Evaluation Manual for the Authorisation of Plant protection products and Biocides

NL part

Plant protection products

Chapter 6 Fate and behaviour in the environment: behaviour in surface water, sediment and sewage treatment plants (STP)

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Chapter 6 Fate and behaviour in the environment; behaviour in surface water, sediment and sewage treatment plants (STP)

Category: Plant protection products

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the behaviour of a Plant Protection Product and its active substance in surface water and sediment and in sewage treatment plants (STP) of a Plant Protection Product and its active substance and how reference values are derived in the NL framework (§2 - §2.5).

This chapter consists of two parts, one part about behaviour in surface water and sediment (I) and a second part about behaviour in sewage treatment plants (STP) (Rioolwaterzuiveringsinstallaties (RWZI) (II).

I BEHAVIOUR IN SURFACE WATER AND SEDIMENT

2. NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation procedure for Plant protection products based on existing substances, included in Annex I, and new active substances. A new substance is a substance not authorised in any of the Member States of the EU on 25th of July 1993.
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 II and III to Directive 91/414/EEC (see Application Form and corresponding instructions).

A Member State may deviate from the EU evaluation on the basis of agricultural, phytosanitary and ecological, including climatological, conditions.

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

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

2.1. Introduction

This chapter describes the procedure to determine estimated or measured concentrations in surface water and sediment following normal agricultural applications (outdoor and glasshouses). For the assessment of applications to hardened surfaces and special indoor cultivations and storage treatments see Part II (STP). Evaluation of the aspect behaviour in surface water and sediment with regard to emission routes to surface water deviates from the EU evaluation methodology, and a NL-specific methodology is followed. This is because only the exposure route via drift (the fraction of pesticide blown away) has been elaborated for the NL situation. The choice of a NL-specific drift table is based on the geographical and climatological circumstances. A NL-specific scenario for loading of surface water via drainage pipes is not yet available. Emission to surface water via atmospheric deposition is described in *Chapter 6 fate and behaviour in the environment: behaviour in air*.

The following water systems are distinguished in risk assessment:

- edge-of-field ditch: relevant for the risk assessment for organisms that depend on surface water and/or sediment (aquatic and sediment organisms, and birds and mammals (through consumption of surface water and secondary poisoning), see also *Chapter 7 Ecotoxicology; aquatic organisms*, and 7. *Ecotoxicology; terrestrial organisms; birds and mammals*.

- WFD water body: relevant for the risk assessment for aquatic organisms, see also *Chapter 7 Ecotoxicology; aquatic organisms*

- Drinking water abstraction points: relevant for the assessment of the drinking water criterion (this Chapter).

For the edge-of-field ditch,a decision tree with corresponding explanatory notes is presented in Appendix 1 to this chapter. This decision tree summarises the approval framework for the behaviour in surface water, sediment (edge-of-field ditch) and sewage treatment plants (described in part II of this chapter).

For the Water Framework Directive water bodies and the drinking water criterion, the schematic decision trees are presented in Appendix 3 and 4a, respectively.

The other points described in this chapter are further elaborations of the EU procedure.

2.2. Data requirements

The data requirements for chemical Plant protection products are in agreement with the provisions in EU framework (see §1.2 of the EU part). The question numbering of the NL Application Form has also been included in §1.2 of the EU part.
NL-specific data requirements and further interpretations of the EU data requirements are given in the text below.

Experiments carried out after 25 July 1993 must have been carried out under GLP.

There may be no doubt about the identity of the tested product or the purity of the tested substance for each study.

The studies must be carried out in compliance with the applicable guidelines. A review of the guidelines and whether or not these are required for particular fields of use is given in Appendix A to Chapter 6.

2.3. Risk assessment

The evaluation methodologies for chemical Plant protection products are in agreement with the provisions described in EU framework (see §1.3 of the EU part).
NL-specific evaluation methodologies and further elaborations of the EU procedures are given in the text below.

2.3.1 Edge-of-field ditch

The exposure concentration (Predicted Environmental Concentration (PEC)) is the model-calculated concentration in surface water and sediment. Calculation of the concentration of the active ingredient of a Plant Protection Product in surface water and sediment should include investigation of the possible emission routes to surface water and sediment.

The exposure concentration as result of drift is calculated with the TOXSWA programme according to the Plant protection products and Biocides Regulations (Rgb) [2] and as indicated in Annex XV part B of the Plant protection products and Biocides Regulations (Rgb). The drift values used for exposure assessment used in NL framework are described in various drift tables (standard values and values with mitigation). These tables are included in Appendix 2 to this chapter.
The acute risk assessment for aquatic organisms is for agricultural uses based on the initial PEC (PIEC, concentration immediately after application). In case of several applications per growing season, the PEC (initial) is determined immediately after the last application. Determination of the chronic risk is in principle also based on the initial PEC (in line with EU methodology). Only in specific cases an average weighted concentration calculated over a period analogous to the duration of the long-term toxicity studies with aquatic organisms, with a maximum of 28 days, can be used. The calculations are based on the maximum specified frequency and the minimum specified interval for the use in question.

For the simultaneous application of several active substances, *e.g.*, as combination formulation or as a tank mix, combination toxicology applies (see Appendix C Combination Toxicology). This has no consequences for the calculation of exposure concentrations, however.

The TOXSWA model (v1.0) is used for determination of the concentration of an active substance in a standard ditch by emission via drift. All processes and process parameters considered in TOXSWA, including drift percentage, are based on research relevant for the Netherlands. This means that the model is tailored to the NL situation. For determination of the PEC, agricultural use in compliance with the prescribed method of application (GAP) is assumed. Loading of surface water and sediment by agricultural use of Plant protection products is for the time being only based on drift of spray mist (drift) while neglecting runoff and drainage.

The most important substance-related input parameters of the TOXSWA model are:
- Geometric mean DT50 for degradation rate in water at 20°C (days)
- Geometric mean DT50 for degradation rate in sediment at 20°C (days)
- Arithmetic K_{om} for suspended organic matter (L/kg) (if not available use Kom soil)
- Arithmetic K_{om} for sediment (L/kg) (if not available use Kom soil)
- Saturated vapour pressure (Pa) usually available at 20 or 25 °C
- Solubility in water (mg/L) usually available at 20 or 25 °C
- Molecular mass (g/mol) usually available at 20 or 25 °C

A conversion factor of 1.724 is used to translate K_{oc} into K_{om}.

The degradation parameters should be derived in line with GD Degradation Kinetics [3] (SFO or pseudo-SFO). When no separate degradation half-lives (DegT50 values) are available for the water and sediment compartment (accepted level P-II values), the system degradation half-life (DegT50-system, level P-I) is used as input for the degrading compartment and a default value of 1000 days is to be used for the compartment in which no degradation is assumed. This is in line with the recommendations in the FOCUS Guidance Document on Degradation Kinetics.
The other model parameters are applied in accordance with the standard settings of the TOXSWA model.

For a summary of the risk assessment methodology for water and sediment we refer to the decision tree with explanatory notes, presented in Appendix 1 to this chapter. National drift values can be applied on the basis the Plant protection products and Biocides Regulations (Rgb) [2]. The loading of surface water and sediment is calculated on the basis of the drift percentage values as presented in Appendix 2 to this chapter.

2.3.2 Water Framework Directive water body

To comply with requirements made in the Water Framework Directive (WFD), in which substances are evaluated against Environmental Quality Standards, an interim decision tree was implemented in September 2009 by decree of the responsible Ministries. For the moment this assessment is only performed for substances that at the proposed uses do not meet the first tier assessment in the edge-of-field ditch and substances for which the bioconcentration trigger (BCF > 100 L/kg) is exceeded in the first tier bioconcentration assessment.

The ecotoxicological threshold in the WFD water body is the MPC-INS (both acute and chronic).
The methodology for estimating exposure concentrations is based on the predicted concentration in the edge-of-field ditch calculated with TOXSWA v1.0 and subsequently taking into account the following processes:
* dilution: based on first estimates from catchment modelling with CASCADE- taking into account single or multiple exposure events
* degradation during the travelling time from ditch to WFD water body.

In specific cases, further refinements are possible based on e.g., substance properties.

The decision tree is presented in Appendix 3. This interim decision tree will in time be replaced by the decision tree for WFD water bodies that is currently under development in the WG “Blootstelling waterorganismen” (expected in 2010/2011).

2.3.3 ***Drinking water abstraction points***

Surface water destined for the production if drinking water should meet the drinking water criterion. For most active substances in Plant protection products this drinking water limit is 0.1 µg/L. For the assessment of surface water destined for the production of drinking water the methodology developed in the WG “Implementatie drinkwatercriterium” is followed (Adriaanse et al, 2008, Alterra report 1635 [4]). The methodology exists of 2 tiers: pre-registration modelling and post-registration monitoring (initially, in-between tiers would be developed, but only the first and highest tier are currently available).
The pre-registration modelling tier (first tier) is based on the model DROPLET [5] that starts with a FOCUS D3 edge-of-field scenario cf. FOCUS 2001 [6] but with Dutch drift values. From the edge-of-field concentration the concentration at the abstraction point is calculated by multiplying with factors accounting for e.g. (i) the relative crop area, i.e. the ratio of the area of the crop and the entire intake area, (ii) market share, reflecting that the pesticide is not used on the entire area of a crop, (iii) difference in timing of applications within the area of use, (iv) degradation and volatilisation from the edge-of-field watercourse to the abstraction point and (v) (in very specific case) additional dilution by a lake or incoming river.

The post-registration monitoring tier (highest tier) for the relevant substances, see below for interpretation) consists of an analysis of monitoring data on all abstraction points. A 90^{th} percentile value is calculated for each individual abstraction point as well as an overall 90^{th} percentile. If insufficient data (<13 per year) are available for an individual abstraction point,

the maximum value is taken for that particular year instead of a 90th percentile.

In fact, for all substances pre-registration modelling should be performed as a first tier. However jumping in tiers is possible.
The interpretation of Ctgb of the WG report/decision tree is therefore as follows:

- The analysis of post-registration monitoring data is only relevant for substances that have been indicated (on a yearly basis) as substances of concern by the VEWIN.
- For substances that have been on the market for over 3 years at the time of the assessment and are not included on the list of substances of concern, there is no need to analyse monitoring data or perform model calculations (a standard paragraph is added to the assessment)
- For new substances on the Dutch market (< 3 years) pre-registration modelling is needed. If modelled concentrations exceed the drinking water criterion, first, drift reducing measures should be proposed. If then the substance still exceeds the drinking water criterion but with a factor < 5, authorisation could be granted under condition of post-registration monitoring.

