

Testimony of L. Val Giddings, Ph.D.<sup>1</sup>  
Public Health Committee, Connecticut General Assembly  
Hartford, CT 06106  
15 March 2013

Thank you for the opportunity to speak here today. I am here at the invitation of a friend who works for the Biotechnology Industry Organization. He asked me to speak with you because of my experience with the science, policy, and regulation of crops and foods improved through biotechnology.

I have worked as a regulator, prepared environmental assessments of transgenic crops, and supervised and reviewed hundreds of such risk assessments. As an expert and consultant I have advised government and United Nations' agencies, companies, and NGOs around the world over more than three decades.

I understand you are considering legislation (Bill 6519) that would require all food sold in Connecticut to carry process specific labels to alert consumers to the presence of ingredients derived from crops improved through certain techniques of modern biotechnology. I have read this proposal carefully. Though obviously well intended, it is based on a number of misunderstandings. Experience with similar legislation enacted into law around the world, furthermore, demonstrates that, if passed, the consequences are likely to be the opposite of what those who support it claim to want. Specifically:

- It will not provide consumers with any more choice than they already have. Consumers who wish to avoid foods derived from crops improved through modern biotechnology may choose foods carrying the "USDA Organic label." Organic producers may not use seeds improved through biotechnology, and consumers therefore have, right now, today, full freedom of choice;
- The label required under Bill 6519 would not provide consumers with any information to which they do not now have access, and runs a grave risk of misleading consumers into thinking GMO content means a food is less safe than other foods, when data shows they are either the same, or safer;
- The principal advocates who have organized the coordinated national campaign to advance proposals like Bill 6519 have been very clear that their intent is to mislead and deceive consumers as to the safety of foods derived from crops improved through biotechnology. Indeed, an independent journalist in Seattle noted recently that such proposals "look like an organic-food industry effort to impose a label on its competitors."

Contrary to what the proponents of these labeling proposals assert, the reality is that crops and foods improved through biotechnology have been subjected to more extensive and rigorous safety reviews, in advance, in depth and detail, than any other foods in human history. The US FDA and authoritative bodies around the world have examined these foods and found nothing to support the claims of proponents of these proposals. Indeed, the American Medical Association just last summer revisited

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this issue, and reaffirmed their conclusion from over a decade ago: “there is no scientific justification for special labeling of bioengineered foods.”

Let me expand on some of these points.

**FACT: Consumers already have access to abundant information about the food they buy, whether or not it has been improved through biotechnology, and the information and freedom to choose to avoid it if they wish.**

Historical reality: To put everything anybody has said they'd like to see on a food label would require an encyclopedia. In order to make sure consumers are not denied any information they seek about the foods they consider buying, food companies routinely place toll-free telephone numbers on every label for consumers to call if they have a question not addressed on the label itself.

The U.S. Food and Drug Administration requires that information that must be placed on a label be limited to that which is relevant to health, safety, and nutrition. They have not mandated “GMO” content labels *because the only differences related to safety that scientists have ever been able to detect show foods derived from biotech improved crops to be safer than other foods*. Labels requiring a GMO label therefore mislead consumers into thinking there might be some risk involved when there is not. Indeed, it is precisely this confusion proponents of labels seek to exploit to achieve their real objective, which is not to inform consumers, but to scare them into avoiding foods carrying a GMO label.

- “[R]ather than have two labels, food companies would simply not carry the product, especially if the new label would be the equivalent of a skull and crossbones... This is why we are so committed to this initiative as victory [in California] will likely eliminate genetically engineered foods from the US.” **Joseph Mercola, March 20, 2012**
- “We believe that just like in Europe, consumers will complain to stores, stores will complain to suppliers, and suppliers will go back to farmers. If [Prop 37] passes, it will dramatically reduce the [U.S.] market share of GE foods and ingredients.” **Ronnie Cummins, Founder and Director, Organic Consumers Association, Oct. 27, 2012**

**FACT: Consumers already have a readily accessible means enabling them to avoid foods made with biotech derived ingredients if they choose.**

HB 6519 would do nothing to increase consumer choice options, because consumers already have a means, in place today, through which they can choose foods grown with methods that did not involve biotechnology improved seeds – the USDA Organic label.

Because farmers have so consistently found that crops improved through biotechnology are so superior to other crops in terms of yield, economics, harvest quality and reduced environmental impact, biotech varieties of corn, cotton, soybeans and canola have rapidly become the predominant varieties of those crops grown in North America. Estimates indicate that they or their derivatives are present in 70-80% of the foods found in supermarkets today. If some consumers prefer foods with ingredients derived

through other sources, however, they can freely choose to buy products marked with the USDA Organic label. This marketing label is awarded to growers who avoid using biotech seeds on their farms.

