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# Translating research results into evidence for risk assessment

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Trusted science for safe food

Regulatory assessments: **all available, relevant information**



Industry data



Grey literature



Academic data  
(peer-reviewed studies)

## ***Why academic data?***

- Increase robustness of risk assessment & decision-making
- Consider potentially more sensitive or relevant designs and endpoints
- Avoid duplication
- Make best use of public resources

## ***Problem: limited use of academic data***

e.g.

**COMMISSION STAFF WORKING DOCUMENT**

### **FITNESS CHECK**

**of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries**

*[...] more can be done to ensure all relevant evidence (e.g. peer-reviewed academic studies) is available for the assessment and decision-making processes [...]*

[EUR-Lex - 52019SC0199 - EN - EUR-Lex \(europa.eu\)](#)

# Obstacles in the uptake of academic data

Step	Identified issues	Actors
Production	<ul style="list-style-type: none"><li>Unawareness of regulatory needs</li><li>Divergent needs across legislations</li><li>Lack of incentives</li></ul>	Funders, researchers
Documentation	<ul style="list-style-type: none"><li>Insufficient documentation complicating assessment of reliability and relevance</li></ul>	Researches, Editors, Publishers, Reviewers, Repository managers
Accessibility	<ul style="list-style-type: none"><li>Deviation from FAIR data principles</li><li>Costly subscriptions</li><li>Lack of tools compiling and monitoring relevant academic data</li><li>Lack of common standards and data platforms</li></ul>	Registrants, EU agencies and scientific committees, MS authorities
Use	<ul style="list-style-type: none"><li>Higher weighting of standard protocols and GLP</li><li>Different practice in uptake of non standard studies by regulator</li><li>Methodological incompatibility</li></ul>	Registrants, EU agencies, MS authorities

\* Adapted from EFSA's scoping document on "Establishing tools and practices to ensure that relevant academic data is easily and readily accessible for safety assessments and is suitable for regulatory purposes"

## The FAIR principles of data:



(Meta)data should be easy to find for humans and computers



Users need to know how data can be retrieved, using standard communications protocols (open, authentication)

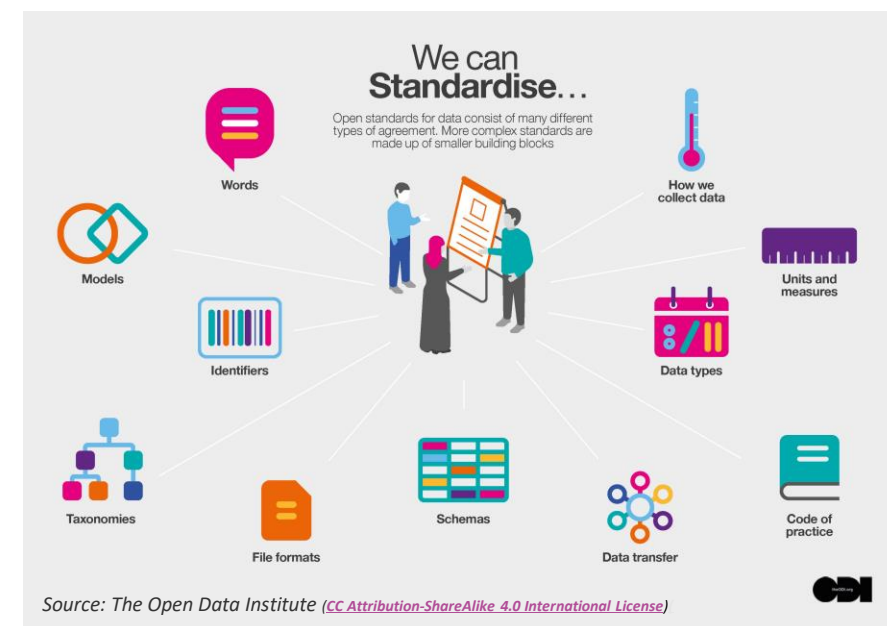


Data needs to work with applications or workflows for analysis, storage and processing, and be possible to integrate with other data



(Meta)data needs to be well-described so that it can be replicated and combined in different settings

## Data standards



## OHTs (OECD Harmonised Templates)

OECD's format for reporting information used for risk assessment of chemicals (hazards, use, exposure)

OECD Template #60: Acute toxicity: oral (Version [9.2]-[November 2021])

