

July 6, 2009

Docket No. APHIS-2007-0016
Regulatory Analysis and Development, PPD
APHIS, Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

Comment on Docket No: APHIS-2007-0016 Re: Syngenta Seeds, Inc.;
Availability of Petition and Environmental Assessment for Determination of
Nonregulated Status for Corn Genetically Engineered To Produce an
Enzyme That Facilitates Ethanol Production

The undersigned trade associations representing the grain handling, grain export, food, feed and pet food industries in the United States and North America appreciate this opportunity to comment again on the petition to deregulate Syngenta's Alpha-Amylase Maize Event 3272. The APHIS action of June 4, 2009, reopening the comment period adopts several conclusions of the applicant, Syngenta, which we believe unnecessarily constrain the agency.

It appears that APHIS and the applicant believe the agency has just two choices – to fully regulate or fully deregulate Event 3272. We continue to believe APHIS has sufficient authority to condition any deregulation of events in a manner that is based on the scientific research and data assessing the risk – including economic harm to the food sector. However, in order to develop the conditions necessary for such action, the docket must include an assessment of risk and a plan for the management of risk.

In the absence of any reasonable response to our initial comments, therefore, our comments will focus on several primary points:

- (1) APHIS's reliance on a White Paper submitted to the agency by the applicant is arbitrary and therefore the docket for Alpha-Amylase Maize Event 3272 remains insufficient for APHIS to deregulate the event;
- (2) APHIS's adoption of the applicant's definition of the agency's regulatory interest may inadvertently strip APHIS of any future role in the regulation and deregulation of plant biotechnology;
- (3) Legal precedent establishes that APHIS has a duty to assess economic risks to the food chain;
- (4) The draft Environmental Assessment (EA) does not meet the standards required by the National Environmental Policy Act (NEPA); and

- (5) Alpha-Amylase Maize Event 3272 is a corn variety intended solely for use in the production of ethanol – an industrial product – and thus should be regulated under Part 340 as a plant made industrial product.

I. The Docket for Alpha Amylase Maize Event 3272 Remains Insufficient

As was the case during the original comment period, the docket and petition for deregulation lacks adequate scientific data or documentation necessary to evaluate the possible impacts on food and feed functionality should this maize event be commingled with commodity supplies of corn. In its June 4, 2009, Federal Register Notice, APHIS agrees with Syngenta’s declaration that such an analysis is beyond the scope of the agency’s regulatory authority. As discussed in detail below, we disagree with this new conclusion.

Docket No. APHIS-2007-0016 represents clear evidence that both Syngenta and APHIS believed the legal authority reached to the consideration of functional impacts to food.

Prior to our previous submission of comments requesting additional data to determine risk to the food supply from negative functionality characteristics, Syngenta voluntarily provided to APHIS and APHIS considered the very limited information about the negative food functionality impacts in processing corn for masa. In fact, the November 6, 2008, draft EA highlighted this information. These two actions suggest that both Syngenta and APHIS believe this data to be relevant to the deregulatory authority.

We, therefore, reiterate our request that APHIS suspend the deregulatory process until the U.S. government agencies responsible for the oversight of agricultural biotechnology can reconsider the docket and the applicant requesting deregulation can present appropriate and necessary information to assess the impact of corn amylase on food, feed and processing and, subsequently, its potential to become a plant pest.

II. The Plant Pest Question and APHIS’s Regulatory Interest

Syngenta has submitted to APHIS a “White Paper” in support of its application. In that document, Syngenta asserts that the enzyme expressed in Event 3272 is not a plant pest, and bases its contention on the argument that the alpha amylase enzyme is not itself a living stage of a listed plant pest or an article similar to or allied with a living stage of a listed plant pest as expressed in Event 3272 corn. Syngenta goes on to claim that the amylase enzyme is not an “article” that is a plant pest within the definition of APHIS regulations implementing the genetically modified organism program, again on the basis of the same “living stage” argument. The applicant further contends that our previous submission poses “classic marketing issues, not plant pest issues.” We disagree with Syngenta’s assurance that no plant pest issues are raised.

In short, Syngenta’s “White Paper” fails to address the fact that all transgenic events containing unique functional characteristics – which Event 3272 does – are potential plant pests absent a proper risk assessment, risk management, and risk responsibility plan.

