

REPORT 2 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-12)
Labeling of Bioengineered Foods (Resolutions 508 and 509-A-11)
(Reference Committee E)

EXECUTIVE SUMMARY

Objectives. Foods containing bioengineered (also referred to as “genetically-engineered”) ingredients are prevalent in U.S. grocery stores. The belief that adverse human health effects can result from consuming bioengineered foods has prompted consumer groups to urge mandatory labeling of foods containing bioengineered ingredients. This report reviews the potential adverse health effects of bioengineered foods, and implications for labeling are addressed.

Data Sources. Literature searches were conducted in the PubMed database for English-language articles published between 2000 and 2012 using the search terms “genetically modified food,” “genetically engineered food,” and “bioengineered food,” combined with the terms “health,” “safety,” and “labeling.” To capture other reports, news articles and press releases, Google searches were conducted using the same search terms. Additional articles were identified by manual review of the captured literature citations.

Results. Bioengineered foods have been consumed for close to 20 years, and during that time, no overt consequences on human health have been reported and/or substantiated in the peer-reviewed literature. However, a small potential for adverse events exists, due mainly to horizontal gene transfer, allergenicity, and toxicity. Pre-market safety assessments are designed to identify and prevent risks to human health. Consumers overwhelmingly support labeling of foods containing bioengineered ingredients. However, the FDA’s science-based labeling policies state that labels need only list such information if the bioengineered food is significantly different from its traditional counterpart, or if its production method materially changes the food’s nutritional profile (for example, if it contains a common allergen).

Conclusions. Despite strong consumer interest in mandatory labeling of bioengineered foods, the FDA’s science-based labeling policies do not support special labeling without evidence of material differences between bioengineered foods and their traditional counterparts. The Council supports this science-based approach, and believes that thorough pre-market safety assessment and the FDA’s requirement that any material difference between bioengineered foods and their traditional counterparts be disclosed in labeling, are effective in ensuring the safety of bioengineered food. To better characterize the potential harms of bioengineered foods, the Council believes that pre-market safety assessment should shift from a voluntary notification process to a mandatory requirement. The Council notes that consumers wishing to choose foods without bioengineered ingredients may do so by purchasing those that are labeled “USDA Organic.”

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2-A-12

Subject: Labeling of Bioengineered Foods
(Resolutions 508 and 509-A-11)

Presented by: Lee R. Morisy, MD, Chair

Referred to: Reference Committee E
(Frederick R. Ridge, Jr., MD, Chair)

1 INTRODUCTION

2
3 Resolution 508-A-11, introduced by the Illinois Delegation, asked that our American Medical
4 Association (AMA) study the impact of food containing genetically engineered ingredients and
5 take further action based on the results of the study. Resolution 509-A-11, introduced by the
6 Indiana Delegation, asked that our AMA study the impact of mandated labeling of food containing
7 genetically engineered ingredients and take further action based on the results of the study. Both
8 resolutions were referred.
9

10 In a 2000 report, the Council on Scientific Affairs reviewed in depth the technology used to
11 produce transgenic crops, as well as issues relevant to the use of bioengineered ingredients in food,
12 including the regulatory framework, human health effects, and potential environmental impacts.¹
13 The Council believes that the information in its 2000 report is still current and valid, and therefore
14 will not revisit many of those issues in this report. Rather, it will focus on the issue raised in
15 Resolution 509-A-11, that of labeling foods containing bioengineered ingredients.
16

17 METHODS

18
19 Literature searches were conducted in the PubMed database for English-language articles published
20 between 2000 and 2012 using the search terms “genetically modified food,” “genetically
21 engineered food,” and “bioengineered food,” combined with the terms “health,” “safety,” and
22 “labeling.” To capture other reports, news articles and press releases, Google searches were
23 conducted using the same search terms. Additional articles were identified by manual review of
24 the captured literature citations.
25

26 BACKGROUND

27
28 Genetic modification of plants has occurred for centuries, as farmers seek to improve yields,
29 disease resistance, and agronomic qualities.^{1,2} Genetic modification by conventional breeding
30 techniques such as crossbreeding, selection, and hybridization can be a lengthy process requiring
31 many generations. Examples of common foods produced through conventional genetic
32 modification include nectarines (which are genetically modified peaches) and tangelos (genetic
33 hybrid of tangerine and grapefruit).³ Late in the 20th century, genetic modification techniques
34 advanced to the molecular level with transgenic technology. Transgenic technology involves the
35 introduction of an advantageous genetic trait into a plant or animal via the direct transfer of a gene

1 or other construct conferring expression of that trait. Examples of the current use of transgenic
2 technology are the production of corn varieties resistant to certain insects, and soybeans resistant to
3 common herbicides.

