NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **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) [1968]**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 |
| **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):** Color Additive Certification; Quality (ICS code(s): 03.120); Processes in the food industry (ICS code(s): 67.020) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Color Additive Certification; Increase in Fees for Certification Services; (5 page(s), in English) |
| **6.** | **Description of content:** Proposed rule - The Food and Drug Administration (FDA or we) is proposing to amend the color additive regulation to increase the fee for certification services. The change in fees will allow FDA to continue to maintain an adequate color certification program as required by the [Federal Food, Drug, and Cosmetic Act (FD&C Act)](https://www.govinfo.gov/app/collection/uscode/2020/title21/chapter9). The fees are intended to recover the full costs of operation of FDA's color certification program. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Quality requirements; Cost saving and productivity enhancement |
| **8.** | **Relevant documents:** 87 Federal Register (FR) 66116, 2 November 2022; Title 21 Code of Federal Regulations (CFR) Part 80:<https://www.govinfo.gov/content/pkg/FR-2022-11-02/html/2022-23844.htm><https://www.govinfo.gov/content/pkg/FR-2022-11-02/pdf/2022-23844.pdf>This proposed rule is identified by Docket Number FDA-2022-N-1635. The Docket Folder is available on Regulations.gov at <https://www.regulations.gov/docket/FDA-2022-N-1635/document> and provides access to primary 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 by or before [4pm](http://time-time.net/times/time-zones/usa-canada/current-eastern-time-est.php) [Eastern Time](https://24timezones.com/time-zone/et) on 3 January 2023. Comments received by the USA TBT Enquiry Point from WTO Members and their stakeholders will be shared with the regulator and will also be submitted to the [Docket](https://www.regulations.gov/docket/FDA-2022-N-1635/document) on Regulations.gov if received within the comment period.Color Additive Certification; Increase in Fees for Certification Services; Interim final rule; opportunity for public comment published 29 March 2005:<https://www.govinfo.gov/content/pkg/FR-2005-03-29/html/05-6155.htm><https://www.govinfo.gov/content/pkg/FR-2005-03-29/pdf/05-6155.pdf>Primary and supporting documents available from [Regulations.gov](https://www.regulations.gov/) at <https://www.regulations.gov/docket/FDA-2005-N-0294/document>. |
| **9.** | **Proposed date of adoption:** To be determined**Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 3 January 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/2022/TBT/USA/22_7408_00_e.pdf> |