108TH CONGRESS
2D SESSION

S. 2546

To amend the Federal Food, Drug, and Cosmetic Act to require premarket consultation and approval with respect to genetically engineered foods, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 17, 2004

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require premarket consultation and approval with respect to genetically engineered foods, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Genetically Engineered Foods Act''.

SEC. 2. FINDINGS.

Congress finds that—

(1) genetically engineered food is rapidly becoming an integral part of domestic and international food supplies;

(2) the potential positive effects of genetically engineered foods are enormous;

(3) the potential for both anticipated and unanticipated effects exists with genetic engineering of foods;

(4) genetically engineered food not approved for human consumption has, in the past, entered the human food supply;

(5) environmental issues have been identified as a major science-based concern associated with animal biotechnology;

(6) it is essential to maintain—

(A) public confidence in—

(i) the safety of the food supply; and

(ii) the ability of the Federal Government to exercise adequate oversight of genetically engineered foods; and

(B) the ability of agricultural producers and other food producers of the United States to market, domestically and internationally, foods that have been genetically engineered;

(7) public confidence can best be maintained through careful review and formal determination of the safety of genetically engineered foods, and monitoring of the positive and negative effects of genetically engineered foods as the foods become integrated into the food supply, through a review and monitoring process that—

(A) is scientifically sound, open, and transparent;

(B) fully involves the general public; and

(C) does not subject most genetically engineered foods to the lengthy food additive approval process; and

(8) because genetically engineered foods are developed worldwide and imported into the United States, it is imperative that imported genetically engineered food be subject to the same level of oversight as domestic genetically engineered food.

SEC. 3. DEFINITIONS.

(a) THIS ACT.—In this Act, the terms ''genetic engineering technique'', ''genetically engineered animal'', ''genetically engineered food'', ''interstate commerce'', ''producer'', ''safe'', and ''Secretary'' have the meanings given those terms in section 201 of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 321) (as amended by subsection (b)).

(b) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

(1) in subsection (v)—

(A) by striking ''(v) The term'' and inserting the following:

''(v) NEW ANIMAL DRUG.—

''(1) IN GENERAL.—The term'';

(B) by striking ''(1) the composition'' and inserting ''(A) the composition'';

(C) by striking ''(2) the composition'' and inserting ''(B) the composition''; and

(D) by adding at the end the following:

''(2) INCLUSION.—The term 'new animal drug' includes—

''(A) a genetic engineering technique intended to be used to produce an animal; and

''(B) a genetically engineered animal.''; and

(2) by adding at the end the following:

''(nn) GENETICALLY ENGINEERED ANIMAL.—

''(1) IN GENERAL.—The term 'genetically engineered animal' means an animal that—

"(A) is intended to be used—

"(i) in the production of a food or dietary supplement; or

"(ii) for any other purpose;

"(B)(i) is produced in the United States; or

"(ii) is offered for import into the United States; and

"(C) is produced using a genetic engineering technique.

"(2) EXCLUSION.—The term 'genetically engineered animal' does not include an established line of a genetically modified animal that—

"(A) is used solely in scientific research; and

"(B) is not intended or expected—

"(i) to enter the food supply; or

"(ii) to be released into the environment.

"(oo) GENETICALLY ENGINEERED FOOD.—

"(1) IN GENERAL.—The term 'genetically engineered food' means a food or dietary supplement, or a seed, microorganism, or ingredient intended to be used to produce a food or dietary supplement, that—

''(A)(i) is produced in the United States; or

''(ii) is offered for import into the United States; and

''(B) is produced using a genetic engineering technique.

''(2) INCLUSION.—The term 'genetically engineered food' includes a split use food.

''(3) EXCLUSION.—The term 'genetically engineered food' does not include a genetically engineered animal.

''(pp) GENETIC ENGINEERING TECHNIQUE.—The term 'genetic engineering technique' means the use of a transformation event to derive food from a plant or animal or to produce an animal.

