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Comments to USDA on Environmental Assessment for the Determination of Nonregulated Status for Monsanto Co. And Forage Genetics Roundup Ready Alfalfa (Events J101 and J163)

USDA/APHIS is evaluating a petition to deregulate Roundup Ready (RR) alfalfa containing a CP4 EPSPS gene that confers tolerance to glyphosate-based herbicides, designated EventsJ101 and J163, and has issued an environmental assessment (EA). Pursuant to the USDA's November 24, 2004, Federal Register notice, vol. 69, no. 226, 68300-68301, the Center for Food Safety (CFS) submits the following comments concerning the inadequacy of the agency's Environmental Assessment (EA) accompanying the Monsanto Co. and Forage Genetics petition for deregulation. CFS appreciates the opportunity to comment on the EA of Roundup Ready alfalfa, as well as the petition for deregulation, and to raise a number of issues concerning possible environmental impact that are not adequately addressed by the EA or the petition.

Center for Food Safety believes that the current U.S. regulatory structure does not provide adequate risk assessment of either human or environmental safety of genetically engineered (GE) crops, and therefore no GE crops should be commercialized until U.S. regulations can assure that all GE crops are safe. Short of such a blanket prohibition on GE crop commercialization and given the potential adoption rates and acreage to be used for RR alfalfa, CFS finds that the significant unanswered or inadequately answered safety questions that our analysis has uncovered warrant a full environmental impact statement (EIS) under the National Environmental Protection Act (NEPA). CFS also makes several recommendations for risk management actions that should be undertaken if APHIS decides to deregulate RR alfalfa. Deregulation should not be allowed until these concerns are throughly addressed.

In general, Monsanto claims in support of its petition to deregulate RR alfalfa (hereafter, petition) that there has been no reported adverse environmental impact from the commercial planting of other Roundup Ready crops. However, even defined narrowly, the increasing number and extent of glyphosate resistant weeds constitutes an environmental impact. Monsanto asserts that glyphosate is generally safer than many other available herbicides, and resistance to glyphosate often leads to replacement or, more likely, supplementation with other herbicides. This may constitute an increased risk. For example, a recent report indicates that herbicide use on RR crops has surpassed herbicide use on their conventional counterparts in the past several years for a number of reasons including glyphosate resistant weeds and weed shifts.[1, 2] Therefore, inadequate action in preventing resistance to glyphosate leads to increasing environmental harm due to increased use of glyphosate and other herbicides. In addition, glyphosate resistant weeds may impact growers of other crops if weeds that they control with glyphosate become resistant. The issue of herbicide resistance will be considered more throughly below.

Summary and Recommendations

Alfalfa is a major crop, the most important forage crop in the U.S., and is planted on approximately 23 million acres annually in the U.S. in pure plantings where RR alfalfa may primarily be used. Because of the large area planted, environmental harm due to changes in the cultivation of alfalfa could be substantial. If RR alfalfa is adopted at levels comparable to other RR crops, a majority of commercialized alfalfa may contain the RR trait within several years. Furthermore, APHIS has not deregulated any other perennial crop to date, and the perennial growth habit raises issues not usually encountered in annual or biennial crops. For these reasons, it is critical for APHIS to perform a thorough EIS of RR alfalfa.

To the contrary, the EA produced by APHIS only superficially considers several possible environmental impacts. First, evidence of a possible substantially increased percentage of hard seed that may increase seed dormancy and possibly weediness in feral alfalfa is not considered. APHIS incorrectly asserts that no significant differences between RR alfalfa and control plants were found, despite substantial, consistent and statistically significant increases of several fold in the percentage of hard seeds in one of the test years. Second, gene flow to feral or wild alfalfa is not adequately addressed. Third, the important issue of weed resistance to glyphosate is not considered at all. In sum, APHIS accepted the evaluation of the petition with no comprehensive independent evaluation. For example:

- APHIS did not evaluate data that suggest that RR alfalfa may produce substantially more hard seed than conventional alfalfa, which may increase weediness in wild or feral alfalfa.

The percentage of hard seed was approximately two to four fold higher for either of the two RR alfalfa events and a variety containing both glyphosate resistance events (three different RR alfalfa genotypes), compared to either the near isogenic conventional counterpart or several other conventional counterparts during the first years of testing. Although not observed in two subsequent years, Monsanto's explanation for the discrepancy is inadequate, and the actual levels of hard seed in RR alfalfa can only be established with further testing. Even Monsanto remarked increased dormancy, which hard seed causes, may contribute to increased weediness (petition, p. 114). The failure to analyze these data by APHIS is not justified.

- APHIS does not adequately consider potential weediness issues for feral alfalfa or gene flow of the RR trait into feral alfalfa. Although feral alfalfa does not seem to be a substantial weed problem in some settings, APHIS does not consider evidence that feral alfalfa may be a significant weed problem in other environments. A national USDA/ National Resource Conservation Service (NCRS) plant database comments that feral alfalfa can displace native species and is invasive in some environmants, and another plant authority lists feral alfalfa as invasive. APHIS did not consider these sources in its evaluation, and Monsanto mis-cited the NRCS in remarking that feral alfalfa is not considered a weed problem. Even if alfalfa was not an important weed, increased hard seed may increase the weediness of feral alfalfa in some environments. It is important to further consider the potential for gene flow from RR alfalfa to feral or wild alfalfa to produce more problematic weeds. In addition, APHIS should more thoroughly consider the importance of glyphosate in controlling feral alfalfa in natural environments.

- APHIS improperly narrowed the scope of the EA by stating that it would not consider effects of foreseeable changes in the use of glyphosate in connection with deregulation of the proposed GE alfalfa (EA, p. 3, 3rd par. - suggesting EPA will consider the matter.) The definition of effects to be analyzed in the Council on Environmental Quality's NEPA-implementing regulations require full consideration of all foreseeable results of the proposed action:

> *50 CFR Sec. 1508.8 "Effects".*
> *Effects include:*
> *(a) Direct effects, which are caused by the action and occur at the same time and place.*
> *(b) Indirect effects, which are caused by the action and are later in time or farther removed in distance, but are still reasonably foreseeable. Indirect effects may include growth inducing effects and other effects related to induced changes in the*

pattern of land use, population density or growth rate, and related effects on air and water and other natural systems, including ecosystems.

Effects and impacts as used in these regulations are synonymous. Effects includes ecological (such as the effects on natural resources and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, or cumulative. Effects may also include those resulting from actions which may have both beneficial and detrimental effects, even if on balance the agency believes that the effect will be beneficial.

- In the case of foreseeable substantial increases in glyphosate use associated with deregulating this product, the most obvious impacts that must be assessed are: 1) the foreseeable selection for glyphosate tolerance weeds and the long-term environmental and ecological impacts of this; and 2) the human health impacts associated with foreseeable use and misuse of this product. (See discussion of health impacts under Detailed Considerations, below.) These plainly fit under the definition contained in section 1508.8, and APHIS cannot define them away to EPA. APHIS recently and correctly recognized in another similar deregulation proposal that, notwithstanding EPA's role, increased glyphosate tolerance is a matter within the scope of APHIS' required NEPA analysis. The agency's Sept. 21, 2004, Federal Register announcement, Docket No. 031012 , Notice of Intent to Prepare an Environmental Impact Statement and Proposed Scope of Study on the Monsanto/Scotts Petition for Deregulation of Genetically Engineered Glyphosate-Tolerant Creeping Bentgrass, states that the scope of the effects analysis includes:

  Will adoption of glyphosate-tolerant creeping bentgrass, coupled with the use of glyphosate products that might be registered for use on this bentgrass, result in the selection of weeds that are tolerant of doses of glyphosate that were previously lethal, or result in a shift to weeds that are more difficult to control? If so, what are the likely weed species, over what time frame would selection occur, and how likely would the weeds spread to and persist in other locations? What alternatives are available to control them in situations where they are unwanted, and will those alternative control methods have significant adverse impacts on the environment?

