

108TH CONGRESS
2^D 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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Genetically Engineered
5 Foods Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

1 (1) genetically engineered food is rapidly be-
2 coming an integral part of domestic and inter-
3 national food supplies;

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

6 (3) the potential for both anticipated and unan-
7 ticipated effects exists with genetic engineering of
8 foods;

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

12 (5) environmental issues have been identified as
13 a major science-based concern associated with ani-
14 mal biotechnology;

15 (6) it is essential to maintain—

16 (A) public confidence in—

17 (i) the safety of the food supply; and

18 (ii) the ability of the Federal Govern-
19 ment to exercise adequate oversight of ge-
20 netically engineered foods; and

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

1 (7) public confidence can best be maintained
2 through careful review and formal determination of
3 the safety of genetically engineered foods, and moni-
4 toring of the positive and negative effects of geneti-
5 cally engineered foods as the foods become inte-
6 grated into the food supply, through a review and
7 monitoring process that—

8 (A) is scientifically sound, open, and trans-
9 parent;

10 (B) fully involves the general public; and

11 (C) does not subject most genetically engi-
12 neered foods to the lengthy food additive ap-
13 proval process; and

14 (8) because genetically engineered foods are de-
15 veloped worldwide and imported into the United
16 States, it is imperative that imported genetically en-
17 gineered food be subject to the same level of over-
18 sight as domestic genetically engineered food.

19 **SEC. 3. DEFINITIONS.**

20 (a) THIS ACT.—In this Act, the terms “genetic engi-
21 neering technique”, “genetically engineered animal”, “ge-
22 netically engineered food”, “interstate commerce”, “pro-
23 ducer”, “safe”, and “Secretary” have the meanings given
24 those terms in section 201 of the Federal Food, Drug,

1 and Cosmetic Act (21 U.S.C. 321) (as amended by sub-
2 section (b)).

3 (b) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—
4 Section 201 of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 321) is amended—

6 (1) in subsection (v)—

7 (A) by striking “(v) The term” and insert-
8 ing the following:

9 “(v) NEW ANIMAL DRUG.—

10 “(1) IN GENERAL.—The term”;

11 (B) by striking “(1) the composition” and
12 inserting “(A) the composition”;

13 (C) by striking “(2) the composition” and
14 inserting “(B) the composition”; and

15 (D) by adding at the end the following:

16 “(2) INCLUSION.—The term ‘new animal drug’
17 includes—

18 “(A) a genetic engineering technique in-
19 tended to be used to produce an animal; and

20 “(B) a genetically engineered animal.”;
21 and

22 (2) by adding at the end the following:

23 “(nn) GENETICALLY ENGINEERED ANIMAL.—

24 “(1) IN GENERAL.—The term ‘genetically engi-
25 neered animal’ means an animal that—

1 “(A) is intended to be used—

2 “(i) in the production of a food or die-
3 tary supplement; or

4 “(ii) for any other purpose;

5 “(B)(i) is produced in the United States;

6 or

7 “(ii) is offered for import into the United
8 States; and

9 “(C) is produced using a genetic engineer-
10 ing technique.

11 “(2) EXCLUSION.—The term ‘genetically engi-
12 neered animal’ does not include an established line
13 of a genetically modified animal that—

14 “(A) is used solely in scientific research;
15 and

16 “(B) is not intended or expected—

17 “(i) to enter the food supply; or

18 “(ii) to be released into the environ-
19 ment.

20 “(oo) GENETICALLY ENGINEERED FOOD.—

21 “(1) IN GENERAL.—The term ‘genetically engi-
22 neered food’ means a food or dietary supplement, or
23 a seed, microorganism, or ingredient intended to be
24 used to produce a food or dietary supplement,
25 that—

1 “(A)(i) is produced in the United States;

2 or

3 “(ii) is offered for import into the United
4 States; and

5 “(B) is produced using a genetic engineer-
6 ing technique.

7 “(2) INCLUSION.—The term ‘genetically engi-
8 neered food’ includes a split use food.

9 “(3) EXCLUSION.—The term ‘genetically engi-
10 neered food’ does not include a genetically engi-
11 neered animal.

