BEFORE THE FOOD AND DRUG ADMINISTRATION

PETITION TO BAN THE ACTIVE INGREDIENTS OXYBENZONE AND OCTINOXATE IN SUNSCREENS AND OTHER PERSONAL CARE PRODUCTS

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CENTER FOR BIOLOGICAL DIVERSITY

May 24, 2018

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Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

With this legal petition, submitted pursuant to the Administrative Procedure Act, 5 U.S.C. § 553(e) and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 309 *et seq*. ("FDCA"), the Center for Biological Diversity requests that the Commissioner of Food and Drugs ban oxybenzone and octinoxate from sunscreen and other personal care products. Alternatively, we submit this petition under section 379o of the FDCA, and its implementing regulations at 21 C.F.R. 10.30, to urge the Food and Drug Administration ("FDA") to consult with the National Marine Fisheries Service as required under Section 7 of the Endangered Species Act ("ESA") to ensure the effects of oxybenzone and octinoxate in sunscreen products and other personal care products do not adversely affect a listed endangered or threatened species. In addition, we request that the FDA conduct an analysis pursuant to the National Environmental Policy Act ("NEPA") to examine the risks of oxybenzone and octinoxate to corals and the human environment. These chemicals are killing corals, are toxic to marine life, and dangerous to humans.

A. Action Requested

The Center requests that the FDA ban the use of oxybenzene and octinoxate in sunscreen and personal care products. The Administrative Procedure Act grants all citizens the right to petition for the "issuance, amendment, or repeal" of an agency rule, 5 U.S.C. § 553(e) and a ban of these toxic chemicals is in line with the FDA's duty to ensure the safety of our nation's supply of drugs and cosmetics. Oxybenzone and octinoxate are toxic to coral reefs and there is no justification for their use when safe alternatives exist.

In the alternative, if the FDA does not ban the use of oxybenzene and octinoxate in sunscreen and other personal care products, the Center requests that the FDA: 1) comply with Section 7 of the ESA, and its corresponding code at 16 U.S.C.A. § 1536, to ensure oxybenzone and octinoxate are not harming ESA-listed species; and 2) conduct an environmental analysis on the impacts of oxybenzone and octinoxate to marine life and the human environment pursuant to NEPA, 42 U.S.C. § 4331 *et seq.*

Sunscreens are vital in protecting people against the harmful impacts of UV radiation and reducing the chances of developing skin cancer and other human health concerns. While the FDA has made significant strides in ensuring the effectiveness of sunscreen products, and has

helped consumers understand the effectiveness and limitations of such products, the FDA has failed to ensure that all sunscreen products are safe for both people and the environment. A growing body of scientific literature indicates that oxybenzone and octinoxate — active ingredients often used in sunscreen lotions and personal-care products — are tremendously toxic to marine organisms. Oxybenzone is particularly toxic to corals at concentrations as low as a few parts per trillion — the equivalent of three drops in an Olympic-size swimming pool may be enough to severely damage or kill coral.[1] Beach-goers and vacationers, eager to snorkel and marvel at coral reefs, may be inadvertently killing the very corals they are observing as the sunscreen they applied to their skin washes off into the ocean.

Recognizing the significant harm that oxybenzone and octinoxate pose to coral reefs, the State of Hawaii earlier this month banned the chemicals from sunscreens sold and distributed on the islands. But while this ban will not take effect until 2021, the FDA can act *now* to protect coral reefs from the extensive damage caused by these chemicals. As the agency responsible for protecting public health, the FDA must ban oxybenzone and octinoxate from consumer sunscreen products. At the very least, because these chemicals' environmental impacts have never been evaluated by the FDA, nor have they been analyzed in light of their impacts to endangered species, a review of their impacts is warranted.

The Center for Biological Diversity ("Center") is a nonprofit environmental organization dedicated to the protection of native species and their habitats through science, education, policy, and environmental law. The Center has more than 1.6 million members and supporters dedicated to the protection and restoration of endangered species and wild places. In particular, the Center has been working diligently to raise awareness of the threats that face corals and coral reefs, seeking protection for corals in U.S. waters whose populations are declining. In 2004, and again in 2009, the Center petitioned the National Marine Fisheries Service to protect vulnerable corals under the Endangered Species Act. The Fisheries Service ultimately listed 22 of those coral species as threatened or endangered; these corals, and many more, are currently threatened by toxic pollutants introduced into the marine environment.

B. Statement of Grounds

1. <u>Sunscreen Chemicals Pose Hazard to Environment</u>

Oxybenzone, also referred to as Benzophenone-3 or BP-3, is a chemical that acts as an ultraviolet (UV) light filter in sunscreen and other personal-care products. Oxybenzone can be found in sunscreen, lotions, shampoos, lip balms, insect replants, mascaras, hand soaps, bath oils, and many more personal-care products humans use an a daily basis.[2] Octinoxate, also called octyl methoxycinnamate, is another UV filter which can be absorbed rapidly through skin. Oxybenzone and derivatives are fast emerging environmental contaminants of concern regularly

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[1] C. A. Downs et al., *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*, 70 ARCHIVES ENVTL. CONTAMINATION & TOXICOLOGY 265 (2015).

[2] Cosmetic Ingredient Review Expert Panel, *Annual Review of Cosmetic Ingredient Safety Assessments: 2002/2003*, 24 INT'L J. OF TOXICOLOGY 1 (Supp. 2005).

found in wastewater effluents, rivers, lakes, and coastal water.[3] Scientists have warned that sunscreen pollutants such as oxybenzone and octinoxate pose an extreme hazard to freshwater and marine wildlife.[4]

Sunscreens are lipophilic (i.e., dissolve in lipids or fats) and oxybenzone and octinoxate can easily bioaccumulate in aquatic animals[5] causing similar effects as other xenobiotic (i.e., foreign to the body) chemical compounds.[6] Recent studies demonstrate that oxybenzone and octinoxate harm corals and other reef organisms by making them sterile and promoting bleaching.[7] Oxybenzone at high concentrations has also estrogenic activity and can affect reproductive success in fish.[8] These chemicals remain in surface waters for several weeks and its predicted half-life increases with depth.[9]

Oxybenzone and octinoxate are also dangerous to humans. These chemicals are endocrine disrupters, which the National Institute of Environmental Health Sciences defines as a "chemical[] that may interfere with the body's endocrine system and produce adverse developmental, reproductive, neurological, and immune effects in both humans and wildlife."[10] Oxybenzone acts similarly to "estrogen in the body; alter[ing] sperm production in animals" and is "associated with endometriosis in women."[11] Endocrine disruptors pervade our environment

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[3] Ana Agüera et al., *New trends in the analytical determination of emerging contaminants and their transformation products in environmental waters*, 20 ENVTL. SCI. POLLUTION RES. 3496 (2013); Pablo Gago-Ferrero et al., *Occurrence of multiclass UV filters in treated sewage sludge from wastewater treatment plants*, 84 CHEMOSPHERE 1158 (2011); Yutaka Kameda et al., *Occurrence and profiles of organic sun-blocking agents in surface waters and sediments in Japanese rivers and lakes*, 159 ENVTL. POLLUTION 1570 (2011); Susan D. Richardson & Thomas A. Ternes, *Water Analysis: Emerging Contaminants and Current Issues*, 86 ANAL. CHEM. 2813 (2014); A. Sánchez Rodríguez et al., *Occurrence of eight UV filters in beaches of Gran Canaria (Canary Islands). An approach to environmental risk assessment*, 131 CHEMOSPHERE 85 (2015); Antonio Tovar-Sánchez et al., *Sunscreen products as emerging pollutants to coastal waters*, 8 PLOS ONE e65451 (2013); Doris E. Vidal-Dorsch et al., *Contaminants of emerging concern in municipal wastewater effluents and marine receiving water*, 31 ENVTL. TOXICOLOGY & CHEMISTRY 2674 (2012).

