



13 February 2025

(25-1029)

Page: 1/3

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

Revision

1.	Notifying Member: <u>UKRAINE</u> If applicable, name of local government involved:
2.	Agency responsible: Ministry of Health of Ukraine
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): Biocidal products
4.	Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5.	Title of the notified document: Draft Law of Ukraine "On Making Available on the Market and Use of Biocidal Products". Language(s): Ukrainian. Number of pages: 47 https://moz.gov.ua/uk/povidomlennya-pro-oprilyudnennya-proyektu-zakonu-ukrayini-pro-nadannya-na-rinku-ta-vikoristannya-biocidnih-produktiv https://members.wto.org/crnattachments/2025/SPS/UKR/25_01362_00_x.pdf
6.	Description of content: The draft Law aims to regulate legal relations related to the approval of active substances of biocidal products, state registration, production, market placement, circulation and the safe use of biocidal products and processed products for human and animal health, and the environment. It aims also to define the rights and obligations of enterprises, institutions, organisations and individuals, along with the relevant powers. The draft Law proposes the designation of an authorized body - a state enterprise (institution or organization) - which, empowered by the central executive authority responsible for the formation and implementation of state healthcare policy, will be tasked with evaluating materials for the approval, renewal, or revision of active substances. The body will also prepare expert opinions with proposals for approval or refusal of approval, renewal, or revision of active substances, as well as expert opinions on the possibility of state registration of biocidal products and processed products. Services for evaluation of materials for approval, renewal or revision, state registration, state registration under a simplified procedure or refusal of registration of active substances shall be provided by the authorised body for a fee, in accordance with the agreement between the applicant and the authorised body. The procedure for setting the fee for services provided by the authorized body in evaluating applications for the renewal of approval of active substances shall be approved by the central executive authority responsible for the formation and implementation of state healthcare policy.

	<p>The procedure for authorizing the body, the criteria that the authorized body (state enterprise, institution, or organization) must meet, the term of authorization, as well as the procedure revoking such authorization, will be approved by the Cabinet of Ministers of Ukraine.</p> <p>The draft Law stipulates that services related to the approval of active substances and state registration of biocidal products will be provided on a fee basis.</p> <p>The fee will be calculated based on the minimum living wage for working-age individuals (or the minimum wage), established on the date the service is paid.</p> <p>The draft Law also provides for the establishment of State Register of Biocidal Products, which will begin operating on 1 January 2029, and the transformation (through modernization) of State Register of Disinfectants into State Register of Biocidal Products.</p> <p>The draft Law is developed to implement Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.</p> <p>The draft Law is also notified in accordance with the requirements of the TBT Agreement.</p>
7.	<p>Objective and rationale: <input checked="" type="checkbox"/> food safety, <input checked="" type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests. The adoption of the draft Law will improve the functioning of the domestic market for biocidal products while ensuring a high level of protection of human, animal and environmental health.</p>
8.	<p>Is there a relevant international standard? If so, identify the standard:</p> <p><input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input checked="" type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>
9.	<p>Other relevant documents and language(s) in which these are available: Laws of Ukraine "On the Public Health System", "On Ensuring Chemical Safety and Management of Chemical Products", "On Veterinary Medicine", "On State Control over Compliance with Legislation on Food, Feed, Animal By-products, Animal Health and Welfare" (available in Ukrainian)</p>
10.	<p>Proposed date of adoption (dd/mm/yy): To be determined.</p> <p>Proposed date of publication (dd/mm/yy): To be determined.</p>
11.	<p>Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): This Law will enter into force on the day following the day of its publication and will be enacted 36 months after its entry into force, except for the 12 paragraph of part 10 of Article 22 and Article 40 of this Law, which shall enter into force on 1 January 2029.</p> <p><input type="checkbox"/> Trade facilitating measure</p>

12. Final date for comments: ☒ **Sixty days from the date of circulation of the notification and/or (dd/mm/yy):** 14 April 2025

Agency or authority designated to handle comments: ☒ **National Notification Authority, ☒ National Enquiry Point. Address, fax number and e-mail address (if available) of other body:**

Ministry of Economy of Ukraine
Department for Trade Agreements and Export Development
12/2 Hrushevskoho Str.
Kyiv, 01008
Tel: +(38 044) 596 6839
Fax: +(38 044) 596 6839
E-mail: ep@me.gov.ua
Website: <https://www.me.gov.ua>

13. Text(s) available from: ☒ **National Notification Authority, ☒ National Enquiry Point. Address, fax number and e-mail address (if available) of other body:**

Ministry of Economy of Ukraine
Department for Trade Agreements and Export Development
12/2 Hrushevskoho Str.
Kyiv, 01008
Tel: +(38 044) 596 6839
Fax: +(38 044) 596 6839
E-mail: ep@me.gov.ua
Website: <https://www.me.gov.ua>