

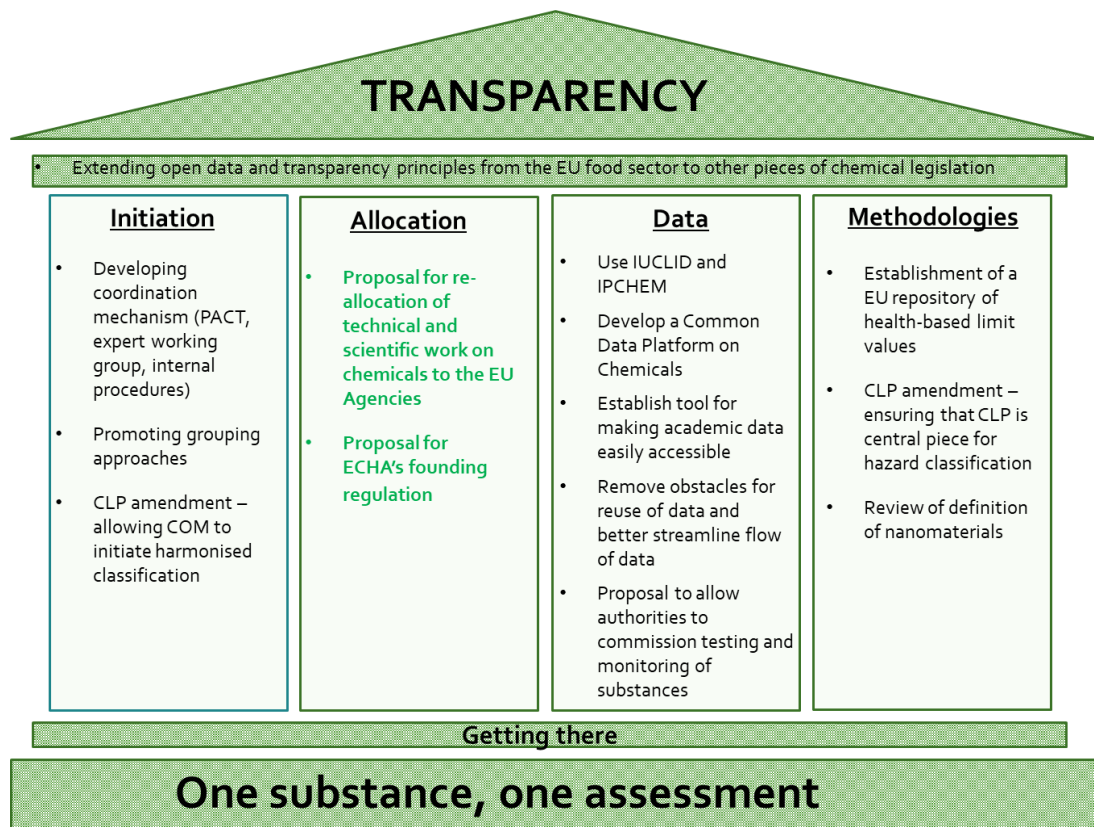


# Information session for stakeholders and citizens on one substance, one assessment

(Re-)attribution of technical and scientific work on chemicals to the  
EU agencies