[4] Jason. B. Blitz, M.D. & Scott A. Norton, M.D., *Possible environmental effects of sunscreen run-off*, 59 J. AM. ACAD. DERMATOLOGY 898 (2008); Nancy Blüthgen et al., *Effects of the UV filter benzophenone-3 (oxybenzone) at low concentrations in zebrafish (Danio rerio)*, 263 TOXICOLOGY & APPLIED PHARMACOLOGY 184 (2012); Michael Coronado et al., *Estrogenic activity and reproductive effects of the UV-filter oxybenzone (2-hydroxy-4-methoxyphenyl-methanone) in fish*, 90 AQUATIC TOXICOLOGY 182 (2008); Downs, *supra* note 1; T. Eichenseher, *The cloudy side of sunscreens*, 40 ENVTL. SCI. & TECHNOLOGY 1377 (2006); Shaun. M. McCoshum et al., *Direct and indirect effects of sunscreen exposure for reef biota*, 776 HYDROBIOLOGIA 139 (2016).

[5] Dimosthenis L. Giokas et al., *UV filters: From sunscreens to human body and the environment* 26 TRAC TRENDS IN ANALYTIC CHEMISTRY 360 (2007).

[6] Marianne E. Balmer et al., *Occurrence of some organic UV filters in wastewater, in surface waters, and in fish from Swiss lakes*, 39 ENVTL. SCI. & TECHNOLOGY 953 (2005).

[7] Roberto Danovaro et al., *Sunscreens cause coral bleaching by promoting viral infections*, 116 ENVTL. HEALTH PERSPECTIVES 441 (2008); Downs, *supra* note 1; McCoshum, *supra* note 4.

[8] Coronado, *supra* note 4.

[9] Davide Vione et al., *Phototransformation of the sunlight filter benzophenone-3 (2-hydroxy-4-methoxybenzophenone) under conditions relevant to surface waters*, 436-464 SCI. OF THE TOTAL ENV'T. 243 (2013).

[10] *Endocrine Disruptors*, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES, http://www.niehs.nih.gov/health/topics/agents/endocrine/. (last visited May 16, 2018)

[11] *The Trouble with Ingredients in Sunscreen*, ENVIRONMENTAL WORKING GROUP, http://www.ewg.org/sunscreen/report/the-trouble-with-sunscreen-chemicals/#.WYILItPyvOQ. (last accessed Aug. 2, 2017).

and work in a variety of nefarious ways. They can mimic naturally occurring hormones like estrogens and androgens, thereby causing overstimulation. They can bind to receptors within cells and block endogenous hormones from binding and can also interfere with the way natural hormones and their receptors are made or controlled.[12] The latest scientific knowledge indicates that endocrine disruptor chemicals persist throughout our nation's waters and are having profound effects on fish, wildlife, and humans.

Oxybenzone was first authorized for use as an active ingredient in sunscreen in 1966 as an active ingredient in concentrations up to 3%.[13] Since then, the FDA has reauthorized oxybenzone for use six times in the past fifty years — in 1973, 1978, 1993, 1999, 2002, and 2011.[14] The 1978 rule updated the maximum percentage of oxybenzone allowed in products to a maximum of 6%; this approval level has remained to this day.[15] The 1978 rule states that "[e]xtensive animal and human toxicological date and wide use attest to its safety for human topical application."[16] It then goes on to detail the extensive animal testing that was conducted to determine that oxybenzone was safe for topical use.[17] Based on these tests and the available data, the Panel concluded that "oxybenzone is a safe sunscreen ingredient for OTC use."[18] No mention of the impact on the environment is made at all. In the following reauthorizations, the FDA made no mention of any environmental impact reports or updates to the testing done in 1978. Most rules dealt with the new monograph for determining safe levels of oxybenzone; the most recent rule from 2011 established the labeling and testing requirements for OTC sunscreen products containing specific ingredients.[19] The 2011 rule narrowed down the oxybenzone standards used for sunscreens to a single standard, regardless of SPF level.[20] In addition, the 2011 rule states, with no support, that the authorization of these chemicals "does not individually or cumulatively have a significant effect on the human environment."[21] Despite five decades of amending and reviewing chemicals used in cosmetics, the FDA has failed to conduct any environmental assessment of oxybenzone, let alone engage with the U.S. Fish and Wildlife Service or the National Marine Fisheries Service to determine the impacts of these chemicals on endangered aquatic wildlife.

a. Harm to Corals

Coral reefs are some of the most biodiverse and productive ecosystems on earth. While they occupy less than one percent of the ocean floor, they are home to more than a quarter of all marine species. In addition, they provide food, tourism jobs, and other services with a global

[12] *See id.*
[13] 31 Fed. Reg. 9812 (May 20, 1966).
[14] 38 Fed. Reg. 5343 (Feb. 27, 1973); 43 Fed. Reg. 38206 (Aug. 25, 1978); 58 Fed. Reg. 28194 (May 12, 1993); 64 Fed. Reg. 27681 (May 21, 1999); 67 Fed. Reg. 41823 (June 20, 2002); 76 Fed. Reg. 35620 (June 17, 2011).
[15] 43 Fed. Reg 38206 (Aug. 25, 1978). Octinoxate is allowed in products at up to 7.5%. 21 C.F.R. § 352.50.
[16] *Id.* at 38239.
[17] *Id.* at 39239-40.
[18] *Id.* at 39241.
[19] 76 Fed. Reg. 35620 (June 17, 2011).
[20] *Id.* at 35646.
[21] Id. at 35658.

economic value of $375 billion a year.[22] However, today more than 75 percent of the world's coral reefs are at risk from local and global stresses, including warming seas, coastal runoff, bleaching, ocean acidification, overfishing, development, and pollution, to name a few.[23] Oxybenzone and octinoxate are toxic to corals and are hastening their decline; these chemicals must be eliminated in order to decrease stress of background pollutants and make reefs more resilient to larger threats.

Recent scientific research has shown that oxybenzone and octinoxate pollution is a substantial threat to corals, and may cause coral bleaching by promoting viral infections.[24] Like any other topically applied personal care product, sunscreens begin to wash off as individuals recreate in the water. In fact, studies estimate as much as 25% of sunscreen applied washes off into aquatic environments.[25] Given the wide use of these chemicals, scientists estimate between 6,000-14,000 tons of sunscreen enter coral reefs around the world every year.[26] Snorkelers and divers visiting coral reefs are the primary source and each year put at least 40% of coastal coral reefs at risk.[27] In many popular near-shore swimming areas, the concentration of oxybenzone in the water can reach alarming levels.[28]

Oxybenzone and octinoxate harm corals, and the concentration of these pollutants at highly visited coastal areas is sufficiently high enough to kill coral larvae and substantially affect coral tissue. These chemicals are insoluble in water and become highly concentrated in the water column or sediments when released from sunscreen lotions. Scientists have documented relatively high concentrations of oxybenzone at popular swimming and snorkeling locations in the Hawaiian Islands. For example, the levels of this pollutant at Hawaii popular beaches range from 0.8 to 19.2 µg/L (11,300 part per trillion (ppt) at Waikiki beach, 4,780 ppt at Waimea bay, and 568 ppt at Ko Olina cove).[29] High levels of oxybenzone pollution have also been found in popular snorkeling areas in the U.S. Virgin Islands (75µg/L to 1.4 mg/L) and the Florida Keys.[30]

Scientists have documented bleaching, genotoxic effects, and skeletal disruption in coral larvae and culture primary cells at concentrations far below these ambient levels with significant

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[22] Losing Our Coral Reefs, Columbia University Earth Institute, State of the Planet blog, Jan 2018, available at http://blogs.ei.columbia.edu/2011/06/13/losing-our-coral-reefs/

[23] Burke, Lauretta et al, Reefs at Risk Revisited, World Resrouces Institute, 2011, at 3. Available at http://www.wri.org/publication/reefs-risk-revisited.

[24] Danovaro, *supra* note 7; Downs, *supra* note 1.

[25] Danovaro, *supra* note 7.

