

1989 Assembly Bill 14

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1989 WISCONSIN ACT 15

AN ACT to create 146.60 of the statutes, relating to: notification of the release into the environment of genetically engineered organisms and providing penalties.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 146.60 of the statutes is created to read:

146.60 Notice of release of genetically engineered organisms into the environment. (1) DEFINITIONS. In this section:

(a) "Confidential information" means information entitled to confidential treatment under sub. (6) (a) 1. or 2.

(b) "Coordinated framework" means the coordinated framework for regulation of biotechnology set forth in 51 CFR 23302 to 23350 (June 26, 1986), as amended by 52 CFR 22892 to 22915 (June 16, 1987), and subsequent amendments to the coordinated framework for regulation of biotechnology.

(c) "Departments" means the department of agriculture, trade and consumer protection and the department of natural resources.

(d) "Federal regulator" means a federal agency or a designee of a federal agency which is responsible for regulating a release into the environment under the coordinated framework.

(e) "Regulated release" means a release into the environment for which the coordinated framework requires that the person proposing to commence the release into the environment do any of the following:

1. Notify a federal regulator of the release into the environment.

2. Secure the approval of or a permit or license from a federal regulator as a condition of commencing the release into the environment.

3. Secure a determination by a federal regulator of the need for notification, approval, licensing or permitting by the federal regulator, if the determination is part of a procedure specified in the coordinated framework.

(f) "Release into the environment" means the introduction or use in this state of an organism or pathogen anywhere except within an indoor facility which is designed to physically contain the organism or pathogen, including a laboratory, greenhouse, growth chamber or fermenter.

(g) "Reviewing department" means the department designated in sub. (2) to review a regulated release.

(2) DEPARTMENT DESIGNATION. (a) The department of natural resources shall be the reviewing department for any regulated release subject to 15 USC 2601 to 2629.

(b) The department of agriculture, trade and consumer protection shall be the reviewing department for any regulated release subject to any federal requirement in the coordinated framework, except a requirement under 15 USC 2601 to 2629.

(c) If a regulated release is subject to 15 USC 2601 to 2629 and to any other federal requirement in the coordinated framework, both departments shall be reviewing departments and shall enter into a memorandum of understanding designating one of them to be the lead reviewing department.

(3) NOTIFICATION. (a) Except as provided under sub. (7), no person may commence a regulated release unless the person provides to the reviewing department for that regulated release all of the following information within 7 days after the person submits or should have submitted

the information specified in subd. 1 to a federal regulator, whichever is sooner:

1. A copy of all information which the person is required to submit to the federal regulator and which is not confidential information.

2. A summary of any confidential information which the person submits or is required to submit to a federal regulator. The summary shall be sufficient enough to enable the reviewing department to prepare the comment authorized under sub. (4) and to provide information to the public and shall have minimal extraneous and irrelevant information.

(b) A reviewing department may request that a person submit to it part or all of any of the confidential information that is the subject of the summary submitted to that reviewing department under par. (a) 2. That person shall submit the information to the reviewing department no later than 3 working days after receiving the request.

(c) Notwithstanding sub. (6) (a):

1. If the department of natural resources receives information under this subsection or sub. (4) (c), it shall provide the department of agriculture, trade and consumer protection with a copy of the information.

2. If the department of agriculture, trade and consumer protection receives information under this subsection or sub. (4) (c), it shall provide the department of natural resources with a copy of the information.

(3m) PUBLIC NOTICE. No later than 5 working days after receiving information under sub. (3), the reviewing department shall send written notice of receipt of the information to the county board chairperson in a county without a county executive or county administrator or the county executive or county administrator and to the town board chairperson, village president or mayor of any town, village or city in which the release is proposed. No later than 5 working days after sending notice under this subsection, the reviewing department shall cause publication of a class 1 notice under ch. 985 in the county to which the notice is sent.

(4) COMMENT. The reviewing department may prepare a formal comment on the regulated release for submission to the federal regulator for that regulated release. The reviewing department shall submit that comment within the time established by the federal regulator for that regulated release. The comment shall address the criteria for notification or the granting of approval, a permit or a license under the applicable requirement in the coordinated framework and for the protection of the public health and the environment. To assist in the preparation of a comment, the reviewing department may do any of the following:

(a) Hold an informational meeting on the proposed regulated release.

(b) Provide an opportunity for the public to comment on the proposed regulated release.

(c) Request information on the proposed regulated release from the person providing the information under sub. (3), in addition to the information provided under sub. (3). That person is not required to submit that information to the reviewing department.

(d) Conduct a technical review of the proposed regulated release.

(e) Seek the assistance of the university of Wisconsin system faculty and academic staff or the department of health and social services in reviewing the proposed regulated release.

(5) MEMORANDUM OF UNDERSTANDING. Within 6 months after the effective date of this subsection ... [revisor inserts date], the department of natural resources shall enter into a memorandum of understanding with the department of agriculture, trade and consumer protection setting forth the procedures and responsibilities of the departments in the administration of this section. The memorandum shall establish procedures that minimize the duplication of effort between the departments and for the person providing information under sub. (3).

