One substance, one assessment

General introduction of 1S1A

Symposium "One Substance Multiple Assessments", 5 April 2022

CSS: 1S1A for simplification and consolidation

- **Simpler and more transparent** assessment*) processes for
  - Reducing the burden for all stakeholders
  - Faster, more consistent and predictable decision making
- Move away from substance by substance **to group approaches**
- **Coordinate** initiation and priority setting of safety assessments:
  - Fully account for assessments across legislations

**): safety assessment, not socio-economic assessment.*

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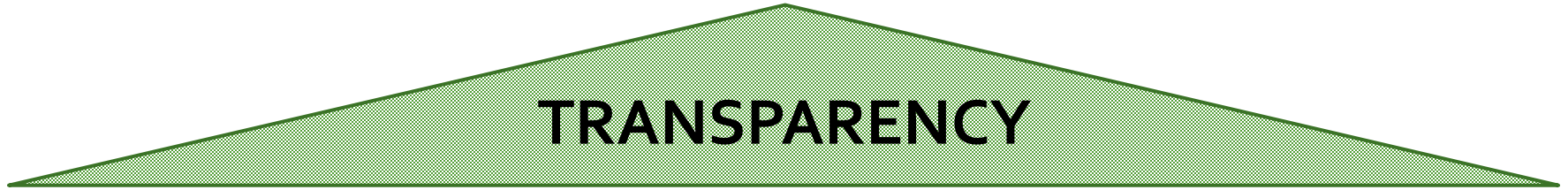

- Different rules and practices

Initiation	Allocation	Data	Methodologies
• Plethora of legislation • By COM, MSs, Industry • At different time	• Agency • Expert group • Scientific Committee • Consultant	• Availability • Formats • Access • Quality	• Guidelines • Guidance

Today

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TRANSPARENCY

- Stakeholders are timely informed and have access to underlying data

Initiation	Allocation	Data	Methodologies
• Synchronised and coordinated • Assessments of groups of substances	• Clear responsibilities • Making best use of available resources and expertise • Good governance and cooperation	• Easily findable, accessible, interoperable, secure, of high quality • Shared and reused by default	• Coherent • To the extent possible harmonised • Hazard assessment centralised under CLP Regulation

Tomorrow

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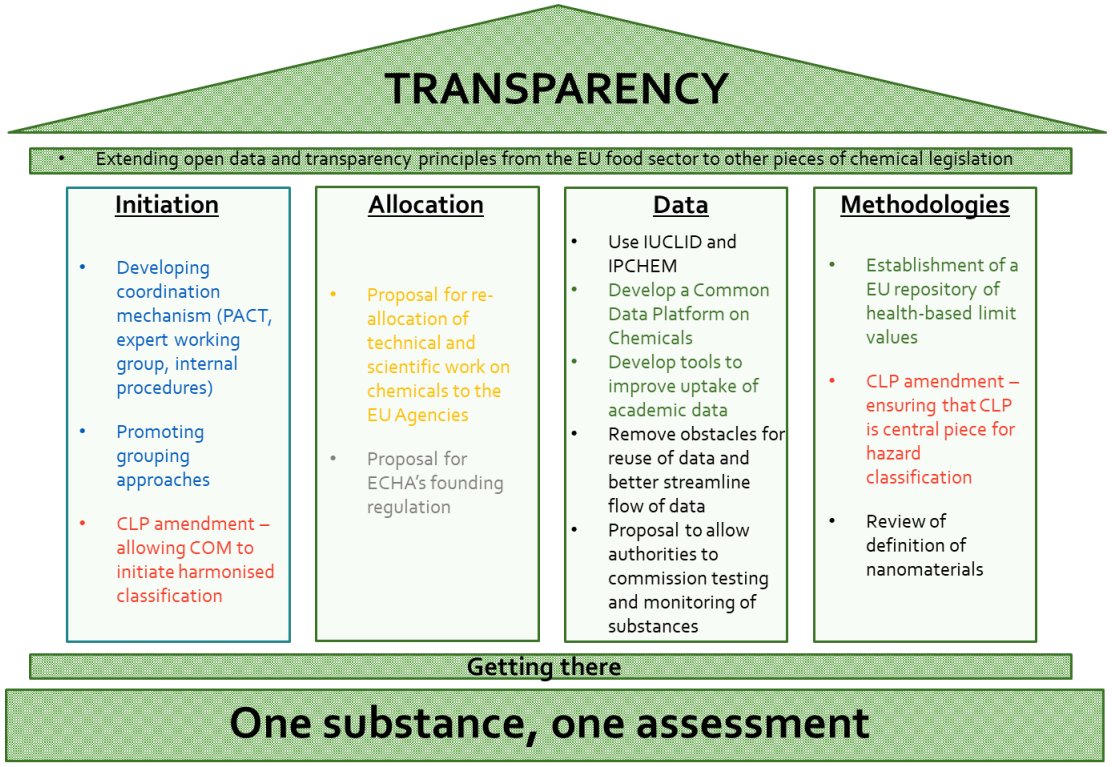
Organisation of work