For the full text please refer to Alterra report 1635 and user manual DROPLET. A decision tree is presented in Appendix 4a.

2.3.4 refinement options for PEC calculations

Options to refine the risk assessment on the exposure side by decreasing the exposure concentrations are:

- supplementary data on the fate of a substance in the aquatic environment (including sediment),
- Mitigation of the exposure by drift reducing technologies

The refinement on the substance fate might consider
1) properties of the active substance and the formulated product,
2) temporal and spatial scale of application of the product.

Supplementary research to establish the fate of the active substance(s) in representative aquatic (model) ecosystems (including sediment) should be in accordance with the requested use of the product and relevant for the Dutch agricultural and climatological situation.

Another way to adjust (predicted) exposure concentrations is the prescription of the use of drift mitigating measures/techniques. These are described in Appendix 2 (Drift Tables)

Refined exposure calculations might be combined with an adequate risk assessment for aquatic organisms, as included in *Chapter 7. Ecotoxicology; aquatic*.

2.3.5. Use of monitoring data

2.3.5.1. Introduction

As highest tier, monitoring data can be used. Monitoring data are taking into account in the risk assessment, provided that these meet qualitative and quantitative requirements as described below.

An essential condition for the application of monitoring data in the evaluation of the permissibility of Plant protection products is that it must with reasonable certainty be possible to establish a likely causal relationship between the use in compliance with legal instructions

for use and the monitoring concentration of a Plant Protection Product in the environment.

When such a relationship is lacking, monitoring data can have a warning function, making a study into the possible risks desirable. This also means that monitoring data in the context of the evaluation of the permissibility will have to meet a number of quality criteria such as, e.g., regarding the number of measurements, set-up of measurements etc.
(see §2.3.5.4).
Currently two existing types of data sets are taken into account for the assessment (for which the quality criteria outlined in 2.3.5.4 below are met):
1. general surface water monitoring for water quality determination from an eco(toxico)logical perspective (water boards, gathered in Pesticide atlas, paragraph 2.3.5.2)

and
2. monitoring of surface water destined for the production of drinking water (VEWIN data, paragraph 2.3.5.3).

Furthermore, general criteria are set up to assess the acceptability of other/additional monitoring data sets not described below (paragraph 2.3.5.4).

2.3.5.2 Monitoring data for surface water (ecotoxicological quality)
Regular screening monitoring data of the various water boards are gathered in the Pesticides Atlas (www.bestrijdingsmiddelenatlas.nl). It is verified that the data in this Atlas comply with the criteria set below for Category 1 data. Furthermore, as part of the Decision Tree Water, a monitoring protocol is currently being set up (expected to be finalised in 2010), which also uses the Pesticide Atlas as data source for monitoring data.

The Pesticide Atlas on internet (www.pesticidesatlas.nl, www.bestrijdingsmiddelenatlas.nl) is used to evaluate measured concentrations of pesticides in Dutch surface water, and to assess whether the observed concentrations exceed threshold values.
Dutch water boards have a well-established programme for monitoring pesticide contamination of surface waters. In the Pesticide Atlas, these monitoring data are processed into a graphic format accessible on-line and aiming to provide an insight into measured pesticide contamination of Dutch surface waters against environmental standards.
In 2009, version 2.0 was released. This new version of the Pesticide Atlas does not contain the land use correlation analysis needed to draw relevant conclusions for the authorisation procedure. Instead a link to the land use analysis performed in version 1.0 is made, in which the analysis is made on the basis of data aggregation based on grid cells of either 5 x 5 km or 1 x 1 km. NB this correlation can therefore only be made based on monitoring data and threshold values up to and including 2006.

Data from the Pesticide Atlas are used to evaluate potential exceeding of the authorisation threshold and the MPC (*ad-hoc* or according to INS) threshold. N.B. For examination against the drinking water criterion, another database (VEWIN) is used, since the drinking water criterion is only examined at drinking water abstraction points.

If an exceeding of a harmonised threshold (authorisation threshold or MPC-INS) is observed, first the analysis of land use with the exceeding is made. If there is a correlation with the proposed use, an adequate risk assessment is required. The applicant should then make the case that the proposed use does not contribute to the exceeding. If there is a correlation of exceeding with already authorised uses, this will be mentioned as a signal for future (re-) registration evaluations of the product.

2.3.5.3 Monitoring data at Drinking water abstraction points (drinking water quality)
The VEWIN assembles the monitoring data of all drinking water companies into a data set comprising all drinking water abstraction points in surface water and supplies these data to Ctgb on a yearly basis. It is verified that the data of the VEWIN comply with the criteria set below for Category 1 data. Furthermore, the VEWIN data are designated by the WG drinking water criterion. A causal or statistical correlation with land use cannot be made because of the more diffuse source of the surface water reaching the drinking water abstraction points. Therefore this criterion of causality up to specific crops or applications is not applicable to this assessment. However, it should be clear that the source of the substance is either agricultural before it will affect authorisations of PPP.

The Ctgb criteria for taking additional monitoring data into account are described below. More elaborate guidance for the use of monitoring data with regard to potential consequances for authorisation will be provided by the Working Group “terugkoppeling montoring naar toelating” (report expected in 2010). .

2.3.5.4. Criteria for taking monitoring data into account in the evaluation of the permissibility of Plant protection products
When an applicant wishes additional monitoring data to be considered in the evaluation, these should meet certain criteria and the monitoring protocol should be discussed with the Ctgb on beforehand.
The most important requirements are that the measurements must be reliable and that the causal relationship with the (agricultural) authorised application must be plausible. This means that as a start monitoring data collected in the treated acreage in the period of application should be considered.
This implies that monitoring data at, e.g., Lobith and Eijsden, where Rhine and Meuse, respectively, enter the Netherlands, are not suitable for the purpose aimed for in Ctgb context. The monitoring points in, e.g., the large national waters should also be considered as insufficiently concrete for use in the evaluation of the permissibility of Plant protection products because these can usually not be linked to authorised fields of use.

N.B. The above refers to the use of monitoring data for the assessment of risk to aquatic organisms (i.e., edge-of-field ditch or WFD water body). However, for the assessment of the drinking water criterion, only data representative for the drinking water abstraction point(s) of concern (located in large water bodies) can be taken into account.

The monitoring data to be used should meet the quality criteria as included in §1.2.1 Data requirements active substance and Appendix 4 to Chapter 3 Analytical methods. The following classification is used to indicate the reliability of monitoring data (category 1: most suitable; category 3: least suitable):

Category 1
Monitoring data obtained on a routine or project basis, where in the study a causal relationship can be established between use in compliance with the statutory use instructions and the measured concentration of a Plant Protection Product in the environment.
The Ctgb always takes category1 data into consideration in the evaluation of the permissibility of Plant protection products, where the (potential) drawbacks of the use of monitoring data should be kept in mind, in particular the difficult interpretation of the data. Generally, routine or project research (with distinction in and/or exclusion of specific sources) is therefore most suitable. These monitoring data can in the end have consequences for the permissibility of the Plant Protection Product in question.

Category 2
As category 1, but an incidental, “random” sample.

Category 2 data are always taken into account but in the decision-making great care is taken in the interpretation. Where in view of the data follow-up actions need to be taken, questions to the authorization holder for clarification and/or supplementary research are more likely than direct consequences regarding permissibility.

Category 3
No background information available about monitoring results as mentioned in category 1.

Category 3 data do not meet the quality criteria described above for Category 1 and 2 data but may -in case the causal relationship with the culture has been demonstrated- have a signal function. Ctgb may pose questions for clarification and/or ask for supplementary research from the authorization holder. These data are not sufficient as basis for decision-making.

N.B. In case there are large deviations between model-estimated concentrations and measured concentrations and negligent use cannot be ruled out, but neither can be seen as only source, the applicant is asked for supplementary field research to explain the differences.
In case there are large upward deviations between model-estimated concentrations and monitoring concentrations and negligent use can be ruled out (e.g. project research into certain emission routes), field values are used instead of model values.

2.3.6.4. Interpretation of monitoring data
According to article 2.10b of the Plant protection products and Biocides Regulations (Rgb), the Board applies the 90 percentile when testing monitoring data. When this value is used a maximum of 10% of the monitoring data exceeds the 90-percentile value.

The 90 percentile value of the general surface water monitoring data is compared with the criteria for toxicity aquatic organisms, as included in the chapter Ecotoxicology; aquatic organisms. In case the criterion is exceeded, a conclusion will be drawn about the permissibility of the particular product.

The 90 percentile value of the monitoring data on drinking water abstraction points is compared with the drinking water criterion. In case the criterion is exceeded, a conclusion will be drawn about the permissibility of the particular product.

2.4. Approval
The assessment of the risk to aquatic organisms has been laid down in regulations. The Wgb (Plant protection products and Biocides Act) 2006 [1] stipulates in Art. 28 (1) (b4 and b5): “a pesticide may only be authorised where this has no unacceptable effect on the environment”.

Furthermore, the assessment of the drinking water criterion is laid down in the Rgb.

The evaluation of products on the basis of existing active substances already included in Annex I or new substances has been laid down in the Plant protection products and Biocides Regulations (Rgb) [2] where it is elaborated that these products are evaluated according to the national specific criteria.

2.4.1. Criteria and reference values

The concentration in surface water and sediment as determined according to the methods in this chapter are used for assessment of the risk to aquatic organisms. The ecotoxicological criteria and reference values have been laid down in the section Ecotoxicology; aquatic organisms where it is stipulated that in the evaluation, including the evaluation based on monitoring data, approval is judged against the Maximum Permissible Concentration as derived via the INS method (MPC-INS, for explanation see Chapter 7 Ecotoxicology; Aquatic).

In the interim decision tree the following methodology was developed: at exceeding of the first tier assessment in the ditch (after drift-reducing measures), the second tier exists of:

- examination of the concentrations in the edge-of-field ditch against the available higher tier data according to the 91/414 standards in the edge-of-field ditch

and simultaneously

- examination against the MPC-INS in water bodies as meant by the WFD.

See interim decision tree water (Appendix 3).

