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VOLUNTARY LABELING OF FOODSTUFFS DERIVED FROM MODERN BIOTECHNOLOGY

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Grocery Manufacturers of America (GMA) contends that foods enhanced through biotechnology with recombinant DNA or rDNA-derived traits should not be labeled differently from other foods; however, it supports voluntary labeling when truthful and not misleading. This paper details criteria to ensure proper labeling, including defining and monitoring the use of avoidance terms such as "GMO-free" and addressing problems associated with applying threshold levels.

Key words: biotechnology; Codex; food labeling; genetically modified organisms (GMOs), recombinant DNA (rDNA).

The objective of food labeling is to provide truthful information to consumers without misleading them. This principle should apply equally to all foods without regard to the methods of production. In 1999, a Working Group was established at the 27th session of the Codex Committee on Food Labeling under the chairmanship of Canada to consider labeling options for foods derived from biotechnology (see MacKenzie in this issue). At the 28th session, held in 2000, the Working Group presented a proposal on labeling foods derived through biotechnology, which contained two options for consideration. These options were drafted as follows,

- *Option 1* requires labeling when products obtained through biotechnology differ significantly from the corresponding food as regards composition, nutritional value, or intended use.

- *Option 2* requires the declaration of the method of production for foods and ingredients composed of or containing genetically modified organisms (GMOs) (also known as genetically engineered organisms [GEOs]); or food or food ingredients produced from but not containing GMOs/GEOs, if they contain protein or DNA resulting from gene technology, or if they differ significantly from the corresponding food.

These options titled Labeling of Foodstuffs Derived from Modern Biotechnology, and known collectively as "CX/FL 00/6," have raised a number of issues for food manufacturers around the world in regard to the labeling of biotechnology-derived crops. This paper clarifies the circumstances and conditions under which language may be used on food labels and in food labeling about the lack of use of modern biotechnology methods in the production of foods.

Alternative Options For Labeling Food Products Derived From Modern Biotechnology

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Of the two options outlined above, Option 2 is likely to mislead consumers and cannot be practically implemented by the commercial food industry. Industry organizations, such as the Grocery Manufacturers of America (GMA),[1] recognize that some consumers wish to purchase foods that do not contain ingredients created through the use of modern biotechnology. In order to accommodate these consumers' desires, while at the same time not misleading any consumers, a modified version of Option 1 is needed. This modified version of Option 1 should incorporate provisions for voluntarily labeling foods as being GM-free and is described next.

Voluntary Labeling of Non-GMO Products

To allow for effective voluntary labeling of non-GMO products that serve consumer needs, the CX/FL00/6 must first be properly revised. Specifically, the proposal presented in CX/FL 00/6 under Option 1 could be amended to read "when a food or food ingredient obtained through modern biotechnology, as defined in Section 2, differs significantly from the corresponding existing food or food ingredient, with regard to composition; or nutritional value; or intended use of the characteristics or properties which make it different from the corresponding existing food or food ingredient, then it should be clearly identified in the labeling." All five of provisions listed under Option 1 (see Codex, 1999, CX/FL 00/6, pp. 9-10) should remain without being changed. Second, the ability of manufacturers to voluntarily make GM-free claims on the label should be supported as long as they are truthful and not misleading. Finally, clear definitions and criteria must be incorporated as a part of the language for both Option 1 and GM-free claims.

Definitions for "GM-free" and related terms are needed prior to implementing Option 1 and GM-free options. Guidance should be developed by Codex that reflects the wording of, or in substance encompasses the principles that appear in, this paper with respect to claims such as "GM free," "GMO free," "Non-GM," "Non-GMO," "No genetically engineered ingredients," and "No ingredients derived through biotechnology," and any other claims of similar import and wording. Criteria are also needed for determining that a food or ingredient meets those definitions that are practical and scientifically based in order to ensure that the consumer is not misled.

