



October 26, 2015

Regulatory Analysis and Development  
PPD, APHIS, Station 3A-03.8  
4700 River Road Unit 118  
Riverdale, MD 20737-1238

Submitted Electronically via Federal eRulemaking Portal (<http://www.regulations.gov>)

Re: Docket No. APHIS-2015-0070— Changes to Requirements for Field Testing Regulated Genetically Engineered Wheat

Dear Sir or Madam:

The Biotechnology Industry Organization (BIO) is pleased to submit these comments in response to the USDA Animal and Plant Health Inspection Service (APHIS) notice requesting public input on proposed changes to requirements for field testing of regulated genetically engineered (GE) wheat (Notice). BIO is the world's largest trade association, representing more than 950 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products, and BIO represents the majority of the biotechnology product developers in North America, including companies conducting field trials of GE wheat.

Research on GE wheat in the United States is thriving, and being conducted by a wide array of large and small businesses, public institutions, and academic scientists. While no varieties of GE wheat have been commercialized in the United States, wheat growers have expressed an eagerness to benefit from the same kinds of advanced crop varieties benefitting other major crops in the U.S.; biotechnology is seen as a significant component in the competitiveness of the wheat industry.<sup>1</sup> It is critically important that APHIS oversight of GE wheat field trials be appropriate to the level of risk posed by such research, and that regulatory burdens imposed by the agency do not unnecessarily impede the development of new products. BIO respectfully submits that the proposed change described in the Notice fails to meet these standards. Moreover, BIO submits that there are legal and procedural flaws in the proposed action that could frustrate the agency's legitimate interests in this area.

### **The Notification Process**

APHIS first promulgated regulations to establish the notification process (7 CFR 340.3) in 1993.<sup>2</sup> APHIS intended that notification serve as a streamlined version of the permitting process that had been in place since the Part 340 regulations were first implemented in 1987. Thus under the 1993 regulations, either permits or notifications were required prior

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<sup>1</sup> See <http://www.wheatworld.org/wp-content/uploads/biotech-case-for-biotech-wheat-20090917.pdf>.

<sup>2</sup> 58 FR 17044-17059 (March 31, 1993).

to any introduction (i.e., movement into or through the U.S., release into the environment, or interstate movement) of a regulated GE plant or other regulated article. Under the notification process as originally established in 1993, developers of regulated GE corn, cotton, potato, soybean, tobacco, and tomato intending to introduce one of these plants were required to meet six eligibility criteria and six performance standards, as well as a number of procedural requirements, notify APHIS of their plans, and submit the requisite information for review. Assuming the field test or other introduction met all of the requisite criteria and standards, the agency was required to acknowledge the introduction as appropriate under notification.<sup>3</sup>

In 1997, APHIS expanded the notification process by rulemaking to include not only the original six crops, but introductions of *any* regulated plant so long as the plant meets the eligibility criteria and the introduction meets the performance standards specified in the rule<sup>4</sup> and set forth below:

### Eligibility Criteria

- “(1) The regulated article is any plant species that is not listed as a noxious weed in regulations at 7 CFR part 360 under the Plant Protection Act (7 U.S.C. 7712), and, when being considered for release into the environment, the regulated article is not considered by the Administrator to be a weed in the area of release into the environment.
- (2) The introduced genetic material is “stably integrated” in the plant genome, as defined in § 340.1.
- (3) The function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease.
- (4) The introduced genetic material does not:
  - (i) Cause the production of an infectious entity, or
  - (ii) Encode substances that are known or likely to be toxic to nontarget organisms known or likely to feed or live on the plant species, or
  - (iii) Encode products intended for pharmaceutical or industrial use.
- (5) To ensure that the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, plant virus-derived sequences must be:
  - (i) Noncoding regulatory sequences of known function, or
  - (ii) Sense or antisense genetic constructs derived from viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species, and that do not encode a functional noncapsid gene product responsible for cell-to-cell movement of the virus.
- (6) The plant has not been modified to contain the following genetic material from animal or human pathogens:
  - (i) Any nucleic acid sequence derived from an animal or human virus, or
  - (ii) Coding sequences whose products are known or likely causal agents of disease in animals or humans.”<sup>5</sup>

