Scheme to fulfil the REACH information requirements
Substances manufactured or imported in quantities between 1 and 10 tonnes per year

Step 1: data gathering

All available relevant information on intrinsic properties.
- Human data.
- Testing data: physico-chemical data, *in vitro* and *in vivo* data.
- Non-testing data: data obtained with predictive tools.

Exposure data.

Step 2: information needs

REACH annexe VII:
standard information requirements for substances ≥ 1 tonne per year and < 10 tonnes per year.
REACH annexe III:
criteria for "phase-in substances[1]" ≥ 1 tonne per year and < 10 tonnes per year, leading to the obligation to fulfil the complete set of annexe VII data requirements (i.e. (eco)toxicological data in addition to the physico-chemical data).
REACH annexe XI:
general rules for adaptation of the standard testing regime.

1. phase-in substance: a substance already manufactured or imported, under certain conditions, before the entry into force of REACH on 1 June 2007.

Step 3: identify information gaps

Does the reliable available information correspond to the information requirements on physico-chemical properties identified in step 2?

Yes

Is the substance a "phase-in substance"?

No

Does the gathered and/or generated information correspond to the information requirements on (eco)toxicological properties identified in step 2?

Yes

Record classification and labelling conclusions.

No

Step 4: generate new data

Fill data gaps by generating new (eco)toxicological data in accordance with REACH annexes VII and XI.

Record classification and labelling conclusions.

Yes

Does the gathered and/or generated information allow to:
– predict that the criteria for category 1 or 2 CMR[2] or PBT[3]/vPvB[4] are likely to be met,
OR
– indicate that use(s) are dispersive or diffuse **AND** predict that classification criteria for any human health or environmental hazard are likely to be met?

2. CMR: Carcinogenicity, Mutagenicity or Reproductive toxicity.
3. PBT: Persistent, Bioaccumulative and Toxic.
4. vPvB: very Persistent and very Bioaccumulative.

No

No more information required.
Record classification and labelling conclusions.

No

Step 4: generate new data

Fill data gaps by generating new physico-chemical data in accordance with REACH annexes VII and XI.

Diagram adapted from a figure given in the "Guidance on information requirements and chemical safety assessment – R.2".

cnrs

Prévention du risque chimique, France, 2007

REACH Registration, Evaluation, Authorisation of Chemicals