The criterion laid down for surface water intended for drinking water production is that the concentration of any pesticide and the metabolites formed from that pesticide must be lower than 0.1 µg/L. A separate decision tree is available for this assessment (see Appendix 4a for agricultural and greenhouse applications and 4b for applications that discharge via STP).

For the criteria and trigger values as applied in the evaluation of surface water reference is made to the Plant protection products and Biocides Regulations (Rgb).
Article 2.10 b and c (new and existing substances) and Article 10.3 (existing substances not including in Annex I) of the Plant protection products and Biocides Regulations (Rgb) describes the authorisation criterion surface water.

The texts specifically referring to the aspect fate and behaviour in water are given below (in Dutch):

§ 4. Bepalingen inzake het milieutoxicologische risico van chemische gewasbeschermingsmiddelen

Artikel 2.10b. 90-percentiel [Treedt in werking per 01-01-2010]
Het college toetst met behulp van een 90-percentiel de blootstelling aan een gewasbeschermingsmiddel van:
a. de bodem, het grondwater, het oppervlaktewater en het sediment, bedoeld in de artikelen 2.8, 2.9 en 2.10, en
b. innamepunten van drinkwater uit oppervlaktewater, bedoeld in bijlage VI, deel I, onderdeel C, punt 2.5.1.3, bij richtlijn 91/414/EEG.

Artikel 2.10c. Driftcijfers [Treedt in werking per 01-01-2010]
Bij de risicobeoordeling voor waterorganismen, vogels, zoogdieren, niet-doelwitarthropoden, niet-doelwitplanten of oppervlaktewater bestemd voor de bereiding van drinkwater, hanteert het college specifieke driftcijfers. Het college stelt deze cijfers vast en maakt ze bekend op

zijn website.

Artikel 10.3. Beoordeling van een gewasbeschermingsmiddel of biocide als bedoeld in artikel 121 van de wet

Het college geeft in de beoordeling van een aanvraag omtrent toelating van een gewasbeschermingsmiddel of biocide als bedoeld in artikel 121 van de wet, ongeacht voor welke vorm van toelating als bedoeld in hoofdstuk 9 van de wet een aanvraag is ingediend, een oordeel over elk onderdeel van bijlage VI bij richtlijn 91/414/EEG onderscheidenlijk bijlage VI bij richtlijn 98/8/EG met inachtneming van de specifieke bepalingen die voor elke vorm van toelating bij wet of bij besluit zijn gegeven.

2.4.2. Decision making

The procedure for taking a decision on approval regarding the risk to aquatic organisms has been elaborated in chapter 7 Ecotoxicology; aquatic.

The criterion laid down for surface water intended for drinking water production is that the concentration of any pesticide and the metabolites formed from that pesticide must be lower than the drinking water threshold laid down in the Drinking Water Directive (0.1 µg/L for organic substances).

2.5. Developments

- In the framework of the WG Water (more specifically, “blootstelling waterorganismen”, “emissies uit bedekte teelten”, and “terugkoppelen monitoring naar toelating”) new methodologies are currently under development. These will be implemented in the coming years. For the moment, assessment is based on either the old situation or on interim methodologies as described in this Chapter. Aspects that will (or might) change as a result of the Working Group’s progress:
  -drift differentiation for field crops (edge-of-field)
  -introduction of drift reducing technique packages/classes (edge-of-field) instead of separate techniques/drift values; and implementation/further development of certification of drift reducing technologies into the mentioned classes
  -introduction of emission route via drainage from adjacent field
  -methodology for emission to WFD water bodies
  -methodology for emission from greenhouses
  -Handling of monitoring data
  -input parameters for degradation in water
- Dust drift from seed treatments

II BEHAVIOUR IN A SEWAGE TREATMENT PLANT (STP)

2. NL-FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation procedure for Plant protection products based on existing substances, included in Annex I, and new active substances.
A new substance is a substance not authorised in any of the Member States of the EU on the 25th of July 1993.
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 II and III to Directive 91/414/EEC (see Application Form and corresponding instructions).

A Member State may deviate from the EU evaluation on the basis of agricultural, phytosanitary and ecological, including climatological, conditions.

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

2.1. Introduction

This chapter describes the data on the behaviour in a sewage treatment plant (STP) for which specific rules apply in the national framework or where the national framework has been elaborated in more detail than the EU framework.
The programme USES (version 2.0) as indicated in Annex XV part B of the Plant protection products and Biocides Regulations (Rgb), is currently generally used to calculate the concentration for emission routes associated with other uses (such as discharge via an STP or emission via hard surfaces/amenity areas).
This programme contains several modules for calculating the concentration in surface water and sediment for emission routes associated with different uses.
Currently the STP assessment applies to application of PPP to

- hardened surfaces
- indoor cultivations of e.g. mushrooms (not glasshouses)
- potato processing industry (no specific scenario available, generic scenario used)

According to the Plant protection products and Biocides Regulations (Rgb) [2] and as indicated in Annex XV part B of the Plant protection products and Biocides Regulations (Rgb) a specific Dutch interpretation is applied for the aspect behaviour in an STP. This is because USES 2.0 is used for calculating the loading of an STP, since there is no European model.

A decision tree with corresponding explanatory notes is presented in Appendix 1 to this chapter. This decision tree summarises the testing framework as regards behaviour in surface water, sediment and an STP.

The other points described in this chapter are further elaborations of the EU procedure.

2.2. Data requirements

The data requirements for chemical Plant protection products are in agreement with the provisions in EU framework (see §1.2 of the EU part). The question numbering of the NL Application Form has also been included in §1.2 of the EU part.
Further elaborations of the EU data requirements are given in the text below.

Experiments carried out after the 25th of July 1993 must have been carried out under GLP.

There may be no doubt about the identity of the tested product or the purity of the tested substance for each study.

The studies must be carried out in compliance with the applicable guidelines.
A review of the guidelines and whether or not these are required for particular fields of use is given in Appendix A to Chapter 6.

2.2.1. Adsorption to sediment and suspended material

Adsorption of the substance under test to sediment and suspended material can be evaluated with the data obtained on soil adsorption (AII7.1.2). The same process is assumed to play a role here as in the adsorption to soil particles. When under AII7.1.2 an adsorption test with sediment has been carried out, this is a refinement of the risk assessment.

Result:
→ K_{om} (K_{oc}/1.724)

A conversion factor of 1.724 is used to translate K_{oc} into K_{om}.
For substances that are (almost) only discharged to surface water via biological treatment plants, the extent of adsorption to activated sludge can be determined as refinement of the risk assessment. This K_p value (partition coefficient solid matter - water) can then be entered in the model that is used to calculate the exposure concentration as result of discharge via an STP.

Test guideline
ISO 18749 Water quality – Adsorption of substances in activated sludge – Batch test using specific analytical methods [7].

Result:
→ partition coefficient (K_p) STP

2.3. Evaluation methodologies

The evaluation methodologies for chemical Plant protection products are in agreement with the methods in EU context (see §1.3 of this chapter).
Further elaborations of the EU procedures are given in the text below.

Because a European model for calculation of the loading of an STP is not available, the USES 2.0 model is used according to the Plant protection products and Biocides Regulations (Rgb) [2] and as indicated in Annex XV part B of the Plant protection products and Biocides Regulations (Rgb).

2.3.1. Surface water and sediment

For substances that are discharged onto an STP, the removal of the substance in a sewage treatment plant is calculated by using the STP model Simpletreat in USES.
The concentration in the effluent followed by a dilution factor gives the concentration in the surface water (output provided directly by USES). For calculation of concentration in the effluent see next paragraph.

For mushroom cultivation, an example calculation is presented in Appendix 3 of Chapter 7 Ecotoxicology; aquatic.
The calculated predicted environmental concentration (PEC) in surface water and sediment is used in the risk assessment for aquatic and sediment organisms.

Drinking water criterion
For emissions via STP, no decision tree has been developed by the WG Implementation of drinking water criterion. Therefore, the Ctgb interim decision tree remains applicable.
See Appendix 4b.
Currently guidance is developed by a sub-group of the WG Implementation of drinking water criterion to address the assessment of the drinking water criterion for applications to hardened surfaces (expected in 2010).

2.3.2. Calculation exposure concentrations for discharge via a sewage treatment plant (STP)

For substances that are discharged to an STP, the removal of the substance in such an STP is calculated with the sewage treatment model Simpletreat in USES.
The concentration in the effluent (and by assuming a certain dilution also the concentration in surface water and sediment) is calculated on the basis of dissipation data and physical-chemical parameters. The disappearance of a Plant Protection Product from the aqueous phase depends on its substance properties.

A specific model scenario in Simpletreat is used for mushroom growing, which also determines the concentration of a Plant Protection Product in the effluent. The calculation method for mushroom growing with examples is presented in Appendix 3 of Chapter 7 Ecotoxicology; aquatic.

Application models (e.g. for mushroom growing; see USES for these models) are used to calculate the exposure concentration in the influent of the STP. A risk estimate for the effects of Plant protection products on an STP is made with data about the effect on waste water treatment (NL: A8.7a).

N.B. An application model for calculation of the concentrations in the influent of an STP is not available for all relevant uses. Currently, only the models for mushroom growing and for use on hard surfaces (pavements) and in amenity areas (public parks/gardens) are used. Dilution takes place because several companies/individuals are discharging waste water from other sources onto the same STP. This is at the moment not yet adequately incorporated into a model for the different relevant types of applications. Furthermore, other input parameters are not available or they are insufficiently reliable. It is therefore currently not possible to estimate the concentration in the effluent of an STP for all types of applications.

2.3.3. Calculation acute exposure concentration for emission via use on hard surfaces

This is a specific case with emission to STP instead of direct emission to edge-of-field ditch. The exposure concentration in surface water and sediment through Plant protection products on hard surfaces is calculated according to the method as included in USES. Any (obligatory) emission reducing technologies on the label (e.g., application according to the DOB methodology) are taken into account for the assessment.

2.4. Approval

The assessment of the risk for biological methods of waste water has been laid down in regulations. The Wgb (Plant protection products and Biocides Act) 2006 [1] stipulates in Art. 28 (1) (b4 and b5): “a pesticide may only be authorised where this has no unacceptable effect on the environment”.

The evaluation of products on the basis of existing active substances already included in Annex I or new substances has been laid down in the Plant protection products and Biocides Regulations (Rgb) [2] where it is elaborated that these products are evaluated according to the national specific criteria.

