



# CENTER FOR FOOD SAFETY

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

September 26, 2013

Secretary Vilsack  
U.S. Department of Agriculture (USDA)  
Animal Health and Plant Inspection Service (APHIS)  
1400 Independence Ave., S.W.  
Washington, DC 20250

Petition for Agency Action, Rulemaking, Investigation, and Otherwise Collateral Relief on  
Recent Genetically Engineered Alfalfa Contamination

*Introduction*

Pursuant to the Right to Petition the Government Clause of the United States Constitution,<sup>1</sup> the Administrative Procedure Act (APA),<sup>2</sup> and United States Department of Agriculture (USDA)'s implementing regulations,<sup>3</sup> petitioner Center for Food Safety (CFS) respectfully submits this petition for agency action, rulemaking, and collateral relief on behalf of its over 350,000 farmer and consumer members, including alfalfa farmers Joseph and Michelle Peila. CFS requests that the Department retract its September 17, 2013 decision and take all regulatory action needed to remedy the current genetically engineered (GE) alfalfa contamination because its original decision was based on erroneous factual information—that the transgenic contamination occurred after GE Roundup Ready alfalfa was approved for commercial sale. In fact, records indicate that the seed used for the rejected contaminated alfalfa itself tested positive for Roundup Ready contamination, and this seed was purchased in 2010, before the deregulation of Roundup Ready alfalfa.

CFS is a nationwide public interest non-profit membership organization with offices in Washington, D.C., San Francisco, CA, and Portland, OR. Since the organization's founding in 1997, CFS has sought to ameliorate the adverse impacts of industrial farming and food production systems on human health, animal welfare, and the environment. CFS also supports and promotes sustainable forms of agriculture, including organic systems.

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For fifteen years CFS has been the leading U.S. organization whose central mission includes improving the regulation of GE organisms. CFS seeks to protect human health and the environment by advocating thorough, science-based safety testing of GE products prior to any marketing; cultivation of GE crops in a manner that minimizes any risk of contaminating conventional food supplies or the environment, and that minimizes negative impacts such as increased use of pesticides and evolution of resistant weeds; and appropriate labeling of foods that are or contain GE products. CFS also seeks to provide consumers with a means of identifying GE foods on the market and to encourage full public participation in defining the issues presented by GE crops. CFS has worked continuously on the Roundup Ready alfalfa issue, specifically, for over a decade.

### *Factual Background and Agency Decision*

As you are aware, Washington state alfalfa farmers Joseph and Michelle Peila, who grow conventional alfalfa, were recently found to be contaminated with GE, “Roundup Ready” transgenes.<sup>4</sup> Their contamination was first discovered by their export company buyer, and later confirmed by further testing by Washington State Department of Agriculture and Mr. Peila independently.

This is the second transgenic contamination episode of the summer in the Pacific Northwest, following on the heels of the discovery of unapproved genetically engineered wheat in Oregon.<sup>5</sup> Both contamination episodes involved Monsanto crops, and both illustrate the negligence of GE crop developers, the weakness of USDA oversight, the growing foreign and domestic market sensitivity to unwanted content, and the urgent need for fundamental regulatory reform. We, along with many others, recently alerted you to these issues and the critical need for your agency to reform its operations.<sup>6</sup>

The purpose of this filing is narrower but equally important. While USDA opened an investigation into the GE wheat contamination incident,<sup>7</sup> which is still ongoing, the agency has apparently decided to abandon conventional and organic alfalfa farmers without even that investigatory step. Upon being alerted by Washington State that testing confirmed that a farmer had been contaminated by transgenic material, and subsequently that exporters had rejected his crops for export shipment, the agency, which decided not to take any action, issued the following curt statement:

#### **Statement**

The recent detection of a fully approved GE alfalfa trait in a Washington farmer’s non-GE alfalfa crop is a commercial issue. Accordingly, the U.S. Department of Agriculture will not take any action.

#### **Background**

When a GE organism is deregulated it is no longer subject to APHIS oversight.

