

A Center of Excellence between OSU and OSDH?

Under the authority of the Food Safety Modernization Act

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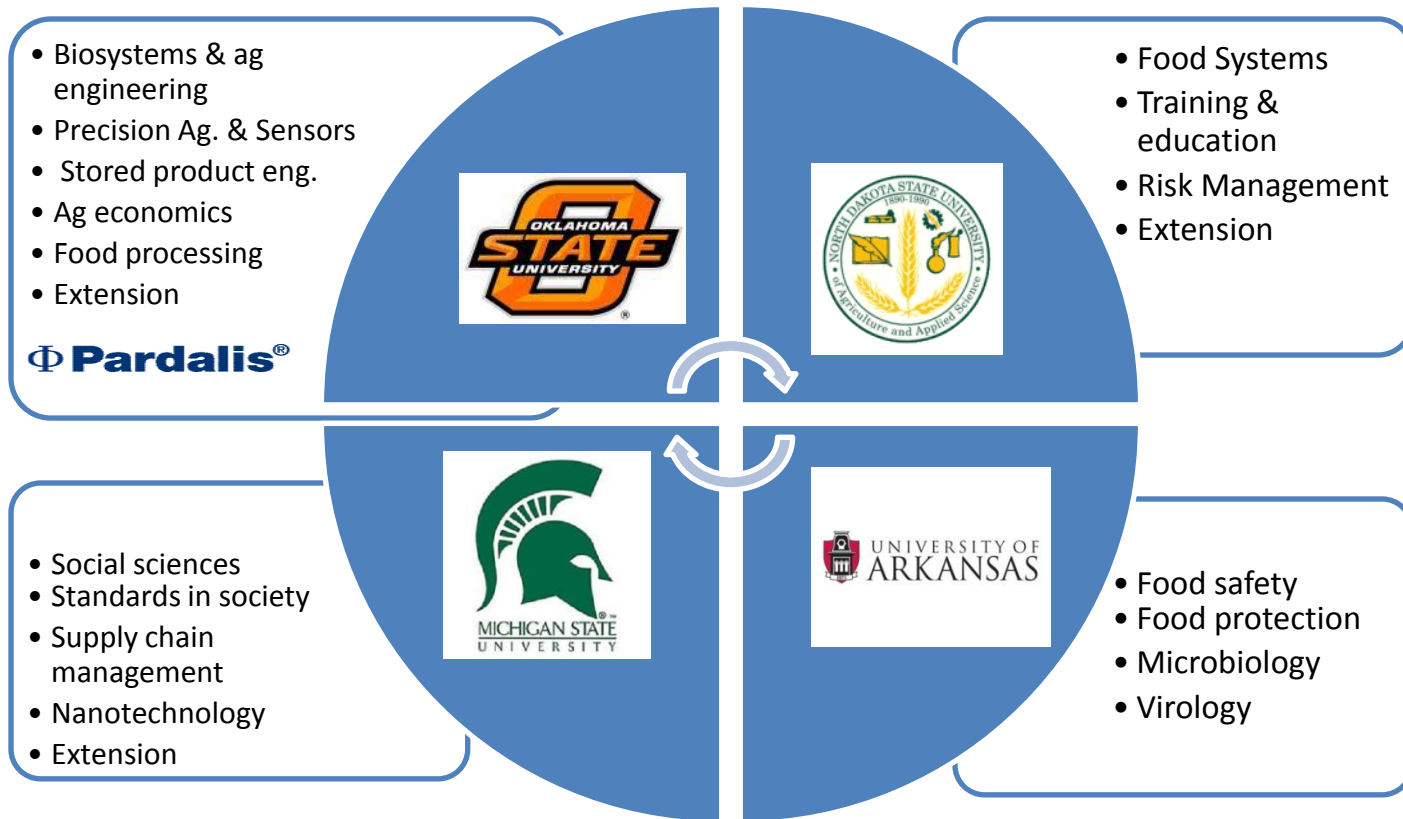
Steve Holcombe, CEO
Pardalis, Inc.

