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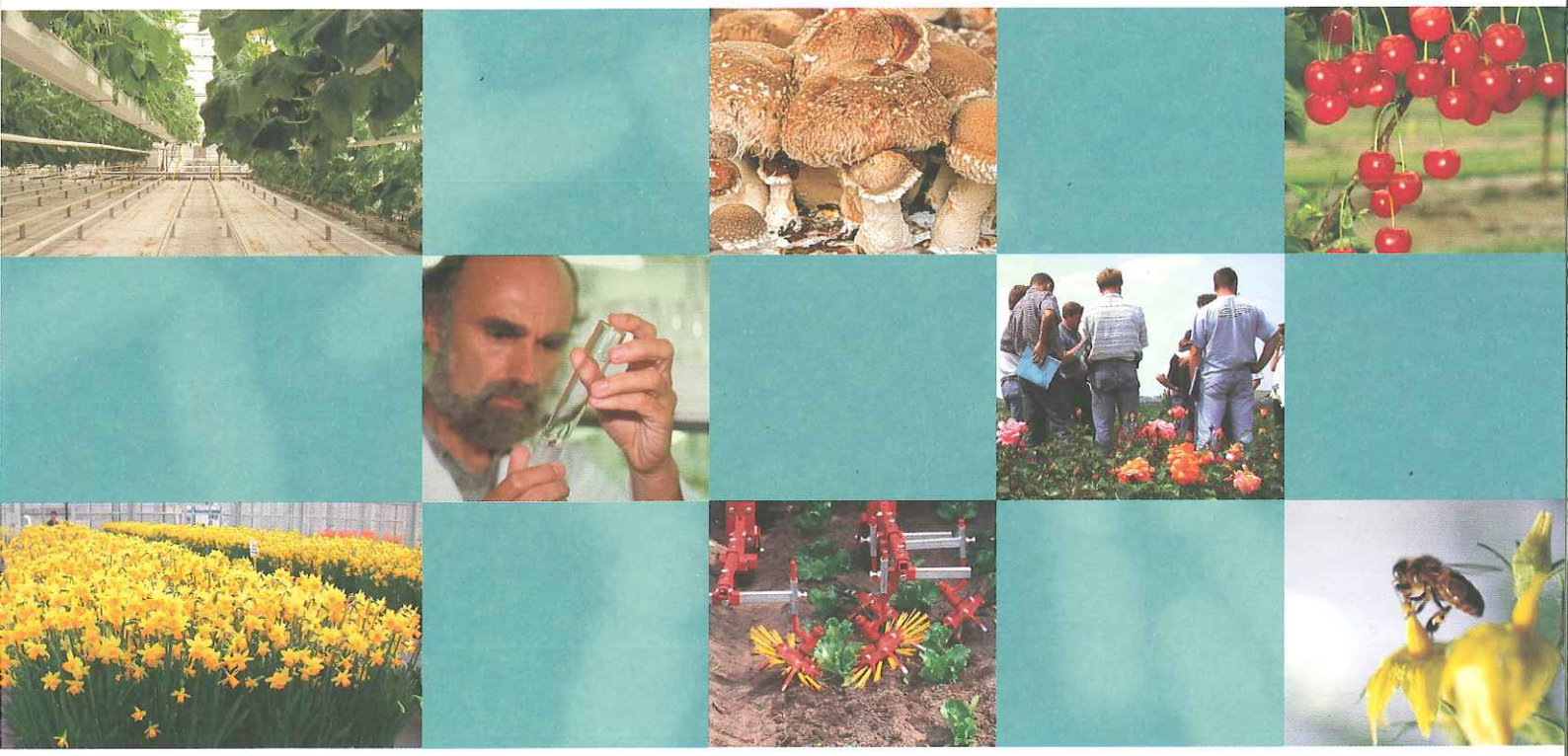
Interpretation of surface water monitoring results in the authorisation procedure of plant protection products in the Netherlands

Including a draft protocol for causal analysis of surface water quality problems caused by plant protection products

Decision Tree Surface Water - Monitoring working group

Editors: H.A.E. de Werd[1] & R. Kruijne[2]



