THE CENTER FOR FOOD SAFETY

660 PENNSYLVANIA AVE., SE , SUITE 302, WASHINGTON, DC 20003
(202) 547-9359 ❧ FAX (202) 547-9429
1009 GENERAL KENNEDY AVE., #2 SAN FRANCISCO, CA 94129
(415) 561-2524 ❧ FAX (415) 561-7651
WWW.CENTERFORFOODSAFETY.ORG

December 20, 2004

Docket N. 04-075-1
Regulatory Analysis and Development
PPD, APHIS
Station 3C71
4700 River Road
Unit 118
Riverdale, MD 20737-1238

CC: regulations@aphis.usda.gov

Comments to USDA on Environmental Assessment for the Determination of Nonregulated Status for Monsanto Co. And KWS SAAT AG's Roundup Ready Sugarbeet (Event H7-1)

USDA/APHIS is evaluating a petition to deregulate Roundup Ready sugarbeet containing a CP4 EPSPS gene that confers tolerance to glyphosate-based herbicides, designated Event H7-1, and has issued an environmental assessment (EA). Pursuant to the USDA's October 19, 2004, Federal Register notice, 69 Fed. Reg. 61466, 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 KWS SAAT AG's petition for deregulation. CFS appreciates the opportunity to comment on the EA of Roundup Ready (RR) sugarbeet, 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 sugarbeet, CFS finds that the significant unanswered or inadequately answered safety questions that our analysis has discovered 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 H7-1 RR sugarbeet. Deregulation should not be allowed until these concerns are throughly addressed.

In general, Monsanto claims in support of its petition to deregulate RR sugarbeet (hereafter, petition) that "there has been no reported adverse environmental impact from the commercial planting of other Roundup Ready crops..." (petition, p. 3). 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.

Although not an issue of risk, we also find that some of the possible benefits from RR sugarbeet are incorrect or overstated. In particular, substantial increases in sugar yield claimed by Monsanto in its petition, and based on limited data, are often contradicted by yield assessment field trials. In addition, independent estimates suggest that herbicide use will increase on RR sugarbeet, not decrease. These issues are discussed in more detail below.

Summary and Recommendations

Sugarbeet is a major crop, planted on approximately 1.4 million acres annually in the U.S. Therefore, environmental harm due to changes in the cultivation of sugarbeet could be substantial. If RR sugarbeet is adopted at levels comparable to other RR crops, a majority of commercialized sugarbeet may contain the RR trait within several years. For these reasons, it is critical for APHIS to perform a thorough EIS of RR sugarbeet.

To the contrary, the EA produced by APHIS only superficially considers several possible environmental impacts. First, the important issue of weed resistance to glyphosate is not considered at all. Second, the possibility of increased disease susceptibility of RR sugarbeet revealed in the petition is inadequately analyzed. Third, evidence for gene flow to a wild sugarbeet relative in California and its consequences are not fully addressed. Fourth, the impact of glyphosate resistant weeds is not evaluated by the EA. Fifth, APHIS makes cursory statements about the impact on organic production with no supporting evidence. Sixth, APHIS fails to make any effort to address the socio-economic impacts caused by deregulation. In sum, APHIS accepted the evaluation of the petition with no critical comment. For example:

- APHIS did not properly evaluate data that suggest that RR sugarbeet may be more susceptible to several important sugarbeet diseases. Disease susceptibility data were improperly aggregated in the petition to appear insignificant, while the properly nonaggregated data suggest that RR sugarbeet may be more susceptible to several important diseases, especially Cercospora leaf spot, the most important disease of sugarbeet in the U.S. Increased susceptibility to Cercospora could lead to increased use of the highly toxic fungicide triphenyltin.

- APHIS accepted the analysis of the petition that gene flow of the CP4 EPSPS gene to the wild relative *Beta macrocarpa* in California is unlikely despite reliable published evidence to the contrary. APHIS further holds that if gene flow were to occur, the RR wild beets that would result could be controlled by other means, without providing any consideration of the potential harm, such as from higher toxicity of other herbicides to sugarbeet growers or growers of rotation crops.

