

Labeling of Biotechnology Products

The NABC 5 optional workshop was co-sponsored by the National Agricultural Biotechnology Council, Indiana Business Modernization and Technology Corporation and the Purdue University Biotechnology Institute held June 5, 1993 at Purdue University, West Lafayette, Indiana.

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Additional copies of *Labeling of Biotechnology Products*, #2 in a series of occasional papers, are available for \$2.50 by writing:

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The National Agricultural Biotechnology Council (NABC), established in 1988, is a consortium of 18 not-for-profit agricultural research and education institutions:

Boyce Thompson Institute	Rutgers University
Cornell University	Texas A & M University System
Int'l. Service for the Acquisition of Agri-Biotech Applications	Tufts University
Iowa State University	University of California
Michigan State University	University of Georgia
North Carolina State University	University of Guelph
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Oregon State University	University of Nebraska, Lincoln
Purdue University	University of Saskatchewan

NABC, through sponsorship of annual meetings, provides an open forum for exploring issues in agricultural biotechnology and an opportunity for persons with different interests and concerns to come together to speak, to listen, to learn, and to participate in meaningful dialogue. The fifth annual meeting (NABC 5), hosted by Purdue University in West Lafayette, Indiana, June 2-5, 1993, addressed *Agricultural Biotechnology: A Public Conversation About Risk*. An optional day's activity was offered immediately following the annual meeting: a workshop on labeling of biotechnology products.

This occasional paper, *Labeling of Biotechnology Products*, is a product of the optional workshop and is the second in the series. It includes a brief overview by Peter E. Dunn, the organizer, papers by three invited speakers and reports with recommendations prepared by the chairs of the two workgroups. NABC hopes this publication will contribute to increased understanding of what this diverse group of about 30 people -

ethicists
scientists
economists
educators
biotechnologists
writers
sociologists
representatives from agribusiness
government personnel

- felt was appropriate to be on a product label and provide suggestions of other ways to disseminate and receive information.

NABC extends our thanks to Pete Dunn for his organizational efforts and for his completion of papers and reports for this occasional paper.

June Fessenden MacDonald
Executive Director
NABC

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Overview: Workshop on Labeling of Biotechnology Products

After the conclusion of the NABC 5 meeting, approximately 30 participants stayed on in West Lafayette for an additional day to participate in an optional workshop on *Labeling of Biotechnology Products*, held on Saturday, June 5, 1993. The workshop was sponsored jointly by the National Agricultural Biotechnology Council (NABC), the Indiana Business Modernization and Technology Corporation, and Purdue's Office of Agricultural Biotechnology (now the Purdue University Biotechnology Institute).

Food safety and the consumer's desire to make an informed choice in selecting foods are critical issues for federal and state officials with oversight responsibility, for producers of biotechnology-derived foods and for consumers. The goals of the Workshop were to review the requirements of existing statutes regulating labeling of food products, to identify issues of concern to consumers and food producers regarding labeling of biotechnology-derived foods, and to formulate recommendations to guide development of national policy on the need for consumer information concerning foods produced through biotechnology. As it turned out, both the timing and the topic for the workshop were particularly fortuitous, as it allowed a focus on issues and questions raised in the U.S. Food and Drug Administration's (FDA's) April 28, 1993 request for information and data on food labeling for foods derived from new plant varieties [*Federal Register* 58 (80): 25837-25841 (1993)].

The first part of the Workshop program consisted of invited presentations by three distinguished plenary speakers. The lead-off speaker, Edward L. Korwek, an attorney from Hogan & Hartson, a Washington, DC law firm, spoke on the *Current Status of Food Labeling*. His presentation was structured around a review of the food labeling requirements of the Federal Food, Drug and Cosmetic Act administered by the FDA.

Susan K. Harlander, Director, Dairy Foods Research & Development for Land O'Lakes, was next on the program and spoke on *Unique Characteristics of Some Biotechnology Products*. A key message from this presentation was that while many products of biotechnology are identical to materials currently in use, other products produced through genetic engineering may differ from current foods in a variety of ways.

The final speaker, Christine M. Bruhn, Director of the Center for Consumer Research, University of California, Davis, spoke on *What Consumers Want to Know About Biotechnology*. From her review of the results of a recent survey, it was clear that consumers do not feel that sufficient information is available to make an informed choice about specific biotechnology products.

Workshop participants then divided into two workgroups. One group, chaired by Rosetta L. Newsome (Director, Scientific Affairs, Institute of Food Technologists), discussed *Biotechnology Product Labels*, and the other, chaired by Marshall A. Martin (Director, Center for Agricultural Policy and Technology Assessment, Purdue University), discussed *Consumer Information*.

This NABC Occasional Paper will provide for the reader who could not attend the Workshop a series of formal papers summarizing the content of the three plenary speakers' presentations, and a summary of the issues and recommendations generated by the Workshop participants. While it is not possible to recreate fully the lively dialogue, the probing questions and the inevitable honest disagreement over both issues and recommendations, or to do justice to the thoughtful contributions of all participants, I hope that this brief occasional paper presents an accurate summary of the Workshop's conclusions.

I wish to thank the Workshop's sponsors for their generous support; the speakers, chairpersons and participants for their thoughtful contributions during the Workshop and their assistance in generating the contents of this occasional paper, and the NABC staff for editing, formatting and publishing the final manuscript. A summary of the Workshop's recommendations was sent to the FDA to assist in their efforts to establish policies and regulations on the labeling of biotechnology-derived foods.

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Current Status of Food Labels*

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* edited from a transcript of the author's oral presentation

I would like to discuss the central question that has been asked for several years now: should genetically engineered foods be labeled? And I will have an answer for you (believe it or not) after a mere half-hour presentation.

My goal here is to try to give you a sense of the difficulties associated with answering this type of generic question. I will do this by means of references to statutory provisions (legal provisions) of the Federal Food, Drug and Cosmetic Act (FFDCA), which is the primary law applicable to this issue. The FFDCA is administered by the U.S. Food and Drug Administration (FDA). I will not focus a great deal on the legal niceties of the law because I know most of you are not lawyers. I think it is important instead to emphasize that the FDA labeling initiative regarding products of biotechnology basically is an effort to implement various sections of this law. The degree to which the FDA does or does not vary from the provisions of the FFDCA is a legal question that is in some people's minds very difficult to answer. You will see, I hope, after this brief discussion that the question is certainly a complex one for a variety of reasons.

Let me go back a bit in time. In May, 1992, the FDA promulgated a food biotechnology policy statement in the *Federal Register* that primarily focused in issues of development of safety information for genetically engineered products. I have used the term "genetically engineered", although the stated focus of the policy was on new plant varieties developed through any genetic technology. The reality is that the focus was really on recombinant DNA-type products and the issues associated therewith. I use the term "genetically engineered" generically, although that in itself presents some definition problems that will be addressed later. The focus of the FDA policy proposal issued in May, 1992 was largely on when and how the FDA will require pre-market clearances for various types of food or food ingredients produced using "genetic engineering". The labeling side of the issue was not really covered in detail except that the agency said that it did not feel that genetically engineered foods necessarily had to be identified in any particular way.

An exception to this generalization was the case in which there were allergenic properties associated with various ingredients of a genetically modified food. These ingredients would have to be identified in some way on the product label. In terms of food label identification, the allergy issue is relatively easy to deal with. The more difficult issues are associated with the question of whether the FDA can require labeling for other than safety considerations associated with genetically modified food or, for that matter, any type of food. In other words, what are the various characteristics of the products that the FDA might require labeling of for reasons other than safety considerations?