ALTERRA
WAGENINGEN UR

[1]Praktijkonderzoek Plant & Omgeving – Bloembollen, Boomkwekerij & Fruit
[2]Alterra

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Surface Waters Decision Tree – Monitoring working group:

H.A.E. de Werd (PPO-WageningenUR) (chairman)
R. Kruijne (Alterra-WageningenUR)
G.J. Wingelaar (NVWA)
W.L.M Tamis (CML)
K. Jilderda (Nefyto)
A.M.A. van der Linden (RIVM)
D. Kalf (Waterdienst)
W. van der Hulst (Waterschap Aa en Maas / Platform Landbouwemissies - Unie van Waterschappen)
G.B.M. Heuvelink (Alterra-WUR) (2009)
C. van Griethuysen (Ctgb)

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Applied Plant Research (Praktijkonderzoek Plant & Omgeving),
part of Wageningen UR
Business Unit Flower bulbs, Nursery stock and Fruits

Address : Lingewal 1, 6668 LA Randwijk, The Netherlands
: Postbus 200, 6670 AE Zetten, The Netherlands
Tel. : +31 488 47 37 02
Fax : +31 488 47 37 17
E-mail : infofruit.ppo@wur.nl
Internet : www.ppo.wur.nl

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Samenvatting

Als onderdeel van de 'Beslisboom Water' zijn modules ontwikkeld voor een vernieuwde toelatingssystematiek voor gewasbeschermingsmiddelen en biociden. De methodiek voor de terugkoppeling van monitoring data van gewasbeschermingsmiddelen in oppervlaktewater naar de toelatingshouder(s) en de toelatingsinstantie is één van deze modules. Deze methodiek is ontwikkeld door de Werkgroep Monitoring, bestaande uit experts en betrokkenen uit onderzoek, het Ctgb en bedrijfsleven. De randvoorwaarden zijn aangegeven door de Projectgroep van de Beslisboom Water, bestaande uit vertegenwoordigers van de betrokken ministeries. De methodiek bestaat uit 3 hoofdonderdelen:

1. Identificatie en ordenen van problematische stoffen
2. Oorzakenanalyse en samenstelling van een Emissiereductieplan (ERP)
3. Terugkoppeling naar het Ctgb en betrokken ministeries

De terugkoppeling van monitoringsresultaten wordt formeel geïmplementeerd middels de beleidsnota 'Duurzame Gewasbescherming, Gezonde groei, Duurzame oogst'. Deze nota verwijst naar het gebruik van monitoringresultaten voor het opsporen en aanpakken van normoverschrijdingen en naar de rol van emissiereductieplannen. Het laten maken van Emissiereductieplannen is ook onderdeel van het Nationaal Actieplan voor Duurzame Gewasbescherming van Nederland.
Dit rapport beschrijft alle drie de onderdelen van de methodiek. Voor een systematische, transparante en gedegen aanpak van de oorzakenanalyses is een gedetailleerd protocol ontwikkeld en getest met realistische test cases. De methodiek is toepasbaar voor actieve stoffen en metabolieten van gewasbeschermingsmiddelen. Voor biociden, farmaceutica en ander chemische stoffen die voor andere doeleinden gebruikt worden is het niet geschikt.

