

IQOS IS A “MODIFIED RISK TOBACCO PRODUCT” – SO WHAT?

Because the tobacco industry has a history of making misleading claims about the relative risks of commercial tobacco products,¹ federal law prohibits the marketing of any “modified risk tobacco product” without authorization from the U.S. Food & Drug Administration (FDA).

The Family Smoking Prevention and Tobacco Control Act defines a “modified risk tobacco product” as “any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.”²

On July 7, 2020, the U.S. Food and Drug Administration authorized Philip Morris International (PMI) to market its IQOS Tobacco Heating System as a modified risk tobacco product. This fact sheet answers frequently asked questions about IQOS and the implications of its designation as a modified risk product.



Q: What is IQOS?

IQOS is a type of heated tobacco product manufactured by PMI, which is sold in more than 40 countries.³ Unlike conventional cigarettes, the IQOS product is sleek-looking and contains a holder, a charger (either separately or combined with the holder) and a heated tobacco stick.⁴ The tobacco sticks (called “HeatSticks” and “HEETS”) are made of ground tobacco leaves, resemble small cigarettes, and are sold in packs.⁵



From left to right: an IQOS charger, holder, and tobacco or "HEET" stick.

A user operates the IQOS device by sticking a cigarette in the holder, which contains an electronically controlled heater. The heater heats the tobacco stick, producing an inhalable aerosol.⁶ IQOS is classified as a cigarette under U.S. federal law.⁷

Q: How is IQOS different from a conventional cigarette or an e-cigarette?

The tobacco industry sometimes markets heated tobacco products as "heat-not-burn" products in an effort to distinguish them from conventional cigarettes. However, the main difference between these products and conventional cigarettes is that heated tobacco products heat the tobacco to a lower temperature than conventional cigarettes, which generally maintain a temperature of 1250° to 1300°F.⁸ According to industry descriptions of heated cigarettes, the products usually heat tobacco to a temperature between 450° and 700°F, and sometimes as low as 99°F.⁹ While the tobacco heating mechanism is different, the heated tobacco still produces an aerosol that contains nicotine and other harmful chemicals.¹⁰

Although they resemble e-cigarettes in their appearance, heated tobacco products function differently than products like JUUL or Puffbar that contain nicotine-containing e-liquids. They also differ from e-cigarettes because they contain processed commercial tobacco leaf as the nicotine or flavor source in the product, while e-cigarettes generally contain extracted nicotine and various other liquids.

Q: Do IQOS come in different flavors?

IQOS products were first released in Japan and are currently sold in a range of flavors in Asia, as well as parts of Europe that are not part of the E.U. (where the sale of flavored cigarettes is now prohibited).¹¹ IQOS markets its “HeatSticks” and “HEETS” cigarettes under the Marlboro label. Marlboro HEETS are marketed using colors to indicate flavor (e.g., purple refers to blueberry flavor and “green zing” indicates a mixture of menthol and lime).¹² In Japan, the Forest Green, Cool Jade, and Tropical Menthol flavors were rolled out in collaboration with a famous pastry chef, who modeled the flavors on macarons.¹³ In the U.S., the only flavored products authorized for sale are menthol flavored. Menthol, like other flavors, has been shown to attract youth and has historically been used by the tobacco industry to target and addict marginalized communities.¹⁴ PMI may have applied for authorization to market additional flavors in the U.S.; however, the application data are not publicly available.¹⁵

Q: Is IQOS sold in the U.S.?

IQOS is one of only two heated tobacco products currently allowed to be sold in the U.S.¹⁶ The IQOS 2.4 tobacco product first became available to consumers in the U.S. in October 2019, after the FDA authorized its sale in April 2019.¹⁷ In December 2020, PMI received FDA authorization to sell its next “generation” of the product, IQOS 3, which contains updated charging and electronic capabilities.¹⁸ To date, PMI has only launched these products in three U.S. markets: Atlanta, Georgia; Richmond, Virginia; and Charlotte, North Carolina. PMI, however, intends to rapidly increase marketing of IQOS 3 across the U.S.¹⁹

Q: PMI received authorization from FDA to market IQOS 2.4 as a modified risk tobacco product. What does that mean?

