



Getting Integrated:
A State
Regulatory
Perspective
on FSMA

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Wisconsin's role in an integrated national food safety system



Federal/state/local: Teammates



DATCP Food Safety Division by the numbers

◆ Food Bureau

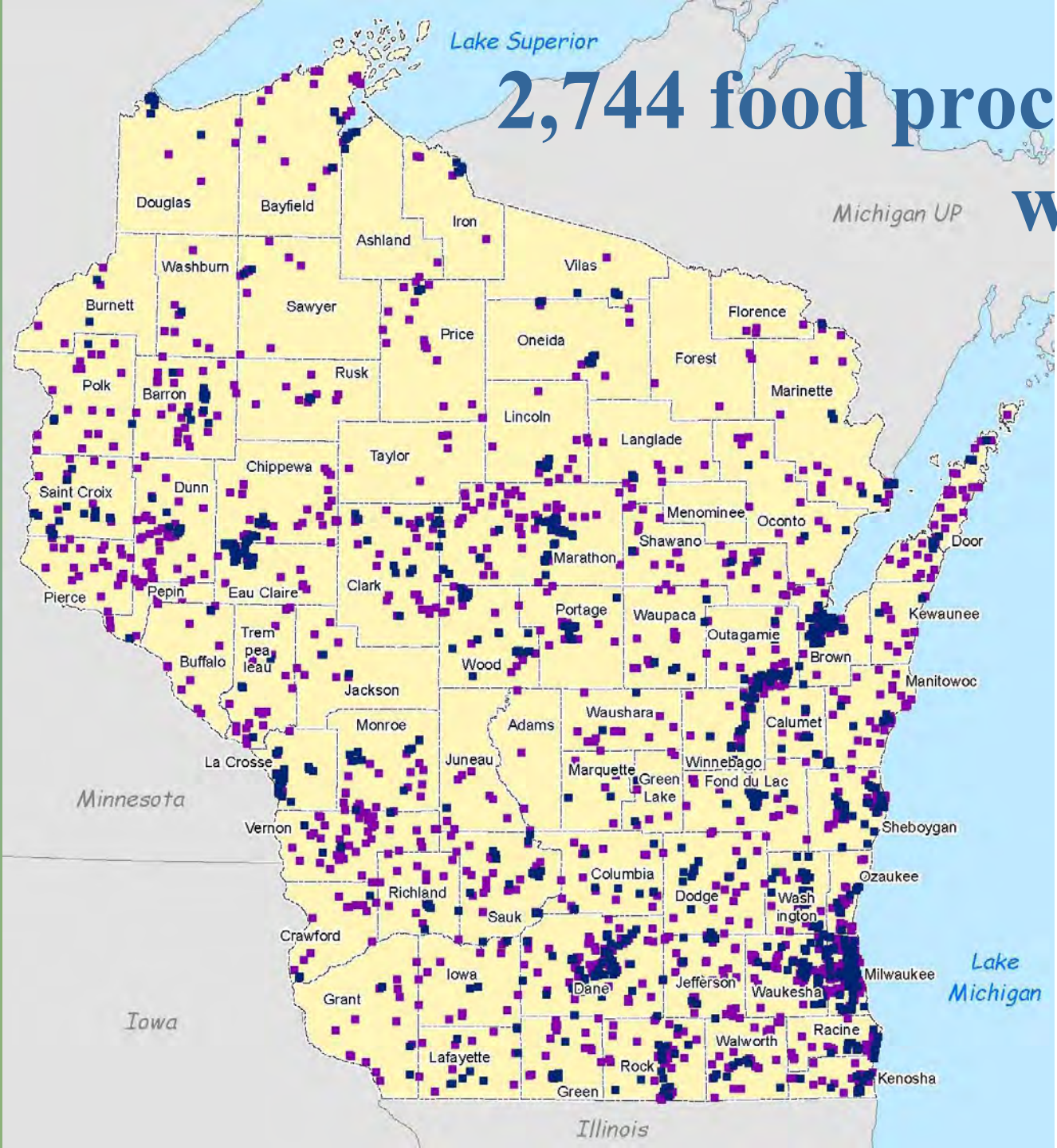
- ◆ Dairy farms
- ◆ Food/dairy processing plants
- ◆ Warehouses
- ◆ Retail food establishments
- ◆ Mandated or specified inspection frequencies
- ◆ 42 field-inspector positions
- ◆ City/county agents

