

Authorisations and Guidance

Guidance on Letter of Access

Applicants who do not themselves own documentation used in support of a product application, which is sent to or available to the Swedish Chemicals Agency, must attach a permission proving that they are entitled to use such documentation, i.e. a Letter of Access (LoA). If several LoA's are submitted, e.g. relating to different studies by different owners, please make sure that they are collected in one folder and easily found.

Requirements for Letter of Access

In order to facilitate the review of product applications, the following requirements should be fulfilled:

- The LoA should state to whom and in what matter it is issued.
- The LoA should be dated.
- The LoA should be signed by an authorised signatory or by someone approved by the authorised signatory. In all cases, verification that the undersigned is or is approved by an authorised signatory, must be attached.
- It must be made evident which studies are covered by the LoA by attaching, or referring to, a list of protected studies.
- The LoA should be submitted as an original or certified copy. A certified copy is a copy of the original document, signed by a person that certifies that the copy is true to the original.
- In case the LoA is issued by a consultant on behalf of the data owner, a copy of the agreement entitling the consultant of such rights must be attached.
- In case the LoA is issued by a member of a task force or joint venture, documentation verifying that the issuer is entitled to act on behalf of the task force or joint venture must be attached.

Please note that product applications may be refused if the applicant has failed to present a permission to use documentation owned by someone other than the applicant.

Swedish Chemicals Agency

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List of protected studies

For the Swedish Chemicals Agency to be able to apply the rules on data protection, the right of ownership or the right to use the studies on which the application is based, must be clarified. The applicant must therefore attach or refer to a list of protected studies, informing the Swedish Chemicals Agency about which studies are covered by the LoA.

Please note that this list must be attached to or referred to in the LoA and the product application, in addition to the reference list, where the applicant has to specify all the studies on which the application is based.

Letter of Access related to compliance checks for plant protection products

If a LoA is submitted to cover data requirements related to a compliance check for plant protection products, it must be clearly indicated which plant and synthesis pathway is referred to, in addition to what is stated above.

Period of validity of the Letter of Access

The Swedish Chemicals Agency wishes to emphasise that the LoA may form the basis for granting a product authorisation and that revoking a LoA does not mean that the product authorisation can be revoked. According to general legal principles of Swedish administrative law, a product authorisation is a positive administrative decision which can only be revoked subject to certain conditions. Therefore, the Swedish Chemicals Agency cannot revoke a product authorisation on the grounds of a contract clause between the principal and agent.

In case the granter of the LoA wishes to restrict the period of time within which the Swedish Chemicals Agency may use the documentation in its examination of a product application, such a stipulation should be evident from the LoA.

Access to data and confidentiality

According to Section 17 of the Swedish 1986 Administrative Procedure Act [Swedish Code of Statutes – SFS 1986:223], the competent authority must communicate to the applicant all relevant information that has been added to the case by anyone other than the applicant. In addition to this, according to Section 16 of the same act, the applicant has a right upon request to access everything that has been added to the applicant's case.

Exceptions to these rules are only made with regard to information that is of such character that the individual interest of confidentiality outweighs the right of the applicant to be informed about and have insight into the case in question, according to Chapter 10, Section 3 of

the Public Access to Information and Secrecy Act [Swedish Code of Statutes – SFS 2009:400]. This assessment is made independently by the competent authority and cannot be based solely on the opinion of the party issuing a LoA.

Principle of public access to official documents

The principle of public access to official documents means that everyone – Swedish and foreign citizens – has the right to study the general documents of Government Offices, provided they are not subject to confidentiality according to what is stated above. Documents received or dispatched by the Government Offices and other government agencies, eg. letters, decisions and inquiries, usually constitute such official documents.

Please note that the principle of public access does not grant any subsequent applicant any right to make use of, or refer to, the information in question.

For further information on the principle of public access, please see the [Swedish Government's website](http://www.regeringen.se/sb/d/504/a/3029) - <http://www.regeringen.se/sb/d/504/a/3029>