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Issue Snapshot: Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products

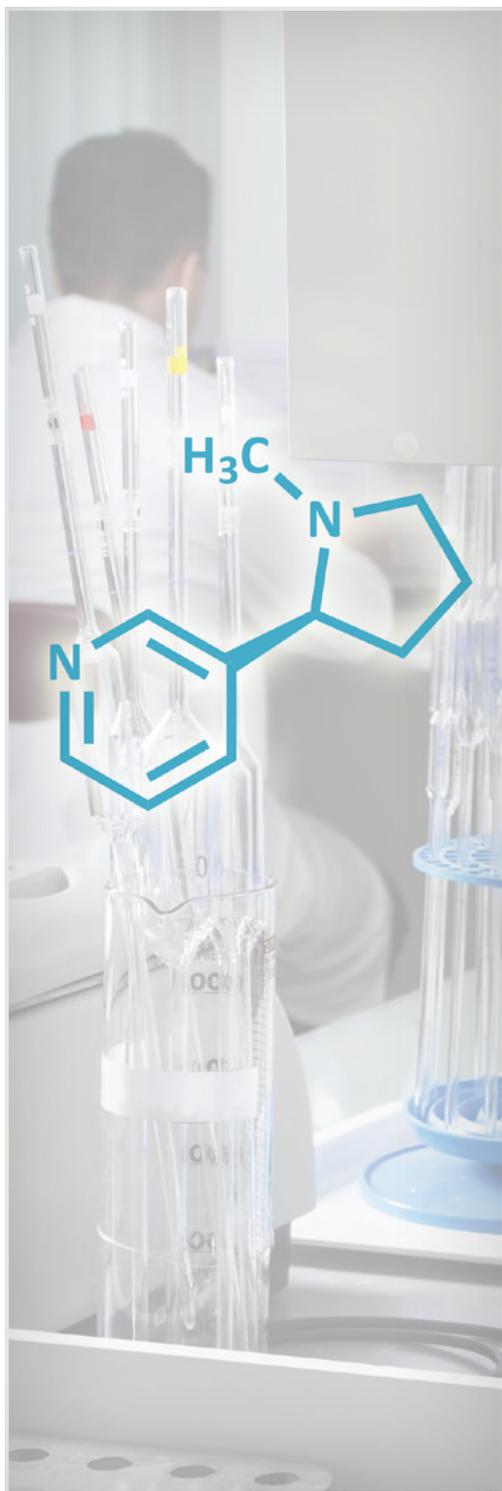
One of the goals of the Federal Food, Drug, and Cosmetic Act is to help people understand the potential harms of tobacco use. The Act requires tobacco product manufacturers and importers to report the amount of harmful and potentially harmful constituents (HPHCs) by brand and subbrand. HPHCs are chemicals or chemical compounds in tobacco products or tobacco smoke that cause, or could cause, harm to smokers or nonsmokers. FDA must publish HPHC quantities in each brand and subbrand of tobacco product in a way that people find understandable and not misleading. Learn more about FDA's progress toward this important goal.

Preliminary HPHC List

FDA's Tobacco Products Scientific Advisory Committee (TPSAC) met in June and July 2010 and recommended criteria to identify HPHCs. In August 2011, FDA published a *Federal Register* notice describing the basics about HPHCs and asking the public to submit relevant scientific information. FDA used this feedback to publish a list of 93 HPHCs in the *Federal Register* in March 2012. This HPHC list focuses on the chemicals that are linked to the five most serious health effects of tobacco use (cancer, cardiovascular disease, respiratory effects, reproductive problems, and addiction). You can find the most current information about the list at FDA.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297752.htm.

Tobacco Industry Reporting Requirements

In March 2012, FDA issued draft guidance that identified a subset of 20 HPHCs for which manufacturers and importers are to test and report to FDA. FDA chose these 20 HPHCs because their testing methods were well established and widely available. They are also representative of the types of HPHCs on the full list established by FDA. Once the affected industries overcome initial challenges, such as a lack of laboratory capacity to test for HPHCs and a lack of standard testing methods across labs, FDA intends to increase the number of HPHCs for



which reporting is required. As of March 2012, FDA requires industry to report on HPHC levels in three categories of tobacco products: cigarettes (including smoke and filler), smokeless tobacco (such as snuff, plug, chew, loose leaf, and snus), and roll-your-own tobacco. FDA is currently evaluating the quality and reliability of the wide variety of data submitted by manufacturers.

Communicating to the Public

Historically, people have learned about tobacco product constituents from advertising and tobacco product labeling. Some studies indicate that people were misled by information about levels of product constituents and their misunderstanding may have made them less likely to quit smoking. FDA carefully considered this when developing research into how consumers perceive and understand levels of tobacco product constituents.

In August 2013, TPSAC met with FDA's Risk Communication Advisory Committee. This joint committee agreed that the methods for displaying the HPHC information that FDA had available could be difficult to understand or be misleading. The committee recommended to delay making a list of HPHC quantities by brand and subbrand available to the public until FDA had conducted more studies about how well people understand such HPHC information and how their beliefs affect their behavior. FDA recently partnered with the National Institutes of Health (NIH) to fund research that will support the development of understandable and accurate public information about levels of HPHCs in tobacco products.

FDA continues this important research into how best to communicate HPHC amounts in each brand and subbrand of tobacco product. In the meantime, we are including messages about harmful and potentially harmful chemicals from tobacco products or smoke in our ongoing public health campaigns.

What's Next?

FDA will continue to take active steps to collect and evaluate HPHC data from manufacturers and to assess how to present this information to the public in a way that is understandable and not misleading. It is a time-intensive process to analyze data from tobacco manufacturers and to conduct rigorous studies to learn the best way to communicate this complex information to the public. As FDA makes progress, we will publish enhanced information about HPHCs in tobacco products.

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