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October 26, 2015

Regulatory Analysis and Development
Plant Protection Division
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Station 3A—03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

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

Dear Reviewing Official:

The National Grain and Feed Association (NGFA)[1] and North American Export Grain Association (NAEGA)[2] respectfully submit this statement to the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) in response to its request for comments on its plans to require the authorization of field testing of regulated genetically engineered wheat under its permit requirements, rather than the current notification process.

NGFA and NAEGA-member companies store, handle, process and export the vast majority of grains and oilseeds used in human and animal food, and are affected directly by marketability-related issues associated with the commercialization of crop biotechnology and other cropping systems. Our comments reflect this perspective.

[1] NGFA, established in 1896, is a U.S.-based nonprofit trade association that consists of approximately 1,050 grain, feed, grain processing, export and other grain-related firms that operate more than 7,000 facilities and handle more than 70 percent of the U.S. grain and oilseed crop. Affiliated with NGFA are 26 state and regional grain, feed and agribusiness associations.

[2] NAEGA, a not-for-profit trade association established in 1912, consists of private and publicly owned companies and farmer-owned cooperatives that are involved in and provide services to the bulk grain and oilseed exporting industry. NAEGA-member companies ship and support the vast majority of the highly competitive, sustainable and fungible U.S. grain export supply.

NGFA and NAEGA concur that APHIS needs to substantially strengthen its monitoring and oversight of field trials, particularly following two separate incidents – one in 2013 and another in 2014 – in which "volunteer" wheat plant material involving different biotech wheat varieties from different research trials were detected in two distinct western plains states. In the 2013 incident, biotech-enhanced wheat plant material was detected growing on a single field on a single farm in Oregon. In 2014, regulated wheat plant material was discovered growing on land controlled by Montana State University in an incident that we understand remains under investigation by APHIS. The first incident, in particular, roiled wheat markets and created uncertainty in the minds of major U.S. wheat export customers for several months.

APHIS now maintains that as part of its investigation in response to both incidents, it believes it is necessary to enhance its requirements to stipulate that field trials of biotech-enhanced wheat be conducted only under a permit system. The agency asserts that the permit approach will give it more flexibility concerning the length of time that monitoring of wheat plant material "volunteers" is conducted after field trials are concluded. Further, APHIS states that the permit system would enable it to better specify conditions to address how such "volunteers" of biotech-enhanced wheat plant material will be managed appropriately – including enabling the agency to require submission of monitoring reports on biotech wheat plant material on a regular basis.

NGFA and NAEGA agree that each of these is an important and appropriate objective that needs to be achieved by APHIS to enhance the integrity of field trials of regulated biotech-enhanced agricultural commodities and products, as well as to improve the agency's oversight and enforcement of the requirements and conditions governing such trials.

However, we believe APHIS has not adequately explained in its one-page notice and request for comments whether the same worthy policy end-points and operational objectives can be achieved through the field trial notification versus the permit process. For instance, APHIS' notice states that authorizing GE wheat field trials only under a permit system "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." Yet, it fails to provide any further explanation of how the permit approach would achieve each of these objectives, or why the notification process should not be strengthened in a similar manner. In addition, we believe it would be appropriate for APHIS to make available the outcome of at least its investigation of the Montana State University field trials and the impact those findings had on the agency's policy recommendation to change to a permit-based approach for GMO wheat.

In this regard, it is our understanding that both permits and notifications are subject to inspection by trained federal and/or state inspectors, who evaluate field tests, facilities, equipment, developers' records and potential incidents. We further understand that all permits ostensibly receive at least one inspection within the state(s) where release occurs each year, while notifications are selected for inspection based upon a statistically valid random sampling. One difference, we understand, is that planting reports are required under supplemental conditions imposed upon permit holders, while such planting reports frequently are requested, but not required, from notification holders. Further, planting or release reports, as well as field test reports, are required to be submitted to APHIS for each location of activities authorized by

permit. But this raises the question of whether APHIS could remove this disparity and correct the deficiencies by simply imposing the same field trial requirements upon both notification and permit holders.

APHIS' notice and request for comments also is devoid of any of the economic analysis of the costs or benefits that would result from a change from a notification to a permit approach for GE wheat.

In addition, the agency in its notice has not addressed any of the significant deficiencies in its oversight of biotech-enhanced field trials cited in detail by the U.S. Department of Agriculture's Office of Inspector General (OIG) in its Sept. 22, 2015 report, entitled "***Controls Over APHIS' Introduction of Genetically Engineered Organisms***," which we respectfully submit should be considered as part of a comprehensive and systematic approach for improving the agency's field trial-permit process. Pertinent to agency's notice and request for comments, OIG's report is particularly instructive in documenting the deficiencies in APHIS' current system for monitoring and enforcing field trial requirements ***regardless of whether the trial is conducted under a notification or permit***, and cites numerous systemic shortcomings involving progress reporting, inspection site selections and sanctions for noncompliance that raise serious questions as to whether either the current notification and permit-based approaches used by APHIS are adequate as they now exist.

