



Biocidal products with precursors for the *in-situ* generation of active substances

It should be noted that placing on the market and use of biocidal products are governed by the Ordinance on Biocidal Products (OBP), meaning that use of a product that has not been authorised is not permitted.

Introduction

Under the terms of the the new European regulations on biocidal products (BPR; EU nr. 538/2012) and the Swiss Federal Ordinance on Biocidal Products (OBP, 813.12), active substances generated *in situ*, and the associated precursors, are considered to be biocidal products and are thus subject to approval.

The present document takes stock of the situation in November 2015 and provides clarification on the duties of companies marketing biocidal products in Switzerland. Under the terms of the BPR and OBP, an active substance is authorised for specific applications known as product types (OBP, Annex 10). For this reason we talk of precursor/active substance/product type combinations.

It is important to note that any precursor substances that are marketed for non-biocidal purposes (for example sodium chloride used as softening salt) are not subject to this regulation and therefore do not require approval under the terms of the OBP.

Summary of actions taken by ECHA:

The EU has taken the following actions to clarify the situation regarding active substances generated *in situ*.

- It asked companies to specify the *in situ* applications on the market (precursor/active substance/product type combinations).
- It published a list of active substances generated *in situ* and adapted the nomenclature of active substances contained in the review programme. The document can be found on the Internet¹.
- It published a new deadline for notifying precursor/active substance/product type combinations not yet under evaluation. The document can be found on the Internet².

Definition of *in situ* generated active substances

In situ generated active substances can be defined as substances which are generated at the place of use from one or more precursors.

Examples of *in situ* active substances

The following precursor/active substance combinations are examples:

Finished formula: Sodium percarbonate and TAED in washing powder. These components form the active substance peracetic acid when the product is dissolved in water. The active

¹ EU Commission document: "CA-March15-Doc.5.1-Final, revised on 23 June 2015"

² http://echa.europa.eu/documents/10162/17287015/biocides_substances_redefined_identity_en.pdf

substance, which has already been notified, has been redefined as “Peracetic acid generated from tetraacetylenediamine (TAED) and sodium percarbonate”. A similar formula combining sodium perborate and TAED has so far not been notified.

Precursor and catalyst: The two components sodium chlorite (powder, precursor) and HCl (liquid, catalyst) are marketed separately and are combined *in situ* to generate the active substance. When the two components are combined they generate the active substance chlorine dioxide *in situ*. The gas is simultaneously dissolved in the water. The active substance is defined as: “Chlorine dioxide generated from sodium chlorite by acidification”.

Generation with a device: Common salt (NaCl) is dissolved in water and the brine is electrolysed to produce the active substance active chlorine (HOCl, OCl⁻). Various methods of electrolysis are available that produce either active chlorine or bleach.

The active substance is defined as: “Active chlorine generated from sodium chloride by electrolysis”.

So far the generation of active chlorine from potassium chloride has not been notified.

Under the Ordinance on Biocidal Products, devices as such cannot be approved as biocidal products. However, to avoid a situation where users of active substances (such as ozone from air) have to apply for authorisation, in this case the device manufacturer can assume the task of applying for authorisation of the end-product. In this case the authorisation holder for the product generated *in situ* is the device manufacturer.

Precursors subject to the OBP

Following the redefinition of the term “biocidal products”, precursor substances fall within the scope of the OBP and are now subject to authorisation. Precursor substances can be seen from the new nomenclature of *in situ* active substances being evaluated under the review programme. For example, the precursor sodium chlorite is specified for chlorine dioxide generated *in situ* from sodium chlorite by acidification. For precursor substances there is a transitional period for the submission of a request for A_N authorisation³ running until 31 August 2017 (Art. 62b para 1 OBP). The same applies to precursors such as NaCl used for the production of active chlorine by electrolysis.

Here it should be noted that the authorisation requirement only applies to salts that serve as precursors for the generation of active substances used as biocidal products.

Implications of the redefinition for the active substance review programme

The new nomenclature of active substances generated from one or more precursors defines an active substance with reference to the precursor or precursors that generate it. The new nomenclature of *in situ* active substances thus clearly defines a precursor/active substance combination and the method used to produce the active substance. Certain active substances can be generated using different precursors. However, only precursor/active substance/product type combinations for which a dossier has submitted are covered by the review programme (i.e. notified). This means that companies that market or use another precursor/active substance/product type combination must submit a dossier for this precursor/active substance/product type combination if they intend to keep it on the market. By way of illustration, in the annex you will find a table with the various possible cases.

