



***Chemicals Strategy for
Sustainability from the
perspective of the
Competent Authority for
REACH and CLP***

Jana Balejčíková

***Ministry of Economy of the
Slovak Republic
Centre for Chemical
Substances and Preparations***

May 5th 2021

- **The European Green Deal – New growth Strategy**
- **Chemicals Strategy for Sustainability - Towards a Toxic-free Environment**
- **Action Plan for achieving Strategy goals in relation to REACH & CLP regulations**
- **REACH & CLP Authorities & the Strategy actions**

The European Green Deal – New growth strategy



Setting 2030 long-term vision

produce / use of safe & sustainable chemicals in a way that better protect people and environment and avoid harm to the planet and to current and future generations while strengthening the competitiveness of the EU's chemicals industry



Five building blocks

Innovation,
competitiveness,
recovery

Strengthen
legislation for
better protection

Simplification &
coherence

Knowledge and
science

Global

Action Plan for achieving of the Strategy goals

- The Commission published ambitious Strategy + Action Plan/Annex in October 2020
- Strategy is complementary to the European industrial strategy, the recovery plan for Europe, the Circular Economy action plan, and other EU Green Deal strategies and initiatives such as the Pharmaceuticals strategy, the Hydrogen strategy and the Batteries initiative etc.
- After two-months of quite intensive discussions on WPE → the European Council expressed a political position on the Strategy and approved its conclusions on 15 March 2021
- Action Plan consists of more than 30 actions which concern several pieces of legislation (including REACH & CLP, also other sectoral legislation on biocides, toys, cosmetics, etc.)

The Council conclusions on the Strategy actions

- ask the Commission to implement the actions laid down in the strategy & targeted amendments to streamline EU chemicals legislation
- to substitute and minimize substances of concern and phase out the most harmful chemicals for non-essential societal uses
- to ban the most harmful chemicals in consumer products such as cosmetics, toys, detergents, childcare items etc.
- highlight the importance of limiting exposure to endocrine disruptors
- to reduce harmful effects of chemical mixtures
- to phase-out hazardous chemicals that affect vulnerable groups
- shift focus onto *"safe and sustainable-by-design"* approach; support for this *life-cycle approach* - aims to boost innovation and sustainability in the chemicals sector
- endorse the EU taking a leading role at the global stage

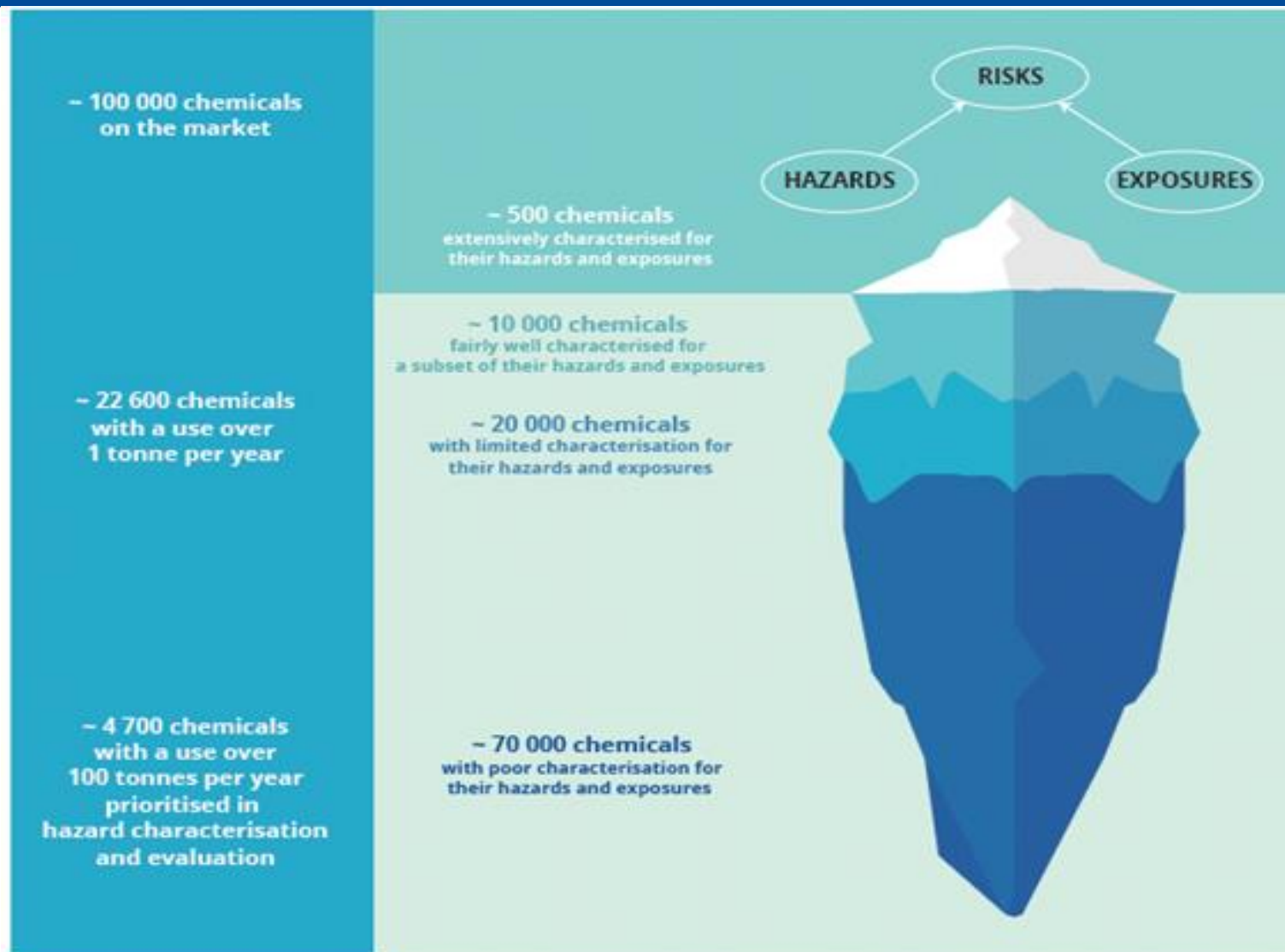
Action Plan for achieving of the Strategy goals

