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Regulatory Analysis and Development, PPD
Animal and Plant Health Inspection Service (APHIS)
Station 3A- 03.8
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RE: **Comments on APHIS Docket No. APHIS-2007-0044**
Environmental Impact Statement; Determination of Regulated Status of Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate

Center for Food Safety submits the following comments on APHIS's "Notice of intent to prepare an environmental impact statement (EIS) and proposed scope of study" for its environmental impact statement regarding determination of regulated status of alfalfa genetically engineered for tolerance to the herbicide glyphosate. This notice was published in the Federal Register: January 7, 2008 (Volume 73, Number 4, pp. 1198-1200).

APHIS raises numerous questions to be addressed in its environmental impact statement on Roundup Ready (RR) alfalfa. While collectively these questions cover a broad range of the issues that need to be examined, a number of issues should be reframed. Other issues not raised by APHIS should also be analyzed in the EIS. Below, we offer comments on the scoping questions suggested by APHIS in the order they are presented, with additional questions that should be addressed, as appropriate.

These comments first address aspects of the Federal Court's decision that provide important guidance to APHIS as it considers the scope of the EIS. First, the court's decision emphasizes the importance of preserving farmers' choice to grow non-GE and/or organic alfalfa. Judge Breyer clearly states that widespread gene transmission from RR to non-GE alfalfa would be "tantamount to the elimination of all alfalfa" for those who want to grow non-GE alfalfa, in which case "they cannot grow their chosen crop." While Judge Breyer noted that contamination could prevent organic growers from marketing their crop, lessening its value and their income, his ruling did not depend on market impacts. "…most importantly, APHIS's comment simply ignores that these farmers do not want to grow or feed their livestock GE alfalfa, regardless of how such alfalfa can be marketed." These aspects of the ruling set a high hurdle that must be recognized and analyzed by APHIS in the EIS. Several of APHIS's scoping questions should be reframed with this in mind.

RR alfalfa must not be deregulated absent a convincing demonstration that growers can be assured of their continued option of growing non-GE alfalfa. The right to grow non-GE alfalfa is not limited temporally or geographically. That is, RR alfalfa is not to be deregulated if a reasonably foreseeable impact of the deregulation is the elimination of the option of farmers living in any region of the country to continue growing non-GE alfalfa, in the near or longer-term future. The right to grow non-GE alfalfa is also not synonymous with the right to grow alfalfa that is contaminated with GE alfalfa at "negligible levels" (however that may be defined) due to "inadvertent gene flow" (as suggested under section 16). Thus, APHIS should formulate an alternative that analyzes the contamination issue where the standard is zero tolerance for contamination.

A second aspect of the decision that bears on APHIS's EIS is the crucial distinction between theoretically attainable, ideal-world performance and real-world outcomes that take full account of the practicalities and limitations of farming as it is practiced. Judge Breyer's decision makes several references to this distinction.

> "The further collection of data can inform APHIS as to the likely extent of any gene transmission and ***the realistic measures, if any***, that may be taken to prevent or at least reduce such contamination."
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> "APHIS failed to consider, however, that because of weather – which is beyond a farmer's control – a farmer cannot always harvest his field at the most optimal time. …. APHIS made no inquiry into ***how often farmers are actually able to harvest their forage crop before seeds mature and no inquiry into the likelihood of gene transmission when they cannot***. Without such data, APHIS's conclusion is arbitrary."
>
> "The assertion that 'good stewardship' may be the only defense against such weeds is equally unconvincing. … This is especially so given that neither the FONSI nor the EA contain any analysis as to what exactly constitutes good stewardship ***and how likely it is to be practiced successfully***. … ***There may be ways to reduce the proliferation of weeds, but if farmers are not engaging (or cannot engage) in those practices, then the availability of those practices does not ameliorate the potential environmental risks***."

In each case, Judge Breyer demands that APHIS take full account of the practicalities and limitations of farming ***as it is actually practiced*** in examining critical issues such as gene transmission and stewardship measures with respect to glyphosate-resistant weeds. One unavoidable conclusion is that APHIS must not rely exclusively or even primarily on the results of carefully-controlled, small-scale field trials of RR alfalfa to evaluate its potential impacts (e.g. the potential for gene transmission or development of additional herbicide-resistant weeds). Some impacts are much more likely to occur at field-production scale than at the small scale of field trials. Some are much more likely to occur under the time and financial-resource constraints that pertain to commercial production conditions but not to well-controlled experimental conditions where "best management practices" are much more easily observed.

Some questions may be answered by extrapolation of current commercial production practices with non-RR alfalfa. For instance, Judge Breyer poses the question of "the likelihood of [seed-based] gene transmission" from RR to non-RR alfalfa (when both are grown for forage), noting that weather conditions sometimes prevent farmers from harvesting forage alfalfa in a timely manner before the seeds mature. APHIS needs to base its analysis on such real-world data.

However, other questions are not so easily answered by reference to conventional alfalfa production practices, and may require analysis of experience with other crop systems. For instance, the paucity of experience with commercial-scale production of RR alfalfa makes it difficult to accurately forecast RR alfalfa's potential to foster increased glyphosate use and the development of additional glyphosate-resistant weeds. Here, analysis of experience with other RR crop systems is needed to inform the analysis of the impacts of RR alfalfa introduction.

This is especially true when one considers that RR alfalfa's impacts may well change over time. Introduction of past Roundup Ready crops have led to reductions in herbicide use over the short-term (two years), followed by increasing herbicide use due in part to development of herbicide-resistant weeds. Since deregulation is absolute, the longer-term impacts are of much greater importance than short-term impacts.

Likewise, gene transmission from Roundup Ready alfalfa to conventional alfalfa will depend in part upon the extent to which RR alfalfa is adopted. In general, past experience with other genetically engineered crops suggests that the scale of contamination increases with adoption rate. Analysis of the history of transgenic contamination of conventional seeds of other crops (e.g. canola, corn and soybeans) over time will provide valuable insight into the potential of the same phenomenon with RR alfalfa.