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Traceability Consortium (research attributes)

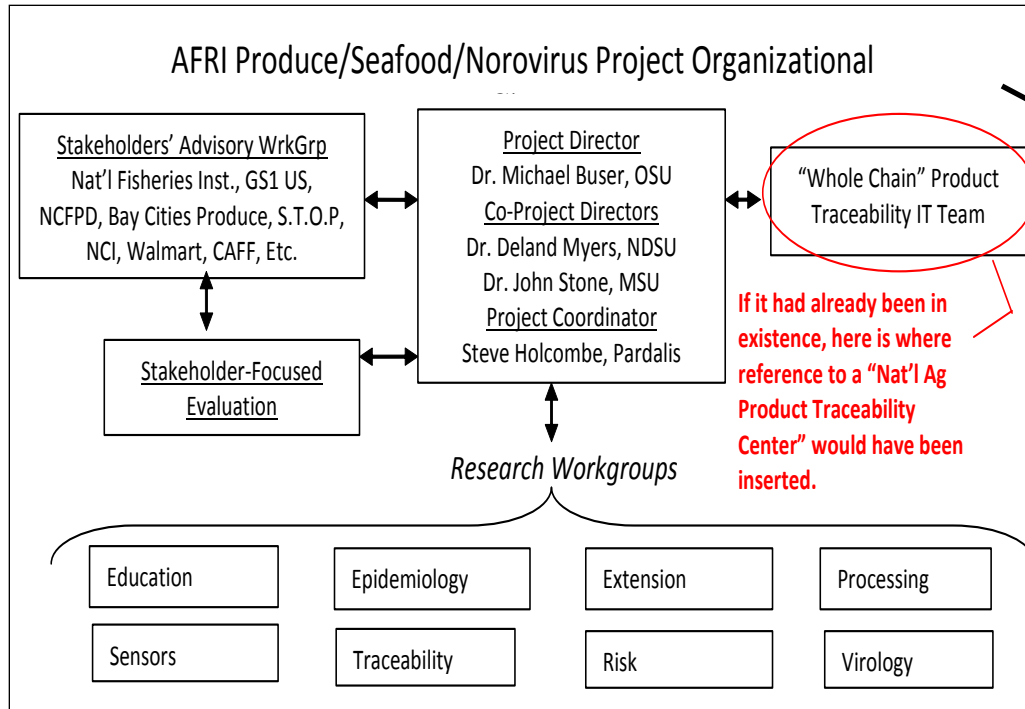


Traceability Consortium

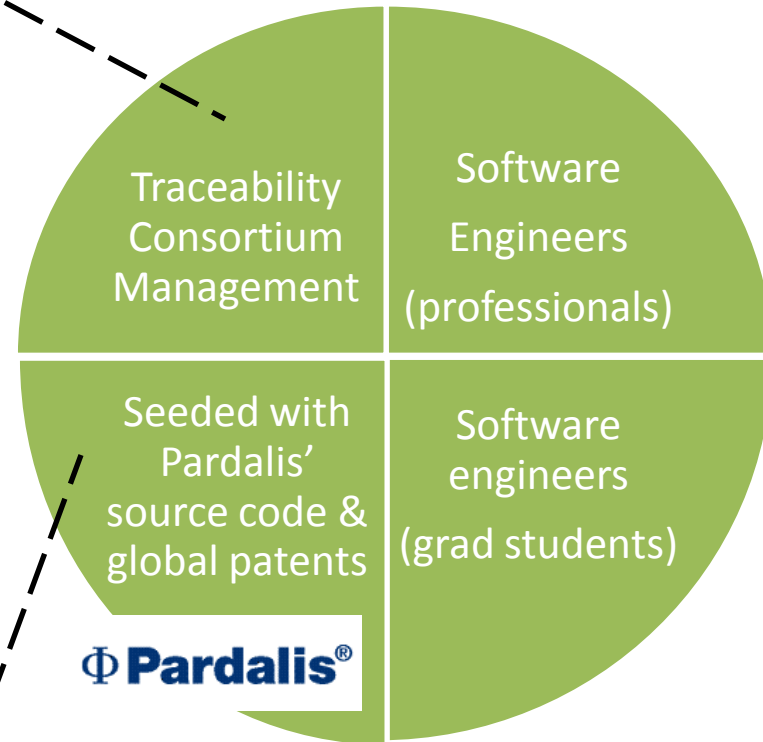
(activities in 2010)