The Case for Voluntary Labeling

Most foods are products of biotechnology in some way. Vegetables as seemingly different as cabbage, brussel sprouts, broccoli, and cauliflower are all genetically derived from the mustard plant. Most commercial corn varieties are hybrids, with seeds produced by breeding different varieties or different species. Food animals, such as cows and pigs, and edible bacteria, such as those in yogurt, also are further examples of traditional biotechnology or traditional genetic methods, such as breeding and selection.

In the last few decades, modern biotechnology, such as recombinant DNA (rDNA) technology, has allowed developers to transfer specific genes or combinations of genes from a variety of sources, such as bacteria, plants, and animals. Recombinant DNA techniques are used to achieve the same types of goals as traditional methods. They are used in the development of food from plants, animals, and bacteria with enhanced agronomic and quality characteristics. For example, the modern methods of effecting genetic changes have resulted in plants that are resistant to pests, diseases, and chemical herbicides, or that have improved drought tolerance. These agronomic (input) traits are most valuable to the farmer. Consumers can also benefit from agronomic advances through price reductions. Other output traits of more obvious value to the consumer include those for improved food processing, texture and flavor, and nutritional content. These last types of foods may contain higher levels of desirable nutrients, such as Vitamins C and A, and less saturated fats.

Given that food from plants with rDNA-derived input traits are no different from other foods, one can argue that Codex should not label them differently but instead should permit food manufacturers to label their traditionally derived food as not having been derived from the use of "genetic engineering." Claims about the absence of the use of rDNA can be characterized as avoidance claims. They are meant to convey information to the consumer who may want foods that are not derived from the use of rDNA.

A Definition of Modern Biotechnology is Needed

Numerous commentators, reports, and international policy statements have defined or discussed such related terms as "biotechnology," "genetic engineering," "deliberately modified heredity traits," "modern biotechnology," "traditional biotechnology," and "bioengineering." Many of these terms or definitions have appeared in policy statements published by international governmental agencies in their proposed legislation to regulate products of "biotechnology." The term "modern biotechnology," typically refers to recombinant DNA methods. Definitions are needed for all terms that are to be permitted on the label.[2]

General Principles For Making Avoidance Claims

Some food manufacturers may want to use of certain avoidance claims, such as "GMO free," in order to communicate to consumers the lack of use of modern biotechnology in the production of foods. Other similar claims may also be used. Nonetheless, because there are a multitude of possible variations in such claims, and their plain meanings can differ significantly, these cases are not addressed in this paper. All of the detailed criteria that may apply to specific claims will need to be addressed in each specific case.

Of importance to any labeling scheme is the requirement that the food shall not contain labeling that is false or misleading. In determining whether a food is misbranded because its' labeling is misleading, criteria must be developed that can be used by food manufacturers and consumers alike. The criteria should address definitions, analytical methodology, and other aspects of importance to consumers.

For example, criteria should address, among other things, not only representations made or suggested by statement, word, design, device, or any combination thereof, but also to the extent to which the labeling fails to reveal facts material in light of such representations or material with respect to consequences which may result from use of the statement. Statements that are ambiguous and liable to mislead should not be permitted. A label must be evaluated not by fragmentizing it or isolating statements claimed to be false but in its entirety, since such statements may not be deemed misleading when read in light of the label as a whole.

Avoidance Claims

Avoidance claims such as "GM free," "Non-GM," "GMO free," and "Non-GMO," and similar claims that imply the absence of the use of modern biotechnology methods in the production of foods can be carefully addressed. At the least, GM or GMO types of "free" or "Non-" claims may be confusingly similar and seem not to be synonymous.[3] Indeed, they may even engender misunderstanding based on their literal meanings, unless they are properly qualified. It may be misleading, if not false, to suggest without qualification that foods with such GM avoidance claims are not themselves genetically modified since most foods are not so modified anyway. In other words, it may be misleading to suggest that a food itself is free of genetic modification, when ordinarily it is not

genetically modified. A current analogous example would be to suggest that celery is free of fat when ordinarily it has no fat. Accordingly, the United States Food and Drug Administration's (US FDA) regulations prohibit a "fat-free" claim for a specific brand of celery, although a statement of more general applicability is allowed, for example, "celery, a fat-free food."

