



13 February 2023

(23-1008)

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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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| <b>1. Notifying Member:</b> <u>DOMINICAN REPUBLIC</u><br><b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>  |
| <b>2. Agency responsible:</b><br><i>Ministerio de Salud Pública y Asistencia Social</i> (Ministry of Public Health and Social Welfare)<br><b>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:</b><br>Ms Anel Payero González, as Legal Coordinator of the Directorate of Standards, Guides and Protocols of the Ministry of Public Health and Social Welfare<br>Tel.: 809-541-3121 Ext. 4402/4401 and 809-854-9894<br>Email: <a href="mailto:anel.payero@ministeriodesalud.gob.do">anel.payero@ministeriodesalud.gob.do</a> / <a href="mailto:normas@ministeriodesalud.gob.do">normas@ministeriodesalud.gob.do</a> |
| <b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:</b>  |
| <b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Cosmetics.<br>Toiletries (ICS code: 71.100.70)  |
| <b>5. Title, number of pages and language(s) of the notified document:</b> <i>REGLAMENTO TÉCNICO QUE REGULA LA COMERCIALIZACIÓN DE PRODUCTOS COSMÉTICOS, DE HIGIENE PERSONAL Y DEL HOGAR</i> (Technical regulation governing the marketing of cosmetic, personal care and household care products); (62 pages, in Spanish)  |
| <b>6. Description of content:</b><br>1. Introduction<br>2. Ministerial Resolution<br>3. Purpose<br>4. Scope of application<br>5. Legal framework<br>6. General provisions<br>7. Accepted references for the manufacture of cosmetics, personal care and household care products<br>8. Mandatory Sanitary Notification for Cosmetics, Personal Care and Household Care Products<br>9. Obligations of the applicant with respect to the Mandatory Sanitary Notification for cosmetics, personal care and household care products  |

10. Documentation and requirements for the mandatory sanitary notification for cosmetic, personal care and household care products
11. Quality documentation of cosmetics, personal care and household care products
12. Labelling and/or packaging
13. Labelling of products marketed through co-marketing campaigns
14. Other labelling regulations
15. Mandatory Sanitary Notification amendments
16. Documentation and requirements for updating packaging, labels and inserts
17. Documentation and requirements for primary packaging changes
18. Documentation and requirements for changing business name
19. Documentation and requirements for ingredient changes
20. Documentation and requirements for amending the name of the applicant
21. Documentation and requirements for change of co-distributor
22. Documentation and requirements for change of packer
23. Documentation and requirements for change of product specifications
24. Documentation and requirements for change to shelf life
25. Documentation and requirements for amending the name of the representative
26. Documentation and requirements for change of name or trademark
27. Documentation and requirements for the renewal of the mandatory sanitary notification for cosmetics, personal care and household care products
28. Establishment that manufactures and distributes cosmetics, personal care and household care products
29. Registration certificate for establishments that manufacture and distribute cosmetics, personal care and household care products
30. Good practices for the manufacture of cosmetics, personal care and household care products
31. Good manufacturing practices and good storage practices
32. Certificate of good manufacturing practices and Certificate of good storage practices
33. Export of cosmetic, personal care and household care products
34. Documentation and requirements for imports of cosmetic, personal care and household care products
35. Import documentation and requirements for cosmetic, personal care and household care products
36. Documentation and requirements for the import of samples of no commercial value
37. Sanitary control and surveillance of cosmetic, personal care and household care products
38. Sanctions and their enforcement procedures
39. Suspension and cancellation of the mandatory sanitary notification for cosmetics, personal care and household care products
40. Definitive cancellation of the mandatory sanitary notification, in the event that at least one of the following irregularities occurs

**7. Objective and rationale, including the nature of urgent problems where applicable:** Consumer information; Labelling; Prevention of misleading practices;

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| Consumer protection; Protection of human health and safety; Protection of the environment; Quality requirements.  |
| <p><b>8. Relevant documents:</b></p> <p><i>NORDOM 778 Cosméticos. Buenas prácticas de manufactura (BPM)</i></p> <p>ISO 22716 Cosmetics-Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices</p> <p><i>RTCA 71.01.35:06 Productos Cosméticos. Registro e Inscripción Sanitaria de Productos Cosméticos.</i></p> <p><i>RTCA 71.03.36:07 Productos Cosméticos. Etiquetado de Productos Cosméticos.</i></p> <p><i>RTCA 71.03.45:07 Productos Cosméticos. Verificación de la Calidad.</i></p> <p><i>RTCA 71.03.49:08 Productos Cosméticos. Buenas Prácticas de Manufactura para los Laboratorios Fabricantes de Productos Cosméticos.</i></p>   |
| <p><b>9. Proposed date of adoption:</b> This technical regulation is mandated by Decree No. 125-22, Article 4 of which states that the Ministry of Public Health and Social Welfare (MISPAS) shall, by means of a resolution, issue the technical regulation within a period of not more than four months.</p> <p><b>Proposed date of entry into force:</b> Article 7 of the aforementioned Decree proposes a transitional period and gives the Directorate-General of Medicines, Food and Healthcare Products (DIGEMAPS) 90 day to process the applications currently filed and pending sanitary registration for cosmetics, and personal care and household care products; 6 months after its adoption</p>  |
| <p><b>10. Final date for comments:</b> 60 days from notification</p>  |
| <p><b>11. Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b></p> <p><i>Servicio Nacional de Información sobre OTC (National TBT enquiry point)</i><br/> <i>Viceministerio de Comercio Exterior (VICOMEX)</i><br/> <i>Ministerio de Industria, Comercio y Mypimes (MICM)</i><br/> Avenida 27 de Febrero No. 306<br/> Torre MICM<br/> Bella Vista<br/> Tel.: (+1 809)-685-5171<br/> Email: <a href="mailto:rdotc@micm.gob.do">rdotc@micm.gob.do</a><br/> Website: <a href="https://micm.gob.do">https://micm.gob.do</a></p> <p><a href="https://members.wto.org/crnattachments/2023/TBT/DOM/23_0985_00_s.pdf">https://members.wto.org/crnattachments/2023/TBT/DOM/23_0985_00_s.pdf</a><br/> <a href="https://members.wto.org/crnattachments/2023/TBT/DOM/23_0985_01_s.pdf">https://members.wto.org/crnattachments/2023/TBT/DOM/23_0985_01_s.pdf</a></p> |