4
5 Food crops produced through transgenic technology are often referred to as “GMOs” (genetically
6 modified organisms). Since plants that are genetically enhanced through conventional breeding
7 techniques can also be considered genetically modified, the Food and Drug Administration (FDA)
8 uses the terms “bioengineered” or “genetically engineered” to refer to transgenically-produced
9 plants. For clarity and consistency with FDA regulatory documentation, this report uses the term
10 “bioengineered” to refer to foods produced through transgenic technologies.

11
12 To date, more than 80 transgenic crops have undergone regulatory clearance in the U.S.; however,
13 only about a dozen are currently marketed for human consumption.^{4,5} The most common
14 transgenic crops in the U.S. are soybeans, corn, sugar beets, and cotton (for cottonseed oil). Each
15 of these crops makes up approximately 90% of the total amount planted each year.⁶ Transgenic
16 varieties of rapeseed (for canola oil), papaya, and squash are also common in the U.S. food supply.
17 It is estimated that approximately 70% of processed foods sold in U.S. grocery stores contain
18 ingredients derived from transgenic crops.⁷

19
20 Approval of the first transgenically-produced animal intended for human consumption has been
21 under consideration by the FDA for several years.⁸ The animal is an Atlantic salmon containing a
22 growth hormone gene from the Chinook salmon and a gene from the ocean pout that activates the
23 transgenic growth hormone gene year round. As a result, the salmon grows to market size in 16-18
24 months rather than 3 years.

25
26 Intense debate has surrounded bioengineered foods, with critics arguing that safety data are lacking
27 and the potential human health effects of consuming bioengineered foods have not been fully
28 explored. Several groups have called for mandatory labeling of foods containing bioengineered
29 ingredients so that consumers are able to avoid such foods if desired. In this report, the potential
30 adverse health effects of bioengineered foods are reviewed and implications for labeling are
31 addressed. More detailed descriptions of transgenic crop production methods and traits,
32 environmental concerns, and potential benefit for global food production can be found in the
33 Council’s 2000 report.¹

34 35 AMA POLICY ADDRESSING LABELING OF BIOENGINEERED FOODS

36
37 AMA Policy H-480.958 “Genetically Modified Crops and Foods” (AMA Policy Database; see
38 Appendix) is broad, covering the belief that regulatory oversight of bioengineered foods should be
39 science-based and involve systematic safety assessments, supporting research into environmental
40 consequences, and encouraging unbiased information and education of consumers. With regard to
41 labeling, the policy states that “as of December 2009, there is no scientific justification for special
42 labeling of genetically modified foods, as a class, and that voluntary labeling is without value
43 unless it is accompanied by focused consumer education.”

44 45 POTENTIAL HUMAN HEALTH EFFECTS OF BIOENGINEERED FOODS

46
47 Bioengineered foods have been consumed for close to 20 years, and during that time, no overt
48 consequences on human health have been reported and/or substantiated in the peer-reviewed
49 literature.^{1,9,10} However, a small potential for adverse events exists. These potential events are
50 centered around horizontal gene transfer, allergenicity, and toxicity.

1 *Horizontal gene transfer*

2
3 Horizontal gene transfer (HGT) is the process by which an organism transfers genetic material to
4 another organism other than its offspring and which is followed by integration and expression of
5 the genetic material.¹¹ This process is common among bacteria and other prokaryotes.¹²
6 Speculation that HGT could occur between ingested bioengineered food and enteric bacteria
7 present in the human mouth, stomach, and gut has been expressed. Of special concern are
8 bioengineered foods made from transgenic plants that express antibiotic-resistance markers
9 (ARMs), which are employed during the development of the transgenic plant to select for those
10 that have incorporated the transgene.¹³ When humans ingest food derived from plants that express
11 an ARM, it is theoretically possible that the ARM could be taken up and stably integrated into
12 enteric bacteria through HGT, resulting in bacteria that are resistant to specific antibiotics. This
13 situation has never been reported, although studies point to its possibility. The *epsps* transgene,
14 which confers resistance to a common herbicide, survives intact through the small intestine of
15 humans when bioengineered food made with Roundup Ready soybeans (resistant to the herbicide
16 glyphosate, commonly called Roundup®) is consumed.¹⁴ Also, M13 bacteriophage DNA has been
17 shown to survive transiently in the gastrointestinal tract of mice and is able to enter the
18 bloodstream.¹⁵ However, these studies demonstrate only the ability of certain DNA molecules to
19 resist degradation by salivary and gastric enzymes; no studies to date have demonstrated the ability
20 of the DNA molecules to become stably integrated into the bacterial genome by HGT.¹⁶