- APHIS must remedy this defect in the scope of the alfalfa EA and make it as broad as the creeping bentgrass deregulation analysis. The mere fact that the bentgrass petition involves a full EIS makes no difference in the required analysis under the CEQ implementing regulations. What amounts to an effect in an EIS is no different from what amounts to an effect in an EA; making such a distinction plainly would be "arbitrary and capricious" and subject to legal challenge.

- Appendix A make a devious attempt to "half-way" include the tolerance issue in the EA as if it were a side matter that can be addressed under "alfalfa biology". The statement is made on p. 21, 1st full par., that "... care should be taken with other glyphosate tolerant crops that may be chosen to follow glyphosate tolerant alfalfa". Not only does that not belong in that Appendix, as it obviously has nothing to do with the topic of the Appendix, it does not substitute for analysis. What that sentence raises is plainly an indirect and cumulative effects issue that needs to be assessed, under 40 CFR § 1508.8, above.

- Furthermore, APHIS makes several comments in its EA concerning the relative safety of herbicides currently used on alfalfa compared to Roundup, and even comments on the benefits of using Roundup as a means to forestall resistance to *other* herbicides. Clearly, APHIS can consider the environmental implications of herbicides when it chooses to do so. The refusal to consider the environmental consequences of herbicides used to control weeds resistant to glyphosate therefore appears at the least to be highly selective, and possibly shows a bias toward deregulation.

For all of these reasons, CFS believes that deregulation should not be granted, and RR alfalfa should be subjected to a full EIS to evaluate the concerns raised in these comments. If APHIS decides to grant deregulation, several restrictions should be placed on the cultivation of RR alfalfa:

1. Further testing of RR alfalfa needs to be performed to confirm or repudiate the dramatic increase of hard seed observed in the first year of testing. The discrepancy between data from the first and subsequent years may be explained by differences in environmental conditions between the years combined with different responses of RR alfalfa to those environmental conditions. This hypothesis is supported by the known sensitivity of the production of hard seed to environmental conditions, and the increased hard seed in both RR alfalfa events, as well as in another variety containing both events, during the first year of testing. Further trials are needed that explore the effects of a range of environmental conditions on hard seed production in RR alfalfa.

2. Gene flow to feral alfalfa needs to be more carefully evaluated. It is clear from considerable data, including from Monsanto, that gene flow will occur. Therefore, it is imperative to thoroughly explore reports that feral alfalfa may be a significant weed in some environments. Furthermore, if additional testing reveals that RR alfalfa produces substantially more hard seed than conventional varieties, then testing needs to be performed to determine whether

that trait could make feral alfalfa a more aggressive weed in some environments.

3. A mandatory resistance management program to prevent the development of Roundup resistant weeds should be implemented. Developing such a program should include active participation of alfalfa growers and farmers of other crops that may be impacted by weeds that develop resistance due to glyphosate overuse in RR crops, academic weed scientists, and APHIS, and should consider mandatory rotation of herbicide types (modes of action), integrated weed management, and other means to prevent resistance.

Until APHIS performs a full EIS on RR alfalfa, it is failing to adequately provide the environmental protection that is its legal mandate.

Detailed Considerations

A. RR Alfalfa Production of Hard (Dormant) Seed

Alfalfa may produce soft or hard seed. The former typically germinates shortly after planting, whereas the latter often remain dormant for one or more years. This is largely because the hard seed coat prevents water from being adsorbed by the seed. Hard seed may be induced to germinate by abrasion prior to planting.

Seed dormancy is often important for many wild plant species because by reserving some seed for germination over several years, the species increases its chances of producing plants under favorable conditions (e.g. adequate soil moisture). Many weeds exhibit various degrees of seed dormancy, and it is a trait often associated with weeds. By contrast, crops are usually desired to have a high percentage of germination in the season when it is planted to assure an adequate stand of the crop. It is believed that crops have been selected over the millennia for low dormancy. Increased dormancy in alfalfa is therefore of concern as a possible indication of increased weediness. Monsanto acknowledges that dormancy may be associated with weediness (petition, p. 114, although, as also acknowledged, dormancy by itself may not be sufficient to cause weediness).

Alfalfa growing outside of cultivation in the U.S. appears to be primarily (or entirely) feral naturalized alfalfa derived from cultivated varieties (we are not aware of data comparing percent hard seed between wild and cultivated alfalfa). It is therefore possible that feral alfalfa is deficient in hard seed production compared to wild alfalfa found in Europe and Asia Minor. Even if this is not the case, increased dormancy in U.S. feral alfalfa may lead to increased weediness.

Monsanto tested the production of hard seed in its RR alfalfa in field tests over three years, and found a substantially increased percent of hard seed in the first year of testing at all seed incubation temperatures. The percent hard seed for the two RR alfalfa events, and a third variety containing both events, was compared to a near-isogenic variety and to several other varieties. The increase in hard seed was dramatic, typically over two fold higher than the near-isogenic control and often over three fold higher than the reference varieties. Typically, the mean for either of the RR events was beyond even the range of values for the non-RR reference varieties. The increases were observed in all experiments, for both RR events separately, and for the variety containing both events.

It is notable that both independently derived RR events showed similarly increased percentages of hard seed. That suggests that the increase may be an unintended result of the CP4-EPSPS gene/protein itself rather than the insertion site or background mutations due to tissue culture used in developing the RR varieties. This is important because if true, it means that any variety that contains the RR gene may have elevated hard seed, increasing the possibility of gene transfer and that increased hard seed would occur in feral varieties.

Monsanto performed two more seasons of dormancy testing, finding that the elevated percentage of hard seed was not found in the two subsequent years. In the second year, 2002, the RR varieties had statistically consistently *lower* percentages of hard seed, but typically only about 10-15% lower. The magnitude of the differences from the first years are demonstrated by the combined data from the first two years, where the RR varieties have statistically consistently higher hard seed. The third year, under an altered protocol, showed no differences in hard seed.

Monsanto attributes the different results in the different test years to environmental effects or "....subtle differences in seed harvesting methods" (petition, p. 127), rather than the glyphosate resistance trait. However, these explanations are inadequate for several reasons.

First the magnitude and consistency of the first year's observations suggest that minor differences in test conditions may not explain the results. For example, Monsanto cites Bass (1988) as supporting the fact that environmental conditions can influence the percentage of hard seed. However, Bass observed only a 24% -69% difference in hard seed between years, while the differences in the between RR alfalfa and the near-isogenic control were typically over 200%, and the differences observed by Bass were apparently not in comparison to an internal control variety grown each year, as in the RR alfalfa experiments.

Secondly, although it is entirely possible, perhaps even likely, that the differences observed between years were due to environmental differences, the simplest explanation is that those environmental differences had a different effect on the RR alfalfa genotype than the others. Monsanto's suggestion that the environmental effects were somehow expressed independently of genotype seems less likely because the different varieties were supposedly grown under the same environmental conditions. And although it is plausible that there were consistent differences in environment (e.g. edaphic or microclimate differences) between the test varieties in the first year, that cannot be assumed, especially since those differences are supposed to be controlled by proper experimental design. For example, Monsanto describes growing the test varieties "...in close proximity at one location ...so that all materials could be grown at a **uniform** single location,..." [Emphasis added]. In addition, if such random differences between test plots occurred, it is unlikely that all of the RR varieties would always have much more hard seed than the non-RR varieties. Random environmental differences would be expected to randomly influence hard seed production in the RR and non-RR alfalfa alike.

