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Gene Editing and Livestock: the Producer Perspective

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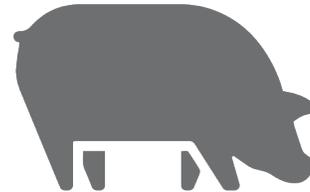
THE GLOBAL VOICE OF THE U.S. PORK INDUSTRY



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U.S. pork
producers are
committed to
doing what's right



Producers are excited about Gene Editing

- The precision of gene editing, combined with investments in genetic mapping of livestock species, offers a powerful new tool.
- Viral diseases of livestock are of huge concern to producers—gene editing has already shown tremendous potential to address this challenge
- Gene editing also has promise to address other major producer and societal concerns



We've come a long way...

Domestication

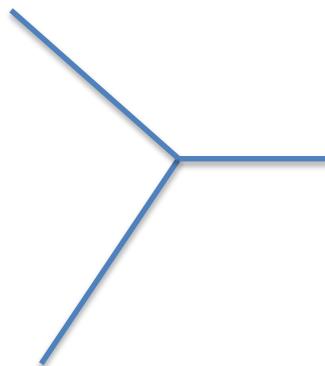
1800's

1960's

Today



...and we've got a lot to lose





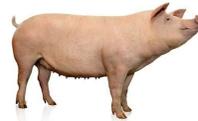
The Potential is immense:

■ Cattle



- Polled factor
- Eliminate or reduce milk allergies
- Resistance to tuberculosis
- Resistance to BRD

■ Pigs



- Resistance to PRRS
- Resistance to African Swine Fever
- Resistance to Foot and Mouth Disease

■ Chickens



- Resistance to avian influenza
- Reduce or eliminate egg allergies
- Reduce salmonella in poultry products





Animal Health: PRRS as Example

- The total cost of PRRS to the U.S. pork industry is estimated to be \$664 million annually. The total additional costs attributed to PRRS for veterinary, biosecurity and other outbreak-related costs are \$477 million annually.
- Vaccines have not been effective against the disease, and genetic selection for innate resistance has not been successful.





Public Health

- The prevention of viral disease would have a huge impact on antibiotic use and efforts to combat antimicrobial resistance
- Zoonotic diseases are a challenge worldwide—breaking the cycle of transmission is a possibility with gene editing
- Food safety applications of gene editing have only begun to be explored—the potential is huge





Other potential benefits include:

- Increased sustainability—improved feed efficiency, novel feedstuffs, altered manure profile all show promise
- Welfare—physical, physiological, and behavioral characteristics that influence welfare are being explored





Unlocking this potential depends on the right regulatory framework

- FDA's Guidance 187—issued in 2009 and updated in 2017—is not the right approach
- It defines the “article” under the FDCA as an rDNA construct intended to affect the structure or function of the animal
 - Regulating DNA as an “animal drug”
 - All GE animals in a lineage are covered





What producers are worried about:

- This approach means all gene edited animals—***and their progeny in perpetuity***—will be walking animal drugs
- All farms breeding GE-derived livestock *can* be considered “drug manufacturing facilities”
- The approval process will be lengthy and cost prohibitive
- ***Each edited lineage will have to be approved separately***





We can only see three potential outcomes:

1. Incredible reduction in genetic diversity within our livestock populations,
2. The FDA, developers, producers caught up in hundreds—or thousands—of approval applications for each edit in each breed/strain/herd or flock, or
3. Producers don't have access to this technology as their competitors in other countries reap the benefits

None of these are acceptable





NPPC's Position

NPPC strongly supports moving regulatory oversight of gene editing in animals from the FDA to the USDA's Animal and Plant Health Inspection Service (APHIS). APHIS, which already regulates gene editing in plants, can ensure proper and risk-based regulatory review under the Animal Health Protection Act. Regulation of gene editing in animals by the FDA as an "animal drug" is not appropriate or practicable.





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Thank You

