The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

COMMUNITY AFFAIRS
Senator Flores, Chair
Senator Farmer, Vice Chair

MEETING DATE: Monday, October 14, 2019
TIME: 4:30—6:00 p.m.
PLACE: 301 Senate Building

MEMBERS: Senator Flores, Chair; Senator Farmer, Vice Chair; Senators Broxson, Pizzo, and Simmons

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**SB 172** Bradley (Identical H 113)	Florida Drug and Cosmetic Act; Preempting the regulation of over-the-counter proprietary drugs or cosmetics to the state, etc. CA 10/14/2019 Favorable IT RC	Favorable Yeas 3 Nays 1
	Presentation of the Survey of Buildings Damaged by Hurricane Michael Final Report by the Florida Building Commission		Presented
	Update on the development of the 7th Edition (2020) Florida Building Code by the Florida Building Commission		Presented
	Other Related Meeting Documents		

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 Community Affairs

BILL:	SB 172
INTRODUCER:	Senator Bradley
SUBJECT:	Florida Drug and Cosmetic Act
DATE:	October 8, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Toman	Yeatman	CA	**Favorable**
2.			IT	
3.			RC	

I. Summary:

SB 172 expressly preempts to the state the regulation of over-the-counter proprietary drugs or cosmetics.

II. Present Situation:

Home Rule

Counties

A county without a charter has such power of self-government as provided by general[1] or special law, and may enact county ordinances not inconsistent with general law.[2] Counties operating under county charters shall have all the powers of local self-government not inconsistent with general law, or with special law approved by vote of the electors.[3] General law authorizes counties "the power to carry on county government"[4] and to "perform any other acts not inconsistent with law, which acts are in the common interest of the people of the county, and exercise all powers and privileges not specifically prohibited by law."[5]

Municipalities

Chapter 166, F.S., also known as the Municipal Home Rule Powers Act,[6] acknowledges the constitutional grant to municipalities of governmental, corporate, and proprietary power

[1] Chapter 125, Part I, F.S.
[2] FLA. CONST. art. VIII, s. 1(f).
[3] FLA. CONST. art. VIII, s. 1(g).
[4] Section 125.01(1), F.S.
[5] Section 125.01(1)(w), F.S.
[6] Section 166.011, F.S.

necessary to conduct municipal government, functions, and services.[7] Chapter 166, F.S., provides municipalities with broad home rule powers, respecting expressed limits on municipal powers established by the Florida Constitution, applicable laws, and county charters.[8]

Section 166.221, F.S., authorizes municipalities to levy reasonable business, professional, and occupational regulatory fees, commensurate with the cost of the regulatory activity, including consumer protection, on such classes of businesses, professions, and occupations, the regulation of which has not been preempted by the state or a county pursuant to a county charter.

Preemption

Local governments have broad authority to legislate on any matter that is not inconsistent with federal or state law. A local government enactment may be inconsistent with state law if (1) the Legislature has preempted a particular subject area or (2) the local enactment conflicts with a state statute. Where state preemption applies, it precludes a local government from exercising authority in that particular area.[9] Florida law recognizes two types of preemption: express and implied. Express preemption requires a specific legislative statement; it cannot be implied or inferred.[10] Express preemption of a field by the Legislature must be accomplished by clear language stating that intent.[11] In cases where the Legislature expressly or specifically preempts an area, there is no problem with ascertaining what the Legislature intended.[12,13]

In cases determining the validity of ordinances enacted in the face of state preemption, the effect has been to find such ordinances null and void.[14] Implied preemption is actually a decision by the courts to create preemption in the absence of an explicit legislative directive.[15] Preemption of a local government enactment is implied only where the legislative scheme is so pervasive as to evidence an intent to preempt the particular area, and strong public policy reasons exist for finding preemption.[16] Implied preemption is found where the local legislation would present the danger of conflict with the state's pervasive regulatory scheme.[17]

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[7] Florida House of Representatives, Publications, The Local Government Formation Manual 2018-2020, p. 16, *available at* https://www.myfloridahouse.gov/Sections/Documents/loaddoc.aspx?PublicationType=Committees&CommitteeId=3025&Session=2020&DocumentType=General%20Publications&FileName=2018-2020%20Local%20Government%20Formation%20Manual.pdf.
[8] Section 166.021(4), F.S.
[9] Wolf, *The Effectiveness of Home Rule: A Preemptions and Conflict Analysis*, 83 Fla. B.J. 92 (June 2009).
[10] *See City of Hollywood v. Mulligan*, 934 So.2d 1238, 1243 (Fla. 2006); *Phantom of Clearwater, Inc. v. Pinellas County*, 894 So.2d 1011, 1018 (Fla. 2d DCA 2005), approved in *Phantom of Brevard, Inc. v. Brevard County*, 3 So.3d 309 (Fla. 2008).
[11] *Mulligan*, 934 So.2d at 1243.
[12] *Sarasota Alliance for Fair Elections, Inc. v. Browning*, 28 So.3d 880, 886 (Fla. 2010).
[13] Examples of activities "expressly preempted to the state" include: operator use of commercial mobile radio services and electronic communications devices in motor vehicles, s. 316.0075, F.S.; regulation of the use of cameras for enforcing provisions of the Florida Uniform Traffic Control Law, s. 316.0076, F.S.; and, the adoption of standards and fines related to specified subject areas under the purview of the Department of Agriculture and Consumer Services, s. 570.07, F.S.
[14] *See, e.g., Nat'l Rifle Ass'n of Am., Inc. v. City of S. Miami,* 812 So.2d 504 (Fla. 3d DCA 2002).
[15] *Phantom of Clearwater, Inc.*, 894 So.2d at 1019.
[16] *Id*.
[17] *Sarasota Alliance for Fair Elections, Inc.*, 28 So.3d at 886.

Licensing and Regulation of Drugs, Devices and Cosmetics in Florida

The Florida Drug and Cosmetic Act (Act) is found in part I of ch. 499, F.S.[18] The Act's purpose is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.[19] The Department of Business and Professional Regulation (DBPR) is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.[20] Administration of the Act must conform to the Federal Food, Drug, and Cosmetic Act[21] and the applicable portions of the Federal Trade Commission Act,[22] which prohibit the false advertising of drugs, devices, and cosmetics.[23]

Chapter 2010-161, s. 27, Laws of Fla., shifted responsibility for operation and enforcement of the Act from the Department of Health to DBPR. Administration of the provisions in the Act occur within DBPR's Division of Drugs, Devices and Cosmetics (division).[24] The division carries out its responsibilities through two program areas:[25]

- The Permitting Program is responsible for the review and approval of permitting applications for multiple permit categories including categories for over-the-counter drug manufacturers and cosmetic manufacturers.[26]
- The Bureau of Compliance & Enforcement is responsible for initial permitting and compliance inspections for permitted facilities and investigation of complaints related to violations of the Act.

In addition to the above, the Act also provides for:[27]

- Criminal prohibitions against distribution of contraband and misbranded prescription drugs;
- Regulation of the advertising and labeling of drugs, devices, and cosmetics; and
- Enforcement avenues for DBPR, including seizure and condemnation of drugs, devices, and cosmetics.

[18] Section 499.001, F.S., provides that ss. 499.001-499.94 is the Florida Drug and Cosmetic Act.
[19] Section 499.002(1)(a), F.S.
[20] Section 499.002(2), F.S.
[21] 21 U.S.C. ss. 301 *et seq*.
[22] *See* 15 U.S.C. §§ 41-58, as amended.
[23] Section 499.002(1)(b), F.S.
[24] E-mail from Colton Madill, Deputy Legislative Affairs Director, DBPR (Oct. 3, 2019) (on file with Senate Committee on Community Affairs).
[25] *Id.*
[26] Section 499.01, F.S., outlines 18 distinct permits based on the type of entity and intended activity, and includes permits for entities within the state, out of state, or even outside of the United States. These are: an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment.
[27] *See* ss. 499.0051, 499.0054, 499.062, F.S.

Over the Counter Drugs and Cosmetics

Part I of Ch. 499, F.S., Definitions

Section 499.003(43), F.S., defines "proprietary drug," or "OTC drug," to mean a patent or over-the-counter drug in its unbroken, original package, which is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded, and can be purchased without a prescription. Section 499.003(12), F.S., defines "cosmetic" to mean an article, with the exception of soap that is: a) intended to be rubbed, poured, sprinkled, or sprayed on or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance; or (b) intended for use as a component of any such article.

