

ICCA Global Policy

- Basis -

The ICCA and its member associations and their companies continues and promotes industry initiatives and cooperative programmes like

➔ **HPV-Chemicals Initiative**

➔ **Responsible Care and Product Stewardship Programmes**

➔ **LRI (Long Range Research Initiative)**



ICCA HPV Initiative

Voluntary Industry Initiative

Target 1000 Chemicals

OECD Review Process

ICCA HPV-Initiative

The goal of the initiative is to prepare **harmonised, internationally agreed data sets and initial hazard assessments.....**

⇒ improve knowledge on existing chemicals

⇒ use a harmonized information system (IUCLID) for

- providing information / data
- ensuring public access to the relevant information

⇒ use an exposure driven tiered approach for further testing

⇒ work on the basis of company consortia in partnership with governments



INTERNATIONAL
COUNCIL OF
CHEMICAL
ASSOCIATIONS

ICCA HPV Initiative

Data sharing

Delivers most comprehensive Data Set

Facilitation for Product Categories

Animal Welfare

Cost Benefits

ICCA HPV Initiative

Company commitment to HPV programme
but no contracts for consortia activities

Protection of confidential and proprietary information?

End-Point Robust Study Summaries available
(Full studies remain company IP)

New testing / shared studies (ownership rights?)

Value recognition – implications for REACH

REACH

Tests involving vertebrate animals : mandatory sharing

Tests not involving vertebrate animals (VA)

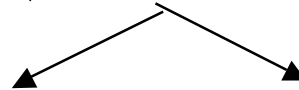
Consortia
(Com)

Mandatory
Data Sharing
(OSOR)



REACH (Council)

(non VA tests)



Phase-in S
(art. 27, 28)

Non phase-in S
(art. 25)

Pre-registration (SIEF) R asks other members

R requests report summaries

Existing studies : O agrees permission
To refer to the full study
If O refuses or

O agrees permission to refer
to summaries

Not existing studies :
Agreement or Agency → P
Other P receives the full report

Agency provides full report
Agency provides full report

(cost sharing if less than 10 years)
(years)

(cost sharing if less than 10
years)

REACH (Council)

Ambiguities :

{
Refer (see ?)
Make available (copy ?)
Provide (distribute ?)
Receive (ownership ?)

{
Report summaries
Full report

Value ?

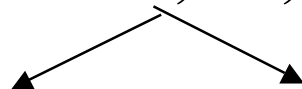
Cost

Trade secrets $\left\{ \begin{array}{l} \text{registrants} \\ \text{public (art. 115, 116)} \end{array} \right.$

Age : 10 or 15 years ?

REACH (Council)

(Art. 73-2d, 115, 116)



Confidential (deemed)

- composition of preparations
- list : function or application
- tonnage
- links / DU

Except

If urgent action is essential

To protect health, safety, environment

Public

- trade name
- classification and labelling
- ?
- guidance

Except

when the agency accepts

potentially harmful for

commercial interest

No right of appeal in the agency

Ombudsman or Court of Justice

REACH (Council)

Legality / Illegality
Of data sharing rules

Know-how and business secrets : KPMG

- Property expropriation ? National, EU legislation and case law
- Confidentiality violation ? Art. 39 TRIPs
- Proportionality ? Appropriate ? Necessary ?
- Objectives of competitiveness and R&D ?

According to final wording of REACH :

- Compensation
 - Opt out
-

REACH

Data Sharing Opt Out (non VA)

European Parliament (art. 23) relates to sharing of non VAS

- disproportionate cost
- data not relevant
- commercially confidential (registrant)
(if another registrant may ask, agency considers justification)

Council (art. 10) relates to join submission of data

- disproportionate cost
 - disclosure commercially sensitive
 - disagreement
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