

Chemical diversity and the data market: a major players' view

In the second of two articles about the European dyes sector, the big players say cost sharing within their consortia is fair



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In the previous article ([see pages 10-11](#)), the financial pressures facing the "Dye-staff" group of SME dyes importers were presented, as set out in a study they commissioned and presented to the REACH competent authorities earlier this year. The companies say the likely reduction in the number of available dyes caused by the high cost of registering them, together with a lack of data, could threaten the survival of Europe's textiles and leather supply chains. A key concern of theirs is the availability of data owned by some major chemical companies.

These major companies are organised into three consortia, for dyes used in the textiles, leather and paper industries, and are managed by the consultant REACH&Colours Italia together with European Pulp and Paper Chemicals Group (EPCG) for paper.

Speaking on behalf of the three consortia, REACH&Colours' CEO and founding partner Michela Kahlberg says they fully agree with the Dye-staff companies that the cost for REACH dossiers is "very high in general, and especially for dyestuffs, many of which are already suffering from increased competition". The Dyes Consortia members are, she says, "working hard to register as many leather, paper and textiles dyes as possible, financing all the work and the costs". They are also "very favourable to scientific and well justified read-across and Qsar methods" to avoid unnecessary vertebrate testing, but the authorities' acceptance of such methods "is still very low".

Cost sharing within the three consortia (see below) is based on "fair principles", say the three consortia.

Adding a personal note, Mrs Kahlberg says that "if today the 'big players' are the main data owners, it is just because they invested in the past in testing their substances for the safety of all, whilst the other companies simply used their results in their safety data sheet. I think that it is fair now to somehow reimburse at least part of their previous investments and share the costs among all interested parties."

Back in 2007 and 2008, says Mrs Kahlberg, "REACH&Colours contacted almost all the main Italian distributors and European producers and importers of organic dyestuffs in order to join forces, agree on common strategies and rules, and co-register under the REACH Regulation these complex substances before the 2018 deadline."

So far, the three dyes consortia say they have jointly collected and

evaluated a huge number of existing studies (of which 99% are private); created a data base with over 1,300 different substances (including some from Elnics, the European List of Notified Chemical Substances) and over 4,000 studies; they have created the legal framework to regulate the different obligations, and have developed an ad-hoc software to manage Sief communications, the collection of existing data and the new information, the cost calculations and the consortia work in general. The consortia members grouped the substances in families with structural similarities in order to avoid further testing and worked on new *in vitro* methods and Qsar modelling "for animal welfare and cost savings as much as possible for the benefit of all". All these activities are, of course, still in progress.

The REACH dyes consortia timeline

June and December 2007: REACH&Colours meets with major Italian dye distributors, including Manifattura Chimica Italiana (MCI) and several other Italian dye firms now part of the Dye-staff group, to create a REACH registration working group to discuss sharing work and costs.

April 2008: EPCG Paper Colorants REACH Consortium founded. Members are Archroma, BASF, Kemira, REACH&Colours Kft and Robama; about 120 substances covered.

October 2008: REACH&Colours emails all main producers/importer of dyes proposing they join together in consortia to organise and share REACH registration work for organic dyes.

June 2010: Textile Dyes Consortium founded. Members are Archroma, DyStar, Huntsman and REACH&Colours Kft; some 400 substances covered.

September 2011: Leather Dyes Consortium established. Members - BASF, Lanxess, REACH&Colours Kft, Stahl and TFL; around 180 substances covered.

December 2012: REACH&Colours Italia presents the three consortia's work to the Italian REACH competent authorities. **January 2013:** face to face meeting in Federchimica between the three consortia (represented by EPCG and REACH&Colours Italia) and the Dye-staff group.

May 2010/4: face to face [presentation](#) to Etad (the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers) in Barcelona of the three consortia's work and rules.

Up to now, says Mrs Kahlberg, about 50 substances have been registered and more than 350 are already under preparation for 2018 (with lead registrants officially elected).

The Sief management [software](#) is online and free of charge, is used to check a range of information including Cas or EC numbers, chemical names, tonnage bands, lead registrants, sameness criteria, identified uses, exposure scenarios and registration costs, as soon as it becomes available, for all the pre-registered substances covered by the three dyes consortia.

