Testimony of Gregory Jaffe
Biotechnology Project Director
Center for Science in the Public Interest
Senate Agriculture Committee Hearing
"Agricultural Biotechnology: A Look at Federal Regulation and Stakeholder Perspectives"
October 21, 2015.

I want to thank Chairman Senator Pat Roberts, Ranking Minority member Senator Debbie Stabenow, and other committee members for inviting me as a witness on behalf of the Center for Science in the Public Interest (CSPI). After more than twenty years of regulating genetically engineered (GE) crops, it is appropriate to review and possibly modify the roles of the Food and Drug Administration (FDA), United States Department of Agriculture (USDA), and Environmental Protection Agency (EPA) in ensuring those crops' safe use. While the current GE crops grown in the United States are safe and beneficial, the federal regulatory oversight system needs significant improvements to ensure safety for future products and to provide consumers with confidence about their safety.

I am here today as the director of CSPI's Biotechnology Project. CSPI is a non-profit consumer organization that was established 44 years ago. CSPI works primarily on food safety and nutrition issues and publishes *Nutrition Action Healthletter* to educate consumers on issues surrounding diet and health. CSPI advocates, based on the best-available science, on behalf of consumers at federal agencies, Congress, and international organizations. CSPI does not receive any funding from industry or the federal government. That policy is important because it eliminates conflicts of interest when we advocate for

new government policies or corporate practices. Our funding primarily comes from our members and donors, as well as from independent philanthropic foundations.

CSPI's Biotechnology Project addresses scientific concerns, government policies, and corporate practices pertaining to GE plants and animals that are released into the environment or that end up in our food. The project's goals are to:

- Educate policymakers, media, interested stakeholders, and the public about the benefits and risks associated with GE crops and animals;
- Advocate for strong, but not stifling, federal regulation to ensure safety to humans and the environment; and
- Provide expertise to help developing countries establish their own biosafety regulations and make science-based decisions about adopting GE crops.

CSPI has long advised consumers, journalists, and policymakers that foods and ingredients made from currently grown GE crops are safe to eat. That conclusion is consistent with those made by numerous international and scientific bodies, including the FDA, the National Academy of Sciences, the Food and Agriculture Organization, and others. The current GE crops also have provided tremendous benefits to farmers and the environment in both the U.S. and around the world. However, actions by developers selling GE seeds and by farmers growing GE crops have led to the highly troublesome development of insects and weeds that are resistant to widely-used pesticides. While GE crops could be used sustainably, instead some have been overused and misused, leading to environmental disruption and consumer opposition.

CSPI has advocated for improvements in the federal oversight of GE crops to ensure safety to humans, animals, the environment, and agriculture. Today, I will limit my testimony primarily to legislative changes that would significantly improve the federal government's oversight.

The Food and Drug Administration

By way of background, FDA is responsible for ensuring the safety of foods under the Federal Food, Drug and Cosmetic Act (FFDCA). Under that law, FDA has established a "voluntary consultation" process whereby developers of GE seeds may provide FDA with safety data to demonstrate that the GE crops are "substantially equivalent" to conventional, traditionally-bred counterparts. FDA set up that consultation process because it has held that GE crops are not "food additives," which undergo pre-market approval, but instead fall within the statute's category of foods that are "generally recognized as safe." The FDA believes that all commercially grown GE food crops have gone through the agency's voluntary consultation process. When the FDA consultation process is completed for a particular GE crop, FDA states in a letter to the crop's developer that FDA has *"no further questions"* about the developer's determination that the GE crop is substantially equivalent to its conventional counterpart. FDA never provides its own opinion or conclusion about the safety of that GE crop, and the crops are never formally approved.

CSPI believes that FDA *should* determine the safety of all GE food crops before foods from those crops enter our food supply. FDA should review the safety data submitted by the developer, conduct its own analysis of those data, and provide the developer and the public with its opinion of whether foods from that GE crop are safe to eat by humans and

animals. That new regulatory process would further ensure safety of future crops and allay consumer concerns about biotechnology. It is also consistent with the process by which most other countries ensure the food safety of GE crops.

While GE crop developers in the United States have always completed the consultation process, there is no guarantee that they will continue complying with the consultation process in the future. Similarly, it is unclear whether GE crop developers in India or China would consult with FDA, especially since they may be exporting finished food products. Therefore, CSPI has long-advocated that Congress pass legislation that would require an FDA pre-market approval process for all GE food crops.

