

The National Agricultural Law Center



University of Arkansas



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Legal Issues in Animal Agriculture: Medication, Identification and Accommodations

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Outline



- **Medication**
 - The use of ‘antimicrobials’ in food animals
- **Identification**
 - Tracing the movement of farm animals from “farm to fork”
- **Accommodations**
 - Legislating/regulating the amount of space given to farm animals

Outline



➤ **Medication**

➤ **The use of ‘antimicrobials’ in food animals**

● **Identification**

- Tracing the movement of farm animals from “farm to fork”

● **Accommodations**

- Legislating/regulating the amount of space given to farm animals

Definition of “Antimicrobial”



- What is it made of?
 - Naturally occurring or manmade substance, or some combination of the two
- What does it do?
 - Kills or prevents the growth of other bacteria, fungi, parasites, and viruses
- Is an “antimicrobial” the same thing as an “antibiotic?”
 - Antibiotics are a type of antimicrobial, but not all antimicrobials are antibiotics.
 - ‘Antimicrobial’ is a umbrella term that encompasses antibiotics as well as other drugs like anti-viral and anti-fungal medications

When Are Antimicrobials Used?

- Treatment of sick animals.

- Disease is present in part of a herd or flock and antimicrobials are administered to decrease the spread of disease while ill animals are treated.

Disease Treatment

Disease Control

- Antimicrobials are administered (usually in feed) to increase growth rates and improve feed efficiency.

Growth promotion & feed efficiency

Disease Prevention

- A known disease risk is present and the antimicrobials are administered to prevent infection of animals.

Estimated U.S. Use of Antimicrobials

From 1999 to 2000, it is estimated that 82.7% of sites with nursery pigs used antibiotics as a growth promoter

- Nat'l Research Council, Bd. on Agric., *The Use of Drugs in Food Animals, Benefits and Risks (1999)*.

87% of the antibiotics used in all animals were for disease treatment, control and prevention

- Animal Health Institute survey of members (referenced in CRS report R40739)

24.6 million pounds of antibiotics were used for nontherapeutic purposes in food animals annually, representing 70% of all antibiotics produced in the U.S.

- 2001 report by the Union of Concerned Scientists (referenced in CRS report R40739)

Federal Regulation of Microbials

FDA's Center for Veterinary Medicine (CVN)



Request to conduct pre-approval clinical trials.

After trials, new animal drug application review, including

- Evaluation of safety and effectiveness for intended animals;
- Evaluation of safety to humans consuming food from the animal
- Determination of how much time is necessary for drug residues to leave the animals' body (withdrawal time) to ensure antibiotic residues are not in food products made from animal.

Approval is granted or denied

FDA's Evaluation of Safety Steps

Focus on Microbial Resistance



- Drug sponsors submit a “hazard characterization,” including
 - Information about drug, including uses and mechanisms of action
 - Mechanisms for the emergence of resistance,
 - Importance of the drug in human medicine,
 - Scientific information and knowledge gaps about the drug; and
 - Antimicrobial resistance and related information.
- Assessment phases
 - “Release:” probability that use will result in resistant bacteria
 - “Exposure:” likelihood of human exposure to bacteria of human health concern
 - “Consequence:” considering importance of the animal drug in human medicine
- FDA ranks drug according to the importance in human medicine, which is then integrated into an overall risk estimation
- Denial or approval, which may include limiting conditions on use

Proposed Legislation: Preservation of Antibiotics for Medical Treatment Act



- Existing Drugs

- FDA must withdraw approval of “nontherapeutic use” of “critical antimicrobial animal drugs.”
- **Test:** Approval must be withdrawn unless there is a “reasonable certainty of no harm to human health due to antimicrobial resistance that is attributable in whole or in part to the nontherapeutic use of the drug”

- New Drugs

- Applications for new drugs must be refused if the sponsor fails to demonstrate the same “reasonable certainty standard”

H.R. 1549/S. 619

Result if PAMTA is Passed

- **Antibiotics are administered to treat sick animals.**

Disease Treatment

- Disease is present in part of a herd or flock and antibiotics are administered to decrease the spread of disease while ill animals are treated.

Disease Control

- Antimicrobials are administered (usually in feed) to increase growth rates and improve feed efficiency.

Growth promotion & feed efficiency

Disease Prevention

- A known disease risk is present and the antibiotics are administered to prevent infection of animals.

FDA Administration View

- Recommends that use for growth promotion and/or feed efficiency be phased out
- Some antimicrobial uses for disease prevention “are necessary and judicious to relieve or avoid animal suffering and death”
- Use of medications should be under vet supervision.
- Agency is looking into “regulatory pathways” to restrict the use of animal antibiotics.



Joshua M. Sharfstein
FDA Principal Deputy
Commissioner of Food and Drugs

Federal Register: 6/28/2010

- On June 28, the FDA published draft guidelines for use of “medically important antimicrobial drugs” in livestock
- Guidelines:
 - Their use should be limited to those uses that are considered necessary for assuring animal health
 - Factors:
 - ✦ Evidence of effectiveness
 - ✦ Evidence that preventive use is consistent with accepted veterinary practice
 - ✦ Evidence that the use is linked to a specific disease agent
 - ✦ Evidence that the use is appropriately targeted
 - ✦ Evidence that no reasonable alternatives for intervention exist
 - Their use should be limited to those uses that include veterinary oversight or consultation

Outline



- ✓ Medication

- ✓ The use of ‘antimicrobials’ in food animals

- **Identification**

- **Tracing the movement of farm animals from “farm to fork”**

- Accommodations

- Legislating/regulating the amount of space given to farm animals

Animal Identification Timeline

3000 BC

- Farmers begin branding animals to show ownership and identification

1930s

- State and federal programs tracing movement of livestock involved in disease outbreaks are started for some diseases in cattle, swine & sheep.