[26] Downs*, supra* note 1 at 266.

[27] *Id.*

[28] Timothy A. Bargar et al., *Synthetic ultraviolet light filtering chemical contamination of coastal waters of Virgin Islands national park, St. John, US Virgin Islands*, 101 MARINE POLLUTION BULL. 193 (2015); Stephanie Bratkovics et al., *Baseline monitoring of organic sunscreen compounds along South Carolina's coastal marine environment*, 101 MARINE POLLUTION BULL. 370 (2015); Rodríguez, *supra* note 3; Yutaka. Tashiro & Yutaka Kameda, *Concentration of organic sun-blocking agents in seawater of beaches and coral reefs of Okinawa Island, Japan*, 77 MARINE POLLUTION BULL. 333 (2013).

[29] *See,* Downs, Haereticus Environmental Laboratory, Address at the Int'l Coral Reef Symposium (2016); *see also*, Booth, H.S., M.M. Manning. 2016 The Sunscreen Sheen: An Assessment of the Presence and Quantity of Organic UV-Filters in the Waters off Waikiki Beach (Poster Presentation #40, ID #: 464) Int'l Coral Reef Symposium, Honolulu Hawaii.

[30] Downs, *supra* note 1; Bargar, *supra* note 25.

harm to corals.[31] For example, coral larvae deformations can be seen at oxybenzone concentrations as low as 6.5 μg/L, and the lethal concentration when 50 % of coral larvae are killed (LC_{50}) is as low as 139 μg/L.[32]

Due to increased tourism and sunscreen use in tropical and subtropical coastal areas, at least 10% of the world's reefs are threatened by sunscreen pollution.[33] McCoshum et al. (2016) studied the effects of sunscreen pollution to coral reef ecosystems by observing the reactions of flatworms with symbiotic algae, diatoms, glass anemones, and pulse corals when exposed to several sunscreen concentrations. This research found that nominal concentrations of sunscreen negatively affect all of the studied species.[34] Previous studies have found that sunscreens at very low concentrations cause rapid coral bleaching (i.e., release of coral symbiotic zooxanthellae) by promoting viral infections.[35] Therefore, sunscreens can potentially induce coral bleaching in coastal areas where tourism and the use of sun blocking lotions are relatively high.[36]

Coral bleaching is a major threat to reefs around the world[37] and is primarily a result of rising sea temperatures, high irradiance, bacterial and virus diseases, pollution, and even ocean acidification.[38] Contaminants such as oxybenzone in sunscreens can promote and increase susceptibility to coral bleaching during stressful conditions which may worsen bleaching events.[39] Coral bleaching has well-known negative consequences for coral reef ecosystems and the people that depend on them, including negative impacts on biodiversity and functioning, lower reef fish diversity and productivity, and disruption of the goods and services they provide to humanity such as coastal protection.[40] Eliminating chemical pollutants such as oxybenzone from entering coastal waters is a fairly simple and manageable solution to eliminate this additional threat that affects coral resilience in an already stressed ecosystem.

Sunscreen pollutants can directly affect the reproductive success and recovery of coral species listed as threatened under the ESA. Studies have shown that oxybenzone directly affect

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[31] Downs, *supra* note 1.
[32] *Id.*
[33] Danovaro, *supra* note 7, at 139.
[34] *McCoshum*, *supra* note 4*,* at 140.
[35] Danovaro, *supra* note 7.
[36] *Id.*
[37] Andrew C. Baker et al., *Climate change and coral reef bleaching: An ecological assessment of long-term impacts, recovery trends and future outlook*, 80 ESTUARINE, COASTAL & SHELF SCI. 435 (2008); Ove Hoegh-Guldberg, *Climate change, coral bleaching and the future of the world's coral reefs*, 50 MARINE & FRESHWATER RES. 839 (1999); T. P. Hughes et al., *Climate change, human impacts, and the resilience of coral reefs*, 301 SCIENCE 929 (2003); Nancy Knowlton, *The future of coral reefs*, 98 PROC. NAT'L ACAD. SCI. 5419 (2001).
[38] K. R. N. Anthony et al., *Ocean acidification causes bleaching and productivity loss in coral reef builders*, 105 PROC. NAT'L ACAD. SCI. 17442 (2008); Andrew H. Baird et al., *Coral bleaching: the role of the host*, 24 TRENDS IN ECOLOGY & EVOLUTION 16 (2009); Baker, *supra* note 35; B. E. Brown, *Coral bleaching: causes and consequences*, 16 CORAL REEFS S129–S138 (Supp. 1997); C. Mark Eakin et al., *Caribbean Corals in Crisis: Record Thermal Stress, Bleaching, and Mortality in 2005*, 5 PLOS ONE e13969 (2010).
[39] Danovaro, *supra* note 7.
Brown, *supra* note 36; T. R. McClanahan et al., *Consequences of Coral Bleaching for Sessile Reef Organisms*, *in* CORAL BLEACHING, 121 (Madeleine J. H. van Oppen & Janice M. Lough, eds., 2009); Morgan S. Pratchett, *Effects of climate-induced coral bleaching on coral-reef fishes: ecological and economic consequences*, 46 OCEANOGRAPHY & MARINE BIOLOGY ANN. REV. 251 (2008).

the reproductive capacity of corals, turning them into "zombies" by making them sterile and impairing recruitment.[41] This is very concerning because ESA threatened coral species such as Elkhorn (*Acropora palmata*) and Staghorn (*Acropora cervicornis*) corals are already experiencing reproductive failure in US waters with a substantial decline in juvenile coral recruitment and low survival rates.[42] Additionally, growing evidence shows that fertilization, recruitment success, and juvenile coral survival rate and growth are negatively affected by ocean acidification.[43] The combination of ongoing stressors with chemical pollution, such as high concentrations of oxybenzone in the water, can act synergistically, amplifying the negative effects of these stressors and further reducing reproductive capacity of these threatened species. Coral larvae and juvenile corals (i.e., recruits) are more sensitive to the toxicological effects of pollution and negative stressors, such as high temperatures and ocean acidification, than adult corals.[44] Sunscreen pollutants must be eliminated in order to improve reproductive success in coral.

Oxybenzone and octinoxate should be banned in sunscreen and personal care products. While some entities are beginning to recognize the enormity of the threats posed by sunscreen pollution, and are taking steps to lessen the flow of sunscreen into the marine environment, more must be done. In 2015, the National Marine Fisheries Service released a final recovery plan for Elkhorn and Staghorn corals, the first coral species protected under federal law.[45] The recovery plan specifically recommends that contaminants that are byproducts of personal care products must be monitored in both the water column and in sediments to assess this growing threat. The National Park Service has developed a public brochure encouraging swimmers, snorkelers and divers to only use zinc-oxide or titanium-oxide based sunscreen products in areas with coral reefs.[46]

Most notably, earlier this month Hawaii banned oxybenzone and octinoxate from sunscreen products sold or distributed in the state. The bill expressly recognizes the threats these chemicals pose to the marine environment:

> Oxybenzone and octinoxate cause mortality in developing coral; increase coral bleaching that indicates extreme stress, even at temperatures below 87.8 degrees Fahrenheit; and cause genetic damage to coral and other marine organisms. These

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[41] Danovaro, *supra* note 7; Downs, *supra* note 1.
[42] Margaret Miller et al., *Coral recruitment and juvenile mortality as structuring factors for reef benthic communities in Biscayne National Park, USA*, 19 CORAL REEFS 115 (2000); R. Ritson-Williams et al., *Larval settlement preferences and post-settlement survival of the threatened Caribbean corals Acropora palmata and A. cervicornis*, 29 CORAL REEFS 71 (2009); D. E. Williams et al., *Recruitment failure in Florida Keys Acropora palmata, a threatened Caribbean coral*, 27 CORAL REEFS 697 (2008).
[43] Rebecca Albright et al., *Ocean acidification compromises recruitment success of the threatened Caribbean coral Acropora palmate*, 107 PROC. NAT'L ACAD. SCI. 20400 (2010).
[44] Kristy J. Kroeker et al., *Impacts of ocean acidification on marine organisms: quantifying sensitivities and interaction with warming*, 19 GLOBAL CHANGE BIOLOGY 1884 (2013); Andrew P. Negri & Mia O. Hoogenboom, *Water Contamination Reduces the Tolerance of Coral Larvae to Thermal Stress*, 6 PLOS ONE e19703 (2011).
[45] NATIONAL MARINE FISHERIES SERVICE, RECOVERY PLAN FOR ELKHORN CORAL AND STAGHORN CORAL IV-10 (March 2015), http://data.nodc.noaa.gov/coris/library/NOAA/CRCP/project/2160/final_acropora_recovery_plan.pdf.
[46] *Protect Yourself, Protect the Reef!*, NATIONAL PARK SERVICE, https://cdhc.noaa.gov/_docs/Site%20Bulletin_Sunscreen_final.pdf.

