

29 June 2021

(21-5210)

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Committee on Technical Barriers to Trade

Original: Spanish

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

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| 1. | Notifying Member: <u>NICARAGUA</u> If applicable, name of local government involved (Articles 3.2 and 7.2): |
| 2. | Agency responsible: <i>Autoridad Nacional de Regulación Sanitaria, ANRS (National Health Regulation Authority)</i> Complejo Nacional de la Salud Dra. Concepción Palacios Costado Oeste de la Colonia Primero de mayo Tel.: (+505) 22647730-22647630 Ext. 1290; 8930-1048 Email: dqrs@minsa.gob.ni Website: www.minsa.gob.ni 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: |
| 3. | Notified under Article 2.9.2 [], 2.10.1 [], 5.6.2 [], 5.7.1 [], other [X]: General legislation on health and safety |
| 4. | Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): HS: 04, 09, 10, 11, 12, 15, 16, 17, 18, 19, 20, 21, 22, 24, 30; ICS: 11.100.01, 11.120.01, 11.120.10, 11.140, 13.280, 65.160, 67.020, 67.040, 67.060, 67.100, 67.140, 67.160, 67.180, 67.190, 67.200, 67.220, 67.230, 67.250, 67.260 |
| 5. | Title, number of pages and language(s) of the notified document: <i>Ley N°. 1068, Ley Creadora de la Autoridad Nacional de Regulación Sanitaria</i> (Law No. 1068, Law creating the National Health Regulatory Authority) (4 pages, in Spanish) |
| 6. | Description of content: The purpose of the notified Law is to create the National Health Regulatory Authority, as a public entity with legal personality, its own assets and technical and administrative autonomy. The National Health Regulatory Authority is attached to the Ministry of Health and has full capacity to acquire rights and contract obligations concerning matters within its competence, and will be the uninterrupted legal successor of the Directorate-General of Health Regulation, established by Decree No. 25-2006 amending and supplementing Decree No. 71-98, Regulations to Law No. 290, Law on the Organization, Competence and Procedures of the Executive, published in Official Journal, <i>La Gaceta</i> , Nos 91 and 92 of 11 and 12 May 2006, which currently operates as the Directorate-General of Health Regulation in accordance with the institutional organizational chart. This entity will be known by the acronym ANRS and will be domiciled in the city of Managua. The purpose of the ANRS will be to facilitate, regulate, implement, develop and coordinate policies, laws, regulations and standards concerning health authorizations, surveillance, promotion, advertising, control and inspection of: medicines (breast milk and breast milk substitutes), vaccines, biological and biotechnological products; natural homeopathic and |

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| | <p>medicinal products; food and beverages; nutritional supplements; medical devices and other health-related technology; all products relating to ionizing radiation; precursor chemicals; cosmetic and hygiene products; and tobacco and tobacco products. Its purpose will also be to: regulate and control donations, foreign medical brigades, medical and non-medical inputs; and regulate health professional practices, audits on the quality of health care services, establishments providing health services, pharmaceutical and non-pharmaceutical establishments, food establishments, and establishments providing disinfection, structural or housing sanitation services using pesticides, toxic, hazardous and other similar substances; and others that may have an impact on health.</p> |
| 7. | <p>Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety</p> |
| 8. | <p>Relevant documents:</p> <ul style="list-style-type: none"> • <i>Ley N°. 292, Ley de Medicamentos y Farmacias y su Reglamento con sus reformas.</i> • <i>Ley N°. 727, Ley para el Control del Tabaco y su Reglamento.</i> • <i>Ley N°. 774, Ley de Medicina Natural, Terapias Complementarias y Productos Naturales en Nicaragua y su Reglamento.</i> • <i>Ley N°. 156, Ley sobre Radiaciones Ionizantes.</i> • International instruments signed and ratified by the Republic of Nicaragua, which are related to health control and regulation matters. Other laws, regulations and standards falling within its competence. |
| 9. | <p>Proposed date of adoption 22 March 2021</p> <p>Proposed date of entry into force: 24 March 2021</p> |
| 10. | <p>Final date for comments: Not applicable</p> |
| 11. | <p>Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p><i>Ministerio de Fomento, Industria y Comercio</i> (Ministry of Development, Industry and Trade) Dirección de Normalización y Metrología (Directorate of Standardization and Metrology) <i>Centro de Información Sobre obstáculos Técnicos al Comercio</i> (TBT Enquiry Point) Carretera a Masaya, Kilómetro 6, frente a Camino de Oriente. Managua, Nicaragua (+505) 2248 9300, Ext. 1314 or 1310 notificacion@mific.gob.ni; normalizacion@mific.gob.ni; imartinez@mific.gob.ni</p> <p>Autoridad Nacional de Regulación Sanitaria (ANRS) Complejo Nacional de la Salud Dra, Concepción Palacios Costado Oeste de la Colonia Primero de mayo Tel.: (+505) 22647730-22647630 Ext. 1290; 8930-1048 Email: dgrs@minsa.gob.ni</p> <p>Website: www.minsa.gob.ni https://members.wto.org/crnattachments/2021/TBT/NIC/21_4349_00_s.pdf</p> |