1 Identificatie en rangschikken 'problematische' stoffen

Als eerste stap wordt bepaald voor welke stoffen een oorzakenanalyse en Emissiereductieplan opgesteld zouden kunnen worden. De selectie en rangvolgorde die hier uit voortkomt, wordt jaarlijks geactualiseerd op basis van de meetresultaten in de Bestrijdingsmiddelenatlas (www.bestrijdingsmiddelenatlas.nl). Hierbij worden alleen stoffen geselecteerd die de milieukwaliteitsnorm (EQS) overschrijden in KRW-waterlichamen. Als er geen EQS beschikbaar is, worden de metingen vergeleken met het Maximaal toelaatbare risico (MTR of ad hoc MTR). KRW prioritaire stoffen krijgen een hogere rangorde dan niet-prioritaire stoffen. Overige normoverschrijdende stoffen krijgen punten toegewezen op basis van het type waterlichaam waar de overschrijdingen geconstateerd zijn, de mate van overschrijding en het percentage meetlocaties met overschrijdende metingen. Overschrijdingen buiten KRW-waterlichamen wegen mee in de puntentelling. Overschrijdingen in KRW waterlichamen leiden tot meer punten dan overschrijdingen buiten KRW waterlichamen. De beperkte continuïteit van monitoring over jaren en verschillen in monitoringstrategieën tussen waterschappen bemoeilijken de interpretatie van meetresultaten. Om jaareffecten en de invloed van en variatie in meetprogramma's op de stoffenlijst te beperken worden steeds de drie meest recente drie opeenvolgende meetjaren gebruikt. Om de consistentie van meetprogramma's over de jaren en tussen regio's te verhogen, initieert het ministerie van I&M in 2013 een nieuw landelijk meetnet voor gewasbeschermingsmiddelen.

2 Oorzakenanalyse

Opzet

Met de oorzakenanalyse worden aannemelijke verbanden tussen specifieke toepassingen en emissieroutes van de stof enerzijds en normoverschrijdingen anderzijds vastgesteld. De oorzakenanalyse wordt uitgevoerd volgens een vast protocol dat 'fact finding' op transparante wijze combineert met bevraging van experts. De oorzakenanalyse start met de samenstelling van een Fact Sheet die 5 onderwerpen behandelt; (i) stofeigenschappen (ii) toegelaten gebruik in Nederland (iii) gebruiksgegeven Nederland; (iv) indicatoren voor de emissie naar oppervlaktewater op basis van de Nationale Milieu-indicator (NMI) eventueel aangevuld met emissie berekeningen voor de risicobeoordeling voor de toelating, en (v) meetresultaten in de Bestrijdingmiddelenatlas. Vervolgens wordt een groep experts gevraagd of zij betere of aanvullende informatie hebben ten opzichte van de factsheet. Het consulteren van experts vindt plaats middels een vaste vragenlijst die via het digitale Gewasbeschermingsplatform.nl uitgezet wordt. Zo worden alle onderdelen van het factsheet kritische bekeken, voordat er conclusies uit getrokken worden. Met Gewasbeschermingsplatform is de interactie met de experts transparant en wordt ook aan de experts de mogelijkheid gegeven op elkaars inbreng te reageren zonder

tijdrovende expertbijeenkomsten. Tegelijkertijd wordt de inbreng van experts op deze wijze gedocumenteerd. Als de uitvoerder van de oorzakenanalyse met de interpretatie van de factsheet en de inbreng van experts de aannemelijke oorzaken van de overschrijdingen vast kan stellen, kan hij/zij de oorzakenanalyse afsluiten met het trekken van eindconclusies en verder gaan met het opstellen van het ERP. Mochten de aannemelijke oorzaken niet of onvoldoende duidelijk zijn, dan voorziet het protocol in de mogelijkheid om aanvullende informatie te verzamelen over een specifiek onderwerp en/of een bepaalde regio's.
Als het mogelijk is wordt in de analyse een onderscheid gemaakt tussen de rol van emissie die plaats vindt binnen het toegelaten gebruik en een goede landbouwpraktijk enerzijds (GAP), en emissie die het gevolg is van illegaal of verkeerd gebruik (non-GAP). Dit onderscheid is relevant voor het bepalen van effectieve maatregelen.