APHIS should strive to collect and assess region-specific data in all aspects of the EIS.

<u>Questions in Section (1):</u>
This set of questions involves analysis of the management and marketing practices for organic, conventional and glyphosate-tolerant alfalfa, including selling prices and premiums for "various quality standards."

<u>Management Assessment</u>
On average, less than 17% of alfalfa hay acreage was treated with herbicides from 1988 to 1992 (Hower et al 1999). APHIS should assess why it is that the great majority of alfalfa hay acreage is not treated with any herbicides. This assessment should include "best management practices" in conventional and organic alfalfa production, in particular the practices that make herbicide use unnecessary. For instance, vigorous, healthy alfalfa outgrows most weeds. Regular cutting every 30-40 days also inhibits establishment of weeds. Factors that promote healthy and vigorous alfalfa – including fertile soil and proper soil pH – also inhibit weed development and make herbicide use unnecessary. APHIS should also assess the reasons for herbicide use on the minority of alfalfa hay acreage that is treated with herbicides. Deficient soil fertility, unfavorable soil pH, and attacks by disease or nematodes are factors that may make alfalfa more susceptible to weed invasions. Attempts to overly prolong the life of thinning alfalfa stands may also lead to weed infestations. RR alfalfa is only one of many options for weed control. Others

include increasing soil fertility, adjusting soil pH, more regular cutting of alfalfa stands, and earlier take-out of stands thinned out by age or disease/nematode problems. APHIS should assess the RR alfalfa system in comparison to current management practices that demonstrably reduce weed problems without use of herbicides. This analysis is consistent with the USDA's commitment to integrated pest management, whose goal is reduction of chemical pesticide use (GAO 2001).

Marketing Assessment

The marketing analysis suggested here is limited to current prices. APHIS should also examine historical data going back at least two decades to evaluate trends in selling prices for conventional and organic alfalfa, in particular premiums offered for organic alfalfa. Based on these data and current trends, APHIS should project the selling price and premiums for organic alfalfa for at least one decade into the future. This analysis should take account of the growing demand for organic alfalfa from the organic dairy and livestock sectors, as well as from major export markets and the alfalfa sprout sector. Historical and projected growth of the organic milk and dairy sector is obviously a key factor that should be analyzed here.

Questions in Section (2):

These questions relate to the current regional distribution of organic and conventional alfalfa production, the incidence of feral and volunteer alfalfa, and the potential impacts of deregulating glyphosate-tolerant alfalfa.

APHIS should conduct a thorough analysis of the trend in acreage of organic alfalfa production by region going back at least two decades, and project the same at least one decade into the future. This analysis should include an historical and prospective assessment of demand for organic alfalfa by sector, particularly demand from the organic dairy and livestock sectors, the alfalfa sprout sector, and major export markets. It has been reported that the acreage of organic alfalfa and hay in the U.S. has grown by 40% over just the past two years, yet is still not keeping up with demand (Dininny 2007).

Contamination of organic alfalfa through the introduction of Roundup Ready alfalfa is a concern expressed repeatedly by organic growers, who face possible loss of markets due to even the low-level presence of transgenic product in their crop (even if this might not affect their status as organic producers). In the EIS, APHIS should examine the real-world feasibility of measures to prevent such contamination wherever Roundup Ready alfalfa is introduced. The growing demand for organic alfalfa means that farmers may wish to grow it in the future in areas where little or no organic alfalfa is currently grown. APHIS's analysis should accept the need to preserve the option of farmers to grow and market organic alfalfa free of unintended transgenic content in all alfalfa-growing areas, now and in the future.

In assessing the potential impacts of glyphosate-tolerant alfalfa introduction on non-agricultural lands, APHIS should assess the current role of glyphosate in managing weeds on these lands, and the remaining options should feral alfalfa become glyphosate-tolerant, or volunteer glyphosate-tolerant alfalfa spread. This analysis will differ by region and type of land. Glyphosate is a more important weed management tool in some areas than in others. Restrictions on the use of other registered herbicides in some states (e.g. California) and in particular situations (near waterways) may limit the choice of herbicides available to control glyphosate-resistant weeds.

In addition, APHIS should analyze the potential impacts of glyphosate-tolerant alfalfa introduction on agricultural lands other than alfalfa. It has been reported, for example, that alfalfa can be a weed problem in sugar beets, onions, vegetable seeds, orchards, vineyards and in rangeland plants grown for seed. Acquisition of glyphosate-tolerance by feral alfalfa or the spread of volunteer RR alfalfa would restrict or eliminate glyphosate as a means to control it in situations where alfalfa poses weed problems.

<u>Questions in Sections (3) and (4)</u>
Genetic engineering is known to introduce random mutations in crop genomes that can give rise to unintended effects, which include generation of novel toxins, increased levels of harmful compounds naturally present at low levels, and decreased nutritional content. Thus, a new genetically engineered crop requires more a more thorough safety review than conventionally bred varieties. APHIS should demand carefully controlled, long-term animal feeding studies, with toxicological endpoints, to assess glyphosate-tolerant alfalfa for potential adverse effects on animal health. This is particularly necessary given the large amounts of alfalfa consumed by certain livestock (e.g. dairy cows and horses). For instance, it has been reported that dairy cows consume up to six tons of alfalfa per year (Jenkins 2007). Such studies should be conducted with glyphosate-tolerant alfalfa that has been treated with glyphosate, for at least three reasons. First, glyphosate will be sprayed on Roundup Ready alfalfa, while it is not sprayed directly on conventional alfalfa. Second, glyphosate-treated, glyphosate-tolerant soybean plants have been shown to have substantially lower tissue (leaf) concentrations of manganese (Gordon 2007) and perhaps other nutritionally important plant components than conventional soybeans, and a similar effect may be present in Roundup Ready alfalfa. This effect, if present, might have implications for the nutritional adequacy of RR alfalfa. Third, glyphosate treatment will likely leave residues of glyphosate on alfalfa hay and seed, and any adverse effects on animals from the presence of glyphosate residues would only be detected if the RR alfalfa had been treated with glyphosate. We note that EPA established a tolerance of 0.5 ppm glyphosate on alfalfa seed to facilitate introduction of glyphosate-tolerant alfalfa; apparently, no glyphosate residues were permitted on alfalfa seed prior to this tolerance decision. We are unaware if any tolerance has been established for glyphosate residues on alfalfa hay. Animal exposure to glyphosate residues from consumption of RR alfalfa requires assessment.