- Sept. 1, 2010 – USDA AFRI Food Safety CAP - \$24.4M/5YR - Prevention, Detection and Control of Food-borne Viruses in Food
- Sept. 22, 2010 - USDA AFRI Food Safety CAP - \$25M/5YR - Prevention, Detection and Control of STEC from Pre-Harvest through Consumption of Beef Products.
- Oct. 30, 2010 - Proposing a National Agricultural Product Traceability Center at Oklahoma State University (proposal by Pardalis Inc.)
- Nov. 14, 2010 – Traceability Consortium – Agreement to form a multi-state traceability project between agricultural experiment stations

National Ag Product Traceability Center (Proposed October 2010)



If it had already been in existence, here is where reference to a "Nat'l Ag Product Traceability Center" would have been inserted.



Previously engineered source code for "whole chain" traceability. Patents issued or pending in Australia, Brazil, Canada, China, Europe, Hong Kong, India, Japan, Mexico, New Zealand and the United States.

Ag Traceability Overview

- The promise of “whole chain” traceability for addressing:
 - Supply Chain Optimization
 - Vertically integrated & federated chains
 - Overcoming the Bullwhip Effect
 - The missing data of fragmented chains
 - You don’t know what you don’t know
 - Data ownership & privacy issues
 - Risks & Liabilities
 - Limits of one-up/one-down
 - Recognized by FDA/USDA
 - Public and industry relations
 - Global Trust Bust says Frank Yiannas, VP of Food Safety, Walmart

One-up/One-down Traceability (Legal Overview)

- One-up/one down: Vendors must know what is going on inside of their four walls.
- Representative laws and industry initiatives:
 - EU General Food Law
 - Hazard Analysis and Critical Control Point (HACCP) plans
 - US Bioterrorism Act of 2002
 - US Food Safety Modernization Act (food safety plans)



One-up/One Down (limitations)

- EU and US Food Recalls
 - Investigations still take weeks to months
 - Innocents tainted by actions of others
 - Need for real-time, trustworthy data to respond to 24 hour news cycles
- Addresses supply chain optimization? No.
- Addresses real-time risk management? No.
- Addresses customer-driven supply chains? No.
- Addresses global trust bust? No.

“Whole Chain” Traceability

(working definition)

A “whole chain” product tracing system consists of information elements provided by persons in the supply chain to other persons in the supply chain (e.g., Value Chain).



Graphic's Source: http://en.wikipedia.org/wiki/File:Value_Demand_v_small2.png

Legal trends

- One-up/one down traceability is the standard but because of its lack of real-time responsiveness there is increasing interest by FDA, USDA FSIS, European Commission in “whole chain” traceability
 - [Product Tracing Systems for Food](#), 74 FR 56843 (food safety)
 - [IFT/FDA Traceability in Food Systems](#) (food safety)
- Representative laws and/or standards:
 - None but murmurings
- Industry Initiatives are still one-up/one-down, too:
 - Produce Traceability Initiative
 - one-up/one down grocery industry initiative
 - US GS1 Rapid Recall Exchange
 - One-up/one down distributor/retailer initiative **but supportive interest by GS1 in Traceability Consortium**

