

107TH CONGRESS  
2D SESSION

# S. 3095

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.

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## IN THE SENATE OF THE UNITED STATES

OCTOBER 10, 2002

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.

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 “(II) GENETIC ENGINEERING TECHNIQUE.—The  
24 term ‘genetic engineering technique’ means the use of a

1 transformation event to derive food from a plant or animal  
2 or to produce an animal.

3 “(mm) GENETICALLY ENGINEERED ANIMAL.—The  
4 term ‘genetically engineered animal’ means an animal  
5 that—

6 “(1) is intended to be used—

7 “(A) in the production of a food or dietary  
8 supplement; or

9 “(B) for any other purpose;

10 “(2)(A) is produced in the United States; or

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

13 “(3) is produced using a genetic engineering  
14 technique.

15 “(nn) GENETICALLY ENGINEERED FOOD.—

16 “(1) IN GENERAL.—The term ‘genetically engi-  
17 neered food’ means a food or dietary supplement, or  
18 a seed, microorganism, or ingredient intended to be  
19 used to produce a food or dietary supplement,  
20 that—

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

22 or

23 “(ii) is offered for import into the United  
24 States; and

1                   “(B) is produced using a genetic engineer-  
2                   ing technique.

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

5                   “(3) EXCLUSION.—The term ‘genetically engi-  
6                   neered food’ does not include a genetically engi-  
7                   neered animal.

8                   “(oo) PRODUCER.—The term ‘producer’, with respect  
9                   to a genetically engineered animal, genetically engineered  
10                  food, or genetic engineering technique, means a person,  
11                  company, or other entity that—

12                  “(1) develops, manufactures, or imports the ge-  
13                  netically engineered animal, genetically engineered  
14                  food, or genetic engineering technique; or

15                  “(2) takes other action to introduce the geneti-  
16                  cally engineered animal, genetically engineered food,  
17                  or genetic engineering technique into interstate com-  
18                  merce.

19                  “(pp) SAFE.—The term ‘safe’, with respect to a ge-  
20                  netically engineered food, means as safe as comparable  
21                  food that is not produced using a genetic engineering tech-  
22                  nique.

23                  “(qq) SPLIT USE FOOD.—The term ‘split use food’  
24                  means a product that—

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

1 “(B) is offered for import into the United  
2 States;

3 “(2) is produced using a genetic engineering  
4 technique; and

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

8 “(rr) TRANSFORMATION EVENT.—The term ‘trans-  
9 formation event’ means the introduction into an organism  
10 of genetic material that has been manipulated in vitro.”.

11 **SEC. 4. GENETICALLY ENGINEERED FOODS.**

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

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

16 **“Subchapter A—General Provisions”; and**

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

18 **“Subchapter B—Genetically Engineered**  
19 **Foods**

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

21 “(a) IN GENERAL.—A producer of genetically engi-  
22 neered food, before introducing a genetically engineered  
23 food into interstate commerce, shall first obtain approval  
24 through the use of a premarket consultation and approval  
25 process.

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

3               “(1) all information that is required to be sub-  
4 mitted for the premarketing approval process, in-  
5 cluding—

6                       “(A) specification of the species or other  
7 taxonomic classification of plants for which ap-  
8 proval is sought;

9                       “(B) identification of the genetically engi-  
10 neered food;

11                      “(C)(i) a description of each type of ge-  
12 netic manipulation made to the genetically engi-  
13 neered food;

14                      “(ii) identification of the manipulated ge-  
15 netic material; and

16                      “(iii) the techniques used in making the  
17 manipulation;

18                      “(D) the effect of the genetic manipulation  
19 on the composition of the genetically engineered  
20 food (including information describing the spe-  
21 cific substances that were expressed, removed,  
22 or otherwise manipulated);

23                      “(E) a description of the actual or pro-  
24 posed applications and uses of the genetically  
25 engineered food;



1 “(F) information pertaining to—

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

4 “(ii) the safety of any specific sub-  
5 stances introduced or altered as a result of  
6 the genetic manipulation (including infor-  
7 mation on allergenicity and toxicity);

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

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

14 “(I) procedures to be followed to initiate  
15 and complete the premarket approval process  
16 (including any preconsultation and consultation  
17 procedures); and

18 “(J) any other matters that the Secretary  
19 determines to be necessary.