**Further**, when scientifically unjustified GMO labels have been imposed by governments, despite the demonstrated safety of these foods, campaigners with vested financial interests have organized boycotts to intimidate supermarkets into dropping or reformulating products to avoid such labels. This scenario has played out across much of Europe. Although indications are that this gambit would not succeed in the U.S., food companies are understandably concerned, and have therefore fought hard to preserve the scientific integrity of food labels in the U.S.

- This isn't about freedom of choice. It's about destroying biotechnology and getting it off the shelves.
  - Bruce Chassy, Assoc. Director, University of Illinois Biotechnology Center.
  
- If these products all have to be labeled, who is going to put it on the market? It's a big risk for food companies and for retailers because they run the risk that the clients don't take the product. The market rejections and the consumer rejections plus the labeling laws will make sure that GMOs will not enter in Europe.
  - Geert Ritsema, Friends of the Earth Europe
  
- "Personally, I believe GM foods must be banned entirely, but labeling is the most efficient way to achieve this. Since 85% of the public will refuse to buy foods they know to be genetically modified, this will effectively eliminate them from the market just the way it was done in Europe."
  - Joseph Mercola at <http://vtdigger.org/2012/04/17/wanzek-genetically-modified-food-is-perfectly-healthy/>

**FACT: Bill 6519 and others like it would mislead consumers into believing foods from biotech improved seeds are more risky than other foods.**

Proponents of mandatory labeling provisions like Bill 6519 claim either that we do not know enough about biotech derived foods, or that there is actual evidence of harm from eating them. They say there are no long term studies of food safety, and that the risks of unknown toxins or allergy are too high, and that foods are not reviewed to assure their safety before they are placed on the market. All these claims are false, and abundantly contradicted by facts.

There are a number of long term animal feeding studies with crops improved through biotechnology. I can provide you with references if you like. It is true, however, that there are no such tests with humans, for a number of reasons. First, if there were any legitimate uncertainty about the safety of these foods, such tests on humans would be unethical. Second, even animal feeding studies involving whole foods are so difficult and costly to conduct, and so complicated (impossible) to interpret, that the scientific consensus is that there are far superior ways to evaluate safety, namely those that are

routinely used on biotech foods. Indeed, the U.S. General Accounting Office looked at this issue more than a decade ago, and concluded that

Monitoring the long-term health risks of GM foods is generally neither necessary nor feasible, according to scientists and regulatory officials we contacted. ...such monitoring is unnecessary because there is no scientific evidence, or even a hypothesis, suggesting that long-term harm (such as increased cancer rates) results from these foods. Furthermore, there is consensus among these scientists and regulatory officials that technical challenges make long-term monitoring infeasible. (US General Accounting Office, GAO-02-566, 2002).

The regulatory system here in the U.S. was put in place in 1986, a full decade before any biotech improved crops were commercially grown. USDA, EPA, and FDA all look at these crops and the products derived from them pursuant to their own legal authorities, which are robust. Opponents of biotechnology make much of the fact that the FDA review is "voluntary" rather than mandatory. This, however, ignores the fact that FDA has an overarching and absolute requirement that prohibits any food being placed on the market that is not safe, and that every biotech derived food to date has gone through this "voluntary" review process and demonstrated its safety. Opponents also neglect to point out that biotech companies have long been on record as supporting that such reviews be mandatory, based on their thinking that they are complying anyway, so why not deprive opponents of the opportunity to mislead folks.

Not only are these products more reviewed than any others in history, they have an unblemished safety record. I am familiar with the various claims of harm that are circulated by the opponents, and would be happy to discuss any of them. None are supported in fact. Indeed, even in that model for how to approach biotech-improved crops and foods that opponents like to urge us to emulate, Europe, scientists and regulatory authorities are a firm part of the worldwide scientific consensus that these crops and foods are safe. Don't take my word for it – listen to what they say:

**Indeed, the use of more precise technology and the greater regulatory scrutiny probably make them even safer than conventional plants and foods; and if there are unforeseen environmental effects - none have appeared as yet - these should be rapidly detected by our monitoring requirements. On the other hand, the benefits of these plants and products for human health and the environment become increasingly clear.**

**--European Commission, Press Release of 8 October 2001, announcing the release of 15 year study incl 81 projects/70M euros, 400 teams**

(<http://ec.europa.eu/research/fp5/eag-gmo.html> and <http://ec.europa.eu/research/fp5/pdf/eag-gmo.pdf> )

The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies...

[http://ec.europa.eu/research/biosociety/pdf/a\\_decade\\_of\\_eu-funded\\_gmo\\_research.pdf](http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf)

Indeed, as our own U.S. National Academy of Sciences has concluded,

“In contrast to adverse health effects that have been associated with some traditional food production methods, similar serious health effects have not been identified as a result of genetic engineering techniques used in food production. This may be because developers of bioengineered organisms perform extensive compositional analyses to determine that each phenotype is desirable and to ensure that unintended changes have not occurred in key components of food.” (p. x).