Issues and technical challenges

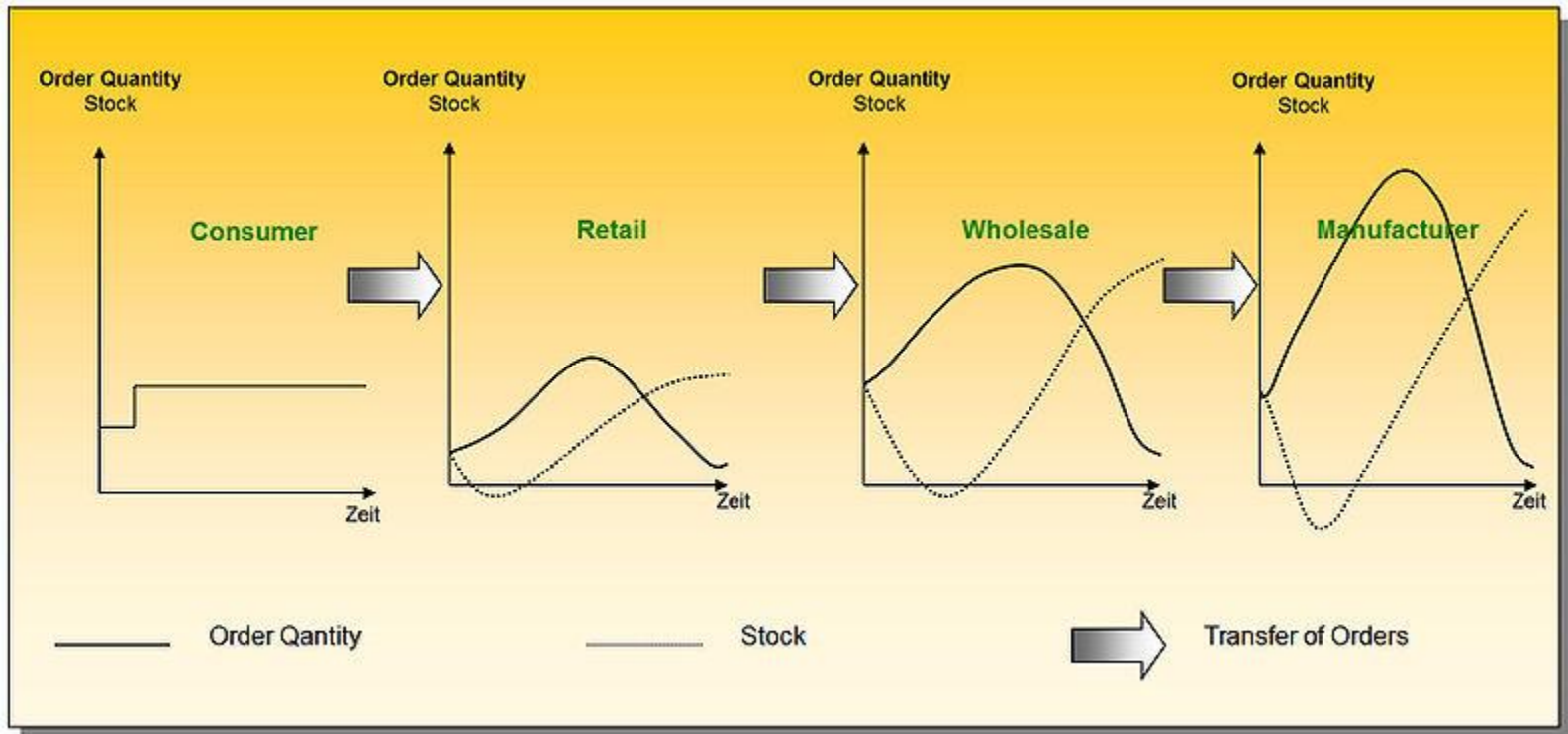
- Increasingly complex and lengthening global supply chains are poorly served by one-up/one-down
- Whole chain traceability made possible by minimal disclosures of product identity data that are traceable and controllable by persons in supply chains (See Appendix)
- Avoiding the Bullwhip Effect

Bullwhip Effect (graphical)