The idea that Syngenta’s narrow definition of a plant pest can override all of the numerous arguments favoring close study ignores the obvious: Neither Syngenta nor APHIS have provided adequate information to assess whether or not Event 3272 represents a genetic sequence that, when expressed in plant or plant products at some point in the future, might prove to be a plant pest. Adopting the very narrow definition promotes the notion that the APHIS process is optional and events such as Event 3272 could simply certify that the enzyme is not living and therefore falls under no regulatory requirement of APHIS. Under such a result, even those events that APHIS routinely and historically has exercised its authority over, such as glyphosate resistant soybeans, could automatically fall outside the APHIS regime.

III. *Geertson Seed Farms, Inc. v. Johanns*

Notwithstanding applicant’s narrow definition of the terms “plant pest” and “article,” federal courts have taken a more expansive view of the criteria for deregulation, and have addressed precisely the issues raised above. As noted in our January comments, the U.S. District Court ruling in *Geertson Seed Farms, Inc. v. Johanns*, made clear that deregulation of products with unique functional characteristics requires a more comprehensive, transparent approach.

In ruling that an Environmental Impact Study (EIS) was required before APHIS deregulated transgenic alfalfa designed to resist the herbicide glyphosate, and that APHIS should have required an EIS, the Court reasoned:

NEPA “is our basic national charter for protection of the environment.” 40 C.F.R. § 1500.1(a). “NEPA emphasizes the importance of coherent and comprehensive up-front environmental analysis to ensure informed decision making to the end that ‘the agency will not act on incomplete information, only to regret its decision after it is too late to correct.’” Blue Mountains Biodiversity Project, 161 F.3d at 1216 (quoting *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 371 (1989)). “An EIS is required of an agency in order that it explore, more thoroughly than an EA, the environmental consequences of a proposed action whenever ‘substantial questions are raised as to whether a project *may* cause significant [environmental] degradation.” *Id.* (internal quotation marks and citation omitted)...

“That is exactly the circumstances of this case.” *Id.* Substantial questions are raised as to whether (1) the deregulation of Roundup Ready alfalfa without any geographic restrictions will lead to the transmission of the engineered gene to organic and conventional alfalfa; (2) the possible extent of such transmission; and (3) farmers’ ability to protect their crops from acquiring the genetically engineered gene. Substantial questions are also raised as to the extent to which Roundup Ready alfalfa will contribute to the development of Roundup-resistant weeds, especially when considered in conjunction with the already deregulated and soon-to-be deregulated Roundup Ready crops, and as to how farmers will address such weeds. APHIS failed to answer these substantial questions, concluding instead that any environmental impact is insignificant because gene transmission is the problem of the organic and conventional farmers and weeds always develop resistance to herbicides. As such reasons are not “convincing” and do not demonstrate that the agency took a

“hard look” at the potential environmental impacts of its deregulation decision...” Geertson Seed Farms, Inc. v. Johanns, No. C 06-01075 CRB, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007).

The situation presented in the matter of Syngenta’s Event 3272 is analogous to the circumstances confronted by the Court in *Geertson Farms*. The Court’s opinion made the case as eloquently:

“[A]n EIS *must* be prepared if ‘substantial questions are raised as to whether a project *may* cause significant degradation of some human environmental factor.’” *Idaho Sporting Cong. v. Thomas*, 137 F.3d 1146, 1149 (9th Cir. 1998) (quoting *Greenpeace Action v. Franklin*, 14 F.3d 1324, 1332 (9th Cir. 1992)). “Thus to prevail on a claim that [APHIS] violated its statutory duty to prepare an EIS, a plaintiff need not show that significant effects will in fact occur. It is enough for the plaintiff to raise substantial questions whether a project may have a significant effect on the environment.” *Blue Mountains Biodiversity Project*, 161 F.3d at 1212 (internal quotation marks and citation omitted). “Put another way, a proposal can be considered controversial if substantial questions are raised as to whether a project may cause significant degradation of some human environmental factor.” *Geertson Seed Farms, Inc. v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007).

