



**S.B. 202**

125th General Assembly  
(As Introduced)

Sen. Mumper

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**BILL SUMMARY**

**Meat and poultry slaughtering and processing establishments**

- Establishes parallel compliance requirements governing meat slaughtering and processing establishments (meat establishments) and poultry slaughtering and processing establishments (poultry establishments) that wish to receive a license to operate, and authorizes an applicant who is denied a license to appeal the denial.
- Adds that a license for either a meat or poultry establishment can only be renewed if the Director of Agriculture finds that the establishment is in compliance with the Meat and Poultry Inspection Law and rules adopted under it.
- Allows the Director to impose progressive enforcement actions for a continuing violation by a meat or a poultry establishment of the Meat and Poultry Inspection Law or rules adopted under it.
- Authorizes the Director to condemn or retain product on hand and immediately withdraw inspection prior to an adjudication hearing until specified conditions at a meat establishment are corrected, and requires the Director subsequently to afford a hearing upon the request of the owner or operator of the establishment.
- Allows the Director to immediately withdraw inspection from a meat or poultry establishment prior to an adjudication hearing if he determines that the owner or operator or an employee of the establishment forcibly assaulted, resisted, opposed, impeded, intimidated, or interfered with any person while that person was performing his duties under applicable provisions of the Meat and Poultry Inspection Law or rules adopted under them.

- Authorizes the Director to apply for an injunction or other appropriate relief concerning a violation of the Meat and Poultry Inspection Law or the rules adopted under it.
- Authorizes, rather than requires, an inspector of either a meat or poultry establishment to notify the applicable licensee of a violation, and adds withdrawal of inspection to an inspector's authorized progressive enforcement actions.
- Prohibits a person from offering for sale meat or meat products that have not been inspected in compliance with the meat establishment provisions of the Meat and Poultry Inspection Law.
- Revises the definition of "retail dealer" or "retail butcher."

**Claims for indemnification for livestock injured or killed by coyotes or black vultures**

- Revises the procedures and requirements governing the filing of a claim for indemnification for the injury or death of livestock caused by coyotes or black vultures, including revising the time when the livestock's owner may file a claim and defining "fair market value" rather than having the owner include the fair market value of the livestock in the claim and a dog warden certify that value.
- Modifies the responsibilities of dog wardens and wildlife officers in investigating claims filed by owners.
- Requires claims to be filed directly with the Department of Agriculture, requires the Department to hear claims that are approved by a dog warden and supported by a wildlife officer, requires the Director to determine an animal's fair market value as defined by the bill, and allows the owner of an animal to appeal the Department's determination of that value.
- Requires claims to be paid from money appropriated for that purpose from the General Revenue Fund rather than from the Agro Ohio Fund, and requires the Department to disapprove claims if insufficient funds are available from that money.



- Requires the Director of Agriculture to adopt rules to administer the livestock indemnification program, including rules that establish requirements governing voluntary animal control plans.

**Acquisition of real property for agricultural easements**

- Adds that the value of an agricultural easement may be determined not only by a general real estate appraiser as in existing law, but also by a points-based appraisal system established by the Director of Agriculture, and authorizes the Director to include specified factors in that system.

**Applications regarding new drugs**

- Eliminates the procedures under which an application may be submitted to the Director of Agriculture for the sale, delivery, offer for sale, holding for sale, or giving away of a new drug.

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## CONTENT AND OPERATION

### *Enforcement of meat and poultry slaughtering and processing establishments*

#### *Overview and background*

The Meat and Poultry Inspection Law establishes generally parallel requirements governing meat slaughtering and processing establishments (meat establishments) and poultry slaughtering and processing establishments (poultry establishments).<sup>1</sup> Included in those requirements is the requirement that meat establishments and poultry establishments be licensed by the Department of Agriculture in order to operate in this state. The Meat and Poultry Inspection Law also requires establishments to be inspected and establishes enforcement procedures when violations are discovered.

The bill modifies several of these provisions. When parallel changes are made in both the meat establishment and poultry establishment provisions, the analysis will discuss them together. The analysis will specify when there are differing requirements for meat establishments and poultry establishments.