December, 2003

- “The Cow that Stole Christmas”: BSE is discovered in cows in United States

2004

- USDA introduces the **voluntary** National Animal Identification System (NAIS) to identify and trace the movement of livestock.

2010

- USDA ends NAIS and begins a “flexible yet coordinated approach that embraces the strengths and expertise of States, Tribal Nations, and producers.” Specifics of this new approach are unknown.

NAIS Components



Premise Identification

- Landowners register “premises,” which is then assigned a unique PIN identifier
- PINs are maintained in **state** databases



Animal Identification

- Animals are identified (individually or as a group) with unique ID numbers that stay with them until slaughter
- Numbers are associated with specific premises in **USDA** database



Animal Tracing

- Data on movement of animals is maintained in **state and private sector** databases

NAIS Concerns



- **Cost**
 - Who will be paying for the components and labor?
- **Privacy/Confidentiality**
 - Who has access to the data (FOIA, subpoena)?
 - Why does the government need the data?
- **Liability**
 - Will the traceback ability increase producer liability for those who would have previously remained anonymous?
- **Religious Freedom**
 - “And [the Antichrist] causeth all, both small and great, rich and poor, free and bond, to receive a mark in their right hand, or in their foreheads. And that no man might buy or sell, save [except] he that had the mark, or the name of the beast, or the number of his name.”

✦ *Rev 13:16-17*

State Identification Systems



- **Wisconsin**

- Requires premise identification for “livestock”
 - ✦ Recent ruling holding state did not establish that interest in animal health cannot be met by lesser restrictions on the Amish farmer’s free exercise of religion (WI v. Miller, 08-CX-5)

- **Indiana**

- Requires premise identification for “livestock”

- **Michigan**

- Requires premise identification for cattle
- Requires animal identification for cattle
 - ✦ All cattle must be identified with RFID electronic ear tags prior to movement from premises

- Other, primarily western states, require other forms of identification, such as branding. Typically this proves ownership, rather than identification

Characteristics of New Federal ID System



- Basic, effective animal disease traceability and response to animal disease outbreaks without overly burdening producers;
- ONLY apply to animals moving interstate;
- Owned, led, and administered by the States and Tribes;
- Federal support focused entirely on animal disease traceability;
- Encourage the use of lower-cost technology;
- Be less federally intrusive and support producers' request to operate on principles of personal accountability

Working Session for New Federal ID System



- “Bookend approach” to identification
- Measured by benchmarks, rather than by premises or animals that are registered/marked
- Primary focus on state veterinarian to identify the animals
- Owned, led, and administered by the states
 - This is important, because it still raises many of the same concerns as the federal system would have in terms of confidentiality and liability
 - Now reliant on state FOIA laws, rather than the federal exemption
- Species specific
- Consequences for failure do not result in a loss of funding, but instead in higher costs to export animals
 - Potential additional testing on animals before they can be moved from state to state

Outline



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✓ Identification

- ✓ Tracing the movement of farm animals “from farm to fork”

➤ **Accommodations**

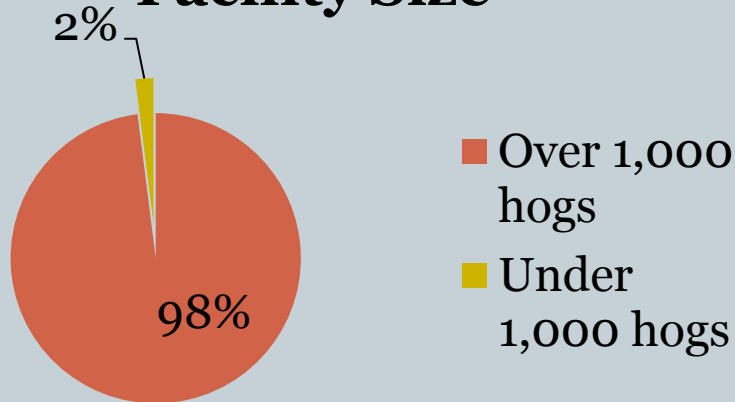
- **Legislating/regulating the amount of space given to farm animals**

U.S. Statistics on Animal Agriculture

Market Hogs

- 500 million sold annually
- Annual market value: \$18 billion

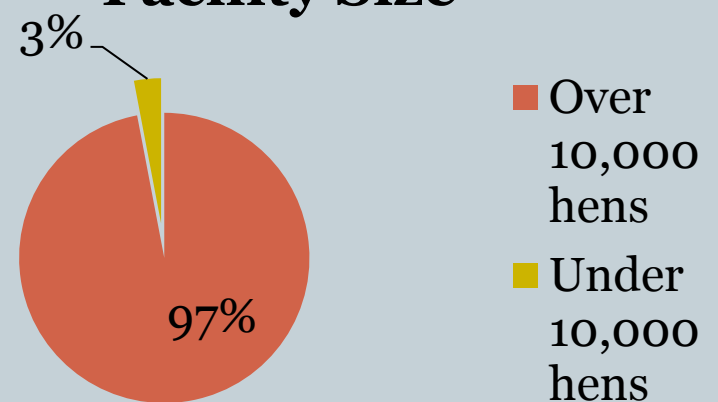
Facility Size



Laying Hens

- 350 million laying hens
- 2 billion dozen eggs produced annually

Facility Size



Typical Space Permitted: Breeding Hogs

- **Size:**

- Crates “allow the sow to stand, lie, eat and drink, but may not allow them to turn around”
 - ✦ Nat’l Pork Board

- **Reasons:**

- Allow producer feed and observe each sow individually to meet her needs
- Protect from other aggressive SOWS.
- Allow piglets opportunity to escape being crushed when the sow lies down



Sow and piglets in “farrowing crate.”