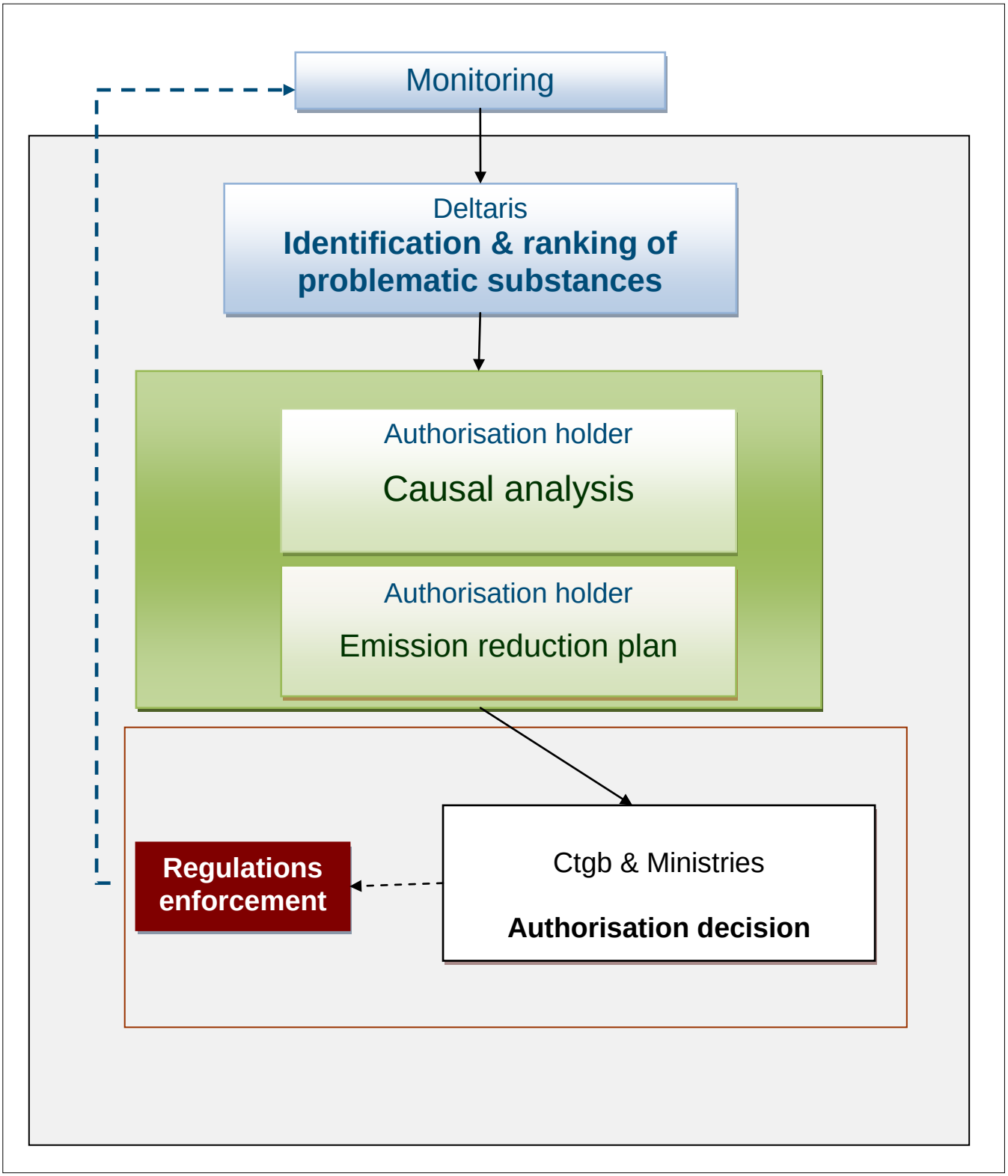
Test
Het protocol voor de oorzakenanalyses is met de voorziene toekomstige gebruikers voor vier stoffen getest. Uit de tests kwam naar voren dat het protocol voor oorzakenanalyses helpt de toelatingshouder om de beschikbare relevante informatie systematisch en transparant op een rij te zetten. Het inzichtelijk maken van de vertaalslag van verzamelde informatie naar onderbouwde conclusies over aannemelijke oorzaken bleek een aandachtspunt te zijn voor volgende bij volgende oorzakenanalyses. De beperkte beschikbaarheid van met name kwantitatieve informatie over emissieroutes speelt hierbij ook een rol. Het al dan niet beschikbaar hebben van gegevens bepaald voor een groot deel in hoeverre relevante emissieroutes benoemd en ten opzichte van elkaar gewogen kunnen worden.