As of April 8, 2021, the FDA had authorized only one heated tobacco product (IQOS 2.4 and three of its tobacco-containing HeatStick components) to be marketed as modified risk tobacco products.²⁰ Only these specific products — and not IQOS 3 — may be marketed with claims that fully switching from regular cigarettes to IQOS can reduce a person’s exposure to harmful chemicals. As of the date this document went to press, PMI had submitted an application to market IQOS 3 as an MRTP, which will remain open for public comment until the FDA closes the comment period.²¹ It is likely that, as with the IQOS 2.4 product, public health professionals will raise concerns about the lack of independent analysis and risk assessment conducted during the FDA’s evaluation of the product’s potential public health risks.²²

Similar reduced exposure claims may **not** be made about other heated tobacco products. In addition, the manufacturer of IQOS may not claim that using IQOS reduces the risk of disease, that the products are endorsed or approved by the FDA, or that the FDA deems the products to be safe for use by consumers.²³ The MRTP marketing authorization does require PMI to conduct post-market surveillance and studies to determine consumer behavior, perception, and health, as well as youth awareness and use of the products.²⁴ However, due to a lack of clear guidelines for how those studies are conducted, along with along history of data manipulation by the industry, third-party, independent, peer-reviewed research is crucial to understanding the products' long term risks.

Although only IQOS 2.4 is currently allowed to be sold as a modified risk tobacco product, consumers are unlikely to differentiate it from IQOS 3 because of the identical brand name, increasing the risk of negative public health ramifications due to consumer misperception.

Q: Is IQOS an FDA-approved method for quitting smoking?

No. The modified risk tobacco product authorization permits only one set of claims: that exposure to harmful chemicals is reduced if a user switches completely to IQOS from combustible cigarettes. IQOS has **not** been authorized for sale as a cessation device or nicotine replacement therapy (NRT). The FDA has not authorized any heated tobacco products or e-cigarettes for sale as cessation devices or NRTs. Moreover, no heated tobacco product or e-cigarette manufacturer has applied for authorization to market their products as cessation devices or NRT.

Q: Is IQOS addictive?

Yes. In authorizing the sale of IQOS 2.4, the FDA acknowledged that studies show that IQOS HeatSticks have nicotine delivery and abuse potential comparable to combustible tobacco cigarettes.²⁵ Youth are especially vulnerable to developing nicotine addiction and can suffer related negative long-term impacts, including impaired memory and reduced attention span.²⁶

Q: Are heated tobacco products less harmful than regular cigarettes?

Research shows that heated tobacco products produce many of the same harmful chemicals that regular cigarettes do, together with others not found in regular cigarette smoke, such as flavoring agents, solvents, food additives, and contaminants.²⁷ While some evidence

shows that heated tobacco product emissions may contain lower levels of harmful chemicals compared to cigarette smoke, that does not mean heated tobacco products are safe. More importantly, there is evidence they may pose unique harms, including exposing the user to toxic chemicals not present in conventional cigarette smoke, raising concern among public health advocates and researchers about the implications of allowing the marketing and sale of IQOS as a modified risk tobacco product.²⁸

Q: Who is using heated tobacco products in the U.S.?

Unsurprisingly, given the limited availability of heated tobacco products in the U.S., use of these products by the U.S. population is currently low. Regular tracking of heated tobacco product use among U.S. adults began in 2017. At that time, 0.7 percent of adults, including 2.7 percent of people who currently smoked regular cigarettes, reported they had ever used a heated tobacco product.²⁹ By 2018, 2.4 percent of adults, including 6.7 percent of people who currently smoked regular cigarettes, reported they had ever used a heated tobacco product.³⁰ In California, the California Adult Tobacco Survey found that use of heated tobacco products in the state is increasing, with 4.2 percent of adults reporting heated tobacco product use from October to November 2020.³¹

In 2020, 1.4 percent of U.S. middle and high school students reported having used heated tobacco products in the past 30 days.³² In California, recent research shows that current use (use in the past 30 days) of heated tobacco products among high school students in California is 0.2 percent; ever use (lifetime use) is 0.7 percent.³³

Although awareness and use of heated tobacco products in the U.S. lags well behind that of e-cigarettes, recent evidence shows cause for concern that similar widespread adoption of these products may increase as public awareness and industry marketing of them grows.³⁴

Q: What's the bottom line for state, local, and Tribal governments?