U.S. Food and Drug Administration Role and Guidance

As mentioned, Florida's drugs, devices and cosmetics regulations conform to the Federal Food, Drug, and Cosmetic Act.[28] The U.S. Food and Drug Administration (FDA) defines "over-the counter drug products" as nonprescription drugs that are safe and effective for use by the general public without seeking treatment by a health professional.[29] FDA reviews the active ingredients and the labeling of classes of drugs instead of individual drug products. Examples of these classes of drugs include those related to acne, allergy, cold and cough, laxative, insect repellant, nasal decongestant, and sunscreen. For each class, an OTC drug monograph[30] is developed and published in the Federal Register. OTC drug monographs are a kind of "recipe book" covering acceptable ingredients, doses, formulations, and labeling.

FDA defines "cosmetic products" in a fashion similar to the definition of cosmetic in Part I of ch. 499, F.S.[31] Examples of cosmetics include skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, and deodorants. Cosmetic products and ingredients do not need FDA premarket approval, with the exception of color additives.[32]

Over the Counter Sunscreen

UV Ray Sun Protection from Sunscreen

According to the American Academy of Dermatology (AAD),[33]one in five Americans will develop skin cancer in their lifetime, and nearly 20 Americans die from melanoma[34] every day.

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[28] 21 U.S.C. ss. 301 *et seq*.
[29] U.S. Food and Drug Administration, *Drug Applications for Over-the-Counter (OTC) Drugs*, *available at* https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs (last visited Oct. 8, 2019).
[30] An OTC monograph establishes conditions under which certain OTC drugs may be marketed without approved new drug applications because they are "generally recognized as safe and effective" (GRASE) and not misbranded.
[31] *See* U.S. Food and Drug Administration, *FDA Authority over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated, available at https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated#What_kinds* (last visited Oct. 8, 2019).
[32] *Id*.
[33] *See* American Academy of Dermatology, *Is Sunscreen Safe*, *available at* https://www.aad.org/public/spot-skin-cancer/learn-about-skin-cancer/prevent/is-sunsceen-safe (last visited Oct. 8, 2019). Information and guidance provided in this section of the analysis is drawn from the cited webpage.
[34] The American Cancer Association describes melanoma as a type of skin cancer that develops when melanocytes (the cells that give the skin its tan or brown color) start to grow out of control. While melanoma is much less common than some other

To prevent exposure to the sun's harmful UV rays, the AAD recommends protecting your skin by "seeking shade, wearing protective clothing and generously applying sunscreen."[35] ADA identifies two types of sunscreen:

- Physical sunscreen which works like a shield and sits on the surface of your skin, and
- Chemical sunscreen which works like a sponge absorbing the sun's rays.[36]

For physical sunscreen, ADA advises looking for the active ingredients zinc oxide and/or titanium dioxide. For chemical sunscreen, it recommends looking for one or more of the following ingredients: oxybenzone, avobenzone, octisalate, octocrylene, homosalate and octinoxate.

FDA Proposed Rule on Sunscreen Products for Over-the-Counter Human Use[37]

On February 26, 2019, the FDA published a proposed rule on Sunscreen Products for Over-the-Counter Human Use.[38] The proposed rule classifies the safety and effectiveness of certain active ingredients and dosage forms, updates sunscreen testing and recordkeeping requirements, and addresses new uses of sunscreens, including the sale of combination sunscreen-insect repellant products. The deadline for the rule comment period has passed and the final rule publication is due by November 26, 2019.

The most recent FDA rule on sunscreens from 1999 identified 16 active ingredients "generally recognized as safe and effective" (GRASE) in sunscreen. In information from the 2019 proposed rule, FDA summarized the existing safety data of these ingredients as follows:

- Zinc oxide and titanium dioxide were proposed to be categorized as GRASE.
- Para-aminobenzoic acid and trolamine salicylate as no longer GRASE.
- The remaining 12 ingredients, which include oxybenzone and octinoxate, were identified as not having enough information to determine whether they are GRASE and the FDA asked the industry for additional data.[39]

City of Key West Ordinance on Sunscreen Products containing Oxybenzone or Octinoxate

In February of 2019, the City Commission of Key West passed an ordinance making it unlawful to sell, offer for sale, or distribute for sale in the City of Key West any SPF sunscreen protection personal care product that contains oxybenzone or octinoxate, or both, without a medically

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types of skin cancers it is considered more dangerous because it's much more likely to spread to other parts of the body if not caught and treated early. *See* American Cancer Society, *What is Melanoma Skin Cancer? available at* https://www.cancer.org/cancer/melanoma-skin-cancer/about/what-is-melanoma.html (last visited Oct. 8, 2019).

[35] According to the ADA, as long as a sunscreen is broad spectrum (provides protection from UVA (aging) and UVB (burning) rays), water resistant (the length of time sunscreen stays on wet skin) and has a SPF 30 or higher (SPF 30 filters out 97% of the sun's UVB rays), it can effectively protect people from the sun.

[36] ADA suggests opting for physical sunscreen if you have sensitive skin and states that chemical sunscreen formulations tend to be easier to rub into the skin without leaving a residue.

[37] 84 C.F.R. § 6204 (2019), *available at* https://www.federalregister.gov/documents/2019/02/26/2019-03019/sunscreen-drug-products-for-over-the-counter-human-use. Information in this section of the analysis is derived from the FDA proposed rule.

[38] According to FDA, changed conditions since publication of the previous final rule (64 FR 27666, May 21, 1999) (now stayed) necessitated additional data review to establish that certain active ingredients listed in the Stayed 1999 Final Monograph are GRASE for use in sunscreen products

[39] While the FDA is asking for more data, it has not said that these ingredients are unsafe.

licensed prescription.[40] The ordinance cites significant harmful impacts from the two chemicals on the marine environment and residing ecosystems around the waters of Key West, including coral reefs that protect the shoreline of Key West, and the Florida Keys. The ordinance definition of "SPF sunscreen protection personal care product" includes but is not limited to lotion, paste, balm, ointment, cream, solid stick applicator, brush applicator, roll-on applicator, aerosol spray, non-aerosol spray pump, and automated and manual mist spray.

A first time violation of the ordinance shall result in one written warning. Second and subsequent violations are punishable pursuant to the city's civil citation procedure, which could result in a maximum civil penalty not to exceed $500.[41] The effective date of the specified sunscreen products prohibition is January 1, 2021.[42]

OPPAGA Research of Sunscreen Chemical Effects on Corals[43] and Marine Life

As directed by the Legislature, the Office of Program Policy Analysis and Government Accountability (OPPAGA) compiled recent peer-reviewed research about the effects of oxybenzone and octinoxate on corals and marine life.[44] In the overview of its findings presented to the Legislature in September of 2019, OPPAGA stated that:

> A small number of scientific studies have shown negative effects[45] of oxybenzone and octinoxate on corals and marine life at concentration levels generally not observed in nature. Sunscreens are not the only source of these chemicals; they also may be introduced to seawater from wastewater effluent, leaching from plastics, and leaching from hull paints on ships. Setting aside the effects of these chemicals, a number of stressors would continue to affect corals, including natural threats such as hurricanes and increases in average ocean temperatures, air pollution, and land-based pollution.

[40] Chapter 26, Article VII., Sec. 26-311, Code of Ordinances, City of Key West Florida (Ord. No.19-03, § 1, 2-5-2019).
[41] Chapter 2, Article VI, Division 3, Code of Ordinances, City of Key West Florida.
[42] Both the state of Hawaii (Senate Bill 2571 (2018)) and the U.S. Virgin Islands (Bill No. 33-0043 (2019)) have passed legislation prohibiting the sale or distribution of sunscreens containing oxybenzone or octinoxate. The Hawaii ban begins on January 1, 2021. The prohibition in the U.S. Virgin Islands begins after March 30, 2020, and includes a ban on the use or possession of sunscreen products containing oxybenzone and octinoxate. Both laws contain findings referencing the chemicals' impacts on marine life and coral.
[43] According to the United States Environmental Protection Agency, Florida's coral reefs represent the third largest barrier reef ecosystem in the world. The Florida Reef Tract extends from St. Lucie Inlet in Martin County to the Dry Tortugas west of the Florida Keys. Roughly two thirds of the Florida Reef Tract lie within Biscayne National Park and the Florida Keys National Marine Sanctuary. *See* United States Environmental Protection Agency, *America's Coral Reefs, available at* https://www.epa.gov/coral-reefs/americas-coral-reefs (last visited Oct. 8, 2019).
[44] Office of Program Policy Analysis and Government Accountability, *Summary of Peer-Reviewed Research on the Effects of Selected Sunscreen Chemicals on Corals and Marine Life, 2008 to Present* (Sept. 2019) (on file with Senate Committee on Community Affairs).
[45] Identified negative effects that may be occurring include the bleaching of coral fragments and coral cells from hard coral and damage to coral DNA and reduced reproductive success.

