

Date: March 19, 2001

To:

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

Comments Pursuant to:

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Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or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

Submitted by:

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Comments:

International Certification Services, Inc. (ICS) is an organic foods certification agency based in North Dakota, USA, doing business worldwide. The program currently does business under the name Farm Verified Organic (FVO) and has done so since 1980. FVO/ICS is accredited by International Organic Accreditation Services, Inc. (IOAS) to the program requirements of the International Federation of Organic Agriculture Movements (IFOAM) Accreditation Program. FVO/ICS also holds accreditation by USDA for compliance under ISO Guide 65 requirements. The company intends to be included in the first of round of certifying agents accredited by USDA under the new National Organic Program (NOP), under the direct auspices of the company's parent name ICS, as a distinct organic certification service specific to the new NOP rules. FVO/ICS will also continue to offer certification under the FVO logo.

FVO/ICS would like to focus its comments to FDA regarding the Draft Guidance into the following three sections:

1) Regarding whether the use of bioengineering is a "material fact":

FDA states that it has not concluded that the use of bioengineering is a material fact, and as such, warrants no additional labeling claims. FVO/ICS strongly disagrees. In the nine years since FDA drew its initial conclusions on this question, substantial evidence has emerged which testifies to the significant and potentially dangerous alterations effected in bioengineered foods, as opposed to their traditional counterparts.

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FDA states in the Draft Guidance that many previous commenters expressed concern about the potential for deleterious long-term consequences of consuming bioengineered foods, but that no such adverse effects were then known, and that much of the opposition to such foods was based on concerns about the unknown. This is no longer the case. A few examples clearly illustrate this point:

- a) Milk produced from cows treated with recombinant bovine growth hormone (rBGH or rBST) has been shown to elevate levels of insulin growth factor 1 (IGF-1) in the milk. Studies now show that increased levels of IGF-1 is directly linked to increased incidence of prostate cancer in humans.
- b) Roundup Ready soybeans have been shown to be significantly nutritionally deficient in phytoestrogen content compared with their non-engineered counterparts.
- c) StarLink corn has an acknowledged potential human allergen (the Cry9C gene), and has entered the food supply in an uncontrolled manner.
- d) Components of potatoes engineered to contain *bacillus thuringiensis* genes, when fed to laboratory rodents, have shown negative effects on liver and nervous system development.
- e) Bacteria bioengineered to produce elevated levels of L-tryptophan also produced a dimer of tryptophan, which when unfiltered and thereby included in the marketed tryptophan product caused permanent neurological damage and/or death to over 1500 persons.
- f) Fiber from Bt-cotton varieties has been shown in some cases to be of a quality unsatisfactory compared to traditional cotton varieties, as regards fiber strength and integrity. (While cotton is obviously not a human food, the material difference of the bioengineered variety is clear.)

(FVO/ICS can provide references at FDA's request.)

While it may be the case that from a taste/sensory perspective most bioengineered foods might not be detectably different by consumers, there is growing evidence that molecularly, nutritionally, and environmentally, these foods do indeed act differently from their traditionally-bred counterparts.

FDA openly admits in Docket No. 00N – 1396 (Pre-market Notice Concerning Bioengineered Foods) that the effects of bioengineering will be varied, and cannot be fully predicted given our current level of understanding of the technology. Because the results of bioengineering vary from food to food, it is an oversimplification to categorically state that there is no material difference between any bioengineered food and its non-engineered counterpart.

The United States Code requires that if a bioengineered food has a significantly different nutritional property, its labeling must reflect the difference between it and its traditional counterpart. What defines a significant difference? How does FDA consider bioengineering to not be a material fact? It is clear that in at least some cases, bioengineered foods have been clearly demonstrated to have different biochemical

profiles with correspondingly altered effects on humans, other organisms, and the environment in general, when compared with non-bioengineered varieties.