Before birth, the sow is confined in a “gestation crate.”

Typical Space Permitted: Laying Hens



**Chickens in a
“battery cage”**

- **Size:**
 - Typically 67 to 86 square inches of usable space per bird
 - ✦ United Egg Producers
- **Reason**
 - Additional space may be more stressful as more aggressive tendencies become manifest

Where Are These Laws In Place?

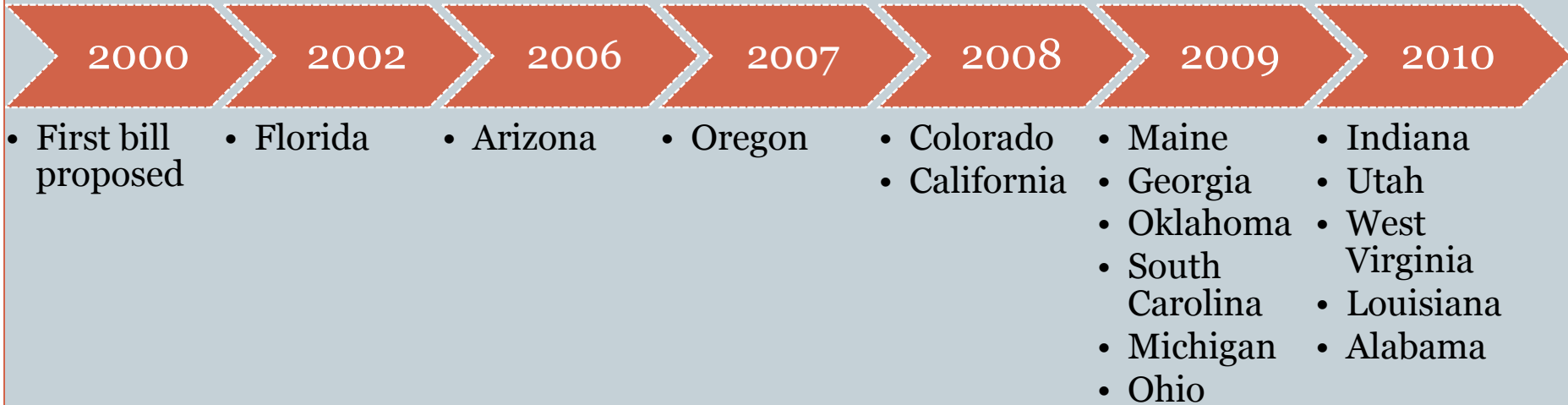
“HSUS Sponsored” Statutes

Florida
Arizona
Oregon
Colorado
California
Maine
Michigan

“Ag Sponsored” Statutes

Georgia
South Carolina
Oklahoma
Ohio
Indiana
Utah
West Virginia
Louisiana
Alabama

Timeline of Farm Animal Confinement Laws



Passage Dates

Florida, 2002

- First state to propose/pass law on farm animal confinement
- Constitutional amendment via ballot initiative
 - 55% in favor, 45% opposed
- Applies to “pigs in pregnancy”
- Unlawful to confine/tether so pig cannot turn around freely
 - Exceptions for vet care and 7 days before pig’s due date
- Penalty: ≥ 1 year and/or $\geq \$5,000$
- Became effective November 2008
 - No prosecutions since then

Arizona, 2006



- First state to cover veal calves & pregnant sows
- Ballot initiative
 - 62% in favor, 38% opposed
- Unlawful to prevent animal from lying down and fully extending limbs or turning around freely
 - Exceptions for vet care, 7 days before due date, animals involved in research, and during transportation, exhibition and slaughter
- Penalty: ≥ 6 months and/or $\geq \$2,500$ ($\geq \$20,000$ for enterprise)
- Becomes effective December 2012

Oregon, 2007



- First legislatively passed statute
- Applies to pregnant sows
 - Original bill would have applied to calves as well
- Makes it unlawful to prevent animal from lying down and fully extending limbs or turning around freely *for more than 12 hours in any 24 hour period*
 - Exceptions for vet care, 7 days before due date, animals involved in research, and during transportation, exhibition and slaughter
- Penalty: $\geq \$720$ ($\geq \$1,440$ for enterprise)
- Becomes effective January 2012

Colorado, 2008

- Legislation that covers veal calves and “confirmed pregnant” sows
 - Initial threatened ballot proposal would cover sows, calves and hens
- Unlawful to prevent animal from standing up, lying down and turning around without touching the sides of its enclosure
 - Exceptions for vet care, 12 days before due date, animals involved in research, and during transportation, exhibition and slaughter
- Penalty: 3 - 12 months, and/or \$250 - \$1,000
 - May also include community service
- Effective date for calves: January 1, 2012
- Effective date for sows: January 1, 2018

