CEFIC LEGAL GUIDANCE ON REACH & IP

USE OF PUBLISHED INFORMATION

First edition – December 2009

A. Preamble

Many authors have already been writing on copyright and other IP rights, Reach and Use of information – Copyright[i]. This Legal Guidance is not intended to duplicate such very good articles but aims at providing guidance to companies engaged in REACH / Consortia and SIEF to "approach" a number of specific queries, providing tips as well. See also earlier Cefic Guidance "Working in SIEF"[ii].

This Legal Guidance is to be used by each company/consortium/SIEF under their own responsibility. Cefic would not accept any direct or indirect liability. This Legal Guidance does not replace proper legal advising.

This guidance may be enriched over the time with additional queries and tips, if so other editions will be published over the time.

B. General approach to this question

When considering which data can be used for REACH and under which condition, the following parameters may be taken into consideration:

1. The need to comply with REACH Regulation
2. Dossiers requirement in terms of completeness of data to be included
3. The way to send Dossiers to ECHA : only via electronic means (IUCLID)
4. The need to respect ownership /copyright or other rights of the others

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Regarding this latter point, companies/SIEFs/Consortium need to apply a "status checking" of the data/information they intend to use for Dossiers. Such use of data may be two folds:

- Either data will be integrated in the Dossiers, thus used and transmitted.
- Or users need to have legitimate possession of / or permission to refer even if such data is not directly integrated into the Dossier. This notion is included in Article 10 of REACH Regulation: *"…the registrant shall be in legitimate possession of or have permission to refer to the full report summarised …for the purpose of registration".* Article 10 specifically refer to study summaries and robust study summaries to be included in the technical Dossier[iii].

ECHA mentions on its web site[iv] in broad terms legitimate possession of / or right to refer to the full study report but, also points out the need to conduct a status check that is indispensible for all data to be used under REACH :

"Registrants shall be in legitimate possession or have permission to refer to data they use in their registration dossier. Following the rules for data sharing, they are entitled to refer to/use this information.

Publicly available data may be used free of charge for registration under REACH. However, this data may be subject to copyright and/or other relevant data protection provisions. Therefore you should ensure compliance with the appropriate national copyright and/or data protection law, by checking the "status" of data prior to its use."

For data which is not "publicly" available the acquisition of the right to refer or to use may be done by way of having data sharing agreements and Letter of Access. Cefic has produced models for this[v]. This route is also recommended for published data.

TIPS to suppress / minimise risks: When the owner – publisher has been identified discuss with him/her (them) as copyright holder(s) to obtain at least a Letter of Access and if needed, sign a data sharing agreement. Keep afterwards these documents for the whole duration of REACH.

In addition, it is worthwhile to draft these legal documents broadly so that data concerned can be used by all SIEF participants, and also in the context of cross reading between SIEFs and for categories of substances. This is a much safer route than just assuming that you can use a document, even when either it has been published or if you already acquired a copy. In case of uncertainty companies should not hesitate to ask for clarification to the identified copyright holder.

C. Information & data published on paper

The Reach Regulation does not require that the full study report be sent to ECHA at Registration, but, requires that the Registrant is in legitimate possession or has permission to refer to that full study report for registration purposes.

When it come to publication on paper it may well be the case that a company / SIEF has acquired lawfully a paper copy of a study or the full study report for example and may be considered in "legitimate possession of it". This may be done by way of purchasing a

periodical containing a full study report or by acquiring a copyrighted conforming copy from a publishing company.

Of course, one has to check the "copyright formula". Typically the use for commercial/registration purposes would not necessarily been included in it. This is so important that companies/publishers when printing or reprinting specific articles or studies may add in the "copyright" formula that *"This publication is for non-commercial research and education only, therefore not for commercial use"* thus not for registration purposes. The advantage of this clarification is that it makes it clearer for people having acquired a publication and that it removes ambiguity.

Is there a limitation for further distribution of bought copies of journal articles legitimately acquired?

One other complication is that the acquisition of a paper copy should be made for sharing with other participants into the Joint Dossier. Typically when a individual company would lawfully acquired a published paper copy any sharing would infringe copyright because rarely is an article acquired in a way that allows further sharing or distribution. Therefore, each company participating would have to have legitimately acquired a copy. The only exception to this is when a library holds a journal license that allows broader access, but, then typically it seems that the "user" will be defined as someone in the employ of the organisation that owns the library.

Similar questions about sharing information may also occur for read across.

Furthermore, it may also apply when journals are published in electronic form.

