

HOUSE BILL NO. 409
INTRODUCED BY R. LENHART

A BILL FOR AN ACT ENTITLED: "AN ACT PROVIDING FOR THE CREATION OF THE MONTANA WHEAT PROTECTION AND PROMOTION ACT; DEFINING TERMS RELATIVE TO GENETICALLY ENGINEERED WHEAT VARIETY INTRODUCTION IN MONTANA; PROVIDING FOR THE ADOPTION OF RULES BY THE DEPARTMENT OF AGRICULTURE; ALLOWING THE DEPARTMENT TO ACCEPT FUNDS FOR THE PURPOSES OF THE ACT; CREATING A GENETICALLY ENGINEERED WHEAT CERTIFICATION ACCOUNT IN THE STATE SPECIAL REVENUE FUND; PROVIDING PUBLIC NOTICE REQUIREMENTS; REQUIRING THAT A CERTIFICATE BE OBTAINED PRIOR TO THE INTRODUCTION OF A GENETICALLY ENGINEERED WHEAT VARIETY IN MONTANA; REQUIRING AN APPLICANT FOR A CERTIFICATE TO SHOW PROOF OF FINANCIAL RESPONSIBILITY; EXEMPTING TEST PLOTS OF CERTAIN ENTITIES FROM CERTIFICATION REQUIREMENTS; PROVIDING AN APPLICATION PROCESS; PROVIDING FOR AMENDMENTS TO AN APPLICATION OR CERTIFICATE AND THE SUBMISSION OF SUPPLEMENTAL MATERIAL; PROVIDING FOR A FILING FEE AND THE USE OF THOSE FEES; PROVIDING FOR A REVIEW OF THE APPLICATION FOR COMPLETENESS BY THE DEPARTMENT; REQUIRING A STUDY, EVALUATION, REPORT, AND ENVIRONMENTAL REVIEW BY THE DEPARTMENT; PROVIDING FOR PUBLIC HEARINGS AND A PUBLIC RECORD; PROVIDING FOR THE FINDINGS NECESSARY FOR A FINAL DECISION BY THE DIRECTOR REGARDING AN APPLICATION; ALLOWING FOR AN ADDITIONAL REVIEW OF THE APPLICATION OR CERTIFICATE IF THERE IS CAUSE; GIVING THE DEPARTMENT THE RIGHT TO ACCESS PROPERTY FOR INSPECTION PURPOSES; ALLOWING FOR THE REVOCATION OR SUSPENSION OF A CERTIFICATE AND THE DESTRUCTION OF CROPS OR SEEDS THAT ARE GENETICALLY ENGINEERED; REQUIRING THE DEPARTMENT TO ESTABLISH A REGISTRY FOR GENETICALLY ENGINEERED WHEAT VARIETIES; PROVIDING FOR CIVIL AND CRIMINAL PENALTIES; AND PROVIDING AN IMMEDIATE EFFECTIVE DATE."

WHEREAS, it is the declared policy of the state, in Article XII, section 1, of the Montana Constitution to enact laws and provide appropriations to protect, enhance, and develop all agriculture; and

WHEREAS, 60% of Montana's wheat, mixed with wheat from North Dakota, Nebraska, and Colorado, is exported primarily to Japan, the Philippines, South Korea, and Taiwan and each of these countries requires mandatory labeling for even trace amounts of genetically engineered organisms; and

WHEREAS, buyers in Japan, South Korea, and the Philippines have indicated an intolerance for any

genetically engineered crops; and

WHEREAS, if introduced into commercial production in Montana, genetically engineered wheat would be difficult to segregate from conventional and organic wheat varieties, potentially contributing to the loss of overseas markets for one of Montana's major agricultural export crops; and

WHEREAS, it is possible for farmers who do not plant genetically engineered wheat to have their conventional or organic wheat inadvertently contaminated with genetically engineered wheat; and

WHEREAS, genetically engineered grains can complicate weed management; and

WHEREAS, it is the purpose of this legislation to protect Montana agriculture by ensuring that a decision to commercially introduce a genetically engineered wheat variety in Montana is done in a careful, fully informed manner that will not adversely affect Montana agriculture or the Montana economy.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. Section 1. Short title. [Sections 1 through 19] may be cited as the "Montana Wheat Protection and Promotion Act".