20 “(2) SPLIT USE FOOD.—

21 “(A) IN GENERAL.—The regulations under  
22 paragraph (1) shall provide for the approval  
23 of—

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

1 “(ii) split use foods that are intended  
2 for human use but are marketed under re-  
3 stricted conditions; and

4 “(iii) other categories of split use  
5 food.

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

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

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

12 “(ii)(I) whether action is needed to  
13 ensure the purity of any seed to prevent  
14 unintended introduction of a genetically  
15 engineered trait into a seed that is not de-  
16 signed for that trait; and

17 “(II) if so, what action is needed and  
18 what industry practices represent the best  
19 practices for maintaining the purity of the  
20 seed;

21 “(iii)(I) whether a tolerance level  
22 should exist regarding cross-mixing of seg-  
23 regated split use foods; and

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

1 “(iv) the manner in which the food  
2 safety analysis under this section should be  
3 conducted, specifying different standards  
4 and procedures depending on the degree of  
5 containment for that product and the like-  
6 lihood of the product to enter the food sup-  
7 ply;

8 “(v)(I) the kinds of surveillance that  
9 are needed to ensure that appropriate seg-  
10regation of split use foods is being main-  
11tained;

12 “(II) the manner in which and by  
13whom the surveillance shall be conducted;  
14and

15 “(III) the manner in which the results  
16of surveillance shall be reported; and

17 “(vi) clarification of responsibility in  
18cases of breakdown of segregation of a  
19split use food.

20 “(C) RECALL AUTHORITY.—The regula-  
21tions shall provide that, in addition to other au-  
22thority that the Secretary has regarding split  
23use food, the Secretary may order a recall of  
24any split use food (whether or not the split use

1 food has been approved under this section)  
2 that—

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

5 “(ii) has entered the food supply in  
6 violation of a condition of restriction under  
7 an approval.

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

14 “(d) REVIEW.—

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

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

23 “(B) if the Secretary determines that the  
24 producer submitted adequate information—

1 “(i) provide public notice regarding  
2 the initiation of the consultation and ap-  
3 proval process;

4 “(ii) make the notice, application,  
5 summaries submitted by the producer, and  
6 research, test results, and other informa-  
7 tion referenced by the producer publicly  
8 available, including, to the maximum ex-  
9 tent practicable, publication in the Federal  
10 Register and on the Internet; and

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

14 “(2) EXCEPTION.—The Secretary may withhold  
15 information in an application from public dissemina-  
16 tion to protect a trade secret if—

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

20 “(B) the applicant—

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

1 “(ii) provides the Secretary with a de-  
2 tailed justification for each trade secret  
3 claim; and

4 “(C) the Secretary—

5 “(i) determines that the information  
6 qualifies as a trade secret subject to with-  
7 holding from public dissemination; and

8 “(ii) makes the determination avail-  
9 able to the public.

10 “(3) DETERMINATION.—Not later than 180  
11 days after receiving the application, the Secretary  
12 shall issue and make publicly available a determina-  
13 tion that—

14 “(A) summarizes the information ref-  
15 erenced by the producer in light of the public  
16 comments; and

17 “(B) contains a finding that the genetically  
18 engineered food—

19 “(i) is safe and may be introduced  
20 into interstate commerce;

21 “(ii) is safe under specified conditions  
22 of use and may be introduced into inter-  
23 state commerce if those conditions are met;  
24 or

1 “(iii) is not safe and may not be in-  
2 troduced into interstate commerce, because  
3 the genetically engineered food—

4 “(I) contains genes that confer  
5 antibiotic resistance;

6 “(II) contains an allergen; or

7 “(III) presents 1 or more other  
8 safety concerns described by the Sec-  
9 retary.

10 “(4) EXTENSION.—The Secretary may extend  
11 the period specified in paragraph (3) if the Secretary  
12 determines that an extension of the period is nec-  
13 essary to allow the Secretary to—

14 “(A) review additional information; or

15 “(B) address 1 or more issues or concerns  
16 of unusual complexity.

17 “(e) RESCISSION OF APPROVAL.—

18 “(1) RECONSIDERATION.—On the petition of  
19 any person, or on the Secretary’s own motion, the  
20 Secretary may reconsider an approval of a geneti-  
21 cally engineered food on the basis of information  
22 that was not available before the approval.

23 “(2) FINDING FOR RECONSIDERATION.—The  
24 Secretary shall conduct a reconsideration on the

1 basis of the information described in paragraph (1)  
2 if the Secretary finds that the information—

3 “(A) is scientifically credible;

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

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

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

12 “(3) INFORMATION FROM THE PRODUCER.—In  
13 conducting the reconsideration, the Secretary may  
14 require the producer to provide information needed  
15 to facilitate the reconsideration.

