

# **Evaluation Manual for the Authorisation of plant protection products and biocides**

**NL part**

**Biocides**

**Chapter 5 Behaviour and fate in the environment;  
behaviour in soil; leaching**

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## **Chapter 5 Behaviour and fate in the environment; behaviour in soil; leaching**

Category: biocides

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## **GENERAL INTRODUCTION**

This chapter describes the data requirements for estimation of the leaching risk of a biocide and the active substance, and which evaluation methodologies are applied for the NL framework (§2 - §2.5).

## **2. NL FRAMEWORK**

The NL framework (§2 - §2.5) describes the authorisation evaluation of biocides based on existing substances, included in Annex I, and new active substances. A new substance is a substance not authorised in any of the EU Member States on 14 May 2000.

The pesticide that contains such substances may be authorised if the criteria laid down in the Wgb (Plant protection products and biocides Act) 2006 [1] are met. The product is tested against the Plant Protection Products and Biocides Regulations (RGB) [2]. The evaluation dossiers must meet Annex IIA, IIB, IIIA and IIIB to 98/8/EC

The NL framework describes the data requirements (§2.2), evaluation methodologies (§2.3), criteria and trigger values (§2.4) for which specific rules apply in the national evaluation system or where the national evaluation system has been elaborated in more detail than the EU framework.

The NL procedure described in §2 - §2.5 of this chapter is used for evaluation of a substance for inclusion in Annex I in case no EU procedure has been described.

### **2.1. Introduction**

This chapter describes the behaviour in the soil for the aspect leaching and serves to determine estimated or measured concentrations in groundwater, which are used for risk estimation for organisms that depend on soil (soil organisms) and for evaluation of the quality of groundwater used for the production of drinking water.

The issues discussed in this chapter concern further elaborations of the EU procedure. When the aspects mentioned below will be elaborated in the EU, these will be followed.

### **2.2. Data requirements**

The data requirements for the NL evaluation are identical to the data requirements for the EU. We therefore refer to §1.2 in the EU part.

### **2.3. Risk assessment**

The evaluation methodology for determination of the PEC groundwater for the NL evaluation is identical to the EU methodology. We therefore refer to §1.3 in the EU part.

### **2.4. Approval**

The assessment of the risk for groundwater organisms and humans has been laid down in regulations. The Wgb (Plant protection products and biocides Act) 2006 [1] stipulates in Art. 49 (1) (b3 and b4): “a pesticide will only be authorised if this has no effect that is unacceptable for the environment”.

The evaluation of products on the basis of old active substances already included in Annex I, or new substances, has been laid down in the Plant Protection Products and Biocides Regulations (RGB) [2] in which it is elaborated that these products are evaluated in compliance with the Common Principles.

#### ***2.4.1. Criteria and trigger values***

The criteria and trigger values RGB correspond with the criteria and trigger values in the Biocides Directive and the TNSG on Annex I inclusion (see § 1.4.1 in the EU part).

#### ***2.4.2. Decision on approval***

Decisions on approval are taken in accordance with the Common Principles of the Biocides Directive (see also § 1.4.1 in the EU part)

## 2.5. Developments

*Developments*

None.

*Lacunae*

- None.

