

The attached document represents CTP's then-current thinking on certain aspects of tobacco regulatory science. The information contained herein is subject to change based on advances in policy, the regulatory framework, and regulatory science, and, is not binding on FDA or the public. Moreover, this document is not a comprehensive manual for the purposes of preparing or reviewing tobacco product applications. FDA's review of tobacco product applications is based on the specific facts presented in each application, and is documented in a comprehensive body of reviews particular to each application.

Given the above, all interested persons should refer to the Federal Food, Drug, and Cosmetic Act, and its implementing regulations, as well as guidance documents and webinars prepared by FDA, for information on FDA's tobacco authorities and regulatory framework. This document does not bind FDA in its review of any tobacco product application and thus, you should not use this document as a tool, guide, or manual for the preparation of applications or submissions to FDA.

## Memorandum

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**Subject:** Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products

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### **Background**

This memo outlines the Office of Science's (OS) current approach to product quantity changes in certain SE Reports<sup>1</sup>. A product quantity change is understood by OS to be an increase or decrease in product quantity and/or portion count. FDA issued a Guidance in December 2016, *Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3)* (SE FAQ), which among other things, includes information on FDA's current thinking at the time that product quantity changes have the potential to affect initiation and cessation and therefore such changes may cause new products to raise different questions of public health; however, based on OS's experience and the currently available scientific evidence, OS's position has changed. Based on a reconsideration of the evidence in the SE FAQ as well as other currently available evidence for non-tobacco products and OS's experience in reviewing product quantity change SE Reports, OS has determined that, at this time, changes in tobacco product quantity do not cause the new tobacco products to raise different questions of public health.

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<sup>1</sup> Discussion limited to statutorily regulated tobacco products.

OS's experience with and the current evidence for product quantity changes for tobacco products is described below and the current approach to product quantity or portion count changes from the Social Science perspective is summarized in the conclusions section at the end of this document.

### **Discussion**

The SE FAQ states that “[c]hanges in product quantity can affect initiation and cessation, such as by affecting consumer harm perceptions, use intentions, and use behavior” and also notes that smaller product quantities may allow for increased product uptake due to lower barriers to trying the product, and larger product quantities can potentially reduce cessation behaviors and increase tobacco product use among current users.<sup>2</sup> To date, for all products except RYO filters, tubes or papers<sup>3</sup>; where there is a proposed change in product quantity of more than 20%<sup>4</sup> and/or when the change represented a change from an “individual sized” product to a “bulk” product or when the change represented moving from an “individual” sized or “bulk” size to a small “trial” sized product, CTP has required applicants to submit evidence demonstrating that such a change in product quantity would not cause the new product to raise different questions of public health. CTP supported its position that increases in product quantity (specifically, increases from “individual” to “bulk” sizes) may raise different questions of public health by relying on one article (Wansink, 1996).<sup>5</sup> CTP supported its position that decreases in product quantity size may raise different questions of public health by relying on articles that address the influence of price on consumer behavior (including with respect to tobacco products), such as Chaloupka & Warner (2000).

In the majority of SE Reports that included a change in product quantity, applicants did not provide any scientific information to address these changes as it related to the social science of consumer behavior and perception. In cases where scientific information was provided, generally it was a single article, the same article relied on by CTP (Wansink, 1996). SE Reports which cited that article either did not provide a rationale for how the findings supported their assertion that such changes did not raise different questions of public health or erroneously argued that tobacco products are “usage invariant” (products for which there is no benefit of using more) and that accordingly changes in quantity do not influence consumer behavior. Upon further cycles of review of SE Reports containing a change in quantity, rarely was any scientific information submitted by manufacturers. In those cases, when scientific information was submitted, the most common form was market sales data of similar sizes of the new and predicate products. However, that aggregated information is of limited value when comparing the new and predicate products. Specifically, use of the product by specific user groups cannot be assessed, differences in price may obscure interpretation of sales data when not presented by unit sales, and aggregated data may otherwise obscure differences in sales of the products due to unequal geographic distribution of sales.