California, 2008

- First state to cover laying hens
- “Proposition 2” ballot initiative: 63% in favor, 37% opposed
 - Advocates spent \$10.6 million (largest donor, HSUS : \$4.1 million)
 - Opponents spent \$8.9 million (largest donor, Cal-Maine foods: \$500,000)
- Applies to pregnant sows, veal calves and laying hens
- Unlawful to prevent animal from lying down, standing up and fully extending limbs or turning around freely
 - Exceptions for vet care, 7 days before due date, animals involved in research, and during transportation, exhibition and slaughter
- Penalty: ≥ 180 days and/or $\geq \$1,000$
 - Offenders may also be charged under general animal welfare laws
- Becomes effective January 2015
- New language: law specifically allows local governing body to adopt and enforce its own animal welfare laws and regulations

Maine, 2009

- Applies to pregnant sows and veal calves
- Unlawful to prevent animal from lying down, standing up and fully extending limbs or turning around freely
 - Exceptions for vet care, 7 days before due date, animals involved in research, and during transportation, exhibition and slaughter
- Penalties
 - Criminal: ≥ 1 year and/or $\geq \$2,000$ ($\$10,000$ for org)
 - Civil: no specified punishment
 - ✦ Offenders may also be charged under general animal welfare laws
- Like CA, specifically allows local governing body to adopt and enforce its own animal welfare laws and regulations
- New provision: Not affirmative defense that animal was kept in compliance with best management practices
- Effective date: January 2011

Michigan Background (2009)



- **June 23, 2009**
 - Original bill proposed
 - HSUS begins extensive lobbying campaign against bill
- **September 16, 2009**
 - Original bill read, voted on, and fails to pass
 - Sponsor immediately proposes new and radically different version
 - New version voted on and passes
- **September 30, 2009**
 - Senate takes up bill, votes on it and passes
- **October 1, 2009**
 - Versions are reconciled and enrolled for governor's signature
- **October 12, 2009**
 - Governor signs into law

Michigan Specifics (2009)














Proposed

- State Dep't of Agric. has sole authority to regulate livestock health and welfare
- Standards adopted and recognized would be the same standards established by the industry groups (Nat'l Pork Board, Nat'l Chicken Council, etc.)
- Create "Animal Advisory Council" in Dep't of Agric., responsible for considering and changing species-specific guidelines
- Presumption that raising animals in compliance with guidelines is humane

Enacted

- Applies to pregnant sows, veal calves, and laying hens
- Unlawful to prevent animal from lying down, standing up and fully extending limbs or turning around freely
 - Hens must have access to at least 1 square foot of floor space apiece
 - Standard exceptions
- Violation is civil offense
 - Allows Dep't of Agric. to bring civil action for injunction against violations
- Effective for calves: October 1, 2012; for hens and sows: October 1, 2019

Overview of Penalties

Florida			B	Crim: ≥ 1 year and/or $\geq \$5,000$	
Arizona			B	Crim: ≥ 6 mths and/or $\geq \$2,500$	
Oregon			L	Crim: $\geq \$720$	
Colorado			L	Crim: Min- 3 mths and/or \$250 Max- 12 mths and/or \$1,000	
California				B	Crim: ≥ 180 days and/or $\geq \$1,000$
Maine				L	Crim: ≥ 1 year and/or $\geq \$2,000$ Civ: No specified punishment
Michigan				L	Civ: Temporary or permanent injunction

California, 2010



- Prohibits shelled eggs from being sold for human consumption in California if the farm or location for production is not in compliance with California animal care standard.
- Takes effect January 1, 2015
- Penalty: >\$1,000 and/or >180 days
- Commerce clause concerns?
 - Bill analysis prepared for the California assembly's committee on agriculture stated that “the committee may wish to consider if this fits the Interstate Commerce Clause test; specifically, this is of compelling interest to California to protect public health.”

“Ag Response” Statutes



- **Georgia & South Carolina (2009)**
 - Prevent local governments from adopting rules & regulations regulating animal husbandry
 - ✦ Reserves that power to the state legislature
- **Oklahoma (2009)**
 - Prevent local governments from adopting rules & regulations regulating animal husbandry
 - ✦ Reserves that power to the Department of Agriculture
- **Alabama (2010)**
 - Prevent local governments from adopting rules & regulations regulating animal husbandry
 - ✦ Reserves that power to the state veterinarian

Ohio: Background (2009)



- **February 9, 2009**
 - HSUS president meets with Ohio agricultural and veterinary groups, announcing plans to bring an animal confinement initiative to OH.
- **June 18, 2009**
 - Resolutions proposed in OH legislature for an initiative to create a constitutional amendment to set livestock welfare standards.
- **June 25, 2009**
 - Resolutions pass both chambers
- **July 13, 2009**
 - Resolutions reconciled and set for the November ballot
- **November 3, 2009**
 - Amendment passes, 64% to 36%.

Ohio Specifics (2009)

- Creates “Livestock Care Standards Board” with authority to establish and implement standards governing the care and well-being of livestock and poultry in Ohio.
 - Consists of: director of the state dep’t of agric., 3 family farmers, 1 food safety expert, 2 representatives of agricultural organizations, 1 vet, the state vet, the dean of the OSU College of Agric., 2 members of consumer groups, and a member of a county humane society
 - No more than 7 board members may be from the same political party.
- Ohio Department of Agriculture has authority to oversee and enforce the livestock care standards.
- Ohio General Assembly has authority to enact laws necessary for creating the Board and overseeing, implementing and enforcing its standards.