Monsanto further argues that differences in the mechanical harvesting equipment used in the first year may explain the differences observed. Monsanto points out that different machines were used for harvesting and cleaning RR alfalfa during the first year than were used for the control varieties, but this equipment difference did not occur the second and third years. The importance of the equipment, according to Monsanto, is that the machines used with the RR varieties may have been abraded differently than the controls, accounting for the observed differences in percent hard seed (abrasion can allow better water permeability, lowering the apparent percent of hard seed). If Monsanto's argument that differences in the abrasion were responsible for the differences in percent hard seed, however, the results should have been the opposite of what was observed. That is because the harvesting and cleaning machinery used with the RR alfalfa was described as cleaning more thoroughly than the machinery used with control varieties, one would expect the apparent percentage of hard RR alfalfa seed to be *lower* not higher. One would expect more thorough cleaning to be associated with more abrasion. Therefore, if Monsanto is correct about the machines causing different levels of abrasion, then in fact the differences in observed hard seed between RR alfalfa and controls may have been *reduced* rather than increased.

Finally, Monsanto argues that even if the RR varieties do produce more hard seed, the fact that non-RR varieties produce variable hard seed without apparently increased weediness argues that it does not matter. However, the data provided by Monsanto (petition, p. 135) show that the three year average percent hard seed produced in Idaho (the state where the RR alfalfa field trials were performed) was about 26%, compared to averages of ~43% - ~71% hard seed for RR alfalfa in the first year of testing (2001) (with most values in the upper 50s% and 60s%). In other words, the differences in the means were similar to that observed between the RR alfalfa varieties and the control varieties in Monsanto's field trials. Only in Alberta, Canada (out of eleven states or provinces) , were hard seed values similar to those for RR alfalfa in Idaho.

In conclusion, none of Monsanto's arguments adequately address the dramatically increased hard seed for RR alfalfa varieties in the first year of testing. Because dormancy can be associated with weediness, it is imperative that further testing for seed hardness be performed under a variety of carefully recorded conditions. If significant increases in percent hard seed are observed in RR varieties, than additional tests should be performed replicating the environmental conditions. Preferably, such experiments should be performed by independent scientists who have experience with seed dormancy experimentation. If a higher percent of hard seed is confirmed under certain environmental conditions, further experiments determining fitness and weediness implications should be performed.

B. Gene Flow of CP4-EPSPS from Cultivated to Feral or Wild Alfalfa

Although several species in the alfalfa genus, *Medicago*, are found in the U.S. as either introduced or native species, there is no good evidence for gene flow from alfalfa to these species. On the other hand, feral alfalfa, *M. sativa* ssp. *sativa*, and yellow alfalfa (or sickle medic), *M. sativa* ssp. *falcata*, are both widely distributed in the U.S. and are considered invasive weeds in some instances.[3] [4] [5] Gene flow has been confirmed between cultivated alfalfa and wild or feral alfalfa (including ssp. *falcata*).[6] Alfalfa grown for forage is usually harvested several times a year, typically at or before approximately 10% bloom. Although this reduces the amount of pollen produced in forage fields, gene flow would still be expected if RR alfalfa is commercialized. Gene flow will also occur from alfalfa fields grown for seed production, where full flowering is allowed. Surveys by Monsanto confirm that feral alfalfa commonly occurs in close enough proximity to commercial fields in the six states surveyed to assure gene flow of the CP4-EPSPS gene to feral alfalfa. We note that it is unclear whether ssp. *falcata* was surveyed, because it is not specifically mentioned. But because of its distinct morphology (e.g., yellow flowers and straight or sickle-shaped seed pods rather than the purple flowers and spiral seed pods of alfalfa) and different common names (e.g. sickle medic or yellow alfalfa), we would expect it to be separately noted, and therefore assume that it was not surveyed. Therefore, feral plants with the ability to cross with cultivated alfalfa are probably more plentiful than noted by Monsanto. It is therefore important to consider the possible environmental consequences of gene flow from RR alfalfa to feral or wild alfalfa (we include ssp. *falcata* under that name in further discussion).

First, both APHIS and Monsanto dismiss the possible environmental consequences of gene flow without adequate consideration. For example, APHIS contends that feral alfalfa is not an important weed, remarking that it is not found on any of several noxious weed indexes. However, feral alfalfa is listed as an invasive weed by the Southern Weed Science Society, as cited in the NRCS plant profiles for alfalfa.[7] In addition, the USDA Natural Resources Conservation Service (NRCS) indicates that feral alfalfa "...may become weedy or invasive in some regions or habitats and may displace desirable vegetation if not properly managed," contrary to the incorrect citation of this reference by Monsanto (the referenced web page leads to several related links, and it is therefore important to examine all of them).[8] Therefore, it appears that both Monsanto and APHIS have prematurely dismissed the weed potential of alfalfa, since neither cites or acknowledges these sources.

Monsanto cites letters from several weed scientists in several states who comment that feral alfalfa is not considered an important weed. However, in addition to being anecdotal evidence, these statements primarily discuss developed areas such as roadsides and drainage ditches rather than natural areas. Under the Plant Protection Act, APHIS must consider the possible impact of GE crops on natural as well as agricultural vegetation. In addition, the NCRS national plants database cited above lists feral alfalfa in all states of the U.S., and ssp. *falcata* in many states as well. Therefore, the limited data on the weediness of feral alfalfa supplied by both APHIS and Monsanto does not adequately survey the wide geographic region or number of habitats where feral alfalfa may occur and constitute a weed problem, and incorrectly cites the USDA-NRCS Plants database (petition, p. 290) as saying that feral alfalfa is not recognized as a noxious or invasive weed species (see above paragraph). APHIS must better assess the possible impact of feral alfalfa on natural areas, preferably with thorough consultation with NRCS and natural-area weed managers.

A second important question regarding gene flow is whether it may cause harm if it occurs, e.g.., whether the transgene may increase weediness or harm non-target organisms. Even if it was found that feral alfalfa is not currently a weed, the gene flow of a trait that increases the fitness of feral alfalfa may increase weediness, making it a more important weed. As noted above, the petition includes evidence that RR alfalfa may produce increased amounts of hard seed, which may in turn increase the fitness or competitiveness of feral alfalfa. Although neither the increase in hard seed nor the possibility of increased weediness from gene flow due to increased hard seed in feral alfalfa have been established, enough evidence was presented to make it necessary to test these possibilities. Monsanto's explanation in attempting to dismiss the evidence for increased hard seed in RR alfalfa is not adequate, as discussed in detail above. Therefore, there is a reasonable possibility that gene flow from RR alfalfa to feral alfalfa (or the escape and naturalization of RR alfalfa) could increase weediness of alfalfa under some circumstances or in some environments.

