HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: CS/HB 959 Dosage Form Animal Health Products
SPONSOR(S): Regulatory Reform & Economic Development Subcommittee, Tuck and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 1056

FINAL HOUSE FLOOR ACTION: 109 **Y's** 0 **N's** **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

CS/HB 959 passed the House on April 28, 2023, and subsequently passed the Senate on May 2, 2023.

The Florida Commercial Feed Law (Commercial Feed Law) authorizes the Department of Agriculture and Consumer Services (DACS) to regulate the distribution of commercial feed and feedstuff in Florida to ensure these products are safe for human consumption. The DACS Division of Animal Industry (Division) is responsible for enforcing the state's animal industry law, which provides animal health regulations and protects the state from animal pests and diseases.

Animal health or dietary supplements are referred to as "dosage form animal health supplements or products," which are similar to dietary supplements for humans used to supplement a regular diet. According to the National Library of Medicine (NLM), such supplements are widely used but have limited oversight and regulation. According to DACS, manufacturers and distributors of dosage form animal health products in Florida are currently governed by the state Commercial Feed Law due to the non-nutritional character of these products and are required to comply with the registration, labeling, and sampling requirements followed by distributors of other no- or low-nutritive value products allowed for use as, or for mixing in, animal feed.

Under federal law, FDA's Center for Veterinary Medicine (CVM) is responsible for the regulation of animal food (feed) products. Products marketed as dietary supplements or "feed supplements" for animals fall under Title 21, the Federal Food, Drug, & Cosmetics Act. These items are considered "foods" or "drugs" depending on the intended use, or in some instances the articles may be, simultaneously, a food and a drug. Under federal law, animal food products must meet labeling requirements that contain information describing the product and any details necessary for the safe and effective use of the food. In addition to meeting the federal labeling requirements, animal food products are also subject to individual state labeling laws.

The bill:

- Includes dosage form animal products as a regulated feedstuff under the Commercial Feed Law, thus requiring such products to be subject to regulation by DACS.
- Clarifies that such products do not include certain drugs, biologics, parasiticides, medical devices, or diagnostics used to treat or administered to animals under federal law.
- Exempts products sold solely as a dosage form animal product, if guaranteed as specified in the Commercial Feed Law, from showing a guaranteed analysis.
- Provides specific product labeling requirements.

The bill may have a positive and negative fiscal impact on state government. The bill may also have a negative fiscal impact on the private sector.

The bill was approved by the Governor on June 2, 2023, ch. 2023-185, L.O.F., and will become effective on October 1, 2023.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Current Situation

Commercial Feed and Feedstuff

The Florida Commercial Feed Law (Commercial Feed Law)[1] authorizes the Department of Agriculture and Consumer Services (DACS) 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 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 DACS 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.

DACS 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:

- Any feeding directions prescribed by DACS 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 avoirdupois.

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[1] *See* ch. 580, F.S.
[2] S. 580.036, F.S.
[3] S. 580.041, F.S.
[4] S. 580.051, F.S.
[5] S. 580.041, F.S.
[6] S. 580.0365, F.S.
[7] S. 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 standards 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] S. 580.051(1), F.S.
[10] *Id.*

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 DACS.[11]

DACS 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 for the conduct of 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.

DACS 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.

DACS 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.

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[11] *Id.*
[12] S. 580.065, F.S.
[13] *Id.*
[14] S. 580.071, F.S.

- 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 this chapter to appear on the label or labeling is not prominently and conspicuously placed thereon in such terms as to render it 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 this chapter.
- 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.

[15] S. 580.081, F.S.
[16] S. 580.112, F.S.

- 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.

DACS 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]

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 humanization of certain species, including horses, dogs, and cats, has resulted in the emergence of animal health supplements, referred to as "dosage form supplements." These supplements are similar to dietary supplements for humans.[23] In dogs and cats, the most popular supplements include joint and digestive health supplements, followed by supplements to aid with cognition, skin/coat and heart health. For horses, owners can use supplements to treat or prevent osteoarthritis, joint disease, digestion, hoof growth, coat, and behavior.[24]

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[17] S. 580.121, F.S.
[18] S. 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] S. 580.121, F.S.
[20] Ss. 775.082, and 775.083, F.S.
[21] S. 580.031(2), F.S.
[22] S. 580.031(10), F.S.
[23] State of Wisconsin Department of Agriculture, Trade and Consumer Protection, *Labeling of Dosage Form Animal Health Supplements for Non-human Food Producing Animals*, https://datcp.wi.gov/Documents/Feed-DosageFormAnimalHealthSuppPolicy.pdf (last visited Mar. 25, 2023).
[24] National Library of Medicine, *Veterinary Pet Supplements and Nutraceuticals*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7802882/ (last visited Mar. 25, 2023).