Ohio, Take 2 (2010)



- **Another proposed constitutional amendment**
 - HSUS was collecting signatures to place it on the ballot in November, 2010
 - Would have required the Livestock Board “to adopt certain minimum standards that will prevent the cruel and inhumane treatment of farm animals....”
 - Minimum standards outlined in proposal would have mirrored CA’s Prop. 2 standards
- **On July 1st, HSUS agreed to suspend the ballot initiative in response to a “compromise” that was reached with OH Farm Bureau**

“Ohio Compromise” (2010)

- Governor will support two new laws and sign an executive order.
 - The laws relate to regulation of dog breeding and toughening existing penalties for cockfighting.
 - Governor will sign executive order to ban possession and sale of "wild and dangerous animals," including "big cats, bears, primates, large constricting and venomous snakes, and alligators and crocodiles."
 - ✦ Existing owners are grandfathered in, but could not breed them or obtain more.
- Sick or injured "downer" animals may not be butchered for food
- Outline “humane methods” for euthanizing animals for slaughter.
- No restrictions on existing farms that raise hens in battery cages.
 - However, the state would issue no permits for new farms using battery cages after this year.
- New hog farms would not be permitted to use "gestation stalls" for pregnant sows after 2010, but existing stalls can remain until 2025.
- Crates for veal calves must be phased out by 2017.
- If these provisions are not followed, HSUS may file the already-gathered signatures to place the issue on the ballot in coming years
 - Pacelle has said that they will be used as “leverage” to ensure the agreement is followed.

Indiana, 2010



- Passed on March 1, 2010
- Allows the state board of animal health to establish standards governing the care of livestock and poultry
- In making the rules, the board will consider:
 - **Health and husbandry of livestock and poultry**
 - **Generally accepted farm management practices**
 - **Generally accepted veterinary standards and practices**
 - **The economic impact the standards may have on**
 - ✦ Livestock and poultry farmers
 - ✦ The affected livestock and poultry sector; and
 - ✦ Consumers

Utah, 2010

- Signed into law on March 23, 2010
- Gives the state “Agricultural Advisory Board” power to advise on the establishment of standards governing the care of livestock and poultry
- In doing so, they will consider
 - **Food safety**
 - **Local availability and affordability of food; and**
 - **Acceptable practices for livestock and farm management**
- Members are appointed from a list of nominees submitted by each organization with a seat on the board

West Virginia, 2010



- “Livestock Care Standards Board:” 13 members; 11 by governor
- Powers of the board:
 - Establish standards governing care and well-being of livestock;
 - Maintain food safety;
 - Encourage locally grown and raised food; and
 - Protect West Virginia farms and families
- In establishing standards, the board will consider:
 - Agricultural best management practices;
 - Biosecurity, disease prevention, and mortality data;
 - Food safety practices; and
 - The protection of local, affordable food supplies for consumers
- The Department of Agriculture administers and enforces the standards established by the board that are approved by the Legislature.

Louisiana, 2010



- **The Louisiana Board of Animal Health is given the powers and duties**
 - To establish standards governing the care and well-being of livestock and poultry kept for the purpose of producing marketable products.
- **In establishing standards, the board shall consider:**
 - The health and husbandry of the livestock and poultry.
 - Generally accepted farm management practices.
 - Generally accepted veterinary standards and practices.
 - Economic on livestock and poultry producers and consumers.
- **Prevent local governments from adopting rules & regulations regulating animal husbandry**
 - Reserves that power to the state commissioner of agriculture
 - Local governments may petition the commissioner of agriculture for adoption of specific standards.

Timelines



2008

- Florida

2011

- Maine

2012

- Arizona
- Oregon
- Colorado veal
- Michigan veal

2015

- California

2018

- Colorado sows

2019

- Michigan hens & sows

Effective Dates

Federal Attempt: Prevention of Farm Animal Cruelty Act (HR 4733)

- Would apply to pregnant sows, veal calves, egg-laying hens
- Would make it unlawful to purchase products made from animals that had been prevented from lying down, standing up and fully extending limbs or turning around freely
 - Exceptions for vet care, 7 days before due date, animals involved in research, and during transportation, exhibition and slaughter
- Would become effective two years after enactment
- Would apply to federal prisons, school lunches, military purchasing- over \$1 billion annually
- Practical effect:
 - USDA purchases food from packers and processors, not from farms
 - Thus, without full traceability of every product, packers must require compliance from all their suppliers to continue selling to the government.

Pending in the States...