12 “(pp) GENETIC ENGINEERING TECHNIQUE.—The
13 term ‘genetic engineering technique’ means the use of a
14 transformation event to derive food from a plant or animal
15 or to produce an animal.

16 “(qq) PRODUCER.—The term ‘producer’, with respect
17 to a genetically engineered animal, genetically engineered
18 food, or genetic engineering technique, means a person
19 that—

20 “(1) develops, manufactures, or imports the ge-
21 netically engineered animal or genetically engineered
22 food;

23 “(2) uses the genetic engineering technique; or

24 “(3) takes other action to introduce the geneti-
25 cally engineered animal, genetically engineered food,

1 or genetic engineering technique into interstate com-
2 merce.

3 “(rr) SAFE.—The term ‘safe’, with respect to a ge-
4 netically engineered food, means—

5 “(1) as safe as comparable food that is not pro-
6 duced using a genetic engineering technique; or

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

9 “(ss) SPLIT USE FOOD.—The term ‘split use food’
10 means a product that—

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

12 “(B) is offered for import into the United
13 States;

14 “(2) is produced using a genetic engineering
15 technique; and

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

19 “(tt) TRANSFORMATION EVENT.—The term ‘trans-
20 formation event’ means the introduction into a plant or
21 an animal of genetic material that has been manipulated
22 in vitro.”.

23 **SEC. 4. GENETICALLY ENGINEERED FOODS.**

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

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

3 **“Subchapter A—General Provisions”;**

4 and

5 (2) by adding at the end the following:

6 **“Subchapter B—Genetically Engineered**

7 **Foods**

8 **“SEC. 421. PREMARKET CONSULTATION AND APPROVAL.**

9 “(a) IN GENERAL.—A producer of genetically engi-
10 neered food, before introducing a genetically engineered
11 food into interstate commerce, shall first obtain approval
12 through the use of a premarket consultation and approval
13 process.

14 “(b) REGULATIONS.—The Secretary shall promul-
15 gate regulations that describe—

16 “(1) all information that is required to be sub-
17 mitted for the premarketing approval process, in-
18 cluding—

19 “(A) specification of the species or other
20 taxonomic classification of plants for which ap-
21 proval is sought;

22 “(B) identification of the genetically engi-
23 neered food;

1 “(C)(i) a description of each type of ge-
2 netic manipulation made to the genetically engi-
3 neered food;

4 “(ii) identification of the manipulated ge-
5 netic material; and

6 “(iii) the techniques used in making the
7 manipulation;

8 “(D) the effect of the genetic manipulation
9 on the composition of the genetically engineered
10 food (including information describing the spe-
11 cific substances that were expressed, removed,
12 or otherwise manipulated);

13 “(E) a description of the actual or pro-
14 posed applications and uses of the genetically
15 engineered food;

16 “(F) information pertaining to—

17 “(i) the safety of the genetically engi-
18 neered food as a whole; and

19 “(ii) the safety of any specific sub-
20 stances introduced, altered, or produced as
21 a result of the genetic manipulation (in-
22 cluding information on allergenicity and
23 toxicity);

24 “(G) test methods for detection of the ge-
25 netically engineered ingredients in food;

1 “(H) a summary and overview of informa-
2 tion and issues that have been or will be ad-
3 dressed by other regulatory programs for the
4 review of genetically engineered food;

5 “(I) procedures to be followed to initiate
6 and complete the premarket approval process
7 (including any preconsultation and consultation
8 procedures); and

9 “(J) any other matters that the Secretary
10 determines to be necessary.

11 “(2) SPLIT USE FOOD.—

12 “(A) IN GENERAL.—The regulations under
13 paragraph (1) shall provide for the approval
14 of—

15 “(i) split use foods that are not ap-
16 proved for human consumption;

17 “(ii) split use foods that are intended
18 for human use but are marketed under re-
19 stricted conditions; and

20 “(iii) other categories of split use
21 food.

