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 Committee on Regulated Industries

BILL:	CS/SB 196
INTRODUCER:	Regulated Industries and Senator Gruters
SUBJECT:	Foods Containing Vaccines or Vaccine Materials
DATE:	March 19, 2025 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Baird	Imhof	RI	**Fav/CS**
2.			AEG	
3.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 196 sets forth labeling requirements for specific food products containing "vaccine or vaccine material" and broadens the definition of "drug" in ch. 499, F.S., to include those food items.

The bill further establishes that any food product containing vaccine or vaccine material without required labeling is a misbranded drug.

CS/SB 196 creates a new section to prohibit certain toxic chemicals in cosmetics. The bill defines certain chemicals and defines specific chemicals from being intentionally added into cosmetics manufactured, sold, offered, or distributed for sale in Florida, including any lead or lead compounds at 1 part per million or above, whether intentionally added or naturally occurring. The bill allows for in-state retailers in possession of cosmetics containing these chemicals to exhaust existing stock, through sales to the public until July 1, 2027. Additionally, the bill requires the Department of Business and Professional Regulation (DBPR), in consultation with the Department of Health, by January 1, 2026, to identify additional chemicals that could be a hazard to the public and make the information publicly available on its website.

Further, the bill prohibits the delineated chemicals in cosmetics, regardless of whether the product also contains ingredients regulated by the United States Food and Drug Administration (FDA), but it does not apply to the specific ingredients as drugs regulated by the FDA. A

violation of the newly created section would be subject to disciplinary action under s. 499.066, F.S.

The bill defines what an "mRNA vaccine" is and it also prohibits the use of a fruit or vegetable as a delivery mechanism for an mRNA vaccine.

Finally, the bill would deem those food products containing vaccine or vaccine material without required labeling as misbranded foods under ch. 500, F.S.

The bill provides an effective date of July 1, 2025.

II. Present Situation:

State and Federal Regulation of Drugs, Devices, and Cosmetics

The regulation of drugs and cosmetics is addressed in ch. 499, F.S., which regulates drugs, devices, and cosmetics by the DBPR.[1] The Florida Drug and Cosmetic Act (the act)[2] is intended to safeguard public health and promote public welfare by protecting against injuries and merchandising deceit involving drugs, devices, and cosmetics or the use of such products. The Division of Drugs, Devices, and Cosmetics (the division) under the DBPR handles Florida regulations. Within the division, s. 499.01211, F.S., created the Drug Wholesale Distributor Advisory Council that provides input to the division and the DBPR regarding all proposed rules regarding the distribution of drugs.

Administration of the act must conform to the Federal Food, Drug, and Cosmetic Act[3] and the applicable portions of the Federal Trade Commission Act[4] which prohibit the false advertising of drugs, devices, and cosmetics. The Florida Drug and Cosmetic Act conforms to the FDA's drug laws and regulations and authorizes the DBPR to issue permits to Florida drug manufacturers and wholesale distributors and register drugs manufactured, packaged, repackaged, labeled, or relabeled in Florida.[5] The FDA preempts the state of Florida from regulating certain areas regarding drugs and cosmetics, including generally, the pre-market approval of drugs and the post-market surveillance of cosmetics, in both instances monitoring for safety issues for the American people.

The FDA process for new or innovative drugs is rigorous and requires an extensive series of clinical trials, first on animals and then on humans, before the new drug application can be formally filed with the FDA.[6] The company then sends the FDA the evidence from these trials to prove the drug is safe and effective for its intended use. The FDA's physicians, statisticians,

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[1] The Drug, Device, and Cosmetic program was transferred to the Department of Business and Professional Regulation from the Department of Health effective November 1, 2012. See ch. 2012-184, Law of Fla., s. 122, at http://laws.flrules.org/2012/184 (last visited March 18, 2025).
[2] See ss. 499.001-499.081, F.S.
[3] Section 499.003(20), F.S., defines the federal act referencing 21 U.S.C. ss. 301 *et seq.* and 52 Stat. 1040 *et seq*.
[4] *See* 15 U.S.C. ss. 41-58, as amended.
[5] Section 499.01, F.S.
[6] U.S. Food & Drug Administration, New Drug Application (NDA), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last visited March 19, 2025).

chemists, pharmacologists, and other scientists review the company's data and proposed labeling. The FDA will only approve a new drug application if it determines that the drug is safe and effective for its proposed use and that the benefits of the drug appear to outweigh the known risks.[7]

The DBPR has broad authority to inspect and discipline permittees for violations of state or federal laws and regulations, which can include seizure and condemnation of adulterated or misbranded drugs or suspension or revocation of a permit.[8]

Florida currently does not have a routine process in place for the testing of cosmetics products or a facility for testing cosmetic products.