The FDA has abundant authority to require labeling of foods for anything that poses a safety concern. The most notable example of the exercise of this authority is the requirement of labels for various synthetic colors such as FD&C (Food, Drug & Cosmetic) yellow-5. Even in this case, however, the label requirement is merely a declaration of the presence of the specific coloring ingredient. It is not a *warning* that this food contains FD&C yellow-5. It is simply a specific identification on the product label that it contains FD&C yellow-5 as part of the ingredient statement. The significance of this requirement is that

colors do not normally have to be specifically declared on food labels. The FD&C yellow-5 example is a notable exception to the general rule. Note clearly the precedent that this label requirement represents. The precedent is one of specific identification on the label of a particular ingredient that may pose health concerns, not necessarily a *warning of hazard*.

Following up on the May, 1992 notice from the FDA, which really did not address the general question of whether or not foods should be labeled, there was a notice almost a year later in April, 1993 in which the FDA has sought further input on the issue of labeling of genetically engineered foods. I encourage any of you who want to enter into this debate to read this notice and you will see how complex the issues are. The FDA does a very good job of outlining the various issues - how one can approach them, the questions that need to be asked, the questions that need to be answered, etc.

I will give you a preview of my answer to the question of whether or not genetically engineered food should be labeled. The answer is simply: I do not know. It depends on the specific characteristics of the “genetically engineered” food in question. Anyone who tries to answer that question generically does not have a good understanding of the complexity of this area. I have reviewed a number of position papers by various organizations on the topic and, in my opinion, they all have failed miserably. The reason why they have failed, as I will try to demonstrate to you, is because it is difficult to generalize in the labeling area. You have to ask very specific questions about what it is you want to have labeled. But until you identify what the characteristics are that you want to have identified on the label, you can not answer the question “Should genetically engineered foods be labeled?”. It is an impossible question to answer. Anyone who generalizes the issue simply can not come up with a reasonable answer. I will try to show you why.

Consider as an example one of the issues raised in the popular press about genetically engineered foods. This issue is source identification: the need to label the source of genes in a food. A common mistake in the case of genetically engineered foods is not to identify what the questionable characteristics of the food might be that would trigger labeling of the types of genes present. Rather, an argument is made of the necessity to identify merely the source of genes present in a food, regardless of the reason why they are present. We see articles and cartoons that provide fictitious menus in which all biotechnology foods are labeled to identify the source of genes. Examples might include spiced potatoes with wax moth genes, juice from tomatoes with flounder genes, blackened catfish with trout genes, pork chops with human genes, scalloped potatoes with chicken genes, corn bread with firefly genes, dessert rice pudding with pea genes and milk with genetically engineered bovine growth hormone. I would argue that this sort of information often is useless to the consumer because it does not convey any material information about the food’s characteristics. I consider it a misstatement of the real issues associated with labeling of foods derived from the use of modern biotechnology to require the general labeling of sources of genes. Unless the source of genes imparts material information to the consumer about some important characteristic of the food, I do not think there is any need for such source information to appear on a food label.

With that introduction, I would now like to summarize for you some of the statutory provisions of the FFDCA. These provisions are very important because, as I stated above, the reason for FDA initiatives in the biotechnology food labeling area is tied to various sections of the FFDCA. Labeling, in terms of FDA law, is related to the concept of “misbranding”. Misbranding means any sort of mislabeling of food that is somehow misleading or false. Misbranding, although serious when it occurs in relation to foods, is not as serious as adulteration of foods, in terms of enforcement priorities. “Adulteration” is a term of art under the law that basically addresses safety concerns associated with the food. If a food contained a contaminant that might

pose safety concerns, that would be adulteration. In general, adulteration is a more serious violation of the FFDCA as an enforcement priority. However, there is an exception to the general adulteration concept involving safety concerns that I have just described to you. Certain quality characteristics of food can also relate to what we call “economic adulteration”. Economic adulteration is generally considered to be more serious than most misbranding violations. In economic adulteration one is trying to substitute something of poor quality for a valuable characteristic or make a food inferior in some way to a comparable product. For example, “butter cookies” is a generic term that suggests that cookies contain butter as a basic characterizing property. An example of economic adulteration is suppliers trying to sell cookies with that sort of name that contain very low levels of butter or no butter at all. If you look at the ingredients statement and determine where butter is placed, it would be very low on the ingredient list in terms of the descending order of predominance labeling required for food products. This example would constitute economic adulteration or quality misrepresentation with respect to food. One thing to keep in mind is that all these provisions in general interrelate, so it is difficult to separate one from the other. If you have a quality misrepresentation then you often have a number of other misrepresentations (misbranding) as well.

I will describe first sections 409 and 409(d) of the FFDCA. These sections relate basically to food additives. The FDA can do practically anything it wants to promulgate labeling requirements for food additives. The conditions for use of a food additive can require statements about the food ingredient being present. They can specify use levels that cannot be exceeded and, to assure the safe use of these ingredients, the FDA can also impose labeling requirements on food additives. The minute something falls in the food additive category, the FDA has a lot of discretion to require labeling for that product or ingredient. But keep in mind, this jurisdiction relates primarily to safety considerations, not to other sorts of characteristics of a food that may be related to the use of the additive, such as quality. This type of consideration would have to be addressed by other provisions of the law.

In the case of genetically engineered food, particularly products created by recombinant DNA techniques, the issue is what is a food additive and what is not? The May 1992 policy statement promulgated by the FDA describes situations where the FDA’s food additive authority may be triggered to require pre-market clearance. If some substance introduced by genetic engineering was judged to be a food additive, the agency could impose almost any labeling requirements that it wanted pertaining to safe use of that food additive. Labeling requirements could be imposed fairly easily if the FDA considered a food additive to be an allergen. Again though, keep in mind, the precedent here is not *warning* labels for allergens, merely ingredient declaration.

The next two provisions, Section 403(a)(1) and Section 201, are probably the statutory workhorses. The FDA uses these sections regularly to promulgate various types of statements requiring food identification. These sections state that a product is misbranded if anything said about it is false or misleading in any particular. That standard is a very general standard. The law goes on further to say that, in considering whether something is false or misleading in particular, one shall consider the representations made or the failure to reveal material facts in light of such representations or the failure to reveal material facts with respect to consequences that may result from use. This is the critical part of the statute that the FDA has considered in the biotechnology area that is relevant to food labeling: the failure to reveal material facts.

What is a material fact? I do not know and I do not think anyone knows in absolute terms what is a material fact. In fact, as I will suggest to you by the end of this discussion, a material fact is anything that the agency says is a material fact. It is

difficult to develop standards for what are material facts. However, developing these standards is the central issue in this area. The question of material facts is related to consequences that may result from use is the issue of safety. Clearly, if there is a safety issue, the agency can require labeling. Of course, what the agency can require labeling of is another issue when there is no safety concern. Even though failure to reveal material facts is the most relevant precedent in this area, in terms of labeling requirement for food, these provisions have not been implemented very regularly. Only in the last few years, with the legislative adoption of the Nutrition Labeling and Education Act, has the agency begun to implement these provisions a little more aggressively. The biotechnology area is going to be another area where it will be interesting to see how these provisions are applied.

There is not a lot of precedent in this area of labeling of material facts. The singular precedent that I recall, which is also mentioned by the FDA in its notice, is food irradiation. This precedent requires labels for retail food stating that the food has been treated with ionizing radiation. If you look at the legal basis for the agency's requirement for that information you will note that the FDA said that irradiation could affect the organoleptic properties of the food and, therefore, the food should be labeled. This is a very interesting concept. In fact, I represented a major food company at the time that was very interested in food irradiation until that labeling requirement came out. We opposed the provision saying if the labeling standard is based on organoleptic quality, then what would not have to be labeled under that standard because anything a manufacturer does to a food has some organoleptic effect. In general, food ingredients have organoleptic functions, either synergistically or otherwise. We stated that under this standard for labeling, the agency had no authority to require organoleptic labeling of foods. Needless to say, the FDA ignored our advice.

