LRB-4468/1 MCP:cjs

# **2021 SENATE BILL 894**

February 1, 2022 - Introduced by Senators Felzkowski and Stroebel, cosponsored by Representatives Dallman and Brooks. Referred to Committee on Government Operations, Legal Review and Consumer Protection.

AN ACT to amend 227.135 (5) and 227.19 (3) (intro.); and to create 160.07 (4m),
227.135 (1m), 227.182 and 227.19 (3) (i) of the statutes; relating to: peer review
of administrative rules, comments to proposed statements of scope, and review
of proposed groundwater enforcement standards.

## Analysis by the Legislative Reference Bureau

## Peer review of administrative rules

This bill creates an external peer review process for administrative rules.

Under the bill, an interested party may request an external peer review of a proposed rule at any time before the proposed rule is submitted to the governor for review. An interested party is any person who will be regulated under the proposed rule or any person whose client, member, or customer will be regulated under the proposed rule. The bill also provides that the Joint Committee for Review of Administrative Rules may request an external peer review of a proposed rule or of any agency rule that has been published in the administrative code. Under the bill, if an agency receives a valid request for peer review of a proposed rule or of a rule that has been published in the code, the agency must initiate the external peer review process. A request for peer review may be made only for rules that are based on or that rely on scientific studies, scientific or technical data, scientific methods, or other similar scientific information. A request is valid if it objects to specific studies or scientific or technical data, specific methods, or specific findings, conclusions, or assumptions that the agency used in developing the rule.

The bill provides that an agency that receives a valid request for peer review of a proposed rule may not continue promulgating the proposed rule until the peer review process is complete. Under the bill, the external peer review process must be completed within six months from the date on which the request for peer review was submitted, except that the deadline for completion may be extended by an additional six months if the initial six months is determined to not be feasible. In addition, the bill requires peer review questions and protocols to be approved prior to use in the peer review process by the agency and any parties requesting the peer review.

Under the bill, an agency that receives a valid request for peer review of a rule must contract with the National Academy of Sciences, Toxicology Excellence for Risk Assessment, or any similar independent scientific entity, or with a group of independent scientists of comparable stature and qualifications, to conduct an external peer review of the studies or scientific or technical data, the methods, or the findings, conclusions, or assumptions that the agency used in developing the rule.

Under the bill, a peer reviewer must have expertise in the subject matter of the rule being reviewed. The bill prohibits all of the following people from acting as peer reviewers: a party requesting the peer review, an employee of the agency or of a requesting party, or the spouse or family member of an employee of the agency or of a requesting party; an interested party or an employee of an interested party; a person who is conducting research that is funded by the agency or by a requesting party; or a person who participated in the development of any study or technical or scientific data being reviewed.

Under the bill, once the peer review process is complete, the peer review panel must prepare a final written report that provides one of two conclusions: 1) the rule is scientifically defensible; or 2) the rule is not scientifically defensible, does not comply with state or federal law, or would be scientifically defensible if the agency made certain modifications to the rule. If the peer review panel concludes that a proposed rule is scientifically defensible, the agency may continue to promulgate the proposed rule. If the peer review panel concludes that a proposed rule is not scientifically defensible, does not comply with state or federal law, or would be scientifically defensible if the agency made certain modifications to the proposed rule, the agency must modify the proposed rule as necessary, in cooperation and agreement with the party that requested the peer review, before continuing to promulgate the proposed rule. If the peer review panel concludes that a rule that has been published in the administrative code is not scientifically defensible, does not comply with state or federal law, or would be scientifically defensible if the agency made certain modifications to the code, the agency must initiate the rulemaking process to make necessary modifications to the code.

Under the bill, if the peer review panel concludes that a rule is scientifically defensible, the costs of the peer review process must be paid by the party that submitted the request for peer review. If the peer review panel concludes that a rule is not scientifically defensible, does not comply with state or federal law, or would be scientifically defensible if certain modifications were made, the agency must pay for the costs of the peer review process.

## Soliciting comments on scope statements

The bill also requires an agency, before submitting a statement of scope of a proposed rule to the Department of Administration and to the governor, to solicit and consider comments on the statement of scope from persons who may be regulated under the proposed rule. For rules that will be based on or rely on scientific studies, scientific or technical data, scientific methods, or other similar scientific information, the promulgating agency must incorporate comments into the statement of scope, if the comments are scientifically valid, are supported by relevant industries, and recommend changes that will ensure compliance with relevant state law and will ensure the accuracy, integrity, objectivity, or consistency of data that will be used to promulgate the rule.

## Notice and review of proposed groundwater standards

Under current law, the Department of Health Services develops recommendations for groundwater enforcement standards for certain substances of public health concern. The Department of Natural Resources incorporates these recommendations into its rules relating to groundwater enforcement standards.

This bill requires DHS, before submitting to DNR a recommended enforcement standard for a substance identified as a public health concern, to provide public notice of the proposed recommendation and the studies or scientific or technical data, the methodologies, and the findings, conclusions, and assumptions that DHS used in developing the recommended enforcement standard.