21
22 Some consumers have reported concerns that consumption of bioengineered foods means that
23 humans will ingest the “foreign” DNA present in transgenes.¹¹ A DNA sequence of particular
24 concern is the cauliflower mosaic virus 35S promoter, commonly used to direct expression of plant
25 transgenes. This promoter is efficient and functional in a variety of organisms, and it has been
26 suggested that it might lead to inappropriate overexpression of genes in species into which it is
27 transferred and promote HGT, or recombine with dormant endogenous viruses present in humans,
28 leading to new infectious viruses.¹⁷ However, almost all genomes of human endogenous
29 retroviruses contain lethal mutations that prevent replication and production of viral particles.¹¹
30 Also, the cauliflower mosaic virus is present naturally in approximately 10% of cabbages and
31 cauliflowers, and so is regularly ingested by humans. No adverse consequences from the
32 consumption of this virus have been reported.¹¹

33
34 Several factors limit the possibility of HGT of plant transgenes into enteric bacteria.¹³ First,
35 depending on the type of food, DNA is broken down during food processing. Second, if it survives
36 food processing, it is then subjected to degradation enzymes in the saliva and gastrointestinal tract
37 when consumed. Third, if DNA were to be taken up by enteric bacteria, it would be subjected to
38 bacterial restriction enzymes that cleave foreign DNA. Further, for stable integration and
39 expression to occur, the DNA fragment would have to be homologous to bacterial DNA (to allow
40 for recombination), and would have to be inserted near the proper regulatory sequences that drive
41 expression. The combination of these barriers results in a nearly impossible chance for stable
42 integration. Nonetheless, in an effort to avoid any chance of enteric bacteria becoming antibiotic
43 resistant, selection methods that do not confer such resistance have been developed and are now
44 commonly used.^{18,19} AMA Policy H-480.958 supports these alternative selection methods.

45
46 It should be noted that all foods, even those that are not bioengineered, contain varying amounts of
47 DNA, both from the ingredients themselves and from microorganisms present in the food. To the
48 extent that HGT, although unlikely, could potentially occur, bacteria present in non-bioengineered
49 foods have as much potential to carry out HGT as bacteria present in bioengineered food.²

1 Toxicity

2
3 A serious concern voiced by consumers and others is whether the protein products of transgenes
4 themselves might be toxic to humans, or whether those proteins may induce unintended effects on
5 plant metabolism that could lead to upregulated expression of toxins. This concern was heightened
6 with the publication of a 1999 study reporting negative effects in the gastrointestinal tract of rats
7 fed with potatoes expressing a lectin transgene conferring insecticide activity.²⁰ However, the
8 experimental design of this study is widely regarded as flawed, with subsequent studies unable to
9 reproduce the findings.¹¹ Further studies using the same transgene found that observed differences
10 in blood biochemistry, hematology, immunological parameters, and organ weights were not
11 adverse, and likely to be caused by increased water uptake in the rats consuming food containing
12 the lectin transgene.²¹ The potential toxicity of lectins has been widely documented, and for that
13 reason, no transgenic plants carrying lectin genes have been commercialized.

