FDA Risk Modeling Tools for Enhancing Fresh Produce Safety: Modeling the Interface between the environment and Produce

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by

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Outline

- The need for Risk Assessment
- The challenges of modeling the interface between the environment and fresh produce.
- FDA's Risk Modeling Tools for Enhancing Fresh Produce Safety
  - FDA-iRISK®,
  - QPRAM, and
  - GIS-Risk
- Data Needs
- FDA Data Acquisition efforts from Field Trials and Sampling
- Conclusion

Risk Assessment is…

- A process to describe what we know and how certain we are of what we know
- From Farm to Fork
- Answers 4 key questions:
  - *What can go wrong?*
  - *How likely is it to occur?*
  - *What are the consequences?*
  - *What factors can influence it?*
- Considers uncertainty

Uses of risk assessment at FDA

- Inform risk managers of where and when to look, to:
  - set priorities / allocate resources
  - identify major risk-contributing steps in farm-to-fork continuum
- Enable risk managers to evaluate effectiveness of interventions:
  - potential or equivalent control measures
  - proposed standards and criteria
  - contribution of compliance to risk management
- Inform risk communicators in:
  - developing communication/outreach messages
  - determining subpopulations at increased risk
  - assessing uncertainty and variability

Examples of FDA risk tools

Quantitative Risk Assessment	Semi-Quantitative Risk Assessment
– *Listeria* in RTE foods *(2003)* – *Vibrio* in raw oysters (2005) – HPAI in poultry & eggs (2010 w/USDA) – FDA-iRISK (2012 w/RSI) – Retail deli cross-contamination (2013 w/FSIS) – *Arsenic* in Apple Juice - Draft 2013 – *Listeria* in soft cheese (w/HC) – draft 2013 – GIS-Risk tool (w/ NASA, ARS, APHIS) – Norovirus in shellfish (w/Canada) – Produce QPRAM (w/RTI)	– Domestic Priorities List (2007) – Produce Risk Ranking Tool (2009) – Drug residues in milk – FSMA Section 204 High Risk Foods Model Risk Profile (Qualitative) – Pathogens in cheese – Pathogens & filth in spices -draft 2013

Division of Risk Assessment Staff

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- Total Diet Study:
  - Mark S Wirtz
  - Stephanie Briguglio
  - Dana Pennesi
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Enteric pathogens are transferred to produce via spatio-temporal interactions with domestic and wild animals, wind, water, soil, machinery, humans and climate.

Cattle

Wild boar

Birds

Contaminated Irrigation Water

People

Soil

Flood

Contaminated Equipment

FDA Models with Applicability to Produce

- **FDA-iRISK®:** An interactive, Web-based, risk assessment modeling tool (freely available at http://foodrisk.org/exclusives/). It quantitatively compares and ranks risks posed by multiple food/hazard combinations taking into account consumption, dose-response relationship, as well as contamination in the food supply system, from production to consumption. It can **provide an industry-wide or farm-level perspective of the risk**.
- **GIS-Risk:** A collaboration between FDA and NASA, to link geographic information systems with predictive risk-assessment models. The ultimate goal is to forecast when, where, and under what conditions microbial contamination of crops is likely to occur, leading to human illness. It **provides a regional perspective of risk**.
- **QPRAM**: The Quantitative Produce Risk Assessment Model (QPRAM) is an agent–based, virtual laboratory that models specific practices and risk factors. QPRAM tracks each unit of produce; keeping a history of how, when, where, and by how much it was contaminated. It **provides a facility** (individual farm or processing facility) **level perspective of risk**.

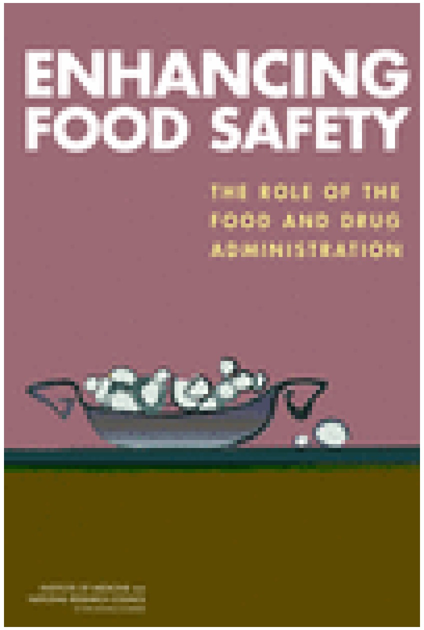
FDA-iRISK®

FOOD SAFETY MODELING TOOL

NAS Recommendation

…to develop tools for risk ranking in a risk-based system for enhancing food safety decision-making.

> *"A good risk-ranking model should be fit for purpose and be scientifically credible, balanced, easy to use, and flexible."*



(National Academy of Sciences, 2010)

FDA-iRISK is:

an interactive, web-based system that enables users to conduct fully quantitative, fully probabilistic risk assessments of food safety hazards relatively rapidly and efficiently.

Users Develop and View Risk Models via Online Interface

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

Novel Capacities

- Allows risk comparisons across many dimensions
  - Hazards (microbial and chemical)
  - Foods/Commodities
  - Production/processing/handling scenarios
  - Populations

- Enables relatively rapid risk assessments and evaluation of intervention effectiveness
- Provides a straightforward user interface
- Allows online access to ensure broad accessibility, saving and sharing data

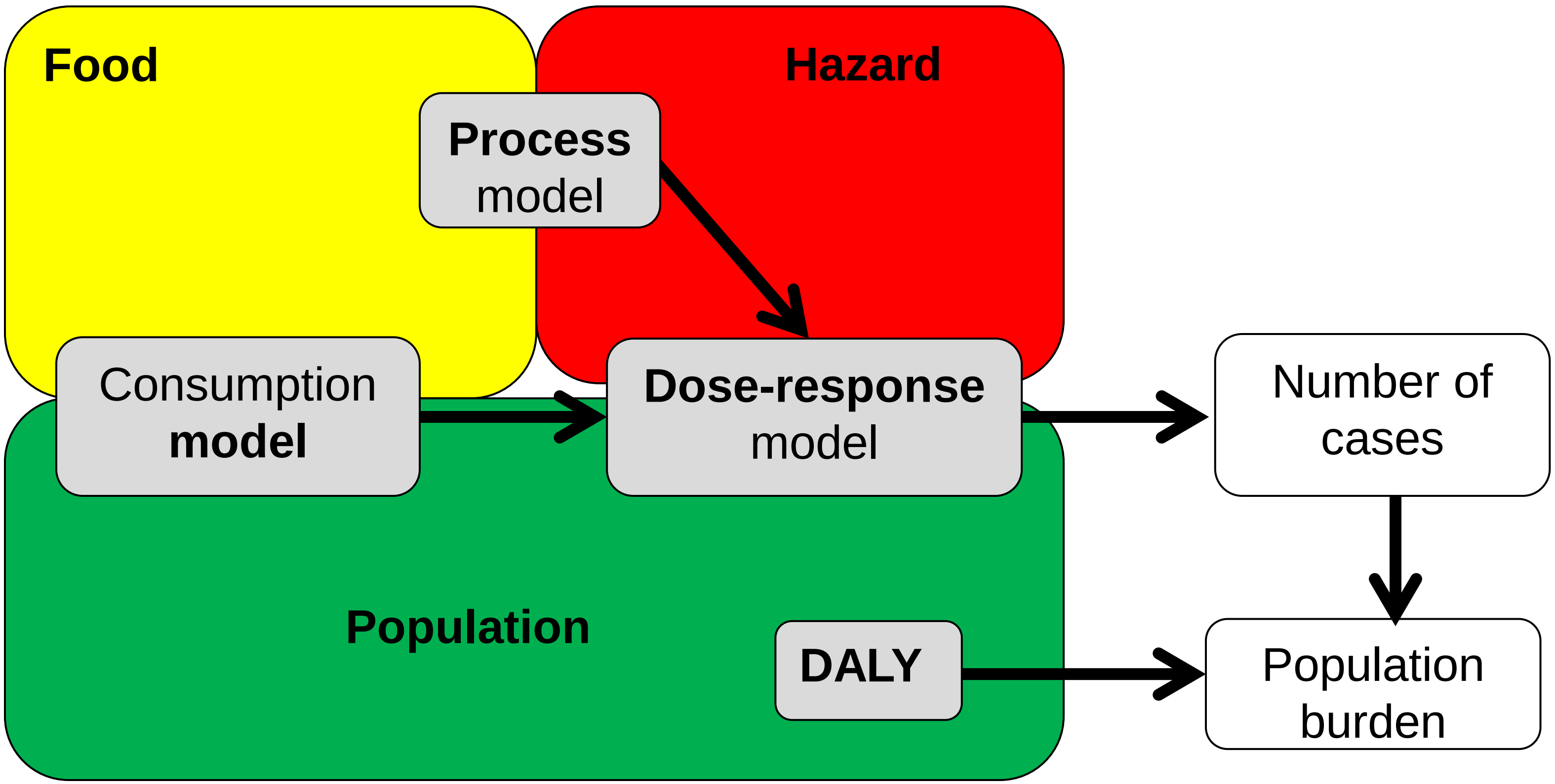
How FDA-iRISK Works

- **Integrates data & information on seven elements…**

    food
    hazard
    population
    process model (food production/ processing/ handling)
    consumption patterns
    dose-response
    health effects

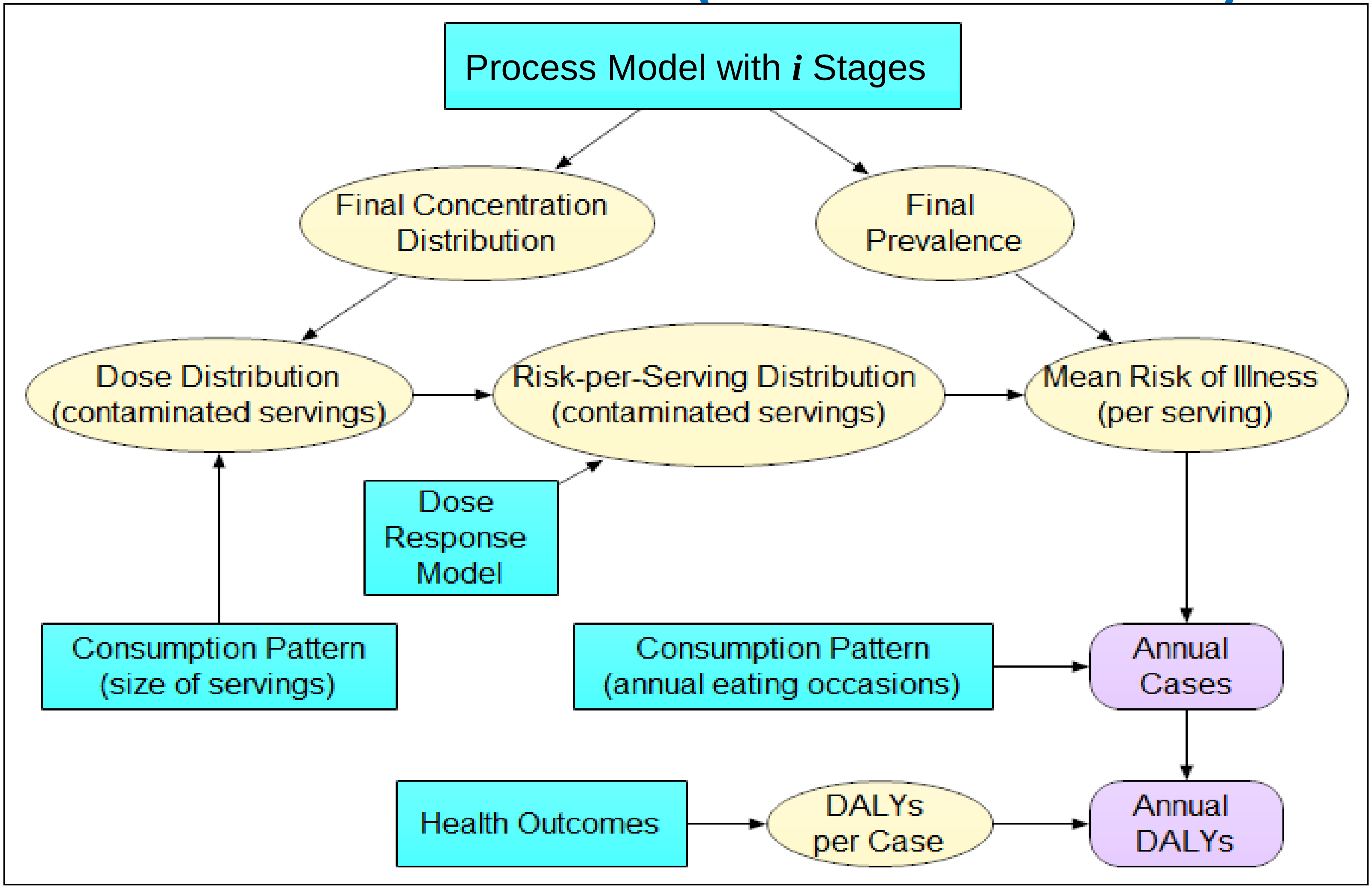
…using the built-in templates & generates risk estimates through Monte Carlo simulations

Relationship of the Seven Elements of a Risk Scenario (Risk Model)



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

iRISK Model Structure (Microbial Hazards*)



Key: User input | iRISK output

* Also applicable to chemical hazards that cause acute effects.