ACTION PLAN

The measures presented in this action plan, , including legislative proposals and targeted amendments to REACH, will all need to be carried out in line with the better regulation principles and subject to evaluations and impact assessments as appropriate.

Key actions to be taken by the Commission	EU legislation	Indicative timing
Set up a high level roundtable with the purpose of promoting efficiency and effectiveness of chemicals legislation, boosting development and uptake of innovative safe and sustainable chemicals, and monitoring the impact of the Strategy's actions.		2021
Innovating for safe and sustainable EU chemicals		
Develop EU safe and sustainable-by-design criteria for chemicals		2022
Establish an EU-wide safe and sustainable-by-design support network		2023
Financial support for the development, commercialisation, deployment and uptake of safe and sustainable-by-design substances, materials and products		As of 2021
Mapping safe and sustainable-by-design skills mismatches and competence gaps, and make recommendations		

Action Plan for achieving of the Strategy goals



Registration & communication

- registration of polymers of concern
- request more information on use and exposure
- request more information on critical hazard properties (carcinogenicity, ED etc.)
- request Chemical Safety Assessment for substances 1-10 tpa
- introduce a Mixture Assessment Factor
- introduce a DMEL for non-threshold substances with a dose-response relationship
- revise requirements for supply chain communication and eSDS

Evaluation

- perform compliance check of all registration dossiers
- improve procedures for filling of data gap including by group assessment
- streamline substance evaluation procedure
- establish a mechanism for EU and national authorities to commission testing and monitoring of substances
- allow revocation of registration numbers

Authorisation & Restrictions

- reform of authorization & restriction processes
- extend definition of Substances of Very High Concern acc. Art. 57 for EDs (without ELoC), PMT/vPvM → general reference to CLP classifications
- extend the use of the Generic Approach for Risk Management (Art. 68(2) on consumer products) for → EDs, PBT/vPvBs (first); immunotoxicants, neurotoxicants, respiratory sensitisers, STOTs (later)
 - ✓ extend to products for professional use
 - ✓ exempt essential uses (concept will be defined first)

Supporting actions/studies planned by Commission

- Studies on → EDs (starting), Mixtures Assessment Factor (call for tender), increased hazard information requirements, environmental footprint, use and exposure, DMEL for non-threshold substances (incl. acceptable level of risk), essential uses
- Studies on (?) → improvement of evaluation procedures, extended use of Generic Risk Approach, streamlining authorisation & restriction processes, European Audit Capacity

Indicative timing of actions

- Publishing Inception Impact Assessment (roadmap) → 4 May 2021, 4 weeks stakeholder consultation
- Supporting actions and studies, Impact Assessment → until mid of 2022
- Public stakeholder consultation for 12 weeks is planned in all EU languages → starting in December 2021
- Drafting proposal for revision of REACH → in 2022
- Commission adoption supposed → at end of 2022
- Founding regulation on ECHA (securing long-term funding) → planned for 2023

Harmonised Classification

- Inclusion of a mandate for Commission to request ECHA to initiate, prepare & submit proposal for CLH dossier
- Prioritisation mechanism for substances subject to HCL & mediation possibility for EU level
- Inclusion of an additional opportunity for commenting during the HCL procedure
- Harmonisation of human health (HH) & environment (ENV) based safety values (e. g. DNEL, PNEC)

Actions for achieving of the Strategy goals related to CLP revision

New Hazard classes

- ED for HH and for the ENV with a categorisation system for both
- PBT/vPvB on the basis of REACH Annex XIII criteria and potentially a categorisation system
- PMT/vPvM and potentially a categorisation system

New criteria

- Assessment of the added value to use toxicity data obtained on terrestrial organisms in the classification criteria for the ENV
- Assessment of the need for specific criteria for immunotoxicity and neurotoxicity (currently covered under 'Specific target organ toxicity' and 'reproductive toxicity') and their amendment (if necessary)

