The EU Chemicals Strategy for Sustainability

ATIEL Technical Seminar
30 November 2023

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#ChemicalsStrategy
#EUGreenDeal

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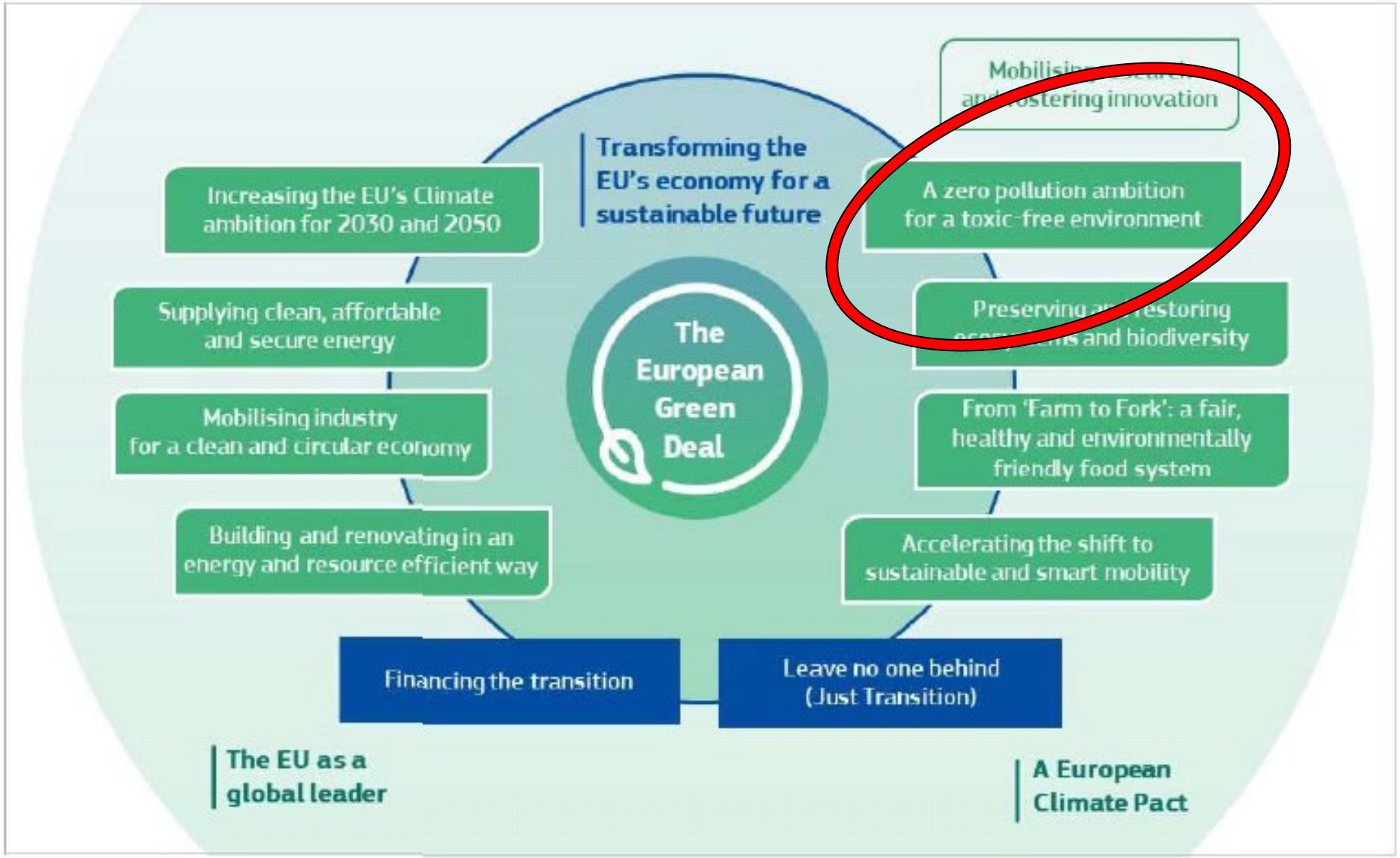
The European Green Deal



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Chemicals Strategy for Sustainability (October 2020):

Five building blocks

Innovation, competitiveness, recovery

Strengthen legislation for better protection

Simplification & coherence

Knowledge and science

Global

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Chemicals Strategy for Sustainability

Over 80 actions, including:

- boosting production and use of **safe and sustainable by design** chemicals;
- "***one substance one assessment***" for risk and hazard assessment of chemicals;
- **banning most harmful chemicals** in consumer and professional products (unless essential);
- **global role** by promoting high standards
- **targeted revisions** of legislation, including **REACH and CLP**, subject to comprehensive **impact assessments**