Based on this standard, the applicant’s publicly available data in this submission is insufficient. Without a publicly available body of data, and close analysis of that data, we believe that Alpha-Amylase Maize Event 3272 may be a plant pest. The lack of publicly available data and the *Geertson Farms* decision far outweigh the applicant’s “take our word for it” argument.

Geertson Farms and the provisions of the Plant Protection Act (PPA) and their application to the issue of environmental factors are not the only bases for questioning the decision-making process undertaken in this application. The National Environmental Policy Act (NEPA) provides a compelling and persuasive basis to examine the issue absent consideration of whether the event is or is not a plant pest. The *Geertson* Court also weighed in on the issue of economic impact, as we argue below.

IV. The Legal Obligation under the National Environmental Policy Act (NEPA)

NEPA requires that APHIS prepare an Environmental Impact Statement (EIS) on important federal actions that significantly affect the quality of the human environment. When an EIS is not absolutely required or is excluded, the Department must prepare an Environmental Analysis (EA), which lays out the data and analysis determining whether the effect on the environment is significant enough to require an EIS. If an EA produces a finding of no significant impact, no EIS is required.

The draft EA regarding Event 3272 fails to conform to the requirements of NEPA because it does not provide sufficient data and analysis in several areas to support the conclusion that deregulation will not have a significant impact on the human environment. APHIS's analysis failed to address the serious economic consequences to the supply of corn for food and uses resulting from Event 3272 placing on the market without adequate controls in place and it failed to adequately examine alternatives to Syngenta's product for purposes of ethanol production. At a minimum, APHIS should

prepare a new EA. Given the potentially profound impacts on the environment and the supply chain attaching to this application, it is likely that a new EA would lead to a decision to take the next logical step and require an EIS.

If deregulated in the absence of a more complete assessment of risks, it is likely that users of corn will have zero tolerance for Event 3272 in corn. It is possible that 3272 will find its way through movement of pollen or via admixture in the supply chain, into the U.S. corn supply and consequently, the food supply chain. International customers of U.S. corn will take their cues from the U.S. industry and similarly demand certification that the supply of corn is free of Event 3272. The only complete defense available to the market, including corn processors and food manufacturers whose products are at risk, is to test every kernel of corn in every truck, railcar and barge load for the presence of Event 3272. This defense is not practical. However, alternative management techniques cannot be developed or deployed until risks are more completely identified. Risk management must also be put in place along with adequate redress provided for should the risk management fail.

In the absence of adequate risk assessment, management and responsibility provided for by either the technology provider or official mandate, the consequence is the addition of tens of millions of dollars in cost to the U.S. corn marketing chain, a much less reliable supply of U.S. corn, and a significant reduction in the competitiveness of U.S. corn in the global marketplace all resulting in a devaluing all corn grown domestically.

Furthermore, the tendency for corn to cross-pollinate with other corn varieties not only increases the opportunities for Event 3272 to enter the food and feed supply but also risks contamination with future corn seed supplies. Yet, the record is notably absent any significant assessment of the applicant's stewardship plan.

Simply stated, the inevitable contamination of the food supply by the Syngenta corn product will have economic implications, all of which APHIS failed to address. Under NEPA, the effects on the human environment that an agency must consider "include ecological ..., aesthetic, historic, cultural, *economic*, social, or health, whether direct, indirect, or cumulative"(emphasis added).

Again, the Geertson Court anticipated these issues in its ruling:

“APHIS’s reasons for finding the development of glyphosate resistant weeds not to be significant are not convincing. Reasoning that weed species often develop resistance to herbicides is tantamount to concluding that because this environmental impact has occurred in other contexts it cannot be significant. Nothing in NEPA, the relevant regulations, or the case law support such a cavalier response...The assertion that “good stewardship” may be the only defense against such weeds is equally unconvincing. Such a conclusion is not the same as a finding that the development of the weeds is not a significant environmental impact. This is especially so given that neither the FONSI nor the EA contain any analysis as to what exactly constitutes good stewardship and how likely it is to be practiced successfully.” *Geertson Seed Farms, Inc. v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007).

