

# International Certification Services, Inc.

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*Corporate Headquarters in Rural North Dakota  
Operating the FVO Organic Certification Program*

*The FVO Program is accredited by IFOAM, Conseil des appellations agroalimentaires du Québec (CAAQ), and (USDA) ISO 65*

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**Date:** 4 January, 2005

**To:**

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

**Comments Pursuant to:**

Docket No. 2004D-0369  
Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Availability

**Submitted by:**

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**Comments:**

International Certification Services, Inc. (ICS) is an organic products certification agency based in North Dakota, USA, doing business worldwide. The program currently does business under the name International Certification Services, as well as Farm Verified Organic (FVO) and has done so since 1980. ICS is accredited by The United States department of Agriculture under the National Organic Program (NOP), International Organic Accreditation Services, Inc. (IOAS) to the program requirements of the International Federation of Organic Agriculture Movements (IFOAM) Accreditation Program. ICS also holds accreditation by USDA for compliance under ISO Guide 65 requirements.

Herewith ICS addresses its comments to FDA's Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Availability. All statements set in quotation marks are passages taken directly from Docket No. 2004D-0369.

***I. Concerning FDA's duties and responsibilities as a federal agency:***

The draft as presented in Docket 2004D-0369 does not reflect that FDA is fulfilling its duties and responsibilities as outlined in the US Code. In fact, the draft seems to be a clear abdication of FDA's mandate as set down in the code, and as such, appears to us to be illegal. We ask that FDA explain how its current thinking on evaluating new bioengineered plants is consistent -

from a legal standpoint as well as by general intention - with its responsibilities as required by the laws set in the US Code, as cited below:

US Code Title 21 – Food and Drugs Chapter 9 – Federal Food, Drug, and Cosmetic Act Subchapter IX – Miscellaneous Sec.393 states FDA’s mission and responsibilities regarding the introduction of foods to the mainstream consumer supply. This section of the US Code clearly states that FDA shall undertake measures to ensure the safety of foods provided to consumers, and that such evaluations as to safety will be made through appropriate review, conducted by a broad range of participants – experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

Furthermore, this section of the US Code goes on to state that FDA shall make its processes for arriving at its conclusions increasingly transparent over time, indicating the responsibility of FDA to respond to questions regarding its determinations.

We interpret the proposed rule in Docket 2004D-0369 as not fulfilling these above-mentioned duties. The draft does not suggest that there will be independent or objective scientific review of the data presented in the voluntarily submitted evaluation notices by product developers to FDA. Nor does the draft allow for adequate input from consumers, or an easy way for concerned parties to access information regarding the release of bioengineered products into the environment and mainstream food supply, prior to their being released.

## ***II. Specific comments invited by FDA in Docket 2004-0369:***

In Docket 2004-0369, FDA specifically invites comments on the following areas, which we cite in turn and follow each with our comments:

“(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;..”

The proposed collection of information is essential to FDA fulfilling its functions and responsibilities. It is FDA’s crucial responsibility to ensure the safety of food to consumers. We agree with FDA, as the docket mentions, that “Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of material from that plant variety.” However, such communication only “helps to ensure” - it does not by itself confer adequate assurance.

FDA must do more. FDA’s aforementioned statement that it should ensure safety “prior to any possible inadvertent introduction” is correct. But the draft does not achieve this. That submissions by developers of new bioengineered plants would be allowed to voluntarily submit such information – as opposed to an absolute requirement of such a submission and a consequent rigorous review process – is outrageous. How does FDA rationalize that it is ensuring safety by such procedures?

Regarding “whether the information will have practical utility,” that depends largely on how FDA uses the information. We repeat that the information gained is essential and

important for FDA to obtain. However, the information in and of itself as detailed in the points mentioned in Docket 2004D-0369 (and the associated Draft Guidance publication) are inadequate to fulfill FDA's stated and mandated goals, for the following reasons:

- a. The evaluation is limited to proteins produced by the bioengineered organism. While proteins may indeed be a significant aspect of concern regarding their reactivity in public and environmental health, they are by no means the only area of concern. Strong documented scientific studies have been conducted that show that unnaturally elevated levels of proteins in certain biosystems cause secondary deleterious effects on the nutritional and consequent metabolic effects of consuming such products. The proteins in and of themselves may not be molecularly different from the non-bioengineered form, but their induced unnatural presence in the new host organism results in a shift of the biochemical profile and balance of the host organism. This is a fundamental concept of biology, which FDA seems to be ignoring. Such ignorance is scientifically unsound and dangerous.

