Tab 1	**SB 172** by **Bradley**; (Identical to H 00113) Florida Drug and Cosmetic Act

The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

INNOVATION, INDUSTRY AND TECHNOLOGY
Senator Simpson, Chair
Senator Benacquisto, Vice Chair

MEETING DATE: Monday, November 4, 2019
TIME: 1:30—3:30 p.m.
PLACE: *Toni Jennings Committee Room,* 110 Senate Building

MEMBERS: Senator Simpson, Chair; Senator Benacquisto, Vice Chair; Senators Bracy, Bradley, Brandes, Braynon, Farmer, Gibson, Hutson, and Passidomo

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 11/04/2019 Favorable RC	Favorable Yeas 8 Nays 2
2	Presentation on the Final Report on the Potable Reuse Committee by Lynn Spivey, Chair		Presented
3	Presentation by the Florida Association of Cosmetology and Technical Schools on the needs and requirements for training and safety		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 Innovation, Industry, and Technology

BILL:	SB 172
INTRODUCER:	Senator Bradley
SUBJECT:	Florida Drug and Cosmetic Act
DATE:	November 4, 2019 REVISED:

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

I. Summary:

SB 172 expressly preempts to the state the regulation of over-the-counter proprietary drugs and 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 grants 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, if regulation of the affected businesses, professions, and occupations 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]

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.[13] Implied preemption is actually a decision by the courts to create preemption in the absence of an explicit legislative directive.[14] 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.[15] Implied preemption is found where the local legislation would present the danger of conflict with the state's pervasive regulatory scheme.[16]

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[7] *See also* Florida House of Representatives, Publications, The Local Government Formation Manual 2018-2020, p. 16 (p. 21 of the online PDF version), *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 (last visited Nov. 1, 2019).

[8] Section 166.021(4), F.S.

[9] *See* James R. Wolf and Sarah Harley Bolinder, *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, quoting *Phantom of Clearwater, Inc., supra* note 10.

[12] *Sarasota Alliance for Fair Elections, Inc. v. Browning*, 28 So.3d 880, 886 (Fla. 2010). 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(16), F.S.

[13] *See, e.g., Nat'l Rifle Ass'n of Am., Inc. v. City of S. Miami,* 812 So.2d 504 (Fla. 3d DCA 2002).

[14] *Phantom of Clearwater, Inc.*, 894 So.2d at 1019.

[15] *Id*., quoting *Tallahassee Memorial Regional Medical Center, Inc. v. Tallahassee Medical Center, Inc.,* 681 So.2d 826, 831 (Fla. 1st DCA 1996), citing *Tribune Co. v. Cannella*, 458 So.2d 1075 (Fla. 1984).

[16] *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.[17] 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.[18] 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.[19] Administration of the act must conform to the Federal Food, Drug, and Cosmetic Act[20] and the applicable portions of the Federal Trade Commission Act,[21] which prohibit the false advertising of drugs, devices, and cosmetics.[22]

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 occurs within DBPR's Division of Drugs, Devices and Cosmetics (division).[23] The division carries out its responsibilities through two program areas:[24]

- 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.[25]
- 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:[26]

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

[17] Section 499.001, F.S., provides that ss. 499.001-499.94 is the Florida Drug and Cosmetic Act.
[18] Section 499.002(1)(a), F.S.
[19] Section 499.002(2), F.S.
[20] 21 U.S.C. ss. 301 *et seq*.
[21] *See* 15 U.S.C. §§ 41-58, as amended.
[22] Section 499.002(1)(b), F.S.
[23] E-mail from Colton Madill, Deputy Legislative Affairs Director, DBPR to staff of the Senate Committee on Community Affairs (Oct. 3, 2019) (on file with Senate Committee on Innovation, Industry, and Technology).
[24] *Id.*
[25] 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.
[26] *See* ss. 499.0051, 499.0054, and 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

Florida's drugs, devices and cosmetics regulations must conform to the Federal Food, Drug, and Cosmetic Act.[27] 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.[28] The FDA reviews the active ingredients and the labeling of classes of drugs instead of individual drug products because there are over 300,000 marketed OTC drug products.[29] 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. According to the FDA, OTC drug monographs are a kind of "recipe book" covering acceptable ingredients, doses, formulations, and labeling.[31]

The FDA defines "cosmetic products" in a fashion similar to the definition of cosmetic in s. 499.003(12), F.S.[32] 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.[33]

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[27] *See supra* note 21.
[28] 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 Nov. 1, 2019).
[29] *Id*.
[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 supra* note 21.
[32] *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 Nov. 1, 2019)
[33] *Id.*

Over-the-Counter Sunscreen

Ultraviolet Ray Sun Protection from Sunscreen

According to the American Academy of Dermatology (AAD),[34] one in five Americans will develop skin cancer in their lifetime, and nearly 20 Americans die from melanoma[35] every day. To prevent exposure to the sun's harmful ultraviolet rays, the AAD recommends protecting your skin by "seeking shade, wearing protective clothing and generously applying sunscreen."[36]

The AAD identifies two types of sunscreen:[37]

- 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.[38]

For physical sunscreen, the AAD 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.[39]

As noted in the review of research on this subject by the Office of Program Policy Analysis and Government Accountability (OPPAGA):[40]

> Active sunscreen ingredients fall into two broad categories: organic radiation absorbers and inorganic sun-blocking agents.[41] 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.[42] 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,

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[34] *See* American Academy of Dermatology, *Detect Skin Cancer: How to Perform a Skin Self-Exam, available at* https://www.aad.org/skin-cancer-find-check and *Is Sunscreen Safe?, available at* https://www.aad.org/sun-protection/is-sunscreen-safe (last visited Nov. 1, 2019).

[35] 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 types of skin cancers it is considered more dangerous because it is 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 Nov. 1, 2019).

[36] *See* https://www.plasticsurgerypractice.com/client-objectives/dermatology/skin-conditions/american-academy-dermatology-statement-safety-sunscreen/ (last visited Nov. 1, 2019). To protect skin and reduce ski cancer risks, the AAD recommends a sunscreen that 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).

[37] *See Is Sunscreen Safe?, available at* https://www.aad.org/sun-protection/is-sunscreen-safe (last visited Nov. 1, 2019).

[38] *Id*. The AAD 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.

[39] *Id*.

[40] See *infra* note 49 and further discussion in the accompanying text.

[41] In this context, "organic" refers to carbon-based chemicals and "inorganic" refers to non-carbon-based chemicals.

[42] 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.

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.

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

On February 26, 2019, the FDA published a proposed rule on *Sunscreen Products for Over-the-Counter Human Use*.[43] 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, the 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.[44]

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

In February 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-licensed" prescription.[45] The city commission cited 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.

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[43] 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 (last visited Nov. 1, 2019). Information in this section of the analysis is derived from the FDA proposed rule. According to the 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 final rule are generally recognized as safe and effective (GRASE) for use in sunscreen products.

[44] While the FDA is asking for more data, it has not said that these ingredients are unsafe. The ingredients are listed in Table 1 of the proposed rule. *See* 84 F.R. § 6204, at 6209 (2019).

[45] Chapter 26, Article VII., Sec. 26-311, Code of Ordinances, City of Key West Florida (Ord. No.19-03, § 1, 2-5-2019, available at http://keywest.legistar.com/LegislationDetail.aspx?ID=3763135&GUID=EFF5D76E-F043-4AFF-A898-42EB20A25953&Options=Advanced&Search= (last visited Nov. 1, 2019). The acronym "SPF" (sun protection factor) is the number assigned to a sunscreen to indicate the factor by which the time required for unprotected skin to become sunburned is increased when the sunscreen is used. *See* https://www.merriam-webster.com/dictionary/SPF (last visited Nov. 1, 2019).