III. Effect of Proposed Changes:

Section 1 amends s. 499.002, F.S., to --- notwithstanding any other law, local ordinance or regulation to the contrary --- expressly preempt to the state, the regulation of over-the-counter proprietary drugs or cosmetics.

Section 2 provides an effective date of July 1, 2020.

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 identified.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Manufacturers and distributors of over-the-counter proprietary drugs and cosmetics will only be subject to statewide regulations of their products.

C. Government Sector Impact:

Local government entities will be unable to adopt or enforce over-the-counter proprietary drugs and cosmetics regulations.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 499.002 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

Summary of Peer-Reviewed Research on the Effects of Selected Sunscreen Chemicals on Corals and Marine Life, 2008 to Present

Scope

As directed by the Legislature, the Office of Program Policy Analysis and Government Accountability (OPPAGA) compiled recent peer-reviewed research about the effects of oxybenzone and octinoxate on corals and marine life and answered five questions.

1. How do oxybenzone and octinoxate reach corals and marine life?
2. What known effects do these chemicals have on corals and marine life?
3. What are the gaps in the current studies regarding these chemicals and their effect on corals and marine life?
4. What additional stressors may also be affecting corals and marine life?
5. What recent regulatory actions have been enacted in the U.S. regarding the sale and use of these sunscreen chemicals?

To answer these questions, OPPAGA reviewed a range of research and interviewed subject matter experts. These findings are presented below. (See Appendix A for descriptions of each study OPPAGA examined.)

Overview of Findings

A small number of scientific studies have shown negative effects of oxybenzone and octinoxate (active ingredients in some sunscreen products) on corals and marine life at concentration levels generally not observed in nature. Sunscreens are not the only source of these chemicals; they may also be introduced to seawater from wastewater effluent, leaching from plastics, and leaching from hull paints on ships. Setting aside the effects of these chemicals, a number of stressors would continue to affect corals, including natural threats such as hurricanes and increases in average ocean temperatures, air pollution, and land-based pollution. The city of Key West, Florida and the state of Hawaii have banned the sale of sunscreens containing these chemicals. The U.S. Food and Drug Administration (FDA) is also planning to review the safety status of all sunscreen products, including oxybenzone and octinoxate.

Background

Active sunscreen ingredients fall into two broad categories: organic radiation absorbers and inorganic sun-blocking agents.[1] Oxybenzone and Octinoxate are both organic ultraviolet (UV) light filters commonly used as active ingredients in sunscreens. They absorb UV rays and emit them at a longer wavelength, resulting in decreased skin penetration of radiation.[2] Oxybenzone, also called benzophenone-3, is a pale-yellow solid at room temperature that is readily soluble. In addition to being an ingredient in sunscreens, it is an ingredient in personal care products (e.g., shampoos, eye makeup preparations, and skin care products). Octinoxate is a colorless to pale-yellow, viscous liquid at room temperature that absorbs UVB radiation from the sun. It is a common ingredient in sunscreens and shampoos in addition to many other types of personal care products.

[1] In this context, "organic" refers to carbon-based chemicals and "inorganic" refers to non-carbon-based chemicals.
[2] In contrast, inorganic chemicals such as zinc oxide and titanium oxide that are also used in sunscreens create a physical barrier between the skin and UV rays.

The FDA regulates sunscreens to ensure they meet safety and effectiveness standards. In general, the FDA identifies approved products, specifies product-labeling criteria, and presents product-effectiveness testing protocols and standards. The FDA is responsible for recognizing over-the-counter sunscreen products suitable for topical administration and has identified 16 sunscreen drug products that may be generally recognized as safe and effective. Oxybenzone and octinoxate are two of these FDA-approved active ingredients in sunscreens. The FDA has set a 6% limit for oxybenzone and a 7.5% limit for octinoxate for sunscreens sold in the US. The FDA also regulates the accuracy of sunscreen product labeling, verifying the degree of water resistance, SPF value, and that the ingredients presented are identified as sunscreens and approved for this use. Further, the FDA requires sunscreen labels to present information qualifying how effective sunscreens are, under what conditions they become less effective, and what risks they present to humans. Finally, the FDA establishes testing procedures for the uniform SPF value of sunscreen drug products.

At the state level, the Department of Business and Professional Regulation's Division of Drugs, Devices, and Cosmetics has a consumer protection role related to sunscreen products. The division is tasked with safeguarding Florida's citizens from injury due to adulterated or contaminated products. Among its required activities, the division permits drug manufacturers, distributors, repackagers, health care entities, and cosmetic manufacturers and the products they manufacture, such as sunscreens.

Questions and Answers

How do oxybenzone and octinoxate reach corals and marine life?

Experts we interviewed at U.S. universities, Florida state agencies, and the National Oceanic and Atmospheric Administration reported that oxybenzone and octinoxate are introduced into seawater from a variety of sources, including wastewater effluent, leaching from plastics, leaching from hull paints on ships, and sunscreen washing off swimmers.

The specific mechanism for how these chemicals get from the water to coral is not well documented in scientific literature. However, these chemicals may be reaching coral through plankton or through mixing due to water dynamics. Both oxybenzone and octinoxate are slightly more dense, or have a slightly higher specific gravity, than fresh water, which suggests they would affect fresh water marine life at the bottom of water bodies.[3] In contrast, seawater's density approximates that of octinoxate, so that chemical may actually float in seawater.

Published studies reported the concentration of these chemicals in seawater and marine life around the world. OPPAGA converted the varying concentrations of these chemicals in seawater from these studies into standardized metrics: "parts per billion" or "parts per trillion." One part per billion (PPB), also reported in the studies as micrograms per liter, is roughly the equivalent of one drop of pollutant in the tank of a large tanker truck. One part per trillion (PPT), also reported as nanograms per liter, is roughly the equivalent of ten drops of pollutant added to a large football stadium filled with water.

Published data on the concentrations of oxybenzone and octinoxate vary widely for the different locations where they have been observed. As shown Exhibit 1, the highest reported concentrations were near the U.S. Virgin Islands (parts per million). The published measurements nearest Florida were in South Carolina (parts per trillion).

[3] The specific gravity of pure water is 1.00 at 4 degrees Celsius; oxybenzone is 1.32 at 25 degrees Celsius and octinoxate is 1.01to 1.02 at 20 degrees Celsius. Seawater has a specific gravity that ranges between 1.020 and 1.035.

Exhibit 1
Locations of Published Studies of Oxybenzone and Octinoxate Concentrations in Water

Source: OPPAGA analysis.

What known effects do these chemicals have on corals and marine life?

Some peer-reviewed studies have shown that sunscreen and certain individual ingredients (including oxybenzone and octinoxate) may have negative effects on coral and marine life. These negative effects include

- the bleaching of coral fragments and coral cells from hard coral[4];
- damage and deformation of coral planulae;
- damage to coral DNA and reduced reproductive success;
- bioaccumulation of chemicals[5];
- behavioral changes;
- immobilization; and
- death/mortality.

Published studies of the effects of oxybenzone and octinoxate on coral and marine life are generally conducted at higher concentrations of these chemicals than observed in nature. Exhibit 2 presents a summary of the effects of oxybenzone and octinoxate on coral and marine life as reported in 18 peer-reviewed studies. (See Appendix A for more detail about these studies.)

[4] The phenomenon of coral bleaching is visible when colonies turn from their normal tan, gray, or green color to a stark white. These corals are not dead. Instead, individual polyps that make up the coral colony have ejected their internal single-celled algal symbionts, also known as zooxanthellae, as a response to environmental stress, leaving largely transparent tissues covering their white skeletons. Bleached corals are deprived of the energy they need for normal growth and reproduction.

[5] Bioaccumulation is defined as the net accumulation of a contaminant in or on an organism from all sources, including water, air, and diet.

