# 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 substances1" ≥ 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

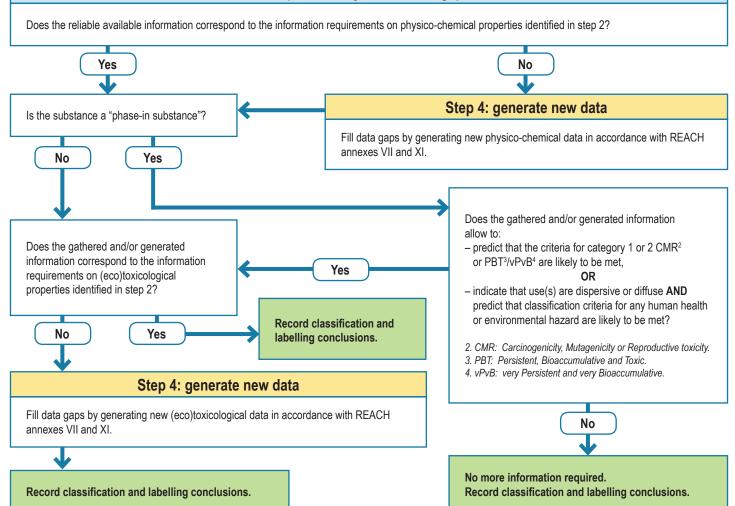


Diagram adapted from a figure given in the "Guidance on information requirements and chemical safety assessment - R.2".



