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Biotechnology: Case Studies of Hypothetical, Genetically Engineered Organisms

Article By:

B&C® Biobased and Sustainable Chemicals Practice Group Bergeson & Campbell, P.C.

Discussed at Second Meeting on Modernizing the Regulatory System for Biotechnology Products to Illustrate Agencies' Roles and Responsibilities

On March 9, 2016, the second public meeting on the July 2, 2015, memorandum entitled "**Modernizing the Regulatory System for Biotechnology Products**," was convened in the ***U.S. Environmental Protection Agency's (EPA)*** Region 6 Office in Dallas, Texas. Representatives from EPA, the U.S. ***Food and Drug Administration (FDA)***, the U.S. Department of Agriculture (***USDA***), and the ***White House*** Office of Science and Technology Policy (OSTP) discussed their current roles and responsibilities regarding biotechnology products under the Coordinated Framework for Regulation of Biotechnology (CF) by reviewing case studies of hypothetical products.

Two documents were released prior to the public meeting: (1) **Table of the oversight of biotechnology products and relevant coordination across EPA, FDA, and USDA**; and (2) **Regulation of Biotechnology Products -- Clarifying Roles and Responsibilities through Hypothetical Case Studies**. A copy of the agenda is available **here**.

According to OSTP's blog item on the meeting, the table document summarizes current responsibilities and the relevant coordination across USDA, EPA, and FDA for the regulatory oversight of biotechnology products. OSTP cautions that it should not be interpreted as a guarantee that specific products in any of the product areas described in the table have been in the past, or will be in the future, determined to be safe by the relative regulatory agencies.

The case studies document states that its intention is to provide general information to developers who believe they have, or are uncertain as to whether they may have, a biotechnology product that is subject to regulation under one or more of the federal laws described in the CF. It also demonstrates how an innovator might navigate the regulatory framework, starting from research activities in the laboratory to full commercialization of the product. OSTP states that all of the case studies are of hypothetical products, selected because they cover multiple biotechnology product areas with different characteristics and intended uses, and because they illustrate how agencies coordinate their oversight under the CF. The case studies discussed included the following hypothetical, genetically engineered organisms:

1. Corn, a field crop used for food. In the first case study, corn with pesticidal properties is engineered with a plant pest component to have pesticidal activity against certain insects.

2. Plum, a fruit tree/crop used as food. In the second case study, plum with pesticidal properties is genetically engineered without a plant pest component to resist a fungus.

3. Canola, a field crop, used as food. In the third case study, herbicide-tolerant Canola is genetically engineered with a plant pest component to tolerate an already registered herbicide.

4. Rose, an ornamental plant. In the fourth case study, a rose is genetically engineered with a plant pest component to increase the production of a pigment in its petals.

5. Microbial Pesticide, a bacterium that is not considered a plant pest. In the fifth case study, a microbial pesticide is genetically engineered to enhance its pesticidal properties.

6. Microbial Pesticide, a phytopathogenic bacterium. In the sixth case study, a microbial pesticide that is genetically engineered to express a pesticidal substance that protects against insects.

7. Algae for Biofuels. In the seventh case study, a unicellular alga is genetically engineered with a plant pest component to produce industrial oils for conversion into biofuels.

8. Rabbit, an animal. In the eighth case study, a rabbit is genetically engineered to make a therapeutic protein (recombinant insulin) for treatment of humans lacking this protein activity.

The first public engagement session took place on October 30, 2015, at FDA's White Oak Campus in Silver Spring, Maryland. A transcript from the meeting is available **online**. The third public meeting will be held on **March 30, 2016**, at the University of California, Davis Conference Center in Davis, California.

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