14
15 Other studies have examined potential toxicity of transgenic crops. In one, mice fed Roundup
16 Ready soybeans had modifications in the nuclei of hepatocytes, suggesting that bioengineered
17 soybeans are able to modify the metabolic activities of hepatocytes.²² In another, results suggested
18 that bioengineered soybeans can influence the function of pancreatic acinar cells in mice.²³
19 However, these studies too have been criticized as being tainted by important flaws.¹¹ In contrast,
20 other groups have demonstrated that neither Roundup Ready soybeans nor Bt corn (expressing a
21 transgene that acts as an insecticide) have any negative effects in mice.^{24,25} The same is true for
22 several other transgenic varieties of soybeans and corn fed to rats.²⁵⁻³⁰ Relevant for humans, the
23 processing of bioengineered foods intended for consumption leads to a complete loss of functional
24 activity for most transgenic proteins.³¹

25
26 Before bioengineered foods reach the market, producers perform safety assessments to evaluate
27 potential toxicity. The safety assessments are based on the concept of “substantial equivalence,”
28 which involves a thorough comparison of the new transgenic crop with its conventionally bred
29 counterpart that is generally accepted as safe based on a history of human consumption.^{1,32,33} If the
30 transgenic crop possesses similar levels and variations of critical nutrients and toxicants as its
31 conventional counterpart, it is considered to be substantially equivalent; the presence of novel
32 DNA or protein does not itself qualify as a difference.¹ Any defined differences subject the
33 transgenic crop to additional testing.^{1,32} Newer profiling techniques that aim to increase the
34 probability of detecting toxicants and unintended effects are increasingly being employed.^{2,11}

36 Allergenicity

37
38 The transgene expressed by transgenic crops has the potential to encode a protein that is allergenic
39 to humans. Potential allergenicity problems have occurred in two documented cases. In both, pre-
40 and post-market safety procedures effectively halted exposure.¹¹ The first case involves a
41 transgenic soybean intended for use in animal feed; the soybeans were engineered to express a
42 methionine-rich protein from the Brazil nut. Pre-market testing verified that the transgenic protein
43 was able to bind to Immunoglobulin E (IgE) from people allergic to Brazil nuts, an indication that
44 the protein is an allergen. As a consequence, and even though it was only intended for animal feed,
45 the transgenic soybean variety was never commercialized.³⁴ The second case involved a variety of
46 corn engineered to express Cry9C, an insecticidal protein. The corn was approved for use as an
47 animal feed, but not for human consumption because upon pre-market testing, Cry9C showed some
48 attributes associated with an allergen.¹¹ Traces of the transgenic corn were detected in some human
49 food products, and after publication of the contamination, some consumers reported adverse
50 effects. However, extended evaluations made by independent institutions could detect no direct
51 implication of Cry9C in the incidents.^{35,36} This variety of corn is no longer commercialized.

1 To date, no evidence has supported an increased degree of allergenicity of bioengineered foods
 2 compared to their non-bioengineered counterparts.^{9-11,37} This is due in part to the safety
 3 assessments to which bioengineered foods are subjected prior to marketing.³³ Thorough pre-
 4 market evaluation is considered to be the most effective tool to protect the public. Current safety
 5 assessments are based on a “weight-of-evidence” approach, where each food product is evaluated
 6 on a case-by-case basis using a number of elements.^{38,39} These elements are:

- 8 • Source of the transgene: Does the gene encoding the new protein come from a commonly
 9 allergenic source such as a food (e.g., peanut, hazelnut, eggs, or milk), respiratory allergen
 10 (e.g., pollen or dust mite), or contact allergen (latex)?
- 11 • Protein sequence: How closely does the sequence of the newly introduced protein match that of
 12 a known allergen?
- 13 • IgE-testing: Does the protein encoded by the transgene bind IgE-antibodies from people known
 14 to be allergic to the source of the transgene?
- 15 • Stability testing: Is the expressed protein highly resistant to digestion by pepsin?
- 16 • Abundance: Is the protein abundant and stable in the food?

17
 18 For each bioengineered food product, the results of these elements are aggregated and interpreted
 19 to determine potential allergenicity.³⁸ It should be noted that absolute avoidance of all risk is not
 20 achievable. Thus the safety assessments that have been developed focus on avoiding risks that are
 21 predictable and likely to cause common allergic reactions. Research to examine more effective
 22 methods of allergenicity assessment is ongoing.^{9,40,41}

24 LABELING OF BIOENGINEERED FOODS

26 *FDA labeling policy*

27
 28 The FDA regulates food labeling using an approach designed to provide consumers with
 29 information relative to health, nutrition, and safety. The Federal Food and Drug Cosmetic Act
 30 (FD&C Act) lays out the FDA’s science-based labeling policy; all foods, whether or not they are
 31 derived from transgenic crops or animals, are subject to the policy.^{42,43} The FDA has the authority
 32 to initiate regulatory action if a product fails to meet the requirements of the FD&C Act.³