A first time violation of the ordinance shall result in one written warning, absent a serious threat to public safety or an irreparable violation. 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.[46] The effective date of the specified sunscreen products prohibition is January 1, 2021.[47]

OPPAGA Research of Sunscreen Chemical Effects on Corals[48] 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.[49] In the overview of its findings presented to the Legislature in September 2019, OPPAGA stated that:

> A small number of scientific studies have shown negative effects[50] 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.

III. Effect of Proposed Changes:

Section 1 amends s. 499.002, F.S., to expressly preempt the regulation of over-the-counter proprietary drugs and cosmetics to the state.

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

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[46] Chapter 2, Article VI, Division 3, Code of Ordinances, City of Key West Florida.

[47] Both the state of Hawaii (Senate Bill 2571/Act 104 (2018)) and the U.S. Virgin Islands (Bill No. 33-0043/Act No. 8185 (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.

[48] 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 Nov. 1, 2019).

[49] 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 Innovation, Industry, and Technology).

[50] 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.

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.

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
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Office of Legislative Affairs
The Department of Business and Professional Regulation
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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.

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THE FLORIDA SENATE

APPEARANCE RECORD

NOV 4 2019 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) SB 172

Meeting Date *Bill Number (if applicable)*

Topic SUN SCREEN *Amendment Barcode (if applicable)*

Name SEX i BUDS CLAY COUNTY FL. HOTELS

Job Title SEX TOY SALES ; HOTELS

Address 2904 - 2910 BLANDING BLVD Phone 904.415-3221

Street

City *State* *Zip* Email

Speaking: ☐ For ☐ Against ☑ Information Waive Speaking: ☐ In Support ☐ Against

(The Chair will read this information into the record.)

Representing JAMES OTTO

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)

11/4/19
Meeting Date

172
Bill Number (if applicable)

Topic FLORIDA DRUG AND COSMETIC ACT

Amendment Barcode (if applicable)

Name JONATHAN WEBBER

Job Title Deputy Director

Address 1700 N. Monroe St. #11-286
Street

Phone 954-593-4449

Tallahassee FL 32303
City *State* *Zip*

Email JWEBBER@FCVOTERS.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing FLORIDA CONSERVATION VOTERS

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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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)

11/4/19
Meeting Date

SB 172
Bill Number (if applicable)

Topic Florida Drug and Cosmetic Act

Amendment Barcode (if applicable)

Name Christopher Emmanuel

Job Title Policy Director

Address 136 S. Bronough St
Street

Phone 8509331225

TLH FL 32301
City *State* *Zip*

Email cemmanuel@flchamber

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Chamber of Commerce

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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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)

11/4/2019
Meeting Date

172
Bill Number (if applicable)

Topic Florida Drug & Cosmetic Act

Amendment Barcode (if applicable)

Name JAKE FARMER

Job Title Director of Government Affairs

Address 227 S Adams St.
Street

Phone 352-359-6835

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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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S-001 (10/14/14)

Duplicate

THE FLORIDA SENATE

APPEARANCE RECORD

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

11/04/2019
Meeting Date

SB 172
Bill Number (if applicable)

Topic Florida Drug and Cosmetic Act

Amendment Barcode (if applicable)

Name Jon Johnson

Job Title Lobbyist

Address 537 E Park Avenue
Street

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Tallahassee FL 32301
City *State* *Zip*

Email jon@teamjb.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing The Florida Society of Dermatology and Dermatologic Surgery (FSDDS)

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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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)

11/4/19
Meeting Date

SB172
Bill Number (if applicable)

Topic FL Drug & Cosmetic Act

Amendment Barcode (if applicable)

Name Holly Parker Curry

Job Title FL Regional Manager

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Street

Tallahassee FL 32303
City *State* *Zip*

Phone 850567-3393

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.

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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)

11/4/19
Meeting Date

172
Bill Number (if applicable)

Topic OTC Proprietary Medicines + Cosmetics

Amendment Barcode (if applicable)

Name Deborah Foote

Job Title Gov't Affairs + Political Director

Address 3254 Newberry Blvd
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Phone

Email

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.

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S-001 (10/14/14)

Duplicate

THE FLORIDA SENATE

APPEARANCE RECORD

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

11/04/2019
Meeting Date

SB 172
Bill Number (if applicable)

Topic SB 172 - Florida Drug and Cosmetic Act

Amendment Barcode (if applicable)

Name Jason Unger

Job Title

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Phone 850-577-9090

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

Email jason.unger@gray-robinson.com

Speaking: ☐ For ☑ Against ☐ Information

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

Representing City of Key West

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.

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S-001 (10/14/14)

The Florida Senate

COMMITTEE VOTE RECORD

COMMITTEE: Innovation, Industry, and Technology
ITEM: SB 172
FINAL ACTION: Favorable
MEETING DATE: Monday, November 4, 2019
TIME: 1:30—3:30 p.m.
PLACE: 110 Senate Building

FINAL VOTE								
Yea	**Nay**	**SENATORS**	**Yea**	**Nay**	**Yea**	**Nay**	**Yea**	**Nay**
X		Bracy						
X		Bradley						
X		Brandes						
	X	Braynon						
	X	Farmer						
X		Gibson						
X		Hutson						
X		Passidomo						
X		Benacquisto, VICE CHAIR						
X		Simpson, CHAIR						
8	2	**TOTALS**						
Yea	**Nay**		**Yea**	**Nay**	**Yea**	**Nay**	**Yea**	**Nay**

CODES: FAV=Favorable
UNF=Unfavorable
-R=Reconsidered
RCS=Replaced by Committee Substitute
RE=Replaced by Engrossed Amendment
RS=Replaced by Substitute Amendment
TP=Temporarily Postponed
VA=Vote After Roll Call
VC=Vote Change After Roll Call
WD=Withdrawn
OO=Out of Order
AV=Abstain from Voting

By Senator Bradley

5-00292-20 2020172__

A bill to be entitled

An act relating to the Florida Drug and Cosmetic Act; amending s. 499.002, F.S.; preempting the regulation of over-the-counter proprietary drugs or cosmetics to the state; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (7) is added to section 499.002, Florida Statutes, to read:

499.002 Purpose, administration, and enforcement of and exemption from this part.—

(7) Notwithstanding any other law or local ordinance or regulation to the contrary, the regulation of over-the-counter proprietary drugs and cosmetics is expressly preempted to the state.

Section 2. This act shall take effect July 1, 2020.

WATEREUSE FLORIDA

The Florida Potable Reuse Commission:
Making New Water in the Sunshine

Lynn Spivey
Director of Utilities, City of Plant City
President, WateReuse Florida
Chair, Florida Potable Reuse Commission

Potable Reuse National Initiatives

Arizona

California

Colorado

Florida

Oklahoma

Texas

Potable Reuse Commission Mission

Consensus based effort by water professionals and a diverse stakeholder group to identify and address technical, regulatory, and implementation barriers to potable reuse in Florida.

Develop a framework document for potable reuse implementation in Florida to augment future water supply and support water quality initiatives.