2.4.1. Criteria and trigger values

For the criteria and trigger values as applied in the risk assessment for biological methods of waste water treatment reference is made to the Plant protection products and Biocides Regulations (Rgb).
Article 2.10 a (new and existing substances) and Article 10.3 (existing substances not including in Annex I) of the Plant protection products and Biocides Regulations (Rgb) describes the authorisation criterion for biological methods of waste water treatment.

The texts specifically referring to the aspect biological methods of waste water treatment are given below (in Dutch):

§ 4. Bepalingen inzake het milieutoxicologische risico van chemische gewasbeschermingsmiddelen

Artikel 2.10a. Rioolwaterzuiveringsinstallatie [Treedt in werking per 01-01-2010]
Het college verleent geen toelating voor een gewasbeschermingsmiddel indien verwacht mag worden dat een zuiveringstechnisch werk als bedoeld in artikel 1.1 van de Waterwet zal worden blootgesteld aan dit gewasbeschermingsmiddel en de concentratie van de werkzame stof of het reactie- of afbraakproduct ervan in het influent meer zal zijn dan 0,1 van de EC50 van het zuiveringstechnisch werk, tenzij met een adequate risicobeoordeling is vastgesteld dat geen onaanvaardbare effecten zullen optreden op de doelmatige werking van voormeld werk.

Artikel 10.3. Beoordeling van een gewasbeschermingsmiddel of biocide als bedoeld in artikel 121 van de wet

Het college geeft in de beoordeling van een aanvraag omtrent toelating van een gewasbeschermingsmiddel of biocide als bedoeld in artikel 121 van de wet, ongeacht voor welke vorm van toelating als bedoeld in hoofdstuk 9 van de wet een aanvraag is ingediend, een oordeel over elk onderdeel van bijlage VI bij richtlijn 91/414/EEG onderscheidenlijk bijlage VI bij richtlijn 98/8/EG met inachtneming van de specifieke bepalingen die voor elke vorm van toelating bij wet of bij besluit zijn gegeven.

2.4.2. Decision making

The concentration in an STP is used in the decision-making regarding the risk assessment for aquatic organisms. For effects on an STP, no reference can be made to European regulations because the UP do not mention criteria for this aspect. Decision-making takes place at the national level. The decision-making has been laid down in Chapter 7 Ecotoxicology; aquatic.

2.5. Developments

- The currently applied methodology for mushroom growing can probably also be applied for other cultures such as chicory forcing and pre-treatment of cut flowers. This is not yet elaborated.
- A separate model is being developed for the calculation of surface water concentrations at drinking water abstraction points after application to hardened surfaces (Vander Linden et al, draft version 2009 [8])

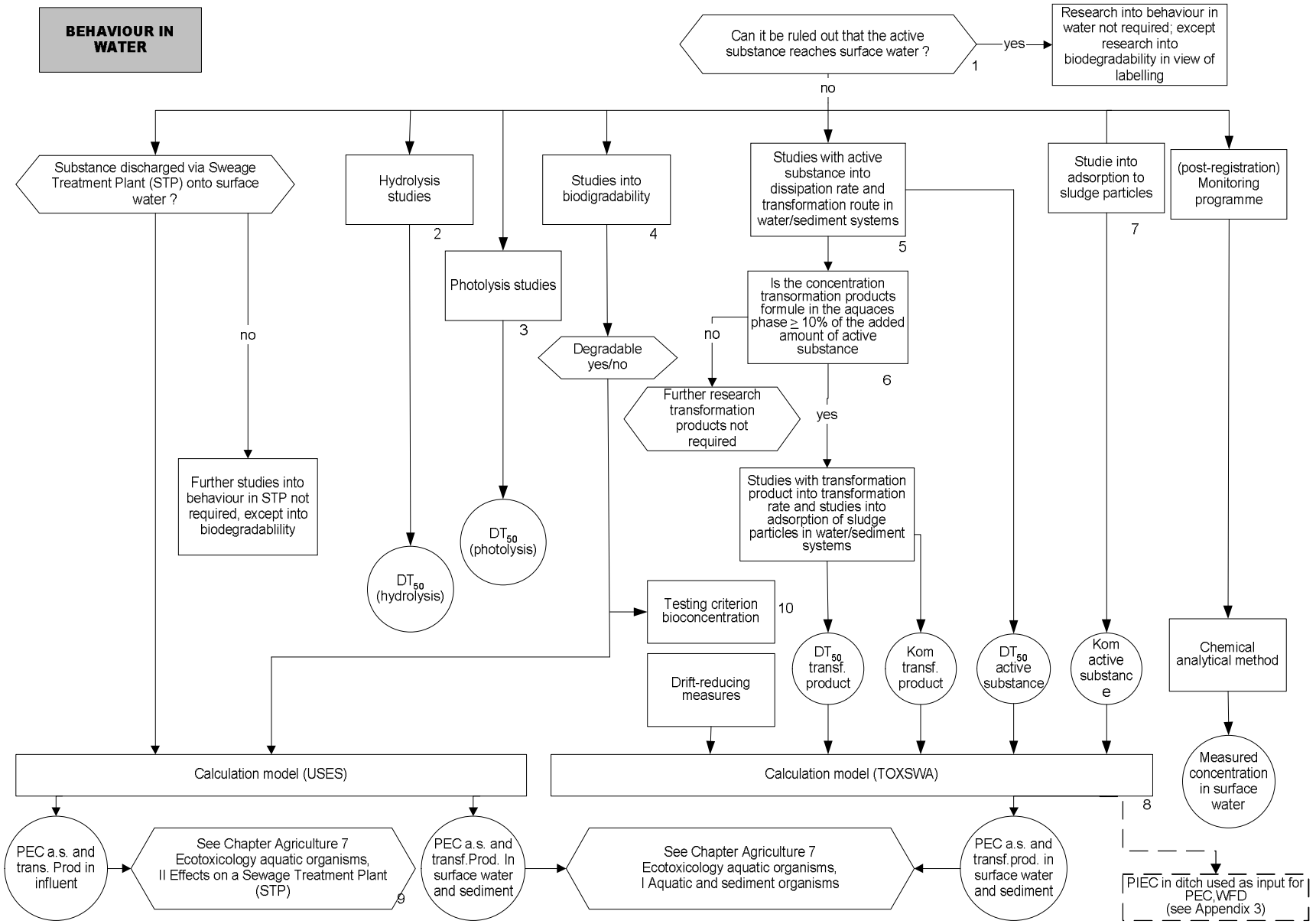
3. APPENDICES

Appendix 1 Explanatory notes decision tree behaviour in surface water, sediment and sewage treatment plant (STP)

1) For each active substance, information concerning behaviour in surface water and sediment (A7.2a) must be provided, unless it can be demonstrated that it can be ruled out that the substance reaches surface water and sediment during good (agricultural) use of the product, according to the WG/GA (Statutory Use Instructions/Directions
   For Use).
2) For the performance of the hydrolysis study, reference is made to question A2.09.1a and A7.2.1.1a. This information is used as background information during the assessment.
3) Data on the photochemical degradation (A2.09.2a/A2.09.3a and A7.2.1.2a) are used as background information in the assessment.
4) Data on “ready biodegradability” are required for testing the bioconcentration factor and for testing the risk to aquatic organisms of substances that reach surface water and sediment via an STP (For detailed information concerning the assessment of substances that are discharged into the surface water via an STP,
   see Part II Chapter 6. Fate and behaviour in the environment; behaviour in surface water, sediment and sewage treatment plants (STP).
5) A study in water must be conducted into the dissipation (disappearance) of the active substance, and the transformation of the active substance into its degradation products. (A7.2.1.3.2a). The routes through which the transformation processes take place, and the rates of the transformations must, where possible, be determined.
6) Toxicologically or ecologically relevant degradation products in the aqueous phase are degradation products formed in the aqueous phase of which the laboratory research into the degradation in a water/sediment system at any point in time showed an amount higher than or equal to 10% of the added amount of active substance. For these metabolites, data on the rate of degradation and bio-concentration are required.
   This also applies for transformation products of which the concentration is at two consecutive sampling dates equal to or higher than 5% of the added amount of active substance.
   Toxicologically or ecologically relevant degradation products in the sediment phase are degradation products formed in the sediment phase of which the laboratory research into the degradation in a water/sediment system after 14 days showed an amount higher than or equal to 10% of the added amount of active substance. For these metabolites, data on the toxicity for sediment organisms are required.
   This also applies for transformation products of which the concentration is at two consecutive sampling dates equal to or higher than 5% of the added amount of active substance or of which the maximum has not yet been reached at the end of the study.

7) The data obtained on adsorption to soil can be used (see A7.1.2a) for evaluation of the adsorption of the test substance to sludge in surface water and sediment, For substances that are discharged into the surface water via an STP, the assessment can be refined by determining the adsorption to activated sludge.
   The exposure (Predicted Environmental Concentration (PEC)) is the value calculated by a calculation model, taking into consideration the frequency of application.
   Exposure calculations are usually performed using the exposure model TOXSWA and the programme USES. USES contains several modules for calculating the concentration in surface water and sediment for emission routes corresponding with different uses.

   When calculating the concentration of a Plant Protection Product in surface water and sediment, the relevant emission routes of the product to surface water and sediment should be determined, and the concentration must then be calculated with the appropriate module.
8) For Plant protection products, the following emission routes are relevant: spray drift (TOXSWA) and to a lesser extent, emission through discharge via an STP and emission via hard surfaces/public parks and gardens (amenity areas) (USES).
9) In the assessment diagram concerning the risk to aquatic organisms, the PEC is related to toxicity data of the different tested aquatic organisms, for which reference is made to the next Chapter 7 Ecotoxicology; aquatic.
10) The criterion for bio-concentration is associated with the degree of biodegradability ‘ready biodegradable’ / ‘not ready biodegradable’ of a substance.
11) The adequate risk assessment can yield supplementary data about the fate of the substance in the aquatic environment (including water bottom/sediment) which may lead to adjustment of the calculated exposure concentration.


