Evaluation Manual for the Authorisation of biocides

NL specific part

Biocides

version 3.3; May 2026

ctgb

Board
for the authorisation
of plant protection products and biocides

NL specific part
Biocides

Changes made in the Evaluation Manual

Evaluation Manual Biocides NL specific part			
Version	**Date**	**Paragraph**	**Changes**
1.0	January 2013- January 2014		To many details and repetitions of the EU part.
2.0	October 2016	General	Overview used of national specific elements described by the Ctgb. All aspect specific chapters have been deleted. This general chapter for all specific aspects should be used. (chapter all scientific aspects NL specific EM 2.0).
2.1	April 2017	A2c	Board decision on how to identify and evaluate recreation crafts is incorporated
		B5	PT21 issue B5 is removed from the list of national interpretations of data gaps. The evaluation of antifouling for commercial harbours is harmonised with the EU, meaning that the wider (environment outside the harbour), is the protection goal.
		B7	PT21 issue B7 concerning the evaluation of saltwater marinas is already covered by issue A2c.
3.0	January 2019		All links checked and updated if required Text updated if required
3.1	February 2019	2.3 National data requirements	A3 Re-nationalization elements from EU agreements: the national requirement on PT14 efficacy has been removed since this has been EU harmonised
3.2	June 2019	2.3 National data requirements	National elements A1a and B2 have been removed and A2b and A2c have been updated
3.3	May 2026	Entire document	Updated by implementation of Board decision C395.I.11

1. INTRODUCTION NL FRAMEWORK

As described in the General Introduction of the biocides evaluation manual consists of three parts

1) the EU part of the BPR Evaluation Manual
2) the NL part of the BPR Evaluation Manual
3) the Evaluation Manual for applications for authorisation of a biocidal product according to Transitional Legislation (TL) in the Netherlands

The General Introduction concerns generic information about legislation, data requirements and scientific assessments. New elements concerning the technical and scientific assessment described in the BPR not pertained to a specific aspect as physical chemical, efficacy, human toxicology, and environment are described in a separate paragraph in the General Introduction.

In the EU framework the specific data requirements including the derivation of endpoints as well as the aspect specific assessments under BPR 528/2012 are presented. As described in the General Introduction the specific NL data requirements, NL aspect specific assessments (national specific elements),or technical modifications (see explanation terms “elements” and ‘’technical modifications’’ in paragraph 2), described in the NL part of the BPR Evaluation Manual, is reverted to where no EU procedure has been laid down (in the BPR or BPR related guidances) or where specific national elements or technical modifications are necessary for the evaluation. This chapter describes the national specific elements and technical modifications.

2. NL FRAMEWORK

An overview of national specific elements and technical modifications for biocides is presented in Table A of section 2.3.
The term 'national specific elements' is applied here to denote methodologies for the assessment and agreements for assessing or approving biocides. These agreements can include standards, risk mitigation measures, different input parameters, refinements and other arrangements used in the assessment to make that assessment suitable for the Dutch situation.
Technical modifications are the modifications that do not require additional assessment in order to adapt the regulations as described in the SPC to Dutch practices and rules (for example: removing a sentence about dengue fever for repellents, because that disease does not occur in the Netherlands).
If it is clear without further substantiation/assessment that an adjustment of the SPC leads to a lower risk of the biocide and/or application as calculated in the original assessment of the RMS, then this is also considered a technical adjustment.

The Netherlands is one of the few countries in Europe with a history of using a system for biocide authorizations for which complete assessments of biocides are made. Therefore, there is in the Netherlands a lot of experience in designing and implementing (own) models for estimating environmental and human risks associated with the use of biocides.

To clarify the situation concerning the harmonization it is important to distinguish between the following situations:
• Elements for which NL consciously chooses to deviate from the European harmonized assessment methodology. These are referred to in this document as national specific deviations.
• Elements for which (due to time constraints) European Member States have agreed that for the time being it is allowed that national specific interpretations can be used. These are in this document mentioned re-nationalization elements.
• Elements for which NL has its own interpretation pending harmonized appointments and methodologies. These are called interpretations of gaps.