Syngenta's argument to the effect that our issue involved merely marketing issues is disingenuous. The Court in *Geertson*, in examining the scope of NEPA, made clear that economic harm was an integral element to any NEPA analysis:

APHIS argues in its brief that the extent of any gene transmission is, in any event, irrelevant because NEPA requires an agency to consider physical environmental impacts, not economic or financial impacts. APHIS overstates the law. To determine whether NEPA requires an agency to consider a particular effect, courts must "look at the relationship between that effect and the change in the physical environment caused by the major federal action at issue." *Metropolitan Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 773 (1983); see also *San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm'n*, 449 F.3d 1016, 1029 (9th Cir. 2006) ("[T]he essential analysis must focus on the closeness of the relationship between the change in the environment and the 'effect' at issue") (internal quotation marks and citation omitted); *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934, 943 (9th Cir. 2005) ("NEPA does not require an agency to assess all impacts of a project, only those that have a 'reasonably close causal relationship' with 'a change in the physical environment'"). Economic effects are relevant "when they are '*interrelated*' with 'natural or physical environmental effects.'" *Ashley Creek Phosphate Co.*, 420 F.3d at 944 (quoting 40 C.F.R. § 1508.14. *Geertson Seed Farms, Inc. v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007).

One of the many ways the environmental and economic elements are interrelated involve the domestic and international marketability of the event in question. Among the most critical elements of economic harm both Syngenta and APHIS have failed to address is the inevitability that the product will be detected in exports to countries where the variety has not yet been approved. We have seen this phenomenon again and again. Unapproved varieties cause substantial losses to exporters, growers and others in the corn supply chain. Indeed, the Court in *Geertson* went on to specifically address this issue:

APHIS's assertion that exports to Japan will not be harmed because Japan allows one percent of its imported alfalfa to be transgenic and "[b]y employing reasonable quality control, it is highly unlikely that the level of glyphosate tolerant alfalfa will exceed 1% in conventional alfalfa hay," AR 5488, is also not convincing. Neither the EA nor the FONSI contain any reference to any material in support of APHIS's conclusion that gene transmission is "highly unlikely" to occur with "reasonable quality control." APHIS does not identify any "quality control" that will prevent gene transmission between neighboring seed farms. It similarly does not identify any material to support its EA statement that nongenetically engineered alfalfa will "likely still be sold and available to those who wish to plant it." AR 5511. *Geertson Seed Farms, Inc. v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007).

The absence of adequate segregation procedures and the inevitable contamination of the food and feed supply will impose tremendous costs on food manufacturers and processors. That the amylase product was the subject of a voluntary safety consultation at FDA will do little to reassure or compensate the participants in the supply chain who will be affected.

Indeed, we have already seen evidence that consumer reactions to altered shelf life and stability of certain food products may impact processors and retailers. The Food Standards Australia New Zealand (FSANZ) review of GE ethanol corn addressed this very issue:

...[T]he presence of corn containing a thermostable a-amylase may, in certain circumstances, affect the shelf life and quality of some finished food products Should conditions be suitable for the [GE ethanol corn] a-amylase enzymes to act on the starch in a food, then these enzymes would change the final food's nutritional profile to one that contains a greater proportion of dextrins, disaccharides and monosaccharides.... Such a change could be noticeable by consumers, through changes to the taste and texture of the final food.

APHIS only partially fulfilled the NEPA requirement for an assessment of alternatives. The EA compared the impacts of the use of GE ethanol corn, if it were deregulated, with the current use of microbial alpha amylases in a number of areas. Based on Syngenta's economic analysis the agency concluded that replacing exogenous microbial alpha-amylases with the Syngenta product would reduce the costs and increase the efficiency of ethanol production. The agency, however, provided no independent economic analysis.

Nor did the EA examine other alternatives to Syngenta's product, aside from exogenous, thermostable microbial enzymes. The agency should have evaluated other enzymes such as those found in-Stargen and BPX. According to their manufacturers, these products result in a significant shortening of the production process through the elimination of the high-temperature liquefaction stage as well as the saccharification stage. Both of these products are readily available, and represent viable alternatives to the product in question.