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<sup>3</sup> See 7 C.F.R. 340.3(a) (1994) (“Certain regulated articles may be introduced without a permit, provided that the introduction is in compliance with the requirements of this section.”); 7 C.F.R. 340.3(b) (1994) (“Regulated articles which meet all of the following six requirements and the performance standards set forth in paragraph (c) of this section are eligible for introduction under the notification procedure.”).

<sup>4</sup> See 62 FR 23945-23958 (May 2, 1997).

<sup>5</sup> 7 CFR 340.3(b).

## Performance Standards

- “(1) If the plants or plant materials are shipped, they must be shipped in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment.
- (2) When the introduction is an environmental release, the regulated article must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release.
- (3) The plants and plant parts must be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use.
- (4) There must be no viable vector agent associated with the regulated article.
- (5) The field trial must be conducted such that:
  - (i) The regulated article will not persist in the environment, and
  - (ii) No offspring can be produced that could persist in the environment.
- (6) Upon termination of the field test:
  - (i) No viable material shall remain which is likely to volunteer in subsequent seasons, or
  - (ii) Volunteers shall be managed to prevent persistence in the environment.”<sup>6</sup>

For an introduction to be authorized under the notification process, the developer must notify APHIS of the planned introduction by submitting basic information about the regulated article, along with location and date of the proposed introduction and certify that the introduction will be conducted in accordance with the provisions of the notification process.<sup>7</sup> According to the regulation, APHIS must respond within a set number of days and must state whether the introduction is appropriate under the notification process.<sup>8</sup> Like the 1993 regulations, the current regulations provide that if a field test or other introduction meets all of the requisite criteria and standards, the agency is required to acknowledge the introduction as appropriate under notification.<sup>9</sup>

Introductions of GE wheat have been eligible for the notification process since the regulations were amended in 1997, expanding availability of the process beyond the original six crops. Thus, APHIS has been authorizing field trials of GE wheat under the notification process for nearly 20 years. Since 1997, APHIS has authorized field trials of GE wheat 550 times, by 30 institutions, on a total of more than 7600 acres (including three trials authorized in the midst of the current comment period). All of these field trials have been conducted without any reported unintended releases.<sup>10</sup>

### **APHIS’ Proposed Action is Inconsistent with its Own Regulations**

Under APHIS’ existing regulations, field trials of GE wheat are eligible for the notification process so long as the introductions meet the requirements described in 7 CFR 340.3(b) and

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<sup>6</sup> 7 CFR 340.3(c).

<sup>7</sup> 7 CFR 340(d)(2); 7 CFR 340(d)(2)(v).

<sup>8</sup> 7 CFR 340(e)(4).

<sup>9</sup> See 7 C.F.R. 340.3(a) (“Certain regulated articles may be introduced without a permit, provided that the introduction is in compliance with the requirements of this section.”); 7 C.F.R. 340.3(b) (“Regulated articles which meet all of the following six requirements and the performance standards set forth in paragraph (c) of this section are eligible for introduction under the notification procedure.”).

<sup>10</sup> We respectfully note that APHIS does not suggest in the Notice that either of the two unauthorized releases described in the Notice derives from a release authorized by APHIS under the notification process.

the performance standards in 7 CFR 340.3(c). The Notice indicates that APHIS has concluded that field trials of GE wheat, as a class, are no longer eligible for the notification process, but fails to identify any requirement or performance standard that GE wheat has failed to meet or provide any other basis for its conclusion under the existing rule. Further, APHIS' regulations do not authorize the Agency to change eligibility criteria for the notification process. In order to make the changes identified in the Notice, APHIS must complete notice and comment rulemaking as required under the Administrative Procedure Act. We respectfully submit that making the change without rulemaking would not be consistent with APHIS' regulations or with the APA.