#### *License and license renewal requirements*

Under existing law for both meat and poultry establishments, the Director must inspect an establishment prior to issuing a license. A meat establishment must be in compliance with the Meat and Poultry Inspection Law. A poultry establishment must be in compliance with the poultry establishment provisions of that Law and rules adopted under them. The bill instead establishes identical

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<sup>1</sup> *Under the meat inspection provisions of the Meat and Poultry Inspection Law retained by the bill, "establishment" means all premises in the state where animals are slaughtered or otherwise prepared for food purposes, meat canneries, sausage factories, smoking or curing operations, and similar places (sec. 918.01(C)). "Animals" means cattle, calves, sheep, swine, horses, mules, other equines, goats, bison, cervidea, other bovidea, camelidae and hybrids thereof, ratites, domestic rabbits, domestic deer, as defined in the Division of Wildlife Law, or other animals determined by the Director of Agriculture by rule for human food purposes (secs. 918.01(D) and 918.12(A), not in the bill).*

*Under the poultry inspection provisions of the Meat and Poultry Inspection Law unchanged by the bill, "establishment" means any premises where poultry is slaughtered or otherwise prepared for food purposes (sec. 918.21(E), not in the bill). "Poultry" means any domesticated bird, pheasant, quail, partridge, peafowl, grouse, captive raised wild turkey, captive raised waterfowl, or other poultry determined by the Director by rule (secs. 918.12(B) and 918.21(L), not in the bill).*

compliance requirements. Under it, both meat and poultry establishments must be in compliance with the Meat and Poultry Inspection Law and rules adopted under it in order to receive a license. (Secs. 918.08(A) and 918.28(A).)

The bill adds that if the Director finds after an inspection that an establishment is not in compliance with the Meat and Poultry Inspection Law and rules adopted under it, he must deny the license application. The applicant may appeal the denial in accordance with the Administrative Procedure Act. (Secs. 918.08(A) and 918.28(A).)

Current law requires a license for a meat establishment or a poultry establishment to expire annually on March 31 and to be renewed according to the standard renewal procedure established in the Standard License Renewal Procedure Law. The bill specifies that a license for either a meat or poultry establishment can only be renewed if the Director finds that the establishment is in compliance with the Meat and Poultry Inspection Law and rules adopted under it. (Secs. 918.08(A) and 918.28(A).)

#### **Enforcement by Director of Agriculture**

Under existing law, if the Director determines that a licensed meat establishment is operating in violation of the Meat and Poultry Inspection Law or rules adopted under it, he must notify the licensee in writing of the violation and give the licensee ten days from the date of notice to cease or correct the violation. The bill specifies that the Director must inspect a meat establishment in order to determine whether it is in violation of the Meat and Poultry Inspection Law or rules adopted under it. Additionally, instead of requiring the licensee to cease or correct the violation, the bill requires him to cease or correct the conditions causing the violation. (Sec. 918.08(C).)

Current law provides that if the violation at a meat establishment continues after the expiration of the ten-day period, the Director may withdraw inspection and order the establishment to cease those operations subject to the Meat and Poultry Inspection Law. Any such order and the appeal of that order are governed by the Administrative Procedure Act. The bill instead provides that if the conditions causing the violation continue after the expiration of the ten-day period, the Director may do either of the following: (1) impose progressive enforcement actions in the same manner as inspectors (see "**Enforcement by inspectors**," below), or (2) suspend or revoke the establishment's license in accordance with the Administrative Procedure Act. (Sec. 918.08(C).)

Similarly, existing law specifies that if the Director determines that a licensed poultry establishment is operating in violation of the poultry establishment provisions of the Meat and Poultry Inspection Law or rules or orders



adopted or made under them, he must notify the licensee in writing of the violation and give the licensee ten days from the date of notice to correct the conditions causing the violation. The bill specifies that the Director must inspect an establishment in order to determine whether it is in violation of the Meat and Poultry Inspection Law or rules or orders adopted or issued under it. (Sec. 918.28(B).)

If the conditions that are causing a violation at a poultry establishment are not corrected within the ten-day period, current law authorizes the Director to revoke or suspend the license in accordance with the Administrative Procedure Act. The bill also gives the Director authority to impose progressive enforcement actions in the same manner as inspectors (see "Enforcement by inspectors," below). (Sec. 918.28(B).)