The bill also provides that if, before DHS submits a recommendation for a groundwater enforcement standard to DNR, an interested party objects to the recommendation based on a failure to comply with state groundwater laws or based on the accuracy, integrity, objectivity, or consistency of the data used to develop the recommendation, DHS must convene a working group to review the recommendation. The working group must consist of the interested party objecting to the recommendation, four members from statewide agriculture associations, one member from the Department of Agriculture, Trade and Consumer Protection, and one member from DNR. If there is a consensus by the working group that changes are needed to ensure compliance with state groundwater laws or to ensure the accuracy, integrity, objectivity, or consistency of the data used to develop the recommendation, DHS must modify the recommendation accordingly before submitting the recommendation to DNR.

For further information see the state fiscal estimate, which will be printed as an appendix to this bill.

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

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

SECTION 1

160.07 (4m) (a) Upon developing a recommendation for an enforcement standard under sub. (4) and before submitting the recommendation to the department, the department of health services shall provide public notice, including by publishing on the department's Internet site, of the proposed recommended enforcement standard and the studies or scientific or technical data, the methodologies, and the findings, conclusions, and assumptions that the department used in developing the recommended enforcement standard.

(b) If, before the department of health services submits a recommendation for an enforcement standard under sub. (3), an interested party, as defined in s. 227.182 (1), submits to the department of health services a written objection to the recommendation based on a failure to comply with this chapter or based on the accuracy, integrity, objectivity, or consistency of the data used to develop the recommendation, the department of health services shall convene a working group to review the recommendation. The working group shall consist of the interested party objecting to the recommendation, 4 members from statewide agriculture associations, one member from the department of agriculture, trade and consumer protection, and one member from the department of natural resources. If there is a consensus by the working group that changes are needed to ensure compliance with this chapter or to ensure the accuracy, integrity, objectivity, or consistency of the data used to develop the recommendation, the department of health services shall modify the recommendation accordingly before submitting the recommendation to the department of natural resources.

**Section 2.** 227.135 (1m) of the statutes is created to read:

227.135 (1m) Before presenting a statement of the scope of a proposed rule to the department of administration and the governor under sub. (2), an agency shall

solicit comments on the statement of scope from persons who may be regulated under the proposed rule. The agency shall consider any comments received in determining whether to adopt the statement of scope as originally proposed, modify the proposed statement of scope, or take any other action. For any statement of scope of a proposed rule that will be based on or rely on scientific studies, scientific or technical data, scientific methods, or other similar scientific information, the agency shall incorporate into the statement of scope any comments received that are scientifically valid, are supported by relevant industries, and recommend changes that will ensure compliance with relevant state law and will ensure the accuracy, integrity, objectivity, or consistency of the data that will be used to promulgate the rule.

**Section 3.** 227.135 (5) of the statutes is amended to read:

227.135 (5) A statement of scope shall expire on the date that is 30 months after the date on which it is published in the register. After a statement of scope expires, an agency may not submit a proposed rule based upon that statement of scope to the legislature for review under s. 227.19 (2), and any such rule that has not been submitted to the legislature for review before that date shall be considered withdrawn on that date as provided in s. 227.14 (6) (c) 1. a. For purposes of this subsection, a revised statement of scope prepared under sub. (4) shall expire on the date that is 30 months after the date on which the revised statement is published in the register. If a valid request for external peer review is made under s. 227.182, the 30-month periods provided under this subsection shall not include the period of time between the agency's receipt of the request for external peer review and the submission of the final written report under s. 227.182 (7).

**Section 4.** 227.182 of the statutes is created to read:

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

		5,~
SE	CTIO	N A

- 227.182 Peer review. (1) Definition. In this section, "interested party" means a person who will be regulated under a proposed rule, or a person whose client. member, or customer will be regulated under a proposed rule.
- (2) APPLICATION. This section applies only to rules that are based on or that rely on scientific studies, scientific or technical data, scientific methods, or other similar scientific information.
- (3) REQUEST FOR PEER REVIEW. (a) If at any time before submitting a proposed rule to the governor for approval under s. 227.185 an agency receives in writing from an interested party a valid request to conduct an external peer review of the proposed rule, the agency shall initiate an external peer review of the proposed rule under sub. (5).
- (b) If at any time before submitting a proposed rule to the governor for approval under s. 227.185 an agency receives in writing from the joint committee for review of administrative rules a valid request to conduct an external peer review of a proposed rule, the agency shall initiate an external peer review under sub. (5).
- (c) If at any time an agency receives in writing from the joint committee for review of administrative rules a valid request to conduct an external peer review of any of the agency's rules that are published in the code, the agency shall initiate an external peer review under sub. (5). The committee may identify one or more specific chapters, sections, or other subunits in the code that are administered by the agency as the rules that are to be the subject of the external peer review.
- (d) A request for external peer review is valid under this subsection if it objects to specific studies or scientific or technical data, specific scientific methods, or specific findings, conclusions, or assumptions that the agency used in developing the rule and that have not previously been the subject of an external peer review under

