

Why Changes to Livestock Antibiotic Laws Make Your Veterinarian So Essential

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Indiana State Board of Animal Health

Recent Changes

- Guidance for Industry
 - # 209
 - # 213
 - # 263
- FDA rules for antibiotic use

GFI #209: Judicious Use of Antimicrobials in Food-Producing Animals

- **FDA's plan to:**
 1. Phase out use of medically important antimicrobials (MIAs) for growth promotion or feed efficiency.
 2. Bring therapeutic uses of medically important antimicrobials under oversight of veterinarians.
- Ensure **safe food** and **sustainable long-term use** of antimicrobials for humans and animals.

Affected by GFIs

- Medically important antimicrobials

Same (or in same class) as antibiotics used to treat humans

Most antibiotics approved for use in animals are medically important with possible exceptions:

bacitracin, mecadox,
bambermycin, tiamulin,
and monensin

Not Affected

- Non-antibiotics:

dewormers

some coccidiostats

electrolytes

probiotics

aspirin

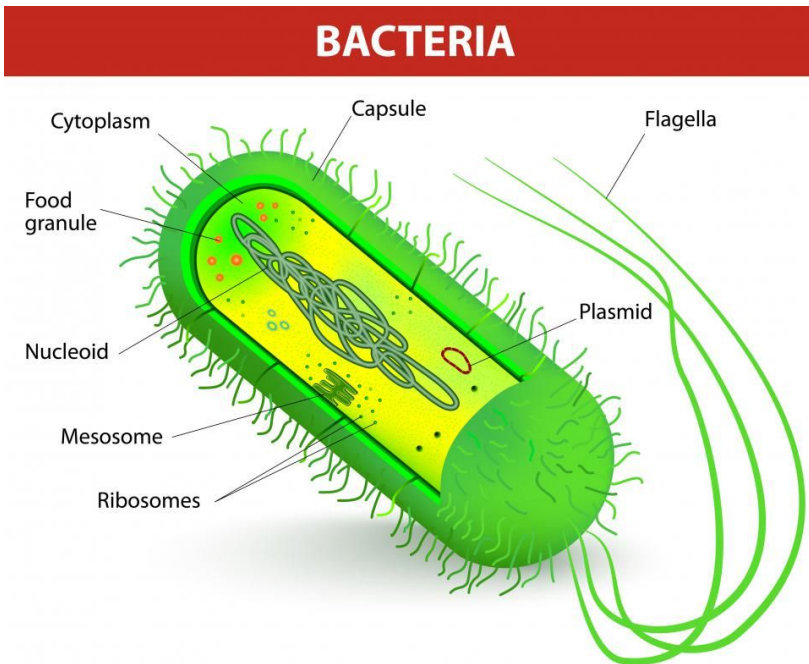
Judicious Use and Antimicrobial Stewardship

Using the right antibiotic,
at the right time,
at the right dose,
for the right duration.

Judicious Use and Antimicrobial Stewardship

- Critical to slowing antimicrobial resistance
- Avoid unnecessary or inappropriate use of antibiotics
- Prevent and control disease with good husbandry, strict biosecurity, herd health plans, regular vaccination protocols.
- Antibiotic use should be confined to cases when treatment is likely to positively alter the disease outcome.

Antimicrobial Resistance



- Anytime an antibiotic is used, selection for resistant bacteria can occur
- Like what is seen in dewormers, particularly in small ruminants
- Bacteria have plasmids that help transmit resistance genes

Next Steps

- **2015:** Veterinary Feed Directives (VFDs) Final Rule
 - Clarified VFD regulations
- **2017:** Guidance for Industry # 213
 - Puts part of GFI #209 into effect
 - Feed and water OTC antibiotics transitioned to Rx or VFD
 - Removed production uses from labels