Exhibit 2
Detailed Effects of Oxybenzone and Octinoxate Exposure on Corals and Marine Life, by Concentration in Water

Effect	Organism(s)	Study
Chemical Concentrations of Parts Per Million		
Coral bleaching	Coral	Danovaro, 2008
Damage to coral planulae, coral bleaching, damage to coral DNA	Coral	Downs, 2015
Reduced reproductive success (flatworms and diatoms) and behavioral changes (anemones and coral)	Flatworms, diatoms, sea anemones, and coral	McCoshum, 2016
Reduced reproductive success	Marine phytoplankton Japanese medaka fish Green alga Aquatic midges	Tovar-Sánchez, 2013 Kim, 2014 Mao, 2018 Campos, 2019
Behavioral changes	Siamese fighting fish	Chen, 2016
Immobilization	Aquatic crustaceans	Jang, 2016
Larvae damage	Sea urchins	Corinaldesi, 2017
Mortality	Aquatic crustaceans	Gakowska, 2018
Chemical Concentrations of Parts Per Billion		
Bioaccumulation	Coral Fish including common carp, brown trout, Ebro barbel, and European Eel Zebrafish	He, 2019 Gago-Ferrero, 2015 Zhou, 2019
Reduced reproductive success	Fathead minnows[1]	Christen, 2011
DNA damage	Zebrafish[2]	Zucchi, 2011 Bluthgen, 2012 Zhang, 2017

[1] Fathead minnows are used in EPA testing to determine toxicity levels.

[2] Zebrafish are considered an excellent vertebrate organism for testing toxic effects of chemicals.

Source: OPPAGA analysis.

What are the gaps in the current studies regarding these chemicals and their effect on corals and marine life?

Researchers we interviewed noted research gaps related to the concentration of these chemicals and exposure conditions, as well as limitations of studies looking at marine life effects.

Concentration. There is little published data on the concentrations of oxybenzone and octinoxate in the water or in the tissues of living marine organisms in Florida. Moreover, the Florida Department of Environmental Protection, which is responsible for regulating water quality, reported that it does not test the water in Florida for these two chemicals. Further, existing studies do not present sufficient data to identify the lowest concentrations of these chemicals that would have a negative effect on marine life.

Exposure. The scientists we interviewed also identified concerns about how published studies have tested exposure to these chemicals. They reported that most of the research to date has examined short-term (acute) exposure to these chemicals and not longer-term (chronic) exposure. Moreover, because many published studies on the effects of these two chemicals are conducted in labs, they do not address some exposure issues noted by experts. These issues include the amount of organic material in seawater, the depth of the water, and water dynamics, all of which would affect the amount of exposure to oxybenzone and octinoxate that coral and marine life would experience.

Effects of multiple chemicals. Scientists we interviewed suggested there is more published research on the potential effects of oxybenzone than the potential effects of octinoxate. However, there have not been studies of the effects of combinations of these ingredients as they would occur in the natural environment on coral and marine life. In addition, studies of combinations of these two sunscreen

chemicals have not addressed the effects of how these chemicals break down under particular conditions and the relative toxicity of these new compounds on coral and marine life.

What additional stressors may also be affecting corals and marine life?

Information from the U.S. National Oceanic and Atmospheric Administration and our interviews with scientists presented additional natural and man-made threats to coral and marine life.

Natural threats include damage from hurricanes and cyclones that break apart corals. Weather patterns, such as El Niño, can increase sea surface temperature, decrease sea level, and alter the salinity of rainfall, all of which negatively affect coral.

Increases in average ocean temperature cause thermal stress on coral that can contribute to coral bleaching and disease. Bleaching reactions are most commonly driven by temperature extremes, tending to occur at temperatures 1-2°C above the normal maximum summer temperatures, increasing in likelihood the longer the temperature extremes last.

Air pollution, particularly carbon dioxide emissions, is absorbed by seawater and causes chemical reactions that increase the water's acidity. This process, called "ocean acidification," reduces calcium carbonate minerals important for some marine organisms' skeletal and shell development.

Land-based pollution sources, including agricultural and land-based runoff, chemical spills, and sewage treatment plant operations, add toxicants, sediments, and nutrients to the seawater, which create additional threats to coral reefs. This pollution can prevent coral and marine life growth and reproduction, disrupt their ecological functions, and cause diseases and death.

What recent regulatory actions have been enacted in the U.S. regarding the sale and use of these sunscreen chemicals?

Some governmental entities in the U.S. are taking steps to address scientific evidence about the potential effects of oxybenzone and octinoxate exposure for living organisms. For example, in Florida, Key West has banned the sale of any type of sunscreen containing these chemicals without a prescription, effective February 5, 2020. The ordinance is based on concern for the health of the area's marine life. Penalties for violations include a written warning and civil citations. The state of Hawaii has a similar ban, effective January 1, 2021, but the law does not specify penalties. The U.S. Virgin Islands recently enacted an ordinance that goes a step further. Effective December 31, 2019, this U.S. jurisdiction will ban the use of sunscreens containing these chemicals.

Moreover, in February 2019, the FDA issued a proposed rule that describes updated requirements for sunscreens. The proposed rule describes new conditions under which over-the-counter sunscreen products may be generally recognized as safe for human use. The FDA's rule documents suggest the agency will be conducting this rule review because of substantially increased sunscreen usage and exposure as well as evolving information about the potential risks for humans associated with these products. The FDA has also issued related guidance about the data needed to determine whether over-the-counter sunscreen ingredients or a combination of active ingredients may be recognized as safe for use.

Appendix A
Detail on Peer-Reviewed Studies Related to the Effects of Oxybenzone and Octinoxate on Coral and Other Marine Life

Introduction

The following tables summarize the parameters and results of scientific studies published in peer-reviewed journals that have examined the effects on corals and marine life of two organic UV-filters commonly used in sunscreen lotions—oxybenzone and octinoxate. The studies are presented in chronological order. For each study, we summarize

- which chemicals were reviewed;
- which concentrations of the chemicals studied were used or detected;
- which organisms were reviewed;
- which physical locations were included;
- the methodology used; and
- the findings.

We reviewed studies that were included as cited references in a 2018 government report developed by the Ministry of Environment and Energy for Sweden and citations provided by the Florida Fish and Wildlife Conservation Commission. The studies selected for our review included those that

- were published in peer-reviewed science journals;
- included examining the effects of either oxybenzone, octinoxate, or both, either independently or as part of a mixture of chemicals; and
- examined the effects of these chemicals on coral and/or marine life.

We omitted studies that examined the effects of these chemicals on humans, were literature reviews or aggregated collections of other studies, or reported observed concentrations of these chemicals in water or in marine organisms but did not test any effects from the presence of these chemicals.

In all cases, these studies included a control group where the organisms being studied were not exposed to any of the treatment chemicals. The concentration ranges shown in the tables are for the treatment groups.

Complete citations for each study are provided in the References section.

Individual Study Summaries

Sunscreens Cause Coral Bleaching by Promoting Viral Infections

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Danovaro, 2008	• Oxybenzone • Octinoxate • Butyl methoxydibenzolmethane • Octocrylene • Ethylhexyl salicylate • 4-methylbenzylidene camphor • Butylparaben	10 to 100 microliters per liter	• Hard coral o *Acropora cervicornis* o *Acropora divaricata* o *Acropora intermedia* o *Acropora pulchra* • Blade fire coral o *Millepora complanata* • Hood coral o *Stylophora pistillata*	• Siladen, Celebes Sea (Pacific) • Akumal, Caribbean Sea (Atlantic) • Phuket, Andaman Sea (Indian) • Ras Mohammed, Red Sea (Indian)

Study methodology

The study examined seven component chemicals of sunscreens and identified four, including oxybenzone and octinoxate, that had negative effects (rapid and complete bleaching) on hard corals. Observations were made on location at four coral reef areas in the Pacific, Atlantic, and Indian Oceans and replicates of the coral were exposed to a range of sunscreen concentrations from 10 to 100 microliters per liter and observed for up to 96 hours.

Study findings

- Human use of coral reef areas is increasing and the impact of sunscreens on coral bleaching will grow considerably in the future.
- Sunscreens cause the rapid and complete bleaching of hard corals, even at extremely low concentrations.
- Among the ingredients tested, oxybenzone caused complete bleaching, even at low concentrations.

Effects of the UV-filter 2-ethyl-hexyl-4-trimethoxycinnamate (EHMC) on Expression of Genes Involved in Hormonal Pathways in Fathead Minnows (Pimephales promelas) and Link to Vitellogenin Induction and Histology

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Christen, 2011	Octinoxate	5.4 to 394 micrograms per liter	Fathead minnows (*Pimephales promelas*)	Testing was performed in a laboratory setting

Study methodology

The study exposed adult fathead minnows (*Pimephales promelas*) in tanks to a range of concentrations of octinoxate for a period of 14 days.

Study findings

- Data demonstrate that octinoxate displays low but multiple hormonal activities in fish.
- Affected hormonal activities include negative interference with maturation of sperm and oocytes (developing fish egg cells).

Global Gene Expression Profile Induced by the UV-filter 2-ethyl-hexyl-4-trimethoxycinnamate (EHMC) in Zebrafish (Danio rerio)

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Zucchi, 2011	Octinoxate	3 to 3,000 micrograms per liter	Zebrafish (*Danio rerio*)	Testing was performed in a laboratory setting

Study methodology

The study applied a gene expression profile to adult male zebrafish (*Danio rerio*) after 14 days of exposure to a range of concentrations of octinoxate.