- APHIS abdicates its responsibility to fully evaluate RR sugarbeet by not assessing the potential environmental harm caused by RR resistant weeds that are becoming ever more common. RR resistant weeds can harm not only sugarbeet growers, but also growers of other crops that have no control over the use of RR sugarbeet. APHIS apparently refused to evaluate the consequences of RR resistant weeds because EPA regulates herbicides. However, the RR crops regulated by APHIS are inextricably linked to the use of the herbicide Roundup, so APHIS regulatory actions will unavoidably impact Roundup use and safety. Furthermore, APHIS makes several comments in its EA concerning the relative safety of herbicides currently used on sugarbeet 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 sugarbeet 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 sugarbeet:

1. RR sugarbeet should be subjected to ongoing tests for susceptibility to Cecospora leaf spot,

powdery mildew, and fusarium yellows. These tests should be performed in several locations, especially the sites where higher disease severity was originally observed. If significantly increased susceptibility is verified, the environmental consequences should be evaluated, especially the likelihood and consequences of increased fungicide use.

2. RR sugarbeet should not be grown in central or southern California to prevent gene flow to *B. macrocarpa*. Alternatively, mandatory practices to prevent gene flow should be adopted such as culling of all bolting sugarbeet and residual sugarbeet roots ("ground keepers"). These restrictions should have adequate monitoring and enforcement to discourage violation.

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 sugarbeet growers, academic weed scientists, and APHIS, and should consider mandatory rotation of herbicide types (modes of action) and other means to prevent resistance.

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

Detailed Considerations

A. RR Sugarbeet Disease Susceptibility

Field trials were performed comparing RR sugarbeet to non-RR varieties for susceptibility to several important sugarbeet diseases. The EA notes that six of 98 field trials recorded differences in disease susceptibility. The EA also specifically mentioned three sites where powdery mildew was increased and three where the disease was decreased. This description is in error, because the petition (Table VI-5, p. 63-65) actually records one trial with increased powdery mildew, two trials with decreased powdery mildew, and two trials with increased Cercospora leaf spot. The EA fails to mention or note the increases in Cercospora at two field trials, with none showing decrease in this disease. In addition, the EA fails to appreciate the need to review disaggregated data that can properly consider the possible influence of environment on disease at different field sites.

The petition notes several instances where the important sugarbeet diseases powdery mildew and Cercospora leaf spot were higher on RR sugarbeet than on varieties used for comparison, noting that the differences in disease were likely due to the event H7-1 genotype. Different disease susceptibility was also noted for Fusarium. Unfortunately, Monsanto does not explain whether the genotype component responsible for the disease susceptibility is the CP4 EPSPS gene or the sugarbeet variety. It is impossible to make this distinction from the petition because the varieties used in the field trials and the disease ratings are not disclosed, so we cannot determine if the conventional non-RR progenitor was used in the field trials. In either case, the possibility of increase in these serious diseases may have significant environmental and human health consequences. If increased disease susceptibility is associated with CP4 EPSPS, then any variety containing that gene may have increased susceptibility. If instead the variety is responsible for increased susceptibility, then increased planting of that variety may occur due to the presence of the RR resistance trait. Adoption of RR sugarbeet may be widespread, as with RR soybeans which are now grown on over 80% of U.S soybean acres. It is important, as we discuss below, that APHIS thoroughly address the potential consequences of these disease trial results.

Increased disease is important for several reasons. First, the increased disease, if not adequately controlled, may reduce yields. Second, the increased use of fungicide for controlling the diseases would cause human and environmental harm. Several fungicides used to control sugarbeet diseases may cause substantial risk. In particular, triphenyltin is highly toxic to humans and other organisms, and was the most widely used fungicide on sugarbeet in 2000, with 1.4 applications on 44% of sugarbeet acres.[3, 4] Triphenyltin has been considered the most efficacious fungicide for Cercospora control where tolerance has not occurred, and alternative fungicides such as benomyl also have undesirable environmental and human health profiles. Further testing should be performed to more thoroughly determine whether the increased disease levels reflected in these field trials are accurate. If the increased disease levels are confirmed, APHIS should carefully consider the potential impact of increased disease and fungicide use.