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

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

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

5 “(ii)(I) whether action is needed to
6 ensure the purity of any seed to prevent
7 unintended introduction of a genetically en-
8 gineered trait into a seed that is not de-
9 signed for that trait; and

10 “(II) if so, what action is needed and
11 what industry practices represent the best
12 practices for maintaining the purity of the
13 seed;

14 “(iii)(I) whether a tolerance level
15 should exist regarding cross-mixing of seg-
16 regated split use foods; and

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

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

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

3 “(v)(I) the kinds of surveillance that
4 are needed to ensure that appropriate seg-
5 regation of split use foods is being main-
6 tained;

7 “(II) the manner in which and by
8 whom the surveillance shall be conducted;
9 and

10 “(III) the manner in which the results
11 of surveillance shall be reported; and

12 “(vi) clarification of responsibility in
13 cases of breakdown of segregation of a
14 split use food.

15 “(C) RECALL AUTHORITY.—The regula-
16 tions shall provide that, in addition to other au-
17 thority that the Secretary has regarding split
18 use food, the Secretary may order a recall of
19 any split use food (whether or not the split use
20 food has been approved under this section)
21 that—

22 “(i) is not approved, but has entered
23 the food supply; or

1 “(ii) has entered the food supply in
2 violation of a condition of restriction under
3 an approval.

4 “(c) APPLICATION.—The regulations shall require
5 that, as part of the consultation and approval process, a
6 producer submit to the Secretary an application that in-
7 cludes a summary and a complete copy of each research
8 study, test result, or other information referenced by the
9 producer.

10 “(d) REVIEW.—

11 “(1) IN GENERAL.—After receiving an applica-
12 tion under subsection (c), the Secretary shall—

13 “(A) determine whether the producer sub-
14 mitted information that appears to be adequate
15 to enable the Secretary to fully assess the safe-
16 ty of the genetically engineered food, and make
17 a description of the determination publicly
18 available; and

19 “(B) if the Secretary determines that the
20 producer submitted adequate information—

21 “(i) provide public notice regarding
22 the initiation of the consultation and ap-
23 proval process;

24 “(ii) make the notice, application,
25 summaries submitted by the producer, and

1 research, test results, and other informa-
2 tion referenced by the producer publicly
3 available, including, to the maximum ex-
4 tent practicable, publication in the Federal
5 Register and on the Internet; and

6 “(iii) provide the public with an op-
7 portunity, for not less than 45 days, to
8 submit comments on the application.

9 “(2) EXCEPTION.—The Secretary may withhold
10 information in an application from public dissemina-
11 tion to protect a trade secret (not including any in-
12 formation disclosing the results of testing to deter-
13 mine whether the genetically engineered food is safe)
14 if—

15 “(A) the information is exempt from dis-
16 closure under section 522 of title 5, United
17 States Code, or applicable trade secret law;

18 “(B) the applicant—

19 “(i) identifies with specificity the
20 trade secret information in the application;
21 and

22 “(ii) provides the Secretary with a de-
23 tailed justification for each trade secret
24 claim; and

25 “(C) the Secretary—

1 “(i) determines that the information
2 qualifies as a trade secret subject to with-
3 holding from public dissemination; and

4 “(ii) makes the determination avail-
5 able to the public.

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

10 “(A) summarizes the information ref-
11 erenced by the producer in light of the public
12 comments; and

13 “(B) contains a finding that the genetically
14 engineered food—

15 “(i) is safe and may be introduced
16 into interstate commerce;

17 “(ii) is safe under specified conditions
18 of use and may be introduced into inter-
19 state commerce if those conditions are met;
20 or

21 “(iii) is not safe and may not be in-
22 troduced into interstate commerce, because
23 the genetically engineered food—

24 “(I) contains genes that confer
25 antibiotic resistance;

1 “(II) contains an allergen; or

2 “(III) presents 1 or more other
3 safety concerns described by the Sec-
4 retary.

5 “(4) EXTENSION.—The Secretary may extend
6 the period specified in paragraph (3) if the Secretary
7 determines that an extension of the period is nec-
8 essary to allow the Secretary to—

9 “(A) review additional information; or

10 “(B) address 1 or more issues or concerns
11 of unusual complexity.