We also note that APHIS correctly does not argue in the Notice that field trials of GE wheat are ineligible because as a class they cannot meet the six eligibility requirements in 7 CFR 340.3(b). Indeed, the successful history of hundreds of past field trials involving wheat, which have occurred without incident, would make any such argument untenable. While it is possible that some individualized field trials of GE wheat might not meet one of the six criteria-- for example, by using a genetic sequence prohibited by the rule-- many particular trials, like the 550 wheat trials previously authorized by APHIS, will continue to meet these requirements. Thus, nothing in or relating to 7 CFR 340.3(b) justifies the ineligibility of all wheat trials for the notification process as a class.

APHIS also does not argue in the Notice that all GE wheat field trials are unable to meet the performance standards in 7 CFR 340.3(c). As with 7 CFR 340.3(b), we think that any such argument would be untenable. APHIS does make a passing reference to two of the performance standards.<sup>11</sup> Yet APHIS does not claim that all field trials of GE wheat, as a class, are unable to meet these performance standards under any circumstances, regardless of the protocols a developer could put in place. Of course, if APHIS believed that some particular field trials were unable to meet a performance standard, then there is no reason why APHIS could not publish guidance describing recommended protocols, or allowing developers to utilize more stringent protocols. In any event, APHIS presents no argument that *any* of the 550 field trials it has authorized failed to meet the required performance standards. Thus, there does not appear to be any factual basis for concluding that all wheat trials are unable to meet the performance standards in 7 CFR 340(c).

In short, APHIS has not argued or shown, as would be needed in order to justify the proposed action, that all field trials of GE wheat fail to meet the eligibility requirements described in 7 CFR 340.3(b) or the performance standards in 7 CFR 340.3(c) and are therefore categorically ineligible for the notification process. The rule does not provide for any discretionary authority to render the rule's notification process inapplicable to wheat or any other GE plants. In short, APHIS is not authorized to change the eligibility criteria for the notification process other than through rulemaking. To attempt such a change without notice and comment would be arbitrary and capricious and a violation of the Administrative Procedure Act. Moreover, to the extent that the proposed action is inconsistent with APHIS' past practice and decisions regarding GE wheat, the contemplated change in practice fails the APA's requirements of (1) a reasoned explanation of departures from agency practice

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<sup>11</sup> "When the introduction is an environmental release, the regulated article must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release." 7 CFR 340.3(c)(6). "The field trial must be conducted such that: (i) The regulated article will not persist in the environment, and (ii) No offspring can be produced that could persist in the environment." 7 CFR 340.3(c)(4).

and precedent and of (2) ensuring that similar situations are treated similarly, absent a persuasive explanation for differential treatment.<sup>12</sup>

### **APHIS' Proposed Action is Illogical and Arbitrary**

APHIS' proposed action is also improper for a separate reason: disqualifying GE wheat from the notification process would be illogical and arbitrary in that it does not follow from its purported justification. The Notice does not contain a reasonable explanation of the need for such a change, nor of how the proposed change would address the need. This defect renders the proposal arbitrary and capricious, and unable to meet the standard for reasoned decisionmaking required under the precedent of the D.C. Circuit and other courts.<sup>13</sup>

APHIS cites two unauthorized releases of GE wheat in 2013 and 2014 as justification for the proposed changes to field trials of GE wheat. Yet in the press release<sup>14</sup> associated with this Notice, APHIS states that it was unable to determine the source of the unauthorized release in one instance, and that APHIS' investigation is ongoing in the other. While APHIS states that it has "carefully assessed its regulatory requirements for field trials" in response to the incidents, the Notice does not explain how the proposed changes would address the causes of these incidents or prevent such incidents in the future, rendering the new changes vulnerable to challenge.

