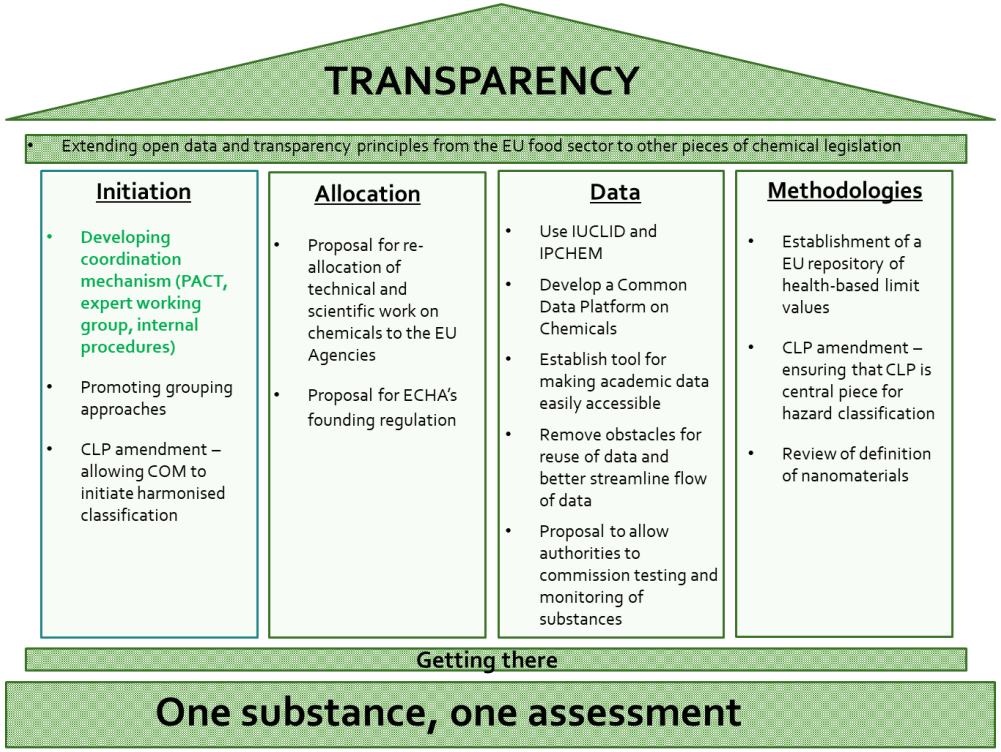
Information session for stakeholders and citizens on one substance, one assessment

Developing a coordination mechanism (extension of ACT/PACT and expert group)

