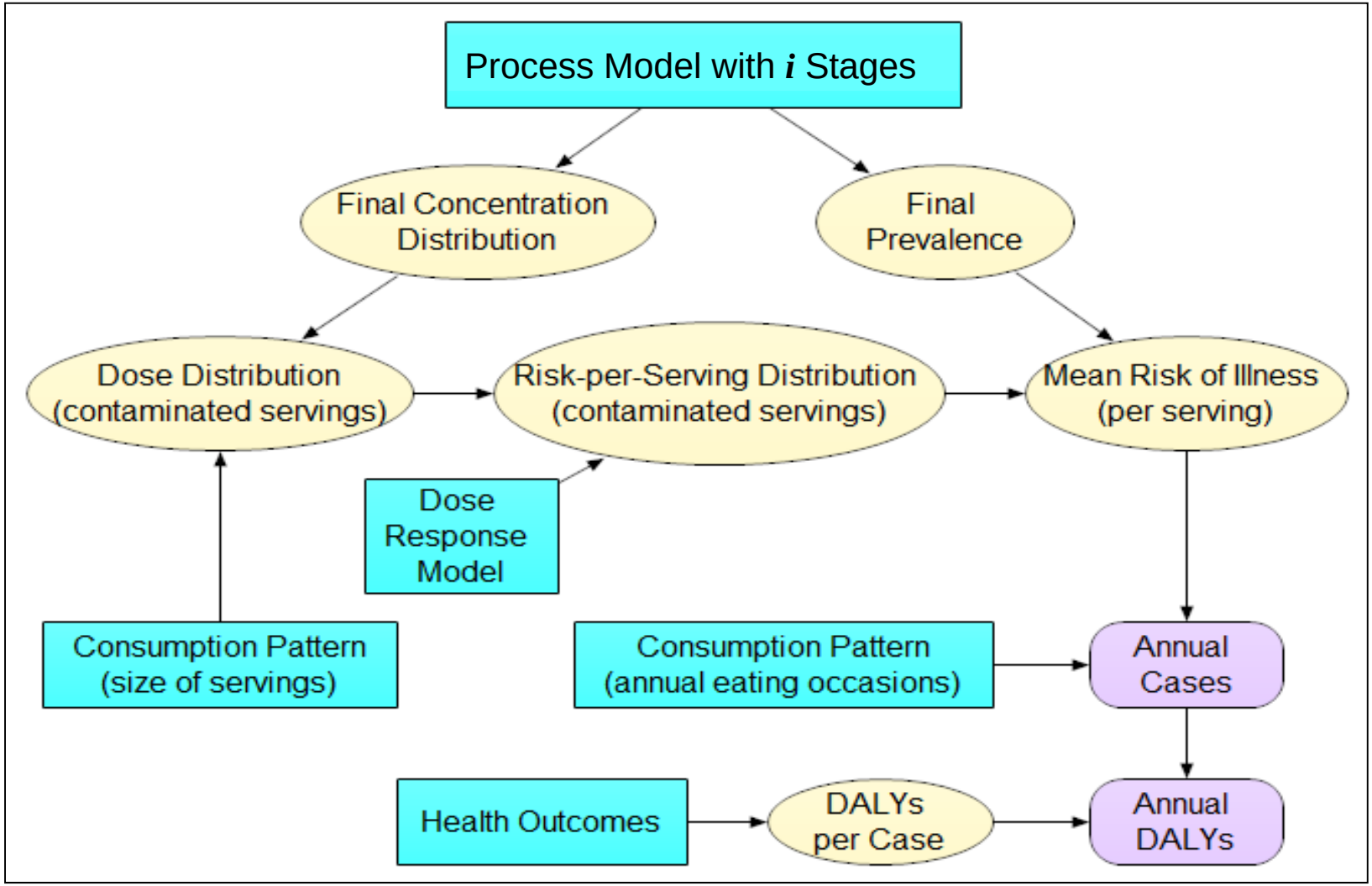
Hazard	Type	
Aflatoxin B1	Chemical	View
Ammonia from Refrigerant Spill	Chemical	View
L. monocytogenes	Microbial Pathogen	View
Salmonella	Microbial Pathogen	View

Integrates Data and Information on Seven Elements



Address the question: What ***risk*** does a hazard / food pair pose to a population?

iRISK Model Structure (Microbial Hazards)



User Inputs (Data)

- Process model
  - Initial prevalence and levels
  - production/processing/handling steps
- Consumption patterns
- Dose-response relationship
- Health outcomes

…all represented by quantitative data

Process Model: "Process Type"

