

Justification for moving GE wheat field trials to permit

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Under USDA's current regulations for products of biotechnology (Title 7 Code of Federal Regulations part 340), wheat has not been granted nonregulated status, and GE wheat is not grown commercially in the United States. During the past two decades, field trials of regulated GE wheat have been conducted according to the Notification process described in 7 CFR part 340.3. However, recent unauthorized releases of GE wheat and findings have led USDA to the conclusion that U.S. agriculture would benefit from the increased oversight provided by the Permit process. This document discusses various factors that USDA considered in making the decision to require permits for oversight of GE wheat field trials.

History of Permits and Notifications

During the first six years of USDA-APHIS' regulation of GE organisms (1987-1992), all field trials of GE plants were authorized through APHIS' permit process. The notification process was proposed in 1992 and implemented in 1993:

- APHIS applied the notification process to six species of crop plants in 1993. The notification process was designed to be used for plants and traits well known to APHIS (corn, soy, cotton, potato, tobacco, tomato). In practice, a notification is a different type of permit since the field trials cannot be planted until APHIS has "acknowledged" the notification after finding that the six eligibility requirements have been met (as described in 7 CFR part 340.3b), and that the six performance standards can be met (as described in 7 CFR part 340.3c).
- In 1997, all other GE plants that meet the eligibility requirements became eligible for notification, and the notification is acknowledged when APHIS believes the performance standards described in 7 CFR part 340.3c can be met. Later, based on accumulated experience, it was determined that some GE plants would be more appropriately authorized under permit:
 - Some species that were once regulated under the notification process (*e.g.*, trees, perennial grasses, and other perennials) are now only authorized under permit because of their increased likelihood of persistence in the environment or because of the existence of sexually compatible weedy relatives.
 - Permits are also used for some types of activities for species that would otherwise be regulated under notification (*e.g.*, large scale trials of crops normally authorized under notification) because the sheer magnitude of the operations and the need for third party auditing and management plans, this could only be accomplished under permit.
 - Permits are issued when requested by the authorized person because of the flexibility and clarity provided by the more robust collaboration between APHIS and the authorized person, and because there is greater flexibility in terms of amendments.

Two Recent Incidents

During 2013 and 2014, USDA investigated two separate incidents involving regulated GE wheat in Oregon and Montana. Although the regulated wheat at both locations contained a glyphosate resistant trait known as MON71800 developed by Monsanto, the wheat at the two locations was genetically distinct. Field trials of GE wheat were never authorized at the site in Oregon, and the last authorization for a field trial of MON71800 at the Montana site expired over 10 years ago. All field trials of GE wheat involving MON71800 were conducted under notification. The last field trial of MON71800 in the United States was authorized in 2005, with most field trials completed by 2004.

It became clear to us following the GE wheat incident in Oregon that the detection of regulated GE wheat where it was not authorized, had great potential to disrupt wheat markets globally. And in fact, some U.S. trading partners continue to apply additional risk mitigation measures to imports of U.S. wheat in response to that 2013 incident. Using permits for field trials of GE wheat provides an additional level of safeguarding based on, and consistent with the biology of wheat.

APHIS' Response, Increased Oversight, and Risk Indicators

The notification process relies on the ability of the developer to maintain compliance with six performance standards that ensure that the regulated GE plant will not spread or persist in the environment after the end of the authorized activity. The key risk mitigation factors specified in the performance standards for notifications (7 CFR part 340.3) include the following:

1. Plants and plant parts must be contained or devitalized when no longer in use
2. The field trial must be conducted such that the regulated article will not persist in the environment and no offspring can be produced that could persist in the environment
3. Upon termination of the field test, no viable material shall remain which is likely to volunteer in subsequent seasons, or volunteers shall be managed to prevent persistence in the environment

In the two recent incidents, volunteer GE wheat plants were found in both Oregon and Montana where they were not authorized. No field trials had been authorized at the location in Oregon where the unauthorized GE wheat was detected. The site in Montana was approved for field trials of GE wheat during 2000-2003. The performance standards were not met, otherwise, regulated material would not have been found where it was not authorized. After the discovery of GE wheat volunteers in Montana, APHIS increased its oversight of outdoor plantings of regulated GE wheat. The increased oversight included inspections of all GE wheat field trials, including some unannounced inspections. Although we did not uncover situations similar to what had occurred in Oregon or Montana, inspection findings were sufficient to convince APHIS that mandated permit conditions, increased monitoring for persistence in the environment, and additional reporting during and after the plantings would reduce the likelihood of additional incidents.

