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For:

Ministry for the Environment
Government of Japan
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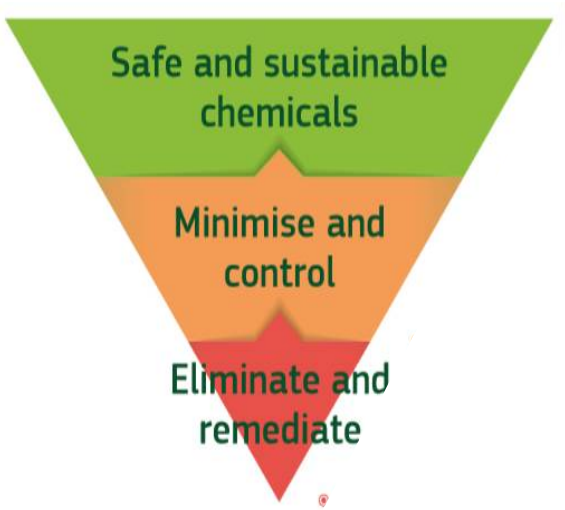
Latest progress in EU new chemicals strategy

#ChemicalsStrategy
#EUGreenDeal

European Commission

2030 vision – towards a toxic-free environment



- Chemicals are produced/used in a way that **maximises their benefits to society** while **avoiding harm to planet & people**
- **Production and use of *safe and sustainable chemicals*** becomes the EU market norm and a global standard

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TOXIC-FREE ENVIRONMENT: 5 building blocks

Innovation, competitiveness, recovery

Strengthen legislation for better protection

Simplification & coherence

Knowledge and science

Global

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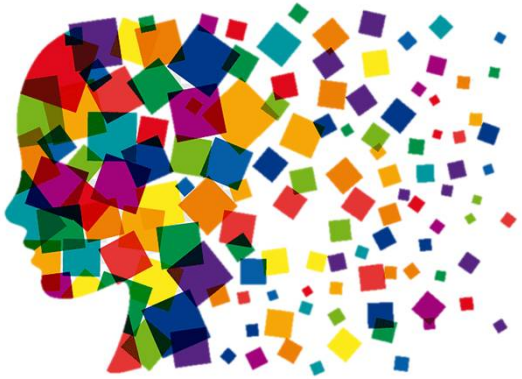
1. Boosting innovation

Promote the transition to safe and sustainable chemicals, materials and products

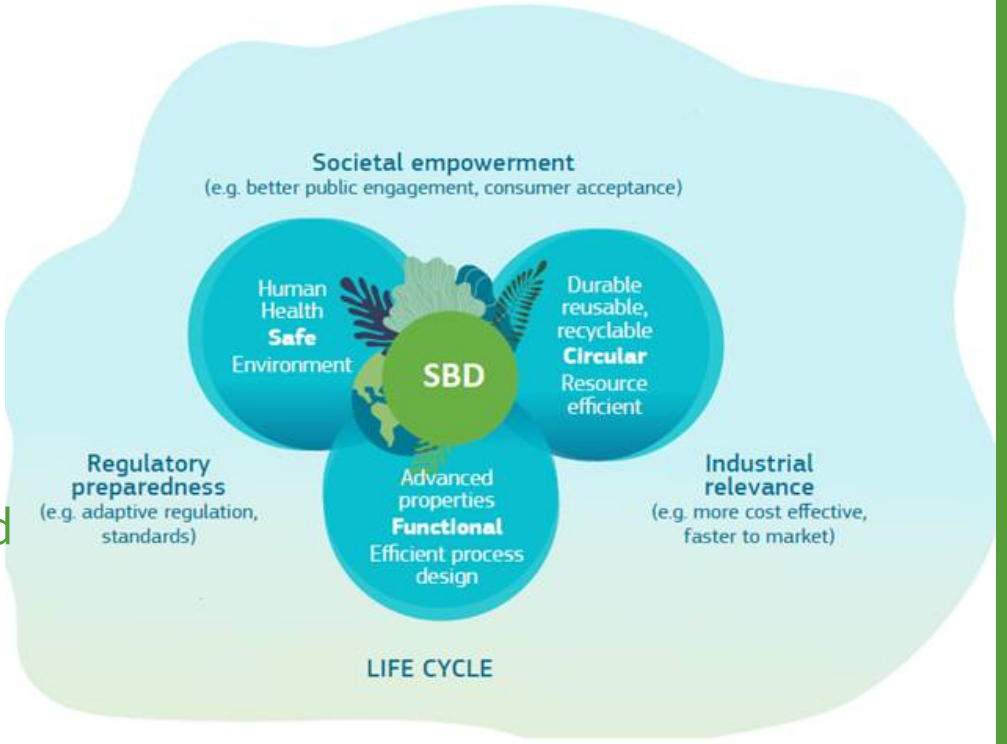


- New chemicals and materials inherently safe and sustainable
- Green transition of chemical sector
- Promoting EU open strategic autonomy for critical chemicals – technologies for climate neutrality

