Workaround for mutual recognition and same biocidal products applications which are necessary to keep existing products on the market following the inclusion decision for the active substance(s) they contain and which are related to "open cases" in R4BP2

Subject

The present workaround is to enable applicants to make applications for mutual recognition or for authorisation of the same biocidal product based on an application for a first authorisation submitted to a Member State before 1 September 2013 and still under evaluation (so-called "open case").

Background

ECHA has identified an issue preventing under certain conditions companies to submit by the legal deadline defined by Article 89(3) the applications for product authorisations (applications for mutual recognition or for same biocidal product) that are necessary to keep their products on the market following the inclusion decision for the active substance(s) they contain. Indeed, if the application for national authorisation of the product has been created in R4BP2 and submitted to a Member State before 1 September 2013, when such applications are still under evaluation (so-called "open case"), they are not able to submit related applications neither via R4BP2 nor via R4BP 3.

Conditions

The workaround should be limited to cases were all the following conditions are met:

- The decision on the first authorisation is still pending at the time of submitting the application for mutual recognition or the application of the same of the biocidal product;
- The application for that first authorisation was recorded in R4BP2 before 1 September 2013
- The dossier supporting that application for first authorisation was submitted to the reference CA before 1 September 2013;
- The application for mutual recognition or authorisation of the same biocidal product was or will be submitted after 1 September 2013 and before the relevant deadline for the subsmission of applications for authorisation of existing products.
- The application for mutual recognition or authorisation of the same biocidal product relates to an existing product on the receiving Member State market.

Description

The following workaround is a temporary solution until the related "open cases" will be migrated from R4BP2 into R4BP 3 (thus enabling companies to submit related applications in R4BP3).

For mutual recognition

1) The applicant fill in a specific application form (see Annex I attached) and send it directly by registered mail to the Competent Authority of the concerned Member State. With this application

form the applicant can prove that it has submitted an application by the applicable deadline. The application form also proves the commitment of the applicant to make the application in R4BP 3 as soon as the related national authorisation has been granted by the MSCA and migrated into R4BP 3 or in the event the related “open case” was migrated to R4BP3.

2) The competent authority records the application form. The recorded application form is the proof of the application and can be used to address related queries from the national enforcement authorities.
3) If the related national authorisation is granted (by the reference MS), it will be recorded in R4BP2 and subsequently migrated into R4BP 3. This will initiate the start of the 2-month period during which the actual application corresponding to the recorded application form should be made in R4BP 3. The same applies if the related “open case”is migrated into R4BP 3.
4) If the related national authorisation is not granted (by the reference MS), this will be recorded in R4BP2. The application made through the paper application form shall be considered non-approved because the related national authorisation has not been granted by the reference MS. The applicant in the completed paper application form shall recognise that the same provision applies as if for a non-approval decision and in particular that the product shall no longer be made available on the market with effect from 180 days after the date of that non-approval decision.

For same biocidal product

5) The applicant fill in a specific application form (see Annex II attached) and send it directly by registered mail to the Competent Authority of the relevant Member State. With this application form the applicant can prove that it has submitted an application by the applicable deadline. The application form also proves the commitment of the applicant to make the application in R4BP 3 as soon as the related national authorisation has been granted by the MSCA and migrated into R4BP 3 or in the event the related “open case” was migrated to R4BP3.
6) The competent authority records the application form. The recorded application form is the proof of the application and can be used to address related queries from the national enforcement authorities.
7) If the related national authorisation is granted, it will be recorded in R4BP2 and subsequently migrated into R4BP 3. This will initiate the start of the 2-month period during which the actual application corresponding to the recorded application form should be made in R4BP 3. The same applies if the related “open case”is migrated into R4BP 3.
8) If the related national authorisation is not granted, this will be recorded in R4BP2. The application made through the paper application form shall be considered non-approved because the related national authorisation has not been granted. The applicant in the completed paper application form shall recognise that the same provision applies as if for a non-approval decision and in particular that the product shall no longer be made available on the market with effect from 180 days after the date of that non-approval decision.

Application form templates for mutual recognition and same biocidal product in reference to an application for national authorisation submitted to R4BP2 are attached.