Horizontal legislative proposal on data

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

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An Jamers, DG ENV, European Commission
Obstacles to access and (re-)use of data

Policy evaluations

• Interested parties in chemical safety assessments not always aware of what information is available and where and how to access and use it

• Re-use rights sometimes too restrictive

• Shortcomings in interoperability and accessibility of chemical data

• Different transparency rules are applied to different assessment steps and data

• Academic studies are not sufficiently exploited
Better **streamline** the flow of chemical data between EU and national authorities

• Remove legislative obstacles for the **re-use** of data

• Make data available in appropriate **formats and tools** to ensure interoperability

• Extend the principle of open data and the relevant **transparency** principles from the EU food safety sector to other pieces of chemical legislation

• Enable EU and national authorities to **commission testing and monitoring** of substances as part of the regulatory framework when further information is considered necessary
Common chemical data platform = de-centralised system providing remote access to existing information systems and data providers

User = COM, agencies, MS, industry, citizen with different levels of access

**Occurrence data**
- IPCHEM
- EEA
  - Env monitoring (IPCHEM module, LUCAS, WFD, Groundwater Directive)
  - Human biomonitoring
  - Food and feed
  - Residual occurrence data in IPCHEM

**Emissions data**
- E-PRTR

**Hazard, exposure, use data**
- IUCLID

**Health based limit values**
To be developed

**Commissioned studies**
- Notification of commissioned studies
- Cfr. food sector
- What information needs to be required?

**Assessment outcome/(P)ACT**
- Assessment outcome + regulatory status
- EUCLEF + (P)ACT

**Analytical tools**
- QSAR toolbox
- Exposure models
- Query functions

**Control vocabularies**
- Existing tools to be used

**Academic data**
- Guidance on reporting requirements
- Search guide

**To be developed**

**To be developed**

**Existing flows remain untouched**

EEA to be more pro-active in connection/collection of MS data
EEA to get more powers to ask for data

Data to be iuculidised

Existing flows remain untouched

**Existing system to be expanded**

EEA to get more powers to ask for data

**To be developed**

**Existing flows possibly to be transferred to EEA if not already there**

**Environmental monitoring (IPCHEM module, LUCAS, WFD, Groundwater Directive)**
- Human biomonitoring
- Food and feed
- Residual occurrence data in IPCHEM

**Data to be iuculidised**

Existing flows remain untouched

**Controlled vocabularies**
- Existing tools to be used

**User**
- COM, agencies, MS, industry, citizen with different levels of access
1. Data dissemination, re-use and transparency

- Data exchange is only possible if data is made **available** and **re-use** of data is allowed

- **Barriers**
  - Technical (cfr formats, vocabularies ~ interoperability)
  - Legal:
    - Horizontal (IPR, sui generis database rights)
    - Specific (regulatory data protection)

- Identification of legislative barriers and solutions to overcome them, taking into account free riding, monetary value of data and legacy data

- **Transparency and confidentiality**
  - Different dissemination and transparency rules under different legislations

- Harmonisation of transparency rules
Intellectual property rights

- Copyright ~ Directive 2001/29/EC (Copyrights Directive)
  - Robust study summaries, applications for authorisation and renewal under REACH could be considered copyrightable
  - No general exception for public authorities. E.g. ECHA cannot re-use copyrightable data on biocidal product authorisation for a REACH application for authorisation, or send it to EFSA for the purpose of approval of a pesticide active substance.

- Sui generis database rights
  - Prevents any extraction or re-use of (part of) a database as long as the author has made a substantial investment in either obtaining the contents, its verification or presentation
  - Majority of submissions under REACH, CLP, BPR (and by extension other legislation) would potentially fall under this right
  → review of Database Directive planned (unrelated to CSS)
Regulatory data protection

- E.g. ‘data owner’ under REACH, or BPR
- Does not extend beyond regulatory framework it is implemented in → e.g. protection set out in BPR does not prevent re-use of data under REACH (if data is not copyrightable)

→ Use of data to validate/question correctness of information in subsequent submissions?
→ No use of data to fill in data gaps in subsequent submissions?
Confidentiality frameworks

• General framework (Regulation on Access to Documents, Aarhus Convention, General Data Protection Regulation) + legislation-specific confidentiality scheme

• Legislation-specific confidentiality scheme (e.g. Regulation (EU) 2019/1381 (Transparency Regulation))

• Sharing of information between EU bodies, which apply different confidentiality schemes gives rise to a number of legal risks.

