

# Scheme to fulfil the REACH information requirements

## Substances manufactured or imported in quantities $\geq 10$ 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  $\geq 1$  tonne per year and  $< 10$  tonnes per year.

**REACH annexe VIII:**  
standard information requirements for substances  $\geq 10$  tonnes per year and  $< 100$  tonnes per year.

**REACH annexe IX:**  
standard information requirements for substances  $\geq 100$  tonnes per year and  $< 1000$  tonnes per year.

**REACH annexe X:**  
standard information requirements for substances  $\geq 1000$  tonnes per year.

**REACH annexe XI:**  
general rules for adaptation of the standard testing regime.

### Step 3: identify information gaps

Does the reliable available information correspond to the information requirements identified in step 2 and allow:

- determination of classification and labelling;
- derivation of (a) Predicted No-Effect Concentration(s)<sup>1</sup> [PNEC(s)];
- derivation of (a) Derived No-Effect Level(s)<sup>2</sup> [DNEL(s)];
- PBT<sup>3</sup>/vPvB<sup>4</sup> assessment?

1. PNEC: the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur.

2. DNEL: the level of exposure to the substance above which a human group should not be exposed.

3. PBT: Persistent, Bioaccumulative and Toxic.

4. vPvB: very Persistent and very Bioaccumulative.

No

### Step 4: generate new information/ propose testing strategy

Fill data gaps in accordance with REACH annexes VII, VIII and the following where needed, and annexe XI.

Yes

Record classification and labelling conclusions.  
Record PBT/vPvB conclusions.  
Record DNEL/PNEC<sup>5</sup>.

5. For substances for which no DNEL/PNEC can be derived, perform a qualitative risk characterisation.

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