Cosmetics

Florida currently has a limited scope of state-level enforcement regarding cosmetics. The predominant regulation is done by the FDA and whatever is not preempted Florida can regulate. The FDA prohibits misbranded and adulterated products, however most of this regulation is done on the post-production level, leaving a regulatory landscape that is seeing the emergence of state-level regulation initiatives regarding cosmetics. The burden of ensuring product safety largely falls on cosmetic manufacturers and their adherence to the guidelines set by the FDA.

States like California, Colorado, Maryland, Minnesota, Oregon, and Washington have recently enacted legislation regarding the regulation of toxic chemicals in cosmetics. For example, the state of Washington created a program that prohibits the use of over 20 toxic chemicals in cosmetics, including lead (at 1 part per million) and formaldehyde, citing research that shows these chemicals can cause cancer in humans.[9]

Drugs and Devices

General Prohibitions

The act prohibits any person from:[10]

- Offering for sale any drug, device, or cosmetic, that is adulterated or misbranded.
- Disseminating any false or misleading advertisement of a drug, device, or cosmetic.
- Refusing from letting the DBPR to enter or inspect an establishment in which drugs, devices, or cosmetics are manufactured, processed, repackaged, sold, brokered, or held.
- Committing any act that causes a drug, device, or cosmetic to be a counterfeit drug, device, or cosmetic; or selling, dispensing, or holding for sale a counterfeit drug, device, or cosmetic.
- Committing an alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a drug, device, or cosmetic, or the doing of any other act with

[7] *Id*.
[8] Sections 499.051, 499.062, 499.065, 499.066, 499.0661, and 499.067, F.S.
[9] Daniel Fortin, *Washington State Proposes Ban on Cancer-Linked Chemicals in Cosmetics*, NBC Right Now Tri-Cities Yakima, available at https://www.nbcrightnow.com/regional/washington-state-proposes-ban-on-cancer-linked-chemicals-in-cosmetics/article_9938e436-ec55-5963-bdc1-bb6bf9593155.html (last visited March 19, 2025).
[10] *See* Section 499.005, F.S.

respect to a drug, device, or cosmetic, if the act is done while the drug, device, or cosmetic is held for sale and the act results in the drug, device, or cosmetic being misbranded.
- Forging, counterfeiting, simulating, falsely representing any drug, device, or cosmetic, or without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part.
- Using, on the labeling of any drug or in any advertisement relating to such drug, any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part when it does not.
- Possessing any drug in violation of part I, ch. 499, F.S.
- Failing to maintain records as required by law and rules adopted under ch. 499, F.S.
- Providing the DBPR with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of the act.
- Failing to obtain a permit or registration, or operating without a valid permit when a permit or registration is required by the act for that activity.
- Obtaining or attempting to obtain a prescription drug or device by fraud, deceit, misrepresentation or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug or device.

Some of these prohibitions will raise to the level of criminal acts under s. 499.0051, F.S.

Misbranding of Drugs

The act specifies that a drug or device is deemed misbranded if:[11]
- Its labeling is in any way false or misleading.
- In package form, it does not bear a label containing certain requirements prescribed by law.
- Any word, statement, or other information required by the act, that appears on the label or labeling is not prominently placed with such conspicuousness as to render the word, statement, or other information likely to be read and understood under customary conditions of purchase and use.
- It is a drug and is not designated solely by a name recognized in an official compendium and its label does not bear certain requirements prescribed by the act.
- It purports to be a drug the name of which is recognized in the official compendium and is not packaged and labeled as prescribed therein. However, the method of packaging may be modified with the consent of the DBPR.
- It is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling of the drug.
- It purports to be, or is represented, as a drug composed wholly or partly of insulin and it is not from a batch with respect to which a certificate has been issued pursuant to s. 506 of the federal act, which certificate is in effect with respect to the drug.
- It purports to be, or is represented, as a drug composed wholly or partly of any kind of antibiotic requiring certification under the federal act and it is not from a batch with respect to which a certificate has been issued pursuant to s. 507 of the federal act, which certificate is in effect with respect to the drug. However, this subsection does not apply to any drug or class of drugs exempted by regulations adopted under s. 507(c) or (d) of the federal act.

