NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **1.** | **Notifying Member:** PHILIPPINES  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  DR. OSCAR G. GUTIERREZ, JR., MPA  Officer-in-Charge Director General  Food and Drug Administration  DEPARTMENT OF HEALTH  **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:**  Engr. Ana Trinidad F. Rivera, MSc  Director IV  Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research  DEPARTMENT OF HEALTH  Email: [cchuhsrr@fda.gov.ph](mailto:cchuhsrr@fda.gov.ph); [cchuhsrr-policy@fda.gov.ph](mailto:cchuhsrr-policy@fda.gov.ph)  [www.fda.gov.ph](http://www.fda.gov.ph) |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **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):** Pesticides and other agrochemicals (ICS code(s): 65.100) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Guidelines on the Filing and Submission of Acceptable Variations on Protocols and Novel Protocols for the Review and Pre-Approval by the Food and Drug Administration Prior to the Conduct of Bio-efficacy Test Studies of Household Pesticides for the Purposes of Securing a Certificate of Product Registration; (10 page(s), in English) |
| **6.** | **Description of content:** The proposed issuance aims to improve the regulatory compliance of pesticide registration applications and facilitate the same through the establishment of a pathway for the review and pre-approval of novel and modified bio-efficacy test protocols, which will be submitted in support of pesticide registration under DOH AO No. 2019-0008. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** An assessment of the implementation of Health (DOH) Administrative Order (AO) No. 2019-0008 showed that pesticide registration applications were found to display deficiencies in the submitted bio-efficacy test study which resulted in disapproved applications. Such applications displayed failure to substantiate claims and failure to justify modifications to accepted standards. In order to assist market authorization applicants, promote regulatory compliance, and ensure the efficient use of resources, this Circular hereby establishes the pre-approval process for modified and novel bio-efficacy test protocols.; Protection of human health or safety |
| **8.** | **Relevant documents:**  • Republic Act No. 9711 "Food and Drug Administration (FDA) Act of 2009"  • Department of Health (DOH) Administrative Order (AO) No. 2019-0008, entitled "New Rules and Regulations in the Registration of Household Pesticide Products and their Active Ingredients"  • DOH AO No. 50 s. 2001 "Revised 2001 Schedule of Fees and Charges"  • Republic Act No. 11032 "The Ease of Doing Business and Efficient Government Service Delivery Act of 2018" |
| **9.** | **Proposed date of adoption:** This Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and filing with the University of the Philippines Law Center Office of the National Administrative Register.  **Proposed date of entry into force:** Upon effectivity |
| **10.** | **Final date for comments:** 29 July 2022 |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  Mr. Neil P. Catajay  Director  Bureau of Philippine Standards  Department of Trade and Industry  3F Trade and Industry Building  361 Sen. Gil Puyat Avenue  Makati City  Philippines  Tel: (632) 751 4700; (632) 7913128  Email: [bps@dti.gov.ph](mailto:bps@dti.gov.ph)  Website: <http://www.bps.dti.gov.ph>  <https://www.fda.gov.ph/wp-content/uploads/2022/06/Draft-for-comments-Pre-approval-of-test-protocol.pdf>  <https://members.wto.org/crnattachments/2022/TBT/PHL/22_4520_00_e.pdf> |