Safe and sustainable-by-design

An approach to the **design, development and use of substances, materials and/or products** that focuses on:

- providing a function (or service)
- while preventing harmful impacts to human health and environment throughout their lifecycle (from raw material to final disposal)



Innovation - main actions

- **Develop** EU safe and sustainable-by-design **criteria**
- EU-wide support **network**
- **Provide EU funding** for the green and digital transition of the production/use of chemicals (Horizon Europe, recovery instruments, cohesion funds, Life)
- Strengthen EU's open **strategic autonomy** for critical chemicals
- Address **skills and competence** gaps
- Establish **key performance indicators** measuring industrial transition
- **Industrial emissions legislation** to promote use of safer chemicals

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Sustainable Products Regulation

- Revises Ecodesign Directive
- Make products on EU market more sustainable
- Addresses harmful chemicals in
  - electronics & ICT equipment, textiles, furniture, steel, cement
- Information requirements and tracking of substances of concern

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2. Strengthening legislation

- **All chemicals** on the market to be used safely and sustainably.
- Substitute and minimise as far as possible **substances of concern**
- Avoid the **most harmful chemicals** in consumer products esp. for vulnerable groups

Endocrine disruptors | **PFAS** | **Mixtures** | **Environmental impact**

New hazard classes | **Concept of 'essential uses'**

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Essential uses – the concept

- The Commission will :
  - define **criteria for essential uses (2021-2022)** 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
    - there are no alternatives that are acceptable from the standpoint of environment and health

- **Criteria** will:
  - guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments
  - take into account the definition of essential uses in the Montreal Protocol on Substances that Deplete the Ozone Layer

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Essential uses – the process

- **Study and consultation** with stakeholders/experts (workshop 3 March 2022)
  - Mapping of relevant legislation (incl. and beyond REACH)
  - Definition of criteria
  - Policy options

  Feeding into:

  ➢ REACH revision (Impact Assessment) and implementation

  ➢ Revision/implementation of other legislation (e.g. Toys Directive, Cosmetics Regulation)

Endocrine disruptors

- CLP Regulation (Classification, Labelling and Packaging of chemicals): new hazard class
- Definition based on WHO criteria; criteria in pesticides and biocides regulations; applicable to all EU chemicals legislation
- REACH registration: more information requirements on critical hazard properties (carcinogenicity, endocrine disruption etc.) to ensure hazard identification and risk assessment
- REACH (art. 57) include endocrine disruptors in the definition of substances of very high concern
- REACH (art. 68.2) include endocrine disruptors in the generic risk approach (substances to be avoided in consumer products)

PFAS

- Persistent chemicals that accumulate in humans, animals and the environment
- Toxic particularly for children's development
- Accumulate in bodies exceeding "tolerable weekly intake" of safe limits, due intake from food and drinking water (EFSA 2020)
- Costs to society from PFAS exposure high (52 to 84 billion EUR Nordic Council of Ministers 2019)
- Pollutes ecosystems and generates costs for remediation of soil and water.
- Main sources of contamination from production and use: for example from fluoropolymer production installations
- PFAS group includes 4 700 substances
- Wide variety of use: consumer products, industrial applications, pesticides and pharmaceuticals
- Limited information about which PFAS are used in which applications and at what levels in Europe

REACH and PFAS

- Group restriction
- Preparatory work for a group restriction on all uses of PFAS (except essential uses): 4 Member States + Norway
  - https://echa.europa.eu/-/restriction-of-per-and-polyfluoroalkyl-substances-pfas-under-reach
- PFAS in fire-fighting foams
- More information ECHA hot topics page
  - https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas

Mixtures – combination effects of chemicals

- Unintentional exposure to a combination of substances can lead to adverse effects on people and the environment.
- REACH: single substance safety information – co-exposure with other substances not taken into account
- A mixtures assessment factor (MAF) is a pragmatic approach to manage the unknown
  - To ensure a level of protection against unintended mixture effects like for a single substance chemical safety assessment.

Environmental impact

Focus on addressing **chemicals that pose risks for the environment**

- New hazard classes in CLP (addressing environmental toxicity, persistency, mobility and bio-accumulation)
- Ensure authorities have sufficient information for environmental risk assessments: stricter information requirements across legislation
- Address the impact of production and use of pharmaceuticals
- Support research and development for decontamination technologies
- Reinforce regulation of chemical contaminants in food