- Developing coordination mechanism (extension of ACT/PACT and expert working group)
- CLP Revision
- REACH 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

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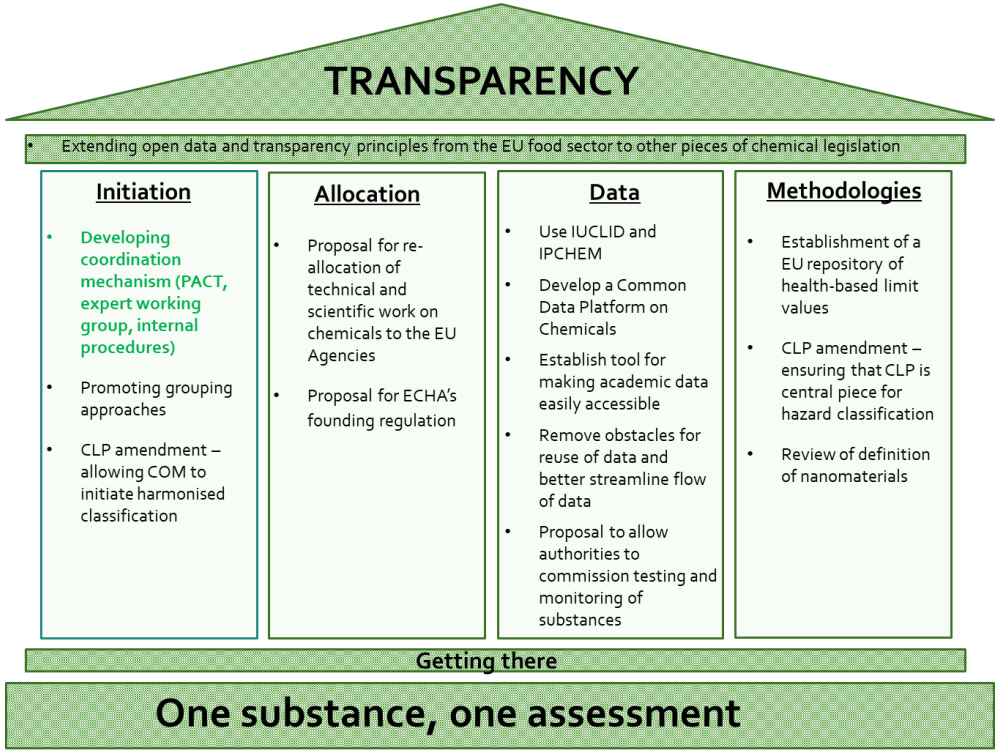
Coordination mechanism



Objective

- **establish cooperation between the COM, EU Agencies and MSs** in supporting implementation of the 1S1A approach
- **ensure that the initiation of the safety assessments are done in a transparent and to the extent possible coordinated and synchronised manner**
  - **when as assessment is proposed or initiated** under one piece of legislation, **full account is taken of the foreseen assessment** or the need for such assessment or any other relevant assessment-related aspects **under other pieces of legislation** or initiative, so that **coordinated action** is ensured as far as possible.
  - to **avoid duplication** of work, clarity at an early stage on the scope of the assessment is pursued, favouring the assessment by groups of substances with structural or functional similarities
  - **these efforts should not lead to regulatory delays**, should not restrict right of **initiative** of MSs, **should not increase** significantly the **administrative burden**

