

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS
FOR THE MINNESOTA DEPARTMENT OF AGRICULTURE

In the Matter of Proposed Rules
Relating to the Release of Genetically
Engineered Agriculturally Related
Organisms

REPORT OF THE
ADMINISTRATIVE LAW JUDGE

The above-entitled matter came on for hearing before Administrative Law Judge (ALJ) Richard C. Luis on February 16 and February 21, 1995 at the Department of Agriculture in St. Paul.

This Report is part of a rule hearing proceeding held pursuant to Minn. Stat. §§ 14.131-14.20 to determine whether the Department of Agriculture has fulfilled all relevant substantive and procedural requirements of law, whether the proposed rules are needed and reasonable and whether or not the rules, if modified, are substantially different from those proposed originally.

The Department of Agriculture (Agency, Department, MDA) was represented at the hearing by Paul A. Strandberg and Joseph P. Lally, Assistant Attorneys General, 900 NCL Tower, 445 Minnesota Street, St. Paul, Minnesota 55101-2127, Gail Ryan, Esq., Department Counsel, Dr. Cheryl Fox, Biotechnologist and Assistant Commissioner William Oemichen.

Approximately 85 persons attended the hearing, 60 on February 16 and 25 on February 21. Twenty-nine members of the public spoke on February 16 and nine spoke on February 21.

The Commissioner of Agriculture must wait at least five working days before taking any final action on the rules; during that period, this Report must be made available to all interested persons upon request.

Pursuant to the provisions of Minn. Stat. § 14.15, Subds. 3 and 4, this Report has been submitted to the Chief Administrative Law Judge for his approval. If the Chief Administrative Law Judge approves the adverse findings of this Report, he will advise the Commissioner of Agriculture of actions which will correct the defects and the Commissioner may not adopt the rule until the Chief Administrative Law Judge determines that the defects have been corrected. However, in those instances where the Chief Administrative Law Judge identifies defects which relate to the issues of need or reasonableness, the Commissioner of Agriculture may either adopt the Chief Administrative Law Judge's suggested actions to cure the defects or, in the alternative, if the Commissioner does not elect to adopt the suggested actions, he must submit the proposed rule to the Legislative Commission to Review Administrative Rules for the Commission's advice and comment.

If the Commissioner of Agriculture elects to adopt the suggested actions of the Chief Administrative Law Judge and makes no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, then the Commissioner may proceed to adopt the rule and submit it to the Revisor of Statutes for a review of the form. If the Commissioner of Agriculture makes changes in the rule other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, then he shall submit the rule, with the complete record, to the Chief Administrative Law Judge for a review of the changes before adopting it and submitting it to the Revisor of Statutes.

When the Commissioner of Agriculture files the rule with the Secretary of State, he shall give notice on the day of filing to all persons who requested that they be informed of the filing.

Based upon all the testimony, exhibits and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

Procedural Requirements

1. On September 26, 1994, the Department of Agriculture published a Notice of Intent to Adopt a Rule Without a Public Hearing in this matter at 19 State Register 679. The Notice specified an October 26, 1994 deadline for members of the public to request a public hearing.

1. On October 26, 1994, the Department received a petition, signed by 41 individuals, requesting a public hearing on the proposed rules. The petition was submitted under the letterhead of the Institute for Agriculture and Trade Policy (IATP). Pursuant to Minn. Stat. § 14.25, the Department initiated this rule hearing proceeding.

2. On December 9, 1994, the Department of Agriculture filed the following documents with the Chief Administrative Law Judge:

- a) A copy of the proposed rules certified by the Revisor of Statutes.
- b) The Order for Hearing.
- c) The Notice of Hearing proposed to be issued.
- d) A Statement of the number of persons expected to attend the hearing and estimated length of the Agency's presentation.
- e) The Statement of Need and Reasonableness.
- f) A Statement of Intention to Give Additional Discretionary Notice.

3. On January 5, 1995, the Department of Agriculture mailed the Notice of Hearing to all persons and associations who had registered their names with the Department for the purpose of receiving such notice.

4. On January 9, 1995, a Notice of Hearing and a copy of the proposed rules were published at 19 State Register 1481.

5. On January 12, 1995, the Department of Agriculture filed the following documents with the Administrative Law Judge:

- a) The Notice of Hearing as mailed.
- b) The Agency's certification that its mailing list was accurate and complete.
- c) The Affidavit of Mailing the Notice to all persons on the Agency's list.
- d) An Affidavit of Mailing of Additional Discretionary Notice.
- e) The names of Department of Agriculture personnel who would represent the Agency at the hearing together with the names of any other witnesses solicited by the Agency to appear on its behalf.
- f) A photocopy of the pages of the State Register on which the Notice of Hearing and Proposed Rules were published.
- g) A photocopy of 18 State Register 2432, the State Register page on which Notice of Intent to Solicit Outside Information or Opinions regarding the proposed rules was published on May 16, 1994. No materials were received by the MDA as a result of that notice.

The documents were available for inspection at the Office of Administrative Hearings from the date of filing to the date of the hearing.

6. The period for submission of written comment and statements remained open through March 13, 1995, the period having been extended by order of the Administrative Law Judge to 20 calendar days following the hearing. The record closed on March 20, 1995, the fifth business day following the close of the comment period. Pursuant to Minn. Stat. § 14.15, Subd. 2, the Administrative Law Judge received an extension beyond 30 days after the close of the record, through May 5, 1995, to complete this Report.

General Statutory Authority and Nature of the Proposed Rules

7. Minn. Laws 1994, Ch. 454, § 7, codified as Minn. Stat. § 18F.12, provides:

The commissioner shall adopt rules governing the issuance of permits for proposed releases of genetically engineered agriculturally related organisms, . . . The rules must include a requirement for environmental review subject to the provisions of chapter 116D and rules adopted under it. The rules must also include provisions requiring concurrent permit review for proposed releases that would require more than one permit under this chapter, chapter 18B or 18C.

Minn. Laws 1994, Ch. 454, § 8, codified as Minn. Stat. § 18F.13, provides:

EXEMPTIONS.

- (a) The commissioner may provide exemptions to the requirements to prepare an environmental assessment worksheet and obtain a permit for release of genetically engineered agriculturally related organisms for which substantial evidence, including past releases, has shown that the organism can be released without adverse effects on humans and the environment.
- (b) The commissioner may provide exemptions from the requirements to prepare an environmental assessment worksheet and obtain a permit for release of genetically engineered agriculturally related organisms for which substantial evidence, including past releases, has shown that the organisms can be released under alternative oversight without adverse effects to humans and the environment.

It is found that Minn. Laws 1994, Chapter 454, provides the Commissioner of Agriculture with general statutory authority to adopt the rules proposed in this proceeding.

8. Chapter 454 of the 1994 Session Laws also amended significantly the portions of Minn. Stat. Chapter 116C regarding the Environmental Quality Board's (EQB) authority over genetically engineered organisms (GEOs). Section 10 provides that the Board shall authorize an agency with a "significant environmental permit" to "administer the regulatory oversight for the release of certain genetically engineered organisms". See Minn. Stat. § 116C.94, Subd. 2. Minn. Stat. § 116C.91, Subd. 7 defines a "Significant environmental permit" as "a permit issued by a state agency with the authority to deny, modify, revoke, or place conditions on the permit in compliance with the requirements of sections 116C.91 to 116C.96, chapter 116D, and the rules adopted under them". A major purpose of the proposed rules is to establish in the Commissioner of Agriculture the power to grant significant environmental permits for the release of genetically engineered agriculturally related organisms. See Finding 12.

9. Minn. Laws 1994, Ch. 454, § 13, a new statute codified as Minn. Stat. § 116C.98, lays out a notification system for the release of certain genetically engineered plants (corn, cotton, potato, soybean, tobacco, tomato and any other plant species designated as specified by the Commissioner of Agriculture). The statute is to be repealed upon adoption of rules by the Commissioner of Agriculture under Minn. Stat. § 18F.13(b), quoted in Finding 8.

It is found that the Department has established statutory authority for the Commissioner of Agriculture to adopt rules providing for notification for the release of agriculturally related genetically engineered organisms in the manner specified at Minn. Stat. § 116C.98.

10. The Department, in its Statement of Need and Reasonableness (SONAR, Ex. 3), argues that the above-noted § 18F.13, which allows for exemption to the requirements to prepare an Environmental Assessment Worksheet (EAW) and obtain a permit for the GEOs when substantial evidence, including past releases, has shown that the organism can be released or it can be released under alternative oversight without adverse effects on human health and the environment, grants the Commissioner the

authority to pass rules allowing for the release of genetically engineered agriculturally related organisms for commercial use. The language in § 18F.13 is very similar to chapter 454, § 10, Subd. 3, codified as Minn. Stat. § 116C.94, Subd. 3 (entitled “Commercialization”), regarding the Environmental Quality Board, which reads:

“The board may adopt rules providing exemptions to the requirements to prepare an environmental assessment worksheet and obtain a permit for releases of genetically engineered organisms for which substantial evidence from past releases has shown to the board’s satisfaction that the organism can be released without jeopardizing public health or the environment.”

It is found that the Commissioner of Agriculture has the statutory authority to adopt rules providing for commercial use exemptions from the requirements to prepare an environmental assessment worksheet and obtain a permit for the release of agriculturally related genetically engineered organisms (GEOs), pursuant to Minn. Stat. §§ 18F.13 and 116C.94, Subd. 3.

11. With respect to the requirement of Minn. Stat. § 18F.12 that the proposed rules “include a requirement for environmental review subject to the provisions of chapter 116D and rules adopted under it”, it is noted that Minn. Stat. Chapter 116D is the Minnesota Environmental Policy Act and that, pursuant to those statutes, particularly § 116D.04, Subd. 5a, which authorizes the EQB to adopt rules regarding environmental review, Minn. Rules pt. 4410.0200-4410.6500 have been adopted by the EQB. Minn. Rules Chapter 4420 and Rule 4410.8000 have been adopted by the Board regarding genetically engineered organisms and releases thereof, respectively.