> chemicals have also been shown to degrade corals' resiliency and ability to adjust to climate change factors and inhibit recruitment of new corals. Furthermore, oxybenzone and octinoxate appear to increase the probability of endocrine disruption.[47]

If signed by the governor, the ban would go into effect in 2021. Concerns similar to those of regarding the negative impacts of oxybenzone exposure on coral reefs and aquatic ecosystems have prompted recommendations against the use of oxybenzone-containing products in marine protected areas of Mexico.[48]

b. Harm to Freshwater Aquatic Life

Freshwater animals are also at significant risk due to oxybenzone and octinoxate pollution. Sunscreens are used when people recreate in lakes, rivers, and streams, and can wash off into freshwater environments just as easily as in marine environments. Furthermore, sunscreens wash off in people's showers and are generally not processed at wastewater treatment plants, meaning that areas downstream of such point sources are disproportionately impacted by sunscreen pollution.[49]

Both freshwater fish and aquatic invertebrates are harmed by sunscreen pollution. A recent study of male Siamese fighting fish showed that oxybenzone promotes severe hormone disruption.[50] The researchers found that the sperm count of males of this species significantly declined under oxybenzone exposure, and the aggression often exhibited by males to protect territory and find a mate was greatly inhibited.[51] These results built upon earlier studies, which concluded that oxybenzone exposure reduces reproductive fitness in fish by disrupting endocrine activity through modulation of estrogen receptor-signal pathways and induction of reproductive pathologies.[52] For example, a study of female rainbow trout found that the number of eggs individuals produced after seven days of oxybenzone exposure was drastically lower, and the hatching success of surviving eggs was compromised.[53] Chronic exposure to oxybenzone also reduces egg production in other fish species[54] and promotes the production of vitelogenin protein in males, which could induce gender shifts.[55]

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[47] SB 2571, available at https://legiscan.com/HI/text/SB2571/2018
[48] XCARET, *Frequently Asked Questions*. XCARET CANCUN MEXICO (2016), http://www.xcaret.com/faqs.php.
[49] M. J. Bueno, *Occurrence and Persistence of Organic Emerging Contaminants and Priority Pollutants in Five Sewage Treatment Plants of Spain: Two Years Pilot Survey Monitoring,* 164 ENVTL. POLLUTION 267 (2012).
[50] Te-Hao Chen et al., *UV-filter Benzophenone-3 inhibits agnostic behavior in male Siamese fighting fish,* 25 ECOTOXICOLOGY 302 (2015).
[51] *Id.*
[52] M Blüthgen, *supra* note 4; Coronado, *supra* note 4; Petra Y. Kunz et al., *The ultraviolet filter 3-benzylidene camphor adversely affects reproduction in fathead minnow (Pimephales promelas)*, 93 TOXICOLOGICAL SCI. 311 (2006).
[53] Coronado, *supra* note 4.
[54] Sujin Kim et al., *Effects of benzophenone-3 exposure on endocrine disruption and reproduction of Japanese medaka (Oryzias latipes)—A two generation exposure study*, 155 AQUATIC TOXICOLOGY 244 (2014); A. C. Nimrod & W. H. Benson, *Reproduction and development of Japanese medaka following an early life stage exposure to xenoestrogens*, 44 AQUATIC TOXICOLOGY 141 (1998).
[55] Coronado, *supra* note 4.

The effects of oxybenzone on freshwater aquatic invertebrates are less studied, but a few studies show lethal effects at chronic and acute exposures. As in fishes, rodents, and humans (see below), organic UV filters like oxybenzone have also disrupted hormonal activity in invertebrates[56] and can be ultimately lethal at low concentrations.[57] For example, chronic exposure to oxybenzone of protozoan ciliates substantially reduces cell viability.[58] Similarly, acute exposure of the freshwater planarian (*Dugesia japonica,* a reference organism in ecotoxicology) to 14 different benzophenone-type UV filters shows that oxybenzone is the most toxic chemical the organism was exposed to.[59] In 48 and 96 hour treatments, this study found that half of the individuals died (LC_{50}, lethal concentration with 50% mortality) at oxybenzone concentrations as low as 0.5 mg/L.[60] The study concluded that due to the common occurrence of benzophenone-type UV filters in aquatic environments, more research is urgently needed to adequately assess their ecological risks.

c. Threats to Human Health

Oxybenzone and octinoxate pose a human health concern. Oxybenzone and derivate compounds have shown several toxicological behaviors at the molecular level and multi-organ system pathologies.[61] Benzophenones, including oxybenzone, are known mutagens that under sunlight exposure increase DNA damage rate.[62] Benzophenones such as oxybenzone can act or become genotoxicants damaging DNA,[63] generate mutagenic reactive oxygen species in the skin,[64] and exhibit pro-carcinogenic activities.[65] A study that analyzed 2,517 urine samples collected from the general U.S. population found that 96% of the samples contained traces of oxybenzone.[66] Human's primary exposure to chemicals like oxybenzone occurs when a topical

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[56] I. Ozáez et al., *Ultraviolet filters differentially impact the expression of key endocrine and stress genes in embryos and larvae of Chironomus riparius*, 557-558 Sci. of the Total Env't 240 (2016); I. Ozáez et al., *The UV filter benzophenone 3 (BP-3) activates hormonal genes mimicking the action of ecdysone and alters embryo development in the insect Chironomus riparius (Diptera)*, 192 ENVTL. POLLUTION. 19 (2014).

[57] Li Gao et al., *Effects of four commonly used UV filters on the growth, cell viability and oxidative stress responses of the Tetrahymena thermophile*, 93 CHEMOSPHERE 2507 (2013); Mei-Hui Li, Acute toxicity of benzophenone-type UV filters and paraben preservatives to freshwater planarian, Dugesia japonica, TOXICOLOGICAL & ENVTL. CHEM. 566 (2012).

[58] Gao, *supra* note 54.

[59] Li, *supra* note 54.

[60] *Id.*

[61] E. Gilbert et al., *Commonly used UV filter toxicity on biological functions: review of last decade studies*, 35 INT'L J. COSMETIC SCI. 208 (2013).

[62] J. Knowland et al., *Sunlight-induced mutagenicity of a common sunscreen ingredient*, 324 FEBS LETTERS 309 (1993); P. Reinhardt et al., *Protection from solar simulated radiation-induced DNA damage in cultured human fibroblasts by three commercially available sunscreens*, 81 CAN. J. PHYSIOLOGY PHARMACOLOGY 690 (2003).

[63] K. Takemoto et al., *Genotoxic activation of benzophenone and its two metabolites by human cytochrome P450s in SOS/umu assay,* 519 MUTATION RES. GENETIC TOXICOLOGY & ENVTL. MUTAGENESIS 199 (2002); H. Zhao et al., *Substituent contribution to the genotoxicity of benzophenone-type UV filters*, 95 ECOTOXICOLOGY. ENVTL. SAF. 241 (2013).

[64] K. M. Hanson et al., *Sunscreen enhancement of UV-induced reactive oxygen species in the skin*, 41 FREE RADICAL BIOLOGY & MEDICINE 1205 (2006).

