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Authors

Kathryn E. Szmuszkovicz
Principal
(202) 789-6037
kes@bdlaw.com

Alan J. Sachs
Principal
(212) 702-5445
aachs@bdlaw.com

Federal Agencies Issue Final Update to Biotechnology Regulatory Framework

On January 4, 2017, the U.S. Environmental Protection Agency, U.S. Department of Agriculture, and U.S. Food and Drug Administration released their final version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology. This update represents the federal government's first comprehensive overview of the regulatory landscape for biotechnology products in 30 years. Having assured the public that the present regulatory system "effectively protects health and the environment," the agencies go on to observe the potential for unnecessary costs and burdens under the existing regulatory processes, particularly highlighting ongoing uncertainty over agency jurisdiction and the lack of predictable timeframes for review. The Agencies also recognize that advances in science and technology have "dramatically altered" the biotechnology landscape in recent years and, in that context, worked to clarify through the new update which biotechnology product areas are within the authority and responsibility of each Agency.

The document incorporates a number of tables, graphics, and several hypothetical case studies intended to help illustrate the role each Agency plays in biotechnology regulation and the different regulatory paths applicable to various product types. Specifically, the document outlines:

- EPA's regulatory authority over chemical pesticides, microorganisms, biochemicals, and plant-incorporated protectants (PIPs) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and Federal Food, Drug and Cosmetic Act (FFDCA), and EPA's oversight responsibilities for a wide range of microbial biotechnology applications under the Toxic Substances Control Act (TSCA);
- FDA's regulation of human and animal food derived from (i) genetically engineered plants; (ii) genetically engineered animals; and (iii) human drugs, biologicals, and medical devices derived from genetically engineered sources under the FFDCA; and
- Regulation by USDA's Animal and Plant Health Inspection Service (APHIS) of biotechnology products that may (i) introduce pests or cause disease to livestock under the Animal Health Protection Act (AHPA), (ii) be deemed plant pests or noxious weeds under the Plant

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Protection Act (PPA), or (iii) be used in veterinary biologics under the Virus-Serum-Toxin Act (VSTA); along with the role played by USDA's Food Safety and Inspection Service (FSIS) in reviewing the safety of meat, poultry, eggs, or fish from genetically engineered animals intended for human consumption.

Consistent with the framework, each agency is expected to take steps to further clarify its particular areas of jurisdiction and requirements for biotechnology products. In addition, an independent study by the National Academy of Sciences (NAS) on future biotechnology products (commissioned by EPA, FDA, and USDA in 2016) remains ongoing and, once issued, is likely to help further inform federal regulatory policies going forward. Among other things, the study is expected to identify areas in which the risks or lack of risk relating to biotechnology are well understood, as well as the regulatory tools and expertise that may be useful to oversight of potential future products of biotechnology.

Beveridge & Diamond's reputation for excellence in agricultural biotechnology law and regulation is based on forty years of working with U.S. and international clients who research, develop, obtain government approvals for, manufacture, promote, and use conventional pesticides, pesticides produced through biotechnology, and other chemical and biotechnology products. We represent both large and small companies, as well as task forces of companies, with an emphasis on entities that invest in research to discover, develop, and defend new technology. We work with each client to identify its business objectives, and then to establish and implement the most effective regulatory, commercial, litigation, and legislative strategies to achieve or exceed those objectives. To learn more, please contact Kathy Szmuszkovicz (kes@bdlaw.com, (202) 789-6037), Alan Sachs (asachs@bdlaw.com, (212) 702-5445), or any member of our Pesticides and Biotechnology practice groups.