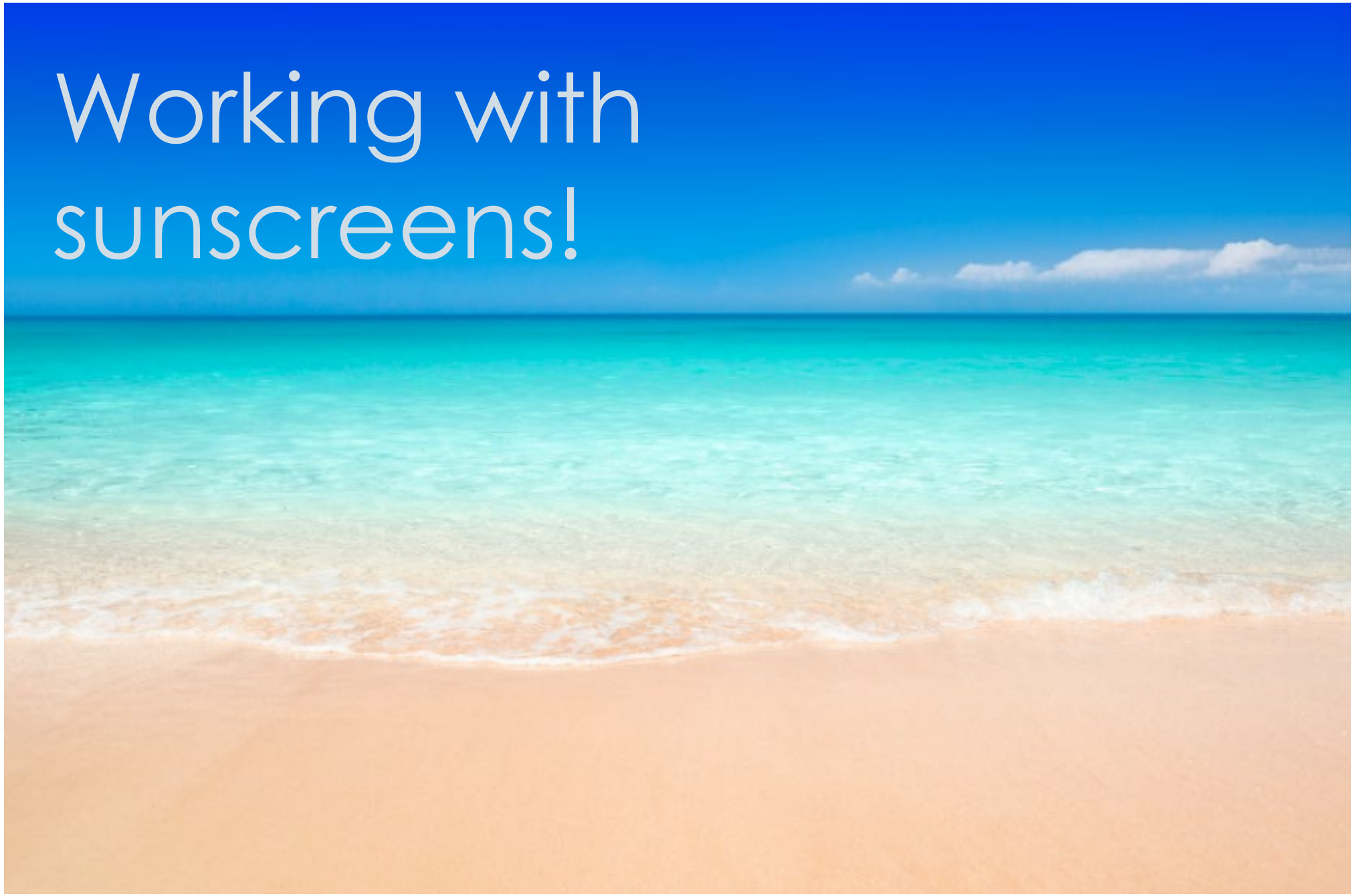
Regulatory Update: Sunscreen

Meredith Petillo, Sr. Director Technical & Regulatory Affairs, IBA

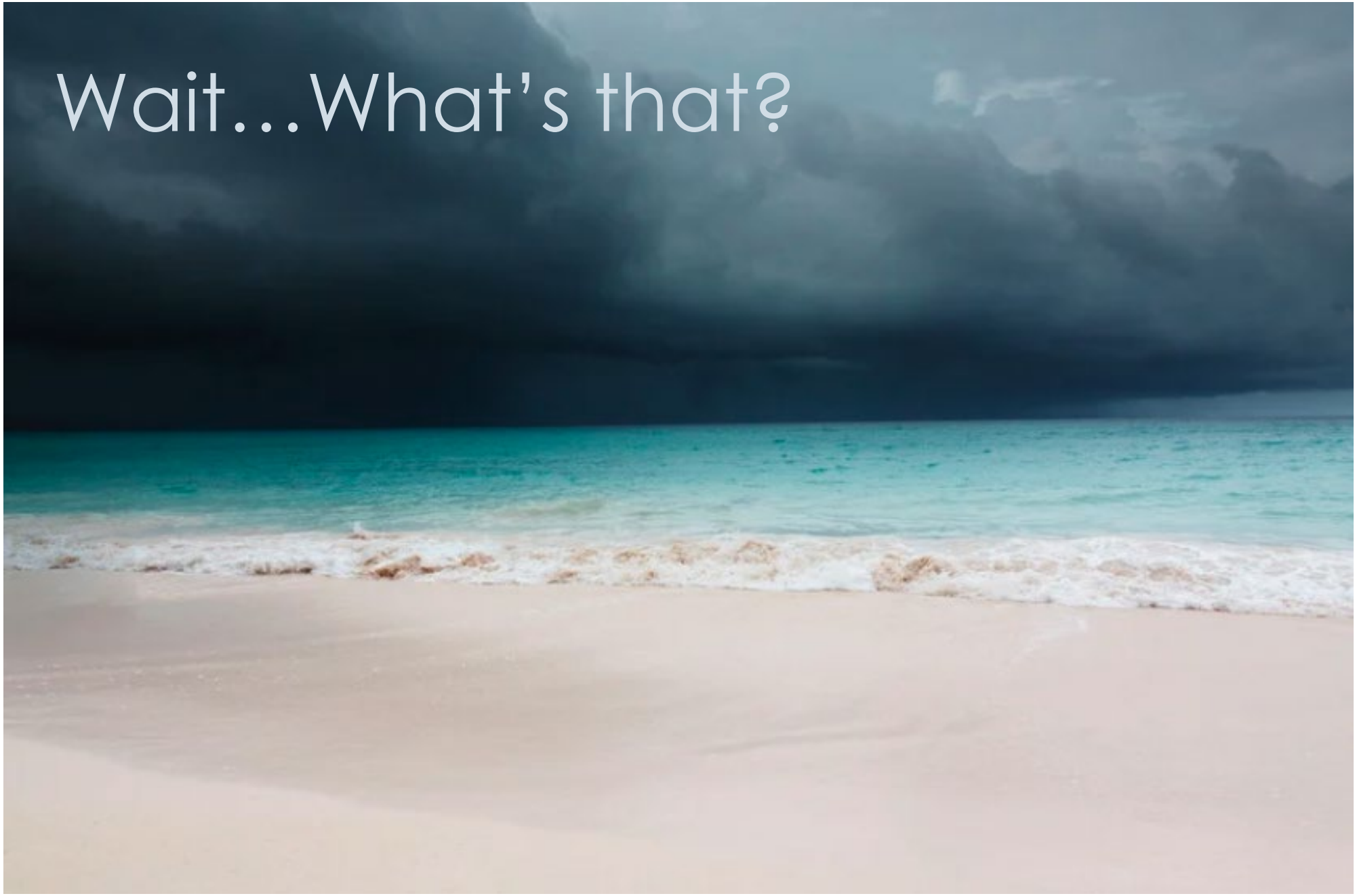
May 15, 2022

iba

Working with sunscreens!



Wait…What's that?



Regulatory Update

U.S. Updates

- FDA Activity
  - OTC Monograph Reform
    - Deemed Final Order
    - Proposed Order
- State Activity
  - environmental bills

Canada Updates

EU & UK Updates

U.S. Federal Updates

OTC Monograph Reform!

2020 Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

- Replaced the Over-The-Counter Drug monograph rulemaking process
- Introduced the Over the Counter Monograph User Fees Program (OMUFA)

Facility Fees			
	FY2021	FY2022	Δ
Monograph Drug Facility (MDF) Facility Fee	$20,322	$24,178	$3,856
Contract Manufacturing Organization (CMO) Facility Fee	$13,548	$16,119	$2,571
OMOR Fee – Tier 1	$500,000	$507,021	$7,021
OMOR Fee – Tier 2	$100,000	$101,404	$1,404

19% Increase!