Potable Reuse Commission Collaborative Effort

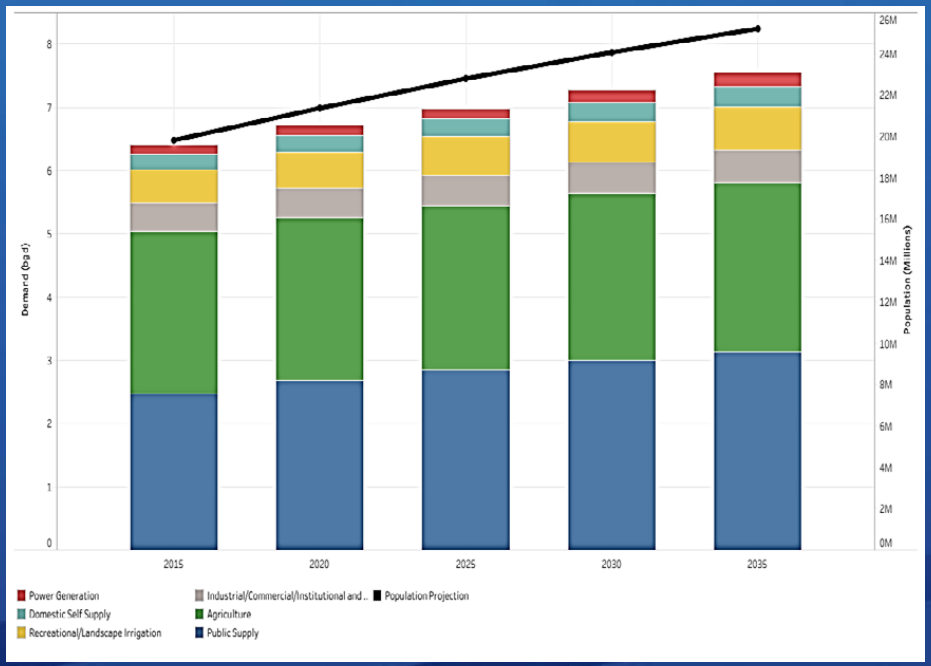
Non Utility VIPS	Utility Representatives
Agriculture Representative **Kerry Kates** Florida Fruit & Vegetable Association	**WateReuse Florida, Chair** **Lynn Spivey** City of Plant City
Florida Department of Health **Dean Bodager** Bureau of Epidemiology Food & Waterborne Disease	**WateReuse Florida, VC** **Bart Weiss** Hillsborough County Public Utilities
Environmental Representative **Garrett Wallace** The Nature Conservancy of Florida	**Florida Section AWWA Utility Council, VC** **Brian Wheeler** City of St. Cloud (previously TOHO Water Authority)
Florida Industries Representative **Jim Spratt,** Associated Industries of Florida	**Florida Section AWWA Utility Council** **Chuck Weber,** City of Tampa
Public Health/Medical State University Representative **Dr. Donna Petersen** Dean, College of Public Health at the University of South Florida	**FWEA Utility Council, VC** **Paul Steinbrecher,** JEA **FWEA Utility Council, VC** **Ed Torres,** City of Altamonte Springs

Water Demands

A water demand projection is a forecast of how much water we will need over the next 20 years

Between 2015 and 2035:

- Population is projected to grow by:
  - ✓27.2% (from 19.8 million to 25.2 million)
- Water demand is projected to grow by:
  - ✓18.1% (from 6.4 bgd to 7.6 bgd)



Reclaimed Water

"Reclaimed water" = water that has received at least secondary treatment and basic disinfection and is reused after flowing out of a domestic wastewater treatment facility

Reclaimed water is not subject to regulation pursuant to s. 373.175 or part II of this chapter until it has been discharged into waters as defined in s. 403.031(13)

Reuse Facilities

In 2018, 479 domestic wastewater treatment facilities reported making reclaimed water available for reuse

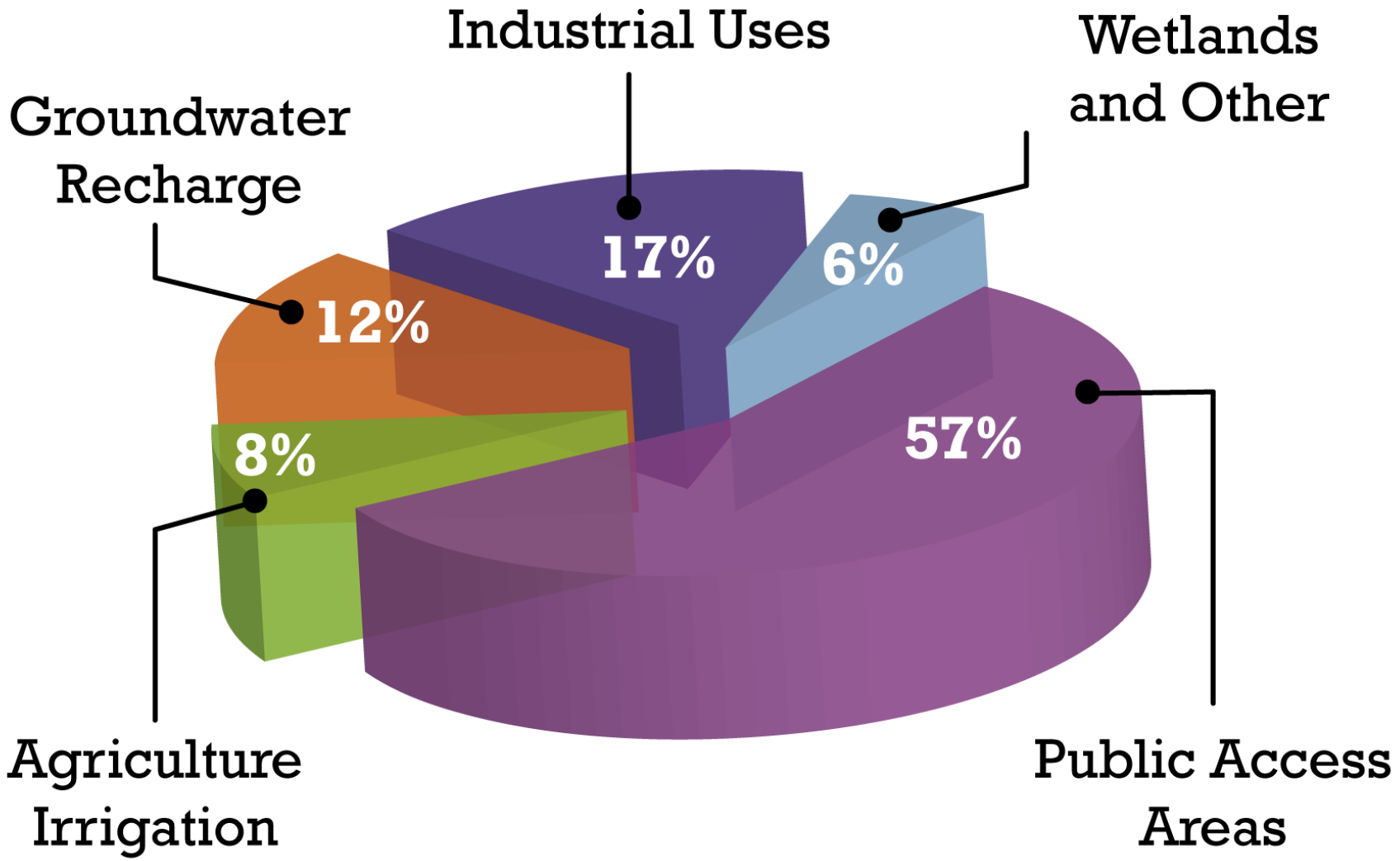
- Permitted wastewater treatment facility capacity of 2,389 mgd; treated 1,542 mgd of domestic wastewater
- Served 427 reuse systems

Approximately 797 mgd of reclaimed water from these facilities was reused for beneficial purposes