--National Academy of Sciences, 2004. Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects. National Research Council, Washington DC. 256pp. ISBN 0-309-53194-2. <http://www.nap.edu/catalog/10977.html>.

Despite this extraordinary consensus of expert opinion and experience (far stronger, I note, than the consensus in support of anthropogenic climate change...) , opponents continue to raise the same abundantly resolved issues time and again. Near the top of the list of such unfounded worries is the spectre of unexpected allergies. This is worth some attention.

Foods derived from crops improved through biotechnology are routinely subjected to far greater scrutiny than applied to any others, as discussed above. Allergenicity is included in this screening. This is of particular, personal importance to me, because my son has a potentially life threatening food allergy: he could be killed by something as simple as a shared cookie at school. This is an issue I take very seriously.

The fortunate facts are that alone among foods brought to the market, all those derived through biotechnology are screened in advance to ensure no new allergies are introduced into any foods to surprise sensitive individuals. The DNA sequences of inserted genes are routinely screened against a database of known allergens to ensure nothing suspect inadvertently gets by. It is therefore clear that from an allergy sensitive point of view, biotech derived foods are far safer than any others. Contrast that with what we saw when kiwi fruits were first introduced in the United States. Despite a known history of allergenicity in kiwi fruits and their relatives, because of a long history of generally safe consumption, no safety screening was required before kiwis could be introduced, sold, and consumed in the U.S. Those concerned about food allergies would find a more deserving focus of their interests on foods other than those derived through biotechnology. Indeed, far from being the source of increased allergenicity risks, biotechnology offers the potential to eliminate the proteins known to cause food allergies to soy, dairy, peanuts, and other foods of concern, as well as the potential to develop tools for diagnosis and treatments that can be developed in no other way. The threat of food allergies is actually reduced significantly by biotechnology.

There are other safety issues that are repeatedly raised as well: claims that rats fed biotech derived soy or corn develop cancer; claims that previously unknown viral DNA sequences have recently been

## **AMA Resolution on Genetically Engineered Crops and Foods adopted by AMA House of Delegates June 2012**

(emphasis added)

### **RECOMMENDATION B:**

Mr. Speaker, your Reference Committee recommends that the Recommendation in Science and Public Health Report 2 be adopted as amended and the remainder of the report filed.

**HOD ACTION: Council on Science and Public Health Report 2 adopted as amended and the remainder of the report filed.**

Council on Science and Public Health Report 2 reviews the potential adverse health effects of bioengineered foods, and implications for labeling are addressed. It recommends that H-480.958 "Genetically Modified Crops and Foods" be amended by insertion and deletion as follows:

### **Bioengineered (Genetically Engineered) Crops and Foods**

(1) Our AMA recognizes the continuing validity of the three major conclusions contained in the 1987 National Academy of Sciences white paper "Introduction of Recombinant DNA-Engineered Organisms into the Environment." [The three major conclusions are: (a) There is no evidence that unique hazards exist either in the use of rDNA techniques or in the movement of genes between unrelated organisms; (b) The risks associated with the introduction of rDNA-engineered organisms are the same in kind as those associated with the introduction of unmodified organisms and organisms modified by other methods; (c) Assessment of the risk of introducing rDNA-engineered organisms into the environment should be based on the nature of the organism and the environment into which it is introduced, not on the method by which it was produced.]

(2) That federal regulatory oversight of agricultural biotechnology should continue to be science-based and guided by the characteristics of the plant or animal, its intended use, and the environment into which it is to be introduced, not by the method used to produce it, in order to facilitate comprehensive, efficient regulatory review of new bioengineered crops and foods.

**(3) Our AMA believes that as of June 2012, there is no scientific justification for special labeling of bioengineered foods, as a class, and that voluntary labeling is without value unless it is accompanied by focused consumer education.**

discovered in biotech crops and foods; and many more. There are far too many to discuss in the time we have available, but I would be pleased to address any that you are specifically interested in

**FACT: Organic and biotech crops have a track record of peaceful coexistence.**

There are those who argue coexistence is not possible; that pollen from biotech crops will be borne by the wind or pollinating insects to neighboring fields, and cost organic producers their certification and make it impossible for them to sell their harvests. Experience shows that these claims are false, and that biotech crops and organic crops can and do coexist happily. Indeed, the Secretary of Agriculture's advisory committee ("AC21") recently spent a whole year considering this issue, and whether or not a mechanism should be developed to compensate organic farmers injured by the nearby growing of biotech crops. Advocates of such a compensatory mechanism had a full year to make a case. At the end of the year they had not produced a single example of a farmer who had suffered any losses. This is because the Organic Standard was deliberately written as a guide to permissible practices which specifically protects organic growers against the inadvertent presence, in any quantity, in their harvests, of material derived through prohibited methods like biotechnology. (The relevant USDA policy memo is attached below).