Study findings

- Octinoxate exposure affects many biological processes with pathways mainly involved in tissue remodeling, immune system response, inflammatory response, DNA damage, and cell development.
- DNA transcriptional changes were observed at environmentally realistic concentrations of 2.2 micrograms per liter.

Effects of the UV Filter Benzophenone-3 (Oxybenzone) at Low Concentrations in Zebrafish (Danio rerio)

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Blüthgen, 2012	Oxybenzone	2.4 up to 438 micrograms per liter	Zebrafish (*Danio rerio*)	Testing was performed in a laboratory setting

Study methodology

The study exposed adult male zebrafish (*Danio rerio*) and zebrafish embryos in a fish tank to a range of concentrations of oxybenzone from 0 to 438 micrograms per liter over a period of 14 days for the adult fish and 120 hours post-fertilization for the embryos.

Study findings

- Low concentrations of oxybenzone lead to gene alterations in zebrafish at different developmental stages.
- Effects on the zebrafish occurred mainly at 84 micrograms per liter of oxybenzone, which is about an order of magnitude higher than the highest environmental levels reported.
- Data suggest that oxybenzone is of lower concern for endocrine disruption on zebrafish relative to other UV filters, especially at environmentally relevant concentrations.

Sunscreen Products as Emerging Pollutants to Coastal Waters

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Tovar-Sánchez, 2013	• Oxybenzone • 4-methylbenzylidene camphor • Titanium • Zinc	Measured: Not detected to 37.6 micrograms per liter	Marine phytoplankton (*Chaetoceros gracilis*)	Majorca Island (Mediterranean Sea) for water samples; organism tested in a laboratory setting

Study methodology

The study determined the concentrations of sunscreen ingredients (including oxybenzone) in seawater near Majorca Island. The study also examined the effects of these ingredients on marine phytoplankton(*Chaetoceros gracilis*) in laboratory testing after exposure for 72 hours.

Study findings

- Sunscreen products are a significant source of organic and inorganic chemicals that reach the sea with potential ecological consequences on the ecosystem.
- Sunscreen ingredients in coastal waters may produce negative effects on the coastal ecosystem either by inhibiting the growth of some marine phytoplankton species or by adding micronutrients that stimulate the growth of other marine phytoplankton species.

Effects of Benzophenone-3 Exposure on Endocrine Disruption and Reproduction of Japanese Medaka (Oryzias latipes)—A Two Generation Exposure Study

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Kim, 2014	Oxybenzone	15 to 500 micrograms per liter	Japanese medaka fish (*Oryzias latipes*)	Testing was performed in a laboratory setting

Study methodology

The study exposed adult Japanese medaka fish (*Oryzias latipes*) and their eggs to a range of concentrations of oxybenzone from 15to 500 micrograms per liter in a fish tank over a period of 28 days.

Study findings

- Observations show that oxybenzone affects reproductive hormone levels in Japanese medaka fish, with a statistically significant decrease in egg production for fish exposed at concentrations as low as 26 micrograms per liter.
- The oxybenzone concentration level where negative effects in Japanese medaka fish were observed is still a couple of orders of magnitude greater than concentration levels of actual on-site concentration levels reported in another study.

Toxicopathological Effects of the Sunscreen UV Filter, Oxybenzone (Benzophenone-3), on Coral Planulae and Cultured Primary Cells and Its Environmental Contamination in Hawaii and the U.S. Virgin Islands

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Downs, 2015	Oxybenzone	2.28 to 22,800 micrograms per liter	Coral (*Stylophora pistillata*)	Testing was performed in a laboratory setting

Study methodology

The study included two parts. The first part examined the reaction of coral (*Stylphora pistillata*) to varying concentrations of oxybenzone for 8-hour and 24-hour exposure periods. The second part collected water samples from sites on St. John Island in the U.S. Virgin Islands and Maui and Oahu islands in Hawaii.

Study findings

- Oxybenzone poses a hazard to coral reef conservation and threatens the resiliency of coral reefs to climate change.
- Coral reef contamination of oxybenzone in the U.S. Virgin Islands ranged from 75 micrograms per liter to 1.4 milligrams per liter, whereas Hawaiian sites were contaminated between 0.8 and 19.2 micrograms per liter.

UV Filters Bioaccumulation in Fish from Iberian River Basins

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Gago-Ferrero, 2015	• Oxybenzone • Octinoxate • Benzophenone-1 • 4,4-Dihydroxy benzophenone • 4-Hydroxybenzophenone • 4-Methylbenzylidene camphor • Ethylhexl dimethyl PABA • Octocrylene	Not detected to 0.2417 micrograms per gram	• Ebro barbel (*Luciobarbus graellsii*) • Common carp (*Cyprinus carpio*) • Wels catfish (*Silurus glanis*) • Andalusian barbel (*Luciobarbus sclateri*) • Brown trout (*Salmo trutta*) • Iberian nase (*Pseudochondrostoma polylepis*) • Iberian gudgeon (*Gobio lozanoi*) • Black Bass (*Micropterus salmoides*) • Bleak *(Alburnus alburnus*) • European eel (*Anguila anguila*) • Pumpkinseed (*Leponis gibbosus*) • Mediterranean barbel (*Barbus guiraonis*) • Pike (*Esox lucius*)	Four river basins in eastern Spain

Study methodology

The study analyzed the concentrations of UV-filter chemicals in fish samples and sediment samples from four Iberian river basins.

Study findings

- The highest concentrations of UV filters were detected in fish from the Guadalquivir River, which accumulated oxybenzone and octinoxate.
- Predator species occupying a higher position in the trophic chain showed higher levels of UV filters, which suggests that biomagnification may play a role in the accumulation of these chemicals in fish.

UV-filter Benzophenone-3 Inhibits Agonistic Behavior in Male Siamese Fighting Fish (Betta splendens)

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Chen, 2016	Oxybenzone	10 to 1000 micrograms per liter	Siamese fighting fish (*Betta splendens*)	Testing was performed in a laboratory setting

Study methodology

Exposed adult male Siamese fighting fish (*Betta splendens*) to varying concentrations of oxybenzone solutions for 28 days.

Study findings

- Oxybenzone can inhibit agonistic behavior in male fighting fish without affecting locomotor activity.
- The effects observed occurred mainly at the highest concentration tested, which is at least two orders of magnitude higher than reported environmental levels.

Sequential Assessment via Daphnia and Zebrafish for Systematic Toxicity screening of Heterogeneous Substances

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Jang, 2016	• Oxybenzone • Octinoxate • Titanium Dioxide	• Oxybenzone from 1.0 to 4.0 micrograms per milliliter • Octinoxate from 0.1 to 0.5 micrograms per milliliter • Titanium Dioxide from 1.0 to 4.0 micrograms per milliliter	• Planktonic Crustacean (*Daphnia magna*) • Zebrafish (*Danio rerio*)	Testing was performed in a laboratory setting

Study methodology

The study exposed planktonic crustaceans (*Daphnia magna*) and zebrafish (*Danio rerio*) to solutions with different concentrations of the chemicals under study for 48 hours for crustaceans and 6 days for zebrafish.

Study findings

- This protocol showed additive toxic effects for mixtures of these chemicals.
- Immobilization response for 50% of the *Daphnia magna* occurred at 2.17 micrograms per milliliter of oxybenzone.
- Immobilization response for 50% of the *Daphnia magna* occurred at 3.03 micrograms per milliliter of octinoxate. The zebrafish were relatively less sensitive to the heterogeneous mixtures of these chemicals.

Direct and Indirect Effects of Sunscreen Exposure for Reef Biota

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
McCoshum, 2016	• Oxybenzone • Octocrylene • Homosalate • Octisalate • Avobenzone	0.26 milliliter per liter	• Flatworms (*Convolutriloba macropyga*) • Photosynthetic diatoms (*Nitzschia sp.*) • Anemones (*Aiptasia*) • Pulse corals *(Xenia sp.*)	Testing was performed in a laboratory setting

Study methodology

The study added sunscreens at various concentrations to growing environments containing flatworms (exposed for 72 hours), photosynthetic diatoms (exposed for 72 hours), anemones (exposed for 7 days), and pulse coral (exposed for 28 days) to determine the effects of the sunscreen on population and colony growth.

Study findings

- Results support previous studies that show negative effects of commercial sunscreen products on aquatic organisms and suggest that certain sunscreen ingredients are deleterious to common reef organisms.