U.S. Federal Updates – OTC Monograph Reform

U.S. Deemed Final Order

- **Essentially maintains the status quo**
- Includes requirements from the 1999 stayed final monograph
- Except for labeling and testing requirements, which come from the 2011 final labeling and effectiveness testing rule
- Largely corresponds to the approach of the prior FDA sunscreen enforcement policy guidance

iba

The Deemed Final Order and the Proposed Order are both hyperlinked via the page below:

Questions and Answers: FDA posts deemed final order and proposed order for over-the-counter sunscreen

U.S. Deemed Final Order

Part B – Active Ingredients

Active Ingredient	Concentration
Aminobenzoic acid (PABA)	Up to 15 percent
Avobenzone	Up to 3 percent
Cinoxate	Up to 3 percent
Dioxybenzone	Up to 3 percent
Ensulizole	Up to 4 percent
Homosalate	Up to 15 percent
Meradimate	Up too 5 percent
Octinoxate	Up to 7.5 percent

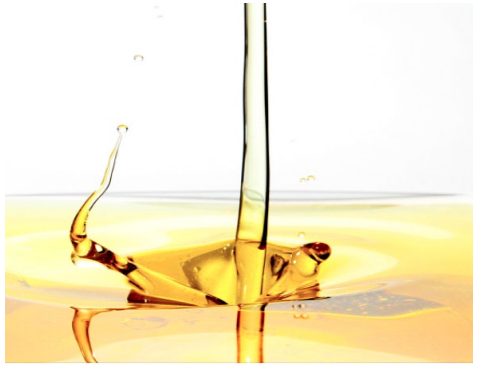
Active Ingredient	Concentration
Octisalate	Up to 5 percent
Octocrylene	Up to 10 percent
Oxybenzone	Up to 6 percent
Padimate O	Up to 8 percent
Sulisobenzone	Up to 10 percent
Titanium dioxide	Up to 25 percent
Trolamine salicylate	Up to 12 percent
Zinc oxide	Up to 25 percent

iba

U.S. Deemed Final Order

Product Formats – What dosage forms are allowed?

However "notwithstanding subsection [505G](a)," by operation of section 505G(m)(2) of the FD&C Act, sunscreens in all dosage forms other than **oil, lotion, cream, gel, butter, paste, ointment, stick, spray, and powder** currently require an application approved under section 505 of the FD&C Act in order to be marketed.



U.S. Deemed Final Order

Maximum SPF

No upper limit

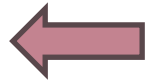
U.S. Federal Updates

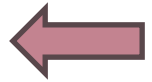
U.S. Proposed Order

GRASE Active Ingredients

Active Ingredient	Concentration
~~Aminobenzoic acid (PABA)~~	~~Up to 15 percent~~
~~Avobenzone~~	~~Up to 3 percent~~
~~Cinoxate~~	~~Up to 3 percent~~
~~Dioxybenzone~~	~~Up to 3 percent~~
~~Ensulizole~~	~~Up to 4 percent~~
~~Homosalate~~	~~Up to 15 percent~~
~~Meradimate~~	~~Up too 5 percent~~
~~Octinoxate~~	~~Up to 7.5 percent~~

Active Ingredient	Concentration
~~Octisalate~~	~~Up to 5 percent~~
~~Octocrylene~~	~~Up to 10 percent~~
~~Oxybenzone~~	~~Up to 6 percent~~
~~Padimate O~~	~~Up to 8 percent~~
~~Sulisobenzone~~	~~Up to 10 percent~~
Titanium dioxide	Up to 25 percent
~~Trolamine salicylate~~	~~Up to 12 percent~~
Zinc oxide	Up to 25 percent





iba

U.S. Proposed Order

iii. Ingredients Proposed as Not GRASE Due to Insufficient Data

The public record does not contain sufficient data to support a positive GRASE determination for **cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone, or avobenzone** at this time.

Accordingly, we propose that sunscreens containing these ingredients are not GRASE under section 505G(b)(1)(C)(ii) of the FD&C Act because the evidence is inadequate to show that sunscreens containing these ingredients are GRASE.