We note that compositional assessments of the type submitted to USDA and FDA by Monsanto are not adequate. First, they were conducted on RR alfalfa plants that were not treated with glyphosate, which as noted above is improper methodology. Second, they measure only a limited range of plant constituents, and thus may completely miss unintended effects involving novel or untested compounds. Thirdly, even these inadequate assessments raise red flags that require further assessment with proper methodology. For instance, transformation event J163 exhibited statistically significant higher levels of lignin than control alfalfa. Lignin is an indigestible antinutrient, and increased levels translate into lower value as animal feed. Alfalfa also has a range of estrogenic compounds, including the potent coumesterol, which can have serious adverse reproductive impacts if present at high enough levels. USDA and FDA impermissibly ignored statistically significant differences in coumesterol levels between RR alfalfa and control plants that appeared in some growing locations by averaging results for tests on plants grown in a wide range of environments. Pleiotropic effects of the transformation process may be triggered, or significantly potentiated, only in certain growing environments. Only further study of this question can establish whether Roundup Ready alfalfa has significant and perhaps adverse compositional changes in certain growing environments.

Questions in Section (5):

As for weediness traits, APHIS should thoroughly examine several potential avenues by which RR alfalfa could increase the weediness of all forms of alfalfa.

First, a tendency to dormancy (i.e. hard seed) correlates with the weediness potential of a crop. APHIS should develop or collect new data to follow up on Monsanto's finding of a two to four-fold increase in the percentage of hard seed in Roundup Ready alfalfa vs. controls. This analysis should answer the questions raised in Center for Food Safety's comments on the deregulation petition for RR alfalfa, which is incorporated here by reference (CFS 2005). We note that USDA's EA did not adequately address the dormancy issue, but rather only cited anecdotal reports and opinions by a handful of agronomists favoring deregulation.

Second, gene flow from RR alfalfa to feral alfalfa may increase its weediness potential. Feral alfalfa is listed as a weed by the Southern Weed Science Society, as cited by the Natural Resources Conservation Service (NRCS). The NRCS report states that feral alfalfa "…may become weedy or invasive in some regions or habitats and may displace desirable vegetation if not properly managed" (as discussed in CFS 2005). Although the author of that report subsequently stated that feral alfalfa is not an invasive or noxious weed, he still maintained that feral alfalfa may "colonize disturbed areas" where it seems to act as a ruderal (i.e. a plant species that is first to colonize disturbed habitat) (as cited in APHIS's FONSI/EA). The author's subsequent comment in no way negated his earlier assertion that feral alfalfa may become weedy or invasive in some regions or habitats and may require management so as not to displace desirable vegetation, which would seem to fit the definition of a weed. APHIS's discussion of this issue in the FONSI/EA was flawed in several ways. First, APHIS relied heavily on selected anecdotal reports from weed scientists who testified that feral alfalfa is not considered an important weed, while ignoring reports from other weed scientists who did consider it a problematic weed. Second, even those weed scientists who did not consider feral alfalfa to be an important weed were referring only to its occurrence in developed areas (e.g. roadways and drainage ditches) rather than natural areas. Finally, it is clear that acquisition of the glyphosate-tolerant phenotype via cross-pollination would restrict the range of management options in any area (developed or natural) where feral alfalfa occurs as a weed and requires management; such changes in management options might include use of more toxic herbicides, which as noted above are restricted in some states and for some uses. In some orchards, for instance, there are few if any feasible weed management alternatives to glyphosate. In areas where weed management options other than glyphosate are available, APHIS should examine the environmental effects of switching from glyphosate to more toxic herbicides, such as 2,4-D, dicamba and others.

Citation of selected anecdotal reports from weed scientists in certain areas (as cited in the FONSI/EA) does not constitute an EIS-adequate analysis of this issue.

Questions in Sections (6) through (9):
These questions relate to the occurrence, impacts and management of weeds, including herbicide-resistant and specifically glyphosate-resistant weeds, in organic, conventional and glyphosate-tolerant alfalfa systems.

APHIS's assessment here should include:

1) The impacts of herbicide-resistant weeds, particularly glyphosate-resistant weeds, on both alfalfa growers and growers of other crops whose fields might become infested;

2) A projection of likely glyphosate usage on alfalfa with introduction of RR alfalfa, and cumulative glyphosate usage on all crops;

3) A cumulative impacts assessment that includes an in-depth analysis of the historical development of glyphosate-resistant weeds and glyphosate usage, particularly as related to the introduction of other Roundup Ready crops;

4) A prospective assessment of the impacts of glyphosate-resistant weeds that accounts for the effect of introducing Roundup Ready alfalfa:
   a) In combination with the growing adoption of other Roundup Ready crops (e.g. especially Roundup Ready corn);
   b) In combination with the recent introduction of glyphosate-tolerant crops that allow for increased use of and expanded application window for glyphosate (e.g. Roundup Ready Flex cotton) (Bennett 2005); and
   c) In combination with the likely introduction in the near future of glyphosate-tolerant crops such as DuPont-Pioneer's Optimum GAT soybeans and corn that may allow for use of greater quantities of glyphosate (CFS 2007b).

5) The assessment should give particular attention to the increasingly common phenomenon of rotation between different Roundup Ready crops. APHIS should quantitatively assess crop-rotation regimes currently used with alfalfa. Rotation of alfalfa to corn, soybeans and cotton is of particular concern, since the percentage of these crops that are Roundup Ready is high and in some cases growing. Continuous selection pressure from reliance on glyphosate as the primary or sole means of weed control in crop rotation regimes involving RR alfalfa and RR corn, soybeans and cotton provide the ideal conditions for further development and spread of glyphosate-resistant weeds (Service 2007). We note that adoption of Roundup Ready corn, in particular, has risen dramatically in recent years, making analysis of the implications of the RR alfalfa-RR corn rotation for development of glyphosate-resistant weeds particularly important.

