Guidelines for applicants on submission of applications of renewal of National authorisation

Document identifier

CG-62-2024-11 AP 14.2 Guidelines for applicants on submission of applications of NA-RNL_vf

Document history

Version	Changes	Date of agreement	Date of applicability
1.0	First edition (original unnumbered version)	26 June 2024 [at CG-62]	9 July 2024

1. Introduction

The renewal of National authorisations (NA-RNL) is based on Article 31 of Regulation (EU) No 528/2012 (the BPR)[1].

This document includes guidance for the applicants on application submission.

It should be noted that renewal (RNL) in line with Regulation (EU) No 492/2014 is not addressed in the document, considering that that regulation is under amendment.

Furthermore, the main principles for the renewal of the Union authorisation (UA-RNL) process have been recommended in the document that was discussed at the CG-62 meeting[2] in order to align with the NA-RNL process. However, the CG only agreed on the document in regard of the NA-RNL process, since the Union authorisation (UA) processes are under the remit of the Biocidal Products Committee (BPC). Thus, the main principles for the UA-RNL process are removed from this document that was agreed by the CG and will be discussed and agreed in the BPC.

2. Submission of the application for renewal

2.1 Aspects to be considered for both product and product family authorisation renewal applications

In accordance with Article 31(3) of the BPR, the application for the RNL should include information generated since the initial authorisation or previous RNL[3] and assessment of whether the conclusions of the initial or previous assessment of the biocidal product/biocidal product family (BPF) remain valid[4], as well as any supportive information to substantiate this conclusion. It needs to be noted that the legal text uses the term "initial authorisation or, as appropriate, previous renewal". However, since the authorisation holders can request amendments of the authorisation[5] and MSs can amend authorisations based on their own initiative[6], this should be interpreted as referring the authorisation as last amended. The summary of the information to be submitted within the RNL application is included in Table 1.

Table 1. Information to be submitted within the RNL application based on the legal requirements.

Information	Reference to the BPR
Without prejudice to Article 21(1), all relevant data required under Article 20[7] of the BPR the applicant has generated since the initial authorisation or, as appropriate, previous renewal	Article 31(3)(a)
The applicant's assessment whether the conclusions of the initial or previous assessment of the biocidal product	Article 31(3)(b)

[1] The authorisations granted in accordance with Article 25 of the BPR (simplified authorisation procedure) are not subject to renewal: CA-March16-Doc.4.6 Final - note for guidance Q&A on simplified procedure.
[2] The CG members were asked to discuss and align views with the BPC members.
[3] Article 31(3)(a) of the BPR
[4] Article 31(3)(b) of the BPR
[5] Article 50 of the BPR and Regulation (EU) No 354/2013
[6] Article 48(1) of the BPR
[7] It also includes a summary of the biocidal product characteristics (SPC)

Information	Reference to the BPR
remain valid and any supporting information[8]	
A draft summary of the biocidal product characteristics containing the information required under Article 22(2) of the BPR	Covered by Article 20 of the BPR

In the application the applicant has to consider the guidance applicable at the submission of the RNL application. The document "CA-July12-Doc6.2.d—relevance of new guidance[9]" is applicable here. The information requirements should be discussed with the receiving Member State (recMS)[10] at the pre-submission meeting.

Any generation of new data and data requested via the post-authorisation requirements to be provided for the RNL should be finalised by the time of the submission of the RNL application.

The applicant should clearly identify any new information available on the product/BPF authorisation since the previous RNL or initial authorisation.