³ <http://www.bag.admin.ch/anmeldestelle/13604/13869/13879/13987/index.html?lang=en>

Precursor/active substance/product type combinations that have already been notified

Certain precursor/active substance/product type combinations⁴ were already contained in the review programme, and only the identity of the substance has been redefined.⁵ For example the active substance “symclosene” (trichloroisocyanuric acid, CAS Number 87-90-1) was already contained in the review programme. Companies that market precursor/active substance/product type combinations that are already contained in the review programme must fulfill the MRA requirements by 1 September 2016 (Art. 62d OBP, 95 BPR). In the EU this requirement has applied since 1 September 2015; in Switzerland, however, the deadline has been extended by one year on the basis of the MRA. Please refer to our website for more details⁶.

Precursor/active substance/product type combinations open for new notification

The notification procedure

Certain precursor/active substance/product type combinations that are on the list of *in situ* active substances published by ECHA (see footnotes 1 and 2) are not currently supported under the review programme. If a company (or consortium) wants to take over the role of a participant in the review programme for such precursor/active substance/product type combinations, it must notify ECHA accordingly and then send a complete active substance dossier. Notification is designed to ensure that substances are not included in the review programme unnecessarily without then actually being evaluated.

Interested companies that intend to continue marketing such a precursor/active substance/product type combination have until **27 April 2016** to submit notification. Notification involves sending various essential data on the precursor and the active substance. The list of precursor/active substance/product type combinations open for new notification⁷ and further information and guidance on the notification procedure⁸ can be found on the ECHA website.

Once the notification has been accepted by ECHA, the company has two years to submit an application to ECHA in the form of an active substance dossier.

Once the dossier has been validated by ECHA, the company that submitted it is added to the Art. 95 list. From this moment all companies marketing the same precursor/active substance/product type combination must fulfil the requirements set down in Article 95 BPR⁶, and must submit an application for A_N authorisation by 31 August 2017 (Art. 62b para 1 OBP).

If no notification meeting the requirements is submitted to ECHA for a precursor/active substance/product type combination by the abovementioned deadline, this combination may only be placed on the market until 31 August 2017, and may only be supplied to end customers until 28 February 2018.

⁴ See Commission Delegated Regulation (EU) No. 1062/2014: <http://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:32014R1062&from=HR>

⁵ See footnote 1

⁶ <http://www.bag.admin.ch/anmeldestelle/13604/13869/13883/14956/index.html?lang=en>

⁷ See footnote 2

⁸ <http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/existing-active-substance/notification-procedure>

After approval of the precursor/active substance/product type combination

Once the decision has been made by the European Commission the precursor/active substance/product type combination will be included in Annex 1 or 2 of the OBP. The holder of A_N authorisation has then until the date of inclusion to submit an application under the harmonised EU procedure to the Common Notification Authority for Chemicals. Seamless marketing of the biocidal product can be guaranteed only if this deadline is adhered to. You will find more information on the transitional regulation on our website⁹.

Example of the procedure: peracetic acid precursor/active substance combination

A company uses the precursor/active substance combination “peracetic acid generated from hydrogen peroxide and acetylcaprolactam” for product type 2. The two relevant liquid precursors that have to be combined *in situ* are already on the market in Switzerland. This precursor/active substance/product type combination has so far not been notified, but is open for notification. The deadline for submitting notification is 27 April 2016.

- If a company or consortium submits a complete notification to ECHA by 27 April 2016, it has two years from acceptance of the notification by ECHA to submit a complete active substance dossier.
- Once the active substance dossier has been validated by ECHA, this precursor/active substance/product type combination will be included in the review programme, and the company or consortium will automatically be added to the Article 95 list.
- From this moment, all companies marketing the same precursor/active substance/product type combination must fulfil the requirements set down in Article 95 BPR, and must submit a request for A_N authorisation by 31 August 2017 (Art. 62b para 1 OBP).
- Following the European Commission’s decision to approve the active substance, and by the date on which the active substance is approved at the very latest, so-called first authorisation must be granted under the harmonised approval process as per BPR to be able to continue marketing the biocidal product.