12 “(e) RESCISSION OF APPROVAL.—

13 “(1) RECONSIDERATION.—On the petition of
14 any person, or on the Secretary’s own motion, the
15 Secretary may reconsider an approval of a geneti-
16 cally engineered food on the basis of information
17 that was not available before the approval.

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

22 “(A) is scientifically credible;

23 “(B) represents significant information
24 that was not available before the approval; and

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

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

7 “(3) INFORMATION FROM THE PRODUCER.—

8 “(A) IN GENERAL.—In conducting the re-
9 consideration, the Secretary may require the
10 producer to provide, within a reasonable period
11 of time specified by the Secretary, information
12 needed to facilitate the reconsideration.

13 “(B) INFORMATION NOT PROVIDED.—If a
14 producer fails to provide information required
15 under subparagraph (A) within the period spec-
16 ified by the Secretary, the Secretary shall take
17 1 or more of the actions described in paragraph
18 (5).

19 “(4) DETERMINATION.—After reviewing the in-
20 formation by the petitioner and the producer, the
21 Secretary shall issue a determination that—

22 “(A) revises the finding made in connec-
23 tion with the approval with respect to the safety
24 of the genetically engineered food; or

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

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

7 “(A) rescind the approval of the genetically
8 engineered food for introduction into interstate
9 commerce;

10 “(B) recall the genetically engineered food;
11 or

12 “(C) take such other action as the Sec-
13 retary determines to be appropriate.

14 **“SEC. 422. MARKETPLACE TESTING AND POST-MARKETING**
15 **OVERSIGHT.**

16 “(a) TESTING.—

17 “(1) IN GENERAL.—The Secretary, in consulta-
18 tion with the Secretary of Agriculture and the Ad-
19 ministrator of the Environmental Protection Agency,
20 shall establish a program to conduct testing that the
21 Secretary determines to be necessary to detect, at all
22 stages of production and distribution (from agricul-
23 tural production to retail sale), the presence of ge-
24 netically engineered ingredients in food.

1 “(2) PERMISSIBLE TESTING.—Under the pro-
2 gram, the Secretary may conduct tests on foods to
3 detect genetically engineered ingredients—

4 “(A) that have not been approved for use
5 under this Act, including foods that are devel-
6 oped in foreign countries that have not been ap-
7 proved for marketing in the United States
8 under this Act; or

9 “(B) the use of which is restricted under
10 this Act (including approval for use as animal
11 feed only, approval only if properly labeled, and
12 approval for growing or marketing only in cer-
13 tain regions).

14 “(b) POST-MARKET OVERSIGHT.—

15 “(1) IN GENERAL.—The Secretary shall estab-
16 lish a program to monitor and evaluate the contin-
17 ued safety after commercialization of genetically en-
18 gineered foods approved under section 421.

19 “(2) ACTIVITIES.—Under the program, the Sec-
20 retary shall—

21 “(A) take appropriate actions to ensure
22 that each split-use food complies with any re-
23 striction or other condition on the approval of
24 the split-use food; and

1 “(B) conduct inspections and monitoring
2 of genetically engineered foods and facilities
3 that produce genetically engineered foods to en-
4 sure that only approved genetically engineered
5 foods are marketed to humans.

6 **“SEC. 423. REGISTRY.**

7 “(a) ESTABLISHMENT.—The Secretary, in consulta-
8 tion with the Secretary of Agriculture, the Administrator
9 of the Environmental Protection Agency, and the heads
10 of other agencies, as appropriate, shall establish a registry
11 for genetically engineered food that contains a description
12 of the regulatory status of all genetically engineered foods
13 approved under section 421.

14 “(b) REQUIREMENTS.—The registry under sub-
15 section (a) shall contain, for each genetically engineered
16 food—

17 “(1) the technical and common names of the
18 genetically engineered food;

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

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

1 genetic manipulation made to the genetically engi-
2 neered food;

3 “(4) the name, title, address, and telephone
4 number of an official at each producer of the geneti-
5 cally engineered food whom members of the public
6 may contact for information about the genetically
7 engineered food;

8 “(5) the name, title, address, and telephone
9 number of an official at each Federal agency with
10 oversight responsibility over the genetically engi-
11 neered food whom members of the public may con-
12 tact for information about the genetically engineered
13 food; and

14 “(6) such other information as the Secretary
15 determines should be included.

