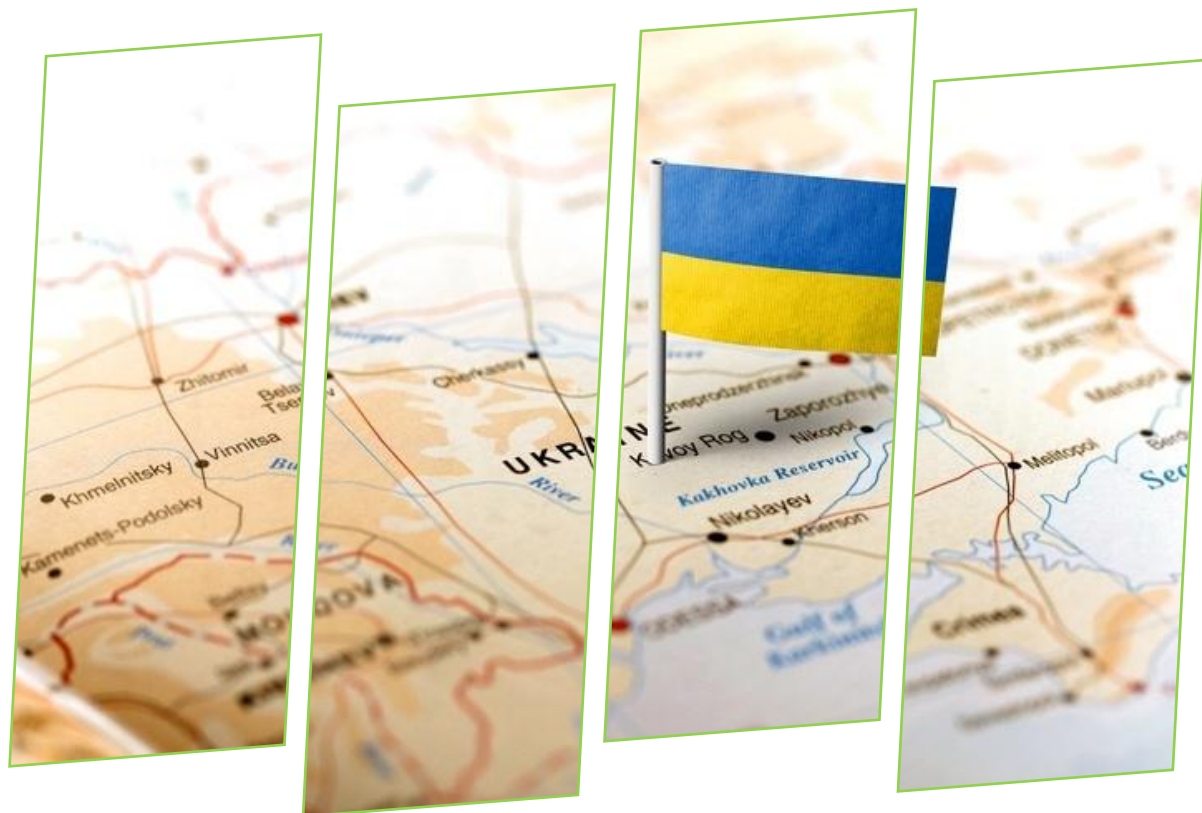




Approved by Resolution No. 847

Technical Regulations on the Safety of Chemical Products (Ukraine REACH)

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APPROVED

by a resolution of the Cabinet of Ministers of Ukraine

No. 847 of July 23, 2024

TECHNICAL REGULATIONS on the Safety of Chemical Products

Chapter 1. General part

Purpose, scope and application

1. The purpose of the Technical Regulation on the Safety of Chemical Products (hereinafter referred to as the Technical Regulation) is to ensure a high level of protection of human health and the environment, free circulation of chemical products, promotion of alternative methods of chemical hazard assessment and innovation while increasing competitiveness, and to define requirements for chemical safety during the production, market placement and use of chemicals, including in mixtures and products.