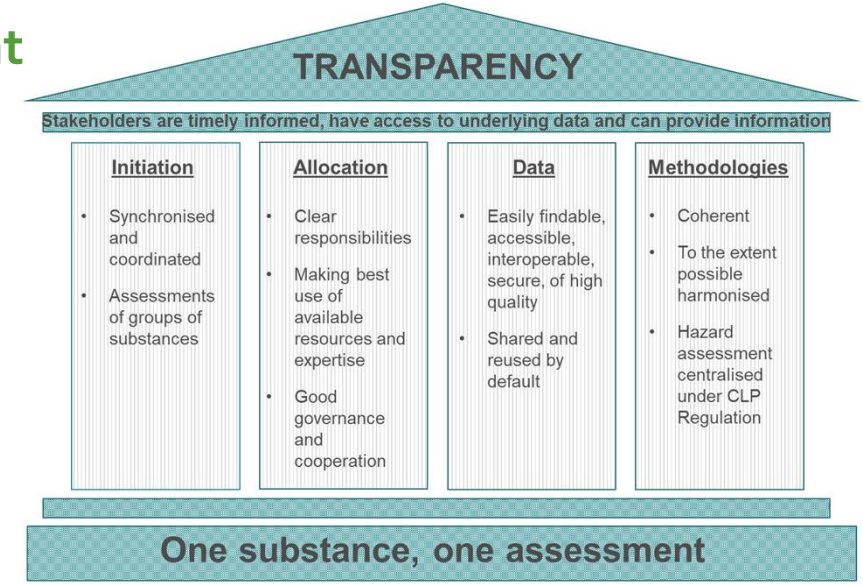
New Hazard classes

- Endocrine Disruptors
- Persistent Bioaccumulative and Toxic (PBT) and very Persistent and very Bioaccumulative (vPvB)
  - (categorisation system)
- Persistent Mobile and Toxic (PMT) and very Persistent and very Mobile (vPvM)
  - (categorisation system)

3. Simplifying and consolidating

- Strengthen **compliance, enforcement and market surveillance** ('zero tolerance to non compliance')

- **'One substance, one assessment'** process to make safety assessment processes
  - simpler and more transparent
  - faster as well as more consistent and predictable



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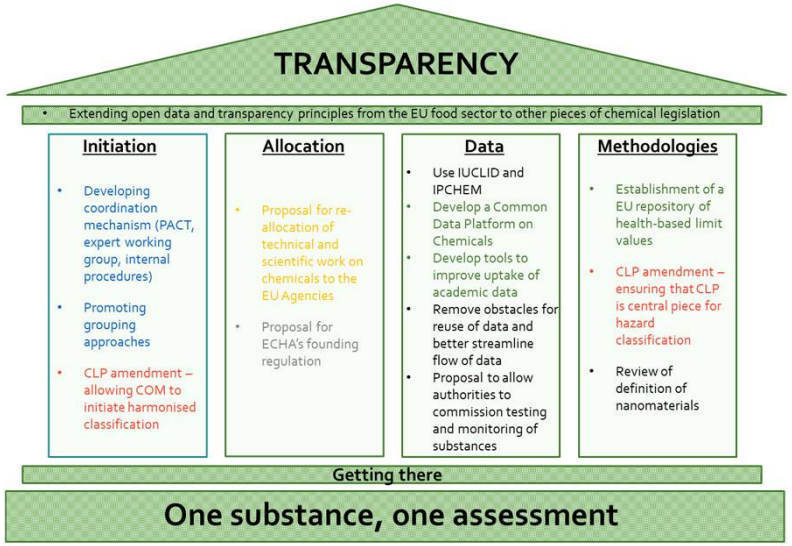
One substance one assessment

	Initiation	Allocation	Data	Methodologies
Today	• Plethora of legislation • European Commission, Member States, Industry • At different times	• Agency • Expert Group • Scientific Committee • Consultant	• Availability • Formats • Access • Quality	• Guidelines • Guidance
Tomorrow	• Synchronised and coordinated • Assessments of groups of substances	• Clear responsibilities • Making best use of available resources and expertise • Good governance and cooperation	• Easy to find, access, operate between different systems, secure, high quality • Shared and reused by default	• Coherent • Harmonised as much as possible • Hazard assessment centralised under CLP Regulation

Organisation of work – one substance one assessment



- Developing coordination mechanism (extension of ACT/PACT and expert working group)
- CLP Revision
- **Horizontal legislative proposal for reallocation of technical and scientific work to Agencies**
- Proposal for ECHA's founding regulation
- **Data, tools and platforms**
- **Horizontal legislative proposal on data flows**

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4. A comprehensive knowledge base

- Establish a **EU research & innovation agenda** for chemicals, incl. to promote innovative testing and (Bio)-monitoring

- Improve **knowledge on chemical properties and uses**
  - by requiring more information (polymers, environmental footprint, low volumes, for specific hazard properties)
  - by tracking substances on concerns in products/materials

5. Setting the example globally

- **Global strategic objectives and targets** beyond 2020
- Promote the use of the **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)** and propose new hazard classes
- Sound management of chemicals **in international cooperation**
- Chemicals **banned in the EU not for export**

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High Level Roundtable

- Industry
- Non-governmental organisations
- Universities, researchers
- Member States (represented by EU presidency)
- International organisations (UN, OECD, WHO)
- 32 members
- **Role: help European Commission implement the chemicals strategy for sustainability; act as ambassador for the strategy.**
- Discussion topics: enforcement, research and innovation, global dimension….

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