[65] G. Kerdivel et al., *Estrogenic potency of benzophenone UV filters in breast cancer cells: proliferative and transcriptional activity substantiated by docking analysis*, 8 PLOS ONE e60567 (2013).

[66] Antonia Calafat et al., *Concentrations of the Sunscreen Agent Benzophene-3 in Residents of the United States: National Health and Nutrition Examination Survey 2003-2004*, 116 Envtl. Health Persp.Vol. 893, 894 (2008).

substance (sunscreen, lotion, etc.) permeates the skin. Several studies have concluded that UV-filters such as oxybenzone and octinoxate are substances of high concern in relation to human health.[67]

In addition, oxybenzone is a reproductive toxicant that promotes estrogenic and anti-androgenic activities. For example, studies in both mammals and humans have shown that oxybenzone activates estrogen receptor proteins and inhibits androgen receptors.[68] Studies in mice and rats have shown that generational exposure to oxybenzone can reduce body weight, increase liver and kidney volume, and reduce immuno-competence.[69] Other studies on mice reactions to oxybenzone exposure (dermal and oral applications) have resulted in decreased sexual activity in females and a lower sperm count in males.[70] These studies were designed to mimic the entrance pathway of the chemical in humans. Octinoxate also increases cell proliferation in cells that grow in response to estrogen exposure.[71] Lifetime estrogen exposure is an established risk factor in the development and progression of breast cancer. One human study coapplying oxybenzone and octinoxate suggest a drop in testosterone levels in men during a one-week application period.[72]

Topical application of sunscreen and personal care products containing oxybenzone to the skin is absorbed and transferred to breast milk, threatening breast-fed babies.[73] The presence of UV-filters in newborn babies and pregnant or nursing mothers is yet another troubling result of the wide-spread use of sunscreens and personal care products containing oxybenzone. Schlumpf et al. (2010) found that UV-filters, including oxybenzone, were present in 85% of

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[67] M. Krause et al., *Sunscreens: Are they Beneficial for Health? An Overview of Endocrine Disrupting Properties of UV-filters*, 35 INT'L J. ANDROLOGY 431, 433 (2012).

[68] José-Manuel Molina-Molina et al., *Profiling of benzophenone derivatives using fish and human estrogen receptor-specific in vitro bioassays*, 232 TOXICOLOGY &. APPLIED PHARMACOLOGY 384 (2008); K. Morohoshi et al., *Estrogenic activity of 37 components of commercial sunscreen lotions evaluated by in vitro assays*, 19 TOXICOLOGY IN VITRO 457 (2005); Lyubomir G. Nashev et al., *The UV-filter benzophenone-1 inhibits 17β-hydroxysteroid dehydrogenase type 3: Virtual screening as a strategy to identify potential endocrine disrupting chemicals*, 79 BIOCHEMICAL PHARMACOLOGY 1189 (2010); T. Suzuki et al., *Estrogenic and antiandrogenic activities of 17 benzophenone derivatives used as UV stabilizers and sunscreens*, 203 TOXICOLOGY &. APPLIED PHARMACOLOGY 9 (2005).

[69] D. Rachoń, G. Rimoldi, W. Wuttke, In Vitro Effects of Benzophenone-2 and Octyl-Methoxycinnamate on the Production of Interferon-γ and Interleukin-10 by Murine Splenocytes. *Immunopharmacol. Immunotoxicol.* **28**, 501–510 (2006); M. Schlumpf *et al.*, Developmental toxicity of UV filters and environmental exposure: a review. *Int. J. Androl.* **31**, 144–151 (2008); Y. Watanabe *et al.*, Metabolism of UV-filter benzophenone-3 by rat and human liver microsomes and its effect on endocrine-disrupting activity. *Toxicol. Appl. Pharmacol.* **282**, 119–128 (2015).

[70] S. Schneider et al., *Octyl Methoxycinnamate: Two Generation Reproduction Toxicity in Wistar Rats by Dietary Administration, in* Food Chem Toxicol Vol. 43, 1083-1092 (2005); M. Axelstad et al., *Effects of Pre- and Postnatal exposure to the UV-filter octyl methoxycinnamate on the reproductive, auditory and neurological development of rat offspring, in* Toxicol Appl Pharmacol Vol. 250, 278-290 (2011).

[71] Darbre, P. D. (2006). Environmental oestrogens, cosmetics and breast cancer. Best practice & research clinical endocrinology & metabolism, 20(1), 121-143

[72] Janjua 2004.

[73] D. L. Giokas, A. Salvador, A. Chisvert, UV filters: From sunscreens to human body and the environment. *TrAC Trends Anal. Chem.* **26**, 360–374 (2007); J. Hany, R. Nagel, Detection of sunscreen agents in human breast-milk. *Dtsch. Lebensm.-Rundsch.* **91**, 341–345 (1995); M. Schlumpf *et al.*, Endocrine active UV filters: developmental toxicity and exposure through breast milk. *Chim. Int. J. Chem.* **62**, 345–351 (2008); M. Schlumpf *et al.*, Exposure patterns of UV filters, fragrances, parabens, phthalates, organochlor pesticides, PBDEs, and PCBs in human milk: correlation of UV filters with use of cosmetics. *Chemosphere*. **81**, 1171–1183 (2010).

breast milk.[74] Not only does a threat exist to a majority of women, that threat is directly transferred to their children upon breastfeeding. Studies have shown a high concentration of oxybenzone in the mothers' urine were associated with decreased birth weights in girls and increased birth weight and head circumference in boys.[75] In addition, a positive correlation has been found between exposure to benzophenones and an increased in endometriosis occurrence in women.[76]

Since the early 2000s, scientists have studies whether oxybenzone can pass the blood-placenta barrier and accumulate in the placenta, similar to the way it does in breast milk.[77] The basis for their belief is data showing that Bisphenol-A, a chemical with similar structure to oxybenzone, was able to pass through the barrier into a woman's placenta.[78] In a more recent study, scientists found that toxins like oxybenzone can bioaccumulate in human tissue and are transferred from mother to fetus.[79] Benzophenones (BP) -consisting of BP 1, 2, 3 and 4- are one of the most frequent groups of UV filters used in personal care products; BP-4 was the highest concentrated toxin detected in 75% of placenta samples.[80] The presence of benzophenone chemical compounds in human fetuses via the placenta is the result of the large amount of sunscreens and other personal care products containing UV filters on the market today.

The mother-fetus transfer of UV filters does not only occur in humans, but also in marine mammals. Alonso et al. (2015) discovered 12 pairs of mother dolphins and their fetus had traces of UV filters in the placenta and muscle tissue.[81] The dolphins were surveyed in an area of Brazil that experiences high tourism and fishing that correlate with high amounts of sunscreen entering the waterways. Furthermore, the data proves that dolphin fetuses have a higher potential for bioaccumulation of sunscreen agents than their mothers.[82] In extreme cases, the fetus died as a result of developmental complications; two were discovered with large holes in their abdominal cavities.[83] Prenatal exposure to toxic UV filters, in both human and marine mammals, causes severe impacts to healthy development and organ growth to infants, and greater complications as they reach sexual maturity.

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[74] M. Schlumpf et al., *Exposure Patterns of UV-filters, fragrances, parabens, phthalates, organochlor pesticides, PBDEs, and PCBs in human milk: Correlation of UV-filters with use of cosmetics, in* Chemosphere Vol. 81, 1171-1183 (2010).
[75] MS Wolff et al., *Prenatal phenol and phthalate exposures and birth outcomes, in* Environ Health Perspect Vol. 116, 1092-1097 (2008); C. Philippat et al., *Exposure to Phthalates and Phenols During Pregnancy and Offspring Size at Birth, in* Environ Health Perspect Vol. 120, 464-470 (2012).
[76] T. Kunisue *et al.*, Urinary concentrations of benzophenone-type UV filters in US women and their association with endometriosis. *Environ. Sci. Technol.* **46**, 4624–4632 (2012).
[77] Krause, *supra* note 64.
[78] *Id.*
[79] J. Valle-Sistac et al., *Determination of Parabens and Benzophenone-type UV Filters in Human Placenta. First Description of the Existence of Benzyl Parabens and Benzophenone-4*, 88 ENVTL. INT'L 243 (2016).
[80] *Id.* at 247.
[81] Mariana Alonso et al., *Toxic Heritage: Maternal transfer of pyrethroid insecticides and sunscreen agents in dolphins from Brazil*, 207 ENVTL. POLLUTION 391 (2015).
[82] *Id.* at 398.
[83] *Id.* at 399.