''(qq) PRODUCER.—The term 'producer', with respect to a genetically engineered animal, genetically engineered food, or genetic engineering technique, means a person that—

''(1) develops, manufactures, or imports the genetically engineered animal or genetically engineered food;

''(2) uses the genetic engineering technique; or

''(3) takes other action to introduce the genetically engineered animal, genetically engineered food,

or genetic engineering technique into interstate commerce.

''(rr) SAFE.—The term 'safe', with respect to a genetically engineered food, means—

''(1) as safe as comparable food that is not produced using a genetic engineering technique; or

''(2) if there is no such comparable food, having a reasonable certainty of causing no harm.

''(ss) SPLIT USE FOOD.—The term 'split use food' means a product that—

''(1)(A) is produced in the United States; or

''(B) is offered for import into the United States;

''(2) is produced using a genetic engineering technique; and

''(3) could be used as food by both humans and animals but that the producer does not intend to market as food for humans.

''(tt) TRANSFORMATION EVENT.—The term 'transformation event' means the introduction into a plant or an animal of genetic material that has been manipulated in vitro.''.

SEC. 4. GENETICALLY ENGINEERED FOODS.

Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended—

(1) by inserting after the chapter heading the following:

"Subchapter A—General Provisions";

and

(2) by adding at the end the following:

"Subchapter B—Genetically Engineered Foods

"SEC. 421. PREMARKET CONSULTATION AND APPROVAL.

''(a) IN GENERAL.—A producer of genetically engineered food, before introducing a genetically engineered food into interstate commerce, shall first obtain approval through the use of a premarket consultation and approval process.

''(b) REGULATIONS.—The Secretary shall promulgate regulations that describe—

''(1) all information that is required to be submitted for the premarketing approval process, including—

''(A) specification of the species or other taxonomic classification of plants for which approval is sought;

''(B) identification of the genetically engineered food;

"(C)(i) a description of each type of genetic manipulation made to the genetically engineered food;

"(ii) identification of the manipulated genetic material; and

"(iii) the techniques used in making the manipulation;

"(D) the effect of the genetic manipulation on the composition of the genetically engineered food (including information describing the specific substances that were expressed, removed, or otherwise manipulated);

"(E) a description of the actual or proposed applications and uses of the genetically engineered food;

"(F) information pertaining to—

"(i) the safety of the genetically engineered food as a whole; and

"(ii) the safety of any specific substances introduced, altered, or produced as a result of the genetic manipulation (including information on allergenicity and toxicity);

"(G) test methods for detection of the genetically engineered ingredients in food;

''(H) a summary and overview of information and issues that have been or will be addressed by other regulatory programs for the review of genetically engineered food;

''(I) procedures to be followed to initiate and complete the premarket approval process (including any preconsultation and consultation procedures); and

''(J) any other matters that the Secretary determines to be necessary.

''(2) SPLIT USE FOOD.—

''(A) IN GENERAL.—The regulations under paragraph (1) shall provide for the approval of—

''(i) split use foods that are not approved for human consumption;

''(ii) split use foods that are intended for human use but are marketed under restricted conditions; and

''(iii) other categories of split use food.

''(B) ISSUES.—For each category of split use food, the regulations shall address—

"(i)(I) whether a protocol is needed for segregating a restricted split use food from the food supply; and

"(II) if so, what the protocol shall be;

"(ii)(I) whether action is needed to ensure the purity of any seed to prevent unintended introduction of a genetically engineered trait into a seed that is not designed for that trait; and

"(II) if so, what action is needed and what industry practices represent the best practices for maintaining the purity of the seed;

"(iii)(I) whether a tolerance level should exist regarding cross-mixing of segregated split use foods; and

"(II) if so, the means by which the tolerance level shall be determined;

"(iv) the manner in which the food safety analysis under this section should be conducted, specifying different standards and procedures that are permitted to be applied for nonfood products grown in food crops depending on the degree of contain-

ment for that product and the likelihood of the product to enter the food supply;

"(v)(I) the kinds of surveillance that are needed to ensure that appropriate segregation of split use foods is being maintained;

"(II) the manner in which and by whom the surveillance shall be conducted; and

"(III) the manner in which the results of surveillance shall be reported; and

"(vi) clarification of responsibility in cases of breakdown of segregation of a split use food.