Monsanto improperly dismisses the importance of the disease trials by combining the results for several diseases, most of which revealed no difference between the RR varieties and the varieties used for comparison. By Monsanto's calculation, 6 of 98 field trials for disease showed changes in disease reaction, or about 6% of field trials. It is improper, however, to aggregate data for different diseases because, as is widely known in plant pathology, resistance or tolerance to different diseases often relies on different mechanisms which may be differentially affected by the H7-1 transformation event. For example, different receptors are known to recognize different disease species or even different races of pathogens. Similarly, different pathogens react differently to toxins or enzymes produced by the plant to defend itself against disease. When comparing disease reaction only with other trials examining the same disease, 2 of 15 Cercospora field trials, or about 13%, exhibited 10% higher disease (petition, Table VI-5, p. 63-65), and 1 of 15 field trials (about

7%) showed higher powdery mildew levels, while 3 showed lower levels.

It is also poor analytic methodology to aggregate data from different locations. A fundamental principle of plant pathology is the so-called "disease triangle," with the disease organism, the plant, and the environment at each vertex, i.e. each with roughly equal weight.[5] Analysis of variance (e.g., ANOVA) often identifies significant "plant x environment" or "plant x location" interactions in field trial data. There can be many reasons for such differences such as weather, climate, soil, or pathogen strain differences at different locations that can dramatically affect disease reactions. Such environmental effects are not incidental, but are of fundamental importance in the development of plant disease. When data from a single location and year are compared, 1 in 3 (33%) trials in Saginaw, Michigan, examining event H7-1 RR sugarbeet had higher levels of Cercospora, and 1 of 2 (50%) in Huron, Michigan had higher Cercospora levels. Similarly, the only field trial in Adams, Washington was reported to have higher levels of powdery mildew on H7-1 (100%, based on 13 observations, more than any other field trial, making the results less likely due to chance), while 3 of 4 (75%) field trials in Lane, Oregon had lower powdery mildew levels. Whether the cases of higher disease levels reflect underlying differences in susceptibility or are stochastic events can only be determined by additional and careful field tests.

One possible explanation for the differences in disease reaction between different locations could be different pathogen strains with different virulence for H7-1. Powdery mildews often have different races, for example, that react very differently to different crop varieties, although apparently little is known about the race structure of the sugarbeet powdery mildew pathogen (*Erysiphe betae*).[6] If the observed disease reaction differences are due to pathogen strain differences, the consequences could be especially important because the higher fecundity that likely accompanies higher infection levels may select for the more virulent strains, especially if the H7-1 event is widely adopted. Even in the case of powdery mildew, where substantially lower disease reaction was observed in Oregon, selection for a more virulent strain could occur. Both Cercospora and powdery mildew produce wind disseminated spores that can be widely spread, so a more virulent strain could become more predominant.

Interestingly, the difference in susceptibility to *Fusarium* sp. occurred only when glyphosate was applied. Monsanto did not reveal whether there was an increase or decrease in this disease. If there was a disease increase, additional testing should be required. The petition argues that such greenhouse assessments are of questionable value because of artificial conditions in the greenhouse. CFS agrees with that assessment, which is all the more reason that Fusarium susceptibility should be assayed in the field prior to deregulation. Apparently none of the field trials evaluated Fusarium disease.

Monsanto further argues that strains of bacteria raised in the laboratory on rich media make extrapolation to field conditions difficult due to acclimation to the artificial media.[7] However, Monsanto fails to disclose that such adapted strains are much more likely to suffer *impaired* virulence rather than increased virulence.

The petition also refers to field trails conducted in Europe for additional support of lack of environmental risk for disease in H7-1 sugarbeet. Comments discussed above about the inappropriateness of drawing conclusions from field trials performed at different times and locations should also be applied in the case of the European field trials. In addition, CFS notes that for numerous pathogens and nematodes, there were no disease symptoms observed in the European field trials. This is a rather surprising result and indicates that either disease and nematode pressure was extremely low, or perhaps very high levels of preventative fungicides and nematicides were applied. In either case, such field trials are virtually useless for determining disease or nematode susceptibility.[8]

In summary, Monsanto's analysis and reporting of disease susceptibility for H7-1 sugarbeet is incorrect. The data are limited, preventing a more definitive analysis. But based on the presented data, it is clear that further field trials are required to resolve the issues raised above. Deregulation should not be approved until such field trials resolve the disease susceptibility issues favorably. Or if increased disease susceptibility is confirmed, APHIS should carefully evaluate the human and environmental impact and deny deregulation if risk would be increased if RR sugarbeet were commercialized.