Under current law, if the Director believes that either a meat or poultry establishment is being operated under such insanitary conditions as to be a hazard to public health, or if he determines that either type of establishment is not in compliance with its hazard analysis critical control point system as required by rules, he may condemn or retain the product on hand and immediately withdraw inspection from the establishment until the insanitary conditions are corrected or until the establishment is in compliance with its hazard analysis critical control point system, as applicable (secs. 918.08(E) and 918.28(D)). The bill changes "hazard analysis critical control point system" to "hazard analysis critical control point plan" to be consistent with federal guidelines (secs. 918.02(G), 918.08(E), 918.25(E), and 918.28(D)). The bill also authorizes the Director to immediately take those actions with regard to a meat establishment prior to an adjudication hearing as required under the Administrative Procedure Act. The Director subsequently must afford a hearing upon the request of the owner or operator of the meat establishment. (Sec. 918.08(E).)

Under the bill, if the Director determines that the owner or operator of, or any person employed by, either a licensed meat or licensed poultry establishment forcibly assaulted, resisted, opposed, impeded, intimidated, or interfered with any person while that person was engaged in, or because of the person's performance of, official duties under applicable provisions of the Meat and Poultry Inspection Law or the rules adopted under them, the Director immediately may withdraw inspection from the establishment prior to an adjudication hearing as required under the Administrative Procedure Act (secs. 918.08(G) and 918.28(E)).

With regard to both meat and poultry establishments, the bill also authorizes the Director, in addition to any remedies provided by law and irrespective of whether or not there exists an adequate remedy at law, to apply to the court of common pleas of the county in which a violation of applicable provisions of the Meat and Poultry Inspection Law or the rules adopted under



them occurs for a temporary or permanent injunction or other appropriate relief concerning the violation (secs. 918.08(H) and 918.28(F)).

### **Enforcement by inspectors**

Under existing law, if an inspector determines that a licensed meat establishment is operating in violation of the meat establishment provisions of the Meat and Poultry Inspection Law or rules adopted under them, he must notify the licensee in writing of the violation. The poultry establishment provisions of that Law have the same notification requirement with regard to violations of those provisions. Instead of requiring an inspector of either type of establishment to notify the applicable licensee of a violation, the bill authorizes the inspector to notify the applicable licensee. (Secs. 918.08(D)(1) and 918.28(C)(1).)

Current law authorizes an inspector of either a meat or poultry establishment to immediately impose progressive enforcement actions against an establishment that violates either the meat establishment provisions or the poultry establishment inspection provisions of the Meat and Poultry Inspection Law or rules adopted under them, as applicable, including withholding the mark of inspection, suspension of inspection, and suspension of inspection held in abeyance (see below). The bill adds withdrawal of inspection to the list of authorized actions. (Secs. 918.08(D)(1) and 918.28(C)(1).)

Under law retained by the bill for both meat and poultry establishments, "suspension of inspection held in abeyance" means a period of time during which a suspension of inspection is lifted because an establishment has presented the Director with a corrective action plan that, if implemented properly, would bring the establishment into compliance with the Meat and Poultry Inspection Law. The bill adds that the corrective action plan also would have to bring the establishment into compliance with rules adopted under that Law. (Secs. 918.08(D)(2) and 918.28(C)(2).)

### **Prohibition**

Current law prohibits a person from selling meat or meat products that have not been inspected in compliance with the meat establishment provisions of the Meat and Poultry Inspection Law. The bill also prohibits a person from offering for sale meat or meat products that have not been inspected in compliance with those provisions. (Sec. 918.11(B).)

### **Definition of retail dealers and retail butchers**

Law unchanged by the bill exempts from the Meat and Poultry Inspection Law a retail dealer or retail butcher who sells only meat or meat products that have



been inspected in compliance with that Law directly to household consumers in retail stores. In addition, only the licensure requirement and the provisions of that Law governing sanitation, adulteration, misbranding, and use of the official mark apply to a retail dealer or retail butcher who sells only meat or meat products that have been inspected in compliance with the meat establishment provisions of the Meat and Poultry Inspection Law and whose operation or sales are other than those traditionally and usually conducted at retail stores or restaurants as prescribed by rules. (Sec. 918.10, not in the bill.)