Approved Uses of Antibiotics

Disease Treatment

- Animals exhibiting clinical signs

Disease Control

- Proportion of group exhibiting clinical signs

Disease Prevention

- Disease is likely to occur

Not Approved

- Growth Promotion/Feed Efficiency
- Non-therapeutic use

Guidance for Industry #263

- June 11, 2023
- CVM GFI #263 Recommendations for sponsors of medically important antimicrobial drugs approved for use in animals to voluntarily bring under veterinary oversight all products that continue to be available over-the-counter
- **Deadline to switch remaining antibiotics from OTC to Rx**

“Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian”

VCPR

- Basis for interaction between veterinarian, client and patient
- Required by law for veterinarians to prescribe Rx and VFD drugs and order ELDU

VCPR

- Veterinarian **assumes responsibility** for making clinical judgments about patient health and owner agrees to comply with veterinarian's instructions
- Has **sufficient knowledge** of the patient by virtue of patient examination and/or visits to the premises where the animal is housed
- Provides for any **necessary follow-up** evaluation/care

The VCPR

- “sufficient knowledge”
- Obtained through animal examination and/or visits to the facility where the animals are raised

(i) A *valid veterinarian-client-patient relationship* is one in which:

(1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;

(2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

(3) The practicing veterinarian is readily available for followup in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

- Animal Medicinal Drug Use Clarification Act
- Provision added to the Federal Food, Drug and Cosmetic Act
- 1994
- Made extra label drug use an FDA-regulated activity
- Federal law did not permit ELDU in animals before this act

AMDUCA

Extra Label Drug Use

- Deviations from the label include, but are not limited to:
 - Use in a species or production class not on the label
 - Use of a different route of administration, indication, frequency, dose, or duration

ELDU

- Allowed only for FDA-approved animal and human drugs.
- A valid **Veterinarian/Client/Patient Relationship** is required.
- **Therapeutic purposes** only (animal is suffering or health threatened). Not for production use.
- Prohibited in feed.
- Not permitted if it results in violative food residue, or any residue which may present a risk to public health.
- FDA prohibition of a specific ELDU precludes such use.

ELDU for VFD Exception?

- Compliance Policy Guide
 - December 2, 2016
- Addresses extra label use of medicated feed in minor species of food producing animals
 - Species other than cattle, swine, chickens, and turkeys
- Allows for regulatory discretion but does not make the extra label use legal.

Reading Drug Labels

Residue Warnings:

Exceeding the daily dosage of 3,000 units per pound of body weight, administering for more than four consecutive days, or exceeding the maximum injection site volume per injection site may result in antibiotic residues beyond the withdrawal time. Milk taken from treated dairy animals within 48 hours after the last treatment must not be used for food. Discontinue use of this drug for the following time period before treated animals are slaughtered for food:

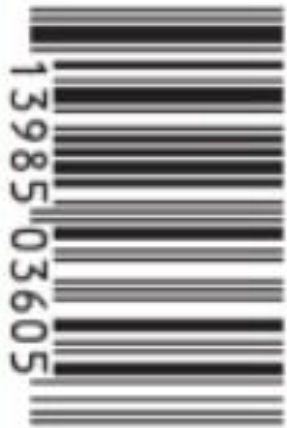
Cattle – 14 days, Sheep – 9 days, Swine – 7 days.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Warning:

Do not use in horses intended for human consumption. Not for use in humans. Keep out of reach of children.

3



7

Lot:

Exp:

11/2022 009634L01

NDC 13985-036-05

500 mL



VET one

PenOne Pro™

(penicillin G procaine injectable suspension)

Injection

300,000 UNITS PER mL

ANTIBIOTIC

FOR INTRAMUSCULAR INJECTION ONLY

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under NADA # 065-010

V1 501178

Net Contents: 500 mL



Read package insert for complete product information before using the drug.

INDICATIONS

PenOne Pro™ is indicated for treatment of bacterial pneumonia (shipping fever) caused by *Pasteurella multocida* in cattle and sheep, erysipelas caused by *Erysipelothrix rhusiopathiae* in swine, and strangles caused by *Streptococcus equi* in horses.