The fact of the essential compatibility of organic and biotech production methods is corroborated by data on the growth of each. According to the Organic Trade Association [website](#) (accessed 12 February 2013) U.S. sales of organic food and beverages have grown from \$1 billion in 1990 to \$29.22 billion in 2011. [OTA website](#) April 23, 2012. At the same time, biotech-improved crops acres have increased around the world from zero to over 384 million acres, grown by 16.7 million farmers, 15 million of whom are small farmers in developing countries.<sup>2</sup> In all that experience, we are unaware of any farmer losing their organic certification due to the adventitious presence of biotech derived material.

We could continue to talk about related issues for much longer than the time available to us today, so I will conclude my remarks here by thanking you again for the opportunity to visit with you today. I am willing to answer any questions you may have.

Appendix I – AMA Resolution on Genetically Engineered Crops and Foods adopted by AMA House of Delegates June 2012

Appendix II - Summary of US Federal Regulatory System for crops improved through biotechnology

Appendix III – USDA Organic Program Policy Memorandum in crops improved through biotechnology

Attachment – Seattle Times Column on labeling proposals like B651

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<sup>2</sup> See <http://www.isaaa.org/resources/publications/briefs/43/executivesummary/default.asp>

(4) Our AMA supports mandatory pre-market\_systematic safety assessments of bioengineered\_foods and encourages: (a) development and validation of additional techniques for the detection and/or assessment of unintended effects; (b) continued use of methods to detect substantive changes in nutrient or toxicant levels in bioengineered\_foods as part of a substantial equivalence evaluation; (c) development and use of alternative transformation technologies to avoid utilization of antibiotic resistance markers that code for clinically relevant antibiotics, where feasible; and (d) that priority should be given to basic research in food allergenicity to support the development of improved methods for identifying potential allergens.

(5) Our AMA supports continued research into the potential consequences to the environment of bioengineered crops including the: (a) assessment of the impacts of pest-protected crops on nontarget organisms compared to impacts of standard agricultural methods, through rigorous field evaluations; (b) assessment of gene flow and its potential consequences including key factors that regulate weed populations; rates at which pest resistance genes from the crop would be likely to spread among weed and wild populations; and the impact of novel resistance traits on weed abundance; (c) implementation of resistance management practices and continued monitoring of their effectiveness; and (d) development of monitoring programs to assess ecological impacts of pest-protected crops that may not be apparent from the results of field tests.

(6) Our AMA recognizes the many potential benefits offered by bioengineered\_crops and foods, does\_not support a moratorium on planting bioengineered\_crops, and encourages ongoing research developments in food biotechnology.

(7) Our AMA recognizes that the government, industry, and the scientific and medical communities have a responsibility to educate the public and improve the availability of unbiased information and research activities on bioengineered foods and of research activities.

(CSA Rep. 10, I-00; Modified: CSAPH Rep. 1, A-10) (Modify Current HOD Policy)

## Appendix II

### **The US Regulatory System for Crops & Foods Improved Through Biotechnology**

**Crops and foods improved through biotechnology have undergone more rigorous safety reviews, in depth and detail, than any other foods in history.**

Complete description of the extensive US regulatory process with details can be found here:

<http://usbiotechreg.epa.gov/usbiotechreg/> , which has been in place since 1986:

[http://www.aphis.usda.gov/brs/fedregister/coordinated\\_framework.pdf](http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf) .

**The U.S. Regulatory Process Involves comprehensive regulatory oversight by USDA, EPA & FDA.**

USDA: database of regulatory reviews for all transgenic crops cleared for commercial planting here:

[http://usbiotechreg.epa.gov/usbiotechreg/database\\_pub.html](http://usbiotechreg.epa.gov/usbiotechreg/database_pub.html) per regulations found here:

<http://www.aphis.usda.gov/biotechnology/index.shtml> . A comprehensive database of all risk assessments for permission to conduct field trials is here: <http://www.nbiap.vt.edu/>

FDA requires all foods placed on the market to be safe. Because of this overarching safety requirement, FDA does not require specific reviews of foods derived from crops improved through biotechnology because the process of production tells one nothing about safety. Safety depends on the characteristics of the end product regardless of how it was produced. FDA has prepared a thorough list of points to consider in evaluating and ensuring the safety of "bioengineered foods". Details can be found here: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096095.htm>

Agricultural Biotechnology companies are on record requesting the consultation process be made mandatory. Without exception, all "bioengineered" foods on the market have gone through the FDA review process, and these all biotech companies are on record they will continue to do this for all such foods. A compilation of summaries on all completed FDA consultations is here:

<http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing>

FDA staff conduct rigorous internal review of all data provided by companies/product developer. They also subject such data to peer review by multiple invited external experts before confirming to the applicant that all safety questions have been satisfactorily answered.