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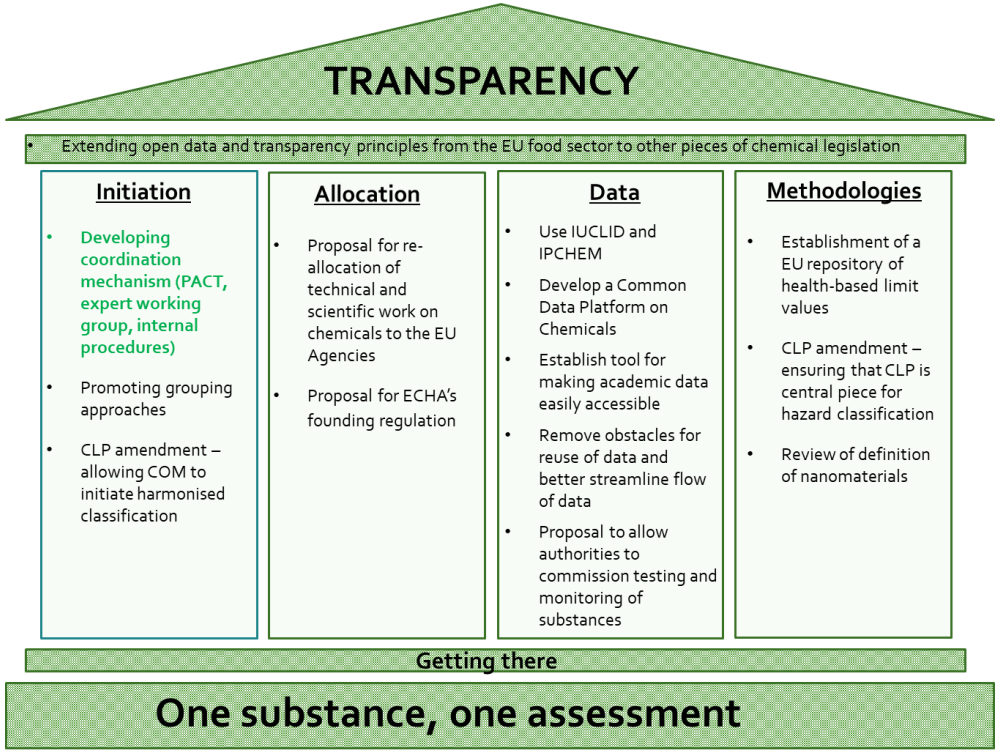
Coordination mechanism



How

- (Public) Activities Coordination Tool (P)ACT
  - Overview of all planned and ongoing initiatives on safety assessment of chemicals
  - Existing **(P)ACT to be progressively expanded to all relevant legislation**
- **Coordination mechanism** within the Commission
  - Inter-service group on 1S1A to oversee its implementation
  - to synchronise to the extent possible actions across legislation as regards safety assessments of chemicals
- **Expert Working Group** of Member States, Commission Services and Agencies
  - Supporting implementation of 1S1A approach
  - Facilitate coordination and discussion of initiatives on chemicals across legislation

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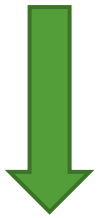
Some policy objectives of the inception IA

- Introduce the possibility to submit proposals for and set harmonised environmental and safety values for some substances.
- Introduce new hazard classes and corresponding criteria for EDs, PBTs, vPBTs, PMTs, vPMTs.
- Introduce a mandate for Commission to request ECHA to develop new harmonised classification and labelling('CLH')dossiers.
- Introduce a prioritisation mechanism for harmonizing the classification of certain chemicals.