*1 June 2022*

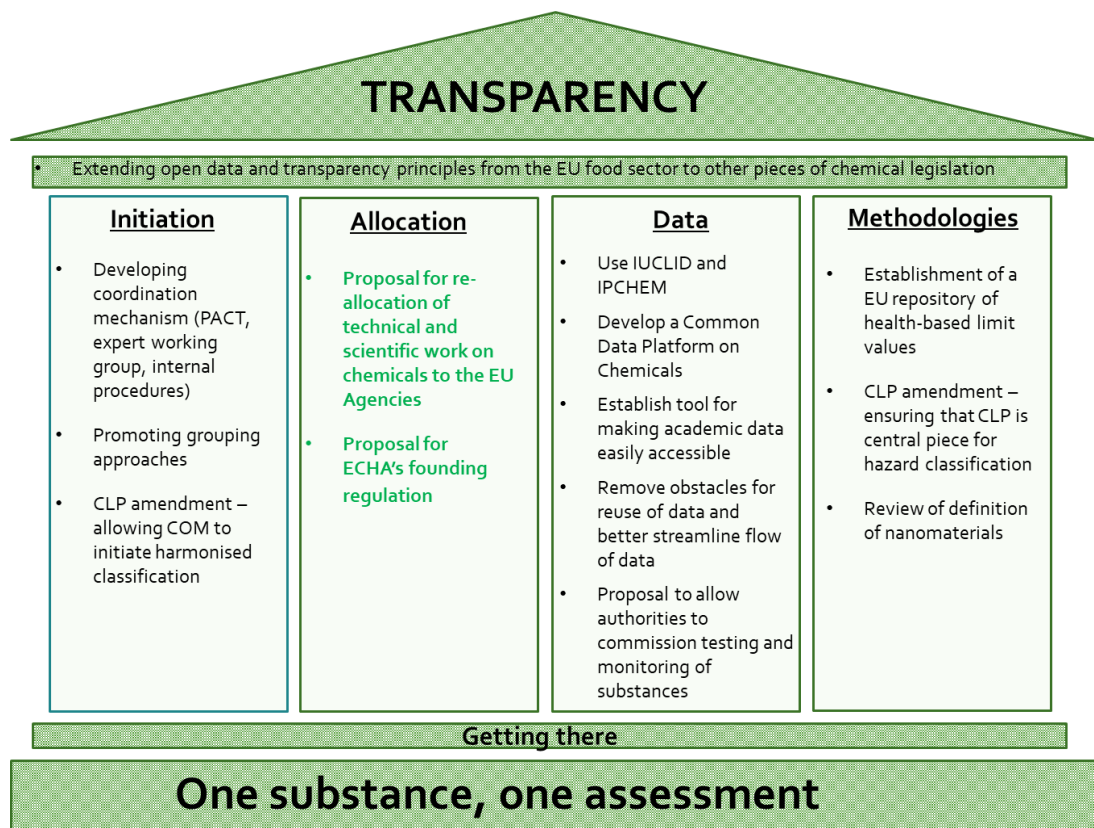
# Re-attribution of tasks



## Objective

- to consolidate the technical and scientific work on chemicals performed at the EU level under or in support of the EU legislation into the EU Agencies with the objective to ensure
  - high quality of deliverables,
  - efficient use of resources, avoid duplication of efforts and harvest on synergies,
  - best use of expertise of the EU Agencies and
  - coherent delivery of safety assessments of chemicals across legislation

