FLORIDA HOUSE OF REPRESENTATIVES BILL ANALYSIS

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BILL #: HB 641 COMPANION BILL: SB 764 (Wright)

TITLE: Food Additives

SPONSOR(S): Tendrich, Gonzalez Pittman

LINKED BILLS: None

RELATED BILLS: None

Committee References

Industries & Professional Activities



Commerce

SUMMARY

Effect of the Bill:

The bill requires food or drink products intended for human consumption that contain synthetic color additives when used as a food additive to display a warning on their packaging. The bill establishes a graduated scale of penalties for manufacturers, retailers, and distributors who fail to comply with the warning requirements. The bill requires fines to be deposited in the Department of Agriculture and Consumer Services (DACS) General Inspection Trust Fund, and requires DACS to conduct inspections.

The effective date of the bill is upon becoming law.

Fiscal or Economic Impact:

None

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ANALYSIS

EFFECT OF THE BILL:

The bill requires food or drink products intended for human consumption that contain synthetic <u>color additives</u>, when used as a food additive, to display a warning on their packaging, stating, "WARNING: This product contains synthetic colors, which may have an adverse effect on activity and attention in children." The bill allows manufacturers to use adhesive stickers for the warning until December 31, 2028. By January 1, 2029, the warning must be printed directly on the packaging. The bill outlines specific synthetic color additives that are covered under this requirement, including <u>Blue 1</u>, <u>Blue 2</u>, <u>Green 3</u>, <u>Red 40</u>, <u>Yellow 5</u>, <u>Yellow 6</u>, and <u>titanium dioxide</u>. (Section <u>1</u>)

The bill establishes a graduated scale of <u>penalties</u> for manufacturers, retailers, and distributors who fail to comply with the warning requirements. Manufacturer fines range from \$1,000 for a first offense, \$2,500 for a second offense, and \$5,000 for third or subsequent offenses, while retailer and distributor fines range from a written warning for a first offense, citation for corrective action for a second offense, \$7,500 for a third offense, \$1,000 for a fourth offense, and up to \$2,500 for fifth or subsequent offenses. The bill requires fines to be deposited in the <u>DACS</u> General Inspection Trust Fund, and requires DACS to conduct inspections as part of its regular food and drink product inspections requirements under the Act. (Section <u>1</u>)

The effective date of the bill is upon becoming law. (Section $\underline{2}$)

FISCAL OR ECONOMIC IMPACT:

STORAGE NAME: h0641.IPA **DATE**: 3/10/2025

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STATE GOVERNMENT:

Indeterminate. The bill may have an indeterminate negative impact on state government. The bill establishes a graduated scale of fines for manufacturers, retailers, and distributors who fail to comply with the warning requirements, requires fines to be deposited in the DACS General Inspection Trust Fund, and requires DACS to conduct inspections. It is unknown how many violations and inspections will occur.

PRIVATE SECTOR:

Indeterminate. The bill may have an indeterminate negative fiscal impact on the private sector. The bill establishes a graduated scale of penalties for manufacturers, retailers, and distributors who fail to comply with the warning requirements, and requires DACS to conduct inspections. It is unknown how many violations and inspections will occur.

RELEVANT INFORMATION

SUBJECT OVERVIEW:

Florida Color Additive Regulations

The purpose of the Florida Food Safety Act (Act)¹ is to safeguard and protect the consuming public from product use and merchandising deceit regarding the intrastate commerce of food. The Act is also meant to promote conformance with the Federal Food, Drug, and Cosmetic Act,² Agriculture Marketing Act of 1946,³ and Federal Trade Commission Act.45

<u>DACS</u> is the agency responsible for the enforcement of the production, manufacture, transportation, and sale of food through the Act. DACS's Division of Food Safety (Division) is directly responsible for assuring the public of a safe, wholesome, and properly represented food supply.⁶ The division accomplishes this through the permitting⁷ and inspection⁸ of food establishments,⁹ the inspection and evaluation of food products, and the performance of specialized laboratory testing on a variety of food products sold or produced in Florida. 10 The Division also proactively monitors food from manufacturing and distribution to retail.¹¹

As part of its responsibilities, DACS can impose a variety of disciplinary actions against food establishments for specified violations.¹² This includes, but is not limited to, revoking or suspending¹³ the permit of a food establishment or imposing Class II¹⁴ administrative fines.¹⁵ DACS, or its duly authorized agent, can also issue and enforce a stop-sale, stop-use, removal, or hold order if DACS or its agent finds any food, food processing equipment, area, or food storage area is in violation of the Florida Food Safety Act. 16

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¹ See ch. 500, F.S.