DESCRIPTION

Each mL contains 300,000 units Penicillin G Potassium*, 139.0 mg Procaine Hydrochloride*, 2.0% Procaine Hydrochloride, 3.0 mg Potassium Phosphate Monobasic, 6.0 mg Potassium Phosphate Dibasic, 0.4% Sodium Formaldehyde Sulfoxylate, 0.4 mg Polysorbate 80, 2.0 mg Lecithin, 0.1% Methyl Paraben, 0.01% Propyl Paraben, 0.15% Sodium Carboxymethylcellulose, q.s. Water for Injection. * Penicillin G Potassium and Procaine Hydrochloride react to form penicillin G procaine.

DOSAGE

PenOne Pro™ should be administered by the intramuscular route. The product is ready for injection after warming the vial to room temperature and shaking to ensure a uniform suspension. The recommended daily dosage of penicillin is 3,000 units per pound of bodyweight (one mL per 100 lbs bodyweight). Continue daily treatment until recovery is apparent and for at least one day after symptoms disappear, usually in two to three days. Treatment should not exceed four consecutive days. No more than 10 mL should be injected at any one site in adult livestock; rotate injection sites for each succeeding treatment.

Restricted Drug - California.

Use Only as Directed.

Store at 2-8°C (36-46°F).

SHAKE WELL
BEFORE USING.

Made in the UK
Norbrook Laboratories Limited
Newry, Northern Ireland

Recordkeeping

- Name of the drug and its active ingredient
- Condition treated
- Species of treated animal
- Dosage administered
- Route of administration
- Treatment duration
- Number of animals treated
- Animal's identification (can be group, herd, per-client basis)
- Withdrawal time for meat, milk, eggs, or any food product

Must be kept for at least 2 years

Labeling for ELDU

- Name and address of veterinarian
- Name of drug, active ingredient
- Direction for use
 - Class/species
 - Dose
 - Frequency
 - Route
 - Duration
- Animal identification
- Withdrawal period
- Cautionary statement



Why Care About ELDU?

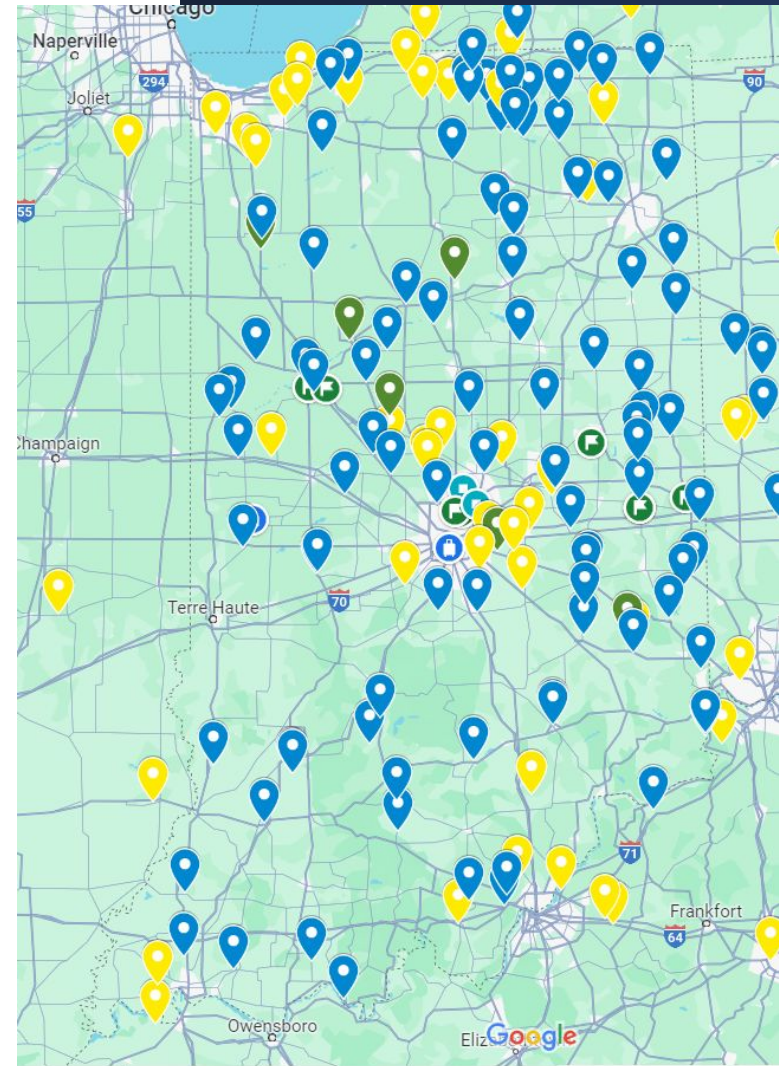
- Antibiotic Resistance
 - Wrong dose
 - Wrong drug for pathogen
- Drug Residues
 - Adulterated food
 - Consequences to animal owner