BEHAVIOUR IN WATER
Can it be ruled out that the active substance reaches surface water ?
1
yes
Research into behaviour in water not required; except research into biodegradability in view of labelling
no
Substance discharged via Sweage Treatment Plant (STP) onto surface water ?
Hydrolysis studies
2
Photolysis studies
3
Studies into biodigradability
4
Studies with active substance into dissipation rate and transformation route in water/sediment systems
5
Studie into adsorption to sludge particles
7
(post-registration) Monitoring programme
no
Further studies into behaviour in STP not required, except into biodegradablility
DT50 (hydrolysis)
DT50 (photolysis)
Degradable yes/no
Is the concentration transormation products formule in the aquaces phase ≥ 10% of the added amount of active substance
6
no
Further research transformation products not required
yes
Studies with transformation product into transformation rate and studies into adsorption of sludge particles in water/sediment systems
Testing criterion bioconcentration
10
Drift-reducing measures
DT50 transf. product
Kom transf. product
DT50 active substance
Kom active substanc e
Chemical analytical method
Calculation model (USES)
Calculation model (TOXSWA)
Measured concentration in surface water
8
PEC a.s. and trans. Prod in influent
See Chapter Agriculture 7 Ecotoxicology aquatic organisms, II Effects on a Sewage Treatment Plant (STP)
9
PEC a.s. and transf.Prod. In surface water and sediment
See Chapter Agriculture 7 Ecotoxicology aquatic organisms, I Aquatic and sediment organisms
PEC a.s. and transf.prod. in surface water and sediment
PIEC in ditch used as input for PEC,WFD (see Appendix 3)

Appendix 2 Drift and emission percentages

Table 1 Drift percentages to be used (standard situations*) according to LOTV 2000

Application	Subdivision	Drift %	Remarks
Upward and sideward spraying techniques			
Fruit crops (large fruit)	without leaves (dormant)	17	
	With leaves (full leaf)	7	
Lane trees	“spillen” (closely spaced)	0.8	
	“opzetters” (widely spaced)	2.8	
Downward spraying techniques			
Field crops (incl. soft fruit)		1	Differentiation of the drift figures to cover crop-free zone is under development
Bush and hedge shrubbery		1	
Bulb growing		1	
Greenhouse applications		0.1	
Special applications	-airplane -mud-bank -dry ditch -Knapsack	5 100 100 0.5	including spray-free zone of 14 metres hand-held equipment, *e.g.,* amateur use/spot treatments
Applications without drift	See explanatory notes	0	

* Drift-mitigation measures will be discussed in more detail in the explanatory notes below.

Explanatory notes drift percentages

General

The proposed drift percentages are derived from research by the Plant Research International (PRI) and are geared to the existing regulations (“Lozingenbesluit” LOTV (Discharge Order 2000)) and associated packages of measures.

On an individual basis an applicant/registration holder can request Ctgb to consider additional (drift-mitigation) measures and corresponding drift percentages for a particular application. These drift percentages must supported by reliable scientific data.
The additional measures should be realistic and enforceable. Below, specific mitigation options are described per crop/application type.

Explanation per crop/application

Upward and sideward spraying

Fruit crops (with the exception of "soft fruit")
Standard drift percentagesare : 17% without leaves (until 1 May), 7% with leaves (from 1 May onwards) (standard situation, see Table 1).
Applicants may consider drift mitigation measures as indicated in Table 2.

Table 2: Drift-mitigation measures in comparison with standard fruit growing situations

Drift-mitigation technique top fruit	Without or with leaves[x]	Reduction applied [%]	Drift percentage [%]	Remarks
Tunnel sprayer	without leaves	85	2.5	
	with leaves	85	1	
Combination windbreak on the edge of the driving track and one-sided spraying of the last tree row	without leaves	59	7.0	
	with leaves	90	0.7	
Sensor-controlled spraying	without leaves	20	13.6	
	with leaves	50	3.4	
One-sided spraying of last tree row	without leaves	43	9.7	
	with leaves	43	4.0	
Emission shield (2.5 m high)	without leaves	60	6.8	
	with leaves	60	2.8	
Cross flow fan sprayer with reflection shields	without leaves	55	7.7	
	with leaves	55	3.2	
6 meter crop-free zone	without leaves	61	6.7	
	with leaves	61	2.7	
Venturi nozzle + one-sided spraying last tree row [xx]	*without leaves*	*86*	*2.4*	*Ventilator: low*
		93	*1.2*	*Ventilator: off*
	with leaves	*88*	*0.8*	*Ventilator: high*
		96	*0.3*	*Ventilator: low*
Wanner equipment with reflection shield and venturi nozzles (Lechler ID 90-015C) [xxx]	without leaves	95% (with regard to experimental reference)	0.98	
	with leaves	95% (with regard to experimental reference)	0.21	

x Without leaves (dormant) is before May 1st; with leaves (full leaf) is after May 1st.
xx The restriction to be included in the WG/GA for this drift-mitigation technique is:
'Permitted is only the use as … in the culture of … on the understanding that application on fields adjacent to waterways is only permitted if the product on the first 20 m adjacent to the waterway is sprayed with a Venturi nozzle where the last tree row must be sprayed from one side.'
Xxx M. Wenneker, R. Anbergen, N. Joosten, J.C. van de Zande, 2006. Emissiereductie bij inzet van een Wannerspuit met reflectieschermen in de fruitteelt; PPO report nr. 2006-13

Growth of lane trees
For the growth of lane trees, separate drift percentages are used based on research by PRI, A distinction is made between the growth of "spillen" (closely spaced trees) and

“opzetters” (widely spaced trees) because of the differences in tree shape, and the resulting differences in drift emission.

"Spillen" form dense rows (plant distance 30 cm), whilst "opzetters" are planted further apart (1 m plant distance), are taller, and often have bare lower trunk.
No mitigation measures have been defined in the Ctgb assessment procedure.

Downward spraying

Field Crops (including "soft fruit" and bush and hedge shrubbery)
Drift percentage: 1%.

In the first tier assessment, the starting point is a 50% drift-mitigation nozzle in the last 14 m of the field, in compliance with the Amendment Regulation Low-drift Nozzles Discharge Order open cultures and livestock farming (LOTV). For this situation, a drift emission of 1 % is available, based on spray drift data of PRI for potatoes with a crop-free buffer zone of 1.5 m (LOTV obligatory minimum). Currently this drift value is also used for all other field crops with downward spraying, irrespective of the specific crop-free buffer zone.
In the decision tree currently under development by the WG Water, drift differentiation between crops on the basis of crop-free buffer zones will be implemented on the basis of PRI data. These differentiated drift values will be implemented in the new exposure model for the Dutch edge-of-field ditch (expected in 2010).

If for the approval of a product drift reduction is necessary, the use of 75 % or 90 % drift reducing nozzles and/or other drift reducing technologies can be requested by the applicant.

The corresponding drift values used for the assessment are 0.5 % (75 % reducing nozzles) and 0.2 % (90 % reducing nozzles) for all field crops, based on the current 1 % at 50 % drift reducing nozzles for all field crops.

Furthermore, on an individual basis for each application and crop combination it is possible to consider additional measures with accompanying drift percentages in the assessment of the authorisation on the basis of specific drift research by PRI submitted by the applicant.

Eligible drift reducing nozzles and techniques, classified according to drift reduction classes, are listed on the website of Helpdesk Water:
http://www.helpdeskwater.nl/emissiebeheer/landbouw_en_veeteelt/lotv/technische_commissie/?ActItmIdt=3575&PagClsIdt=16468#PagCls_16468

Bush and hedge shrubbery
Drift percentage: as for field crops (1%)
PRI has indicated that in the "Lozingenbesluit" this crop is considered to be a common field crop, and that the same percentage can be used. In practice, a specific spraying technique is often used, *i.e.*, a hand-held spray boom, which leads to a lower drift percentage (0.5 %, see knapsack, below). If a request is made to Ctgb for individual applications, the use of this technique can be taken into consideration in the assessment for authorisation. The drift table contains the drift percentage that corresponds with the obligatory measure from the LOTV.

Flower bulb growing
Drift percentage: as for field crops (1%)

Greenhouse Applications

For the exposure particularly by condensation water and volatilisation, an overall emission value of 0.1%, simulated as spray drift input, is used for the calculation. Considering the basis for this percentage, studies are required. Currently a WG is working on the development of a model that can take into account the (pulse) emission from greenhouses with the corresponding emission values (expected finalisation 2010).

Special Applications

- For mud-banks and dry-ditch beds, a drift value of 100 % applies.
- For aircraft applications, the LOTV is normative. The LOTV mentions that during aircraft applications, a spray-free zone of 14 m must be used. The corresponding drift percentage is set at 5%. Aircraft application is taken into account by default in the risk assessment for the following crops:
  - Potatoes
  - Brussels sprouts
  - Sown onions
  - Sugar beets
  - Cereals
  - Legumes (*peulvruchten*)
  - Flax
  - Poppy seed *(blauwmaanzaad)*
- Knapsack (handheld equipment)
  For hand held equipment (*rugspuit/spuitlans*) a drift percentage of 0.5 % is assumed. This technique is mostly used in applications by amateurs (*particulier gebruik*)

Applications without drift

A drift percentage of 0% applies for:

1) Enclosed spaces (not greenhouses):
   a. storage cells and
   b. shower rooms and comparable enclosed spaces;
3) witloof chicory (forcing)
4) Specific field applications:
   a. application of granules using a specially mounted granule sprinkler,
   b. drenching,
   c. dipping,
   d. foaming,
   e. placing of bait,
   f. injection of soil/plant,
   g. treatment of plant base
   h. smearing,
   i. jointing,
   j. treatment of furrow,
   k. dosing pistol or comparable apparatus, and
   l. seed treatment.

Developments

Differentiated drift percentages

As mentioned above, it is anticipated that Ctgb will switch to differentiated percentages for each crop, based on properly substantiated new scientific insights. Current field studies by

PRI will then have been completed. Implementation of these differentiated percentages will be upon instruction from the ministries to use the new Dutch exposure surface water model,

Drift studies in fruit crops
The current drift figures for the situation with and without leaves in fruit growing are currently being evaluated, which may possibly lead to adjustment of these figures and the derived absolute drift percentages of the honoured drift-mitigation measures.

Appendix 3 Interim decision tree Water

To comply with requirements made in the Water Framework Directive (WFD), in which substances are evaluated against Environmental Quality Standards, an interim decision tree was implemented in September 2009 by decree of the responsible Ministries.