2. The FDA has the Authority and Obligation to Ban Oxybenzene and Octinoxate from Sunscreen Products

The FDA regulates cosmetics and over-the-counter drugs through its authority under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 *et seq*. The Act was designed primarily to protect the health and safety of the public at large. *POM Wonderful LLC v. Coca-Cola Co*., 134 S. Ct. 2228, 2234 (2014). The FDA retains the authority to ban a sunscreen product if it fails to demonstrate that it is "generally recognized as safe and effective" (GRASE).[84] Here, FDA must ban oxybenzone and octinoxate from sunscreens and other personal care products because they jeopardize coral reefs and the health and livelihoods of millions of people who rely on them.

Oxybenzone and octinoxate are causing grave and unnecessary damage to coral reefs throughout the United States and the world. The FDA approved the use of oxybenzone and octinoxate in sunscreen and personal care products before the extent of their damage to coral reefs became known. Now that the science regarding harms to the marine environment and human health is clear, and that nontoxic alternatives are widely available, FDA has the authority and duty to ban these chemicals.[85] While coral reefs are under barrage from a number of threats, including ocean warming, overfishing, coastal runoff, and ocean acidification, with one simple step the FDA can act *now* to protect coral reefs from even more extensive damage.

Oxybenzone and octinoxate contribute to coral bleaching, DNA damage, planula deformity, mortality, and skeletal endocrine disruption.[86] Oxybenzone is particularly toxic to corals at concentrations as low as a few parts per trillion — the equivalent of three drops in an Olympic-size swimming pool may be enough to severely damage or kill coral.[87] These chemicals are dangerous to other aquatic species as well. Scientists have documented oxybenzone in a number of fish and other species, and studies suggest the potential for increasing concentrations in species higher up in the trophic level, with humans poised to ingest the highest concentrations from the larger species that are regularly fished for human consumption.[88]

The health of coral reefs is closely tied to the health of humans; not only are coral reefs an incredibly diverse and rich marine ecosystem, but they are incredibly valuable to humankind, supporting billions of people whose lives depend on these natural resources for a source of food and income.[89] Estimates show that coral reefs provide each year nearly $375 billion in net benefits in goods and services to world economies, including, tourism, fisheries and coastal

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[84] The term "GRASE" means generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of a drug. 21 U.S.C. 360fff.

[85] In a similar vein, the FDA recently banned artificial trans fats in processed foods because they were not longer "generally recognized as safe." See "Trans Fat," FDA website, https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm292278.htm (last accessed May 21, 2018).

[86] Downs et al (2015) Toxicolopathological 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. Arch Environ Contam Toxicol. DOI 10.1007/s00244-015-0227-7

[87] *Id.*

[88] DiNardo and Downs 2017.

[89] Cesar, H, and Burke, L. and Pet-Soede, L (2003) The Economics of Worldwide Coral Reef Degradation.

protection.[90] In southeast Florida alone, NOAA estimates that coral reefs have an asset value of $8.5 billion, generating $4.4 billion in local sales, $2 billion in local income, and over 70,000 full and part-time jobs.[91] The loss of coral reefs would have catastrophic impacts to communities throughout the United States and the world.

In addition, as detailed above, oxybenzone and octinoxate are chemicals with a host of negative human health impacts. Oxybenzone is an emerging human and environmental contaminant found in nearly the entire American population. Oxybenzone can also react with chlorine, producing hazardous by-products that can concentrate in swimming pools and wastewater treatment plants.[92] Moreover, adverse reactions could very well be increased by the closed loop of ingesting fish contaminated with oxybenzone and/or washing the ingredient off our bodies and having it return in drinking water as treatment plants do not effectively remove the chemical as part of their processing protocols. In humans, oxybenzone has been reported to produce contact and photocontact allergy reactions, and is an endocrine disruptor with possible developmental, reproductive, neurological, and immune effects.[93]

The dangers posed to coral reefs, the marine environment, and human health from oxybenzone and octinoxate are unacceptable. The state of Hawaii has already recognized that these chemicals must be eliminated, and FDA has the duty and authority to ban them from sunscreens and personal care products nationwide.

3. The FDA is Required to Consult with the National Marine Fisheries Service ("NMFS") Regarding Oxybenzone and Octinoxate.

The very real threat of oxybenzone and octinoxate to corals, wildlife, and humans is well documented in independent scientific studies, yet the FDA continues to reauthorize their use as active ingredients in sunscreen and other personal care products with no assessment of their impact on imperiled wildlife. The Endangered Species Act (ESA) requires that the FDA consult with expert wildlife agencies to ensure that the authorization of these harmful chemicals does not jeopardize species listed as threatened or endangered under the ESA. Here, the FDA must consult with NMFS under Section 7 of the ESA in order to ensure oxybenzone and octinoxate do not harm listed corals.

a. The Endangered Species Act

When President Nixon signed the ESA into law, he stated, "[n]othing is more priceless and more worthy of preservation than the rich array of animal life with which our country has been blessed. It is a many-faceted treasure . . . and it forms a vital part of the heritage we all

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[90] *Id.*
[91] NOAA, National Marin Sanctuaries, Florida Keys National Marine Sanctuary website, https://floridakeys.noaa.gov/corals/economy.html
[92] DiNardo and Downs 2017.
[93] *Endocrine Disruptors*, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES, http://www.niehs.nih.gov/health/topics/agents/endocrine/ (last visited May 16, 2018).

share as Americans."[94] Enacted in 1973, the ESA grew from a Congressional desire to "devote whatever effort and resources were necessary to avoid further diminution of national and worldwide wildlife resources." *Tennessee Valley Authority v. Hill*, 437 U.S. 153, 177 (1978). "Senators and Congressmen uniformly deplored the irreplaceable loss to aesthetics, science, ecology, and the national heritage should more species disappear." *Id.* (citation omitted). When looking to the legislative history, it clear that Congress intended "beyond doubt" that imperiled species be afforded the "highest of priorities." *Id.* at 174.

The overall purpose of the ESA is to "provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved" and to "provide a program for the conservation of such endangered species and threatened species." 16 U.S.C. § 1531. This is exactly what the ESA does: protect species. Since its inception, the ESA has saved more than 99 percent of the species afforded its protections.[95] A few examples of these successes are the American peregrine falcon, the El Segundo blue butterfly, the bald eagle, the southern sea otter, and the humpback whale.[96] All of these species experienced significant population recovery, some to the point that they were delisted.[97] These are just a few of the species that the ESA has brought back from the brink of extinction. The ESA gives us the ability to protect those plants and animals that are so dear to us and gives us a statutory framework with which to do so. The fact that these success stories exist is a "significant demonstration of the Act's profound ability to make a moral judgment, to implement a plan, and to save a species."[98]

To afford imperiled species the highest of priorities, Congress declared that "all federal departments and agencies shall seek to conserve endangered species and threatened species" and "utilize their authorities in furtherance of the purposes of this chapter." 16 U.S.C. § 1531.