CSPI believes that a mandatory pre-market approval by FDA should have the following four components:

- First, all engineered food crops, irrespective of their intended use (for instance, that would covers food crops such as amylase corn or food crops producing pharmaceuticals), should go through the approval process.
- Second, the mandatory approval process should be legally included in the FFDCA as opposed to being established in an agency policy that could be changed at any time.
- Third, after FDA has received public comments and completes it safety review, FDA must provide the developer and the public with its opinion about the GE crop's safety.
- Finally, until FDA determines that the GE crop meets the safety standard, it would be illegal to market foods or ingredients made from that crop (i.e., switching the burden of proof so the developer must prove safety to introduce a GE crop on the

market instead of the current situation whereby FDA is required to prove a GE food is unsafe to take it off the market). The safety standard would remain the "substantial equivalence" to conventionally bred crops that is currently used in the voluntary consultation process.

In addition to ensuring the safety of GE crops in the future, a mandatory approval process at FDA would also provide consumers with confidence that eating GE foods and ingredients is safe. Currently, critics of GE crops can— and do—state that, unlike in many other countries, FDA does not determine if a GE crop is safe. The Pew Research Center announced in early 2015 that while 88% of scientists who belong to the American Association for the Advancement of Science believe that foods from GE crops are safe, only 37% of U.S. adults believe they are safe.[1] An opinion on the safety of a GE crop by a reputable agency such as FDA would go a long way to alleviate consumers' safety concerns.

The United States Department of Agriculture

USDA regulates GE crops under its "plant pest" authority provided by the Plant Protection Act. Those provisions were not passed by Congress to regulate GE crops but are used because of the remote possibility that a GE crop could become a "plant pest." The USDA regulations require that GE crop developers either file a notification or obtain a permit to conduct field trials. Then, when the developer is ready to commercialize its engineered variety, the developer petitions USDA for nonregulated status, providing scientific evidence that the engineered variety is not a "plant pest" (that is, an organism

[1] Funk C, Rainie L. Public and Scientists' Views on Science and Society. Pew Research Center. (2015). *Available at:* http://www.pewinternet.org/2015/01/29/public-and-scientists-views-on-science-and-society/ . Accessed 10/19/2015.

that is harmful to plants or agriculture). To date, USDA has granted 117 petitions for nonregulated status and never once found a commercial GE crop that is a "plant pest" and requires continued oversight.[2] Developers and USDA spend significant resources determining that a GE crop is not a plant pest when they could use those resources to analyze and address real impacts from GE crops, such as development of resistant weeds and pests, or gene flow to wild relatives and non-GE farms. It is difficult to find any credible scientists who think adding one or two new genes to a domesticated crop would turn it into a "plant pest."

In the last few years, however, a large loophole has emerged that allows developers of GE crops to avoid USDA's lengthy and expensive regulatory process. If a GE plant variety is developed without using any components of a listed "plant pest," then USDA has no authority to regulate the GE crop, even its experimental field trials. Developers can avoid USDA oversight if they both use the "gene gun" as their method of transformation instead of agrobacterium (which is a "plant pest"), and design the DNA construct being introduced into the crop without using any sequences from "plant pests" (such as a promoter DNA sequence from cauliflower mosaic virus). USDA has confirmed numerous GE crops that have qualified for this exemption, and at any point in the future those experimental plants could become commercial products without any public announcement (unless those GE developers either submit to FDA's voluntary consultation process or include a Bt gene regulated by EPA as a pesticide). USDA's decision to exempt certain GE crops is not based

[2] United States Department of Agriculture Animal and Plant Health Inspection Service. Petitions for Determination of Nonregulated Status. *Available at:* https://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml. Accessed 10/19/2015.

on a scientific analysis that the particular GE crops are not risky and need no regulation, but instead the decision is solely because the crop is not captured by the narrow legal hook USDA uses to regulate. Such arbitrary and non-scientific decisions undermine the regulatory system and its reputation with the public in the United States and our trading partners abroad. It also could result in the release of a GE crop that might cause major harm to the environment or agricultural interests.

In 2008, USDA began a process to revise its regulations that might have added its "noxious weed" authority as additional legal authority that could subject some GE crops to oversight. A "noxious weed" is any plant or plant product that can directly or indirectly damage agricultural interests, public health, or the environment. An expansive interpretation of that definition could include a GE seed that results in herbicide-tolerant weeds. However, USDA interprets "noxious weed" narrowly, such that a crop that spurs the development of resistant weeds would not be a "noxious weed." Therefore, it is unlikely that USDA would find any GE crops would be "noxious weeds."