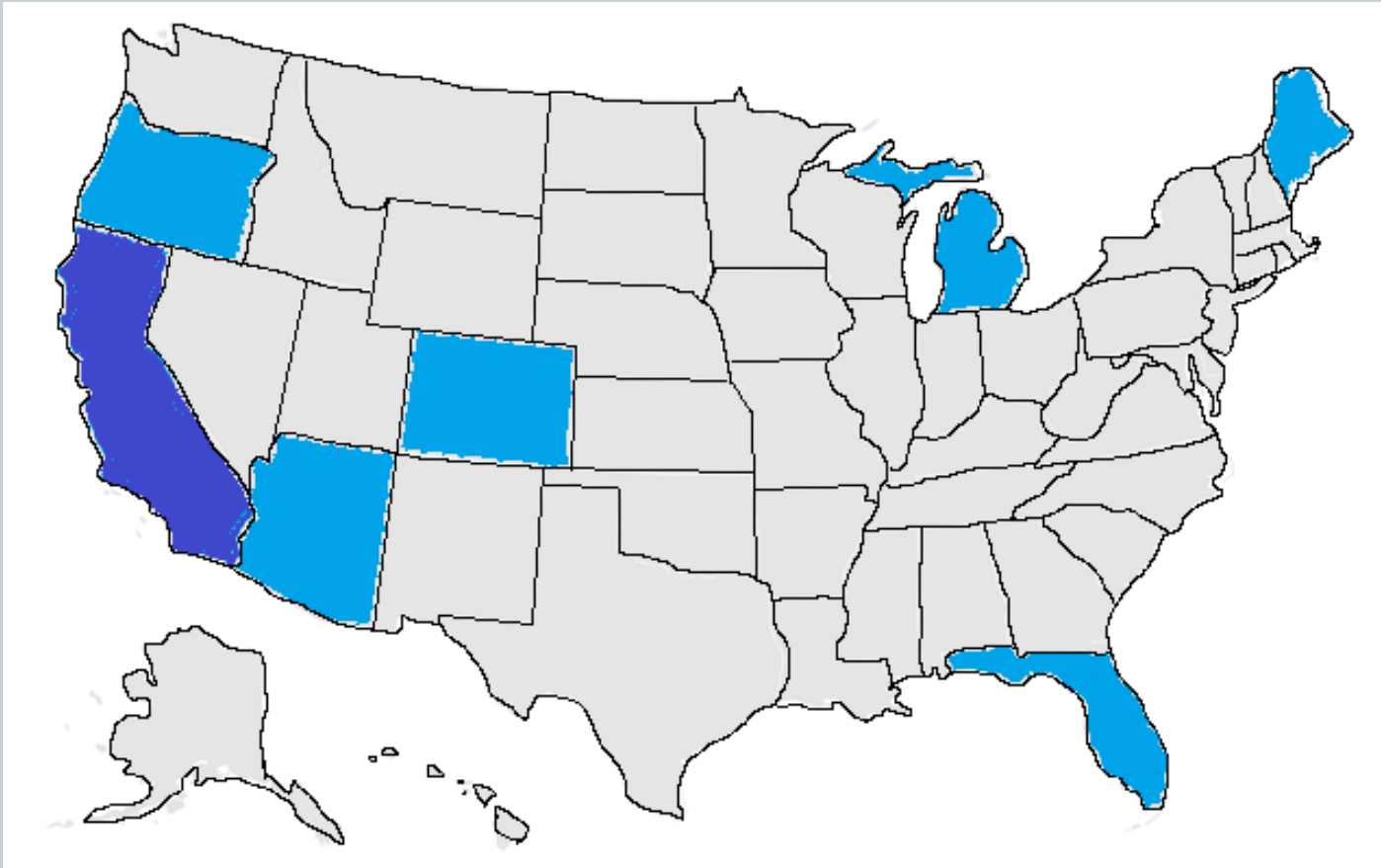
- Bills to create farm animal welfare boards:
 - **Kentucky** (S.B. 105); **Idaho** (S.B. 1331); **Missouri** (H.B. 2291); **Oklahoma** (H.B. 2345); **Vermont** (H.767)
- Bills to legislate space given to farm animals:
 - **Illinois** (S.B. 1337); **Massachusetts** (H.B. 815); **New York** (A.B. 8163, A.B. 8597); **Rhode Island** (H.B. 7769)
- Other:
 - Proposed constitutional amendment protecting the “right of citizens to raise domesticated animals in a humane manner without the state imposing an undue economic burden on animal owners.” (Missouri H.J.R. 86)

Past, Present... Future?