In its SONAR, the Department notes that the Commissioner’s authority to regulate agriculturally related GEOs is “linked” to the overall EQB authority for regulation of all genetically engineered organisms, and it acknowledges the need to conform to EQB rules adopted under Minn. Stat. Chapters 116C and 116D. Noted specifically is the EQB rule that exempts applicants from an EQB release permit if they have a “significant environmental release permit” from another agency (Minn. Rules 4420.0075), and the effort in drafting the proposed rules to assure that release permits issued by the Commissioner of Agriculture for agriculturally related GEOs meet the requirements specified. It is found that the proposed rules provide a framework for the Commissioner to grant all significant environmental permit “within the meaning of Minn. Stat. Ch. 116C.

12. In general, the Department prepared the proposed rules with a view to providing a comprehensive set of requirements to permit the release of GEOs outside containment facilities, to provide partial or complete release permit exemptions, to specify notification procedures for certain plants and to devise a system for the commercial release of GEOs in accordance with the legal authorization and statutory and regulatory purposes outlined above in Findings 8-12.

Small business considerations

13. Minn. Stat. § 14.115 requires an agency to consider the degree of impact on small businesses and alternative methods for lessening that impact in connection with the passage of agency rules.

In its SONAR, MDA stated that small businesses should benefit from the proposed rules in that they eliminate previous duplication and unneeded paperwork. The rules propose using existing information and documents wherever possible, particularly documents which are already required by the federal regulatory process. In the past, the state regulatory process resulted in duplication in the production of documents and an additional waiting period in many cases, whereas the Department anticipates the new rules will result in easier, less time consuming procedures for all business affected.

14. Minn. Stat. § 14.115, Subd. 2 provides that an agency shall consider several mechanisms for reducing the impact of its rules on small businesses. In the SONAR, the Department examined each mechanism separately as it relates to the rules on the release of agriculturally related GEOs, as follows:

(a) The establishment of less stringent compliance or reporting requirements for small businesses—the MDA maintained it looked at the compliance and reporting requirements as they relate to small businesses and found them to be based on the nature of the GEO, the environment to which it is released and other factors unrelated to the size of the company. It notes that in some cases a commercial use exemption will be granted or reduced regulatory oversight will be allowed, in which cases compliance and reporting requirements would be less restrictive due to factors relating to the release but not related to the company requesting the release. Therefore, less restrictive requirements based on the size of the company would be inappropriate.

(b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses—the proposed rules establish schedules and deadlines designed to result in sufficient time for application review and to address issues related to the proposed releases. The Department maintains the time allowances are short enough to allow for timely project initiation and seasonal activities related to field projects and that most of the deadlines in the rules are for agency review and response. It notes the applicant controls the start of the process by filing an application. The length of time needed to review any application is related to the type of application, public notice and comment periods, and to the issues related to the project, which are factors not affected by the size of the company. Therefore, the MDA maintains that a reduction in time schedules for small businesses is inappropriate.

(c) The consolidation or simplification of compliance or reporting requirements for small businesses—the MDA established procedures in the rules to allow for review of a release permit application, notification or commercial use exemptions in a timely manner. None of the timelines should delay projects or commercial use, according to the Agency. The

rules allow for reduced reporting or compliance for particular uses and types of GEOs. Reduced compliance is based on factors other than the size of the business. The Department maintains that additional reduction in compliance or reporting requirements for small businesses would not be appropriate since release conditions are not affected by the size of the business.

(d) The establishment of performance standards for small businesses to replace design or operational standards required in the rule—no specific design or operational standards for releases of GEOs have been proposed in the rules. The test for (permitted) release of a GEO (see Minn. Stat. § 18F.07, Subd. 2) is that it does not cause unreasonable adverse effects on the environment. Thus, the statute proposes a performance-based standard which all applicants, including small businesses, must meet. The Department notes that persons maintaining containment facilities must adhere to National Institutes of Health (NIH) guidelines, which do not distinguish among sizes of facilities. Therefore, the Department maintains it is inappropriate to substitute reduced guidelines for containment.

(e) The exemption of small businesses from any or all requirements of the rule—because the requirements for release of GEOs are based on considerations of unreasonable adverse effects on human health or the environment, the size of a company has no effect on the determination required. Therefore, it is not appropriate to exempt any company from the rules. The Department maintains that any alternative method to reduce further the impact of rules designed to prevent unreasonable adverse effects to human health or the environment would be contrary to Minn. Stat. Chapters 18B, 18C, 18F, and 116C.

It is found that MDA has complied with Minn. Stat. § 14.115 (Small Business Considerations).

15. A major issue for numerous commentators testifying at the hearings and filing written comments was the Department's refusal to require that any food containing an agriculturally related GEO be labeled accordingly. The labeling issue is discussed subsequently, but in connection with the requirement to consider a rule's impact on small businesses, the decision not to label has the effect, some commentators argued, of damaging the credibility of food co-ops, whose members rely on the co-ops to advise them about what is in their food. (See, oral remarks and written testimony of Pat Kerrigan and Sharon Murphy). Absent a labeling requirement, a store is unable to advise whether a food contains a GEO, which may make the product unacceptable to a customer for health-related, philosophical or religious reasons. It is maintained that since substantial numbers of persons shop at co-ops in order to access advice regarding what is in the food offered prior to making a buying decision, the absence of a labeling requirement in the rules will cause co-ops to lose the business of such persons. This was an impact affecting small businesses not considered by the Department.

It is noted that the concerns expressed are the same no matter where a person shops—if co-ops will lose business because genetically engineered food is not labeled as such, so will all food retailers. The problem is that the small business considerations statute does not require an agency to consider the impact of rules they do not propose—and they have not proposed labeling. And, as noted subsequently (See Findings 24 and 90), labeling is not required by the statutes authorizing these proposed rules.

16. The other small business consideration allegedly overlooked by the Department in preparing the rules is that affecting farms that qualify as small businesses (most do) under § 14.115. The Agency maintains also that the proposed rules will have no “direct and substantial adverse impact” on agricultural land within the meaning of Minn. Stat. § 14.11, Subd. 2, so it is not required to comply the requirements of Minn. Stat. §§ 17.80 to 17.84. Specifically, § 17.83 requires an agency proposing to adopt a rule which it determines may have a direct and substantial impact on agricultural land to include certain language in the notice of hearing and SONAR describing the adverse effect(s) and the action considered to avoid those effects. This analysis was not prepared by the Department.

The concern is that any agriculturally related GEO released under a permit granted by the Commissioner, or under the notification or commercial release exemption procedures, could migrate and cause unknown effects on surrounding agricultural land. While the concern was not addressed directly by the Department, the Administrative Law Judge finds no violation of the statutes designed to consider effects on small businesses or to protect agricultural land resulting from that lack of comment. The proposed rules are designed to guard against adverse effects of any released GEO, including migration to other parts of the environment. The authorizing statutes direct the Department to allow releases only in the absence of adverse effects, and in developing rules to achieve that, the Department obviously sought to avoid “direct and substantial adverse effects on agricultural land” or any concomitant effect on small businesses that operate farms. Acknowledgment in advance that the proposed rules have such effects is tantamount to admitting the Department went outside its statutory authority, which requires avoiding adverse effects on humans and the environment. Therefore, it is found that the MDA violated no substantive principles of law in “failing” to comply with Minn. Stat. §§ 14.11, Subd. 2, 14.115 or 17.80 to 17.84 in connection with potential adverse effects on farming operations or on agricultural land.

Specific Analysis of the Proposed Rules

General

17. Any rule provision not discussed specifically below is found to be necessary and reasonable.

In its Final Comments filed on March 13 and Response to Comments filed March 20, 1995, the MDA proposed a number of revisions to the rules as published originally in the State Register. In subsequent Findings, the Administrative Law Judge (ALJ) will comment on all such changes, except for any clerical, spelling or other changes overlooked inadvertently. Any clerical changes not discussed specifically are found to

be needed and reasonable because they provide clarity to the proposed rules and are found not to be substantial changes.

18. The Agency proposes changing the title of the rules as published in the State Register, from “Rules Relating to Genetically Engineered Organisms” to “Rules Relating to the Release of Genetically Engineered Agriculturally Related Organisms”. The proposed title change is a clarification and specification found to be necessary, reasonable, and not a substantial change. It confines the scope of the rules to the actual authorization specified in Minn. Stat. § 18F.12. Leaving the title as published results in an implication that the rules proposed by the MDA govern all GEOs, which is outside the Department’s authority and actually would infringe on the authority of the Environmental Quality Board. Changing the title corrects that potential defect.

Scope—Part 1558.0010

19. Proposed Rule 1558.0010 outlines the scope of the rules that follow. It specifies three categories of release—those requiring permits, releases under the notification procedures and releases under the commercial use exemption. This Part clarifies the statutory authority granted at § 18F.12, to adopt rules governing the issuance of permits for the proposed release of agriculturally related GEOs, pesticides, fertilizers, soil amendments and plant amendments (Subp. 2) and at 18F.13 regarding plants covered by the notification procedures “exemption” to obtaining a permit (Subp. 3).

Subparts 1, 2 and 3 of Part 1558.0010 are found to be necessary and reasonable.

