



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 11 2014

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

Mr. Sid Abel
Biotechnology Regulatory Services
4700 River Road
USDA, APHIS
Riverdale, MD 20737

Dear Mr. Abel:

In accordance with our authorities under the National Environmental Policy Act (NEPA) and Section 309 of the Clean Air Act, EPA has reviewed the draft Environmental Impact Statement (EIS) developed by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) concerning Dow AgroScience's Petitions (09-233-01p, 09-349-01p, and 11-234-01p) for Determinations of Nonregulated Status for 2,4-D-Resistant Corn and Soybean Varieties.

APHIS developed the draft EIS in response to petitions from Dow AgroScience (DAS) to deregulate three genetically engineered (GE) Enlist™ crops. These crop varieties are developed to resist several herbicides, including the Enlist Duo herbicide (a formulation of 2,4-D and glyphosate). The draft EIS identifies four alternatives for deregulating one corn and two soybean Enlist™ crop varieties. Under APHIS's regulations, APHIS can only consider plant pest risks when making a determination of nonregulated status. As noted in the draft EIS, APHIS has concluded that DAS-68416-4 soybean, DAS-44406-6 soybean, and DAS-40278-9 corn are unlikely to pose plant pest risks, i.e., risks caused by plant pests that can cause injury, damage, or disease to plants or plant products.

While Enlist™ corn and soybean can resist damage from the application of the Enlist Duo™ herbicide, APHIS's selection of a particular alternative does not in itself allow the use of Enlist Duo™ herbicide on Enlist™ corn and soybean plant varieties. APHIS has no authority to regulate herbicide use. Instead, the EPA regulates the use of herbicides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. §136 et seq.) and is making a separate decision which may or may not approve registration for use of Enlist Duo™ herbicide on these plants. As part of the approval process, the EPA determines how the herbicide may be used and requires that the labeling of the product contain directions and precautionary statements, which ensure that it will not cause unreasonable adverse effects on the environment when used according to its labeling. (Under FIFRA, it is unlawful to use an herbicide in a manner inconsistent with its labeling.)

The draft EIS includes a description of DAS's proposed label language for Enlist Duo™ addressing spray drift management™ (see Appendix 7, particularly Table 7-3). Please note that EPA has not completed its assessment of the risks posed by off-target movement of residues of Enlist Duo™, particularly via spray drift. As noted in the draft EIS, the EPA's reviews consider additional potential impacts of using Enlist Duo™ including risks to endangered and threatened species and their designated critical habitat, which are not addressed in the draft EIS. When the EPA completes its review and if the EPA determines that Enlist Duo™ meets the statutory standard for registration, the EPA may decide to impose limitations on the use of Enlist Duo™ that differ from those proposed by DAS and described in the draft EIS.

EPA has rated the draft EIS as LO ("Lack of Objections"). A summary of EPA's rating is enclosed. Please feel free to contact me or have your staff contact Cliff Rader, Director, NEPA Compliance Division, at (202) 564-7159 if you have any questions or would like to discuss our comments.

Sincerely,

A handwritten signature in black ink that reads "Susan E. Bromm" followed by a long, sweeping horizontal flourish.

Susan E. Bromm
Director
Office of Federal Activities

Enclosure

SUMMARY OF EPA RATING DEFINITIONS*

This rating system was developed as a means to summarize the U.S. Environmental Protection Agency's (EPA) level of concern with a proposed action. The ratings are a combination of alphabetical categories for evaluation of the environmental impacts of the proposal and numerical categories for evaluation of the adequacy of the Environmental Impact Statement.

ENVIRONMENTAL IMPACT OF THE ACTION

“LO” (Lack of Objections)

The EPA review has not identified any potential environmental impacts requiring substantive changes to the proposal. The review may have disclosed opportunities for application of mitigation measures that could be accomplished with no more than minor changes to the proposal.

“EC” (Environmental Concerns)

The EPA review has identified environmental impacts that should be avoided in order to fully protect the environment. Corrective measures may require changes to the preferred alternative or application of mitigation measures that can reduce the environmental impact. EPA would like to work with the lead agency to reduce these impacts.

“EO” (Environmental Objections)

The EPA review has identified significant environmental impacts that should be avoided in order to provide adequate protection for the environment. Corrective measures may require substantial changes to the preferred alternative or consideration of some other project alternative (including the no action alternative or a new alternative). EPA intends to work with the lead agency to reduce these impacts.

“EU” (Environmentally Unsatisfactory)

The EPA review has identified adverse environmental impacts that are of sufficient magnitude that they are unsatisfactory from the standpoint of public health or welfare or environmental quality. The EPA intends to work with the lead agency to reduce these impacts. If the potentially unsatisfactory impacts are not corrected at the final EIS stage, this proposal will be recommended for referral to the Council on Environmental Quality.

ADEQUACY OF THE IMPACT STATEMENT

Category “1” (Adequate)

The EPA believes the draft EIS adequately sets forth the environmental impact(s) of the preferred alternative and those of the alternatives reasonably available to the project or action. No further analysis or data collection is necessary, but the reviewer may suggest the addition of clarifying language or information.

Category “2” (Insufficient Information)

The draft EIS does not contain sufficient information for EPA to fully assess environmental impacts that should be avoided in order to fully protect the environment, or the EPA reviewer has identified new reasonably available alternatives that are within the spectrum of alternatives analyzed in the draft EIS, which could reduce the environmental impacts of the action. The identified additional information, data, analyses, or discussion should be included in the final EIS.

Category “3” (Inadequate)

The EPA does not believe that the draft EIS adequately assesses potentially significant environmental impacts of the action, or the EPA reviewer has identified new, reasonably available alternatives that are outside of the spectrum of alternatives analyzed in the draft EIS, which should be analyzed in order to reduce the potentially significant environmental impacts. EPA believes that the identified additional information, data, analyses, or discussions are of such a magnitude that they should have full public review at a draft stage. EPA does not believe that the draft EIS is adequate for the purposes of the NEPA and/or Section 309 review, and thus should be formally revised and made available for public comment in a supplemental or revised draft EIS. On the basis of the potential significant impacts involved, this proposal could be a candidate for referral to the CEQ.

*From EPA Manual 1640, Policy and Procedures for the Review of Federal Actions Impacting the Environment.