◆ Meat Bureau

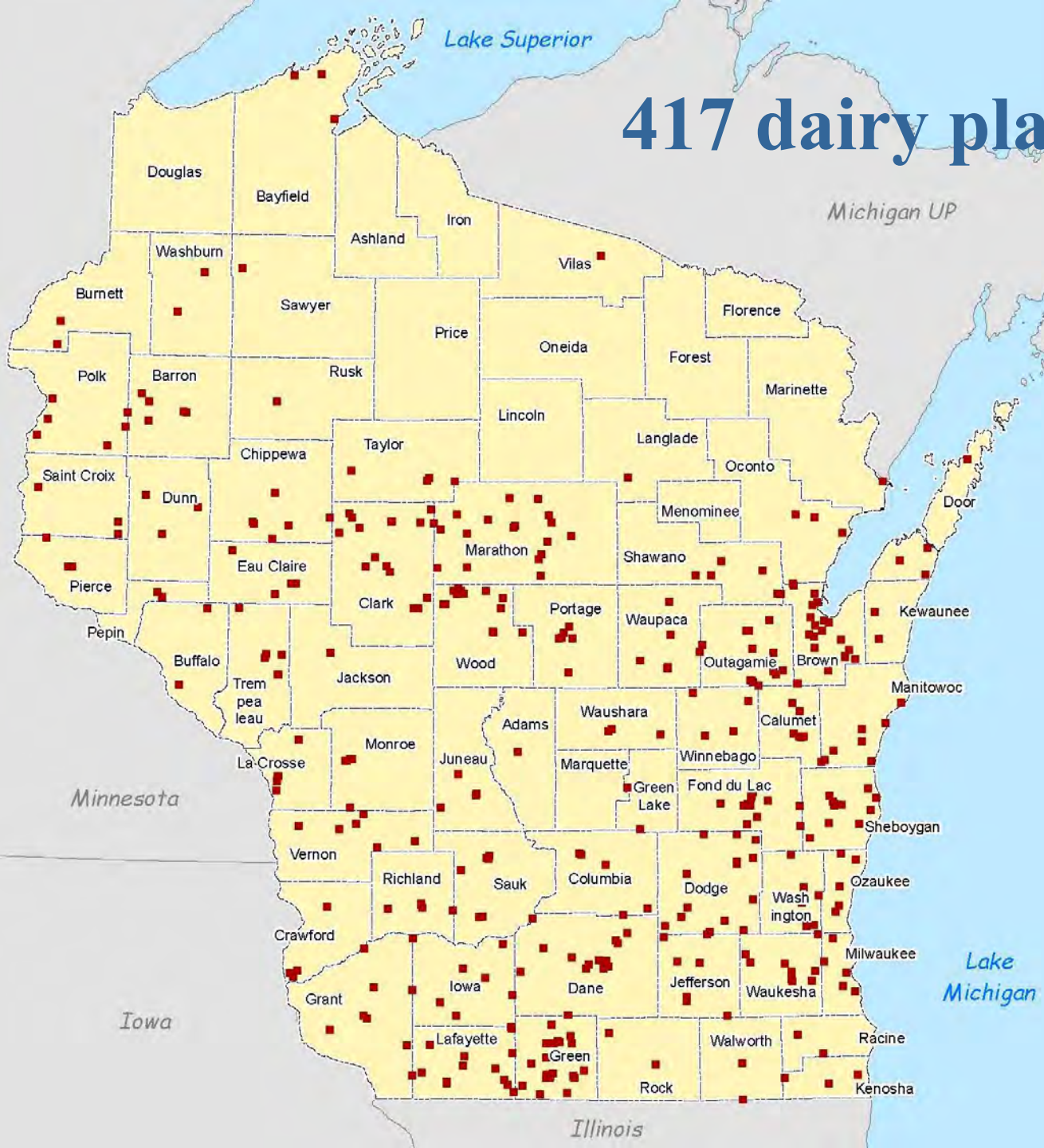
- ◆ Just under 300 plants
- ◆ Daily inspection
- ◆ 56 field-inspector positions



