



BILLING CODE: 3410-34-P

**DEPARTMENT OF AGRICULTURE**

**Animal and Plant Health Inspection Service**

**7 CFR Part 340**

**[Docket No. APHIS-2015-0057]**

**RIN 0579-AE15**

**Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms**

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; withdrawal.

SUMMARY: We are withdrawing a proposed rule that would have revised our regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms. We are taking this action after considering the comments we received following the publication of the proposed rule.

DATES: We are withdrawing the proposed rule published January 19, 2017 (82 FR 7008) as of

[Insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Mr. Sidney Abel, Assistant Deputy

Administrator, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147,

Riverdale, MD 20737-1238; (301) 851-3896.

SUPPLEMENTARY INFORMATION: On January 19, 2017, we published in the *Federal Register* (82 FR 7008-7039, Docket No. APHIS-2015-0057) a proposal<sup>1</sup> to amend the regulations in 7 CFR part 340 regarding the importation, interstate movement, and environmental release of certain genetically engineered (GE) organisms.

We solicited comments concerning our proposal for 120 days ending May 19, 2017. We extended the deadline for comments until June 19, 2017, in a document published in the *Federal Register* on February 10, 2017 (Docket No. APHIS-2015-0057, 82 FR 10312-10313). We received 203 comments by that date. They were from GE developers, growers of GE crops, GE industry and agricultural trade associations, universities and academic researchers, organic producers and trade associations, consumer safety and environmental advocacy groups, a Federal agency, and private citizens.

Many commenters objected to the scope of the proposed rule. Some thought that our criteria for designating GE organisms as regulated organisms were too expansive, potentially resulting in our regulating a wider range of GE organisms than necessary and thereby increasing, rather than reducing, the regulatory burden for the biotechnology industry. Other commenters, however, thought that certain exemptions and exclusions contained in the proposed rule would effectively narrow the scope of our regulatory authority over GE organisms and increase the risk of the unintended presence of GE crops in organic and other non-GE crops.

The January 2017 proposed rule represented a major change from our existing “regulate first/analyze later” approach to one that entailed assessing new GE organisms to determine if they posed plant pest or noxious weed risks and then regulating only organisms that did present

---

<sup>1</sup>To view the proposed rule, supporting documents, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0057>.

risks. Some commenters expressed concern that the proposed risk assessment process could prove lengthy, cumbersome, and confusing, thereby hindering innovation and preventing GE products from getting to market in a timely manner. Though we did provide exclusions that would have allowed GE organisms with certain plant/trait combinations to bypass the risk assessment process, these commenters viewed the exclusions as too narrow. Other commenters, however, took the opposite view. These commenters objected to our proposed exemption from the risk assessment process of products having plant/trait combinations corresponding to specific organisms that had been granted nonregulated status based on previous risk assessments. A number of these commenters also thought the proposed process as a whole would be insufficiently rigorous, with some objecting specifically to our proposal to no longer require the submission of field test data as part of the assessment process.

Another issue that drew many comments was our proposal to incorporate our noxious weed authority into the biotechnology regulations in part 340. Noting that noxious weeds are also regulated under the Plant Protection and Quarantine regulations in 7 CFR part 360, commenters expressed concern that this proposal could result in the creation of two parallel but inconsistent regulatory systems and thus more regulatory uncertainty.

Finally, many commenters expressed opposition to genetic engineering in general, as well as concerns about a wide range of issues, many of which were outside the scope of the proposed rule. For example, commenters stated that the Animal and Plant Health Inspection Service (APHIS) should consider non-safety-based risks, such as economic and social impacts, including impacts on the marketability of non-GE products. Other commenters requested that APHIS regulations include provisions related to the labeling of GE products and raised concerns regarding health effects of GE products and increased pesticide use.

Based on the scope of comments received on the January 2017 proposed rule, we have decided to withdraw the rule and to begin a fresh stakeholder engagement aimed at exploring alternative policy approaches. Because of rules limiting *ex parte* communications with respect to active rulemakings, publication of the 2017 proposed rule has constrained our ability to talk about alternatives with stakeholders. Withdrawing the proposed rule will lift this constraint and provide for a more open and robust policy dialogue.

Therefore, we are withdrawing the January 19, 2017, proposed rule referenced above. As we explore a full range of policy alternatives, we will consider the comments we received on the proposed rule, as well as new scientific knowledge, and continue to seek the active and open input of stakeholders.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 1<sup>st</sup> day of November 2017.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017-24202 Filed: 11/6/2017 8:45 am; Publication Date: 11/7/2017]