The FDA also said that it felt that if the fact of irradiation was not stated, then the consumer might misperceive or assume that the product had been conventionally processed. That is another very interesting concept behind requiring labeling. This suggests that there is a reason why consumers need to know that a food item is irradiation-processed. I would say that, if there are no safety issues associated with irradiation-processing, then how can one say the food should be labeled because consumers might need to know that it is not conventionally-processed. In fact, there were not any safety issues regarding irradiation since the agency cleared the process for use as a "food additive". So what is the relevance of information that irradiation processing has been used? In later initiatives, the agency has taken the position that for cultural or religious or other reasons it might be material to know how a food is processed or what the source of the food may be. As a result, we find examples of very ambiguous standards which, if imposed across the board on all food ingredients, would require that almost everything about how a food is prepared is stated on the label.

What I am suggesting to you is that I think the FDA has been very creative in the interpretation of some of the statutory labeling provisions. I do not mean to suggest that there are not characteristics of any food, whether or not it is genetically engineered, that should not be labeled. That is not the point. The point is that whatever standards are adopted, they must be applied consistently across the board. If they cannot be applied in such fashion, then there is no sense in adopting standards that apply to one particular technology or to one particular ingredient or situation because of some *a priori* notion of what consumers "want to know".

The rest of the provisions of the law are relatively easy to deal with in comparison to the sections I have just described. Section 403(b) basically says a food is misbranded if it is offered under the name of another food. Earlier, we considered the

example of a “butter cookie” which contained little or no butter. Such a product could violate this section if it does not contain enough butter to adequately satisfy the characteristics of a true “butter cookie”. In such a case, it is being offered under the name of another food. This example demonstrates the principle that I alluded to earlier; one can violate one or more provisions of the law simultaneously.

Section 403(c) has always been the scourge of the industry; it basically requires “imitation” labeling for certain products. I cannot think offhand of any food that is labeled “imitation” today. This is because once it must be labeled as “imitation” it is “dead in the water” as a product. No consumer would buy the product without a lot of trepidation or understanding of why it is an “imitation” product. Thus, whenever labeling as “imitation” has been raised by the agency, producers reevaluate and say “oh no, we will reformulate; we will change the composition of the product so that is not an imitation.” “Imitation” is a very difficult term to define either scientifically or legally. Imitation labeling, though it is an interesting concept, has really never played an important role in the marketplace, at least in terms of foods that must be labeled with the term “imitation”.

Section 403(g) is another provision that has been used frequently. It concerns standards of identity for foods. In this instance, it is primarily the economic adulteration provisions that come into play, as well as other sections pertaining to the FDA’s authority to promulgate regulations covering “standardized foods”. The basic concept behind standardized foods is that, because they are economically so important, the FDA specifies a recipe for how they are obtained and/or made. Examples are chocolate and vanilla extract. Therefore, if you want to call a product “chocolate”, it must be made in a certain way. One good example is “white chocolate”. White chocolate basically is a misnomer because the standardized recipe or requirement for a product called chocolate is that it must be made in a certain way. Since white chocolate does not contain all the standardized ingredients that “chocolate” has, the name is not correct. Although the agency never challenges use of the name, technically such a product may be adulterated and/or misbranded. Its name “white chocolate” suggests the product meets the standard of identity for chocolate, but it does not.

The legal or labeling principle here is that once you call an ingredient or product by a name that corresponds to a standardized food, you cannot vary how it is made or how it is derived, unless it varies according to the prescribed standard. There are various products of biotechnology that may fall under this principle. For example, vanilla extract could be produced by microbial genetic engineering. If you examine the vanilla standard there is a good chance that you would not be able to call such a genetically engineered product “vanilla extract” because the standardized recipe has a source requirement that is not microbial. Therefore, if the source varies you could not call it “vanilla extract”. Using the standardized name would be misbranding and would violate the law. Genetic engineering will, I think, trigger several such issues under various standardized food requirements. As a result, the importance of this provision 403(g) will become more obvious as time goes along.

Perhaps the most significant provision for biotechnology foods is section 403(i). This provision states that foods shall be identified by their common or usual name and, moreover, that food ingredients shall be designated on the labels of fabricated foods in descending order of predominance by weight and shall be identified by their common or usual name. This “naming” issue is a very significant one in the genetic engineering area because it is argued that by altering food composition through genetic engineering you somehow change the basic nature of the food. For example, several companies have proposed modifying various types of dietary oils so that they have enhanced proportions of unsaturated components because of certain health

characteristics that are claimed for foods rich in unsaturated oils. One can argue for soybean oil, or for any number of other oils, that if one increased the amount, beyond a certain level, of polyunsaturates that the oil should no longer be called “soybean oil”. Questions that arise are: 1. what is the accepted standardized profile of polyunsaturated fatty acids in soybean oil and 2. how much can one vary from that profile such that the oil could still be called by the common or usual name soybean oil? The FDA has considered these questions, but the issue has not been resolved. It is a very difficult question that comes down to how much can you vary the basic nature of a product, however that basic nature is defined, before you can no longer call it by the name by which it is traditionally recognized.

Another question that may arise is whether such a compositionally altered product is inferior in some way. It may not be nutritionally inferior, but such oil alterations may still misrepresent the basic nature of the product so that its utility as an ingredient may be altered.

An interesting case is represented by the requirement for labeling products that contain glutamate. The FDA has discussed extensively the issue of requiring glutamate labeling on protein hydrolysates. It refers to this example in the food biotechnology labeling initiative by saying that it required glutamate labeling. In this case the FDA did not require labeling because of safety issues, which is very interesting in the light of the glutamate scares that have been publicized. In fact, the agency said it felt the glutamate content was material information which the public needed to know. This raises the question of why it is material for the public to know that a product contains glutamate. I would argue to you that in the absence of safety concerns or some other important characteristic, glutamate content is immaterial.

The agency also said, with respect to protein hydrolysates, that it wanted source labeling identifying the particular source of the product. One could not identify “hydrolyzed vegetable protein” as an ingredient; rather the FDA required identification of the source of the protein, such as “hydrolyzed soy protein” or whatever. Here the agency took the position that, because the amino acid profile of different hydrolyzed proteins depended upon the source, it would be a misrepresentation to generically label it as “vegetable protein”. The amino acid profile could be different depending on the specific source of the protein and that issue was central to the basic nature of the final food. I would argue that the average consumer does not know or understand amino acid profiles of proteins and, therefore, the vegetable source of the protein is totally irrelevant information in terms of the consumer, unless there is also a safety issue related to the source.

It is interesting to observe over time how the FDA interprets these various provisions of the statute. I do not necessarily suggest the various interpretations are wrong. Rather, I want to emphasize that the question is what is the standard for requiring labeling? Does the standard make sense? Legally, scientifically, from a policy standpoint, does the standard make sense? If a standard is adopted, it needs to be applied consistently across the board. The agency should not single out one case and then somehow not apply the rule to other similar situations.

Finally, let us consider sections 402(b)(1)-(b)(4). These sections are the quality standards. They refer to valuable constituents omitted or substituted for in food. Butter is again a good example. When a food does not contain butter, or when some other type of ingredient is used to replace the butter, that could represent economic adulteration as well as misbranding. Again, as I keep emphasizing, various provisions of the law can be triggered depending on what change is made or if damage or inferiority is trying to be concealed. Again, inferiority is related to the suggestion that a product is better than it really is or is

deceptive as to quality or value. To repeat, this is economic adulteration and is generally a more serious enforcement issue than misbranding which usually is simply making misleading statements as to a fact, such as “natural”.

