Authorisation for parallel trade during the transitional period

An authorisation for parallel trade during the transitional period is possible for biocidal products containing notified active substances which may be placed on the market under national transitional regulations in Switzerland (Authorisation A_N or A_C) and in the EEA.

Preliminary remarks

As of 1 March 2018 the concept of an authorisation for parallel trade is also applicable to biocidal products that may be placed on the market under national transitional regulations in Switzerland and in the EEA during the transitional period, i.e. until all the active substances in the biocidal product are approved. Biocidal products that may be placed on the market during the transitional period have to contain at least one notified active substance[1]. Such products with a transitional authorisation A_N or A_C may be marketed in Switzerland. In the various Member States of the EEA such biocidal products may be marketed in some instances by means of a transitional authorisation or based only on an online notification or even purely under self-regulation.

The concept of an authorisation for parallel trade for biocidal products that may be placed on the market during the transitional period does not fall within the ambit of the BPR[2] and consequently is not specified therein.

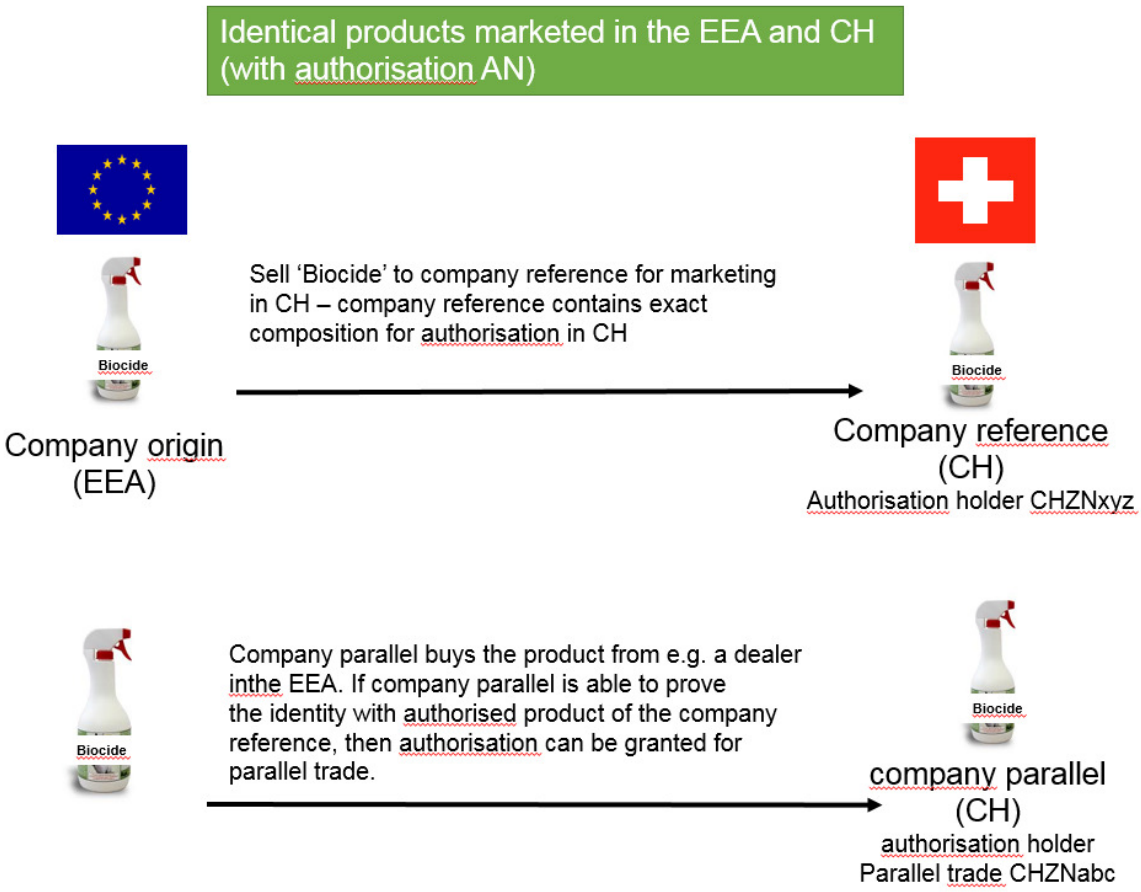
An importer of a biocidal product that is already authorised as an A_N or A_C for another company, can in principle likewise apply for an authorisation A_N for the same product. The effort for such a request and the associated costs are relatively low. For an authorisation A_N, however, the exact composition of the product or a letter of access must be submitted to the Notification Authority.