The Notice does state that the proposed change "will help prevent future compliance issues, protect plant health and the environment, and allow for flexibility in the length of the volunteer monitoring period and the specific permit conditions used to address how volunteers of GE wheat will be appropriately managed," and that requiring a permit "allows APHIS to require the submission of volunteer monitoring reports on a regular basis." We respectfully submit that these justifications are not persuasive. First, some of the language quoted above is merely general and conclusory.<sup>15</sup> Second, as to the remaining language, the justifications regarding GE volunteers and volunteer monitoring are not persuasive. For one thing, the Notice does not suggest that the release incidents to which APHIS is responding were related to GE wheat volunteers. Moreover, the Notice does not explain why the notification process itself cannot be used to incorporate volunteer monitoring and conditions concerning management of GE wheat volunteers.

If anything, APHIS' proposed changes appear to be a reaction to the two recent wheat-related incidents, but the limited evidence and reasoning described in the Notice do not suggest any basis for concluding that the proposed changes would have the desired effects.

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<sup>12</sup> See, e.g., *Missouri Public Serv. Comm'n v. FERC*, 783 F.3d 310, 316 (D.C. Cir. 2015); *United States Postal Service v. Postal Regulatory Comm'n*, 785 F.3d 740, 744, 750, 756 (D.C. Cir. 2015); *Westar Energy, Inc. v. FERC*, 473 F.3d 1239, 1241-43 (D.C. Cir. 2005)..

<sup>13</sup> See, e.g., *Gen. Chem. Corp. v. United States*, 817 F.2d 844, 849, 850, 852, 853 n.4, 855 (D.C. Cir. 1987); *Delaware Dep't of Natural Resources and Environmental Control v. EPA*, 785 F.3d 1, 15-19 (D.C. Cir. 2015).

<sup>14</sup> See

[https://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology/sa\\_news/ct\\_news!/ut/p/a1/rZFJb4MwFIR\\_Sw85Ir86LOEISRtIoI3aRgEuyJjNVbAJcbr9-hqaHrNUqk9eZuZZ36AERSjh5I1VRDLBybY\\_J2a6ePTwrQvYn8\\_vXPAf7oOVtVxgwIYSxGcES-M6\\_3TueLoVAIA-weDPXG9m2SGAb17nhxPLgUv-DUpQQrlsZY1i0tZsn1LBZcFlumVZR7rPEexJKg5dWgp62I8gY0IWtOZiK6qfR168q3sqh02f11KWozIDircAbM00qaXpNsXahGa2RvJSN3IjL\\_H4OP8CwUFwDtEgOMMgVpCskyNUwvMff724ohbchdOwUrFE1hrjpUDRkRWKflkpGXvd7RJHddBT\\_5Ao-pcS2ma9XjeTsfknfb2UzWYVODffBkjMBQ!!/?1dmy&urle=wcm%3apath%3a%2Faphis\\_content\\_library%2Fsa\\_our\\_fo cus%2Fbiotechnology%2Fsa\\_permits\\_notifications\\_and\\_petitions%2Fsa\\_permits%2Fchanges%2Bto%2Bwheat%2B permitting%2Brequirements](https://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology/sa_news/ct_news!/ut/p/a1/rZFJb4MwFIR_Sw85Ir86LOEISRtIoI3aRgEuyJjNVbAJcbr9-hqaHrNUqk9eZuZZ36AERSjh5I1VRDLBybY_J2a6ePTwrQvYn8_vXPAf7oOVtVxgwIYSxGcES-M6_3TueLoVAIA-weDPXG9m2SGAb17nhxPLgUv-DUpQQrlsZY1i0tZsn1LBZcFlumVZR7rPEexJKg5dWgp62I8gY0IWtOZiK6qfR168q3sqh02f11KWozIDircAbM00qaXpNsXahGa2RvJSN3IjL_H4OP8CwUFwDtEgOMMgVpCskyNUwvMff724ohbchdOwUrFE1hrjpUDRkRWKflkpGXvd7RJHddBT_5Ao-pcS2ma9XjeTsfknfb2UzWYVODffBkjMBQ!!/?1dmy&urle=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_fo cus%2Fbiotechnology%2Fsa_permits_notifications_and_petitions%2Fsa_permits%2Fchanges%2Bto%2Bwheat%2B permitting%2Brequirements).

