NOTIFICATION

|  |  |
| --- | --- |
| **1.** | **Notifying Member:** COLOMBIA  **If applicable, name of local government involved:** |
| **2.** | **Agency responsible:** *Instituto Colombiano Agropecuario*,ICA (Colombian Agricultural Institute) |
| **3.** | **Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):** Homeopathic medicines for veterinary use |
| **4.** | **Regions or countries likely to be affected, to the extent relevant or practicable:**  **[X] All trading partners**  **[ ] Specific regions or countries:** |
| **5.** | **Title of the notified document:** *Proyecto de Resolución del Instituto Colombiano Agropecuario - ICA "Por medio de la cual se establecen los requisitos y el procedimiento para el registro ante el ICA de los medicamentos homeopáticos de uso veterinario y se dictan otras disposiciones"* (Draft Colombian Agricultural Institute (ICA) Resolution establishing the requirements and procedure for the registration with the ICA of homeopathic medicines for veterinary use and adopting other provisions) **Language(s):** Spanish **Number of pages:** 30  <https://members.wto.org/crnattachments/2018/SPS/COL/18_2729_00_s.pdf> |
| **6.** | **Description of content:** The notified draft Resolution establishes the requirements and procedure for the registration with the ICA of homeopathic medicines for veterinary use.  The draft text covers the following: Purpose; Scope; Definitions; Registration of homeopathic medicines for veterinary use; Labelling; Review of registration request; Procedures for issuing registration certificates; Issuance of registration certificates; Amendments to registration; Obligations; Prohibitions; Cancellation of registration; Authorization to import raw materials for the manufacturing of homeopathic medicines for veterinary use exclusively for export; Other provisions; Official control; Penalties; Transitional provision; and Period of validity. |
| **7.** | **Objective and rationale: [ ] food safety, [X] animal health, [ ] plant protection, [ ] protect humans from animal/plant pest or disease, [ ] protect territory from other damage from pests.** |
| **8.** | **Is there a relevant international standard? If so, identify the standard:**  **[ ] Codex Alimentarius Commission *(e.g. title or serial number of Codex standard or related text)*:**  **[ ] World Organisation for Animal Health (OIE) *(e.g. Terrestrial or Aquatic Animal Health Code, chapter number)*:**  **[ ] International Plant Protection Convention (*e.g. ISPM No.*):**  **[X] None**  **Does this proposed regulation conform to the relevant international standard?**  **[ ] Yes [ ] No**  **If no, describe, whenever possible, how and why it deviates from the international standard:** |
| **9.** | **Other relevant documents and language(s) in which these are available:**  *Decreto 1071 de 2015* (Decree No. 1071 of 2015)  *Buenas Prácticas Clínicas establecidas por VICH* (Good clinical practices established by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products - VICH)  (Available in Spanish) |
| **10.** | **Proposed date of adoption *(dd/mm/yy)*:** Date on which the Resolution is signed  **Proposed date of publication *(dd/mm/yy)*:** Date of publication in the Official Journal |
| **11.** | **Proposed date of entry into force: [ ] Six months from date of publication, and/or (*dd/mm/yy*):** Upon publication in the Official Journal  **[ ] Trade facilitating measure** |
| **12.** | **Final date for comments: [X] Sixty days from the date of circulation of the notification and/or (*dd/mm/yy*):** 28 July 2018  **Agency or authority designated to handle comments: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and email address (if available) of other body:**  Ministerio de Comercio, Industria y Turismo  *Dirección de Regulación* (Regulation Department)  Calle 28, N° 13A - 15, tercer piso  Bogotá, D.C. Colombia  Tel.: (+57) 1 606 7676, Ext. 1566/1340  Email: mortizb@mincit.gov.co  mgonzalezs@mincit.gov.co  Website: <http://www.mincit.gov.co/>  *Instituto Colombiano Agropecuario*,ICA (Colombian Agricultural Institute)  *Subgerencia de Regulación Sanitaria y Fitosanitaria* (Sanitary and Phytosanitary Regulation Division)  *Dirección Técnica de Asuntos Internacionales* (Technical Division for International Affairs)  Carrera 41 # 17 - 81, Piso 2 (Zona Industrial - Puente Aranda)  Bogotá, D.C., Colombia  Tel.: (+57) 1 332 3700 Ext. 1510  Fax: (+57) 1 288 4800  Website: <http://www.ica.gov.co/> |
| **13.** | **Text(s) available from: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and email address (if available) of other body:**  Ministerio de Comercio, Industria y Turismo  *Dirección de Regulación* (Regulation Department)  Calle 28, N° 13A - 15, tercer piso  Bogotá, D.C., Colombia  Enquiry point:  Tel.: (+57) 1 606 7676, Ext. 1690  Email: mortizb@mincit.gov.co  Website: http://www.mincit.gov.co/ |