20. Subpart 4 of Part 1558.0010 proposes to grant the Commissioner authority to issue commercial use exemptions for “Agriculturally related genetically engineered organisms, pesticides, fertilizers, soil amendments or plant amendments” that meet certain requirements. The authorizing statute, Minn. Stat. § 18F.13, allows the Commissioner to grant exemptions to permit requirements only for qualifying genetically engineered agriculturally related organisms. Section 18F.12 allows for adoption of rules governing issuance of permits for releases of all the other items listed in Subp. 4, but § 18F.13, relied on as the authority for adopting rules governing notification procedures and commercial use exemptions, mentions only exemptions from permit requirements for the release of agriculturally related GEOs. A question exists as to whether the inclusion of genetically engineered agriculturally related pesticides, fertilizers, and soil and plant amendments are outside the notification or commercial use exemption statutes. The ALJ concludes they are not, because the statutory definition of those terms all fall within the statutory definition of agriculturally related genetically engineered organisms. See Minn. Stat. §§ 18B.01, Subd. 10b (regarding pesticides) and 18C.005, subds. 12b, 12c and 12d (regarding fertilizers, plant amendments and soil amendments respectively) and compare to Minn. Stat. § 18F.02, subds. 2a and 5. The definitions are tied together in proposed rule 1558.0020, Subps. 2 and 12, the definitions of “Agriculturally related organisms” and “Genetically engineered organism; GEO”, respectively. It is found that including the items listed in addition to agriculturally related genetically engineered organisms in the scope of the commercial use exemption complies with statutory authority.

Definitions—Part 1558.0020

21. Regarding Subpart 2 of Part .0020, the definition of “Agriculturally related organisms”, the Department repeated the statutory definition and proposes no changes. The Department’s proposed definition is found to be necessary and reasonable. It is recommended that the letter “s” be dropped from the word “fruits” and the “;” between “forage” and “grain” be deleted, as necessary and reasonable clerical changes to conform the rule text with the statute. These are not substantial changes.

22. Anne R. Kapuscinski, Ph.D., a professor of Fisheries and Conservation Biology at the University of Minnesota, specializing in aquaculture and biotechnology, provided extensive oral and written commentary on the proposed rules, including a recommendation to add the language “genetically engineered fish, molluscs, crustaceans and other aquatic animals” immediately after “wild animals” among items listed as excluded from the definition of agriculturally related organisms. Dr. Kapuscinski’s recommended addition to Subp. 2 is found to be unnecessary because it is cumulative. As noted by the MDA in its Comments and Response, Kapuscinski’s concern, that persons will argue that the MDA, not the Department of Natural Resources, regulates genetically engineered aquatic animals, is alleviated by the specific exclusion from coverage of “wild animals” (as defined at Minn. Stat. § 97A.015, Subd. 55) and “private aquatic life”.

23. Two commentators, Amanda Hand (Ex. 47) and Carolyn Carr (T. pp. 288-290) cite the definition of agriculturally related organisms as authorization for requiring labeling because the definition specifies that such organisms include organisms used in agricultural processing. Ms. Hand interprets the definition, taken from statute, to authorize, at a minimum, the labeling in supermarkets of raw produce containing a GEO, and possibly the labeling of processed agricultural products like tomato catsup. Ms. Carr argued that the definition of agriculturally related organisms was broad enough in including organisms used in the processing of agricultural products to include food. Therefore, labeling is authorized.

The MDA’s position is that coverage under the definition stops at the point of viability, or expression as a living being. Under that interpretation, which the ALJ finds reasonable, the Commissioner can regulate viable or living agricultural products, such as fresh pollen, but not honey. A tomato containing viable seeds is within the coverage of the rules, but a processed food such as catsup is not. The MDA’s direct statutory authority to regulate releases of agriculturally related GEOs used in the processing of agricultural products is limited by the concept of (what is) an “organism”—and the Department’s decision to consider only living, viable beings as organisms stops short of including most foods. The Agency’s decision not to involve itself in labeling in this proceeding is found not to be a violation of statute or otherwise defective. The labeling issue is discussed in further detail at Finding 90.

24. At Subpart 6, the definition of a “containment facility”, the references in the last two lines should be to 1558.0080, Subps. 1 and 2, rather than Subps. 2 and 3. The MDA’s proposal to make the necessary clerical changes are found to be clarifying in nature and not substantial.

25. At Part 1558.0020, Subpart 11, the definition of “genetic engineering”, the MDA published the statutory definition (found at § 18F.02) in the State Register. In response to a suggestion from Dr. Kapuscinski, the Department proposes to add the phrase “or any progeny containing the new genetic material or regrouping.” after the word “humans” to alleviate a concern that the original definition might exempt organisms once they are hybridized. The additional language is found to be needed and reasonable to clarify the rule’s intent and does not constitute a substantial change.

26. In response to comments, the MDA considered, but does not propose for adoption, adding definitions for “class” and “environment”. A definition of “class” would clarify that the concept of class exemptions refers to the standard dictionary definition of the word as opposed to the usage of the word in scientific nomenclature for organizing types of organisms. Leaving the term undefined denotes that the standard dictionary definition (a group, set or kind marked by a common attribute or attributes) is the one that applies, as intended.

“Environment” is defined in various Minnesota statutes, however, and also in the Environmental Quality Board’s GEO rules. It is suggested that the Department add a definition for the term, as follows:

“‘Environment’ has the meaning given it at part 4420.0010, Subp. 11.”

This definition, taken from the EQB rules as suggested by Dr. Kapuscinski, clarifies the MDA rules and is found to be necessary, reasonable, and would not be a substantial change. Identifying the location of the definition avoids duplication while supplying the needed clarification.

27. Several commentators and the ALJ suggested adding the statutory definition of “Unreasonable adverse effects on the environment” (found at § 18F.02, Subd. 9) to the rules. The Department agrees, and proposes to add the statutory definition as a new subpart to 1558.0020. This addition is found to be necessary and reasonable and not a substantial change.

28. Dr. James Woodman, representing the Minnesota Biotechnology Association, suggested inserting the phrase “release and commercial use” in place of “release” at various locations in the rule. The MDA declines to propose the replacement language because it maintains the term “release” includes commercial uses, so additional clarification is unnecessary. The Administrative Law Judge agrees. The first subpart in the rules (1558.0010, Subp. 1) specifies that release categories include commercial use.

29. Dr. Kapuscinski recommends citation in the rules of the statutory definition of all mentioned agriculturally related organisms, as was done for “nursery stock”, at Part 1558.0020, Subp. 2. This proposal is found to be necessary and reasonable because it adds clarity to the rules. Reference to statutory definitions, if such is the MDA’s intent, in proposed Rules 1558.0020, Subp. 2 would not constitute a substantial change. The ALJ recommends adopting Dr. Kapuscinski’s recommendation, but to not do so does not constitute a defect.

30. A general language change suggested by Dr. Kapuscinski is to drop the word “unreasonable” when referring to adverse effects. At various places, Minn. Stat.

Ch. 18F refers to “adverse effects”, “unreasonable adverse effects” and “significant adverse effects”. The appropriateness of these terms at various locations in the rules, including consistency with the authorizing statute(s), will be discussed subsequently, but it is found that dropping all references to “unreasonable adverse effects” is inappropriate because it would be inconsistent with Minn. Stat. § 18F.07, Subd. 2, which refers to that standard in connection with making a decision on a release permit application.

Considerations—1558.0030

31. As noted in the SONAR, a section is needed to delineate clearly the considerations that are used to judge environmental concerns associated with proposed releases of GEOs. The Department intends to use the considerations to help make a determination regarding an application for release. They are also used to determine various exemptions which may be given under the statute and the rules. The considerations were adapted from EQB rules, with some clarifying language changes to meet the needs of agriculturally related genetically engineered organisms. The use of these considerations as part of a determination to allow or deny releases also meets one of the requirements for an agency to be designated as one that issues a “significant environmental permit”, as discussed earlier.

32. The fact that the “Considerations” in the proposed rules differ at all from the comparable EQB rules caused Dr. Kapuscinski and Carolyn Carr, a University of Minnesota graduate student who recorded the deliberations of the EQB advisory group that developed that agency’s GEO release rules, to question whether the MDA justified properly all the departures from the EQB’s considerations. They maintain that the SONAR did not provide sufficient detail to explain the “adaptations to meet the needs of agriculturally related GEOs.” In its Final Comments and Response to Comments (March 13 and March 20, 1995, respectively), the MDA explained in greater and adequate detail the differences between the Considerations proposed at Part 1558.0030 and those in the EQB rules at Parts 4410.8000 and 4420.0035. The proposed departures from EQB considerations outlined by the MDA are found to be necessary and reasonable. The SONAR is not defective because the level of detail provided in the comments was greater. A general reference to a need to adapt the proposals to particular needs of agriculturally related GEOs, as stated in the SONAR, is found to be sufficient, when combined with a side-by-side comparison of the proposals to the comparable EQB rules, to show the reasonableness of the changes. It is noted also that John Hynes, Permit Compliance Manager for the Environmental Quality Board, testified that the Considerations as published in the State Register were substantially the same as the Considerations in the comparable EQB rules.

33. Several clerical and language changes were proposed by the Agency in its Final Comments and Response with respect to Part 1558.0030. At Subp. 1.C., the term “environmental effects” is deleted and “effects on human health or the environment” is inserted at the second line of the subpart. This change conforms the language to other parts of the proposed rules and to Minn. Stat. § 18F.13. The proposed change, when modified as discussed in the next paragraph, is found to be necessary and reasonable and does not constitute a substantial change.

However, because the considerations are applicable to decisions to grant or deny commercial use exemptions (Part 1558.0070), authorized under Minn. Stat. § 18F.13(a), it is necessary to drop the words “human health” and insert the word “humans” in revised Subp. 1.C. This change corrects the fact that the proposed revised subpart narrows the scope of the statute impermissibly by confining inquiry to effects on “human health” rather than on “humans”. The impermissible narrowing of the statutory authority constitutes a defect because substantive principles of law are violated. The defect can be corrected by taking the action noted in the first sentence of this paragraph. For further discussion, see Finding 78.