The extension of the authorisation for parallel trade to biocidal products with A_N/A_C authorisations is intended to prevent a foreign manufacturer of a biocidal product from designating a predefined price to an exclusive agent in Switzerland who could market the biocidal product free from competition.

[1] cf. Art. 9 para. 1 let. c OBP

[2] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

Procedure



A prerequisite for the authorisation for parallel trade is that the product is identical to the reference product[3] (cf. art. 13a para. 1bis OBP).

Identical means:

a) It has been manufactured by the same company, by an associated undertaking or under licence in accordance with the same manufacturing process;

b) The products are identical in specification and content in respect of the active substances and the type of formulation;

c) The products are identical in respect of the non-active substances present;

d) The products are either the same or equivalent in packaging size, material or form, in terms of the potential adverse impact on human health, animal health or the environment.

The parallel import of such products is allowed after the Notification Authority Chemicals has granted the authorisation. A corresponding application for this must be submitted to the Notification Authority.

The **application** for authorisation for parallel trade during the transitional period must **include the following information** (see annex 8a OBP):

[3] A reference product is understood to mean that identical product that is already authorised with an A_N or A_C authorisation in Switzerland.

- original label and instructions for use with which the biocidal product is placed on the market in the country of origin
- name and address of the applicant
- name to be given to the biocidal product which is to be placed on the market in Switzerland;
- a draft label for the biocidal product intended to be placed on the Swiss market, in two official languages;
- a sample of the biocidal product which is to be imported, if this is considered necessary by the Notification Authority;
- name and authorisation number of the reference product;

The Notification Authority may also require the following additional documents:

- a translation of the essential parts of the original instructions for use;
- additional documentation proving that the biocidal product is identical with the reference product.

As the exact composition of the product in the country of origin is known neither to the applicant nor to the Swiss authorities, in certain circumstances with applications for the authorisation for parallel trade it may be difficult to determine the identity of the product.

The following information may serve as an indication for determining the identity:

- Product label: active substance content and type of formulation
- Safety data sheet: identification of the manufacturer and the non-active substances
- In the case where this information still leaves the authority in doubt in regard to the identity of the product then a supplementary analytical determination of the identity may be requested. Such analyses may be contracted out to analytical laboratories.

If the authorisation for parallel trade is granted by the Notification Authority with the understanding of the assessment authority, then the authorisation permits the biocidal product to be placed on the market and used professionally and commercially **under the same conditions and requirements** as for the reference product.

The period of validity of the authorisation for parallel trade of a biocidal product corresponds to the **period of validity of the authorisation of the reference product (art. 8 para. 1 let. c VBP)**. This also applies if the authorisation of the reference product is requested to be withdrawn by the authorisation holder, insofar as the requirements of the authorisation of the reference product are still fulfilled.

Following expiry of the period of validity of the authorisation for parallel trade the periods of grace for liquidating stocks are 360 days for placing on the market and an additional 360 days for supplying end consumers cf. art. 26a OBP.

The Notification Authority revokes the authorisation for parallel trade when the authorisation for the reference product is revoked on grounds of safety or efficacy.

Fees

The processing of an application for an authorisation for parallel trade is subject to fees of **CHF 600.- to 2 300.-** [4].

The fees are usually about CHF 1 000.-. If the authorities require an increased effort due to missing proof of identification then the fees may be in the higher range.

Remark

The procedures for the authorisation of biocidal products can be modified at short notice. Consequently, we advise interested parties to regularly consult the website of the Notification Authority Chemicals and to subscribe to the Consumer Protection Newsletter of the FOPH.

[4] Within 30 days after receipt of the invoice