

SUBSTANCE CHARACTERISATION

AN OVERVIEW

WHITE PAPER

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November 2011

the **REACH** CENTRE

Substance characterisation is an analytical process through which the chemical identity and composition of a substance may be demonstrated.

Under REACH, there are four scenarios where characterisation is warranted:

1. Submission of an Inquiry
2. Making a REACH registration
3. Submission of a PPORD Notification (substances for **P**roduct and **P**rocess **O**rientated **R**esearch and **D**evelopment)
4. Application for Authorisation

Every manufacturer or importer intending to undertake any of the above activities must characterise their substances fully.

The nature of a given substance will determine which analytical tests are appropriate and clearly, technical expertise is essential at this stage. It can be difficult to decide just how much analytical information will be sufficient. The question to ask is *'Would an independent, technically qualified individual, with little or no prior knowledge of the substance, be able to use the information provided to identify it chemically and be convinced of its composition?'*

Both spectroscopic and chromatographic techniques should be used where this is scientifically meaningful and practically possible. More specific analytical tests may be necessary for some substances. Spectral data are used to define the *identity* of the substance whilst chromatography defines its overall *composition*. It should be noted that in some instances, e.g. UVCBs (substances of **U**nknown or **V**ariable composition, **C**omplex reaction products or **B**iological materials), analytical data alone may be insufficient and additional background information should be included.

Good quality spectra and chromatograms should be provided and fully interpreted, and all experimental work must be documented such that a competent person might be able to repeat the work.

Scientific justification for tests not deemed to be appropriate must be given. In practice, this tends to be limited to the principal spectroscopic and chromatographic techniques listed in Annex VI of REACH (Section 2: *Identification of the Substance*).

ECHA has stated its intention to evaluate at least 5% of dossiers submitted in 2010 by the end of 2013.¹ Whilst no data relating specifically to ECHA's assessment of the analytical information provided in *registration* dossiers is yet available, there are some statistics from the *Inquiry* process that may offer an insight into the Agency's expectations with respect to substance characterisation. During the first 5 months of 2009, around 450 *Inquiries* were received by ECHA, 23% of which were rejected on the grounds that the dossiers were incomplete (e.g. missing spectral data) or the substance identity had not been sufficiently described.² By 2011 the quality of *Inquiry* dossiers had improved but overall, 55% still failed to meet the requirements outlined by ECHA.³

Establishing substance identity is a precursor to sameness checking. Ultimately, it determines SIEF membership and justifies data sharing. Clearly it is a fundamental activity for all manufacturers and importers seeking to meet their individual obligations within the regulatory framework. Since many key discussions within SIEFs depend on a detailed knowledge of the relevant substance's identity and composition, it is prudent to undertake any analytical activity at an early stage in order to be appropriately prepared.

¹ <http://chemicalwatch.com/8601/echa-agrees-work-programme-for-2012?q=dossier%20evaluation>

² ECHA; 2nd Meeting of the Competent Authorities for REACH and CLP (CARACAL), 15-16th June 2009 (Ref CA/57/2009)

³ ECHA Newsletter, No. 5, Oct. 2011, http://echa.europa.eu/doc/press/newsletter/echa_newsletter_2011_5.pdf

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