

Chemicals under the EU Green Deal



Daniel Torán

**Regulatory Advisor
Global Product Compliance (GPC)**

daniel@eu.gpcregulatory.com

Table of contents

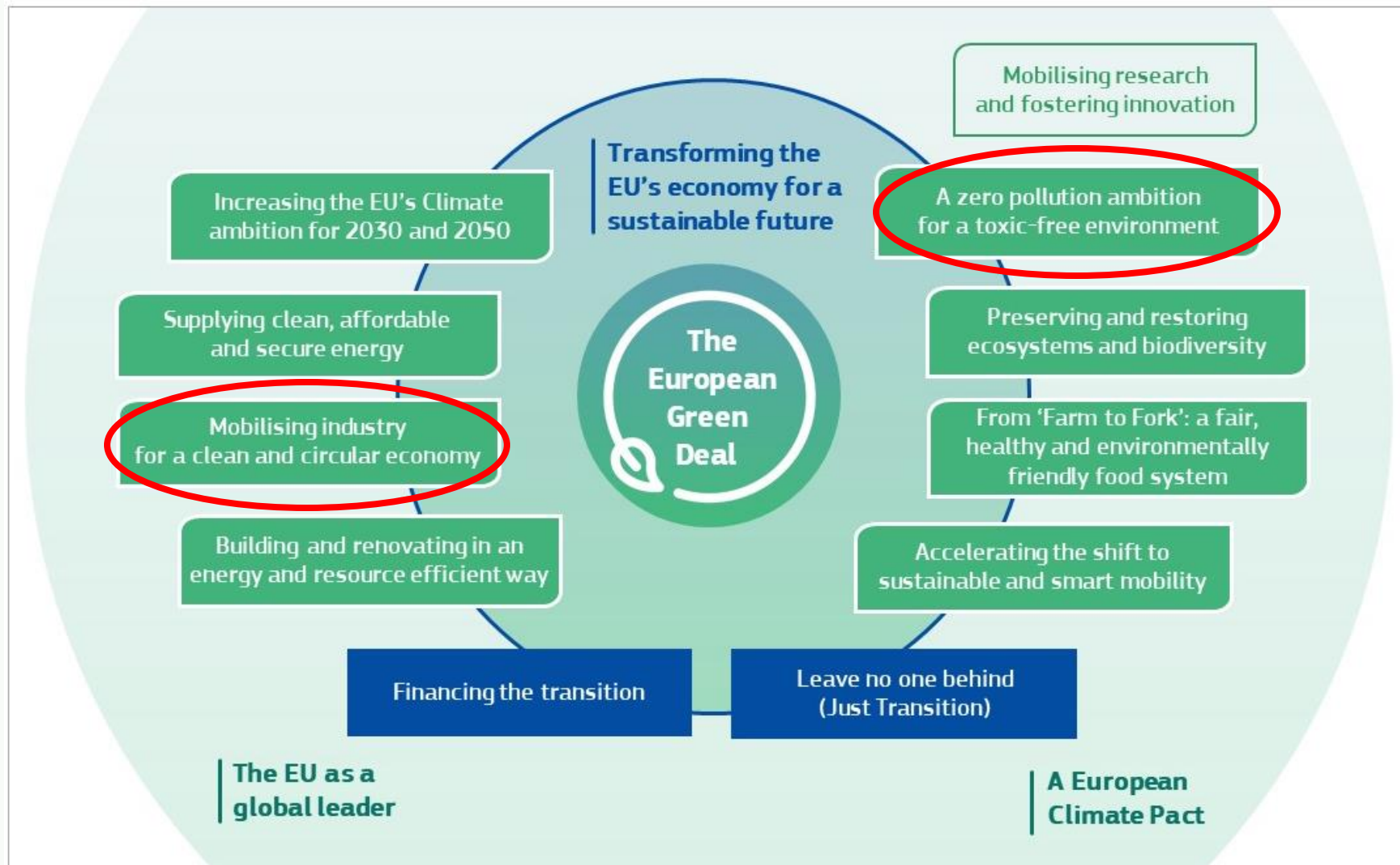
- The European Green Deal
- Chemicals Strategy for Sustainability
 - Regulatory and legislative action
 - REACH Revision
 - CLP Revision
 - PFAS Restriction
 - Non-regulatory action
- Other initiatives
 - Sectoral chemical legislation
 - General product legislation
- Business preparation



