



21 March 2018

(18-1718)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>UNITED STATES OF AMERICA</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Food and Drug Administration (FDA), Health and Human Services (HHS) [1373] Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: Please submit comments to: USA WTO TBT Enquiry Point Email: usatbttep@nist.gov
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Tobacco products; Tobacco and manufactured tobacco substitutes (HS 24). Domestic safety (ICS 13.120), Tobacco, tobacco products and related equipment (ICS 65.160).
5. Title, number of pages and language(s) of the notified document: Tobacco Product Standard for Nicotine Level of Combusted Cigarettes (26 page(s), in English)
6. Description of content: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to obtain information for consideration in developing a tobacco product standard to set the maximum nicotine level for cigarettes. Because tobacco-related harms ultimately result from addiction to the nicotine in such products, causing repeated use and exposure to toxicants, FDA is considering taking this action to reduce the level of nicotine in these products so they are minimally addictive or nonaddictive, using the best available science to determine a level that is appropriate for the protection of the public health. FDA is using the term "nonaddictive" in this document specifically in the context of a potentially nonaddictive cigarette. We acknowledge the highly addictive potential of nicotine itself depending upon the route of delivery. As discussed elsewhere in this document, questions remain with respect to the precise level of nicotine in cigarettes that might render them either minimally addictive or nonaddictive for specific members or segments of the population. We envision the potential circumstance where nicotine levels in cigarettes do not spur or sustain addiction for some portion of potential smokers. This could give addicted users the choice and ability to quit more easily, and it could help to prevent experimenters (mainly youth) from initiating regular use and becoming regular smokers. The scope of products covered by any potential product standard will be one issue for comment in the ANPRM. Any additional scientific data and research relevant to the empirical basis for regulatory decisions related to a nicotine tobacco product standard is another issue for comment in the ANPRM.

7.	Objective and rationale, including the nature of urgent problems where applicable: Prevention of deceptive practices and consumer protection; Protection of human health or safety
8.	Relevant documents: 83 Federal Register (FR) 11818, 16 March 2018; Title 21 Code of Federal Regulations (CFR) Part 1130. Will appear in the Federal Register when adopted.
9.	Proposed date of adoption: To be determined Proposed date of entry into force: To be determined
10.	Final date for comments: 14 June 2018
11.	Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body: https://members.wto.org/crnattachments/2018/TBT/USA/18_1584_00_e.pdf