Veterinarians

- Sick Animals
- Emergencies
- VFDs
- Prescriptions
- ELDU
- Recordkeeping
- Herd Health
- Vaccination protocols
- Parasite Control
- Consulting
- Nutrition
- CVIs

Veterinary Shortage Situation

- Veterinary deserts
- Large animal vs. Small animal
- Real or perceived
 - AVMA
 - Veterinarian poll



Companion Animal Vets

- AVMA data do not support the projected companion animal veterinarian shortage that has been reported. Instead, between 2022 and 2030, the number of veterinarians providing services for companion animals will grow by more than 20%, from about 80,000 to more than 98,000.
- Three new veterinary schools graduating their first classes in 2023, 2024, and 2025

Food Animal Vets

- According to the USDA, in 2023, the shortage of rural veterinarians reached an all-time high, with 237 shortage areas in 47 states deemed as having a critical shortage of large animal vets.
- Contributing Factors
 - High debt-to-salary ratio
 - Long hours/on-call duty
 - Rural areas with fewer amenities
 - Enough business to support a fulltime practice without long drives
 - Lack of mentorship
 - Physical work
 - Family duties

Veterinary Shortage Solutions

- VMLRP
- State or University sponsored programs

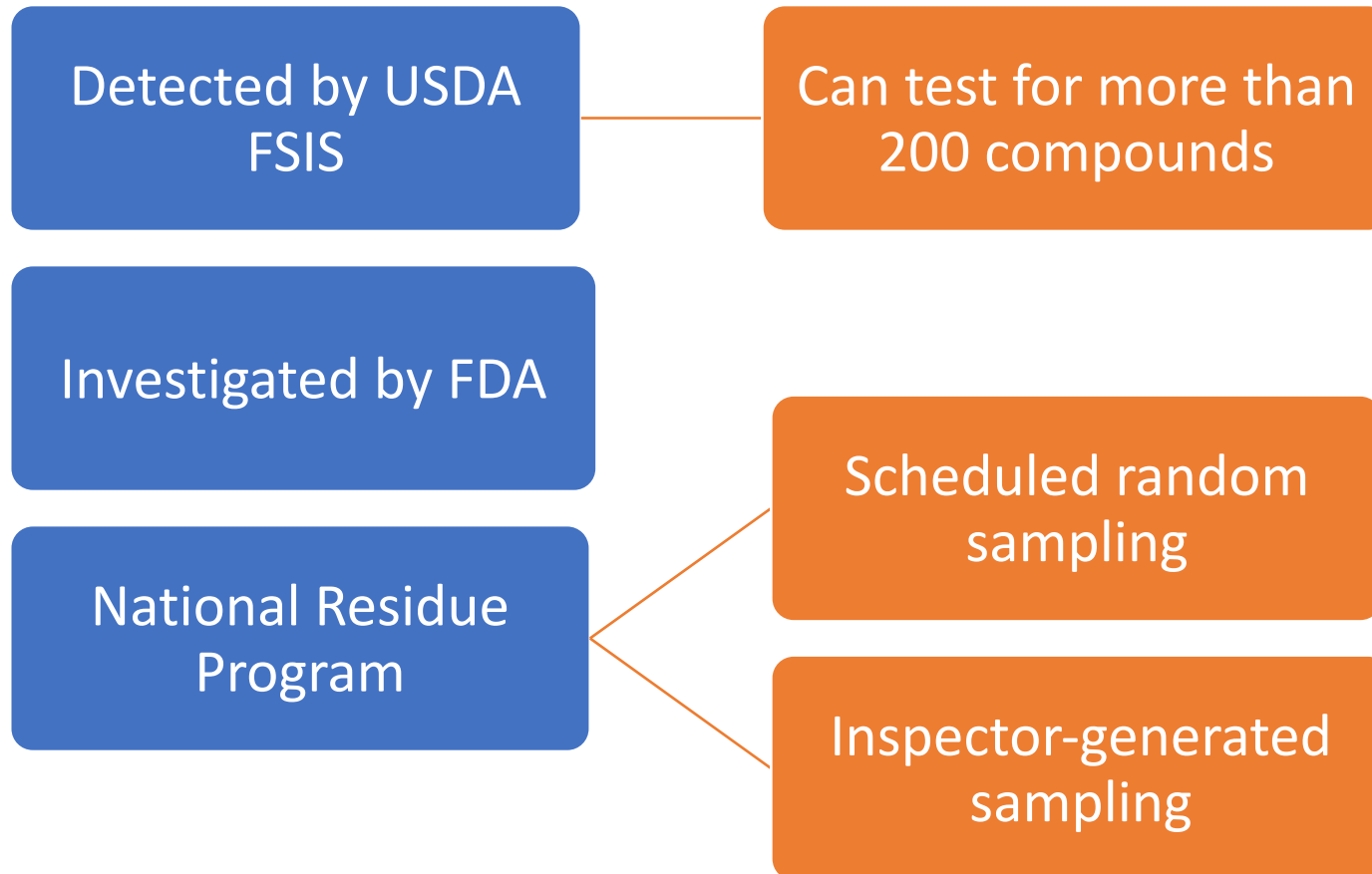
In Indiana:

- Indiana Center for Animal Policy
 - Collaboration between BOAH & Indiana Board of Veterinary Medicine
 - Legislation to lower barriers to veterinary profession

Residues

- A residue is a chemical compound in food animal and egg products including approved and illegal veterinary drugs, pesticides, and environmental products.
- Results in adulterated food

Tissue Residues

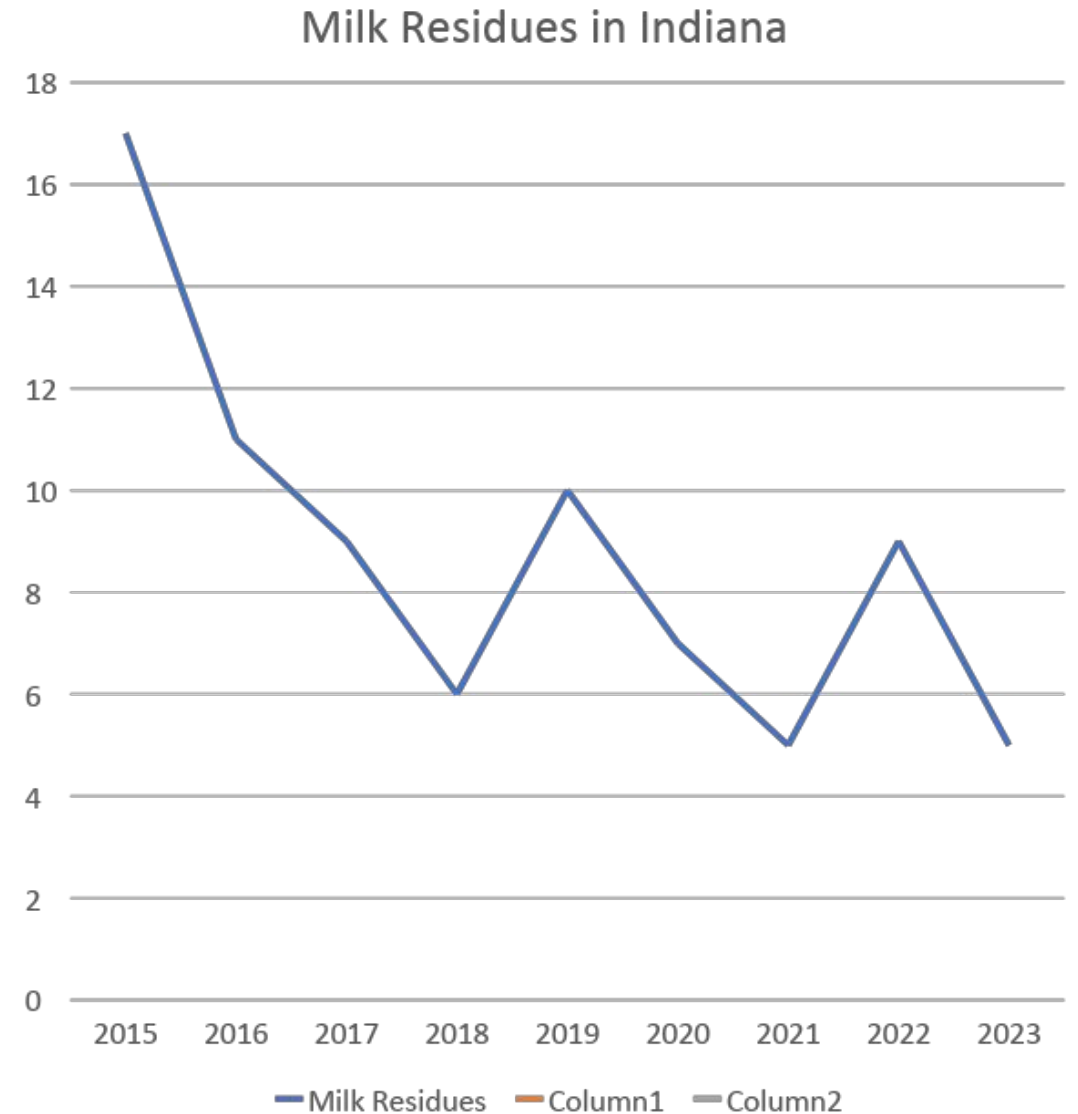


Tissue Residues

	Number of Tissue Residues	Percent from Dairy Industry
2015	24	38%
2016	18	56%
2017	11	80%
2018	12	100%
2019	10	80%
2020	5	80%

Milk Residues

- Every tanker truck of milk is tested
 - Approximately 55,000-60,000 screened loads per year
- Positive test results in a fine and on farm visit by BOAH representative for first offense.



Animal Disease Traceability (ADT)

- Plan for livestock disease events
 - Goal: trace animals rapidly and efficiently
 - Sets requirements for interstate movements
- Components:
 1. Animal Identification
 2. Premises Identification
 3. Documentation/Record Keeping

Official ID

- An ear tag with the US shield
- “UNLAWFUL TO REMOVE”
- Permanent, tamper resistant
- Connected to premises ID
- Any ear tag with the US shield.



Movements Requiring Official ID

Crossing State Lines

- Includes entering/exiting Indiana

Change of Ownership

- Sales, leases, trades

Exhibitions/Rodeos

Dairy cattle of all ages (including crosses)