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

19 “(A) revises the finding made in connec-  
20 tion with the approval with respect to the safety  
21 of the genetically engineered food; or

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

24 “(5) ACTION BY THE SECRETARY.—If, based on  
25 a reconsideration under this section, the Secretary



1 determines that the genetically engineered food is  
2 not safe, the Secretary shall—

3 “(A) rescind the approval of the genetically  
4 engineered food for introduction into interstate  
5 commerce;

6 “(B) recall the genetically engineered food;  
7 or

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

10 “(f) EXEMPTIONS.—

11 “(1) IN GENERAL.—The Secretary may by reg-  
12 ulation exempt a category of genetically engineered  
13 food from the regulations under subsection (b) if the  
14 Secretary determines that the category of food does  
15 not pose a food safety risk.

16 “(2) REQUIREMENTS.—A regulation under  
17 paragraph (1) shall—

18 “(A) contain a narrowly specified defini-  
19 tion of the category that is exempted;

20 “(B) describe with specificity the geneti-  
21 cally engineered foods that are included in the  
22 category; and

23 “(C) describe with specificity the genes,  
24 proteins, and adjunct technologies (including  
25 use of markers or promoters) that are involved

1           in the genetic engineering of the foods included  
2           in the category.

3           “(3) PUBLIC COMMENT.—The Secretary shall  
4       provide an opportunity for the submission of com-  
5       ments by interested persons on a proposed regula-  
6       tion under paragraph (1).

7   **“SEC. 422. MARKETPLACE TESTING.**

8       “(a) IN GENERAL.—The Secretary, in consultation  
9       with the Secretary of Agriculture and the Administrator  
10      of the Environmental Protection Agency, shall establish  
11      a program to conduct testing that the Secretary deter-  
12      mines to be necessary to detect, at all stages of production  
13      and distribution (from agricultural production to retail  
14      sale), the presence of genetically engineered ingredients in  
15      food.

16      “(b) PERMISSIBLE TESTING.—Under the program,  
17      the Secretary may conduct tests on foods to detect geneti-  
18      cally engineered ingredients—

19           “(1) that have not been approved for use under  
20       this Act, including foods that are developed in for-  
21       eign countries that have not been approved for mar-  
22       keting in the United States under this Act; or

23           “(2) the use of which is restricted under this  
24       Act (including approval for use as animal feed only,

1 approval only if properly labeled, and approval for  
2 growing or marketing only in certain regions).

3 **“SEC. 423. REGISTRY.**

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

11 “(b) REQUIREMENTS.—The registry under sub-  
12 section (a) shall contain, for each genetically engineered  
13 food—

14 “(1) the technical and common names of the  
15 genetically engineered food;

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

20 “(3) a technical and nontechnical summary of  
21 the type of, and a statement of the reason for, each  
22 genetic manipulation made to the genetically engi-  
23 neered food;

24 “(4) the name, title, address, and telephone  
25 number of an official at each producer of the geneti-

1 cally engineered food whom members of the public  
2 may contact for information about the genetically  
3 engineered food;

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

10 “(6) such other information as the Secretary  
11 determines should be included.

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

15 **SEC. 5. GENETICALLY ENGINEERED ANIMALS.**

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

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

20 “(a) IN GENERAL.—Section 512 shall apply to ge-  
21 netic engineering techniques intended to be used to  
22 produce an animal, and to genetically engineered animals,  
23 as provided in this section.

24 “(b) APPLICATION.—An application under section  
25 512(b)(1) shall include—

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

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

11          “(3) a plan to eliminate or mitigate the poten-  
12          tial effects to the environment from the release of  
13          the genetically engineered animal.

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

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

18                         “(A) provide public notice regarding the  
19                         application, including making the notice avail-  
20                         able on the Internet;

21                         “(B) make the application and all sup-  
22                         porting material available to the public, includ-  
23                         ing availability on the Internet; and

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

4           “(2) EXCEPTION.—

5           “(A) IN GENERAL.—The Secretary may  
6           withhold information in an application from  
7           public dissemination to protect a trade secret  
8           if—

9                   “(i) the information is exempt from  
10                  disclosure under section 522 of title 5,  
11                  United States Code, or applicable trade se-  
12                  cret law;

13                  “(ii) the applicant—

14                          “(I) identifies with specificity the  
15                          trade secret information in the appli-  
16                          cation; and

17                          “(II) provides the Secretary with  
18                          a detailed justification for each trade  
19                          secret claim; and

20                  “(iii) the Secretary—

21                          “(I) determines that the informa-  
22                          tion qualifies as a trade secret subject  
23                          to withholding from public dissemina-  
24                          tion; and

1                   “(II) makes the determination  
2                   available to the public.