Presence of approved GE traits in a non-GE crop is a commercial issue and the agriculture industry has approaches to minimize their occurrence and manage them when they occur.<sup>8</sup>

### *USDA's Decision Is Contrary to Law and Fact*

The Department's decision to abruptly curtail any investigation and/or take no other regulatory action is in error, and is based on an overly narrow, fundamentally flawed legal interpretation of USDA's statutory authority and duty over GE crops and their adverse impacts. First, as a general matter, USDA has continuing regulatory authority over GE crops by their nature and because of their adverse impacts, including transgenic contamination. The Plant Protection Act (PPA) grants the agency authority over the broadly defined agronomic harms of GE crops in order to protect "the agriculture, environment, and economy of the United States."<sup>9</sup> The statute specifically includes economic harm to export markets.<sup>10</sup> The PPA grants the agency broad powers to prevent and remedy these harms, using, among other tools, inspections, seizures, warrants, and subpoenas.<sup>11</sup> This specifically includes the authority to conduct investigations "necessary for the administration and enforcement" of the PPA.<sup>12</sup>

Second, and more specifically, USDA's decision here is also based on an erroneous factual assumption—that the transgenic contamination occurred after GE Roundup Ready alfalfa was approved for commercial sale. Instead, Mr. Peila has confirmed through DNA testing that the contaminated seed was seed that he purchased in the summer of 2010. That seed, sold and labeled as conventional seed, was subsequently planted by Mr. Peila in the fall of 2010.

As you are well aware, it is undisputed that Roundup Ready alfalfa was a regulated article, as defined by USDA's regulations, in 2010. As such it was not approved for commercial sale or distribution. Commercial approval via Roundup Ready alfalfa's deregulation did not occur until 2011.<sup>13</sup> Thus, the seed purchased by Mr. Peila in the fall of 2010 was contaminated with unapproved Roundup Ready alfalfa.

Pursuant to the PPA and USDA's implementing GE crop regulations at 7 C.F.R. Part 340, regulated articles are strictly prohibited by law from being "introduced" into the environment absent a field trial permit, authorized by 7 C.F.R. § 340.4, or field trial notification, authorized by 7 C.F.R. § 340.3.<sup>14</sup> "Introduce" or "Introduction" means movement into or within the United States, including release into the environment.<sup>15</sup> "Release into the environment" means "[t]he use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure."<sup>16</sup> There is no provision permitting escape or unintentional presence, at any level. Rather, the relevant GE crop regulations mandate a "zero tolerance" standard for contamination and/or persistence in the environment. "[T]he regulated article[s] must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials..."<sup>17</sup> "The field trial must be conducted such that...[t]he regulated article will not persist in the environment..."<sup>18</sup> "Upon termination of the field test...[v]olunteers shall be managed to prevent persistence in the environment."<sup>19</sup> Any regulated articles "introduced not in compliance" with the PPA's field trial requirements are subject to "immediate application of such remedial measures or safeguards" as are needed.<sup>20</sup> There is no threshold below which a violation has not occurred.

Accordingly, based on these facts, USDA is plainly required to investigate this contamination episode. One or more parties—presumably the grower of the regulated article and/or the distributor of the contaminated conventional seed—violated the law. A field trial operator illegally “planted [Roundup Ready alfalfa] in such a way that” it became “inadvertently mixed with non-regulated” conventional alfalfa, in violation of 7 C.F.R. § 340.3(c)(2). A distributor of the contaminated conventional seed “introduced” the regulated article prior to its deregulation, in violation of 7 C.F.R. § 340.0(a)(1). It is also possible that the PPA was violated willfully rather than inadvertently. Further, if contaminated alfalfa seed was distributed to one farmer prior to approval, it stands to reason that others may similarly have been sold such seed unlawfully. As such, USDA should exhaustively investigate this matter to determine which party or parties is/are responsible for this PPA violation, and should then be subject to PPA criminal and civil penalties.<sup>21</sup> These penalties can include up to five years imprisonment and \$1 million in fines for willful violations of the PPA.<sup>22</sup>

Because the contaminated seed was sold unlawfully, before any commercial approval via deregulation, there is no meaningful difference between this situation and the GE wheat situation that USDA is currently investigating. Absent reversal, USDA has acted in an arbitrary and capricious manner in determining otherwise in its September 17, 2013 decision. The agency has failed to consider all the facts, ignored this evidence, and failed to make a rational connection between the evidence and its conclusion.<sup>23</sup>