If ECHA has not received notification by 27 April 2016, or if the notification is refused on the grounds of shortcomings, all biocidal products with peracetic acid generated from hydrogen peroxide and acetylcaprolactam on the market in Switzerland can continue to be placed on the market only until 31 August 2017 and supplied to end customers until 28 February 2018 (Art. 62b para 1 and para 3 OBP).

⁹ <http://www.bag.admin.ch/anmeldestelle/13604/13869/13879/14037/index.html?lang=ene>

Overview: Situation regarding biocidal products with *in situ* generated active substances in Switzerland

1. Precursor/active substance/product type combination already part of EU review programme¹⁰

	Case distinguisher	Required product authorisation	Requirements in terms of Article 95 list	Notification status	Example
1.1	A _N authorisation was previously required for products with the active substance under the old definition	The active substance generated was already subject to the OBP → Products on the market must have A _N authorisation	The supplier of the precursor (or a person within the supply chain) must be put on the ECHA's Article 95 list by 1 September 2016 ¹¹	Notification is no longer possible	Products with the active substance "symclosene" (new definition "active chlorine released from trichloroisocyanuric acid") for product types 2, 3, 4, 5, 11, 12
1.2	A _N authorisation was previously not required for products with the active substance under the old definition	Until the 20 June 2014 revision, the precursor was not subject to the OBP. Transitional regulation Art. 62b OBP → For products on the market, A _N authorisation must be applied for by 31 August 2017 ¹²	The supplier of the precursor (or a person within the supply chain) must be put on the ECHA's Article 95 list by 1 September 2016 ¹¹	Precursor/active substance combinations for product types not covered by the review programme are open for notification (deadline 27 April 2016)	Peracetic acid generated from sodium percarbonate and TAED for product types 2, 3 and 4

¹⁰ Footnote 1 where applicable Note redefinition

¹¹ Applicable deadline as per MRA CH-EU <http://www.bag.admin.ch/anmeldestelle/13604/13869/15343/index.html?lang=en>

¹² If application not made on time: sale within 180 days of 31 August 2017 = 28 February 2018

2. Precursor/active substance/product type combination was not previously contained in review programme, but is now open for notification¹³

	Case distinguisher	Required product authorisation	Requirements in terms of Article 95 list	Notification status	Examples
2.1	The precursor/active substance/product type combination is notified within the specified period	Until the 20 June 2014 revision, the precursor/active substance/product type combination was not subject to the OBP → Transitional regulation Art. 62b OBP → A _N authorisation must be applied for by 31 August 2017	If the precursor/active substance/product type combination has been notified and the active substance dossier subsequently submitted has been validated, the supplier of the precursor (or a person within the supply chain) must be put on the ECHA's Article 95 list ¹⁴	Opened (deadline 27 April 2016)	Peracetic acid generated from hydrogen peroxide and acetylcaprolactam for product types 1, 2, 3, 4, 5, 6, 11, 12 ¹⁵ Peracetic acid generated from sodium percarbonate and TAED for product types 1, 2, 3, 4, 5, 6, 11, 12
2.2	The combination is not notified within the specified period	Until the 20 June 2014 revision, the combination was not subject to the OBP → Transitional regulation Art. 62b OBP → For products on the market, A _N authorisation would have to be applied for by 31 August 2017, but this is not possible without notification → Sale until 28 February 2018	None	Notification no longer possible once deadline has elapsed. --> Registration as new active substance possible	Various. Defined after deadline has elapsed.

¹³ As per footnote 2. From the list published by ECHA

¹⁴ <http://echa.europa.eu/regulations/biocidal-products-regulation/in-situ-generated-active-substances> (retrieved on 17 June 2015): "However, where the application (i.e. for the active substance approval) has not yet been validated, the substance is not "relevant" and the requirement to comply with Article 95(2) i.e. the obligation for a supplier to be on the list ... does not apply... However, as soon as a "complete substance dossier" has been submitted and accepted, the substance would be included in the Article 95 list and consequently Article 95(2) would apply."

¹⁵ This is a different system of precursors from that contained in the review programme under the new definition ("Peracetic acid generated from tetracetylenediamine (TAED) and sodium percarbonate" for product types 1, 2, 3, 4, 5, 6, 11, 12)