

**Possible Core Elements of the Most “Appropriate for the Protection of the Public Health” Rule  
FDA Could Issue to Reduce Nicotine Levels in Cigarettes and Other Smoked Tobacco Products**

The following proposed elements of a possible FDA tobacco control rule to reduce nicotine levels in cigarettes and possibly other smoked tobacco products are meant to increase the likelihood and size of the potential net health gains to the population as a whole from the rule (as explained in the lettered bullets following each numbered element and by the related assumptions). [Do they each make sense? Are the assumptions valid?]

**1. To maximize public health gains, the nicotine-reduction rule should apply to all cigarettes (including RYO) and to all other tobacco or tobacco products that are similarly smoked or could be smoked as cigarette substitutes.<sup>1</sup>**

- (A) Will reduce existing smoking of not just cigarettes but also similarly harmful combustible tobacco products.
- (B) Will prevent cigarette smokers from switching to smoking similarly harmful, still-legally-available full-nicotine combustible tobacco products, which they could do if the new rule reduced nicotine only in cigarettes.

*Related Assumptions:*

- Although they are unlikely to serve as cigarette smoking substitutes, there are no public health reasons to exclude any of the following smoked tobacco products from the nicotine-reduction rule:
  - Expensive, bona fide premium cigars (e.g., wrapped in whole tobacco leaf with no filter), which cannot be deeply inhaled when smoked, like cigarettes and could not otherwise serve as daily-use substitutes for full-nicotine cigarettes (except, perhaps, among the wealthy).
  - Other bona fide cigars (wrapped in whole tobacco leaf with no filter) containing only bona fide cigar tobaccos with high pH levels that make deep, active inhalation difficult or impossible.
  - Hookah tobacco (which cannot be rolled into cigarettes for smoking).

[Excluding some of these smoked products might be supported or explained by political considerations, an FDA desire to focus, first, on preventing and reducing only cigarette and cigarette-like smoking, or perhaps technical achievability (e.g., if reducing nicotine in bona fide premium cigars would inevitably make them unpalatable to premium cigar smokers). But the focus here is only on whether there are public health reasons for excluding any smoked tobacco products from a nicotine-reduction rule.]

**2. To reduce nicotine availability most effectively, the nicotine-reduction rule should set maximum amounts of nicotine allowed in the subject smoked tobacco products’ tobacco, by weight, and in the product as a whole, and should not allow any nicotine in any of the non-tobacco elements of the products.**

For example: No combustible cigarette subject to this rule shall have an amount of nicotine in excess of X mg/gm in any tobacco-containing filler and shall not have any nicotine in any other component or

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<sup>1</sup> A nicotine-reduction rule that also applied to non-smoked tobacco products could produce larger public health gains. However, to conform with FDA’s stated plans and strategies, this project’s nicotine-reduction rule will consider regulating only cigarettes and other smoked tobacco products – leaving full-nicotine non-smoked tobacco-nicotine products still legally available to smokers and other adult consumers.

part of the cigarette; and no individual cigarette shall contain more than Z mg of nicotine in total. [With parallel limits on other smoked tobacco products subject to the rule.]

- (A) Limiting total amount of available nicotine will make the subject products less physically addictive and less able to satisfy existing nicotine addictions.
  - (B) Will prevent ways of sneaking extra nicotine into the product (e.g., by putting nicotine in the filter or paper or by increasing weight of tobacco).
  - (C) Will avoid loopholes that the industry or users could exploit if only machine-tested nicotine yields were restricted.
  - (D) Will avoid testing and enforcement difficulties if only yields were restricted.
- 3. To further ensure strong nicotine-delivery reductions, the rule should also set a limit on the amount of nicotine a smoked tobacco product may yield to smokers using available testing procedures.**
- (A) Will serve as an extra precaution to prevent possible loopholes or evasion, and will facilitate enforcement (i.e., a tobacco product could be found in violation of rule if FDA determines it either contains excess amounts of nicotine or delivers excess amounts of nicotine).
- 4. To ensure minimum nicotine delivery, the nicotine rule should set the maximum nicotine amounts at the lowest levels that are currently technically achievable using available procedures or technologies – e.g., to 0.4 mg/gm or lower for nicotine content and 0.03 mg or lower for nicotine yields (but without going to zero for yields, which is prohibited by the TCA).**
- (A) Will reduce actual or potential physical addictiveness of the tobacco products as much as reasonably and legally possible.
  - (B) Will make compensation by smokers impossible or as difficult as possible.
  - (C) Will make it more difficult for the subject tobacco products to be redesigned to deliver the remaining nicotine powerfully enough to create or sustain addiction.<sup>2</sup>
  - (D) Setting higher maximum levels does not promote any public health purpose.
- 5. To maximize public health gains, the new nicotine limits should go into effect on an established effective date, and not be gradually phased in through gradual step-by-step reductions over time.**
- (A) Will avoid delaying public health gains.
  - (B) Will prevent compensation by smokers that could occur before the lowest nicotine levels were reached.
  - (C) A more gradual, phased-in implementation would not serve any public health purpose.

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<sup>2</sup> The Tobacco Control Act requirement that any new or substantially changed product must obtain a permissive new product order to enter the market legally will also work to prevent redesigning or restructuring the cigarettes and other smoked tobacco product subject to the nicotine-reduction rule so that they could still create or sustain addiction.