16 “(c) PUBLIC AVAILABILITY.—The registry under
17 subsection (a) shall be made available to the public, includ-
18 ing availability on the Internet.”.

19 **SEC. 5. GENETICALLY ENGINEERED ANIMALS.**

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

23 **“SEC. 512A. GENETICALLY ENGINEERED ANIMALS.**

24 “(a) IN GENERAL.—Section 512 shall apply to ge-
25 netic engineering techniques intended to be used to

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

3 “(b) APPLICATION.—An application under section
4 512(b)(1) shall include—

5 “(1) specification of the species or other taxo-
6 nomic classification of the animal for which approval
7 is sought;

8 “(2) an environmental assessment that analyzes
9 the potential effects of the genetically engineered
10 animal on the environment, including the potential
11 effect on any nongenetically engineered animal or
12 other part of the environment as a result of any in-
13 tentional or unintentional exposure of the genetically
14 engineered animal to the environment; and

15 “(3) a plan to eliminate or mitigate the poten-
16 tial effects to the environment from the release of
17 the genetically engineered animal.

18 “(c) DISSEMINATION OF APPLICATION AND OPPOR-
19 TUNITY FOR PUBLIC COMMENT.—

20 “(1) IN GENERAL.—On receipt of an applica-
21 tion under section 512(b)(1), the Secretary shall—

22 “(A) provide public notice regarding the
23 application, including making the notice avail-
24 able on the Internet;

1 “(B) make the application and all sup-
2 porting material available to the public, includ-
3 ing availability on the Internet; and

4 “(C) provide the public with an oppor-
5 tunity, for not less than 45 days, to submit
6 comments on the application.

7 “(2) EXCEPTION.—

8 “(A) IN GENERAL.—The Secretary may
9 withhold information in an application from
10 public dissemination to protect a trade secret
11 (not including any information disclosing the
12 results of testing to determine whether the ge-
13 netically engineered food is safe) if—

14 “(i) the information is exempt from
15 disclosure under section 522 of title 5,
16 United States Code, or applicable trade se-
17 cret law;

18 “(ii) the applicant—

19 “(I) identifies with specificity the
20 trade secret information in the appli-
21 cation; and

22 “(II) provides the Secretary with
23 a detailed justification for each trade
24 secret claim; and

25 “(iii) the Secretary—

1 “(I) determines that the informa-
2 tion qualifies as a trade secret subject
3 to withholding from public dissemina-
4 tion; and

5 “(II) makes the determination
6 available to the public.

7 “(B) RISK ASSESSMENT INFORMATION.—
8 This paragraph does not apply to information
9 that assesses risks from the release into the en-
10 vironment of a genetically engineered animal
11 (including any environmental assessment or en-
12 vironmental impact statement performed to
13 comply with the National Environmental Policy
14 Act of 1969 (42 U.S.C. 4321 et seq.)).

15 “(d) DENIAL OF APPLICATION.—Under section
16 512(d)(1), the Secretary shall deny an application if—

17 “(1) the environmental assessment for a geneti-
18 cally engineered animal is not adequate; or

19 “(2) the plan to eliminate or mitigate the po-
20 tential environmental effects to the environment
21 from the release of the genetically engineered animal
22 does not adequately protect the environment.

23 “(e) ENVIRONMENTAL ASSESSMENT.—

24 “(1) IN GENERAL.—Before determining wheth-
25 er to approve an application under section 512 for

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

4 “(A) conduct an environmental assessment
5 to evaluate the potential effects of such a ge-
6 netically engineered animal on the environment;
7 and

8 “(B) determine that the genetically engi-
9 neered animal will not have an unreasonable
10 adverse effect on the environment.

11 “(2) CONSULTATION.—In conducting an envi-
12 ronmental assessment under paragraph (1), the Sec-
13 retary shall—

14 “(A) consult, as appropriate, with the De-
15 partment of Agriculture, the United States Fish
16 and Wildlife Service, and any other Federal
17 agency that has expertise relating to the animal
18 species that is the subject of the application;
19 and

20 “(B) disclose the results of the consulta-
21 tion in the environmental assessment.