"(C) RECALL AUTHORITY.—The regulations shall provide that, in addition to other authority that the Secretary has regarding split use food, the Secretary may order a recall of any split use food (whether or not the split use food has been approved under this section) that—

"(i) is not approved, but has entered the food supply; or

''(ii) has entered the food supply in violation of a condition of restriction under an approval.

''(c) APPLICATION.—The regulations shall require that, as part of the consultation and approval process, a producer submit to the Secretary an application that includes a summary and a complete copy of each research study, test result, or other information referenced by the producer.

''(d) REVIEW.—

''(1) IN GENERAL.—After receiving an application under subsection (c), the Secretary shall—

''(A) determine whether the producer submitted information that appears to be adequate to enable the Secretary to fully assess the safety of the genetically engineered food, and make a description of the determination publicly available; and

''(B) if the Secretary determines that the producer submitted adequate information—

''(i) provide public notice regarding the initiation of the consultation and approval process;

''(ii) make the notice, application, summaries submitted by the producer, and

research, test results, and other information referenced by the producer publicly available, including, to the maximum extent practicable, publication in the Federal Register and on the Internet; and

''(iii) provide the public with an opportunity, for not less than 45 days, to submit comments on the application.

''(2) EXCEPTION.—The Secretary may withhold information in an application from public dissemination to protect a trade secret (not including any information disclosing the results of testing to determine whether the genetically engineered food is safe) if—

''(A) the information is exempt from disclosure under section 522 of title 5, United States Code, or applicable trade secret law;

''(B) the applicant—

''(i) identifies with specificity the trade secret information in the application; and

''(ii) provides the Secretary with a detailed justification for each trade secret claim; and

''(C) the Secretary—

"(i) determines that the information qualifies as a trade secret subject to withholding from public dissemination; and

"(ii) makes the determination available to the public.

"(3) DETERMINATION.—Not later than 180 days after determining adequacy of an application under paragraph (1)(A), the Secretary shall issue and make publicly available a determination that—

"(A) summarizes the information referenced by the producer in light of the public comments; and

"(B) contains a finding that the genetically engineered food—

"(i) is safe and may be introduced into interstate commerce;

"(ii) is safe under specified conditions of use and may be introduced into interstate commerce if those conditions are met; or

"(iii) is not safe and may not be introduced into interstate commerce, because the genetically engineered food—

"(I) contains genes that confer antibiotic resistance;

''(II) contains an allergen; or

''(III) presents 1 or more other safety concerns described by the Secretary.

''(4) EXTENSION.—The Secretary may extend the period specified in paragraph (3) if the Secretary determines that an extension of the period is necessary to allow the Secretary to—

''(A) review additional information; or

''(B) address 1 or more issues or concerns of unusual complexity.

''(e) RESCISSION OF APPROVAL.—

''(1) RECONSIDERATION.—On the petition of any person, or on the Secretary's own motion, the Secretary may reconsider an approval of a genetically engineered food on the basis of information that was not available before the approval.

''(2) FINDING FOR RECONSIDERATION.—The Secretary shall conduct a reconsideration on the basis of the information described in paragraph (1) if the Secretary finds that the information—

''(A) is scientifically credible;

''(B) represents significant information that was not available before the approval; and

"(C)(i) suggests potential impacts relating to the genetically engineered food that were not considered in the earlier review; or

"(ii) demonstrates that the information considered before the approval was inadequate for the Secretary to make a safety finding.

"(3) INFORMATION FROM THE PRODUCER.—

"(A) IN GENERAL.—In conducting the reconsideration, the Secretary may require the producer to provide, within a reasonable period of time specified by the Secretary, information needed to facilitate the reconsideration.

"(B) INFORMATION NOT PROVIDED.—If a producer fails to provide information required under subparagraph (A) within the period specified by the Secretary, the Secretary shall take 1 or more of the actions described in paragraph (5).