- Represents ~48% of the total domestic wastewater flow in the state

Total reuse capacity associated with these systems = 1,735 mgd

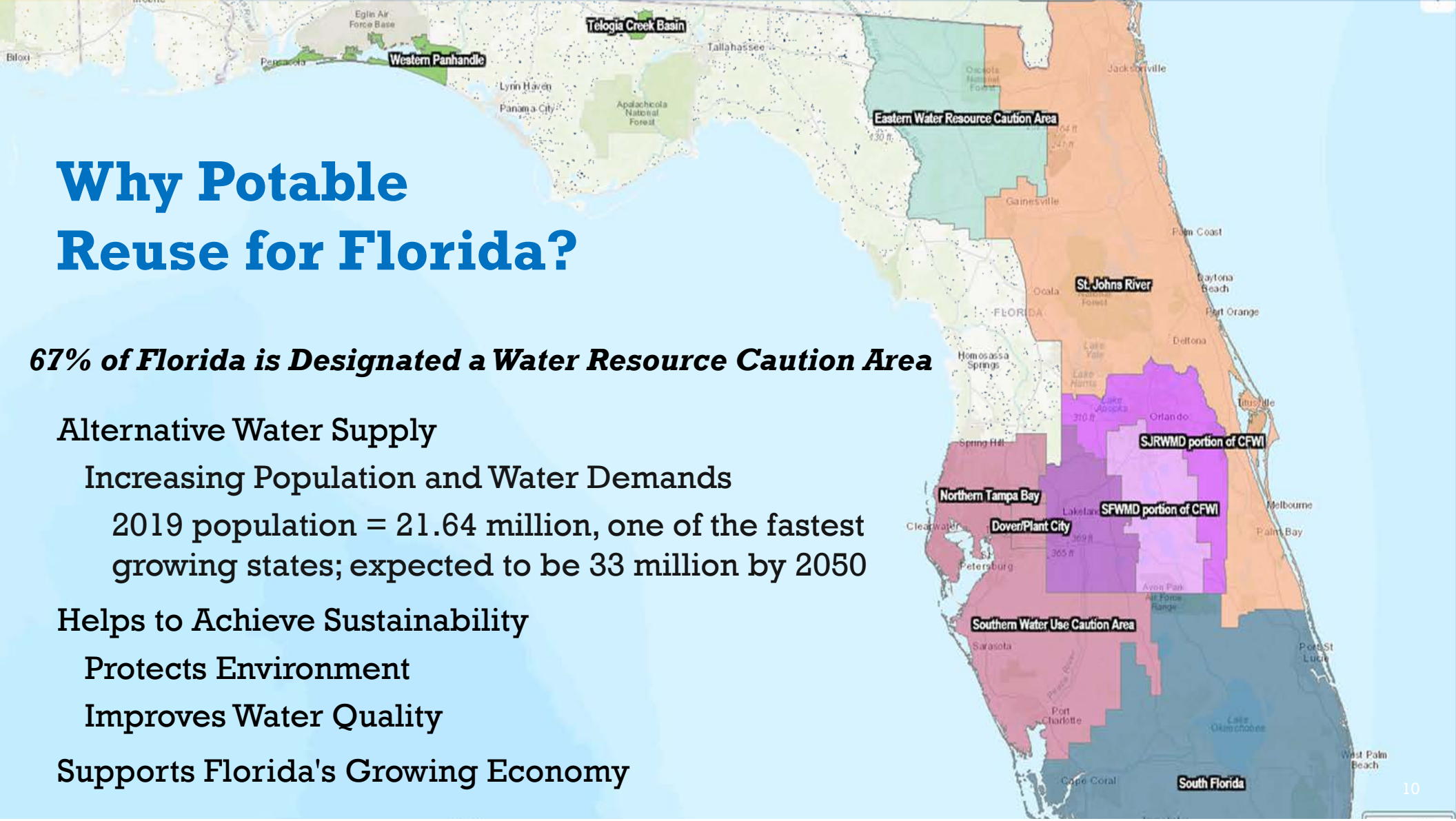
- Represents ~67% of the total domestic wastewater treatment capacity in the state


Industrial Uses
Wetlands and Other
Groundwater Recharge
17%
6%
12%
8%
57%
Agriculture Irrigation
Public Access Areas

Why Potable Reuse for Florida?

67% of Florida is Designated a Water Resource Caution Area

- Alternative Water Supply
  - Increasing Population and Water Demands
    - 2019 population = 21.64 million, one of the fastest growing states; expected to be 33 million by 2050
- Helps to Achieve Sustainability
  - Protects Environment
  - Improves Water Quality
- Supports Florida's Growing Economy



Potable Reuse Ongoing and Pilot Projects in Florida

Florida IPR and DPR Projects

Sponsor	Program	Status
City of Clearwater	Groundwater Replenishment Pilot Test and Full Scale Design	Operated Jul 2013-Jun 2014 (12 months)
Hillsborough County	Direct Potable Reuse Demonstration	Jul 2016
Hillsborough County	SHARP	2016-Ongoing
City of Altamonte Springs	pureALTA	2016-Ongoing
JEA	Pilot Testing 1 MGD H_2O Production Facility	Completed 2019 Design Phase. Online 2021
City of Daytona Beach	Advanced Water Purification Demonstration	March 2017 – Nov 2020 (construction and operation)
City of Tampa	Tampa Augmentation Project – Recharge and Recovery	Preliminary Design

PRC Framework Document Overarching Goals

Develop science-based recommendations

Protect public health and the environment

Provide a regulatory path for potable reuse projects in Florida

The Process

PCR Framework guidance from Water Research Foundation

Internationally recognized Non-profit research organization – credible and scientific

Water Research Foundation has extensive experience in potable reuse technical/scientific research

WRF led 3 one-day interactive workshops

Provided opportunities for stakeholders to present questions or concerns

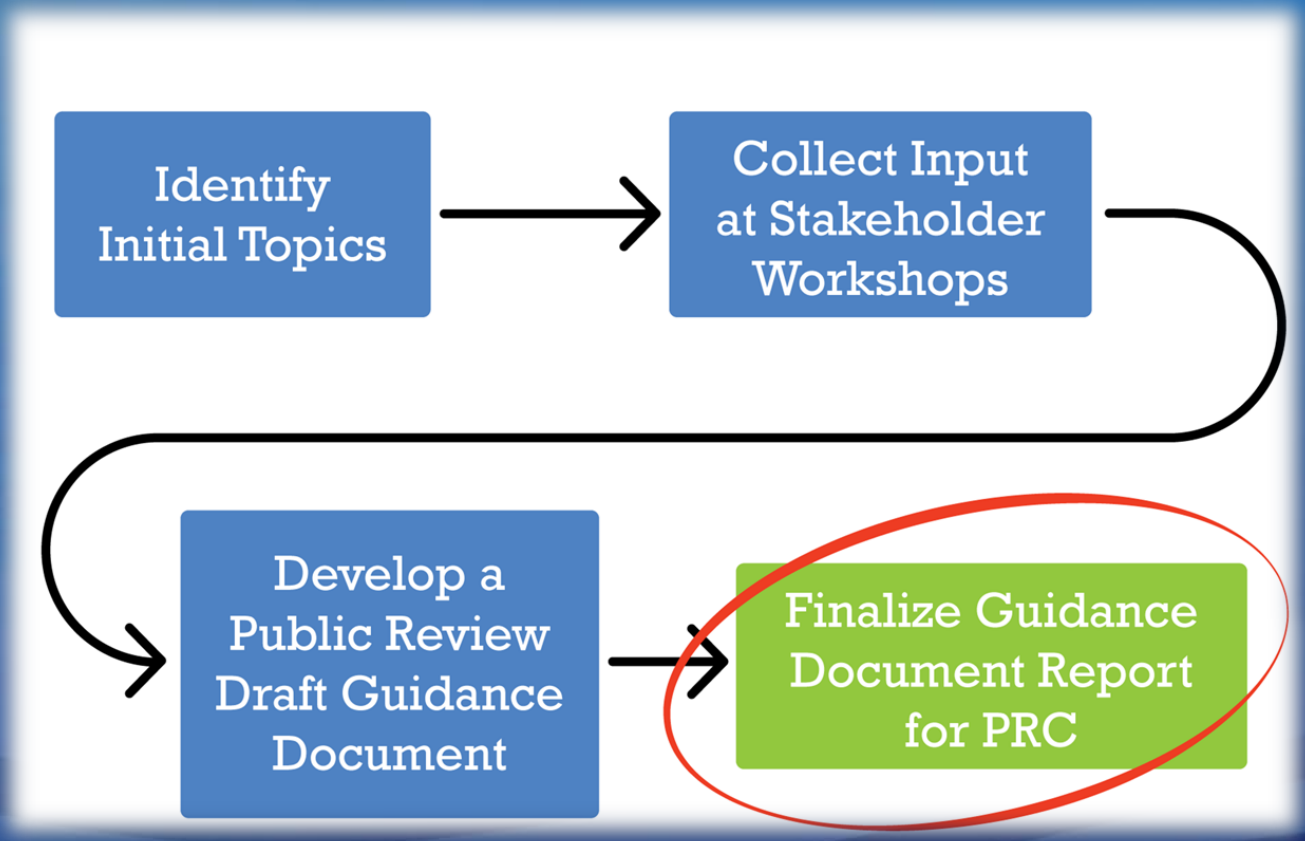
Approach:

Workshop #1: Recommended a list of topics and options

Workshop #2: Summarized recommendations based on stakeholder input and current state-of-science

Workshop #3: Review comments on draft report recommendations

Our Process


Identify Initial Topics
Collect Input at Stakeholder Workshops
Develop a Public Review Draft Guidance Document
Finalize Guidance Document Report for PRC

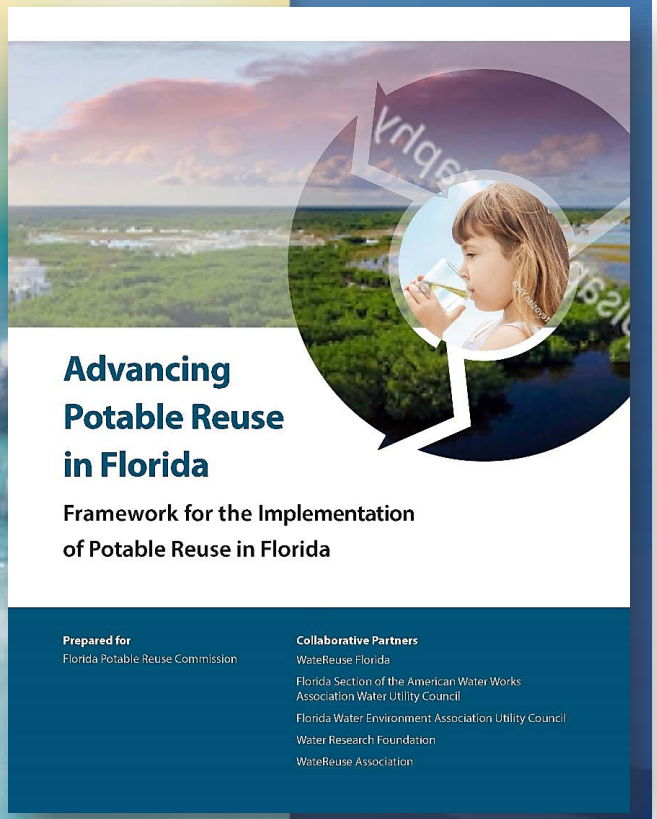
Framework Development: An Open Process with Public Involvement

Publicly noticed 18 meetings in Florida Administrative Register

Hosted three workshops which included more than 30 organizations and more than 150 attendees

Process and progress highlighted in more than 30 state and national presentations

Florida Potable Reuse Framework



CONTENTS

Critical Component of the Florida Specific Guidance

Part 3 – Florida Potable Reuse Regulatory Framework

Chapter 9 – Overview of Regulatory Framework

Chapter 10 – Regulatory Changes the PRC Recommends to Promote Potable Reuse While Protecting Public Health and the Environment

Summary of Proposed Regulatory Recommendations

Proposed Florida Recommendations

Drinking Water Related Regulations

Include all potable reuse requirements in rules addressing drinking water by moving existing potable reuse specific requirements to drinking water related regulations

Include reclaimed water as a source water and address pathogen removal and inactivation requirements in reclaimed water for potable reuse

Address emerging constituents in potable reuse by employing appropriate treatment technology and adding the "representative emerging constituent protocol" to existing environmental monitoring requirements

Proposed Florida Recommendations (cont.)

Reclaimed Water Recharge

Review existing recharge rules in parallel with new rules for potable reuse for consistency

Industrial Pretreatment

Extend industrial pretreatment requirements to potable reuse

Require wastewater utility to develop source control program for sources identified as needed for drinking water production

"Off-Spec" Reclaimed Water

Address "off-spec" reclaimed water through alternative disposal, retreatment, or non-potable reuse

Proposed Florida Recommendations (cont.)

Drinking Water Standards Compliance

Define in rule that compliance with drinking water quality standards is at the point where finished water from the DWTF is discharged to a potable distribution system

Water Use Permit for DPR

Ensure existing law that no new water use permit is needed for a DPR project and that existing WUPs are not adversely impacted as potable reuse statutes and rules are adopted

Proposed Florida Recommendations (cont.)

Protecting Springs

- Ensure existing spring protections continue
- FDEP to clarify that the quality of reclaimed water intended for IPR projects which is released to springshed groundwater complies with surface water quality standards (may be necessary as other rules are amended)

Overall Review of Existing Regulations

- FDEP review of reclaimed water treatment, groundwater recharge, and potable water treatment, and updates regulations as necessary with input

Proposed Florida Recommendations (cont.)

IPR Definition

Include groundwater recharge in IPR definition

Coordination MOU

DEP and WMDs to enter into MOU which allow for the coordinated review of all potable reuse permits if applicant requests

Incentivizing & Protecting Public Investment in Potable Reuse

Form working group to determine if changes are needed to existing law that would incentivize and protect public investments in potable reuse projects

Our Next Steps

- Publish the report
- Legislation
- Rulemaking
- Technical Advisory Committee/Working Groups
- **Public Education and Outreach**

Potable reuse is an emerging alternative water supply option that can help to safely meet Florida's future water needs by providing resiliency during natural drought cycles for decades to come. The Potable Reuse Commission (PRC) will develop the framework for the implementation of potable reuse in Florida.

Florida Water Environment Association
UTILITY COUNCIL
wef Member Association

American Water Works Association
FloridaSection

For more information:

Lynn Spivey, Florida Potable Reuse Commission, Chair

Lynn Spivey
President, WateReuse Florida
lspivey@plantcitygov.com

WATEREUSE FLORIDA

prc.watereuseflorida.com

EXECUTIVE SUMMARY

Florida's need for a safe and sustainable alternative safe water supply

> *"Everyone understands that water is essential to life. But many are only just now beginning to grasp how essential it is to everything in life – food, energy, transportation, nature, leisure, identity, culture, social norms, and virtually all the products used on a daily basis." – World Business Council for Sustainable Development*

Floridians understand the value and importance of water, as well as the need for a reliable, high quality and safe water supply. The Florida Potable Reuse Commission (PRC) was created to develop a framework for potable reuse implementation in Florida that will augment future water supply and support water quality initiatives. The framework will support the implementation of potable reuse in Florida that protects public health, is compatible with Florida's unique environment, and is a viable water resource option available for communities to meet their future water demands.

Water is vital to our health, environment, prosperity and future. Though much of the state receives an average of 50 or more inches of rain per year, most of that falls within a four-month period beginning in June and ending in September. More than 75% of our water supply comes from groundwater, and the availability of additional fresh groundwater is becoming limited in many areas of the state. Floridians currently utilize nearly 6.5 billion gallons of water per day and are projected to need an additional 1.1 billion gallons of water per day by 2035. Our continued growth, status as a world travel destination, and economic success depend on the identification of safe, sustainable alternative water supplies.

The evolution to a One Water perspective

> *"All the water that will ever be is, right now." – National Geographic, October 1993*

As Florida's need, and indeed the world's need, for more water has grown, the realization that "all the water that will ever be is, right now" has resulted in a *one water* perspective. Water is a finite natural resource. We can't make more if we run out. Every drop is valuable, and its use should be carefully considered.