33
 34 Three key provisions in the FDA’s labeling policy pertain to the issue of labeling bioengineered
 35 foods. First, the law requires that all food labels include a name that accurately describes the basic
 36 nature of the food.^{3,43} Regarding bioengineered foods, name changes are only appropriate when the
 37 food is significantly different from its traditional counterpart, such that the common or usual name
 38 no longer adequately describes the new food. Changes to the name of the product are not
 39 appropriate if the resulting bioengineered food is not materially different from its traditional
 40 counterpart (i.e., unless the bioengineered food differs in nutritional quality, taste, etc.).

41
 42 Second, significant differences in food arising from production processes must be disclosed in
 43 labeling.^{3,43} Thus, if the transgenic production method materially changes a food’s nutritional
 44 profile or results in a safety concern, this must be disclosed on the label. For example, if a
 45 bioengineered food were to contain a commonly recognized allergen not present in its non-
 46 bioengineered counterpart, the presence of the allergen must be stated on the label. Under this
 47 provision, the FDA cannot require labeling based solely on differences in the production process if
 48 the resulting products are not materially different or do not pose a safety risk. While the definition
 49 of a “material difference” is not specified in the FD&C Act, precedent guides the FDA in its
 50 interpretation of the term.³ Generally, the FDA has limited the scope of the materiality concept to

1 information about the attributes of the food itself. The fact that a food or any of its ingredients
2 were produced using transgenic methods is not considered material, and therefore does not
3 constitute information that must be disclosed in labeling. The FDA therefore has neither a
4 scientific nor a legal basis to require such labeling.^{3,42}

5
6 Third, the FDA allows voluntary labeling about production methods as long as the labeling is not
7 false or misleading.³ In 2001, the FDA released a Draft Guidance for Industry to provide
8 information to manufacturers wishing to use informative statements about whether foods contain
9 bioengineered ingredients.⁴⁴ Examples of acceptable statements for foods that do not contain
10 bioengineered ingredients are: “This product does not contain ingredients that were produced using
11 biotechnology” or “This oil is made from soybeans that were not genetically engineered.” The
12 FDA discourages the use of acronyms such as “GMO-free” since some consumers may not know
13 what the acronym stands for, and since “genetically modified” can refer to conventional techniques
14 to alter genotype.

15
16 The FDA believes that its current labeling policies, combined with pre-market safety assessments,
17 are sufficient to ensure the safety of bioengineered foods.³ Before marketing foods with
18 bioengineered ingredients, companies voluntarily notify the FDA, leading to a two-part
19 consultation process between the agency and the company that initially involves discussions of
20 relevant safety issues and subsequently the company’s submission of a safety assessment report
21 containing test data on the food in question.⁴⁵ The FDA has considered making the pre-market
22 notification process mandatory, but has stated that it does not believe such a rule is needed since
23 the voluntary process has fully protected the public.^{46,47} To date, all manufacturers of
24 bioengineered foods intended for marketing have engaged in the voluntary notification process.⁷

25
26 Although the approval procedures for transgenic animals intended for human consumption are
27 different than those for transgenic plants, the same labeling principles apply. Thus, if
28 bioengineered food produced from a transgenic animal is materially different from its non-
29 bioengineered counterpart in its nutritional or safety profile, it must be labeled as such. As in the
30 case of bioengineered foods produced from transgenic plants, the FDA does not consider the
31 methods used to develop the animal as “material.”⁴⁸

32 33 *Consumer perspectives on labeling*

34
35 Fears that bioengineered foods pose a safety threat to consumers, as well as a “right to know” what
36 is being consumed and to be afforded the choice to avoid bioengineered foods, are the basis for
37 arguments that bioengineered foods should be labeled as such.⁴² Several surveys have attempted to
38 characterize consumers’ wishes with regard to labeling bioengineered foods. In surveys asking
39 whether consumers are satisfied with U.S. food labeling policies, only 18% report that information
40 is missing; among this group, only 3% report that information about bioengineering should be
41 included in the label.⁴⁹ However, when direct questions about labeling of bioengineered food are
42 asked of consumers, such as whether they support mandatory or voluntary labeling policies, the
43 overwhelming majority favor mandatory labeling policies.^{7,50-52}