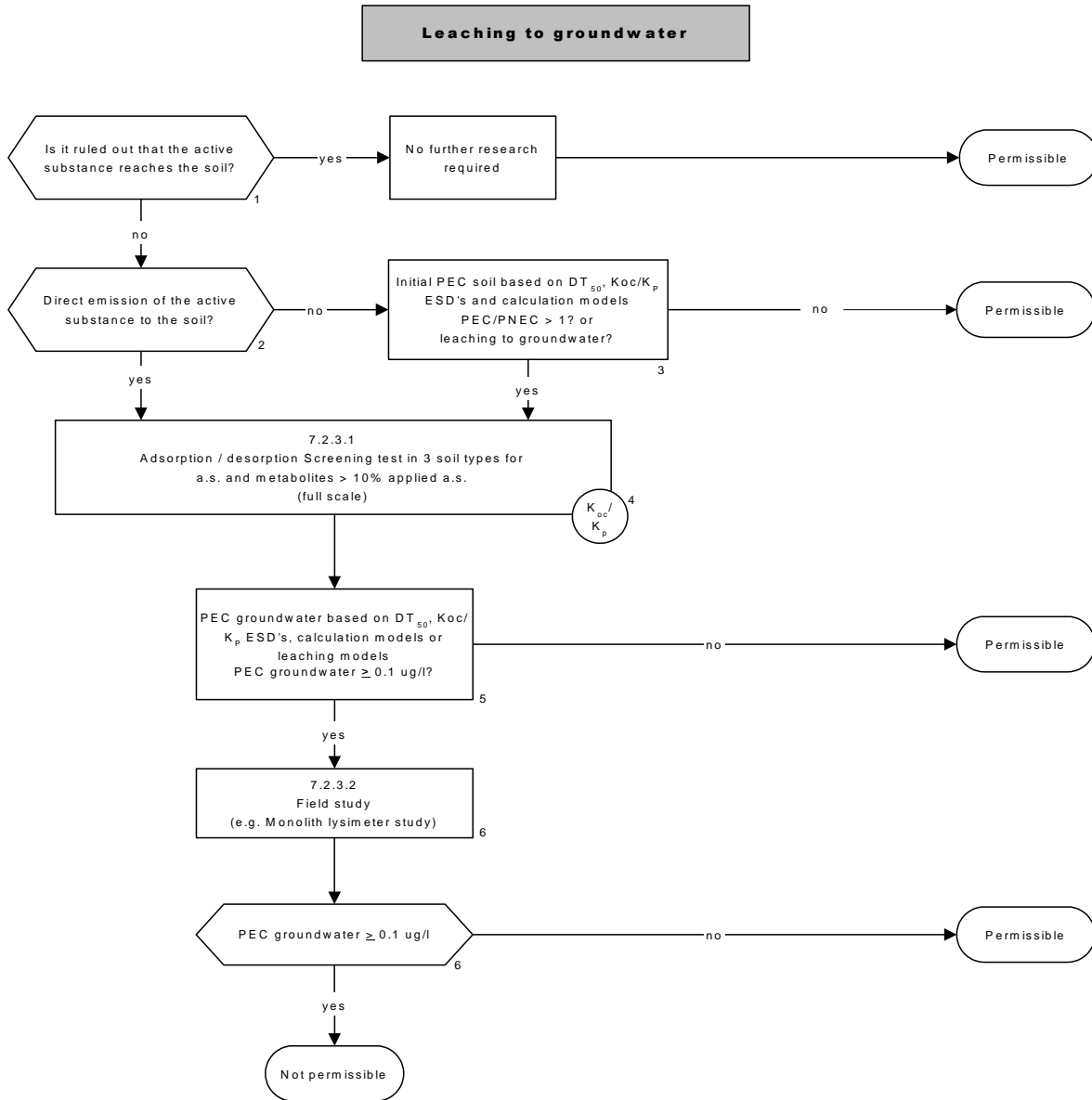
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## Appendix 1 Explanatory notes decision tree Leaching