6) The assessment should examine recent trends in the use of herbicides other than glyphosate (either separately or in tank mixes with glyphosate) to control glyphosate-resistant weeds

7) The assessment should consider the cumulative impacts on weed control costs of the introduction of RR alfalfa against the backdrop of currently grown RR crops, for both growers of alfalfa and growers of other crops.

8) The assessment should address not only the glyphosate-resistant weed populations cited by the Weed Science Society of America (WSSA 2007) in the U.S. (8 species with confirmed glyphosate-resistant biotypes), but also encompass other weed species that have biotypes with confirmed glyphosate-resistance in other countries (5 additional weed species), as well as other weed species that are becoming difficult to control with glyphosate, such as lambs quarters and quack grass (for discussion, see CFS 2005). We note that many of these weeds are important alfalfa weeds.

9) APHIS should assess the potential for spread of glyphosate-resistant weeds via resistant weed seed present in alfalfa seed, and how this might be exacerbated by introduction of RR alfalfa. We note that the small size of alfalfa seed makes it difficult to fully remove weed seed from alfalfa seed in standard cleaning operations (certification standards allow up to 0.2% weed seed in alfalfa seed). Resistant weed seed could be spread by planting certified alfalfa seed, or by unintentional alfalfa/weed seed dispersal during transport of seed/hay, etc.

10) The assessment of glyphosate-resistant weed management options should be a real-world analysis. That is, it should be informed by an historical assessment of the success or failure of past efforts to limit the spread of resistant weeds through voluntary weed management or stewardship programs. It is not sufficient to sketch out theoretical measures or "best management practices" that may limit the spread of glyphosate-resistant weeds if followed perfectly, if in fact history demonstrates that such programs have not been effective.

11) For this reason, the assessment should not be restricted to evaluation of potential voluntary weed resistance management or stewardship plans (e.g. the Addendum to section VIII of the petition), but rather also present one or several scenarios incorporating ***mandatory*** herbicide-resistant weed management programs administered by APHIS.

We note that APHIS has repeatedly failed to provide anything approaching an adequate analysis of herbicide-resistant weeds and associated herbicide use in past decision documents. In particular, APHIS's treatment of herbicide-resistant weeds in its programmatic EIS for regulation of genetically engineered crops was grossly deficient (for critique, see CFS 2007a, incorporated here by reference). A much more serious, fact-based assessment is called for in this EIS.

Questions in Section (10)

This set of questions addresses gene flow from Roundup Ready alfalfa to conventional, organic and feral alfalfa (henceforth, collectively referred to as "non-RR alfalfa") and means to control or manage it.

APHIS should conduct a systematic assessment of gene flow, beginning with identification of all known or conceivable points in the alfalfa seed and forage production process at which Roundup Ready alfalfa seed or the Roundup Ready trait could enter conventional or organic alfalfa. This assessment should include indirect RR trait transfer via establishment of RR-trait bearing alfalfa on agricultural lands, developed areas and natural areas, and subsequent transfer of the trait back to non-RR alfalfa. This assessment should address:

1) Pollination of conventional, organic and feral alfalfa by pollinators bearing RR alfalfa pollen. APHIS should do thorough surveys of natural pollinators, as well as pollinators introduced for pollination of alfalfa and other crops, in each area where alfalfa is grown. APHIS should collect the best available information on the pollination range of various pollinators, or develop new data where presently available information is inadequate. Assessments of RR alfalfa gene flow via cross-pollination should be based on the longest reported pollination distances.

2) Dispersal of RR seed to areas outside the RR alfalfa field by wind (including areas directly bordering fields, and taking account of the small size and light weight of alfalfa seed), undigested seed excreted by livestock and birds that have consumed RR alfalfa seed, and irrigation water. This assessment should consider seed dispersal in extreme weather conditions (e.g. severe weather events, high winds).

3) RR seed blown off transport trucks carrying RR alfalfa seed or forage. This assessment should include a projection of the magnitude of RR alfalfa escape to be expected, informed by an analysis of the provenance of currently-existing feral alfalfa populations, which many believe arose from escape of alfalfa seed during transport of alfalfa forage harvests, and subsequent naturalization. This analysis should be carried out for both RR alfalfa seed and forage. Forage as a source of RR seed should be analyzed based on real-world data, and cannot be dismissed with reference to typical alfalfa harvesting patterns, since alfalfa forage is sometimes not cut before seed sets due to adverse weather or time constraints.

4) Transfer of RR seed residues in harvesting or planting equipment that is subsequently used to harvest or plant non-RR alfalfa.

5) Transfer of RR seed residues from seed cleaning facilities into conventional seed that is subsequently cleaned at the same facility. For 4) and 5), APHIS should assess the real-world feasibility of thoroughly removing RR seed residues from farm equipment and seed cleaning facilities, especially given the extremely small size of alfalfa seed.

6) Establishment of volunteer RR alfalfa in fields rotated from RR alfalfa seed or forage production to conventional alfalfa seed or forage production. Here, APHIS should assess the quantity of alfalfa seed left on the ground after harvest (range, not simply a "typical" figure), and the viability of such seed in various rotation scenarios. In particular, if the RR alfalfa stand is plowed under, what is the viability of unharvested seed after plowing, at soil depths of perhaps 6-12 inches, particularly of hard seed? What is the potential for subsequent plowing to bring viable seed to a soil depth that allows for sprouting? We note that RR alfalfa has larger quantities of hard seed than conventional alfalfa under certain environmental or soil conditions, as indicated in Monsanto's petition; thus, this analysis requires further study of the soil or other environmental factors fostering increased hard seed prevalence in RR alfalfa.