Other actions

- Assessment of the need to limit the labelling derogation for some products (e.g. cosmetics)
- Inclusion of the obligation for distributors to notify to the poison centers their mixtures classified for physical or HH hazards and the obligation of duty holders to notify substances
- Obligation to periodically update CLP inventory
- Clarification of how to apply the bridging principles for classification
- Clarification of responsibility for compliance for online sales
- Possibility of adapting labelling requirements for mixtures supplied in certain forms (e.g. in bulk, small containers)

Indicative timing of actions

- Publishing Inception Impact Assessment (roadmap) → May - June 2021 (will be published this week); 4 weeks stakeholder consultation
- Public stakeholder consultation for 12 weeks is planned in all EU languages → starting in June of 2021
- Supporting actions & Impact Assessment of legislative proposals → until the end of 2021
- Commission adoption of CLP changes supposed → beginning of 2022
- At UN GHS level → planned to address the specific actions identified in the Action Plan over the course of next 2 years

REACH & CLP Authorities & the Strategy actions

- As public authority → took part in public consultation in the preparatory phase of the Strategy in June 2020
- In cooperation with Ministry of Environment and Slovak Trade Inspection → Ministry of Economy provided Preliminary Opinion on the Strategy in November 2020
- Participation in discussions on WPE (January – March 2021) in the process of the European Council's political approval of the Strategy conclusions
- For CARACAL meeting → provided opinion on the Strategy actions at its early stage of discussion

REACH & CLP Authorities & the Strategy actions

SK comment to AP 4.1 document on Chemicals Strategy for Sustainability (REACH related actions)

SK CA would like to thank the Commission for presenting the EU Chemical strategy for Sustainability. We appreciate the possibility to comment on this very ambitious framework at its early stage.

We welcome the idea of the simplification and strengthening of the legal framework for regulation of chemicals. Regarding that, we support establishing a simpler 'one substance - one assessment' approach for the hazard and risk assessment of chemicals. It will require coordination of EU activities with the activities taking place at the global level (e.g. within the OECD). Better coordination and harmonization of the chemical safety assessment procedures carried out by various EU agencies, scientific committees or expert groups is desirable to ensure the consistency of ongoing work and to avoid its duplication.

We believe that a thorough impact assessments are needed when preparing new legislative proposals, therefore a possible revision of REACH need to be targeted and in line with the findings and proposed actions identified in the second REACH Review. In the process of regulation of chemicals, we consider as very important to identify the most appropriate regulatory management option as well as to consider its proportionality and impact at a very early stage of the process.

Moreover, developing a coordinated approach on combination effects of chemicals reflecting the latest scientific understanding, improving and updating registration data and enhancing regulatory management process into a more systematic and predictable one are all vital for a proper regulatory management of chemicals.

REACH & CLP Authorities & the Strategy actions

- support the main goals of the quite ambitious Strategy
- consider as a basis for the long-term framework for a development of safe and sustainable chemicals while contributing to innovation and competitiveness of the EU industry
- support strengthening of regulation of PFAS and the adoption of the most effective measures to minimize releases of PFAS; define the essential uses concept & address PFAS in a group approach concept
- support strengthening of the legislation for EDs, PBT/vPvB and PMT/vPvM substances → we appreciate discussions on hazard classes/criteria in CLP at the UN GHS level to ensure compliance with the GHS principles

REACH & CLP Authorities & the Strategy actions

- developing a coordinated approach on combination effects of chemicals requires → improving/updating registration data and enhancing regulatory management process into a more systematic and predictable one
- support establishing 'OS- QA' approach for the better coordination and harmonisation of the chemical safety assessment procedures carried out by various EU agencies, scientific committees → to ensure the consistency and avoid duplication of work
- welcome the idea of the simplification and strengthening of the legal framework for regulation of chemicals
- legislative proposals for REACH/CLP revisions → needed to be carried out in line with better regulations principles; appropriate impact assessment & evaluation needed

More discussions and clarifications needed at advanced expert level; timeframe proposed → quite challenging and tight

- Discussions have begun and are continuing at various levels → most relevant for REACH & CLP authorities - CARACAL and its subgroups, expert groups e.g. PBT EG, Helpnet, Forum etc.
- All information on the consultations (REACH & CLP) will be sent to CARACAL and REACH committee
- Discussions going beyond REACH & CLP authorities will take place → EC formal EG for 'OS-OA' approach, discussions on essential use concept, etc.
- High-level Roundtable discussions on the Strategy → to realise the objectives and to monitor its implementation in dialogue with the stakeholders (industry including SMEs, science and the civil society); first meeting will take place on 5 May 2021

Chemicals Strategy for Sustainability - Towards a Toxic-free Environment

https://ec.europa.eu/environment/strategy/chemicals-strategy_en

<https://www.consilium.europa.eu/en/press/press-releases/2021/03/15/council-approves-conclusions-on-the-eu-chemicals-strategy-for-sustainability/>

<https://www.echa.europa.eu/-/safer-chemicals-conference>

<https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/84998de9-01ff-4434-b566-85367d2fae5b>

<https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Revision-of-EU-legislation-on-registration-evaluation-authorisation-and-restriction-of-chemicals->



Thank you for your attention!

contact & information

email: chemicals@mhsr.sk

www.economy.gov.sk