(6) CONFIDENTIAL TREATMENT OF RECORDS. (a) Except as provided in pars. (b) and (c), the departments shall keep confidential any information received under this section if the person submitting the information notifies the departments that any of the following applies to that information:

1. The federal regulator to which the information has been submitted has determined that the information is entitled to confidential treatment and is not subject to public disclosure under 5 USC 552 or under the coordinated framework.

2. The person submitting the information to the departments has submitted a claim to the federal regulator that the information is entitled to confidential treatment under 5 USC 552 or under the coordinated framework, and the federal regulator has not made a determination on the claim.

(b) Paragraph (a) shall not prevent the departments from exchanging information under sub. (3) (c) or (4) (c) or from using the information for the purposes of sub. (4) (d) or (e), subject to the requirements under par. (d). Any person receiving such information is subject to the penalty specified under sub. (9) (b) for the unauthorized release of that information.

(c) The departments shall allow public access to any information which has been granted confidentiality under par. (a) if any of the following occurs:

1. The person providing the information to the departments expressly agrees to the public access to the information.

2. After information has been granted confidentiality under par. (a) 2., the federal regulator makes a determination that the information is not entitled to confidential

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treatment under 5 USC 552 or under the coordinated framework.

3. Either of the departments determines that:

a. The person providing the information to the departments has not submitted that information under par. (a) or a claim under par. (a) 2 to the federal regulator; or

b. The federal regulator to which the information has been submitted has determined that the information is not entitled to confidential treatment and is subject to public disclosure under 5 USC 552 or under the coordinated framework.

(d) 1. The departments shall establish procedures to protect information required to be kept confidential under par. (a). Under the procedure, the departments may not submit any information under sub. (4) (d) or (e) to any person who is not an employe of either of the departments unless that person has signed an agreement which satisfies the requirements of subd. 2.

2. The agreement required under subd. 1 shall provide that information which is the subject of the agreement is subject to confidential treatment, shall prohibit the release or sharing of the information with any other person except at the direction of the reviewing department and in compliance with this section, shall acknowledge the penalties in sub. (9), s. 134.90 and any other applicable state law identified by the departments for the unauthorized disclosure of the information and shall contain a statement that the person receiving the information, any member of his or her immediate family or any organization with which he or she is associated has no substantial financial interest in the regulated release which is the subject of the information. Any person submitting the information under sub. (3) or (4) may waive any of the requirements under this subdivision.

(7) EXEMPTIONS. (a) This section does not apply to any of the following which is intended for human use and regulated under 21 USC 301 to 392 or 42 USC 262:

1. Drug.
2. Cosmetic.
3. Medical device.
4. Biological product.

(b) A reviewing department may waive part or all of the requirements under sub. (3) for a specified regulated release if the reviewing department determines that the satisfaction of that requirement is not necessary to protect the public health or the environment.

(c) A reviewing department may exempt a class of regulated releases from part or all of any requirement under sub. (3) if the department determines that the satisfaction of that requirement or part of a requirement is not necessary to protect the public health or the environment.

(8) ENFORCEMENT. The attorney general shall enforce subs. (3) and (6). The circuit court for Dane county or for the county where a violation occurred in whole or in part has jurisdiction to enforce this section by injunctive and other relief appropriate for enforcement. In an enforcement action under this section, if it is determined that a person commenced a regulated release and did not comply with sub. (3), the court shall issue an injunction directing the person to prevent or terminate the regulated release.

(9) PENALTIES. (a) Any person who fails to submit the information required under sub. (3) and has not commenced a regulated release shall forfeit not more than \$100 for each violation. Any person who commences or continues a regulated release without having submitted the information required under sub. (3) shall forfeit not less than \$10 nor more than \$25,000 for each violation. Each day of continued violation under this paragraph is a separate offense.

(ag) Any person who intentionally violates sub. (3) after commencing a regulated release shall be fined not less than \$100 nor more than \$25,000 or imprisoned for not more than one year in the county jail or both.

(am) For a 2nd or subsequent violation under par. (ag), a person shall be fined not less than \$1,000 nor more than \$50,000 or imprisoned for not more than one year or both.

(ao) Each day of continued violation under pars. (ag) and (am) is a separate offense.

(b) Any person who intentionally violates any requirement under sub. (6) (a) or (b) shall be fined not less than \$50 nor more than \$50,000 or imprisoned for not less than one month nor more than 6 months or both.

(bm) In pars. (ag) and (b), “intentionally” has the meaning given under s. 939.23 (3).

(c) Paragraphs (a) and (ag) do not apply to any person who provides the information required under sub. (3) to either of the departments.

(10) RELATION TO OTHER LAWS. The authority, power and remedies provided in this section are in addition to any authority, power or remedy provided in any other statutes or provided at common law.

SECTION 2. Initial applicability. Section 146.60 (3) of the statutes, as created by this act, applies to any regulated release, as defined in section 146.60 (1) (e) of the statutes, as created by this act, for which the initial application for notification, permitting or licensing under the coordinated framework, as defined in section 146.60 (1) (b) of the statutes, as created by this act, is made after the effective date of this SECTION.