Sunscreen Products Impair the Early Developmental Stages of the Sea Urchin Paracentrotus lividus

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Corinaldesi, 2017	• Oxybenzone • Homosalate • Titanium Oxide	10 to 50 microliters per liter of sunscreen	Sea urchins (*Paracentrotus lividus*)	Testing was performed in a laboratory setting with samples of sea urchins from a coastal area of the central Adriatic Sea

Study methodology

The study included two parts. The first part assessed the UV protective efficacy of three sunscreens on protecting human skin. The second part tested for the effects of these same sunscreen products on sea urchins in the laboratory exposed to varying concentrations of these sunscreen products in tanks for an exposure period of 24 hours.

Study findings

- Results suggest that although these sunscreen products protect human skin cells from UVA-induced radiation damage, they may negatively affect the recruitment and survival of sea urchins.

Evaluation of Ecotoxicological Effects of Benzophenone UV Filters: Luminescent Bacteria Toxicity, Genotoxicity and Hormonal Activity

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Zhang, 2017	Four benzophenones including oxybenzone	For Oxybenzone, 1.11 to 508.31 micrograms per liter	• Marine bacterium (*Vibrio fischeri*) • Zebrafish (*Danio rerio*)	Testing was performed in a laboratory setting

Study methodology

The study analyzed the biological effects of four commonly used benzophenones for acute toxicity, genotoxicity, and endocrine disrupting effects. The marine bacterium (*Vibrio fischeri*) was exposed to various concentrations of the test chemicals and reactions were observed every 15 minutes. The zebrafish (*Danio rerio*) larvae were continuously exposed for 144 hours.

Study findings

- Oxybenzone displayed no noticeable adverse effects in laboratory setting assays, although multiple hormonal activities were observed in zebrafish larvae. These hormonal activities indicate potential harmful effects of these chemicals.

Estimation of Physicochemical Properties of 2-ethylhexyl-4-methoxycinnamate (EHMC) Degradation Products and Their Toxicological Evaluation

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Gakowska, 2018	Octinoxate	3.4×10^{-4} Molar	Aquatic crustaceans (*Daphnia magna* and *Artemia Salina*)	Testing was performed in a laboratory setting

Study methodology

The study subjected juvenile aquatic crustaceans (*Daphnia magna* and *Artemia Salina*) to toxic solutions with octinoxate, and the mortality rate was checked after 24 and 28 hours (for *Daphnia magna*) and after 24 hours (for *Artemia Salina*).

Study findings

- Octinoxate can degrade into oxidation products and chloroorganic products. The oxidation products have a small range of dispersal into the environment. The chloroorganic products show properties of persistent organic pollutants. Both products show significantly higher toxicity than octinoxate alone.

Evaluating the Joint Toxicity of Two Benzophenone-Type UV Filters on the Green Alga Chlamydomonas reinhardtii with Response Surface Methodology

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Mao, 2018	• Benzophenone-1 (BP-1) • Benzophenone-3 (Oxybenzone)	For oxybenzone, 0.2 to 5.4 milligrams per liter	Green Alga (*Chlamydomonas reinhardtii*)	Testing was performed in a laboratory setting

Study methodology

The study exposed cell cultures of green alga (*Chlamydomonas reinhardtii*) to various combinations of concentrations of oxybenzone and benzonphenone-1 with checks of the alga's photosynthetic pigments measured after 3 days.

Study findings

- Photosynthetic pigments were found to be negatively affected by the two BPs, which leads to a reduction in cell growth.

Two-Generational Effects of Benzophenone-3 on the Aquatic Midge Chironomus riparius

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Campos, 2019	Oxybenzone	2.0 to 8.0 milligrams per kilogram	Adult aquatic midges and their offspring (*Chironomus riparius*)	Testing was performed in a laboratory setting

Study methodology

The study exposed aquatic midges (*Chironomus riparius*) to a range of concentrations of oxybenzone in the sediment over two generations for a test lasting 28 days.

Study findings

- Results show no effects, even at the highest concentration studied, on the emergence rate and the developmental time of the parental generation.
- However, emergence rate and developmental time were impaired for the next generation offspring.

Toxicological Effects of Two Organic Ultraviolet Filters and a Related Commercial Sunscreen Product in Adult Corals

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
He, 2019	• Octinoxate • Octocrylene	0.1 to 1000 micrograms per liter	Hard coral (*Seriatopora caliendrum* and *Pocillopora damicornis*)	Testing was performed in a laboratory setting

Study methodology

The study used wash-off water containing various concentrations of octinoxate and octocylene to expose adult life stage samples from two hard coral species, *Seriatopora caliendrum* and *Pocillopora damicornis,* over a 7-day period.

Study findings

- Results confirm the bioaccumulation potential for these chemicals and show that the other ingredients in sunscreens may increase the bioavailaiblity of active ingredients to coral.
- The concentrations of octinoxate and oxybenzone in these tests were close to or much higher than the highest concentrations reported at the surface for seawater.
- The bioaccumulation of these chemicals in coral tissue may prolong their effects on the coral.

Parental Transfer of Ethylhexyl Methoxy Cinnamate and Induced Biochemical Responses in Zebrafish

Author and Date	Chemicals Reviewed	Concentration Range Studied or Measured	Organisms Reviewed	Locations Studied
Zhou, 2019	Octinoxate	1.0 to 100 micrograms per liter	Zebrafish (*Danio rerio*)	Testing was performed in a laboratory setting

Study methodology

The study exposed Zebrafish (*Danio rerio*) to varying concentrations of solutions of octinoxate for four months and then their offspring were divided into two groups; one group was exposed to the same octinoxate concentration as their parents, and the other group was washed and transferred to solutions without octinoxate.

Study findings

- The study shows that octinoxate will not only accumulate in zebrafish, but it will also transfer to offspring through reproduction.
- Additionally, the next generation offspring exhibit stronger biochemical responses than their parents, regardless of continued exposure to octinoxate.

References

Amine, H., Gomez, E., Halwani, J., Casellas, C., and Fenet, H. "UV filters, ethylhexyl methoxycinnamate, octocrylene and ethylhexyl dimethyl PABA from untreated wastewater in sediment from eastern Mediterranean river transition and coastal zones," *Marine Pollution Bulletin* 64 (2012): 2435-2442.

Apel, C., Tang, J., and Ebinghaus, R. "Environmental occurrence and distribution of organic UV stabilizers and UV filters in the sediment of Chinese Bohai and Yellow Seas," *Environmental Pollution* 235 (2018): 85-94.

Bargar, T. A., Alvarez, D. A., and Garrison, V. H. "Synthetic ultraviolet light filtering chemical contamination of coastal waters of Virgin Islands national park, St. John, U.S. Virgin Islands," *Marine Pollution Bulletin* 101 (2015): 193-199.

Bell, L. J., Ucharm, G., Patris, S., Diaz-Cruz, M. S., Roig, M. P. S., and Dawson, M. N. "Final Report: Sunscreen Pollution Analysis in Jellyfish Lake, Coral Reef Research Foundation, Palau." (2017).

Blüthgen, N., Zucchi S., and Fent, K. "Effects of the UV filter benzophenone-3 (oxybenzone) at low concentrations in zebrafish (*Danio rerio*)," *Toxicology and Applied Pharmacology* 263 (2012): 184-194.

Bratkovics, S., Wirth, E., Sapozhnikova, Y., Pennigton, P., and Sanger, D. "Baseline monitoring of organic sunscreen compounds along South Carolina's coastal marine environment," *Marine Pollution Bulletin* 101 (2015): 370-377.

Campos, D., Silva, A. R. R., Loureiro, S., Grabicova, K., Stanova, A. V., Soares, A. M. V. M., and Pestana, J. L. T. "Two-generational effects of Benzophenone-3 on the aquatic midge *Chironomus riparius*," *Science of the Total Environment* 669 (2019): 983-990.

Capela, D., Vila M., Llompart, M., Dagnac, T., Garcia-Jares, C., Alves, A., and Homem, V. "Footprints in the sand – Assessing the seasonal trends of volatile methylsiloxanes and UV-filters," *Marine Pollution Bulletin* 140 (2019): 9-16.

Chen, T., Wu, Y., and Ding, W. "UV-filter benzophenone-3 inhibits agonistic behavior in male Siamese fighting fish (*Betta splendens*)," *Ecotoxicology* 25 (2016): 302-309.

Christen, V., Zucchi, S., and Fent, K. "Effects of the UV-filter 2-ethyl-hexyl-4-trimethoxycinnamate (EHMC) on expression of genes involved in hormonal pathways in fathead minnows (*Pimephales promelas*) and link to vitellogenin induction and histology," *Aquatic Toxicology* 102 (2011): 167-176.