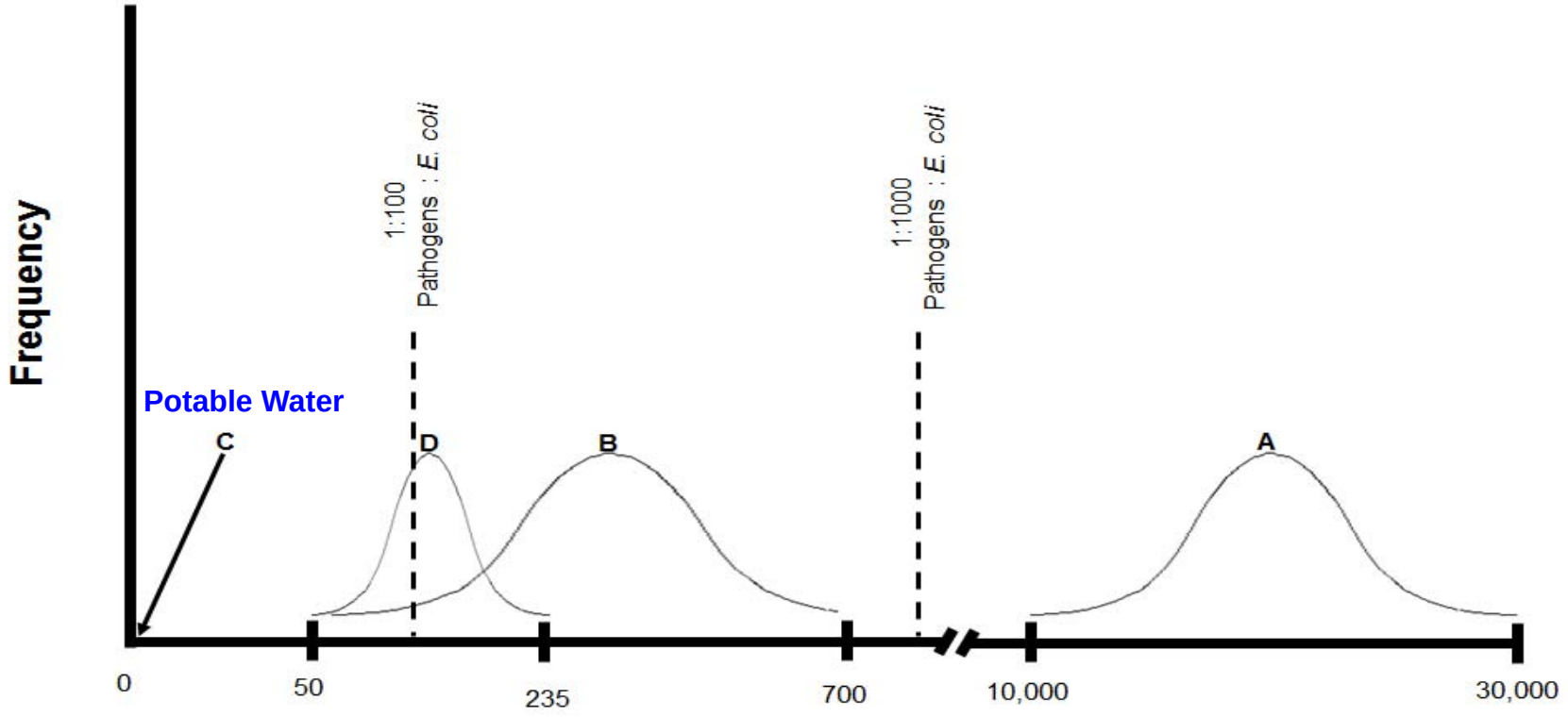
- **Describes a typical process step where contamination occurs, increases, or decreases**
  (built-in choices for users to select, as part of process model)

1. Increase by growth	4. Pooling	7. Redistribution (partial)
2. Increase by addition	5. Partitioning	8. Redistribution (total)
3. Decrease	6. Evaporation or Dilution	9. No change

A Case Study using FDA-iRISK

Developed Risk Scenarios to Evaluate Proposed Irrigation Water Provisions in Proposed Produce Rule Required by FSMA

Risk Scenarios:
Proposed Irrigation Water Provisions



Model Scenarios

Farm C: Use of Municipal Quality Water = 0 *E. coli* / 100 ml of water

Farm D: Within Proposed Monitoring Limits = 50-235 *E. coli* / 100 ml of water
EPA Recreational Water Std ≈ 8 GI illnesses / 1000 swimmer full body contact

Farm B: Moderate Exceedance of Proposed Monitoring Limits 50-700 *E. coli* / 100 ml of water

Farm A: Gross contamination of agricultural water (e.g. Taco John's foodborne illness outbreak linked to faulty plumbing which allowed dairy effluent to contaminate irrigation water). 10,000-30,000 *E. coli* / 100 ml of water

Not shown: Farm F (very high contamination) 700-4840 MPN/100 ml, and Farm E (high contamination) 700-2420 MPN/100 ml