"(4) DETERMINATION.—After reviewing the information by the petitioner and the producer, the Secretary shall issue a determination that—

"(A) revises the finding made in connection with the approval with respect to the safety of the genetically engineered food; or

''(B) states that, for reasons stated by the Secretary, no revision of the finding is needed.

''(5) ACTION BY THE SECRETARY.—If, based on a reconsideration under this section, the Secretary determines that the genetically engineered food is not safe, the Secretary shall—

''(A) rescind the approval of the genetically engineered food for introduction into interstate commerce;

''(B) recall the genetically engineered food; or

''(C) take such other action as the Secretary determines to be appropriate.

''SEC. 422. MARKETPLACE TESTING AND POST-MARKETING OVERSIGHT.

''(a) TESTING.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Agriculture and the Administrator of the Environmental Protection Agency, shall establish a program to conduct testing that the Secretary determines to be necessary to detect, at all stages of production and distribution (from agricultural production to retail sale), the presence of genetically engineered ingredients in food.

''(2) PERMISSIBLE TESTING.—Under the program, the Secretary may conduct tests on foods to detect genetically engineered ingredients—

''(A) that have not been approved for use under this Act, including foods that are developed in foreign countries that have not been approved for marketing in the United States under this Act; or

''(B) the use of which is restricted under this Act (including approval for use as animal feed only, approval only if properly labeled, and approval for growing or marketing only in certain regions).

''(b) POST-MARKET OVERSIGHT.—

''(1) IN GENERAL.—The Secretary shall establish a program to monitor and evaluate the continued safety after commercialization of genetically engineered foods approved under section 421.

''(2) ACTIVITIES.—Under the program, the Secretary shall—

''(A) take appropriate actions to ensure that each split-use food complies with any restriction or other condition on the approval of the split-use food; and

''(B) conduct inspections and monitoring of genetically engineered foods and facilities that produce genetically engineered foods to ensure that only approved genetically engineered foods are marketed to humans.

''SEC. 423. REGISTRY.

''(a) ESTABLISHMENT.—The Secretary, in consultation with the Secretary of Agriculture, the Administrator of the Environmental Protection Agency, and the heads of other agencies, as appropriate, shall establish a registry for genetically engineered food that contains a description of the regulatory status of all genetically engineered foods approved under section 421.

''(b) REQUIREMENTS.—The registry under subsection (a) shall contain, for each genetically engineered food—

''(1) the technical and common names of the genetically engineered food;

''(2) a description of the regulatory status, under all Federal programs pertaining to the testing and approval of genetically engineered foods, of the genetically engineered food;

''(3) a technical and nontechnical summary of the type of, and a statement of the reason for, each

genetic manipulation made to the genetically engineered food;

''(4) the name, title, address, and telephone number of an official at each producer of the genetically engineered food whom members of the public may contact for information about the genetically engineered food;

''(5) the name, title, address, and telephone number of an official at each Federal agency with oversight responsibility over the genetically engineered food whom members of the public may contact for information about the genetically engineered food; and

''(6) such other information as the Secretary determines should be included.

''(c) PUBLIC AVAILABILITY.—The registry under subsection (a) shall be made available to the public, including availability on the Internet.''.

SEC. 5. GENETICALLY ENGINEERED ANIMALS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 512 the following:

''SEC. 512A. GENETICALLY ENGINEERED ANIMALS.

''(a) IN GENERAL.—Section 512 shall apply to genetic engineering techniques intended to be used to

produce an animal, and to genetically engineered animals, as provided in this section.

''(b) APPLICATION.—An application under section 512(b)(1) shall include—

''(1) specification of the species or other taxonomic classification of the animal for which approval is sought;

''(2) an environmental assessment that analyzes the potential effects of the genetically engineered animal on the environment, including the potential effect on any nongenetically engineered animal or other part of the environment as a result of any intentional or unintentional exposure of the genetically engineered animal to the environment; and

''(3) a plan to eliminate or mitigate the potential effects to the environment from the release of the genetically engineered animal.