Corinaldesi, C., Damiani, E., Marcellini, F., Falugi, C., Tiano, L., Bruge, F., and Danovaro, R. "Sunscreen Products Impair the Early Developmental Stages of the Sea Urchin *Paracetrotus lividus*," *Scientific Reports* 7(1) (2017): 7815 DOI:10.1038/s41598-017-08013-x.

Danovaro, R., Bongiori, L., Corinaldesi, C., Giovannelli, D., Damiani, E., Astolfi, P., Greci, L., and Pusceddu, A. "Sunscreens cause coral bleaching by promoting viral infections," *Environmental Health Perspectives* 116(4) (2008): 441-447.

Downs, C. A., Kramarsky-Winter, E., Segal, R., Fauth, J., Knutson, S., Bronsetin, O., Ciner, F. R., Jeger, R., Lichtenfled, Y., Woodley, C. M., Pennington, P., Cadenas, K., Kushmaro, A., and Loya, Y. "Toxicopathological Effects of the Sunscreen UV Filter, Oxybenzone (Benzophenone-3), on Coral

Planulae and Cultured Primary Cells and Its Environmental Contamination in Hawaii and the U.S. Virgin Islands," *Archives of Environmental Contamination and Toxicology* 70 (2016): 265-288.

Fisch, K., Waniek, J. J., and Schulz-Bull, D. E. "Occurrence of pharmaceuticals and UV-filters in riverine run-offs and waters of the German Baltic Sea," *Marine Pollution Bulletin* 124 (2017): 388-399.

Gackowska, A., Studziński, W., Kudlek, E., Dudziak, M., and Gaca, J. "Estimation of physicochemical properties of 2-ethylhexyl-4-methoxycinnamate (EHMC) degradation products and their toxicological evaluation," *Environmental Science and Pollution Research* 25 (2018): 16037-16049.

Gago-Ferrero, P., Díaz-Cruz, M. S., and Barceló, D. "UV filters bioaccumulation in fish from Iberian river basins," *Science of the Total Environment* 518-519 (2015): 518-525.

He, T., Tsui, M. M. P., Tan, C. J., Ma, C. Y., Yiu, S. K. F., Wang, L. H., Chen, T. H., Fan, T. Y., Lam, P. K. S., and Murphy, M. B. "Toxicological effects of two organic ultraviolet filters and a related commercial sunscreen product in adult corals," *Environmental Pollution* 245 (2019): 462-471.

Jang, G. H., Park, C., Kang, B. J., Kim, Y. J., and Lee, K. H. "Sequential assessment via daphnia and zebrafish for systematic toxicity screening of heterogeneous substances," *Environmental Pollution* 216 (2016): 292-303.

Kim, S., Jung, D., and Choi, K. "Effects of benzophenone-3 exposure on endocrine disruption and reproduction of Japanese medaka (*Oryzias latipes*)—A two generation exposure study," *Aquatic Toxicology* 155 (2014): 244-252.

Mao, F., He, Y., and Gin, K. Y. "Evaluating the Joint Toxicity of Two Benzophenone-Type UV Filters on the Green Alga *Chlamydomonas reinhardtii* with Response Surface Methodology," *Toxics* 6, 8 (2018): 1-12.

Mao, F., You, L., Reinhard, M., He, Y., and Gin, K. Y. H. "Occurrence and Fate of Benzophenone-Type UV Filters in a Tropical Urban Watershed," *Environmental Science & Technology* 52 (2018): 3960-3967.

McCoshum, S. M., Schlarb, A. M., and Baum, K. A. "Direct and indirect effects of sunscreen exposure for reef biota," *Hydrobiologia* 776 (2016): 139-146.

Mitchelmore, C. L., He, K., Gonsior, M., Hain, E., Heys, A., Clark, C., Younger, R., Schmitt-Kopplin, P., Feerick, A., Conway, A., and Blaney, L. "Occurrence and distribution of UV-filters and other anthropogenic contaminants in coastal surface water, sediment, and coral tissue from Hawaii," *Science of the Total Environment* 670 (2019): 398-410.

Picot-Groz, M., Fenet, H., Bueno, M. J. M., Rosain, D., and Gomez, E. "Diurnal variations in personal care products in seawater and mussels at three Mediterranean coastal sites," *Environmental Science and Pollution Research* 25 (2018): 9051-9059.

Rodríguez, A. S., Sanz, M. R., and Rodríguez, J. R. B. "Occurrence of eight UV filters in beaches of Gran Cararia (Canary Islands): An approach to environmental risk assessment," *Chemosphere* 131 (2015): 85-90.

Schaap, I. and Slijkerman, D. M. E. "An environmental risk assessment of three organic UV-filters at Lac Bay, Bonaire, Southern Caribbean," *Marine Pollution Bulletin* 135 (2018): 490-495.

Tang, Z., Han, X., Li, G., Tian, S., Yang, Y., Zhong, F., Han, Y., and Yang, J. "Occurrence, distribution and ecological risk of ultraviolet absorbents in water and sediment from Lake Chaohu and its inflowing rivers, China," *Ecotoxicology and Environmental Safety* 164 (2018): 540-547.

Tashiro, Y., and Kameda, Y. "Concentration of organic sun-blocking agents in seawater of beaches and coral reefs of Okinawa Island, Japan," *Marine Pollution Bulletin* 77 (2013): 333-340.

Terechovs, A. K. E., Ansari, A. J., McDonald, J. A., Khan, S. J., Hai, F. I., Knott, N. A., Zhou, J., and Nghiem, L. D. "Occurrence and bioconcentration of micropollutants in Silver Perch (*Bidyanus bidyanus*) in a reclaimed water reservoir," *Science of the Total Environment* 650 (2019): 585-593.

Tovar-Sánchez, A., Sánchez-Quiles, D., Basterretxea, G., Benedé, J. L., Chisvert, A., Salvador, A., Moreno-Garrido, I., and Blasco, J. "Sunscreen Products as Emerging Pollutants to Coastal Waters," *PLOS ONE* 8(6) (2013): 1-8.

Tsui, M. M. P., Lam, J. C. W., Ng, T. Y., Ang, P. O., Murphy, M. B., and Lam, P. K. S. "Occurrence, Distribution, and Fate of Organic UV Filters in Coral Communities," *Environmental Science & Technology* 51 (2017): 4182-4190.

Zhang, Q., Ma, X., Dzakpasu, M., and Wang, X. C. "Evaluation of ecotoxicological effects of benzophenone UV filters: Luminescent bacteria toxicity, genotoxicity and hormonal activity," *Ecotoxicology and Environmental Safety* 142 (2017): 338-347.

Zhou, R., Lu, G., Yan, Z., Jiang, R., Shen, J., and Bao, X. "Parental transfer of ethylhexyl methoxy cinnamate and induced biochemical responses in zebrafish," *Aquatic Toxicology* 206 (2019): 24-32.

Zucchi, S., Oggier, D. M., and Fent, K. "Global gene expression profile induced by the UV-filter 2-ethyl-hexyl-4-trimethoxycinnamate (EHMC) in zebrafish (*Danio rerio*)," *Environmental Pollution* 159 (2011): 3086-3096.

From: Madill, Colton <Colton.Madill@myfloridalicense.com>
Sent: Thursday, October 3, 2019 10:14 AM
To: Toman, John <Toman.John@flsenate.gov>
Subject: RE: SB 172 on Florida Drug and Cosmetic Act

Hi John,

Please see below a summary of the Division of Drugs, Devices and Cosmetics. Please let me know if this is what you are looking for, or if you need any additional information.

"The Division of Drugs, Devices and Cosmetics safeguards the health, safety, and welfare of the citizens of the state of Florida from injury due to the use of adulterated, contaminated, misbranded drugs, drug ingredients, medical gases and cosmetics by administering the provisions of the Florida Drug and Cosmetic Act (Chapter 499, F.S.). The division carries out its responsibilities through two program areas: Permitting and Compliance & Enforcement. The permitting program is responsible for the review and approval of permitting applications for multiple permit categories, including but not limited to: prescription drug manufacturers, over-the-counter drug manufacturers, cosmetic manufacturers, prescription drug wholesale distributors, medical gas manufacturers and medical gas wholesale distributors. The Bureau of Compliance and Enforcement is responsible for initial permitting and compliance inspections for permitted facilities and investigation of complaints related to violations of the Florida Drug and Cosmetic Act."