The system in the European Union (as also Canada, Japan, Australia, New Zealand, and many other countries) is similarly rigorous. Risk Assessment research has been extensive, as shown in this from the EU:

**Indeed, the use of more precise technology and the greater regulatory scrutiny probably make them even safer than conventional plants and foods; and if there are unforeseen environmental effects - none have appeared as yet - these should be rapidly detected by our monitoring requirements. On the other hand, the benefits of these plants and products for human health and the environment become increasingly clear.**

**--European Commission, Press Release of 8 October 2001, announcing the release of 15 year study including 81 projects/70M euros, 400 teams**

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The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies...

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"...because the technique is so sophisticated, in many ways it is probably safer for you to eat GM products - plants that have been generated through GM - than normal plant foods, if you have any sort of reaction to food, because you can snip out the proteins that cause the negative reaction to certain parts of the population."

--Sir David King, Chief Science Advisor, UK

The Guardian Unlimited, 27 November 2007

<http://www.guardian.co.uk/gmdebate/Story/0,,2217712,00.html>

## Appendix III

United States Department of Agriculture 1400 Independence Avenue SW. Policy Memo 11-13 Agricultural Marketing Service  
Room 2646-South Building National Organic Program Washington, DC 20250 *PM 11-13 GMOs Internal Rev02 10 31 11*  
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### Policy Memorandum

**To:** Stakeholders and interested parties

**From:** Miles McEvoy, Deputy Administrator

**Subject:** Genetically modified organisms

**Date:** Original Issue Date – April 15, 2011

The National Organic Program (NOP) has recently received questions concerning the use of genetically modified organisms (GMOs) under the U.S. National Organic Standards. This policy memorandum addresses frequently asked questions concerning GMOs and reiterates the statements made in a 2004 letter from USDA Undersecretary Bill Hawks to the National Association of State Departments of Agriculture.

Compliance with the organic standards entails that operations have verifiable practices in place to avoid contact with GMOs. Since organic certification is process-based, presence of detectable GMO residues alone does not necessarily constitute a violation of the regulation. The NOP relies on organic certifiers and producers to determine preventative practices that most effectively avoid contact with GMOs on an organic operation.

The use of GMOs is prohibited in organic production and handling. The NOP regulations prohibit the use of GMOs as “excluded methods” under 7 CFR § 205.105, “Allowed and prohibited substances, methods, and ingredients in organic production and handling.” Excluded methods are defined as: A variety of methods to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. (7 CFR § 205.2-Terms defined)

This policy memo reiterates that the use of GMOs is prohibited under the NOP regulations and answers questions that have been raised concerning GMOs and organic production and handling.

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**Issue:** If a producer adheres to all aspects of the NOP regulations, including never utilizing genetically modified seeds, but a certifying agent tests and detects the presence of genetically modified material in the crop, is that crop's status determined to be no longer certified organic?

**Reply:** Organic certification is process based. That is, certifying agents attest to the ability of organic operations to follow a set of production standards and practices which meet the requirements of the Organic Foods Production Act of 1990 and the NOP regulations. The NOP regulations prohibit the use of excluded methods (i.e., "GMOs") in organic operations. If all aspects of the organic production or handling process were followed correctly, then the presence of a detectable residue from a genetically modified organism alone does not constitute a violation of this regulation. This policy was established at the promulgation of the NOP Regulation in the Preamble to the Final Rule (FR Vol. 65, No. 246, p. 80556), December 21, 2000. The Preamble stated that:  
As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of the organic operation or its organic products.

**Issue:** Is the inadvertent presence of GMOs in organic seeds a violation of the NOP regulations? Can organic producers use seeds that contain the inadvertent presence of GMOs?

**Reply:** 7 CFR § 205.105 of the NOP regulations prohibits the use of GMOs as excluded methods in organic production and handling. The use of excluded methods, such as planting genetically modified seeds, would require a specific intent, and would render any product ineligible for organic certification. However, the inadvertent presence of GMOs in organic seeds does not constitute a use because there was no intent on the part of the certified operation to use excluded methods. The presence of detectable GMO residues alone in an organic seed does not constitute a violation of the NOP regulations.

**Issue:** How do organic producers avoid contact with GMOs?

**Reply:** Organic producers utilize a variety of methods to avoid contact or the unintentional presence of GMOs including testing seed sources for GMO presence, delayed or early planting to get different flowering times for organic and GMO crops, cooperative agreements with neighbors to avoid planting GMO crops adjacent to organic crops, cutting or mowing alfalfa prior to flowering, posting signs to notify neighboring farmers of the location of organic fields, and thorough cleaning of farm equipment that has been used in non-organic crop production.

**Issue:** What are organic producers required to do in order to avoid the presence of GMOs in their products?

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**Reply:** In order to become a certified organic operation, a producer must submit an organic system plan to a NOP accredited certifying agent for approval. The producer's organic system plan must include a description of management practices and physical barriers established to prevent contact of organic crops with prohibited substances. Certifying agents evaluate the preventative practices and buffer zones to determine if they are adequate to avoid contact with GMOs.