Line no.	Field name	Field type Display type	Picklist Freetext template
60.	Results and discussion	Header 1	
61.	Preliminary study	Text (2,000 char.) Display: Detailed	
62.	Effect levels	Block of fields (repeatable) Start	
63.	Key result	Check box Display: Basic	
64.	Sex	List (picklist) Display: Basic	Picklist values: female; male; male/female; not specified
65.	Dose descriptor	List sup. (picklist with remarks) Display: Basic	Picklist values: LD0; LD50; LD100; LDLo; approximate LD50; discriminating dose; LD50 cut-off; other:



International Uniform Chemical Information Database

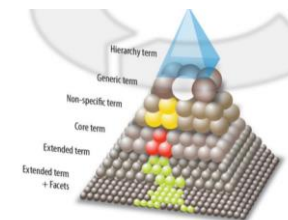
integrated into

## SSD2 (Standard Sample Description 2)

EFSA's format for reporting analytical monitoring results in food and feed samples

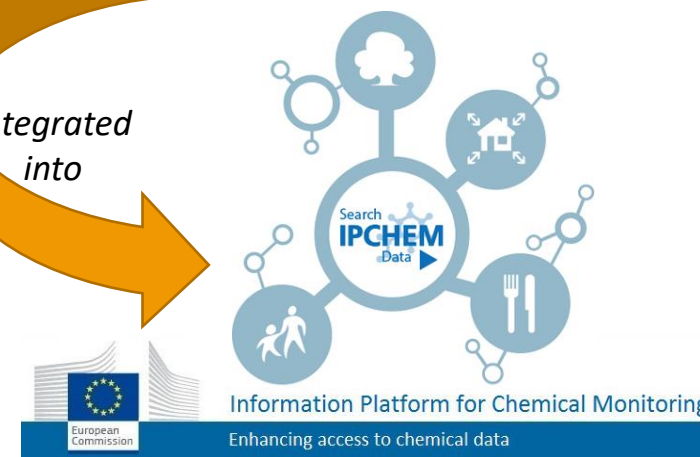
### SSD2 data model

Element Code	Section Code	Section	Element Name	Element Label	Type <sup>(1)</sup>	S/R/C	M	Controlled terminology
D.08	D	Sample taken	sampD	Day of sampling	xs:integer (2)	S		
D.09	D	Sample taken	sampSize	Sample taken size	xs:double	S		
D.10	D	Sample taken	sampSizeUnit	Sample taken size unit	xs:string (5)	S		UNIT
D.11	D	Sample taken	sampInfo	Additional Sample taken information	CompoundType <sup>(2)</sup>	C		
E.01	E	Matrix sampled	sampMatType	Type of matrix	xs:string (5)	S	M	MTXTYP
E.02	E	Matrix sampled	sampMat	Matrix	CompoundType <sup>(2)</sup>	C	M	MTX



