Ukraine Chemical legislation
Ukraine REACH & CLP

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

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Duration: 20 min
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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 20\textsuperscript{th} April 2023

- \textbf{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).

- \textbf{Proposed EiF:} 9\textsuperscript{th} July 2023 (didn’t happen)

- \textbf{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

- 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
Ukraine chemicals safety legislation

Ukraine REACH Draft Annexes

- 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
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

2. UKRAINE REACH

3. CONCLUSIONS
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:
  
  \[
  \text{AUTHORITY FEE} = 2\,684 \times 50 \times 1 \times 0.5 \times 1 = 268\,400 \text{ hryvnia} = \text{ca. 7 000 EUR}
  \]

- Example registration fee for EU-REACH registered substance for a large size company for over 1000t/y member of joint submission:
  
  \[
  \text{AUTHORITY FEE} = 2\,684 \times 50 \times 1 \times 0.5 \times 1 = 67\,100 \text{ hryvnia} = \text{ca. 1 750 EUR}
  \]

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1. UKRAINE CHEMICAL SAFETY LEGISLATION

2. UKRAINE REACH

3. CONCLUSIONS
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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