pma

April 17, 2016

Mr. Sidney W. Abel
Assistant Deputy Administrator
Regulatory Analysis and Development
Biotechnology Regulatory Services
APHIS, Station 3A-03.8
4700 River Road, Unit 147
Riverdale, MD 20737-1236

Re: Environmental Impact Statement; Introduction of the Products of Biotechnology; Docket ID No. APHIS-2014-0054

Dear Mr. Abel:

The Produce Marketing Association (PMA) greatly appreciates the opportunity to comment on USDA's Notice of Intent (NOI) regarding potential changes to the regulations on genetically engineered organism (APHIS-2014-0054). PMA is the largest trade association representing companies that market fresh fruits and vegetables. Our association represents more than 2,700 member companies located in 45 countries. In the U.S., our members operate throughout the supply chain from growing to shipping, processing/manufacturing, distribution, wholesaling, retail and foodservice. Collectively, our members handle more than 90 percent of fresh produce sold to domestic consumers.

We recognize the need and importance of updating the nearly 30 year-old Part 340 regulations. However, there are a number of items described in the proposal that have raised significant concerns and, we believe, threatens our industry's ability to innovate and respond to increasing demand for fresh produce while maintaining, or even reducing, our inputs.

Before we describe some of our overarching concerns regarding the definitions and inclusion of the noxious weed authority we want to address the four "Alternatives" the agency offered in the NOI. As we mentioned earlier, the regulations are in need of being updated and Alternative 1 would maintain the current approach, which we believe is inefficient and requires federal oversight for products that do not pose a risk. Alternatives 2 and 3 are not preferred due to some of the foundational changes proposed in the document, which we will address below. However, if these concerns are addressed then these options, specifically Alternative 2, would be worth further consideration.

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Alternative 4, eliminating a dedicated regulatory scheme for products of biotechnology, deserves further consideration and may be a viable option. It would provide the agency with the flexibility to exercise its authorities when it determined that the risk or uncertainty was sufficient for further consideration. In addition, the necessity for further evaluation would be based on the plant product rather than the process of developing the product. It may be this Alternative that would have the least negative impact on innovation but provide the agency with the greatest authority to regulate plant products with noxious weed and/or plant pest concerns. However, further consideration of Alternative 4 with an eye toward unintended consequences is necessary.

The foundational concerns PMA has about the NOI can be broken into four areas.

- The definition of "Biotechnology" in the NOI, along with the expansion of the part 340 regulations beyond what we typically considered "GMOs" and instead regulate "organisms developed using biotechnology";
- The inclusion of the Noxious Weed Authority in the decision process of biotechnology product regulation;
- The lack of "benefits" in the evaluation process;
- Increased risk of litigation challenging the decisions of the USDA.

The proposed expansion of the regulatory authority associated with part 340, as suggested by the definitions used for "biotechnology" and "product of biotechnology" is alarming. While protecting U.S. agriculture and natural resources from advances that may bring new plants pests or noxious weeds to bear makes sense, basing the need to evaluate them on how they were developed (the process) is not in keeping with safeguarding measures, but is more reflecting of marketing programs. Organic production, pole caught tuna, cage free chickens, are about a production process and not about the safety of a product.

The definition of "biotechnology" along with the intent to potentially regulate the biotechnology product would capture many breeding practices that have been safely used for decades. Lab techniques like "doubled haploids" have been in use for more than 40 years to develop breeding lines and ultimately commercial fruit and vegetable varieties. Similarly, *in vitro* "embryo rescue" was first documented in 1904 and has a long history as a tool in many variety development programs. These are not new techniques with unknown consequences, yet they appear to be captured under the regulatory approaches favored by the agency.

Furthermore, new techniques like gene editing, while requiring more advanced procedures, are typically used to develop a plant product that could be achieved through traditional breeding approaches. The difference is that the resulting product can be developed and identified more efficiently from a time and resources standpoint with greater precision. Again, this raising the question about why there is an interest from the agency to regulate based on process rather than product. Agriculture is constantly under pressure to produce more food and fiber with fewer agricultural inputs and natural resources. Our only way to reach those goals will be through advanced varieties and inhibiting that advancement is contrary to the USDA's mission.

Currently, USDA has the ability to use its Noxious Weed Authority (part 360) when it deems it necessary. Bringing it's use under the part 340 umbrella will likely require its consideration when evaluating plant products. The Noxious Weed Authority is incredibly broad and subjective, providing it's user tremendous flexibility in how it is interpreted. Furthermore, there are no

specifics provided in the NOI on how a "weedy" determination would be considered for biotechnology products. The approach and decision protocol would need to be clearly described, vetted and discussed before stakeholders should be expected to consider the NWA as a component of part 340.

The term "benefits" and it's use in the evaluation process are not included in the proposal. When elements of a regulatory process insert considerable subjectivity into the evaluation, such as we see with the NWA, and only risks are considered, the argument for approval or non-regulatory status is very difficult to make. Risk is inherent in everything we do. It is part of every change or innovation. However, it should be balanced by the perceived or expected benefits. Without the inclusion of benefits in the USDA process and only the assessment of risk, those more inclined to precautionary approaches are in a strengthened position.

This takes us to the final foundational concern, "litigation." Perhaps each concern listed above could be individually overcome. However, when considered in sum, it creates a matrix that likely predestines each new product under the broad biotechnology definition to court challenges. The proposed breadth of oversight across biotechnology products means nearly all modern, including 100-year-old technology, would require evaluation, putting many current lines and the future of agriculture at risk. The expansive NWA with it's reference to, "plant or plant product that can directly or indirectly injure or cause damage," leaves open a huge array of possible interpretations that would not be up only to USDA but groups that are anti-modern agriculture and judges that will interpret and guide USDA on how it should interpret the authority. Finally, without the inclusion of benefits it is very possible that any level of risk would be too great for regulatory approval in a legal challenge.

Beyond a legal case itself, the potential for entering a litigious environment would likely be enough to stifle innovation as most crops, especially specialty crops, do not have a sufficient economic benefit in new variety sales to warrant the risk. PMA believes that with the exception of Alternative 4 the other alternatives would cause significant disruption to the industry and would leave U.S. agriculture at a tremendous disadvantage to foreign competition.

These comments are respectfully submitted by the Produce Marketing Association. Thank you for the opportunity to comment.

Very truly yours,

Robert J. Whitaker

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