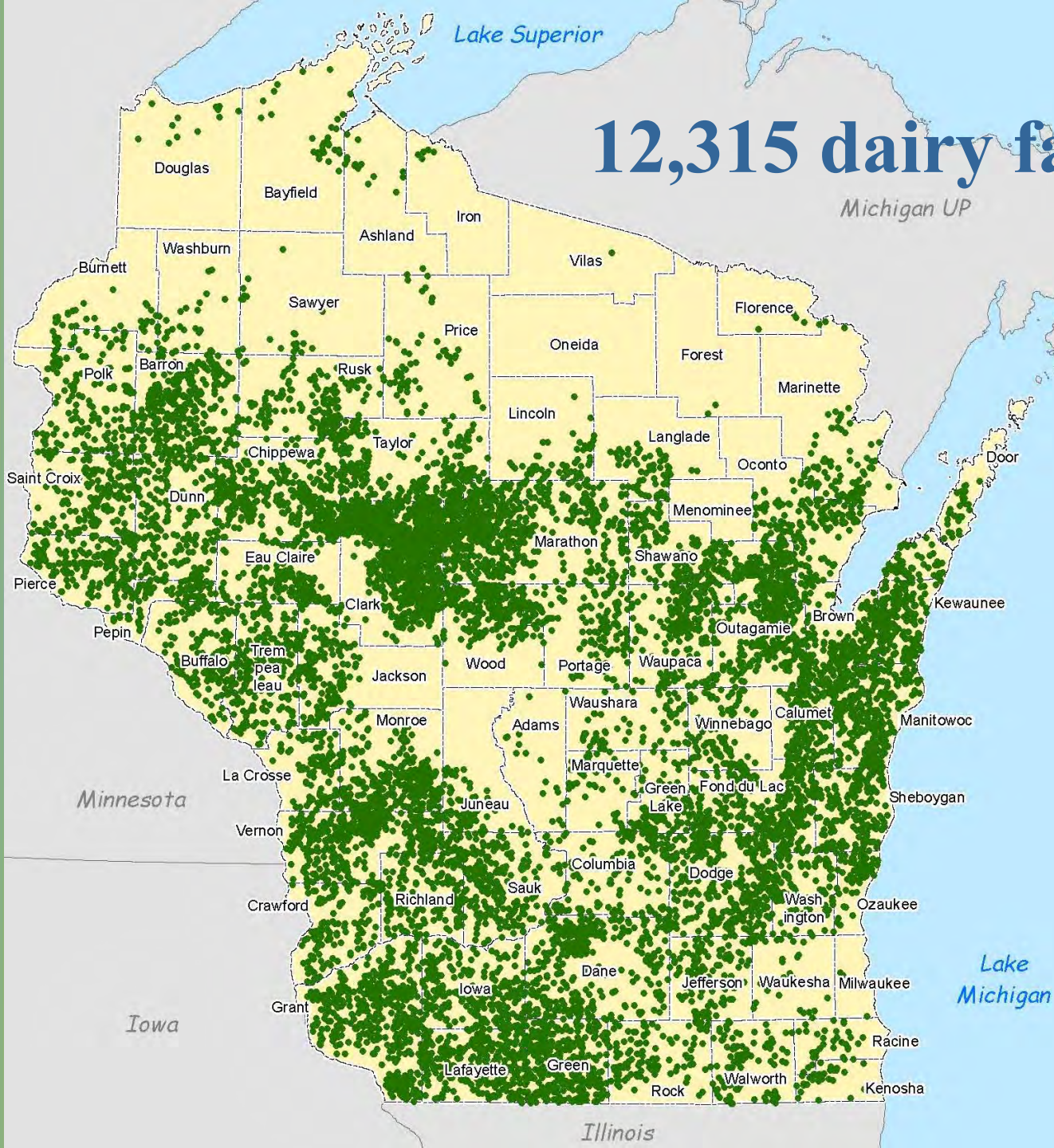
2,744 food processors and warehouses



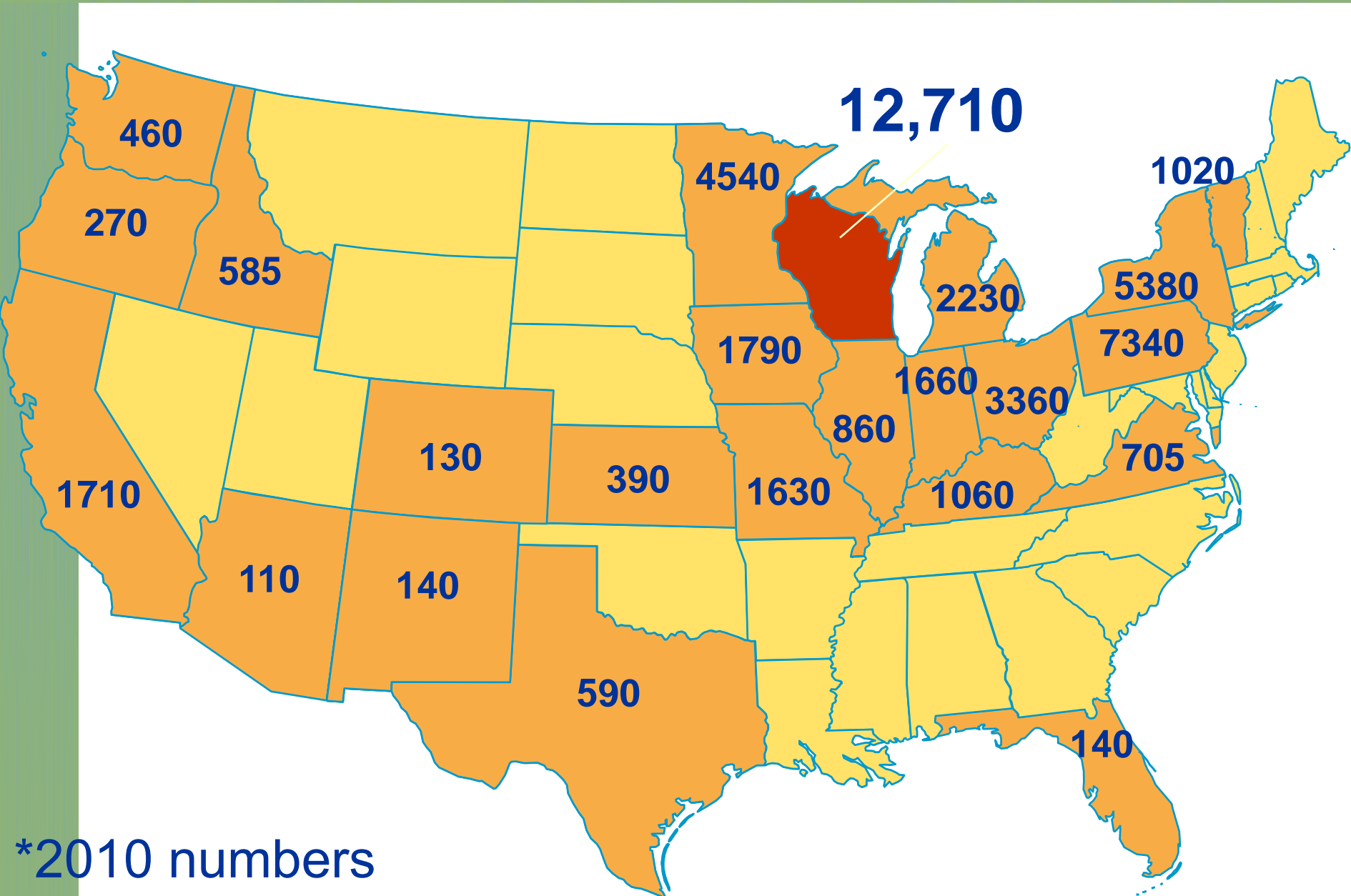
417 dairy plants



12,315 dairy farms



Licensed dairy herds in 23 major dairy states*



*2010 numbers

FDA presence in Wisconsin

	FDA food establishments	FDA staff in state
1. California	8,460	464
2. Texas	4,226	184
3. New York	3,517	385
4. Washington	3,288	194
5. Florida	2,899	130
6. Wisconsin	2,276	33



Legislative reform in Washington

- ◆ FDA Food Safety Modernization Act
 - ◆ Passed by Congress 2009 - 2010
 - ◆ FDA enhancement
 - ◆ Industry/farm concerns addressed
 - ◆ Political inserts
- ◆ What next?
 - ◆ Show me the \$
 - ◆ Studies
 - ◆ Pilot projects
 - ◆ Public meetings
 - ◆ Rule-making
 - ◆ Guidance documents



FDA vs. state inspections

◆ Current:

- ◆ FDA Contract inspections: FSMA may have a **LARGE** impact
- ◆ State inspections: FSMA impact is uncertain

◆ Future:

- ◆ How much differentiation between inspection types?
- ◆ Manufactured Foods Regulatory Program Standards



Registration of food facilities

- ◆ Only facilities required to register by Bioterrorism Act of 2002, and involved with FDA-regulated food
