

REACH-ing an Agreement on Data Protection, Data Sharing, and Data Compensation

The latest IBC conferences sponsored by Steptoe & Johnson on the European Union's proposed reform of chemicals legislation ("REACH"), held in Brussels and Boston, highlighted some of the most important and contentious issues facing industry. These include, multiple registration/duplicative testing, registration/prioritization mechanisms, impacts on innovation, confidentiality, data compensation, compatibility with international trade rules and overlapping international initiatives, and the potential for inconsistent application across the EU Member States.

The issue of data protection, in particular, has given rise to considerable debate. Objections concerning inadequate data protection have consistently been raised in response to proposed and/or adopted EU chemicals legislation, particularly those measures requiring the development of dossiers containing extensive information necessary for the assessment of risk to health and the environment.

Despite the fact that the EU Directives concerned with the approval for sale of biocides and plant protection products (PPPs) have been in operation for a number of years, debate about how data protection, data sharing and compensation should be addressed persists. The procedures that are being developed for REACH almost certainly will influence the pending revision of legislation on PPPs, which the EU Council agreed to fast-track last November, and may encourage revision of biocides legislation along similar lines. With regards to biocides, the European Court of Justice confirmed last December, in two cases, that Annex II of Regulation 2032/2002 (part of the second phase of the 10-year working programme examining all active substances already on the market) would not be suspended pending a final judgment on the legality of the programme. The programme includes controversial provisions regarding the data treatment and the status of "free riders." It is imperative that REACH properly addresses these issues.

Under the current REACH proposal, potential registrants become members of a Substance Information Exchange Forum (SIEF), to which they must share their proprietary data. There is no effective data protection under REACH as "exclusive use" rights are not acknowledged or protected. There are also many ambiguities regarding data compensation "rights."

A need exists for an effective and workable procedure to bring data owners together under approved cost sharing and data compensation formulas. With the details of REACH still very much open to debate (as discussed in this issue's [article on the recent European Parliament Hearing](#)), the time is ripe for affected stakeholders to fully develop a model for the procedures necessary to accommodate all aspects of data protection. Industry has experience, in the US and elsewhere, in this area, and is best-placed to develop and propose workable models. If this opportunity is not taken up it is highly likely that a system for the treatment of data will be imposed.