It is a distinction without a difference that USDA has subsequently permitted commercial approval of GE, Roundup Ready alfalfa, because the unlawful conduct took place before such regulatory approval was granted. In this regard the Bayer LLRICE601 “LibertyLink” rice contamination of 2006-2007 is telling. In that contamination episode, farmers learned of widespread contamination of their southern long-grain rice with unapproved LLRICE601 in August 2006.<sup>24</sup> Immediately Japan banned all long-grain rice imports from the U.S.<sup>25</sup> Several days later the European Union announced it would no longer accept long-grain rice from the U.S. unless it was tested and certified free of GE grains.<sup>26</sup> Rice farmers across the South experienced a severe shortage of uncontaminated seed rice for the 2007 season.<sup>27</sup> Farmers in Texas, Louisiana, Missouri, Arkansas, and Mississippi were forced to sue Bayer for compensation for their losses, which were estimated at a billion dollars.<sup>28</sup> After the initial bellwether trials all resulted in juries awarding the farmer plaintiffs millions of dollars,<sup>29</sup> Bayer agreed to a \$750 million dollar settlement.<sup>30</sup>

Importantly, after the LLRICE601 contamination was announced in August 2006, USDA deregulated the GE rice, *post hoc*, in November 2006.<sup>31</sup> Even assuming the questionable legality of that approval decision, USDA did not then deny any further authority over the contaminating, formerly regulated article, as it has attempted to do here. Instead, USDA undertook a lengthy, fourteen-month investigation of the rice contamination incident, which did not end until October 2007.<sup>32</sup> That investigation took 8,500 staff hours, including site visits to 45 locations in 11 states and Puerto Rico, which for the most part took place after the GE rice in question was deregulated. USDA failed to take action against Bayer for any PPA violations not because, as it claims here, it lacked authority post-deregulation, but only because, despite its lengthy investigation, the Department was unable to come up with clear evidence of who was responsible.<sup>33</sup>

At that time, USDA stated:

An investigation to determine the circumstances surrounding the release and whether any USDA regulations were violated is nearly complete. Deregulation, or regulatory approval of a particular product, is handled separately from determinations of compliance with APHIS regulations. USDA has approved LLRICE601 for deregulation, while an investigation of compliance is ongoing.<sup>34</sup>

USDA must act similarly here; failing to do so would be wholly inconsistent with the agency's own past positions and actions and therefore arbitrary and capricious.<sup>35</sup>

Further, if deregulating a regulated article could immunize those that have previously violated the PPA from any recourse, it would allow and encourage interested parties to violate the PPA's mandates in the belief that they could subsequently seek and be granted deregulation. A statutory interpretation that leads to such an absurd conclusion is also arbitrary and capricious.<sup>36</sup>

It would be similarly absurd to conclude that USDA relinquishes any potential future authority over GE crops post-deregulation. If previously deregulated crops caused significant agronomic, economic, and/or environmental harms, the PPA requires USDA to protect against those harms; any other interpretation would be contrary to the PPA's plain language and Congress's intent. The PPA provides USDA broad post-commercialization remedial enforcement authority<sup>37</sup> to hold, seize, quarantine, or apply other measures to destroy or dispose;<sup>38</sup> issue subpoenas<sup>39</sup> and conduct inspections;<sup>40</sup> and impose monetary penalties.<sup>41</sup> USDA's regulations provide that "[i]f additional information becomes available that APHIS believes justifies changing its [deregulation] decision, it will issue a revised decision."<sup>42</sup> USDA also has acknowledged that under "existing regulations and policies...the Administrator may place a deregulated GE organism back under the regulations if the Administrator concludes that the GE organism poses a plant pest risk."<sup>43</sup>

The PPA's mandate that USDA base its decisions on "sound science" also supports the conclusion that USDA retains duty and authority to address the harms of GE crops after their commercialization.<sup>44</sup> According to the National Academy of Sciences,

short-term experiments and general characterization of plant traits may not pick up all environmental effects of transgenic crop plants. It is therefore important to conduct postcommercialization testing to determine if the precommercialization testing protocols adequately assessed risks (i.e., validation of precommercialization decisions). It also is important to set up long-term, postcommercialization monitoring programs to record trends in predicted effects, and to detect effects that were not predicted by precommercialization testing.<sup>45</sup>