Toepassing
Toelatingshouders van stoffen die op de lijst voorkomen, kunnen in de volgende situaties verzocht worden om een oorzakenanalyse en ERP:

- als onderdeel van een reguliere herbeoordeling van een bestaande toelating.
- als onderdeel van een nieuwe toelatingsaanvraag voor een stof die al als gewasbeschermingsmiddel op de Nederlandse markt toegelaten is.
- als onderdeel van een tussentijdse herbeoordeling van een lopende toelating naar aanleiding van een hoge positie op de lijst van normoverschrijdende stoffen.

3 Terugkoppeling
De toelatingshouder neemt het voortouw in acties om de normoverschrijdingen terug te dringen. Een ERP kan beperkingen van de toelating bevatten, voorlichtingscampagnes om goed gebruik te stimuleren, etc.. Of het toegelaten gebruik aangepast wordt, zal mede afhankelijk zijn van de belangrijkste oorzaken van de normoverschrijdingen. Deze kunnen binnen of buiten het toegelaten goed landbouwkundig gebruik liggen. De oorzakenanalyse wordt samen met het ERP aangeleverd aan het Ctgb en de betrokken ministeries, de ministeries van Economische zaken en van Infrastructuur en Milieu). Zij beoordelen of de juiste werkwijze gevolgd is en of het inhoudelijk goed in elkaar zit. Als het aannemelijk is dat toepassing van de stof binnen de wettelijke mogelijkheden tot de normoverschrijdingen geleid heeft, is het mogelijk dat een aangevraagde toelating niet verleend wordt, of een bestaande toelating niet ongewijzigd verlengd wordt. Ook als van het ERP onvoldoende resultaat verwacht wordt, of op basis van metingen onvoldoende effectief blijkt, kunnen de verantwoordelijke autoriteiten beslissen een de toelating van een stof niet te verlenen of niet te verlengen.

Conclusie
Toepassing van deze methodiek maakt het mogelijk problematisch stoffen in oppervlaktewater systematisch en transparant te identificeren en prioriteren. De systematische aanpak van de oorzakenanalyse draagt bij aan het bepalen van effectieve maatregelen om de overschrijdingen terug te dringen. Hierbij worden diverse experts ingezet om bij te dragen aan goed onderbouwde maatregelen in het ERP. De methodiek erkend de verantwoordelijke rol van de toelatingshouders in het tegengaan van ongewenste neveneffecten van hun producten. Als laatste stap kunnen de autoriteiten besluiten een toelatings- of verlengingsaanvraag niet positief te beoordelen of een lopende toelating in te trekken.



The use of surface water monitoring results in the authorisation procedure of plant protection products. Dotted lines indicate optional steps. The design of monitoring programmes is not part of the procedure described in this report. A causal analysis will not always lead to an Authorisation decision.
**The Emission Reduction Plan is included in the overall scheme. Development of guidelines or a format for the ERP was no part of the assignment of the Monitoring Working Group.*

Summary

As part of the 'Surface Waters Decision Tree' project new and renewed modules for the authorisation procedure for plant protection products (PPPs) and biocides has been developed. One module is the procedure for feedback of monitoring data to the authorisation holder and the PPP authorisation authority.

This report describes the methodology to be adopted for this procedure.

The feedback of monitoring results in the authorisation procedure consists of 3 main steps:

1. Identification and ranking of problematic substances
2. Causal analysis and composition of an Emission Reduction Plan (ERP)
3. Feedback to the board for authorisation and the involved ministries

In this report, a methodology for all three steps is described. For the causal analysis within step 2, a more detailed protocol has been developed, based on realistic test cases. The format of the ERP is not defined by the Monitoring working group and therefore no part of this report.
The procedure is applicable to active ingredients and metabolites of PPP, not to biocides, pharmaceuticals and (chemical) substances with other types of use.

1. Identification and ranking of 'problematic' substances

Water quality is monitored by regional and national water authorities in the Netherlands. All monitoring results are in principle processed annually and are input into the Pesticides Atlas ('Bestrijdingsmiddelen-atlas', or BMA). Following each update of the BMA, a list of 'problematic substances' in surface waters is then derived from these data and the substances in question ranked according to substance category and frequency, location and level of exceedance.

