

Department for Environment, Food and Rural Affairs

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REACH Registration preparations – minimising animal testing

This is an updated version of the guidance note originally published on 14 December 2009.

Now that REACH Substance Information Exchange Fora (SIEFs) are getting going and preparations are underway for the first registrations of phase-in substances by 1 December 2010, the attention of many companies will be turning to completing the joint registration dossiers for those substances. The primary role of SIEFs is to enable the sharing of existing data on substances, and within that REACH makes it mandatory to share all existing animal test data to avoid the need for duplicate tests.

Inevitably, there will be gaps in the information needed to complete the dossiers, and agreement will have to be reached within the SIEFs about how to fill these. For substances in quantities of 100 tonnes or more per year, proposals for additional testing to fill data gaps will have to be submitted to the European Chemicals Agency (ECHA) for approval. Where these involve animal tests, ECHA must publish them on its website for 45 days and receive comments from any interested third parties.

When putting together testing proposals, you will need to comply with REACH requirements on the use of animal tests. REACH is clear that animal tests must only be used as a last resort, when no suitable non-animal alternative tests are available. Where animal tests are necessary, once done they may not be repeated. The preferred means of obtaining information on the properties of a substance must always be by use of non-animal test methods wherever possible.

There are many ways to avoid animal testing, by using alternative methods, as presented in REACH Annex XI. **Chemical grouping and read-across** approaches can be used where justified, which involves the grouping of chemicals with similar or predictably variable structural features and intrinsic properties and sharing data from one or a few across the whole group. **(Q)SAR** ((Quantitative) Structure Activity Relationship – computer-based mathematical models based on properties and structures of known chemicals) and ***in vitro*** tests (use of living tissue, organs, or cells, but not live animals) can be used providing certain conditions are met regarding the reliability of the information obtained. Also information needs could be met by a ***weight of evidence*** assessment, in which evidence from several separate sources of information leads to the conclusion that a substance has/has not a particular property, while the information from each single source alone is insufficient to support this conclusion.

You should also check carefully whether any of the derogations permitted in REACH Annexes VII to X, which specify the registration information requirements, could apply to your situation, and thus avoid unnecessary animal tests. The standard tests are set out in column 1 of the annexes, and column 2 provides the circumstances in which the information (often from an animal test) is not required.

REACH also provides for the use of existing data from other sources, even if these are not conducted according to Good Laboratory Practice (GLP) standards, the Council Test Methods Regulation (No. 440/2008) and its first amendment by Commission Regulation (EC) No. 761/2009, or OECD-approved methods, to waive testing (see REACH Annex XI section 1.1.2), as long as the information is sufficient for classification and labelling, and/or risk assessment purposes.

Exposure-based waiving of certain tests may be permitted in cases where it can be shown that exposure is insignificant or absent for the substance concerned. The REACH annexes themselves also provide means for avoiding duplication of animal tests, where a test becomes almost immediately redundant by the conducting of more comprehensive tests, such as 28-day repeat dose tests not being needed if 90-day tests are proposed. Careful scrutiny of the relevant REACH Annexes for your registration requirements will indicate where such duplications can be avoided.

You should also bear in mind that under EU Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes, and the UK's Animals (Scientific Procedures) Act 1986 (as amended) which implements it, animal tests must not be done if there is a suitable non-animal alternative test available. The REACH requirements for animal testing are covered by the current Home Office regulatory inspection regime for the 1986 Act.

When considering further tests for REACH, then, you should consider carefully the following points:

- whether animal tests are necessary, and actively look for non-animal alternatives to use instead wherever possible (e.g. the *in vitro* skin irritation model (B46) over the rabbit Draize skin test (B4) in the Test methods Regulation).
- It is important to remember that the non-animal alternatives test methods do not necessarily have to be adopted OECD- Test Guidelines; if they are included in the REACH Test methods Regulation (as amended), then they can be used for REACH testing requirements.
- Other test methods valid to international standards that do not appear in the Test methods Regulation, or the REACH annexes, can also be used.
- Where animal tests are absolutely necessary, and there is a choice, use the most refined method available, to reduce the numbers of animals involved (e.g. the local lymph node assay (TG429) is more refined than the guinea pig maximisation test (TG406) for skin sensitisation).

The UK REACH Competent Authority has published more detailed information and guidance on use of non-animal alternative test methods, which is available at <http://www.hse.gov.uk/reach/resources/18animaltesting.pdf>

Further guidance on the use of animal testing in REACH registration is also available from the UK REACH Competent Authority at <http://www.hse.gov.uk/reach/resources/16registration.pdf>

The European Chemicals Agency has published guidance on data sharing at http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.pdf, on registration at

http://guidance.echa.europa.eu/docs/guidance_document/registration_en.pdf?vers=26_11_08, and on information requirements at http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1254136138#A. Additionally, ECHA has produced a series of guidance fact sheets, which provide “at a glance” information: http://guidance.echa.europa.eu/guidance3_en.htm.

The UK REACH Competent Authority national helpdesk can be contacted at ukreachca@hse.gsi.gov.uk for information and advice on REACH.