FDA-iRISK is:

A risk ranking tool to compare public-health impact of microbial and chemical hazards (and more…)

One Hazard in Different Foods

Salmonella

Fresh Produce

Shell Eggs

Nuts

Multiple Hazards in a Single Food

Leafy Greens

Norovirus

Cyclospora

Enterohemorrhagic *E. coli*

Multiple Hazards in Multiple Foods

L. monocytogenes in Soft Cheese

Salmonella in Peanut Butter

Scombrotoxin in Raw Tuna

Arsenic in Juices

FDA-iRISK Output Example: Compare Health Effects of Multiple Hazard-Food Scenarios

Scenario	Eating Occasions	Total Illnesses	Mean Risk of Illness	DALYs	Per Eating Occasion
Salmonella in Peanut Butter (post roasting), Total Population (Acute, Computed)	1.70E+10	3320	1.95E-7	62.5	3.67E-9
L. monocytogenes in Soft Ripened Cheese, Pregnant Women (Acute, Computed)	1.20E+7	0.805	6.70E-8	11.1	9.25E-7
L. monocytogenes in Soft Ripened Cheese, Adults 60+ (Acute, Computed)	1.80E+8	2.25	1.25E-8	5.79	3.22E-8
L. monocytogenes in Soft Ripened Cheese, Intermediate-Age Population (Acute, Computed)	1.70E+9	0.213	1.25E-10	1.06	6.24E-10

Current FDA-iRISK®: Benefits

- **Predict risks / compare burdens of illnesses**
  - **Rank them, e.g. 50 food-hazard pairs**
- **Quantify / compare effectiveness of interventions**
  - **Predict reductions in risks and burdens**

Faster, user-friendly information for timely decisions

Portal to FDA-iRISK®

FoodRisk.org

Google™ Custom Search

HOME | ABOUT US | EXCLUSIVES | EVENTS | IRAC | CONSUMER RESOURCES | CONTACT | HOSTED TOOLS

SEARCH

TOOLS & RESOURCES

- Tools
- Risk Assessment Models
- Risk Assessment Repository
- Databases
- Datasets
- Learning Resources
- Software

SELECTED TOPICS

- Overview of Risk Analysis
- Risk Assessment
- Risk Management
- Risk Communication
- Epidemiology & Surveillance
- Economics

Home » Exclusives » FDA-iRISK(R): a Comparative Risk Assessment Tool

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.

The FDA-iRISK® application can be found at http://irisk.foodrisk.org .

Peer-reviewed journal article on FDA-iRISK® and case studies on microbial hazards

Quick Start Guide

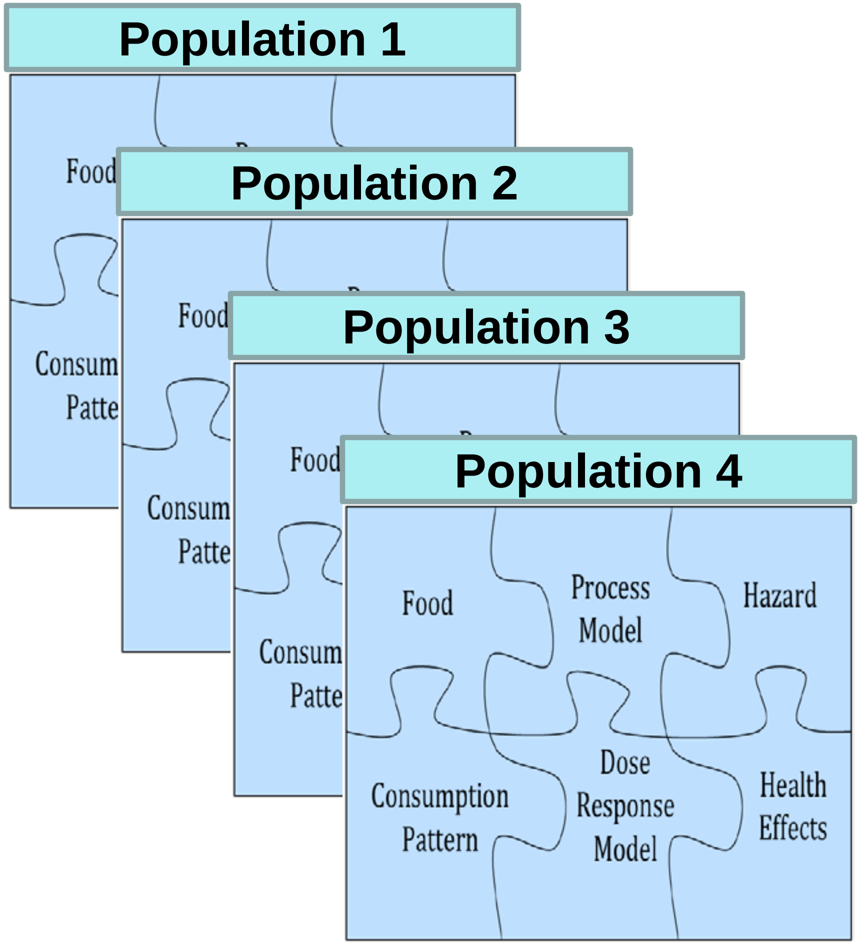
User Guide

For more information about FDA-iRISK®, please see FDA's fact sheet for a general audience or a technical audience.

What can it do?

FDA-iRISK®

- Quickly compare risk from many types of hazards.
  - various points in supply chain
  - different populations
- Predict effectiveness of interventions.
- Express results using a variety of metrics.
- Peer Reviewed



Public version available at http://foodrisk.org since October 2012

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- Risk Sciences International,
- RTI International, and
- external peer reviewers.

QPRAM

PRODUCE SAFETY MODELING TOOL

QPRAM (a virtual farm model)

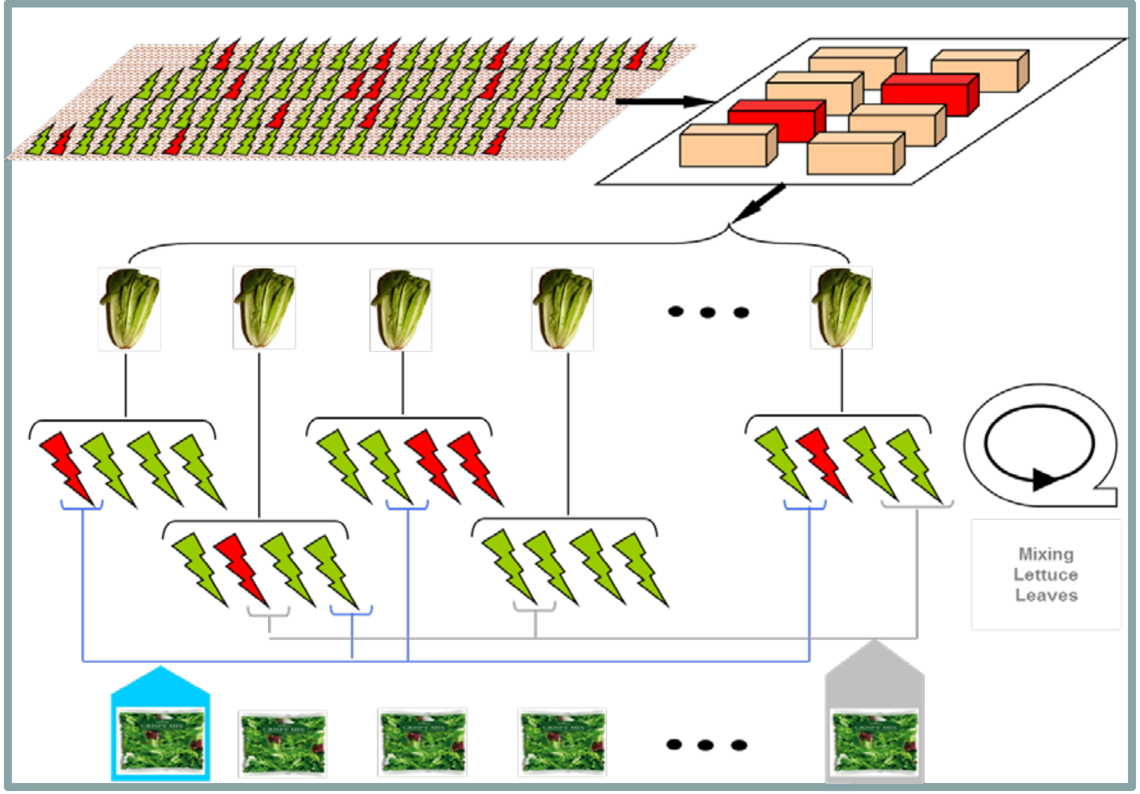
What can it do?

QPRAM: Quantitative Produce Risk Assessment Model

Purpose: Model contamination of fresh produce during growth, harvest, processing, transport, retail, and preparation for consumption

- An individual facility perspective of contamination events.
- Represents potential interactions among produce units and specific risk factors in the produce environment.
- Explicitly models change in the contamination status of units of fresh produce (e.g., heads of lettuce) with respect to time during multiple stages

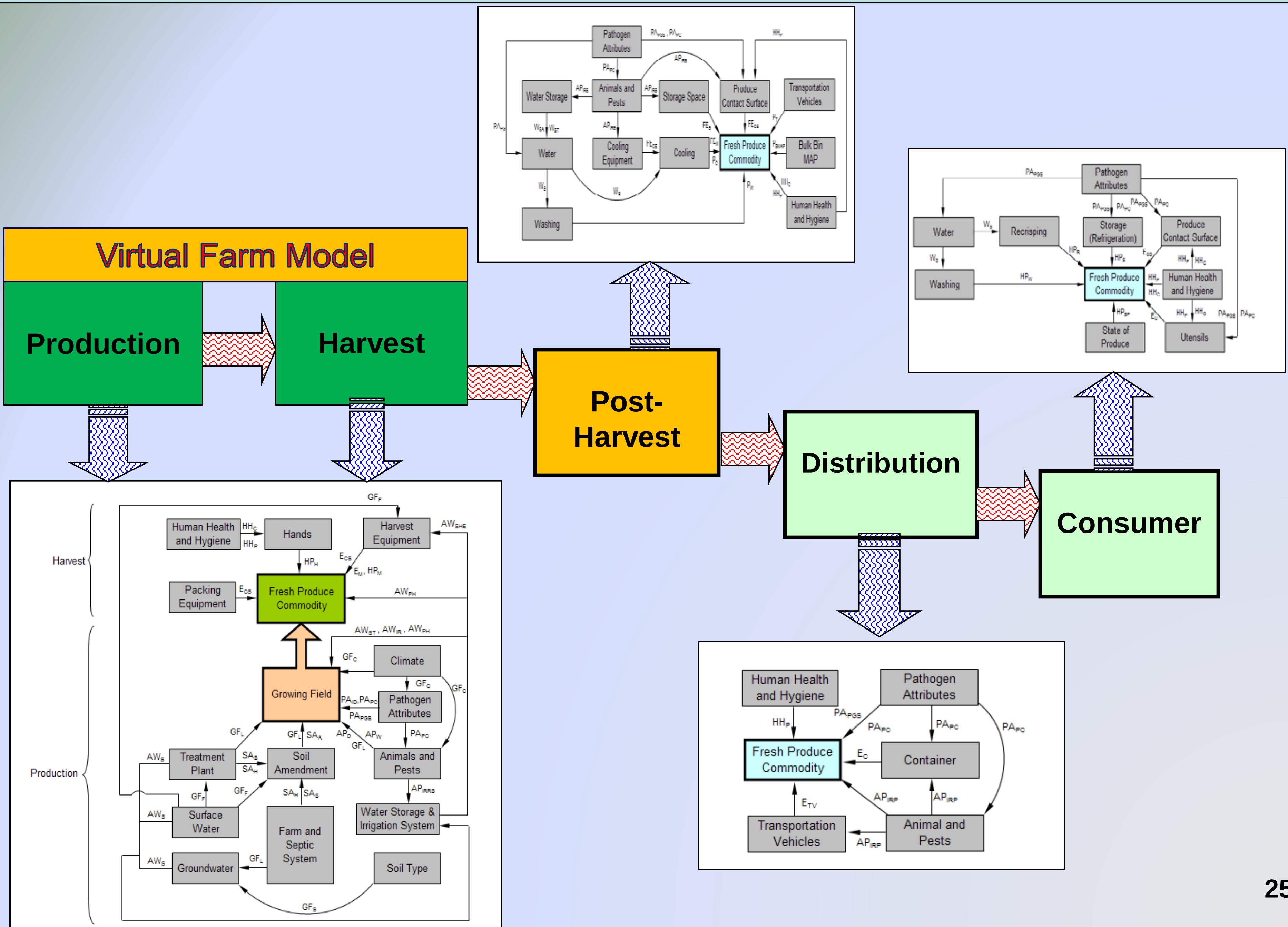
Model tracks individual units



Model interaction of produce, domestic and wild animals, wind, water, soil, machinery and humans

Conceptual model underlying QPRAM

QPRAM



QPRAM Models the interaction of produce, domestic and wild animals, wind, water, soil, machinery and humans, and tracks contamination.