What criteria is FDA using to determine whether such a difference exists? How and by whom is the adequacy or completeness of the data judged? Is there scientific peer review of the data presented? Has FDA received studies which suggest the same or similar results of bioengineering as mentioned above in (a) – (f)? If not, what is the best way to present such information to FDA, and what is the review process?

The companies who have developed these foods and the seed from which they are produced guard their technology, the rights to the seed, their patents on these life forms, as well as the research data on these products. If there is not a material difference between the product and the corresponding traditional variety, on what basis could *patents for such goods have been issued? These bioengineered products have been expressly made to perform in a technically and functionally different manner than their traditional parent varieties. How could such a difference be manifest if there was not a molecular difference in the bioengineered product?*

FDA may wish to confine its own rulings to the molecular components of the food only, as opposed to the effects of changes as they manifest themselves in the field. This might simplify FDA's responsibility, but it is impossible to do this unless FDA ignores basic tenets of cellular biology. In the examples cited above of problems arising with bioengineered foods, none of the effects described was an intentional outcome of the seed developer. The desired field effect results in other changes, many of which are unforeseeable; FDA often admits this in its discussion in Docket No. 00N – 1396. The living cell contains a myriad of biochemical components, only a minority of which are known, and the interactions among which are very incompletely understood. Alteration of one aspect necessarily brings with it other changes within the organism. Furthermore, bioengineering is still an abrupt technology, with a significant degree of inaccuracy. The situation is akin to having a jigsaw puzzle of 10,000 pieces, placing a few hundred of them on the table, and thinking that we know what the picture looks like. In any case, neither FDA nor anyone else can conclusively state what the effects are (especially in the long term), for even any of the direct changes known to be manifested in the food by the bioengineering.

FVO/ICS shares the concerns of commenters who fear potential adverse and/or unknown consequences of bioengineered foods. We want to know how FDA has weighed the evidence which suggests that bioengineering is a desirable and safe technology at this time, versus the evidence that suggests bioengineering has unfavorable effects on nutrition and/or the environment. While not all of the effects are yet known, there is adequate evidence to justify our concerns. What is FDA's rationale for continuing to refute such concerns? Food safety should be FDA's primary responsibility and concern; the Draft Guidance and the related Docket No. 00N – 1396 make it appear that FDA is *prioritizing the welfare of bioengineering companies over the welfare of the public and the environment. From where does FDA receive its authority to set its priorities as such?*

In summary, while FDA may not have had enough data in 1992 to conclude that a material difference between bioengineered foods and non-engineered foods exists, now nine years later there is sufficient and mounting evidence that considerable differences do exist, and these merit careful attention so that food safety is ensured. It is the opinion of FVO/ICS that bioengineering is a material fact. FDA needs to revise its thinking on this issue, in light of such information. When considering a field as new, as powerful, and as variable as bioengineering is, to not act in accordance with the Precautionary Principle is irresponsible. There already is widespread and increasing sentiment worldwide in favor of this approach, as reflected in the Cartagena Protocol on Biosafety; we strongly urge the United States to join this agreement.

2) Regarding the content of label claims for foods containing or not containing products of bioengineering:

In all cases, FVO/ICS believes that labeling claims must be accurate and truthful. There are two approaches which can be used when labeling foods as to their content of bioengineered ingredients. One approach refers to the production method, the other to the actual content of the product. Both can and need to be involved in any infrastructures that support labeling claims.

The former refers to the production of the food from its source to its final package, i.e. from seed through field production to harvest and post-harvest handling, to storage and eventual use in processing or in packaging to the final consumer. In each of the steps of the production system, in order for any labeling claims to be truthful, all possible measures must be taken to ensure that the claims reflected by the labeling statement have been met. This involves segregation, identification, and documentation of product lots throughout the chain of custody.