There are many familiar examples of these sorts of issues which have been reported by the press. Strength, purity, quality, and size (jumbo, big) are familiar issues. The “freshness” label has had a lot of publicity. Recall the orange juice case, labeled “fresh” orange juice, when in fact the juice was derived from concentrate or previously frozen orange concentrate or the like. There is a lot of controversy about what constitutes “fresh” these days. “Grade” is another controversial parameter, there are various grades of products (e.g., Grade A). “Naturalness” has always been the subject of a lot of controversy. Again, not an easy concept to define. What is natural, what is not, how much is it processed, does it contain artificial ingredients? As you can see, these labeling areas are very slippery slopes; once one starts down them it is difficult to back up in any sort of reasonable manner because the terms are very hard to define. Statements of origin are another issue. For example, what does the term “Italian dressing” suggest. Most people today would say the term “Italian” does not mean it comes from Italy. But again, that relies upon consumer understanding and experience which may suggest that the consumer would not be misled. These issues come up regularly about labeling food as representative of a particular “style”. An example is “Italian-style dressing” to suggest a product did not come from Italy.

In conclusion, I think it is useful to go over again some basic labeling concepts. First of all, although all the provisions I have reviewed suggest that the consumer has a limited right-to-know about his or her food, the fact is there is no labeling provision in the FFDCA that says the consumer has an absolute right-to-know everything about his or her food. Consumers state “I have a right to know”. In fact, they do not. The law says that you have a right to know certain things about your food, but the reality is that this issue often turns on interpretation. Invariably one’s “right-to-know” is not an easy issue to address; it is not that clear-cut. There is no absolute consumer “right-to-know,” per se, however. Again, I am not trying to suggest that there are not legitimate topics that we should know about as consumers, or that particular segments of the population should not know about. Rather the critical issue is what are the labeling standards and how do you apply them?

Secondly, food additive status does not mean the additive must be declared as an ingredient. I have heard so many people say, “Well, because something is a food additive it must be declared on the ingredient statement.” No, this is incorrect! In fact, the ingredient labeling provisions are totally unrelated to food additive status. The fact that something is a food additive does not mean it has to be labeled. It does not follow that if some component of a biotechnology product is a food additive, therefore it must be labeled. Food additive status means, legally, that a substance or process requires pre-market clearance from the FDA. The ingredient labeling provisions are another section of the law that basically say that the common or usual name of the ingredient must be declared on the product label in descending order of predominance by weight.

The question then arises as part of ingredient labeling whether, if “genetic engineering” is used and introduces an ingredient, that ingredient must be labeled by its common or usual name. In general, plant breeding per se has never been viewed as introducing “ingredients” that must be labeled on food. Conceptually, arguably, one is adding “ingredients” to the genetically modified food crop. But the ingredient provision of the statute relates specifically to “fabricated” foods: it requires listing of the common or usual name of the ingredients of “Fabricated” foods. What does the term “fabricated” suggest? It suggests that the producer is manipulating the food in a manufacturing situation and adding ingredients as part of a final recipe. It does not cover breeding a crop and “adding ingredients.” The distinction is that whole foods produced by plant breeding are not “fabricated

foods”. Thus far, according to the agency, plant breeding does not trigger automatically the ingredient listing requirement we have discussed.

Third point: what is the jurisdiction of the FDA, the U.S. Department of Agriculture (USDA), the Bureau of Alcohol, Tobacco and Firearms (ATF), and the Environmental Protection Agency (EPA)? Most of these agencies have concurrent jurisdiction over “foods”. We have only talked about one agency of these four, the FDA. The USDA has its own labeling requirements, and they can differ from those that we have just described. The USDA and the FDA have sometimes been at odds about how foods should be labeled because their statutory authorities are different. These differences are sometimes difficult to reconcile. Meat and poultry products are subject to USDA jurisdiction as well as to FDA oversight. The ATF regulates alcohol products and these are subject to different labeling standards. Again, all the labeling statutes I have discussed do not apply to the EPA. The EPA has its own standards. That is not to say always that the FDA does not have jurisdiction, it does. But there are other agencies that have their own laws too and they operate under different standards.

Finally, labels and labeling: the standards are usually the same from an FDA standpoint. Information provided directly on the immediate container of a food product, that is the so-called “label”. Anything that is used in conjunction with marketing a food is considered labeling. As a result, if you want to make statements about food products in brochures or press releases or other informational sources, the FDA can claim that the article to which that labeling relates misbrands that food. Therefore, the principles that we have talked about apply not only to labels on foods, but to anything that is used to market that food in furtherance of selling it.

The food provisions we discussed do not always apply to advertising. However, the distinction between advertising and labeling is often very difficult to delineate and the truth of the matter is that most everything that is distributed in furtherance of marketing of food products probably is labeling. In some areas, The Federal Trade Commission (FTC) has taken jurisdiction over advertising, but, in general, the FDA tends to focus on immediate containers of foods and the labels attached thereto. Everything else the FTC often has regulated.

To go back to the fundamentals question: should genetically engineered foods be labeled? I have no idea. A very easy answer is “No,” as the question is framed. The reason why the answer is easy is because there are too many scientific, legal, and policy questions involved in the determination to say “Yes.” Anyone who answers such a general question “Yes” usually does not know what they are talking about.

Unique Characteristics of Biotechnology Products

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Are biotechnology-derived foods any different than foods derived from traditional agricultural breeding and selection methods? Do biotechnology-derived foods have unique characteristics that may require special consideration? Under what conditions biotechnology-derived foods should be labeled? What kind of information would be useful to consumers and how should this information be conveyed on the label? To answer these questions requires an understanding of biotechnology, an understanding of how biotechnology-derived foods fit within the context of traditional agricultural practices and an understanding of the regulatory framework which assures the safety of the food supply.

Understanding biotechnology

What is biotechnology? The Office of Technology Assessment (OTA) defines biotechnology as “any technique that uses living organisms or parts of organisms to make or modify products, to improve plants or animals or to develop microorganisms for specific uses.” This is a very broad definition which could encompass many of the techniques (e.g., fermentation, breeding and selection, induced mutagenesis) used for centuries to improve the food supply. What separates traditional biotechnology from the “new” biotechnology is genetic engineering. Genetic engineering allows the transfer of deoxyribonucleic acid (DNA, the genetic blueprint) from one organism to another. Because the DNA in every living organism is structurally and functionally identical, genetic engineering techniques developed in the early 1970’s can be used to isolate, characterize and transfer DNA between viruses, microorganisms, plants, animals and even humans. The same basic techniques can be used to improve any living organism. Genetic engineering allows the transfer of single, well-characterized genes across species barriers in predictable, precise and controllable ways. The process is much faster than traditional methods currently used to genetically improve the food supply.

Understanding traditional agricultural practices

Prior to the discovery of genetic engineering, how were traditional techniques used to genetically improve the food supply? Traditional fermentation processes utilize living bacteria and yeast (starter cultures) to produce valuable products such as cheese, yogurt, sausage, sauerkraut, bread and wine. Starter cultures do not always possess the right combination of desirable properties, and are frequently exposed to various mutagenic agents, such as ultraviolet light or EMS (ethylmethylsulfonate) in order to improve their metabolic characteristics. Following mutagenesis, improved strains are selected based on specific properties such as improved flavor-producing ability, resistance to bacterial viruses (bacteriophage), or ability to grow at reduced or elevated temperatures. In addition to the property of interest, mutagenic agents create numerous and random changes in the DNA. Since the function of most microbial genes has not been identified, there is no way to monitor unanticipated changes in non-target genes. The fact that strains have been “genetically improved” is not revealed on the label. In fact, in most cases, the label does not even include the scientific names of the organisms used in the fermentation.