22 “(f) SAFETY DETERMINATION.—In determining the
23 safety of a genetic engineering technique or genetically en-
24 gineered animal, the Secretary shall consider the potential
25 effects of the genetically engineered animal on the environ-

1 ment, including the potential effect on nongenetically engi-
2 neered animals.

3 “(g) PROGENY.—If an application for approval of a
4 genetic engineering technique to produce an animal of a
5 species or other taxonomic classification, or genetically en-
6 gineered animal, has been approved, no additional applica-
7 tion shall be required for animals of that species or other
8 taxonomic classification produced using that genetic engi-
9 neering technique or for the progeny of that genetically
10 engineered animal.

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

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

19 “(1) take specified actions to eliminate or miti-
20 gate any potential harm to the environment that
21 would be caused by a release of the genetically engi-
22 neered animal, including actions specified in the plan
23 submitted by the applicant; and

1 “(2) conduct post-approval monitoring for envi-
2 ronmental effects of any release of the genetically
3 engineered animal.

4 “(j) RECALL; SUSPENSION OF APPROVAL.—

5 “(1) RECALL.—The Secretary may order a re-
6 call of any genetically engineered animal (whether or
7 not the genetically engineered animal, or a genetic
8 engineering technique used to produce the genetically
9 engineered animal, has been approved) that the Sec-
10 retary determines is harmful to—

11 “(A) humans;

12 “(B) the environment;

13 “(C) any animal that is subjected to a ge-
14 netic engineering technique; or

15 “(D) any animal that is not subjected to a
16 genetic engineering technique.

17 “(2) SUSPENSION OF APPROVAL.—If the Sec-
18 retary determines that a genetically engineered ani-
19 mal is harmful to the health of humans or animals
20 or to the environment, the Secretary may—

21 “(A) immediately suspend the approval of
22 application for the genetically engineered ani-
23 mal;

24 “(B) give the applicant prompt notice of
25 the action; and

1 “(C) afford the applicant an opportunity
2 for an expedited hearing.

3 “(k) RESCISSION OF APPROVAL.—

4 “(1) RECONSIDERATION.—On the motion of
5 any person, or on the Secretary’s own motion, the
6 Secretary may reconsider an approval of a genetic
7 engineering technique or genetically engineered ani-
8 mal on the basis of information that was not avail-
9 able during an earlier review.

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

14 “(A) is scientifically credible;

15 “(B) represents significant information
16 that was not available before the approval; and

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

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

23 “(3) INFORMATION FROM THE PRODUCER.—

24 “(A) IN GENERAL.—In conducting the re-
25 consideration, the Secretary may require the

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

4 “(B) INFORMATION NOT PROVIDED.—If a
5 producer fails to provide information required
6 under subparagraph (A) within the period spec-
7 ified by the Secretary, the Secretary shall take
8 1 or more of the actions described in paragraph
9 (5).

10 “(4) DETERMINATION.—After reviewing the in-
11 formation by the petitioner and the producer, the
12 Secretary shall issue a determination that—

13 “(A) revises the finding made in connec-
14 tion with the approval with respect to the safety
15 of the genetically engineered animal; or

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

18 “(5) ACTION BY THE SECRETARY.—If, based on
19 a review under this subsection, the Secretary deter-
20 mines that the genetically engineered animal is not
21 safe, the Secretary shall—

22 “(A) rescind the approval of the genetic
23 engineering technique or genetically engineered
24 animal for introduction into interstate com-
25 merce;

1 “(B) recall the genetically engineered ani-
2 mal; or

3 “(C) take such other action as the Sec-
4 retary determines to be appropriate.

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

13 “(1) the applicant submits information required
14 by the Secretary that addresses the food safety of
15 the animal;

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

19 “(3) based on the information provided under
20 paragraph (1), any public comment, and other infor-
21 mation available to the Secretary, the Secretary—

22 “(A) makes a determination that the ani-
23 mal is safe; and

24 “(B) publishes the determination in the
25 Federal Register and on the Internet.”.