In the latter approach (i.e. labels referring to product content), analytical testing of the goods is required. The state of the art of such analytical technology is limited to relatively well-defined detection limits; while these limits may become more sensitive in the future as technological know-how increases, the limits as they exist need to be borne in mind when wording labeling claims. Non-detection does not necessarily mean zero presence. Nonetheless, analytical testing is a very useful tool for both presenting product to consumers which meets with their reasonable expectations for food content, as well as for assessing whether label claims made regarding the production method are reasonable.

When considering the impact that bioengineered foods have already had on the entire food production system, FVO/ICS strongly believes that both methods described above have useful and necessary places.

Bioengineering is, in our opinion, the most powerful technology mankind has ever developed. Man's knowledge of this powerful science is still limited, but it is clear to all who study it (including FDA, as it notes in its Docket No. 00N-1396) that it presents new and unforeseen challenges to our ability to understand and control it. As such, FVO/ICS calls on FDA to pool its resources with other regulatory agencies to ensure maximum

effectiveness in executing government policies affected by bioengineering, and to ensure maximum effectiveness in overseeing food safety issues.

The USDA has already published rules regarding organic production, and these categorically exclude bioengineering as a production practice. These National Organic Program rules include labeling requirements for organic foods; to wit, any product labeled as organic with the USDA seal is being certified to be of a production method that does not include bioengineering ("excluded methods"). FVO/ICS fully expects that the US Government will do its part to ensure that its own interdepartmental rules harmonize enough to make compliance with its rules possible for certifying agents and producers. We also note that a prohibition on bioengineering has already been incorporated by Codex Alimentarius in organic production guidelines.

The NOP rule was published after over a decade of intensive debate and consideration, with the substantial input from hundreds if thousands of American citizens. There is growing demand for organic products in the marketplace, and this demand expects that organic products will indeed be free of bioengineered material, as witnessed by some 280,000 comments to that effect upon the first published proposal of the NOP rule. As FDA correctly notes in this Draft Guidance, organic labeling already implies a "non-GMO" label. Therefore, it seems reasonable to us that a right to have non-GMO or similar labels has already been conferred on manufacturers and marketers. We wholly support the right to label foods as not containing bioengineered material. We do not believe that such claims would necessarily be misleading to consumers. Such claims could be applied to foods produced organically, as well as to mainstream conventional production systems that do not choose to use bioengineered products or methods.

A final product could rightly be labeled as GMO-free if that species has yet to be produced as a bioengineered species. For example, rye flour could be called GMO-free because there is yet no rye seed which has been bioengineered. If it was grown on a farm that did not use any bioengineered inputs, it would be reasonable to call the rye harvested and the flour made therefrom GMO-free.

For producers whose methods do not intentionally include any bioengineered materials but a visually indistinguishable product also exists in the market in bioengineered form, it would similarly be reasonable for the labeling of the products produced by them to state that no such methods were employed throughout the production system. However, in at least some of these cases, a GMO-free label may not be completely accurate, as contamination by bioengineered material may have occurred due to forces outside their own production system. Further assurance to the consumer of the product could then be afforded via laboratory analysis of the product for bioengineered material, and the label could rightly state the level at which such material was or was not detected. Again, this would be a reasonable and truthful labeling claim.

As a side note, FVO/ICS recognizes that the already existent pervasiveness of bioengineering at various levels of the food production system begs the questions: "When does a method or product stop being considered bioengineered? When is a production

method free of bioengineering?" Food production system inputs and the cycling of materials throughout the entire realm of food production is a complex web of interactions. In a desire to protect itself from the presence and effects of bioengineering, the organic certification community has discussed this question intensively over the past four years, and several feasible models have been drawn, although consensus has still not been reached. FVO/ICS offers here one such schematic as Addendum #1 to this submission of comments, as suggested guidance on this issue. Another proposal is available from the Organic Materials Review Institute, a non-profit organization based in Eugene, Oregon. We request that FDA, in conjunction with USDA and EPA, consider these issues as well.

