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Institute for Reference Materials and Measurements
Reference Materials Unit

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The European REACH regulation and the production of Reference Materials

REACH is a new European Community Regulation on chemicals and their safe use (EC 1907/2006). It deals with the Registration, Evaluation, Authorisation and Restriction of chemical substances. The new law entered into force on 1 June 2007. The regulation aims to protect human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. Enterprises which manufacture in or import into the EU more than one tonne of a chemical substance per year will be required to register it in a central database administered by the new EU Chemicals Agency (ECHA).

There have been opinions in commercial newsletters that the introduction of REACH would have far-reaching impacts on producers and distributors of reference materials, especially for reference materials containing very toxic and/or bioaccumulative substances. As the regulation is very complex (the English version of EC 1907/2006 contains 849 pages), IRMM has contacted the competent Directorate General within the European Commission (DG Environment) and asked for clarification. The outcome of this consultation is:

- Registration of chemicals is only necessary if the yearly production exceeds 1 ton per year. This tonnage limit is independent of the nature of the substance and is not influenced by toxicity, bioaccumulativeness etc. Natural substances are also exempted from registration, if they are not dangerous and have not been chemically modified.
- Authorisation to use or put a substance on the market is required for substances identified as substances of very high concern (SVHC) and included in Annex XIV of REACH. This Annex will contain a list of substances subject to authorisation. Carcinogenic, mutagenic, reprotoxic, bioaccumulative, persistent substances as well as endocrine disruptors are candidates for that list, but are not automatically included. Competent Authorities of the EU Member States or the ECHA, on a request by the European Commission, may suggest substances being classified as SVHC. If this suggestion is taken up, the substances are finally included in Annex XIV of the REACH regulation. The candidate list of substances for eventual inclusion in Annex XIV will be published and periodically updated by ECHA. The first candidate list was published on ECHA's website in October 2008. It is important to note that authorisation for preparations containing an SVHC is only required if the mass fraction is above 0.1 %.

- Title VIII of REACH provides for possible restrictions on the manufacturing, placing on the market and use of certain dangerous substances (on their own, in preparations, or in articles). This is not a new feature of chemicals legislation. The current Annex XVII of REACH reflects the restrictions made already by Directive 76/769. Member States or the Commission can propose more substances for inclusion in REACH Annex XVII when there is an unacceptable risk to human health or the environment arising from the manufacture, use of placing on the market of substances, which needs to be addressed on a Community-wide basis.

In short, the consequences for reference material producers seem to be:

- No registration of reference materials is required for materials produced at less than 1 ton per year, regardless of the nature of the substance and/or certified parameters. The vast majority of reference materials will fall under this category.
- Reference material distributors will need to confirm whether their customers have the necessary authorisation in the case of CRMs for SVHC. However, given the mass fraction limit of 0.1 %, this practically affects only pure substances and not even most of their solutions. In order to fulfil their obligation under REACH, RM producers need to follow the updates of Annex XIV of REACH.
- Reference Material producers will need authorisation to handle SVHCs, if they are used in the production process, e.g. for spiking matrix materials or for the preparation of solutions.

Detailed information and guidance on REACH can be found on the ECHA-website (www.echa.europa.eu).



Prof. Dr. Hendrik Emons
Head of Unit