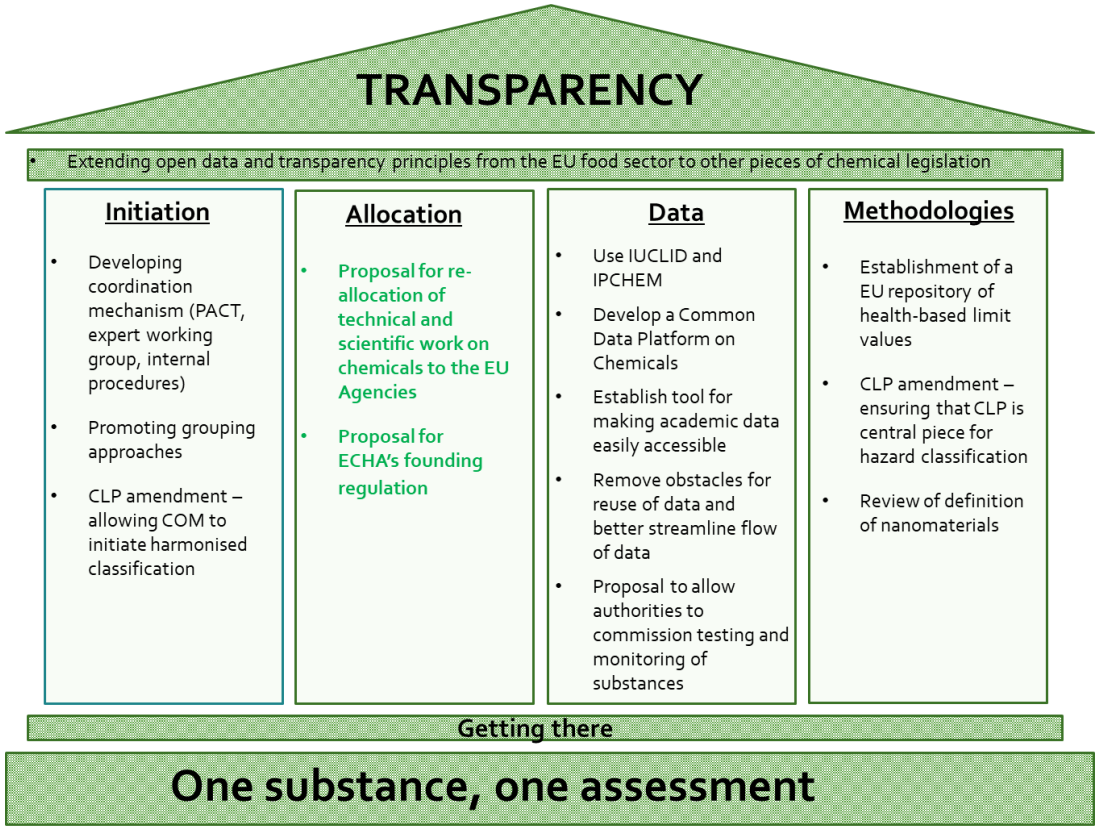
How do these objectives link to 1S1A?

1S1A = **making the CLP Regulation the central piece for hazard classification**



- EDS
- PBTs, vPvBs: transfer from REACH to CLP  harmonisation of criteria for CLP, REACH, Biocides, Plant Protection Products
- PMTs, vPvMs
- Harmonised DNELs and PNECs: use of these values in all relevant legislation (e.g. for workers protection)

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** to make 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
- 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 or EMA**

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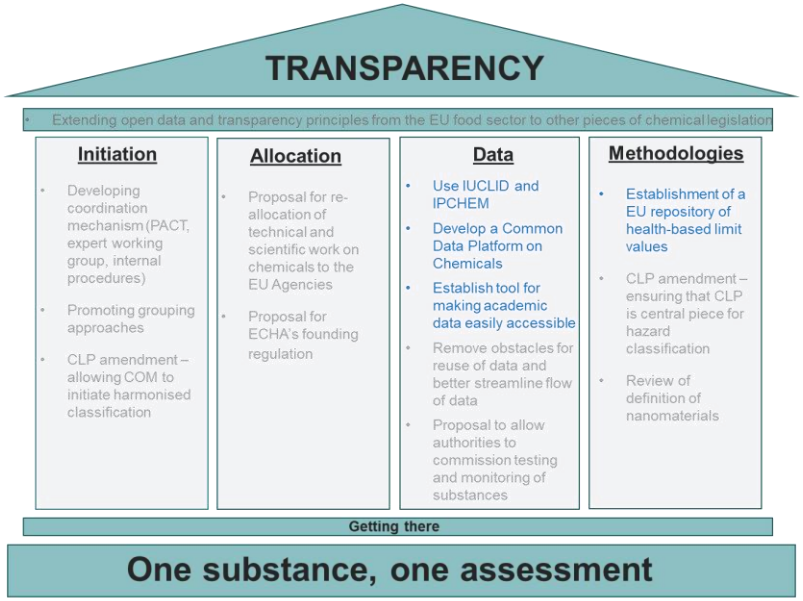
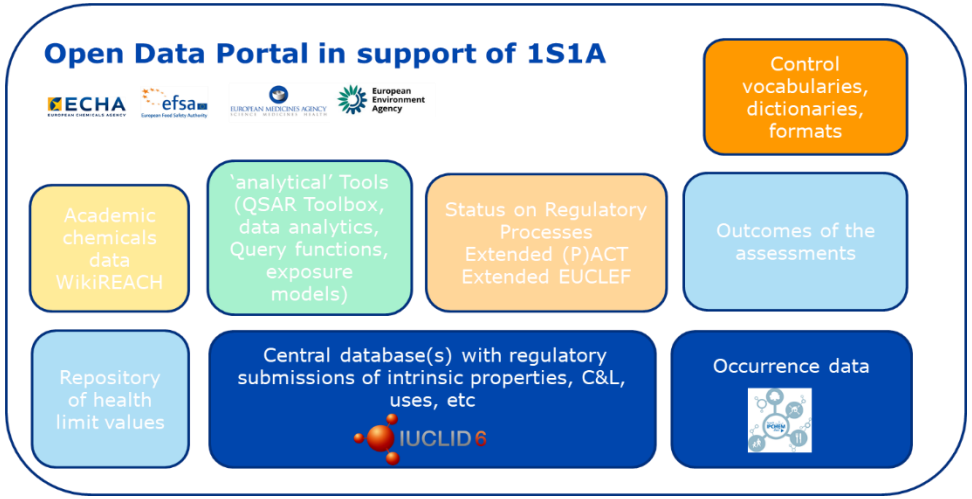
Common open data platform on chemicals

