



US Secretary of Agriculture Tom Vilsack
Regulatory Analysis and Development, PPD
APHIS, Station 3A-03.8, 4700 River Road Unit 118
Riverdale, MD 20737-1238

October 26, 2015

RE: Docket No. APHIS-2015-0070

Organic Seed Alliance (OSA) respectfully submits these comments in response to the Animal and Plant Health Inspection Service's (APHIS) proposal regarding "Changes to Requirements for Field Testing Regulated Genetically Engineered Wheat." We welcome the agency's proposal to increase oversight of genetically engineered (GE) wheat, and encourage swift action on developing strong permit conditions to avoid future contamination events, as discussed below.

OSA is a national organization that advances the ethical development and stewardship of the genetic resources of agricultural seed. We accomplish this mission through research and education with farmers across the US, and through advocacy efforts that aim to protect the genetic integrity of seed used in organic farming systems. This demands close attention to the issue of genetic engineering and USDA's oversight of these technologies in agriculture.

Given the short timeframe of this comment period, we engaged a number of agricultural organizations in developing the following recommendations to ensure a broad group of stakeholders were weighing in on this important topic. The undersigned organizations and businesses support the USDA's proposal to require all future field trials of GE wheat be conducted under APHIS permits that include requirements for stringent post-harvest monitoring. We also support new permit requirements that would ensure that GE crop material is not inadvertently mixed with non-regulated plant material and that GE traits will not persist in the environment in either volunteer plants or out-crossed into wild relatives. The two recent detections of unauthorized GE wheat amply demonstrate the inadequacy of the current field trial regime to ensure containment.

We still request an extension of this comment period to allow wheat growers and other stakeholders to weigh in on appropriate permit conditions. The USDA has requested the submission of detailed, locality-specific data on wheat growth, crop management, and crop use. Thirty days during harvest season is not enough time for stakeholders to respond to that request. We request an extension to 90 days.

The US is the world's biggest exporter of wheat, an \$8 billion business. Market rejection of GE wheat both domestically and abroad is longstanding. Export customers have made it clear that if the US approves GE wheat, they will purchase *all* of their wheat from other countries where no GE wheat is grown. Following the discovery of unapproved GE wheat in Oregon, which exports 90 percent of its wheat, Japan and South Korea suspended imports. The European Union also called for testing. This event provided a mere snapshot of ongoing market sensitivity to GE wheat.

That is why we welcome the news that the USDA will improve oversight of GE wheat trials. Requiring permits for GE wheat field trials is a step in the right direction. However, requiring permits alone is not enough. Updated regulations coupled with improved oversight are desperately needed to protect our seed and food supply, and the livelihoods of farmers.

Evidence of current regulatory shortcomings was provided in a September 2015 Office of Inspector General (OIG) audit of APHIS's policies and procedures governing GE crops. The OIG reached the same conclusion as it did in 2005, the first time it audited the agency's oversight of GE crops, finding that current regulations and oversight are inadequate for preventing contamination. In particular, the OIG found that the USDA "still does not have adequate controls in place to account for and sufficiently monitor all field trial locations...As a result, at any given time, APHIS is not aware of the status of all planted field trial locations, and not all planted locations are included in the universe of sites to be selected for inspection. Consequently, inadvertent releases of GE organisms are at risk of occurring."

Given ongoing gaps in regulations and oversight, we ask that all GE wheat trials be stopped. This recommendation and others regarding GE wheat permit conditions are as follows:

- **GE wheat field trials should be stopped until regulatory improvements are made**

USDA admits that despite extensive investigation, it does not know the origin of unauthorized GE wheat found in Oregon. The agency is still investigating unauthorized GE wheat found in Montana. Even without an understanding of how the GE wheat appeared where it did, it is reasonable to conclude that the current field trial requirements are inadequate. Yet there are at least 18 GE wheat field trials currently underway. We believe the USDA should stop all GE wheat field trials until the following four actions are complete: (1) the new GE wheat permit requirements are in place, (2) the investigation into the Montana GE wheat event is complete, (3) the newest recommendations from the USDA's OIG are implemented, and (4) the USDA's new proposal for updating its regulations under the Plant Protection Act is complete and implemented, as discussed below.

- **Permits must establish mandatory contamination prevention conditions**

Permit requirements should include descriptions of how field tests will be performed, specific measures for ensuring confinement of the crops to reduce risks, and detailed plans for destroying crops at the end of the season. In addition, active monitoring and testing will be necessary to ensure compliance. USDA should carefully review written containment protocols and consult with independent experts before finalizing permit conditions. The USDA should also inspect field trials several times, as is currently done for pharmaceutical crops, including after the crop is destroyed and in subsequent growing seasons to look for volunteers. This is especially important in light of the numerous routes seed can be transferred in the environment, including by birds, which were the focus of a 2013 inquiry in Canada involving the potential transfer of GE wheat. Furthermore, permit applicants should be required to:

- Provide global positioning service (GPS) coordinates for all field trial sites to the USDA and coordinating state agency or tribal authority.

