

25 - 26.10.2023 | DAY 2
Chemical Regulations and
Sustainability Symposium 2023



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Ukraine Chemical legislation

Ukraine REACH & CLP

Ukraine Chemical Legislation

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Duration: 20 min

1. UKRAINE CHEMICAL SAFETY LEGISLATION

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Ukraine chemicals safety legislation

The Law on Chemical Safety

- **THE LAW OF UKRAINE “On ensuring chemical safety and management of chemical products”**
 - Identifier: 2804-IX or 2804-20
 - Approved on December 1, 2022, by Verkhovna Rada of Ukraine
 - Implementation will take place on the 29th of June 2024 (**TBD**)
- **Background:** *The Chemical Safety Law serves as a foundational framework, reflecting Ukraine's aspirations towards European integration. The Law represents a novel regulatory domain for Ukraine.*

Ukraine chemicals safety legislation

The Law on Chemical Safety: Objectives

- Establish a EU-like national chemical management system
- *Adopt foundational EU REACH and CLP regulations**
- Integrate international hazardous chemical classifications
- Develop a unified database for hazardous chemicals
- Enhance market management of chemical products based on risk and threat assessments
- Implement restrictions on products with carcinogens, mutagens, bioaccumulative and environmentally hazardous substances
- Grant Ukrainians access to information on substance and product hazards

**The Law On Chemical Safety lays the groundwork for a national chemical management system, harmonizing with the European framework and setting the stage for the integration of core technical regulations - REACH and CLP*

Ukraine chemicals safety legislation

Ukraine CLP draft

- **Draft Resolution of the Cabinet of Ministers of Ukraine "On Approval of the Technical Regulation on Hazard Classification, Labeling and Packaging of Chemical Products"** submitted to the WTO on the 20th April 2023
 - **Purpose:** to approve the Technical Regulation on Hazard Classification, Labeling and Packaging of Chemical Products, which fully harmonizes the legislation of Ukraine in the relevant area with EU legislation (Regulation No. 1272/2008) and international UN standards (GHS system).
 - **Proposed EiF:** 9th July 2023 (didn't happen)
- **Competent authority:** Ministry of Environmental Protection and Natural Resources of Ukraine

Ukraine chemicals safety legislation

Ukraine CLP Draft Annexes

- ANNEX I Classification And Labelling Requirements For Hazardous Substances And Mixtures
- ANNEX II Special Rules For Labelling And Packaging Of Certain Substances And Mixtures
- ANNEX III List Of Hazard Statements, Supplemental Hazard Information And Supplemental Label Elements
- ANNEX IV List Of Precautionary Statements
- ANNEX V Hazard Pictograms
- ANNEX VI Harmonised classification and labelling for certain hazardous substances
- ANNEX VII Harmonised information relating to emergency health response and preventative measures*

**EU CLP Annex VII “Translation table from classification under Directive 67/548/EEC to classification under this Regulation” hasn’t been included in the Ukraine CLP Draft*

Ukraine chemicals safety legislation

Ukraine REACH draft

- **Draft Resolution of the Cabinet of Ministers of Ukraine "On Approval of the Technical Regulation on Safety of Chemical Products"** submitted to the WTO on the 20th September 2023 (until 19th November 2023)
 - **Purpose:** the technical regulation fully harmonizes the legislation of Ukraine in the relevant field with EU legislation (EU Regulation No. 1907/2006).
 - **Proposed EiF:** to be determined
- **Competent authority:** Ministry of Environmental Protection and Natural Resources of Ukraine

Ukraine chemicals safety legislation

Ukraine REACH Draft Annexes

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- ANNEX I General Provisions For Assessing Substances And Preparing Chemical Safety Reports
- ANNEX II Requirements For The Compilation Of Safety Data Sheets
- ANNEX III Criteria For Substances Registered In Quantities Between 1 And 10 Tonnes
- ANNEX IV Exemptions From The Obligation To Register In Accordance With Article 10(1)
- ANNEX V Exemptions From The Obligation To Register In Accordance With Article 10(2)
- ANNEX VI Information Requirements Referred To In Article 10
- ANNEX VII Standard Information Requirements For Substances Manufactured Or Imported In Quantities Of One Tonne Or More
- ANNEX VIII Standard Information Requirements For Substances Manufactured Or Imported In Quantities Of 10 Tonnes Or More
- ANNEX IX Standard Information Requirements For Substances Manufactured Or Imported In Quantities Of 100 Tonnes Or More