This one water evolution has resulted in a recognition that water should not be labeled by its source – stormwater, groundwater, reclaimed water – but should be considered simply "water." The water present today is the same water as existed with the dinosaurs and it will be the same water that exists with future generations. Whatever its source, the technology exists to treat it for any purpose, including drinking.

Potable reuse can help meet future water supply needs

Communities in Florida have been utilizing reclaimed water for landscape irrigation and industrial uses since the early 1970s. Today, Florida is the national leader in water reuse, utilizing 48 percent of the total domestic wastewater in the state for nonpotable uses.

Guiding principles

The PRC's report presents a consensus-based effort by water professionals and a diverse stakeholder group to identify and address technical, regulatory, and implementation barriers to potable reuse in Florida. The PRC includes representatives from WateReuse Florida, Florida Water Environment Association Utility Council, Florida Section American Water Works Association Water Utility Council, and stakeholders representing agriculture, environment, public health, associated industries, and the Florida Department of Health. In addition, the Florida Department of Environmental Protection and representatives from the South Florida Water Management District, Southwest Florida Water Management District and St. Johns River Water Management District participated in the PRC as *ex officio* members. Collectively, these stakeholders recognized that advancing potable reuse within Florida required a common and united purpose.

The PRC examined Florida's existing regulatory framework of statutes, rules, and practices that apply to the processes involved in the potable reuse of reclaimed water to determine what changes to that framework would better facilitate potable reuse. In this effort, the PRC adhered to the following principles:

- Protect public health
- Protect the environment
- View reclaimed water as a potential source water for potable use
- Where possible, achieve public health and environmental protection through existing regulatory programs
- Respect existing state and federal permitting programs applicable to potable reuse

The PRC also recognized the need for this process to be conducted in a way to encourage broad stakeholder participation and to provide information in a public forum. Monthly public meetings, workshops and teleconferences were held during which the public was given an opportunity to comment, ask questions, voice concerns, and provide input to the framework.

The PRC is recommending the framework in this document to proactively ensure potable reuse is implemented safely in a manner that is protective of the environment, and with consideration for the interests of Florida's industry, agriculture, and other stakeholders.

Potable reuse treatment processes are proven, safe, and protective of public health and the environment

Potable reuse has the potential to contribute to a diversified, resilient, and sustainable water supply portfolio that includes conservation, nonpotable reuse, desalination, stormwater and traditional groundwater and surface water supplies. As previously noted, experience with potable reuse is expanding in other states and abroad, including Australia and Singapore. This experience and other factors, such as advancements in technology and recent research efforts, demonstrate the safety and benefits of potable reuse.

The PRC acknowledges reclaimed water is an alternative water supply that requires appropriate treatment and water quality assurances. The treatment processes used in potable reuse have existed for decades and are proven effective in producing high quality, safe drinking water that is protective of public health and the environment. A common feature of these treatment processes is the use of a

SUMMARY OF REGULATORY RECOMMENDATIONS

The PRC identified a number of proposed regulatory changes (Section 10) that would require the Florida Legislature to enact legislation to provide authority and direction to the Florida Department of Environmental Protection (FDEP) to revise existing rules and/or adopt new rules to advance potable reuse within the State of Florida.

Place potable reuse requirements in drinking water regulations

The PRC recommends moving Florida's existing reclaimed water regulations that apply to potable reuse (in Chapter 62-610, Florida Administrative Code [F.A.C.]) into the appropriate drinking water regulation rule chapters of Division 62, F.A.C. The PRC also recommends that new regulations addressing potable reuse also be placed within Florida's drinking water program regulations. The goal in doing so is to separate nonpotable reuse from potable reuse and place potable reuse requirements under the appropriate drinking water regulation chapters in Division 62, F.A.C. and to have a clear, concise, and enforceable point of regulatory compliance.

Revise existing drinking water regulations to specify reclaimed water as a water supply source and employ appropriate treatment technologies to address pathogens and emerging constituents

Existing drinking water regulations address differences in various sources of water. For example, treating surface water versus groundwater requires more disinfection because it is more common to find waterborne pathogens in surface waters like rivers or lakes than in aquifers. Similarly, reclaimed water, which comes from treated wastewater, may have elevated concentrations of pathogens such as bacteria and viruses. It may also have higher concentrations of emerging constituents, such as pharmaceuticals and personal care products. In addition, other chemicals could potentially be present in reclaimed water coming from discharges by industrial and commercial users.

Require potable reuse to meet drinking water standards

To protect public health, the PRC recommends revising Florida's drinking water regulations (Division 62 F.A.C.) to consider reclaimed water as a source water. With this recommendation, drinking water produced from all potable reuse projects would be required to meet existing primary and secondary drinking water standards.

Provide pathogen treatment to meet drinking water standards

In addition, the PRC recommends that FDEP adopt potable reuse treatment requirements for pathogens within the drinking water regulations. This would be done by having a water utility examine the potential for pathogens in the reclaimed water source, and then apply appropriate treatment technology to reduce, remove or inactivate those pathogens to acceptable water quality standards consistent with current drinking water rules. With this recommendation, pathogens in potable reuse projects would be treated to meet drinking water standards.

Other recommendations to improve potable reuse regulation while protecting the public health and environment

In addition to the items discussed above, the PRC also recommends the following:

- **Continue to exempt DPR from needing to obtain a consumptive use permit (CUP) or water use permit (WUP).** Existing Florida Statutes do not require a CUP or WUP for reclaimed water use because no water is withdrawn from the environment. This should continue to apply to DPR as the potable reuse framework is implemented.
- **Clarify that IPR projects must comply with existing spring discharge standards.** Currently Rule 62-610.850, F.A.C., provides "reuse and land application projects shall not cause or contribute to violations of water quality standards in surface waters." Revisions to this rule may be necessary as the other potable reuse recommendations are implemented to clarify that existing surface water quality standards apply to groundwater discharges of reclaimed water migrating into spring flow as a result of an IPR project.
- **Expand existing definition of IPR to include groundwater recharge when used to augment the supply of water available for drinking water.** The current, Chapter 62-610, F.A.C., definition of "indirect potable reuse" is limited only to the discharge of reclaimed water to surface waters. This should be expanded to include groundwater so that all types of IPR projects fit within the definition.
- **Specify point of compliance with drinking water standards.** For potable reuse, confusion could occur as to where in the process drinking water standards must be met. To ensure clarity and protect public safety, the statutes and rules should specify that compliance is determined at the point where finished potable water is finally discharged from the drinking water treatment facility.
- **FDEP and the water management districts should enter into a memorandum of agreement to coordinate permitting for IPR projects**. A number of permits are required from FDEP and the water management districts to authorize IPR projects. Coordination among these agencies on these permits avoids duplication and ensures consistency. Coordination also ensures protection of public health and the environment and reduces the burden upon the permit applicant. This coordination review would only occur at the applicant's request.
- **FDEP should review the current groundwater recharge requirements in Chapter 62-610, F.A.C.** in conjunction with the effort to move the IPR requirements in that chapter to the drinking water sections of Division 62. The goal of this review would be to ensure continued environmental and public health protection.

Next steps

Florida must have additional sustainable alternative water supplies to meet the future needs of its residents, agriculture, and industry, and to secure a robust economic future. Potable reuse is one such alternative supply. Potable reuse has been implemented in other states and countries and has been proven to be safe and protective of the environment.

This proposed framework is recommended to protect public health and the environment. The proposed recommendations will also provide regulatory and financial surety to water and wastewater utilities, and consistency in permitting and implementation of potable reuse projects. Failure to implement this framework may jeopardize the ability to meet future water supply needs efficiently and cost-effectively,

engage in activities that positively impact public perception of potable reuse. To that end, FDEP and the water management district should be prepared to communicate openly and candidly with the public and stakeholders not only about the challenges associated with implementing potable reuse, but also that potable reuse has been and can be done safely. There is no new water on the planet. We must efficiently and effectively optimize every source of water available to ensure our future.

