



Biotech Roundtable: Gene Editing in Ag Biotech Regulatory Considerations

24 October 2017 • Research Triangle Park, N.C.



Keith Matthews
202-719-4462
kmatthews@wileyrein.com



Regulatory Considerations

“Governments all over the world are struggling with the regulatory status of gene-edited organisms. Are they regulated? Should they be regulated?”

Custers, R., The regulatory status of gene-edited agricultural products in the EU and beyond, Emerging Topics in Life Sciences (15 September 2017),

<http://www.emergtoplifesci.org/content/early/2017/09/14/ETLS20170019.full-text.pdf>



Regulation of Ag Biotech in the United States

Regulation of Ag Biotech in the United States

Since 1986 governed by the Coordinated Framework for the Regulation of Biotechnology

51 Fed. Reg. 23302 (June 26, 1986); 57 Fed. Reg. 6753 (Feb. 27, 1992)

In 2017, the Obama Administration issued an update to the Coordinated Framework, *Update to the Coordinated Framework*,

https://www.epa.gov/sites/production/files/2017-01/documents/2017_coordinated_framework_update.pdf

Regulation of Ag Biotech in the United States (cont.)

Accompanying the *Update to the Coordinated Framework was a National Strategy for Modernizing the Regulatory System for Biotechnology Products*,

https://www.epa.gov/sites/production/files/2016-12/documents/biotech_national_strategy_final.pdf

Regulation of Ag Biotech in the United States

(cont.)

Also commissioned under the auspices of the *Update to the Coordinated Framework* was a report by the National Academies of Sciences, *Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System*,

<http://nas-sites.org/biotech>

Regulation of Ag Biotech in the United States

(cont.)

Federal Agencies

- FDA

- Federal Food, Drug, and Cosmetic Act (FFDCA)
 - Food Safety
 - Animal Drugs

- USDA

- Plant Protection Act (PPA)
 - Plant Pests

Regulation of Ag Biotech in the United States

(cont.)

Federal Agencies

- EPA
 - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
 - Pesticides



Jurisdictional Scope

Jurisdictional Scope of Regulation

- FDA
 - Foods
 - Food Safety Assessment
- Animal Drugs
 - Health Assessment
 - Environmental Assessment

Jurisdictional Scope of Regulation (cont.)

- USDA

- Plants

- Plant Pests

- Altered or produced through genetic engineering
and
 - Produced using plant pests (donor or recipient)
or
 - Other reason to believe may be a plant pest

Jurisdictional Scope of Regulation (cont.)

EPA

- Organisms Genetically Engineered for a Pesticidal Purpose
 - Plants
 - Microorganisms
 - Insects

Jurisdictional Scope of Regulation (cont.)

EPA

- Organisms Genetically Engineered for a Pesticidal Purpose
 - “Pesticide” is defined as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.”
 - Also note definition of “plant regulator.”



Regulatory Approaches

Regulatory Approaches

None of the Agencies has set forth a final plan for how, or whether, gene edited ag products will be regulated.

Regulatory Approaches (cont.)

FDA

FDA published two notices on January 19, requesting comment on

(1) “the use of gene editing techniques to produce new plant varieties that are used for human or animal food” (82 Fed. Reg. 6564); and

(2) a draft guidance for industry on regulation of genetically engineered animals that addresses gene editing (82 Fed. Reg. 6561).

Regulatory Approaches (cont.)

USDA

USDA's current actions related to gene edited plants or plant pests have been addressed by Mr. Firko.

Regulatory Approaches (cont.)

EPA

?



Regulation of Gene-Edited Ag Products in the EU

For questions contact:

Keith Matthews

Wiley Rein LLP

202.719.4462

KMatthews@wileyrein.com