NEW SECTION. Section 2. Definitions. As used in [sections 1 through 19], the following definitions apply:

- (1) "Certificate" means the document issued by the department pursuant to [section 7].
- (2) (a) "Commercially introduce a genetically engineered wheat variety" means to:
 - (i) sell, license, or market a genetically engineered wheat variety in this state; or
 - (ii) bring into this state any genetically engineered wheat variety for the purpose of planting, licensing, or marketing.
- (b) The term does not include:
 - (i) research projects on genetically engineered wheat varieties being conducted by state and federal agencies, a unit of the Montana university system, and bona fide nonprofit research organizations or their agents, provided that the research organization complies with [section 8]; or
 - (ii) genetically engineered wheat varieties being moved or transported through the state with no intent to unload or deliver in the state, provided that the genetically engineered wheat variety is packaged in hermetically sealed containers.
- (3) "Director" means the director of the department of agriculture appointed pursuant to 2-15-3001.

(4) "Genetically engineered wheat variety" means wheat:

(a) altered at the molecular or cellular level by means that are not possible under natural conditions or processes, including but not limited to:

(i) recombinant DNA and RNA techniques;

(ii) cell fusion;

(iii) microencapsulation;

(iv) macroencapsulation;

(v) gene deletion and doubling;

(vi) introducing a foreign gene; and

(vii) changing the positions of genes, other than by a means consisting exclusively of breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture;

(b) made through sexual or asexual reproduction, or both, involving a genetically engineered wheat variety that has been altered as described in subsection (4)(a) if the wheat possesses any of the altered molecular or cellular characteristics of the organism described.

(5) "Person" means an individual, a partnership, a firm, an association, a municipality, a public or private corporation, the state or a subdivision of the state, a trust, an estate, or any other legal entity.

NEW SECTION. Section 3. Adoption of rules by department. (1) The department shall adopt rules to implement the provisions of [sections 1 through 19]. The rules must include but are not limited to:

(a) the content and form of the application;

(b) implementation of a monitoring program; and

(c) the duration of certificates and information on the certification process.

(2) In adopting rules, the department shall use the best science and research available.

NEW SECTION. Section 4. Acceptance and expenditure of gifts and other funds. The department may accept grants, gifts, contract payment, or other funds designated for the purpose of [sections 1 through 19]. The funds must be deposited in the account established in [section 5] and may be expended for the purposes of [sections 1 through 19].

NEW SECTION. Section 5. Genetically engineered wheat certification account. (1) There is an account in the state special revenue fund to be known as the genetically engineered wheat certification account.

(2) The department may direct the board of investments to invest the funds collected under subsection (1) of this section pursuant to the provisions of 17-6-201. The income from the investments must be credited to the account.

(3) There must be deposited in the account:

(a) all revenue from the fees provided for in [section 11]; and

(b) money received by the department in the form of legislative appropriations, reimbursements, federal funds, or appropriations from any source or money received pursuant to [section 4] that is intended to be used for the purposes of [sections 1 through 19].

(4) Funds in the account may be used by the department for the administration and enforcement of [sections 1 through 19].

NEW SECTION. Section 6. Public notice requirements. (1) The department shall give public notice when the following actions have occurred:

(a) an application has been submitted pursuant to [section 9];

(b) an application for amendment of an application or a certificate has been submitted pursuant to [section 10];

(c) the department's study pursuant to [section 12] has been completed and is available to the public;

(d) the director has scheduled a public hearing pursuant to [section 13 or 14];

(e) the director has issued a final decision on an application for a certificate pursuant to [section 14];

(f) the director has received a request for an additional review for cause pursuant to [section 15]; or

(g) the director has issued a response to the request for additional review for cause pursuant to [section 15].