After glyphosate resistance is transferred to feral alfalfa, Roundup will no longer be effective for controlling it in non-agricultural environments. The petition notes several alternative herbicides that may be used to control feral glyphosate-resistant alfalfa. The noted alternative herbicides that may be used to control glyphosate-resistant alfalfa (petition, p. 293) are 2,4,-D, two dicamba salts, and chlorpyralid. Most have somewhat higher toxicity on the Cornell environmental index quotient with the EIQ of dicamba (EIQ of ~28) almost twice that of glyphosate (EIQ of ~15).[9] Furthermore, Monsanto and APHIS do not address options for control in natural areas, especially riparian areas, where glyphosate may be the preferred herbicide because it has lower aquatic environmental impact than many others.

C. RR Alfalfa, Glyphosate-Resistant Weeds, and Weed Shifts

APHIS does not address the potential development of glyphosate-resistant weeds as a possible environmental impact. Perhaps this is because, as indicted on page three of the EA, the "...separate issue of the potential use of the herbicide glyphosate in conjunction with these [Roundup Ready alfalfa] plants" is not considered to be part of APHIS regulatory purview. Although pesticides are regulated by EPA, the use of herbicide tolerant GE crops cannot be disassociated from the use of the herbicide or other weed control practices that are influenced by the use of the RR crop. In particular, there is no other reason for a farmer to purchase an RR crop unless he/she intends to use a glyphosate-based herbicide with it, especially considering the technology fee associated with RR seed. Therefore, since glyphosate use is inextricably tied to RR crops such as RR alfalfa, the use of the herbicide and the environmental consequences of that use, including impact on the use of other herbicides and weed control methods, is unavoidably affected by APHIS decision on deregulation of RR alfalfa. Assessment of the environmental consequences of glyphosate resistant weeds is therefore also an APHIS responsibility. Clearly, herbicides have substantial documented environmental impacts, and therefore these impacts must be considered by APHIS. The assessment by APHIS of the risks from herbicide resistance to glyphosate due to the use of RR alfalfa is therefore imperative. The lack of such assessment is an abdication of APHIS' legal responsibility.

It is also disingenuous for APHIS to avoid consideration of the impacts of herbicide resistance in the case of RR alfalfa because it considers the relative safety of glyphosate in the EA (P. 3, "Glyphosate is one of the most environmentally friendly herbicides commercially available."). APHIS therefore can also consider the possible risk implications of herbicide use if resistance to glyphosate develops. In addition, APHIS considers the impact of herbicides when claiming that glyphosate controls larger broadleaf weeds than some current herbicides, and APHIS claims that RR alfalfa would allow reduced herbicide use (EA, p. 12). Perhaps most surprisingly, the EA claims (p.12) that "...glyphosate would provide a different herbicide mode of action in the growers' crop rotation, **which is important in preventing the development of herbicide resistant weeds."** [Emphasis added] In other words, APHIS finds that it is important in its risk assessment to acknowledge the value of using glyphosate to help prevent the development of resistance to *other* herbicides, but not the converse situation, i.e. the importance of using other herbicides (and other methods) to prevent weed resistance to glyphosate. This is even more remarkable considering

APHIS determination that glyphosate has lower risk than other herbicides, so that it would seem even more important to consider resistance to glyphosate where, presumably, loss of its efficacy would lead to increased use of more harmful herbicides.

Although APHIS does not evaluate the environmental risks associated with herbicide resistance, Monsanto does discuss the potential for weeds to develop glyphosate resistance (but without discussing the potential environmental consequences of resistance). Therefore, most of our comments about resistance are directed to Monsanto's petition.

Glyphosate resistant or tolerant[10] weeds will likely lead to greater use of Roundup and other herbicides which may be more harmful, or lead to increased cultivation that contributes to erosion and water pollution. In some cases resistance can lead to the loss of an herbicide, but in most cases the herbicide can continue to be used because not all weeds are affected. In the latter case, however, resistant weeds force the use of additional control methods that may increase harm. Resistance or tolerance can develop when the resistance or tolerance phenotype is selected, especially by the heavy use of the herbicide. In addition to being a serious risk issue, glyphosate resistance[11] may impose significant costs to growers from increased use of glyphosate or other weed controls.

Glyphosate herbicides are also currently used on some non-RR alfalfa. Resistance due to the use of RR alfalfa could threaten the efficacy of this current use.

It is also important to understand that newer broad spectrum herbicide classes, or new modes of action, are not generally being developed. New herbicides developed in the last decade are newer versions of herbicide classes that had been developed decades ago. The dearth of new herbicide modes of action is due at least in part to lower investment in research for new herbicides, and this may in turn be due to the dramatic success of RR crops and the low cost of glyphosate. Many, including farmers, seem to believe that if herbicides like glyphosate are lost or reduced in efficacy, they will simply be replaced with newer herbicides as happened in the past. That does not seem to be very likely, because little research is being conducted to develop new herbicide modes of action.[12] [13] Even if replaced, such newer herbicides are almost always substantially more expensive to farmers than older herbicides, like glyphosate, that are no longer covered by patent protection. They are also less likely to effectively control as wide a spectrum of weeds as glyphosate. Therefore, farmers and APHIS need to appreciate and consider the importance of careful stewardship of glyphosate and other weed control options currently available.

Monsanto provides an extended discussion of herbicide resistance in general, and glyphosate resistance specifically, and proposes a resistance management approach in its petition (Appendix 1). In its discussion, Monsanto makes several arguments that glyphosate resistance is much less likely than for other herbicides. However, although this may be true compared to some other herbicides, such as ALS inhibitors or ACCase inhibitors, there is no doubt that glyphosate resistance or tolerance can occur. For example, there are now seven known glyphosate resistant weeds, and at least one other with significant tolerance, and several more that are problematic and may be developing resistance or tolerance. Most of these tolerant or resistant weeds have developed in just the last four years.[14] Glyphosate-tolerant morning glory has been identified in Georgia in 2004.[15] And most recently, glyphosate-resistant ragweed was confirmed in Missouri in December 2004.[16] In the U.S., glyphosate-resistant horseweed (*Conyza canadensis*) was first reported in Delaware in 2001 in continuously grown RR crops. In the four years since it was identified, glyphosate resistant horseweed has reportedly spread to over 1,500,000 acres in Tennessee alone, has moved westward at least to Indiana and Arkansas, and is now found in 12 states.[17]

Monsanto notes that glyphosate has been used for decades with very few cases of resistance, inferring that this supports the reduced likelihood that many glyphosate-resistant weeds will develop. However, the amount of crop acres treated as well as the amount of glyphosate applied was relatively low until RR crops were commercialized only eight years ago. Therefore, in essence, glyphosate was not subject to a high degree of selection for resistance until only the last few years.

In addition, and equally important, the pattern of glyphosate use has changed with RR crops. In particular, prior to RR crops, glyphosate herbicides were used much more sporadically, and often in conjunction with other herbicides or cultivation, all of which may delay resistance. But with the advent of RR crops, glyphosate may be the only herbicide or weed control method used, and it may be applied several times per year. As Monsanto notes, the lack of residual activity, rapid degradation and tight soil binding can reduce the selection pressure for resistance to glyphosate compared to many other herbicides. However, the newer use pattern under RR crops can prolong selection pressure by allowing several applications per year, compared to previous pre-crop-emergence or post-harvest use, as was often the case for glyphosate prior to RR crops. And the reduction in use of other weed control in conjunction with glyphosate also facilitates selection for RR resistance. The commonly high level of effectiveness of glyphosate on many weeds is an indication of this high level of selection for resistance genes when they exist or develop through spontaneous mutation.

