

**WHEAT EXPORT TRADE EDUCATION COMMITTEE
U.S. WHEAT ASSOCIATES
NATIONAL ASSOCIATION OF WHEAT GROWERS**

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March 19, 2001

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

Ladies and Gentlemen:

We are pleased to have the opportunity to submit the following comments on behalf of the U.S. wheat industry in response to **[Docket No. 00D – 1958] Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Biotechnology; Availability.**

The U.S. wheat industry has developed a unified biotechnology position statement that addresses the labeling issue. That policy states: "We support voluntary labeling of food products, provided it is consistent with U.S. law and international trade agreements and is truthful and not misleading. We oppose government-mandated labeling of wheat products in both the U.S. and international markets based upon the presence or absence of biotechnologically-derived traits that do not differ significantly from their conventional counterpart." It also states, "We support the establishment of a reasonable threshold level for adventitious or accidental inclusion of biotechnologically-derived traits in bulk wheat or wheat food products in both the U.S. and international markets."

We support the issuance of the Food and Drug Administration (FDA) proposed rule and draft guidance document with the comments and exceptions noted:

- We prefer the use of the term "biotechnology" over such terms as "genetic modification" and "genetic engineering," especially since most, if not all, cultivated food crops have been genetically modified. We concur with FDA consumer focus group data that indicate that consumers do not understand the acronyms "GMO" and "GM" and prefer label statements with spelled out words that mean "bioengineering" or "biotechnology." We also concur with FDA data that indicate that consumers do not have a good understanding that all foods have been genetically modified and that biotechnology is only one of a number of technologies used to genetically modify crops. The reality is that absent other information, a label indicating genetic modification mistakenly raises questions about the safety of biotech foods that have been reviewed and found to be safe by regulatory agencies worldwide.

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- We believe that a label statement that implies that a food is superior because it is not bioengineered would be misleading. We also believe that a label statement may be misleading if it suggests that a food or ingredient (i.e. flour) itself is not bioengineered when there is no marketed bioengineered variety of that category of foods or ingredients (i.e. wheat).
- We also believe that there is potential for the term "free" in claim for absence of bioengineering to be inaccurate. We agree that because of the potential for adventitious presence of bioengineered material, it is necessary to conclude that the accuracy of the term "free" can only be ensured when there is a definition or threshold above which the term could not be used. Even the most highly purified products, such as pharmaceuticals, are allowed a certain amount of impurities. If a zero tolerance were invoked, then every loaf of bread will have to be labeled as bioengineered, even though there are no bioengineered wheat varieties yet grown commercially. We are not able to provide information with which to establish a threshold level of bioengineered constituents or ingredients in foods for the statement "free of bioengineered material."
- We recommend that the USDA Grain Inspection, Packers and Stockyards Administration (GIPSA) validate analytical methods and testing procedures to differentiate between bioengineered foods and food ingredients and those obtained using traditional breeding methods.
- We believe that the practices and record keeping required by USDA regulations that substantiate the "certified organic" statement are sufficient to substantiate a claim that food was not produced using bioengineering.

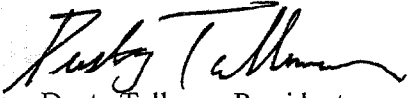
We are concerned about the possibility of U.S. wheat producers bearing the economic burden of mandated labeling. According to a December KPMG Consulting Report, mandatory labeling of biotech foods could increase production costs and food prices by as much as 10 percent. According to a European Commission working paper, "Economic Impacts of Genetically Modified Crops on the Agri-Food Sector," published in December, the analysis indicates that segregation and labeling could generate additional costs of 6-17% of a product's farmgate price. Voluntary labeling helps ensure that the costs of a labeling system will be borne by consumers who want labeling, rather than by consumers at large. The companies that wish to label their products as free for bioengineering should have to pay the costs of segregation, quality control and verification and pass those costs on to their customers.

In conclusion, labeling of foods derived from biotechnology ingredients is already required under existing regulations if the food has been significantly changed in terms of its dietary, nutritional or safety characteristics. These regulations are based on quantifiable chemical characteristics of the food product and not on the way the product was made. The current policy is objective, verifiable and enforceable because the chemical properties of the food can be measured, confirmed and defended. This proposed rule and draft guidance document is a positive step for consumers. It will help ensure that food labels are truthful and not misleading. This clarification should ensure that consumers who want labels receive consistent, valid information.

Sincerely,



Bruce Hammes, Chairman
Wheat Export Trade Education Committee
U.S. Wheat Associates



Dusty Tallman, President
National Association of Wheat Growers