Section 7 of the ESA outlines the responsibilities of federal agencies in carrying out the purpose of the Act. Section 7 has been called the "heart of the ESA" and is the main tool in assuring the protection of endangered and threatened species. *W. Watersheds Project v. Kraayenbrink,* 632 F.3d 472, 495 (9th Cir. 2011). This section "obliges federal agencies to consult with the Secretary before taking any action that may affect an endangered or threatened species and to use the information learned . . . to insure that the subject species are not harmed."[99] To do so, the statute specifically states that every federal agency shall:

> insure that any action authorized, funded, or carried out by such agency (hereinafter . . . referred to as an 'agency action') is not likely to jeopardize the

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[94] President Nixon, *Statement on Signing the Endangered Species Act*, THE AMERICAN PRESIDENCY PROJECT, (Dec 28, 1973) http://www.presidency.ucsb.edu/ws/?pid=4090.
[95] CENTER FOR BIOLOGICAL DIVERSITY, A WILD SUCCESS: A SYSTEMATIC REVIEW OF BIRD RECOVERY UNDER THE ENDANGERED SPECIES ACT (June 2016).
[96] Laura Beans, *10 Success Stories Thanks to the Endangered Species Act*, ECOWATCH, (Dec. 9, 2013), https://www.ecowatch.com/10-success-stories-thanks-to-the-endangered-species-act-1881837279.html.
[97] ENDANGERED SPECIES COALITION, BACK FROM THE BRINK (2013), http://www.endangered.org/cms/assets/uploads/2013/06/2013-Back-from-the-Brink-Top-Ten.pdf.
[98] *Id.* at 4.
[99] John W. Steiger, *The Consultation Provision of Section 7(a)(2) of the Engandered Species Act and Its Application to Delegable Federal Programs*, 21 ECOLOGY L.Q. 246 (1994).

> continued existence of any endangered . . . or threatened species or result in the destruction or adverse modification of habitat of such species . . . .

16 U.S.C. § 1536(a)(2).

The purpose of section 7 is twofold, imposing two obligations on federal agencies.[100] The first obligation is the "*duty to insure* that any action" by the agency does not jeopardize the listed species or modify the critical habitat.[101] The second, yet equally important obligation, is the "*duty to consult* with the Secretary in carrying out the duty to insure."[102] Section 7 is the "heart of the ESA," *Western Watersheds Project v. Kraayenbrink*, 620 F.3d 1187 (9th Cir. 2010), and ensures that a federal agency that is funding, authorizing, or conducting an activity must work with FWS or NMFS to ensure that the activity produces no more than minimal harm to protected species in addition to not "adversely modify[ing] or destroy[ing] its critical habitat." 16 U.S.C. § 1536.

Section 7 requires each action agency to "consult" with FWS or NMFS to procure their "expert opinion" on species impacts. 16 U.S.C. § 1536(a)(2). The FWS is usually responsible for terrestrial species and NMFS for marine species. *See* 50 C.F.R. § 402.01(b). Under the procedural obligations of Section 7, the agency must request information from either the FWS or NMFS to see if any listed species "may be present" in the area, and if so, the agency must then prepare a biological assessment to determine whether the listed species will be adversely affected by the action proposed by the agency. 16 U.S.C. § 1536(c). If the assessment concludes that the action may affect a listed species, then formal consultation with either the FWS or NMFS is required. 50 C.F.R. § 402.14. The consultation "provides the opportunity for the agencies to look before they leap into carrying out possibly harmful activities."[103]

When discussing what constitutes "agency action," the term is to be "construed broadly." *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1021 (9th Cir. 2012). It was "meant to cover comprehensively every manner in which an agency may exercise its power." *Whitman v. Am. Trucking Ass'n, Inc.,* 531 U.S. 457, 478 (2001). Furthermore, the ESA's implementing regulations require an action agency to reinitiate formal consultation with the consulting agency when "new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered" (the "new information" reinitation trigger). 50 C.F.R. § 402.16(b).

b. <u>FDA Must Consult with NMFS Regarding Its Approval of Oxybenzone and Octinoxate</u>

Currently, there are 22 coral species listed as threatened under the ESA and an additional three (all foreign) are listed as endangered.[104] All of these species face serious threats, not only

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[100] *Id.*
[101] *Id.*
[102] *Id.* at 247.
[103] *Id.*
[104] *Corals*, NATIONAL OCEANIC & ATMOSPHERIC ADMINISTRATION, http://www.nmfs.noaa.gov/pr/species/invertebrates/corals.htm (last visited Aug. 10, 2017).

from warming seas and ocean acidification, but, as indicated above, from the use of oxybenzone and octinoxate as active ingredients in commercial sunscreens. ESA Section 7 requires that agencies consult with experts to "insure that *any* action authorized or funded or carried out by such agency . . . is not likely to jeopardize" any species listed as threatened under the ESA. 16 U.S.C. § 1536(a)(2). New information demonstrating serious harms to corals from sunscreen pollutants, coupled with the FDA' ongoing authority over the authorization of oxybenzone and octinoxate, mandates consultation pursuant to ESA Section 7.

Here, the FDA has authorized the use of two toxic chemicals in sunscreen and other personal care products, and the agency retains "ongoing" discretion to influence or change the use of these chemicals for the benefit of the protected species. Such "ongoing" agency action is sufficient to trigger Section 7's consultation requirement. For instance, in *Pacific Rivers Council v. Thhomas*, the Ninth Circuit held that the Forest Service's Land Resource Management Plans ("LRMPs")—documents which established standards and guidelines governing projects in certain forest areas for a period of fifteen years—"constitute continuing agency action requiring consultation under § 7(a)(2) of the ESA." *Pacific Rivers*, 30 F.3d at 1051-52. The court rejected the Forest Service's argument that the LRMPs did not constitute ongoing agency action "throughout their duration, but only when they were adopted in 1990 or if they are revised or amended in the future." *Id.* at 1053. Instead, the court found that because the LRMPs have "ongoing and long-lasting effect even after adoption, ... the LRMPs represent ongoing agency action." *Id*. Similarly, in *Washington Toxics*, the Ninth Circuit reaffirmed the applicability of "ongoing" agency action when it stated that "[b]ecause EPA has continuing authority over pesticide regulation, it has a continuing obligation to follow the requirements of the ESA." *Washington Toxics Coalition v. Environmental Protection Agency*, 413 F.3d 1024, 1033 (9th Cir. 2005)

In this case, the approval of oxybenzone and octinoxate as active ingredients in sunscreen is similarly long-lasting, and FDA also has a "continuing obligation to follow the requirements of the ESA." *Washington Toxics*, 413 F.3d 1033; see also *Defenders of Wildlife v. EPA*, 420 F.3d 946, 969 (9th Cir. 2005) (finding an action to be ongoing when it "comes within the agency's decision making authority and remains so"). When the FDA reauthorizes the use of oxybenzone and octinoxate through the approval of standards or OTC monographs, the reauthorization falls under the agency's "decision making authority." That action "remains so" as the FDA is involved in regulatory oversight over the use and standards of the chemicals in sunscreen and personal care products. Because the ESA "requires federal agencies to ensure that none of their activities . . . will jeopardize the continued existence of listed species or adversely modify a species' critical habitat" and "imposes on *all* agencies a duty to consult with [NMFS] before engaging in any discretionary action that may affect a listed species or critical habitat," and because the FDA has "continuing authority" over chemical approval in personal care products, the agency here is subject to Section's 7 consultation requirement. *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1020 (9th Cir. 2012)

Not only does the FDA retain ongoing authority over the authorization of chemicals authorized for use in sunscreen products, but recent studies have demonstrated the serious harm that oxybenzone and octinoxate pose to corals, including corals listed as threatened and endangered under the ESA. As discussed above, an extremely small amount of these toxic

pollutants has the ability to dramatically alter corals. As beachgoers swim in the ocean, sunscreen washes off and oxybenzone and/or octinoxate mixes into the ocean. This is a substantial threat to corals as studies show that oxybenzone attributes to coral bleaching by promoting viral infections. When as much as 25% of sunscreen washes off into aquatic environments, a large amount of damage can be done, especially in high traffic swimming areas, like Hawaiian beaches. In those popular spots, the concentration of oxybenzone in the water can reach alarming levels. High concentration levels are enough to substantially affect coral tissue and kill coral larvae. Coral all over the world is bleaching and dying at disturbing speeds. The current bleaching event is not only "the longest bleaching event in recorded history," but is also "the worst ever, with reefs affected from Florida to Australia."[105] A recent survey of parts of the Great Barrier Reef have "suggested that more than a third of the corals in the region might have died, leaving a marine graveyard behind."[106] Warming seas and ocean acidification also contribute to this catastrophe, but sunscreen pollutants add another, and completely avoidable, threat into an already crowded field.