THE FLORIDA SENATE

APPEARANCE RECORD

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

Nov. 4th, 2019
Meeting Date

Bill Number (if applicable)

Topic Potable Reuse Commission

Amendment Barcode (if applicable)

Name Lynn Spivey

Job Title Director of Utilities

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing FL PRC

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)

Florida Association of Cosmetology and Technical Schools

F.A.C.T.S.

Report to Florida Senate

Innovations, Industry and Technology Committee

Senator Wilton Simpson

Chair

Issues with Reducing Training Hours

Presented By

Michael L. Halmon

Chair

American Association of Cosmetology Schools

Nov 4, 2019

This document is intended to provide the legislature with accurate information and the consequences as it relates to reduction in hours for the Barber, Full Specialist, Skin Care and Nail Specialty Program.

The proposed reduction in hours to the Full Specialist, Skin Care and Nail Specialty programs will not reduce barriers to entry. It will in fact increase the barriers and place the public at greater risk of injury from undertrained individuals.

Barber Program

Proposed Reduction from 1200 hours to 900 Hours

- FACTS will support a reduction to 900 hours in the Regular Barber Program. Any further reduction would be opposed as the ability to properly train a student to enter the filed and practice the professions safely would be not be possible. A Barber must not only be trained in the theoretical of safety, they must also have the hands on practical skills necessary to safely provide services to the public.

Concerns of Reducing Hours for Full Specialist, Skin Care and Nail Special

- ***Loss of Financial Aid:*** The reduction from 500 to 300 hours in the Full Specialist Program as an example will result in students **losing $4,130 in Pell Grants. (Free Money only available to programs 600 hours of more)** Many of these students are from a lower socio-economic environment and are in need of grant money to pay for their education and living expenses while in school. Without receiving a Pell Grant ***students will be unable to attend school***.

- ***Employers will not Hire Undertrained Individual:*** Graduates from all of these programs provide services to the hundreds of Salons and Spas in Florida, as well as Florida's extensive Hotel and Cruise Line industries. As an example, due to the increased consumer demand for Skin Care, a significant number of Plastic Surgeons and Dermatologists have added the Skin Care Specialist to their practices to meet that demand. These Medical Doctors will not compromise their standards of practice by hiring under-trained Skin Care Specialists.

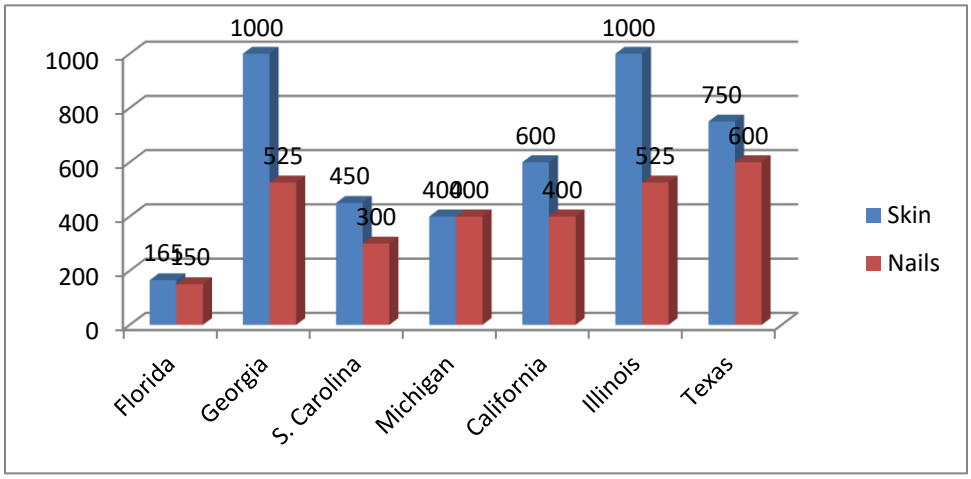
  Employers will be motivated to hire individuals who were trained out of state with more hours of training, (Alabama and Georgia have 1000 hours) rather than Florida trained Specialists, which defeats the very purpose of the Bill.

- ***Safety and Sanitation:*** The complexity of the training to ensure safety and sanitation is necessary at the current levels. It takes significantly more than the reduced hours as proposed in the 2019 session to adequately educate (course work) and train (practical experience) these Specialty Students on the techniques and safety measures necessary to ensure public safety. For example, Skin Care Specialists must learn about the Anatomy and Physiology of the skin, as well as the Disorders and Diseases of the Skin. They must

apply this knowledge to assess a client's needs and then use techniques, products and machines to safely perform the required services. That education and training cannot be perfected if training hours are reduced.

- The Skin Specialist applies Chemical Peels to the skin, Micro-Dermabrasion removes the outer layer of the skin and hair removal which can result in infections and severe harm to a client if undertrained. Students need the hours to not only study the theory of safety and sanitation, but to practice these skills to safely perform them.
- Nail Specialists work with sharp instruments that can harm a client and spread infections. The use of unsanitary instruments have been linked to the spread of Mrsa, Hepatitis, Tuberculosis, and even HIV.
- These professions can be the first line of defense in referring suspicious skin care disorders to Dermatologists that often times are diagnosed as skin cancer.
- FACTS opposes ANY reduction in hours to this program.

A Comparative Look with Proposed Hours



The following data represents the % of claims submitted to the ABMP (Associated Bodywork & Massage Professional) which is an Insurer of practitioners in the Skin sector.

Service	% of Total Claims
Hair Removal	28%
Chemical Peels	21%
Facials	18%
Eyelash Extensions, tinting, lift	13%
Microdermabrasion	6%
Extractions	5%
Steamer Burns	4%
Miscellaneous	2%
Accidental	2%
Dermaplaning	2%
Product (Home Use)	<1%

Report to Florida Senate

Innovations, Industry and Technology Committee

Senator Wilton Simpson, Chair

Issues with Reducing Training Hours

Presented by

Michael L. Halmon

The Barber Program

- Reducing from 1200 hours to 900 Hours is cautiously supported.
- Any Reduction Below 900 Hours would be opposed.
- FACTS has challenged rule making that proposed a 500 hour Restricted Barber Program.

Full Specialist Certification

- Reducing the Hours from 500 to 300 (for example) would eliminate eligibility for Federal Pell Grants ($4,130).
- Safety of the public is at far greater risk.
- Florida is already has the lowest training hours in the country for these practices.
- Employers will not hire undertrained graduates.

Public Safety

- Skin Care Specialists Apply Acid Chemical Peels.
- Skin Care Specialists use Microdermabrasion machines (Removes outer layer of skin).
- Skin Care Specialists use over 10 various machines. (Galvanic Current, Ultra Sonic, Steamer to name a few).
- Skin Care Specialists perform Extractions.
- Skin Care Specialist can be first line of defense in referring clients to Dermatologists for what oftentimes is diagnosed as Skin Cancer.