44
45 Consumer groups have been outspoken in their support of a mandatory labeling policy for
46 bioengineered foods.^{53,54} A petition calling for mandatory labeling was submitted to the FDA by
47 the Center for Food Safety in the fall of 2011 and more than 400 organizations have expressed their
48 support for the “Just Label It” campaign.^{55,56} The FDA responded in the spring of 2012, saying that
49 it had not yet made a decision on the petition and would continue to consider it. Others have
50 criticized the FDA’s approval and labeling policies as inadequate in the face of advancing plant and
51 animal transgenic technologies and have called for reform.^{57,58} Additionally, more than a dozen

1 states and the U.S. House and Senate have considered legislation focused on mandatory labeling of
2 bioengineered plants and animals. Only Alaska has passed a law, requiring that bioengineered
3 salmon be labeled (bioengineered salmon are not currently marketed).

4
5 Mandatory labeling of foods would involve significant costs, especially the costs of testing for the
6 presence of bioengineered ingredients, segregating the crops, and monitoring for truthfulness of
7 labeling and enforcement of the regulations that exist.^{59,60} These costs would likely be passed to
8 the consumer; it is estimated that mandatory labeling would increase the average household's
9 annual grocery bill by \$140-\$200 per year.^{7,50} Surveys of U.S. consumers reveal that while some
10 are willing to pay a premium for foods that do not contain bioengineered ingredients, the majority
11 of consumers are not willing to pay for increases commensurate with the costs of mandatory
12 labeling policies.^{50,61,62}

13
14 Regarding consumers' "right to know" argument, courts have found that consumer curiosity alone
15 is not enough to require special labeling.^{63,64} The reasoning behind these rulings is that 1) special
16 labeling places an unfair financial burden on industries that would have to investigate, document,
17 and label the "level" of bioengineering in their product; 2) it may mislead consumers into thinking
18 that bioengineered foods are less safe than their conventional counterparts; 3) it places a burden on
19 the FDA itself, which would have to divert resources away from safety-based labeling to address
20 consumer curiosity; and 4) it places no end on the information consumers could request
21 manufacturers to disclose.

22
23 In Europe, all food with bioengineered ingredients must be labeled as such. Several other countries
24 have also adopted mandatory labeling policies.^{59,65} Examination of these policies reveals that
25 mandatory labeling fails to result in consumer choice because stores have chosen not to sell foods
26 with bioengineered ingredients, rather than be seen as supportive of bioengineered foods. In
27 countries that have adopted mandatory labeling, it is often difficult, if not impossible, to find food
28 items bearing such labels.⁶⁶ This is considered to be unfair to those who prefer to buy presumably
29 lower-cost bioengineered foods.⁶⁶

30
31 Consumers wishing to avoid bioengineered foods can purchase foods that are certified USDA
32 Organic. This labeling term indicates that no bioengineered ingredients were used in the food.

33 34 CONCLUSION

35
36 Despite strong consumer interest in mandatory labeling of bioengineered foods, the FDA's science-
37 based labeling policies do not support special labeling without evidence of material differences
38 between bioengineered foods and their traditional counterparts. The Council supports this science-
39 based approach, and believes that thorough pre-market safety assessment and the FDA's
40 requirement that any material difference between bioengineered foods and their traditional
41 counterparts be disclosed in labeling, are effective in ensuring the safety of bioengineered food.
42 To better detect potential harms of bioengineered foods, the Council believes that pre-market safety
43 assessment should shift from a voluntary notification process to a mandatory requirement. The
44 Council understands that some consumers may wish to choose foods that do not contain
45 bioengineered ingredients, and notes that consumers may do so by purchasing food products that
46 are labeled USDA Organic.