[11] *See* Section 499.007, F.S.

Misbranding or Misrepresenting Food

In Florida a food is deemed to be misbranded:[12]

- If its labeling is false or misleading in any particular manner;
- If it is offered for sale under the name of another food;
- If it is an imitation of another food, with exception;
- If its container is so made, formed, or filled as to be misleading;
- If in package form, unless it bears a label containing certain information;[13]
- If any word, statement, or other information required by or under authority of ch. 500, F.S.,
- does not meet certain requirements;[14]
- If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by statute or by rule;
- If it purports to be or is represented as:
  - A food for which a standard of quality has been prescribed by rules as provided by s. 500.09, F.S., and its quality falls below such standard unless its label bears a statement that it falls below such standard; or
  - A food for which a standard or standards or fill of container have been provided by rule as provided by s. 500.09, F.S., and it falls below the standard or fill container unless its label bears a statement that it falls below such standard.
- Unless the label bears the common or usual name of the food and specific requirements if it is fabricated from two or more ingredients.[15]
- If it purports to be or is represented for special dietary uses, unless its label contains certain information.[16]
- If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact.
- If it is a fresh fruit or vegetable, package of honey, or bee pollen not labeled in accordance with the provisions of s. 504.012, F.S., or not otherwise labeled in such a manner as to indicate to an ultimate purchaser the country of origin.
- If it is offered for sale and its label or labeling does not comply with federal requirements pertaining to nutrition or allergen information.
- If it is offered for sale and its label or labeling does not comply with federal labeling requirements pertaining to nutritional content claims and health claims.
- If it is bottled water and does not meet certain labeling requirements.[17]
- If it is an animal product that fails to have directly thereon or on its container the official USDA inspection legend.

An operator may not knowingly and willfully misrepresent the identity of any food or food product to any of the patrons of such establishment. The identity of a food product is misrepresented if:

- The description of the food or food product is false or misleading;

[12] Section 500.11, F.S.
[13] Section 500.11(1)(e), F.S.
[14] Section 500.11(1)(f), F.S.
[15] Section 500.11(1)(i), F.S.
[16] Section 500.11(1)(j), F.S.
[17] Section 500.11(1)(o), F.S.

- The food or food product is served, sold, or distributed under the name of another food or food product; or
- The food or food product purports to be or is represented as a food or food product that does not conform to a definition of identity and standard of quality if such standard has been established by custom and usage.[18]

Vaccines

General Regulation

The Advisory Committee on Immunization Practices (ACIP) develops recommendations on the use of vaccines in the United States.[19] The ACIP is comprised of medical and public health experts, and works with professional organizations, such as the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians to develop annual childhood and adult immunization schedules.[20]

The Centers for Disease Control and Prevention (CDC) reviews the ACIP's recommendations; once approved by the CDC Director and the U.S. Department of Health and Human Services, they are published as the CDC's official recommendations for immunizations of the U.S. population.[21] New vaccines are considered for addition to the schedule after licensure by the United States Food and Drug Administration (FDA).[22]

The FDA oversees the safety, effectiveness, and quality of vaccines used in the United States. Once a vaccine is developed, the pre-clinical phase begins, which consists of laboratory research and testing on animals. If the pre-clinical phase shows the vaccine is likely to be safe and work well in humans, it is tested on humans through clinical trials. While clinical trials are underway, the FDA assesses the manufacturing process to ensure that the vaccine can be produced reliably and consistently. Once a manufacturing process is developed and pre-clinical and clinical trials are successfully completed, developers submit a Biologics License Application to the FDA, which includes details on the manufacturing process and data from pre-clinical and clinical trials. The FDA evaluates the application and decides whether to license the vaccine for use in the United States. The FDA continues to monitor and regulate vaccines and manufacturers after licensing.[23]

