The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Committee on Agriculture, Environment, and General Government

BILL:	CS/SB 1056
INTRODUCER:	Appropriations Committee on Agriculture, Environment, and General Government; and Senator Gruters
SUBJECT:	Dosage Form Animal Health Products
DATE:	April 17, 2023
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Burse	Becker	AG	**Favorable**
2.	Blizzard	Betta	AEG	**Fav/CS**
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1056 defines a "dosage form animal product" as a regulated feedstuff under the Florida Commercial Feed Law, requiring such products to be subject to related fees, quality, safety, and labeling requirements, pursuant to ch. 580, Florida Statutes. The Department of Agriculture and Consumer Services (department) administers and enforces the Florida Commercial Feed Law.

The bill includes specific labeling requirements and clarifies that a dosage form animal product does not apply to drugs that are administered or used to treat animals as defined under federal law.

The bill is expected to have an indeterminate impact on state revenues and a negative operational fiscal impact on state expenditures. See Section V. Fiscal Impact Statement.

The bill takes effect July 1, 2023.

II. Present Situation:

The Florida Commercial Feed Law

The Florida Commercial Feed Law (Commercial Feed Law)[1] authorizes the Department of Agriculture and Consumer Services (department) to regulate commercial feed and feedstuff for quality, safety, labeling requirements, and standards.[2] A distributor of commercial feed is required to obtain a master registration[3] and place on file with the department, a copy of the label for each brand of feed to be distributed in Florida.[4]

Distributors are required to pay a licensing fee that is based on the weight of feed distributed in the state.[5] The Commercial Feed Law preempts to the department all authority in the state to regulate, inspect, sample, and analyze any commercial feed or feedstuff, including assessment of penalties for violations.[6]

Samples of feed distributed in Florida must be periodically tested by a certified laboratory to determine compliance with state standards.[7] The minimum standards for feed and feedstuff are those set forth in the "Official Publication 2001" published by the Association of American Feed Control Officials.[8]

Any commercial feed distributed in this state, except a customer-formula feed and feed distributed through an integrated poultry operation or by a cooperative to its members, must be accompanied by a legible label bearing all information required by the federal Food and Drug Administration (FDA) and the following information:[9]

- An accurate statement of the net weight.
- The name and principal address of the registrant.
- The brand name and product name, if any, under which the commercial feed is distributed. The word "medicated" must be incorporated as part of the brand or product name if the commercial feed contains a drug.

The department is authorized to require feeding directions and precautionary statements to be placed on the label for the safe and effective use of medicated and other feed as deemed necessary.[10]

Labels on medicated feed must include all of the following:

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[1] *See* ch. 580, F.S.
[2] Section 580.036, F.S.
[3] Section 580.041, F.S.
[4] Section 580.051, F.S.
[5] Section 580.041, F.S.
[6] Section 580.0365, F.S
[7] Section 580.091, F.S
[8] R. 5E-3.013, F.A.C. The Association of American Feed Control Officials (AAFCO) is an independent organization that has been guiding state, federal and international feed regulators with ingredient definitions, label standards and laboratory standard s for more than 110 years, while supporting the health and safety of people and animals. AAFCO members are charged by their local, state or federal laws to regulate the sale and distribution of animal feeds and animal drug remedies.
[9] Section 580.051(1), F.S.
[10] *Id.*

- Any feeding directions prescribed by the department to ensure safe usage.
- The stated purpose of the medication contained in the feed as stated in the claim statement.
- The established name of each active drug ingredient.
- The level of each drug used in the final mixture expressed in metric units as well as the required weight measurement.

Commercial feed labels must also include a guaranteed analysis stated in terms that advise the consumer of the composition of the feed or feedstuff or support claims made in the labeling. In all cases, the elements or compounds listed in the analysis must be determinable by laboratory methods approved by the department.[11]

The department is authorized to adopt rules to enforce the Commercial Feed Law, which must be consistent with the rules and standards of the United States Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA). The rules must include:

- Establishing definitions and reasonable standards for commercial feed or feedstuff, and permissible tolerances for pesticide chemicals, chemical additives, nonnutritive ingredients, or drugs in or on commercial feed or feedstuff in such amounts as will ensure the safety of livestock and poultry, and the products thereof used for human consumption.
- Adopting standards for the manufacture and distribution of medicated feed.
- Establishing definitions and reasonable standards for the certification of laboratories testing and analyses as required.
- Establishing product labeling requirements for distributors.
- Limiting the use of drugs in commercial feed and prescribing feeding directions to be used to ensure safe usage of medicated feed.
- Establishing standards for evaluating quality-assurance/quality-control plans, including testing protocols, for exemptions to certified laboratory testing requirements.
- Establishing standards for the sale, use, and distribution of commercial feed or feedstuff to ensure usage that is consistent with animal safety and well-being and, to the extent that meat, poultry, and other animal products for human consumption may be affected by commercial feed or feedstuff, to ensure that these products are safe for human consumption.
    - Such standards must be developed in consultation with the Agricultural Feed, Seed, and Fertilizer Advisory Council created under s. 570.451, F.S.

