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Biotechnology Regulatory Services
U.S. Department of Agriculture
4700 River Road, Unit 147
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SUBJECT: DOCKET No. APHIS-2007-0044

We are writing to comment on the Final Environmental Impact Statement—December 2010 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 (Van Deynze et al., 2008; Van Deynze et al., 2004a; Van Deynze et al., 2004b).

First, we would like to comment on the recent events that are shaping this discussion. “GE organisms are subject to APHIS oversight if they are regulated articles as defined in 7 Code of Federal Regulations (CFR) § 340.0. Importation, interstate movement, or release into the environment of GE organisms requires authorization from APHIS. The determination is based on the data required in 7 CFR §340.6(c), which are provided by the applicant and supported by the best available science.” This is the USDA’s only premise to regulate biotech traits. Science has been the mainstay of regulation that has served US agriculture and food safety well. We were therefore aghast at the comments made by Secretary Vilsack in a recent meeting that “science is subjective”. To the contrary, science is statistically sound and results are presented with a certain level of probability based on empirical data. Unlike math and engineering, experiments in agriculture, food and biology do not have absolutes, thus neither 100% certainty, nor 0% chance of failure is achieved. Despite this, accurate conclusions and sound decisions are made. For example, in our publication on gene flow in alfalfa (Van Deynze et al. 2008), we used over 1.2 million data points to predict gene flow, allowing growers to select proper isolation distances with 99% (not 100%) confidence. With science-driven advances in technology and policy, American and global agriculture has made tremendous advances to feed our growing population while reducing our footprint on the environment. Our comments are based on peer-reviewed science that is well documented in the EIS.

Accordingly, we would like to state that the only viable option is APHIS’ preferred Alternative 2; to deregulate Glyphosate-Tolerant Alfalfa Events J101 and J163 without restrictions, 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 further agree that Alternative 1 is not acceptable as there is no scientific evidence that glyphosate-tolerant (GT) alfalfa will harm the environment or is unsafe. The original Environmental Assessment (EA), the federal and supreme courts and now the EIS agree on this point. Furthermore, neither Alternatives 2 nor 3 would 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 (for seed, hay, export, domestic or organic) 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. Based on the best available science (which is voluminous for this case), only Alternative 2 is acceptable and Alternative 3 must be rejected.

Support for Alternative 2
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). These publications address potential issues outlined in each of the Appendices. 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 and others.

We 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 (<0.5%) 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). No certified organic seed is documented as being 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 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.

Coexistence principles developed on science and dialogue
Coexistence strategies for alfalfa production systems have been developed, tested and validated on a commercial scale 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 GT alfalfa (Van Deynze et al., 2004b). 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 with consultation from members of the export and organic industries. On October 10, 2007, a meeting was convened by the National Alfalfa and Forage Alliance (NAFA) to specifically address coexistence in alfalfa. The meeting was attended by 70 growers, industry and public scientists representing conventional, organic and biotech production systems across the US. At these meetings and up to the present, Best Management Practices have been refined to allow farmers to coexist and have a choice of which 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 NAFA at http://www.alfalfa.org/CSCoexistenceDocs.html. W ell publicized, peer-reviewed paper was written and published by a panel of scientists to document the biology of alfalfa in relation to gene flow (Van Deynze et al. 2008). This was disseminated at the National Alfalfa Symposium to growers and industry personnel. It is available free of charge through NAFA. Furthermore, as an independent agency, the Association of Official Seed Certifying Agencies (AOSCA, www. aosca.org) has developed its own best management stewardship program for growers. This is only a partial list of the grower meetings and dialogue that have gone into developing the Best Management practices for alfalfa. Meetings were not only open to all growers, but specific members of the organic industry and export marketers were personally invited and consulted to develop these procedures. In fact, key organic dairy and organic seed cooperative representatives were contacted and asked to provide feedback to develop these procedures. The NAFA Best Management Practices are required for all GT alfalfa seed production including a 1-mile isolation when using leafcutter bees and a 3-mile isolation when using honeybees as pollinators. Experimental data on a commercial scale show that this a sufficient distance to mitigate possible gene flow to near-zero levels (Van Deynze et al. 2008). Conventional seed growers who are concerned about adventitious presence can consult with their local seed certification agency to help them plan field isolation practices and they can utilize the AOSCA program to produce conventional varieties. Alfalfa farmers are well-informed, experienced seed growers who can apply these strategies to their specific farm situation. Thus, the petition should be granted in full (Alternative 2) and the existing management practices and certification procedures should be allowed to operate to meet diverse market needs.

Why Alternative 3 is not acceptable.