² 21 U.S.C. §§ 301-399d.

³ 7 U.S.C. §§ 1621-1629.

⁴ 5 U.S.C. §§ 41-58, as amended.

⁵ S. 500.02, F.S.

⁶ FDACS, Division of Food Safety, https://www.fdacs.gov/Divisions-Offices/Food-Safety (last visited March 8, 2025).

⁷ S. <u>500.12</u>, F.S.

⁸ S. 500.147, F.S.

⁹ S. 500.03(1)(p), F.S., defines "food establishment" as a factory, food outlet, or other facility manufacturing, processing, packing, holding, storing, or preparing food or selling food at wholesale or retail. The term does not include a business or activity regulated under s. 413.051, s. 500.80, chapter 509, or chapter 601. The term includes tomato packinghouses and repackers but does not include any other establishments that pack fruits and vegetables in their raw or natural states, including those fruits or vegetables that are washed, colored, or otherwise treated in their unpeeled, natural form before they are marketed.

¹⁰ S. <u>500.09(6)</u>, F.S.

¹¹ S. 500.81(3)(b)1., F.S.

¹² S. <u>500.121</u>, F.S.

¹⁴ The fine for each Class II violation cannot exceed \$5,000. S. <u>570.971(1)(b)</u>, F.S.

¹⁵ S. 500.121, F.S.

¹⁶ S. 500.172, F.S.

The Act deems food to be adulterated if it bears or contains a color additive,¹⁷ which is unsafe.¹⁸ Any color additive is deemed unsafe, unless there is in effect a regulation limiting the quantity of such substance, and the use conforms to the terms prescribed by the regulation.¹⁹

The Act deems food to be misbranded if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact. However, to the extent that compliance is impracticable, DACS is authorized to establish exemptions from this labeling requirement.

The Act provides the following prohibitions regarding adulterated or misbranded food:20

- The manufacture, sale or delivery, holding or offering for sale of any food that is adulterated or misbranded.
- The adulteration or misbranding of any food.
- The receipt in commerce of any food that is adulterated or misbranded, and the delivery for pay or otherwise.

Adulterated or misbranded food are subject to seizure and condemnation by DACS²¹ and the other disciplinary actions authorized by the Act.

Federal Color Additive Regulations

The Federal Food, Drug, and Cosmetic Act (FDCA) authorizes the Food and Drug Administration (FDA) to oversee and regulate the production, sale, and distribution of food, drugs, medical devices, and cosmetics, and protect the public from adulterated and misbranded products manufactured and sold in the US.²²

The FDA regulates color additives²³ in food, requiring pre-approval, specifying permitted uses and maximum amounts, and mandating labeling requirements, including the use of specific names for certified color additives and

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¹⁷ S. 500.03(1)(g), F.S., defines "color additive" as materials that include "a. Is a dye pigment, or other substance, made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source, or b. When added or applied to a food, is capable, alone or through reaction with another substance, of imparting color thereto; except that such term does not include any material that is exempt under the federal act."

¹⁸ S. <u>500.10(1)(b), F.S.</u>

¹⁹ S. <u>500.13(1), F.S.</u>

²⁰ S. 500.04, F.S.

²¹ S. <u>500.173, F.S.</u>

²² National Library of Medicine, National Center for Biotechnology Information, *Food, Drug, and Cosmetic Act*, https://www.ncbi.nlm.nih.gov/books/NBK585046/#:~:text=The%201938%20Federal%20Food%2C%20Drug.across%2015%20states.%5B1%5D (last visited March 8, 2025).