- A single access point to data and information on chemical in the EU
- As a minimum, it ensures:
  - All authorities are aware of each other's regulatory action
  - All authorities have easy access to the same chemical data
  - All authorities and stakeholders have easy access to the best-available tools for safety assessments
  - Authorities, stakeholders and general public are timely informed about the regulatory processes and their outcomes





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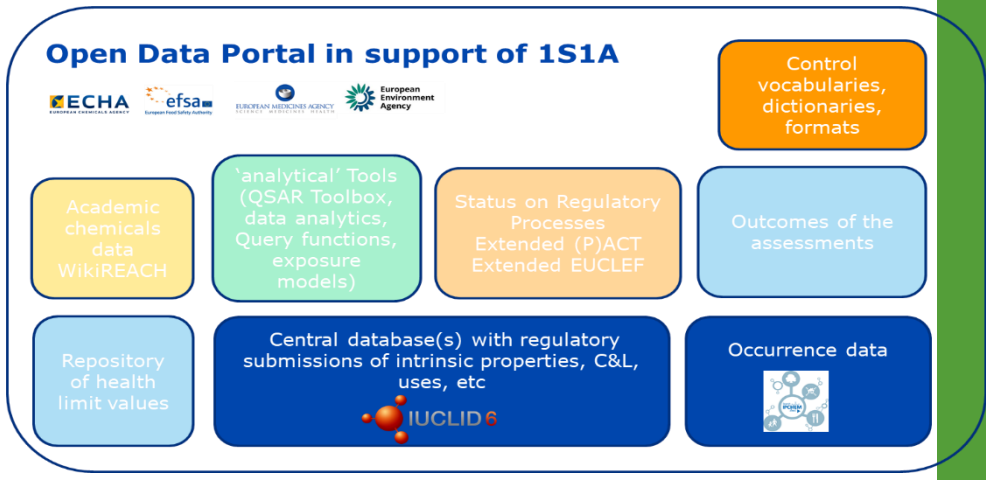
Platform building blocks, closer-up

- A single access point to data and information on chemical in the EU, differentiated authorities and public access
- Host to (P)Act coordination + support to assessment through *easy access to the same chemical data, best-available tools for safety assessments, regulatory processes and outcomes*
  - **fostering 'ecosystem' of analytical tools, API, secondary datasets**
- *Stakeholders and general public are timely informed about the regulatory processes and their outcomes*
- Toxicological data based on IUCLID
- Chemical occurrence: exploiting IPCheM, EEA Reportnet flows
- Actively addressing challenges e.g. work on substance identification, control vocabularies
- Close relation with other 1S1A work: e.g. work on data sharing and formats will create possibility for the data from the specific source to be effectively included in the datasets on offer, be used and references (access rules)



Better use of academic data in regulatory assessments
Why action is needed?

Recent policy fitness checks[1] identified issues related to the way academic data is used in regulatory assessments:

- The need to improve performing and reporting applied in peer-reviewed studies to meet regulatory requirements

- The need to improve implementation of the regulatory requirement to consider all available information when carrying out assessments

[1] COM(2019)264 EUR-Lex - 52019DC0264 - EN - EUR-Lex (europa.eu) and SWD (2019) 199 EUR-Lex - 52019SC0199 - EN - EUR-Lex (europa.eu)

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