1 June 2022

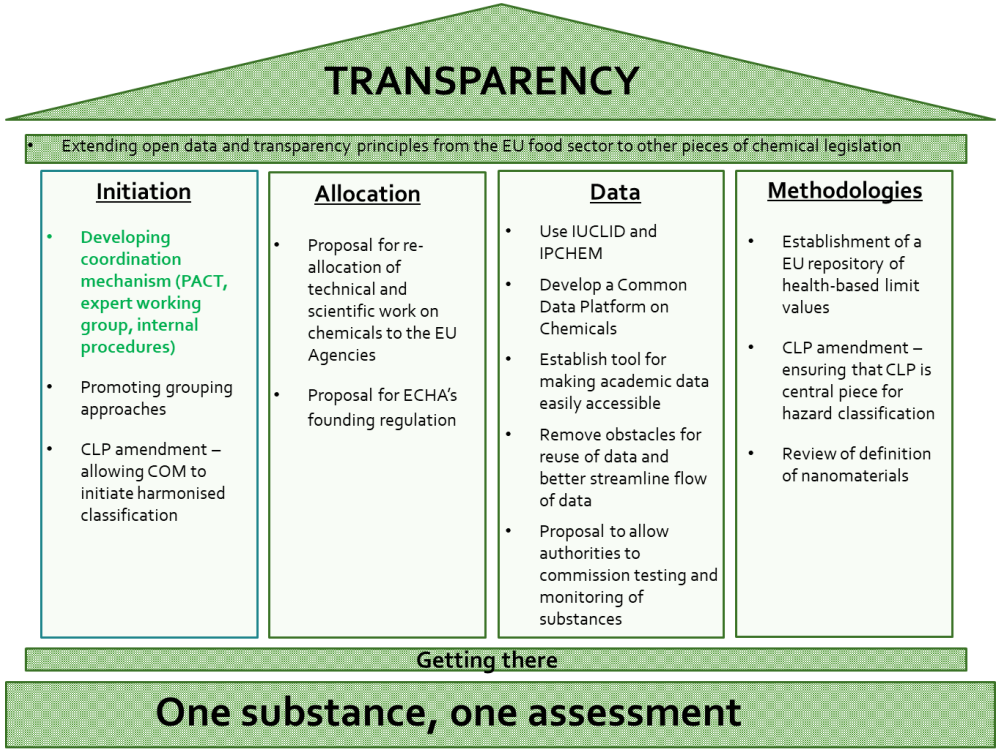
Coordination mechanism



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

Coordination mechanism



How

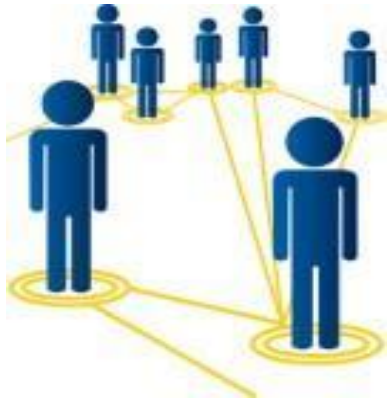
- (Public) Activities Coordination Tool (P)ACT
  - Overview of all planned and ongoing initiatives on safety assessment of chemicals
  - Existing (P)ACT to be progressively expanded to all relevant legislation
- Coordination mechanism within the Commission
  - Inter-service group on 1S1A to oversee its 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

What is ACT?

- user-friendly, searchable tables accessed via web
- provide up-to-date and structured information on planned, ongoing, completed authority activities on (groups of) substances

Valuable information and other actions on a substance I am working on?

We need to coordinate our activities



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What is PACT?

- user-friendly, searchable table publicly available via website

Can interested parties prepare for the regulatory processes and can industry adapt their business strategies?

We need to communicate on the progress of our activities

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Scope
ACT vs. PACT

Processes *currently* covered

Process	Screening	DEV	SEV	ED	PBT	CLH	RMOA	SVHC	Annex XIV	AfA	Restriction	POP
Submitter	MSCA	ECHA	MSCA	MSCA ECHA	MSCA ECHA	MSCA	ECHA MSCA	ECHA MSCA	ECHA	ECHA	ECHA MSCA	MSCA ECHA
PACT	✗	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✗
ACT	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

REACH regulation
CLP regulation
POPs regulation

*Currently available elsewhere in ECHA website

Differences in level of detail, type of information (confidential vs. public), timing (drafts vs. final), frequency of update

- *PACT is a filtered, slimmer and **delayed** version of ACT*
- *ACT provides everything available in PACT plus more*

Candidates for extended (P)ACT

Legislation	Process
Worker protection legislation (2004/37/EC, 98/24/EC, 2009/148/EC)	Setting EU OELs; Setting national OELs
ROHS Directive (2011/65/EU)	Review of exemptions
Directive on end-of-life vehicles (2000/53/EC)	Review of exemptions
Proposal for regulation on batteries and waste batteries	Restriction process
Environmental quality standards directive (2008/105/EC)	derivation/setting of EU and national EQS; addition/removal of a substance to watch list
Ground water directive (2006/118/EC)	Derivation of EU and national limit values; addition/removal of substance to watch list
Drinking water directive (2020/2184)	Safety assessment of contact materials

Candidates for extended (P)ACT

Legislation	Process
Biocidal product regulation (528/2012)	Evaluation of active substance; Opinion of BPC on active substance approval
Plant protection product regulation (1107/2009)	Safety assessment as part of a substance (re-)approval process
Food contact material regulation (1935/2004)	Safety assessment
Regulations on food additives, food enzymes and food flavourings	Safety assessment
Directive on extraction solvents used in the production of foodstuffs and food ingredients	Safety assessment
Regulation on contaminants in food (315/93)	Safety assessment
Directive on feed contaminants (2002/32/EC)	Safety assessment
Regulation on additives for use in animal nutrition (1831/2003)	Safety assessment
Regulation on maximum residue levels of pesticides in food (396/2005)	Safety assessment as part of the MRLs setting

Candidates for extended (P)ACT

Legislation	Process
Regulation on veterinary medical product (2019/6)	Environmental safety assessment of product
Regulation/Directive on medicinal products for human use	Environmental safety assessment of product
Regulation on medicated feed (2019/4)	Safety assessment of product
Regulation on residue limits of pharmacologically active substances in foodstuffs of animal origin (470/2009)	Safety assessment
Regulation on cosmetic products (1223/2009)	Safety assessment
Directive on the safety of toys (2009/48/EC)	Safety assessment

Expert Group on 1S1A

Membership & Invited experts	The group shall be composed of: - Member States' competent authorities, - Norway, Iceland, Lichtenstein and - Relevant EU Agencies (European Chemicals Agency, European Food Safety Authority, European Environmental Agency, European Medicine Agency, European Agency for Safety and Health at Work). Member States' competent authorities and relevant EU Agencies shall nominate up to 2 representatives and shall be responsible for ensuring that their representatives provide a high level of expertise in the field of chemical policy and that there is timely and appropriate coordination/consultation of their relevant colleagues. DG ENV, in consultation with the other relevant Commission services, may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the group or sub-groups on an ad hoc basis.

