NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** UNITED STATES OF AMERICA  **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) [2003]  **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: [usatbtep@nist.gov](mailto:usatbtep@nist.gov) |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****X],** **5.7.1 [****], 3.2 [****], 7.2 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Tobacco product manufacturing; Cigars, cheroots, cigarillos and cigarettes of tobacco or of tobacco substitutes (HS code(s): 2402); Product and company certification. Conformity assessment (ICS code(s): 03.120.20); Domestic safety (ICS code(s): 13.120); Tobacco, tobacco products and related equipment (ICS code(s): 65.160) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Requirements for Tobacco Product Manufacturing Practice; (90 page(s), in English) |
| **6.** | **Description of content:** Proposed rule - The Food and Drug Administration (FDA, we, or Agency) is proposing to establish tobacco product manufacturing practice requirements for manufacturers of finished and bulk tobacco products. This proposed rule, if finalized, would set forth the requirements with which finished and bulk tobacco product manufacturers must comply in the manufacture, preproduction design validation, packing, and storage of finished and bulk tobacco products, to assure that the public health is protected and that tobacco products are in compliance with chapter IX of the [Federal Food, Drug, and Cosmetic Act (FD&C Act)](https://www.govinfo.gov/content/pkg/USCODE-2021-title21/html/USCODE-2021-title21-chap9.htm). |
| **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; Quality requirements |
| **8.** | **Relevant documents:**  88 Federal Register (FR) 15174, 10 March 2023; Title 21 Code of Federal Regulations (CFR) Part 1120:  <https://www.govinfo.gov/content/pkg/FR-2023-03-10/html/2023-04591.htm>  <https://www.govinfo.gov/content/pkg/FR-2023-03-10/pdf/2023-04591.pdf>  The Food and Drug Administration (FDA, the Agency, or we) is announcing a [public oral hearing entitled "Proposed Requirements for Tobacco Product Manufacturing Practice."](https://www.govinfo.gov/content/pkg/FR-2023-03-10/html/2023-04592.htm) The [Federal Food, Drug, and Cosmetic Act (FD&C Act)](https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act) authorizes FDA to prescribe current good manufacturing practice (cGMP) or hazard analysis and critical control point methodology (HACCP) regulations related to the manufacture, preproduction design validation, packing, and storage of tobacco products to protect public health and ensure compliance with the FD&C Act. In accordance with this provision, FDA is proposing requirements for tobacco product manufacturing practice (TPMP) elsewhere in this issue of the Federal Register. The FD&C Act further requires FDA to afford an opportunity for an oral hearing on the proposed regulation. We are holding this public oral hearing to carry out this statutory mandate and obtain information and views on the proposed TPMP requirements. The public oral hearing will be held virtually on 12 April 2023, from [9:30 a.m. to 5 p.m.](http://time-time.net/times/time-zones/usa-canada/current-eastern-time-est.php) [Eastern Time](https://24timezones.com/time-zone/et).  <https://www.govinfo.gov/content/pkg/FR-2023-03-10/html/2023-04592.htm>  <https://www.govinfo.gov/content/pkg/FR-2023-03-10/pdf/2023-04592.pdf>  The Food and Drug Administration (FDA) [announces a forthcoming public advisory committee meeting](https://www.govinfo.gov/content/pkg/FR-2023-03-10/html/2023-04593.htm) of the [Tobacco Products Scientific Advisory Committee (TPSAC)](https://www.fda.gov/advisory-committees/committees-and-meeting-materials/tobacco-products-scientific-advisory-committee). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues related to tobacco products. This meeting will be held to discuss and provide an opportunity for recommendations on the [Requirements for Tobacco Product Manufacturing Practice (TPMP)](https://www.fda.gov/news-events/press-announcements/fda-proposes-new-requirements-tobacco-product-manufacturing-practices) proposed rule. The meeting will be open to the public. The meeting will be held on 18 May 2023, from [9 a.m. to 2 p.m.](http://time-time.net/times/time-zones/usa-canada/current-eastern-time-est.php) [Eastern Time](https://24timezones.com/time-zone/et).  <https://www.govinfo.gov/content/pkg/FR-2023-03-10/html/2023-04593.htm>  <https://www.govinfo.gov/content/pkg/FR-2023-03-10/pdf/2023-04593.pdf>  This proposed rule is identified by Docket Number FDA-2013-N-0227. The Docket Folder is available on Regulations.gov at <https://www.regulations.gov/docket/FDA-2013-N-0227/document> and provides access to primary and supporting documents as well as comments received. Documents are also accessible from [Regulations.gov](http://www.regulations.gov/) by searching the Docket Number. WTO Members and their stakeholders are asked to submit comments to the [USA TBT Enquiry Point](mailto:usatbtep@nist.gov). Comments received by the USA TBT Enquiry Point from WTO Members and their stakeholders by [4pm](http://time-time.net/times/time-zones/usa-canada/current-eastern-time-est.php) [Eastern Time](https://24timezones.com/time-zone/et) on 6 September 2023 will be shared with the regulator and will also be submitted to the [Docket](https://www.regulations.gov/docket/FDA-2013-N-0227/document) on Regulations.gov if received within the comment period. |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 6 September 2023 |
| **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/2023/TBT/USA/23_1877_00_e.pdf> |