The ecotoxicological threshold in the WFD water body is the MPC-INS (both acute and chronic). The need for examining the MPCwater (MAC) and MPCwater (AA) in "the" WFD waterbody is triggered by an exceeding of the first tier 91/414 threshold values in the edge-of-field ditch. This exceeding in the first tier can be due to acute or chronic risk. It is decided that in both cases a Tier 2 risk assessment based on both MPCwater (MAC) and MPCwater (AA) is to be performed.
N.B. in the case that the bioconcentration trigger (BCF > 100 L/kg) is exceeded in the first tier bioconcentration assessment, also an MPC according to INS has to be derived and examined against the predicted environmental concentration in the WFD water body.
The second tier assessment in the edge-of-field ditch does not apply in this case.

Tier 2
Edge-of-field ditch
The refined risk assessment for the edge-of-field ditch consists of examining the PIEC in the edge-of-field ditch against the ecotoxicological threshold values from higher tier testing (e.g., mesocosm, HC5).

WFD water body
In the WFD water body, examining is against the MPC-INS value. No procedure for deriving a PEC value in the WFD water body is yet available. Therefore, an estimation of the PEC in the WFD waterbody has to be provided. For the interim-decision tree for surface water only a PECmax in the WFD waterbody will be calculated. The methodology for estimating exposure concentrations is based on the predicted concentration in the edge-of-field ditch calculated with TOXSWA v1.0 and subsequently taking into account the following processes:
* dilution: based on first estimates from catchment modelling with CASCADE- taking into account single or multiple exposure events
* degradation during the travelling time from ditch to WFD water body.

The formula applied to arrive at the predicted **initial** concentration at the WFD water body is: (in line with Ctgb interim decision tree for drinking water)

$$\mathbf{PEC_{max,\ WFD} = PEC_{max,\ edge\text{-}of\text{-}field\ ditch} * e^{(-residence\ time * k)} / dilution\ factor}$$

With a dilution factor of **3 (multiple applications) or 5 (single applications)** and a residence time of **5 days**.

Refinement options (Tier 3)
If for the above Tier 2 risk assessment a risk cannot be excluded (for edge-of-field or for WFD water body), refinements can be made in specific cases.
However, in first instance, drift mitigation measures should be proposed (e.g. drift reducing

nozzles).

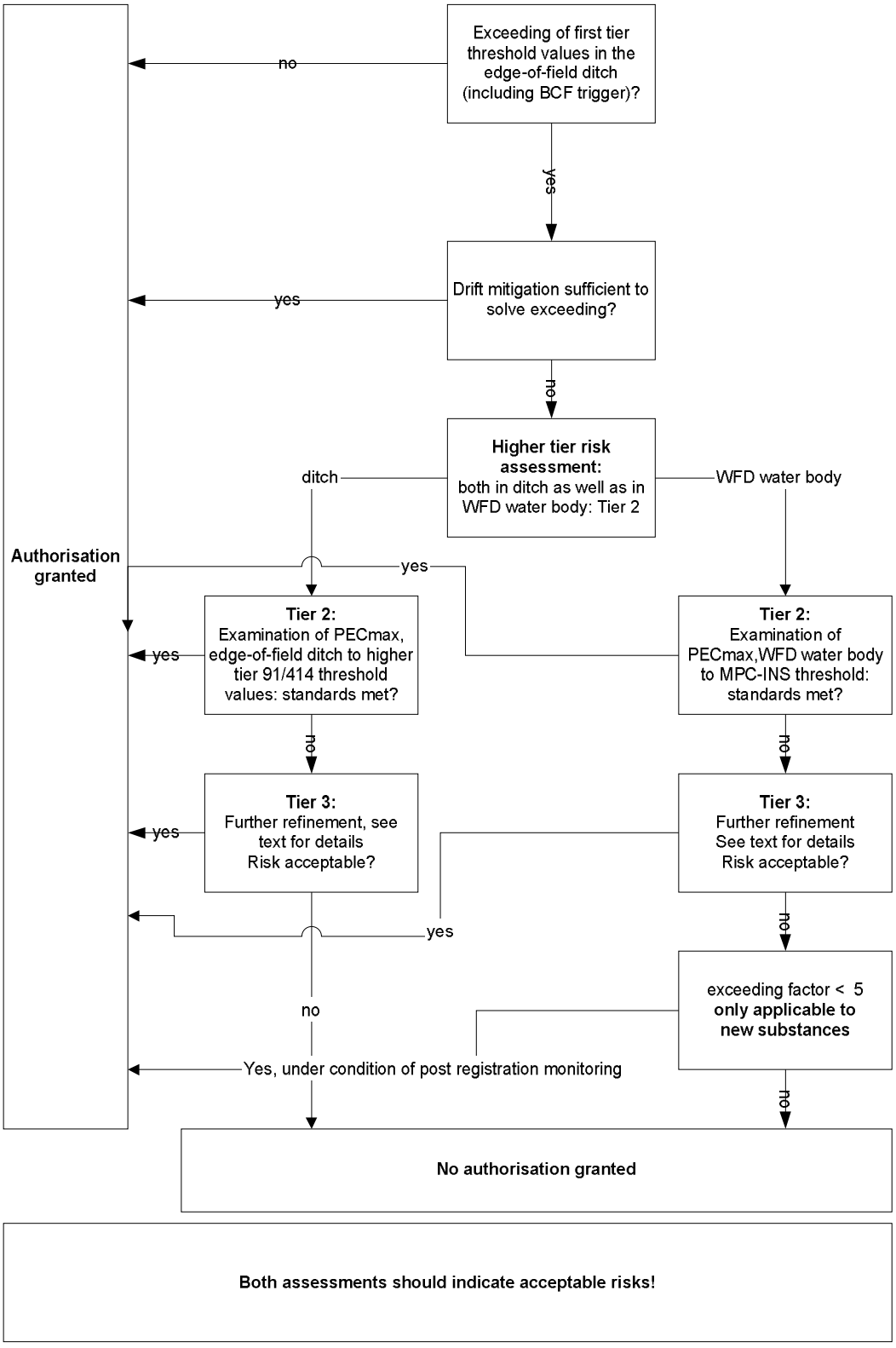
If a risk still cannot be excluded, the following further refinement options are available

Edge-of-field ditch:
No further refinement possible, except further emission restriction by amendment of the label/instructions for use (e.g. dose, or frequency, or…)

WFD water bodies

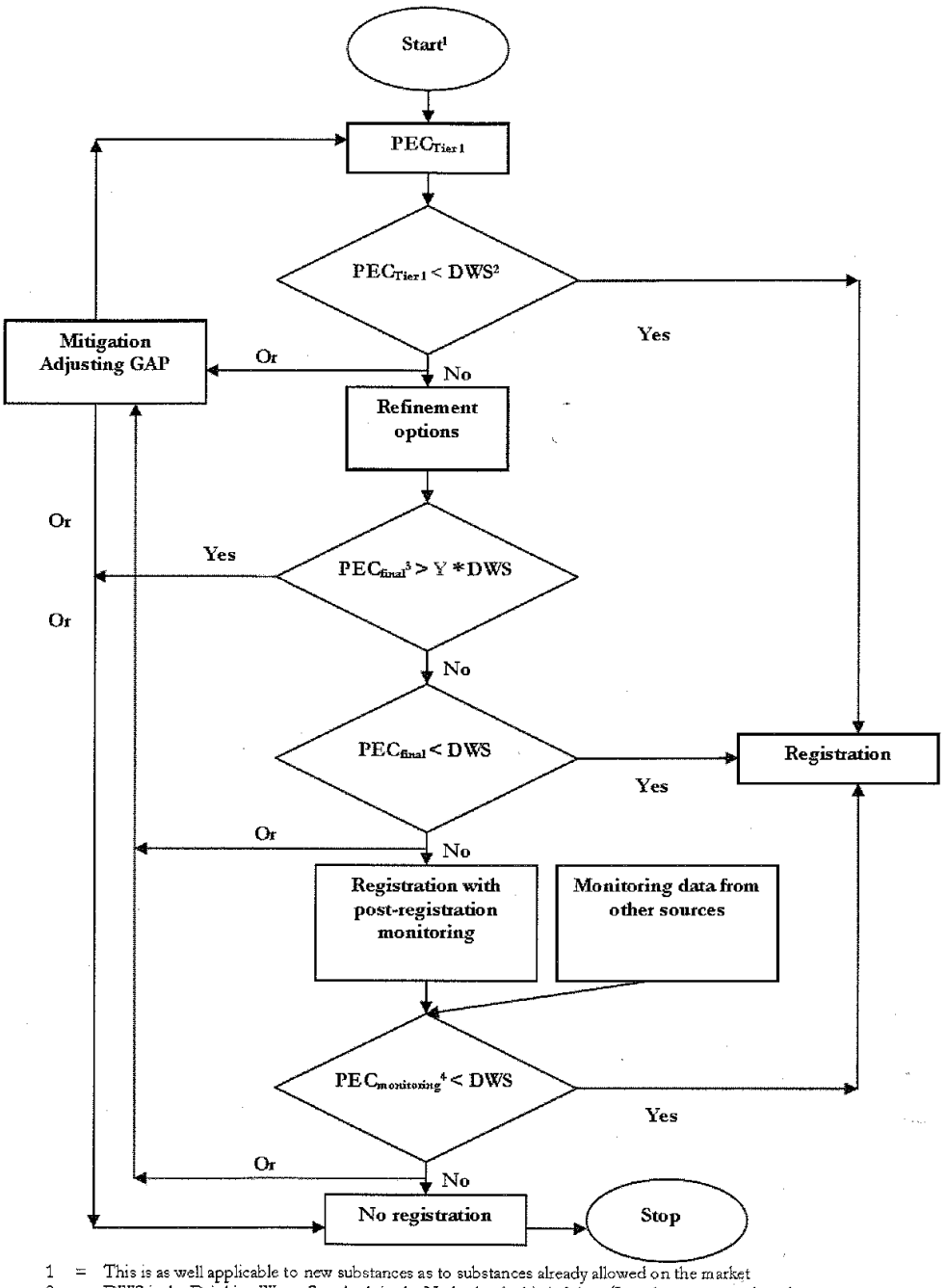
- For multiple applications for which it can be demonstrated that 2 or more applications have no ecotoxicological relevant coherence, e.g. in case the interval is longer than the life cycle of relevant organisms – further case-to-case elaboration required (expert judgement) – a dilution factor of, e.g., 5 can be chosen instead of 3. NB. Such application schemes are not common.
- For applications of substances for which sorption is a relevant factor in the disappearance (rule of thumb: substances with a Kom > 10.000 L/kg), adequate use of the second option under 'disappearance resulting from transport/residence time' by dissipation (DT50 water) is a possibility, provided that the criterion for sediment organisms in the edge-of-field ditch is met separately.
- For applications of substances where hydrolysis is a relevant dissipation factor, the third option under "disappearance resulting from transport/residence time' by hydrolysis can adequately be used.
- Relevant application period and application frequency should be taken into account in a further substantiation – if any – of the estimation of the annual average exposure concentration in the water body.
- In case the criterion exceedance is small (maximum factor 5, in line with drinking water decision tree) a temporary authorisation could be granted under certain conditions (**only for new substances on the Dutch market** for which (adequate) monitoring data are not yet available) under condition of post-registration monitoring. Some examples of such conditions:
  - it is meaningful to start a monitoring programme (the substance can be detected above the limit of detection, i.e., not very rapidly disappearing from the water phase). NB. Starting up such a monitoring programme only seems meaningful in case the MPRwater (chronic) is exceeded because if the MPRwater (acute) is exceeded, the maximum exposure concentration must be measured directly in the WFD water bodies; this will be very difficult in practice.
  - the field of use covers a restricted acreage.