The combination of the very high amounts of glyphosate used on RR crops, the broad spectrum of glyphosate weed activity limiting the need for other weed control methods, and the ability to spray the crop without injury, make the current pattern of use, and the very high resulting selection pressure, virtually unprecedented in the history of pesticide use. The widespread use of glyphosate resulting from RR crops not only promotes the development of glyphosate-resistant or tolerant weeds and weed shifts, but suggests that these weeds may spread more rapidly than otherwise. Rate of spread depends also on the means of propagule dispersal, and the habitats that the weeds are adapted to. But the extremely widespread use of glyphosate will select for, and thereby provide reproductive advantage to, glyphosate-resistant and tolerant weeds after they arise, assisting their dispersal. This can be especially important when resistance or tolerance would otherwise impose a fitness cost when not exposed to the herbicide, as is the case for glyphosate tolerant morning glory, because without continuing selection by the herbicide, the tolerant biotypes of the weed would be reduced due to reduced competitiveness.

In its discussion of glyphosate resistance in alfalfa weeds, Monsanto argues that frequent mowing prevents the flowering of many weeds, thereby limiting reproduction necessary for the propagation of resistant varieties. It is important to note that several important weeds are acknowledged to flower freely in alfalfa, including chickweed, downy brome, dandelion, broadleaf plantain, crabgrasses, and shepherd's purse. Most are important weeds in alfalfa and other crops (for example, downy brome is an extremely important winter wheat weed), and broadleaf plantain is in the same genus (*Plantago*) as another weed that has already developed resistance to glyphosate. In addition, other weeds may also flower between cuttings, especially in regions where cutting is only performed a few times per year, or in poorly managed fields. Therefore, plenty of opportunity exists for resistance to be selected and propagated in RR alfalfa where sound resistance management is not employed.

Monsanto goes to significant length to demonstrate that target-site based resistance to glyphosate (i.e. changes in the native plant EPSPS enzyme) is unlikely. Regardless of the mechanism, resistance has been quite feasible in several species so far. However, target-site based resistance seems to be at least partially responsible for resistance in goosegrass. And as noted in the petition, other possible (but as yet undetermined) mechanisms such as reduced glyphosate translocation or uptake may be responsible for resistance.

Several weeds of alfalfa have developed resistance to glyphosate. In the U.S. two alfalfa weeds, horseweed (*Conyza canadensis*) and common ragweed (*Ambrosia artemisiifolia*) are currently known to be resistant to glyphosate.[18] In other parts of the world several other species of alfalfa weeds that are also found in the U.S. have also developed resistance including goosegrass (*Eleusine indica*), Italian ryegrass (*Lolium multiflorum*), and buckhorn plantain (*Plantago lanceolata*) (in addition, *Lolium rigidum* has also developed resistance to glyphosate in the U.S. and elsewhere and may be a alfalfa weed).[19] While resistant biotypes of these weeds are not currently found in the U.S., the occurrence of resistance elsewhere may indicate that the species has a propensity to develop resistance to glyphosate. In addition, there have been several reports of important alfalfa weeds that have become difficult to control with glyphosate in some areas. These weeds include several pigweeds (*Amaranthus* spp.), tall waterhemp (*Amaranthus tuberculatus*), and lambsquarters (*Chenopodium album*). Resistance or tolerance has not been confirmed, but weed control specialists are concerned.[20] [21] Even if these weeds are not currently tolerant or resistant to glyphosate, difficulty in controlling them may give them an advantage in developing resistance by allowing survival of recessive alleles or alleles involved in multi-gene resistance.

Monsanto discusses the importance of crop rotation as a sound agronomic practice, such as a means of facilitating disease and weed control, but not for preventing resistance. Another important implication for alfalfa crop rotations is how they affect glyphosate use, because continuous use of an herbicide or herbicide mode of action increases the likelihood of resistance. Little alfalfa is currently rotated to other RR crops that could prolong selection for resistance. However, corn is one of the most important alfalfa rotation crops. Currently only about 7% of corn is glyphosate resistant. But if approval in the EU occurs, allowing export to Europe, RR corn acreage may increase substantially, increasing the likelihood of rotation from RR alfalfa to RR corn (and an increase in RR corn acres may be facilitated by possible use restrictions under the Food Quality Protection Act of the widely used triazine herbicides on corn). Another important alfalfa rotation crop, wheat, may also have commercial RR varieties eventually. In particular, RR spring wheat was recently close to commercialization. In any case, alfalfa is a perennial, typically grown for three to five years consecutively, providing continuous pressure on some weeds (typically weed pressure is lower for a few years after an alfalfa stand is established, and different weeds may predominate as the stand thins, but overlap between some weeds during planting and in subsequent years can occur).

Monsanto cites a recent study (Wilson and Stahlman, 2003) where resistance did not develop after five years as evidence that resistance does not easily develop to glyphosate. Similarly, another three year study comparing several weed control strategies, including continuous use of glyphosate on RR soybeans and RR corn (Stoltenberg, 2002), is similarly cited. The petition notes that no resistant weeds were discovered after three years in the Stoltenberg research. However, the Stoltenberg and Wilson and Stahlman research was performed on field plots totaling only very limited acreage. Research on such limited acreage, relying only on relatively small field trials which are a tiny fraction of the commercial crop, cannot legitimately be used to project the likelihood of resistance in commercialized crops. Alleles for resistance are often relatively rare in previously unselected weeds, and therefore may well not be present in such a small sample.

In fact, many weed scientists have objected to Monsanto's claims that these limited studies imply that resistance is unlikely.[22] Due to their concern about farming practices using RR crops that are inimical to sound resistance management, these scientists have posted a web page objecting to Monsanto's pronouncements and recommending rotation of herbicide modes of action and integrated weed management to prevent or delay resistance to glyphosate. In addition, Prof. Stoltenberg has written that it would be inappropriate to infer from his limited studies that weeds are unlikely to develop resistance (Dave Stoltenberg, email communication to Doug Gurian-Sherman on December 21, 2004).

It is difficult to understand why Monsanto refuses to acknowledge or endorse the overwhelming consensus among weed scientists for preventing resistance to glyphosate. However, we note that the favored resistance management approach by Monsanto, and one that is not endorsed by weed scientists, is to use glyphosate at the highest rate possible (petition, Appendix 2). This approach, perhaps not by coincidence, would also serve the purpose of boosting glyphosate sales. This conflict between sound science and the pressures of narrow self interest are not surprising, but should serve as a clear warning to APHIS to view the petition for deregulation with a critical eye.

Furthermore, even in the small scale field trials, a substantial weed shift was observed in California field trials, where within only a few years, burning nettle was found to increase in RR alfalfa test plots due to tolerance for glyphosate.[23] Such weed shifts are expected when a single means of control are over-relied upon, but are surprising over the relatively short duration and spacial scale of field trials.

Resistance and weed shifts are two examples of the lack of sustainability of the overly simplified approaches to farming represented by the current use of RR crops. The environmental implications of this simplified farming approach should be part of APHIS evaluation in a proper risk assessment in the form of an EIS. Glyphosate-resistant weeds and weed shifts are a virtually inevitable outcome of the lack of appropriate weed resistance-management advocated by Monsanto, and the lack of adequate resistance management required by APHIS. Resistance and weed shifts will in turn cause an increase of the use of both glyphosate and other herbicides initially displaced by Roundup, where the latter will be need to control the glyphosate-resistant or tolerant weeds. Therefore, claims of environmental benefit due to displacement of some more harmful herbicides by glyphosate should be tempered by the likelihood that these suggested benefits will be significantly reduced or eliminated over time.