TIPS to suppress / minimise risks: As mentioned above, it is recommended to obtain signed Letter of Access or data sharing agreements which includes the right to use information by all registrants to the same Dossier and provides the right to thereafter license the right to make reference of the Dossier by others willing to acquire it and the possibility of read across. All this is foreseen in Cefic models referred above.

If I acquired legitimately a paper copy what would be the consequence of having to send it via IUCLID?

Let us take the hypothetical case that a paper copy was lawfully acquired for registration purposes (including sharing), if in the course of the Registration the said company/SIEF is required for example at the time of its examination to send via IUCLID in pdf form the said study, this may constitute a non authorised treatment by copyright rules and conditions applicable to the lawfully acquired copy. Also, it might be that the company / SIEF has not anymore legitimate possession, according to certain national law applicable or the conditions imposed at the time of the purchasing of the said copy when completing its Dossier.

Indeed, this difficulty may be created by the fact that the Dossier and related information / data may only be sent via electronic means to ECHA, and not in paper dossier. If this is considered as a non authorised treatment two issues are raised here: the loss of legitimate possession with time and the copyright because of way the publication is treated (i.e. reproduced to populate IUCLID Dossier). Even if in some cases it may not be considered as an infringement of copyright, there may be cases into which it does.

Therefore, Cefic considers that the authorities should reflect on the feasibility and how to organise this so that the transmission of a full study report or any other information as described here above is not a destroying factor of the legitimate possession that a company /SIEF enjoy on a given day if it has lawfully acquired a paper copy.

However, it is noted that ECHA may not require to receive original studies in all cases, and thus only in rare instances.

TIPS to suppress / minimise risks: Make reference in your Dossier to Studies for which you have acquired legitimate possession in paper form for example, rather than reproducing and attaching these to the Dossier. Do not forget to properly indicate the source.

Does legitimate possession concern key studies and / or supporting studies?
Having legitimate possession is needed for all Studies which are used. Therefore companies may evaluate which studies they will use for a particular Dossier not only taking into consideration the completeness criteria but, also the legitimate possession criteria.

What about systems by which copyright licenses or clearance may be obtained?
Reference was made by some companies to systems such as the Copyright Clearance Center in New York, which is a non profit organisation offering centralised licensing arrangements for photocopying or copies acquired via the British Library, or any other equivalent system. These systems ought to be explored by companies or consortia/SIEFs involved to evaluate if copies acquired via any of these systems may be used under REACH and be considered as being possessed legitimately.

TIPS to suppress / minimise risks: To check possibility to use national / international copyright licensing or clearance systems for the studies and data.

What about an exemption inserted in national copyright law, in application of the European Copyright Directive (Article 5 (3)(a)) for the possibility to be able to produce a reproduction of a copyright–protected document for research purposes or other purposes.
As this faculty of having exemption in national law was not applied in every national legislation in the EU, even though it has been done for example in Germany general reliance on this rule cannot be made, and it is worth to check in copyright on a case by case basis. Besides, even when such exemptions are included in the national legislation some authors doubt it could be used for REACH purposes as the purpose of preparing a Dossier is of commercial nature, so an exemption on research for example may not be applicable.

TIPS to suppress / minimise risks: To check if an exemption is in place under the national law applicable and if it would apply to REACH Dossiers.

What about making use of the content of published information?
ECHA gave indication in its REACH Fact Sheet of 24 April 2009 that *"Those compiling submissions cannot assume that published information may be used for REACH registration for free, although it may be possible to use the content of published article in a different form."*. This is quite of interest as there are many instances into which companies may produce a summary of a published article, including the conclusions

contained in it. Indeed, it is quite appreciable that ECHA would accept description of its content that is not 1:1.

TIPS to suppress / minimise risks: Reformat / paraphrase the content of for example an article to reflect accurately the content without "cut and pasting" whole paragraphs. Potential risk of copyright infringement exists if reproduction is made of a "substantial part" of the said article without the authorisation of the copyright owner.

However, this may be quite time consuming. In addition, it was mentioned by some company that for toxicity data for example this could be not accurate enough, and thus may not be an acceptable option with regard to the completeness of the Dossier.

D. Information and data published on internet or available on intranet with specific access rights

Information published on internet is not necessarily available for free. There are generally conditions of use included and companies willing to use "published information" need to contact the internet address generally included on the web site for this. It may well be possible that for "transparency" and willingness of rendering public scientific information companies published studies on the internet while reserving rights for registration purposes.