FVO/ICS does not support labeling requirements that mandate comments as to the superiority of one production system over another. While we do have a clear opinion on this issue, we prefer that FDA simply allow for accurate labeling as to content as described above, and let the consumer decide. For FDA to require that there be a statement to the effect that there is no difference between bioengineered and non-bioengineered foods appears to be an extra protection and/or favoring by FDA of bioengineered foods over non-bioengineered foods. We make this statement because our observations of public sentiment very clearly show that consumers overwhelmingly either do not want to consume bioengineered foods, or at least believe such foods should be positively labeled as such.

This sentiment from the general public makes it highly unlikely that any producer or marketer of goods known to be bioengineered will voluntarily label said foods as such, for fear that the product will not sell as well as if it were unlabeled. This compounds the key problem that consumers' basic right to choose what they eat is being threatened by poorly regulated flow of bioengineered material throughout the food chain.

The United States Code states:

21 USC 312 (n)

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, **but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.** (bold typeface added)

In light of the evidence and discussion mentioned under section 1 above, we question how FDA is able to interpret the above section of the US Code in any way other than to require that bioengineered foods be distinguished from other foods.

Failure to institute mandatory labeling regulations undercuts clear public sentiment for a right-to-know about bioengineered foods. We believe that if food products are known to contain bioengineered material, this must be stated on the product label.

Voluntary labels prevent food allergic consumers from consistent safety information. Consumers should have the right to choose to avoid certain foods if they wish to do so. Full and mandatory labeling ensures that the consumer can make a clear choice. The onus for labeling of bioengineered foods or the lack thereof should not fall only on those who do not choose to use such materials in the products, especially since the reason those producers need to have a non-GMO label at all is because there has been inadequate control of the bioengineered products in the first place.

Another negative consequence of voluntary labeling instead of mandatory labeling is that voluntary labeling prevents post-market surveillance traceability and food producer liability. A food safety system that adequately works to prevent foods from causing health impacts requires both pre-market and post-market oversight. In the case of bioengineered foods, the FDA has repeatedly stressed that should a hazardous bioengineered food come onto the market it will be able to remove that product from the market. (The Starlink fiasco has shown how the current system fails in this regard, and points to necessary improvements in the regulatory system.) Such a system of post-market surveillance and enforcement, however, makes mandatory labeling of all genetically engineered foods critical. Mandatory labeling not only provides consumers with marketplace choice, but it is essential for the traceability of bioengineered food products throughout the food supply. Health concerns arising from a commercially sold bioengineered food will only be traceable with labels.

Furthermore, labels ensuring traceability of products through the food supply also ensure that producers of bioengineered foods will be held accountable for the foods they bring to market. Without mandatory labeling, should a bioengineered food prove to be dangerous it will be hard for an injured consumer to prove "causation" of injury from such a food. By relying entirely on a voluntary labeling scheme, FDA is in effect protecting bioengineered food producers from potential legal liability.

In summary of this section, FVO/ICS believes that labels attesting to non-GMO content of foods are already a right of producers, and that such labels can be worded to be accurate and truthful. Reference to the production method and/or analytical testing can be used to this end, as applicable. Such labeling could be a benefit to producers and marketers, should they choose to avail themselves of their right to do so. More importantly, labeling and tracking the flow of bioengineered foods should be mandatory, the onus for this being on the producers of the seed and the users and handlers of it and the products therefrom.

3) Regarding FDA's request for comments as mentioned in the Draft Guidance, section II, titled: "Suggested Documentation for Substantiating Whether Foods Have or Have Not Been Developed Using Bioengineering."

FVO/ICS will address FDA's questions in turn:

(1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility:

FVO/ICS believes that FDA does need to collect information regarding use and non-use of bioengineered components in foods. However, we also feel that FDA's focus on the issue, as presented in the Draft Guidance is partially misdirected.

In the Draft Guidance, FDA states that,

"...the method of development of a new plant variety, including plants developed using bioengineering, is not information that is material under section 201(n) of the act and, therefore, would not be required in the labeling of food. This conclusion is consistent with our historic interpretation of section 201(n) of the act, in that the method of plant breeding is not required to be disclosed in labeling."