U.S. Proposed Order

GRASE Active Ingredients – 8 deferred

Active Ingredient	Concentration
~~Aminobenzoic acid (PABA)~~	~~Up to 15 percent~~
~~Avobenzone~~	~~Up to 3 percent~~
~~Cinoxate~~	~~Up to 3 percent~~
~~Dioxybenzone~~	~~Up to 3 percent~~
~~Ensulizole~~	~~Up to 4 percent~~
~~Homosalate~~	~~Up to 15 percent~~
~~Meradimate~~	~~Up too 5 percent~~
~~Octinoxate~~	~~Up to 7.5 percent~~

Active Ingredient	Concentration
~~Octisalate~~	~~Up to 5 percent~~
~~Octocrylene~~	~~Up to 10 percent~~
~~Oxybenzone~~	~~Up to 6 percent~~
~~Padimate O~~	~~Up to 8 percent~~
~~Sulisobenzone~~	~~Up to 10 percent~~
Titanium dioxide	Up to 25 percent
~~Trolamine salicylate~~	~~Up to 12 percent~~
Zinc oxide	Up to 25 percent

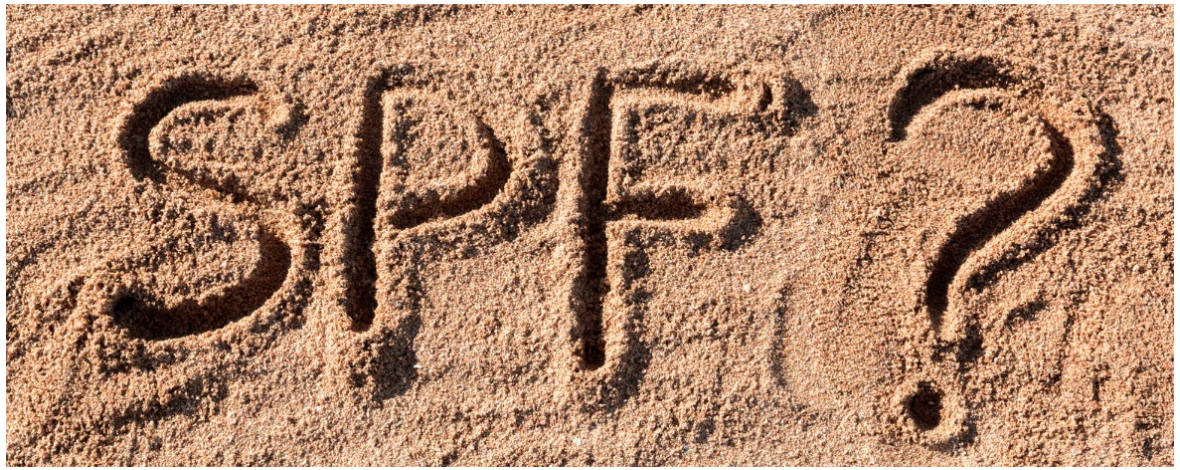
U.S. Proposed Order

Maximum SPF

Label claim: SPF 60+

Formulated SPF values up to 80

Proposes a requirement that all sunscreen SPF 15 and higher satisfy broad spectrum requirements



iba

U.S. Proposed Order

Product Formats – What dosage forms may be allowed?

We are proposing the following dosage forms as GRASE for use in sunscreens: **oils, lotions, creams, gels, butters, pastes, ointments, and sticks.** We are also proposing GRASE status for **spray sunscreens**, subject to testing necessary to minimize potential risks from unintended inhalation (particle size restrictions) and flammability (flammability and drying time testing), together with related labeling requirements.

U.S. Proposed Order

Product Formats – What dosage forms may NOT be allowed?

We are proposing that there is **insufficient data** to classify sunscreen in the **powder dosage form** as GRASE and expect that sunscreen powders would also be subject to particle size restrictions if found to be GRASE in a final order.

…sunscreens in **all dosage forms other than the 10 dosage forms identified above** currently require an application approved under section 505 in order to be marketed (**sunscreens in dosage forms that require an NDA** in order to be marketed include, **for example, wipes, towelettes, body washes, and shampoos**). This order does not propose to change this requirement.

CANADA

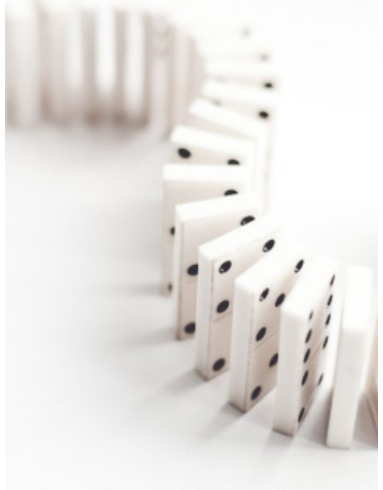
Recent studies by the U.S. Food and Drug Administration (FDA) looked at the possible absorption of certain sunscreen ingredients through the skin. Many of these ingredients are also found in sunscreens available in Canada. The studies measured the concentration levels of common sunscreen ingredients in the blood of people who applied large quantities of sunscreen.