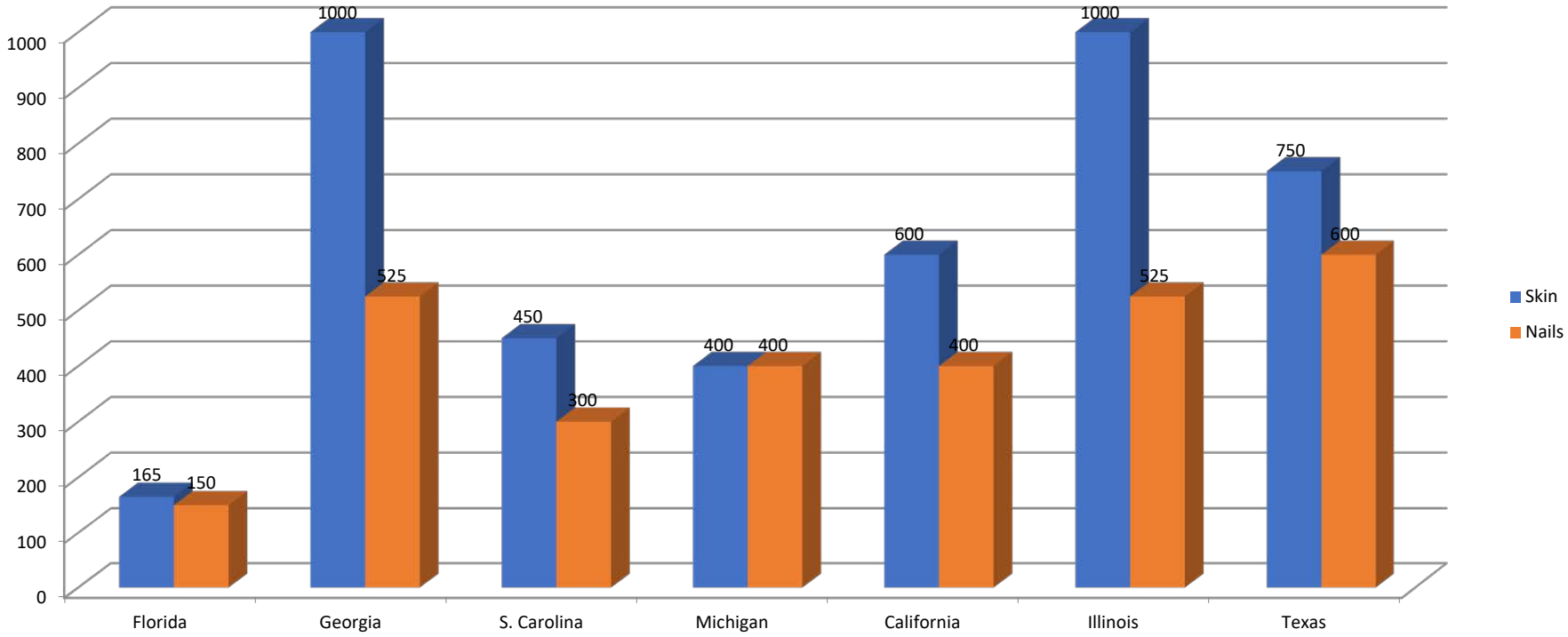
Public Safety

- Nail Care Specialists use many sharp instruments that can cut the hands and feet.
- Failure to properly maintain proper sterilization of their implements can cause the spread of infectious disease such as Mersa, HIV, Hepatitis to name a few.
- Sanitation is not simply the reading and comprehension of the material. It REQUIRES hands on PRACTICAL training to ensure proficiency in the various areas of practice.

Personal Injury Claims

Service	% of Total Claims
Hair Removal	28%
Chemical Peels	21%
Facials	18%
Eyelash Extensions, tinting, lift	13%
Microdermabrasion	6%
Extractions	5%
Steamer Burns	4%
Miscellaneous	2%
Accidental	2%
Dermaplaning	2%
Product (Home Use)	<1%

A comparative Look



Summary

- FACTS would not support a reduction to the Full Specialist, Skin, and Nail Hours.
- We believe that the Full Specialist performs services that can result in serious injury to the public if not properly trained.
- We believe that a reduction in these hours will not remove a barrier to entry, it will actually CREATE a barrier.

THE FLORIDA SENATE

APPEARANCE RECORD

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

11-4-19
Meeting Date

Bill Number (if applicable)

Topic ISSUES WITH REDUCING TRAINING HOURS

Amendment Barcode (if applicable)

Name MICHAEL HALMON

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing FLORIDA ASSOCIATION of COSMETOLOGY & TECH SCHOOLS

Appearing at request of Chair: ☑ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

CourtSmart Tag Report

Room: EL 110 **Case No.:** **Type:**
Caption: Senate Innovation, Industry and Technology Committee **Judge:**

Started: **11/4/2019 1:32:38 PM**
Ends: **11/4/2019 2:37:46 PM** **Length: 01:05:09**

1:32:38 PM Meeting called to order by Chair Simpson
1:32:51 PM
1:32:51 PM Roll call by Administrative Assistant Lynn Koon
1:33:23 PM Quorum present
1:33:31 PM Pledge of Allegiance
1:33:36 PM Comments from Chair Simpson and Introduction of Intern Stephen Baird
1:33:58 PM Introduction of Tab 1, SB 172 by Chair Simpson
1:34:09 PM Explanation of SB 172, Florida Drug and Cosmetic Act by Senator Bradley
1:35:24 PM Comments from Chair Simpson
1:35:32 PM Speaker Jason Unger, City of Key West in opposition
1:39:00 PM Speaker Deborah Foote, Government Affairs and Political Director, Sierra Club of Florida in opposition
1:41:37 PM Speaker Holly Parker Curry, FL Regional Manager, Surfrider Foundation in opposition
1:44:23 PM Jonathan Webber, Deputy Director, Florida Conservation Voters waives in opposition
1:44:31 PM Jake Farmer, Director of Government Affairs, Florida Retail Federation waives in support
1:44:38 PM Christopher Emmanuel, Policy Director, Florida Chamber of Commerce waives in support
1:44:50 PM Speaker James Otto
1:46:05 PM Comments from Chair Simpson
1:46:12 PM Closure by Senator Bradley
1:50:30 PM Roll call by Administrative Assistant, Lynn Koon
1:50:47 PM SB 172 reported favorably
1:51:09 PM Introduction of Tab 2 by Chair Simpson
1:51:25 PM Presentation by Lynn Spivey, Director of Utilities, Florida Potable Reuse Committee
2:03:45 PM Comments from Chair Simpson
2:03:51 PM Question from Senator Bradley
2:05:09 PM Response from Ms. Spivey
2:08:14 PM Follow-up question from Senator Bradley
2:08:34 PM Response from Ms. Spivey
2:10:08 PM Question from Senator Gibson
2:11:19 PM Response from Ms. Spivey
2:11:55 PM Follow-up question from Senator Gibson
2:12:06 PM Response from Ms. Spivey
2:12:39 PM Comments from Senator Gibson
2:13:03 PM Response from Ms. Spivey
2:14:11 PM Follow-up question from Senator Gibson
2:14:23 PM Response from Ms. Spivey
2:15:25 PM Follow-up question from Senator Gibson
2:15:32 PM Response from Ms. Spivey
2:16:44 PM Follow-up question from Senator Gibson
2:17:01 PM Response from Ms. Spivey

2:18:13 PM Question from Senator Farmer
2:18:20 PM Response from Ms. Spivey
2:19:18 PM Follow-up question from Senator Farmer
2:19:27 PM Response from Ms. Spivey
2:19:45 PM Comments from Chair Simpson
2:19:58 PM Introduction of Tab 3 by Chair Simpson
2:20:08 PM Presentation by Michael Halmon, FACTS Board Member, FL Association of Cosmetology & Tech Schools
2:33:20 PM Comments from Chair Simpson
2:33:26 PM Question from Senator Gibson
2:33:32 PM Response from Mr. Halmon
2:33:48 PM Follow-up question from Senator Gibson
2:33:56 PM Response from Mr. Halmon
2:34:29 PM Additional question from Senator Gibson
2:34:48 PM Response from Mr. Halmon
2:34:56 PM Additional question from Senator Gibson
2:35:05 PM Response from Mr. Halmon
2:36:27 PM Question from Senator Albritton
2:36:33 PM Response from Mr. Halmon
2:37:23 PM Comments from Chair Simpson
2:37:28 PM Senator Benacquisto moves to adjourn, meeting adjourned