Monsanto's approach to resistance management excludes the most widely accepted method of rotating herbicide modes of action.[24] [25] Instead, Monsanto relies heavily on a high dose strategy to prevent resistance. Monsanto stresses that using a high rate of glyphosate and treating weeds when they are most vulnerable (usually when they are smallest) is important in preventing resistance. Besides ignoring the more accepted method, this high dose approach is unlikely to work where dominant resistance genes are present. It is also generally impractical, and therefore likely doomed to failure.

Although a high dose strategy has been successful so far in preventing insect resistance to Bt crops, the most common mechanism for Bt resistance involves target-site changes that generally require a homozygous state for effective resistance (i.e., resistance is usually recessive). There is no evidence provided that resistance mechanisms to glyphosate are recessive. Additionally, a true high dose may not be achievable with glyphosate as applied to many weeds. A high dose in the case of Bt has been defined several ways, such as a concentration of at least 50 fold higher than the concentration required to kill 50% of the exposed insect population (LC_{50} X 50). No evidence has been presented that such a dose is achievable with glyphosate on most weeds. If Monsanto is proposing a high dose strategy for resistance management, APHIS should require data that

demonstrate that relevant parameters, such as a sufficiently high dose and low frequency of resistance alleles, are operative in the important weeds of alfalfa.

The high dose strategy of Monsanto is also impractical because it requires growers to treat weeds only when they are at their most vulnerable growth stage, i.e. usually when they are small, and when they are not under stress. This is because larger weeds are typically less susceptible to glyphosate, and stress reduces glyphosate's efficacy. In effect, both larger weeds and stress reduce the possibility of a high dose. However, in practice, avoiding applying Roundup to larger or stressed weeds is often not possible without multiple applications and the luck of favorable weather that allows timely access to fields. Multiple flushes of many weeds and the lack of residual activity of glyphosate means that in some cases, several applications may be required to treat weeds only when they are small. Therefore this strategy is also not in keeping with the often stated benefit of RR crops of reducing herbicide use (although recent data indicate that RR crops do not necessarily reduce herbicide use).

Voluntary resistance management approaches, such as suggested by Monsanto, are currently applied to many pesticides with little evidence of success. Farmers, working with small and unpredictable profit margins (that may be reduced even further in the future if subsidies fall under international trade pressures), are under tremendous pressure to do everything possible to successfully compete with their neighbors, and therefore often feel that they cannot forego what they consider to be their most cost-efficient methods of production. Therefore, sound resistance management, if it means using a more expensive or less effective herbicide mode of action or integrated weed management practice, is only likely if the "playing field" is leveled by making it a mandatory condition of using RR technology. A mandatory resistance management program also need to be directed, monitored and enforced by USDA rather than Monsanto.[26]

In contrast with the failure of voluntary resistance management programs, the mandatory resistance management program applied to Bt crops has so far prevented resistance to a valuable insecticide and prolonged its use. Therefore, we recommend that APHIS design a mandatory resistance management program for RR alfalfa (and all other RR crops), with the help of alfalfa growers, growers of other crops that may be impacted by glyphosate-resistant weeds, and independent scientists. Such a program would likely employ mandatory rotation of herbicide modes of action and integrated weed management.

Finally, APHIS should consider the impact of glyphosate-resistant weeds on growers of crops other than alfalfa. Many of the major weeds of alfalfa, including pigweeds, kochia, lambsquarters, nightshade, foxtails, other annual and perennial grasses, and other weeds are also important weeds of many non-RR crops where glyphosate-based herbicides are used. For example, glyphosate is labeled for virtually all of the major crops of Minnesota (an important alfalfa growing state), such as several small grains (wheat, barley, oats and rye), oil seeds (canola and sunflower), dry edible beans, peas, corn, soybeans, sugar beets and potatoes.[27] [28] Many of the important weeds of alfalfa are also important weeds in many of these crops. Glyphosate is also labeled for many other crops important in other alfalfa-growing states. Poor stewardship of glyphosate due to lack of appropriate action by APHIS to prevent the development of glyphosate-resistant weeds could be costly to such growers of other crops who have no control over the use of glyphosate on RR alfalfa. APHIS should evaluate the impact of possible glyphosate resistance of these and other weeds of alfalfa on crops grown in alfalfa producing states in making its deregulation decision.

D. Health Effects of Glyphosate

On the human health impacts, the EA acknowledges that the product will displace other herbicides, without assessing this quantitatively in terms of how this will increase incidences of applicator use and misuse of glyphosate. It is clear that a dramatic increase in glyphosate use and misuse is foreseeable. Published epidemiological research has shown that applicator use and misuse of glyphosate has resulted in harm to human health. The EA completely fails to address the foreseeable increased use and misuse by a relatively poorly educated, often non-English speaking, farm labor force. While these are health impacts, they result from the foreseeable environmental impact of spray misapplication, thus under NEPA they must be assessed as effects of the action (see the inclusion of health effects in 40 CFR § 1508.8, above).

While glyphosate often is touted as safe, published documentation of its toxicity must be considered in the EA. A paper by V.F. Garry, et al., entitled "Birth defects, season of conception, and sex of children born to pesticide applicators living in the Red River Valley of Minnesota, USA" from *Environmental Health Perspectives*, June 3, 2002, vol. 110 supp. (the National Institute of Health's peer-reviewed environmental health journal) is a key epidemiological study showing a link between glyphosate use and neurobehavioral birth defects in the offspring of farmers who apply it. The paper states (p. 445):

> *No other commonly used pesticide [besides glyphosate and phosphine, a fumigant] compared by major organ and/or functional system was uniquely associated with specific adverse birth or developmental effects.*

The paper's findings are labeled "tentative," but the authors conclude (p. 447), "Further detailed neurodevelopmental studies are required to resolve these issues." Further, a paper by L.P. Walsh et al., entitled, "Roundup inhibits steroidogenesis by disrupting steroidogenic acute regulatory protein expression" from *Environmental Health Perspectives*, Aug., 2000, vol. 108, reports on an *in vitro* study showing glyphosate inhibits certain hormones involved in human reproduction. Another paper reportedly showed that glyphosate exposure nearly doubled the risk of late spontaneous abortion in Ontario farm populations. (Arbuckel, T., et al. 2001. An exploratory analysis of the effect of pesticide exposure on the risk of spontaneous abortion in an Ontario farm population. *Environmental Health Perspectives* 109: 851-60.) The EA completely abstains from analysis of the implications of these health studies, instead glibly asserting that glyphosate is safe. This not only violates NEPA, it demeans farm workers and rural families.

E. <u>Impact on Organic and Other Growers</u>

The USDA has failed to analyze the socio-economic impacts on farmers and food processors seeking to avoid GE alfalfa and products derived from alfalfa in their crops and commodities. The agency's EA fails to address these impacts on both farmers, users and exporters of both organic and conventional, non-GE alfalfa.

In a minor attempt to address these issues, the agency makes cursory and unsupported statements concerning the impacts on organic farmers stating "(a) non-transgenic alfalfa will likely still be sold and will be available to those that wish to plant it." This statement is purely speculative in nature. APHIS has provided no evidence that it has taken a "hard look" at the status of the alfalfa seed market. No analytical information is present concerning: (1) the ability of non-transgenic seed producers to avoid transgenic contamination of their foundation alfalfa seed; (2) the ability of seed sellers to ensure that seed being sold can be guaranteed to be non-transgenic alfalfa seed; and (3) the willingness of corporations such as Monsanto to produce and sell non-transgenic varieties that are currently under their patent control. Indeed, current indications are that once transgenic seed is on the commercial market the ability to access non-transgenic seed is significantly hampered. Such results not only have economic impacts on the farmers seeking non-transgenic seed, but also will severely limit the ability of farmers to convert to organic systems using alfalfa and/or expand such acreage. Absent such analysis and information, the agency's EA cannot support its finding of no significant impact.