This Technical Regulation is based on Regulation (EU) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EEC and 2000/21/EC.

2. This Technical Regulation applies to chemical products that are imported, placed on the market or manufactured in Ukraine.

3. Chemical products may not be made available on the Ukrainian market if they do not meet the requirements of this Technical Regulation.

4. This Technical Regulation is based on the principle that manufacturers, importers and downstream users must ensure that they produce, place on the market or use chemicals that do not adversely affect human health or the environment. The provisions of the Technical Regulation are based on the principle of prevention.

5. The requirements of this Technical Regulation do not apply to:

- 1) radioactive substances;
 - 2) chemical products that are under customs control when they are temporarily stored in free customs zones or warehouses for the purpose of re-export or transit and are not processed or treated;
 - 3) non-isolated intermediates;
 - 4) transportation of dangerous goods by air, sea, road, rail or inland waterways.
6. Waste is not considered a chemical product or article.

7. In some cases, the requirements of this Technical Regulation may not be applied to chemical products by decision of the Ministry of Environment, if it is necessary in the interests of state defense.

8. The requirements set forth in Chapters 2, 5 and 6 of this Technical Regulation do not apply in cases where the chemical substance is used in the composition or for production of:

- 1) medicinal product;
- 2) veterinary medicinal product;
- 3) food products, including flavors and food additives;
- 4) feed, including feed ingredients and feed additives.

9. The requirements set out in Chapter 4 of this Technical Regulation do not apply to chemical products in the following forms in a finished state intended for use by the final user:

- 1) medicines;

- 2) veterinary medicines;
- 3) cosmetic products;
- 4) invasive medical devices, as well as medical devices whose use involves direct physical contact with the human body;
- 5) food products, including flavors and food additives;
- 6) feed, including feed ingredients and feed additives;
- 7) tobacco products and nicotine-containing products.

10. The requirements set forth in Chapters 2, 5 and 6 of this Technical Regulation do not apply to the following chemical products:

- 1) chemicals listed in Annex IV to this Technical Regulation, as the available information indicates that these chemicals pose a minimal risk;
- 2) chemical substances that are listed or meet the definitions in Annex V to this Technical Regulation, since their registration is considered inappropriate or unnecessary;
- 3) chemical substances, including as part of other chemical products, which were registered in accordance with this Technical Regulation, exported from Ukraine and then re-imported to Ukraine by any participant in the supply chain, provided that evidence is provided that the exported chemical substance is identical to the re-imported one, as well as that the importer was provided with information on the exported chemical substance in accordance with Articles 167, 170, 171 and 180 of this Technical Regulations;

4) chemical substances, including as part of other chemical products, which were registered in accordance with this Technical Regulation and then recovered in the territory of Ukraine, provided that the chemical substance resulting from the recovery process is identical to the chemical substance registered in accordance with Chapter 2 of this Technical Regulation, and information in accordance with Articles 167, 170, 171 and 180 of this Technical Regulation was provided to the business entity that recovers the chemical substance.

11. The requirements set out in Articles 17-64, except for Articles 28-39 of Chapter 2, as well as the provisions of Chapter 7 of this Technical Regulation, do not apply to on-site isolated intermediate and transported isolated intermediate.

12. The requirements set forth in Chapter 2 and Chapter 6 of this Technical Regulation do not apply to polymers.

Definition

13. For the purposes of this Technical Regulation, the following terms shall have the following meanings:

identified use - means a use of a substance on its own or in a mixture, or a use of a mixture, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;

article - means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

producer - means a business entity that produces, uses and provides chemical products on the market;

producer of an article - means a business entity that manufactures or assembles an article in Ukraine;

on-site isolated intermediate - means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an) other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;

transported isolated intermediate - means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;

existing chemical substance - means a chemical substance that was made available on the Ukrainian market before the entry into force of this Technical Regulation or that is listed in the State Register of Chemical Substances;

use and exposure category - means an exposure scenario covering a wide range of processes or uses, where