Contaminated Irrigation Water

Cattle

Wild boar

Birds

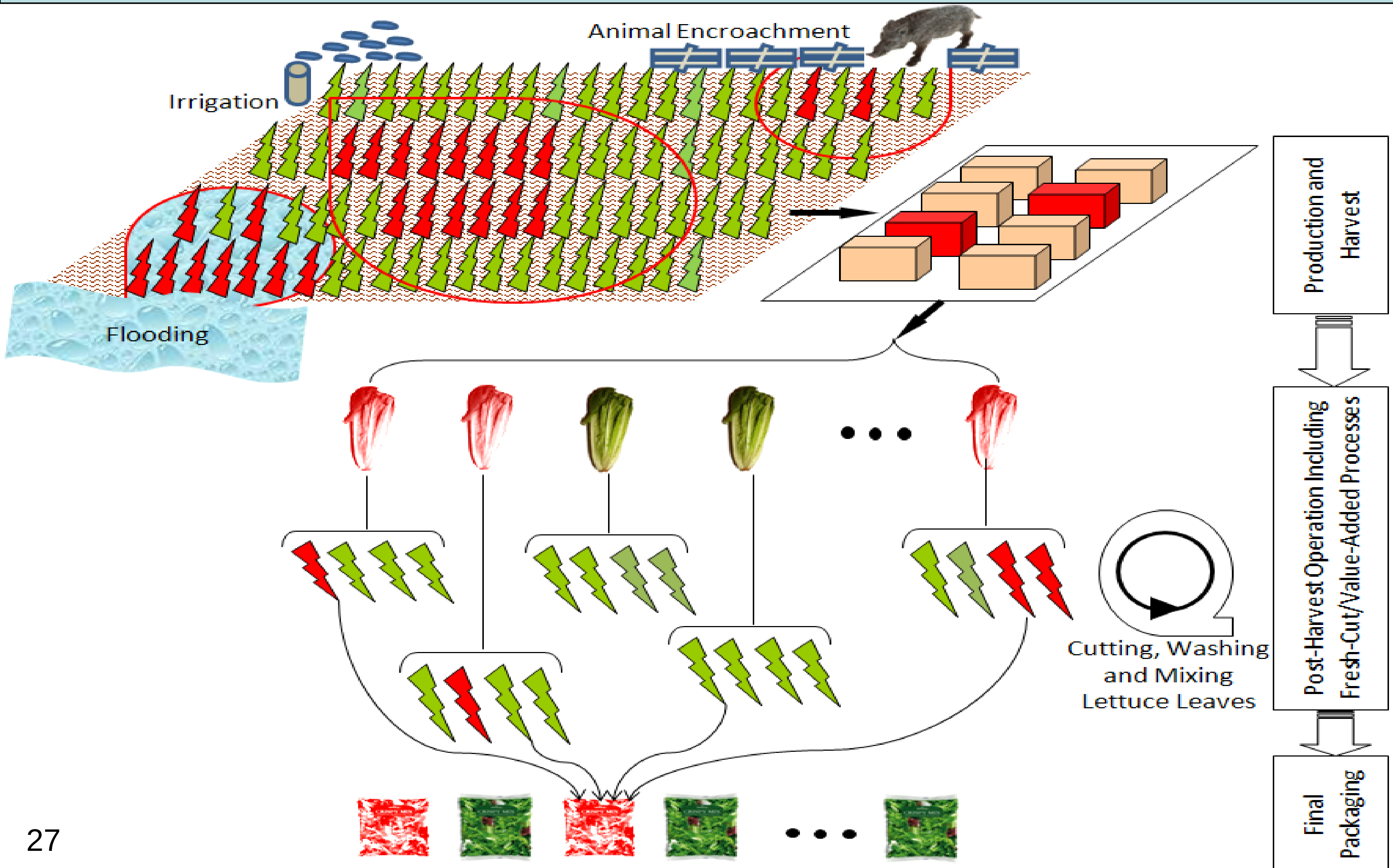
People

Soil

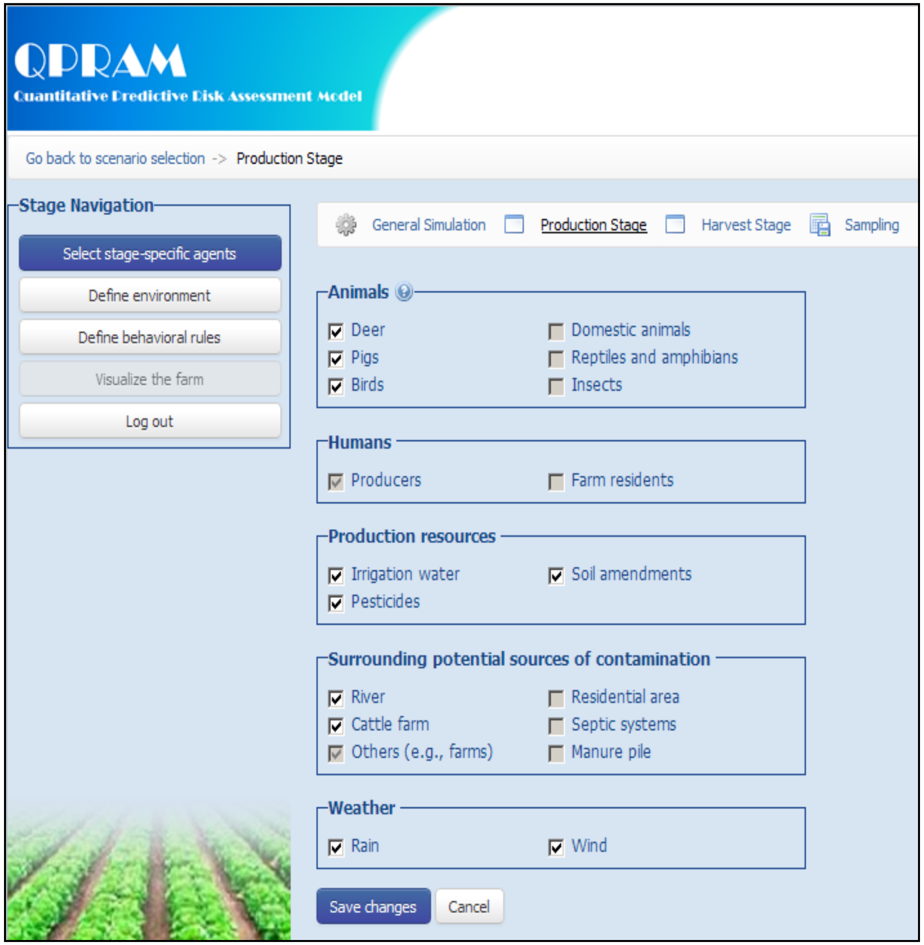
Flood

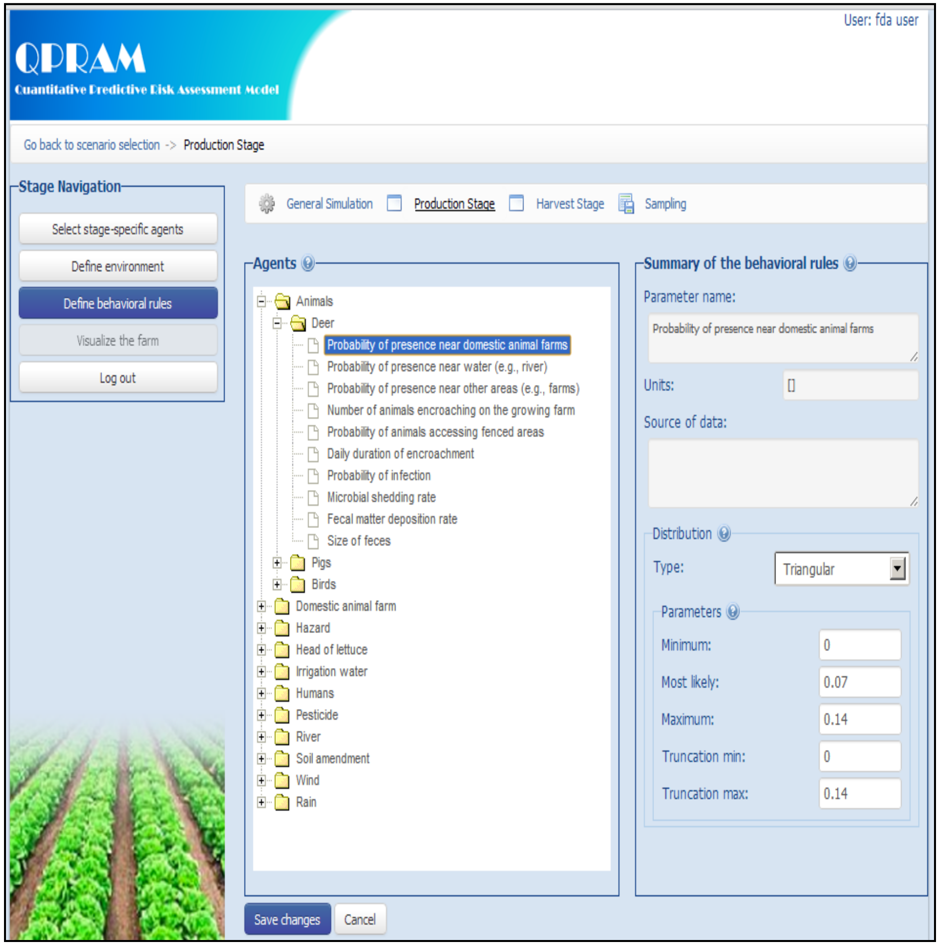
Contaminated Equipment

QPRAM uses the agent-based modeling (ABM) framework



QPRAM Provides a flexible framework for selecting risk factors





Defining a scenario in the production stage

Farm and surrounds | Field access | Initial contamination

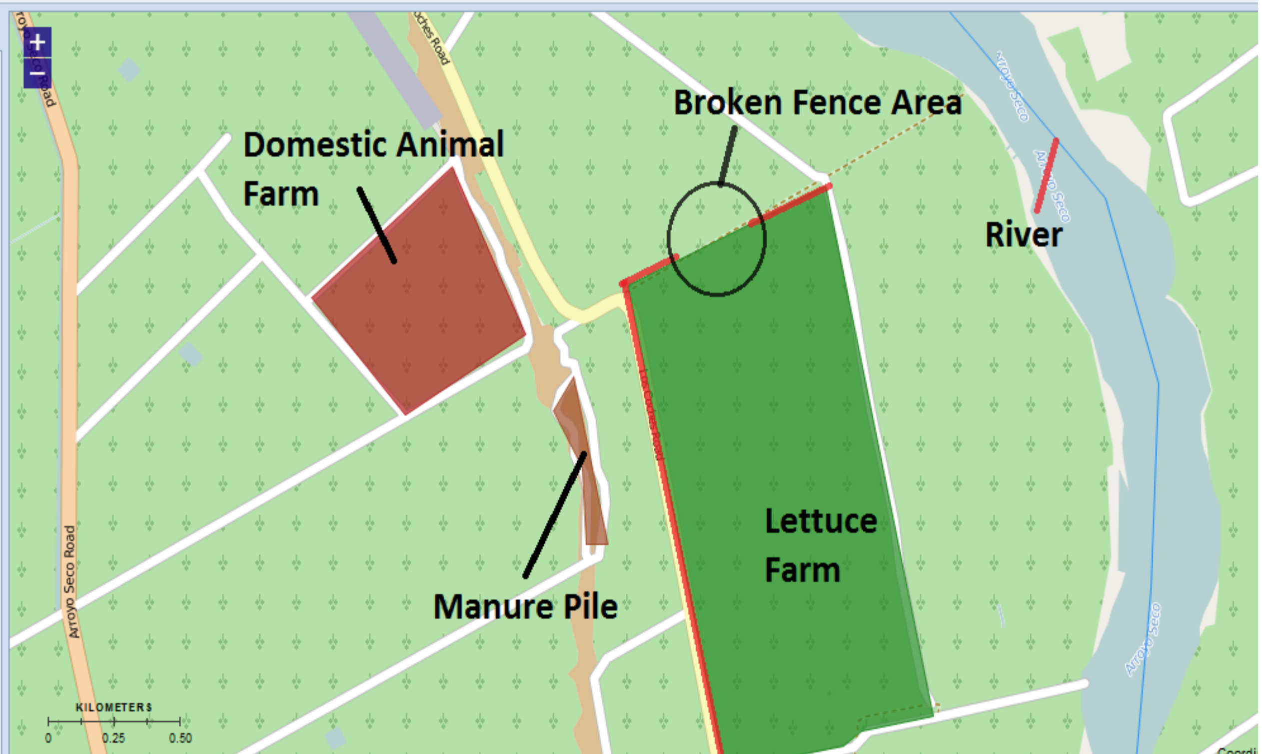
You can define your interest areas (i.e. farm and surrounding sources of contamination) using the interactive map tool below.

- Enter your area address or zip code into the search box to zoom the map to your location of interest.
- Select an interest area from the list in the left panel (e.g. farm).
- Draw the interest area on the map. Depending on the interest area type, you will either draw a polygon or a line. Double-click to finish drawing.
- Click 'Save' to add the interest area to your scenario.
- The 'Summary' tab will show a list of the interest areas you have added. Click 'Delete' next to an interest area to remove it from your scenario.

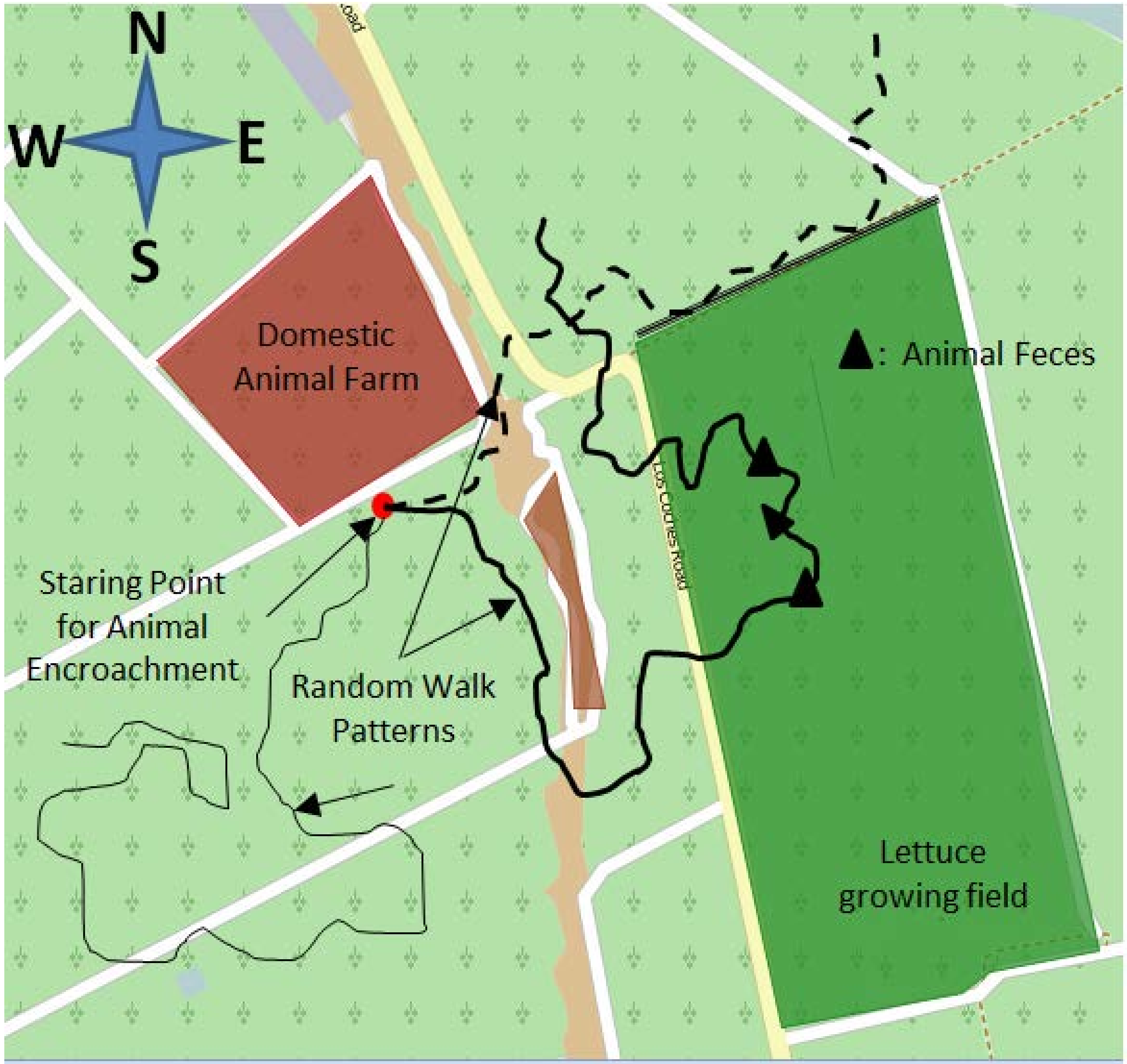
Interest areas | Summary

Name	Area/Length	(X,Y)	#
River	4248.49 m		Delete
Manure pile	23247.40 m2		Delete
Domestic animal farm	234567.84 m2		Delete
Growing field (farm)	952851.85 m2		Delete