Publishers of content on the internet are increasingly organising for this.

It is only quite symptomatic that in November 2009 the OECD will submit to the Hazard Assessment Task Force for their approval and after that to the Joint Meeting for adoption a document on *"Data ownership in the context od SIDS Initial Assessment"*. The Document that is currently under consideration outlines the status of data ownership regarding experimental studies for the OECD HPV Chemical Programme as well as for communicating this status to users of the assessments produced in the programme.

Moreover very recently the OECD announced an "up grading" of the OECD's eChemPortal. Even with currently available information it is clear that OECD has announced that ownership for example of Robust Study Summaries remains with the "contributor" or author and users need to seek their permission, OECD is not there to grant such permission.

TIPS to suppress / minimise risks: Always check the copyright formula. If not available on the web site, companies could take contact with the person responsible for this as referenced on the web site. There are many instances in which typical copyright formulas on the web would imply that publication may not be used for registration purpose. However, one may not exclude that some authors, publishers, groups of interest make publication for which they totally "abandon" their right and allow any kind of use of the said publication.

E. Government-possessed data

What about data prepared and submitted by industry to authorities for registration purpose and published by these authorities? Is this information still "protected"?

As in Reach any registration legislation must include wording on what is protected or not once information is sent to the Authorities and how it can be used by others. Typically certain type of information may be protected for a certain period of time and then can be referred to for free. This protection is included in legislation by way of application of Article 39.3 of the WTO TRIPs Agreement[vi] relating to "Regulatory Data Protection". Therefore, any information to which a company may have access via these systems is not necessarily available for REACH Regulation. If so, there may also be some conditions. This has to be checked on a case by case basis.

For example, non EU governments have made declaration about the availability of data (either published or not) detained by themselves against a fee and the respect of formalities (e. g. sign an LoA and/or data sharing agreement). This has been the case for countries such as Japan or more recently Korea.

TIPS to speed up data search and acquiring of an LoA an a multiple number of studies/data: Companies in SIEFs – Consortia may screen what is available in these countries data base and contact relevant authorities with their list of demand as there is no need then to contact the owner of a study. This may be a quicker way of being granted the right to refer/have access rather than going to the company / consortium which has filed such data and is the owner of it. This information may be published or not.

F. Other issues / questions:

Literature Search: there is a need for REACH to make literature search. To use literature search that is already conducted and if there is no specific form or expression for it, would normally not infringe copyright; in particular if the search can be easily conducted and there is no "originality in it". Remember that copyright only protect an "original form of expression" and not data itself included in it. Reference or citation of titles of publications for literature search may be done without infringing copyright, in most of the cases.

TIPS to suppress / minimise risks: Use your own format for presenting the result of your literature search.

Data - facts included in an Article or a Study: facts, ideas, information and data as such are typically not copyrighted. However, if data is very specific as for example a very unique formulation, it may be copyrighted as it being a novel expression. However, this concerns facts only.

It is worth noting that under certain national law like in Germany there may be a legal protection of printed or electronic database itself.

TIPS to suppress / minimise risks: When useful for your Dossier use facts only and avoid to copy and paste a whole chart or even part of it.

What if the publication does not address all fields required in order to fill in the IUCLID template?

A publication is an interpretation developed originally by the authors following review by peers. This is not the same as the original study report, which can differ, and even for

political or external relations considerations, the publication may alter some of the work. Further, the publication is a subset of the information developed in a study. This means that the likelihood that a publication can actually result in a full and valid IUCLID 5 file is often quite low.

What about if there are some concurrent ways to legitimately acquire possession or the right to refer to particular information? Where should I go?

Typically this may be when companies have already sent information for registration purpose to third country authorities (see above), published information in a journal, placed it on internet and have developed it within a trade group. Companies may go to "any of these points" and be granted the right to use the said information provided the person or entity granting it has the right to do so.

For Cefic, its members, groups and affiliated organisations:
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[i] Dominik Jaensch (VCI), REACH : Use of full study reports for registration purposes – Legitimate possession and reference rights according to Article 10 of REACH, StoffR 3 2009.
[ii] See Cefic web site at www.cefic.org
[iii] See Article 3 (paragraphs 27, 28 & 29) of the REACH Regulation for the Definition of Full study report, Robust study summary and Study summary.
[iv] http://echa.europa.eu/sief/data_sharing_en.asp
[v] See Cefic web site at www. Cefic.org
[vi] Trade Related Aspects of Intellectual Property Rights