



20 September 2024

(24-6504)

Page: 1/2

Committee on Technical Barriers to Trade

Original: Spanish

NOTIFICATION

Addendum

The following communication, dated 20 September 2024, is being circulated at the request of the delegation of Mexico.

Title: *Proyecto de norma oficial mexicana PROY-NOM-059-SSA1-2015, buenas prácticas de fabricación de medicamentos* (Draft Mexican Official Standard PROY-NOM-059-SSA1-2015: Good manufacturing practices for medicinal products)

Reason for Addendum:	
<input type="checkbox"/>	Comment period changed - date:
<input type="checkbox"/>	Notified measure adopted - date:
<input type="checkbox"/>	Notified measure published - date:
<input type="checkbox"/>	Notified measure enters into force - date:
<input type="checkbox"/>	Text of final measure available from ¹ :
<input type="checkbox"/>	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
<input checked="" type="checkbox"/>	Content or scope of notified measure changed and text available from ¹ : https://dof.gob.mx/nota_detalle.php?codigo=5738508&fecha=06/09/2024#gsc.tab=0 Draft amendments to various points of Mexican Official Standard NOM-059-SSA1-2015: Good manufacturing practices for medicinal products, published on 5 February 2016. https://members.wto.org/crnattachments/2024/TBT/MEX/modification/24_06142_00_s.pdf New deadline for comments (if applicable): 60 days from notification
<input type="checkbox"/>	Interpretive guidance issued and text available from ¹ :
<input type="checkbox"/>	Other:

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/interpretive guidance can be obtained.

Description: Mexico hereby advises of the publication of the draft amendments to various points of Mexican Official Standard NOM-059-SSA1-2015: Good manufacturing practices for medicinal products, published on 5 February 2016, which establishes a reliance scheme to optimize the entry process for safe, effective and quality new treatment options for illnesses requiring advanced therapies (mainly biotechnological medicines) such as cancer and diabetes mellitus.