- ANNEX X Standard Information Requirements For Substances Manufactured Or Imported In Quantities Of 1 000 Tonnes Or More
- ANNEX XI General Rules For Adaptation Of The Standard Testing Regime Set Out In Annexes VII To X
- ANNEX XII General Provisions For Downstream Users To Assess Substances And Prepare Chemical Safety Reports
- ANNEX XIII Criteria For The Identification Of Persistent, Bioaccumulative And Toxic Substances, And Very Persistent And Very Bioaccumulative Substances
- ANNEX XIV List Of Substances Subject Which Are Being Withdrawn From The Market
- ANNEX XV Dossiers
- ANNEX XVI Socio-Economic Analysis
- ANNEX XVII Restrictions On The Manufacture, Placing On The Market And Use Of Certain Dangerous Substances, Mixtures And Articles Which Present An Uncontrollable Risk To Human Health And/Or The Environment That Cannot Be Controlled
- **ANNEX XVIII Correspondence Table**

Ukraine chemicals safety legislation

Ukraine REACH vs. EU REACH

**APPENDIX XVIII of the DRAFT UKRAINE REACH REGULATION
contains a correspondence table between the provisions of EU
REACH and Ukraine REACH**

1. UKRAINE CHEMICAL SAFETY LEGISLATION

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Ukraine REACH Draft

Substances Within the Scope of Ukraine REACH

All substances, unless specifically exempted, are within the scope of the Ukraine REACH Regulation

Ukraine REACH Draft

Basic Requirements

- Basic Ukraine REACH requirements:

Pre-register and **Register** substances manufactured in or imported into Ukraine at **1 t/a or more**

- Same as the EU REACH Regulation → ***“No Data, No Market”*** (Art. 17)

Ukraine REACH Draft

OR - Same Requirements as in the EU REACH

- Ukraine REACH provides the possibility for non-Ukrainian manufacturers and formulators to assign an **Only Representative to take care of the Ukraine REACH importer obligations**
 - Pre-Registration & Registration
 - PPORD notification
 - Inquiry
 - Authorisation
- **Only Representation defined in Ukraine REACH Article 28-30**
- **The Only Representative “*shall have sufficient background in the practical handling of substances and the information related to them*”**

Ukraine REACH Draft

Pre-Registration

- The **deadline** for Pre-Registering substances is **one year from the EiF date of Ukraine REACH**
 - *Ukraine REACH Art. 142: one-year transitional period to benefit from the deferred registration deadlines*
- Substances placed on the Ukrainian market for the first time after the pre-registration deadline can be **late-pre-registered**
 - *Ukraine REACH Art. 145: within six months of the date of first manufacture or import of an existing chemical*

Ukraine REACH Draft

Registration of the EU Registered Substances

- **Art. 26-27 specify simplified procedure of state registration for substances registered according to the EU REACH**
- The application for simplified registration shall contain
 - A technical dossier
 - A copy of the Chemical Safety Report as an annex to the dossier, where required
 - Confirmation of the registration by an applicant or its only representative in the EU (OR) through the REACH-IT system of the European Chemicals Agency.

**What does simplified registration mean in terms of joint submission?
What kind of rights to use the data are required for simplified registration?**

Ukraine REACH Draft

Registration deadlines

Draft Decree On the approval of the Technical Regulation on the safety of chemical products

- Registration over 1000 t - by 1st June 2025
- Registration 100-1000 t - by 1st June 2026
- Registration 1-100 t - by 1st June 2027

Ukraine REACH Draft

Authority fees for registration

- Registration fee is calculated based on subsistence minimum on the day of the submission (2 684 hryvnia in 2023 = 70 EUR) multiplied by the applicable coefficients
- Example registration fee for full registration for a large size company for over 1000t/y member of joint submission:

$$\text{AUTHORITY FEE} = 2\,684 * 50 * 1 * 0,5 * 1 = 268\,400 \text{ hryvnia} = \text{ca. } 7\,000 \text{ EUR}$$
- Example registration fee for EU-REACH registered substance for a large size company for over 1000t/y member of joint submission:

$$\text{AUTHORITY FEE} = 2\,684 * 50 * 1 * 0,5 * 1 = 67\,100 \text{ hryvnia} = \text{ca. } 1\,750 \text{ EUR}$$

Criteria	Coefficient
Tonnage band	1 - 10 tons per year - 2.5 10 – 100 tons per year - 5 100 – 1000 tons per year - 25 1000 tons per year or more - 50
Submission type	Individual - 2 Joint - 1 EU registered – 0.5
Type of registration	Full - 2 Intermediate – 0.5 EU registered – 0.5
Company size	Micro - 0.25 Small - 0.5 Medium - 0,75 Large - 1

1. UKRAINE CHEMICAL SAFETY LEGISLATION

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Conclusions

To be determined

- The Law On Chemical Safety lays the groundwork for a national chemical management system, harmonizing with the European framework
- The EiF dates of REACH and CLP - **TBD**
- A specially established central executive authority in the field of chemical safety similar to the European Chemicals Agency - **TBD**
- Practicalities of REACH and CLP compliance - **TBD**
 - Simplified procedures for EU compliant chemicals?
 - IT solution?
 - Lead registration nominations ...
 - Development of guidances, helpdesk service etc. ...
- National support for the local manufacturers (funding?) - **TBD**
 - Existing data costs might be too expensive for the local industry

Thank You for Your Attention!

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