Traditional breeding and selection techniques in plant and animal agriculture take advantage of the tremendous genetic diversity available in different species. In corn, for example, genetic improvement can be achieved using cross hybridization. In traditional breeding, the 60,000 to 100,000 genes from one parental species are mixed and randomly sorted with an equivalent number of genes from another parent of the same species. Improved plants or animals are then selected from the offspring of the cross and back-crossed with parental strains to eliminate undesirable traits. An example is hybrid seed corn, the preferred variety in the U.S., which took over 20 years to develop using traditional breeding and selection techniques.

Mutagenesis has also been used to genetically improve crops. An interesting example of how mutagenesis has been used in the plant area is the single-serving lettuce developed by the U.S. Department of Agriculture (USDA). Lettuce seeds were exposed to the mutagenic agent EMS, and plants were selected that produced a much smaller head size, probably due to mutation in gene(s) controlling leaf size. Once these lettuce heads reach the marketplace, they will probably not be identified with a label indicating that mutagenesis was used in the process.

The traditional methods used to improve microorganisms, plants and animals have some limitations. The random process of mixing and sorting 60,000 to 100,000 genes during the breeding event is imprecise and uncontrollable. Although one might be screening for improved yield, there are lots of other mutations that go undetected. In addition to being a time consuming process, it is not possible to transfer a valuable trait from wheat into corn due to natural species barriers. Therefore, the gene pool cannot be expanded using traditional methods.

The U.S. Food and Drug Administration (FDA) has the authority to evaluate new plant varieties developed by traditional breeding methods before they reach the marketplace, but the agency has not exercised this authority. The FDA does not routinely assess new plant varieties for safety because established agronomic practices used by plant breeders and farmers (e.g., performance, yield, disease resistance), and food processors (e.g., chemical composition, nutritional quality, presence of natural toxicants, processing characteristics) have been considered sufficient to ensure human safety.

Understanding the regulatory framework

As outlined by Ed Korwek in another paper in this volume (see page 3), the FDA has broad authority for regulating the food supply. Although the FDA has always had the authority to regulate new plant varieties, they have not exercised this authority in the past. On May 29, 1992 (*Federal Register*, Vol. 57, No. 104), the FDA published a statement of policy regarding foods derived from new plant varieties. These guidelines relate specifically to plants, including genetically engineered plants, as well as those derived from traditional breeding processes, but do not include applications involving transgenic animals or starter cultures. The policy indicates that no new regulations are required for oversight of biotechnology-derived food crops and that regulation will be identical in principle to that applied to foods developed by traditional plant breeding. Regulatory status is dependent upon objective characteristics of the food and its intended use rather than the process by which it was produced.

As in the past, producers have an obligation to ensure that foods are safe and in compliance with applicable legal requirements. Producers are encouraged to informally consult with the FDA prior to marketing new foods and a “decision free” approach provides guidance as to when contact with the FDA would be required. For example, insertion of a gene which codes for a component not currently consumed in the human diet could be a trigger for FDA consultation. A crop with such a gene

might be considered to have a new food additive and be subject to oversight under the Federal Food, Drug and Cosmetic Act (FFDCA).

The guidelines contain no requirement that foods derived from new plant varieties be labeled. On April 28, 1993, the FDA published a request for additional comments on the labeling issue (*Federal Register*, Vol. 58, No. 80). A step-by-step analysis of the questions proposed in the *Federal Register* announcement provides an introduction to possible consumer concerns about biotechnology-derived foods, as well as potential logistical challenges facing food producers and processors if mandatory labeling were proscribed. This discussion will include some of the applications of biotechnology currently on the horizon and how some of the questions raised by the FDA might apply to these foods. In some cases, particularly in the case of potentially allergenic proteins in an unexpected food source, labeling might be a reasonable alternative. In other cases, particularly those for which no safety issue is involved, labeling may be impractical and costly, and provide no additional consumer benefit.

A small number of biotechnology-derived processing aids (e.g., enzymes) have been approved by the FDA and are currently being used commercially. An example is the enzyme rennet, the first biotechnology-derived product which was approved for use in 1990 for the production of cheese. The traditional source of rennet for cheese making is the stomach of veal calves. Biotechnology has been used to duplicate the calf gene which codes for the enzyme and genetically engineer a microorganism to produce the enzyme via fermentation. The enzyme is identical to calf rennet, an ingredient which is “generally recognized as safe” (GRAS) by the FDA. The label on the final cheese product does not indicate the source of the rennet used in manufacture. Biotechnology can be used to enhance production of many other enzymes and microbially-derived food ingredients where the final product will be identical to a counterpart that is already a GRAS food ingredient. Since the products are identical to their natural counterpart, labeling is probably not a significant issue.

For other biotechnology-derived foods, labeling issues will be more complicated. The FDA has requested additional information on specific characteristics of foods derived from genetically engineered plants that distinguish them from other foods.

Should labeling be required for foods that contain proteins not previously found in foods?

Bacillus thuringiensis (*Bt*), a soil microorganism, produces a protein which is toxic to certain insects. The organism has been used as a natural biopesticide for over 20 years. The gene which codes for the toxic protein has been genetically engineered into tomatoes, corn, cotton and many other crops, and the engineered crops are resistant to insect damage. Humans may have consumed very small quantities of the *Bt* toxic protein if fruit and vegetables harvested from fields where *Bt* was used as a natural pesticidal agent were not washed thoroughly prior to consumption. However, the quantities ingested would be extremely low. Therefore, *Bt* might be considered a new protein in the diets of humans. Some important questions to ask might be: How much of the protein is going to end up in the food? Are there any conditions under which the protein might be toxic to humans? The same questions need to be asked whenever genetic material from exotic plants or microorganisms not previously a part of the traditional food supply is engineered into the food crops. There are numerous examples of plants which have been engineered to resist microbial, fungal and viral diseases that fall into this category.

Should labeling be required for proteins that are new to a particular food but present in another food?

Antifreeze proteins are small molecular weight proteins present in the serum of Arctic fish that inhibit ice crystallization and allow fish to survive subzero temperatures. Antifreeze genes have been transferred into vegetables to prevent freeze damage. Mushiness and loss of texture in frozen fruits and vegetables are caused by ice crystal formation which damages cell walls during freeze-thaw cycles. Arctic fish, and thus antifreeze proteins, have been consumed as part of the food supply. Similarly, a growth hormone gene from one fish put into a different species of fish (e.g., carp growth hormone gene into a rainbow trout) might be classified in the same category. Metabolic enzymes from unrelated species are another category of gene products that represent proteins commonly a part of the diet.

Should foods containing higher or lower concentrations of proteins already present in the food be labeled?

An emerging technique which has found application in plant genetic engineering is antisense technology that has been used to selectively inactivate single genes. In effect, antisense can be used to decrease or totally eliminate production of a specific protein. This has been used to inactivate an enzyme involved in softening of tomato fruit, thus extending the shelf-life and improving the quality. One might imagine genetically engineering plants to contain elevated levels of amino acids, vitamins such as beta-carotene, or antioxidants. It is possible to increase the level of structural components such as starch in potatoes; a relatively small increase in solids content dramatically decreases the absorption of oil into French fries or potato chips during deep fat frying. Supplementation of pigs with recombinant DNA-derived porcine somatotropin decreases fat content of pork.

Certain microbial starter cultures are capable of producing natural inhibitory agents (e.g., bacteriocins) that function as antibiotics. For example, many of the lactic acid bacteria used to make cheese, yogurt, and fermented meat and vegetable products naturally produce these antibiotic-like compounds. Bacteriocins are not very effective as natural preservatives in foods because they are present at fairly low levels. Strains could be genetically engineered to overproduce bacteriocins to help ensure the safety and extend the shelf-life of fermented products.