FDA needs to recognize that all organisms exist with a biological mandate toward homeostasis; when the organism's internal balance is disturbed, compensatory reaction by the organism results to restore that balance. When bioengineering is the source of the disruption, the organisms is likely to resort, if necessary, to respond with an equally foreign homeostatic response. The results must be studied cautiously and thoroughly if the public is to be protected. Two examples:

- i. Bacteria were bioengineered to produce twice-normal levels of the amino acid tryptophan. Overloaded cells, in a homeostatic attempt to handle the load, created dimers of tryptophan – a previously unobserved and therefore unexpected and unknown effect. The dimer proved to be a potent neurotoxin that killed numerous consumers and turned some 1500 others into quadraplegics for life.
  - ii. Recombinant Bovine Somatotropin (rBST or rBGH) – although molecularly indistinguishable from its natural cellular counterpart – has been shown, by way of its elevated level in the host dairy animal, to result in elevated levels of insulin growth factor 1 (IGF-1), which in turn has been scientifically linked to increased incidence of prostate cancer in humans. Again, and unforeseen negative effect of the bioengineering, in this case having nothing to do with a protein per se.
- b. That the examples given above were not intended side effects of the bioengineering is understandable. The manufacturers and marketers of these (and other bioengineered) products, however, face a variety of pressures which constitute a direct conflict of interest with their ability to present to FDA an unbiased view of the products from which they seek to profit. It is, we believe, impossible for them under the circumstances to be a fair judge of the suitability of their products for market. To balance this bias, FDA needs to fulfill its mandate as given in the US Code, by diligently reviewing all such proposed bioengineered products through a transparent, objective, rigorous regimen of scientific review and public scrutiny. We reiterate that the US Code requires that such evaluations as to safety will be made through appropriate review, conducted by a broad range of participants – experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products. The current proposal in Docket 2004D-0369 falls pitifully short of this. We want FDA's response to be about how it will correct this.

- c. We want to know how FDA has determined that its rather narrow scope of concern – i.e., potential protein-related allergens – has been determined to be adequate as a scope of review. What scientific body has advised this approach? Were any other areas of concern noted? If so, what where they, and why are they not included in the guidance?

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

We have largely answered this in the foregoing comments to point (1) above. Because the methodology and assumptions used are seriously flawed, we believe the estimate of FDA's burden of work is well under what will be required to actually reasonably ensure public safety.

The results of such a lack of diligence on FDA's part leaves several sectors of the public vulnerable:

- a. Markets – especially international markets – will resist importation of US goods, as they have done all along with respect to bioengineered crops. Although perhaps more difficult to detect, public outcry in already wary markets will continue to restrict trade. US producers will lose markets, which has already shown to be the case.
- b. Organic food producers – operating under USDA's own National Organic Program – will have their products compromised further by allowance of bioengineered products contaminating their goods. A main reason consumers buy organic goods is to avoid consuming bioengineered products. Additional contamination by will result – if nothing else – in damage to consumer confidence in organic products, thereby hampering and injuring one of the fastest growing market sectors for US farmers and food producers.
- c. Legal action against developers and users of bioengineered products will occur if negative effects of bioengineered goods become manifest. FDA states in Docket 2004D-0369 that the increase in bioengineering “...could result in the inadvertent, intermittent, low-level presence in the food supply of proteins that have not been evaluated...” In fact, as history has shown, leak into the gene pool of bioengineered material will definitely result under the type of loose controls heretofore in place. Lack of diligence on FDA's part will implicate them in legal claims, regardless of what the laws might state if they are based on the type of thinking FDA is reflecting in Docket 2004D-0369.

“(3) ways to enhance the quality, utility, and clarity of the information to be collected;”

We have alluded in our comments to point (1) above to the proper way to use the information to be collected. Review and evaluation should be undertaken by a variety of objective, scientific, and publicly-minded persons though an iterative process with the developer of the bioengineered plants, to arrive at a point where safety has been assured to greatest extent feasible.

“(4) 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.”

The best way to minimize burden on the respondents is for them – within a clear regulatory framework set by FDA – to minimize risks to safety. Such minimization of risk will effectively reduce review and evaluation time and allay doubts as to whether or not a proposal is safe.

One of the easiest and most sensible routes to take is for FDA to simply prohibit the use of food crops for development of such novel bioengineered plants. Plants engineered to produce pharmaceutical materials need not be done through food crops.

Another risk-reducing factor is the method of control of production of the bioengineered plants. Open-field trails are ill advised and downright irresponsible, unless previously tested in more controlled settings and the materials issuing therefrom, rigorously analyzed and tested.

We advise FDA set guidelines for minimization of risk, which can be used by developers of bioengineered materials as part of a mandatory and thorough review process. Such guidelines should be formulated with the help of a broad range of participants – experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

Historically private companies have had to devote significant resources to pass through FDA review processes; while burdensome at times, that burden was with good reason. The burden of safety should remain on the developer, overseen by FDA. Unfortunately, what FDA appears to be doing by the guidance is reversing the priority. FDA is prioritizing minimization of the burden on developers of bioengineered goods over public safety. How does FDA see this as their rightful course of action?

### ***III. Conclusion***

We appreciate the opportunity to offer our comments and share our concerns. The proposed approach by FDA to regulating newly-introduced bioengineered plants into the environment and food stream is seriously flawed, and needs significant reconsideration and revision if FDA is to fulfill its legally-mandated responsibilities of protecting public safety and acting in the public interest. We would be pleased to contribute to efforts to improve the current situation.

End of comments.

Respectfully submitted,

International Certification Services, Inc.