34. At two locations in Subp. 1 under “Considerations”, the MDA proposes deleting the originally-published language, “including, but not limited to,” and substituting “such as”. These proposed changes, at Subps. 1C(3) and 1.E., are found to be necessary and reasonable and do not constitute substantial changes. If the proposed changes were not made, the MDA risked a Finding that the subparts granted unlawful overly-broad discretion to the Commissioner.

35. At 1558.0030, Subpart 1.C.(5), the words “adversely affect” are transposed to read “affect adversely”. This proposal is a clarifying grammatical change found to be necessary and reasonable and does not constitute a substantial change.

In the same subpart, the MDA proposes to delete the phrase “harmful genes” and insert the word “transgenes” in its place. This subpart caused considerable discussion at the hearing in which deletion of the word “harmful” was suggested and possible replacements included “novel” or “unusual”, as used in the EQB rules. Dropping the use of an adjective and referring simply to “transgenes” is found to be a reasonable and necessary clarification and does not constitute a substantial change. The new usage (“transgenes” are genes that move from organism to another), while arguably broader than the concept of “harmful” genes, still falls within the statutory purpose of protecting against adverse effects on humans and the environment.

36. The final clause in the originally-published 1558.0030, Subp. 1E ended with a “;”, which the Department proposes be changed to a period. This change is clerical and serves to clarify the rule in a necessary and reasonable manner. It is not a substantial change.

37. Subpart 2 under “Considerations” refers to federal documents. In order to prevent duplication of the federal oversight process, any person applying for release of GEOs may use documents presented by them in the federal application process to address some or all of the considerations laid out in the previous subpart. In response to a suggestion by the Administrative Law Judge, the MDA proposes to insert the word “Relevant” at the beginning of the subpart and to insert the words “submitted by the applicant as part of the federal regulatory process” between the words “documents” and “may”. The subpart would then read: “Relevant federal documents submitted by the applicant as part of the federal regulatory process may be used to address some or all of the considerations in subpart 1.” The proposed additions for Subp. 2 are found to be necessary and reasonable because they help clarify the Department’s intent. They are found not to be substantial changes.

38. Dr. Kapuscinski is critical of the Considerations with respect to their allegedly giving insufficient weight to the protection of humans from the adverse effects of the release of genetically engineered agriculturally related organisms. She argues that the proposals are written with a view to protecting the environment, as “admitted” in the SONAR (page 6), which explains that the Considerations “are used to judge the environmental concerns associated with the release of GEOs”, but say nothing about judging effects on humans. Minn. Stat. §§ 18F.01 and 18F.13 make it clear that the effects on humans of any releases are subjects for consideration.

Kapuscinski recommends the convening of an interdisciplinary panel to draft additional considerations that would adequately guide the assessment of the potential for adverse effects of GEO releases on humans. She suggests what disciplines should be represented on the panel in order to address, at minimum, effects on humans posed by incorporating agriculturally related GEOs into farming, the processing of GEO products in the state, the distribution and sale of GEOs or GEO products in Minnesota and consumption of GEOs or GEO products. See Finding 88.

39. In its Response to Comments, the Department notes that human health issues were included in its considerations, and that this fact was acknowledged in a comment filed after the hearing by the Minnesota Department of Health. The Department cites parts of the rules, including specific references in Part 1558.0030, where human health concerns are considered. Specifically, the Department notes that the addition of specific language referencing the effects on human health in Subp. 1.C., (caveat: note the defect discussed at Finding 34), the reference at Subp. 1C.(2) to nontarget organisms (which includes humans) and the requirement at Subp. 1.G. that the Commissioner consider Conclusions reached or conditions imposed by federal or state agencies on previous releases (noting that federal agencies require investigation into human health risks and the evaluation of those risks before issuing permits) all relate to the statutory requirement that adverse effects on humans be considered.

The fact that the Department may not list in its proposed Considerations all of what must be considered to assess properly adverse effects on humans resulting from release of agriculturally related GEOs does not make the rule defective. However, Dr. Kapuscinski’s concern should be given full consideration. The ALJ agrees with her recommendation that an interdisciplinary panel be convened to discuss, and possibly draft, additional considerations that would guide the assessment of the potential for adverse effects on humans of releasing agriculturally related GEOs.

40. The introduction to Part 1558.0030, Subp. 1.C., regarding which a defect was noted at Finding 34, contains also the phrase “. . . including, but not limited to . . .”

It is recommended that the phrase “including but not limited to” be deleted and that the single word “including” or the words “such as” be substituted in its place. Such a change does not diminish the intent or effect of the subpart, which is to list all currently known factors in the assessment of possible adverse effects. It does not preclude consideration of additional relevant factors. The suggested language change, combined with correction of the defect noted at Finding 34, results in a subpart that is found to be necessary and reasonable, and the change is found not to be substantial.

Release Permit Procedures—Part 1558.0040

41. In response to a written comment from Patricia Bloomgren of the Department of Health, the Department proposes to delete the word “unreasonable” at 1558.0040, Subp. 1.B., which alters the subpart to allow the Commissioner to request additional information necessary to determine the potential for adverse effects on human health or the environment of proposed releases. The subpart refers to application procedures, and not arriving at a final determination, so a decision as to whether the effects are “unreasonably” adverse has not yet been reached. Based on that reasoning, it is found that the deletion of the word “unreasonable” in this subpart is necessary and reasonable and does not constitute a substantial change. Restricting the inquiry to effects on “human health” here, rather than effects on “humans” is not a defect because the governing statute on the permitting process (§ 18F.07) requires avoidance only of “unreasonable adverse effects on the environment”.

42. The second sentence of 1558.0040, Subp. 2 begins with the words “The commissioner may reject an application if . . .”. The Administrative Law Judge asked the MDA to consider use of the word “shall” instead of “may” in this sentence. The Department has declined to do so because if “shall” were used, qualifiers would have to be added at the end of the sentence to make exceptions for minor omissions. Since the impact of this provision works in favor of applicants, it is found that use of the word “may” in Subp. 2 does not constitute a defect.

43. Proposed Part 1558.0040, Subpart 3 (Application distribution) is the first of several parts in the rules drawing comment on the most controversial issue in this proceeding—the public’s rights to know and offer comment. Many commentators are deeply concerned about a system that appears to offer fewer opportunities for public access and input as the relative seriousness of the decisions increases. Dr. David Andow, an Associate Professor of Entomology at the University of Minnesota, summarized this concern best by noting that as the extent of the release broadens from a permitted release through the notification process to commercial use, the amount of notice and information available to the general public and the opportunities to comment on the effects of such releases seems to diminish.

Proponents of the process advanced by the MDA, mostly farmers and agri-business groups, point out that the federal review process is adequate and assures safety, that Minnesota is one of only two states (North Carolina is the other, but its permitting process is scheduled to “sunset” on September 30, 1995) with a permitting system overlaying Federal regulation, and that the process must not slow down the release of GEOs or this State’s competitive position in agriculture will drop relative to other states and Canada. Examples include the availability and use in the Dakotas and Manitoba of certain herbicides containing GEOs that aid the growth of potatoes and canola—to delay the production of such processes in Minnesota hurts economically our farmers and companies marketing the herbicides.

No one involved in this hearing process offered to predict for certain whether a separate state review process is an anti-business, bureaucratic anachronism or the wave of the future. The fact that only two states have a review in addition to the federal processes can be interpreted both ways—either Minnesota and North Carolina are

hopelessly behind, or they are pacesetters in recognizing that it is prudent to proceed with extreme caution because the potential consequences of any GEO release may not be known.

44. The debate noted in the previous Finding is highlighted by a written comment received from State Representative Phyllis Kahn and a response received from State Senator Steve Dille. Representative Kahn and Senator Dille were co-authors of the original (1989) genetic engineering bill. Kahn was chief house author of the 1991 and 1994 amendments and Dille was co-author in 1991 and chief Senate author in 1994. They take differing views on the legislation with respect to the necessity for public comment in the process.

Representative Kahn recommends full public notice and opportunity to comment at every key decision point in the process, particularly at 1558.0040, Subp. 13 (partial or complete exemptions from the permit procedures), in the notification process at 1558.0060, Subp. 1.A.(2) and for individual commercial use exemptions. Senator Dille responds:

Rep. Kahn raised the issue of public involvement at key decision points. There is more than ample opportunity for public involvement on both the state and federal level. There are no genetically engineered organisms being released that have not been the subject of numerous public comment periods. Additional public comment periods at the state level are not needed and will result in unnecessary delays without any gain in public involvement.

As noted in subsequent Findings, the Department has attempted to balance the considerations of commercial efficiency and the public's access to knowledge and opportunity for input, both in the rules as published originally and in proposed changes submitted during the comment and response periods.

45. At 1558.0040, Subp. 3, the MDA proposed to change the word "information" to "data" in order to be consistent in word usage with the rest of these rules and with Minn. Stat. Ch. 13 (Government Data Practices Act). This proposed change is found to be necessary and reasonable and does not constitute a substantial change.

46. Subpart 3 deals with application distribution (notice to the public) when persons apply for a permit to release agriculturally related genetically engineered organisms. In response to concerns expressed by several persons that the distribution list, which notifies persons that an application has been filed, was not wide enough (Carolyn Carr, Amanda Hand, Ann Kapuscinski, Audrey Robinson, Gladys Schmitz and Michelle Thom), the Department points out that the subpart as drafted originally allows for distribution of the application to "any other person upon request to the commissioner". Because this statement implies that a mailing list is kept by MDA, but there was no language making that explicit in the originally-published rules, the Department offers an additional sentence to follow the word "commissioner". The sentence reads "Those persons shall be added to the mailing list maintained by the commissioner of persons interested in receiving information on the release of GEOs". The additional language is found to be necessary and reasonable and not a substantial

change. It increases the awareness on the part of the interested public that notices of applications for permits are available to all.