#### *USDA Has Knowingly Abandoned Farmers*

USDA's attempted abdication of any responsibility in its action here is exacerbated by the fact that the agency well understands the seriousness of the harm: that transgenic contamination is a

multifaceted injury, an environmental impact that also causes significant economic harm to the agricultural economy both domestically and abroad, the fundamental loss of choice for farmers and consumers, and irreparable contamination of the wild. Further, unlike standard chemical pollution, transgenic contamination is a living pollution that can propagate itself over space and time via gene flow. “Once the gene transmission occurs and a farmer’s seed crop is contaminated with the Roundup Ready gene, there is no way for the farmer to remove the gene from the crop or control its further spread.”<sup>46</sup>

Alfalfa is the fourth most widely grown crop in the U.S. (at approximately 20 million acres), behind corn, soybeans, and wheat; it is grown in every U.S. state. Alfalfa is pollinated by bees, which can travel and cross-pollinate plants between fields many miles apart, causing almost certain contamination. Alfalfa also thrives as a feral plant and is ubiquitous in roadsides, irrigation ditches, and range lands across the U.S. West. Feral alfalfa with the Roundup Ready trait acts as a transgenic “bridge” over space and time, facilitating contamination of conventional alfalfa or further spread of the Roundup Ready trait in unmanaged areas. The U.S. exports approximately \$200 million annually in alfalfa seed and hay to countries that reject GE-contaminated shipments. Transgenic contamination episodes like this one will cause the permanent loss of these markets for American farmers. The organic sector is the fastest growing sector of the U.S. agricultural economy and keeps some 15,000 family farms operating. Organic dairies receive a substantial premium for their products, but Roundup Ready alfalfa contamination will devastate them, since they are required to use organic feed.

Finally, USDA’s decision here must be seen in light of this administrative history: specifically, the Department’s knowledge of Roundup Ready alfalfa and the likelihood of transgenic contamination harm from it. As the Secretary is well aware, CFS and USDA litigated the legality of the GE crop’s proposed approval in two separate cases, over 8 total years, from 2006 to 2013. When USDA first proposed commercial approval of GE alfalfa in 2005, CFS successfully challenged that ill-advised decision in court and succeeded in getting alfalfa planting halted, even though Monsanto appealed the case all the way to the U.S. Supreme Court, through 2010. That Supreme Court decision, the first ever on any GE crop, left the ban on planting in place.

Because of CFS’s case, USDA was forced under court order to rigorously analyze GE alfalfa’s impacts on farmers and the environment; remarkably, it was the first time the agency had ever conducted such an analysis, for any GE crop, in 17 years of approving them. The court-ordered Environmental Impact Statement, published by USDA in 2010, itself concluded that transgenic contamination of conventional and organic alfalfa farmers like this instance would occur, and would cause significant economic harm.

To attempt to mitigate that acknowledged harm, in December 2010, USDA proposed a limited commercial approval, whereby Roundup Ready alfalfa cultivation would be restricted to certain geographic planting zones. Unfortunately, USDA capitulated to industry pressure and reversed its position less than a month later, issuing an unconditional approval in January 2011, despite its own analyses showing the harms that would be incurred by farmers. In so deciding, USDA relied heavily on industry assurances that its “best practices” would prevent GE contamination from occurring, despite overwhelming scientific evidence to the contrary.

*Conclusion*

For the foregoing reasons, we call on the Secretary to reverse its September 17, 2013 decision and take all regulatory action needed to remedy the current GE alfalfa contamination incident, including investigating the source of the contamination, analyzing the extent and impact of the contamination, levying fines and penalties on the violating parties, re-opening its 2011 deregulation decision for public comment, and taking other action as necessary to remedy the violation(s) of law.

Submitted on this day of September 26, 2013,

A handwritten signature in black ink, consisting of a stylized 'G' followed by several horizontal strokes.