In this report a 'problematic substance' is defined as a plant protection product (PPP) or it's metabolite (see also chapter 2, boundary conditions), that exceeds the relevant quality standard (MAC-EQS, AA-EQS or MPC; see glossary) in one or more Dutch surface water bodies falling under the European Water Framework Directive (WFD) according to the monitoring data in the Pesticides Atlas.

The Effects Working Group of the Water Decision Tree lays down how water quality standards are to be applied for calculating the risk the substance poses to aquatic organisms prior to authorisation of a PPP.

2. Causal analysis and Emission Reduction Plan

Causal analysis

The goal of the causal analysis is to identify whether there is a plausible relation between authorisation of a PPP and exceedance of water quality standards, by way of a detailed analysis of the relation between application of the substance to a crop or group of crops, relevant emission pathways and the quality standard exceedances observed. This causal analysis is carried out according to an established protocol that combines fact-finding and expert consultation in a transparent manner. The protocol covers a wide range of topics, including 1) substance properties, 2) authorisation, 3) agricultural usage, 4) emission pathways, and 5) the monitoring results.

If and when possible, emission pathways resulting from Good Agricultural Practice (GAP) are distinguished from those resulting from illegal or improper use (non-GAP). The distinction between GAP and non-GAP is relevant for determining whether or not the cause of the water quality problem relates to the substance authorisation. It will depend on the substance concerned and the information available from enforcement agencies (regional water authorities and/or the inspection agency of the Ministry of Economic Affairs and other experts whether the role of non-GAP can be adequately assessed. Identification of relevant emission pathways provides the basis for determining appropriate mitigation measures.

For the analysis of possible causes, two sources of predicted emissions and one main source of PPP monitoring data can be used. Predicted emission indicators are derived from the Dutch Environmental Risk Indicator for Plant Protection Products ('Nationale Milieu Indicator'). If and when available, these can be complemented with emission calculations made in the pre-authorisation process. Monitoring data are taken from the Pesticides Atlas (BMA). These 'standard information sources' can be augmented with additional data on particular regions and/or topics. Before conclusions are drawn, the information gathered is checked by experts to assess its validity and whether there is any need for improvement.

Emission Reduction Plan

The authorisation holder implements the results of the causal analysis in an emission reduction plan (ERP). The relevant type of action is highly dependent on the emission pathway(s) involved and the contribution of non-GAP. An emission reduction plan may, for example, comprise actions with which the authorisation holder endeavours to change users' behaviour, either directly or via other stakeholders. Alternatively, it may consist of a request to the registration authority (Ctgb), to add a restriction to the product label, in cases where GAP application is responsible for exceedance of quality standards. A combination of different types of actions is also possible. If no plausible relation with the authorisation(s) of a substance is found, an ERP may consist of research activities to further analyse the cause of the exceedances.

When applicable

Registration holders of listed substances can be requested for a causal analysis and ERP in the following situations:

- Regular re-authorisation: an authorisation holder files for a prolongation of an existing authorisation. The request for a causal analysis applies for all substances identified as problematic substances.
- For the highly ranked substances:
    - Interim review of existing authorisations, independent of the regular authorisation period.
    - New authorisation requests for substances already on the market as a PPP.

3. Feedback procedure

The Ctgb and/or involved ministries assess whether the emission reduction plan is likely to lead to sufficient improvement of water quality within an acceptable period of time. The Ctgb then decides on (re-) authorisation of the product(s). Measures may be product-specific, since usage and predicted emissions may vary across products with the same active ingredient.

WFD (Water Framework Directive) mitigation measures

If no plausible relation between exceedances and authorisation is established, the Ctgb cannot make the autonomic decision to reject a (re-)authorisation based on the monitoring data, as part of the Dutch authorisation procedure. However, if exceedances at WFD-reporting locations are not sufficiently reduced, the EU will demand that measures are taken anyway. If no acceptable alternatives are proposed, this may result in mandatory authorisation adjustment none-the-less, as part of a package of mitigation measures to be reported to the EU. This 'WFD route' is not part of the feedback procedure described in this report.