The first genetically engineered organism to receive regulatory approval is a strain of *Saccharomyces cerevisiae* (baker's yeast) that produces elevated levels of carbon dioxide, the compound responsible for leavening of bread. This is accomplished by insertion of additional copies of genes coding for two enzymes that are naturally present in yeast and are responsible for starch metabolism. The strain was approved for use in England in March 1990.

Should products containing unexpressed genetic material be labeled?

In all genetic engineering experiments there is unexpressed DNA which does not code for proteins but which ends up in the transgenic plant or animal. Promoters, signal sequences, ribosome-binding sites and termination sequences are examples of unexpressed DNA which are required for adequate expression and regulation of cloned DNA. These elements do not code for protein products, but they do remain part of the genome of the transgenic organism. Depending upon where the DNA inserts into the chromosome, these elements might affect the expression and regulation of genes on the same chromosome.

Should foods with improved nutritional or food processing characteristics be labeled?

There are numerous examples of crops where biotechnology has been used to improve the nutritional quality or processing characteristics of a food. Most cereal grains are deficient in certain amino acids. Genetic engineering can be used to construct varieties of corn, rice and wheat that overproduce these amino acids; the result is a higher quality protein which provides more nutritious cereal-based products. Changing the ratio of amino acids in cereal grains could have a dramatic impact on the nutritional quality of the diet, particularly in Third World and developing countries. As we understand more about the role of saturated and unsaturated fats in health and chronic disease, it will be possible to use biotechnology to alter the degree of saturation or chain length of fatty acids in oil seeds such as canola and soybean. It may be possible to increase the level of vitamins, trace elements, minerals or antioxidants using biotechnology. It may even be possible to improve the digestibility and bioavailability of nutrients using genetic engineering.

Improved food processing of foods is also a goal of biotechnology. Many starches are chemically or enzymatically modified to confer specific processing characteristics. Genetic engineering could be used to allow the plant to modify the starch as part of the plant's normal metabolism.

Should ingredients that have been derived from genetically engineered plants but not affected by the genetic modification be labeled?

Many crops which serve as source material for food ingredients may be genetically engineered to enhance unrelated properties such as disease-resistance, insect-tolerance or stress-resistance. For example, the gene(s) introduced to confer disease- or virus-resistance in corn may not affect starch biosynthesis in any way. Ingredients might also be derived from stress-tolerant plants engineered to thrive in colder or warmer climates, or in saline or alkaline soils where the biosynthesis of the ingredients of interest is not influenced by inserted genetic information. Milk and meat from bovine somatotropin (bST)-supplemented cows might also fit in this category, as the protein hormone bST affects metabolism but does not affect the composition of the final products.

Should foods containing genes derived from foods known to be commonly allergenic be labeled?

Potential allergenicity of proteins derived from introduced gene(s) is an issue of concern to many people and the FDA will be requesting further comments in this area. A key question will be what foods should be considered allergenic? Much is known about commonly allergenic products such as peanut, fish and shellfish, and milk. Clearly, if corn has been genetically engineered to contain a commonly known allergenic protein (e.g., peanut protein) the FDA will require labeling of the product. This could be handled in a relatively straightforward manner by indicating the presence of peanut protein on the ingredient label. There are approximately 125 known allergens although a comprehensive data base is not readily available. Other issues include the technical feasibility of testing for the presence of allergenic potential. Is it possible to predict allergenic potential of proteins? There is particular concern about the allergenicity of proteins from sources not previously a part of the food supply.

Should foods be labeled relative to the source of DNA?

Biotechnology provides a means for introducing DNA from unrelated species into plants. Even though proteins derived from animal genes are made up of amino acids and would be digested just like any other protein, additional concerns arise when these transfers occur. As discussed earlier, antifreeze proteins from Arctic fish have been inserted into vegetables. It may be possible in the future to transfer animal genes into plant food sources. Strict vegetarians and members of some religious groups may not want to consume a vegetable product with animal-derived proteins in it. Labeling for religious or dietary preferences is not currently considered within the purview of the FDA; certification mechanisms are in place for religious groups with dietary laws.

Interestingly, due to conservation of certain genes throughout evolution, many living organisms from diverse species already possess identical genes; therefore, it could be difficult to determine whether or not a plant has been genetically engineered or to determine the source of the DNA.

What are the practical difficulties and economic impact of labeling genetically engineered foods?

Labeling of biotechnology-derived foods and ingredients raises several challenges for the food processing industry:

1. In many cases, it will be impossible to distinguish between constituents that are introduced via genetic engineering versus traditional plant breeding techniques, particularly in those cases where the cloned gene products are already present in that food. In addition, for most plant varieties the normal range of concentrations of specific constituents and the variability of those constituents among and between species are not currently available as a basis for comparison of native and engineered varieties.
2. Rapid, reliable and inexpensive methods would need to be developed to identify engineered varieties. These do not currently exist for many of the genes or gene products which are of interest to biotechnologists.
3. In the absence of analytical methods for determining whether or not a plant is engineered, tracking systems for plants and plant-derived ingredients at every stage of the food chain (from the seed to the processor to the grocery store to the consumer) would need to be instituted. For example, a genetically engineered variety of corn may serve as the source of several different ingredients used in processed foods (e.g., starch, corn oil, etc.). If a label were to be required on the final product, farmers would need to segregate seed and maintain separate harvesting systems for native vs. engineered varieties. Food processors routinely receive the same ingredient from several suppliers and they would need to maintain systems for tracking and segregating supplies in storage facilities and processing plants. Logistically, it might be easier to label fresh vs. processed products; however, this would also require segregation and some kind of certification system. The impact and total cost for instituting tracking and separate handling systems is not known; however, the cost of the systems would probably be passed on to consumers through higher food prices.
4. Labeling would encourage more vertical integration in the food industry, as food processors would want to control the source of their raw materials and document the history of their products from the seed to the processing plant. This would influence the structure of agriculture.
5. Labels or symbols on labels are commonly used to alert consumers when a safety issue might exist for certain individuals (e.g., labeling of products containing aspartame due to the negative health effects on individuals with phenylketonuria). A label indicating that a product was derived using biotechnology might be perceived by consumers as a warning signal even when no safety issue exists.

Mandatory labeling of biotechnology-derived foods is obviously a complex issue. How it will be resolved will have a dramatic impact on every sector of the food system from the farmer, to the processor, to the retailer, to the end consumer. Readers are encouraged to participate in the ensuing dialogue and public debate about these issues. All of us who eat food have a vested interest in the outcome of the debate.

What Consumers Want to Know About Biotechnology

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Consumer attitudes toward biotechnology are generally positive. However, the public has concerns and questions which should be addressed. These are highlighted by special interest groups who build on fears. Unless balanced by facts and scientific perspective, the number of consumers with concerns could increase. My assessment of consumer interest is based on a review of the literature, including the Hoban and Kendall study, and experiences discussing biotechnology in meetings with chefs, the media and the public.

The majority of consumers respond favorable to biotechnology. The recent Hoban and Kendall study (1992) found that 67% believe they will benefit from biotechnology in the next five years. About 75% of the people thought biotechnology would have a positive effect on farm economics, and food quality and nutrition. Over half thought the effect on environmental quality, farm chemical use, and fish and wildlife would be beneficial.

Some consumers are concerned about the ethics and safety of transferring genetic material. People are uncertain what gets transferred when a gene is snipped from one species and inserted into another. Cartoons of fishy tomatoes or potatoes with wings play on the public's limited knowledge of gene transfer. The distinction between transferring a trait and changing the type of organism must be made clear. Additionally, the oneness of nature and "a communality" of chemicals across organisms should be noted.