Data for Lettuce-EHEC Risk Assessment

Elements	Model Input
Contami-nation (process model)	Prevalence and levels Preharvest to consumption
	Knowledge about the stages in food supply system where contamination can increase or decrease
Consump-tion	Serving size: Triangular (Minimum:0 Mode:5.8 Maximum:125) g
	Number of servings produced: 2.6E+05 servings leaf lettuce from 1 acre
	Number of servings consumed: 1.3E+05 servings leaf lettuce from 1 A, assuming 52% food loss (from harvest loss to consumer loss)
Dose-Response	Beta-Poisson (alpha: 0.248 beta:48.80)
Health Impact	DALY template of overall disease burden from EHEC infection in the total population

Data for Process Model

Process Stages	Model Input
Contamination from irrigation prior to harvest – *E. coli* levels (e.g., Farm D)	*E. coli* introduced via irrigation water varies from 50 to 235 (w/most likely 126) MNP/100 ml
	6.5% samples positive for EHEC
	Calculate 2.5 ml water/ g lettuce (13,500 gal/A water used in irrigation)
Contamination from irrigation prior to harvest – EHEC: *E. coli* ratio	1:100
	1:1, 1:10 1:100 ratio for sensitivity analysis
Inactivation in field between irrigation and harvest	Varies 0.11 to 2.44 (w/most likely 0.50) log CFU/g reduction during 3-5 (w/most likely 4) days
Contamination at harvest from other environmental sources	Prevalence 0.08% Levels varies -5 to -0.49 (w/most likely -2) log CFU/g

Other stages: growth/decline in facility, spreading during washing, growth at retail and home, cross contamination from handling, up to consumption.

Risk Estimates for Fresh-Cut Lettuce from a Farm with Different Irrigation Water Scenarios

Scenario	Final Concentration (log cfu or pfu/g microbial, g/g chemical)	Final Prevalence	Mean Risk of Illness	Total EO or Consumers	Total DALYs	Annual DALYs	DALYs per EO or Consumer
EHEC in Lettuce Fresh-Cut from Farm A (1:100 EHEC vs. E. coli)	-0.69	0.11	0.0042	1.3E+5	200	200	0.0016
EHEC in Lettuce Fresh-Cut from Farm F (1:100 EHEC vs. E. coli)	-0.24	0.00073	9.3E-6	1.3E+5	0.44	0.44	3.5E-6
EHEC in Lettuce Fresh-Cut from Farm E (1:100 EHEC vs. E. coli)	-0.19	0.00034	3.5E-6	1.3E+5	0.17	0.17	1.3E-6
EHEC in Lettuce Fresh-Cut from Farm B (1:100 EHEC vs. E. coli)	-0.039	9.4E-6	9.9E-8	1.3E+5	0.0047	0.0047	3.7E-8
EHEC in Lettuce Fresh-Cut from Farm D (1:100 EHEC vs. E. coli)	-0.024	5.6E-6	8.5E-8	1.3E+5	0.0041	0.0041	3.2E-8
EHEC in Lettuce Fresh-Cut from Farm C (Baseline)	-0.016	4.4E-6	7.8E-8	1.3E+5	0.0037	0.0037	2.9E-8

Scenario details are included on following pages.

Note: Results from the scenarios developed in early 2012 using iRISK-BETA.

Sensitivity Analysis: Influence of EHEC:*E coli* Ratio

EHEC vs. *E coli* ratio	Farm A	Farm B	Farm D
1:1	10,400	24.7	11.05
1:10	3,250	0.598	0.143
1:100	**546.0**	**0.0129**	**0.0111**

Predicted Illnesses (Lettuce per Acre) Associated with Different Farms

Sensitivity Analysis: Influence of Time between Irrigation and Harvest

Time in Field	Farm A	Farm B	Farm D
2 days	1248.0	0.0156	0.0117
3-5 days	**546.0**	**0.0129**	**0.0111**
8 days	143.0	0.0107	0.0103

Predicted Illnesses (Lettuce per Acre) Associated with Different Farms

Concluding Thoughts

- Lettuce-EHEC risk assessment a case study applying FDA-iRISK to rapidly address policy needs
- Targeted and specific risk management questions critical to defining scope and selecting appropriate tool
- FDA-iRISK project ongoing to build library of food-hazard scenarios and interventions

Acknowledgements

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Thank you for your attention