<sup>15</sup> See, e.g., *Delaware Dep't of Natural Resources and Environmental Control*, 785 F.3d at 17 (rejecting vague rationale for decision).

## **Concerns Regarding Possible Efforts to Revoke or Prevent Renewal of Previously Acknowledged Notification**

We are concerned by recent reports that APHIS employees may be considering attempting (even during the pendency of this notice and comment process) to revoke, or to curtail the renewal of, previously acknowledged notifications by purporting to suggest that such notifications are no longer effective as of January 1, 2016. First, any such administrative action would be inconsistent with 7 C.F.R. 340.3(e)(4), which provides that APHIS' acknowledgment that an environmental release is appropriate under notification "will apply to field testing for 1 year from the date of introduction, and may be renewed annually by submission of an additional notification to APHIS." The regulations do not provide any exception to this provision that would seem to be applicable here.

Second, any such administrative attempt to revoke previously acknowledged notifications or to prevent their renewal would appear to be inconsistent with section 558(c) of the Administrative Procedure Act, which provides:

"Except in cases of willfulness or those in which public health, interest, or safety requires otherwise, the withdrawal, suspension, revocation, or annulment of a license is lawful only if, before the institution of agency proceedings therefor, the licensee has been given—

- (1) notice by the agency in writing of the facts or conduct which may warrant the action; and
- (2) opportunity to demonstrate or achieve compliance with all lawful requirements."<sup>16</sup>

In addition, section 558(c) provides: "When the licensee has made timely and sufficient application for a renewal or a new license in accordance with agency rules, a license with reference to an activity of a continuing nature does not expire until the application has been finally determined by the agency."<sup>17</sup> A "license" within the meaning of this provision "includes the whole or a part of an agency permit, certificate, approval, registration, charter, membership, statutory exemption or other form of permission."<sup>18</sup>

Finally, given that the proposed administrative action in question is currently under consideration as part of an administrative notice and comment process, we respectfully submit that premature or ad hoc action or conclusions on the question under review would be procedurally improper and would risk triggering a finding that the agency's decision was predetermined in violation of the Administrative Procedure Act, thus stymying the agency in its pursuit of its legitimate and important regulatory goals.

## **Conclusion**

We thank APHIS for this opportunity to comment on the proposed action described in the Notice. We respectfully submit that APHIS must revise its regulations before it can change the eligibility of GE wheat trials for the notification process and impose new conditions on field trials of GE wheat.

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<sup>16</sup> 5 U.S.C. s. 558(c).

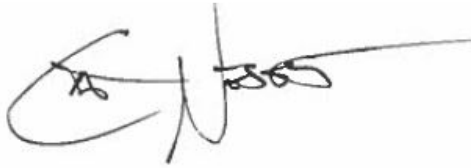
<sup>17</sup> *Id.*

<sup>18</sup> 5 U.S.C. s. 551(8). APHIS action on a notification is a form of permission within the meaning of the statute. See 7 C.F.R. 340.3(e)(5) ("A person denied *permission* for introduction of a regulated article under notification may apply for a permit for introduction of that regulated article without prejudice.") (emphasis added).

As an alternative, we respectfully encourage APHIS to publish the assessment of its regulatory requirements referenced in the Notice, to help the public better understand the interests at stake. Building upon this analysis, APHIS could work collaboratively with wheat researchers to identify common-sense, appropriate conditions for the conduct of field trials. The agency could then publish those recommendations as guidance, to help researchers continue to meet the performance standards for notification and to further APHIS' important concerns and regulatory goals.

Thank you for your time and consideration.

Respectfully,

A handwritten signature in black ink, appearing to read 'Clint Nesbitt', with a long horizontal flourish extending to the right.

Clint Nesbitt  
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