

Renewal of national authorisations for biocidal products containing difethialone or difenacoum

1.1 Introduction

Applications for the renewal of a national authorisation must be submitted at least 550 days before the expiry date of the authorisation. The application shall be submitted through R4BP 3 to ECHA. If the application is in the correct format, ECHA will forward the application to the receiving MSCA.

For biocidal products containing the active substance difethialone, authorisation holders should have submitted their renewal applications before 29th April 2013. However, since the BPR had not entered into operation at that time, in practice the authorisation holders need to submit their renewal applications as soon as possible after 1st September 2013.

For biocidal products containing the active substance difenacoum, the deadline for making the renewal application is 27th September 2013.

1.2 Submitting an application for renewal of national authorisation via major changes submission wizard

This sub-chapter covers how to submit your application via R4BP 3 and what supporting documents need to be included in the submission wizard. For more detailed submission instructions please see Manual 2 – Using R4BP 3 for biocide applications.

1.2.1 Pre-requisite

In order to be able to follow the instructions on the submission of your application for renewal via R4BP 3, your authorisation must have been migrated from R4BP2 to R4BP 3. In case your authorisation has not yet been migrated to R4BP 3, please consult the ECHA website for Q&As on migration (<http://echa.europa.eu/support/qas-support/qas/-/qadisplay/1fBp/view/R4BP3/MigrationtoR4BP3>).

1.2.2 Application wizard for renewal of national authorisations (via NA-MAC)

Currently, there is no specific application wizard available in R4BP 3 for the renewal of national authorisations of biocidal products. Therefore, to make an application you have to use the application wizard for 'National authorisation **major** change on request'.

1.2.3 Supporting documents

To distinguish your renewal application from a real major change application, you need to upload the supporting document – "renewal of a national authorisation" (see Step 4 in section 1.2.3).

N.B.: Please note that by uploading this supporting document you commit yourself to provide on request from the receiving Competent Authority all relevant data, as may be required in accordance with Article 31(3) of the BPR or with the forthcoming Commission Regulation laying down supplementary rules for the renewal of authorisations subject to mutual recognition, and to use when applicable the relevant formats and software packages (e.g. IUCLID 5.5) in accordance with Article 79 of the BPR.

1.2.4 Submission in practice

To launch the correct application wizard, click on the 'ASSETS' tab on the R4BP 3 taskbar. Then, search for the specific national authorisation (NA) asset to be renewed by filling in some search criterion (e.g. the asset number, asset type (NA), etc.). Clicking on the asset number hyperlink in the 'Assets list' will open the 'Asset details' page. On this page click 'Create new case' and then select 'National authorisation **major** change on request' from the list of processes (Figure 1).

Figure 1: Launching the application wizard for NA-MAC

Asset details

Asset details	Asset owner
Product name: Quinoclamine Biocidal Product	Company name:
Asset number: DE-0000369-0000	Company UUID:
Asset type: National authorisation	Valid from:
Asset status: Active	To:
Market area: DE-Germany	
Evaluating authority: DE-Germany	
National reference number: -	
Source case number: BC-EG000087-62	

Click to show the list of processes

Create new case ?

Select the correct process

- National authorisation administrative change on request
- Mutual recognition in sequence (of same biocidal product)
- National authorisation minor change on request
- National authorisation major change on request

The application wizard will guide you through the various steps of the application form. When navigating through the wizard, actions have to be performed in a particular order. Forward navigation occurs by clicking on the 'Next' button and is disabled until the mandatory fields, marked with an asterisk (*), have been filled in correctly. Backward navigation occurs by pressing the 'Back' button and allows you to change previously saved data. You can cancel the process at any point by pressing the 'Cancel' button.

The wizard will guide you through six steps that are further described in Manual 2 - Using R4BP 3 for biocide applications:

- Step 1. **Set submission details (of the case owner):** Select a contact person from the drop down list. Note that the asset owner, evaluating authority and payment details cannot be altered.
- Step 2. **Upload dossier: This step is not necessary at the current stage.** Please click 'Next'.
- Step 3. **Upload SPC: This step is not necessary at the current stage.** Please click 'Next'.

Step 4. **Upload supporting document(s):** Click on the '+Browse' button and select the 'supporting document - renewal of a national authorisation'. Click on 'Upload' to upload the document. Choose a 'language' and an 'access level' from the drop down list next to the uploaded file.

N.B.: Please note that by uploading this supporting document you commit yourself to provide on request from the receiving Competent Authority all relevant data, as may be required in accordance with Article 31(3) of the BPR or with the forthcoming Commission Regulation laying down supplementary rules for the renewal of authorisations subject to mutual recognition, and to use when applicable the relevant formats and software packages (e.g. IUCLID 5.5) in accordance with Article 79 of the BPR.

Step 5. **Confirm submission:** Carefully verify that the data entered in the previous steps is correct. If the information entered is not correct, you can update any of the fields by clicking the 'Back' button. When all of the information is verified, confirm the legal declaration and submit your application.

Step 6. Receive the submission number.



Further information on how to track the status of your application in R4BP 3, is summarised in the Summary sheet 3 of this manual.

1.3 Submission Checklist

- Ensure you have selected the correct application type from the 'Create new case' process list found through the appropriate NA asset, 'National authorisation **major** change on request'.
- Is the case owner and contact person indicated correctly (Step 1 of the wizard)?
- Ensure you have uploaded the supporting document on the renewal of a national authorisation at the respective step.