NOTIFICATION

Revision

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 (Articles 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  Environmental Protection Agency (EPA)  **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 [****], 2.10.1 [****], 5.6.2 [****], 5.7.1 [****], 3.2 [****], 7.2 [****], other****[X]:** EPA is primarily proposing to amend procedural requirements that apply to its activities in carrying out risk evaluations under the Toxic Substances Control Act (TSCA). However, the Agency is also proposing certain amendments to the process and requirements that manufacturers (including importers) would be required to follow when they request an Agency-conducted TSCA risk evaluation on a particular chemical substance. |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Chemical substances; Environment and environmental protection in general (ICS code(s): 13.020.01); Production in the chemical industry (ICS code(s): 71.020); Products of the chemical industry (ICS code(s): 71.100) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (35 pages, in English).; (35 page(s), in English) |
| **6.** | **Description of content:** Proposed rule - The Environmental Protection Agency (EPA, "the Agency") is proposing to amend the procedural framework rule for conducting [risk evaluations](https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca) under the [Toxic Substances Control Act (TSCA)](https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act). The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or non-risk factors, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, under the conditions of use. EPA has reconsidered the procedural framework rule for conducting such risk evaluations and determined that certain aspects of that framework should be revised to better align with applicable court decisions and the statutory text, to reflect the Agency's experience implementing the risk evaluation program following enactment of the 2016 TSCA amendments, and to allow for consideration of future scientific advances in the risk evaluation process without need to further amend the Agency's procedural rule. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; Protection of animal or plant life or health; Protection of the environment |
| **8.** | **Relevant documents:** 88 Federal Register (FR) 74292, 30 October 2023; [Title 40 Code of Federal Regulations (CFR) Part 702](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-R/part-702):  <https://www.govinfo.gov/content/pkg/FR-2023-10-30/html/2023-23428.htm>  <https://www.govinfo.gov/content/pkg/FR-2023-10-30/pdf/2023-23428.pdf>  This proposed rule is identified by Docket Number EPA-HQ-OPPT-2023-0496. The Docket Folder is available on [Regulations.gov](http://www.regulations.gov/) at <https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0496/document> and provides access to primary and supporting documents as well as comments received. Documents are also accessible from 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 14 December 2023 will be shared with the regulator and will also be submitted to the [Docket](https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0496/document) on Regulations.gov if received within the comment period. |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** 14 December 2023 |
| **10.** | **Final date for comments:** 14 December 2023 |
| **11.** | **Texts available from: National enquiry point [****] or address, telephone or fax numbers and email and website addresses, if available, of other body:**  <https://members.wto.org/crnattachments/2023/TBT/USA/23_13256_00_e.pdf> |