B. RR Sugarbeet Bolting Potential

Data presented by Monsanto (petition, p. 73) indicate that its H7-1 varieties may bolt at higher rates than varieties used for comparison. In particular, variety Beta 991 RR bolted at over three times the rate of the next varieties (another RR variety and a control) in 2001 field trials. This variety bolted at a 0.19% rate while the next highest varieties (2 of 6) bolted at 0.06%. In most cases, bolting rates for controls were undetectable to two decimal places.

Bolting is significant because bolters lower yield and, more importantly, may allow gene flow to occur in sugarbeet production fields. This is a concern in California sugarbeet production areas,

where the wild sugarbeet relative *Beta macrocarpa* is found, and is a weed problem in sugarbeet and rotation crops.

The petition dismisses the higher bolting levels of Beta 991 RR by saying that this result was inconsistent over the two years of trials (occurring in one year and not the other), and therefore may be due to background genetics. However, once again, this analysis is dubious because bolting values were very low for all varieties in the first year (2000), although Beta 991 RR also equaled the highest levels that year (0.03%). Bolting is sensitive to environmental conditions, especially temperature, and it may be that 2000 experienced higher temperatures and was therefore generally not favorable to bolting. Bolting values were somewhat higher in 2001, so that year may have been a better test. Unfortunately, neither the relevant weather conditions, nor a statistical analysis of significant difference was provided, so no clear judgment can be made. However, the conclusion of the petition that the observed higher bolting is inconsequential is not supported by the data, and can only be resolved by further field trials.

C. RR Sugarbeet Yield and Herbicide Use

Monsanto cites sugar yield data in support of its claim that RR sugarbeet is beneficial. Such data are important in part because yield will impact grower profit. The petition selectively cites data indicating a 15% increase in sugar yield, with two Roundup applications compared to three for conventional herbicide applications. However, other reports show much smaller, often insignificant gains, or higher yields for conventional varieties. For example, Kaffka and Peterson show only a one percent increase in sugar yield with RR sugarbeet compared to the conventional counterpart, with only a single application of Roundup or conventional herbicides.[9] These researchers also believed that the slightly higher RR sugarbeet yields were likely an artifact. In addition, one pound of Roundup active ingredient was applied per acre compared to 0.3 pounds of conventional active ingredients. Similarly, in 2001, researchers in Oregon reported only a 2% increased sugar yield compared to the conventional progenitor. And in many cases the conventional varieties yielded more than the RR variety. For example, ACH Mustang had an estimated 2% higher sugar yield than ACH 9931 RR (Roundup Ready), while an average of two other conventional varieties under conventional herbicide treatment from another seed company yielded almost 7% more sugar than the average of three RR varieties.[10] In Idaho field trials some RR sugarbeet varieties yielded more sugar than some conventional varieties, but the highest yielding varieties were conventional.[11]

The foregoing examination of RR sugarbeet yields is not intended to draw conclusions about yield, but to indicate that the petition probably substantially overstates the relative yield of RR sugarbeet compared to conventional varieties. Unfortunately, Monsanto did not provide a comprehensive and detailed summary of available yield trials, but chose to highlight a few studies that gave particularly favorable results. Calculations using such probably inflated yield values would give inflated grower profit projections.

In addition, herbicide use is projected to increase with RR sugarbeet based on projections, from 0.89 pounds/A with conventional varieties and herbicide, to 1.50 pounds/A with RR sugarbeet, for an overall increase of about 931,000 pounds/year.[12]

It is also instructive to examine both herbicide use trends and yields in RR soybeans, because weed control is not a static process, but changes over time. The trends in RR soybeans therefore may provide some foreshadowing of events with RR sugarbeet if they are deregulated. The efficacy of glyphosate herbicides is likely to be highest for the first several years after commercialization, prior to weed shifts that favor the most recalcitrant weeds, and the development of resistance. As noted above, recent data suggest that as of the past several years, more glyphosate is used on RR soybeans than herbicides on conventional soybeans.[13] The report attributes this increase to weed shifts, glyphosate resistant weeds, and other trends such as lower herbicide costs (herbicide resistance is discussed at length below).