Source: http://en.wikipedia.org/wiki/File:Bullwhip_effect.png

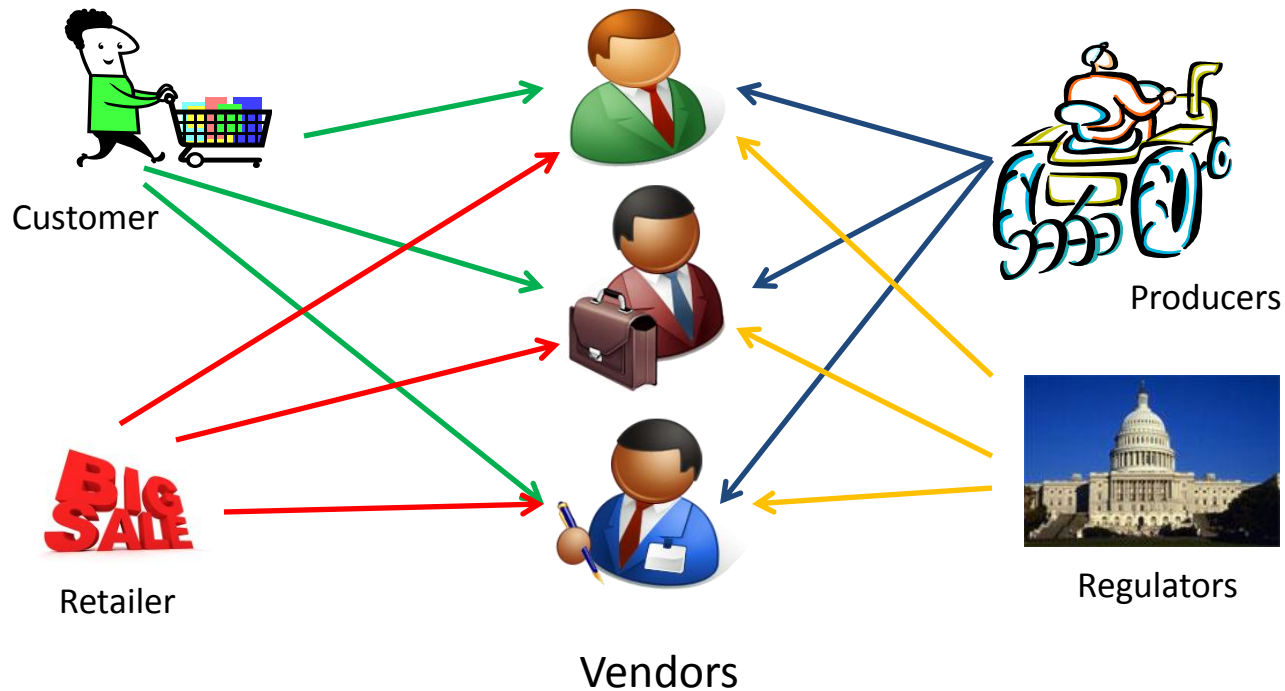
Bullwhip Effect (charted)