7) Establishment of volunteer RR alfalfa in or near fields rotated from RR alfalfa seed or forage production to other RR crops (e.g. corn, cotton, soybeans, canola). This assessment should be informed by a quantitative breakdown of the acreage of current alfalfa rotated to Roundup Ready versions of each of these crops. It should also include a projection of the increased acreage of Roundup Ready crops following RR alfalfa to be expected in the future, based on current trends in adoption of RR crops (particularly Roundup Ready corn and sugar beets). The assessment should also take account of the trend to increasing reliance on glyphosate as the primary or sole means of weed control in RR cropping systems (Service 2007), which would tend to favor the survival of volunteer RR alfalfa.

8) Transfer of the glyphosate-tolerance trait from volunteer RR alfalfa or feral alfalfa that has acquired the glyphosate-tolerance trait, back to non-RR alfalfa.

APHIS should provide a quantitative or semi-quantitative assessment of the gene flow potential associated with each of the modes or points identified above, and any others that are relevant. Where credible, independent data are lacking for such an assessment, APHIS should conduct or commission independent parties to conduct studies to gather such data.

Despite the short history of RR alfalfa cultivation, particularly of larger-scale plantings, the RR trait has already shown up at least several times in conventional alfalfa seed. Cal/West Seeds reported that conventional alfalfa seed grown for it in Wyoming, California and Washington in 2005 was found to be contaminated with the RR trait. In 2006, Dairyland Seed reported the RR trait in conventional seed grown for it in Montana, Wyoming and Idaho (Jenkins 2007). APHIS should commission testing of a representative range of conventional alfalfa seed varieties in various alfalfa-producing regions to determine the extent of RR trait presence, and determine the route and cause of contamination wherever possible. At the very least, APHIS should conduct an assessment of the episodes noted above and any other similar episodes of which it is aware to determine the route and cause of contamination in each case. This analysis should be used to inform APHIS's assessment of gene flow potential and the efficacy or lack of efficacy of stewardship measures to prevent it.

APHIS should also examine the history of transgenic contamination of other crops (e.g. canola, corn and soybeans) to provide further real-world context in assessing the potential for gene flow from RR alfalfa to non-RR alfalfa. There is widespread presence of transgenic content in certified conventional soybean, corn and canola seed (UCS 2004), but little or no explanation of how precisely that has occurred. This analysis should consider certified seed that farmers purchase for planting as well as breeder and foundation seed stocks. In particular, APHIS should assess the reasons for the widespread presence of transgenic canola in certified conventional canola seed (UCS 2004; Smyth et al 2002). This assessment would be especially informative for APHIS's assessment of RR alfalfa given the similarities of canola and alfalfa in several key respects that have gene flow implications (small seed, insect-pollinated over several miles, existence of sexually-compatible wild/feral relatives).

Based on the real-world analysis suggested above, gene flow from Roundup Ready alfalfa to conventional or organic alfalfa should be projected as a function of the extent of RR alfalfa adoption, since it is widely acknowledged that gene outflow increases with the size of the gene source (RR alfalfa acreage). APHIS should develop several scenarios projecting the extent of transgenic presence in conventional alfalfa to be expected with different RR alfalfa adoption rates over the next decade.

As regards the question:
"To what extent can organic or conventional alfalfa farmers prevent their crops from being commingled with unwanted, unintended, or unexpected glyphosate-tolerant alfalfa?"

This question wrongly places the burden for preventing contamination on growers of existing alfalfa varieties. Instead, the question should be:

"To what extent, if any, can or will RR alfalfa growers prevent their crop from contaminating organic or conventional alfalfa fields under realistic, field conditions?"

Questions in Sections (11) and (12)

These questions address the economies of growing organic, conventional and RR alfalfa, as well as the economic and trade impacts to be expected from the introduction of glyphosate-tolerant alfalfa. Questions addressing the economies of growing organic, conventional, or RR alfalfa should take the following factors into consideration:

1) The economies of growing RR alfalfa should include the costs of implementing effective measures to prevent (not just mitigate) transfer of the RR trait to conventional, organic and feral alfalfa. As noted above, the costs for preventing adverse economic impacts from movement of the RR trait must not externalized (i.e. foisted on growers of conventional and organic alfalfa).

2) The projected economies of growing RR alfalfa should take into account the potential for increased weed control costs due to the projected spread of glyphosate-resistant weeds in alfalfa and other crops from the additional glyphosate use and associated selection pressure exerted by it with introduction of RR alfalfa. Such increased costs will be borne not only by growers of RR alfalfa, but also by growers of conventional alfalfa and growers of other crops whose fields become infested with resistant weeds.

As a general consideration, APHIS must key its assessment to the market realities associated with the acceptance or non-acceptance of the presence of RR alfalfa or the Roundup Ready trait in conventional or organic alfalfa by purchasers of alfalfa. A growing number of alfalfa buyers, both domestic and foreign, wish to avoid alfalfa supplies with any level of transgenic content. This applies particularly to organic alfalfa, but also to conventional alfalfa. APHIS must not assume market acceptance based on official foreign government approval of RR alfalfa, or tolerance levels that sanction its low-level presence. Likewise, APHIS must not assume market acceptance for organic alfalfa with low-level transgenic presence based on process-based organic certification standards. There is a long history of market rejection of GM crops, or conventional/organic supplies with GM content, irrespective of governmental approval of the relevant GM crops, and irrespective of organic certification standards that do not automatically strip an organic producer of his/her organic status for low-level presence of the same.

Some issues that APHIS should address include:

1) Survey domestic and foreign alfalfa purchasers to determine their rank-order preference for organic alfalfa, conventional alfalfa, and Roundup Ready alfalfa. Survey prices offered for each type of alfalfa. Project prices offered for each type of alfalfa at least one decade into the future, taking account of current demand trends, particularly demand for organic alfalfa.

2) Assess, and project at least one decade into the future, the loss of premiums for organic alfalfa resulting from the presence of the glyphosate-tolerance trait in non-RR alfalfa supplies. Take account of the rising demand for organic alfalfa.

