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Biotechnology Regulatory Services  
U.S. Department of Agriculture  
4700 River Road, Unit 147  
Riverdale, MD 20737–1236

SUBJECT: DOCKET No. APHIS-2007-0044

We are writing to comment on the Draft Environmental Impact Statement—November 2009 on Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Non-regulated Status. Dr. Kent Bradford is a Professor of Plant Sciences and Director of the Seed Biotechnology Center, University of California, Davis; Dr. Allen Van Deynze is a Senior Scientist at University of California, Davis, and Dr. Peggy Lemaux is a Cooperative Extension Specialist at University of California, Berkeley and Chair of the UC Statewide Biotechnology Workgroup. We have been directly involved in developing and disseminating scientific knowledge and co-existence strategies for the alfalfa varieties genetically engineered with events J101 and J163, as documented by the several refereed publications that we have co-authored on this subject.

First, we would like to state that we agree with APHIS’ decision that the only viable alternative is to deregulate Glyphosate-Tolerant Alfalfa Events J101 and J163, based on well-documented scientific and socio-economic considerations. We also believe the alternatives proposed by APHIS are adequate for consideration for the EIS and that the scope of the notice of intent adequately covers the relevant issues.

APHIS correctly rejects alternatives based on science and lack of authority to regulate certain options. We would like to further point out that rejected alternatives 2-4 would not guarantee 100% purity in any situation due to the dynamic biological environment that exists in agriculture. Markets in agriculture have continued to thrive with non-zero practical thresholds. The level of purity and quality of alfalfa hay and seed is market-driven and growers (not APHIS) choose which market to pursue, such that the quality of product is a self-imposed decision that growers must meet using knowledge of specific production practices and a wealth of experience and scientific information. Consistent with APHIS regulations, safe products that have gone through a risk assessment are not isolated from conventional commodity products in the US.

In terms of peer-reviewed articles, the majority of potential issues have already been summarized in the four 2004 to 2008 peer-reviewed publications that are attached (Putnam, 2006; Van Deynze et al., 2008; Van Deynze et al., 2004a; Van Deynze et al., 2004b). (Note: the complete and proper reference for “Gene flow in alfalfa: biology, mitigation, and potential impact on production” is Van Deynze et al. (2008) and not Putnam 2008 as used in the Draft EIS D-16). These publications address potential issues outlined in Section IV, Environmental consequences, A-H. Specifically the scope of the US alfalfa hay and seed
industry, biology, genetics, production practices, weed control, gene flow and co-existence principles are described in detail in these peer-reviewed articles.

We would like to highlight that unlike the vast majority of biotech crops grown today, the primary commodity for alfalfa is forage hay and not the seed or grain. In 2007, there were approximately 21.3 million acres of alfalfa hay and haylage and only approximately 100 thousand acres of alfalfa seed production in the United States (USDA, 2009). The annual crop value for hay and seed are approximately $8.0 billion and $80 million, respectively. Of this, the most recent estimate from 2005 for organic hay is 204,000 acres (0.9% of total hay). There is no documented certified organic seed produced in the United States, although there is likely a small amount grown organically. There is no doubt that the organic market will grow with demand from organic dairies, but even if it grew 10-fold it will likely remain the minority of total production. Seed-seed and hay-seed interfaces are likely to make up the minority (<2%) of potential gene flow situations. In terms of importance based on acres and value, it is clear that the hay-to-hay interface is the most prevalent, yet we provide scientific evidence that this situation is manageable and provides the least opportunity for gene flow (Fig. 1).