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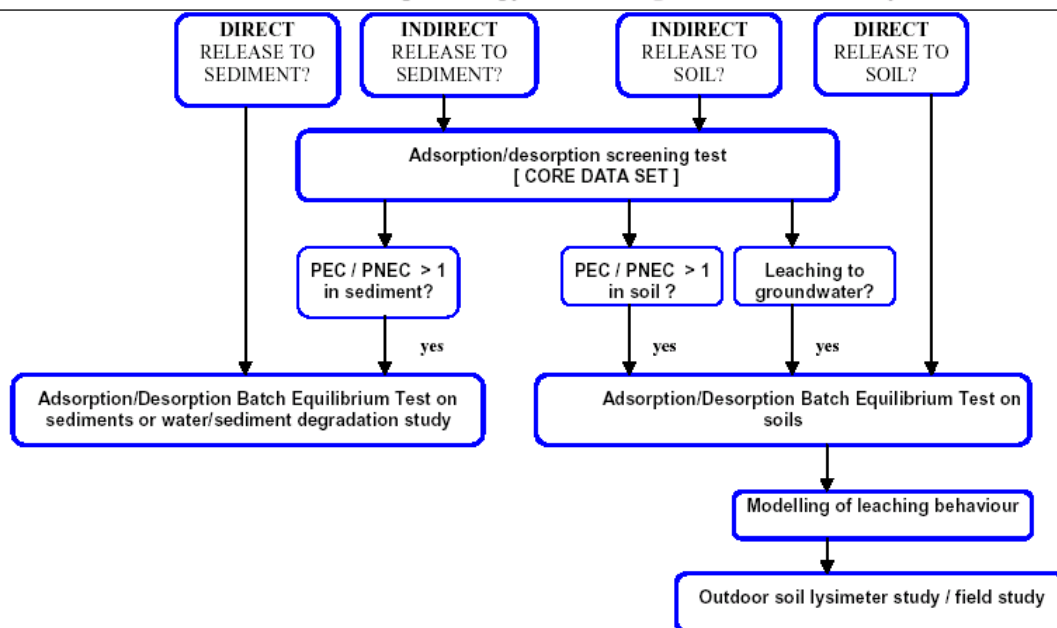
- 1) Data on behaviour in soil should be submitted for each substance, unless it can be demonstrated that it is ruled out that the substance reaches the soil when the biocide is used in practice consistent with the WG/GA (Statutory Use Instructions/Directions for Use). The standard dossier requirements should always be met in EU and NL framework. This concerns photolysis and hydrolysis in water, biodegradation and adsorption/desorption. For environment, the standard data requirements cannot be waived. Whether certain emission routes are relevant has been elaborated in emission scenario documents.
- 2) Direct emission to soil is direct application of a product on the soil, direct emission to soil, or a product reaching the soil in the waste phase. Indirect emission is, e.g., the application of STP sludge with biocides on the soil or deposition from air to soil.
- 3) An initial risk assessment is carried out if it cannot be ruled out that emission to soil occurs, but direct emission to the soil is not expected.  
The exposure (Predicted Environmental Concentration (PEC)) is the model-calculated value in which the emission scenario has been taken into account.  
Exposure calculations are generally carried out with the exposure model EUSES or more specific models applied in some ESDs (see § 1.3.1 in the EU part). EUSES contains several modules for calculating the concentration in soil for emission routes corresponding with various uses. When calculating the concentration in groundwater, the uses and emission routes of a biocide to soil will have to be established and a concentration calculation shall be carried out with the corresponding module.  
Input values for the PEC calculations are  $DT_{50}$  values (half-life values for photolysis, hydrolysis and biodegradation) and  $K_p$  values (partition coefficient for the partitioning over water and soil or  $K_{oc}$  values. These values are entered into calculation models. Depending on the questions and the results of the calculations, further studies must be submitted to specify these values.
- 4) In case direct emission to soil occurs or if in case of indirect emission the initial risk assessment shows that the product is not permissible, or the criterion for groundwater is exceeded, supplementary adsorption/desorption studies in 3 relevant soils, as indicated in the decision tree, are required. If degradation studies show (chapter Persistence) that metabolites are formed in a concentration >10% of the applied substance, extensive adsorption/desorption screening studies should be carried out with these relevant metabolites in three soils. The criteria for selection of suitable soil types takes regional conditions for the envisaged use of the substance (e.g. pKa) into account.
- 5) The average/median value of the  $K_p$  or  $K_{oc}$  is used as input value.  
If the criterion for groundwater is exceeded or if the PEC groundwater is  $\geq 0.1 \mu\text{g/l}$ , a field study, e.g. lysimeter study, is required.
- 6) When evaluating field/lysimeter studies, the year-average concentration is judged against the criterion for groundwater ( $0.1 \mu\text{g/l}$ ).





## Appendix 2 Evaluation strategy for adsorption and mobility

FIG 2 Testing strategy for adsorption and mobility (page 17)



Note: If necessary to characterise more accurately the partitioning behaviour of a substance in a sewage treatment plant, an adsorption/desorption equilibrium test can also be performed with activated sludge.

#### 4. REFERENCES

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- 1 Regeling voor de toelating, het op de markt brengen en het gebruik van gewasbeschermingsmiddelen en biociden (Wet gewasbeschermingsmiddelen en biociden) (Plant protection products and biocides Act, Wgb 2006); NL acts, decisions, orders, etc. can be obtained via <http://wetten.overheid.nl/>;
- 2 Regeling van de Minister van Landbouw, Natuur en Voedselkwaliteit van 26 september 2007, nr. TRCJZ/2007/3100, houdende nadere regels omtrent gewasbeschermingsmiddelen en biociden (Plant Protection Products and Biocides Regulations (RGB), published in the Government Gazette (Staatscourant) 188 of 28 September 2007 came into effect on 17 Oktober 2007; including Regeling van 20 oktober 2009 tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met de aanwijzing van beoordelingsmethoden), published in the Government Gazette (Staatscourant) 16032 of 26 Oktober 2009 came into effect on 1 January 2010; NL acts, decisions, orders, etc. can be obtained via <http://wetten.overheid.nl/>