Source: http://en.wikipedia.org/wiki/File:Bulwhip_efect.jpg

Whole Chain Traceability

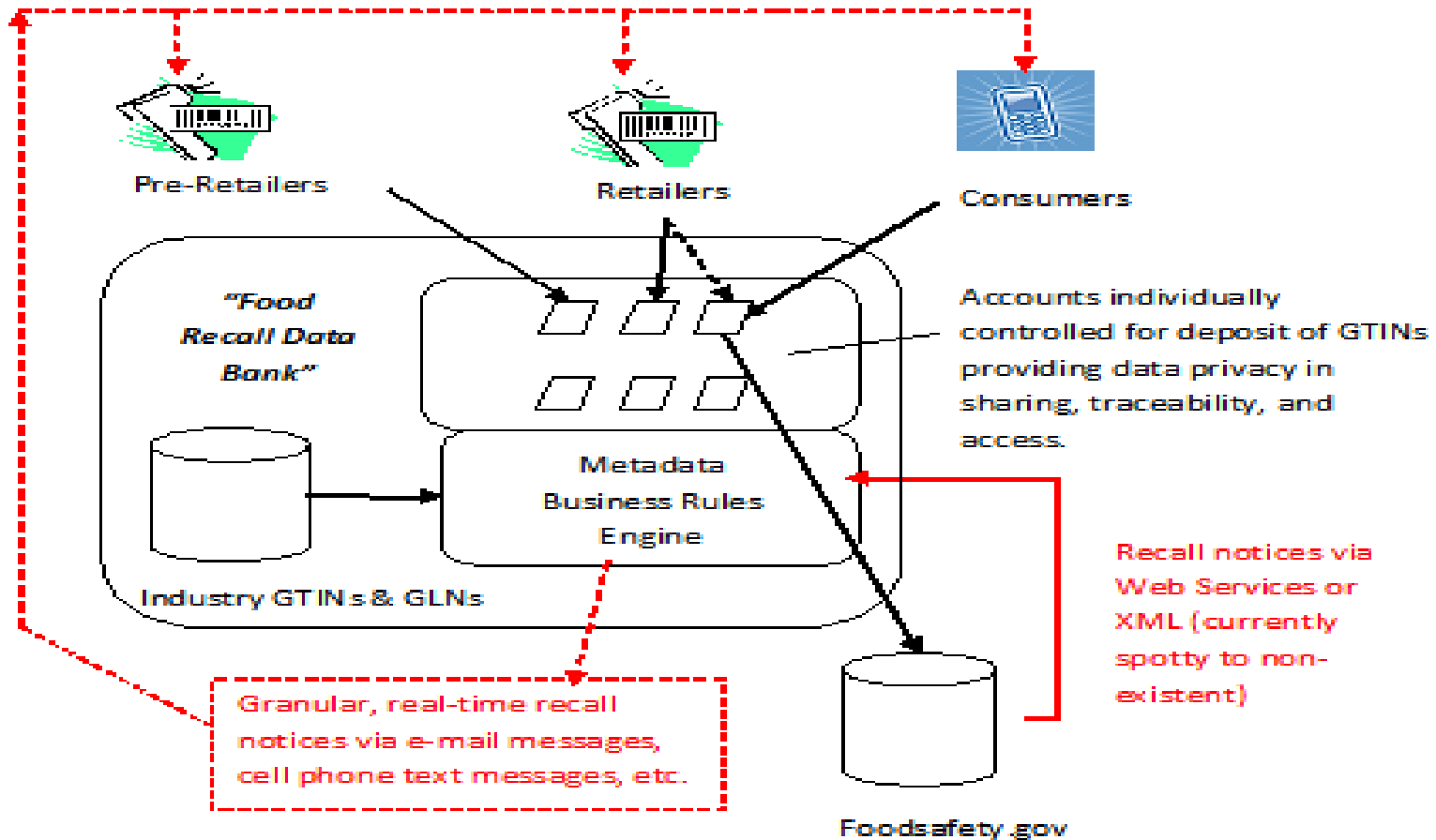
A starting point for the Value Chain



Source: Redefining Customer Experience: CRM, VRM and “Disruptive Technologies.” by Michael Hinshaw (text). Picture inspired by work by Eve Maler.

Whole Chain Traceability

A **technically achievable** starting point for the Value Chain



Solution of National Agricultural Product Traceability Center of Excellence



- No such Center currently exists in US, EU or China
- **Food Safety Modernization Act : The FDA shall designate 5 Integrated Food Safety Centers of Excellence to serve as resources for public health professionals to respond to foodborne illness outbreaks. Sec. 399V–5 (a).**
- Center would anchor the multi-disciplinary U.S. “Traceability Consortium” and a global traceability ecosystem
- Center would address both (a) Industry Stakeholder needs and (b) Regulatory needs



COE Eligible Entities

- To be eligible to be designated as a Center of Excellence an entity shall:
 - be a State health department;
 - partner with 1 or more institutions of higher education that have demonstrated knowledge, expertise, and
 - meaningful experience with regional or national food production, processing, and distribution, as well as leadership in the laboratory, epidemiological, and environmental detection and investigation of foodborne illness; ...

Sec. 399V–5 (b) (1).



COE “Working Group”

Not later than 180 days after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall establish a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food industry, including food retailers and food manufacturers, consumer organizations, and academia to make recommendations to the Secretary regarding designations of the Centers of Excellence. Sec. 399V–5 (b) (2)



COE Activities

- (1) providing resources, including timely information concerning symptoms and tests, for frontline health professionals interviewing individuals as part of routine surveillance and outbreak investigations;
- (2) providing analysis of the timeliness and effectiveness of foodborne disease surveillance and outbreak response activities;
- (3) providing training for epidemiological and environmental investigation of foodborne illness, including suggestions for streamlining and standardizing the investigation process;
- (4) establishing fellowships, stipends, and scholarships to train future epidemiological and food-safety leaders and to address critical workforce shortages;
- (5) training and coordinating State and local personnel;
- (6) strengthening capacity to participate in existing or new foodborne illness surveillance and environmental assessment information systems; and
- (7) conducting research and outreach activities focused on increasing prevention, communication, and education regarding food safety.

Sec. 399V–5 (c)

Traceability Consortium

(Activities in 2011 – so far)

- Continued applications for competitive research funding with Traceability Consortium
 - Biotechnology Risk Assessment Grant (BRAG) program
- Pursue private and other funding opportunities with Traceability Consortium
 - Syngenta Crop Protection (chemical inventory monitoring)
 - University of Shanghai (livestock trace and/or irrigation monitoring)
 - EU funded TAS3 (personal data store) project
 - EU funded OKKAM (internet of things) project
- Explore forming a COE between OSU and OSDH
 - Further explore forming regional COE project between Oklahoma and Arkansas
 - Further explore internationally aligning with EU funded projects and Chinese funded projects