Beef cattle 18 months of age and older

Where to Obtain Official ID

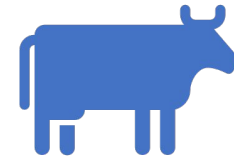


Veterinarians



Tag Suppliers

Be sure to specify tags that bear the US shield



Official Tagging Sites

All Indiana-licensed livestock markets

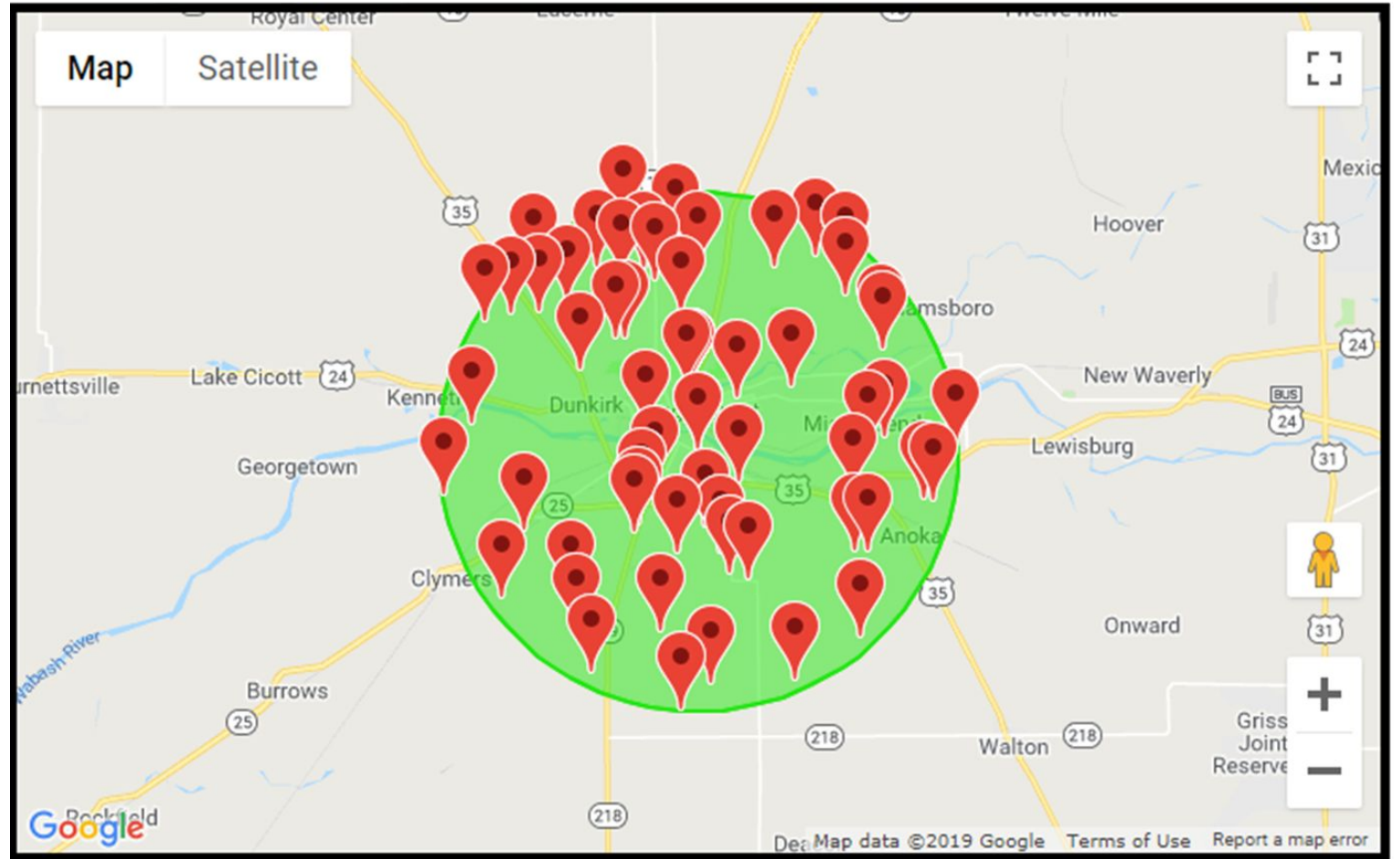
Premises Identification

- Indiana requirement (since 2006)
- All sites associated with the sale, purchase and/or exhibition of: cattle/bison, swine, sheep, goats, cervids
- Premises ID number (premid) required to order official ID tags

To register new premises, get your premid, or update information:

Contact BOAH at (317) 544-2400 or www.in.gov/boah

Premises Identification



Recordkeeping for Producers

- Recordkeeping replaces a CVI for **in-state** movement
- Producers are required to keep records of livestock movement for 5 years
 - Purchases, sales, barter, trade, leases
- Records must include:
 - Names and addresses of buyer and seller
 - Sale date
 - Animal IDs
 - Breed
 - Sex
 - Reason for movement