General Framework

European Green Deal and
Chemicals Strategy for
Sustainability

The European Green Deal



Chemicals Strategy for Sustainability





Regulatory and Legislative Action

**CLP Revision
REACH Revision
PFAS Restriction**

Revision of the CLP Regulation

Problem	Proposed Solution
Incomplete information about hazards to human health and the environment	Introduction of new hazard classes (PBTs/vPvB)
	Assessing the need for specific neurotoxicity and immunotoxicity criteria
	Expansion of CLP scope (new products covered)
	Clarifications of the rules on mixture classifications

Revision of the REACH Regulation

Shortcomings	Proposed Solution
Knowledge gaps	Revision of registration requirements (content and scope)
Lacking compliance on information requirements	Revisions of provisions for dossier and substance evaluation
Lack of supply-chain communication	Improvement of safety data sheets (harmonized electronic formats)
Lack of assessment of the risk from unintentional mixtures	Introduction of a Mixtures Assessment Factor in the substance assessment
Slow and inflexible authorisation procedure	Clarifying, removing or merging with restriction
Restriction procedure: too slow and case-by-case; evaluation too complex	Extension of generic risk approach beyond CRM Essential use criteria (including for derogations)

PFAS Restriction

- Currently, some specific restrictions on PFAS

PFOS	POPs Regulation Annex I (Stockholm Convention on POPs)	In force
PFOA	POPs Regulation Annex I (Stockholm Convention on POPs)	In force
Restriction on C9-14 PFCAs	REACH Annex XVII (Restriction)	Entry into force: February 2023
PFHxA	REACH Annex XVII (Restriction)	Supported by ECHA Committees
PFHxS	REACH Annex XVII (Restriction)	Supported by ECHA Committees

PFAS Restriction

- Two upcoming restrictions

PFAS in Fire Fighting Foams	REACH Annex XVII (Restriction) ECHA at the request of the EC	Annex XV Report open for comments (Deadline: September 2022)
All PFAS	REACH Annex XVII (Restriction) (DE, DK, NL, NO, SE)	Dossier not submitted yet (Expected: January 2023)



Non-regulatory action

Essential Use Criteria
Safe and Sustainable by Design

Safe and Sustainable by Design Criteria (1/2)

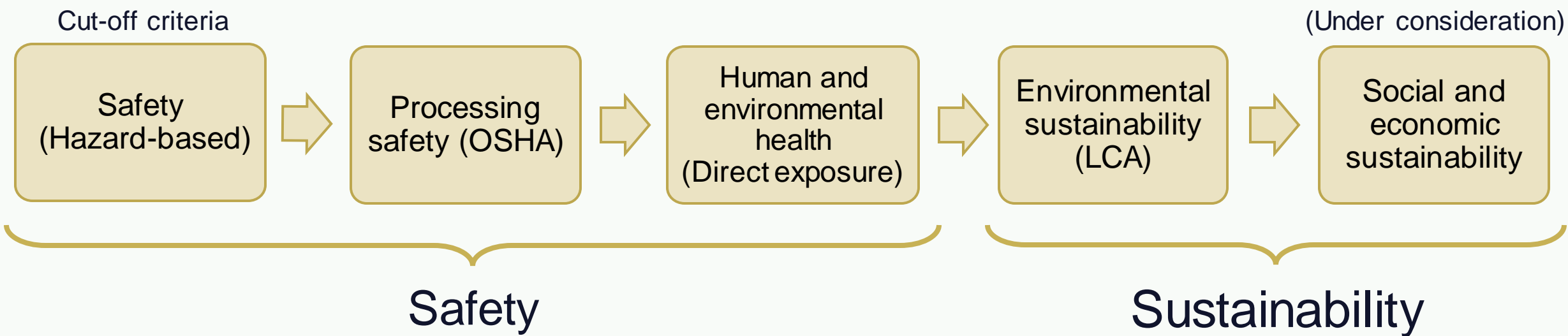
- Preliminary definition in the Chemicals Strategy for Sustainability:

“[A] pre-market approach to chemicals that focuses on providing a function (or service), while **avoiding volumes and chemical properties that may be harmful** to human health or the environment, in particular groups of chemicals likely to be (eco) toxic, persistent, bio-accumulative or mobile.

Overall sustainability should be ensured by **minimising the environmental footprint** of chemicals in particular on climate change, resource use, ecosystems and biodiversity from a **lifecycle perspective.**”

Safe and Sustainable by Design Criteria (2/2)

- Current operationalization:



Essential Use Criteria

Under the Strategy, provision to develop essential use criteria:

“[D]efine criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is **necessary for health, safety or is critical for the functioning of society** and if there are **no alternatives** that are acceptable from the standpoint of environment and health.

These criteria will guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments”



Other initiatives

Sectoral Chemicals Legislation
General Product Legislation

Sectoral Chemical Legislation

Piece of legislation	Main changes
Toy Safety Directive	<ul style="list-style-type: none">• Extension of generic risk management (including limit values for all toys and a revision of current derogations for CMRs)• Integration of limit values from other legislation and setting out positive lists• Conversion into a Regulation
Cosmetic Products Regulation	<ul style="list-style-type: none">• Extension of generic risk management beyond CMRs• Revision of the definition of nanomaterials• Labelling changes
Food Contact Materials	<ul style="list-style-type: none">• Shift from positive lists of components to requirements for final materials (including GMP)• Prioritisation of the assessment of substances• Possible development of a new regulatory framework

Ecodesign Regulation Proposal (1/2)

- Part of the Circular Economy Action Plan
- Framework Regulation, expanding Ecodesign to all products
- Objectives:
 - Improving the sustainability of products
 - Establishing uniform conditions for market access
 - Boosting information exchange along supply chains
- Means – Delegated acts:
 - Setting of performance requirements
 - Setting of information requirements

Ecodesign Regulation Proposal (2/2)

- Criteria that may be used to establish requirements (“Product parameters”) include the presence of substances of concern for reasons beyond chemical safety.
- These are defined in relation to:
 - REACH and CLP (Current and upcoming hazard categories)
 - Effects on re-use and recycling



Business Preparation

Summary – Legislation Tracker

Initiative	Status	Timeline
REACH	Consultation closed (15 April)	Draft expected in Q4 2022
CLP	Consultation closed (15 November 2021)	Draft expected Q4 2022
Toy Safety Directive	Consultation closed (25 May 2022)	Draft expected Q4 2022
Cosmetics Products Regulation	Consultation closed (21 June 2022)	Draft expected Q4 2022
Food Contact Materials legislation	Public consultation in Q2 of 2022	Draft expected in Q2 2023
Ecodesign Regulation	Commission draft presented (30.03)	Parliament and Council negotiations
PFA restriction (REACH)	Preparation of restriction dossier (SE, NO, DK, DE, NL)	Submission expected for 13.01.2023 (As per restrictions roadmap)
Safe and Sustainable by Design criteria	Discussions ongoing. Mapping study and workshop on methodology completed.	Q3 Workshop on case-study criteria Q4 Publication of framework and criteria for case-studies
Essential use criteria	Discussions ongoing (not public)	Unknown

Preparing for upcoming changes

- Improving compliance with existing regulations
- Keeping track of ongoing discussions and proposals
- Working towards substitution of hazardous substances

Conclusions

- Regulation development is still in its early stages, but is evolving rapidly
- There is high pressure to phase out the most hazardous chemicals
- There are important opportunities for manufacturers who can meet rising demand for more sustainable chemicals