George Kimbrell  
Senior Attorney  
Center for Food Safety

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<sup>1</sup> “Congress shall make no law...abridging...the right of the people...to petition the government for a redress of grievances.” U.S. Const. amend. I. The right to “petition for a redress of grievances [is] among the most precious of the liberties safeguarded by the Bill of Rights.” *United Mine Workers of Am., Dist. 12 v. Ill. State Bar Ass’n*, 389 U.S. 217, 222 (1967). It shares the “preferred place” accorded in our system of government to the First Amendment freedoms, and has “sanctity and a sanction not permitting dubious intrusions.” *Thomas v. Collins*, 323 U.S. 516, 530 (1945). “[A]ny attempt to restrict those [First Amendment] liberties must be justified by clear public interest, threatened not doubtfully or remotely, but by clear and present danger.” *Id.* The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government. *United States v. Cruikshank*, 92 U.S. 542, 552 (1875).

<sup>2</sup> 5 U.S.C. § 553(e) (2012).

<sup>3</sup> 7 C.F.R. § 1.28 (2013).

<sup>4</sup> See Carey Gillam, *Washington State Testing Alfalfa for GMO Contamination*, Reuters (Sept. 11, 2013), <http://www.reuters.com/article/2013/09/11/us-usa-alfalfa-gmo-idUSBRE98A16H20130911>.

<sup>5</sup> Andrew Pollack, *Modified Wheat Is Discovered in Oregon*, N.Y. Times (May 29, 2013), [http://www.nytimes.com/2013/05/30/business/energy-environment/genetically-engineered-wheat-found-in-oregon-field.html?\\_r=0](http://www.nytimes.com/2013/05/30/business/energy-environment/genetically-engineered-wheat-found-in-oregon-field.html?_r=0).

<sup>6</sup> See generally *Letter to USDA from 150 Food and Agricultural Businesses, Farmers, and Consumer Organizations, RE: Discovery of Unapproved Genetically Engineered Wheat in Oregon*, July 25, 2013, available at <http://www.beyondpesticides.org/gmos/WheatLetterUSDA.pdf>.

<sup>7</sup> APHIS, USDA, *USDA Investigating Detection of Genetically Engineered (GE) Glyphosate-Resistant Wheat in Oregon* (May 29, 2013), [http://www.aphis.usda.gov/newsroom/2013/05/ge\\_wheat\\_detection.shtml](http://www.aphis.usda.gov/newsroom/2013/05/ge_wheat_detection.shtml).

<sup>8</sup> Northern Ag Network, *No Action in GMO Lawsuit Case* (Sept. 19, 2013), <http://www.northernag.net/AGNews/tabid/171/articleType/ArticleView/articleId/8499/No-Action-in-GMO-Lawsuit-Case.aspx>.

<sup>9</sup> 7 U.S.C. § 7701(1) (2012).

<sup>10</sup> *Id.* § 7701(6).

<sup>11</sup> *Id.* §§ 7714, 7731, 7733.

<sup>12</sup> *Id.* § 7732.

<sup>13</sup> APHIS, USDA, *USDA Announces Decision to Fully Deregulate Roundup Ready Alfalfa* (Jan. 27, 2011), <http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2011/01/0035.xml>.

<sup>14</sup> 7 C.F.R. § 340.0 (2013).

<sup>15</sup> *Id.* § 340.1.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.* § 340.3(c)(2).

<sup>18</sup> *Id.* § 340.3(c)(5)(i).



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<sup>19</sup> *Id.* § 340.3(c)(6)(ii).

<sup>20</sup> *Id.* § 340.0(b).

<sup>21</sup> 7 U.S.C. § 7734.

<sup>22</sup> *Id.*

<sup>23</sup> *See Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

<sup>24</sup> USDA, *Genetically Engineered Rice* (Aug. 18, 2006), <http://www.usda.gov/wps/portal/usdahome?contentidonly=true&contentid=2006/08/0306.xml>. The contaminated rice strains contained the GE trait, which confers tolerance to the herbicide Liberty, or glufosinate.

<sup>25</sup> *Japan Bans 'Contaminated' US Rice*, BBC News (Aug. 21, 2006), <http://news.bbc.co.uk/2/hi/science/nature/5271384.stm>.