New tobacco products like IQOS raise important questions for public health advocates and policymakers. How can these products be better regulated? While their manufacturers would like to distinguish them from both cigarettes and e-cigarettes, the reality is that heated tobacco products pose the same public health risks as other tobacco combustible products, meaning their sale and use should be comprehensively regulated just like other tobacco products. Tribes, states, and localities should analyze their tobacco laws to determine whether they

cover heated tobacco products and, if necessary, update them to ensure that heated tobacco products are included. The Public Health Law Center's *Comprehensive Tobacco Retailer Licensing Ordinance* contains definitions of "tobacco product" and "electronic smoking device" that cover heated tobacco products and any substances used with them.

For more information about heated tobacco products and policy options, see the Public Health Law Center (PHLC)'s publication, *Heated Cigarettes: How States Can Avoid Getting Burned*, August 2018, available on the Center's website.

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Endnotes

- 1 The Public Health Law Center recognizes that traditional and commercial tobacco are different in the ways they are planted, grown, harvested, and used. Traditional tobacco is and has been used in sacred ways by Indigenous communities and tribes for centuries. Comparatively, commercial tobacco is manufactured with chemical additives for recreational use and profit resulting in disease and death. For more information visit: <http://www.KeepItSacred.itcmi.org>. When the word "tobacco" is used throughout this document a commercial context is implied and intended.
- 2 21 U.S.C. § 387k (b)(1).
- 3 Shu-Hong Zhu et al., *Early Adoption of Heated Tobacco Products Resembles that of E-cigarettes*, 21 TOBACCO CONTROL 1 (2021), doi:10.1136/tobaccocontrol-2020-056089; Stanton A. Glantz, *PMI'S Own Data Shows IQOS is as Bad for Lungs as a Cigarette, Including Depressing Lung Function*, UCSF Center for Tobacco Control Research and Education (Apr. 20, 2020), <https://tobacco.ucsf.edu/pmi-percentE2-percent80-percent99s-own-data-shows-iqos-bad-lungs-cigarette-including-depressing-immune-function>.
- 4 U.S. Food & Drug Administration, *PMTA Coversheet: Technical Project Lead Review (TPL)*, <https://www.fda.gov/media/124247/download> (last accessed April 8, 2021).
- 5 *Id.*
- 6 *Id.*
- 7 *Id.* Heated tobacco products are considered e-cigarettes in Japan, Korea, and Italy. See Karma McKelvey et al., *Heated Tobacco Products Likely to Appeal to Adolescents and Young Adults*, 27 TOBACCO CONTROL (Suppl. 1), https://tobaccocontrol.bmj.com/content/27/Suppl_1/s41.
- 8 Conventional cigarettes reach a peak temperature of around 1500°F and smolder around 1250°F to 1300°F. Richard R. Baker, *Temperature Distribution Inside a Burning Cigarette*, 247 NATURE 405 (1974), <https://www.nature.com/articles/247405a0>.