 - ◆ Factories, warehouses (manufacture, process, pack or hold food).
 - ◆ Does not include farms, restaurants, retail, non-profit food establishments preparing or serving food directly for consumer
- ◆ Registration = consent to inspection
- ◆ No FDA fee; there are state license fees
- ◆ Communication: lists accurate and shared?
- ◆ Suspension of registration: applies to inter-state and intra-state commerce

Mandatory hazard analysis and risk-based preventive controls

- ◆ New section of FD&CA
- ◆ Analogous to HACCP
 - ◆ Registered facilities
 - ◆ Hazard analysis, including intentional adulterants
 - ◆ Preventive controls
 - ◆ Monitoring
 - ◆ Corrective actions
 - ◆ Verification that preventive controls work, including re-analysis
 - ◆ Record-keeping and retention (2 years)
- ◆ State inspectors must be fluent in HACCP
- ◆ Training!



Exemption from HACCP-type requirements

- ◆ Facilities that are subject to Produce Safety Standards (new section 419 of FD&CA) OR
- ◆ Very small businesses (as legally defined) OR
- ◆ Direct sales to “qualified end-users” >50% of total sales, and total sales <\$500,000 AND
 - ◆ Documented HACCP-type system OR
 - ◆ Documented compliance with State or local food safety law AND display of address on label or placard
 - ◆ “Qualified end-user”= consumer OR restaurant / retail in same state or < 275 miles away

A looming problem for state regulators:

- ◆ Who is exempt?
 - ◆ Federal law can't pre-empt state or local law
 - ◆ Two classes of facilities for our inspectors to regulate: HACCP and non-HACCP
 - ◆ Pickle bill, etc.



Performance standards for contaminants

- ◆ Must be developed for most significant food-borne contaminants
- ◆ Will apply to specific foods or classes of foods
- ◆ Will be the standard for regulatory sampling and analysis
- ◆ Our challenges:
 - ◆ Lab capacity
 - ◆ Sampling by staff
 - ◆ Interpretation of results



Produce safety standards

- ◆ Mandatory for safe production and harvesting of designated produce crops
- ◆ Public input required (> 3 meetings, diverse areas)
- ◆ Regulations must:
 - ◆ Be scale-appropriate
 - ◆ Address key GAPs areas
 - ◆ Be consistent with conservation and environmental standards
 - ◆ Not conflict with or duplicate the national organic program
 - ◆ Not require 3rd-party audit