The type of wheat involved in the Oregon and Montana incidents (Roundup Ready® Wheat event MON71800) completed the FDA food safety consultation process, and FDA has no concerns about the safety of MON71800 when used as food or feed. Nonetheless, the only petition received by USDA for

deregulation of GE wheat was for MON71800, but that petition was withdrawn in mid-2003 so MON71800 still remains regulated. As regulated articles, field trials of GE wheat must be conducted using management practices to ensure that regulated articles do not spread from the authorized area, or persist in the environment following termination of the field trial.

During 2014-2015 as APHIS was inspecting all active field trials of regulated GE wheat, observations made by APHIS, in light of the known biology of wheat dormancy and the two recent incidents, indicated that the risk of persistence of GE wheat following completion of field trials could be better managed through permit conditions. Requiring permits—with specific permit requirements based on the biology of wheat, the location of the field trial, and local management practices—will go a long way to reducing the likelihood of future incidents.

Scientific Basis: Dormancy

Wheat is capable of extended dormancy and reported survival times vary widely depending on environmental conditions. In dry regions, wheat seed can survive in the soil beyond two years (Anderson and Soper, 2003; Beckie et al., 2001; De Corby et al., 2007; Harker et al., 2005; Leeson et. al, 2005; Nielson et al., 2009; Pickett, 1989; Pickett, 1993; Seerey et. al., 2011; Willenborg and Van Acker, 2008). There was even a report of seed survival of up to five years in certain situations (Beckie et al., 2001). Therefore a two year monitoring period may be insufficient where rainfall is limited and irrigation is not employed. Our primary interest in taking this action is to provide oversight of regulated GE wheat consistent with our statutory and regulatory authority, and to help USDA and those conducting field trials of GE wheat ensure that regulated GE wheat does not spread from the authorized area or persist in the environment. Given the biology and agroecology of wheat, regulating field trials of GE wheat under permit decreases the likelihood of additional regulatory incidents.

Findings during the past year have convinced USDA that increased oversight is warranted. More effective oversight, and better management of field trials of regulated GE wheat can be accomplished by authorizing these field trials under permit as opposed to notification. In the recent past, we've become aware of—and mitigated—risks that could result in additional releases of regulated material. Our subsequent increased oversight of regulated activities has demonstrated value.

Recent External Reviews of APHIS' Regulatory Program

During the past two years, USDA's Biotechnology Regulatory Services program has worked with both the General Accountability Office (GAO) and USDA's Office of Inspector General (OIG) on reviews and audits of the program. Both the GAO engagement and the OIG audit found that oversight of field trials and other outdoor use of regulated genetically engineered organisms should be enhanced. Specifically, they noted that several measures (e.g., a longer duration of volunteer monitoring, required volunteer monitoring reports) that can only be required under permit (and not notifications) needed to be implemented to prevent spread or persistence in the environment.

The Decision to Require Permits is within the Discretion of the Administrator

The regulations (7 CFR part 340.3) state that “Certain regulated articles may be introduced without a permit.” This section also states that “acknowledgement may be renewed annually by an annual submission to APHIS,” and that “Regulated articles that meet the eligibility requirements “are eligible” for notifications. The APHIS Administrator has discretion when evaluating notifications, and may determine that the permit process is the preferred option, since neither “may” nor “eligible” imply a guarantee for acknowledgement of a notification. In fact, Section 340.3e5 states “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” clarifying that the Administrator has discretion to require a permit as opposed to a notification.

Increased confidence

This change will impact a small number of regulated activities and about a dozen applicants. In 2014, APHIS authorized 572 requests for field trials of various crops, mostly corn, soy and cotton. Of the 572, only 21 authorizations were for wheat. And those 21 authorizations were granted to only 11 different entities, six companies, four universities, and one USDA agency.

The difference between authorizing field trials with permits as opposed to notifications is small, but important. Both constitute regulation, both use the same application/issuance tool (ePermits), both are subject to inspection, both are subject to the same enforcement actions and fines for noncompliance. And both are subject to the same regulatory goals, primarily, to minimize the likelihood of persistence in the environment following completion of the field trial. However, with permits, APHIS can apply site-specific conditions, incorporating science, risk, wheat biology, and the site-specific agroecology of wheat. In particular, in dry land agriculture with no tillage, a longer volunteer monitoring period with specific reporting requirements can be established. And unlike notifications, permits’ greater volunteer monitoring and reporting requirements help both the permittee and APHIS collect relevant data to employ and evaluate risk-based confinement conditions.

Conclusion

Like several species before it, outdoor plantings of wheat—which for 18 years (1997-2015) was authorized under notification—will now be authorized only under permit. APHIS will work closely with permittees when establishing permit conditions. Our goal will be to establish permit conditions that meet the needs of both APHIS and the permittee by protecting plant health while not constraining the field work unnecessarily.

References

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