- 9 Conventional cigarettes are often referred to as “combustible cigarettes,” which could be considered a misnomer from a scientific perspective. Complete combustion occurs at a temperature much higher than temperatures reached by conventional cigarettes (> 2370°F). In fact, a cigarette user is exposed to many toxicants as a result of incomplete combustion and the degradation from heating tobacco. U.S. DEP’T OF HEALTH AND HUMAN SERV., HOW TOBACCO SMOKE CAUSES DISEASE: THE BIOLOGY AND BEHAVIORAL BASIS FOR SMOKING-ATTRIBUTABLE DISEASE: A REPORT OF THE SURGEON GENERAL 37 (2010), <https://www.ncbi.nlm.nih.gov/books/NBK53014>.
- 10 The chemical composition of the aerosol generally includes nicotine, inorganic compounds (e.g., carbon monoxide), polycyclic aromatic hydrocarbons (e.g., benzene), and volatile organic compounds (e.g., bormaldehyde). Grant O’Connell et al., *Heated Tobacco Products Create Side-Stream Emissions: Implications for Regulation*, J. ENVTL. ANALYTICAL CHEM. 1000163 (2015); Reto Auer et al., *Heat-Not-Burn Tobacco Cigarettes: Smoke by Any Other Name*, 177 J. AM. MED. ASS’N INTERNAL MED. 1050 (2017); Noel Leigh et al., *Tobacco-Specific Nitrosamines (TSNA) in Heated Tobacco Product IQOS, 27 TOBACCO CONTROL s37* (2018); Stanton Glantz, *PMI’s Own In Vivo Clinical Data on Biomarkers of Potential Harm in Americans Show that IQOS Is Not Detectably Different from Conventional Cigarettes*, 27 TOBACCO CONTROL s9 (2018).
- 11 Alex Liber, *Starting Today, Flavored Cigarettes Can No Longer Be Sold In the EU*, THE TOBACCO ATLAS (May 20, 2020), <https://tobaccoatlas.org/2020/05/20/starting-today-flavored-cigarettes-can-no-longer-be-sold-in-the-eu>.
- 12 See, e.g., Truth Initiative, *Tobacco is a Social Justice Issue: Racial and Ethnic Minorities* (Feb. 03, 2017), <https://truthinitiative.org/research-resources/targeted-communities/tobacco-social-justice-issue-racial-and-ethnic-minorities>.
- 13 Stanford University Research into the Impact of Tobacco Advertising, *IQOS Flavors*, http://tobacco.stanford.edu/tobacco_main/images_heat.php?token2=fm_heat_st731.php&token1=fm_heat_img42410.php&theme_file=fm_heat_mt083.php&theme_name=IQOS&subtheme_name=IQOSpercent20Flavors.
- 14 See, e.g., Andrea C. Villanti et al., *Association of Flavored Tobacco Use With Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013-2015*, 2 JAMA Netw Open e1913804 (2019), doi:10.1001/jamanetworkopen.2019.13804 and Tobacco Control Legal Consortium, *The Verdict Is In: Findings from United States v. Philip Morris* (2006), <https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-verdict-is-in.pdf>.
- 15 The FDA is currently reviewing millions of products under the Premarket Tobacco Product Application (PMTA) process laid out by the Tobacco Control Act.
- 16 IQOS and Eclipse are the brand names of the two heated tobacco product systems the FDA has authorized for sale in the U.S. On July 19, 2018, the FDA granted a substantial equivalent marketing order for R.J. Reynolds’ Eclipse and Eclipse Menthol heated tobacco products (Substantial Equivalence Marketing Orders Archive, U.S. Food & Drug Admin., <https://www.fda.gov/tobacco-products/substantial-equivalence/substantial-equivalence-marketing-orders-archive>). On April 30, 2019, the FDA granted a marketing order for Philip Morris International’s IQOS heated tobacco product (Premarket Tobacco Product Marketing Orders, U.S. Food & Drug Admin., <http://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders>). For more detailed explanation of these designations, see the Public Health Law Center’s *The FDA’s Premarket Review of Tobacco Products Fails to Fully Protect Public Health*.
- 17 On April 30, 2019, the FDA approved a premarket tobacco product application (PMTA) and granted a marketing order for Philip Morris International’s IQOS heated tobacco product; on July 7, 2020, the FDA also authorized a Modified Risk Tobacco Product (MRTP) marketing order for IQOS. (Premarket Tobacco Product Marketing Orders, U.S. Food Drug Admin., <http://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders>). For more detailed explanation of these designations, see the FDA Premarket Review of Tobacco Products webpage on the Public Health Law Center’s website.
- 18 See U.S. Food & Drug Admin., Letter to Philip Morris Products S.A. from Matthew R. Holman, Director, Office of Science, Center for Tobacco Products (Dec. 7, 2020), <https://www.fda.gov/media/144700/download>; see also Press Release, Altria, *FDA Authorizes Sale of the IQOS 3 Tobacco System Device in the United States* (2020). Available at: <https://investor.altria.com/press-releases/news-details/2020/FDA-Authorizes-Sale-of-the-IQOS-3-Tobacco-Heating-System-Device-in-the-United-States/default.aspx>.