47. At Subp. 4 of 1558.0040 (Application review), the ALJ suggested substitution of the word “shall” for the word “may” in the sentences describing the decision by the Commissioner to issue or deny issuance of a GEO release permit. However, the rule itself lists the conditions under which the Commissioner may exercise discretion. For that reason, the ALJ does not find that either use of the word “may” in this subpart constitutes a defect.

48. As drafted originally, the final paragraph of the Application Review Subpart stated:

“The Board of Animal Health must be consulted on permits that relate to livestock and domestic animals.”

This language is consistent with a requirement of Minn. Stat. § 18F.04. The Administrative Law Judge suggested the Department add additional language to specify the level of consultation. In response the Department proposes to insert the words “during the review” between “consulted” and “on” in the above-quoted paragraphs. The additional language, which makes the drafted rule more specific, is found to be necessary and reasonable and does not constitute a substantial change.

49. Subpart 5 (Data privacy) specifies that information that is submitted and marked “Confidential Business Information” in connection with applications for GEO releases is to be considered not public data under the federal and state statutes mentioned in the rule. The originally-published rule language then states “This information may be provided to interdisciplinary reviewers if they sign a nondisclosure agreement and . . .”. In its comments, the Department argued that the word “may” is appropriate in this context.

There may be times when conflicts of interest are identified. In other instances, a reviewer may not be in competition with the applicant but a co-worker of a reviewer on a project may be in competition with the applicant. In such instances, the MDA wants the Commissioner to exercise discretion which does not compromise the interdisciplinary review process because another reviewer in that area of expertise would then be sought as a replacement. Given that rationale, use of the word “may” at the location noted in 1558.0040, Subp. 5 is not a defect.

50. Subpart 6 (Permit conditions) begins, as drafted originally, “The commissioner may prescribe terms and conditions including, but not limited to . . .”. In response to a suggestion by the Administrative Law Judge, the Department proposes to substituting “such as” for “including, but not limited to,” in this subpart. The proposed change is found to be necessary and reasonable and does not constitute a substantial change. It avoids a defect which would have resulted from giving unbridled discretion to the Commissioner to prescribe terms and conditions of permits. It is recommended, as a clerical change, that the “,” after the words “such as” be deleted. A comma after the word “conditions” instead would be appropriate. These clerical changes are found to be necessary and reasonable and do not constitute substantial changes.

51. In the first sentence of Subp. 7 (Violation of the permit), the Department proposes to change the word “may” to “shall” to remove the potential discretion on the part of the permit holder to violate terms or conditions of the permit. In the next sentence, the Commissioner “may” modify, suspend, or revoke the permit under certain conditions. The Department argues that the word “may” should be retained at that point because there may be minor violations that would not require intervention that constitute merely technical violations of the permit conditions, and the Department wishes to have the latitude to address that type of violation. Insertion of the word “shall” where proposed in the first sentence is found to be necessary and reasonable and does not constitute a substantial change. Declining to remove the word “may” where discussed in the second sentence of the subpart is found not be a defect because it operates in favor of the regulated public.

52. In response to comments by Gerald Schoenfeld of Northrup King and the Administrative Law Judge, the Department commented in detail regarding the different options available to the Commissioner if violations of the permit occur, as specified at Subp. 7. The word “may” is retained in two sentences, which read:

“If adverse effects can be mitigated by modification of the conditions for release, the permit may be reinstated. Revocation may result in termination and disposal of all GEOs.”

The sentence just ahead of the above-quoted language requires that if adverse effects are observed, the permit will be suspended. The Department argues that the word “may” is appropriate in both instances where it has been retained in that all the circumstances surrounding a particular violation cannot be anticipated. Perhaps a violation could be mitigated, but the responsible party has shown a consistent disregard for following the permit’s terms and conditions. In such cases, it may not be appropriate to reinstate the permit. Because of the number and complexity of possible permutations, the Commissioner seeks to preserve flexibility in addressing violations, which retention of the word “may” would allow in these instances. The Administrative Law Judge agrees with the Department’s reasoning. Retention of the word “may” in the first sentence does not constitute a defect.

In the second sentence, however, the rule language affords the Commissioner unfettered discretion to require termination and disposal of all GEOs. This is a defect violating substantive requirements of law. The problem is that the rule as published allows the Commissioner to require “termination and disposal” of GEOs, or not to so require, without a standard for decision. This could result in different outcomes for the same quality of violation. As noted in the MDA’s Final Comments, filed March 13, 1995, termination and disposal of all GEOs is necessary when the GEOs pose a risk. To cure the defect of unbridled discretion in this subpart, the second sentence could be changed to read:

“Revocation shall result in the termination and disposal of all GEOs if the commissioner determines that the GEOs pose a significant environmental risk.”

The suggested language cures the defect in the rule, is found to be necessary and reasonable, and does not constitute a substantial change.

53. Carolyn Carr recommends a public notice period and notice of the decision on permit renewals to be specified at 1558.0040, Subp. 10. Also, she recommends language specifying that the renewing applicant must provide a statement arguing that the proposed release is substantially the same as the one permitted earlier. The Department declined to add language to the subpart as published originally, explaining that a renewal must meet the same standards (no evidence of unreasonable adverse effects on human health or the environment) as an original application and that the factors used to make the determination must be the same as considered originally. Not adding additional requirements or clarifying language to Subp. 10 as published in the State Register is found not to constitute a defect.

54. Subpart 13 of 1558.0040 provides for partial and complete exemptions from the permit requirements for individual releases or classes of releases. The Department proposes two changes to that subpart from the originally-published rules. The first, in Subp. 13.A., broadens the scope of review by requiring submission of information necessary to determine significant adverse effects not only on the environment but “on human health or the environment”. This change is not substantial because it is consistent with provisions of Minn. Stat. Ch. 18F, the authorizing statutes, whose purpose is protection of humans as well as the environment. The change is found to be necessary and reasonable.

However, for the reasons noted at Finding 34, the words “significant” and “health” must be dropped and “humans” substituted for “human” in the second sentence of proposed Subp. 13.A. in order to conform fully to the intent of the statute (§ 18F.13) authorizing the exemptions. These changes are found to be necessary and reasonable and not substantial changes. Leaving the rule as proposed constitutes a defect because it results in an impermissible narrowing of the coverage of the statute. United Hardware Distributing Company v. Commissioner of Revenue, 284 N.W.2d 820 (Minn. 1979). See also Finding 78.

At Subpart 13.B., the MDA proposes to insert the words “30 day” between “a” and “public comment” to clarify the length of the public comment period. This change is found to be necessary and reasonable and not a substantial change because it serves merely to clarify the rule published in the State Register.

55. While public notice in the EQB Monitor is required at Subp. 13.B. for all requests for individual or class exemptions from permitted release requirements, the rules provide a comment period for class exemptions only. Ms. Carr, Lula Guthrie and Representative Phyllis Kahn support a comment period for individual exemptions as well. Ms. Carr suggests also publication of the Agency’s decision and notice of releases conducted after class exemptions have been granted. The MDA declines to adopt any of the recommendations noted here. It maintains that its authority to adopt Subp. 13 derives from Minn. Stat. § 18F.13, which contains no requirement for notice or public comment. As explained in its Final Comments and Response to Comments, the goal of individual release permits is to expedite releases that have been reviewed and approved already (mostly by federal agencies with oversight authority respecting GEOs). The MDA argues that additional public comments on releases of the type contemplated by Subp. 13 are redundant because the earlier, related permits would have involved an appropriate comment period. It is argued that flexibility (a faster

decision) is necessary to accommodate the anticipated rapid increase in numbers of releases to avoid unreasonable delays and duplication of oversight. It is contemplated that the procedures in Subp. 13 will be applied only to organisms not covered under the notification procedures, but for which there is substantial information regarding environmental releases based on a prior (federal) review, laboratory studies or earlier permitted releases.

The ALJ finds that the Commissioner of Agriculture is not required by statute to provide a public comment period in determining decisions to exempt individual releases from permit requirements pursuant to proposed Minn. Rule 1558.0040, Subp. 13. The decision not to require such comment is found not to be a defect. In addition, it is not a defect to not require that the Agency's decision on the exemptions issued under Subp. 13 be published or that notification to the public be given of releases after class exemptions have been granted.

Environmental Assessment Worksheet—Part 1558.0050

56. An environmental assessment worksheet (EAW) is needed in order to assess the environmental impact of a proposed release and to meet statutory requirements for the Department to be designated as an agency that issues a "significant environmental permit" under Minn. Stat. Ch. 116C and the rules adopted under that statute. It is found that the EAW requirements proposed in the rules meet the general needs of the above requirement and the specific needs of the Department in order to assess whether an unreasonable risk of adverse effects to human health or the environment exists.

57. In the last sentence of 1558.0050, Subp. 3, the MDA proposes to substitute the words "a 30 day" for "the" between the words "and" and "public comment period" in order to provide specificity to the comment period provided in the subpart. This clarifying insertion is found to be necessary and reasonable and does not constitute a substantial change.

58. Proposed Subpart 4 of 1558.0050 reads:

EAW findings. The commissioner shall issue findings of fact based on the EAW. The findings must determine if there is a potential for significant environmental effects. If there is a potential for significant environmental effects, an EIS must be prepared. The findings may also be used to determine if the permit should be granted or denied, and if any permit conditions are needed to mitigate or lower risks that have been identified by the EAW.