3) Assess, and project as above, the effect that the presence of RR alfalfa in organic or GM-free conventional supplies would have on organic or GM-free premiums and the financial viability of organic alfalfa or GM-free alfalfa cultivation with reduced premiums.

4) Assess opportunity costs from loss of the option to cultivate GM-free conventional and organic alfalfa occasioned by the introduction of RR alfalfa, and project at least one decade into the future, taking into account the projected adoption rate of RR alfalfa as well as the growth in demand for organic alfalfa. This should include an assessment of the likely shift of organic/GM-free conventional alfalfa seed and forage production to countries whose farmers can guarantee GM-free supplies.

5) APHIS should assess the costs of testing alfalfa forage and alfalfa seed meant for GM-free or organic markets for GM content. This assessment should include testing costs now borne by conventional alfalfa/organic seed dealers as well as testing costs borne by farmers serving GM-free or organic markets (see Jenkins 2007 for reference to Vince Holtz, alfalfa seed grower who tests for GM content). This assessment should include cost projections based on projected adoption of RR alfalfa at least one decade into the future.

6) APHIS should also assess costs borne by conventional/organic farmers in attempting to avoid transgenic contamination, including but not limited to: purchase or lease of land to create larger buffers separating them from RR alfalfa producers; and any other changes in cultivation practices (e.g. temporal isolation) forced on conventional/organic growers to avoid transgenic contamination. This assessment should include cost projections based on projected adoption of RR alfalfa at least one decade into the future.

7) APHIS should formulate and analyze various mechanisms by which RR alfalfa growers and/or companies selling RR alfalfa can be required to compensate organic and conventional alfalfa farmers for loss of markets or loss of income (i.e. premiums) from transgenic contamination of alfalfa supplies for markets that reject such supplies due to presence of GM content

8) APHIS should also formulate and analyze various mechanisms by which RR alfalfa growers and RR alfalfa seed suppliers can be required to compensate organic and conventional growers for their increased expenses associated with GM content testing and attempts to avoid transgenic contamination of their alfalfa, as outlined above.

9) APHIS should assess the long-term consequences of RR alfalfa introduction on the viability of private and any remaining public-sector alfalfa breeding programs in the U.S. Based on past experience with other GM crops (see next point), one can expect rampant contamination of conventional alfalfa seed stocks, even at breeder and foundation seed levels, with the glyphosate-tolerance trait. What are the costs of breeding out an inadvertently-introduced RR alfalfa trait? What are the financial consequences of contamination for U.S. breeders of conventional alfalfa? What losses may be expected from a shift of alfalfa breeding programs to other countries where transgenic contamination of experimental alfalfa varieties can be avoided? What are the long-term consequences to U.S. conventional and organic alfalfa producers of loss of U.S.-based alfalfa breeding programs?

10) In analyzing the issues presented above, APHIS should inform its assessment by examining the full range of economic impacts (including lost income, opportunity costs, etc.) that introduction of other transgenic crops have had on growers of conventional/ organic versions of the same. For instance:

    a) Assess the economic impacts of transgenic canola introduction on conventional and organic growers in Canada (see, for example, Smyth et al 2002) and the U.S. As noted above, canola bears many key similarities to alfalfa, including small seed size, insect-pollination over miles, and existence of sexually-compatible wild/feral relatives.

    b) Examine the economic impacts on conventional and organic corn growers of widespread transgenic contamination of conventional and organic corn in the U.S. Impacts to be addressed include market rejection of GM corn and GM-corn contaminated conventional/organic supplies in Europe and other countries; loss of organic markets due to U.S. organic corn farmers' difficulty or inability to produce GM-free corn; and shift of organic corn production overseas where it can be grown without transgenic contamination.

    c) Assess the economic impacts from the difficulty of growing GM-free organic soybeans in the U.S. This should include an assessment of why the U.S., the world's leading exporter of soybeans, must import roughly half of the organic soy needed to meet domestic demand, despite the premiums offered for GM soy production. One issue that should be addressed is the range and quality of soybeans seed options suitable for organic soybean production.

    d) Assess the economic impacts on rice growers from contamination of their conventional supplies with LibertyLink 601, LibertyLink604 and LibertyLink 62 transgenic content.

In conducting this assessment, we urge USDA to contact dealers in organic and GM-free supplies, such as Illinois-based Clarkson Grain Co. For contamination of certified conventional seeds with GM content, see UCS (2004). We note that in past assessments of GM crop deregulation petitions, APHIS has shown a disturbing ignorance or disregard of the impacts of transgenic crop introduction on organic/GM-free crop cultivation and marketing.

APHIS also poses the following question:

What are the potential changes in the choice of seeds available for organic and conventional alfalfa farmers that may occur with the use of glyphosate-tolerant alfalfa?

In addition to changes in seed choices for organic and conventional alfalfa growers due to widespread transgenic contamination (discussed above), APHIS should also address the issue of market power in the alfalfa seed industry and its potential effect on choice of seeds. It has been reported that Forage Genetics has purchased many alfalfa breeding programs, such as Northrup King's, Waterman Lewis, and America's Alfalfa (ABI). The greater the proportion of quality alfalfa germplasm owned by Forage Genetics and Monsanto, the less these companies have to fear from competitors offering conventional varieties. This market power would allow them to phase out quality conventional alfalfa seed varieties, "forcing" adoption of RR varieties even by growers who would prefer to continue buying conventional seed. We note that market power in the cotton seed industry is leading to just this outcome, with drastically declining choices of both quality conventional cotton seed and quality seed that contains just one GM-trait (which is less profitable than the dual-trait stacks that are replacing them), despite continued demand for these more affordable, but less profitable, types of seed (Freese 2007). APHIS should seek assistance from the USDA's Economic Research Service in conducting an assessment of the alfalfa seed industry to assess the potential for declining availability of quality conventional seeds for conventional producers due to market power in the event that RR alfalfa is deregulated.

<u>Questions in Section (13)</u>

These questions address the potential impacts from increased use of glyphosate with introduction of Roundup Ready alfalfa, including cumulative impacts of such use in combination with the existing uses of glyphosate.