''(c) DISSEMINATION OF APPLICATION AND OPPORTUNITY FOR PUBLIC COMMENT.—

''(1) IN GENERAL.—On receipt of an application under section 512(b)(1), the Secretary shall—

''(A) provide public notice regarding the application, including making the notice available on the Internet;

''(B) make the application and all supporting material available to the public, including availability on the Internet; and

''(C) provide the public with an opportunity, for not less than 45 days, to submit comments on the application.

''(2) EXCEPTION.—

''(A) IN GENERAL.—The Secretary may withhold information in an application from public dissemination to protect a trade secret (not including any information disclosing the results of testing to determine whether the genetically engineered food is safe) if—

''(i) the information is exempt from disclosure under section 522 of title 5, United States Code, or applicable trade secret law;

''(ii) the applicant—

''(I) identifies with specificity the trade secret information in the application; and

''(II) provides the Secretary with a detailed justification for each trade secret claim; and

''(iii) the Secretary—

''(I) determines that the information qualifies as a trade secret subject to withholding from public dissemination; and

''(II) makes the determination available to the public.

''(B) RISK ASSESSMENT INFORMATION.—This paragraph does not apply to information that assesses risks from the release into the environment of a genetically engineered animal (including any environmental assessment or environmental impact statement performed to comply with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.)).

''(d) DENIAL OF APPLICATION.—Under section 512(d)(1), the Secretary shall deny an application if—

''(1) the environmental assessment for a genetically engineered animal is not adequate; or

''(2) the plan to eliminate or mitigate the potential environmental effects to the environment from the release of the genetically engineered animal does not adequately protect the environment.

''(e) ENVIRONMENTAL ASSESSMENT.—

''(1) IN GENERAL.—Before determining whether to approve an application under section 512 for

approval of a genetic engineering technique intended to be used to produce an animal, or of a genetically engineered animal, the Secretary shall—

"(A) conduct an environmental assessment to evaluate the potential effects of such a genetically engineered animal on the environment; and

"(B) determine that the genetically engineered animal will not have an unreasonable adverse effect on the environment.

"(2) CONSULTATION.—In conducting an environmental assessment under paragraph (1), the Secretary shall—

"(A) consult, as appropriate, with the Department of Agriculture, the United States Fish and Wildlife Service, and any other Federal agency that has expertise relating to the animal species that is the subject of the application; and

"(B) disclose the results of the consultation in the environmental assessment.

"(f) SAFETY DETERMINATION.—In determining the safety of a genetic engineering technique or genetically engineered animal, the Secretary shall consider the potential effects of the genetically engineered animal on the environ-

ment, including the potential effect on nongenetically engineered animals.

''(g) PROGENY.—If an application for approval of a genetic engineering technique to produce an animal of a species or other taxonomic classification, or genetically engineered animal, has been approved, no additional application shall be required for animals of that species or other taxonomic classification produced using that genetic engineering technique or for the progeny of that genetically engineered animal.

''(h) SCOPE OF APPROVAL.—The scope of the genetic engineering technique that the Secretary may approve shall be limited to the precise procedures described in the application for approval.

''(i) CONDITIONS OF APPROVAL.—The Secretary may require as a condition of approval of an application that any producer of a genetically engineered animal that is the subject of the application—

''(1) take specified actions to eliminate or mitigate any potential harm to the environment that would be caused by a release of the genetically engineered animal, including actions specified in the plan submitted by the applicant; and

''(2) conduct post-approval monitoring for environmental effects of any release of the genetically engineered animal.

''(j) RECALL; SUSPENSION OF APPROVAL.—

''(1) RECALL.—The Secretary may order a recall of any genetically engineered animal (whether or not the genetically engineered animal, or a genetic engineering technique used to produce the genetically engineered animal, has been approved) that the Secretary determines is harmful to—

''(A) humans;

''(B) the environment;

''(C) any animal that is subjected to a genetic engineering technique; or

''(D) any animal that is not subjected to a genetic engineering technique.