**Issue:** Could a farm's organic certification status be threatened if sufficient buffers and barriers are not established and inadvertent contact with GMO material occurs?

**Reply:** Organic producers that implement preventive measures to avoid contact with GMOs will not have their certification threatened from the inadvertent presence of the products of excluded methods (GMOs). Crops grown on certified organic operation may be sold, labeled and represented as organic, even with the inadvertent presence of GMOs, provided that all organic requirements under 7 CFR Part 205 have been followed.

**Issue:** Is there a working definition of the word "contamination" within the NOP?

**Reply:** There is no definition in the NOP regulations for the word "contamination," even though it is mentioned frequently in the standards. The use of excluded methods in organic production is prohibited, as cited in 7 CFR § 205.105.

**Issue:** What actions are authorized or required when organic crops or products are found to contain unintended or inadvertent genetically modified substances?

**Reply:** The inadvertent presence of genetically modified material does not affect the status of the certified operation and does not result in loss of organic status for the organic product, provided it was produced in accordance with all of the organic requirements under 7 CFR Part 205. Certifying agents are responsible for working with organic producers to identify the source of the inadvertent GMOs and to implement improvements to avoid contact with GMOs in the future.

**Issue:** Are organic products tested for genetically modified substances?

**Reply:** Under 7 CFR § 205.670(b) certifying agents may test organic products when there is reason to believe that excluded methods were used in the production or handling of an organic agricultural product. Certifying agents may also collect and test organic products from organic handlers to ensure that practices are in place to prevent commingling or contamination during handling and processing.

**Issue:** Are organic products free of GMO contaminants?

**Reply:** Organic standards are process based. The NOP regulations prohibit the use of genetically modified organisms, prohibit commingling or contamination during processing and

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handling, and require preventative practices to avoid contact with GMOs. Organic agricultural products should have minimal if any GMO contaminants; however, organic food products do not have a zero tolerance for the presence of GMO material.

**Issue:** Has a tolerance level (e.g. 5%) been established for the presence of GMOs in organic agricultural products?

**Reply:** The NOP regulations do not establish GMO tolerance levels. The NOP regulations establish a tolerance for the presence of pesticides registered by the U.S. Environmental Protection Agency (EPA) that is set at 5% of the EPA tolerance level for the specific residue detected. No federal agency, including EPA or USDA has established tolerance levels for the inadvertent presence of the products of excluded methods (GMOs).

**Issue:** Processed foods sold as “organic” must contain at least 95% organic ingredients. Are GMOs allowed in the remaining 5% of ingredients? Likewise, processed foods sold as “made with organic (specified ingredients or food group(s))” must contain at least 70% organic ingredients. Are GMOs allowed in the remaining 30% of ingredients for these products?

**Reply:** The use of GMOs is prohibited in all ingredients in “organic” and “made with organic (specified ingredients or food groups(s)).” There is no provision within the NOP regulations that allows the use of excluded methods (GMOs) in ingredients or processing aids under the “organic” or “made with organic (specified ingredients or food group(s))” label categories.



## H-480.958 Bioengineered (Genetically Engineered) Crops and Foods

### H-480.958 Bioengineered (Genetically Engineered) Crops and Foods

(1) Our AMA recognizes the continuing validity of the three major conclusions contained in the 1987 National Academy of Sciences white paper "Introduction of Recombinant DNA-Engineered Organisms into the Environment." [The three major conclusions are: (a) There is no evidence that unique hazards exist either in the use of rDNA techniques or in the movement of genes between unrelated organisms; (b) The risks associated with the introduction of rDNA-engineered organisms are the same in kind as those associated with the introduction of unmodified organisms and organisms modified by other methods; (c) Assessment of the risk of introducing rDNA-engineered organisms into the environment should be based on the nature of the organism and the environment into which it is introduced, not on the method by which it was produced.]

(2) That federal regulatory oversight of agricultural biotechnology should continue to be science-based and guided by the characteristics of the plant or animal, its intended use, and the environment into which it is to be introduced, not by the method used to produce it, in order to facilitate comprehensive, efficient regulatory review of new bioengineered crops and foods.

(3) Our AMA believes that as of June 2012, there is no scientific justification for special labeling of bioengineered foods, as a class, and that voluntary labeling is without value unless it is accompanied by focused consumer education.

(4) Our AMA supports mandatory pre-market systematic safety assessments of bioengineered foods and encourages: (a) development and validation of additional techniques for the detection and/or assessment of unintended effects; (b) continued use of methods to detect substantive changes in nutrient or toxicant levels in bioengineered foods as part of a substantial equivalence evaluation; (c) development and use of alternative transformation technologies to avoid utilization of antibiotic resistance markers that code for clinically relevant antibiotics, where feasible; and (d) that priority should be given to basic research in food allergenicity to support the development of improved methods for identifying potential allergens. The FDA is urged to remain alert to new data on the health consequences of bioengineered foods and update its regulatory policies accordingly.