- sub. (5), or if it objects on the basis that the rule does not comply with state or federal law. If more than one valid request for peer review is received under par. (a), the requests shall be consolidated into one external peer review.
- (4) No agency action during peer review. An agency that receives a valid request for peer review under sub. (3) for a proposed rule shall stop work on the proposed rule and may not continue promulgating the proposed rule notwithstanding any provision authorizing or requiring the agency to promulgate the proposed rule, until a final report has been submitted under sub. (7).
- (5) Independent external peer review under sub. (3), the agency shall contract with the National Academy of Sciences, Toxicology Excellence for Risk Assessment, or any similar independent scientific entity, or with a group of independent scientists of comparable stature and qualifications, to conduct an external peer review of the studies or scientific or technical data, the scientific methods, and the findings, conclusions, and assumptions that the agency used in developing the rule and of the state and federal laws relevant to the rule. The contract terms shall ensure that individual peer reviewers have expertise in the subject matter of the rule being reviewed and that the external peer review process is completed within 6 months from the date on which the request for peer review was received under sub. (3), except that the deadline for completion may be extended by an additional 6 months if the initial 6 months is determined to be not feasible. Peer review questions and protocols shall be approved, prior to use in the peer review, by the agency and any parties requesting the peer review.
  - (6) Individual peer reviewers. A peer reviewer may not be any of the following:

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

- (a) The party requesting the peer review, an employee of the agency or of the requesting party, or the spouse or family member of an employee of the agency or of the requesting party.
  - (b) An interested party or an employee of an interested party.
- (c) A person who is conducting research that is funded by the agency or by the requesting party.
  - (d) A person who participated in the development of any study or technical or scientific data being reviewed.
  - (7) FINAL WRITTEN REPORT. Following completion of the peer review process, the peer review panel shall prepare and submit a final written report to the agency and to the party that requested the external peer review. The report shall include all of the following:
  - (a) An analysis, supported by the majority of the panel, of the panel's confidence in the studies or scientific or technical data, the scientific methods, and the findings. conclusions, and assumptions that the agency used in developing the rule.
    - (b) One of the following conclusions, supported by the majority of the panel:
    - 1. The rule is scientifically defensible.
  - 2. The rule is not scientifically defensible, does not comply with state or federal law, or would be scientifically defensible if the agency made certain specified modifications to the rule.
    - (c) The findings of each individual peer reviewer.
  - (8) AGENCY ACTION AFTER PEER REVIEW IS COMPLETED. (a) If the final written report under sub. (7) concludes that a proposed rule is scientifically defensible, the agency may continue to promulgate the proposed rule

 $\mathbf{2}$ 

- (b) If the final written report concludes that a proposed rule is not scientifically defensible, does not comply with state or federal law, or would be scientifically defensible if the agency made certain modifications to the proposed rule, the agency shall, before continuing to promulgate the proposed rule, modify the proposed rule, in cooperation and agreement with the party that requested the peer review, as necessary to make the proposed rule comply with state and federal law and be scientifically defensible.
- (c) If the final written report concludes that a rule that is published in the code is not scientifically defensible, does not comply with state or federal law, or would be scientifically defensible if the agency made certain modifications to the code, the agency shall initiate the rulemaking process to make modifications to the code as necessary to make the rule comply with state and federal law and be scientifically defensible.
- (9) Costs. If the final written report under sub. (7) concludes that a rule is scientifically defensible, the costs of conducting a peer review under this section shall be paid for by the party that submitted the request for peer review under sub. (3). If the final written report concludes that a rule is not scientifically defensible, does not comply with state or federal law, or would be scientifically defensible if the agency made certain modifications to the proposed rule, the agency shall pay for the costs of conducting the peer review under this section.

**Section 5.** 227.19 (3) (intro.) of the statutes is amended to read:

227.19 (3) FORM OF REPORT. (intro.) The report required under sub. (2) shall be in writing and shall include the proposed rule in the form specified in s. 227.14 (1); the material specified in s. 227.14 (2), (3), and (4); including any statement, suggested changes, or other material submitted to the agency by the small business

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

regulatory review board; a copy of any economic impact analysis prepared by the agency under s. 227.137 (2); a copy of any revised economic impact analysis prepared by the agency under s. 227.137 (4); a copy of any independent economic impact analysis prepared under s. 227.137 (4m); a copy of any energy impact report received from the public service commission under s. 227.117 (2); a copy of any final written report from a peer review panel under s. 227.182; and a copy of any recommendations of the legislative council staff. The report shall also include all of the following:

**Section 6.** 227.19 (3) (i) of the statutes is created to read:

227.19 (3) (i) If a final written report by a peer review panel regarding the proposed rule is submitted with the report required under sub. (2), an explanation of the changes, if any, that were made in the proposed rule in response to that report.

## **SECTION 7. Initial applicability.**

(1) This act first applies to a rule whose statement of scope is presented for approval under section 227.135 (2) of the statutes on the effective date of this subsection.

16 (END)