(2) Public notice of activities described in subsection (1) must be given by the following methods:

(a) mailing a copy of a notice to the following:

(i) the applicant;

(ii) persons on a mailing list developed by:

(A) including those who request in writing to be on the list;

(B) soliciting persons for the mailing list from participants in past certification proceedings; and

(C) notifying the public of the opportunity to be put on the mailing list through periodic publication in the public press and in regional and state newsletters, bulletins, or state law journals;

(b) publishing a notice in the major daily newspapers of general circulation within the state; and

(c) any other method reasonably calculated to give actual notice of the action in question to a person potentially affected by the action, including press releases or any other forum or medium designed to elicit public participation.

(3) The department may update the mailing list in subsection (2)(a)(ii) by requesting written indication of continued interest from those persons currently on the list. The department may delete from the list the name of any person who fails to respond.

NEW SECTION. Section 7. Certificate required -- financial responsibility. (1) A person may not commercially introduce a genetically engineered wheat variety in Montana unless:

(a) the company owning the patent on the genetically engineered wheat variety has obtained a certificate from the department; and

(b) the applicant has furnished proof of financial responsibility as provided in subsection (2).

(2) Proof of financial responsibility must be furnished by an applicant by showing, to the satisfaction of the department, the applicant's ability to pay for damages as a result of liability that might reasonably be attached to or result from the commercial introduction of the genetically engineered wheat variety proposed to be certified pursuant to [sections 1 through 19].

NEW SECTION. Section 8. Exemption for test plots. A certificate provided for in [section 7] is not required for research projects on genetically engineered wheat varieties being conducted by state and federal agencies, a unit of the Montana university system, or bona fide nonprofit research organizations and their agents, provided that the research entity:

(1) files a research plan with the biosafety committee of Montana state university-Bozeman or a similar entity created by the department that accurately describes the location of each field experiment, provides an accurate and complete experiment plan, and updates that plan when seeding is performed and harvesting is completed. The research plan is public information except for any portion that is determined by the department to be a trade secret as defined in 30-14-402.

(2) allows the biosafety committee or a similar entity created by the department unimpeded access to each experiment;

(3) provides no less than a 300-foot buffer zone between the test crops and other adjacent crops;

(4) notifies any person growing crops within 1 mile of the test plot that the test plot exists and provides that person with a copy of the research plan described in subsection (1);

(5) complies with the provisions of the federal Plant Protection Act, 7 U.S.C. 7701 through 7758, regulations adopted pursuant to 7 CFR parts 319, 330, 340, and 360, and any other law or regulation concerning the introduction of organisms and products altered or produced through genetic engineering.

NEW SECTION. Section 9. Application -- filing and contents. (1) A person seeking a certificate for commercial production of a genetically engineered wheat variety as provided in [section 7] shall file an application with the department on forms provided or approved by the department. The application must contain the following information:

- (a) identification of the genetically engineered wheat variety, including:
 - (i) a description of each type of genetic modification made to the genetically engineered wheat variety;
 - (ii) identification of the introduced or altered genetic materials; and
 - (iii) the techniques used in making the modification;
- (b) the effect of the genetic modification on the composition of the genetically engineered wheat variety, including information on specific substances and traits expressed, removed, or altered as a result of the modification;
- (c) a description of the actual or proposed applications and uses of the genetically engineered wheat variety;
- (d) information establishing:
 - (i) that the marketability in foreign and domestic markets of the genetically engineered wheat variety as a whole is equivalent to that of comparable conventional wheat varieties;
 - (ii) the ability to segregate the genetically engineered wheat from conventional and organic wheat varieties in all wheat production channels, including but not limited to seedstock production, commercial production on farms, harvesting, custom harvesting, on-farm storage, commercial storage, transport, and processing;
 - (iii) the demonstrable value of the genetically engineered wheat variety to producers, consumers, and the Montana economy;
- (e) identification of any specific substances introduced or altered as a result of the genetic modification, including information on allergenicity and toxicity;
- (f) a summary and overview of issues that have been or will be addressed by other regulatory programs for the review of the genetically engineered wheat variety;
- (g) a feasibility analysis that describes the manner in which the genetically engineered wheat variety will

be:

(i) prevented from entering markets in countries or other jurisdictions where the sale of the genetically engineered food is not approved or legal or where the genetically engineered food is not or otherwise marketable; and

(ii) marketed to prevent the inadvertent introduction of the genetically engineered trait carried by the genetically engineered wheat variety into any seed, plant, animal, or other organism that is not specifically designed to incorporate the trait;

(h) a summary of each research study, test result, and other material referenced by the applicant; and

(i) other information that the applicant considers relevant or that the department by order or rule may require.

(2) The department may require that copies of the studies, test results, and other materials referred to in subsection (1)(h) be filed with the department, and any copies filed with the department must be available to the public for inspection.

(3) If the application does not contain the information required in this section, the application is void.

NEW SECTION. Section 10. Amendment to application or certificate -- supplemental material. (1)

An application for an amendment to an application or a certificate must be in a form and contain information as prescribed by the department by rule.

(2) An application may be amended by an applicant any time prior to the report made by the department under [section 12]. If the proposed amendment is a major amendment as determined by the department, the department may require additional filing fees or may require a new application and filing fee.

(3) The applicant shall submit supplemental material in a timely manner as requested by the department or as offered by the applicant to explain, support, or provide details with respect to an item described in the original application. The supplemental material may be submitted without filing an application for an amendment. The department's determination as to whether information is supplemental or whether an application for amendment is required is conclusive.

NEW SECTION. Section 11. Filing fee -- accountability -- use of funds. (1) The department shall by rule establish a filing fee for applications that is commensurate with the costs of enforcing and administering [sections 1 through 19]. The filing fee must be deposited in the account provided for in [section 5] for use by the department in administering and enforcing [sections 1 through 19]. Failure to pay the filing fee voids the

application.

(2) The revenue derived from the filing fees must be deposited in the account provided for in [section 5] and may be used by the department for administration and enforcement of [sections 1 through 19].

NEW SECTION. Section 12. Completeness review -- study -- evaluation -- report -- environmental review. (1) After receipt of an application, the department shall notify the applicant within 90 days that:

- (a) the application is accepted as complete; or
- (b) the application is not complete and list the deficiencies.

(2) If the application is not complete as provided in subsection (1)(b) and is returned to the applicant, the applicant shall correct the deficiencies and resubmit the application to the department. The department shall notify the applicant in writing within 30 days regarding the completeness of the resubmitted application. If the application is still not complete, the applicant shall correct the deficiencies outlined by the department and resubmit the application a third time.

(3) If, after the resubmission of two consecutive applications, the department determines that the third application is still incomplete, the department shall void the application.

(4) Upon receipt of an application complying with [section 9], the department shall commence an intensive study and evaluation of the application and the effects of allowing the introduction of a genetically engineered wheat variety, considering all applicable criteria provided in [section 14]. The department shall also evaluate the possibility of export market premiums for Montana producers who do not produce a genetically engineered wheat variety. The department shall use, to the extent it considers applicable, valid and useful existing studies, data, and reports submitted by the applicant or an interested person or compiled by a state or federal agency.

(5) (a) The department shall conduct an environmental review pursuant to Title 75, chapter 1, parts 1 through 3.

(b) The department may adopt rules prescribing fees for the completion of the environmental review as provided in 75-1-202 and 75-1-203.

(6) After the department has accepted a complete application and after the department has completed its intensive study and evaluation described in subsection (4) and the environmental review pursuant to subsection (5), the department shall make a report to the director that must contain the department's studies, evaluations, recommendations, environmental review, and other pertinent documents resulting from its study, evaluation, and environmental review.