For instance, among other things, OIG found that – irrespective of whether the field trial was conducted under a notification or permit approach:

- APHIS does not have adequate controls to account for and sufficiently monitor all field trial locations, or review the final field test reports to ensure all possible planting locations are accounted for and all plantings are being reported. Specifically, OIG identified 103 out of 599 approved permits and notifications that had not been reported. "…[W]e concluded that permit and notification holders do not always submit the required reports in a timely manner, or sometimes do not submit them at all," OIG's report states, adding that some field trials could not be inspected because planting reports were submitted after the crops were harvested.

- The agency's current data file does not identify actual GE release sites, but only the states in which each responsible person proposes a release. "Therefore, the manual process currently in place would only tell the agency if a planting has occurred in one of the proposed states, but would not provide the specific location of all approved sites," OIG found.

- The agency database system does not include a method to refer reporting-related incidents to its Compliance Evaluation and Enforcement Branch for review and possible enforcement action.

- APHIS' reporting system does not analyze the final field test reports to account for all locations approved in the permits or notifications. In one case, OIG reported that one notification's final field test report did not identify 12 of 21 plantings that were reported

> to the agency, and did not account for 34 of 46 approved sites at which the responsible person could conduct field tests. OIG reported this deficiency is attributable to the fact that final field test reports are not reviewed and compared to the original permit or notification to verify that all agency-approved release sites are identified in the report. Nor does the agency compare the final field test report to the planting reports to ensure that the responsible party reported all releases and plantings, OIG found.

It is our understanding that in response to the most recent OIG audit, APHIS has launched a Signature Business Process Improvement plan to enhance compliance oversight of authorized and regulated GE field trials that it hopes to make operational by Aug. 31, 2016. Further, we are aware that APHIS' Biotechnology Regulatory Services in July 2015 implemented procedures designed to identify and address late planting reports. At a minimum, we believe the agency should explain in its current notice and request for comments how these initiatives will improve its ability to better track field trials and take enforcement action when warranted, regardless of whether a notification or permit-based approach is used.

Finally, APHIS has not explained adequately in its notice why – if a permit-based approach is advisable and necessary for the proper conduct of field trials involving biotech-enhanced wheat – the same permit approach is not warranted also for field trials involving biotech-enhanced commodities other than wheat. We believe such an evaluation and explanation is warranted, particularly since documented field escapes also have occurred for GMO corn, rice and other commodities.

NGFA/NAEGA Recommendations

For each of these reasons, we strongly urge APHIS to withdraw its notice at this time and engage in outreach and dialogue with affected stakeholders, including technology owners, producers, grain handlers, exporters, and others, about the agency's rationale for seeking such a change. We believe such a process would create a better understanding among affected stakeholders and lead to more informed decision-making by APHIS as it determines how to proceed.

In this regard, we believe it is unacceptable and inadvisable for APHIS to announce a seemingly preordained outcome, as it appears to do in its notice and request for comments when stating that it plans to "notify the public through an announcement on our web site of the effective date of our decision whether to authorize GE wheat field trials only with a permit and any additional information regarding any change if APHIS decides to authorize wheat only under permits."

Finally, we believe it is important to stress the importance of APHIS placing a priority on risk communication and crisis management with external stakeholders. Sound practices developed in advance for informing and working with foreign governments and the marketplace, including such affected stakeholders as producers, grain handlers and exporters, to manage and mitigate the consequences of field escapes of GE commodities or products, as well as other emergencies involving regulated GE plant material, should be institutionalized by APHIS. We believe significant lessons were learned following the detection of GE wheat plant material in Oregon, and appreciate that APHIS after consultation with affected stakeholders made major improvements in this regard during the second incident involving GE wheat plant material in

Montana. We strongly urge the agency to continually review and improve these international communications strategies with stakeholders so that they are in place to deploy if and when needed in the future.

Conclusion

In conclusion, NGFA and NAEGA strongly concur with APHIS' end-point objectives for strengthening its oversight of GE field trials for wheat, and believe the same objectives should apply across the board to other regulated GE commodities and plant material.

However, for the reasons previously expressed, we respectfully recommend that the agency withdraw, enter into additional dialogue with stakeholders, and then subsequently reissue its notice and request for comments in a way that:

- provides more information and specific justification for its proposal, as well as discusses alternative approaches considered and why they do or do not have merit;

- better explains why oversight of field trials for GE wheat under a permit versus notification approach is necessary, and why similar enhancements could not be made by modifying the notification process.

- addresses in a more comprehensive way the steps it is taking to correct the serious deficiencies in its field trial reporting and oversight process cited by OIG, as well as the timetable for implementation; and

- evaluates whether its preferred approach(es) should be confined to GE wheat or expanded to traits of other GE commodities involved in regulated field trials.

Thank you for the opportunity to comment on this important issue.

Sincerely,

Randall C. Gordon
President
National Grain and Feed Association

Gary C. Martin
President and Chief Executive Officer
North American Export Grain Association