



Know the rules, play your market.

Case study: cost and data sharing

Monica Locatelli – TEAM mastery s.r.l.

TEAM mastery



- TEAM mastery is an Italian company, born in 2008 as a dedicated REACH consultant company
- It is based in COMO, near to one of the cores of manufacturing chemistry in Europe

Consortia

Lead Registration dossiers

Inquiries

Joint submissions

Authorisation dossiers

Disputes



Know the rules, play your market.

Data sharing in the REACH Regulation

Article 11

Joint submission of data by multiple registrants

.....the information specifiedshall first be submitted by the one registrant acting with the agreement of the other assenting registrant(s) (hereinafter referred to as the lead registrant).

.....Each registrant shall subsequently submit separately

Article 26

Studies involving vertebrate animals shall not be repeated.

Article 29

Substance Information Exchange Forums

Article 30

Sharing of data involving tests

If they cannot reach such an agreement, the cost shall be shared equally
Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.

Implementing Regulation on joint submission and data sharing

Itemisation of the data to be shared

justification of any cost

a cost-sharing model, which shall include a **reimbursement mechanism**

documentation shall be kept for 12 years

One substance, one registration



Know the rules, play your market.

Guidance on Data Sharing



GUIDANCE

Guidance on data-sharing

Version 3.1

January 2017

Transparent

Transparency can be demonstrated :

- **Regular and open SIEF communications**
- **Clear spreadsheets with costs related to the studies**
- **Clear spreadsheets with costs related to admin an technical work**
- **Clear communication of the number of registrants**
- **Clear communication on the cost-sharing system, overall**

Fair and not discriminatory

The guidance of 2016 is clearly defining “Fair and non discriminatory” in the following two principles:

“NOT FOR PROFIT” PRINCIPLE

“REIMBURSEMENT”

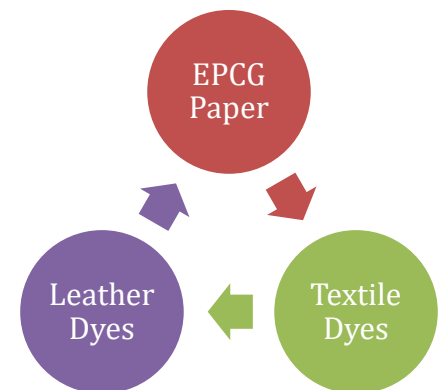
Case study: REACH Dyes Consortia

- three consortia with about 600 substances to be registered,
- mainly < 10 tons/year (deadline 2018),
- complex for analytical identification,
- huge number of existing studies to be managed (over 10.000)
- over 1700 different chemical structures to be analysed

“Technical comprehensive work:” since 2009 !!!

The three Consortia operate independently, but they have common rules :

- Legal framework (contract)
- General rules on costs and cost-sharing
- Development of ad-hoc softwares
- Studies/data gathering, evaluation and data entry
- Grouping of chemical structures, read-across and QSAR
- SIEF communications and administration



REACH Dyes Consortia Overview

Rules on Study Value

- **ONLY THE KEY STUDY** is valued for compensation (not mandatory: see Guidance on data sharing)
- Replacement cost, based on **FLEISCHER LIST** paper, 2007 (Official reference, fair, not varying by lab/data owner.....)
- Studies are valued with correcting factors increasing and decreasing the value, as per Guidance on data sharing
- Co-registrants only pay **ACCESS** to data **FOR THEIR REQUIRED TONNAGE BAND** (fair, non discriminatory)

REACH Dyes Consortia Overview

Technical and administrative work

- Calculated on the **HOURS OF WORK FOR EACH ACTIVITY** by the Lead Registrant and the consultant
- Shared using a **POINT SYSTEM**, proportionate according to lower tonnage bands compared with the higher ones
- Separate administrative **COST FOR LOA MANAGEMENT**
- Separate administrative **COST FOR SIEF MANAGEMENT**

Costs and mark-ups

- Other voices for mark-up:



- ✓ *Risk Premium (when present must be justified)*
- ✓ *Inflation (to be considered when using historical costs)*
- ✓ **Interest (itemisation, a special cases)**

- **All charges are re-allocated every year among all the previous registrants (SIEF and Consortium Members)**

Data sharing disputes

What to do in case a SIEF member asks for an access and receives a cost that is not fair, not transparent or discriminatory?

