

# FDA And USDA Clash Over Definition Of Genetically Modified Food



By *Chuck Dinerstein, MD, MBA* — April 23, 2018



Courtesy Architect of the Capital [1]

The regulatory concerns about genetic modification of animals that I [wrote](#) [2] about a while ago have moved towards a Congressional spotlight. Pigs have been genetically modified to resist porcine reproductive and respiratory syndrome virus by deleting a gene. Does deleting a gene make them genetically modified - yes and no, depending on which regulatory agency you ask.

## The virus

The viral disease is carried by pigs and results in an acute phase with increased fetal and perinatal deaths as well as a more chronic respiratory phase in the piglet survivors and their moms. As with our own experience with viral infections, they are difficult to eradicate. It is highly transmissible, it has multiple antigenic properties making a single vaccine challenging to produce, and it has a chronic state where pigs continue to serve as sources of infection. There is no treatment for the acute phase. Antibiotics are ineffective, and their use increases the risk of resistant bacteria. A vaccine confers a variable degree of protection on about 80% of animals, and so like humans, the best treatment is prevention with rapid identification and isolation of the infected pigs. Computer models and economic reports place the cost of this illness at about \$660 million for American farmers and consumers.

## The genetic modification

The porcine reproductive and respiratory syndrome virus attacks specific white blood cells, the ones that acutely fight infection. A protein, CD163, aids the virus in its attachment to the white blood cells and their subsequent infection. By knocking out the gene controlling the production of CD163 the virus was no longer able to attach or infect the cells. These genetically modified pigs

were not only resistant to the virus but “were healthy under normal husbandry conditions and other biological functions conducted by the CD163 were found to be intact.” The genetic modification was to knock out or make the function of CD163 inoperative; it did not involve the insertion of a new or foreign gene.

### **The current confusion**

In 1980 regulation of genetically modified organisms was apportioned to the EPA, USDA, and FDA. The EPA addressed environmental concerns, the USDA addressed the introduction of “plant pests” into our food chain, and the FDA addressed concerns about what we are ingesting. Because CRISPR-Cas9 can introduce genetic changes without leaving traces of how it is introduced it meets most of the USDA’s concerns about introducing pests into our food supply. Further testing has demonstrated the stability of the genetic change also allaying USDA concerns about the impact of these modifications over several generations. So from their point of view, these genetically modified pigs are not genetically modified at all. As I characterized them previously, they are biosimilar. Biosimilar enough to introduce into our food supply.

The FDA takes a different position. For them, a biosimilar is not the same; changing a single base pair, turning off or deleting a gene, inserting a foreign gene are all genetic modifications. More importantly, these genetic modifications are considered a drug, subject to the same regulatory process and testing as any other drug. To be clear, the pig is not a drug; it is their genetically modified DNA that is of concern.

To make the confusion worse, plants with changes in a single base pair or turning off or deleting a gene are not considered genetically modified. It is unclear why the animal genetic modification is treated differently. These differences in definition have a regulatory impact in terms of the additional costs and time necessary to demonstrate a drug’s safety.

Congress is faced with several decisions. It cannot merely transfer jurisdiction away from the FDA to the USDA. The USDA is not equipped to regulate genetically modified animals; their oversight is about the impact of those animals on our food supply, not our health. The FDA’s distinction between plant and animal genetic would require a new scientific consensus within the FDA which cannot be legislated. Considering a more cohesive agreement and definition of genetic modification in the age of CRISPR-Cas9 could at least be facilitated by a scientific panel – something Congress could create. I am afraid the argument will deteriorate into a discussion of time to market and cost for these innovations. It would move us away from a science-based inquiry into political opinions; about evil Big Agriculture, sustainable farming or the safety of GMOs, topics that can be highlighted in an election year. I am afraid that Congress is far more comfortable with those political conversations than with science.

**Source URL:** <https://www.acsh.org/news/2018/04/23/fda-and-usda-clash-over-definition-genetically-modified-food-12867>

**Links**

[1]

[https://en.wikipedia.org/wiki/United\\_States\\_congressional\\_conference\\_committee#/media/File:United\\_States\\_Capitol\\_-\\_west\\_front.jpg](https://en.wikipedia.org/wiki/United_States_congressional_conference_committee#/media/File:United_States_Capitol_-_west_front.jpg)

[2] <https://www.acsh.org/news/2018/04/10/why-crispr-ok-plants-not-animals-12820>