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REACH: Claiming confidentiality for information in the registration dossier

New procedures apply after 30 September 2010

REACH registrants can request the European Chemicals Agency (“ECHA”) to keep some of the information in the technical dossier confidential. In addition, where a member of the public has used its right to request ECHA to disclose information which a registrant provided, the registrant may be able to claim that that information is confidential. In both cases, it is important to follow the correct procedures. This alert gives a summary of recent guidance issued by ECHA on one type of confidentiality claim together with an overview of other aspects of preserving confidentiality that may be of relevance to registrants.

Information in the registration dossier

REACH requires ECHA to make certain information contained in the registration dossier publicly available on the internet unless it considers that a request for confidentiality is justified. ECHA has recently issued guidance to registrants on how to request confidentiality for information in the registration dossier. The guidance is contained in Part 16 of the [REACH-IT Data Submission Manual](#), entitled *Confidentiality Claims: How to make confidentiality claims, and how to write Art 119(2) confidentiality claim justifications*.

Registrants who have submitted confidentiality claims before 30 September 2010 will be given the opportunity to update their claims in light of the recommendations and guidelines in the manual. [Confidentiality claims lodged after 30 September should be in accordance with the manual.](#)

Background

Article 119 of REACH lists information in the registration dossier which ECHA must make publicly available on its website. A registrant may claim that some, but not all, of this information is confidential and should not be publicly available. ECHA will decide whether such claims are justified.

Article 119(1) lists the following information for which *confidentiality cannot be claimed*:

- The IUPAC name for dangerous substances (subject to the exceptions in Article 119(2), see above)
- If applicable, the EINECS name of the substance
- The classification and labelling of the substance
- Physicochemical data concerning the substance and on pathways and environmental fate
- The result of each toxicological and ecotoxicological study
- Any derived no-effect level or predicted no-effect concentration in the chemical safety report

- Guidance on safe use
- Analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans

In contrast, the following information, listed in Article 119(2), will not be made available on ECHA's website *if the registrant submits a justification accepted as valid by ECHA as to why publication is potentially harmful for the commercial interests of the registrant or any other party concerned:*

- If essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives known to be dangerous
- The total tonnage band within which the substance has been registered
- The study summaries or robust study summaries required in the registration dossier
- Certain information in the safety data sheet
- The trade name of substance
- IUPAC (International Union of Pure and Applied Chemistry) names for dangerous substances which are non-phase-in or only used as intermediate/in scientific R&D/ in PPORD

How to make a confidentiality claim under Article 119(2)

To claim confidentiality, there is provision for a flag to be set against each piece of information entered in IUCLID. Fees in the following ranges (with the lower end of each range relevant for smaller companies) must be paid for each piece of information for which confidentiality is claimed. The Manual contains more detail of how the fees are calculated.

Information claimed confidential	Fee
Degree of purity and/or identity of impurities or additives	€338 to €4500
Tonnage Band	€113 to €1500
Study summary or robust study summary	€338 to €4500

Information claimed confidential	Fee
Other information in the Safety Data Sheet	€225 to €3000 (for all use(s)/use(s) advised against)
Trade name(s) of the substance	€113 to €1500
IUPAC Name of non-phase in substances which are dangerous	€113 to €1500
IUPAC Name of dangerous substances used as intermediates, and/or in scientific research, and/or in product and process oriented research and development	€113 to €1500

A justification going beyond a simple statement that the information is a business secret must be entered for each claim. In particular, it should be demonstrated that disclosure of the information would potentially harm the registrant's or a third party's commercial interests. This requires it to be shown that:

- The information is known only to a limited number of persons, and typically that the registrant or third party has taken specific measures to keep the information secret
- The registrant or third party has a commercial interest worthy of protection
- There is a causal link between publication of the information and the potential harm

It should also be indicated whether confidentiality is claimed only until a certain date or the occurrence of a particular event (which must be specified) or for an unlimited time. In addition a contact name must be given to enable ECHA to be in contact with the registrant during the assessment of the claim.

The Manual recommends that each of the above elements should be described in no more than two or three sentences and that the justification as a whole should not exceed one A4 page. Templates and examples are provided. **Since ECHA will only accept very brief claims for confidentiality, companies should consider carefully what grounds of justification they provide.**

If a confidentiality flag is set and no justification is provided, registrants may re-submit their dossier once only to include justification.

Companies should therefore be sure to both set the flag and provide justification as they otherwise risk losing the opportunity to claim confidentiality.

Challenging a decision rejecting a confidentiality claim

If ECHA rejects a confidentiality claim, it must notify a decision rejecting a confidentiality claim to the registrant in writing (where appropriate by electronic means).

The registrant may “request a review” from ECHA within two months of receipt. This is an “administrative review” and not an appeal to the Board of Appeal, which has no jurisdiction over confidentiality claim decisions.

ECHA must take a decision within two months of the request; the registrant may challenge the decision before the General Court or complain to Ombudsman

Other confidentiality issues

As indicated above, Article 119 of REACH lists the information from the registration dossier which ECHA must make available on its website, subject to the possibility of claiming confidentiality for certain items of such information. Article 77(2)(e) of REACH requires ECHA in addition to maintain all other information it holds on registered substances, the classification and labelling inventory and the harmonised classification and labelling list established in accordance with the CLP Regulation. EU citizens or companies have a right of access to such information subject to a limited number of exceptions. ECHA must disclose information on request unless disclosure would undermine the protection of: the public interest, the privacy of personal data, commercial interests, court proceedings and legal advice or the purpose of inspections, investigations and audits (subject to any overriding public interest in disclosure).

REACH Art 118(2) provides that the following are “normally deemed to undermine the protection of commercial interests” unless “urgent action is necessary to protect human health, safety or the environment, such as emergency situations”:

- Details of full composition of mixture
- Precise use, function or application of substance or mixture

- Precise tonnage of substance or mixture manufactured/placed on market
- Links between manufacturer/importer and his distributors/DUs

Where ECHA receives a request for access to a document which originates from a third party (e.g. a REACH registrant or CLP notifier), it will refuse the request if one of the exceptions above applies and will grant the request if the document has already been disclosed or it is clear that the disclosure would not affect one of the interests mentioned above; in all other cases, ECHA must consult the third-party author. If ECHA intends to give access against the explicit opinion of the author, it must so inform the author and draw his attention to his right to challenge the disclosure before the EU General Court or make a complaint to the Ombudsman.

Confidentiality in the C&L Inventory

ECHA has also recently indicated that companies who are not registering substances under REACH by 30 November 2010 but who are obliged to notify the classification and labelling of substances to ECHA as of 3 January 2011 may keep the IUPAC name confidential in the case of non-phase in substances and substances used only as intermediates and/or in scientific R&D and/or in PPORD. Such confidentiality claims can only be made using IUCLID. An alternative name must be provided for dissemination by ECHA.

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