- 19 See Press Release, Altria, *supra* note 18.
- 20 On July 7, 2020, the FDA authorized a modified risk tobacco product (MRTP) marketing order for IQOS 2.4 (Premarket Tobacco Product Marketing Orders, U.S. Food & Drug Admin., <http://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders>). For more detailed explanation of these designations, see the [FDA Premarket Review of Tobacco Products](#) webpage on the Public Health Law Center's website.
- 21 U.S. Food & Drug Admin, *Philip Morris Products S.A. Modified Risk Tobacco Product (MRTP) Applications* (last updated May 13, 2021), <https://www.fda.gov/tobacco-products/advertising-and-promotion/philip-morris-products-sa-modified-risk-tobacco-product-mrtp-applications>.
- 22 See, e.g., Micah L. Berman and Allison M. Glasser, *The Public Health Standard in Action — Analysis of the US Food & Drug Administration's IQOS Review*, *JAMA ONCOLOGY* (2020), doi:10.1001/jamaoncol.2020.3316.
- 23 U.S. Food & Drug Admin., *Modified Risk Tobacco Products* (webpage), <https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products>; Press Release, U.S. Food & Drug Administration, *FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information* (2020), <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information>.
- 24 U.S. Food & Drug Admin., *Press Release: FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information* (July 7, 2020), <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information>.
- 25 U.S. Food & Drug Admin., *PMTA Coversheet: Technical Project Lead Review (TPL)*, <https://www.fda.gov/media/124247/download> (accessed Apr. 9, 2021); see also Rola Salman et al., *Free-Base and Total Nicotine, Reactive Oxygen Species, and Carbonyl Emissions From IQOS, a Heated Tobacco Product*, *21 NICOTINE TOBACCO RESEARCH* 1285 (2019), doi: 10.1093/ntr/nty235.
- 26 Chadi et al. *Understanding the Implications of the "Vaping Epidemic" Among Adolescents and Young Adults: A Call for Action*, *40 SUBST. ABUSE* 7 (2019), doi: 10.1080/08897077.2019.1580241.
- 27 Auer 2017 and Glantz 2018, *supra* note 10; Gideon St. Helen et al., *IQOS: Examination of Philip Morris International's Claim of Reduced Exposure*, *27 TOBACCO CONTROL* s30 (2018), doi: 10.1136/tobaccocontrol-2018-054321.
- 28 Unlike cigarette smoke inhalation, animal and human studies indicate inhalation of IQOS emissions increases the risk for liver toxicity. Lauren Chun et al. *Possible Hepatotoxicity of IQOS*, *27 TOBACCO CONTROL* s39 (2018), doi: 10.1136/tobaccocontrol-2018-054320.
- 29 Kristy Marynak et al., *Awareness and Ever Use of "Heat-Not-Burn" Tobacco Products Among U.S. Adults*, *2017*, *55 AM. J. PREV. MED.* 551 (2018), doi: 10.1016/j.amepre.2018.04.031.
- 30 Teresa Wang et al., *Awareness and Ever Use of Heated Tobacco Products Among U.S. Adults, 2018* (poster presented at Society for Research on Nicotine and Tobacco Annual Meeting (Feb. 2019, San Francisco).
- 31 California Tobacco Control Program, *Key Findings from the Online California Adult Tobacco Survey: 2019–2020 Results* (2021), https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CTCB/CDPHpercent20Documentpercent20Library/ResearchandEvaluation/DataHub/OnlineCATS2020Factsheet_Mar2021ADA.pdf.
- 32 Andrea Gentzke et al., *Tobacco Product Use Among Middle and High School Students — United States, 2020*, *69 MORBIDITY & MORTALITY WKLY REP.* 1881 (2020), doi: 10.15585/mmwr.mm6950a1.
- 33 Shu-Hong Zhu et al., *Results of the Statewide 2019–20 California Student Tobacco Survey*, Center for Research and Intervention in Tobacco Control, U. Cal. San Diego (2021).
- 34 Zhu 2021, *supra* note 3.