Alfalfa hay is grown across all of the continental U.S. and in general, it occurs wherever alfalfa-consuming livestock are fed. In contrast, alfalfa grown for seed is geographically specialized; it is not scattered uniformly throughout the country. The key states for seed are California, Idaho, Oregon, Washington and several other western states. Even within these states, the production regions for seed are typically limited and concentrated into locales where the climate is particularly suited to seed production. Even in those counties where seed is important, the seed-seed or hay-seed interactions are a minority of situations and confined to specific fields in specific areas. Alfalfa seed production is a highly coordinated undertaking. Most seed growers produce seed under contract and the seed field locations are carefully planned in advance to obtain the appropriate previous crop history and physical isolation from other alfalfa seed and hay fields. The American Organization of Seed Certifying Agencies (AOSCA) and the Federal Seed Act requires that certified alfalfa seed production practices ensure a minimum 99% genetic

![Figure 1](image-url)
varietal purity. For example, minimum isolation between a certified alfalfa seed production field and any nearby alfalfa seed, hay or feral plants is a primary requirement in the production of certified seed. Coexistence principles have been practiced and developed in the seed and hay industries for over 50 years. They are the basis of the seed industry and they have served the industry well on a global scale. Alfalfa farmers work with Seed Associations to ensure they can deliver high quality products.

The basis of coexistence across production systems is process-driven, as are the National Organic Program and seed certification programs. Although there are many details, it comes down to good communication with neighbors and good seed. It requires an understanding of gene flow and how to maintain seed and hay purity. A seed generation is required for gene flow, i.e. for gene flow to occur, pollen must fertilize a flower, make a viable seed, that in-turn must germinate and produce a viable plant that produces a viable seed (Putnam, 2006). This has large implications for potential gene flow in alfalfa.

**Gene flow**

Seed-to-seed gene flow studies are well documented in alfalfa (Van Deynze et al., 2008; Van Deynze et al., 2004b). Basically gene flow decreases exponentially with distance and is a function of the pollinator. A summary of studies to date can be seen in Figure 1. Leafcutter bees are the primary pollinator in the Pacific Northwest and honeybees in California, with a very small number of seed fields using alkali bees. These studies have been validated by sampling 300 commercial seed lots across the Western United States in 2006-2007 with three bee pollinators (Fitzpatrick et al., 2007). For all three pollinator species and pollinator species blends for all samples in the surveys, the observed commercial gene flow (adventitious presence, AP) was four to five times lower than that predicted in the smaller-field research experiments. The majority of these samples were also taken using Best Management Practices being developed by the alfalfa industry (Fitzpatrick et al., 2007). Percent AP was 0.00 to 0.18%, well below seed industry standards for seed off-types. While the potential for seed-mediated gene flow exists, Best Management Practices in the cleaning and management of seed harvesting and processing equipment are effective in managing admixtures between GE and conventional alfalfa seed. Coupled with cultural and rotational practices to manage volunteer seedlings, it is likely that seed-mediated gene flow will be very low (<1.0%).

Hay-to-hay interface is the most likely to occur. As shown in Figure 1, gene flow in this situation is an order of magnitude lower than with seed-to-seed. This is because, although hay may bloom prior to harvest, a germinating viable seed, required for the culmination of gene flow is highly unlikely (Putnam, 2006; Teuber et al., 2007). The most important factor for hay growers to maintain purity is to begin with certified seed for planting.

As in Van Deynze et al. (2008), Bagavathiannan and Van Acker (2009) present a comprehensive document on the biology of alfalfa with emphasis on potential gene flow due to ferality. Unfortunately, Bagavathiannan and Van Acker (2009) make deductions based on biology vs. actual production data. Furthermore, their conclusions on coexistence are based on zero tolerance for GE, a non-practical threshold for agriculture and one that is in practice in only a few exceptional cases. Even U.S. nutrition standards follow practical, non-zero thresholds for impurities and specific quality claims. Additionally, less than 5% of the alfalfa market (including export, domestic and organic) in the U.S. is estimated to be GE-sensitive (Putnam, 2006). Feral alfalfa has been shown to be a possible source of gene flow (Hammon et al., 2006). Data from the Hammon study indicated that there was no correlation between
distance and gene flow up to 1.7 miles. Feral plants have a large disadvantage over commercial fields since they are not managed. As a result, there is a reduced chance of synchronous flowering and a very high chance feral plants are destroyed by insects and consequently, seldom produce viable seed (Hammon et al., 2006). Feral plants and natural populations do exchange genetic material. Although improved cultivars have perceived naturally advantageous traits, such disease and insect resistance; this cross-pollination has not resulted in outbreaks of uncontrollable feral populations. This is likely due to a constantly changing environment that prevents selection for a single trait. The polyploid genetics and outcrossing nature of alfalfa also prevent fixing of genes or traits in one specific direction. The very low relative abundance of pollen and pollinators and the high degree of environmental stress on the feral plants relative to those within commercial seed production fields will reduce the likelihood and commercial importance of Seed-to-Feral and subsequent Feral-to-Seed or Feral-to-Hay gene flow risks to near zero.

