

# Association of Food and Drug Officials

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March 19, 2001

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## ***RE: Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering***

The Association of Food and Drug Officials' Board of Directors, herein referred to as AFDO, is pleased to offer comments on this draft guidance document to assist the food industry about the voluntary labeling of food to indicate whether or not the food was developed using bioengineering.

Generally, we believe the guidance draft provides necessary and useful information to food businesses that desire to voluntarily provide label information about whether or not bioengineering was used to develop or produce the food. Overall, the draft is quite complete and understandable. For this reason, we will limit our comments to few key points to emphasize our support or point out areas where we have concerns or believe further guidance is necessary.

We agree that whether or not a food is the product of bioengineering, or does or does not contain bioengineered components, is not a "material fact" which would trigger mandatory labeling. However, we also agree that this guidance is necessary and *useful for those food businesses that desire to voluntarily* provide label information about whether or not bioengineering was used to develop or produce the food.

We note that the principles verification of label claims and evaluation of these claims in the context of the entire label are repeated throughout the guidance draft and believe these premises provide the foundation essential to this guidance. We also find the concrete examples that are provided in the draft valuable in clarifying, expanding, and strengthening these principles.

We agree that labels that indicate that the food contains no bioengineered ingredients will be very difficult to verify and equally difficult to present in a way that does not imply that the food is superior. We believe the draft's suggestion is prudent that label claims about the absence of bioengineered ingredients should be restricted to comments about production or processing of the ingredients rather than their content. However, even claims about process need to be made cautiously to assure that these claims are both accurate and not misleading. Because we believe there is a high potential for labels to be misleading if a label claims either the total absence of bioengineered

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ingredients or total isolation from the bioengineering process, we recommend that FDA strengthen its language to "strongly recommend" that the term "Free" (e.g., "GMO Free") not be used in bioengineering label statements.

Any claim about the absence of the use or effect of biotechnology in the production or processing of food *should not be allowed unless there is a system in place* to assure that a food or food ingredient produced or developed without the use of biotechnology are isolated throughout the processing and distribution system. For many agricultural commodities that are used widely as food ingredients (e.g., corn, soybeans), segregated handling is not the current norm. Developing preventive procedures and food handler understanding and compliance to ensure segregation of bioengineered ingredients from non-bioengineered ingredients will be a difficult and expensive process.

Unless there is a reliable analytical test for the presence of a specific bioengineered ingredient or until a verifiable isolated handling system is in place from the field to the packaging or retail sale location, we believe that the use of affidavits attesting to "non-use of biotechnology" would not be useful or effective and should not be allowed. The use of affidavits would be effective only if used at each point in the production-distribution continuum where the potential exists for commingling of ingredients developed with and without the use of biotechnology. If affidavits or other verifiable record system were not in place at every potential commingling point, the affidavit system would be ineffective and may cause the label to be misleading.

We expect that in the future there will be an increased ability to analytically detect the presence (or absence) of bioengineered ingredients in support of label claims. To assist food businesses in developing labels that are not misleading when making claims about the presence or absence of ingredients developed using biotechnology, we believe it would be helpful to both food businesses and consumers to establish a reliably attainable analytical threshold value that defines the presence of bioengineered ingredients whenever possible. This threshold should be periodically redefined and communicated as the analytical ability to reliably detect lower levels of bioengineered ingredients increases.

Whether voluntary label claims focus on the presence or absence of biotechnically developed ingredients, direct or implied claims about benefits related directly to the labeled food should:

- Use established criteria for scientific substantiation of the benefit claim
- Be evaluated in the context of the entire label
- Use the final version of this guidance in conjunction with existing requirements to assure that product labels are accurate, complete and not misleading.

As stated previously, we think this guidance is necessary, useful, and understandable. We appreciate and thank you for the opportunity to comment on this draft guidance.

Sincerely,



Steven B. Steinhoff

President

Association of Food and Drug Officials

**1 From**

Date 3-9-01

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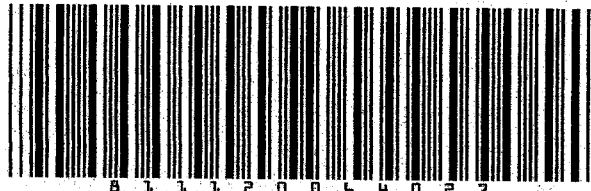
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