V. Alpha-Amylase Maize Event 3272 is a Plant Made Industrial Product

Deregulation of Syngenta's Alpha-Amylase Maize Event 3272, based on 7 CFR Section 340.6, is not warranted under the very guidance issued by APHIS. According to a Biotechnology Regulatory Services (BRS) Factsheet published by APHIS in February 2006:

A pharmaceutical or industrial crop is a plant that has been genetically engineered to produce a medical or industrial product, including a human or veterinary drug, biologic, industrial or research chemical, or enzyme...BRS policy makes clear that these GE plants are handled differently than those being developed for use as food or feed.

Pursuant to Syngenta's application it is clear that Event 3272 has been developed exclusively for use in the production of ethanol – an industrial product. The fact that Syngenta sought a nutritional equivalence finding from the FDA does not change the fact that Event 3272 is designed solely for industrial use. By APHIS's own rules, it has no choice but to regulate Event 3272 as a Plant Made Industrial Product.

Conclusion

As reflected in our comments, APHIS has not fully considered all of the issues presented to it in this one event. In addition to the legal obligations that the agency has yet to

address fully, APHIS has an ultimate responsibility to ensure that its actions are aligned with the best interest of U.S. agriculture and the mission the U.S. Department of Agriculture as expressed in the mandate of the Commodity Credit Corporation Charter Act, which among other things calls on the Secretary to operate the CCC in a manner to “stabilize, support, and protect farm income and prices,” and well as to “maintain balanced and adequate supplies of agricultural commodities and aid in their orderly distribution.” The Secretary’s ability to carryout his duties and deploy the specific authorities granted to the office would be adversely affected by the deregulation of Event 3272 absent such full consideration.

We therefore respectfully request that APHIS immediately suspend all efforts to deregulate Event 3272.

* * *

The National Grain and Feed Association (NGFA), a not-for-profit trade association established in 1896, consists of 1050 member companies from all sectors of the grain, feed, processing and exporting business that operate about 6,000 facilities nationwide and handle more than 70 percent of all U.S. grains and oilseeds. The NGFA’s membership encompasses all sectors of the industry, including country, terminal and export elevators; feed and feed ingredient manufacturers; cash grain and feed merchants; end users of grain and grain products, including processors, flour millers, biofuels manufacturers and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries. The NGFA also consists of 35 affiliated state and regional grain and feed associations, as well as two international affiliated associations.

The North American Export Grain Association (NAEGA), a not for profit trade association, established in 1912, consists of private and publicly owned companies and farmer-owned cooperatives that are involved in and provide services to the bulk grain and oilseed exporting industry. NAEGA’s mission is to promote and sustain the development of commercial export of grain and oilseed and their primary products. Through a reliance on member action and support, NAEGA acts to accomplish this mission from its office in Washington D.C., and in markets throughout the world.

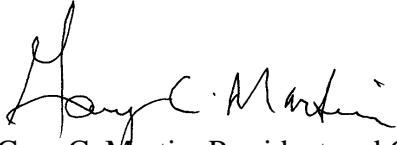
The North American Millers’ Association (NAMA) is the trade association of the wheat, corn, oat and rye milling industry. It is comprised of milling member companies operating mills in the United States and Canada and associate member companies representing the industries providing products and services to the mills. The aggregate production capacity of NAMA milling members is more than 160 million pounds of product daily, which is about 95% of the total U.S. capacity.

The Pet Food Institute is the voice of the U.S. pet food industry, serving as a public education and media relations resource; representative before the U.S. Congress and state and federal agencies; organizer of seminars and educational programs; and liaison with other organizations. Formed in 1958, PFI represents an industry worth \$17 billion in domestic retail sales and an additional \$1.3 billion in exports. PFI member companies make 98 percent of all dog and cat food produced in the United States.

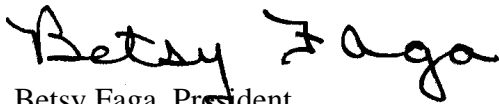
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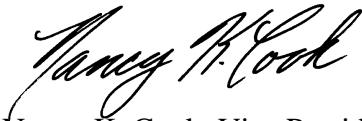
Kendell Keith, President
National Grain and Feed Association



Gary C. Martin, President and CEO
North American Export Grain Association



Betsy Faga, President
North American Miller's Association



Nancy K. Cook, Vice President
Pet Food Institute

cc: The Honorable Tom Vilsack, Secretary
United States Department of Agriculture