2.1. Mutual recognitions

The issue of harmonization and national components of biocidal products is visible in the mutual recognition of biocidal product authorizations. This involves two situations:

I. Mutual recognition in the Netherlands of an authorization issued in another Member State (NL 'Concerned Member State': CMS)
II. Mutual recognition in other Member States of biocidal products assessed by the Ctgb (NL 'Reference Member State': RMS)

In the case of mutual recognition, the approval and the corresponding assessment by the Member State that has conducted the assessment (RMS) are, in principle, adopted by the Ctgb within the framework of the harmonization objectives of the BPR.
In exceptional cases, adjustments may be necessary in the summary of product characteristics (SPC or label). Two situations can occur: adjustments without additional assessment and adjustments that do require an additional assessment. This can be an additional assessment in the determination of the risk or risk management.

Definition of national specific element for mutual recognitions: an amendment of the SPC whereby the Ctgb must carry out an additional assessment and/or risk management in order to reach a decision on the authorisation of a biocide in the Netherlands. A national specific element must comply with the provisions of Article 2.7 or 37.1 of the BPR.

Definition of technical modification for mutual recognitions: an amendment of the SPC whereby the Ctgb does not need to carry out an additional assessment and/or risk

management in order to reach a decision on the authorisation of a biocide in the Netherlands. Technical modifications for biocides fall within the risk assessment and risk management as established by the refMS. It also concerns a technical modification if it is clear, without additional assessment, that the risk of the biocide and/or the application with that technical amendment is covered by the authorization of the refMS.

For biocides a three-step approach is selected. This is important when NL will mutually recognize biocides (NL = CMS). The three-step approach to applications for mutual recognition for biocidal leads to the following actions:

1. An evaluation of the RMS is accepted in principle
2. It is checked whether a national component applies, if that is the case it is presented in an additional assessment
3. Only for parts where an unacceptable risk in NL is expected, the assessment of the RMS is checked, wherein the table of national elements (see annex) is used.

If according Ctgb, the biocide does not appear to meet the conditions for the granting of an authorization under Article 19 of the BPR after the check in step 3 the issue should be resolved by the Member State (RMS) which has made the first assessment (informal disagreement). If the issue cannot be resolved informally then a formal procedure can be initiated (formal disagreement) by the Coordination Group according to art. 35 of the BPR. If the Coordination Group does not agree, the matter shall be submitted to the CA meeting and eventually voted upon in the Standing Committee on Biocidal Products.

2.2. The application of national specific elements and technical modifications

National specific derogations
For the recognition of NL authorizations from another Member State (NL = CMS), the Ctgb will perform an additional assessment if its national specific derogations apply (step 2 of the three-step approach).

If Ctgb is the evaluating Member State (NL = RMS), both the European and the NL scenario will be included in the assessment when national specific derogations are applied. This is an agreement that is confirmed by Europe in May 2016 (CA-64 meeting). Other Member States are experiencing thus little "burden" of the NL deviations.

Re-nationalization elements
A re-nationalization element is not taken over by the Netherlands as a CMS if it is an element which is specified in an NL own element included in Table A3. If Ctgb performs an assessment (NL = RMS) for which a re-nationalization element from Table A3 applies, Ctgb will include its own element in addition to standardized EU methodology (according to the agreement in CA-64).

National interpretations of gaps
For Mutual Recognition (NL = CMS) Ctgb applies the national implementation of gaps defined by other Member States (unless it leads to large or unacceptable risks to humans, animals or the environment). The national implementation gaps of other member States are also included in the assessment if this leads to different regimes for authorized biocides.
National specific interpretations of gaps by Ctgb are generally also be adopted by other countries in case Ctgb performs the initial assessment of a product (NL = RMS).

2.3. National data requirements

The national specific elements and technical modifications are classified as follows:

Table A: National specific derogations

A1 - National specific exemptions from NL legislation
A2 - National specific exemptions from Ctgb policy
A3 - Re-nationalization elements

Table B: A selection of relevant national implementation gaps.