<sup>26</sup> Europa Press Release Database, *Commission Requires Certification of US Rice Exports to Stop Unauthorised GMO Entering the EU* (Aug. 23, 2006), [http://europa.eu/rapid/press-release\\_IP-06-1120\\_en.htm](http://europa.eu/rapid/press-release_IP-06-1120_en.htm); see also *Cost of Genetically Engineered Plants: Hearing Before the Subcomm. on Domestic Policy of the H. Comm. on Oversight and Gov't Reform*, 110th Cong. (Mar. 13, 2008) (statement of Harvey Howington, conventional and GE grain grower).

<sup>27</sup> David Bennett, *Arkansas' Emergency Session on CL 131 Rice*, Delta Farm Press (Mar. 1, 2007), <http://deltafarmpress.com/arkansas-emergency-session-cl-131-rice>.

<sup>28</sup> *See, e.g., In re Genetically Modified Rice Litigation*, 666 F. Supp. 2d 1004 (E.D. MO 2009); *In re Genetically Modified Rice Litigation*, No. 4:06MD1811 CDP, 2009 WL 4801399 (E.D. MO Dec. 9, 2009); see also Greg Edwards, *A Billion-Dollar Rice Dispute*, St. Louis Bus. J. (May 13, 2007), <http://www.bizjournals.com/stlouis/stories/2007/05/14/tidbits1.html?page=all>.

<sup>29</sup> Margaret Cronin Fisk & Joe Whittington, *Bayer Fouled U.S. Long-Grain Rice Crop, Causing Export Plunge, Jury Told*, Bloomberg News (July 13, 2010), <http://www.bloomberg.com/news/2010-07-13/bayer-fouled-u-s-long-grain-rice-crop-causing-export-plunge-jury-told.html>.

<sup>30</sup> Andrew Harris & David Beasley, *Bayer Agrees to Pay \$750 Million to End Lawsuits Over Gene-Modified Rice*, Bloomberg News (July 1, 2011), <http://www.bloomberg.com/news/2011-07-01/bayer-to-pay-750-million-to-end-lawsuits-over-genetically-modified-rice.html>.

<sup>31</sup> APHIS, USDA, *USDA Deregulates Line of Genetically Engineered Rice* (Nov. 24, 2006), [http://www.aphis.usda.gov/newsroom/content/2006/11/rice\\_deregulate.shtml](http://www.aphis.usda.gov/newsroom/content/2006/11/rice_deregulate.shtml).

<sup>32</sup> USDA, Report of LibertyLink Rice Incidents 1 (2007), available at [www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf](http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf); see Rick Weiss, *Probe into Tainted Rice Ends*, Wash. Post (Oct. 6, 2007), [www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf](http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf);

<sup>33</sup> *Id.*

<sup>34</sup> APHIS, USDA, *USDA Deregulates Line of Genetically Engineered Rice* (Nov. 2006), [http://www.aphis.usda.gov/newsroom/content/2006/11/rice\\_deregulate.shtml](http://www.aphis.usda.gov/newsroom/content/2006/11/rice_deregulate.shtml).

<sup>35</sup> *See Mount Graham Red Squirrel v. Madigan*, 954 F.2d 1441, 1457 (9th Cir. 1992).

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<sup>36</sup> *United States v. Wilson*, 503 U.S. 329, 334 (1992) (citing *United States v. Turkette*, 452 U.S. 576, 580 (1981)).

<sup>37</sup> 7 U.S.C. § 7732.

<sup>38</sup> *Id.* § 7714(a)(1)(A).

<sup>39</sup> *Id.* § 7733.

<sup>40</sup> *Id.* § 7731(b).

<sup>41</sup> *Id.* § 7734.

<sup>42</sup> 7 C.F.R. § 340.6(e)(3).

<sup>43</sup> Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms, 73 Fed. Reg. 60008, 60024 (Oct. 9, 2008).

<sup>44</sup> 7 U.S.C. § 7701(4); *see also id.* § 7712(b).

<sup>45</sup> Bd. on Agric. & Natural Res., Div. on Earth & Life Studies, Nat'l Research Council, *Environmental Impacts of Transgenic Plants: The Scope and Adequacy of Regulation* 192 (2002), available at [http://www.nap.edu/openbook.php?record\\_id=10258&page=192](http://www.nap.edu/openbook.php?record_id=10258&page=192).

<sup>46</sup> *Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624, at \*5 (N.D. Cal. Feb. 13, 2007).