Yields for RR soybeans have been flat since around the time that RR soybeans were introduced after increasing over the previous several decades.[14, 15] It is unclear what has caused these trends, but they demonstrate in any case that the introduction has not improved yields for this most extensively planted RR crop.

D. Gene Flow From RR Sugarbeet to Sexually Compatible Wild Relatives

In its EA, APHIS dismisses the likelihood or importance of gene flow from RR sugarbeet to the wild relative *Beta macrocarpa*. Historical data on gene flow suggest that APHIS is incorrect in its assessment of gene flow, and has not adequately considered its consequences.

The only wild relative of sugarbeet in the U.S. that is sexually compatible is believed to be *Beta macrocarpa*, which is found at several locations in California, including sugarbeet production areas in the Imperial Valley. Sugarbeet seed production occurs in Oregon where *B. macrocarpa* is not found. Therefore, because sugarbeet is biennial and is harvested for sugar production after only one growing season, gene flow to *B. macrocarpa* (wild beets) in California is most likely to occur from beets that flower, or bolt, during their first year of growth, or from sugarbeet plants that grow from roots left from the previous year (so-called "ground keepers") or from feral beets.

Because weed beets can be a problem in sugarbeet or other crops, gene flow could eliminate the use of glyphosate herbicides to control such weed beets. Although other herbicides or cultivation are available for control of weed beets, the loss of glyphosate as a possible control option may result in the use of more harmful herbicides. For example, Monsanto recommends in its petition that the herbicides methylsulfuon, 2,4 D, or dicamba could be used as alternatives if gene flow occurred. But all forms of 2,4 D have slightly to moderately higher environmental hazard, and dicamba has almost twice the hazard compared to glyphosate, according to the Cornell environmental index.[16]

Monsanto makes several arguments in claiming that gene flow to wild beets in California is unlikely. CFS finds that these arguments are seriously flawed. Monsanto cites two scientists who claim that weed beet flowering time has no overlap with sugarbeet bolters and that most first generation hybrids are sterile. These two points, however, are contradicted by detailed published data showing the presence of sugarbeet alleles in several weed beet populations.[17] The introgression of these alleles could only occur with successful gene flow. In their paper, Bartsch and Ellstrand observed some overlap in flowering time between weed beets and sugarbeet. The difference in observed flowering times may be explained by normal variation, which can be influenced by environmental conditions.

Monsanto also argues that newer varieties do not bolt as frequently as older varieties, and that bolters and ground keepers will be culled by hand weeding. However, as noted above, there is some evidence that some RR sugarbeet may bolt at higher rates than the control sugarbeet varieties used in the bolting trials. Furthermore, voluntary management practices have not been successful in preventing the development of weeds resistance to glyphosate in RR soybeans or managing their spread, or preventing gene flow to wild beets in the past. APHIS should therefore consider a geographical restriction that does not allow the farming of RR suagrbeet in Southern California. In lieu of a geographic restriction against producing RR sugarbeet in Southern California, APHIS should institute mandatory bolter and ground keeper management that requires growers' training prior to growing RR sugarbeet and imposes penalties such as fines and loss of the right to grow RR sugarbeet if bolters, ground keepers or other volunteers, are allowed to flower. APHIS should also provide for periodic inspections of production fields.

E. Glyphosate-Resistant Weeds

APHIS does not address the potential development of glyphosate-resistant weeds as a possible environmental impact under the National Environmental Protection Act (NEPA). 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] plants" is not considered to be under 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 sugarbeet, the use of the herbicide and the environmental implications for that use, including impact on the use of other herbicides and weed control methods, is unavoidably affected by APHIS decision on deregulation of RR sugarbeet. 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 sugarbeet 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 sugarbeet because it considers the safety of glyphosate compared to herbicides currently used on sugarbeet in the EA, claiming that glyphosate is less harmful than other sugarbeet herbicides. In this case, APHIS considers the relative impacts of other herbicide use compared to glyphosate on RR sugarbeet. 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 sugarbeet would allow reduced herbicide use (contradicted by data discussed above) (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 preventing resistance to glyphosate. This is even more remarkable considering APHIS determination that glyphosate has lower risk than some current sugarbeet 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[18] 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 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[19] may impose significant costs to growers from increased use of glyphosate or other weeds controls.