1. Ask for **explanations**
2. **Discuss** a way forwards
3. **As a last resort:** open a dispute

Data sharing disputes

- What to do:

Collect all written documentation

<https://comments.echa.europa.eu/comments/cms/article303.aspx>

Information to ECHA in case of dispute regarding the sharing of existing vertebrate animal studies between SIEF members

SIEF participants must share data involving tests on vertebrate animals in order to meet their information requirements for the purpose of registration. When receiving a request to share a vertebrate animal study, the owner of the study must provide the proof of the costs for that study or the study itself, pursuant to Article 30(1) of the REACH Regulation. The parties shall also make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way.

This obligation applies to:

1. The sharing of existing studies within the SIEF prior to registration;
2. The sharing of existing studies in registrations already submitted to ECHA.

In application of Article 30(3) of the REACH Regulation, the webform below enables SIEF members to inform ECHA of a data sharing dispute in the context of a registration dossier in preparation or of a registration dossier already submitted.

The SIEF member submitting this webform shall provide **documentary evidence** demonstrating the efforts made by **all the parties** compelled to reach an agreement on the sharing.

The documentary evidence may therefore consists of:

- correspondence requesting the conditions of access to the data;
- correspondence from the holder of the data describing the conditions for the sharing of the data;
- correspondence challenging on valid grounds the conditions imposed by the holder of the data;
- any further justification of or modification of the conditions provided by the holder of the data;
- correspondence challenging these justifications that the other participants would consider unfair, non transparent or discriminatory.

An informed and balanced assessment of the case requires the party submitting this webform to provide ECHA with any copies of the letters and other

Data sharing disputes

- What to do:

Collect all written documentation

https://comments.echa.europa.eu/comments_comments.aspx

- What can be asked for:

Access to tests on vertebrate

- What a SIEF member obtains

A token to joint the Lead dossier

A code to indentify the studies with access granted in IUCLID



IT WORKS ?



Data sharing disputes

- Opt out
 - For all non-vertebrate tests the member has to provide his own data
- The member has to
 - perform a number of data independently
 - compile a complete IUCLID dossier
 - fill up the summaries, derive PNEC and DNEL
 - If applicable, make its own CSR and Risk Assessment

Remember...



LEAD election

What happens if a dossier is sent without Lead Election, very poor, not compliant and the real Lead can not register its dossier?

NOT SOLUTION YET

NO LEGAL FRAMEWORK

ECHA IS WORKING TO FIND THE BEST SOLUTION

The link to report a case is:

<https://echa.europa.eu/it/contact/reach>



Read Across

- Obligation on data-sharing is applied when the substance is the same
- It is not mandatory for participants in different SIEFs to share data
- It is in line with the objectives of reduction of animal
- Every request for access to studies across different SIEFs will have to be negotiated on a case-by-case basis
- 12-year-rule applies also for read-across purposes.

Recommendations

If you are a Lead Registrant:

- As soon as you can, communicate with the SIEF for Lead Election and open the Joint submission
- Keep track of all the documentation you exchanged with SIEF members
- Keep track of all your expenses bound to your dossier, be ready to communicate them in a clear way
- Objectively evaluate your expenses also if they are bound to internal resources
- Answer on time to the requests of data sharing

Recommendations

If you are a Joint member:

- **Be aware of all the related costs behind a dossier**
- Ask clear questions and set reasonable deadlines for answers
- **Open a dispute only as a last resort**



Know the rules, play your market.

**Thank you for attention and.....
good luck for the 2018 deadline!**