According to the National Library of Medicine (NLM), such pet supplements and nutraceuticals are widely used and generate millions of dollars in revenue for manufacturers. Despite the widespread use of these veterinary products, oversight and regulation remain limited as compared to human dietary supplement regulations. The NLM also provides that scientific information on veterinary pet supplements and nutraceuticals is increasing; however, there is a lack of quality control, safety and efficacy data for the majority of the substances marketed in pet supplements and the resulting products for purchase currently available. Despite this lack of evidence, the use of veterinary supplements and nutraceuticals continues to increase."[25]

Food and Drug Administration

The U.S. Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN)[26] regulates the safety of dietary supplements in humans. The term "dietary supplement" is defined in the Dietary Supplement Health and Education Act (DSHEA) of 1994,[27] as a product taken by mouth in humans that contains a "dietary ingredient" intended to supplement the diet. A "dietary ingredient" can include vitamins, minerals, herbs or other botanicals, amino acids and substances such as enzymes, organ tissues and metabolites. The definition of ''dietary supplement'' does not explicitly state whether it includes or excludes products intended for use in animals other than man.[28]

The FDA Center for Veterinary Medicine (CVM)[29] is responsible for the regulation of animal food products. The CVM has mechanisms for food additive approval, which apply to any product unless it is generally recognized as safe for that intended use (i.e. forages, grains and most mineral and vitamins). This regulation applies to animal food additives that could affect the target animal's safety.

Under Section 201(s) of the Federal Food, Drug, and Cosmetic Act (FD&C Act),[30] the definition of a food additive does not include any ingredient in or intended for use in a dietary supplement. Although the dietary ingredient used in the dietary supplement must not adulterate the supplement, it does not have to be Generally Recognized As Safe (GRAS) for its intended use in the supplement. However, non-dietary ingredients (binders, fillers, etc.) are not exempt from the food additive definition. If any product claims to cure, treat, prevent or mitigate disease, the product should be considered a "new animal drug."

Pet food, including pet treats but not pet supplements, falls under the Association of American Feed Control Officials (AAFCO) and is regulated on a federal and state level. For now, AAFCO only regulates labeling of "food-type" supplements, although it will monitor for any ingredient misrepresentation of all animal supplements. Seven states, including Texas, Oregon, Michigan, North Dakota, South Dakota, Virginia and Wyoming have enacted "remedy laws" to regulate pet supplements that do not qualify as "foods" according to the AAFCO definition.[31]

The DSHEA controls the way the FDA regulates "food for humans." Among other things, it restricts substances from being food additives or drugs if the product meets the definition of a dietary supplement. Supplements intended for companion animals (i.e. not food animals for human

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[25] *Id*.
[26] U.S. Food and Drug Administration, *Center for Food Safety and Applied Nutrition*, https://www.fda.gov/about-fda/fda-organization/center-food-safety-and-applied-nutrition-cfsan (last visited Mar. 25, 2023).
[27] Pub. L. No. 103-417.
[28] National Library of Medicine, *Veterinary Pet Supplements and Nutraceuticals*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7802882/ (last visited Mar. 25, 2023).
[29] U.S. Food and Drug Administration, *Center for Veterinary Medicine*, https://www.fda.gov/about-fda/fda-organization/center-veterinary-medicine (last visited Mar. 25, 2023).
[30] 21 U.S.C. § 301-399.
[31] National Library of Medicine, *Veterinary Pet Supplements and Nutraceuticals*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7802882/ (last visited Mar. 25, 2023).

consumption) do not fall under the DSHEA and therefore undergo less regulatory oversight than human dietary supplements.[32]