²³ The FDCA defines "color additive" "as any material, not exempted under section 201(t) of the act, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting a color thereto. Substances capable of imparting a color to a container for foods, drugs, or cosmetics are not color additives unless the customary or reasonably foreseeable handling or use of the container may reasonably be expected to result in the transmittal of the color to the contents of the package or any part thereof. Food ingredients such as cherries, green or red peppers, chocolate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as color additives; but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a color additive. Food ingredients as authorized by a definitions and standard of identity prescribed by regulations pursuant to section 401 of the act are color additives, where the ingredients are specifically designated in the definitions and standards of identity as permitted for use for coloring purposes. An ingredient of an animal feed whose intended function is to impart, through the biological processes of the animal, a color to the meat, milk, or eggs of the animal is a color additive and is not exempt from the requirements of the statute. This definition shall apply whether or not such ingredient has nutritive or other functions in addition to the property of imparting color. An ingested drug the intended function of which is to impart color to the human body is a color additive. For the purposes of this part, the term color includes black, white, and intermediate grays, but substances including migrants from packaging materials which do not contribute any color apparent to the naked eye are not color additives."

collective terms for exempt ones.²⁴ Color additives include both synthetic substances and substances derived from natural sources. Color additives may be used in food to enhance natural colors, add color to colorless and 'fun' foods such as cake decorations, and help identify flavors (such as purple for grape flavor or yellow for lemon). Color additives are sometimes called food dyes.²⁵

The FDA classifies color additives as either "certified"²⁶ for use in foods, drugs, cosmetics, and medical devices or "exempt from certification."²⁷ Color additives subject to certification are generally synthetic organic dyes, lakes, or pigments. Color additives exempt from certification generally include those derived from plant or mineral sources.²⁸

The FDA certified additives are often referred to as "FD&C" or "D&C" colors. The FDA's color certification program ensures that certifiable color additives meet specific purity and composition standards before they can be used in regulated products. These are synthetic color additives that require batch certification by the FDA. Examples of certified color additives include FD&C Red No. 3, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Green No. 3, FD&C Blue No. 1, FD&C Blue No. 2, and FD&C Red No. 40.

FD&C Red No. 3 is a synthetic food dye that gives certain foods and drinks a bright, cherry-red color, and is found in certain candy, cakes and cupcakes, cookies, frozen desserts, and frostings and icings, and ingested drugs. The FDA requires manufacturers to list FD&C Red No. 3 in the statement of ingredients when added to food. The FDA will no longer allow for the use of FD&C Red No. 3 in food and ingested drugs. On January 15, 2025, the FDA issued an order to revoke these authorizations.²⁹ Manufacturers who use FD&C Red No. 3 in food and ingested drugs will have until January 15, 2027 or January 18, 2028, respectively, to reformulate their products.³⁰

<u>Titanium dioxide</u> (TiO2) is a synthetically produced white pigment, manufactured from naturally occurring ores. It is regulated by the FDA as a color additive and used in a variety of FDA regulated foods, such as bakery products and candy. The FDA is currently reviewing a Color Additive Petition filed on April 14, 2023. The petition asks the FDA to repeal section 21 CFR 73.575 to no longer provide for the use of titanium dioxide in foods.³¹ Certification of this color additive is not necessary for the protection of the public health and therefore it is exempt from the certification requirements of the FDCA.³²

Under the FDCA, a color additive is considered adulterated³³ if it bears or contains, a color additive which is unsafe,³⁴ and is considered misbranded³⁵ if its packaging and labeling are not in conformity with the FDCA packaging and labeling requirements.

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²⁴ See 21 C.F.R., parts 70-82.

²⁵ U.S. Food & Drug Administration, *Color Additives Questions and Answers for Consumers*, https://www.fda.gov/food/color-additives-questions-and-answers-consumers (last visited March 8, 2025).

²⁶ 21 C.F.R. part 74.

²⁷ 21 C.F.R. part 73.