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Chemicals Strategy for Sustainability

Important milestones:

- Recommendation on design and assessment of chemicals and materials as **safe and sustainable**: adopted on 8 December 2022
- "***one substance one assessment***" :
  - Extension of (P)ACT
  - New expert group created
  - Preparatory work ongoing for:
    - Regulation on data transparency
    - "Omnibus" regulation to reattribute tasks
    - New Basic Regulation for European Chemicals Agency (ECHA)
- **High Level Roundtable:**
  - Meetings on **enforcement, safe and sustainable chemicals; transition pathway**
- **Transition Pathway** for the Chemicals Industry: published on 27 January 2023
  - focus on transition to climate neutral and digital economy but also making the link to chemical safety and implementation of revised REACH regulation

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CLP revision

- Adding **new hazard classes** on endocrine disruptors, PBT/vPvB/PMT/vPvM in CLP
- Clarify **rules for mixtures and complex substances**
- Addressing **online sales**
- Simplified **labelling**

⇨***New hazard classes** adopted on 22 December 2022 (“comitology” procedure)*

⇨*Remaining issues currently discussed in **Council and European Parliament***

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REACH revision

- Announced in **Chemicals Strategy for Sustainability**
- Commission decided **not to present a proposal** at the end of its mandate
- Further steps will have to be decided by the **new Commission** upon its nomination

The following slides present the state of discussions under the current Commission, which may change under the next Commission.

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REACH revision

- To address the following **problems**:
  - Significant **unaddressed risks** for health and the environment from chemicals (e.g. endocrine disruptors, persistent substances)
  - REACH **regulatory processes** and decision-making are **not efficient enough**
  - **Insufficient compliance** with REACH requirements

Tackling unadressed risks

- Adapt information requirements
- Notification of all polymers and registration of polymers requiring registration (PRR)
- Mixture Allocation Factor (MAF)
- Definitions: intermediates, nanomaterials
- Evaluation: various changes, including cancellation of registration numbers in case of persistent incompliance
- Safe Data Sheets need to be provided electronically

Reforming regulatory processes

- Extending Generic Approach to Risk Management (GRA)
- Simplifying authorisation and restriction processes
- Introducing the essential use concept

Generic Risk Management Approach (GRA)

- Extension of existing **empowerment** under REACH Art 68(2) to introduce hazard based restrictions by comitology
  - **New hazard classes**: endocrine disruptors, PBT/vPvB substances, immunotoxicants, neurotoxicants, respiratory sensitisers and substances with specific organ toxicity
  - Extended scope: consumer and **professional uses**
  - Derogations for **essential uses**

Reform of Authorisation and Restrictions

- Earlier information on use, exposure and alternatives
- Simplify REACH autorisation and restrictions
  - By allowing the Commission to upfront exclude essential uses from scope of authorisation requirement
  - Limiting applicant by applicant authorisation
  - Strengthen the role of substitution plans

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Implement the essential use concept

- Derogations from generic restrictions only for essential uses
- Additional/complementary criterion to existing criteria for derogations from specific restrictions and Annex XIV obligations
- Simplification for clearly essential and clearly non-essential uses through upfront scope exclusions/not allowing derogations resp.
- Details on other uses to be further discussed/decided

Study on substitution planning

Problem to be addressed:

- In certain complex uses **some actors can substitute** a substance while **others cannot**, because:
  - **Exact use patterns** and quality requirements differ
  - **Testing and scaling up** of production of alternatives take time
  - **Legal requirements** (e.g. airworthiness approval for airplanes; authorisation for medicines) may take time and prevent earlier substitution

⇨*It is **not feasible to regulate all details** per company (see failure of REACH authorisation)*

⇨ *It **does not make sense to wait** with phasing out until all users can substitute*

Study on substitution planning

Envisaged tool:

- Derogations from restrictions taking into account substitution plans
- Taking inspiration from transition pathways

Objectives:

- More flexible and decentralized decisions on details; better investment planning
- Foster co-operation between users of substances and alternative providers
- Investment certainty to both users of the substance and alternative providers
- Trigger innovation for alternatives while avoiding disruptive bans for essential uses
- Create a win/win situation for health, environment and competitiveness

Timelines for work on substitution planning

- Commission study starting in **January 2024 (12 months)**
- Two **stakeholder workshops** in 2024
  - First workshop on **1 March 2024**
- **Pilot project** starting later in 2024

⇨*May feed into the REACH revision (tbd)*

Strengthen Enforcement

- **Audit** of national enforcement systems
- Facilitate action by **customs authorities** and giving a mandate to OLAF to pursue fraud
- Clarifying responsibilities for sales through **online-platforms**
- Better **access to justice**

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