FVO/ICS strongly disagrees with FDA in this interpretation. Breeding plants and other organisms via bioengineering is qualitatively different from all other antedated or more traditional breeding techniques. The random and inaccurate state of bioengineering technology and the interspecies recombinations involved have never been seen before, and as such, cannot be lumped together with all other known methods of breeding.

In any event, it is likely that producers and manufacturers who do not choose to use products of bioengineering will want to differentiate their products from products that do include bioengineering. Concomitant with this should be the **required** labeling of all foods that are of bioengineered origin, for the reasons stated in section 2 above.

FDA is correct that producers and manufacturers who claim to not use bioengineered goods should have to document the source of their foods. This is a reasonable expectation and requirement, similar to that which already falls on the certified organic producer and manufacturer. However, we must make it very clear that the source material must indeed be verifiably non-bioengineered. Here is where the onus of segregation of the foods must shift to the producer and handler of the bioengineered products.

The owner of the bioengineered goods, and the producers and handlers of them, must be held accountable for their use and/or misuse of those goods, especially as regards the potential trespasses of said materials onto the private property and goods of other entities. This means that seed developers and breeders, farmers of bioengineered seed, post-harvest handlers, and manufacturers must all be responsible for the safe and segregated use of these materials in their respective roles.

To place the burden for segregation entirely on the party who wishes to exclude bioengineered goods from their products is unreasonable and probably impossible, as the points of control rest outside of their own systems. Bioengineered seed is the responsibility of the seed suppliers and users, not the victims. Seed sources must be kept segregated and identity-preserved. Analytical testing should be mandatory for all developers and handlers of seed to verify effective segregation to the maximum extent possible given the analytical technology available. The cost and responsibility for implementing effective segregation procedures and verifying them through third-party

inspection and analytical testing should be a mandatory requirement imposed by FDA on those parties. The financial (and at least part of the logistical) burden for this must be assumed by the entity which developed and introduced the bioengineered seed.

Furthermore, the bioengineered organisms themselves have often been shown to cause contamination of non-bioengineered varieties in the field, due to cross-pollination. Such trespasses eventually land back within the realm of FDA's responsibility, as the cross-pollinated product then ends up as food that is effectively bioengineered. This has been painfully demonstrated by the fiasco involving Starlink corn, which now has been found to have contaminated seed stocks and food products over a very wide range. In fact, *additional requirements for testing corn for Starlink presence continue to be mandated by governmental and private regulatory agencies and associations.* Starlink is only one of many instances of uncontrolled mixing of bioengineered goods in the food supply. What is needed is for FDA to work in concert with EPA and USDA to ensure that efforts and regulations are duly coordinated to protect the food supply. We request that FDA explain how such issues will be addressed by them to achieve this desired effect. This seems especially relevant when considering that the NOP rule specifically prohibits seed being used in an organic production system if it contains bioengineered material.

Finally, harvest and post-harvest handling of bioengineered crops needs to likewise be segregated and tracked, to ensure proper protection of non-bioengineered stocks.

If any of the above mentioned steps in the chain of custody of the bioengineered materials cannot be controlled, then the offending product should be banned from field production. If field production continues, then it must be the responsibility of the developer and owner of the offending germplasm, financially, legally, and logistically, for identifying those products which contain or do not contain bioengineered material.

This means that while the producer or manufacturer who wishes to label goods as not being bioengineered may indeed be responsible for documenting the source of the material, the onus for evaluating whether said food (or seed) contains bioengineered material should rest solely on the producer of the bioengineered material. *A manufacturer or farmer could document their source of non-bioengineered corn, but the documentation from the source attesting to said purity must be provided by the intentional developer/user of the bioengineered seed.*

Thus, we take issue with FDA's statement in the Draft Guidance that only those who choose to label goods as not being bioengineered will bear the reporting burden. The burden must be shared by those who cause the problem in the first place, in a manner in which the burden falls appropriately on those parties whose actions create the scenario that begs a labeling distinction at all.