47 48 RECOMMENDATION

49
50 The Council on Science and Public Health recommends that the following statement be adopted in
51 lieu of Resolutions 508-A-11 and 509-A-11, and the remainder of the report be filed:

1 That Policy H-480.958 “Genetically Modified Crops and Foods” be amended by insertion and
2 deletion as follows:

3
4 Bioengineered (Genetically Modified-Engineered) Crops and Foods

5
6 (1) Our AMA recognizes the continuing validity of the three major conclusions contained in the
7 1987 National Academy of Sciences white paper "Introduction of Recombinant DNA-Engineered
8 Organisms into the Environment." [The three major conclusions are: (a) There is no evidence that
9 unique hazards exist either in the use of rDNA techniques or in the movement of genes between
10 unrelated organisms; (b) The risks associated with the introduction of rDNA-engineered organisms
11 are the same in kind as those associated with the introduction of unmodified organisms and
12 organisms modified by other methods; (c) Assessment of the risk of introducing rDNA-engineered
13 organisms into the environment should be based on the nature of the organism and the environment
14 into which it is introduced, not on the method by which it was produced.)

15
16 (2) That federal regulatory oversight of agricultural biotechnology should continue to be science-
17 based and guided by the characteristics of the plant or animal, its intended use, and the
18 environment into which it is to be introduced, not by the method used to produce it, in order to
19 facilitate comprehensive, efficient regulatory review of new ~~genetically modified~~ bioengineered
20 crops and foods.

21
22 (3) Our AMA believes that as of ~~December 2009~~ June 2012, there is no scientific justification for
23 special labeling of ~~genetically modified~~ bioengineered foods, as a class, and that voluntary labeling
24 is without value unless it is accompanied by focused consumer education.

25
26 (4) Our AMA supports ~~efforts for the~~ mandatory pre-market systematic safety assessments of
27 ~~genetically modified~~ bioengineered foods and encourages: (a) development and validation of
28 additional techniques for the detection and/or assessment of unintended effects; (b) continued use
29 of methods to detect substantive changes in nutrient or toxicant levels in ~~genetically modified~~
30 bioengineered foods as part of a substantial equivalence evaluation; (c) development and use of
31 alternative transformation technologies to avoid utilization of antibiotic resistance markers that
32 code for clinically relevant antibiotics, where feasible; and (d) that priority should be given to basic
33 research in food allergenicity to support the development of improved methods for identifying
34 potential allergens. The FDA is urged to remain alert to new data on the health consequences of
35 bioengineered foods and update its regulatory policies accordingly.

36
37 (5) Our AMA supports continued research into the potential consequences to the environment of
38 ~~genetically modified~~ bioengineered crops including the: (a) assessment of the impacts of pest-
39 protected crops on nontarget organisms compared to impacts of standard agricultural methods,
40 through rigorous field evaluations; (b) assessment of gene flow and its potential consequences
41 including key factors that regulate weed populations; rates at which pest resistance genes from the
42 crop would be likely to spread among weed and wild populations; and the impact of novel
43 resistance traits on weed abundance; (c) implementation of resistance management practices and
44 continued monitoring of their effectiveness; ~~and~~ (d) development of monitoring programs to assess
45 ecological impacts of pest-protected crops that may not be apparent from the results of field tests;
46 and (e) assessment of the agricultural impact of bioengineered foods, including the impact on
47 farmers.

48
49 (6) Our AMA recognizes the many potential benefits offered by ~~genetically modified~~
50 bioengineered crops and foods, does not support a moratorium on planting ~~genetically modified~~
51 bioengineered crops, and encourages ongoing research developments in food biotechnology.

1 (7) Our AMA ~~recognizes that the~~ urges government, industry, consumer advocacy groups, and the
2 scientific and medical communities ~~have a responsibility~~ to educate the public and improve the
3 availability of unbiased information and research activities on ~~genetically modified~~ bioengineered
4 foods ~~and of research activities~~. (CSA Rep. 10, I-00; Modified: CSAPH Rep. 1, A-10) (Modify
5 Current HOD Policy)

Fiscal note: Less than \$500

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Appendix. AMA Policy on Bioengineered Foods

H-480.958 Genetically Modified 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, 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 genetically modified crops and foods.

(3) Our AMA believes that as of December 2009, there is no scientific justification for special labeling of genetically modified foods, as a class, and that voluntary labeling is without value unless it is accompanied by focused consumer education.

(4) Our AMA supports efforts for the systematic safety assessment of genetically modified 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 genetically modified 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 genetically modified 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 genetically modified crops and foods, not support a moratorium on planting genetically modified crops, and encourage 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 on genetically modified crops and of research activities. (CSA Rep. 10, I-00; Modified: CSAPH Rep. 1, A-10)