- Notify USDA of the date that trials are destroyed and how. The USDA should inspect trials post-harvest. Permit holders should also be required to test and gather data outside the trial site to ensure complete containment was achieved.
- **Permit holders should be required to notify farmers, seed companies, and plant breeders in the vicinity of GE crop field trials**

Area growers need to be able to take precautions to avoid contamination and test their crops to ensure containment is successful. The USDA should design such requirements so that they minimize the unnecessary disclosure of legitimate confidential business information, but regulations should not favor the protection of industry trade secrets over the protection of farmers and the markets they supply. For starters, USDA should require the exact location and duration of the field trials be shared with farmers, seed production companies, and plant breeders who could be impacted by trials in the vicinity.

- **USDA should have the appropriate tools in hand to test for regulated crops**

Upon establishing the new field trial requirements, USDA should require applicants to provide the department either the unique DNA sequence or the test for identifying the unique sequence should there be suspected or confirmed contamination events. These materials should also be made available to state testing facilities and laboratories so that farmers, seed companies, and plant breeders have access to appropriate tests in a timely manner to monitor and respond to potential contamination as well as reassure customers.

- **State and tribal authorities should be provided information contained in GE field trial permits granted in their states, including the exact location and duration, and the purpose and nature of the regulated crop**

Current regulations require APHIS to provide state departments of agriculture copies of the permit applications but allow the redaction of confidential business information. In practice, this means state and tribal authorities do not know the exact locations of the field trials occurring in their states. In April 2014, USDA collected public comments on a proposal to share more field trial information with state and tribal governments. This proposal was withdrawn. The USDA should develop a new proposal that at minimum allows state authorities to know the exact location of field trials.

- **USDA should make public all field trial violations and penalties**

In 2014, media reports showed inconsistencies in violations reported on the APHIS website (21) and in two Freedom of Information Act (FOIA) requests by Capital Press (170) and Reuters (483). This finding not only signals a need for better organization within the agency but for improved accountability to the public through reporting of field trial violations. The USDA should provide updated violation and penalty information on its website twice a year.

- **USDA should move quickly to update regulations under the Plant Protection Act**

USDA has already taken some steps to implement recommendations provided by a 2005 Office of Inspector General audit of the agency's biotechnology program, in addition to section 10204 of the

2008 Farm Bill (known as the Pryor amendment). But the agency reports that other recommendations will be implemented as part of the update to its biotechnology regulations. In light of USDA's withdrawal of its 2008 proposal for updating these regulations and starting over, we are concerned about the delay in implementing these recommendations. We encourage the USDA to move quickly to develop a new and stronger regulatory proposal that adequately protects farmers, the environment, and the public from the direct and indirect impacts of GE crops; that holds GE crop developers liable for problems and damages resulting from their products; and that ensures the recommendations from the most recent OIG audit (2015) and Pryor amendment (2008) are fully implemented.

We urge you to protect US farmers and the markets they supply by acting quickly to improve current policies and oversight. Please let us know how we can support you in this effort.

Sincerely,

Alternative Energy Resources Organization (Montana)
Blue Heron Bakery (Washington)
California Certified Organic Farmers (California)
Center for Food Safety (DC)
Clif Bar & Company (California)
Cuarto Puertas (New Mexico)
Dakota Rural Council (North Dakota)
Dawson Resource Council (Montana)
EcoFarm (California)
Episcopal Farm to Altar Table (California)
Farm Aid (Massachusetts)
Farm and Ranch Freedom Alliance (Texas)
Food and Water Watch (DC)
Friends of Family Farmers (Oregon)
Grand Forks County Citizens Coalition (North Dakota)
Grass Valley Grains (California)
Hawaii Public Seed Initiative (Hawaii)
Institute for Agriculture and Trade Policy (Minnesota)
Kirschenmann Family Farms, Inc. (North Dakota)
Looking Back Farms, Inc. (North Carolina)
Maine Organic Farmers and Gardeners Association
Mandaamin Institute (Wisconsin)
Mendocino Grain Cooperative (California)
Michigan Organic Food and Farm Alliance
Midwest Organic and Sustainable Education Service (Wisconsin)
Missouri Farmers Union (Missouri)
Missouri Grain Project (Missouri)
Montana Organic Association
National Co-op Grocers (Iowa)
National Family Farm Coalition (DC)
Natures Path (British Columbia)
Northeast Organic Dairy Producers Alliance (Massachusetts)
Northeast Organic Farming Association New Hampshire

Northeast Organic Farming Association New York
Northeast Organic Farming Association Vermont
Northern Plains Resource Council (Montana)
Ohio Ecological Food and Farm Association
Oregon Rural Action
Oregon Tilth
Organic Farmers' Agency for Relationship Marketing (Wisconsin)
Organic Farming Works LLC (Minnesota)
Organic Seed Alliance (Washington)
Organic Seed Growers and Trade Association (Maine)
Provender Alliance (Oregon)
Real Food Store (Montana)
Root and Radicle Seed Co. (Washington)
Rural Advancement Foundation International – USA (North Carolina)
Seattle Farm Co-op (Washington)
Seed Matters (California)
Slow Food USA (New York)
Southern Exposure Seed Exchange (Virginia)
Stillwater Protective Association (Montana)
Sustainable South Sound (Washington)
The Land Institute (Kansas)
United Natural Foods Inc.
Urban Futures Farm (Washington)
Western Colorado Congress
Western Organization of Resource Councils (Montana)
Wild Farm Alliance (California)
Wild Garden Seed (Oregon)

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