AMERICAN SEED TRADE ASSOCIATION, INC.

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BY FACSIMILE and BY HAND DELIVERY

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering ("Draft Guidance"); Docket No. 00D-1598

Dear Sir or Madam:

The American Seed Trade Association ("ASTA") provides herein these brief comments on the above-captioned document. 66 Fed. Reg. 4839 (2001). ASTA has previously filed comments on FDA's policies regarding foods that are derived from the use of bioengineering and is pleased to have again this opportunity. In general, ASTA supports FDA's stance on labeling as reflected in its Draft Guidance. Specifically, it generally supports the positions and comments of the Grocery Manufacturers of America ("GMA") and others in a joint food industry Citizen Petition submitted on May 5, 2000 (Docket No. 00P-1284/CP1). ASTA also generally endorses the joint food industry comments submitted by GMA in response to the above captioned notice.

By way of background, founded in 1883, the American Seed Trade Association is one of the oldest trade organizations in the United States. Its membership consists of about 900 companies involved in seed production and distribution, plant breeding, and related industries in North America. Its mission is to enhance the development and free movement of quality seed worldwide. Many of ASTA's members, large and small, are engaged in research and development activities designed to enhance the quality, variety, productivity, and availability of agricultural seeds. Some of this research involves the use of molecular and other new techniques for genetic modification, although the industry still relies heavily on traditional breeding methods such as hybridization to produce new plant varieties and to otherwise accomplish desirable genetic changes. The Association remains committed to the development and commercialization of all genetically altered plants that comply with applicable federal and international laws and regulations.

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Turning now to a discussion of the Draft Guidance, we want to emphasize at the outset that, generally, mandatory labeling should not be required for foods produced from the use of bioengineering. In other words, we endorse FDA's position that there is no basis for concluding that foods produced by bioengineering differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new genetic techniques present greater or different concerns than foods developed by traditional plant breeding. See 57 Fed. Reg. 22984, 22991 (1992) and 58 Fed. Reg. 25837, 25839 (1993). Moreover, we endorse the position that methods of plant breeding have not usually been considered to be material information that must be disclosed on a food label. 57 Fed. Reg. at 22991.

Nevertheless, we also agree with FDA that, as with other foods, some circumstances may exist where labeling may be required, such as where the bioengineered-produced food is significantly different from its traditional counterpart. In this case, the common or usual name may no longer adequately describe the food. Other circumstances where labeling applicable to all foods may be required include where an issue exists regarding how the food or its constituents is to be used or the consequences of its use; or where a food is produced by genetic engineering has significantly different nutritional properties than other foods or contains allergens.

A number of other specific areas of the Draft Guidance also deserve comment. FDA seems to use interchangeably throughout the Draft Guidance the terms "genetically engineered," "biotechnology," or "bioengineered" to describe foods that are obtained from the use of newer plant genetic methods. Although we think that more technically correct and accurate terms, such as "recombinant DNA" or "modern biotechnology," are more appropriate, we do understand that such terms may be confusing to consumers. We therefore support the use of these alternative terms provided that they are not understood to refer to traditional genetic methods such as plant breeding.

On the other hand, the terms that FDA mentions, such as "bioengineered," should not usually be used to describe foods, i.e., "Genetically Engineered Food." This is because foods themselves are not genetically engineered; only the foods produced from plants (or other organisms) are bioengineered. As pointed out in the joint food industry comments submitted by GMA on the Draft Guidance, such claims can be confusing. They can refer to a change in composition of the food or to how the food is produced, or both. They can be avoided by framing the claims as source or production claims along the lines of "This food is not produced using bioengineering." Keep in mind, too, that compositional claims, without qualification, can wrongly imply material changes in the food's composition, which typically is not the case. Moreover, such composition-based claims standing alone also can imply that the bioengineering

process is applied to food itself, rather than to the plant used to produce the food. As noted in FDA's 1993 request for data and information on food labeling, plant breeding methods, including bioengineering, are not processes applied to finished food. 58 Fed. Reg. at 25839.

With regard to other specific label claims, such as "GMO free" and "GM free," we agree with FDA that these claims are not understood by consumers and that they also can be misleading, if not false. They can imply the absence of genetic modification, although most, if not all, cultivated food crops, have been genetically modified. A "free"-type claim can also be confusing because it implies a compositional criterion that probably cannot be met, namely, the zero presence of adventitious bioengineered components. Such "free" claims, if used, therefore may need to be qualified to avoid the impression that a zero level of adventitious presence is implied, namely, by using a combination of a source and a compositional claim, such as "We do not use ingredients produced using biotechnology," as FDA notes in its Draft Guidance. Draft Guidance at 9. The term "GMO free" may also be misleading, if not false, because most foods do not contain organisms, except foods such as yogurt.

These types of "free" claims and other such compositional claims might be difficult to substantiate without testing. Moreover, since validated test methods are not yet widely available for many foods, we agree with FDA that it would be easier to document handling practices to substantiate claims of how a food is processed than to substantiate a compositional claim by testing. Then, too, the widespread occurrence of adventitious presence of bioengineered material in food, developed with or without the use of bioengineering, may mandate that the substantiation of almost any food claim involving the lack of use of modern biotechnology may have to be at least based on handling and production practices. We therefore also agree with FDA that certified organic production and handling requirements is a way to substantiate a claim that a food is not produced using modern biotechnology. In fact, it may be the preferable way in light of adventitious presence issue and other issues.

With respect to the question of whether claims about the absence of use of bioengineering in the production of food or a food ingredient constitute implied claims of superiority, we believe that they may unless they are qualified. Claims such as "Not produced through the use of bioengineering" can be construed to be avoidance claims, because they encourage consumers not to buy foods that are produced using bioengineering. They therefore can imply that food produced through the use of bioengineering is, for example, less safe or of lower quality than other food. We therefore hope the agency will reconsider whether a disclaimer used in conjunction with such avoidance claims, to disavow any safety or other adverse health implications, will be helpful in ameliorating the possible negative impact of such claims.

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Thank you for this opportunity to submit comments. We hope that the views herein are useful in developing a final guidance in this area.

Cordially yours,

Dean Urmston/kd

Dean Urmston
Executive Vice President
American Seed Trade Association