Second, the agency claims there will be no impacts on organic farmers because the presence of a detectable residue of a product of excluded methods (i.e. transgenic) does not necessarily constitute a violation of the National Organic Standards. This analysis is incomplete and devoid of any analysis about the current organic marketplace. During the implementation of the Organic Food

Production Act the USDA made it clear that the agency views the organic rule as a marketing standard based upon consumer expectations. This approach was stated in its treatment of "excluded methods" (i.e. genetic engineering). The USDA has stated:

> Products created with modern biotechnology techniques have been tested, approved by the appropriate regulatory agencies, and can be used safely in general agricultural production. At the same time, consumers have made clear their opposition to use of these techniques in organic food production. This rule is a marketing standard, not a safety standard. Since use of genetic engineering in the production of organic foods runs counter to consumer expectations, foods produced through excluded methods will not be permitted to carry the organic label. 65 Fed. Reg. 13534-35 (March 13, 2000) (emphasis added).

Therefore, it is not clear whether the marketplace in organic will accept any "adventitious presence" of genetically engineered alfalfa or other crops. Indeed, many manufacturers and farmers undertake significant efforts (and financial burdens) to ensure that their seed or products do not use canola contaminated with "adventitious presence." If the USDA is going to make such an assertion, it needs to analyze whether the marketplace and market-based standards will actually tolerate "adventitious presence" and the impact that such a tolerance will have on organic agricultural producers, processors, and consumers.

F. Potential Socio-Economic Impacts

The agency has failed to address a number of other socio-economic impacts that must be considered as part of the NEPA process. Indeed, the CEQ regulations implementing NEPA state that such impacts must be analyzed.[29] Federal courts have also upheld that NEPA requires, where economic analysis forms the basis of choosing among alternatives, that the analysis not be misleading, biased or incomplete. Seattle Audubon Society v. Lyons, 871 F. Supp. 1291, 1324 (W.D. WA 1994). As one court has noted, "In some instances environmental costs may outweigh economic and technical benefits and in other instances they may not. But NEPA mandates a rather finely tuned systematic balancing analysis in each instance." Sierra Club v. Sigler, 695 F.2d 957, 978 (5th Cir. 1983).

Therefore, USDA/APHIS should fully analyze in an environmental impact statement the socio-economic impacts that will be directly associated with any agency decision to deregulated varieties of genetically engineered alfalfa. Among the issues that need to be addressed include: (1) impact of RR alfalfa on U.S. alfalfa exports and export of U.S. alfalfa products; (2) the impact of commercial introduction of an alfalfa variety that is subject to utility patent protection and likely displacement of non-genetically engineered varieties from the marketplace and how this decrease in diversity will impact the environment; and (3) the impacts deregulation will have on seed pricing, (4) the impact on exports to Europe of meat and dairy products from animals fed RR alfalfa due to recent EU regulations requiring labeling of such products from animals fed GE crops.

The commercial introduction of genetically engineered alfalfa varieties will have a dramatic economic impact on the viability of U.S. alfalfa exports. Alfalfa is exported primarily from west coast states, and these states stand to face significant impact if such exports are lost. Although Monsanto has said that it may not introduce RR alfalfa until regulatory approval in Japan, such approval does not ensure acceptance from skeptical consumer markets that will ultimately decide whether RR alfalfa is accepted.

Recent analysis of possible economic impacts due to export restrictions if RR wheat is introduced into the U.S. or Canada provides some indication of possible impacts on alfalfa exports, although some differences between the crops exist. Economic modeling in Canada, indicating that the introduction of genetically engineered wheat would likely lead to substantial net loss of export revenue, may provide some indication of the potential export problems for RR alfalfa.[30] Concerning the U.S., one agricultural economist has noted, "There is the potential for lost access to some markets and profits. This downside is magnified if the U.S. grain handling system in unable to maintain segregation of GM and non-GM varieties of the same commodity. The smallest detection levels of GM materials can cause an entire shipment to be rejected by an end user. A loss of confidence in the ability of the United States to segregate GM and non-GM wheat could shut all U.S. producers out of many overseas markets."[31] As demonstrated by the events surrounding StarLink corn, ProdiGene, and GT200 canola, the current U.S. agricultural commodity handling system is unlikely to be prepared to sufficiently segregate genetically engineered and non-genetically engineered alfalfa to the point at which foreign importers will have confidence in the integrity of such shipments. Accordingly, in allowing the commercialization of genetically engineered alfalfa varieties, USDA will have acted in manner significantly harming the U.S.alfalfa export market and the state economies dependent on such exports.

APHIS has also not considered adequately the potential impact of RR alfalfa on dairy cows and horses that use large amounts of alfalfa. As discussed concerning APHIS responsibility to consider environmental consequences due to the impact of RR alfalfa on pesticide use, APHIS similarly has a responsibility to adequately consider potential impacts on dairy cows and horses. In particular, there is no analysis of possible unintended effects on RR alfalfa plants due to either the presence of the RR gene or the GE process that may be harmful to animals.

Alfalfa produces a number of substances that may adversely affect animals. For example, alfalfa produces isoflavones similar to those found in soybeans that have estrogenic effects, which may have effects on animal fertility if expressed at high levels.[32] These and other secondary metabolites could have adverse effects if their expression is increased substantially. As observed with the possible increase in hard seed as an unintended effect under some environmental conditions, increases in harmful substances may occur in some environments but not others. Therefore, it is important to examine the potential unintended effects on feed quality from RR alfalfa grown in several different environments. This is especially true because much alfalfa feed is used "on farm" or locally, and therefore local environmental conditions may be important. Feeding studies on livestock using other RR crops in the past are not adequate because 1) additional animals, particularly horses, are involved that may not have been as important for other RR crops, 2) unintended effects are dependent on a combination of the gene (including the insertion site, which differs by insertion event), crop and environment, so data from other RR crops is not adequate. For all of these reasons, RR alfalfa should not be deregulated until these important feed issues are adequately considered in an EIS.

Another important economic consideration concerns honey bees and honey production. Although the CP4-EPSPS protein may not harm honey bees, unintended effects should be considered because alfalfa may be a significant source of honey in some areas, especially where alfalfa is grown for seed. None of the references cited by APHIS consider RR alfalfa specifically, and therefore could not identify possible harmful unintended effects on honeybees. Honey sales may also be adversely impacted, as discussed concerning both alfalfa exports and organic alfalfa, if the transgene or transgenic protein can be detected in honey produced from RR alfalfa. Although the sugar in honey would not be expected to contained detectable genetic material, impurities in honey may contain contaiminating transgenes and should be examined for this possibility.

G. Additional Environmental Concerns

The agency's EA makes only passing reference to impacts on non-target organisms. Of particular concern are several species of pollinators, such as leafcutter bees and alkali bees that may be particularly affected by RR alfalfa, and in particular by unintended effects. It references a no harm decision from the Fish & Wildlife Service. The analysis is incomplete in that the EA fails to identify what if any species or issues it requested the FWS to address.