→ establish ‘originator’ principle: obligation for receiving agency to respect confidentiality granted by the supplying agency?

→ or, one centralised database with all scientific information, and database provider/supervisor responsible for assessment for assessing any decision on confidentiality?
Transparency Regulation

• **Pro-active public disclosure** of all studies/info supporting any request for scientific output by EFSA

• **Intellectual property rights** continue to apply but cannot be used to prohibit public disclosure

• Duly justified **confidential data** are not publicly disclosed

• COM, EFSA and MS have access to full confidential version of submitted request

→ Under 1S1A, identification and assessment of options for harmonising transparency rules across legislation based most stringent existing ones

→ Take into account **free-riding, monetary value of data and legacy data**
2. Data generation mechanism

• CSS: enable EU and national authorities to commission testing and monitoring of substances as part of the regulatory framework when further information is considered necessary

• Burden of proof remains with industry

• No new information requirements

• ‘Data’ = measurements, test data, modelling data

• cfr. substance evaluation (REACH), verification tool (Transparency Regulation)

→ Assess overlap with existing mechanisms and additional possibilities of data generation mechanism
Use cases

- CLP Regulation – hazard identification, **intrinsic properties**
- REACH – substance evaluation vs/+ authorities generating data themselves
- Information on intrinsic properties of chemicals under **environmental legislation** (not in scope of REACH), e.g. Water Framework Directive (WFD), sewage and drinking water etc.
- High throughput **in vitro screening** to generate mechanistic data
- Environmental **occurrence data** (watch list is limited to WFD purposes)
- Soil biomonitoring, human biomonitoring (**more stability** than projects such as LUCAS, HBM4EU, PARC, …)
- Longe-range transport potential of chemicals under **POPs Regulation**
Aspects to consider

• Actors
  • COM, MS

• Execution
  • Commercial laboratories, COM (JRC), COM-MS collaboration, experts/consultants, industry (samples)

• Governance
  • One central body (COM or Agency) vs several parties (e.g. EU Agencies)

• Budget/resources
  • COM budget, industry contributions, MS contributions
3. Notification of studies

- Cfr. Transparency Regulation
  - Business operator commissioning/laboratory being commissioned a study needs to **notify** information to EFSA (name, scope of study, planned start and completion dates)
  - Information is stored in **database** by EFSA
  - Only for studies for regulatory purposes
  - Study taken up in database needs to be taken up in autorisation/approval dossier and vice versa; otherwise, not considered compliant and autorisation/approval will be delayed

→ Similar requirement and mechanism useful/needed for the rest of the chemical sector?
4. Academic data

- **CSS:** *develop tools to improve uptake of academic data*

- Use of academic data in regulatory assessments
  - Published in scientific literature
  - Not carried out specifically to inform regulatory assessments
  - Often using non-standard (non-guideline) experimental (animal and non-animal) or computational methods
  - From traditional to mechanistic data
Guidance setting minimum quality and reporting requirements

- helps researchers to design, perform and report studies, facilitating regulatory uptake
- broad scope (e.g. in vivo, in vitro, computational modelling, omics etc.)
- entry point for academics to identify requirements
- builds on existing resources
- provides pointers to specific quality documents
- highlights the benefits for the data generators to implement the guidance (developing editorial/funders policy)
Search guide for finding and retrieving academic data

- implementing the requirements to consider “all available information” in regulatory assessments
- helps assessors to find, access and evaluate academic data from scientific sources
- builds on established tools and practice
- solutions may include:
  - pre-defined search and screening criteria
  - automated solutions, including study repositories and alerts
  - open access platforms, databases in harmonised format
  - policy mechanism to implement it
5. Legislative proposal & supporting study

- Horizontal legislative proposal
  - Commission adoption of proposal Q1-Q2 2023
  - Omnibus Regulation amending provisions on data handling and reporting in individual pieces of chemicals legislation

- Supporting study
  - Start May 2022 Mapping of current flows and reporting of data. Identification of options for improvement of inefficiencies.
  - Analysis of possibilities to make data more available to general public
  - Assessment of need and added value of mechanism for data generation and monitoring
  - ~ feasibility study on establishment on open chemical data platform
Thank you

Env-1S1A@ec.europa.eu
An.Jamers@ec.europa.eu