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[18] Section 509.292(1), F.S.
[19] Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP), *General Committee-Related Information*, available at https://www.cdc.gov/vaccines/acip/committee/index.html (last visited March 18, 2025). Established under Title 42 U.S.C. § 217a, ACIP members are appointed by the Secretary of the U.S. Department of Health and Human Services and consist of a mix of medical and public health experts from private industry and the public sector. There are 15 voting members (14 are industry experts and one consumer member), 6 non-voting, ex-officio members consisting of specific federal government employees, and 30 non-voting representatives from professional health care organizations.
[20] Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP), *ACIP Recommendations*, available at https://www.cdc.gov/vaccines/acip/recommendations.html (last visited March 18, 2025).
[21] *Id*.
[22] College of Physicians of Philadelphia, *The History of Vaccines: The Development of the Immunization Schedule*, available at http://www.historyofvaccines.org/content/articles/development-immunization-schedule (last visited March 18, 2025).
[23] U.S. Food and Drug Administration, *Vaccine Development – 101*, https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101 (last visited March 15, 2025).

All vaccines must be licensed (approved) by the FDA in order to be marketed in the United States.[24] However, during public health emergencies, the FDA may authorize vaccines for emergency use, which speeds up the process of bringing a vaccine to market.[25]

Plant-Based mRNA Vaccines

In 2021, scientists at UC Riverside were awarded a $500,000 grant form the National Science Foundation to study plant-based messenger ribonucleic acid (mRNA) vaccines. The research projected was charged with covering three concepts:[26]

- Showing that DNA containing the mRNA vaccine can be successfully delivered into the part of plant cells where it will replicate;
- Demonstrating that plants can produce enough mRNA to rival a traditional vaccine shot; and
- If findings prove possible, determining the right dosage.

Prior to the $500,000 grant, Juan Pablo Giraldo, an associate professor at UC Riverside, was granted over $1,000,000 to develop a project that is using nanomaterials to deliver nitrogen into chloroplasts through their leaves and control its release.[27] The $500,000 grant provided by the National Science Foundation, was awarded to further Giraldo's original research for repurposing naturally occurring nanoparticles for gene delivery to plants.[28] However, since this study began in 2021, there are still many unsolved difficulties in the research, including optimizing plant growth for consistent antigen yield, preventing dosage variability, and more importantly actually being able to reproduce a safe human vaccine in a plant.

If the research proves successful, potential advantages of plant-based mRNA vaccines would be cheaper costs associated with producing and storage of vaccines. A current challenge that was well-reported during the COVID-19 Pandemic was the expiration of the mRNA vaccines that needed to be stored at cold temperatures.[29] (Plant-based mRNA vaccines could be stored at room temperature).

As of the beginning of 2025, there are no approved plant-based mRNA vaccines.

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[24] U.S. Food and Drug Administration, *Ensuring the Safety of Vaccines in the United States*, https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Ensuring-the-Safety-of-Vaccines-in-the-United-States.pdf (last visited March 18, 2025).

[25] Food and Drug Administration, *Emergency Use Authorization*, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (last visited March 15, 2025). Medical countermeasures are FDA-regulated products (biologics, drugs, and devices) that may be used in the event of a public health emergency.

[26] UC Riverside, *Grow and Eat your own Vaccines?*, Jules Bernsein, September 16, 2021, available at https://www.universityofcalifornia.edu/news/grow-and-eat-your-own-vaccines (last visited March 18, 2025).

[27] *Id*.

[28] *Id*.

[29] *See* Mohammad Uddin, *Challenges of Storage and Stability of mRNA-Based COVID-19 Vaccines*, Vaccines (Basel), September 2021, available at https://pmc.ncbi.nlm.nih.gov/articles/PMC8473088/pdf/vaccines-09-01033.pdf (last visited March 18, 2025).

III. Effect of Proposed Changes:

Section 1 of the bill amends the definition of "drug" to also mean a "food as defined in s. 500.03, [F.S.] which contains a vaccine or vaccine material." This would allow foods that contain a vaccine or vaccine material to be defined as a drug; those foods would have the same regulations as drugs.

Further, the bill defines a "vaccine or vaccine material" to mean: "a substance authorized or approved by the United States Food and Drug Administration which is intended for use **in humans** to stimulate the production of antibodies and provide immunity against disease and which is prepared from the causative agent of a disease, its products, or a synthetic substitute and is treated to act as an antigen without inducing the disease."