Alternative 3 outlines a plan to have different regulations for 3 classes of States depending on their alfalfa use. It proposes a training program, reporting and monitoring system for all GT alfalfa planted. It further restricts GT alfalfa to be planted in counties where seed production does not occur and 5 miles from other alfalfa. First of all, the USDA cannot effectively administer this level of scrutiny of the production system, nor should it. American agriculture does not need another set of regulatory strictures and the administrative bureaucracy required to monitor it. Secondly, Alternative 3 will not guarantee 100% purity, and 100% purity is not achieved in any agricultural (feed or food) products. For example, low practical thresholds are tolerated for pesticides even in organic food. It is up to those producing and those utilizing agricultural products to jointly agree on purity standards that are achievable and that meet the market and product quality requirements. It has traditionally been the expectation that the producer seeking a higher value market for a higher purity product has the responsibility to achieve that standard. For example, the seed production industry has always maintained a higher standard for genetic purity than is expected for commodity product production. However, it has always been the seed producers’ responsibility to have sufficient isolation or to take other measures to meet their market requirements. In contrast, Alternative 3
favors and enables the market objectives of a small minority of growers in a way that would dramatically impact alfalfa production in the US. There is little or no documented production of organic alfalfa seed in the US and organic alfalfa hay remains less than 1-2% of total alfalfa production. Nonetheless, in the absence of any adverse health or safety issues, Alternative 3 would require conventional growers to forego major benefits from improved varieties, improved quality hay and improved impact on the environment in order to enable this small fraction of growers to meet their market goals. We note that organic hay usually has lower yield and is of poorer quality than conventional or GT hay (Long et al., 2007). To note the benefits of GT-alfalfa as described are noticeably missing from the EIS. Of course benefits (high yield, thus less land required for production, reduced toxicity of pesticides, and disadvantages should be considered in a risk assessment. With what justification would a large fraction of farmers be denied the use of a safe technology only to assist a small minority in achieving a higher quality standard and market value?

Furthermore, according to the National Organic Program (NOP) guidelines, the mere presence of GE alfalfa would not require rejection of organic certification of the crop. The NOP guidelines are production-based, and have defined thresholds for the presence of other prohibited inputs, such as synthetic pesticides, rather than a zero-tolerance standard. These guidelines with thresholds have served coexistence well, and have allowed the organic food industry to flourish (claimed 20% growth per year) at the same time that over 90% of the growers have adopted the GE crops that have been commercialized. This parallel growth alone demonstrates that specific regulations to compel coexistence, as proposed in Alternative 3, are unnecessary to protect the organic market.

It is worth considering the following scenarios implied by Alternative 3. Consider two neighboring farmers who both produce alfalfa hay. If they grow different varieties of alfalfa, it does not create any market issues for either farmer, as the genetic purity of the seeds is not an issue for the hay market. However, suppose that one farmer decides to seek a higher value market by growing alfalfa seeds. Now, the presence of his neighbor’s alfalfa crop could create a problem for the genetic purity of his seed crop. Traditionally, it would still be the responsibility of the grower seeking to produce seed to arrange the required isolation distance needed, or take other measures to meet the chosen market standards. This approach is illustrated in the extensive dialog and isolation standards adopted voluntarily by the alfalfa seed industry prior to the introduction of GT alfalfa (see above). However, according the precedent being established in Alternative 3, once one grower decided to switch to seed production, she/he would have the right to demand that the neighbor stop growing alfalfa for hay, as any cross pollution could cause economic injury to the seed producer. And, if the neighbors wished to grow GT alfalfa, the seed grower could demand that none could be grown in the entire county. This type of restrictive imposition on neighbors has never been utilized in the seed production industry (which involves a larger area than organic production currently occupies), and yet sufficient seeds of high quality are produced each year for both domestic needs ($12 billion market) and 16% of total global exports ($1.2 billion total value) (ISF, 2008). This has been achieved through voluntary, market-driven well-defined seed certification standards and practical coexistence among agricultural sectors, not through arbitrary and coercive regulations.

Consider further that Alternative 3 would establish the precedent that if a grower voluntarily decided to seek organic certification, that grower might be able to require growers in a five-mile radius around his farm to stop using GE crops, since any cross pollination from the GE crop would potentially cause economic (not safety to human or environment) harm. A 5-mile isolation buffer would mean that a single
grower could dictate the crop variety choices of farmers in the surrounding 50,265 acres or 78.5 square miles (area of a circle with radius of 5 miles). Strategically placed fields could eliminate farmers’ choices for entire production regions. This is unprecedented in agriculture and antithetical to true coexistence.