The studies demonstrate that more information is needed to determine if the ingredients in sunscreens pose a safety risk when absorbed. However, at this time, the FDA states:

- *sunscreen absorption doesn't equal risk*
- *the findings don't mean that any of the ingredients are unsafe for use*
- *people shouldn't stop using sunscreen*

Health Canada has reviewed these findings and agrees with the FDA.

What's next?



https://www.canada.ca/en/health-canada/services/sun-safety/sunscreens.html

U.S. – States Activity

Environmental Activity

FLORIDA
2019 Key West bans oxybenzone and octinoxate
2020 Florida governor signed a law prohibiting local government bans

HAWAII
2018 Bans oxybenzone and octinoxate (effective January 1, 2021)
2021 Maui County proposed ban on sale, distribution, or use of non-mineral sunscreens (effective October 1, 2022)
Further statewide bans appear to be on pause

iba

EU

What UV filters should we be watching?

- Titanium Dioxide
- Benzophenone-3 (oxybenzone)
- Octocrylene
- Homosalate

EU

What UV filters should we be watching?

- Titanium Dioxide
  - From October 1st 2021: **maximum 25% as UV filter**
    - Nanomaterial (1-100 nm): 0% in loose powder & sprays
    - 100 nm – 10 µm: 0% in loose powder form face products and hair aerosol spray products
    - > 10 µm: note that the threshold for particle size distribution is ≥1% of <10 µm particles
- Endocrine Disruptors
  - The review of potential endocrine disruptors has become a hot topic for the European Commission.
  - Oxybenzone (Benzophenone-3), Octocrylene, and Homosalate have been reviewed and a regulatory draft is ongoing

iba

EU

What UV filters should we be watching?

- Endocrine Disruptors
  - The review of potential endocrine disruptors has become a hot topic for the European Commission.
  - Oxybenzone (Benzophenone-3), Octocrylene, and Homosalate have been reviewed and a regulatory draft is ongoing

EU

- Benzophenone-3 (oxybenzone)
  - Today: Max. 6% as a UV filter (+ warning « Contains Benzophenone-3 » / 0.5% for product protection purposes)
  - Future:
    - Max. 6% in face, hands and lips products excluding propellant and pump spray products
    - Max. 2.2% in body products, including propellant and pump spray products
    - Max. 0.5% otherwise (and no warning)

- Octocrylene
  - Today: Max. 10% in all products
  - Future:
    - Benzophenone as an impurity and/or degradation product of Octocrylene shall be kept at trace level
    - Max. 9% in propellant spray products
    - Max. 10% in other products

Expected adoption date: June/July 2022

Expected implementation for products to be placed on the market: December 2022/January 2023 (6 months)

Expected implementation for products already on the market: June/July 2023 (12 months)

EU

Homosalate

- Today: Max. 10% in all products

- Future:
  - SCCS: Max. 0.5% is safe in all products
  - Industry: Suggested 7.34% in face cream and pump spray (and 0.5% in other products)
  - SCCS: agreed

  - EC: April 6 published draft Commission Regulation
    - The following modification of entry 3 of Annex VI: Homosalate is restricted to face products with exception of propellent spray products up to a maximum concentration of 7.34 %.
    - Application deadlines of 24 months for placing on the market and 48 months for making available from the market.

Expected adoption date (speculative): 4th quarter 2022

Expected implementation for new products to be placed on the market: Q4 2024

Expected implementation for products already on the market: Q4 2026 (withdrawal of non compliant products still on the market)

iba

UK

Similarly, UK Is Seeking Data On UV Filters Suspected Of Endocrine Disruption

- Benzophenone-3 (oxybenzone), octocrylene, and homosalate
- Specifically focusing on their endocrine-disrupting potential

That's a lot….so what do we do?

Wait and see?

Proactive reformulation?

Regional skus?

Use caution with "boosters"

iba

The future for Sunscreen Regulation will remain complicated but we are in this together

Questions?

IBA

concierge@independentbeauty.org

Independentbeauty.org

Meredith Petillo

Sr. Director Technical & Regulatory Affairs

mpetillo@independentbeauty.org