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Expert Group on 1S1A

Tasks / Mandate	Supporting implementation of the 'one substance, one assessment' approach: - establish cooperation between the Commission Services, EU Agencies and Member States on the actions related to 'one substance, one assessment' and identified in the Chemicals Strategy for Sustainability. These actions are situated in the areas of initiation of safety assessments, allocation of safety assessment tasks, generation, availability, accessibility, sharing and interoperability of data, harmonisation of methods used in safety assessments and implementation of transparency rules; - exchange views, experiences and good practices on achieving the objectives of a 'one substance, one assessment' approach, *i.e.* coherent and efficient delivery of safety assessments across legislation; - assist the Commission Services in the preparation of legislative proposals and policy initiatives in the field of 'one substance, one assessment'; Facilitating the coordination and discussion of initiatives on safety assessments of chemicals across chemical legislation, with particular focus on substances and group of substances that are in the scope of several pieces of chemical legislation or initiatives: - support the further development and enhancement of the use of the (Public) Activities Coordination Tool ((P)ACT) across EU legislation to help authorities plan and carry out their tasks; - promote that, when an assessment is proposed or initiated under one piece of legislation, full account is taken of any 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; - monitor, discuss and exchange views on early warning signals on chemicals within the framework of the early warning and action system on chemicals (announced under the Strategy). The group shall ensure with its work that the implementation of the 'one substance, one assessment' process makes decision-making faster, does not lead to longer timeframes for safety assessments, does not restrict right of initiative of Member States and rights and obligations of industry, and does not increase significantly the administrative burden. Further, legal deadlines must be respected.

Expert Group on 1S1A

Operation	The group shall be chaired by a representative of DG ENV. DG ENV shall also provide secretarial services. The group shall act at the request of the Chair, in consultation with the other relevant Commission services Meetings of the group are convened by the Chair. Meetings of the group shall be held on Commission premises or via videoconference. DG ENV may set up sub-groups for the purpose of examining specific questions. The sub-groups are composed of members of the group. The members' representatives in the sub-group may differ from the members' representatives in the group to ensure adequate expertise for examining the specific questions. The group shall adopt its opinions, recommendations or reports by consensus. Any suggestions, advice, common views and conclusions obtained at the expert group meetings are non-binding and serve to support the work of the Member States, EU Agencies and the Commission Services. In agreement with the Chair, the group may, by simple majority of its members, decide that deliberations or certain parts of the deliberations shall be made publically accessible via videoconference/video streaming.

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Expert Group on 1S1A

Agenda & meeting documents	The secretariat shall draw up the agenda under the responsibility of the Chair and send it to the members of the group. The agenda shall be adopted by the group at the start of the meeting. Whenever relevant, the secretariat under the responsibility of the Chair will consider including on the agenda an information session for stakeholders and citizens. The information session will be made accessible via videoconference/video streaming. The secretariat shall send: - the invitation to the meeting and the draft agenda to the group members no later than twenty calendar days before the date of the meeting. - documents on which the group is consulted to the group members no later than twenty calendar days before the date of the meeting. In urgent or exceptional cases, the time limits for sending the documentation may be reduced to ten calendar days before the date of the meeting Minutes on the discussion on each point on the agenda and on the opinions delivered by the group shall be meaningful and complete. Minutes shall be drafted by the secretariat under the responsibility of the Chair.

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Expert Group on 1S1A

Transparency	The group shall be registered in the Register of Commission expert groups and other similar entities ('Register of expert groups') As concerns the group composition, the following data shall be published on the Register of expert groups: - the name of Member States' authorities; - the names of the authorities of Norway, Iceland and Lichtenstein, - the name of EU Agencies; All relevant documents, including the agendas, the minutes and the participants' submissions, shall be made available on the Register of expert groups or *via* a link from the Register to a dedicated website, where this information can be found. Access to dedicated websites shall not be submitted to user registration or any other restriction. In particular, DG Environment shall publish the agenda and other relevant background documents in due time ahead of the meeting, followed by timely publication of minutes. Exceptions to publication shall only be foreseen where it is deemed that disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) N° 1049/2001 Applications for access to documents held by the group shall be handled in accordance with Regulation (EC) No 1049/2001

Thank you for your attention