NEW SECTION. Section 13. Hearing date -- locations -- record. (1) Upon receipt of the department's report pursuant to [section 12], the director shall set the dates for a minimum of two hearings to begin not less than 30 days or more than 120 days after receipt of the report by the director. The director shall preside over the hearings.

(2) The department shall hold one hearing in Helena. The department shall hold one or more hearings in the major wheat-producing areas of the state.

(3) Any studies, investigations, reports, or other documentary evidence, including those prepared by the department, that any person wishes the director to consider or that the director expects to use or rely upon must be made a part of the record.

(4) A record must be made of the hearing and of all testimony taken. The record must be made available to the public within a reasonable timeframe.

NEW SECTION. Section 14. Decision of director -- findings necessary for certification. (1) (a) Within 90 days after the public hearing described in [section 13], the director shall make complete findings and render a final decision upon the record, either granting or denying the application for a certificate. The findings and the final decision must be in writing.

(b) A decision granting a certificate may be made in the following manner:

(i) the application may be approved as filed; or

(ii) the application may be approved with terms, conditions, or modifications considered appropriate and necessary by the director.

(2) The director may not grant a certificate either as proposed by the applicant or as modified by the director unless the director finds and determines that:

(a) the department has received adequate information to enable the director to fully assess the potential impacts of commercial use of the genetically engineered wheat variety; and

(b) issuing the certificate will result in important economic development and the benefits of issuing the certificate exceed any costs to agriculture and the Montana economy.

(3) In determining whether the benefits of issuing the certificate outweigh any costs to agriculture and the Montana economy, the director shall consider:

(a) whether the marketability in foreign and domestic markets of the genetically engineered wheat variety is equivalent to or greater than that of comparable wheat varieties;

(b) whether the genetically engineered wheat variety can be effectively segregated from conventional

and organic wheat varieties in all production channels, including but not limited to seedstock production, commercial production, harvesting, custom harvesting, on-farm storage, commercial storage, transport, and processing;

(c) the demonstrable value of the genetically engineered wheat variety to producers, consumers, and the Montana economy;

(d) whether any traits or substances introduced or altered as a result of the genetic modification will result in a threat to public health and safety or noxious weed management;

(e) whether the inadvertent introduction of the genetically engineered trait into other seeds, plants, animals, or organisms, other than those specifically designed to incorporate the trait, can be prevented;

(f) whether Montana wheat producers will lose the export market or suffer from a reduced export market for their product; and

(g) any other factors that the director considers relevant.

NEW SECTION. Section 15. Review for cause -- hearing. (1) Any person may request that the director conduct an additional review and hearing on the basis of information that was not available during the original review or that was not considered during the review.

(2) The department shall conduct an additional review on the basis of the information described in subsection (1) if the director finds that the information:

(a) is credible and represents significant information that was not available or was not considered during the earlier review;

(b) suggests potential negative impacts relating to the genetically engineered wheat variety that were not considered in the earlier review; or

(c) demonstrates that the information considered during the earlier review was inadequate for the director to make findings and a final decision pursuant to [section 14].

(3) In conducting the review, the director shall issue a response to the information submitted under this section that:

(a) revises the director's findings and decision pursuant to [section 14] and amends or voids the certificate; or

(b) determines that no revision or voiding of the certificate is needed and includes a statement of the basis for the determination.

(4) The director shall hold a hearing to receive public comment on the new information prior to issuing

a response as provided in subsection (3).

NEW SECTION. Section 16. Right to inspect. (1) The department has the right to access property that is or has been planted with a genetically engineered wheat variety that is subject to a certificate for the purposes of ensuring that the terms and conditions of the certificate are being followed.

(2) Failure to allow access to property may result in the revocation of the certificate pursuant to [section 17].

