

A close-up photograph of a microscope's objective lenses, showing the 'Plan' and '0.25' markings on the lens barrels. The image is set against a blue background.

REACH Data Management

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REACH Data Management

- **Information required**
- **Sources of data**
- **Confidential & non-confidential**
- **Data to be managed**
- **Further considerations**

Data Management

REACH is concerned with the registration of approximately 30,000 substances

- Substances alone in preparations and articles**
- Some companies will have a large number of substances to pre-register and register**
- A percentage of which will go into Evaluation, Authorisation, and possibly Restriction**
- Each stage will require the use of large amounts of data incorporated into a variety of reports for wide distribution**

All of which must be managed

Data Management

Information required:

Registration dossiers prepared by industry.

- **Physchem, (eco)toxicity data, environmental fate, exposure scenarios & risk assessments**

Registration phased over 11 years

(M)SDS,s and Chemical Safety Reports.

Data requirement dependent on tonnage and use/application

The larger the tonnage and/or hazard the larger the data dossier

Data Management

Sources of data:

Data in the form of studies, summaries, application information, exposure and risk assessments, risk management recommendations, from those involved throughout the REACH process.

Company internal files

Members of SIEF's

Other registrants

Up stream suppliers

Downstream Users

Other regulatory compliance programmes

Other with information to add (NGO's)

REACH - Data Management

Internal

Safety Data Sheets
Chemical Safety Reports
Technical data/information
Dossiers
Contact information
Pre-registrations
Registrations
Results from evaluations
authorisations & restrictions
Tonnage on the market
Contact with consortia and
project managers

External (e.g. the EChA)

Pre-registrations
List of available data
Names of data owners
Registrations
Hazard classification
Dossiers
CSR's
Results from Evaluations &
Authorisations
Restrictions
Tonnage on the market

Data Management

Data to be considered Confidential

- ❖ **Contracts and agreements**
- ❖ **Formulation information**
- ❖ **Function and use (limited)**
- ❖ **Declared annual tonnages**
- ❖ **Updated tonnage information**
- ❖ **Commercial relationships with up and downstream users**

In cases of emergency the Agency can disclose information it has on file

Data Management

Data NOT considered Confidential

Data taken from the public domain

Results of Internet searches

Data placed into a SIEF

Names of companies placing studies into a SIEF

Substances pre-registered

Results from the registration phase.

Testing proposals

Authorisations and restrictions

Chemical Safety Reports

Safety Data Sheets (extended)

Data Management

Requirements

Carry out a review of REACH, determine your level of involvement, how much data is involved.

Mandatory actions to be taken through out the life of REACH

Data management is essential - for each and every substance included in REACH

Data storage, indexing, sorting, access & use

**Some companies will have established data management systems, manual or electronic
- others not**

Records open to inspection by the authorities

Data Management

Take one substance

Assume a company owns 30 pieces of information relevant to REACH.

All to be made available in a SIEF.

Information will be on file with the Chemicals Agency so available to others with an interest in that substance.

To be included in the Registration Technical dossier.

Data Management

Take one substance

Company is a member of a SIEF for this substance

Assume a total of 20 SIEF members

The company has 30 items of information (studies) of relevance to REACH

Already 600 data points to action and monitor

There will be more & more

Data Management

Take one substance

Other SIEF members will have relevant data

Assume each member has 20 items of information which it will place in a SIEF and which could be taken into consideration by the company

This could add another 380 action points

Data Management

Take one substance

The company data could be used by other companies who are not a member of the SIEF but are registrants

Data could be used to support other substances with a similar structure “use of cross over data”

There may be a significant number of Downstream Users who are not part of a recognised SIEF who want to use the data/information

All adds to the number of action points

Data Management

Further considerations

Information owned by the company is considered protected for which they will seek financial compensation.

Each study will have an agreed value.

Expectation of the commission for “fair treatment” to SME’s. This may lead to different fees payable for use of data.

Data Management

Protected data

Different periods of data protection can be applied

Shared with a number of other companies under existing contracts/agreements

With different level of access

Could be used to support substances under other regulations e.g. EPA, EU BPD, Plant Protection, HPV.

Introduces more data action points

Data Management

All substances under REACH

Reality check !

How many substances does your company have that will be covered by REACH

How many individual sites are involved

Are you a manufacturer, importer, formulator, downstream User or all of them

Do you have data managements systems in place
- will they handle the extra work

Data Management

Further considerations

Substances alone in preparations and in articles

Complications due to mergers and acquisitions

Existing contracts and agreements will need to be reviewed and revised

Different languages

Lots and lots and lots of action points !!