''(2) SUSPENSION OF APPROVAL.—If the Secretary determines that a genetically engineered animal is harmful to the health of humans or animals or to the environment, the Secretary may—

''(A) immediately suspend the approval of application for the genetically engineered animal;

''(B) give the applicant prompt notice of the action; and

''(C) afford the applicant an opportunity for an expedited hearing.

''(k) RESCISSION OF APPROVAL.—

''(1) RECONSIDERATION.—On the motion of any person, or on the Secretary's own motion, the Secretary may reconsider an approval of a genetic engineering technique or genetically engineered animal on the basis of information that was not available during an earlier review.

''(2) FINDING FOR RECONSIDERATION.—The Secretary shall conduct a reconsideration on the basis of the information described in paragraph (1) if the Secretary finds that the information—

''(A) is scientifically credible;

''(B) represents significant information that was not available before the approval; and

''(C)(i) suggests potential impacts relating to the genetically engineered animal that were not considered before the approval; or

''(ii) demonstrates that the information considered before the approval was inadequate for the Secretary to make a safety finding.

''(3) INFORMATION FROM THE PRODUCER.—

''(A) IN GENERAL.—In conducting the reconsideration, the Secretary may require the

producer to provide, within a reasonable period of time specified by the Secretary, information needed to facilitate the reconsideration.

"(B) INFORMATION NOT PROVIDED.—If a producer fails to provide information required under subparagraph (A) within the period specified by the Secretary, the Secretary shall take 1 or more of the actions described in paragraph (5).

"(4) DETERMINATION.—After reviewing the information by the petitioner and the producer, the Secretary shall issue a determination that—

"(A) revises the finding made in connection with the approval with respect to the safety of the genetically engineered animal; or

"(B) states that, for reasons stated by the Secretary, no revision of the finding is needed.

"(5) ACTION BY THE SECRETARY.—If, based on a review under this subsection, the Secretary determines that the genetically engineered animal is not safe, the Secretary shall—

"(A) rescind the approval of the genetic engineering technique or genetically engineered animal for introduction into interstate commerce;

''(B) recall the genetically engineered animal; or

''(C) take such other action as the Secretary determines to be appropriate.

''(l) ANIMALS USED IN DEVELOPMENT.—An animal that is used in connection with an investigation intended to support approval of an application under section 512 and this section or that is otherwise used in connection with the development of a genetic engineering technique or production of a genetically engineered animal for which approval is sought shall be deemed unsafe for the purposes of sections 501(a)(5) and 402(a)(2)(C)(ii) unless—

''(1) the applicant submits information required by the Secretary that addresses the food safety of the animal;

''(2) the Secretary publishes the information in the Federal Register and provides a public comment period of not less than 60 days; and

''(3) based on the information provided under paragraph (1), any public comment, and other information available to the Secretary, the Secretary—

''(A) makes a determination that the animal is safe; and

''(B) publishes the determination in the Federal Register and on the Internet.''.

SEC. 6. PROHIBITED ACTS.

(a) UNLAWFUL USE OF TRADE SECRET INFORMATION.—Section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) is amended in the first sentence—

(1) by inserting ''421,'' after ''414,''; and

(2) by inserting ''512A,'' after ''512,''.

(b) ADULTERATED FOOD.—Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following:

''(i) GENETICALLY ENGINEERED ANIMALS.—If it is a genetically engineered animal, or is a genetically engineered animal produced using a genetic engineering technique, that is not approved under sections 512 and 512A.

''(j) GENETICALLY ENGINEERED FOODS.—

''(1) IN GENERAL.—If it is a genetically engineered food, or is a genetically engineered food produced using a genetic engineering technique, that is not approved under section 421.

''(2) SPLIT USE FOODS.—If it is a split use food that does not maintain proper segregation as required under regulations promulgated under section 421.''.

SEC. 7. TRANSITION PROVISION.