In its SONAR, the MDA identified the reasons for requiring an EAW. Under Subpart 4, the Commissioner issues findings based upon the results of the EAW. The proposed rule does not specify outcomes for the permit process arising from the Commissioner's findings in particular cases. The subpart indicates that where a "potential for significant environmental effects" is found, an EIS must be prepared. The next sentence authorizes the findings to be used for granting or denying a permit and imposing permit conditions to lower risks identified in the EAW.

By not specifying outcomes in the subpart, the language can lead to unintended results. Under the proposed language, the Commissioner could find that a potential for significant environmental impact exists and grant the permit while the EIS is being prepared. In a similar vein, the Commissioner could prepare findings indicating no impact and deny the permit for no other reason. The Commissioner could also refuse to use the findings to make a decision on the permit application as the rule is written. The language of subpart 4 is too flexible to place any check upon the Commissioner's discretion. This overly-broad discretion is a defect in the proposed rule.

To cure the defect in Subpart 4, the MDA must propose language that removes the unbridled discretion from the Commissioner's possible actions. The Judge suggests the following language:

The Commissioner shall issue findings of fact based on the EAW. The findings must determine if there is a potential for significant environmental effects. If there is a potential for significant environmental effects, a permit can only be obtained after preparation of an EIS. If there is a finding of no potential for significant environmental effects, and the Commissioner chooses to decide on the permit application at this stage, the Commissioner must base the decision to grant or deny the permit or impose conditions on granting a permit on the findings made under this part.

The suggested language clarifies the role of the EIS in the permit process and eliminates the defect arising from overly-broad discretion. The new language cures the defects in the proposed subpart and does not constitute a substantial change. The language also is found to be necessary and reasonable.

59. Subpart 5 of 1558.0050 specifies that an Environmental Impact Statement, if required, must be written and reviewed under the procedures in part 4410.2000. In its Comments, the Agency proposed to add "-4410.2300" at the end of the subpart in order to cover all the sections dealing with EIS preparation and review. The proposed change is found to be clarifying in nature, necessary and reasonable. It does not constitute a substantial change.

60. Carolyn Carr, Sr. Gladys Schmitz and Michelle Thom commented on Environmental Impact Statements, Schmitz and Thom advocating that generic EISs be conducted on this rule package, and Carr suggesting that the rules provide EIS procedures, particularly for commercial-scale releases. Carr notes that Minn. Stat. § 116D.04, Subd. 2a requires an EIS for a project where there is "potential for significant environmental effects". From this, she reasons that the exemptions provided in the proposed rules are in conflict with MDA's obligation to conduct its review "subject to the provisions of Chapter 116D and rules adopted under it", as stated at Minn. Stat. § 18F.12. The Administrative Law Judge finds no such conflict, because the exemptions provided at Minn. Stat. §§ 18F.13(a) and 13(b) are applicable only upon a determination that there will be no adverse effects to humans and the environment resulting from a proposed release. The statutory trigger under § 116D.04, Subd. 2a, "potential for significant environmental effects", is never reached.

In its response to Ms. Carr, the MDA noted that it disagrees with the underlying assumption that commercial releases inherently pose a “potential for significant environmental effects”. It notes further that GEOs under consideration for commercial use exemptions have already met federal requirements, including environmental assessment under the National Environmental Protection Act (NEPA). Under the proposed rules, GEOs receiving commercial use exemptions will have undergone environmental review and already have been determined to have no significant environmental effects. The rules also provide for rejection of an exemption if environmental problems are identified.

Notification Procedures for Certain GEOs—Part 1558.0060

61. In response to comments from Representative Kahn, Carolyn Carr, Michelle Thom and Anne Kapuscinski calling for a public comment period before the Commissioner of Agriculture adds any plant species to those eligible for notification procedures, a process allowing the release of genetically engineered plants that meet specific standards without requiring that they follow the full permit procedure, the MDA offers the following proposed sentence to be inserted at the end of the originally-published Subp. 1.A.(2) of 1558.0060:

“Supplemental notice of federal register items announcing changes in the list of plants species will be published in the EQB Monitor and sent to the MDA GEO mailing list.”

The text of the Agency’s Response to Comments, which contains the additional proposed language outlined above, adds that “MDA will accept comments during the federal comment period”. Part of the justification for the proposed changes is “the notice of the federal comment period will not add to the duplication which is an important consideration.” It is unclear from the comment whether the last-quoted sentence regarding the Department’s acceptance of comments is also proposed to be added to the rule, following the sentence quoted in the above paragraph.

The Administrative Law Judge finds that the sentence quoted in the first paragraph of this Finding, if added to the end of the rule, is necessary and reasonable and does not constitute a substantial change. If both that sentence and the sentence suggested in the preceding paragraph are added at the end of the subpart as published in the State Register, the language resulting is found also to be necessary and reasonable and does not constitute a substantial change. These are not substantial changes because, as the Department noted in its Response to Comments, no extra time is added to what was intended to be an expedited process. The ALJ recommends addition of the second sentence to clarify that the Department will accept comments during the time of the Federal review. It is suggested further, for clarity purposes, that the words “Department of Agriculture’s” be substituted for the acronym “MDA” in the first sentence proposed for addition. This change is necessary, reasonable and not a substantial change.

62. Kirk Kelley suggested that there be a public comment period for any release under the notification procedure. The Department responds that such a change is not in the spirit of the section which is to allow for less oversight. There is a very low risk of

adverse effects with such releases because of the eligibility criteria and performance standards, and there is adequate alternative regulatory oversight. The section of the authorizing statute (Minn. Stat. § 116C.98), which is taken directly from federal regulations, implies a need to reduce duplication. The MDA's decision not to add the comment period suggested by Mr. Kelley is within its discretion, and does not constitute a defect.

63. The Department points out that Subp. 1.F. of 1558.0060 contains a typographical error. The word "animals" should be changed to "animal". This clerical change is found to be necessary and reasonable and not a substantial change.

64. At Subpart 9.A. of 1558.0060, the person notified by the Commissioner of Agriculture upon release in response to the notification procedure is proposed to be changed from "the chief executive of the county" to "the chair of the county board". This change is found to be necessary and reasonable and not a substantial change. The language comes from federal regulations and was repeated in the statute, but the proposed change merely clarifies the statute.

In this connection, it was recommended by Robert Shimek, representing the White Earth Land Recovery Project, that notice of the proposed release be mailed also to the Tribal Council of any reservation affected by a release pursuant to the notification procedures. The Administrative Law Judge recommends, but does not require, that the MDA make this change. The subpart, with or without the new language is found to be necessary and reasonable. The new language would not constitute a substantial change. It is only appropriate to notify sovereign governmental units if they are in the vicinity of GEO releases, and the Tribal Councils on this State's reservations are the governing bodies of such sovereign units.

65. Proposed Subpart 2.E. of 1558.0060 reads: "There must be no viable vector agent associated with the genetically engineered plants". In the SONAR, the Department stated that it repeated Minn. Stat. § 116C.98 verbatim at 1558.0060 because Subd. 6 of Minn. Stat. § 116C.98 provides for the repeal of the statute once rules governing the same subject are adopted. And, since the statute went into effect the day following its enactment, the MDA decided it was reasonable to include the section as written in the statute for this notification procedure in order to provide appropriate continuity.

A problem arises because the comparable statutory provision to the subpart quoted above reads "There must be a viable vector agent associated with the genetically engineered plants". The two provisions are clearly in conflict with each other and it would violate substantive principles of law to adopt a rule that was in direct conflict with a statute.

66. Minn. Stat. § 645.26, Subd. 2 provides "When, in the same law, several clauses are irreconcilable, the clause last in order of date or position shall prevail". It is clear from an examination of the statute that clauses following the statute quoted in the preceding Finding are irreconcilable with the language mandating that a viable vector agent be associated with the genetically engineered plants. A prime example is the very next clause, which provides that field trials of genetically engineered plants must be conducted such that the plants will not persist in the environment and that no

offspring can be produced that could persist in the environment. The presence of a viable vector agent allows for persistence in the environment, which is irreconcilable with subsequent clauses, so a situation arises where § 645.26, Subd. 2 allows the clauses last in order of position to prevail. It is found that the MDA, under these circumstances, can adopt the rule as proposed.

Turning to the proposed rule itself, it found to be necessary and reasonable. In order to be consistent with the rest of the rule, this clause must provide that there be no viable vector agent associated with the genetically engineered plants.

67. The MDA, with the cooperation of the Environmental Quality Board's staff and the Office of the Revisor of Statutes, has supplied the record with evidence that the word "no" was dropped mistakenly and replaced with the word "a" after the Board had submitted its draft bill to the Revisor's Office. This mistake was not noticed until the Session Laws were published.

On March 10, 1995 a Revisor's bill, Senate File 1118, was introduced to correct erroneous text in current Minnesota statutes. Section 33 of that bill would correct the mistake appearing in the current statute at § 116C.98, Subd. 3.(e), which correction substitutes the word "no" for the word "a". In its "Explanation" to the proposed bill, the Revisor's Office explains that the amendment to Minn. Stat. § 116C.98, Subd. 3 corrects a drafting error that rendered the subdivision meaningless and conflicts with federal regulations.

The action taken by the Office of the Revisor of Statutes, when enacted into law, will remove the problem of inconsistency between the statute and rule. If the statute is passed prior to adoption of the rule, the issue noted in the two preceding Findings no longer exists.

Commercial Use Exemption—Part 1558.0070

68. Part 1558.0070 outlines exemption procedures used to release organisms for commercial use. Exemptions for commercial use are authorized under Minn. Stat. § 18F.13a and are consistent with Minn. Stat. § 116C.94, Subd. 3 (the commercial use exemption statute applicable to the Environmental Quality Board). The purpose of this Part is to allow for commercial release without a permit if the requirements are met, and for class exemptions when there are many similar releases. The Commissioner also retains the right to rescind the exemption should there be any unreasonable adverse effects on human health or the environment associated with the resulting commercial use.