NEW SECTION. Section 17. Revocation or suspension of certificate -- destruction of seeds or crop -- liability of certificate holder. (1) A certificate may be revoked or suspended by the department, following notice and an opportunity for a hearing before the director, for:

(a) any materially false statement in the application or in accompanying statements or studies required by the applicant if a true statement would have warranted the director's refusal to grant a certificate;

(b) failure to comply with the terms or conditions of the certificate;

(c) reasons identified in the review under [section 15];

(d) violation of any provisions of [sections 1 through 19], rules adopted pursuant to [sections 1 through 19], or orders of the department; or

(e) failure to allow access to property currently planted with a genetically engineered wheat variety for the purpose of inspection as provided in [section 16].

(2) (a) When a certificate is revoked, the department shall take appropriate action or require the certificate holder to take appropriate action to destroy the crop or any seeds of the genetically engineered wheat variety.

(b) The department shall develop by rule appropriate actions for destruction of a genetically engineered wheat variety depending on the type of genetic engineering that was conducted.

(3) The certificate holder is liable for any damages suffered by a producer that are the result of the revocation of the certificate or the destruction of the crop or seeds.

NEW SECTION. Section 18. Registry. (1) The department shall establish a registry that contains a description of the regulatory status of all genetically engineered wheat varieties that have been submitted to the department for certification and that contains:

(a) the technical and common names of each of the genetically engineered wheat varieties;

- (b) a description of the regulatory status of each of the genetically engineered wheat varieties under all relevant federal programs pertaining to the testing and approval of genetically engineered foods;
 - (c) a technical and nontechnical summary of the types of genetic changes made to each of the genetically engineered wheat varieties and the reasons for the changes;
 - (d) identification of an appropriate public contact person for each entity that has created each of the genetically engineered wheat varieties; and
 - (e) identification of an appropriate public contact person at the department with oversight responsibility over the genetically engineered wheat varieties.
- (2) The department shall make the registry available and accessible to the public.

NEW SECTION. Section 19. Civil penalties for violation -- exemption. (1) (a) A person who introduces a genetically engineered wheat variety into commercial production without obtaining a certificate required under [section 7], who introduces a genetically engineered wheat variety into commercial production other than in compliance with the certificate or violates any other provisions of [sections 1 through 19] or any rule or order adopted pursuant to [sections 1 through 19], or who knowingly submits false information in any report or application required by [sections 1 through 19] is liable for a civil penalty not to exceed \$25,000 for each violation.

- (b) Each day of a continuing violation constitutes a separate offense.
 - (c) The penalty is recoverable in a civil suit brought by the attorney general on behalf of the state in the district court of the first judicial district, Lewis and Clark County.
- (2) In addition to any penalty provided in subsection (1), whenever the department determines that a person is violating or is about to violate any of the provisions of [sections 1 through 19], it may refer the matter to the attorney general who may bring a civil action on behalf of the state in the district court of the first judicial district, Lewis and Clark County, for injunctive or other appropriate relief against the violation and to enforce [sections 1 through 19] or a certificate issued pursuant to [section 7]. Upon a proper showing, a permanent or preliminary injunction or temporary restraining order must be granted.
- (3) The department shall enforce [sections 1 through 19] and may bring civil actions for enforcement.
 - (4) All civil fines and penalties collected must be deposited in the account provided for in [section 5].
 - (5) Persons whose crops or seeds have been contaminated with a genetically engineered wheat variety through no fault of their own are not subject to the penalties provided in this section.

NEW SECTION. **Section 20. Codification instruction.** [Sections 1 through 19] are intended to be codified as an integral part of Title 80, chapter 5, and the provisions of Title 80, chapter 5, apply to [sections 1 through 19].

NEW SECTION. **Section 21. Severability.** If a part of [this act] is invalid, all valid parts that are severable from the invalid part remain in effect. If a part of [this act] is invalid in one or more of its applications, the part remains in effect in all valid applications that are severable from the invalid applications.

NEW SECTION. **Section 22. Effective date.** [This act] is effective on passage and approval.

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