Glyphosate herbicides are also currently used on about 13% of sugarbeet acres, mostly as a pre-plant or pre-emergence treatment.[20] Resistance due to the use of RR sugarbeet 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 ready 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.[21, 22] 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. Therefore, farmers and APHIS need to appreciate and consider the importance of careful stewardship of the 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.[23] Glyphosate-tolerant morning glory has been identified in Georgia in 2004.[24] And most recently, glyphosate-resistant ragweed was confirmed in Missouri in December 2004.[25] 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 600,000 acres and has moved westward at least to Indiana and Arkansas.[26]

Monsanto notes that glyphosate has been used for three 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. On the other hand, 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 limit 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.

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.

Weeds in the U.S. that are so far known to be resistant to glyphosate are not considered to be important weeds of sugarbeet. However, there have been several reports of important sugarbeet weeds that have become difficult to control with glyphosate in some areas. These weeds include several pigweeds (*Amaranthus* spp.), tall waterhemp (*Amaranthus tuberculatus*), and lambsquater (*Chenopodium album*). Resistance or tolerance has not been confirmed, but weed control specialists are concerned.[27, 28] Even if these weeds are not currently tolerant or resistant to glyphosate, difficulty in controlling them may give them an advantage in developing resistance. Pigweeds, along with kochia (*Kochia scoparia*), are often considered some of the most troublesome weeds in the most important sugarbeet growing areas.[29, 30]

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 sugarbeet crop rotations is how they affect glyphosate use, because continuous use of an herbicide or herbicide mode of action increases the likelihood of resistance. The vast majority of sugarbeet are rotated to other crops, typically for at least two years. Rotation to other RR crops will prolong and thereby increase selection pressure on weeds to develop resistance, providing the weeds can survive in the rotation crop(s). Significantly, according to Monsanto's data, soybeans are the most important rotation crop for sugarbeet, especially in the most important sugarbeet production states. Because over 80% of soybeans are glyphosate resistant, most of these rotation acres are expected to be RR varieties.

In particular, soybeans are rotated with 379,000 acres of sugarbeet per year, by Monsanto's estimate. By comparison, horseweed developed resistance in Delaware, a state that grows only about 200,000 acres of soybeans per year, after only three years of growing RR soybeans.[31, 32] Because many of the most important weeds of sugarbeet, such as pigweeds, lambsquarter, and kochia, are also important weeds in soybeans, selection will continue during rotation between sugarbeet and soybeans. Monsanto emphasizes that RR sugarbeet rotations to other RR crops represent only a small fraction of the total crop rotation acreage. However, the percentage of total rotation acres is not important in considering the impact on resistance, because much of the included acreage is not planted to RR crops. Instead, the acreage in continuous RR crops where selection for glyphosate resistance can occur should be evaluated.

Monsanto improperly extrapolates from a single recent report (Wilson and Stahlman, 2003) that it claims ". . . shows that neither the percentage of growers adopting the Roundup Ready sugar beet system nor the extent of rotational Roundup ready crop acreage following Roundup ready sugar beet production will result in an increased likelihood of developing glyphosate-resistant weeds." (Petition, p. 110). Similarly, another three year study comparing several weed control strategies, including continuous use of glyphosate on RR soybeans and RR corn (Stoltenberg, 2002), is 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 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.

Monsanto's approach to resistance management excludes the most widely accepted method of rotating herbicide modes of action.[33, 34] Instead, Monsanto relies exclusively 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 as a means to prevent resistance, the 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 the 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. As noted by Monsanto, target site alteration does not seem to be the most common mechanism for glyphosate resistance. The proposed mechanism of reduced translocation could, to the contrary, be a dominant or partially dominant trait. Secondly, a true high dose may not be achievable with glyphosate as applied to many weeds. A high dose in the case of Bt is typically defined as at least 10 fold higher (often more) than the dose required to kill 99% of the population (LD_{99}). 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 sugarbeet.