2.2 Aspects to be considered only for product family authorisation renewal applications

There are differences in an authorisation of a biocidal product and a BPF, reflected in several guidance documents. After the implementation of the BPF concept there have been many clarifications related to the definition of BPF[11] (e.g., on similar uses and similar levels of risk and efficacy[12]). A BPF consisting of products/uses which fulfil the criteria in Article 19(1) of the BPR, and products/uses that may be authorised under 19(5) of the BPR, as they do not fully meet the conditions of Article 19(1)(b)(iii) and (iv) of the BPR, does not meet the definition provided in Article 3(1)(s)(iv) of the BPR regarding similar levels of risk, and cannot be grouped and authorised in a BPF. Biocidal product families (BPFs) not fulfilling the definition, that have been authorised as such in the past, need to be split at the moment of their RNL[13]. When a RNL application is submitted, the applicant will be requested to split the group of products. The initial RNL application will continue, but only with those products/uses which fulfil the conditions in Article 19(1) of the BPR, and a new RNL application/applications should be submitted, covering the product(s)/use(s) that may be authorised in accordance with Article 19(5) of the BPR. The applicant should submit the new application(s) within the timelines set by the recMS.

In accordance with point 6 of Section 1 of the Annex to Regulation (EU) 354/2013 (Changes Regulation), authorised products falling within the specifications of a frame-formulation established in accordance with Directive 98/8/EC in accordance with the same terms and conditions could be authorised as a BPF as an administrative change (i.e., via case type NA-MRG). Applicants should consider guidance documents applicable at the time of submission of the RNL application to decide whether it is necessary to split the BPF and consult with the recMS in case of doubts. Even if such a BPF authorised this way does not

[8] E.g., new information or revision regarding the active substance(s) and/or any of the non-active substances are available. Particular attention needs to be paid for the dermal absorption agreement at the CG-50-2022-07 AP 16.2 Dermal absorption value in PAs_vf; Procedure for the submission, evaluation and dissemination of data generated after active substance approval and CA-June22-Doc.4.2 Consequences for biocidal products authorisations procedures of relevant information becoming available

[9] Available in: BPR - Public - Library (europa.eu)

[10] For NA applications renewed in accordance with Article 31 of the BPR

[11] Article 3(1)(s) of the BPR

[12] Including documents CA-July19-Doc4.2-Final_rev3 and Template overview of the biocidal product family

[13] CA-July19-Doc4.2-Final_rev3

need to be split, the applicant needs to consider whether the data generated in the past for the authorisation of the individual products is adequate for the BPF. Moreover, for the RNL of BPFs authorised this way all data needs to be submitted in the RNL application, not just relevant data required under Article 20 of the BPR the applicant has generated since the biocidal products were authorised before their merge into a BPF, or since the authorisation of the BPF was amended last. This is due to the differences in an authorisation of a biocidal product and a BPF, reflected in several guidance documents.

3. The assessment report and IUCLID file

The new format of the PAR template and confidential annexes should be used for a single biocidal product or a BPF[14] for all RNL applications submitted after 4 December 2021. The applicant can provide the consolidated assessment report (AR) for the RNL itself, otherwise the recMS should prepare such a consolidated AR. The consolidated AR should include information from all previous authorised changes too.

As a part of the AR the history table should contain the initial authorisation and all amendments made since the initial authorisation (including the previous RNL and all amendments of the authorisation since then)[15].

The agreements in relation to the review of the redacted AR for dissemination with regard to the accessibility for embedded files (if any)[15] needs to be followed.

All information to be submitted for the RNL should be included in the IUCLID dossier. It is recommended that the applicant submits the consolidated IUCLID file including information from all previous applications (i.e., amendments, previous RNL, notification of products in the BPF in accordance with Article 17(6) of the BPR). The applicant should make clear which information is new. In order to identify new information MSs are recommended to use the IUCLID dossier comparison tool to compare the dossiers.

4. Applicability of the document

The approach included in this document is applicable for all product RNL applications submitted after the publication of these guidelines.

5. Further actions

The recommendations provided for the UA-RNL process will be discussed and agreed by the BPC.

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[14] Formats and templates - ECHA (europa.eu).
[15] CG-59-2023-01 AP 14.1 Way forward regarding disseminated redacted PARs_final, available at https://webgate.ec.europa.eu/s-circabc/w/browse/d56ae80b-47ac-4fc8-aa2d-c775fe90e137