Under current law, "retail dealer" or "retail butcher" means any place of business where the sales of products are made to consumers only, at least 75% of the total dollar value of sales of products represents sales to household consumers, and the sales of products to consumers other than household consumers does not exceed \$28,800 per year. The bill changes the limit on the sale of products to consumers other than household consumers from \$28,800 per year to the adjusted dollars limitation for annual retail sales published in the Federal Register by the Food Safety and Inspection Service in the United States Department of Agriculture. (Sec. 918.01(P).)

### **Claims for indemnification for livestock injured or killed by coyotes or black vultures**

#### **Overview**

Current law establishes an indemnification program for owners of certain animals that have been injured or killed by a coyote or a black vulture. An owner's claim must meet several requirements and be verified and approved by specified persons in order for a payment on the claim to be made. The dog warden and, if applicable, the wildlife officer of the area where the owner's animal was injured or killed must follow certain procedures in verifying the owner's claim for indemnification. Finally, the Department of Agriculture must perform specified tasks regarding the review and payment of the claims. The bill revises the procedures for filing a claim from the owner's submittal to the Department's final review and processing of the claim.

#### **Responsibilities of owners of livestock**

Current law requires an owner of horses, sheep, cattle, swine, mules, goats, domestic rabbits, or domestic fowl or poultry that have an aggregate fair market value of \$10 or more and that have been injured or killed by a coyote or a black vulture to notify the dog warden within three days after the loss or injury has been discovered. The bill makes the following revisions in this requirement: (1) replaces the list of animals with a definition of "animal" that includes all of the currently listed animals, (2) similarly, defines "predator" as a coyote or a black



vulture, (3) replaces the requirement that an animal have an aggregate fair market value of \$10 or more with a requirement that the owner believe that the animal has a fair market value of \$25 or more, (4) defines "fair market value" as the average price that is paid for a healthy grade animal at a livestock auction selected by the Director of Agriculture and licensed under the Livestock Dealers Law, (5) defines "grade animal" as an animal that is not eligible for registration by a breed association or in a registry, and (6) requires the owner to notify the dog warden by telephone and document by photograph the wounds sustained by the animal within 72 hours after the loss or injury has been discovered rather than simply notify the dog warden within three days after the discovery. (Sec. 955.51(A) and (B).)

Under existing law, in order to file a claim, an owner must wait for the dog warden's and the wildlife officer's determinations on the cause of the injury or death of an animal (see below). If the dog warden finds that the loss or injury was made by a coyote or a black vulture and the wildlife officer affirms that finding or states that he is uncertain of the dog warden's finding, the owner may proceed with a claim, and the dog warden must provide the owner with duplicate copies of the claim form prescribed by the Director and assist the owner in filling it out. The bill instead provides that after notifying the dog warden of the loss or injury, if the owner chooses to file a claim, he must complete a claim form for indemnification in quadruplicate as prescribed by the Director and provided by the dog warden. The owner may request, and the dog warden must provide, assistance in filling out the form. For purposes of the Department of Agriculture's review and certification of claims (see below), the owner must send to the Department, within 30 days after discovery of the animal, the original copy of the claim form, all photographs documenting the wounds of the animal, and any other pertinent facts in his possession. The bill requires the owner to retain a copy of the claim form and provide a copy of the form to both the dog warden and the wildlife officer that investigates the claim, if applicable. (Sec. 955.51(B).)

Under current law, the owner must set forth in the claim form the kind, grade, quality, and what he has determined is the fair market value of the animals, fowl, or poultry, the nature and amount of the loss or injury, the place where the loss or injury occurred, and all other pertinent facts in the possession of the claimant. If the animals, fowl, or poultry die as a result of their injuries, their fair market value is the market value of uninjured animals, fowl, or poultry on the date of the death of the injured animals, fowl, or poultry. If the animals, fowl, or poultry do not die as a result of their injuries, their fair market value is their market value on the date on which they received their injuries. The bill eliminates these provisions, but enacts similar provisions regarding the date of death or injury in the statute that specifies the Department's responsibilities (see below). (Sec. 955.51(A).)