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. This 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, many applications may be required to treat weeds only when they are small.

Finally, voluntary resistance management approaches, such as suggested by Monsanto, are currently applied to many pesticides with little evidence of success. On the other hand, 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 sugarbeet, with the help of sugarbeet growers and independent scientists. Such a program would likely employ mandatory rotation of herbicide modes of action.

Finally, APHIS should consider the impact of glyphosate-resistant weeds on growers of crops other than sugarbeet. Many of the major weeds of sugarbeet, such as pigweeds, kochia, lambsquater, and others are also important weeds of other crops where glyphosate-based herbicides are used. For example, glyphosate is labeled for virtually all of the major crops of Minnesota, such as several small grains (wheat, barley, oats and rye), oil seeds (canola and sunflower), dry edible beans, peas, corn, soybeans, alfalfa and potatoes.[35, 36] Many of the important weeds of sugarbeet are also important weeds in many of these crops. Glyphosate is also labeled for many other crops important in other sugarbeet 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 sugarbeet. APHIS should evaluate the impact of possible glyphosate resistance of these and other weeds of sugarbeet on crops grown in sugarbeet producing states in making its deregulation decision.

F. Impact on Organic and Other Growers

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

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 sugarbeet 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 sugarbeet seed market. No analytical information is present concerning: (1) the ability of non-transgenic seed producers to avoid transgenic contamination of their foundation beet seed; (2) the ability of seed sellers to ensure that seed being sold can be guaranteed to be non-transgenic beet 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 sugarbeet 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. <u>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</u>. 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 sugarbeet 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.

Third, the agency has failed to address a number of other socio-economic impacts that must be addressed as part of the NEPA process. Indeed, the CEQ regulations implementing NEPA state that such impacts must be analyzed.[37] Among the issues that need to be addressed include: (1) impact of RR sugarbeet on U.S. sugar exports and export of U.S. products using sugar derived from transgenic beets.; (2) the impact of commercial introduction of a sugarbeet 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.

G. <u>Additional Environmental Concerns</u>

The agency's EA makes only passing reference to impacts on non-target organisms. 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 sugarbeet is likely to impact on the habitat of many migratory birds. An increased use of glyphosate on sugarbeet 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.[38] 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.

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,

Douglas Gurian-Sherman
Senior Staff Scientist

Joseph Mendelson III
Legal Director

References and Notes

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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 limiting consideration of herbicide use on conventional soybean acres to weed control only with herbicides. 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, while 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. The Cornell environmental index quotient for triphenyltin is 70.1, higher than any other fungicide or herbicide, and compared to 15 for glyphosate.

4. USDA/NASS, Agricultural Chemical Usage Field Crops, May 2001, http://usda.mannlib.cornell.edu/reports/nassr/other/pcu-bb/agcs0501.txt

5. Agrios, G.N., "Plant Pathology: Second Edition," 1978, Academic Press, NewYork, NY

6. It is also not clear how the CP4 EPSPS gene could effect typical dominant resistance genes that usually determine different crop variety susceptibility based on pathogen race. But other mechanisms may pertain.

7. *Fusarium* spp. are fungi rather than bacteria, but the effect of culturing on laboratory media pertains to fungi as well.

8.Another formal possibility, that the variety used in the field trials was completely resistant to the diseases and nematodes tested is unlikely, because such varieties do not exist.

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13. Benbrook C., op. cit
14. USDA, National Agricultural Statistics Service, Historical field crop yield data for soybeans, http://www.nass.usda.gov:81/ipedb/oilseeds.htm
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38. *See generally*, DJ. Santtilo et al., *Response of songbirds to glyphosate-induced habitat changes on clear-cut,* 53:1 JOURNAL OF WILDLIFE MANAGEMENT, 64 (1989); J. F. Connor et al., *Winter Utilization by Moose of Glyphosate-Treated Cutovers.* 26 ALCES 91 (1990).