When new information on the harms to listed species as a result of agency action becomes available, the agency is obligated to reinitiate consultation. 50 C.F.R. § 402.13; *see, e.g*., *Salmon Spawning & Recovery All. v. Gutierrez,* 545 F.3d 1220 (9th Cir. 2008) (NMFS obligated to reinitiate Section 7 consultation where new information reveals impacts to listed species in a manner not previously considered). Here, numerous studies have come to light in the past several years indicating the terrible toll that sunscreen products are having on threatened coral reefs. This new information reveals that the approval of oxybenzone and octinoxate has effects on corals far surpassing any envisioned by FDA in its previous evaluations. FDA must consult with NMFS to examine whether the newly available data indicates that the continued use of these toxic sunscreen products is harmful to listed species, consistent with the requirements of Section 7 of the ESA. 16 U.S.C. § 1536.

4. FDA Must Conduct a NEPA Analysis on Oxybenzone and Octinoxate

In addition to its failure to conduct a Section 7 consultation pursuant to the ESA, the FDA has failed to analyze the impacts of oxybenzone and octinoxate under the National Environmental Policy Act (NEPA). Because the approval of oxybenzone and octinoxate as ingredients in personal care products has significant environmental impacts on coral reefs and other aquatic ecosystems, the FDA should examine these risks and disclose them to the public.

a. The National Environmental Policy Act

NEPA is "our basic national charter for protection of the environment," 40 C.F.R. § 1500.1(a), and was designed to "force an agency to consider the environmental consequences of its proposed activity." *Sierra Club v. Babbitt,* 65 F.3d 1502, 1505 (9th Cir. 2005). NEPA's twin aims are to ensure that federal agencies consider the environmental impacts of their proposed actions and to ensure that those same agencies inform the public that environmental concerns have been considered. The Act requires that for every major federal action "significantly

[105] Justin Worland, *A Most Beautiful Death*, TIME, http://time.com/coral/ (last visited Aug. 10, 2017).
[106] *Id.*

affecting the quality of the human environment," all agencies of the federal government must include a detailed statement on the "environmental impact of the proposed action," as well as "any adverse environmental effects which cannot be avoided should the proposal be implemented." 16 U.S.C. § 4332.

Furthermore, before making that detailed statement, the federal agency "shall consult with and obtain the comments of any Federal agency which has jurisdiction by law or special expertise with respect to any environmental impact involved" with the proposed action. *Id.* The scope of this requirement is "exceptionally broad," *Found for N. Am. Wild Sheep v. United States Dep't of Agric.*, 681 F.2d 1172, 1177 (9th Cir. 1982), and is intended to "compel agencies . . . to take seriously the potential environmental consequences of a proposed action." *Ocean Advocates v. United States Army Corps of Eng'rs*, 402 F.3d 846, 864 (9th Cir. 2005).

NEPA requires that agencies take a "hard look" at the environmental effects of their planned action, even after a proposal has received initial approval – agencies are required to prepare a supplemental analysis if: "(i) The agency makes substantial changes in the proposed action that are relevant to environmental concerns; or (ii) There are *significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts*." 40 C.F.R. § 1502.9(c)(1) (emphasis added). Existence of significant and previously poorly-understood threats dramatically alters the environmental baseline – "without establishing. . . baseline conditions. . . there is simply no way to determine what effect [an action] will have on the environment and, consequently, no way to comply with NEPA." *Half Moon Bay Fishermans' Mktg. Ass'n v. Carlucci*, 857 F.2d 505, 510 (9th Cir.1988).

FDA regulations state that all the agency's "policies and programs will be planned, developed, and implemented to achieve the policies declared by NEPA and required by CEQ's regulations to ensure responsible stewardship of the environment for present and future generation." 21 C.F.R. § 25.10. But despite this admonition to comply with NEPA, the FDA has failed to examine the environmental impacts of oxybenzone and octinoxate in over 50 years.

b. NEPA Analysis Is Warranted

The last time EPA examined the impacts of oxybenzone and octinoxate, there was no information on the dangers of these chemicals to coral reefs and other aquatic species, and very little information on human impacts. In the last 10 years, dozens of studies have been published that highlight threats to coral reefs, the marine environment, and human health. As detailed above, oxybenzone and oxtinoxate have severe and long-lasting impacts,[107] and because FDA's approval of them "significantly affect[s] the quality of the human environment" the agency should comply with NEPA and take a "hard look" at their environmental effects. 16 U.S.C. § 4332

The approval of oxybenzone and octinoxate result in significant environmental impacts, necessitating NEPA analysis. *See* 40 C.F.R. § 1502.9(c)(1) (significant new information relevant to environmental concerns warrants supplemental NEPA analysis). A summary of the science

[107] See *supra* pages 5-12.

demonstrating those impacts is summarized above, and not necessary to repeat here. Suffice to say, these sunscreen pollutants are incredibly damaging. In order for the public to truly understand the threats we are causing to coral reef ecosystems when we lather with sunscreen and enter the ocean, the FDA must conduct a full environmental analysis.

To the extent that the FDA attempts to rely on a categorical exclusion for its failure to conduct NEPA analysis,[108] this argument fails because categorical exclusions are inappropriate when an action significantly affects the quality of the human environment and adversely affects species listed under the ESA. 21 C.F.R. § 25.21 (categorical exclusions are inapplicable when "the specific proposed action may significantly affect the quality of the human environment"). In this case, as detailed above, oxybenzone and octinoxate have serious deleterious impacts to coral reefs, including ESA-listed species, and cause harm to humans in the form of hormone disruption.

C. Environmental Impact

We claim a categorical exclusion under 21 C.F.R. § 25.31(b) for the revocation of the OTC monograph for oxybenzone and octinoxate.

D. Economic Impact

Economic impact information will be submitted upon request of the Commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners, which are unfavorable to the petition.

CONCLUSION

The use of the toxic pollutants oxybenzone and octinoxate in sunscreen and other personal care products poses an unnecessary and avoidable risk to human health and the marine environment. Alternatives are available and effective. There are many sunscreens on the market that do not include oxybenzone and octinoxate and properly protect humans from harmful UV radiation.[109] Recent data highlights the damaging effects that these chemicals have on corals, coral reefs, and the plant and animal life that depend on them for survival. As we introduce more

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[108] The FDA currently categorically excludes OTC monographs, such as the one determining appropriate levels of oxybenzone, from ordinarily requiring the "preparation of an EA or an EIS" when the action on a monograph "does not increase the use of the active moiety" or if it does, then the "estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion." 21 C.F.R. 25.31.

[109] *EWG's Guide to Sunscreens*, ENVIRONMENTAL WORKING GROUP, (last visited May 22, 2018), http://www.ewg.org/sunscreen/#.WYyzoNKGPRa.

and more of this needless chemical into the aquatic environment, the more irreparable damage it causes.

The FDA must ban these toxic sunscreen chemicals in order to protect coral reefs. In the alternative, the FDA must consult with NMFS, pursuant to section 7 of the ESA, to ensure that its approval of oxybenzone and octinoxate does not jeopardize listed species. Furthermore, the approval of these chemicals in personal care products cannot be categorically excluded from environmental examination under NEPA and the FDA must conduct a full environmental analysis to inform the public and decision makers about their risks to coral reefs and the marine environment. The FDA must not wait any longer to carry out its statutorily required duties; damage to corals and the aquatic environment is ongoing, and continues to grow every day products containing sunscreen pollutants enter the environment.

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