Existing law states that if the animals, fowl, or poultry that are injured or killed are registered in any accepted association or registry, the owner or the owner's employee or tenant must submit with the claim form the registration papers showing the lines of breeding, age, and other relevant matters. If the animals are the offspring of registered stock and eligible for registration, the registration papers showing the breeding of the offspring must be submitted. Under the bill, the owner, instead of the owner or the owner's employee or tenant, must submit this registration information with the claim form. (Sec. 955.51(B).)

### **Responsibilities of dog wardens**

The bill makes several changes regarding the role of dog wardens in the indemnification process in addition to those discussed above. Current law states that if the dog warden finds after an investigation that a coyote or a black vulture did not cause the loss of or injury to livestock, the owner has no claim for indemnification. The bill generally retains this provision, but replaces the term "finds" with the term "determines" and makes conforming changes throughout the bill's provisions pertaining to livestock indemnification. (Sec. 955.51(C).)

Current law specifies that if the dog warden determines that a coyote or a black vulture caused the loss or injury, the dog warden must notify the wildlife officer of that determination. The bill adds that the dog warden must notify the wildlife officer by telephone. It also specifies that for the purposes of the Department's review and certification of claims (see below), the dog warden must send to the Department his determination of whether the animal was killed or injured by a predator and any other documents, testimony, or information that he has received relating to the loss or injury of the animal. (Sec. 955.51(C).) (For additional changes regarding the dog warden's responsibilities, see **Review of claims under current law**," below.)

### **Responsibilities of wildlife officers**

Current law requires a wildlife officer, after being notified by the dog warden of the dog warden's finding on a claim, to confirm the finding, disaffirm it, or state that he is uncertain about the finding. If the wildlife officer affirms the finding of the dog warden or states that he is uncertain about that finding, the owner may proceed with a claim. The bill makes several changes in these provisions. First, it replaces the term "finding" with the term "determination" and makes conforming changes. Second, it specifies that if the wildlife officer affirms the determination of the dog warden or states that he is uncertain about that determination, he must so notify the Department in writing for the purposes of the Department's review and certification of claims (see below). Finally, the bill states that if the wildlife officer disaffirms the determination of the dog warden, the owner has no claim for indemnification. (Sec. 955.51(D).)



### **Review of claims under current law**

Under current law, if the dog warden finds all the statements that the owner made on the claim form to be correct and agrees with the owner as to the fair market value of the animals, fowl, or poultry, he promptly must so certify and send both copies of the form, together with whatever other documents, testimony or information the dog warden has received relating to the loss or injury, to the Department (sec. 955.51(B)). However, if the dog warden does not find all the statements to be correct or does not agree with the owner as to the fair market value, the owner may appeal to the Department for a determination of the owner's claim. In that case the owner must secure statements as to the nature and amount of the loss or injury from at least two witnesses who viewed the results of the killing or injury and who can testify about the results. The owner also must submit both copies of the form to the Department no later than 20 days after the loss or injury was discovered. The dog warden must submit to the Department whatever documents, testimony, and other information the dog warden has received relating to the loss or injury. The Department must receive any other information or testimony that will enable it to determine the fair market value of the animals, fowl, or poultry injured or killed. The bill eliminates these provisions and replaces them as discussed below. (Sec. 955.51(C).)

### **Responsibilities of Department of Agriculture**

Under current law, the Department must hear claims submitted to it by dog wardens and by owners on appeal as discussed above. The bill instead requires the Department to hear claims that are approved by the dog warden and supported by the wildlife officer. The bill retains a requirement that the Department hear claims in the order of their filing. It also retains authority for the Department to allow the claims in full or in part, or to disallow any claim, as the testimony shows to be just, but adds as the testimony and information submitted with a claim show to be just. (Sec. 955.52(A)(1).)