APHIS should provide a thorough analysis of trends in agricultural use of glyphosate. APHIS should quantitatively assess glyphosate usage for individual crops (field crops, but also vegetables, orchard-grown fruits, etc.) over the past two decades. APHIS is urged to use official USDA data for this analysis, including data from the National Agricultural Statistics Service Agricultural Chemical Usage reports. Where possible, regional trends in glyphosate use should be assessed.

APHIS should examine the extent to which glyphosate usage has been increased due to the introduction of past Roundup Ready crops (soybeans, cotton, corn and canola). This analysis should include trends in Roundup Ready crop adoption since their introduction. Both overall glyphosate use and glyphosate use per acre per season should be determined, broken down by conventional vs. Roundup Ready versions (see, for instance, Benbrook 2004).

Informed by this analysis, APHIS should project glyphosate usage (on alfalfa and other crops) at least one decade into the future if:

1) RR alfalfa is not deregulated

2) RR alfalfa is deregulated: This should include several scenarios involving different rates of RR alfalfa adoption, informed by alfalfa-specific factors as well as historical trends with other RR crops
3) For all other alternative studied by APHIS in the EIS

This analysis should account for:

1) Trends in glyphosate-tolerant crop adoption (particularly corn and sugar beets)
2) Introduction of new Roundup Ready crops that foster or allow for greater usage of glyphosate – higher rates of application as well as extended time period during which glyphosate can be applied over the top. One example of such a crop is Roundup Ready Flex cotton.
3) Pending introduction of new glyphosate-tolerant crops by Monsanto and other firms (e.g. DuPont-Pioneer's Optimum GAT soybeans and corn; Bayer's new glyphosate-tolerant cotton, both pending deregulation), taking into account any greater usage of glyphosate that may be facilitated by such crops.
4) Research and development of new glyphosate-tolerant crops, as reflected, for instance, in USDA GM crop field trial data, which may lead to future introduction of new glyphosate-tolerant crops.

APHIS should address the potential impacts of glyphosate and Roundup use associated with introduction of RR alfalfa together with projected uses on other crops on amphibian populations, particularly frogs. We note that this assessment should include analysis of various glyphosate formulations, since some (e.g. versions of Roundup) have been shown to have greater toxicity to amphibians than glyphosate alone. Recent studies (Relyea 2005a, 2005b) demonstrate that common versions of Roundup herbicide that contain a surfactant (i.e. POEA, or polyethoxylated tallowamine) to aid penetration of the active ingredient (glyphosate) into plant tissue are extremely toxic to the tadpoles and juvenile stages of certain species of frogs, killing 96-100% of tadpoles after three weeks exposure and 68-86% of the juveniles after just one day.

APHIS should also assess the state of the science with regard to the impacts of glyphosate application to glyphosate-tolerant crops on soil microorganisms, nutrient uptake, susceptibility to diseases, food and feed quality and plant yield. A growing body of research suggests that application of glyphosate may make RR plants more susceptible to disease and prone to mineral deficiencies than conventional crops, as well as reducing their yields.

When Roundup is sprayed on RR crops, much of the herbicide ends up on the surface of the soil, where it is degraded by microorganisms. However, some is absorbed by the plant and distributed throughout its tissues. Small amounts of glyphosate "leak" from the roots of RR plants and spread throughout the surrounding soil (Motavalli et al 2004; Kremer et al 2005; Neumann et al 2006). This root zone is home to diverse soil organisms, such as bacteria and fungi, that play critical roles in plant health and disease; and it is also where the roots absorb essential nutrients from the soil, often with the help of microorganisms.

The presence of glyphosate in the root zone of RR crops can have several effects. First, it promotes the growth of certain plant disease organisms that reside in the soil, such as *Fusarium* fungi (Kremer et al 2005). Even non-RR crops planted in fields previously treated with glyphosate are more likely to be damaged by fungal diseases such as Fusarium head blight, as has been demonstrated with wheat in Canada (Fernandez et al 2005). This research suggests that glyphosate has long-term effects that persist even after its use has been discontinued. Second, glyphosate can alter the community of soil microorganisms, interfering with the plant's absorption of important nutrients. For instance, glyphosate's toxicity to nitrogen-fixing bacteria in the soil can depress the absorption of nitrogen by RR soybeans under certain conditions, such as water deficiency, and thereby reduce yield (King et al 2001). Some scientists believe that this and other nutrient-robbing effects may account for the roughly 6% lower yields of RR versus conventional soybeans (Elmore 2000; Benbrook 2001).

Other research shows that Roundup Ready crops themselves are less efficient at taking up essential minerals such as manganese through their roots (Gordon 2006), and that glyphosate inside plant tissues can make such minerals unavailable to the plant (Bernards et al 2005). The resultant mineral deficiencies have been implicated in various problems, from increased disease susceptibility to inhibition of photosynthesis.

While much of this research involves RR soybeans, similar impacts may occur with RR alfalfa. In this assessment, USDA must develop data on RR alfalfa that has been treated with glyphosate. This is necessary because many of the impacts noted above are found only when the RR plant has been treated with glyphosate.

APHIS should assess potential adverse impacts from application of glyphosate to RR alfalfa with various glyphosate application methods. Glyphosate spray drift can significantly impair or kill conventional crops that are grown in the vicinity of a glyphosate-treated field. Drift can adversely affect crops grown at significant distances from the glyphosate-sprayed field, and is particularly a problem when glyphosate is applied by plane (see Freese 2007, Section 2.4 for discussion and references with respect to RR cotton). Approximately 7% of alfalfa hay acreage that is treated with herbicides is treated by aerial application of the herbicide (Hower et al 1999), a significant acreage. APHIS should also assess how spray drift from aerial application of glyphosate to RR alfalfa might "force" nearby growers of conventional alfalfa or other conventional crops to purchase RR alfalfa or RR versions of other crops not because they desire the RR trait, but rather to protect their crop from damage due to spray drift.