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

11                  “(d) DENIAL OF APPLICATION.—Under section  
12 512(d)(1), the Secretary shall deny an application if—

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

15                  “(2) the plan to eliminate or mitigate the po-  
16                  tential environmental effects to the environment  
17                  from the release of the genetically engineered animal  
18                  does not adequately protect the environment.

19                  “(e) ENVIRONMENTAL ASSESSMENT.—

20                  “(1) IN GENERAL.—Before determining wheth-  
21                  er to approve an application under section 512 for  
22                  approval of a genetic engineering technique intended  
23                  to be used to produce an animal, or of a genetically  
24                  engineered animal, the Secretary shall—

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

5           “(B) determine that the genetically engi-  
6           neered animal will not have an unreasonable  
7           adverse effect on the environment.

8           “(2) CONSULTATION.—In conducting an envi-  
9           ronmental assessment under paragraph (1), the Sec-  
10          retary may consult, as appropriate, with the Depart-  
11          ment of Agriculture, the United States Fish and  
12          Wildlife Service, and any other Federal agency that  
13          has expertise relating to the animal species that is  
14          the subject of the application.

15          “(f) SAFETY DETERMINATION.—In determining the  
16          safety of a genetic engineering technique or genetically en-  
17          gineered animal, the Secretary shall consider the potential  
18          effects of the genetically engineered animal on the environ-  
19          ment, including the potential effect on nongenetically engi-  
20          neered animals.

21          “(g) PROGENY.—If an application for approval of a  
22          genetic engineering technique to produce an animal of a  
23          species or other taxonomic classification, or genetically en-  
24          gineered animal, has been approved, no additional applica-  
25          tion shall be required for animals of that species or other



1 taxonomic classification produced using that genetic engi-  
2 neering technique or for the progeny of that genetically  
3 engineered animal.

4 “(h) CONDITIONS OF APPROVAL.—The Secretary  
5 may require as a condition of approval of an application  
6 that any producer of a genetically engineered animal that  
7 is the subject of the application—

8 “(1) take specified actions to eliminate or miti-  
9 gate any potential harm to the environment that  
10 would be caused by a release of the genetically engi-  
11 neered animal, including actions specified in the plan  
12 submitted by the applicant; and

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

16 “(i) RECALL; SUSPENSION OF APPROVAL.—

17 “(1) RECALL.—The Secretary may order a re-  
18 call of any genetically engineered animal (whether or  
19 not the genetically engineered animal, or a genetic  
20 engineering technique used to produce the geneti-  
21 cally engineered animal, has been approved) that the  
22 Secretary determines is harmful to—

23 “(A) humans;

24 “(B) the environment;

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

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

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

9           “(A) immediately suspend the approval of  
10          application for the genetically engineered ani-  
11          mal;

12          “(B) give the applicant prompt notice of  
13          the action; and

14          “(C) afford the applicant an opportunity  
15          for an expedited hearing.

16          “(j) RESCISSION OF APPROVAL.—

17          “(1) RECONSIDERATION.—On the motion of  
18          any person, or on the Secretary’s own motion, the  
19          Secretary may reconsider an approval of a genetic  
20          engineering technique or genetically engineered ani-  
21          mal on the basis of information that was not avail-  
22          able during an earlier review.

23          “(2) FINDING FOR RECONSIDERATION.—The  
24          Secretary shall conduct a reconsideration on the

1 basis of the information described in paragraph (1)  
 2 if the Secretary finds that the information—

3 “(A) is scientifically credible;

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

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

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

12 “(3) INFORMATION FROM THE PRODUCER.—In  
 13 conducting the reconsideration, the Secretary may  
 14 require the producer to provide information needed  
 15 to facilitate the reconsideration.

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

19 “(A) revises the finding made in connec-  
 20 tion with the approval with respect to the safety  
 21 of the genetically engineered animal; or

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

24 “(5) ACTION BY THE SECRETARY.—If, based on  
 25 a review under this subsection, the Secretary deter-

1 mines that the genetically engineered animal is not  
2 safe, the Secretary shall—

3 “(A) rescind the approval of the genetic  
4 engineering technique or genetically engineered  
5 animal for introduction into interstate com-  
6 merce;

7 “(B) recall the genetically engineered ani-  
8 mal; or

9 “(C) take such other action as the Sec-  
10 retary determines to be appropriate.”.