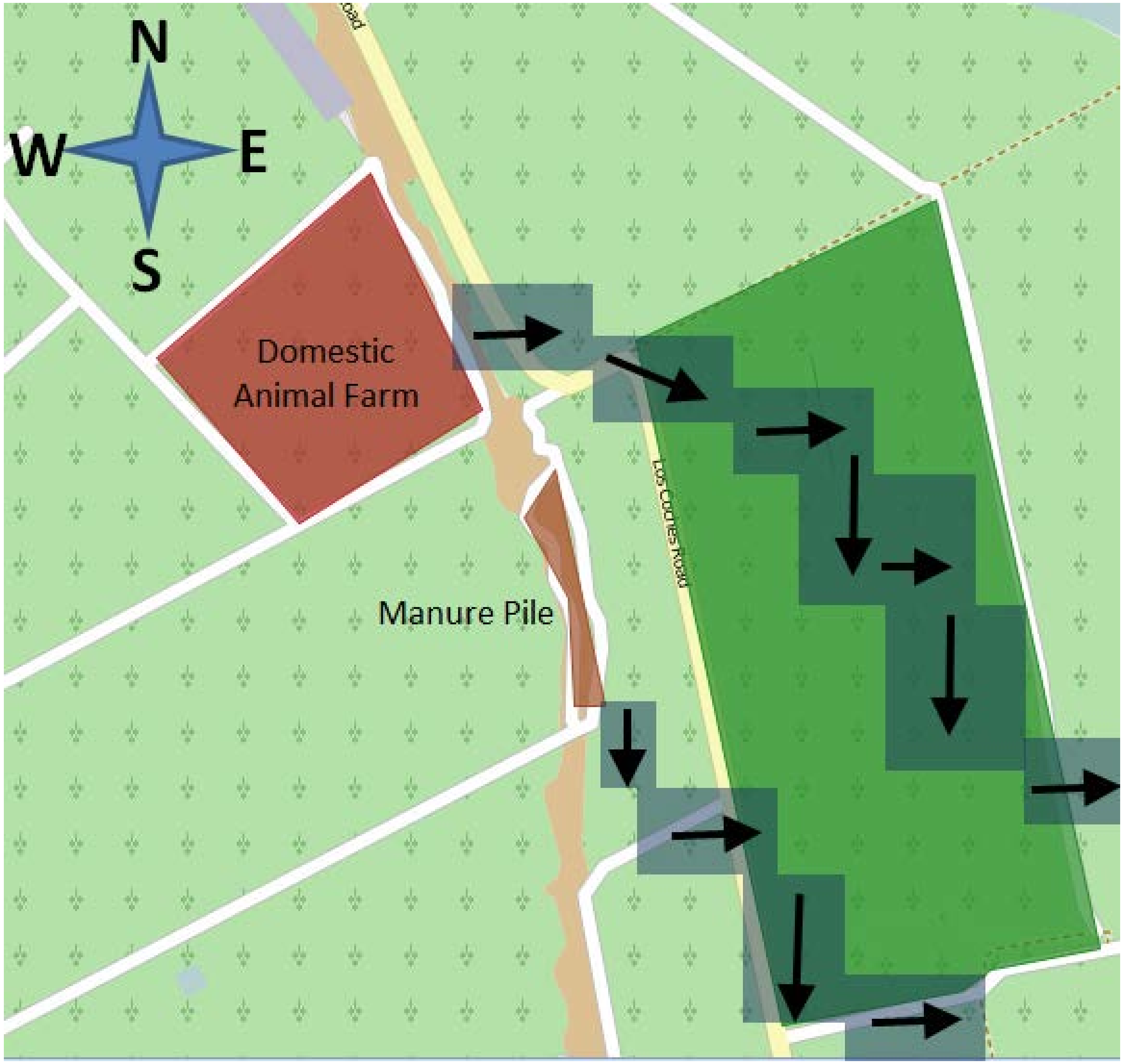
Clear Selection



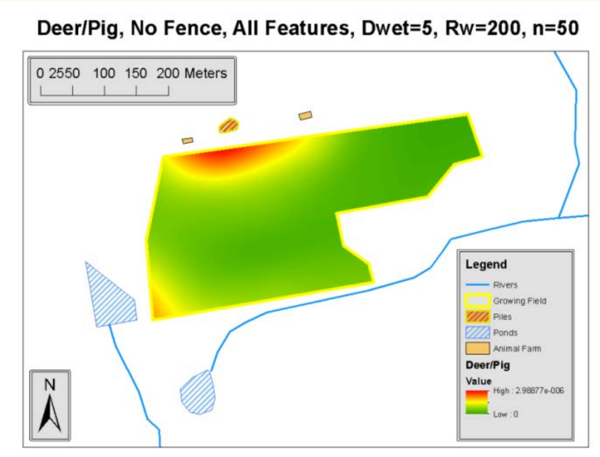
Example risk factor: wild animal movement



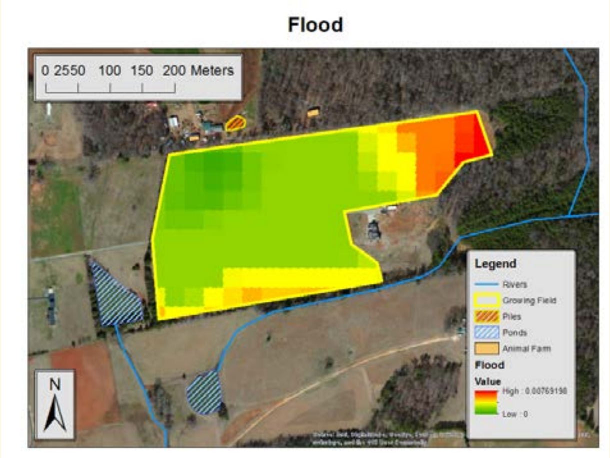
Example risk factor: run-off from neighboring animal farms



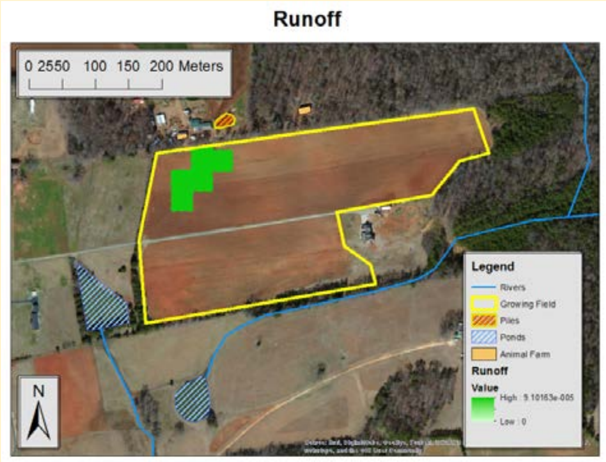
Site-specific, risk-based approach for microbiological sampling



High risk locations due to wild animal encroachment

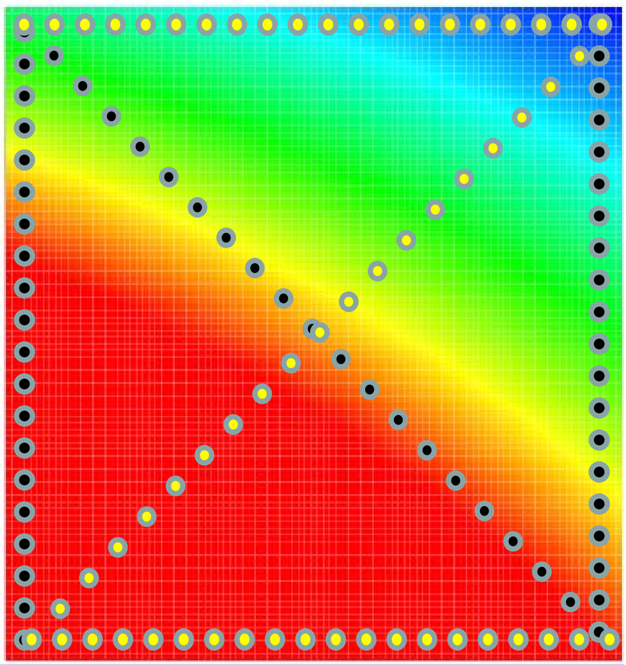


High risk locations due to a potential flooding from the neighboring water bodies

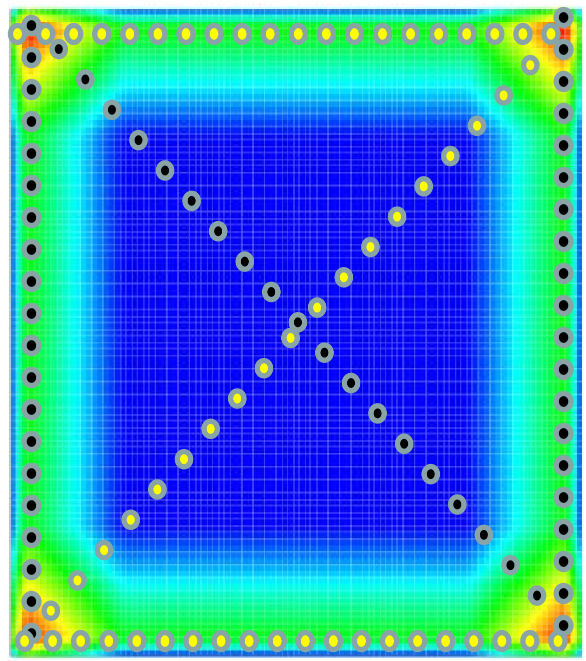


High risk locations due to a potential run-off from a neighboring animal farm

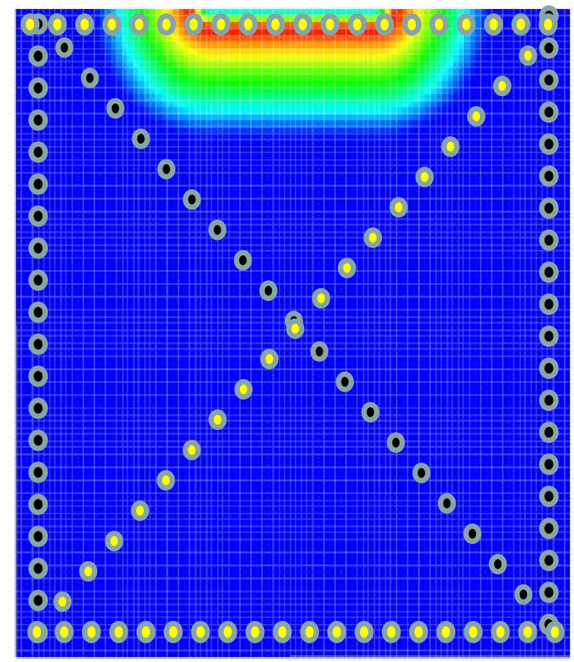
QPRAM Site-specific, risk-based approach for microbiological sampling



High risk locations due to a potential flooding event in the lower left area.



High risk locations due to wild animal access - no fence



High risk locations due to wild animal access- broken fence

Site specific sampling scenarios. What is the best sampling pattern?

QPRAM (Virtual Farm Model)

What can it do?

- Provide an individual facility perspective of contamination events.
- Represent potential interactions among produce units and specific risk factors.
- Explicitly model change in the contamination status of units of fresh produce with respect to time during multiple stages.
- Facilitate trace-back studies
- Test intervention efficacy.
- Enable risk-based sampling via a tool designed for microbial contamination in the growing field.

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Next steps in QPRAM model development

- Developing the post-harvest processing modules for selected produce commodities
- Updating the model database (more data from field trial studies)
- Updating algorithms for growth and survival of pathogens
- Enhancing the microbiological sampling tool
- Peer Review

GIS-RISK

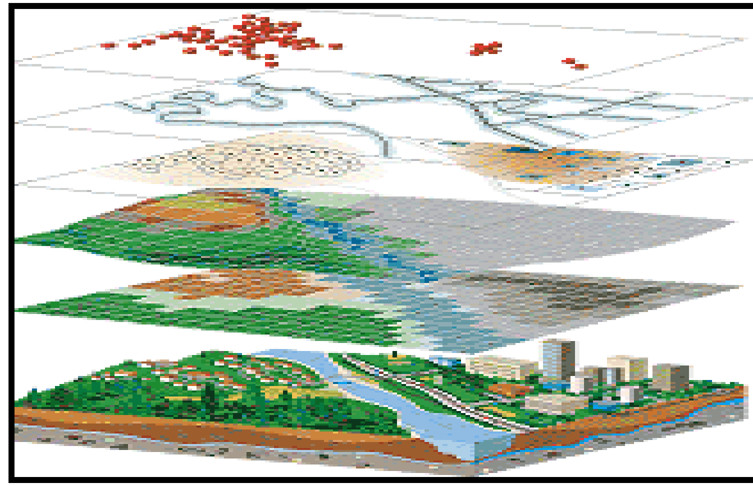
PRODUCE SAFETY MODELING TOOL

GIS-RISK (PGRAM)

What can it do?

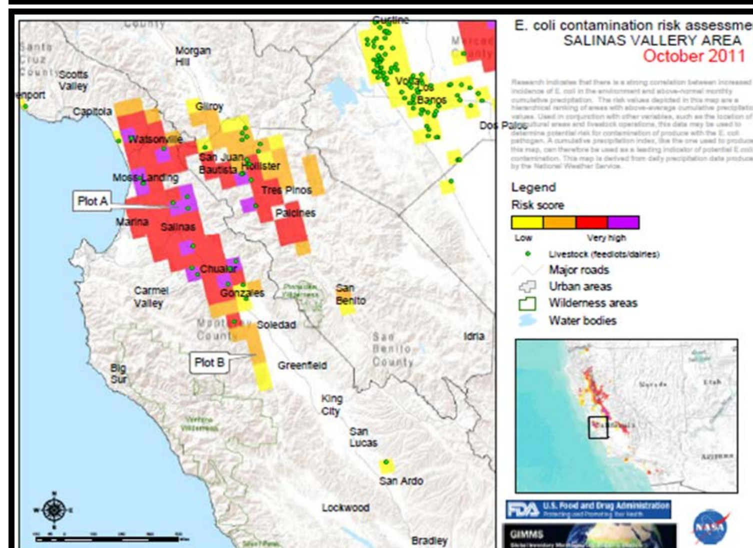
Purpose: Forecast where and when enteric pathogen contamination is likely.