In practice, it is virtually impossible and makes little sense to create a complete list of national interpretations of gaps (Table B). In all Dutch assessments for the authorization of biocides many interpretations of issues are given over the years which are not aligned in Europe yet. Table B therefore provides only a limited selection of relevant gaps to be solved on a national level.

Table B will disappear in the course of time. National interpretations of gaps in Table B can thereby be included in Table A or disappear because of harmonization. Inclusion in Table A occurs only after a decision by the board or by inclusion in other NL legislation and notification in Brussels.

Table A: National specific derogations

A1 National specific exemptions from NL legislation				
No.	Aspect	PT	Technical modification	Reason, laid down in
A1	EFF	14	No control of rats by non-professionals	No public interest (article 19.5 BPR) Plant Protection Products and Biocides Law (in Dutch: WGB) article 71 Decree Plant Protection Products and Biocides (in Dutch: BGB) article 17 (vakbekwaamheid)
A2 National specific exemptions from Ctgb policy				
No.	Aspect	PT	Technical modification	Reason, laid down in
A2a	EFF	14	First generation anticoagulants not authorized for use against brown rats (*Rattus norvegicus*).	Resistance against these products was found in brown rats (*Rattus norvegicus*) in NL. Ctgb Board decision.C-290, June 2016
No.	Aspect	PT	National specific element	Reason, laid down in
A2b	ENV	14	Use of rodenticides that are authorised under article 19.5 BPR, will be regulated via a national specific integral IPM system.	Article 19.5 BPR
A2c	ENV	21	All antifouling products for leisure craft need to be safe for fresh water and sea water.	Article 37.1.a BPR
A3 Re-nationalization elements from EU agreements				
No.	Aspect	PT	Re-nationalization element	Agreement

Table B: National interpretations of gaps (selection of relevant elements)

B National interpretations of gaps (not exhaustive, selection of relevant elements)				
No.	Aspect	PT	National interpretation of gap	Agreement
B1	ENV	3	Customised calculation for the environmental risk assessment for hoof dips	Hoof baths in NL are smaller and hoof dips are used at a lower frequency than described in the EU scenario. This results in a lower risk for the Dutch environment. Rebuttal, 31 August 2012 (13685N)
				Drinking water disinfection at other locations is not desirable. C-213.5.5, januari 2010 Drinking Water Decree (in Dutch: Drinkwaterbesluit) Chapter 4, article 35.
B8	ENV		Inclusion of monitoring data and background concentrations in the assessment of substances.	Use current methodology pending EU harmonisation.
B9	APCP		LOQ for analytical methods of biocides in surface waters set to 0,1 ug/L	Drinking Water Regulation (in Dutch: Drinkwaterregeling) article 16

3. APPROVAL

The actual decision whether a biocide can be authorised follows from the aspect specific assessments discussed in the EU exposure part for the different aspects in different chapters taking into account the national specific elements or technical adjustments.

4. DEVELOPMENTS NL FRAMEWORK

Table A and B above show the situation as at March 2026.

It is important that the tables are up-to-date. Once new EU harmonized guidance is established or new agreements have been reached in Europe on methods, it must be ascertained whether the tables with national specific elements should be adapted for the implementation of this guidance.

Table A can be adjusted in response to:
- New appointments in EU which NL does not implement (adjustment in Table A1 or A2, notification required by mutual recognition)
- New guidance where NL wants to deviate from EU guidance (adjustment in Table A1 or A2, notification required by mutual recognition)
- Initial assessments by another Member State which is taken over by NL (current national specific deviations in Table A2 can therefore be omitted)
- Changes to NL legislation (amendment in Table A1)
- Decisions by the Board to adopt or abandon national specific deviations (alignment in Table A2 or A3)

Table B can be adjusted as a result of:
- New harmonization agreements
- New harmonized guidance
- Initial assessments by another Member State which is taken over by NL
- New assessments under NL – transitional law (additions to List B)

So, developments in EU framework will also affect the data requirements and testing framework with criteria and trigger values (derivation of endpoints and limit values) in NL framework because the largest possible harmonisation of data requirements and testing framework for criteria and trigger values is aimed for.