69. At 1558.0070, Subpart 2.B., the Department recommended two changes—insertion of the words "at least" between "monitor" and "30" and deletion of the word "sale", replacing it with the words "commercial use" at the end of the subpart. These changes, which clarify the intent of the MDA and provide consistency with earlier usage, are found to be necessary and reasonable and do not constitute substantial changes. As discussed in subsequent Findings, this subpart was proposed for deletion in connection with submission of the MDA's Response to Comments on March 20, 1995.

70. At proposed Subp. 2.D., the MDA proposes the insertion of the words "30 day" between "a" and "public" in the last sentence of the subpart. This proposed

change is found to be clarifying in nature, necessary and reasonable and does not constitute a substantial change.

71. The ALJ questioned the use of the word “may” at three different locations in Part 1558.0070, but is convinced by the Department’s Final Comments that the usage of the word is appropriate in each various context. The primary justification for retaining the word “may” at the various locations questioned is to allow appropriate flexibility for the Commissioner. It is found that retention of the word “may” as noted is not a defect because the standards for decision are contained in the text of the same subparts and the discretion exercised favors the applicant.

The Department recommends a clarifying change to Subp. 2.F. of 1558.0070, by inserting the words “evidence of” between “any” and “unreasonable” in the subpart. The proposed change provides consistency with standards specified in other parts of the proposed rules and is found to be necessary, reasonable and not a substantial change.

72. A major concern during this rulemaking process is that the Department initially proposed no public comment period for individual commercial use exemptions under 1558.0070, Subp. 2. See the comments of David Andow, Carolyn Carr, Amanda Hand, Representative Phyllis Kahn, Anne Kapuscinski, Don Sherper, Robert Shimek, David Somers and Michelle Thom.

The Department explains that the concern expressed must be analyzed in the context of the entire regulatory process. First, projects go through the permitting process on both the federal and state level, and in many cases the permits are redone each year with a new comment period for each permit and for each location in Minnesota, since each location requires a separate EAW and permit. The Department cited the example of a type of soybean for which a dozen EAWs have been done in Minnesota, all with public comment periods. Any delisting (meaning that it is no longer a regulated article) is not accomplished until additional environmental assessments have been done by the United States Department of Agriculture and the product has been reviewed by the U.S. Food and Drug Administration for any food or feed safety issues. Given all this, the Department maintains that the likelihood of additional concerns being raised during Minnesota’s review for a commercial use exemption is highly unlikely. It is noted also that at this point the public has had numerous opportunities to comment and, while several commentators have indicated the commercial use exemption is a large step in the regulatory process (David Andow, Carolyn Carr, Anne Kapuscinski, and Michelle Thom), the Department maintains that in many ways, because of all the prior review, it is the least risky of any step.

73. The MDA maintains that because of all the safeguards noted in the preceding Finding, additional regulation on the state level is not needed nor does it add additional safeguards missing in the federal procedure. It is also necessary to streamline the review. Delays in granting of commercial use exemptions may affect large companies that market nationally only marginally, particularly since no other state has any additional oversight (all other states accept federal rulings regarding delisting without additional review or comment). However, for a small regional company, the result of a delay could be the loss of an entire season of sales. In light of the number of layers of regulatory oversight already in place at both the state and federal level before

commercial use exemptions are granted, the Department believes additional delay is unreasonable.

In addition, the Department points out that the authorizing statute, § 18F.13(a), does not require additional state oversight beyond a pre-exemption investigation into whether there is evidence of adverse effects on humans and the environment.

74. In response to the large number of commentators that expressed concern that public notice and comment would not be generally adequate or that were concerned about comment periods in specific sections of the rule, and with a view to maintaining an efficient process that does not increase unreasonably the length of the regulatory review, the Department, in its Response to Comments, proposes replacing 1558.0070, Subp. 2.B., both as drafted originally and as modified (see Finding 70) with the following language:

“B. Supplemental notice of federal register items regarding delisting or deregulation of GEOs will be published in the EQB Monitor and sent to the MDA GEO mailing list. MDA will accept comments during the federal comment period.”

The Department maintains that this addition allows for adequate notice of potential items to be commercialized and allows persons interested in commenting to send comments directly to the Department. It does not lengthen the regulatory process on the state level.

75. In addition to the change outlined in the preceding Finding, the Department proposes inserting a sentence reading “There will be public notice in the first available EQB Monitor for individual exemptions.” before the last sentence in 1558.0070, Subp. 2.D. The Department offers this language to substitute for the deleted Subp. 2.B. in an effort to alleviate concern that exemptions are being given without any way for the public to find out about them while still giving the Department the flexibility to deal with individual exemptions while keeping the public informed. The comment period for class exemptions is specified to be 30 days (this specificity was absent from the State Register version).

76. The changes detailed in the preceding two Findings are found to be necessary and reasonable. For clarity purposes, the ALJ suggests changing “MDA” to “Department”, a clerical change found to be necessary, reasonable and not substantial.

However, deleting Subp. 2.B. as published originally in the State Register or as modified in the Department’s Final Comments of March 13, constitutes a substantial change defect in that it removes the requirement that notice of the exemption of GEOs to allow for commercial use be published 30 days prior to sale or commercial use. The additional language proposed for Subp. 2.D. and the proposed new 2.B. do not alleviate the defect because a publication in the EQB Monitor as finally proposed could occur less than 30 days before commercial use (it is assumed the decision to grant the exemption has been made already).

Elimination of the 30 day requirement in this subpart is a substantial change because it results in a rule fundamentally different from that contained in the original publication of the proposed rules in the State Register. In addition, persons who could

not have been reasonably expected to comment on the proposed rules at the hearing (because the 30 day requirement was announced originally) are affected adversely by the change. By deleting the 30 day notice provision after the hearing, the Department has effectively prevented concerned persons from objecting to the change.

The defect noted in this Finding can be cured by reinstatement of the deleted (as modified) Subp. 2.B., and adoption of it along with adoption of the language proposed for Subparts 2.B. and 2.D. in the Agency's March 20 Response to Comments.

77. At Subparts 2.C., 2.E. and 2.F. of 1558.0070, the proposed rules specify that the Commissioner may require additional use conditions or marketing limits for mitigation or lessening risk (2.C.), that the Commissioner may reject an application for a commercial use exemption (2.E.) and that the Commissioner may modify, suspend or revoke the commercial use exemption (2.F.), all with reference to unreasonable adverse effects on human health or the environment. It is found that the phrase "unreasonable adverse effects on human health or the environment" at Subps. 2.C. and 2.E. of Part 1558.0070 is outside the statutory authority granted in the statute cited in the SONAR as authority for the commercial use exemption. (Minn. Stat. § 18F.13(a)). The statute, quoted in full at an earlier Finding, requires a showing that the organism can be released "without adverse effects on humans and the environment". Modification of adverse effects by the word "unreasonable" and restriction of the effects on humans by limiting considerations to the effects on human health constitute defects because they narrow inappropriately the intended broad effect of the statute. United Hardware Distributing Company v. Commissioner of Revenue, 289 N.W.2d 820 (Minn. 1979).

As proposed by the MDA, Subps. 2.C. and 2.E. narrow the authorizing statute by confining the scope of the Commissioner's authority to refuse to grant a commercial use exemption. The statutory grant of authority is broad, in that the concept of "adverse effects" is not modified in any way and that effects on humans rather than merely "human health" are to be taken into consideration. The defects noted can be remedied by substituting the words "without adverse effects on humans and the environment" for the offending language noted.

Subpart 2.F. does not violate the authorizing statute because it covers situations (modification, suspension, revocation) arising after a commercial use exemption is granted. The statute requires consideration of "adverse effects on humans. . ." only when the granting of an exemption is under consideration.

Part 1558.0080

78. This Part is needed to delineate specific uses that do not require a release permit, notification or commercial use exemption. The uses specified (containment facilities, facilities found by the Commissioner to provide adequate containment to prevent unreasonable risks of release into the environment for the specific use proposed, and the movement of GEOs) do not constitute releases under Minn. Stat. Chapters 18B, 18C, or 18F. These categories are specified in the rule in order to avoid

any confusion about what is considered a release. Proposed Part 1558.0080 is found to be necessary and reasonable.

79. The MDA proposes a punctuation change at 1558.0080, Subp. 2, to remove the semicolon after the word “facility” and replace it with a comma, and to remove the comma after the next word, “but”. This proposed change is found to be clerical in nature, necessary and reasonable. It does not constitute a substantial change.

Other Public Comments

80. In his oral and written comments (Ex. 45), Dr. David Andow proposed a major revision of the rules involving a re-grouping of various types of releases. The Department commented that Andow’s proposals would result in a cumbersome and lengthy review process as well as significant duplication of the federal oversight process. In the commercial use area, the time frame under Andow’s scheme would last from 90 to 150 days for completion of Minnesota review once all federal review had been completed. The Department anticipates completing the process for individual exemptions in roughly half that time. The MDA maintains that Andow also calls for duplication of the review process for all applications regardless of the level or intensity of federal oversight and regardless of any similarity to previous reviews, which would result in a dilution of MDA resources into the consideration of releases presenting relatively low risk.

As proposed by the MDA, the Department argues that the rule will allow acceptance of oversight where it is adequate, prevent duplication, and give Department staff the opportunity to focus its resources on releases requiring greater scrutiny. Numerous commentators expressed concern that Minnesota should not have rules that go beyond the federal framework or result in loss of competitiveness (Senator Steve Dille, Jerry Glover, Greg Kiecker, Jerry Larson, Don Loeslie, Hector Quemada, Gerald Shoenfeld, David Somers and James Woodman). The Department is concerned that Dr. Andow’s proposals do not enhance the ability of MDA to protect against unreasonable adverse effects on human health and the environment, but add unneeded duplication that could affect significantly the competitiveness of Minnesota firms. It treats Andow’s proposals as setting up a whole new permitting process rather than reducing the duplication of federal oversight.