Section 2 of the bill amends what qualifies as a misbranded drug. The bill provides that a drug is misbranded if "it is a food as defined in s. 500.03,[F.S.] and contains a vaccine or vaccine material, but its label does not bear, in type of uniform size and prominence, the words "contains vaccine or vaccine material" and does not specify that the food is classified as a drug under the Florida Drug and Cosmetic Act."

Section 3 of the bill creates a new section of law that prohibits certain toxic chemicals in cosmetics. The bill:

- Defines certain chemicals and defines specific chemicals from being intentionally added into cosmetics manufactured, sold, offered, or distributed for sale or use in Florida, including any lead or lead compounds, at 1 part per million or above, whether intentionally added or naturally occurring.
- Allows an in-state retailer in possession of cosmetics containing these chemicals to exhaust its existing stock through sales to the public until July 1, 2027.
- Requires the DBPR, in consultation with the Department of Health, by January 1, 2026, to identify additional chemicals that could be a hazard to the public and make the information publicly available on its website.
- Prohibits the delineated chemicals in cosmetics, regardless of whether the product also contains ingredients regulated by the FDA, but it does not apply to the specific ingredients in drugs regulated by the FDA.
- Allows that a violation of the newly created section would be subject to disciplinary action under s. 499.066, F.S.
- Requires the DBPR to adopt necessary rules regarding the use of formaldehyde, including identifying a list of chemicals used in cosmetics (no more than 10) which release formaldehyde and which are subject to restriction that will apply on or after July 1, 2026, and providing that the restrictions on any remaining listed chemicals may take effect on or after July 1, 2027.
- In adopting the rules, the DBPR is required to consider the input received from stakeholders.

Section 4 of the bill defines "mRNA vaccine" to mean "a vaccine that uses laboratory-produced messenger ribonucleic acid to trigger the human body's immune system to generate an immune response."

Section 5 of the bill prohibits "the use of fruit or vegetable as a delivery mechanism for an mRNA vaccine."

Section 6 of the bill amends what qualifies as misbranded food. The bill provides that food is deemed to be misbranded if "it contains a vaccine or vaccine material as defined in s. 499.003, [F.S.] unless its label bears, in type of uniform size and prominence, the words "contains vaccine or vaccine material" and specifies that the food is classified as a drug under the Florida Drug and Cosmetic Act"

Sections 7 and 8 conform cross-references to amendments made by the bill.

Section 9 of the bill provides an effective date of July 1, 2025.

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:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 499.003, 499.007, 500.03, 500.04, and 500.11.

The bill creates section 499.0095 of Florida Statute.

IX. Additional Information:

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

CS by Regulated Industries on March 19, 2025:
The committee substitute does the following:

- Defines "mRNA vaccine" to mean "a vaccine that uses laboratory-produced messenger ribonucleic acid to trigger the human body's immune system to generate an immune response."
- Prohibits "the use of fruit or vegetable as a delivery mechanism for an mRNA vaccine."
- Creates a new section to prohibit certain toxic chemicals in cosmetics.
- Defines certain chemicals and defines specific chemicals from being intentionally added into cosmetics manufactured, sold, offered or distributed for sale or use in Florida, including any lead or lead compounds, at 1 part per million or above, whether intentionally added or naturally occurring.
- Allows an in-state retailer in possession of cosmetics containing these chemicals to exhaust its existing stock through sales to the public until July 1, 2027.
- Requires the DBPR, in consultation with the Department of Health, by January 1, 2026, to identify additional chemicals that could be a hazard to the public and make the information publicly available on its website.
- Prohibits the delineated chemicals in cosmetics, regardless of whether the product also contains ingredients regulated by the FDA but it does not apply to the specific ingredients in drugs regulated by the FDA. A violation of the newly created section would be subject to disciplinary action under s. 499.066, F.S.
- Requires the DBPR to adopt necessary rules regarding the use of formaldehyde, including identifying a list of chemicals used in cosmetics (no more than 10) which release formaldehyde and which are subject to restrictions that will apply on or after July 1, 2026 and providing that the restrictions on any remaining listed chemicals may take effect on or after July 1, 2027.
- In adopting the rules, the DBPR is required to consider the input received from stakeholders.

B. Amendments:

None.