NOTIFICATION

Addendum

The following communication, dated 20 June 2022, is being circulated at the request of the delegation of Ecuador.

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**Title**: *Proyecto de Normativa Técnica Sanitaria para la aprobación de ensayos clínicos y la certificación de productos de uso y consumo humano y sus establecimientos, durante emergencias sanitarias o situaciones de emergencia, nacionales o internacionales* (Draft Sanitary Technical Regulation for the approval of clinical trials and the certification of products for human use and consumption and their establishments, during health emergencies or national or international emergency situations).

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| **Reason for Addendum:** | |
| [ ] | Comment period changed - date: |
| [ ] | Notified measure adopted - date: |
| [ ] | Notified measure published - date: |
| [X] | Notified measure enters into force - date: 30 May 2022 |
| [ ] | Text of final measure available from[[1]](#footnote-1): |
| [ ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [ ] | Content or scope of notified measure changed and text available from1:  New deadline for comments (if applicable): |
| [ ] | Interpretive guidance issued and text available from1: |
| [X] | Other:  Draft Sanitary Technical Regulation for the approval of clinical trials and the certification of products for human use and consumption and their establishments, during health emergencies or national or international emergency situations.  <https://members.wto.org/crnattachments/2022/TBT/ECU/22_4175_00_s.pdf> |

**Description**: Draft Sanitary Technical Regulation for the approval of clinical trials and the certification of products for human use and consumption and their establishments, during health emergencies or national or international emergency situations.

By means of this Addendum No. 1, the Republic of Ecuador advises that the Sanitary Technical Regulation for the approval of clinical trials and the certification of products for human use and consumption and their establishments, during health emergencies or national or international emergence situations, has been issued pursuant to Resolution ARCSA-DE-2022-008-AKRG of 10 May 2022 by the National Agency for Sanitary Regulation, Control and Surveillance (ARCSA, Doctor Leopoldo Izquieta Pérez), in order to facilitate trade. The notified measure will enter into effect on the date of its publication in the Official Journal (30 May 2022).

Text available from: *Ministerio de Producción, Comercio Exterior, Inversiones y Pesca* (Ministry of Production, Foreign Trade, Investment and Fisheries), *Subsecretaría de Calidad* (Under-Secretariat for Quality), *Organismo Nacional de Notificación* (National Notification Authority)

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1. This information can be provided by including a website address, a PDF attachment, or other information on where the text of the final measure/change to the measure/interpretative guidance can be obtained. [↑](#footnote-ref-1)