In summary, while we agree with that FDA the proposed collection of information is necessary for the proper performance of FDA's functions and that the information will have practical utility, we also believe that FDA has failed to include the critical part of the accountability here, namely the control and verified segregation of the bioengineered

materials in the first place. As such, the burden is unequally and unfairly weighted on the non-users of bioengineered materials, and can only be fairly adjusted when the other side is taken into account.

(2) Regarding the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used:

FVO/ICS believes that FDA's estimate of the reporting burden is too low and underestimates the ongoing responsibilities incurred by labeling, for the following reasons:

The "niche" market of organic foods and of non-bioengineered foods is growing rapidly. The niche is becoming increasingly mainstreamed, especially as larger food processors enter the organic market. We expect that as consumer awareness increases regarding the real and potential pitfalls and disadvantages of bioengineering, that demand for non-bioengineered products will also increase.

Also, we do not agree that the burden will be a one-time event. Labeling changes may be a one-time event, but the ongoing documentation requirements of food sources to verify that goods are not bioengineered will be ongoing. As stated above, much of the burden for this needs to shift to the bioengineering developers/producers/users, but the non-users will still bear some burden.

Lastly, we wish to point out that we do not agree with FDA that "most of the non-organic products whose producers have stated they will not use bioengineered ingredients are made by large firms for whom the verification process is not likely to impose a significant burden relative to the size of their operation." We see increasing numbers of small manufacturers who do not use organic ingredients but wish to market non-GMO products. Examples are small businesses manufacturing tofu and other soyfoods, and popcorn manufacturers. There is no reason to believe that other new small businesses will not arise who may wish to market goods as non-bioengineered, and to fail to consider them confers an undue advantage to large corporations.

(3) Regarding ways to enhance the quality, utility, and clarity of the information to be collected:

We have already mentioned the main ways in which this can be effected. We repeat them here for clarity: (i) FDA needs to undertake an interdisciplinary approach to regulating bioengineered organisms and their products, and this should be done in concert with EPA and USDA, to make sure that all rules harmonize with each other. We call specific attention to the need to support USDA's National Organic Program, which categorically excludes bioengineering. (ii) FDA must factor into its equation for assessing burden the fact that developers, producers, and manufacturers of bioengineered goods must be accountable for the control and segregation of their respective bioengineered products. The onus for maintaining and verifying segregation of bioengineered goods

from non-bioengineered needs to rest primarily on these parties, not on those parties who expressly wish to exclude bioengineered materials from their systems.

(4) Regarding ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology:

FDA should use all means possible to streamline and make more efficient the collection of vital data, as described throughout these comments. Burden should be shifted from the victims of bioengineering to those who have committed either direct, indirect, willful, or unintentional trespass on those who do not wish to partake of such technology or its products.

In closing, FVO/ICS thanks FDA for the opportunity to respond to this Draft Guidance, and we express our desire to assist in future discussions and rule-making processes however possible.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'David Gould', written over a horizontal line.

David Gould
Farm Verified Organic / International Certification Services
Certification Committee

Addendum #1

BASIC CRITERIA FOR GMO'S IN CERTIFIED PRODUCTION

Each box contains a list of categories of materials used in the named aspect of the production system, divided by a line.

No item above the line may show detectable levels of gmo material.
Any box can be applied as a subset of any other box.

microbes:

cell product cell
growth media

livestock:

flesh products (egg, dairy, honey, wool) feed, additives, and supplements drug

processed product:

ingredient processing aid

agricultural product:

harvested product seed soil amendments of animal origin (e.g. bone meal) pest control products and formulae disease control products and formulae weed control products and formulae nematode control products and formulae uncomposted fertilizer and soil amendments
composted animal and green manure with no bioengineered microorganisms



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