As under existing law, the Department makes the final determination of the fair market value of any animal that is the subject of a claim. The bill specifies that if the animal that is the subject of a claim dies as a result of the injuries that it received from a predator, the amount of indemnity is the fair market value of the animal on the date of its death. If the animal does not die as a result of its injuries, the amount of indemnity is the fair market value of the animal on the date that it received its injuries. If the animal is registered or eligible for registration by a breed association or in a registry, the amount of indemnity is 125% of the fair market value of the animal on the date that it was killed or injured. If the date of death or injury of an animal cannot be determined, the amount of indemnity must be based on the fair market value of the animal on the date that the animal was discovered by its owner. (Sec. 955.52(A)(1).) Under the bill, if the owner of an



animal does not agree with the Department's determination of the animal's fair market value, he may appeal the determination in accordance with the Administrative Procedure Act (sec. 955.52(A)(2)).

Current law requires the Department to certify any claim or part of a claim. The bill adds that the Department must certify a claim that it has found to be valid. Under existing law, claims that are certified must be paid out of the Agro Ohio Fund created under law unchanged by the bill. The bill instead requires claims to be paid out of money that has been appropriated from the General Revenue Fund for those purposes. It retains a provision under which no claim can be paid if a claim for the same loss or injury has been paid or is payable under a policy or policies of insurance and a provision under which a claim may be paid for the amount of any deductible paid or payable by the claimant under insurance. The bill also provides that a claim cannot be paid if the owner of an animal who otherwise would receive indemnity under a claim has been paid more than \$500 within the immediately preceding year from the money appropriated for that purpose. However, that owner may be paid if he has implemented a voluntary animal damage control plan that meets the requirements established in rules adopted under the bill (see below). (Sec. 955.52(A)(3).)

Under the bill, if at any time the money that has been appropriated from the General Revenue Fund for the purposes of paying certified claims for a fiscal year is not sufficient to pay those claims, the Department must disapprove the claims. Any claim that has been disapproved due to lack of money cannot be resubmitted. (Sec. 955.52(B).)

The bill authorizes the Department either to assist owners in developing and implementing a voluntary animal damage control plan to prevent and minimize loss or injury to animals by predators or to enter into an agreement with another state agency, a federal agency, or a person to provide such assistance. The Department may use no more than 50% or \$25,000, whichever is less, of the money that is appropriated from the General Revenue Fund for the purposes of paying certified claims to pay the costs incurred by the Department for either providing assistance or entering into an agreement to provide that assistance. (Sec. 955.52(C).)

Finally, under the bill, the Director of Agriculture must adopt rules in accordance with the Administrative Procedure Act that are necessary to administer the livestock indemnification program, including rules that establish requirements governing voluntary animal damage control plans (sec. 955.52(D)).



### *Acquisition of real property for agricultural easements*

Existing law authorizes the Director of Agriculture, municipal corporations, counties, and townships to purchase or acquire by gift, devise, or bequest agricultural easements to retain the use of land predominantly in agriculture.<sup>2</sup> It also authorizes charitable organizations that are exempt from federal income taxation and organized for certain land preservation or protection purposes to acquire and hold agricultural easements. If a municipal corporation, county, township, or charitable organization cannot fund the purchase of an easement on its own, it may apply for a matching grant from the Director. The Director must use money from the Clean Ohio Agricultural Easement Fund exclusively to purchase agricultural easements in the name of the state and to provide matching grants to charitable organizations, municipal corporations, counties, and townships for the purchase of such easements. (Sec. 901.21, not in the bill.)

Current law specifies that a matching grant that is made by the Director to a municipal corporation, county, township, or charitable organization for the purchase of an agricultural easement and that consists of money from the Clean Ohio Agricultural Easement Fund may provide up to 75% of the value of the agricultural easement. The value of an easement is to be determined by a general real estate appraiser who is certified under the Real Estate Appraisers Law. The bill adds that the value of an agricultural easement also may be determined through a points-based appraisal system established by the Director under the bill (see below). (Sec. 901.22(D)(1).)