Even if such claims are qualified to imply instead that the foods are derived from plants or animals that are not genetically modified, the claims still may be misleading. Most foods have been derived from sources that are genetically modified through cultivation or domestication. Similarly, with regard to the claim "GMO free," few foods, except products like yogurt, contain entire "organisms." Therefore, it may also be misleading, if not false, to suggest that a food, which ordinarily would not contain entire organisms, is "organism free," regardless of whether the acronym "GM" accompanies such a claim. Also, such claims, standing alone, can improperly imply a compositional difference rather than a difference in the way the food was produced or developed.

A case can be made that the following conditions for labeling food with GMO and GM "free" and "Non-" claims and similar claims should be adopted by Codex. Each sentence below contains "general requirements" for making such avoidance claims and the accompanying paragraph contains the basis for such claims.

Claims such as "GM free" that imply the absence of "genetic modification" in the production of foods (including food ingredients) may be truthful and not misleading when such terms are qualified or explained, as necessary, in an appropriate context, so that consumers understand that the words "genetic modification" refer to recombinant DNA methods.

Most, if not all, cultivated food crops, as well as animals and bacteria used in the production of food, have been genetically modified in some way. The use of such claims, therefore, can imply that no genetic modification whatever has been used in the production of the food or food ingredients, which is not the case for most foods. Such claims, therefore, need to be modified, depending upon consumer understanding of the meaning of such claims, to clarify that the claims refer to recombinant DNA.

It is false and misleading to claim that a whole food or food ingredient is "GMO free" or "Non-GMO" where the food or ingredient does not ordinarily contain entire organisms. Only certain foods contain entire "organisms;" for example, yogurt contains the edible bacteria, *Lactobacillus acidophilus*, among other organisms. Other foods, such as raw agricultural commodities,[4] a category including fruits and vegetables, contain seeds. Most foods, however, do not contain entire "organisms," dead or alive, recombinant DNA-derived or not.

It is false and misleading to claim that a whole food or food ingredient is "GM free" or "Non-GM" where the whole food or food ingredient is not ordinarily modified by recombinant DNA techniques. Appropriate qualification may be necessary to clarify that the food on which such claims appear is not ordinarily derived by recombinant DNA methods.

When appropriately qualified, claims that a whole food or food ingredient is "GM free" or "Non-GM" may be truthful and not misleading provided their meaning is clear in terms of whether they refer to compositional differences or to source differences, or both.

The terms could refer (1) to a compositional difference in the recombinant DNA-derived food compared to other foods, or (2) to the use of recombinant DNA methods, or both. Both "GM free" and "Non-GM" can imply that recombinant DNA methods are not used in the production of the food

or its ingredients, or that the food does not contain any detectable levels of food components or ingredients made from the use of rDNA methods, or both.

Implied Superiority Claims

Another important aspect of labeling is whether GM or GMO "free" or "Non-" claims, or other claims about the lack of modern biotechnology in the production of foods, constitute implied superiority claims; for example, with respect to food quality or safety. The circumstances surrounding the use of these terms will dictate whether superiority is claimed.

Claims that a whole food or food ingredient is "GM free" or "Non-GM" may be truthful and not misleading if they do not imply superiority.

The circumstances surrounding the use of these types of claims are important in deciding whether superiority is implied. Based on existing knowledge, implying superiority of foods made through traditional breeding practices would be false or misleading. Unqualified "GM free" or "Non-GM" statements or other similar claims imply that food made by traditional breeding practices is safer or of higher quality than food made from recombinant DNA techniques. Hence, appropriate qualification may be necessary to avoid misleading consumers.