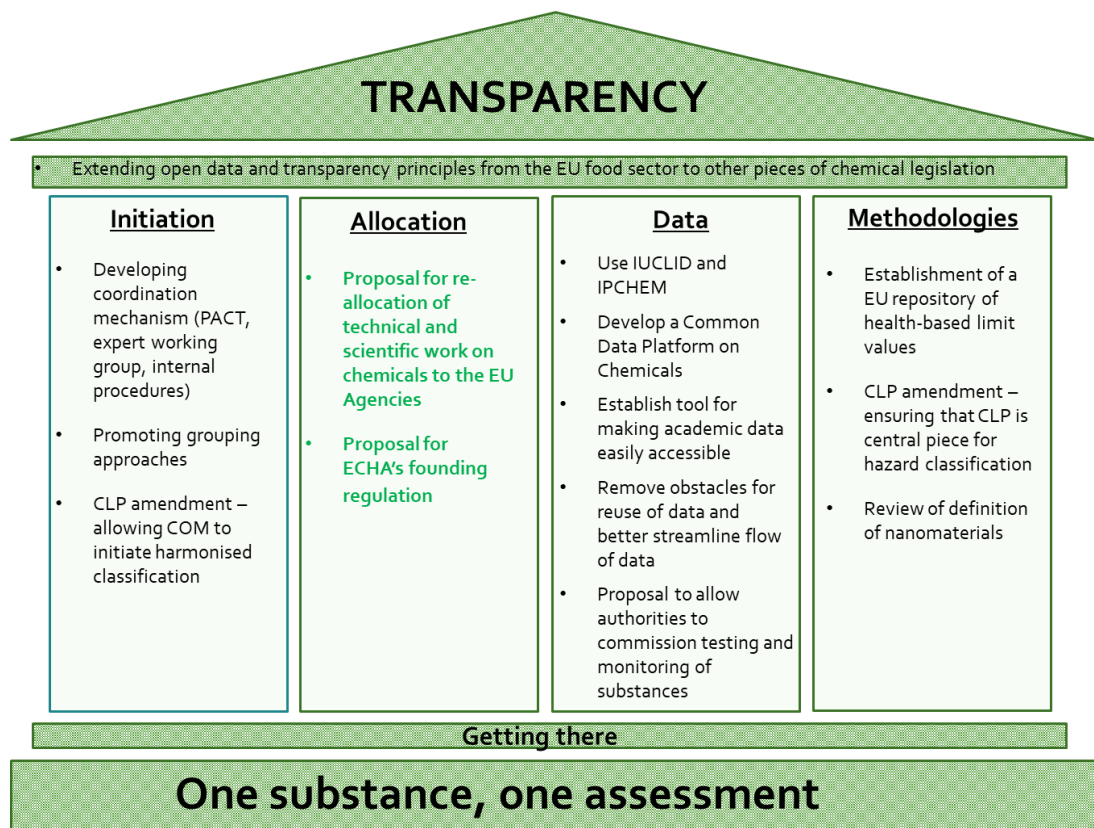
# Re-attribution of tasks



## Scope

- The 'technical and scientific work on chemicals' is considered in a broad sense
- Technical and scientific work performed at the EU level and under or in support of EU legislation will be considered
- General principle – move away from entrusting the work to contractors and COM bodies or services
- Also attributing responsibilities for operating new tools developed as part of the strategy – extended PACT, open data platform, repository of health based limit values and tool to improve uptake of academic data
- RE-attribution will be considered to ECHA, EFSA, EEA, EMA or OSHA

# Re-attribution of tasks



## How

- As part of the revision of individual pieces of legislation
- As part of the horizontal legislative proposal for reallocation of EU technical and scientific work on chemicals to the EU Agencies
  - By 2022
  - Omnibus regulation amending provisions on allocation of tasks and responsibilities
  - Proposal to be accompanied by a staff working document assessing the impacts on resources and capacity needs and a financial fiche for attribution of necessary resources for performing tasks

What	When
Consultation on call for evidence	15/3-12/4 2022
Targeted stakeholder consultation	Q2 2022
Finalise identification of technical and scientific work on chemicals under all relevant legislation for reattribution	Q2-3 2022
Assess resource and capacity needs for the technical and scientific work (in the form of staff working document)	Q2 2022
Commission adoption of a legislative proposal and financial fiche	Q4 2022

# Feedback on call for evidence

In total 65 submissions



- It must not result in a single agency being responsible for the risk evaluations of all chemicals
- Reattribute based on the expertise and maintain the expertise
- Ensure adequate resources
- Improve organisation of scientific committees to better manage the workload
- Include among the tasks for re-attribution hazard assessment in food contact materials, evaluation of cosmetics ingredients, toy safety and derivation of EQS

# Guiding principles for (re-)attribution of tasks

- Consider attributing the work to one of the EU agencies that are mandated to perform such work



- Hazard, exposure and risk assessment of chemicals (except plant protection products and medicinal products) in all products except in food and feed and related products (food contact materials);
- Management of committees;
- Data collection, management and IT tools



- Hazard, exposure and risk assessment of plant protection products and chemicals in relation to food and feed safety;
- Management of committees and panels
- Data collection, management and IT tools



- Hazard, exposure and risk assessment of medicinal products and of their residues in food;
- Management of committees and panels
- Data collection, management and IT tools



- Collection and management of chemical occurrence data in the environment and emission data
- Assessment of state of environment
- Management of network of experts
- Data collection, management and IT tools