Appendix 1 flow chart decision tree



Appendix 4a Decision tree Drinking Water Criterion - for agricultural crop treatments

For the assessment of the drinking water criterion, Ctgb uses the decision tree as developed by the Working Group Implementation Drinking Water Criterion (Adriaanse *et al.*, 2008, Alterra report 1635) from January 2010 onwards.
The decision tree from the report is presented below:



1 = This is as well applicable to new substances as to substances already allowed on the market
2 = DWS is the Drinking Water Standard; in the Netherlands this is 0.1 µg/L at the moment when the report was issued
3 = In case no refined assessment has been applied the PEC_{final} is $PEC_{Tier\ 1}$
4 = Before making a decision it has to be analysed whether the substance is of Dutch origin or not

Tier I calculation:
The equation to calculate the pesticide concentration in the surface water at the abstraction points ($PEC_{Tier\ I}$) reads:

$$PEC_{TierI} = \sum_{all}^{crops} ((PEC_{FOCUS\_NL,D3} \cdot f_{corrFOCUSscen}) f_{use\_intensity}) \cdot f_{timing} \cdot f_{dissipation} \cdot f_{add\_dilution}$$

With:

$PEC_{Tier\ I}$ PEC in surface water at location where it is abstracted for drinking water preparation (µg/L)

$PEC_{FOCUS\_NL,D3}$ global maximum PEC edge-of-field for the FOCUS D3 scenario based upon Dutch drift deposition data (µg/L)

$f_{corrFOCUSscen}$ correction factor for implicit choices concerning contributing areas made in FOCUS D3 scenario (-)

$f_{use\_intensity}$ factor considering the use of the pesticide (-)

f_{timing} factor considering the difference in timing of application within the area of use (-)

$f_{dissipation}$ factor considering the dissipation from the edge-of-field watercourse to the abstraction point (-)

$f_{add\_dilution}$ factor considering additional dilution, e.g. by considerable water flows entering the intake area, or by lakes via which water travels to the abstraction point

Further detailed explanation of these terms is given in Adriaanse et al (2008).

Tier II evaluation of monitoring data:
The quality criteria to which monitoring data should comply are elaborated in paragraph 5.2.6 of Alterra report 1635. The procedure of evaluation of monitoring data described applies to post-registration monitoring data but can be extrapolated to the evaluation of existing (VEWIN) monitoring data (paragraph 5.3) since no clear guidance is given there.

In short, the procedure is as follows (for details see Alterra report 1635):
-13 measurements should be available for each drinking water abstraction point each year for the calculation of a 90-percentile value for each calendar year.
- if (due to exceptional circumstances) less than 13 measurements per year are available, the maximum value should be taken and should be below 0.1 µg/L
- if 12 measurements are available per year, the maximum value should also be taken and should be below 0.15 µg/L (explained in note *b* on page 68 of the report)

Next to the 90-percentile for each year, a 90-percentile value over a 5-year period is to be calculated for each abstraction point. If the 90-percentile over the 5-year period exceeds the threshold, an adequate risk assessment should be provided. If the 90-percentile value for one year exceeds, a problem analysis should be provided.
No overall 90-percentile over the various drinking water abstraction points is calculated. Each individual abstraction point should meet the drinking water limit.

The Ctgb uses the possibility of jumping to higher tiers for the assessment of the drinking water. This means that in practice three categories of substances are distinguished:

1. **New substances** on the Dutch market (< 3 years authorised in NL): A Tier I PEC is calculated according to the methodology in Alterra report 1635. A Tier II cannot be performed yet as there are no monitoring data for new substances. If Tier I fails (with less than a factor 5 exceeding), post-registration obligation will be imposed in order to collect Tier II data for future evaluations of the substance. *(if the VEWIN during the authorisation period indicates that the substance is regarded as a substance of concern on the basis of new, adequate and sufficient monitoring data the substance will move to the third category)*

2. Old (> 3 years authorised in NL) **substances of no concern**: if there are no indications from the VEWIN that the substance is a potential problem for drinking water production, then no Tier I calculations are deemed necessary. The substance meets the drinking water criterion based on the Tier II information (as the available VEWIN monitoring data indicate no problems). *(if the VEWIN during the authorisation period indicates that the substance is regarded as a substance of concern on the basis of new, adequate and sufficient monitoring data the substance will move to the third category)*

3. Old (> 3 years authorised in NL) **substances of concern**: the VEWIN indicated that the substance is a potential problem for drinking water production by including it on a yearly updated list on the basis of monitoring data. In this case, Tier II is used directly (jumping of Tier I) the available monitoring data of the VEWIN of the most recent 5 years at all drinking water abstraction points will be analysed on the basis of the criteria set out in the Alterra report.

The list of substances of concern will be yearly updated by the VEWIN and be published by the Ctgb.

For further details refer to Alterra report 1635.

Appendix 4b Decision tree Drinking Water Criterion - use on hardened surfaces and other STP routes

Alterra report 1635 only provides guidance for agricultural applications (direct emission to edge-of-field ditches). For emission via STP, no generic methodology is available. For the specific use on hardened surfaces, a methodology is being developed but has not been provided to the Ctgb yet (Van der Linden et al, draft 2009). Therefore the interim decision tree of the Ctgb, as laid down in C-163.5, still applies until more guidance is available.
The Tier 1 possibility as provided in C-163.5, however, does not apply to uses that emit via STP, since the PIEC in the edge-of-field ditch according to TOXSWA is used as a basis for further calculations. Furthermore, the used travelling time and dilution are also not suitable for surface water receiving discharge water from an STP.
Therefore, for new substances, Tier 1 is not applicable. As a worst-case, the concentration in surface water as predicted by USES 2.0 could be examined directly to the drinking water criterion. When a risk cannot be excluded based on this conservative assessment, the applicant should submit adequate risk assessment as no refinement methodology is available. The adequate risk assessment should then be judged on a case-by-case basis. It is advisable to follow guidance in the draft report by Van der Linden et al (draft 2009).

For “old” substances (> 3 years on Dutch market), the subdivision between substances of no concern or substances of concern is made as indicated in Appendix 4a. The procedure followed for the evaluation of monitoring data is in accordance with C-163.5.

For completeness, the interim Ctgb decision tree is presented below, although not entirely applicable as explained above.

C-163.5 (L) **Drinking water criterion (October 2005, not up-to-date)**

1. The CBb has earlier this year passed judgement about application of the drinking water criterion in case of the authorisation of the product *RoundUp ready to use*.
   The judge argues as follows: “*The Ctgb has made insufficient efforts to meet the obligation to test RoundUp ready to use against C.2.5.1.3. Uniform Principles. The Ctgb should have asked the authorisation holder for data in view of the need to be able to establish whether the authorisation of RoundUp ready to use would have no effects that are unacceptable for the environment. Without testing against the drinking water criterion as arising from C.2.5.1.3 Uniform Principles, the Ctgb can not lawfully have taken the view that it has been established that authorisation of RoundUp ready to use has no effect that is unacceptable for the environment*.”
2. Extensive discussions were held in C-161 about the consequences of the judgement about testing against the drinking water criterion, and the secretariat has been asked to prepare a document. Insofar as possible, the questions raised in the draft minutes of C-161 will be answered. The proposal how to deal with the ‘*drinking water criterion’* has been discussed with Vewin (Association of Dutch Water Companies). This has led to this paper, which has been presented to Vewin. A reaction by Vewin has until now not yet been received.

3. There is a list of active substances in Plant protection products that caused problems in the drinking water supply in the period 1995-2001. A number of these active substances is meanwhile no longer authorised in Plant protection products or is a metabolite of such a product. Currently, the list consists of 17 active substances in Plant protection products (including glyphosate, see Appendix 1 ***NB this appendix is not valid anymore***).
   The *Steering Group Drinking Water Quality* will lay down this list to be offered to the Ctgb.
4. The following procedure is proposed for dealing with the *drinking water criterion* when considering active substances: the drinking water criterion only applies for '*pesticides'* as mentioned in the *Directive regarding the quality of water intended for human consumption* (Council Directive 98/83/EC of 3 November 1998)[1]. Where the active substance does not occur on the list of 17 existing active substances, and it is neither a new substance, problems with the drinking water supply are not to be expected and the *text II drinking water criterion* proposed by BJZ from the memorandum of 20 September 2005 is included[2].
   Where the active substance is included in the list or is a new substance it can on the basis of the available data be investigated whether the proposed use causes an exceedance of the drinking water criterion in the field ditch (first tier). The required calculation is carried out with the TOXSWA calculation model. Where no exceedance of the 0.1 µ/L criterion is calculated, it is assumed that the substance causes no problems at the drinking water intake point. Where this is the case, consultations are held with the applicant about the extent to which Statutory Use Instructions and restrictions can lead to a reduced loading of the field ditch[3]. Where the calculations after that indicate that the drinking water criterion in the field ditch is still exceeded, the last tier may offer a solution: testing against monitoring data (see Appendix 2).
   Normally, monitoring data for new substances will not yet be available. The approach described here and presented in Appendix 2 will apply until a *decision tree drinking water criterion* has been developed by the *Working Party Implementation drinking water criterion* (see below).