APHIS asks: Does the level of glyphosate tolerance within glyphosate-tolerant alfalfa plants have a major impact on the amount of glyphosate applied on the glyphosate-tolerant alfalfa crop on a routine basis?

This assessment should include projections of the amount of glyphosate applied to RR alfalfa in the future, including increased rates of application due to the expected emergence of glyphosate-resistant weeds. We note that glyphosate usage per acre of soybeans has increased dramatically since the introduction of RR soybeans, in the later years due chiefly to efforts to control glyphosate-resistant weeds.

Questions in Section (14)
These questions relate to the potential impacts of glyphosate-tolerant alfalfa introduction on threatened or endangered species and their habitat.

Assessment of the potential impacts of glyphosate-tolerant alfalfa introduction on threatened and endangered species and their habitat must include analysis of the impacts of increased glyphosate usage that will accompany it. This is because Roundup Ready crops are invariably cultivated with use of glyphosate-based herbicides, the chemical they are specifically engineered to tolerate. The assessment should also consider cumulative impacts from glyphosate use associated with RR alfalfa together with that from existing uses. The assessment should consider not only glyphosate, but commercial glyphosate formulations (e.g. those containing polyethoxylated tallowamine), which have been shown to have greater toxicity than glyphosate alone to amphibians and other organisms.

APHIS's assessment should be fully compliant with the procedural duties of the Endangered Species Act (ESA), including consultation with U.S. Fish and Wildlife Service (FSW) to identify any threatened or endangered species in all areas where RR alfalfa might be cultivated, at least all areas where conventional alfalfa is currently grown; preparation of a biological assessment; and formal consultation with FSW. APHIS should also consult with the U.S. Environmental Protection Agency (EPA), and in particular consider its Reregistration Eligibility Decision (RED) on glyphosate, which states that "many endangered plants may be at risk from the use of glyphosate…." APHIS should give particular attention to the threatened and endangered plant and animal species cited in Plaintiff's Motion for Summary Judgment.

APHIS should assess the impacts on threatened or endangered species of glyphosate use associated with RR alfalfa on plants growing in or near alfalfa fields, taking account of nearby land susceptible to glyphosate spray drift. APHIS's assessment should include projection of the impacts to be expected based on projected increased use of glyphosate associated with various RR alfalfa adoption rates at least one decade into the future.

Question in Section (15):
What are the potential health and safety risks to field workers or other workers that would come into contact with glyphosate-tolerant alfalfa?

This question needs to be reformulated to include the health and safety risks to field workers or other workers from the use of glyphosate directly associated with cultivation of glyphosate-tolerant alfalfa. For instance, APHIS should take account of reports demonstrating that glyphosate-based herbicides have numerous health impacts on field workers (Cox 1998), as well as scientific studies suggesting adverse health impacts on children of glyphosate applicators (Garry et al 2002).

Questions in Section (16)
"Can any of the potential negative environmental impacts resulting from the deregulation of glyphosate-tolerant alfalfa be reasonably mitigated and what is the likelihood that mitigation measures will be successfully implemented?"

APHIS must consider impacts to the human environment from deregulation of glyphosate-tolerant alfalfa, including social and economic impacts associated with unintentional transfer of the RR gene and trait to non-RR alfalfa (discussed above). The standard for what constitutes "mitigation" or "reasonable mitigation" must be preservation of the option to grow non-RR alfalfa that is not contaminated with the RR gene in any and all areas where RR alfalfa seed or forage is grown. APHIS must assess the likelihood that such mitigation measures will be successfully implemented based on a real-world analysis that takes account of commercial alfalfa production practices. APHIS's assessment should include analysis of the efficacy of various stewardship measures given reasonable, fact-based estimates of the frequency at which farmers will NOT comply with them. For instance, APHIS must not assume that RR alfalfa forage growers will invariably harvest it before seed sets because that is the typical practice. Instead, allowance must be made, based on real-world data, for farmers' frequent failure to harvest forage alfalfa in a timely manner before seed sets due to adverse weather conditions or time constraints. This is merely one example. APHIS should make such allowances for inevitable deviations from stewardship measures for all phases of the cultivation, harvesting, transport and marketing of RR alfalfa.

"The EIS will consider the stewardship measures outlined in the Addendum to section VIII of the petition, as well as any other mitigation measures APHIS considers applicable and viable. Such measures, some of which may be outside the jurisdiction of APHIS, are designed to reduce inadvertent gene flow of glyphosate-tolerant alfalfa to negligible levels as well as to monitor and minimize the potential development of glyphosate-tolerant weeds."

Voluntary stewardship programs have often proven grossly deficient in achieving their goals. A prime example is the gross failure of voluntary stewardship programs to slow the spread of glyphosate-resistant weeds. In view of the likely failure of voluntary stewardship, APHIS should formulate **mandatory** stewardship management plans with the goals of preventing transfer of the RR trait to non-RR alfalfa and stopping the further spread of glyphosate-resistant weeds. Such plans should be administered by APHIS, perhaps in collaboration with the EPA, and include enforcement mechanisms allowing for APHIS-imposed fines for non-compliance and compensation to non-RR alfalfa growers for financial losses or costs associated with the unintended presence of RR alfalfa in their crops. APHIS must not rely on voluntary stewardship measures developed by interested third parties that it cannot enforce.

The level of RR alfalfa's presence in non-RR alfalfa that is considered "negligible" will likely be very different for different parties. What APHIS or an RR alfalfa seed producer or farmer may consider a "negligible level" of RR alfalfa contamination may be unacceptable to an organic alfalfa grower. APHIS should survey a wide range of alfalfa growers and seed suppliers who do not wish to grow RR alfalfa to determine what level, if any, of RR alfalfa presence in non-RR alfalfa is acceptable to them. We note that APHIS has a duty to preserve the option of farmers to grow non-RR alfalfa that is not contaminated with the RR trait.

Question in Section (17)
What are the impacts of the mitigation measures on coexistence with organic and conventional alfalfa production and export markets?

This question is addressed in comments on various sections above.

Respectfully submitted,

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