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<sup>2</sup> The SE FAQ cited the following in support of its position: Rogers, E.M. (2003). *Diffusion of innovations* (5th ed.). New York: Free Press; Ford, A., Moodie, C., & Hastings, G. (2012). The role of packaging for consumer products: Understanding the move towards ‘plain’ tobacco packaging. *Addiction Research and Theory*, 20, 339-347. doi:10.3109/16066359.2011.632700; Chaloupka, F. J., & Warner, K. E. (2000). *The economics of smoking*. NBER Working Paper no. 7047. Cambridge, MA.: National Bureau of Economic Research. Wertenbroch, K. (1998). Consumption self-control by rationing purchase quantities of virtue and vice. *Marketing Science*, 17, 317-337.

<sup>3</sup> RYO filters, tubes, and paper are “low convenience” products because they require other products (i.e., RYO tobacco) and additional preparation before use. They are also “low salience” products because rolling papers are small, require little storage space, and are not highly visible. In addition, there is no benefit for using more of these products—thus they are usage-invariant (Wansink, 2002). Thus, stockpiling (or increases in product quantity) does not impact consumer use (Chandon & Wansink, 2002). Therefore, from the social science perspective, changes in quantity of these RYO products do not cause the new products to raise different questions of public health. See September 22, 2017, Technical Project Lead Review for SE0014064.

<sup>4</sup> Change of 20% and less are unlikely to be noticed by consumers, thus changes of this amount or less do not have noticeable changes in consumer purchase decisions and use. See November 2, 2015, Technical Project Lead review for SE0010524.

<sup>5</sup> Although not cited in the SE FAQ, both Ford et al. (2012) and Wertenbroch (1998) discuss the article.

Given its experience with reviewing product quantity changes in SE Reports, OS determined that reassessing the evidence and the initial position that changes in product quantity may raise different questions of public health was warranted. With respect to product quantity increases, the currently available scientific evidence examines the effects of product quantity in other consumer products on consumer behavior and perception but is not specific to tobacco products generally or the specific category of tobacco product under social science review. This evidence suggests that changes in product quantity of consumer products may influence consumer behavior but was not specific enough for OS to determine if such changes always lead to changes in behavior, and if not under what condition it would; what threshold (if any) would trigger a change in consumer behavior; what tobacco products would be affected by a quantity change and which would not, and how findings about consumer behavior and use of other consumer products may translate to tobacco use intention and behavior. Additionally, the Wansink article does not provide any guidelines for how to determine what should be considered “trial”, “individual”, or “bulk” sizes for tobacco products, nor does such information currently exist elsewhere to OS’s knowledge. With respect to product quantity decreases, even though some of the evidence is specific to tobacco products, the studies do not separate out the effect of reduced price from size on consumption or initiation. Thus, based upon the currently available science and CTP’s experience in reviewing SE Reports, from a Social Science perspective, product quantity changes do not cause new tobacco products to raise different questions of public health.

The SE FAQ as currently written (Edition 3), does not reflect CTP’s current thinking on product quantity changes. Future evidence specific to tobacco products, as well as evidence specific to the magnitude of change that impacts consumer decisions and public health may impact the Social Science evaluation and conclusions for future SE Reports. As more scientific evidence becomes available either through work conducted or supported by CTP, as well as other sources, this finding will be re-evaluated and the conclusions may change.

### **Conclusion**

Based on the currently available scientific evidence regarding consumer perception and use, OS has concluded that at this time, based upon available evidence, changes in product quantity and portion count do not cause new tobacco products to raise different questions of public health. This conclusion will be revisited as additional scientific information becomes available. Therefore, in the context of SE review, a social science deficiency should not be conveyed to an applicant on the basis of product quantity for new tobacco products. CTP should consider revising the current SE FAQ guidance document to reflect this conclusion.

### **References**

Chandon, P. & Wansink, B. (2002). When are stockpiled products consumed faster? A convenience-salience framework of postpurchase consumption incidence and quantity. *Journal of Marketing Research*, 39, 321-335.

Wansink, B. (1996). Can package size accelerate usage volume? *Journal of Marketing*, 60, 1-14.