(5) Our AMA supports continued research into the potential consequences to the environment of bioengineered crops including the: (a) assessment of the impacts of pest-protected crops on nontarget organisms compared to impacts of standard agricultural methods, through rigorous field evaluations; (b) assessment of gene flow and its potential consequences including key factors that regulate weed populations; rates at which pest resistance genes from the crop would be likely to spread among weed and wild populations; and the impact of novel resistance traits on weed abundance; (c) implementation of resistance management practices and continued monitoring of their effectiveness; (d) development of monitoring programs to assess ecological impacts of pest-protected crops that may not be apparent from the results of field tests; and (e) assessment of the agricultural impact of bioengineered foods, including the impact on farmers.

(6) Our AMA recognizes the many potential benefits offered by bioengineered crops and foods, does not support a moratorium on planting bioengineered crops, and encourages ongoing research developments in food biotechnology.

(7) Our AMA urges government, industry, consumer advocacy groups, and the scientific and medical communities to educate the public and improve the availability of unbiased information and research activities on bioengineered foods. (CSA Rep. 10, I-00; Modified: CSAPH Rep. 1, A-10; Modified: CASPH Rep. 2, A-12)

## Learned Societies and National Academies Endorsing Safety of Genetically Modified Crops

The scientific consensus on the safety of genetically modified crops is overwhelming. Below is a list, not intended to be exhaustive, of learned societies and national academies around the world who have found that genetically modified crops are as safe as their conventional counterparts.

American Association for the Advancement of Science  
American Medical Association  
American Society for Microbiology  
Australian Academy of Sciences  
Brazilian Academy of Sciences  
British Medical Association  
Chinese Academy of Sciences  
Council for Agricultural Science and Technology  
European Commission  
European Food Safety Authority  
Federation of Animal Science Societies  
Food and Agriculture Organization of the United Nations  
French Academy of Science  
Indian National Science Academy  
Institute of Food Technologists  
International Council for Science  
International Union of Food Science and Technology  
Italian National Academy of Science  
Mexican Academy of Sciences  
National Academies of Science (United States)  
Organization for Economic Cooperation and Development  
Pontifical Academy of Sciences  
Royal Society (United Kingdom)  
World Health Organization

*"There is no substantiated case of any adverse impact on human health, animal health or environmental health, so that's pretty robust evidence, and I would be confident in saying that there is no more risk in eating GMO food than eating conventionally farmed food."*

Prof. Anne Glover, Chief Science Advisor to the European Commission, "No risk with GMO food, says EU chief scientific advisor," [www.euractive.com](http://www.euractive.com)

## **The US Regulatory System for Crops & Foods Improved Through Biotechnology**

**Crops and foods improved through biotechnology have undergone more rigorous safety reviews, in depth and detail, than any other foods in history.**

Complete description of the extensive US regulatory process with details can be found here:

<http://usbiotechreg.epa.gov/usbiotechreg/>, which has been in place since 1986:

[http://www.aphis.usda.gov/brs/fedregister/coordinated\\_framework.pdf](http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf).

**The U.S. Regulatory Process Involves comprehensive regulatory oversight by USDA, EPA & FDA.**

USDA: Database of regulatory reviews for all transgenic crops cleared for commercial planting here:

[http://usbiotechreg.epa.gov/usbiotechreg/database\\_pub.html](http://usbiotechreg.epa.gov/usbiotechreg/database_pub.html) per regulations found here:

<http://www.aphis.usda.gov/biotechnology/index.shtml>. A comprehensive database of all risk assessments for permission to conduct field trials is here: <http://www.nbiap.vt.edu/>

FDA requires all foods placed on the market to be safe. Because of this overarching safety requirement, FDA does not require specific reviews of foods derived from crops improved through biotechnology because the process of production tells one nothing about safety. Safety depends on the characteristics of the end product regardless of how it was produced. FDA has prepared a thorough list of points to consider in evaluating and ensuring the safety of "bioengineered foods". Details can be found here: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096095.htm>.

Agricultural biotechnology companies are on record requesting the consultation process be made mandatory. Without exception, all "bioengineered" foods on the market have gone through the FDA review process, and these biotech companies are on record they will continue to do this for all such foods. A compilation of summaries on all completed FDA consultations is here:

<http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing>

FDA staff conduct rigorous internal review of all data provided by companies/product developers. They also subject such data to peer review by multiple invited external experts before confirming to the applicant that all safety questions have been satisfactorily answered.