The bill requires the Director to establish a points-based appraisal system for use in determining the value of an agricultural easement. He may include any or all of the following factors in the system:

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<sup>2</sup> *Under law retained by the bill, "agricultural easement" means an incorporeal right or interest in land that is held for the public purpose of retaining the use of land predominantly in agriculture; that imposes any limitations on the use or development of the land that are appropriate at the time of creation of the easement to achieve that purpose; that is in the form of articles of dedication, easement, covenant, restriction, or condition; and that includes appropriate provisions for the holder to enter the property subject to the easement at reasonable times to ensure compliance with its provisions (sec. 901.21(A)(1) by reference to sec. 5301.67, not in the bill). "Agriculture" is defined as those activities occurring on land devoted exclusively to agricultural use, which is land that is eligible for agricultural use property tax valuation under the Current Agricultural Use Value Law, or on land that constitutes a homestead (sec. 901.21(A)(2), not in the bill).*



(1) Whether the applicable county auditor has determined that the land is land that is devoted exclusively to agriculture for the purposes of the Current Agricultural Use Value Law;

(2) Changes in land values following the completion of the applicable county auditor's reappraisal or triennial update;

(3) Soil types and productivity;

(4) Proximity of the land to land that is already subject to an agricultural easement, conservation easement created under the Conservation Easements Law, or similar land-use limitation;

(5) Proximity of the land to water and sewer lines, road interchanges, and nonagricultural development;

(6) Parcel size and roadway frontage of the land;

(7) Existence of an agreement between the supervisors of a local soil and water conservation district and anyone who occupies land within the district regarding natural resource conservation or flood prevention or of an operation and management plan developed by the owner or operator of agricultural land or a concentrated animal feeding operation and approved either by the Chief of the Division of Soil and Water Conservation in the Department of Natural Resources or by the supervisors of the local soil and water conservation district;

(8) Existence of a comprehensive zoning plan that is adopted by a board of county commissioners under the County Rural Zoning Law, by a board of township trustees under the Township Zoning Law, or by the planning commission of a municipal corporation under the Planning Commissions Law; and

(9) Any other factors that the Director determines are necessary for inclusion in the system (sec. 901.22(D)(2)).

#### **Applications regarding new drugs**

Under current law, no person can sell, deliver, offer for sale, hold for sale, or give away (distribute) any new drug unless:

(1) An application with respect to the drug has become effective under section 505 of the Federal Food, Drug, and Cosmetic Act; or

(2) If the drug is not subject to that Act, the drug has been tested and found to be safe for use under the conditions prescribed, recommended, or suggested in its labeling, and, prior to selling the drug or offering it for sale, there has been filed



with the Director of Agriculture an application setting forth full reports of investigations that have been made to show whether or not the drug is safe for use, a full list of the articles used as components of the drug, a full statement of the drug's composition, a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug, samples, as the Director may require, of the drug and the articles used as components of the drug, and specimens of the labeling proposed to be used for the drug. (Sec. 3715.65(A).)<sup>3</sup>

Under existing law, an application that is filed with the Director must become effective 60 days after it is filed, except that if the Director finds after due notice to the applicant and after giving the applicant an opportunity for a hearing that the drug is not safe for use under the conditions prescribed, recommended, or suggested in the drug's proposed labeling, the Director must, prior to the effective date of the application, issue an order refusing to permit the application to become effective. The order may be revoked by the Director. (Sec. 3715.65(B).)

The bill eliminates the procedures by which a new drug can be distributed if it is not subject to the Federal Food, Drug, and Cosmetic Act and has been tested and found to be safe and if an application has been filed with the Director. Thus, under the bill, a new drug can be distributed only if an application with respect to the drug has become effective under section 505 of the Federal Food, Drug, and Cosmetic Act. (Sec. 3715.65(A) and (B).)

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<sup>3</sup> Law unchanged by the bill defines "new drug" as any drug the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof or any drug the composition of which is such that the drug, as a result of investigation to determine its safety for use under such conditions, has become so recognized, but that has not, other than in an investigation, been used to a material extent or for a material time under such conditions (sec. 3715.01(A)(10), not in the bill). "Drug" means any of the following: (1) articles recognized in the United States Pharmacopoeia and National Formulary, or any supplement to them, (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals, (3) articles, other than food, intended to affect the structure or any function of the body of humans or other animals, or (4) articles intended for use as a component of any of the foregoing articles, other than devices or their components, parts, or accessories (sec. 3715.01(A)(4), not in the bill).

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## HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	02-26-04	p. 1582

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