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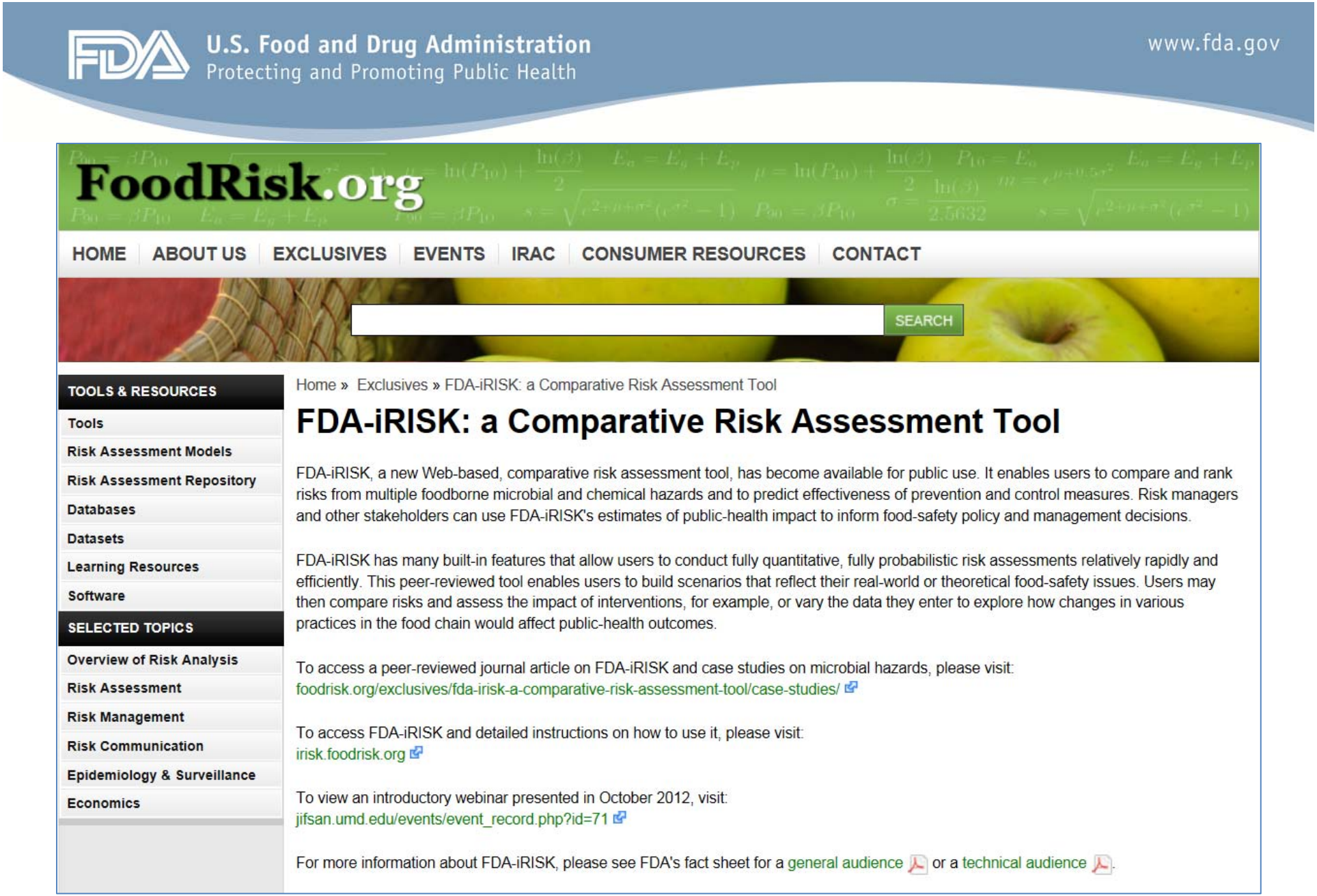
For more information about FDA-iRISK, visit
http://foodrisk.org
http://irisk.foodrisk.org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FDA-iRISK: a Comparative Risk Assessment Tool
FDA-iRISK, a new Web-based, comparative risk assessment tool, has become available for public use. It enables users to compare and rank risks from multiple foodborne microbial and chemical hazards and to predict effectiveness of prevention and control measures. Risk managers and other stakeholders can use FDA-iRISK's estimates of public-health impact to inform food-safety policy and management decisions.
FDA-iRISK has many built-in features that allow users to conduct fully quantitative, fully probabilistic risk assessments relatively rapidly and efficiently. This peer-reviewed tool enables users to build scenarios that reflect their real-world or theoretical food-safety issues. Users may then compare risks and assess the impact of interventions, for example, or vary the data they enter to explore how changes in various practices in the food chain would affect public-health outcomes.
To access a peer-reviewed journal article on FDA-iRISK and case studies on microbial hazards, please visit:
foodrisk.org/exclusives/fda-irisk-a-comparative-risk-assessment-tool/case-studies/
To access FDA-iRISK and detailed instructions on how to use it, please visit:
irisk.foodrisk.org
To view an introductory webinar presented in October 2012, visit:
jifsan.umd.edu/events/event_record.php?id=71
For more information about FDA-iRISK, please see FDA's fact sheet for a general audience or a technical audience.