People are concerned that any modification disrupts nature and unforeseen consequences could ensue. Biotechnology is not unique in eliciting this concern. Only about half of those interviewed found traditional cross-pollination and one-third found animal breeding acceptable.

Ethical concerns relate to applications of biotechnology to animals

This is an age in which people are concerned about treating other creatures humanely. They are sensitive to allegations that animals may be exploited to serve human's demands.

It is natural to be concerned that a new technology might have risks, whereas traditional practices are considered safe, or at least the risks are routine and judged to be relatively small. In 1906 Luther Burbank expressed concern about the techniques of crossbreeding:

We have recently advanced our knowledge of genetics to the point where we can manipulate life in a way never intended by nature. We must proceed with utmost caution in the application of this new found knowledge.

Consumers today view as potentially risky the unfamiliar and uncommon practices of transferring genes from one organism to another. Consumers want to know that risks have been examined and safety is comparable to that of other products on the market.

Many express concern that the company releasing the biotechnology product is responsible for safety testing. They believe this responsibility should rest with the regulatory authority. There is a need then to address the regulatory process and note the oversight role of federal agencies.

Benefits of a new technology should be equitably distributed and available to all, regardless of size or location of operation. People value the traditional view of the family farm. A technology is considered less desirable if it is available preferentially to corporate agriculture. Frequently the argument is presented that companies will charge prices for new technology products that go beyond the reach of the family farmer.

People want the tools of science to be applied to issues of concern

People have indicated they will evaluate individual applications of this technology. In the Hoban and Kendall study, over 60% felt that use of biotechnology to make cotton plants resistant to damage from weed control chemicals was acceptable. This application of biotechnology is more acceptable than the general public response to crossbreeding.

Use of biotechnology to help improve farm animal disease-resistance was acceptable to about 50% of the sample, and was more acceptable than the general use of crossbreeding to improve animals. About 45% found biotechnology acceptable when it was used to produce farm animals with leaner meat.

In the Hoban and Kendall study, people indicated that they are least interested in learning about the science of biotechnology, rather they want to know the risks and benefits of the technology, the human health-care uses and other potential benefits. Biotechnology does address issues the public cares about, such as food quality and environmental issues. Although the general public may lack depth in scientific training, people of all ages, philosophies and formal education are interested in learning more about biotechnology. The scientific community must respond, or the slate will be clear for those who persuade by fear, and human kind will be the loser if they prevail.

Potential allergies from food modified by recombinant DNA is of particular concern

Although the Food and Drug Administration's (FDA's) proposed policy addresses the presence of allergens, the public must not realize this since the allergy question always arises in public discussions. People are concerned that they may be allergic to a food the FDA does not recognize as an allergen. The perceptions of allergies are higher than actual occurrence, according to Dean Darrel Metcalfe, National Institute of Allergy and Infectious Disease. He notes that about one in three people think they have food allergies, however in double-blind tests, less than three percent of children and less than one percent of adults actually have food allergies. In the public's view, food allergies are widespread and restaurants or markets selling genetically engineered food will receive numerous questions about potential allergic reactions.

Does the public want to know when biotechnology is used in a product?

Those surveyed by Hoban and Kendall indicate they do, but one must note that biotechnology ranks fifth out of seven items, some of which are not currently labeled. There is a tendency to respond affirmatively when asked if you want something. When consumers were asked this question there was no indication that providing the information would entail costs, either in higher prices or limited availability. Therefore this strongly affirmative response should not be taken at face value.

Paul B. Thompson, Texas A&M, suggests that there are two philosophic approaches to labeling, either an evaluation of performance or structure. A performance focus evaluates the impact of a label based on the end-state produced. If one thought the public would avoid a labeled product out of fear or ignorance, and this avoidance was not health enhancing, then clearly labels should not be used. In contrast, a structure focus specifies the conditions of consumer choice with no consideration of the consequences of that choice. Under this approach, informed consent is paramount and a label is appropriate.

Biotechnology-driven labels will stimulate patterns of conduct by consumers, processor and manufacturers

The label could be interpreted by the consumer as a warning on a risky product. It could result in higher food prices, in part because of the necessity of handling a different line of commodities. It may hinder the utilization and availability of biotechnology-derived products because manufacturers do not want to devote time and resources to product control. In the long run, labeling could reduce utilization of a tool that may successfully address issues of public importance. By the performance approach, mandatory labels may not promote public well-being and should not be used.

Optional negative labeling, or "No biotechnology" labels, have been suggested as an alternative. This option preserves choice; however it also is not without complications. Certification that specifies the extent of product modification would be required. This type of labeling could be perceived as a warning, like "no cholesterol," or "no pesticides," or it could be presented as a product style, like Kosher or regional labeling.

Thompson contends that consumer confidence is enhanced by participation and consent in the purchase decision. Hoban and Kendall's work and consumer studies in other areas indicates the public is more accepting for a process or an ingredient when the reasons for its application are presented. The potential for voluntary labeling with explanatory information should be explored. Labels such as "Developed using biotechnology for superior flavor," would be appropriate for sweeter fruit. "Modified by biotechnology for more environmentally benign farming," could be used for plants carrying a *Bacillus thuringiensis (Bt)* gene. Statement development and use would require regulatory oversight; however they preserve choice and bring the label into an informational rather than warning status.

Summary

Consumers are positive about biotechnology, however they want to be assured that potential risks are foreseen and controlled. They want the tools of science applied to issues they perceive as important, and the benefits fairly distributed without exploitation of other creatures or the environment. A voluntary label describing the reasons for applications of biotechnology would be positively viewed by the public.

References

- Hoban, T.J. IV and P.A. Kendall. 1992. Consumer attitudes about the use of biotechnology in agriculture and food production. North Carolina State University.
- Schutz, H.G., C.M. Bruhn and K.V. Diaz-Knauf. 1989. Consumer attitudes toward irradiated foods: effects of labeling and benefits information. *Food Technology* 43(10) 80-86.

Lacy, W.B., L. Busch and L.R. Lacy. 1991. Public perceptions of agricultural biotechnology. In "Agricultural Biotechnology," B.R. Baumgardt and M.A. Martin, eds. Purdue Univ. Agric. Exp. Sta., West Lafayette Ind. p. 139.

Office of Technology Assessment (OTA). 1987. New Developments in biotechnology: Public perceptions of biotechnology. OTA-BP-BA-45. Office of Technology Assessment, U.S. Congress. U.S. Government Printing Office, Washington, DC.

Workgroup Reports and Recommendations

Biotechnology Product Labels
chair: Rosetta L. Newsome

Consumer Information
chair: Marshall A. Martin

Following a brief reflection on the plenary session presentations, the group considered the question of whether all biotechnology foods should be labeled. After a vote, the clear consensus of the group was that, while it is not appropriate to require uniform labeling of all products of biotechnology, some labeling of biotechnology products may be required. A further clear consensus of the group was the necessity of developing creative and informative new programs and modes of delivery to assist the public in interpreting and evaluating benefits and risks associated with specific biotechnology products.

Workgroup participants then divided into two subgroups. One subgroup, chaired by Rosetta Newsome, discussed *Biotechnology Product Labels*. The other, chaired by Marshall Martin, discussed *Consumer Information*.

Biotechnology Product Labels

Participants in this workgroup subdivided further into two subgroups to identify issues regarding product labels and to develop recommendations. Each group approached the topic differently; however upon sharing the results of their separate deliberations, the following consensus issues and recommendations were formulated.

ISSUES:

- Should all biotechnology products be labeled regardless of the specific gene, gene product or other modification introduced?
- What are the most appropriate mechanisms/routes to provide to the consumer information: 1) to enhance understanding of the methods of biotechnology; 2) to explain the properties of specific biotechnology products; 3) to interpret information found on product labels, advertisements and point of purchase consumer information; and 4) in general, to facilitate informed decision-making.