Based upon the court ruling that required the GT alfalfa EIS, surely this type of economic impact due to the certification of an organic farm by the NOP would require a full Environmental Impact Statement, according to how NEPA was applied in this case. In fact, given that the ban on use of GE crops in the NOP rules has now resulted in the consideration of Alternative 3 specifically to favor economically one group of farmers over another, one can ask whether the entire NOP should not have required an EIS prior to its implementation. It is worth recalling that the USDA initially did not propose to ban the use of GE crops from organic certification, as there was no scientific justification for it. The ban was included at the demand of the organic community, and therefore constitutes a voluntary, self-imposed market standard that was included in the NOP. In analogy with the seed industry, which also has its own self-imposed certification standards, it should be the responsibility of organic growers to meet their own standards, or if they cannot be achieved, to establish thresholds and standards that are achievable, as in the case of inadvertent presence of prohibited pesticides.

As we documented above, voluntary agreements on isolation distances and market requirements are capable of managing coexistence to the benefit of all parties. Regulatory imposition of draconian requirements would create conflicts among growers, rather than minimize them. For example, the proposed requirement that alfalfa seed could not be grown in counties in which GT alfalfa hay is produced would create an impossible situation in California, the source of one-third of the US alfalfa seed supply and also the largest alfalfa hay-producing and -consuming state. In Fresno County, the most productive agricultural county in the country, alfalfa hay growers would have to forego the benefits of GT alfalfa, or would this important source of alfalfa seed production (32% of the state’s production) be eliminated? In Imperial County, on the other hand, which produces 67% of the state’s alfalfa seed, agreements are already in place through voluntary dialog not to produce GT alfalfa in the county in order to enable seed producers to meet diverse market needs. Indeed, Monsanto and Forage Genetics have since 2007 addressed specific concerns over export markets for regions such as the Imperial Valley in California. This again demonstrates that Alternative 3 is not required due to voluntary coexistence within the agricultural industry. Banning important crops from entire counties or imposing 5-mile buffers (far beyond what can be justified on the basis of existing data) is not coexistence. In fact, we are dismayed that APHIS is even considering Alternative 3 rather than recognizing that American farmers and the seed industry have cooperated in producing high quality alfalfa hay and seed for diverse organic, export and conventional markets for over 50 years.

We also note that the full EIS comes to the same conclusion as the Environmental Assessment conducted by APHIS in conjunction with the original deregulation of GT alfalfa, that there are no adverse impacts on human health and safety and no biological impacts that are not shared with other weed control strategies. And any socioeconomic impacts are dependent upon market forces, not upon GT alfalfa per se, as they are for any new technology. Logically, in light of this conclusion, the preferred alternative for APHIS is to grant the petition in full and deregulate GT alfalfa without restrictions. By doing so, APHIS has satisfied the court’s requirement to take a hard look at additional economic impacts, which the court defined as environmental impacts. On the other hand, choosing to implement Alternative 3 is the equivalent of admitting that neither the EA nor the EIS was competent or science-based and that therefore APHIS is incapable of doing its job, or that, despite the scientific evidence, additional restrictions will be imposed.
solely to influence the relative market advantages for certain segments of the agricultural community. Selecting Alternative 3 means that after three additional years of study and input, APHIS admits that the U.S. does not have a science-based biotechnology regulatory policy. Instead, like the European Union, APHIS will base regulations upon political pressure and the unsubstantiated beliefs of special interest groups.

Secretary Vilsack recently characterized the proposed Alternative 3 as a strategy to encourage coexistence and prevent these issues from being decided in the courts. In contrast to that expectation, Alternative 3 guarantees further legal battles rather than coexistence. It is virtually certain that farmers, who have had their crop choices arbitrarily restricted, not on a scientific basis but in order to provide a marketing advantage to a small segment of the industry, would seek judicial relief. On the other hand, it is equally evident that enacting Alternative 3 would only encourage further suits by those who oppose GE to extend similar types of restrictions to all current and future GE crops. By adopting Alternative 2, APHIS would reassert its authority for science-based biotechnology regulation and reduce the likelihood of further suits based on the misapplication of NEPA (Conko and Miller, 2010).

Over 100 years of experience with certified seed production and 15 years of experience with biotech crops has shown that farmers can coexist to meet their market goals. Multiple technologies (including biotechnology) and diverse markets are crucial to the advancement of agriculture to better feed the world economically and sustainably. It is crucial that the U.S. demonstrate its leadership and commitment to science and technology. The only choice for APHIS is to fully deregulate GT alfalfa and allow U.S. farmers to benefit from the lower cost and higher quality forage that it enables.

Sincerely,

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References