- Information on chemicals risks
- Tools for employers

# Guiding principles for (re-)attribution of tasks

- Ensure fit with the core focus of the EU Agencies' work on chemicals in terms of use of substance in specific products, the route of exposure assessed and type of sectors covered;
- Maximise synergies and coherence with ongoing activities, by attributing activities on the basis of similarity with
  - Substances, data and data flows currently managed by the Agency;
  - Existing expertise and competence;
  - Output being provided by the Agency;
  - Existing processes and procedures implemented by the Agency;
  - Methodologies developed and applied by the Agency;
  - Existing IT tools and planned developments;
  - Networks of experts or committees governed or managed by the Agency.
- Strive that the (re-)attribution of tasks brings synergies and benefits to the Union beyond a mere shift of responsibilities

# Re-attribution of tasks

No	Legislation/work package	Work	Type of tasks	How	Status	Who
1	Sustainable product regulation (proposal)	<ul style="list-style-type: none"> <li>Support several technical tasks and operate IT systems</li> </ul>	New	Revision	Legislative process	To be seen
2	POPs Regulation (2019/1021)	<ul style="list-style-type: none"> <li>Collection of POPs monitoring data</li> <li>Technical assistance in reviewing Annexes IV and V</li> </ul>	Existing	Horizontal proposal	Exploration	<ul style="list-style-type: none"> <li>• EEA</li> <li>• ECHA</li> </ul>
3	ROHS Directive (2011/65/EU)	<ul style="list-style-type: none"> <li>Assessments underpinning restrictions of hazardous substances in electrical and electronic equipment</li> <li>Review of exemptions from the restrictions</li> </ul>	Existing	Revision	Exploration	ECHA
4	Directive on end-of-life vehicles (2000/53/EC)	<ul style="list-style-type: none"> <li>Assessments underpinning review of exemptions from restriction on lead, mercury, cadmium or hexavalent chromium</li> </ul>	Existing	Revision	Exploration	ECHA
5	Batteries Regulation (proposal)	<ul style="list-style-type: none"> <li>Restricting hazardous substances in batteries (the same as REACH restriction process but includes also risks in the waste and recycling stage)</li> <li>Reviewing exemptions from the restrictions</li> </ul>	New	Revision	Legislative process	ECHA
6	Waste Framework Directive (2008/98/EC)	<ul style="list-style-type: none"> <li>Ad-hoc technical support to the amendment of the European List of Waste</li> </ul>	Existing	Horizontal proposal	Exploration	ECHA
7	Packaging and Packaging Waste Directive (94/62/EC)	<ul style="list-style-type: none"> <li>Assessments underpinning restrictions of substances in packaging</li> </ul>	New	Revision	Exploration	ECHA



# Re-attribution of tasks

No	Legislation/work package	Work	Type of tasks	How	Status	Who
8	Environmental Quality Standard Directive (2008/105/EC) + Water Framework Directive (2000/60/EC) (linked with SCHEER)	<ul style="list-style-type: none"> <li>Assessments underpinning amendment of priority list of substances and derivation of Environmental Quality Standards</li> <li>Technical and scientific work related to amendment of 'watch list' and coordination of 'watch list' activities</li> <li>Harvesting chemical monitoring data in waters</li> </ul>	Existing	Horizontal proposal	Exploration	<ul style="list-style-type: none"> <li>ECHA</li> <li>ECHA</li> <li>EEA</li> </ul>
9	Groundwater Directive (2006/118/EC) (linked with SCHEER)	<ul style="list-style-type: none"> <li>Assessments underpinning review of Annexes I and II</li> <li>Technical and scientific work related to 'watch list'</li> <li>Harvesting chemical monitoring data in waters</li> </ul>	Existing	Horizontal proposal	Exploration	<ul style="list-style-type: none"> <li>ECHA</li> <li>ECHA</li> <li>EEA</li> </ul>
10	EEA founding regulation (1210/90) (linked with water legislation)	<ul style="list-style-type: none"> <li>Harvesting/collecting chemical monitoring data in the environment</li> </ul>	Existing	Horizontal proposal	Exploration	EEA
11	EPRTTR regulation (2006/166)	<ul style="list-style-type: none"> <li>Operation of broadened and deepened E-PRTR</li> </ul>	New	Revision	Legislative process	EEA
12	SEVESO Directive (2012/18/EU)	<ul style="list-style-type: none"> <li>Operation of database of establishments</li> <li>Operation of database of industrial major accidents</li> </ul>	Existing	Revision	Exploration	EEA
13	Industrial Emissions Directive (2010/75/EU)	<ul style="list-style-type: none"> <li>Revision of BREFs related to chemicals</li> </ul>	Existing	Revision	Legislative process	ECHA
14	Mercury regulation (2017/852)	<ul style="list-style-type: none"> <li>Import consent procedure</li> </ul>	Existing	Horizontal proposal	Exploration	ECHA