- Regional spatial and temporal perspective.
- Recognize spatial and temporal correlations between environmental factors and historical data on produce contamination.
- Predict/forecast future produce contamination.



Current activities:

- NASA-GSFC - model development
- USDA-ARS - collecting environmental survey data (pathogens in watersheds)
- USDA-APHIS: developing spatio-temporal maps of livestock, wildlife, and crop locations and populations.
- **Industry**: providing historical produce contamination data, for use to improve model predictiveness.



Informs us where and when to be wary of potential produce contamination

The Approach

GIS-RISK

PAST
Collect Historical data

PRESENT
Acquire Real-time Satellite or rain/humidity/temp gauge data

FUTURE
Climate Forecast data

Geographic Information System (GIS)

Remote Sensing and collection Systems

Future Climate Prediction

Forecasting / Predictive Geospatial Risk Assessment Model of Produce contamination by enteric pathogens

Early warning system for industry and government About Future Potential locations and dates of produce contamination

GIS: - Analysis of Layers of Data

Location Characteristics

- Crop, Adjacent land use
- Topography: Slope, Soil type, soil temp.
- Wind speed and direction
- Climate: rainfall, Temp., Hum., Solar irrad.

Location of positive samples

- Water, soil, produce, animals

Potential Pathogen Sources:

- Cattle , Poultry, Swine, Feedlots, grazing land
- Bird and Feral (wild) animal habitats
- Humans,

Water Sources:

- Surface water, Ground water, Shallow wells, irrigation canals

Practices:

- Growing, Soil Amendment, Irrigation, Harvest

Other: Satellite derived vegetation index data to examine the landscape dynamics through time in relation to climate/rainfall variability

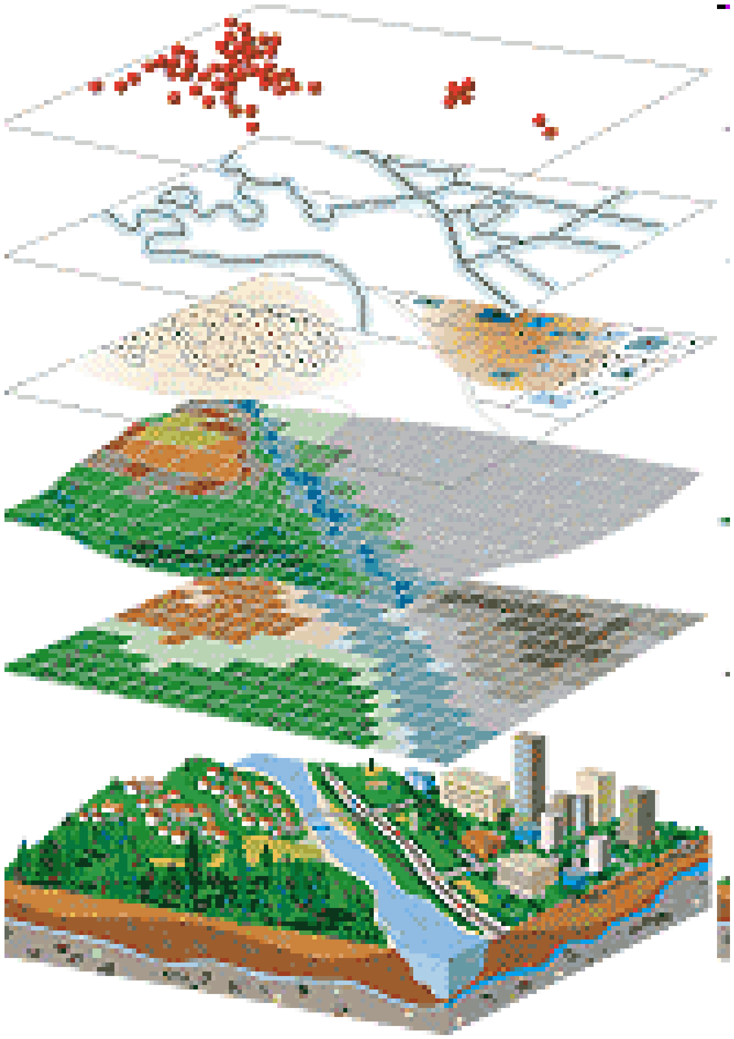


Photo from ESRI.com

Factors Considered

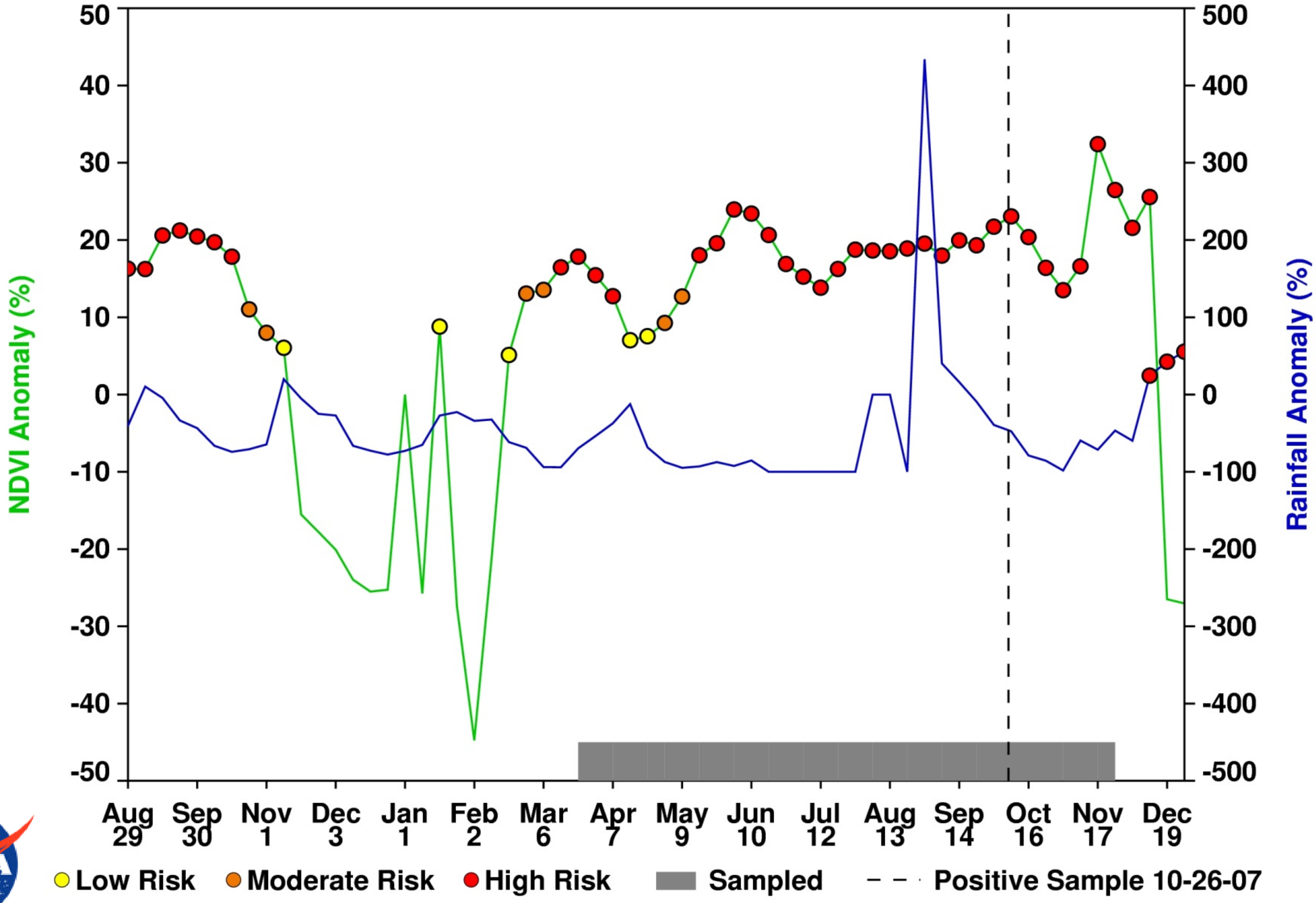
Environmental Factor	Source	Description
Soil texture (clay, silt, sand)	Soil Survey Geographic Database (SSURGO), Natural Resources Conservation Service, USDA	Mean percent content of clay, silt, and sand, in a one km radius surrounding the sample site
Soil organic content	SSURGO	Mean organic content for one km radius surrounding sample site
Precipitation	National Center for Atmospheric Research (NCAR)	Hourly and daily gridded precipitation data, aggregated to monthly data. Metrics for monthly cumulative precipitation and monthly precipitation anomalies were also created.
Land surface temperature	MODIS sensor	Land surface temperature is the temperature measured on the surface level and can be regarded as the temperature of the surface skin. Monthly data
NDVI	MODIS sensor	NDVI is a measure of vegetation greenness and is often used as an indicator of vegetation stress due to lack of precipitation
Grazing land	Farmland Monitoring and Mapping Program, California Department of Conservation	Land use categories derived from field surveys. Grazing land is defined as land on which the current vegetation is suited for grazing livestock.
Proximity to cattle/poultry operation	California Department of Water Resources	Land use survey of agricultural lands conducted by DWR. Includes class for farmsteads, dairies, livestock feed lots, and poultry farms
Land cover	Multi-Resolution Landcover Consortium	Land cover classification of satellite imagery, produced by consortium of federal agencies including NASA
Imperviousness index	Multi-Resolution Landcover Consortium	Imperviousness measurement produced by consortium of federal agencies including NASA
Humidity	NASA remote sensing data	
Elevation	NASA SRTM	Elevation value for the sample site location
Slope	NASA SRTM	Slope gradient for the sample site location

Data Layers used in CA example

- 2011 NASS Cropland Data Layer (NASS Cropland Layer updated annually)
- Crop mask contains all agricultural land instead of "fruits and vegetables" only
- Feedlot, dairy and poultry locations from CA Dept of Water Resources Land Use Survey:
  - http://www.water.ca.gov/landwateruse/lusrvymain.cfm
- Pathogen risk based on 32 day cumulative precipitation and NDVI anomalies updated every 8 days
- Analysis Domain included CA, NV, AZ