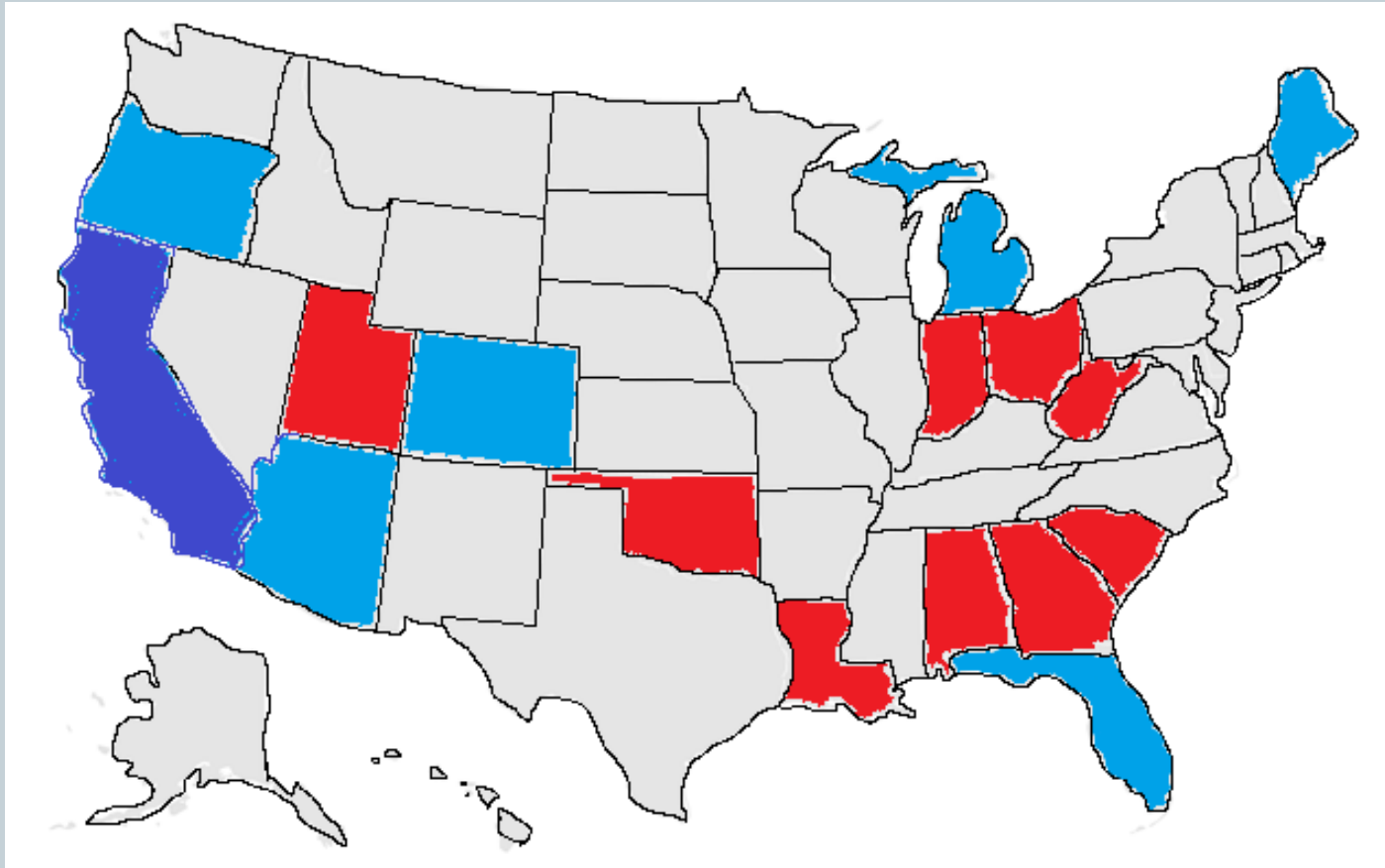


Blue:

Current
Confinement
Statutes



Past, Present... Future?



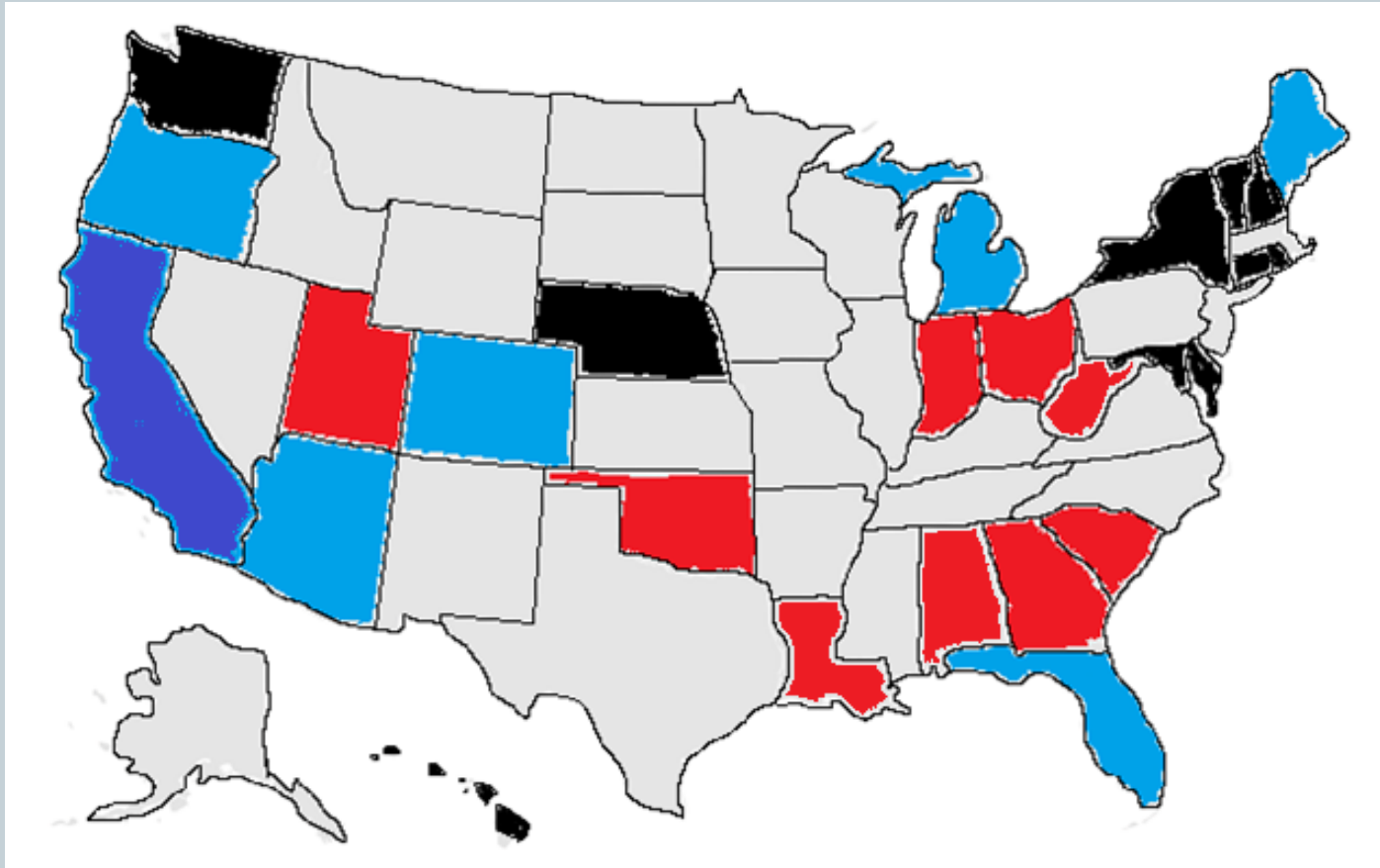
Blue:

Current
Confinement
Statutes

Red:

“Related”
Statutes

Past, Present... Future?