The department is required to establish the standards that a laboratory must meet to become certified in any of the following areas of testing:[12]

- Nutrient.
- Mycotoxins.
- Microbiological organisms.
- Pesticide residues.
- Drugs.

[11] *Id.*
[12] Section 580.065, F.S.

The department is guided by the methods published by the Association of Official Analytical Chemists, the United States Environmental Protection Agency (EPA), the FDA, or other generally recognized authorities in developing the standards for the laboratory certifications.[13]

The Commercial Feed Law prohibits distribution of an adulterated commercial feed or feedstuff. Commercial feed or feedstuff is deemed adulterated if it includes any of the following:[14]

- Any poisonous, deleterious, or nonnutritive substance that may render it injurious to animal or human health.
  - However, if the substance is not an additive, the feed shall not be considered adulterated if the quantity of the substance does not ordinarily render it injurious to animal or human health.
- Any food additive or added poisonous, deleterious, or nonnutritive substance that is unsafe within the meaning of s. 406 of the Federal Food, Drug, and Cosmetic Act, other than a pesticide chemical in or on a raw agricultural commodity.
- Any food additive or color additive that is unsafe within the meaning of s. 409 or s. 512 of the Federal Food, Drug, and Cosmetic Act.
- A raw agricultural commodity that bears or contains a pesticide chemical that is unsafe within the meaning of s. 408(a) of the Federal Food, Drug, and Cosmetic Act.
  - However, where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under s. 408 of the Federal Food, Drug, and Cosmetic Act, and that raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the processed feed will result, or is likely to result, in pesticide residue in the edible product of the animal which is unsafe within the meaning of s. 408(a) of the Federal Food, Drug, and Cosmetic Act.
- Any new animal drug that is unsafe within the meaning of s. 512 of the Federal Food, Drug, and Cosmetic Act.
- Any filthy, putrid, or decomposed substance or is otherwise unfit for feed.
- If it is prepared, packaged, or held under unsanitary conditions in which it may have become contaminated with filth or rendered injurious to health.
- If it is the product of a diseased animal or of an animal that has died by a means other than slaughter which is unsafe within the meaning of s. 402(a)(1) or (2) of the Federal Food, Drug, and Cosmetic Act.

The Commercial Feed Law prohibits misbranded commercial feed or feedstuff. A commercial feed or feedstuff is deemed misbranded, as follows:[15]

- If its labeling is false or misleading in any particular.
- If it is distributed under the name of another commercial feed or feedstuff.
- If it is not labeled as required by this chapter or the rules promulgated hereunder.
- If it does not conform to the definition of identity and standard of quality as prescribed by rule.
- If any word, statement, or other information required by ch. 580, F.S, to appear on the label or labeling is not prominently and conspicuously placed thereon in such terms as to render it

[13] *Id.*
[14] Section 580.071, F.S.
[15] Section 580.081, F.S

likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- If it is not appropriate for its intended or purported use.
- If a nutrient test, conducted by a laboratory certified in nutrient testing, shows the presence of any ingredient not listed on the label or the absence of any ingredient shown on the label.

The following acts are prohibited by the Commercial Feed Law:[16]
- Distribution of any commercial feed or feedstuff that is adulterated or misbranded.
- Adulteration or misbranding of any commercial feed or feedstuff.
- Distribution of commercial feed or feedstuff that has not been sampled or analyzed by a department-certified laboratory.
- Distribution of agricultural commodities such as whole seed, hay, straw, stover, silage, cobs, husks, and hulls which are adulterated.
- Dissemination of any false advertisement with reference to the distribution of any commercial feed or feedstuff.
- Refusal to permit entry, inspection, or collection of samples of commercial feed or feedstuff by authorized department personnel.
- Removal or disposal of a lot of commercial feed or feedstuff that has had a stop-sale, stop-use, removal, or hold order issued, prior to release by the department or the court.
- Use of any label that does not comply with the provisions of ch. 580, F.S.
- Forging, counterfeiting, simulating, or false representing of any label.
- Placing or permitting to be placed any false advertisement or misleading statement on a label.
- Redistribution of a customer-formula commercial feed.
- Using or placing of fasteners that may be injurious to animals on any commercial feed or feedstuff or bags of any commercial feed or feedstuff, except those distributed exclusively for poultry.
- Failure or refusal to register, pay inspection fees, or file reports, or perform any other affirmative act required by this chapter, or rule promulgated hereunder.
- Distribution of a feed or feedstuff which is prohibited by federal law or regulation.

The department is authorized to impose one or more of the following penalties against any person who violates the Commercial Feed Law:[17]
- Issuance of a warning letter.
- A Class I fine for each occurrence.[18]
- Revocation or suspension of the master registration, laboratory certification, or quality assurance/quality-control plan approval.
- Probation for up to six months.

The severity of the penalty imposed must be commensurate with the degree of risk to human or animal safety or the level of financial harm to the consumer that is created by the violation.[19]

[16] Section 580.112, F.S.
[17] Section 580.121, F.S.
[18] Section 570.971, F.S., provides that for each violation in the Class I category, a fine not to exceed $1,000 may be imposed.
[19] Section 580.121, F.S.