Gene flow due to adventitious presence in seed can be effectively managed though crop rotation and the use of certified seed. Although certified seed programs do not test for GE, they guarantee a high level of seed purity for variety type and seed contaminants (Van Deynze et al., 2008).

Coexistence

Coexistence strategies for alfalfa production systems have been developed and tested by growers and the seed industry with input from seed and hay exporters, growers, processors, seed companies and public scientists. For example, the science-based information outlined above was published and disseminated in 2005 at grower (Western Alfalfa Seed Grower Association symposiums) and seed industry (California Seed Association, American Seed Trade Association) meetings prior to commercialization of Roundup Ready alfalfa (Van Deynze et al., 2004b). For example, over 3000 copies of these publications were disseminated at the meetings over the past 3 years. Specific stakeholder meetings were held in Idaho and California (http://ucce.ucdavis.edu/files/filelibrary/5283/22000.pdf) and the publications were used to develop Best Management Practices. On October 10, 2007, a meeting was held by the National Alfalfa and Forage Alliance to specifically address coexistence in alfalfa. The meeting was attended by 70 growers, industry and public scientists representing conventional, organic and GE production systems. At these meetings and up to the present, Best Management Practices have been refined to allow farmers to coexist and have a choice of what production system is best for their particular markets. The resulting whitepapers addressing alfalfa hay and seed export markets, and organic production are available from the National Alfalfa and Forage Alliance at http://www.alfalfa.org/CSCoexistenceDocs.html. Furthermore, as an independent agency, AOSCA has developed its own best management stewardship program available for growers. Alfalfa farmers are well-informed, experienced seed growers who can apply these strategies to their specific farm situation.

The basis of coexistence in agriculture and the Best Management Practices are practical thresholds based on scientific data. Zero impurities or 100% purity is very difficult to impossible to achieve in commodity or even specialty biological systems, although thresholds near 1% are routinely achieved and used in agriculture. As a result, organic and seed certification programs do not require zero impurities as thresholds. The most relevant analogy is the certified seed system which has been effective in delivering high quality products for a century worldwide. As an example, the scientific data show that to achieve hay that is 99% pure (<1% GE), one should use crop rotation, plant certified seed, control feral alfalfa and harvest prior to viable seed formation. In fact gene flow between hay fields is rare with less than 0.001% gene flow expected (Putnam, 2006). To achieve <1% GE in a seed field, adjacent seed fields are a
concern. To address this, growers perform at least a 2-year crop rotation, control feral alfalfa blooming around the field, begin with certified seed and ensure at least a 900-ft isolation when using leafcutter bees as pollinators and a minimum of 1-mile isolation with honeybees as pollinators (Van Deynze et al., 2008). The NAFA Best Management Practices are required for all Roundup Ready Seed production including a 900-ft isolation with leafcutters and a 3-mile isolation with honeybees. Experimental data show that this a sufficient distance to mitigate possible gene flow to near-zero levels (see Figure 1). Conventional seed growers who are concerned about AP can consult with their local seed certification agency to help them plan field isolation and they can utilize the AOSCA program to produce conventional varieties.

Our conclusions from the above are:

- Roundup Ready alfalfa can benefit a large segment of the U.S. alfalfa seed hay and livestock industries
- Gene flow concerns are limited to <2% of the alfalfa acreage
- Development of weed resistance to Roundup is not specific to alfalfa
- The vast majority of U.S. markets are not sensitive to GE
- Gene flow in alfalfa is well-understood and controllable
- Effective strategies and management programs are in place to allow coexistence of production systems and markets

Sincerely,

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References