11 **SEC. 6. PROHIBITED ACTS.**

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

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

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

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

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

25 “(j) GENETICALLY ENGINEERED FOODS.—

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

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

9   **SEC. 7. TRANSITION PROVISION.**

10          (a) IN GENERAL.—A genetic engineering technique,  
11          genetically engineered animal, or genetically engineered  
12          food that entered interstate commerce before the date of  
13          enactment of this Act shall not require approval under the  
14          Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301  
15          et seq.), but shall be considered to have been so approved,  
16          if—

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

20                    (A) a notice stating that the genetic engi-  
21                    neering technique, genetically engineered ani-  
22                    mal, or genetically engineered food entered  
23                    interstate commerce before the date of enact-  
24                    ment of this Act, providing such information as  
25                    the Secretary may require; and

1 (B) a request that the Secretary conduct a  
 2 review of the genetic engineering technique, ge-  
 3 netically engineered animal, or genetically engi-  
 4 neered food under subsection (b); and

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

9 (b) REVIEW BY THE SECRETARY.—

10 (1) IN GENERAL.—Not later than 21 months  
 11 after the date on which the Secretary receives a no-  
 12 tice and request for review under subsection (a), the  
 13 Secretary shall review all relevant information in the  
 14 possession of the Secretary, all information provided  
 15 by the producer, and other relevant public informa-  
 16 tion to determine whether a review of new scientific  
 17 information is necessary to ensure that the genetic  
 18 engineering technique, genetically engineered animal,  
 19 or genetically engineered food is safe.

20 (2) NOTICE THAT APPLICATION IS RE-  
 21 QUIRED.—If the Secretary determines that new sci-  
 22 entific information is necessary to determine whether  
 23 a genetic engineering technique, genetically engi-  
 24 neered animal, or genetically engineered food is safe,  
 25 the Secretary, not later than 2 years after the date

1 of enactment of this Act, shall issue to the producer  
 2 a notice stating that the producer is required to sub-  
 3 mit an application for approval of the genetic engi-  
 4 neering technique, genetically engineered animal, or  
 5 genetically engineered food under the Federal Food,  
 6 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

7 (c) FAILURE TO SUBMIT APPLICATION.—

8 (1) IN GENERAL.—Except as provided in para-  
 9 graph (2), a genetically engineered animal or geneti-  
 10 cally engineered food with respect to which the Sec-  
 11 retary issues a notice that an application is required  
 12 under subsection (b)(2) shall be considered adulter-  
 13 ated under section 402 or 501, as the case may be,  
 14 of the Federal Food, Drug, and Cosmetic Act (21  
 15 U.S.C. 342, 351) unless—

16 (A) not later than 45 days after the pro-  
 17 ducer receives the notice, the producer submits  
 18 an application for approval; and

19 (B) the Secretary approves the application.

20 (2) PENDING APPLICATION.—A genetically en-  
 21 gineered animal or genetically engineered food with  
 22 respect to which the producer submits an application  
 23 for approval shall not be considered to be adulter-  
 24 ated during the pendency of the application.

1 **SEC. 8. REPORTS.**

2 (a) IN GENERAL.—Not later than 2 years, 4 years,  
3 and 6 years after the date of enactment of this Act, the  
4 Secretary and the heads of other Federal agencies, as ap-  
5 propriate, shall jointly submit to Congress a report on ge-  
6 netically engineered animals, genetically engineered foods,  
7 and genetic engineering techniques.

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

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

13 (2) a summary (including discussion of new de-  
14 velopments and trends) of the legal status and ac-  
15 ceptability of genetically engineered foods in major  
16 markets, including the European Union and Japan;

17 (3) information on current and emerging issues  
18 of concern relating to genetic engineering tech-  
19 niques, including issues relating to—

20 (A) the ecological impact of, antibiotic  
21 markers for, insect resistance to, nongermi-  
22 nating or terminator seeds for, or cross-species  
23 gene transfer for genetically engineered foods;

24 (B) foods from genetically engineered ani-  
25 mals;



1 (C) nonfood crops (such as cotton) pro-  
2 duced using a genetic engineering technique;  
3 and

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

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

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

17 (6) a projection of—

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

23 (B) the adequacy of the resources of the  
24 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.

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