Exemption from produce safety standards

- ◆ Direct-farm marketing
- ◆ > 50% of sales to consumers, restaurants, retail
 - ◆ In same state OR within 275 miles of farm
- ◆ Total sales < \$500,000
- ◆ Packaging / placards indicate source
- ◆ Can be withdrawn for public health reasons
- ◆ Cannot pre-empt state or local laws, but
 - ◆ We have little if any oversight of produce farms!
 - ◆ Who will evaluate farms for compliance with standards?

Food defense:

Preventing intentional adulteration

- ◆ Regulations will:
 - ◆ Specify how to determine if mitigation strategies are necessary
 - ◆ Specify mitigation strategies for identified vulnerable points
 - ◆ Apply only to high-risk foods that are in bulk or batch form, before final packaging
- ◆ Farms (except dairy producers) are exempt
- ◆ Guidance will be published
- ◆ Our challenges: training and evaluation resources if we are asked for help

Sanitary transportation of food

- ◆ FDA required to conduct a study and write regulations
- ◆ State role in enforcing regulations is unclear



Mandated inspection frequencies



- ◆ Based on risk, compliance history, establishment's controls
- ◆ Domestic high-risk: at least once in 1st 5 years, then at least every 3 years
- ◆ Domestic non-high-risk: at least once in 1st 7 years, then at least once every 5 years
- ◆ FDA may use contract state or local inspections to meet requirements

State inspections now more frequent than required in new act

Selected Food Establishments Licensed by DATCP Division of Food Safety

	Risk level	DFS schedule	New act
Grade A dairy farms	Partially risk-based	3-12 months	N/A
Grade A dairy plants	Potentially hazardous	3 months	36 months
Grade B dairy plants	Potentially hazardous	6 months	36 months
Food processing	Potentially hazardous	8 months	36 months
Retail food	Potentially hazardous	8 months	N/A
Food processing	Not potentially hazardous	12 months	60 months
Food warehouses	Potentially hazardous	12 months	36 months
Retail food	Not potentially hazardous	12 months	N/A
Grade B dairy farms	Not risk-based	24 months	N/A
Retail food	No processing	24 months	N/A
Food warehouses	Not potentially hazardous	24 months	60 months

Traceability

- ◆ FDA record-keeping regulations targeting high-risk foods
 - ◆ One step forward only
 - ◆ Public meetings required before regulations
 - ◆ Pilot studies for traceability system will be ongoing
- ◆ State regulators will need training for enforcing new regulations during contract inspections



Record-keeping exemptions

- ◆ Many:
 - ◆ Product is made and packaged on-farm and labeled with address
 - ◆ Grocery stores – record farm source only
 - ◆ Low-risk commingled raw agricultural commodities
 - ◆ Farms selling directly to consumers
- ◆ State personnel will need training in any enforcement role

Other key provisions – limited implications for state regulators

- ◆ No port-shopping – FDA and DHS collaboration
- ◆ Foreign Supplier Verification Program
 - ◆ FDA staff overseas
 - ◆ Voluntary qualified importer program
- ◆ FDA authority to require a recall of unsafe foods
 - ◆ Warehouses are not exempt
 - ◆ Must notify consumers about similar, unaffected, foods
- ◆ Broader exposure of Reportable Food Registry info
 - ◆ Consumer-accessible
 - ◆ Grocery postings
- ◆ Increased administrative detention authority
 - ◆ Lower burden of proof

A state-level “update” list

- ◆ State laws and regulations: Consistent with federal counterparts? Appropriate?
- ◆ Licensing data-base: Are data shareable?
- ◆ Training in subjects that we may enforce
 - ◆ HACCP-type preventive systems
 - ◆ Produce safety standards
 - ◆ Performance standards
 - ◆ Food defense
 - ◆ Record-keeping: requirements and exemptions
 - ◆ Sanitary food transportation

