**SITUATION**

The FDA is making a regulatory land grab in an effort to gain oversight of Cell-Cultured Protein (CCP) and Gene Edited (GE) livestock. The Meat and Poultry Inspection Act clearly indicates that CCP—produced from cultured cells taken from pigs and other livestock—should be under the oversight of the U.S. Department of Agriculture's Federal Safety Inspection Service (FSIS). FDA will have a role in ensuring that ingredients used in the manufacture of CCP products are safe (just like they currently do for ingredients used in the preparation of traditional meat products). When it comes to actually making products from these cells, only FSIS has the capability to provide continuous, risk-based inspection and apply strict labeling standards that will ensure consumer awareness of what CCP is and how its produced.

Likewise, there is no statutory requirement that the FDA regulate GE in food producing animals, much less that they do so as an “animal drug”. The FDA’s proposed regulatory framework is the result of a decades-old administrative decision, based on older transgenic biotechnology. This regulatory path will result in a lengthy and expensive approval process, and functionally make any GE animal a living animal drug—and every farm raising them a drug manufacturing facility. It does not allow for a risk-based approach that takes into consideration the familiarity or complexity of the genetic changes and the fact that they could be achieved through conventional breeding techniques (though at the expense of time and genetic improvement from decades of animal breeding). The FDA approach is also out of step with the regulatory pathways under development in the rest of the world.

**NPPC POSITION**

* NPPC strongly supports USDA having chief regulatory oversight of cell-cultured protein (CCP) and gene editing (GE) in agricultural animals. **CCP needs to be inspected—and have any label claims approved—by the USDA’s Food Safety and Inspection Service (FSIS).** FSIS has the expertise and capability to provide continuous inspection to facilities producing CCP, and make sure that the product names and label claims are transparent, fact-based and appropriate. **The USDA’s Animal and Plant Health Inspection Service (APHIS), which already regulates GE in plants, can ensure proper and risk-based regulatory review under the Animal Health Protection Act. Regulation of GE in animals by the FDA as an “animal drug” is not appropriate or practicable.**

**FAST FACTS**

- Gene editing offers pork producers remarkable promise to improve the health and welfare of their pigs and the safety of the pork they produce.
- A sound, risk based, and pro-innovation regulatory review process is essential for producers to have this opportunity.
- The FDA is seeking to regulate gene editing as an animal drug. This is not a good fit for this technology.
- Regulating gene editing as an animal drug will make this scientific breakthrough unavailable to livestock farmers.
- The FDA would like to regulate CCP and provide minimal oversight to production facilities, giving them a free pass to avoid careful scrutiny and make virtually unregulated label claims.