Executive Summary

Recent “alarmist reports” and studies regarding the state of the US sunscreen market and the merits of UV-protective products available to consumers are sending a potentially confusing message, which could discourage sunscreen use at a time of epidemic skin-cancer rates, the Personal Care Products Council suggests. The group hosted a webinar July 11 to clarify sunscreen regulations and promote daily use.

The Personal Care Products Council has gone on record repeatedly since May to combat what it sees as misinformation and potentially confusing messaging being propagated about sunscreen products, their safety and benefits.

In a July 11 webinar titled “Don’t Get Burned – Everything You Need to Know about Sunscreen,” the trade group’s Chief Scientist Beth Lange and board-certified dermatologist Elizabeth Hale emphasized the importance of daily, year-round sunscreen use at a time of soaring skin-cancer rates.

They provided tips for selecting and using sunscreen products and addressed a number of “myths” related to sun-exposure dangers and protective practices.

“Sunscreens are just such a critical part in fighting against skin cancer and premature aging, and we really would hope that using a sunscreen becomes a habit, very much like you wouldn’t get in a car and not put on a seat belt nowadays,” Lange said.

Additionally, the presenters sought to clarify US sunscreen regulations and dispel reservations that consumers may have following recent reports that have called sunscreen products’ virtues into question.
Asked about reports issued in May by NGO the Environmental Working Group and “unbiased product reviews and ratings” magazine Consumer Reports, which raised concerns about sunscreen ingredients, protective claims and delivery formats, Lange didn’t pull any punches.

“I think it’s important to note that neither of these are science-based organizations,” she said.

The PCPC exec noted that FDA regulates sunscreens as over-the-counter drugs, requiring manufacturers to meet minimal SPF and broad-spectrum protection standards in order to claim benefits related to skin cancer and premature aging prevention, in addition to sunburn defense.

According to Consumer Reports, nearly half of the sunscreen products it has analyzed over the past four years have tested short of their claimed SPFs of at least 30 (Also see "Consumer Reports To Alert FDA: Half Of Sunscreens Perform Short Of SPF Claims" - Rose Sheet, 24 May, 2016.).

“It’s really difficult when you get these alarmist reports out there to know whether they even used a scientific approach and whether they are consistent with the testing companies have to do,” she said. According to PCPC, Consumer Reports declined to share its testing details with the trade association.

“It’s frustrating because a lot of these alarmist reports will scare consumers and make them unsure about wearing protection,” Lange continued. “Sunscreens are just such a critical part in fighting against skin cancer and premature aging, and we really would hope that using a sunscreen becomes a habit, very much like you wouldn’t get in a car and not put on a seat belt nowadays.”

EWG’s sunscreen report and shopping guide suggested that nearly four out of five sunscreens on the US market offer inadequate UVA protection, compared with offerings in other markets around the globe, or contain potentially hazardous ingredients.

The NGO continues to be leery of UV filter oxybenzone, due to limited evidence linking it to endocrine disruption and sensitization risks, as well as retinyl palmitate, which it claims has been shown to be carcinogenic when exposed to sunlight (Also see "EWG's Claims About US Sunscreen Market, Skin-Cancer Prevention Analyzed" - Rose Sheet, 26 May, 2016.).
PCPC rejected the group’s assertions regarding those ingredients in a May 25 release, upholding retinyl palmitate’s safe and beneficial use as an antioxidant and skin-conditioning agent and maintaining that oxybenzone is one of the few FDA-approved sunscreen actives that provides effective broad-spectrum protection, with a safety profile backed by the American Academy of Dermatology.

Generally, EWG is more comfortable with “mineral”-based sunscreens, or those formulated with titanium dioxide or zinc oxide, versus what it characterizes as “chemical” sunscreens. (Also see "EWG’s Abiding Sunscreen Concerns Cast Shadow Over 13 Kids' Formulas" - Rose Sheet, 26 May, 2016.)

In her remarks, Lange stressed that “there is no such thing as a chemical-free sunscreen.” And regardless of the UV filters employed, she said, “sunscreens are designed to stay on the surface of the skin and not be absorbed – otherwise they aren’t going to be protective. You want them on the surface of the skin [where] they form a film and work by scattering, reflecting and absorbing those UV photons.”

**New UV Filters Not Expected In Near Future**

As for EWG’s position that sunscreens in the US tend to be inferior to options available in the EU and other markets, Lange acknowledged that some UV filters that manufacturers can use freely outside of the US – where sunscreens tend to be regulated as cosmetics – have yet to be found generally recognized as safe and effective by FDA.

Sponsors must meet the GRASE threshold with their ingredient data before active ingredients can be added to FDA’s OTC drug monograph for sunscreen products. While the Sunscreen Innovation Act enacted in late 2014 imposed a deadline framework on FDA to expedite its review of UV filters, the agency has stressed that the legislation did nothing to lower the bar for demonstrating GRASE, which can be more difficult to attain than a new drug approval, it says (Also see "FDA Drafts Guidance On Safety-Data Musts For GRASE Sunscreen Actives" - Rose Sheet, 20 Nov, 2015.).

Next-generation UV filters offering superior UVA protection are among those stalled in the FDA review process, according to EWG.

PCPC doesn’t anticipate FDA approval of any new sunscreen actives in the near future, Lange said.
At the same time, she emphasized that a given SPF value, which reflects a proportionate amount of UVA protection under FDA’s broad-spectrum requirements, is generally consistent in its meaning from one market to the next.

“SPF is SPF, no matter where in the world you are buying the product,” she said. “An SPF 30 in Europe is an SPF 30 in the US. They may have a different menu to make that sunscreen formulation, but it’s still the same protection.”

PCPC also took the opportunity to debunk other sunscreen myths, including the notion that wearing sunscreen causes a Vitamin D deficiency, that a “base tan” prevents sunburn and that it’s too late for adults to start protecting their skin with sunscreen.

On the latter point, Lange cited research suggesting that even individuals in their 60s who begin applying sunscreen regularly have been associated with lower cancer rates and less pronounced signs of skin aging.

**Water Resistance: Nice Feature But Not Essential**

PCPC and the Consumer Healthcare Products Association posted a statement July 6 responding to a JAMA Dermatology article which, similar to recent NGO reports, suggested that sunscreens on the US market may not be up to snuff.

According to an analysis conducted by researchers out of Northwestern University’s and Duke University’s medical schools, a “significant proportion” of the most highly rated sunscreen products by reviewers on Amazon.com do not adhere to AAD guidelines, largely attributed to lack of water resistance.

In their response, the trade groups note that “effective sunscreens are not required to share identical attributes.” SPF levels vary, as do other performance characteristics and cosmetic benefits, they say.

The study’s conclusion that many highly regarded sunscreen offerings are not water-resistant as recommended by AAD “is not an important finding,” according to the associations. They point out that while water resistance is a sensible feature for sport or beach sunscreens, it’s not necessary and in many cases not desired in products designed for daily, low-activity.

During the webinar, the presenters similarly recognized water resistance as a feature that may be appealing, but is not essential to ensure sunscreen
effectiveness. FDA has established standard testing to substantiate water-resistant claims, but does not require water resistance as a condition of market entry.

PCPC maintains that variety in the sunscreen market helps to ensure uptake of UV-protective products as part of consumers’ daily personal-care regimens.

As Hale put it, “the best sunscreen is the one you will actually use.”