Feedback to monitoring

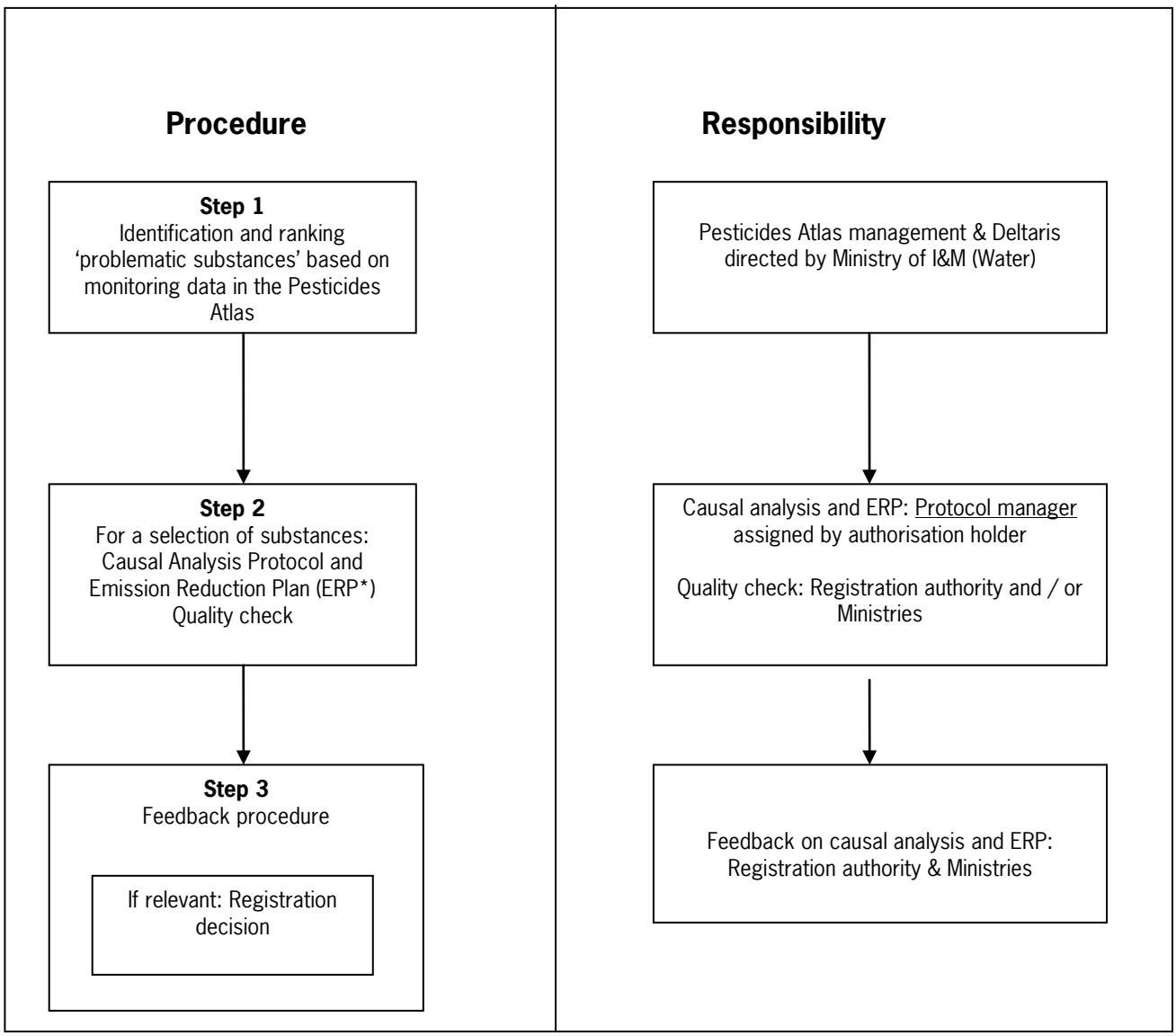
The use of monitoring results in the authorisation procedure may lead to recommendations on future water quality monitoring. This is illustrated by two examples:

a. If no plausible cause for quality standard exceedances is found, more detailed or adjusted monitoring may be initiated by the water authorities: research monitoring.
b. An authorisation holder may, as a part of an emission reduction plan, request or initiate more intensive monitoring in a certain period or area, to be able to analyse the effect of this action at an early stage or to gain more insight into emission pathways.