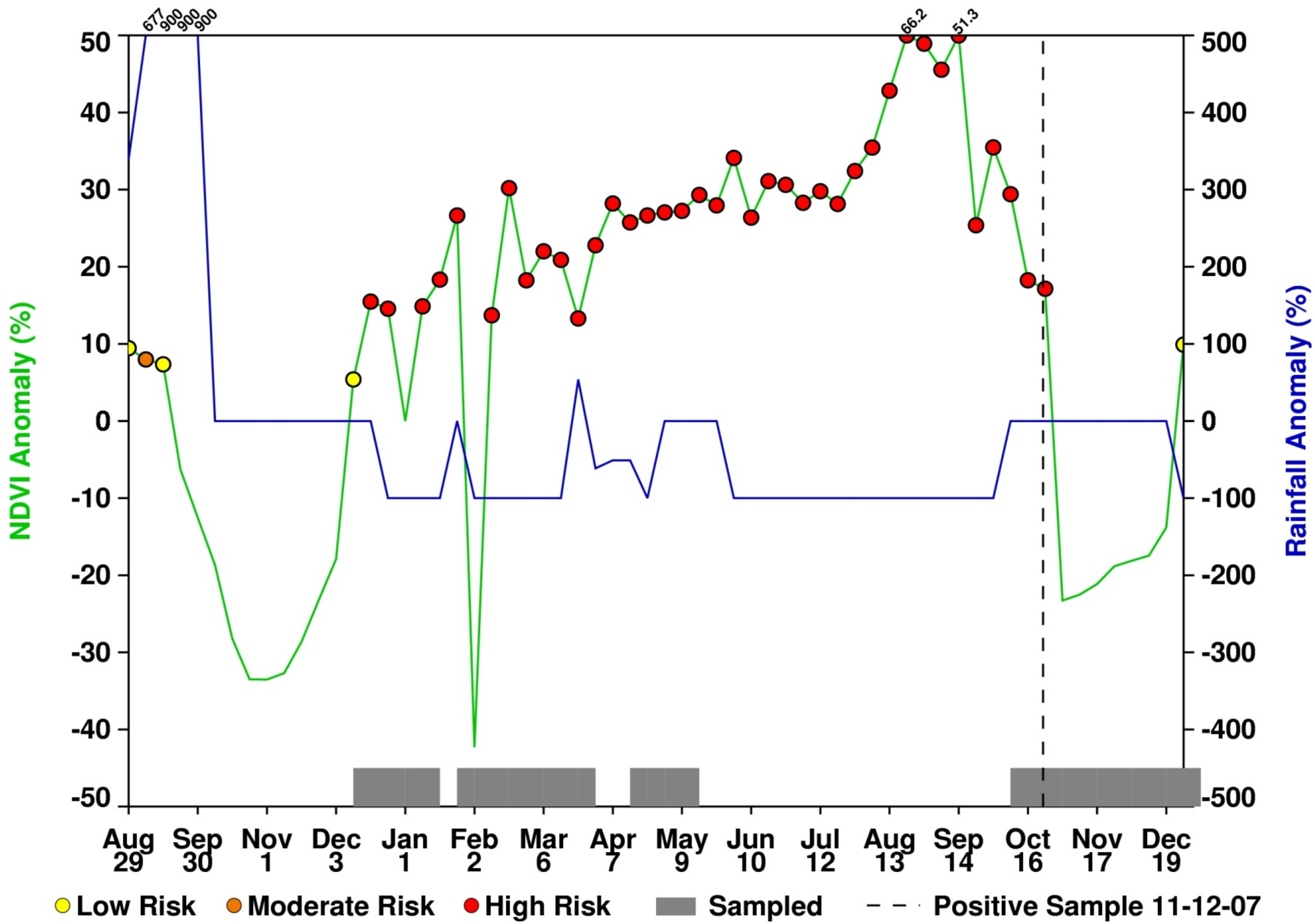
GIS-RISK

Predicted Pathogen Risk at location 1 in California

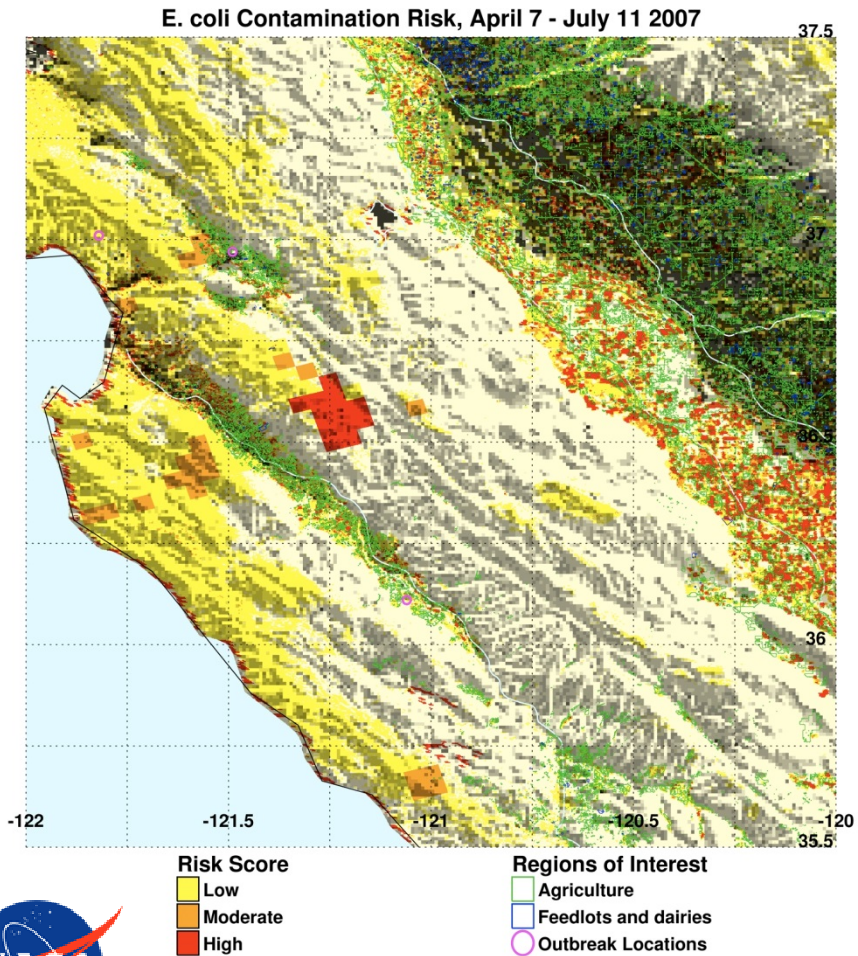


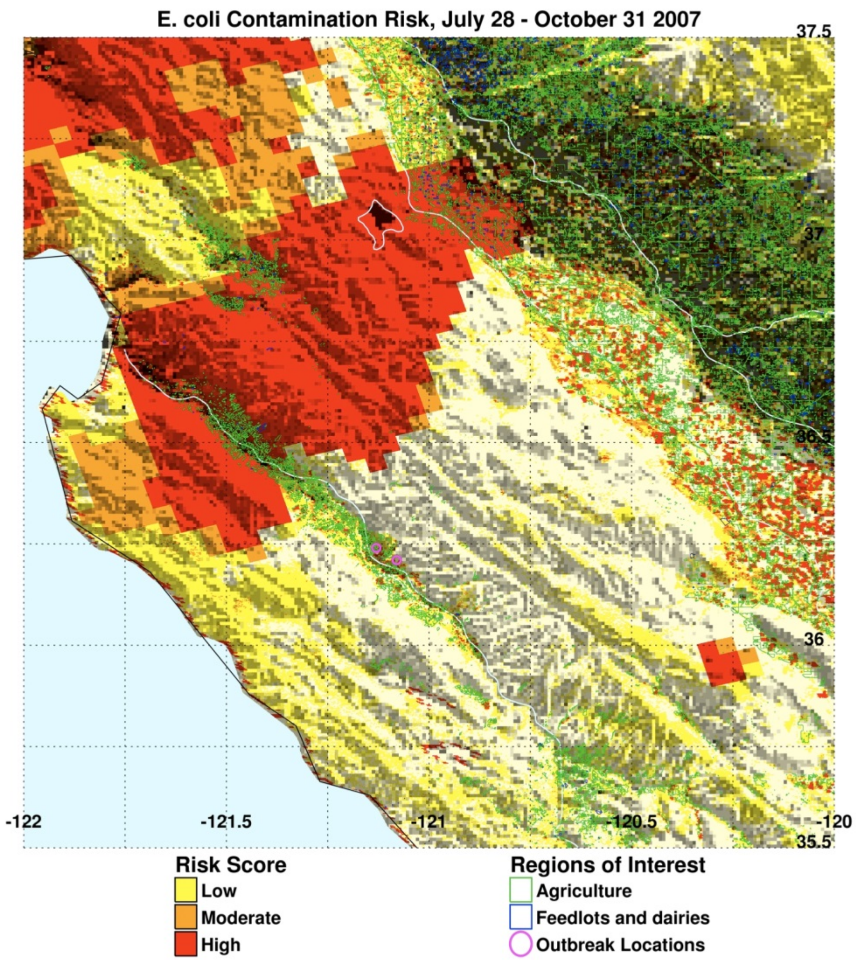
GIS-RISK

Predicted Pathogen Risk at location 2 in California



Composite Risk: Salinas Valley





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USDA-ARS

- Robert Cooley
- Lisa Gorski
- Robert Mandrell

USDA-APHIS

- Ryan Miller
- Kathe Bjork
- Chris Burdette (CSU)

What's needed to advance quantitative risk assessment modeling?

- **Articulation of key questions to answer**
  - …so the right tools/models are developed, validated, deployed
- **Collaboration and leveraging of resources – government, industry, academic, international**
  - Encourage data sharing
  - Improved understanding and modeling of the complex food supply system.
  - Systematic/ targeted collection of relevant data
    - Example: Prevalence and enumeration data for specific hazards in specific commodities at specific points in food supply chain (farm, processor, transportation, retail)

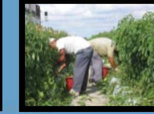
The right risk assessment, with data, will:

- Inform risk managers of where and when to look, to:
  - set priorities / allocate resources
  - identify major risk-contributing steps in farm-to-fork continuum
- Enable risk managers to evaluate effectiveness of interventions:
  - potential or equivalent control measures
  - proposed standards and criteria
  - contribution of compliance to risk management
- Inform risk communicators in:
  - developing communication/outreach messages
  - determining subpopulations at increased risk
  - assessing uncertainty and variability

Data Needs for Risk Models

- QRA is data intensive!
- Obtain the most up-to-date, and peer reviewed data from:
  - Published literature (meta-analysis), Expert elicitation
  - In-house research & surveys (ORA), Gov't surveys (NHANES)
  - Commissioned studies (IEH, ARS), Data calls via FRN
  - Industry, Academia, Informal; educational site visits
  - Field trials
- Consider variability and uncertainty
  - Varying crops and pathogens
  - Spatial and Temporal Variation
    - at various regions/locations in the USA, during varying seasons.
    - under varying environmental conditions (temperature, solar irradiation, moisture/humidity, pH, salinity, windiness, climate, composition and concentration of microbial flora, soil series, water turbidity)



RISK ASSESSMENT DATA NEEDS - 1

- **Practices**
  - **Farm** (water sources, irrigation method & frequency, soil amendment, culture, workers, equipment & tools, wildlife mgt., harvest practices, etc.)
  - **Processing** (steps, wash water, treatments, equipment)
  - **Transport** (amount, temp., duration etc.)
  - **Retail & Consumption** (storage, preparation, etc.)
  - **Effectiveness of intervention methods**

- **Need for Spatial and temporal variation:**
  - Data from various locations in the USA,
  - Data at varying times/seasons in each location

RISK ASSESSMENT DATA NEEDS - 2

- **Pathogen Prevalence, subtype & enumeration data**
  - Farm (produce, irrigation water, soil, manure and other components)
  - Processing, Transport, Retail & Consumption.
- **Pathogen Survival data (duration & likelihood)**
  - Farm, Processing, Transport, Retail & Consumption.
- **Data with Spatial and temporal variation:**
  - Data from various locations in the USA,
  - Data at varying times/seasons in each location
    - varying environmental conditions (temperature, solar irradiation, moisture/humidity, pH, salinity, windiness, climate, composition and concentration of microbial flora, soil series, water turbidity)

DATA NEEDS – Transfer Coefficients

- Transfer coefficients of enteric pathogen (EP). Examples:
  - From soil to produce
    - via irrigation water splash, direct contact, wildlife, farm worker, equipment, wind, flood, etc.
  - From animal feces to produce
    - via irrigation water splash, direct contact, wildlife, insects, birds, equipment.
  - From animal to produce
    - via direct contact by wildlife, flies, birds or human
  - From domestic/wild animal to surface water
    - via rain and flood water runoff/splash, direct contact, etc
- Consider variation by type of produce, pathogen, irrigation, soil, and animal, as well as location, season, and time.

DATA NEEDS – Pathogen disposition

For each hazard, and at each intervention/action process along the farm to fork continuum, we need to know:

- What is happening? (addition, growth, decrease, cross contamination, dilution/concentration)
- What is the proportion of produce units that are contaminated ? (before and after)
- What is the level of contamination of a contaminated unit? (before and after)
- What is the increase or decrease in contamination level per produce unit?
- What is the increase or decrease in the proportion of contaminated produce units during the process?

Any sampling data and knowledge that can help FDA to derive this information will be most appreciated.

FDA Data Acquisition from Field Trials and Sampling

- **UC Davis, WCFS Field Trials:**
  - Overhead irrigation mediated E. coli 0157:H7 transfer from wildlife feces to Romaine lettuce.
  - E. coli 0157:H7 survival duration on leaf surface.
- **Virginia Tech Field Trials** – Salmonella in Tomatoes.
- **USDA-ARS Field trials** – EC, SE, LM in Tomatoes and Lettuce
- **USDA-ARS Watershed sampling** for EC, SE, LM, NV
- **Industry Collaboration** – A novel partnership, providing invaluable sampling data for model validation and calibration.
- **USDA-APHIS FLAPS Model**

WCFS, CA Field Trial

GOAL: Simulate and quantify the transfer of E. coli O157:H7 bacteria from fecal deposits to adjacent heads of lettuce, via the splash of overhead sprinkler irrigation water.

WESTERN CENTER *for* FOOD SAFETY

Objectives: The field trial involves :

- Growth of Romaine lettuce using standard commercial practices (standard bed and furrow design, foliar irrigation, etc.) and
- Spiking of rabbit feces with an attenuated rifampicin resistant strain of *E. coli* O157:H7 (ATCC 700728), for use in two experiments as follows to:

1. **determine transfer coefficient:** measure the likelihood and amount of *E. coli* O157:H7 that transfers onto mature Romaine lettuce from wildlife scat lying on the soil surface due to foliar irrigation ; and
2. **determine survival rates:** measure the daily survival likelihood and amount of *E. coli* O157:H7 in a fecal-water matrix after direct inoculation onto mature Romaine lettuce leaves (i.e.,)

Output: Key variables that influence the value of the *E. coli* O157:H7 transfer coefficient are: age of feces, distance of feces from lettuce, distance of sprinkler head from feces, wind direction and speed, etc)

VA Tech Field Trial

GOAL: Simulate and quantify the transfer of *Salmonella* bacteria from contaminated amended soil, and contaminated water, to tomato plants.

Objectives::

1. Determine the likelihood & amount of *S. enterica* Newport (SeN) contamination and survival on/in tomatoes using two different cultural systems (plasticulture vs. bare ground) and staked vs non staked, with drip irrigation.
2. Determine the likelihood and amount of SeN transfer to tomato plants grown in raw poultry litter versus conventional fertilizers.
3. Determine the likelihood and amount of SeN contamination in/on tomato plants that were drip irrigated with pond water vs. well water.

Plots will be 30 ft. in length & arranged in a randomized complete block design with 4 reps. per treatment

Output: Transfer coefficients for S. *enterica* Newport from soil to tomatoes, and from water to tomatoes. Results will be used to parameterize QPRAM

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USDA-ARS, MD Field Trial

GOAL: Simulate and quantify the transfer of *Salmonella* and *E coli* bacteria from contaminated amended soil, to tomato and lettuce plants.

Objectives:

Researchers at ARS-Beltsville, will conduct field trials that involve:

1. Growth of fresh produce using standard commercial practices (standard bed and furrow design, foliar irrigation, etc.)
2. Determine the likelihood and amount of pathogen (Salmonella and E coli) transfer to, and survival in/on fresh produce plants grown in raw manure amended soil versus conventionally amended soil, under varying conditions of culture and irrigation.

Output: Transfer coefficients for Salmonella and E. coli bacteria from contaminated amended soil to tomatoes and lettuce plants. Results will be used to parameterize QPRAM. A variation of VA Tech and UC Davis trials.

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

USDA-ARS, CA Sampling

GOAL: Sample and determine the incidence and concentration of E. coli O157:H7, generic E. coli, Salmonella, Listeria monocytogenes, and Norovirus in the watersheds of California, and measure the spatial and temporal variation.