RECOMMENDATIONS:

- Uniform mandatory labeling of biotechnology products is not needed unless food safety or nutritional quality is at issue.
- Issues of food safety and nutrition can be best handled using techniques such as decision trees, which would focus attention on questions of allergies, altered nutritional value, increased toxicity, or potential unintended consequences of the genetic modification.
- The development of appropriate decision trees will greatly facilitate resolving questions of whether specific products require special labels.

- Use of decision trees will facilitate resolution of the questions raised in the Food and Drug Administration's (FDA's) April 28, 1993 request for data and information on labeling issues (*Federal Register* 58 (80): 25837-25841), specifically they will facilitate resolution of the questions (#1-6) identified under section IIIA1(b) *Required Labeling*.
- When utilizing decision trees, the following principles should be applied uniformly to determine whether labeling of a specific biotechnology product is required:
 - a. Labeling requirements should be limited to safety and nutritional issues, such as transfer of potential allergens or altered vitamin content.
 - b. Based on current understanding, labeling requirements should be the same for all foods, fresh as well as processed, whether or not the food is a product of biotechnology.
 - c. Labeling requirements should be determined by the consumption of the product rather than by the process by which the product was developed.
 - d. The source of introduced genes is not material except when it affects any safety or nutritional issue.
- When a label is required to provide information on a compositional change that might result from genetic engineering, material information would include: what the product contains, how much it contains, and the relationship of this composition to the average for the product.
- In general, voluntary labeling should be allowed, but should NOT be permitted if such labeling may be interpreted to relate to or address safety or nutritional claims or implications. Voluntary labeling may address issues such as enhanced flavor or quality, or religious concerns, if these claims can be validated as factual.
- It is important to develop consumer information/education material to clarify the concept that a nucleotide coding sequence (a gene) copied from the genome of a microbe, plant or animal is not inherently a microbial, plant, or animal product and does not necessarily convey microbial, plant or animal characteristics on the new host organism.

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Consumer Information

ISSUES:

- Providing information and education on biotechnology is key whether or not labeling is required for better biotechnology products.
- Providing more information for informed decision making is just the beginning; there are diverse perspectives on biotechnology and its applications that must be aired and resolved.
- There is a need for development of long-term information and education programs by an objective, science-based organization.
- The "public" is a heterogeneous constituency with diverse concerns and varying levels of understanding of biotechnology, requiring diverse forms of information and a range of information channels.

Participants in the group identified critical components in the design and delivery of an effective, high-impact consumer information and education program on agricultural biotechnology. Key components of the resulting model were: the source of information/programming (spokespersons), the message(s) to be delivered, the various recipients of the message (audiences), effective channels available for delivery of the message(s), and desirable responses (goals) to be produced by the program. Recommendations were then developed for implementing such a program.

Sources of information/programming; spokespersons

- Food industry representatives or spokespersons (e.g., key opinion leaders, popular authoritative figures easily recognized by the public)
- Members of the immediate family and relatives, including children who share what they learn at school
- Consumer and environmental organizations
- Private sector information groups
- University spokespersons, extension educators, teachers
- Government officials
- Professional societies
- Special interest groups
- Physicians, other health professionals
- Journalists (print, radio and video)
- Farmers and 4-H leaders
- Celebrities

Key messages

- Technically accurate information to guide decision making
- Product attributes (e.g., safety, quality, efficacy, utility)
- Product benefits and costs (to individuals, to society)
- Socioeconomic impacts
- All living creatures share a common set of chemical constituents
- Religious, ethical and moral considerations (e.g., animal welfare, global hunger)
- Cultural issues (e.g., environmental, animal rights/well-being, special diets, organic foods, natural order of living things)
- Changes in the composition and nutritional value of foods

- Sources of further information
- Scientists are concerned individuals who try to address contemporary issues
- Scientists have considered and evaluated potential risks of biotechnology-derived foods
- How products are tested and regulated
- Biotechnology provides exciting potential benefits for all of us
- Recombinant DNA is a tool that can be used in a positive way to improve food quality and enhance environmental responsibility
- Scientists are still learning about potential unintended attributes and the environmental fate of genetically modified organisms, thus each product must be individually evaluated on its own potential merits and risks
- Influence of biotechnology on cost of production

Key audiences

- Consumers, especially women
- Journalists (print, radio, TV)
- General education (news media, political agents, school boards, etc.)
- Parents
- Students in K-12 and advanced technical curricula
- Religious communities
- Retail grocers, restaurant owners, food industry personnel, chefs, etc.
- Social service groups
- Agribusiness groups, farmers
- Legislators
- Professionals (e.g., attorneys, health-care professionals, dietitians, nutritionists)
- Teachers
- Community leaders
- Key decision makers

Potential channels to deliver messages

- Mass media (TV, radio, newspapers, magazines)
- Extension education programs and meetings
- Point of purchase information (e.g., signs, brochures, topical handouts)
- Libraries, museums, fairs, exhibits
- Brochures, brief topical handouts
- Cooking schools, cooking academies
- Computer assisted/multimedia presentations, interactive electronic programs, video games
- K-12 schools
- Third party spokespersons, opinion leaders
- Study circles
- Speaker's bureau
- Presentations to civic groups
- "800" telephone number

- "Captain Biotech" comics
- Restaurant menus
- Theme parks (e.g., Disney World)
- Scientific meetings
- Professional society meetings

Desired responses

- Enhanced capacity to make an informed choice
- Knowledge of how to gain additional information
- Social awareness
- Increased knowledge of technical, nutritional, food safety and socioeconomic issues, and more extensive participation in discussions
- Changes in consumer behavior
- Education of persons who can competently discuss issues (both technical and socioeconomic)
- Politically and technically astute legislation

RECOMMENDATIONS

General Guidelines

- Be proactive and outgoing rather than reactive and defensive
- Information about biotechnology products should be made available, whether or not labeling is required
- Regardless of labeling, consumer information is important
- Develop sensitivity to ethics and value judgments
- Practice principles of risk communication
- Identify and use existing channels and programs, and develop new ones

Framework

- Use a communication model as a framework for planning, coordinating and evaluating education/information programs

Logistics

- Evaluate/design effective pathways for various desired response loops (resource use effectiveness, scale/size of audience, detailed information)
- Survey audiences to get a sense of needs and wants
- Initiate a process for funding a coordinated network for information hearing
- Install and maintain an "800" number for information (e.g., 1-800-BIOTECH)
- Provide training to media spokespeople
- Provide media training to spokespeople who can speak to the benefits and science of biotechnology
- Develop good written materials for consumers
- Develop teaching materials for primary and secondary schools
- Visit legislators
- Conduct "before" and "after" surveys to measure impact of educational programs

Organization and leadership

- Identify core groups to implement the plan
- Develop grassroots network of farm, professional, university and government activists to act on or disseminate information
- Have a coalition of "sources" to develop messages for targeted audiences
- Set up a "clearinghouse" for information
- Private industry should fund informational programs to develop and deliver information targeted to women, special interest groups, K-12, and politicians
- Establish advisory board to provide oversight on educational programs, to track consumer attitudes and evaluate program effectiveness
- Information should be made available from a variety of sources. The message, audience and channels utilized should vary
- Create community, state and regional information boards to hold public meetings and seminars

Source of funding

- Private industry contribute to a "blind trust" which grants funds based upon proposals to evaluate the effectiveness of consumer education programs
- Ask the Food Marketing Institute to add biotechnology questions to annual survey
- Industry/government/public interest group coalition efforts
- Consortium of public interest groups to provide advice and guidance
- Main stream foundations
- Advertising council
- Government funding

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