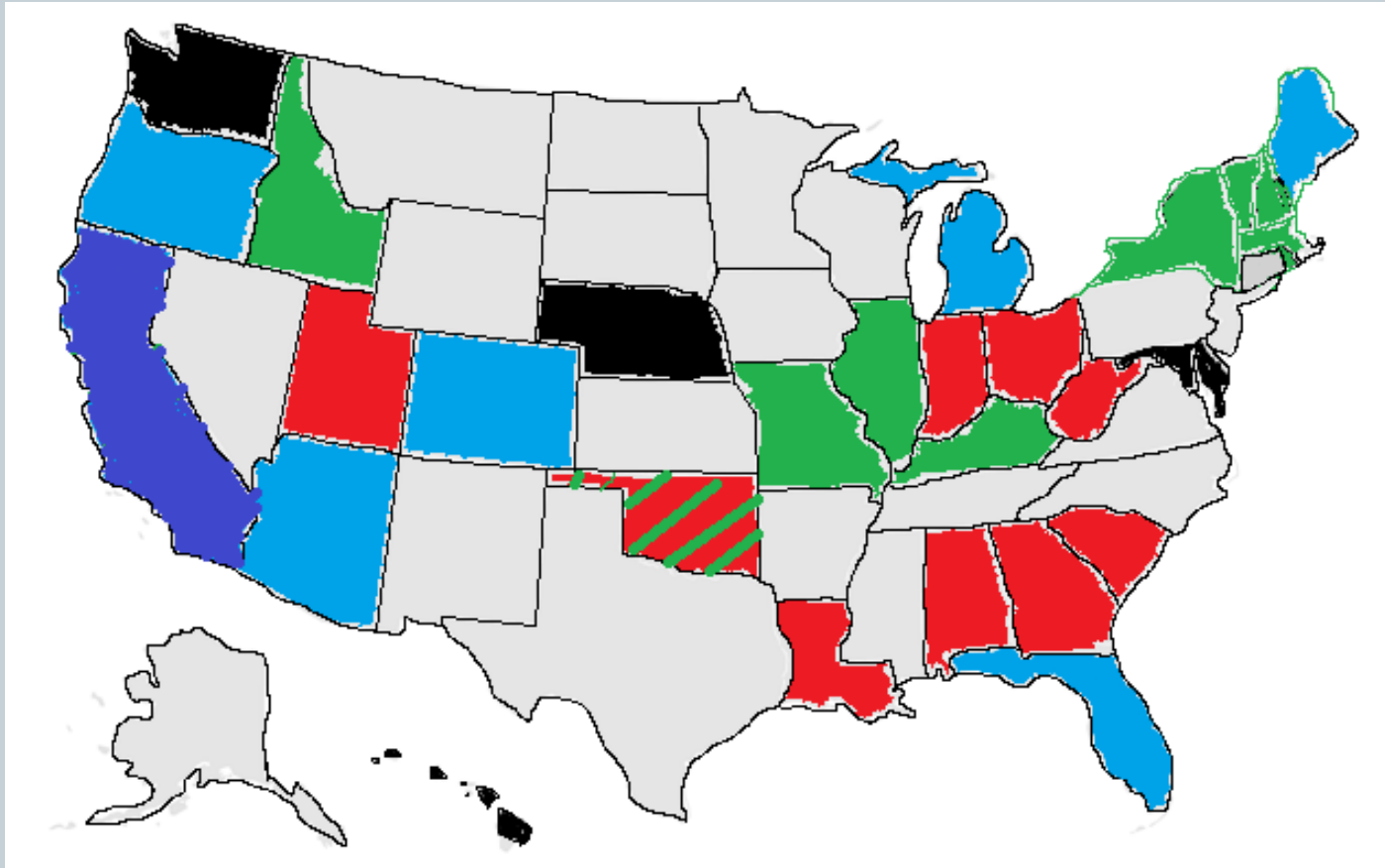


Blue:
Current
Confinement
Statutes

Red:
“Related”
Statutes

Black:
Inactive
Proposed
Legislation

Past, Present... Future?



Blue:

Current
Confinement
Statutes

Red:

“Related”
Statutes

Black:

Inactive
Proposed
Legislation

Green:

Active
Proposed
Legislation

[Un]intended Consequences?



“...turn around freely, lie down, stand up, and fully extend their limbs.”

- J.S. West & Co., a Modesto-based company, recently completed construction on a new chicken house
 - \$3.2 million project
- Includes a curtained area for nesting, a pair of metal tubes for perching and a "scratch pad" to help the bird clean itself.
 - Similar to ones installed in the EU, where a ban on small cages will take effect in 2012
 - 116 inches of space per bird
- Production costs:
 - If processed with conventional eggs, it will add 12 to 15 cents/dozen
 - If processed separately, it will add between 22 and 25 cents/dozen
- HSUS contends that hens need at least 216 square inches each to meet the measure's requirement.
- Pacelle says the only way to comply with the new laws is to go cage-free.
- HSUS has threatened court action to force “compliance”



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