# Re-attribution of tasks

No	Legislation/work package	Work	Type of tasks	How	Status	Who
15	Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) (for chemical assessment tasks linked with Water Framework/Groundwater/EQS Directive, Toys Directive, Tobacco Directive, Medical Devices and Cross-Border Health Threats Regulation)	<ul style="list-style-type: none"> <li>• Chemical assessment work of the committee                             <ul style="list-style-type: none"> <li>○ Support of toy safety directive</li> <li>○ Support of Water Framework Directive, Ground Water Directive, Environmental Quality Standard Directive</li> <li>○ Rapid risk assessment of serious cross-border chemical health threats</li> <li>○ Medical devices regulation (guidance on the benefit-risk assessment of the presence of phthalates)</li> <li>○ Nanotechnologies</li> </ul> </li> <li>• Non-chemical assessment work of the committee                             <ul style="list-style-type: none"> <li>○ Environmental risk assessments (e.g. water reuse)</li> <li>○ Support to tobacco product directive</li> <li>○ Risks resulting from onshore oil and gas exploration</li> <li>○ Medical devices (e.g. safety of breast implants)</li> <li>○ Animal testing</li> <li>○ Physical risk (LEDs, UV-C radiation, electromagnetic fields)</li> <li>○ EU environment foresight system (FORENV)</li> <li>○ Statements</li> <li>○ Support of toy safety</li> <li>○ Nanotechnologies</li> </ul> </li> </ul>	Existing	Horizontal proposal	Exploration	To be seen
16	Scientific Committee on Consumer Safety (SCCS) (linked with cosmetics regulation)	<ul style="list-style-type: none"> <li>• Chemical assessment work of the committee                             <ul style="list-style-type: none"> <li>○ Support to cosmetics regulation</li> </ul> </li> </ul>	Existing	Revision	Scenarios available	ECHA

# Re-attribution of tasks

No	Legislation/work package	Work	Type of tasks	How	Status	Who
17	Regulation on serious cross-border threats to health ( <a href="#">proposal</a> ) (linked with SCHEER)	<ul style="list-style-type: none"> <li>ECHA, EEA, EFSA, EMA, ECDC, EMCDDA - contribution to the public health risk assessment</li> </ul>	Existing	Revision	Legislative process	ECHA, EFSA, EEA, EMA
18	Medical devices regulation (2017/745) (linked with SCHEER)	<ul style="list-style-type: none"> <li>Preparation and review of the guidelines on phthalates</li> <li>Preparation and review of the guidelines on CMR and endocrine-disrupting substances</li> <li>Secretariat of expert panels, expert laboratories and EU Reference Laboratories (EURLs)</li> </ul>	Existing	Horizontal proposal	Exploration Exploration Adopted	<ul style="list-style-type: none"> <li>ECHA</li> <li>ECHA</li> <li>EMA</li> </ul>
19	Tobacco directive (2014/40/EU)	<ul style="list-style-type: none"> <li>Assessment of chemical components (content and emissions) of tobacco and related products</li> <li>Host/manage the product database</li> <li>Inform the general public on product characteristics, properties and health risks</li> <li>Collect and assess adverse effects reports</li> <li>Monitor data in product notifications and assist national competent authorities in ensuring product compliance</li> <li>Develop/update negative/positive lists of product additives</li> </ul>	Existing + New	Revision	Exploration	TBD
20	Fluorinated greenhouse gases regulation (517/2014)	<ul style="list-style-type: none"> <li>Setting up and operation of an electronic system for the management of the quota system, licensing of imports and exports and reporting</li> </ul>	New	Revision	Legislative process	TBD
21	Carcinogens and mutagens directive (2004/37/EC), Chemical agents directive (98/24/EC) and asbestos at work directive (2009/148/EC)	<ul style="list-style-type: none"> <li>Assessments underpinning setting the EU occupational exposure levels</li> </ul>	Existing	Horizontal proposal	Exploration	ECHA