81. The Administrative Law Judge finds that many of Dr. Andow’s suggestions have merit, and should be considered by the Department. With respect to how much public notice and comment should be provided at various points of the rule, Dr. Andow is correct in that decisions in this area involve balancing of several complicated factors such as the public’s right to know, the public’s desire to know, industry’s right to confidentiality, the additional time and effort that industry must expend to meet these requirements and regulatory costs, including the time and effort spent to inform the public. His view of the role of the regulatory agency, to protect the public interest while not unduly burdening industry and also limiting agency costs to the extent possible, is accurate. Andow considers the decision to exempt for a commercial use to be the most significant section of the proposed rules.

At each of the decision points he identifies in the rulemaking process, Andow has supplied specific language to try to identify who is eligible to apply, the eligibility criteria, application procedures, the decision process and public participation. He also advocates a specific listing of information that the public should be notified about in connection with each significant decision made in the process.

82. In response to Dr. Andow, James Woodman, Ph.D., Executive Director of Biotech Consulting, pointed out that many of Dr. Andow's suggestions result in rules which would be redundant, given the federal regulatory framework, and unduly restrictive to the commercialization of GEOs in Minnesota. Woodman stresses that the legislature did not intend the rules and regulations to exceed the federal regulatory framework. To the extent they do, Woodman believes Andow's proposals go beyond legislative intent.

83. As a specific example, where Andow allegedly makes recommendations going beyond legislative intent, Woodman cites Andow's recommendation that an applicant for commercial use exemption must state "the intended commercial use" of the organism for which release is sought. Woodman responds that once a GEO is determined to be safe, its intended commercial use is irrelevant unless the intended commercial use poses a risk to human health or the environment. The commercial product does not have to meet a "socially useful" test, as Andow seems to advocate. The ALJ notes that the test, under § 18F.13, is whether release of the GEO can be done without adverse effects on humans and the environment, but he agrees with Woodman—the meeting of some sort of utility standard is unnecessary. Since agriculturally related organisms can be found in a broad diversity of products, requiring the applicant to state the intended commercial use would act as a prohibition to commercial development. For example, Woodman invites the reader to imagine the difficulty of identifying all the commercial products that could contain starch, proteins or oil derived from genetically engineered corn.

84. Andow recommends that without prior state release reports, no commercial use permits should be granted without prior consent of an interdisciplinary panel from appropriate areas of expertise to determine whether the federal data pertains to Minnesota conditions. Woodman suggests that such a process is unnecessary, redundant and discriminatory against small companies. Under federal law, the United States Department of Agriculture, Food and Drug Administration and Environmental Protection Agency must determine that a GEO does not pose a risk to human health and the environment anywhere in the United States. Under the proposed rules, Minnesota's Commissioner of Agriculture must take into account the numerous considerations found at proposed Part 1558.0030. Andow's proposal to add a further review process on top of those conducted by the federal agencies and MDA is tantamount to charging that the federal and state officials have been failing in their responsibilities, according to Woodman. Woodman adds that to assume that an interdisciplinary panel of "well intentioned 'Minnesota experts'" would provide a meaningful contribution to the process strikes him as "provincial at best". Any Minnesota citizens, including scientists at the University of Minnesota, are believed by Woodman to have ample opportunity to contribute their viewpoints and concerns through the federal public comment process.

85. Dr. Andow's comments include a suggestion that class exemptions be subject to a notification procedure. Dr. Woodman argues that this proposal is contrary to statute because once the Commissioner grants a class exemption, the applicant is no longer subject to a state permit. As an analogous example, Woodman notes that the legislature granted a class exemption for human gene therapy at Minn. Stat. § 116C.97, subd. 1, but did not include an elaborate notification system to accompany the exemption.

86. The MDA's rejection of the majority of Dr. Andow's recommendations is within its discretion, does not render its proposals unnecessary or unreasonable and does not constitute a defect in its proposals. If the Commissioner proposes to adopt additional rule changes as suggested by Dr. Andow, he must submit the proposals to the Chief Administrative Law Judge for review. See page 2.

87. Dr. Anne Kapuscinski argues in her remarks that the considerations proposed at Part 1558.0030 are inadequate to meet the statutory obligation of protecting humans from adverse effects of GEO releases. Dr. Kapuscinski recommended that the MDA meet its statutory requirement of protecting human health by establishing an interdisciplinary panel to develop further considerations. Dr. Woodman responded to Kapuscinski by pointing out that her proposed state review panel appears to exceed the federal regulatory decision process, which was not the legislature's intent. Woodman implies that Kapuscinski's recommendation that the panel include experts on food labeling, economists, social scientists, ethicists and theologians, is contrary to the federal regulatory framework implied for adoption by the legislature, which framework does not require a socio-economic impact analysis. Rather, the inquiry centers on determinations of safety and efficacy. The ALJ recommends a convening of a panel pursuant to Dr. Kapuscinski's recommendation in order to revisit what is proper to consider with respect to "adverse effects on humans" that could result from the release of agriculturally related GEOs. However, the rule is not defective if such a panel is not required upon final adoption. See Finding 39.

88. At all locations in the proposed rules, Dr. Kapuscinski recommends substituting "adverse effects on humans and the environment" for "unreasonable effects on human health or the environment". The ALJ has found defects in the above Findings where proposed rules were in conflict with Minn. Stat. § 18F.13. However, that statute applies only to the granting of notifications and exemptions, and the less-inclusive language has not been found defective with respect to the release permit process, the development of EAWs or at times in the notification and commercial use processes occurring after the decision to grant such relief, because different standards of review are applicable then.

89. The issue of whether rules requiring labeling of products containing agriculturally related GEOs is appropriate for adoption in this rulemaking proceeding because the MDA was granted authority over organisms "used in agricultural production or processing of agricultural products" at Minn. Stat. § 18F.02, subd. 2a, merits additional comment. In its Response to Comments, the Department notes that Minn. Stat. Chapters 18F and 116C give no authority for labeling. Labeling laws in Minnesota statutes are found at Minn. Stat. §§ 31.101-31.12. Minn. Stat. § 31.101, which grants the Commissioner of Agriculture the authority to publish and amend rules for the

“efficient administration and endorsement of the Minnesota food law”, relies in its text on being in uniformity with applicable federal laws and rules. The MDA maintains that its regulatory authority over GEOs does not extend to foods, unless such foods contain viable GEOs. Minn. Stat. § 31.12 deals with labeling specifically. In relevant part, it requires:

“. . . it shall be the duty of the Commissioner, by rulings not inconsistent with law, to require that any article of food, or the package, receptacle, or container thereof, before it be sold, transported, used, offered for sale or transportation, or had in possession with intent to use, sell or transport within the state, shall be labeled, stamped stenciled, marked, or branded in such a manner as to plainly exhibit to the purchaser any or all of the following data or information: The percentages and true composition of such food article, its quality, strength, quantity, source of its manufacturer or production or the person by or for whom the same is manufactured, produced, packed, or shipped. . . .”

In the absence of a specific directive in the statutes authorizing this rulemaking proceeding to require labeling of food (labeling is not required for any other products containing GEOs), the only authority for requiring the identification of the presence of GEOs in any product appears to the authority granted the Commissioner to issue “rulings not inconsistent with law” under the above-quoted statute to require labeling of the “true composition” of any food articles. This statutory implication may grant the Commissioner the discretionary authority, in making rules involving the “processing” of agriculturally related organisms, to adopt rules requiring labeling. However, if such discretion does exist, it is clear the Commissioner of Agriculture has declined to exercise it in this proceeding. That decision does not render defective, in and of itself, the rules that are proposed.

90. Minn. Stat. § 31.11 grants the Commissioner authority to adopt rules relating to the “sale” of food to protect and preserve the public health and to enforce the “laws. . . relating to food. . .”. The Administrative Law Judge suggests that a rulemaking proceeding under § 31.11 is the more appropriate forum for consideration of whether food containing GEOs should be so labeled.

Based on the foregoing Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

1. That the Department of Agriculture gave proper notice of the hearing in this matter.
2. That the Department of Agriculture has fulfilled the procedural requirements of Minn. Stat. § 14.14, subds. 1, 1a and 2, and all other procedural requirements of law or rule.
3. That the Department has demonstrated its statutory authority to adopt the proposed rules and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, 14.15, subd. 3 and 14.50 (i)(ii), except as noted at except as noted at Findings 34, 53, 55, 59, and 78.

4. That the Department has documented the need for and reasonableness of its proposed rules with an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 2 and 14.50 (iii).

5. That the amendments and additions to the proposed rules which were suggested by the Department after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.15, subd. 3, and Minn. Rule 1400.1000, Subp. 1 and 1400.1100, except as noted at Finding 77.

6. That the Administrative Law Judge has suggested action to correct the defects cited in Conclusions 3 and 5, as noted at Findings 34, 53, 55, 59, 77 and 78.

7. That due to Conclusions 3, 5 and 6, this Report has been submitted to the Chief Administrative Law Judge for his approval pursuant to Minn. Stat. § 14.15, subd. 3.

8. That any Findings which might properly be termed Conclusions are hereby adopted as such.

9. That a finding or conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Department from further modification of the proposed rules based upon an examination of the public comments, provided that no substantial change is made from the proposed rules as originally published, and provided that the rule finally adopted is based upon facts appearing in this rule hearing record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed rules be adopted except where specifically otherwise noted above.

Dated this 5th day of May, 1995

RICHARD C. LUIS
Administrative Law Judge

Reported: Lori Case, Janet Shaddix and Associates
Transcript Prepared.