(a) IN GENERAL.—A genetic engineering technique, genetically engineered animal, or genetically engineered

food that entered interstate commerce before the date of enactment of this Act shall not require approval under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), but shall be considered to have been so approved, if—

(1) the producer, not later than 90 days after the date of enactment of this Act, submits to the Secretary—

(A) a notice stating that the genetic engineering technique, genetically engineered animal, or genetically engineered food entered interstate commerce before the date of enactment of this Act, providing such information as the Secretary may require; and

(B) a request that the Secretary conduct a review of the genetic engineering technique, genetically engineered animal, or genetically engineered food under subsection (b); and

(2) the Secretary does not issue, on or before the date that is 2 years after the date of enactment of this Act, a notice under subsection (b)(2) that an application for approval is required.

(b) REVIEW BY THE SECRETARY.—

(1) IN GENERAL.—Not later than 21 months after the date on which the Secretary receives a no-

tice and request for review under subsection (a), the Secretary shall review all relevant information in the possession of the Secretary, all information provided by the producer, and other relevant public information to determine whether a review of new scientific information is necessary to ensure that the genetic engineering technique, genetically engineered animal, or genetically engineered food is safe.

(2) NOTICE THAT APPLICATION IS REQUIRED.—If the Secretary determines that new scientific information is necessary to determine whether a genetic engineering technique, genetically engineered animal, or genetically engineered food is safe, the Secretary, not later than 2 years after the date of enactment of this Act, shall issue to the producer a notice stating that the producer is required to submit an application for approval of the genetic engineering technique, genetically engineered animal, or genetically engineered food under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) FAILURE TO SUBMIT APPLICATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), a genetically engineered animal or genetically engineered food with respect to which the Secretary issues a notice that an application is required

under subsection (b)(2) shall be considered adulterated under section 402 or 501, as the case may be, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 351) unless—

(A) not later than 45 days after the producer receives the notice, the producer submits an application for approval; and

(B) the Secretary approves the application.

(2) PENDING APPLICATION.—A genetically engineered animal or genetically engineered food with respect to which the producer submits an application for approval shall not be considered to be adulterated during the pendency of the application.

SEC. 8. GENETICALLY ENGINEERED CROPS.

To the maximum extent practicable, the Secretary of Agriculture shall ensure that standards for the regulation of genetically engineered field test crops to prevent cross-pollenation with non-genetically engineered crops and prevent adverse effects on the environment are based on the most recent scientific knowledge available.

SEC. 9. REPORTS.

(a) IN GENERAL.—Not later than 2 years, 4 years, and 6 years after the date of enactment of this Act, the Secretary and the heads of other Federal agencies, as appropriate, shall jointly submit to Congress a report on ge-

netically engineered animals, genetically engineered foods, and genetic engineering techniques.

(b) CONTENTS.—A report under subsection (a) shall contain—

(1) information on the types and quantities of genetically engineered foods being offered for sale or being developed, domestically and internationally;

(2) a summary (including discussion of new developments and trends) of the legal status and acceptability of genetically engineered foods in major markets, including the European Union and Japan;

(3) information on current and emerging issues of concern relating to genetic engineering techniques, including issues relating to—

(A) the ecological impact of, antibiotic markers for, insect resistance to, nongerminating or terminator seeds for, or cross-species gene transfer for genetically engineered foods;

(B) foods from genetically engineered animals;

(C) nonfood crops (such as cotton) produced using a genetic engineering technique; and

(D) socioeconomic concerns (such as the impact of genetically engineered animals and genetically engineered foods on small farms);

(4) a response to, and information concerning the status of implementation of, the recommendations contained in the reports entitled ''Genetically Modified Pest Protected Plants'', ''Environmental Effects of Transgenic Plants'', ''Animal Biotechnology Identifying Science-Based Concerns'', and ''Biological Containment of Genetically Engineered Organisms (2004)'', issued by the National Academy of Sciences;

(5) an assessment of the need for data relating to genetically engineered animals and genetically engineered foods;

(6) a projection of—

(A) the number of genetically engineered animals, genetically engineered foods, and genetic engineering techniques that will require regulatory review during the 5-year period following the date of the report; and

(B) the adequacy of the resources of the Food and Drug Administration; and

(7) an evaluation of the national capacity to test foods for the presence of genetically engineered ingredients in food.

SEC. 10. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as are necessary to carry out this Act and the amendments made by this Act.

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