Violations of the Commercial Feed Law are a second-degree misdemeanor, punishable by a 60 day term in prison and a $500 fine.[20]

The Commercial Feed Law defines "commercial feed" as all materials or combinations of materials that are distributed or intended to be distributed for use as feed or for mixing in a feed for animals other than humans, except:[21]

- Unmixed whole seeds, including physically altered entire unmixed seeds, when such seeds are not chemically changed or are not adulterated;
- Unground hay, straw, stover, silage, cobs, husks, and hulls, and individual chemical compounds or substances, when such commodities, compounds, or substances are unmixed with other substances and are not adulterated; and
- Feed mixed by the consumer for the consumer's own use made entirely or in part from products raised on the consumer's farm.

"Feedstuff" is defined as edible materials, other than commercial feed, that are distributed for animal consumption and that contribute energy or nutrients, or both, to an animal diet.[22]

Dosage-Form Animal Products

The National Animal Supplement Council (council) defines dosage form animal health products as articles (other than food) intended to affect the structure or any function of the body other than providing nutrition.[23] The council lists the following as examples of dosage form animal health products:

- Hip & Joint Support;
- Calming Aids;
- Antioxidants;
- Organ-Specific Support such as heart, bladder or brain;
- Immune Support; and
- Most Herbal Products.[24]

Vermont

In May 2021, Vermont Governor Phil Scott signed Act No. 41 (S.102) into law.[25] The law provides rules and fees for registration, labeling requirements, and conditions under which dosage form animal health products are considered misbranded or adulterated.[26] The law also provides additional rules and administrative penalties for person distributing dosage form animal health product within the state.[27]

[20] Sections 775.082, and 775.083, F.S.
[21] Section 580.031(2), F.S.
[22] Section 580.031(10), F.S.
[23] *See* https://www.nasc.cc/news/how-to-read-a-label/ (last visited March 8, 2023).
[24] *Id.*
[25] *See* https://legislature.vermont.gov/bill/status/2022/S.102 (last visited March 8, 2023).
[26] *See* https://legislature.vermont.gov/Documents/2022/Docs/ACTS/ACT041/ACT041%20As%20Enacted.pdf (last visited March 8, 2023).
[27] *Id.*

III. Effect of Proposed Changes:

The bill includes "dosage form animal products" as a feedstuff under the Commercial Feed Law, requiring such products to be subject to fees, quality, safety, and labeling requirements that are regulated by the department.

The bill defines a "dosage form animal product" as a feedstuff that includes any product intended to affect the structure or function of an animal's body, other than providing nutrition to the animal. The term includes oils, tinctures, capsules, tablets, liquids, and chewables.

The term does not include:
- A mineral or vitamin;
- A product represented as a primary meal for the intended animal species;
- Any product intended as a treat; or
- A dental product providing mechanical or abrasive action, or both;

Additionally, the term does not include drugs, biologics, parasiticides, medical devices, or diagnostics used to treat animals under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), as amended by the United States Department of Agriculture under the federal Virus-Serum-Toxin Act (21 U.S.C. Sec. 151 et seq.), as amended, or by the United States Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.), as amended.

The bill exempts dosage form animal products that are sold solely as a dosage form animal product and guaranteed as specified in the Commercial Feed Law from showing a guaranteed analysis. Additionally, the bill requires labeling on a dosage form animal product to contain the following:
- An accurate statement of the net weight;
- The name and principal address of the registrant;
- The brand name and product name, if any, under which the dosage form animal product sold at retail as the department may require by rule;
- The date of manufacture or expiration date of the dosage form animal product sold at retail;
- The amount of each active ingredient per serving;
- The common, or usual name of each inactive ingredient contained in the dosage form animal product;
- A statement that identifies how the product supports the structure or function of the animal;
- Precautionary statements and warnings required to ensure the safe and effective use of the dosage form animal product;
- Recommended dosage by animal weight; and
- The statement "Not for human consumption."

The bill takes effect October 1, 2023.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

This bill may affect dosage form animal health products that are currently on sale. These products may need to be recalled to be accurately labelled and will cost distributors and business owners negatively.

C. Government Sector Impact:

Revenues associated with violations of the bill are indeterminate. The bill will require additional resources for registration, inspection, and enforcement activities. The department estimates the need for three positions and $276,193 from the General Revenue Fund to implement the provisions in the bill.[28]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

[28] Florida Department of Agriculture and Consumer Services, Agency Analysis of Senate Bill 1056 (March 9, 2023).

VIII. Statutes Affected:

This bill amends the following sections of the Florida Statutes: 580.031 and 580.05.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Appropriation Committee on Agriculture, Environment, and General Government on April 18, 2023:
The committee substitute:

- Defines "dosage form animal product" as a regulated feedstuff under the Florida Commercial Feed Law, requiring such products to be subject to regulation by the department;
- Provides that products sold solely as dosage form animal products are exempt from guaranteed analysis requirements;
- Provides specific labeling requirements; and
- Makes the effective date of the bill October 1, 2023.

B. Amendments:

None.