# Re-attribution of tasks

No	Legislation/workpackage	Work	Type of tasks	How	Status	Who
22	Cosmetics regulation (1223/2009) (linked with SCCS)	<ul style="list-style-type: none"> <li>Assessments underpinning the safety of cosmetics products</li> </ul>	Existing	Revision	Scenarios available	ECHA
23	Toy safety directive (2009/48/EC) (linked with SCHEER)	<ul style="list-style-type: none"> <li>Assessment underpinning chemical limit values in toys for children</li> <li>Assessment underpinning setting the limit values for 'heavy metals'</li> <li>Assessment underpinning amendments to the lists of allergenic fragrances that are prohibited in toys</li> <li>Assessment underpinning a derogation for the use of CMR substances in toys</li> </ul>	Existing	Revision	Exploration	ECHA
24	European Union Observatory for Nanomaterials (EUON)	<ul style="list-style-type: none"> <li>Operation of EUON</li> </ul>	Existing	Horizontal proposal	Exploration	ECHA
25	EUCLEF	<ul style="list-style-type: none"> <li>Operation of EUCLEF</li> </ul>	Existing	Horizontal proposal	Exploration	ECHA
26	Information Platform for Chemical Monitoring (IPCHEM)	<ul style="list-style-type: none"> <li>Overall operation of IPCHEM</li> <li>Role of module coordination to liaise with data providers to collate data, implement data policy and QC/QA                             <ul style="list-style-type: none"> <li>Food/feed data</li> <li>Environmental (bio)monitoring data</li> <li>Human biomonitoring data</li> <li>Products and articles and indoor air</li> </ul> </li> </ul>	Existing	Horizontal proposal	Exploration	<ul style="list-style-type: none"> <li>TBD</li> <li>EFSA</li> <li>EEA</li> </ul>
27	(Public) activities coordination tool / (P)ACT	<ul style="list-style-type: none"> <li>Operation of the extended public activities coordination tool</li> <li>Provision of information to extended (P)ACT</li> </ul>	Existing	Horizontal proposal	Exploration	<ul style="list-style-type: none"> <li>ECHA</li> <li>EFSA, EMA</li> </ul>

# Re-attribution of tasks

No	Legislation/work package	Work	Type of tasks	How	Status	Who
28	Repository of health-based limit values	<ul style="list-style-type: none"> <li>Setting up and operation of the repository of health based limit values</li> </ul>	New	Horizontal proposal	Exploration	ECHA (TBD)
29	Academic studies	<ul style="list-style-type: none"> <li>Repository of searches of academic studies or underlying academic data</li> </ul>	New	Horizontal proposal	Exploration	To be seen
30	Common Data Platform on Chemicals	<ul style="list-style-type: none"> <li>Setting up and operation of the common data platform on chemicals</li> <li>Providing data to the platform</li> </ul>	New	Horizontal proposal	Exploration	<ul style="list-style-type: none"> <li>ECHA</li> <li>EFSA, EMA, EEA, ECHA</li> </ul>
31	Mechanism for initiating testing and monitoring	<ul style="list-style-type: none"> <li>Commissioning testing and monitoring of substances</li> </ul>	New	Horizontal proposal	Exploration	To be seen
32	Adopting formats and preparing control vocabularies	<ul style="list-style-type: none"> <li>Preparing formats</li> <li>Preparing control vocabularies</li> </ul>	New	Horizontal proposal	Exploration	ECHA, EEA, EFSA, EMA
33	Increased transparency duties	<ul style="list-style-type: none"> <li>Making data more publically available</li> </ul>	New	Horizontal proposal	Exploration	ECHA, EMA, EEA
34	EU Chemical Early Warning and Action System	<ul style="list-style-type: none"> <li>Operation and contribution to the system</li> </ul>	New	Horizontal proposal	Exploration	To be seen

Thank you for your attention