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Background on Determinations for “Deregulated Status”

The United States Department of Agriculture (USDA) is one of the three federal agencies most directly involved in the regulation of genetically engineered plants. USDA’s Animal and Plant Health Inspection Service (APHIS) oversees the field testing and interstate shipments of genetically engineered plants.

Under the authority of the Federal Plant Protection Act, 7 U.S.C. § 7701, et seq., APHIS considers most genetically engineered plants as “regulated articles.” As a result, APHIS must be notified prior to any interstate shipment or field test of these “regulated articles.” A person or company cannot freely ship in interstate commerce (therefore cannot commercialize) a particular genetically engineered plant variety until that plant variety has been “deregulated” by APHIS.

In order to obtain “deregulation” of a plant variety, the manufacturer of the genetically engineered plant must submit a petition for deregulation pursuant to APHIS regulations found at 7 C.F.R. § 340.6. The petition needs to discuss, among other things, the plant’s genetics, all reports for field trials on the variety, and potential environmental issues. Per § 340.6 the timeline for action on such a petition is as follows:

- (1). Petition if filed by a manufacturer and receives a petition number;
- (2). USDA Reviews the petition to ensure that it is completed in conformance with its regulations. If incomplete, the manufacturer is sent a notice identifying deficiencies;
- (3). After it is determined the petition filed is complete, the USDA publishes a notice in the Federal Register during which time public comment is solicited from the public for 60 days;
- (4). At this time it is also the practice of APHIS to make available for public comment an environmental assessment for the proposed determination of the plant varieties non-regulated status. [This review is done to comply with the National Environmental Policy Act, 42 U.S.C. § 4321, et seq. Under NEPA an environmental assessment (EA) is the first step to complete an environmental review. After receiving public comments, the APHIS determines whether to perform a full environmental impact statement (EIS) (subject to much more thorough environmental review and public input) or stop with the EA after making a finding of no significant impact. It is important to note that APHIS has never required an EIS for the deregulation of any genetically engineered crop.];
- (5). APHIS then reviews all comments received concerning the receipt of the petition and the accompanying EA;

- (6). APHIS then must make a final decision on the petition no later than 180 days from the date of a received completed petition; and
- (7). APHIS makes its determination of non-regulated status public by publishing a notice in the Federal Register.

Example: Vector Tobacco's Genetically Engineered Low-Nicotine Tobacco

One recent example of the timing of the deregulation process from start to finish is that of Vector Tobacco's genetically engineered low nicotine tobacco. Here is the timeline:

May 1, 2001 - APHIS received a petition for deregulated status from Vector Tobacco for its genetically engineered low nicotine tobacco (APHIS Petition No. 01-121-01p)

October 22, 2001 - APHIS deems the petition complete.

February 12, 2002 - APHIS announced that the petition was available for public review as well as the accompanying environmental assessment. 60-day comment period commenced. 67 Federal Register 6480.

April 15, 2002 - The public comment period closes.

September 16, 2002 - APHIS makes determination that the petition is approved and the tobacco is granted "deregulated status."

December 3, 2002 - USDA publishes the determination of non-regulated status. 67 Federal Register 71929.

In the tobacco case it took a little over five months for USDA to find that the original petition was complete. It also took APHIS more than the allotted 180 days from the time the petition was deemed complete. Importantly, there was also a lag time of three months from the time of USDA's determination of "deregulated status" until public notice about the decision was published in the Federal Register.

The status of current or past petition's for deregulation can be found at: <http://www.aphis.usda.gov/bbep/bp/petday.html>

Status of Genetically Engineered Wheat

On December 19, 2002, APHIS received a petition for deregulated status from Monsanto for wheat. APHIS assigned this as petition number 02-353-01p and lists the status as "under review for completeness." If the APHIS review proceeds along a timeline similar to the tobacco example, Monsanto could expect to have "deregulated status" around late April 2004.