Threshold *De Minimis* and Testing Considerations

Closely related to the use of GMO and GM "free" and "Non-" claims, and similar statements, is the level, if any, of adventitious rDNA-derived material that is allowable before a food cannot be labeled with these types of claims or with terms of similar import. This *de minimis* level has sometimes been called the "threshold" above which a food containing such rDNA-derived material may not be labeled with claims, such as "GMO free."[5] The *de minimis* presence of unavoidable rDNA-derived materials could occur during cultivation, harvesting, transport and storage, or processing. A further complication is that "free" type claims seem to suggest a zero threshold, whereas "Non-" type claims seem to allow an undefined level of rDNA-derived materials. Finally, an additional complexity pertaining to the use of thresholds is the necessity for validated, standardized testing methods, with appropriate sensitivity and reference materials, to detect the level of adventitious materials.

At this time, there are numerous issues to be overcome in order to establish such threshold levels. Definition of appropriate threshold levels that might be applicable to different types of GMO and GM claims is therefore beyond the scope of this paper. Perhaps another approach that could be useful in this area is to specify a percentage level that reflects the lack of rDNA-derived materials, such as, perhaps, "99% free from recombinant DNA-derived ingredients."

The use of validated testing methods is the preferable way to establish the source of foods or food components, particularly the presence of rDNA adventitious materials. Since validated methods are not yet commercially available for all foods and for different types and levels of rDNA-derived materials, a combination of testing and certification schemes may be necessary to verify and document the source of food and food components throughout the food chain to ensure, for example, that "free" and "Non-" type claims are substantiated and, therefore, not false. In this general regard, substantiation requirements for making GM and GMO "free" and "Non-" type claims are essential.

Claims that a food or its ingredients, including foods such as raw agricultural commodities, are not derived from or made through the use of recombinant DNA techniques can be truthful and not

misleading when adequate testing records, or other appropriate documentation as may be necessary, or both, exist to establish the source and handling of the food or its ingredients.

Validated, reliable testing is the preferable way to identify foods or food components derived from the use of rDNA methods. For many foods, however, and particularly for highly processed foods such as oils, it may be difficult to differentiate by validated analytical methods between foods and food components obtained from the use of recombinant DNA techniques and those obtained from traditional methods. If validated test methods are not available or reliable because of the way foods are produced or processed, it may be necessary to document the source of such foods differently.

Conclusions

Food labels can provide useful information so that consumers can make effective choices. However, proper implementation of food labels, and their associated claims, is complex—to some extent the devil is in the details, which will need to be worked out for each specific case. The GMA believes that a voluntary labeling system with tightly defined standards can safeguard consumer choice without imposing undue costs and "breaking down the system." The Codex Alimentarius Commission has a significant role to play in developing such labeling policies.

Endnotes

[1] GMA is the world's largest association of food, beverage, and consumer product companies. The organization applies legal, scientific, and political expertise from its member companies to vital food, nutrition, and public policy issues affecting the industry. The association also leads efforts to increase productivity, efficiency, and growth in the food, beverage, and consumer products industry.

[2] The following are possible brief explanations of these ambiguous terms: "GM free"—genetically modified free, implying the food is free of genetic modification; "GMO free"—genetically modified organism free, implying that a food is free of genetically modified organisms; "Non-GM"—Non-genetically modified food; "Non-GMO"—Non-genetically modified organism food. It is unclear how the first two "free" claims are different in meaning from the last two "Non-" claims. In this context, the claims may be confusingly similar.

[3] By way of analogy, the US FDA has stated that "alcohol-free" may be used only when the product contains no detectable alcohol, whereas "non-alcoholic" beverages could actually contain traces (less than 0.5% by volume) of alcohol (United States Food and Drug Administration [US FDA], 1995).

[4] The term "raw agricultural commodity" is any food in its raw or natural state, including fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

[5] The European Union has adopted a 1% per food ingredient "threshold" before a food would have to be labeled as "genetically modified" (Commission Regulation (EC) 49/2000).

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