Objective:

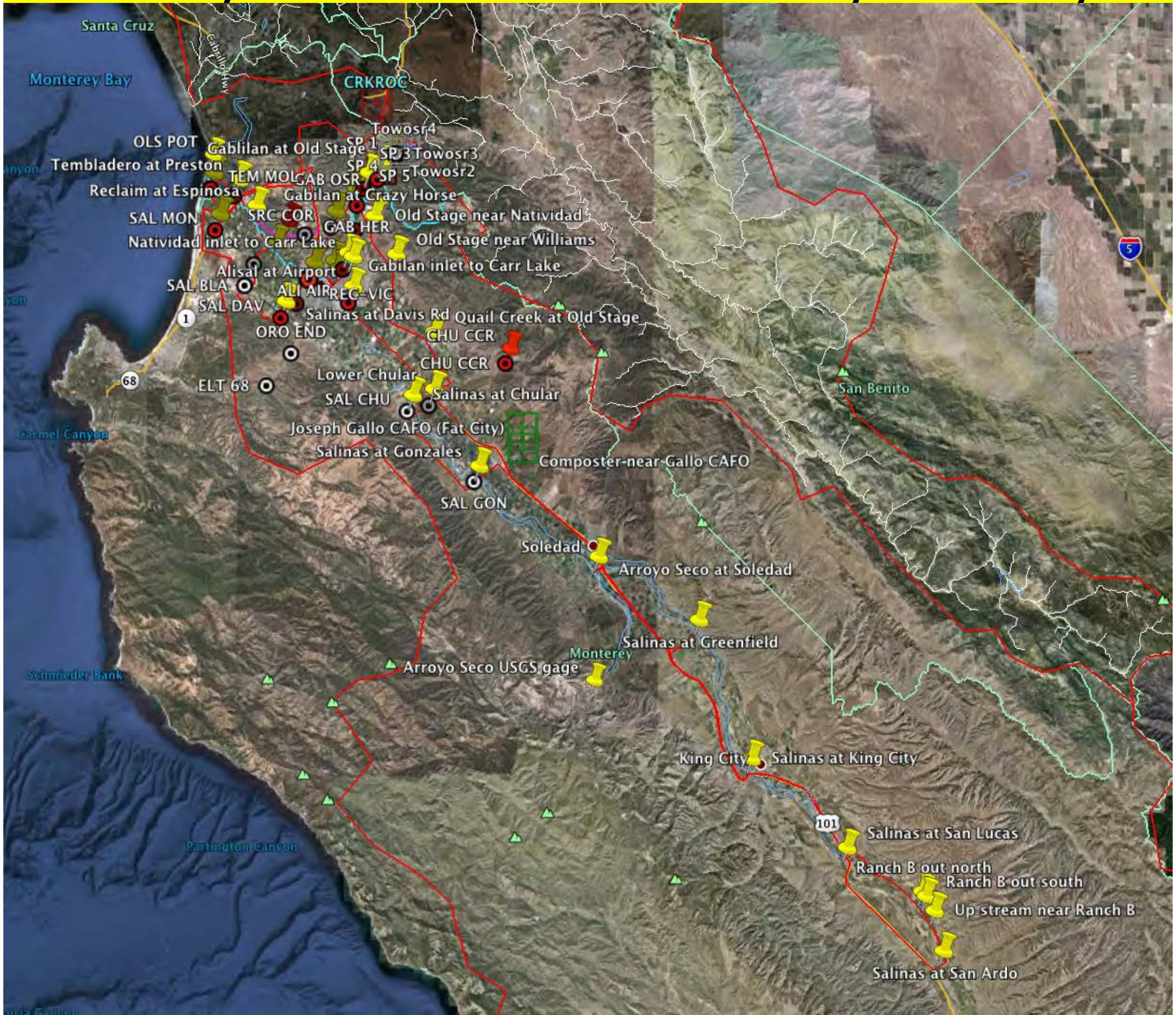
- **Year 1:** Periodic Sampling for E. coli and Salmonella (twice a month)
- **Year 2:** Intensive sampling for E. coli O157:H7, generic E. coli, Salmonella, Listeria monocytogenes, and Norovirus, (every week, or twice a week)

QUESTION: How does pathogen presence and concentration in specific locations in the watershed, depend on season, rainfall, temperature, topography, and proximity to livestock and wildlife?

Output:
For each sample: Date, GPS loc, positive/negative, concentration/enumeration
For each location: GPS loc, period (week/month/year) #sampled, #positive.
Data will be used in PGRAM to better predict produce contamination.

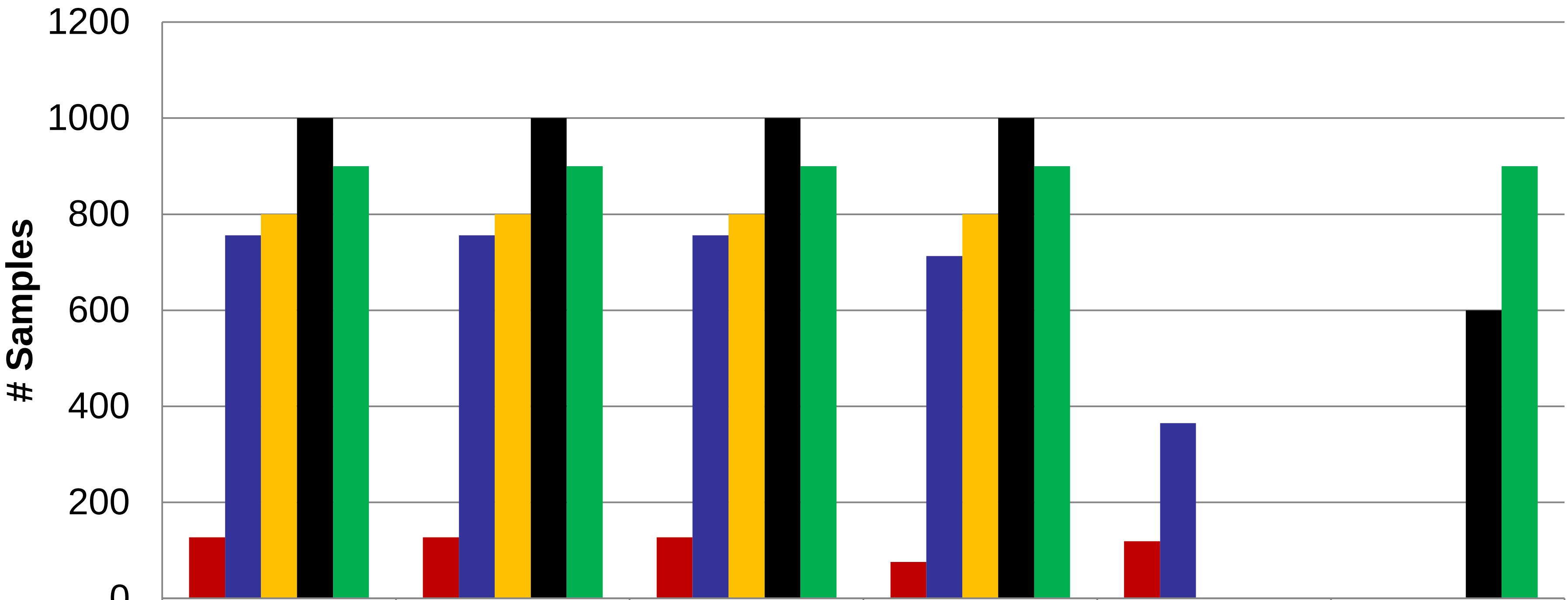
USDA-ARS, CA Sampling

Study Locations - Monteray County



USDA-ARS, CA Sampling

Number of Samples Tested



	Ecoli	STEC	Salmonella	Listeria	Norovirus	Campylobacter
2011	127	127	127	76	119	0
2012	756	756	756	713	365	0
2013	800	800	800	800	0	0
2014	1000	1000	1000	1000	0	600
2015	900	900	900	900	0	900

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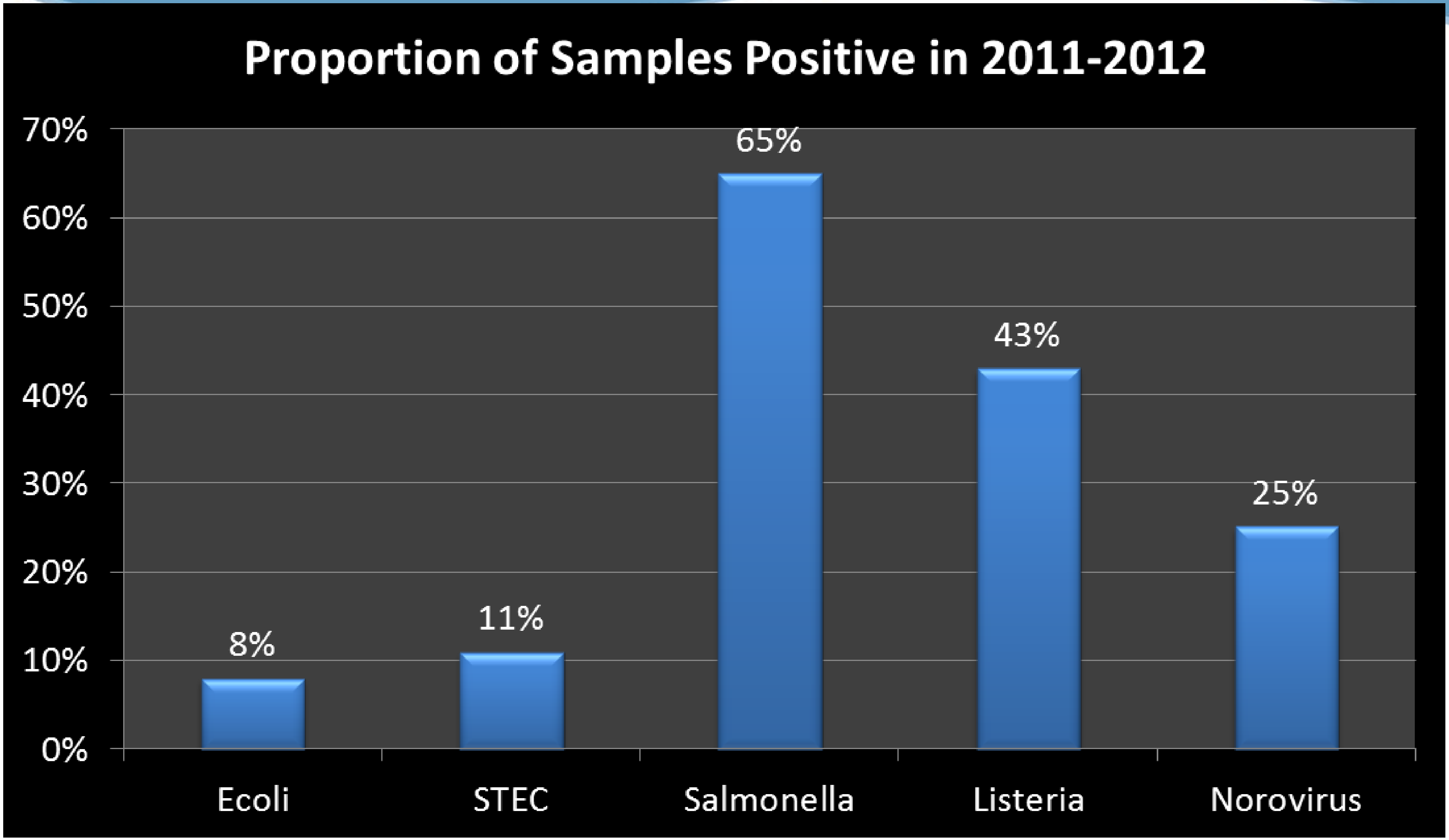
USDA-ARS, CA Sampling



Adapted from:

- Cooley et. al. Prevalence of Shiga toxin Producing *Escherichia coli*, *Salmonella enterica* and *Listeria monocytogenes* at Public Access Watershed Sites in a California Central Coast Agricultural Region, Front. Cell. Infect. Microbiol., 04 March 2014 | doi: 10.3389/fcimb.2014.00030.

Industry Sampling data

Goals:

- Acquire Salmonella, E. coli, Listeria, and norovirus sampling data from Industry collaborators,
- Use the data to parameterize, validate, and calibrate FDA's predictive geospatial risk assessment model (PGRAM),
- Test the model's ability to predict enteric pathogen contamination of produce.

Novel: Innovative collaboration mechanism .

Output:

- Parameterize and calibrate PGRAM to better forecast/predict produce contamination.
- Use forecasts to target sampling and other interventions, to enhance food safety.

Industry Sampling data

Goal: FDA acquire sampling data from Industry collaborators, and use the data to parameterize, validate, and calibrate FDA's predictive geospatial risk assessment model (GIS-Risk), and to test the model's ability to predict enteric pathogen contamination of produce.

1. Use 2006-2007 data to parameterize GIS-Risk, and predict 2008 contaminations.
2. Use 2006-2008 data to parameterize GIS-Risk, and predict 2009 contaminations
3. Use 2006-2008 data to parameterize GIS-Risk, and predict 2009 contaminations
4. Use 2006-2009 data to parameterize GIS-Risk, and predict 2010 contaminations
5. Use 2006-20010 data to parameterize GIS-Risk, and predict 2011 contaminations

Validate and test the predictive model via RCA's with industry.

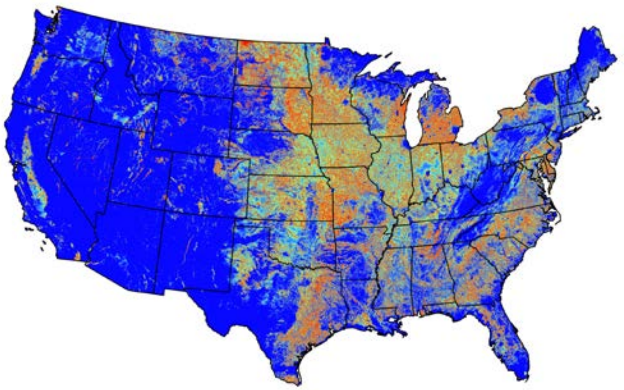
USDA-APHIS Collaboration

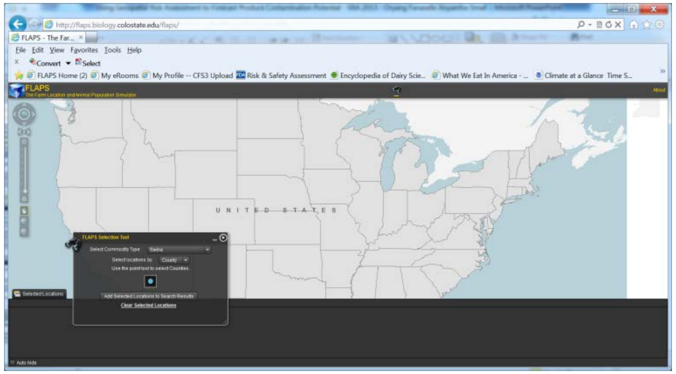
Goal:

Develop the Farm Location and Animal Population Simulator (FLAPS) model to provide fine-grained spatial data of the distribution of swine, poultry, and cattle farms in the USA.

Approach:

- The FLAPS model is designed to use Census of Agriculture data and a variety of spatial-, statistical-, and simulation-modeling techniques to forecast the distribution and populations of poultry, cattle, swine, and feral swine, at a 100 m resolution for the conterminous U.S.
- FDA is able to access output data from the FLAPS model (i.e., the spatially-explicit simulation of farm locations and populations) through a web-based user interface..