The system in the European Union (as also Canada, Japan, Australia, New Zealand, and many other countries) is similarly rigorous. Risk assessment research has been extensive, as shown in this from the EU:

**Indeed, the use of more precise technology and the greater regulatory scrutiny probably make them even safer than conventional plants and foods; and if there are unforeseen environmental effects - none have appeared as yet - these should be rapidly detected by our monitoring requirements. On the other hand, the benefits of these plants and products for human health and the environment become increasingly clear.**

**--European Commission, Press Release of 8 October 2001, announcing the release of 15 year study including 81 projects/70M euros, 400 teams**  
(<http://ec.europa.eu/research/fp5/eag-gmo.html> and  
<http://ec.europa.eu/research/fp5/pdf/eag-gmo.pdf> )

The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than conventional plant breeding technologies...

[http://ec.europa.eu/research/biosociety/pdf/a decade of eu-funded gmo research.pdf](http://ec.europa.eu/research/biosociety/pdf/a%20decade%20of%20eu-funded%20gmo%20research.pdf)

"...because the technique is so sophisticated, in many ways it is probably safer for you to eat GM products - plants that have been generated through GM - than normal plant foods, if you have any sort of reaction to food, because you can snip out the proteins that cause the negative reaction to certain parts of the population."

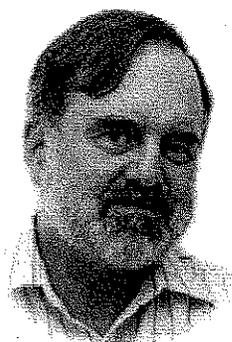
--Sir David King, Chief Science Advisor, UK  
The Guardian Unlimited, 27 November 2007  
<http://www.guardian.co.uk/gmdebate/Story/0,,2217712,00.html>

[http://seattletimes.com/html/opinion/2020542841\\_bruce13gmofoodsinitiative522xml.html](http://seattletimes.com/html/opinion/2020542841_bruce13gmofoodsinitiative522xml.html)

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## Initiative 522: a test of what you believe about genetically modified foods

When it comes to genetically modified foods, people are trying to make an economic case in a matter that is mostly about belief.



By Bruce Ramsey

Times editorial columnist



“I’m a GMO novice here,” said state Rep. Cathy Dahlquist, R-Enumclaw. “What are the scientific health risks of consuming GMO products? I mean, why should I care?”

Like Dahlquist, I am a novice on genetically modified organisms. On March 6, I watched two hours of legislative hearings on Initiative 522, which would require certain foods to be labeled, “*Partially produced with genetic engineering.*”

If the hearing was any indication of the fall campaign over I-522, voters should prepare themselves for tricky arguments.

Most of the dispute was not whether there are health risks — supporters mostly said they didn’t know — but about people’s *belief* in risks. It was said that if our farmers grow genetically modified wheat when it becomes available, foreign markets might reject it. “We cannot afford to lose those customers,” said wheat farmer Lynn Polson.

If the foreign markets won’t buy it, Washington farmers won’t grow it. Rep. Cyrus Habib, D-Kirkland, wanted to know what Initiative 522 has to do with bulk grain exports. The initiative is mainly about labeling food for final sale.

People are trying to make an economic case in a matter that is mostly about belief.

The most fetching argument for 522 is that people have a right to know what's in their food. And if 522 were about the ingredients in our food, that would settle the question. But it isn't about that, said Prof. Alan McHughen, a plant molecular geneticist at the University of California, Riverside. "This bill is about the process."

Take sugar. Some sugar sold in the United States is made from genetically modified beets. Some is from unmodified cane. I-522 would mandate a different label for each — but there is no difference in the sugar. "The process does not impart any physical characteristic that I can test," McHughen said.

Here is a case where there is a difference, but a trivial one. Okanagan Specialty Fruits of Summerland, B.C., has developed an apple that won't turn brown when cut. That is the only difference, the company says; otherwise their Arctic Apple is the same as other apples.

The company's claims are being reviewed by Health Canada and by the U.S. Department of Agriculture. Assume the company is correct. Should the law require its labels to say, "genetically modified"?

It *is* genetically modified, and it is different.

This label is a warning. It is saying, in effect, "Before you buy this apple, your government wants you to know this fact about it." But why would my government want me to know this if it makes no difference to people's health? (If it does, there is no argument.)

The answer seems to be that it makes a difference to people's beliefs. The label mandated by 522 is not like listing the sugar in breakfast cereal. It is more like the labels "kosher" and "halal," or "USDA Organic," except that its implication is negative and its use is not voluntary.

Who wants it? So far, the largest donors to the campaign for 522 are PCC Natural Markets, Seattle; Organic Consumers Association, Finland, Minn.; Dr. Bronner's Magic Soaps, Escondido, Calif.; and Mercola Health Resources of Hoffman Estates, Ill. The biggest company to support 522 in Olympia March 6 was Whole Foods Market.

Initiative 522 begins to look like an organic-food industry effort to impose a label on its competitors.

Maybe a product will come along that convinces everyone: "OK, now we need labels." But like Rep. Dahlquist, I'm not convinced this is it.

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