Best,

Colton L. Madill
Deputy Legislative Affairs Director
Office of Legislative Affairs
The Department of Business and Professional Regulation
Phone: 850.487.4827
Email: colton.madill@myfloridalicense.com

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

10/14/2019
Meeting Date

SB 0172
Bill Number (if applicable)

Topic Florida Drug and Cosmetic Act

Amendment Barcode (if applicable)

Name Dr. Marc Inglese, MD

Job Title Dermatologist

Address Dermatology Associates of Tallahassee 1704 Riggins Rd
Street

Phone (850) 877-4134

Tallahassee FL 32308
City *State* *Zip*

Email inglesemd@gmail.com

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Society of Dermatology & Dermatologic Surgery

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

10/14
Meeting Date

SB 172
Bill Number (if applicable)

Topic FL Prus + Cosmetic Act

Amendment Barcode (if applicable)

Name Holly Parker Curry

Job Title FL Regional Manager

Address 1229 Mitchell Ave
Street

Phone 850-567 3393

Tallahassee, FL 32303
City *State* *Zip*

Email hparker@surfrider.org

Speaking: ☐ For ☒ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Surfrider Foundation

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

10/14/19
Meeting Date

172
Bill Number (if applicable)

Topic FL Drug and Cosmetic Act

Amendment Barcode (if applicable)

Name JAKE FARMER

Job Title Director of Government Affairs

Address 227 S Adams Street
Street

Phone 352 359 6835

Tallahassee FL 32301
City *State* *Zip*

Email Jake@frf.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Retail Federation

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

10 — *Meeting Date*

172 — *Bill Number (if applicable)*

Topic Preemption

Amendment Barcode (if applicable)

Name Deborah Foote

Job Title Gov't Affairs Dir

Address 200 W College #314 — *Street*

Tallahassee FL 32301 — *City* *State* *Zip*

Phone 251 533 1798

Email deborah.foote@sierraclub.org

Speaking: ☐ For ☑ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Sierra Club FL

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

Florida Building Code, 7th Edition (2020), & Hurricane Michael Final Report

Senate Community Affairs Committee
October 14, 2019

Thomas Campbell
Executive Director, Florida Building Commission

Florida Building Code, 7th Edition (2020), Update Process

- Section 553.73(7), F.S., governs the triennial update process for the Florida Building Code.
- The base document for the Florida Building Code, 7th Edition (2020), is the Florida Building Code, 6th Edition (2017).
- Currently, the triennial update process for the Florida Building Code is a two step process and is subject to the rulemaking requirements of Chapter 120, Florida Statutes.

Florida Building Code, 7th Edition (2020), Update Process (Cont'd)

- The first step requires the Florida Building Commission to review all changes to certain model codes for possible inclusion in the next edition of the Florida Building Code. **In order to approve a change from the model codes the Commission is required to make a finding that the change is necessary to accommodate a specific need of this state. (Completed October 2018)**

- The second step allows members of the public to submit proposed code modifications for possible inclusion in the next edition of the Florida Building Code. **(Completed August 2019)**

Florida Building Code, 7th Edition (2020), Update Process (Cont'd)

- Commission staff is now in the process of developing a draft Florida Building Code, 7th Edition (2020), to begin the last steps of the Chapter 120, F.S., rulemaking process.
  - The public will have an opportunity to comment on the draft Florida Building Code, 7th Edition (2020), at the Commission's February 2020 and April 2020 meetings. The final draft of the Florida Building Code, 7th Edition (2020), should be available for public review by mid-June 2020.
- The tentative effective date for the Florida Building Code, 7th Edition (2020), is December 31, 2020.

HB 447's Changes to the Florida Building Code's Triennial Update Process

- Section 6 of HB 447 added the following language to the end of section 553.73(7)(a), F.S.,
  - Every 3 years, the commission may approve updates to the Florida Building Code **without a finding that the updates are needed in order to accommodate the specific needs of this state.**
- However, section 6 of HB 447 does not become effective until July 1, 2020.
- Therefore, during future Florida Building Code triennial update processes, the Commission will have the discretion to approve any change from certain model codes without a finding that the change is necessary to accommodate the specific needs of this state.

HB 447 Implementation

- The Commission will be holding rule workshops for Fla. Admin. Code R. 61G20-2.002, to implement HB 447's change to section 553.73(7), F.S., and discuss other possible changes to the Florida Building Code's triennial update process.
  - The rule workshops are currently scheduled for October 15, 2019, and December 10, 2019.
  - Anyone interested in proposing changes to the Florida Building Code's triennial update process should submit comments to staff for inclusion in the October workshop's agenda.
  - Any changes made to the Florida Building Code's triennial update process will be applicable to the triennial update process for the Florida Building Code, 8th Edition (2023), and other future editions of the Florida Building Code.

Hurricane Michael Final Report

- The Commission has an annual recurring contract with the University of Florida to perform a survey and damage assessment of residential buildings damaged by a Category III, IV, or V hurricane.

- The UF team was deployed for Hurricane Michael and the lead researcher for the project was Dr. David Prevatt.

- Dr. Prevatt's final report for Hurricane Michael was received by the Commission in June 2019.

- The observations and recommendations in the Hurricane Michael Final Report were consistent with those from the final reports for Hurricane Matthew and Hurricane Irma.

Hurricane Michael Final Report (Cont'd)

- Dr. Prevatt's Key Observations:
  - The largest contributing factor to devastating damage is the first floor elevation of a structure relative to the surge inundation height.
  - Homes built to the Florida Building Code sustained significantly less damage than those built prior to the implementation of the Florida Building Code.
  - However, there were three areas in which homes built to the Florida Building Code suffered consistent failures:
    - Vinyl siding failures.
    - Soffit failures.
    - Partial roof covering failures.

Hurricane Michael Final Report (Cont'd)

- Dr. Prevatt's Key Takeaways:
  - Significant structural damage in Mexico Beach was mainly experienced by an aged building stock that pre-dated modern building codes in Florida. Overall, modern homes performed well.
  - Impacts to the building go far beyond observable structural damage. Homes that performed well structurally often have interior damage that make them unlivable and sometimes unrepairable due to roof cover loss and water intrusion.
  - The Florida Building Code needs to be enforced and continually improved to avoid the disaster conditions that have been observed in Mexico Beach.

Tentatively Approved Hurricane Related Amendments

- During the update process for the Florida Building Code, 7th Edition (2020), the Commission has tentatively approved several amendments related to hurricanes.
  - A new requirement mandating the sealing of roof decks which should mitigate water intrusion if roof coverings are lost during a storm.
  - Additional mitigation requirements for all buildings with wood roof decks.
  - Additional installation requirements for soffit systems and more stringent wind resistance requirements for vinyl siding.

Tentatively Approved Hurricane Related Amendments (Cont'd)

- Addition of "in progress" inspections for exterior wall coverings (soffits, siding, veneers, and etc.).

- Adoption of ASCE 7-16 which includes increased requirements for the fastening of low slope roof decks, classification of metal roof shingles based on wind resistance, and an enhanced wind speed map for essential facilities.

www.**myfloridalicense**.com

Contact Information

Gabe Peters
Legislative Affairs Director
850-487-4827

CourtSmart Tag Report

Room: SB 301 **Case No.:** **Type:**
Caption: Community Affairs **Judge:**

Started: 10/14/2019 4:31:08 PM
Ends: 10/14/2019 5:09:06 PM Length: 00:37:59

4:31:07 PM Quorum Present
4:31:38 PM Senator Bradley SB 172
4:34:05 PM Senator Pizzo with a question
4:35:10 PM Senator Bradley comments regarding the environment
4:36:28 PM Senator Pizzo with a follow-up
4:37:23 PM Senator Bradley regarding FDA
4:38:15 PM Senator Farmer with questions
4:39:00 PM Senator Bradley
4:39:55 PM Senator Farmer with a follow-up
4:40:36 PM Senator Bradley
4:40:42 PM Senator Simmons with questions
4:41:52 PM Senator Bradley
4:43:07 PM No Amendments
4:43:12 PM Jake Farmer Florida Retail Federation waives in support
4:43:52 PM Deborah Foote Sierra Club of Florida stands against the bill
4:45:14 PM Holly Parker Curry Surfrider Foundation is against the bill
4:45:58 PM Dr. Marc Inglese-Florida Society of Dermatology and Dermatologic Surgery
4:48:40 PM Senator Pizzo in debate
4:51:25 PM Senator Farmer in debate
4:54:04 PM Senator Bradley to close on the bill
4:54:53 PM SB 172 is reported favorably
4:55:56 PM Presentation by Tom Campbell of the Florida Building Commission on Hurricane Michael and update on development of FL Bldg Code 2020
5:08:43 PM Meeting Adjourned