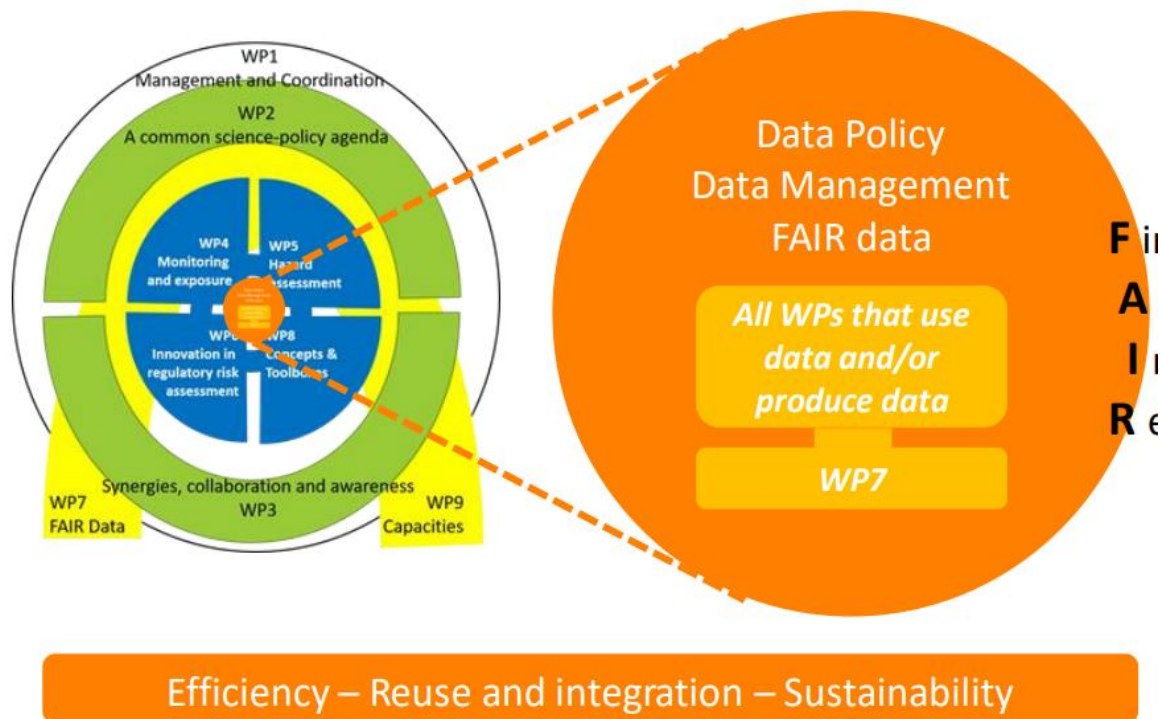
FoodEx2  
controlled vocabulary

integrated into

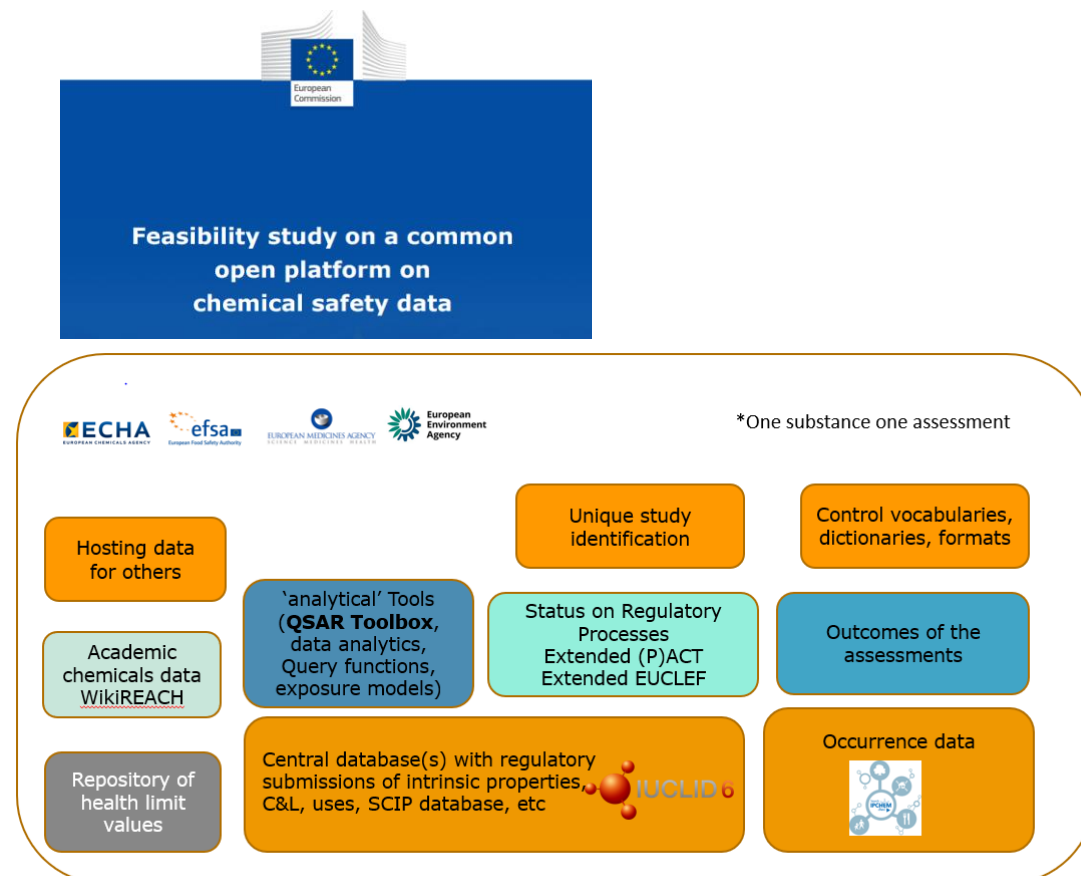


# Example ongoing projects

## European Partnership for the Assessment of Risk from Chemicals (PARC)



## Common data platform on chemicals (Chemicals Strategy for Sustainability (CSS), One Substance One Assessment (OSOA))



# Way forward? Discussion