The organic dyes are very complex molecules. Echa, says Mrs Kahlberg, is "very conservative" in terms of testing. The three consortia's work is mainly focused on avoiding some tests by performing them on representative substances and in few cases using the results in read-across for the most similar ones, supporting this strategy with estimations based on Qsar models. But it is not possible, she says, to group the dyes in categories or very homogeneous families using then the same dossier for registering a lot of different substances. "Case by case, endpoint by endpoint, only a very skilled toxicologist or eco-toxicologist can evaluate and justify in depth the reasons why a certain study can be used in read-across to assess that endpoint. Every dossier is different and requires a lot of work and testing."

How the three dyes consortia work

Each consortium member (CM) has to proportionally share the work with the other members. Every CM has to autonomously finance and finalise a certain number of dossiers every year for the next four years. For many substances where a lead registrant has been elected, the integrated testing strategy has been decided and testing has started. Therefore, says Mrs Kahlberg, "each CM should have the competence (or pay a service provider) to prepare a dossier, including its chemical safety report, and must order, evaluate and purchase the (often very expensive) new studies necessary to fulfil the data gaps at its own risk. As well as the money that each CM must provide, a range of internal, very specialised and competent resources (such as chemists, toxicologists, ecotoxicologists, regulatory and legal experts) have to be devoted to this work within each company.

The dyes consortia are open to any new members as long as they meet the joining criteria, says Mrs Kahlberg. A requesting member needs to sign the consortium agreement and accept the fees, terms and conditions, and agree to finance and finalise a certain number of dossiers every year for the next four years.

The valorisation of the studies, says Mrs Kahlberg, follows the replacement value criteria. The actual price is calculated using the [Fleischer List](#). Key studies (Klimish 1 and 2) are the only ones valorised, with supporting studies and Klimish 3 or 4 given free of charge. The study value is then halved due to the limited rights granted to the Sief members (no ownership) and a 15% surcharge is applied, "since the decision to conduct a study involves the risk that the study results could adversely affect, or prevent, future substance marketing; hence the data owner contributing a report to the Sief exposed itself to the risk that the investments could result in a study of minor (or no) benefit and the other joint participants are not exposed to this risk in view of the fact that they already know the study result."

The cost of the studies, says Mrs Kahlberg, "is equally shared among the members which need them by law for their tonnage band. The general administrative and technical costs borne by the consortia members are divided by the number of prepared dossiers and the total value is shared to each dossier. As well as the general costs, each LR communicates its specific work for the dossier preparation and this figure is also added to the dossier's value.

Technical and administrative costs are shared 50% equally and 50% following a 1-3-5-7 point system based on tonnage band, where a >1,000 tonne/year registrant pays a share seven times higher than a 1-10 tonne/year registrant does.

During the year of the joint submission, all participants (consortium and Sief members) will share the costs equally, says Mrs Kahlberg. Starting from the following year, a yearly 8% surcharge to the actual value of the LoA will be applied in order to compensate for inflation, investments made, accumulated experience, risk already taken and administration costs. Cost re-sharing will be done on a yearly basis and any will be in fact re-shared among all the previous registrants (Sief and consortium members). The administration fee is not charged to the Sief members during the year of the submission.

Mrs Kahlberg says the average cost for a 10-100 tonne/year dossier for an organic dye is today around €250,000 - 300,000, which is then shared among all co-registrants. "The relatively high cost of individual LoAs, she says, "is due to the low number of current co-registrants." The costs for each dossier will be continuously re-shared and if 10 companies join it, the cost for each co-registrant will be one tenth; if 100 join it, the cost will be one hundredth."

Qsars

REACH&Colours and the University of Milan-Bicocca (Unimib) have partnered to produce new [Qsar software](#) able to model the quantitative relations between the molecular structure and specific properties of dye molecules. These include most of the big players and owners of many toxicity and ecotoxicity studies. The 4,000 or so studies owned by the three consortia's members will, together with studies that will be conducted for the registration of more than 600 dyes by the 2018 deadline, form the basis of the database on which the new software is being developed. The predictive models will be obtained by sophisticated variable selection methods (genetic algorithms, sequential replacement, etc), validation tools and predictive modelling.

REACH&Colours presented the project at the 9th World Congress on Alternatives and Animal Use in the Life Sciences and has been contacted by Ecvam (European Centre for the Validation of Alternative Methods) and Ecopa (the European Consensus-Platform for Alternatives) for possible cooperation.

At present, the Qsar model is able to predict the data for three specific endpoints: bacterial reverse mutation assay (in particular the Ames test), acute fish toxicity; and skin sensitisation. The team is now working to develop other models where a sufficient number of real tests exist.

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