Congress should pass new legislation that would require USDA to regulate all GE crops, whether developed here or abroad, and ensure that the review addresses the real potential risks and impacts of those crops instead of expending resources addressing nonexistent "plant pest" risks. Such legislation could authorize USDA to issue permits for GE-crop field trials and issue licenses for GE seeds that are actually marketed. To obtain a permit or a license, GE crop developers would have to provide evidence that their crops would not adversely affect the environment or agricultural interests. USDA could weigh both the potential benefits and potential impacts of the GE crop as well as impose risk-

management conditions to limit any adverse impacts. License for commercialized seeds sold to farmers would allow USDA to impose post-market monitoring, such as collecting data on the development of resistant weeds or pests. Congress could also provide USDA with authority to exempt individual GE crops or groups of GE crops when their risk profiles did not require oversight. An advantage of such regulatory oversight is that no GE crops would avoid regulation, except when scientifically justified.

The Environmental Protection Agency

The Federal Fungicide, Insecticide and Rodenticide Act (FIFRA) requires EPA to register all pesticides sold in the United States. More than twenty years ago, EPA promulgated a regulation under FIFRA that established how it would regulate GE crops that had been engineered to produce a biological pesticide (such as the Bt-corn and Bt-cotton varieties currently on the market). Those plant-incorporated protectants (PIPs) are assessed in a mandatory review for impacts on the environment and human health. EPA also determines if any tolerance level is needed for the residues of the pesticide on food products derived from the crops. EPA's registration process helps ensure that any PIP will not result in unreasonable risk to human health or the environment when used appropriately.

While EPA's oversight of GE crops with PIPs has been better than the oversight of GE crops by both FDA and USDA, EPA has had to creatively interpret its current statutory language to manage the most likely environmental impact that could result from GE crops -- the development of resistant insects and weeds. For example, when EPA registered the Bt corn products, it had to determine that Bt toxins were a "public good" in order to impose

"insect resistance management" (IRM) obligations as part of their registration. (IRM is a series of actions that farmers need to take to delay the development of resistant insects.) EPA determined that it needed to protect the Bt toxins for both future farmers and organic farmers because it is a relatively benign pesticide in comparison to what it replaces. EPA's decision to include IRM was the first time EPA interpreted FIFRA to allow restrictions to prevent resistance (as opposed to setting forth restrictions to protect harm to non-target organisms or environmental impacts to soil, water, etc…).

While CSPI supports EPA's interpretation of its legal authority to allow for pesticide-use restrictions to prevent development of resistant insects or weeds, the relative novelty of EPA's position requires it to negotiate with the different seed developers exactly what resistance management obligations to impose, instead of just imposing them. If Congress would clarify that developing of resistant pests or weeds is an environment impact that EPA should manage under FIFRA (for both PIPs and conventional pesticides), EPA could impose necessary scientifically-sound conditions regardless of whether the registrants agree to them. It would also ensure that EPA actions is this area are required and not subject to the EPA's discretion.

This issue is relevant today because EPA currently is negotiating with the developers of Bt corn to impose additional use conditions on Bt corn rootworm PIPs to arrest the spread of resistant corn rootworms. An EPA Science Advisory Panel determined that actions to arrest Bt corn rootworm resistance include eliminating the use of soil insecticides in fields planted with Bt corn rootworm seeds as well as rotating the crops grown in the field. The evidence shows that the use of soil insecticides does not increase a

farmer's yield but instead masks the presence of resistant pests (which could multiply and spread resistance). With Congressional clarification that safety to the environment includes resistance management, EPA would be in a much better position to impose scientifically-sound restrictions on soil insecticide use.

An amendment to FIFRA would also allow EPA to prevent resistant weeds that develop when herbicides are used in conjunction with herbicide-tolerant GE seeds (as well as with all other uses of herbicides). Farmers in the U.S. have been using glyphosate-tolerant crops with glyphosate herbicide on hundreds of millions of acres over the past twenty years. Their overuse and misuse has resulted in 14 resistant weed species on more than 60 million acres of farmland. For the first time, EPA registered Dow AgroSciences' seeds that were engineered to be tolerant to both 2,4-D and glyphosate, and imposed some minimal resistance-management obligations on Dow and farmers. That was a good first step, but EPA needs to require additional actions to delay resistance (such as integrated weed management, rotation of herbicides with different modes of action, and rotation of crops), if it expects to protect existing herbicides for the next generation of farmers (no new herbicides with new modes of action are on the immediate horizon to replace herbicides that become ineffective). Clarifying that environmental impacts include resistance would greatly help EPA impose restrictions to prevent the development of resistant weeds.

H.R. 1599

Finally, CSPI understands that the Senate Agriculture Committee may look to the H.R. 1599—the Safe and Affordable Food Act—as a starting point for any introduced bill

surrounding GE crops. CSPI does not support the "Safe and Affordable Food Act" because it does not provide an adequate mechanism to ensure that the crops are safe. The convoluted regulatory process that H.R. 1599 establishes in order to make the FDA voluntary consultation process "mandatory" does not include the four necessary components discussed above that CSPI believes are needed in a scientifically-sound mandatory approval process.