It is also incomplete in that the agency appears not to have analyzed any impacts that might be occur on migratory birds as required by Migratory Bird Treaty Act. The use of RR alfalfa is likely to impact the habitat of many migratory birds and other organisms, because alfalfa can be an important resource for wildlife.[33] An increased use of glyphosate on alfalfa growing areas and surrounding habitat will alter the ecology of treated areas. For example, the Farm Scale trials in England found that use of RR sugarbeet decreased food sources for birds. In most cases, the plant species diversity will decrease, and along with it, the numbers of insects and birds utilizing these areas of habitat.[34] Under Executive Order 13816, all federal agencies are also required to take into consideration the impacts of action on migratory birds prior to undertaking federal actions and other activities.

Further, the present EA fits a disturbing pattern: deregulation of GE crops has rested exclusively on short, narrowly focused EAs. Several commenters have criticized the quality of APHIS's deregulation EAs. Indeed, the National Academy of Sciences, following a thorough review, has concluded (National Research Council/National Academy of Sciences. 2002. *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation.* Washington, DC., at p. 189):

> *APHIS assessments of petitions for deregulation are largely based on environmental effects considered at small spatial scales. Potential effects from scale-up associated with commercialization are rarely considered.*

This assertion presents a stunning indictment of APHIS's NEPA work, indicating the agency is using "quick and dirty" EAs in lieu of full EISs in which "potential effects from scale-up associated with commercialization" are fully considered on a nationwide basis (some of the scale-up issue raised are dure to the inability of relatively small field trials to reliably detect all ecological effects, and point to the need to monitor GE crops after commercialization). As APHIS eventually recognized in the case of the Monsanto/Scotts RR creeping bentgrass product mentioned previously - the only other perennial GE crop proposed for deregulation - the agency should recognize that a full EIS also is called for RR alfalfa.

APHIS additionally has committed to preparing a full EIS prior to the step of allowing any unconfined field release of a proposed biological control agent for a cotton pest, the sterile GE pink bollworm, in a very limited cotton-growing area near Phoenix, Arizona. (APHIS Notice of Intent to prepare an Environmental Impact Statement on the proposal by USDA APHIS to conduct field releases of a transgenic pink bollworm, *Pectinophora gossypiella* (Lepidoptera: Gelechiidae), Docket No. 01-024-1, 63 FR 5086-5087, dated Feb. 4, 2002.) This step is far short of approving deregulated status for a widespread, perennial, RR forage crop as proposed in the current docket.

Further, NEPA requires preparation of a full EIS whenever a potentially significant impact is present even if in the judgment of the action agency that impact is outweighed by potential benefits (40 CFR § 1508.8 , above: "Effects may also include those resulting from actions which may have both beneficial and detrimental effects, even if on balance the agency believes that the effect will be beneficial"; and 40 CFR § 1508.27(b)((1) - under Definition of "significantly": ".....A significant effect may exist even if the Federal agency believes that on balance the effect will be beneficial").

Conclusion

For the reasons stated herein and others that would arise should public scoping of this matter occur, the Center for Food Safety believes that the EA is both substantive and legally inadequate. CFS believes that a full environmental impact statement is necessary before any deregulation can occur.

Respectfully Submitted,

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References and Notes

[1]. Benbrook, C., "Genetically Engineered Crops and Pesticide Use in the United States: The First Nine Years," Biotech InfoNet, http://www.biotech-info.net/

[2]. Another recent report by the National Center for Agricultural Policy ("Impacts on U.S. Agriculture of Biotechnology-Derived Crops Planted in 2003 - An Update of Eleven Case Studies," NCFAP, www.ncfap.org) concludes that herbicide use is down on RR crops compared to conventional counterparts. However, there are serious methodological errors in the comparison of herbicide use in conventional and RR soybeans (we have not examined other RR crops evaluated in the NCFAP report). The problem lies in counting herbicide use on conventional soybeans only to those acres where weed control was exclusively by herbicides, excluding any conventional soybean acreage where any cultivation is used to control weeds in conjunction with herbicides. That is, the report did not consider conventional acres that also (or exclusively) used tillage to control weeds. Therefore, the report includes only the conventional soybean acres that had the highest herbicide use, because acres that use some tillage to control weeds may substitute tillage for some herbicide use. On the other hand, NCFAP based the projected use of herbicides on RR acres on the most common spray program recommended by state weed scientists that NCAFP consulted (personal communication between D. Gurian-Sherman and S. Sankula, author of the report). However, because only about 33% of all soybean acres (RR and conventional) were no-till in 2002, although about 75% or 80% of soybean acres used RR seeds, most RR soybeans used some tillage (either conservation or conventional tillage). It is therefore likely that some of the state programs used for the report included a combination of Roundup and some tillage, which biases for lower Roundup use. So, although the conventional soybean acres were biased toward the highest herbicide use, the

RR acres were probably biased to some extent in the opposite direction. Determining the extent of that bias is beyond the scope of these comments.

[3] National Resource Conservation Service, "Plant Fact Sheet" for Alfalfa, *Medicago sativa*, USDA, NRCS. 2004. The PLANTS Database, Version 3.5, http://plants.usda.gov/cgi_bin/plant_profile.cgi?symbol=MESA , then access the "Plant Facts" link

[4] USDA, NRCS. 2004. The PLANTS Database, Version 3.5, for Alfalfa, *Medicago sativa* ssp *sativa*, http://plants.usda.gov/cgi_bin/plant_profile.cgi?symbol=MESAS

[5] USDA, NRCS. 2004. The PLANTS Database, Version 3.5, for Yellow Alfalfa, *Medicago sativa* ssp *falcata*, http://plants.usda.gov/cgi_bin/plant_profile.cgi?symbol=MESAF

[6] Jenczewski E, et al. (1999) Evidence for gene flow between wild and cultivated *Medicago sativa* (Leguminosae) based on allozyme markers and quantitative traits. American J. Bot. 86(5):677-687

[7] USDA, NRCS. 2004. The PLANTS Database references, op cit

[8] National Resource Conservation Service, "Plant Fact Sheet" for Alfalfa, *Medicago sativa*, op cit

[9] Kovach, J. et al. A method to measure the environmental impact of pesticides. http://www.nysipm.cornell.edu/publications/EIQ.html

[10]. Tolerance is often distinguished from resistance in that substantial injury occurs, but the weed is able to recover, even at doses at or above the maximum label rate.

[11]. Resistance will subsequently be used to indicate both resistance and tolerance, unless there is a reason to distinguish them, in which case the more specific term will be used.

[12]. Powles SB, Preston C, Bryan IB, Jutsum AR (1997) Herbicide resistance: impact and management. Adv. Agron. 58:57-93

[13]. Martinez-Ghersa MA, Worster CA, Radosevich SR (2003) Concerns a weeds scientist might have about herbicide-tolerant crops: a revisitation. Weed Technology 17:202-210

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selected *de novo* or from RR soybean or RR cotton fields, may become a more important alfalfa weed if no-till increases.

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[25] Matten, S. (2003) U.S. EPA's voluntary labeling guidelines for pesticide resistance management based on rotation of mode of action. Pesticide Outlook 3:111-113

[26] Current Bt resistance management programs have been administered and enforced by the GE companies. Under this system, compliance has been less than desired.

[27]. See: "Roundup Original" and other Roundup labels: www.cdms.net/ldat/ld23p003.pdf

[28]. USDA/NASS, Minnesota Crop Group, www.nass.usda.gov:81/ipedbcnty/c_mncrops.htm

[29]. When an environmental impact statement is prepared and economic or social and natural or physical environmental impacts are related, then the environmental impact statement will discuss all of these effects on the human environment. 40 C.F.R. § 1508.14

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