1 **SEC. 6. PROHIBITED ACTS.**

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

6 (1) by inserting “421,” after “414,”; and

7 (2) by inserting “512A,” after “512,”.

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

11 “(i) GENETICALLY ENGINEERED ANIMALS.—If it is
12 a genetically engineered animal, or is a genetically engi-
13 neered animal produced using a genetic engineering tech-
14 nique, that is not approved under sections 512 and 512A.

15 “(j) GENETICALLY ENGINEERED FOODS.—

16 “(1) IN GENERAL.—If it is a genetically engi-
17 neered food, or is a genetically engineered food pro-
18 duced using a genetic engineering technique, that is
19 not approved under section 421.

20 “(2) SPLIT USE FOODS.—If it is a split use
21 food that does not maintain proper segregation as
22 required under regulations promulgated under sec-
23 tion 421.”.

24 **SEC. 7. TRANSITION PROVISION.**

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

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

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

9 (A) a notice stating that the genetic engi-
10 neering technique, genetically engineered ani-
11 mal, or genetically engineered food entered
12 interstate commerce before the date of enact-
13 ment of this Act, providing such information as
14 the Secretary may require; and

15 (B) a request that the Secretary conduct a
16 review of the genetic engineering technique, ge-
17 netically engineered animal, or genetically engi-
18 neered food under subsection (b); and

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

23 (b) REVIEW BY THE SECRETARY.—

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

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

9 (2) NOTICE THAT APPLICATION IS RE-
10 QUIRED.—If the Secretary determines that new sci-
11 entific information is necessary to determine whether
12 a genetic engineering technique, genetically engi-
13 neered animal, or genetically engineered food is safe,
14 the Secretary, not later than 2 years after the date
15 of enactment of this Act, shall issue to the producer
16 a notice stating that the producer is required to sub-
17 mit an application for approval of the genetic engi-
18 neering technique, genetically engineered animal, or
19 genetically engineered food under the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

21 (c) FAILURE TO SUBMIT APPLICATION.—

22 (1) IN GENERAL.—Except as provided in para-
23 graph (2), a genetically engineered animal or geneti-
24 cally engineered food with respect to which the Sec-
25 retary issues a notice that an application is required

1 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—

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

8 (B) the Secretary approves the application.

9 (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.

14 **SEC. 8. GENETICALLY ENGINEERED CROPS.**

15 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-pollination with non-genetically engineered crops and prevent adverse effects on the environment are based on the most recent scientific knowledge available.

21 **SEC. 9. REPORTS.**

22 (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-

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

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

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

8 (2) a summary (including discussion of new de-
9 velopments and trends) of the legal status and ac-
10 ceptability of genetically engineered foods in major
11 markets, including the European Union and Japan;

12 (3) information on current and emerging issues
13 of concern relating to genetic engineering tech-
14 niques, including issues relating to—

15 (A) the ecological impact of, antibiotic
16 markers for, insect resistance to, nongermi-
17 nating or terminator seeds for, or cross-species
18 gene transfer for genetically engineered foods;

19 (B) foods from genetically engineered ani-
20 mals;

21 (C) nonfood crops (such as cotton) pro-
22 duced using a genetic engineering technique;
23 and

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

4 (4) a response to, and information concerning
5 the status of implementation of, the recommenda-
6 tions contained in the reports entitled “Genetically
7 Modified Pest Protected Plants”, “Environmental
8 Effects of Transgenic Plants”, “Animal Bio-
9 technology Identifying Science-Based Concerns”,
10 and “Biological Containment of Genetically Engi-
11 neered Organisms (2004)”, issued by the National
12 Academy of Sciences;

13 (5) an assessment of the need for data relating
14 to genetically engineered animals and genetically en-
15 gineered foods;

16 (6) a projection of—

17 (A) the number of genetically engineered
18 animals, genetically engineered foods, and ge-
19 netic engineering techniques that will require
20 regulatory review during the 5-year period fol-
21 lowing the date of the report; and

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

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

4 **SEC. 10. AUTHORIZATION OF APPROPRIATIONS.**

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

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