### Data sharing under REACH for non-phase-in substances and not pre-registered substances

The inquiry process

# Potential registrants of non-phase-in substances

# Potential registrants who decide to register without pre-registration

They must stop manufacture or import of their substance after 31 May 2008, before making their inquiry. They are mandatory participants of the relevant SIEF<sup>1</sup>.



#### Inquiry prior to registration

Prior to registration, the potential registrant must inquire the European Chemicals Agency (ECHA) whether a registration has already been submitted for that substance. He indicates which information requirements would require new studies involving vertebrate animals and which information requirements would require other studies. ECHA will inform him if there are other potential registrants.



The substance has already been registered and the relevant information has been submitted  ${\bf less}$  than 12 years  $^2$  earlier.



The substance has already been registered and the relevant information has been submitted **more** than 12 years<sup>2</sup> earlier.

The substance has not previously been registered.



#### Sharing of existing data between registrants

ECHA informs the potential registrant without delay of:

- the name(s) and address(es) of the previous registrant(s);
- relevant study summaries<sup>3</sup> or robust study summaries<sup>4</sup> already submitted by them.

At the same time, ECHA informs the previous registrant of the name and address of the potential registrant.

Then, the following process applies:

- the potential registrant is required to request studies involving tests on vertebrate animals from previous registrant(s). He also has the right (but not the obligation) to request information involving other types of tests;
- the potential and the previous registrant shall seek to reach an agreement on data and cost sharing. This can be achieved either by direct agreement or by submission of the matter to an arbitration board whose decision the parties agree to accept:
  - when an agreement is reached, the previous registrant makes available to the new registrant the agreed information. He also gives the new registrant the permission to refer to the full study report;
  - in case of failure to reach an agreement, the potential registrant informs ECHA and the previous registrant of the failure. Within the following month, ECHA gives the potential registrant permission to refer to the information he requested. The previous registrant has the right to be compensated for the use of his information by the potential registrant. The previous registrant may also decide to make the full study available to the potential registrant. In this case, he has a claim for an "equal" share of the cost incurred by him.

The applicant is not required to request the information from the previous registrants.

The potential registrant could normally access the results of the studies and the study summaries/robust study summaries. He is allowed to register without having access to the full study report. In case of study summaries or robust study summaries for which ECHA has accepted as valid the justification for not publishing them, the registrant should make an express

If the same property is covered by a newer study, it is the responsibility of the registrant to consider whether the information in the older study is still relevant.

inquiry to ECHA to have access to such

The applicant has to carry out all tests required to satisfy his registration requirements, alone or with other possible applicant(s).





studies.

REACH registrants are required to jointly submit information on the hazardous properties of the substance (studies and proposals for testing) and its classification and labelling and can, if they agree, also jointly submit the chemical safety report and/or the guidance on safe use. However, registrants are allowed to opt out from the joint submission under specific conditions.

1. SIEF: Substance Information Exchange Forum. 2. The 12 year period starts running from the moment when the information was submitted to the relevant authorities. This means that, when the information has been submitted after the original registration (for instance, following an update), the 12 year period extends beyond 12 years after the registration date.

3. Study summary: a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study. 4. Robust study summary: a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report.