According to the FDA, the DSHEA does not apply to animal products.[33] Thus, products marketed as dietary supplements or "feed supplements" for animals still fall under the FD&C Act. These items are considered "foods" or "drugs" depending on the intended use, or in some instances the articles may be, simultaneously, a food and a drug. The FD&C Act defines the term "food" as an article used for food or drink for man or other animals including components of such articles. Thus, any nutrient ingredient (e.g., vitamins, minerals, and amino acids) which is added to a food is also a food by definition. The FD&C Act also defines the term "drug" as including any article intended for use as a component of a drug. A nutrient ingredient used as a component of a dosage form drug must meet the requirements for a drug. A nutrient ingredient used as a component of all other medicated products must meet the requirements for a food. While a nutrient ingredient of a non-dosage form product is also a drug when it is intended for use as a component of a drug, the nutrient will be primarily regulated as a food and need not be shown to serve an active drug purpose provided no drug claims are made or implied for the nutrient.[34]

The regulatory status of an article is determined by CVM on a case-by-case basis. Under the FD&C Act, "animal feeds/foods" refers to feed for livestock, poultry, or other animals, and pet food. These articles may ordinarily be thought of as foods under the Act, and also, in some cases, as food additives. However, based upon the claims made for these articles, their intended uses may bring them within the definition of a drug under the Act. In such instances, the articles may, as a matter of law, be both a food and a drug simultaneously.[35]

According to DACS, manufacturers and distributors of dosage form animal products in Florida are currently being regulated under the Commercial Feed Law due to the products' non-nutritional character. As a result, marketers of "dosage form animal health products" are required to comply with the registration, labeling, and sampling requirements followed by distributors of other no- or low-nutritive value products allowed for use as, or for mixing in, animal feed.[36]

Proposed Changes

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

Specifically, the bill:

- Defines "dosage form animal product" as a feedstuff that includes any product intended to affect the structure or function of the animal's body other than by providing nutrition to the animal. The term includes oils, tinctures, capsules, tablets, liquids, and chewables.
- Specifies that the term does not include:
  - A mineral or vitamin, a product represented as a primary meal for the intended animal species, any other product intended as a treat, or a dental product providing mechanical or abrasive action or both.
  - Drugs, biologics, parasiticides, medical devices, or diagnostics used to treat, or administered to, animals:

[32] State of Wisconsin Department of Agriculture, Trade and Consumer Protection, *Labeling of Dosage Form Animal Health Supplements for Non-human Food Producing Animals*, https://datcp.wi.gov/Documents/Feed-DosageFormAnimalHealthSuppPolicy.pdf (last visited Mar. 25, 2023).
[33] 61 C.F.R. § 17706.
[34] U.S. Food and Drug Administration, Nutritional Ingredients in Animal Drugs and Feeds, https://fda.report/media/70108/Guide-1240.3420-Nutritional-Ingredients-in-Animal-Drugs-and-Feeds.pdf (last visited Mar. 25, 2023).
[35] U.S. Food and Drug Administration, *FDA/CVM Program Policy and Procedures Manual Guide 1240.3605*, https://www.fda.gov/media/69982/download (last visited Mar. 25, 2023).
[36] Florida Department of Agriculture and Consumer Services, Agency Analysis of House Bill 959, pgs. 1 and 2 (Mar. 9, 2023).

- 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 U.S. Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.), as amended.

- Exempts dosage form animal health products that are sold solely as a dosage form animal health product, if guaranteed as specified in the Commercial Feed Law, from showing a guaranteed analysis.
- Requires the label 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 is distributed.
  - The date of manufacture or expiration date of the dosage form animal product sold at retail as the department may by rule require.
  - 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.
  - The statement "Not for human consumption."

The effective date of the bill is October 1, 2023.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The DACS may receive additional revenue through fee payments and enforcement of penalties. The amount is indeterminate.

2. Expenditures:

   The bill may have a negative fiscal impact on DACS due to increased costs associated with the enforcement and inspection of dosage form animal products. DACS estimates year one recurring expenditures of $262,147 and nonrecurring expenditures of $14,046 to support three (3) full time equivalent positions for additional workload. A review of the department's budget reversions and vacant positions shows there are sufficient existing resources that can be redirected to implement the provisions of the bill.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will require distributors of dosage form animal products to comply with Commercial Feed Law regulatory requirements governed by DACS, including the payment of fees and enforcement of penalties.

Dosage form animal health products currently sold may need to be recalled to be accurately labelled, which may have a negative fiscal impact to the distributors and business owners of those products.

D. FISCAL COMMENTS:

None.