Evaluation Manual for the Authorisation of biocides

NL specific part

Biocides

version 2.0; October 2016

ctgb

Board for the authorisation of plant protection products and biocides

NL specific part
Biocides

Evaluation manual biocides NL part Version 1; January 2010 - January 2014		NL specific part Version 2.0; October 2016	
Paragraph and page number	To many details and repetitions of the EU part.	Paragraph and page number	Overview used of national specific elements described by the Ctgb .
General		General	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).

1. INTRODUCTION NL FRAMEWORK

As described in the general introduction of 1) the EU part of the BPR Evaluation Manual, 2) the NL part of the BPR Evaluation Manual and 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 or NL aspect specific assessments (national specific elements, see explanation term “elements” 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 are necessary for the evaluation. This chapter describes the national specific elements.

2. NL FRAMEWORK

An overview of national specific elements for biocides is presented below. The term ‘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.

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)

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 evaluating Member State 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 evaluating Member State 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 than 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 on in the Standing Committee on Biocidal Products.

2.2. The application of national specific elements

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 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	National legislation	Reasons, laid down in
A1a	EFF	4, 5	Biocides should not be used for the production and distribution of drinking water, except under conditions specified in article 20 of the Dutch Drinking Water Decree.	Decree Plant Protection Products and Biocides (in Dutch: BGB) article 14 Drinking Water Regulation (in Dutch: Drinkwaterregeling) article 20
A1b	EFF	14	No control of rats by non-professionals	Plant Protection Products and Biocides Law (in Dutch: WGB) article 71 Decree Plant Protection Products and Biocides (in Dutch: BGB) article 17 (vakbekwaamheid)
A1c	ENV		Spreading of sewage sludge on land is prohibited in NL so no assessment needed	Decision use fertilizers (In Dutch: Besluit gebruik meststoffen)
A1d	ENV	3 4 18	aboveground spreading of slurry or manure is banned, for NL only the injection of manure is assessed	Decision use fertilizers (In Dutch: Besluit gebruik meststoffen)
A2 Nationaal specific exemptions from Ctgb policy				
No.	Aspect	PT	Ctgb policy	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
A2b	ENV	14	Outdoor use of anticoagulants for the control of rats is regulated via a national specific IPM protocol.	Products for the control of rats outdoors are necessary but their use needs to be limited because of the high risks identified. Ctgb Board decision C-253.1.9, May 2013
A3 Re-nationalization elements from EU agreements				
No.	Aspect	PT	Re-nationalization element	Agreement
A3a	EFF	14	Some MSs are of the opinion that for a claim 'for use against rats' only testing against brown rats (Rattus norvegicus) is required, whereas others require testing against both brown and roof rats (*Rattus norvegicus* and *Rattus rattus*).	EU agreement (as laid down in efficacy guidance PT14) is that each MS can follow its own country specific requirements.[1] In NL separate efficacy data against both brown rats and roof rats (*Rattus norvegicus* and *Rattus rattus*) is required.

[1] The PT14 guidance is under major revision. In the draft guidance, it has been agreed that for use against rats requires testing against *Rattus norvegicus* and *Rattus rattus*.

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)
B2	EFF	5	Disinfection of drinking can only be done in institutions[2] as mentioned in article 35 of the Drinking Water Decree.	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.
B4	ENV	11 12	Calculate emissions from the paper industry by applying NL specific details instead of using the more general EU details	Dilution factors for the Dutch paper industry are exactly known
B5	ENV	21	the environmental risk of antifoulings is not assessed for commercial harbours	Letter of VROM of 30 June 2004
B6	ENV	21	Assessment of freshwater marinas	Since 2014, the Ctgb applies a scenario for the assessment of freshwater marinas which is not harmonised yet. Submission to the EU is foreseen.
B7	ENV	21	Assessment of saltwater marinas	The Ctgb includes saltwater marinas in the assessment of antifoulings. It is not clear whether this will also be done in the EU.
B8	ENV		Inclusion of monitoring data and background concentrations in the assessment ofsubstances.	Use current methodology pending EU harmonisation.
B9	Fce		LOQ voor analysemethoden van biociden in oppervlaktewateren gesteld op 0,1 ug/L	Drinking Water Regulation (in Dutch: Drinkwaterregeling) article 16

[2] Priority institutions as laid down in article 35 of the Dutch Drinking Water Decree (Drinkwaterbesluit) are: hospitals, (health)care facilities, camping sites, buildings with accommodation function or cell (prison) function, bath houses, asylum seekers centres and marinas.

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.

4. DEVELOPMENTS NL FRAMEWORK

Table A and B above show the situation as at May 1, 2016.

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.