[1] On 25 December 2003 Directive 98/83/EC replaced Directive 80/778/EEC *concerning the quality of water intended for human consumption*. The now applicable Directive describes *pesticides* as: "*organic insecticides, herbicides, fungicides, nematicides, acaricides, algicides, rodenticides and slimicides, similar products (such as growth regulators) and their respective metabolites and degradation and reaction products*". In addition, Directive 75/440/EEC *concerning the required quality of surface water intended for production of drinking water applies in the Member States,* where in Annex II *pesticides-total* is defined as: *parathion, HCH and dieldrin*. This last Directive will be withdrawn on 22 December 2007 on the basis of the Framework Directive W*ater* (Directive 2000/60/EC).

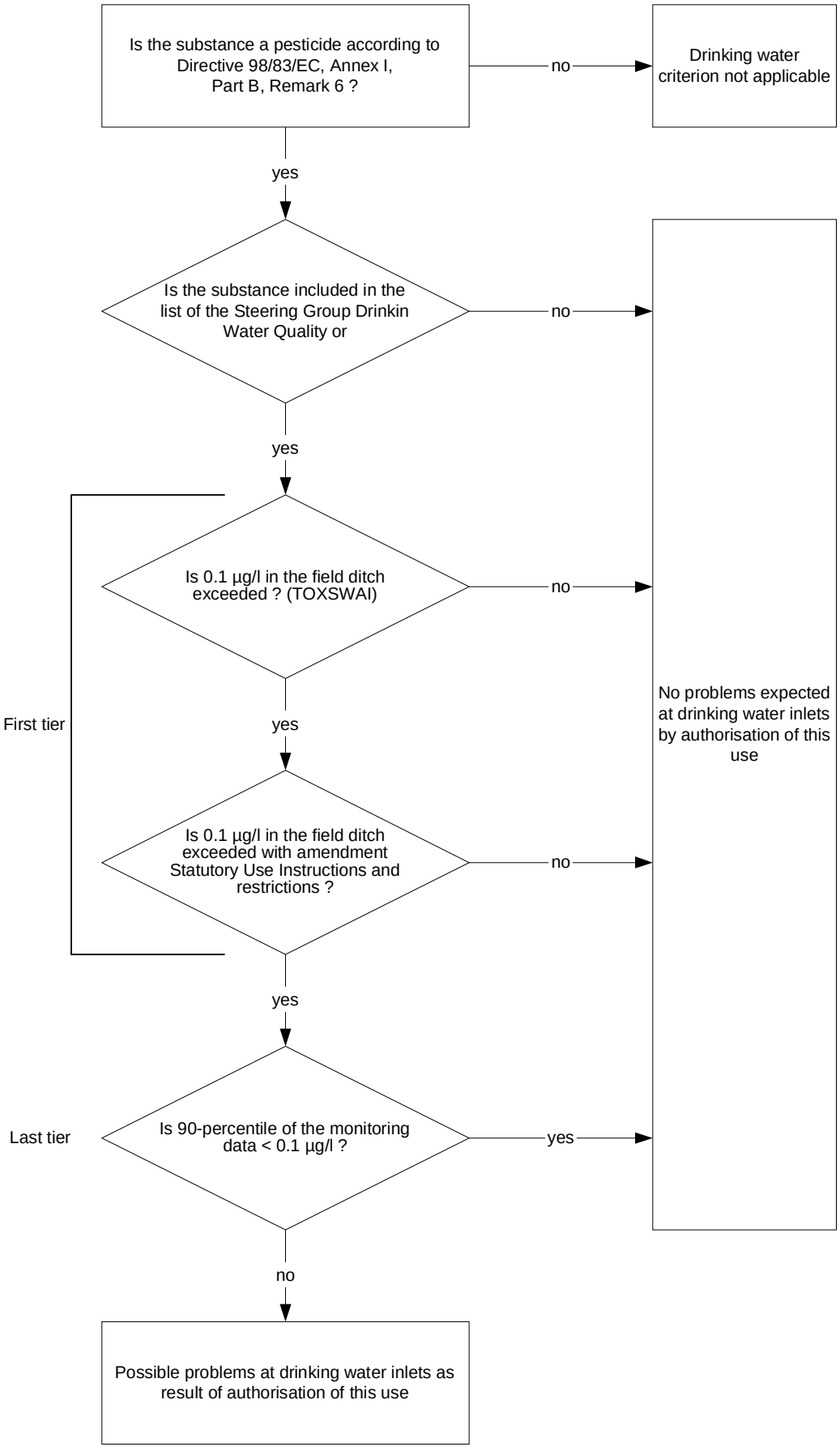
[2] "The judgement of Court of Appeal on Trade and Industry of 19 August 2005 (Awb 04/37) means that the CTB will before authorisation, on the basis of the scientific and technical knowledge, and on the basis of the data submitted with the application, also have to test against the drinking water criterion as regards surface water intended for drinking water to establish whether the product has no effect that is unacceptable to the environment. A calculation mode for this aspect is not available. This means that possibly available data cannot be evaluated adequately. It is therefore impossible to arrive at a scientifically justified expectation for this criterion. The Ctgb has not been given the instruments for testing surface water from which drinking water is produced against the drinking water criterion. However, to meet the judgement – from which it is to be concluded that the CTB should make an effort to arrive at a judgement about this point - and as transition period, to prevent that not a single authorisation can be granted during the period that a model is developed and data need to be generated for the application for authorisation, the CTB has considered whether the product in question and the active substance could give cause for concern as regards the drinking water criterion. Based on a list of substances for which consensus exists among a number of organisations, including CTB and Vewin, a number of substances that give cause for concern have been identified. The current application concerns a product of which the active substance has not been identified. In view of this, the CTB holds the view that there are in this case no concrete indications for concern about the consequences of this product, if used in accordance with the Statutory Use Instructions, for surface water from which drinking water is produced. The CTB expects no exceedance of the drinking water criterion in the light of this approach. The product does not seem to have an effect that is unacceptable for the environment on this point."

[3] A USES module has been developed for calculation of the environmental loading as result of the use of herbicides on hard surfaces (pavements).

5. *When will the new evaluation methodology be available?* The methodology consists of different '*tiers*' (see 4), of which the first and the last have thus largely been finalised. The *first* tier concerns testing against the drinking water criterion in the field ditch, the *last* tier is testing against monitoring data. There are one or two tiers between the first and last tier in which degradation and dilution and total use of the substance will be incorporated. VROM (Ministry of Housing, Spatial Planning and the Environment) expects that the
   1st and 4th tier will be ready by the end of 2005, work on the 2nd and 3rd tier will be started in 2006.
   The Working Party Implementation Drinking Water Criterion, which is engaged in the development of this decision tree, is guided by LNV (Ministry of Agriculture, Nature and Food Quality) and VROM (Ministry of Housing, Spatial Planning and the Environment) .
6. *Must attention be paid to the sum criterion of 0.5 µg/L?* This sum criterion is mentioned in Directive 98/83/EC *concerning the quality of water intended for human consumption* and the uniform principles refer to this Directive.
   The CTB representative in the Working Party Implementation Drinking Water Criterion will put this point forward. The Working Group will have to consider this matter.
7. *Can the problem be placed with the applicant by raising supplementary questions?* Here the decision of the CBb is referred to.
   The judge states the following: "…*that the CTB should have asked the applicant on the basis of Article 4 Pesticides Act 1962 and Article 18 Regulation Authorisation Pesticides 1995 (data requirements) for data in view of the need to be able to establish, in compliance with Article 3 Pesticides Act 1962, whether authorisation would have no effect that is unacceptable to the environment, including whether no exceedance of the drinking water can be expected in case of authorisation."* The judge thus means that we can (and should) ask the authorisation holder for data.
8. The CTB will base the handling of an application of problem substances or new substances on *expert judgement*. This can be done, e.g., by assuming analogy with comparable substances and its studies and –where available- degradation data in water as long as the *decision tree drinking water criterion* is not yet ready. This may lead to (additional) restrictions in the authorisation. Supplementary monitoring data since 2001 may also be known or restrictions may have been imposed since 2001.

Appendix 1 (old list, not valid, see new list of substances of concern on Ctgb website)

No.	Substance	Expiry date
1	Isoproturon	09/09/9999
2	Bentazone	01/07/2011
3	Mecoprop-P	01/06/2008
4	Metoxuron	30/06/2007
5	MCPA	09/09/9999
6	Ethoprophos	01/03/2008
7	Metribuzin	01/04/2006
8	Terbutylazine	31/08/2007
9	Dichlobenil	01/10/2008
10	Glyphosate	01/07/2012
11	S-Metolachlor	31/03/2015
12	Chlorpropham	09/09/9999
13	Dicamba	01/09/2008
14	Malathion	09/09/9999
15	2,4-D	09/09/9999
16	Metazachlor	09/09/9999
17	Chloridazon	01/09/2007


Is the substance a pesticide according to Directive 98/83/EC, Annex I, Part B, Remark 6 ?
no
Drinking water criterion not applicable
yes
Is the substance included in the list of the Steering Group Drinkin Water Quality or
no
yes
Is 0.1 µg/l in the field ditch exceeded ? (TOXSWAI)
no
First tier
yes
Is 0.1 µg/l in the field ditch exceeded with amendment Statutory Use Instructions and restrictions ?
no
yes
Last tier
Is 90-percentile of the monitoring data < 0.1 µg/l ?
yes
no
Possible problems at drinking water inlets as result of authorisation of this use
No problems expected at drinking water inlets by authorisation of this use

4. REFERENCES

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/

3 FOCUS (2006) "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference
Sanco/10058/2005 version 2.0, 434 pp

4 Adriaanse et al.(2008) Development of an assessment methodology to evaluate agricultural use of plant protection products for drinking water production from surface waters. Alterra report 1635.

5 Van Leerdam, R.& Adriaanse, P. 2009 (draft) Evaluation of agricultural use of plant protection products for drinking water production from surface waters in the Netherlands - User's manual of DROPLET to calculate concentrations at drinking water abstraction points.

6 FOCUS (2001). "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.

7 ISO 18749 Water quality – Adsorption of substances in activated sludge – Batch test using specific analytical methods

8 Vander Linden et al, draft version 2009, Surface Water Intended for the Abstraction of Drinking Water after Use of Plant protection products on Hard Surfaces: Evaluation of Plant protection products, RIVM Report 601450021/2009