Certificates of Veterinary Inspection



Required to ship animals across state lines



Requirements set by destination state



Veterinarians must be accredited by USDA to write CVIs

Certificates of Veterinary Inspection

State Form 55300 (6-13)
Indiana State Board of Animal Health
Discovery Hall, Suite 100
1202 East 38th Street, Indianapolis, IN 46205
(317) 544-2400

INDIANA CERTIFICATE OF VETERINARY INSPECTION

Contact State of Destination for Movement Requirements and Certificate Validity
FOR FOREIGN SHIPMENTS (Outside United States or Leaving United States) USE FEDERAL FORM

Certificate Number
32-1234-null

OFFICIAL USE ONLY: The Veterinarian issuing this certificate is accredited and has been authorized to inspect animals and issue certificates.

ENTRY PERMIT #: _____

INSPECTION DATE: **09/07/2017** SHIPMENT DATE: _____ Large Animal Small Animal

CONSIGNOR - Contact Person at Origin				CONSIGNEE - Contact Person at Destination				CARRIER (Transporter)			
First Name Jane		Last Name Doe		First Name John		Last Name Smith		Business Name			
AND/OR		AND/OR		AND/OR		AND/OR		Physical Address			
Business Name				Business Name Dusty Ranch				Physical Address			
Physical Address of Animals 1234 Cattle Drive				Physical Address of Animals 5678 Ranch Road				City _____ State _____ Zip Code _____ Phone Number _____			
City Northfield		State IN		Zip Code 46711		County Adams		City _____ State _____ Zip Code _____		Transport Method _____ Purpose of Movement Breeding	
Phone Number (260) 123-4567		Location ID#		Phone Number		Location ID#		Interstate <input type="checkbox"/> Intrastate <input type="checkbox"/>		Print Reconsigned <input type="checkbox"/>	
Consignor's Address (if different)				Consignee's Address (if different)							
Disease Certification Statements				Flock/Herd Accredited Free For: Herd/Flock # _____ <input type="checkbox"/> Tuberculosis <input type="checkbox"/> Brucellosis <input type="checkbox"/> Scrapie <input type="checkbox"/> NPIP <input type="checkbox"/> Johne's <input type="checkbox"/> PRV <input type="checkbox"/> CWD <input type="checkbox"/> Other (specify) _____				Current State/Area Status: Tuberculosis: _____ Brucellosis: _____ <input type="checkbox"/> Other (specify) _____			

SPECIES	# OF HEAD	OFFICIAL PERMANENT ID	OTHER ID (REGISTRY NAME, NUMBER OR DESCRIPTION)	AGE	SEX	BREED	TB DATE OBSVD	TB TEST RESULT	BRUC TEST DATE	BRUC TEST RESULT	BRUC VACC TATTOO	EIA TEST DATE	EIA LAB NAME	EIA TEST RESULT	ACCESSION #	OTHER	Copy	Delete
Beef Cattle	1	9400030000000000		3	M	Simmental						N/A	N/A	N/A				
TOTAL	1	Add Row	Delete Last Row															

OWNER/AGENT STATEMENT
"The animals in this shipment are those certified to and listed on this certificate."

VETERINARY CERTIFICATION - I certify, as an accredited veterinarian that the above described animals have been inspected by me and that they are not showing signs of infectious, contagious and/or communicable disease (except where noted). The vaccinations and results of tests are indicated on the certificate. To the best of my knowledge, the animals listed on this certificate meet the state of destination and federal interstate requirements. No further warranty is made or implied.

Date: **09/07/2017** Printed Name: **Josh Smith** Phone: (000) 000-0000 Email: **vetclinic@clinic.com**

Address: **12345 W 6789 S** City: **My City** State: **IN** Zip: **46711**

USDA Accreditation # **00000000** State of License: **IN** License # **99011234**

SIGNATURE: _____

CERTIFICATE AND CERTIFICATE #
OFFICIAL AFTER DIGITALLY SIGNED

Questions?

www.in.gov/boah

animalhealth@boah.in.gov

317-544-2400