Output:

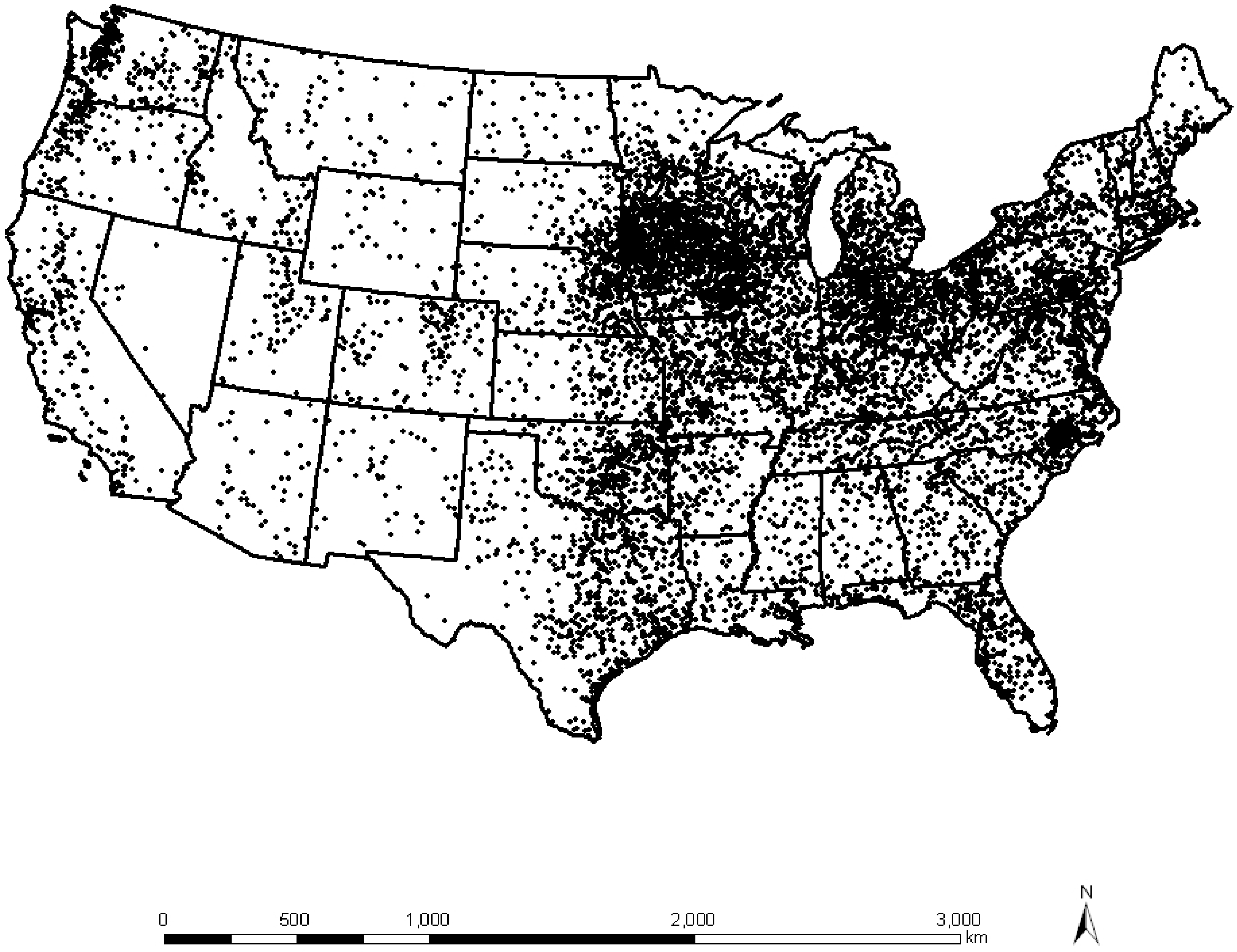
- Forecast of the distribution and populations of poultry, cattle, and swine farms, and feral swine, at a 100 m resolution for the conterminous U.S

FLAPS Overview

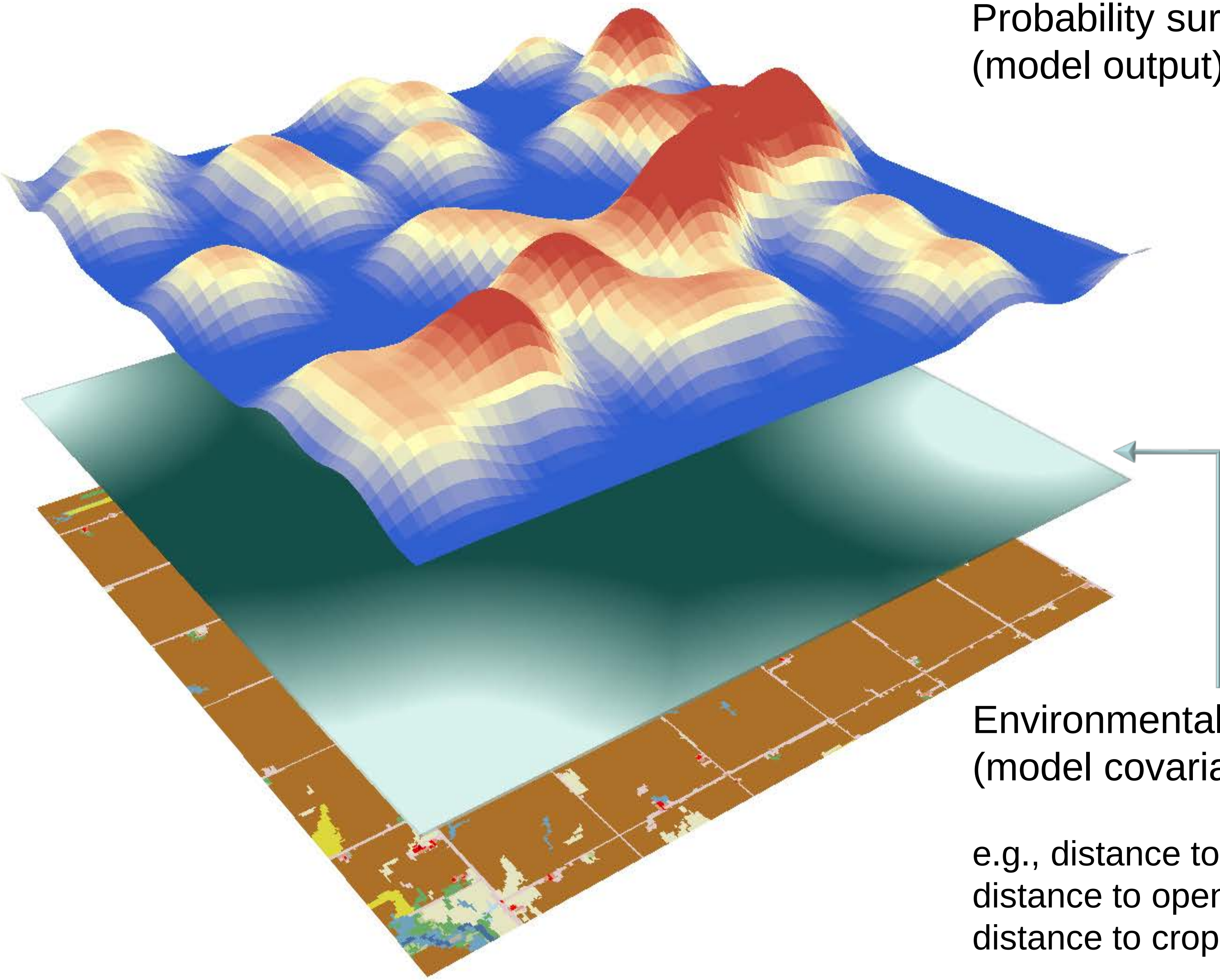
- Utilizes 2007 NASS data
- Generalized design (applicable to other NASS commodities?)
- User interface
- Locations estimated probabilistically (rather than rule-based)
- Locations estimated from samples of actual farm locations (10,000 sample locations/species)
- Fine spatial resolution (100m)

USDA-APHIS Collaboration

Swine farm, presence/absence sample (n = 10,000)



USDA-APHIS Collaboration



Probability surface (model output)

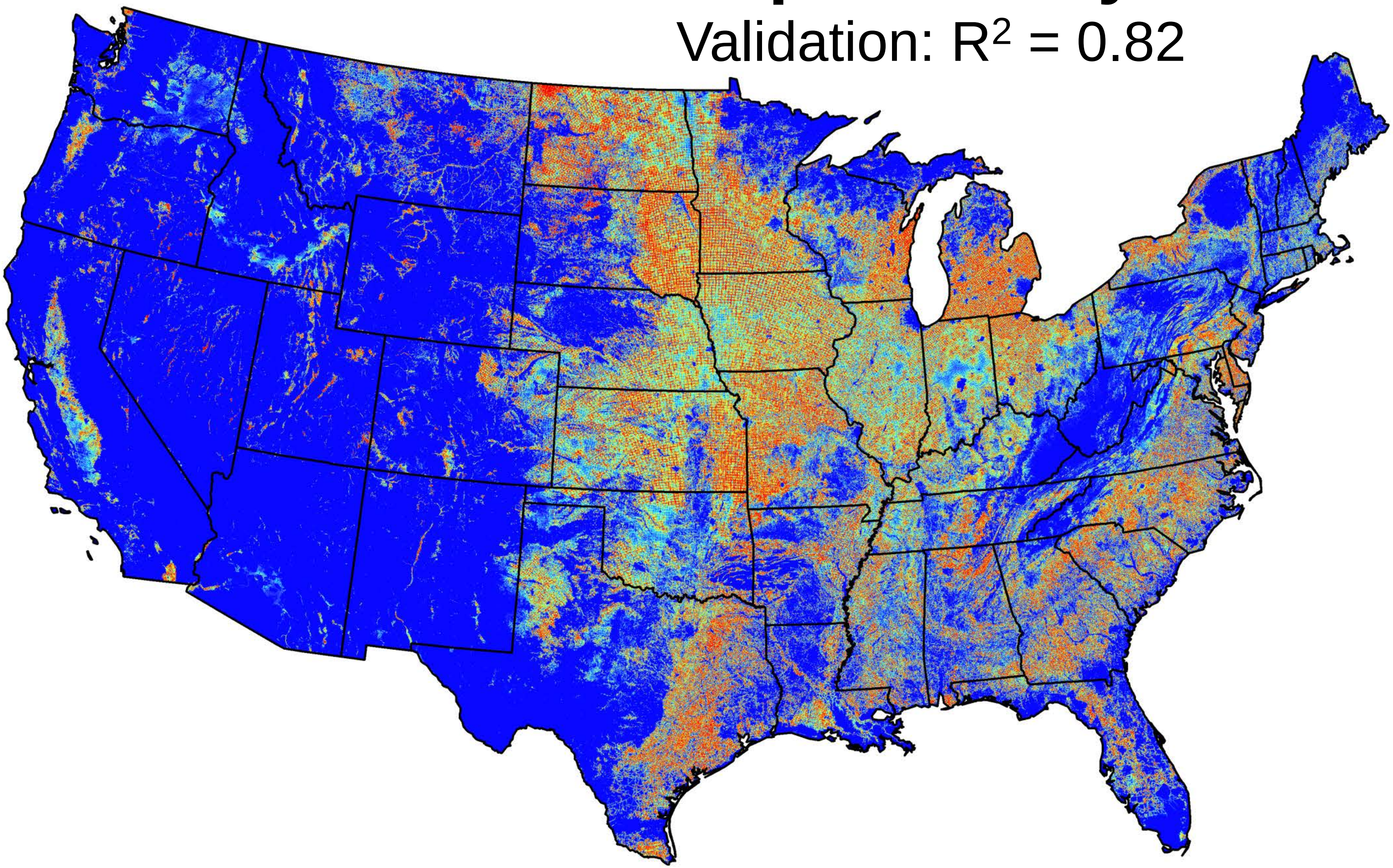
Environmental data (model covariates)

e.g., distance to road, distance to open areas, distance to cropland, etc.

USDA-APHIS Collaboration

Swine probability surface

Validation: $R^2 = 0.82$



Simulation Output

state	latitude	longitude	population	commodity
NV	39.520819	-118.764466	260	dairy
NV	39.505687	-118.644494	1567	dairy
NV	39.502445	-118.794729	1037	dairy
WY	41.31499	-106.624	1599	beef
WY	41.31391	-106.744	1872	beef
WY	41.31283	-106.753	346	beef
NE	40.62651	-98.2828	869	swine
NE	40.59732	-98.673	304	swine
NE	40.55517	-98.3055	1122	swine
AR	36.16918	-93.1132	9454	layers
AR	36.16053	-93.0343	25	layers
AR	36.15296	-93.0689	13450	layers
VA	37.48454	-78.2994	141	broilerssold
VA	37.46833	-78.2108	798309	broilerssold
VA	37.45536	-78.2281	1282130	broilerssold

CONCLUSION

FDA Models with Applicability to Produce

- **FDA-iRISK®:** An interactive, Web-based, risk assessment modeling tool (freely available at http://foodrisk.org/exclusives/). It quantitatively compares and ranks risks posed by multiple food/hazard combinations taking into account consumption, dose-response relationship, as well as contamination in the food supply system, from production to consumption. It can **provide an industry-wide or farm-level perspective of the risk**.
- **GIS-Risk:** A collaboration between FDA and NASA, to link geographic information systems with predictive risk-assessment models. The ultimate goal is to forecast when, where, and under what conditions microbial contamination of crops is likely to occur, leading to human illness. It **provides a regional perspective of risk**.
- **QPRAM**: The Quantitative Produce Risk Assessment Model (QPRAM) is an agent–based, virtual laboratory that models specific practices and risk factors. QPRAM tracks each unit of produce; keeping a history of how, when, where, and by how much it was contaminated. It **provides a facility** (individual farm or processing facility) **level perspective of risk**.

Conclusion

- A risk model allows virtual exploration of the events that lead to contamination, or an outbreak, and the ability to measure changes in contaminations or illnesses if different actions or measures are taken.
- Using Risk models, FDA is developing better scientific & risk based approaches to:
  - Identify "riskiest" stages of the farm-to-fork continuum for hazard-commodity pairs
  - Identify opportunities within each stage to reduce the risk of contamination
  - Compare/evaluate the effectiveness of various interventions and control measures
  - Perform "what if" scenarios to inform trace-back investigations
  - Predict where and when environmental contamination is a threat to food safety.

- The models integrate a multitude of data and information to predict effectiveness of prevention and control practices.

Some Lingering Questions

- How does produce become contaminated (i.e., routes of contamination) during on-farm growth, harvesting, and postharvest operation? Are there spatial and temporal factors that impact the likelihood of contamination?
- Are the produce types spatially distributed?
- Is pathogen presence in the farm environment spatially distributed?
- Does the likelihood of contamination vary spatially and seasonally among produce commodity types, and by pathogen? What does it depend on?
- What on-farm interventions reduce the likelihood of contamination of produce?
  - What is the spatial variation in application of the interventions/GAPS?
  - What is the spatial variation in compliance to the interventions/GAPS?
- What on-farm interventions reduce the likelihood of harvesting contaminated product?
  - What is the spatial variation in application of the interventions/GAPS?
  - What is the spatial variation in compliance to the interventions/GAPS?

For more information please visit our Foods website at:
http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm

Thank You!