Data Management

To summarise

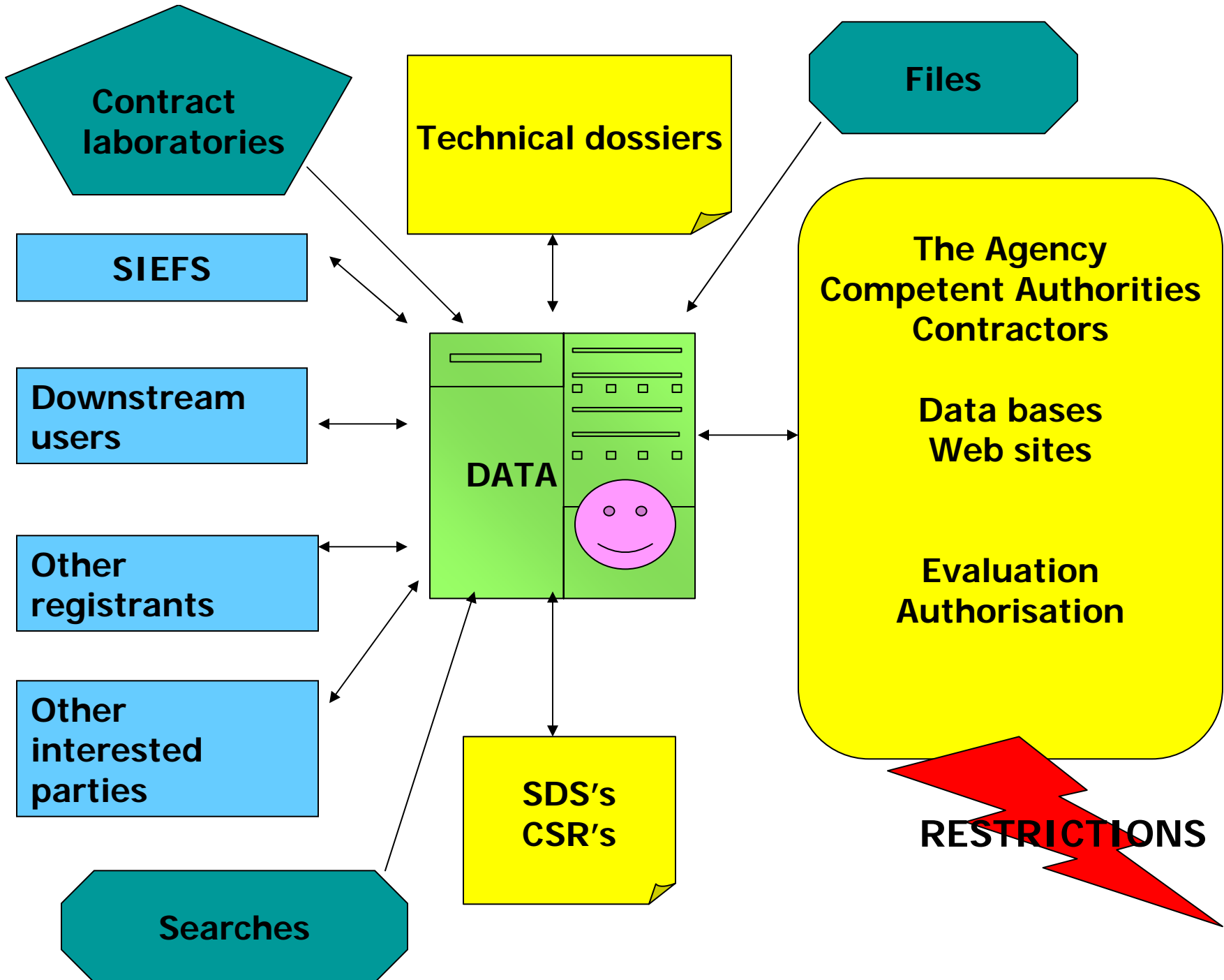
REACH will require a dramatic change in the way many companies manage the data required to ensure compliance with REACH

Use of a sophisticated, user-friendly, electronic data handling system is essential.

Will require dedicated REACH personnel and significant IT input

There will be a **large** number of contact points to monitor

Strongly suggest to start now !





**Thank you
for your attention**

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