²⁸ U.S. Food & Drug Administration, Color Additives in Foods, <a href="https://www.fda.gov/food/color-additives-information-consumers/color-additives-information-color-additi

 $[\]frac{foods\#:\sim:text=Certified\%20color\%20additives\%20are\%20synthetically,extract\%20(red\%20or\%20purple)}{March 8, 2025).} (last visited March 8, 2025).$

²⁹ 21 CFR Part 74.

³⁰ U.S. Food & Drug Administration, *FD&C Red No. 3*, https://www.fda.gov/industry/color-additives/fdc-red-no-3#:~:text=Share-,FD&C%20Red%20No.,Cosmetic%20Act%20(FD&C%20Act). (last visited March 9, 2025)

³¹ U.S. Food & Drug Administration, *Titanium Dioxide as a Color Additive in Foods*, https://www.fda.gov/industry/color-additive-

foods#:~:text=Titanium%20dioxide%20(TiO2)%20is,may%20be%20added%20to%20foods. (last visited March 8, 2025). 32 21 C.F.R. § 73.575.

^{33 21} U.S.C. § 342.

³⁴ 21 U.S.C. § 379(e), provides that "unsafe color additives" "shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or devices or cosmetics, be deemed unsafe for the purposes of the application of section 342(c), 351(a)(4), or 361(e) of this title, as the case may be, unless—(1)(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of

The FDA requires food manufacturers to list all ingredients on the label, with the ingredients used in the greatest amount first, followed in descending order by those in smaller amounts. The label must list the names of any FDA-certified color additive. With the exception of carmine/cochineal extract, color additives exempt from certification can be listed collectively as "artificial colors," "artificial color added," "color added," or equally informative terms, without naming each one. Because of potential allergic reactions in some people, carmine/cochineal extract are required to be identified by name on food labels.³⁶

When an FDA investigation determines that a color additive violation has occurred, the agency can take a number of actions to enforce the FD&C Act and to protect the public health. In the absence of voluntary action (for example, product recall) by the responsible firm to correct the problem, the FDA has several advisory, administrative, and judicial options which include warning letters, detentions, issuance of import alerts, and seizures.

Other States

In response to concerns about potential health effects, several states, notably California, have introduced and passed legislation to ban specific food dyes, like Red 3, and other additives, including in school meals. In October 2023, California became the first state to prohibit certain color additives. The law banned the manufacture, distribution, and sale of foods and beverages containing food and color additives, including brominated vegetable oil, potassium bromate, propylparaben, and Red Dye No. 3.37

In 2024, California passed legislation banning food with certain food and color additives from being sold in schools. The law prohibits the sale of food and beverages containing the following substances: Blue Dye No. 1, Blue Dye No. 2, Green Dye No. 3, Red Dye No. 40, Yellow Dye No. 5, and Yellow Dye No. 6.38 So far, Texas, Hawaii, and Virginia have introduced similar legislation this session that seeks to ban the use of certain additives in food and beverages sold in schools.

Several other states have proposed food and color additive bans. These states include Arkansas, Delaware, Missouri, New Jersey, New York, Oklahoma, Utah, Virginia, and West Virginia.³⁹

OTHER RESOURCES:

National Library of Medicine: Potential impacts of synthetic food dyes on activity and attention in children: a review of the human and animal evidence.

Ohio State University Wexner Medical Center: How food dye can affect children.

certification; or (2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section."

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^{35 21} U.S.C. § 343.

³⁶ See 21 C.F.R., subpart B.

³⁷ AB-418 The California Food Safety Act (2023-2024).

³⁸ AB-2316 The California School Food Safety Act (2023-2024).

³⁹ University of Arkansas National Agricultural Law Center, *FDA bans Red Dye No. 3*, https://nationalaglawcenter.org/fda-bans-red-dve-no-

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BILL HISTORY

COMMITTEE REFERENCE	ACTION	DATE	STAFF DIRECTOR/ POLICY CHIEF	ANALYSIS PREPARED BY
<u>Industries & Professional Activities</u>			Anstead	Thompson
<u>Subcommittee</u>				
Commerce Committee				

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