The causal analysis may also lead to more general recommendations on the design of monitoring programmes. Feedback to monitoring is indicated in the figure above by the dotted line from the Feedback

procedure (Step 3) to Monitoring.

Regulation enforcement
In cases where non-GAP application is part of the cause of quality standard exceedance, law enforcement agencies will be informed by the publication of the Ctgb authorisation decision.



Main steps and responsibilities in the procedure for using monitoring results for authorisation.
** The Emission Reduction Plan is included in the overall scheme. Development of guidelines or a format for the ERP was no part of the assignment of the Monitoring Working Group.*

1 Introduction and reading guide

1.1 A 'Water Framework Directive-proof' authorisation procedure for plant protection products

1.1.1 Surface water monitoring data in the authorisation procedure: 3 steps

The use of surface water monitoring data in the authorisation procedure for plant protection products (PPP) requires transparent and unambiguous methodologies. These are described in this report in the following three steps:

1. A procedure for the **identification of 'problematic substances'** based on surface water monitoring results.
2. A protocol for **causal analysis** of exceedance of quality standards in surface water, used as a basis for an **Emission Reduction Plan** (ERP)
3. A procedure for **feedback** of the outcomes to the involved ministries and registration authority.

1.1.2 The Water Framework Directive and the Plant Protection Products Directive

In the context of implementing the European Water Framework Directive (WFD; 2000/60/EC) in the Netherlands, responsible officers of three former Dutch ministries (Ministry of Housing, Spatial Planning and the Environment; Ministry of Agriculture, Nature and Food Quality; Ministry of Transport, Public Works and Water Management) concluded that the requirements laid down in this Directive must be compatible with Regulation 1107/2009/EC and its predecessor Directive 91/414/EEC. As this was not yet the case, the project 'Surface Waters Decision Tree' (in Dutch, 'Beslisboom Water') was initiated to develop a new decision tree for surface water for use in the Dutch authorisation procedure for plant protection products. The procedures and products emerging from this project are not in themselves WFD instruments, but will support achievement of the water quality standards defined in the WFD.

In cases where post-authorisation monitoring data reveal quality standard exceedance, the obligation arises to take corrective measures. For a selection of substances the authorisation holder(s) will be obliged to carry out a causal analysis and compose an ERP, based on the outcome. The role of ERP's to reduce standard exceedances is part of the Dutch National Action Plan. This action plan describes the initiatives to comply with the European Sustainable Use Directive (Directive 2009/128/EC). The second Dutch policy document on Sustainable Crop Protection also refers to the ERP and includes a reference to the compulsory use of the Protocol for causal analysis described in this report.
The responsible ministries have decided that if there is a plausible relation between PPP authorisation and quality standard exceedance, it is legitimate to implement, among other things, a review of the current authorisation.

Organisation of the Surface Waters Decision Tree
Within the Surface Waters Decision Tree project, a Monitoring working group was set up to further develop a post-authorisation procedure for interpreting the results of chemical monitoring of PPPs in Dutch surface waters with respect to possible consequences for the authorisation of PPPs. The result is described in this report.

The structure of the Decision Tree project is shown in Figure 1.1. This project was originally initiated and coordinated by three ministries, but as of October 2010 several Dutch ministries were reorganised and the project became the responsibility of the new Ministry of Economic Affairs ('EZ') and the Ministry of

Infrastructure and Environment ('I&M'). The Project group is the delegated principal towards the working groups. It prepares policy decisions for the Steering group in consultation with the working groups. The policy decisions are made by the Steering group.

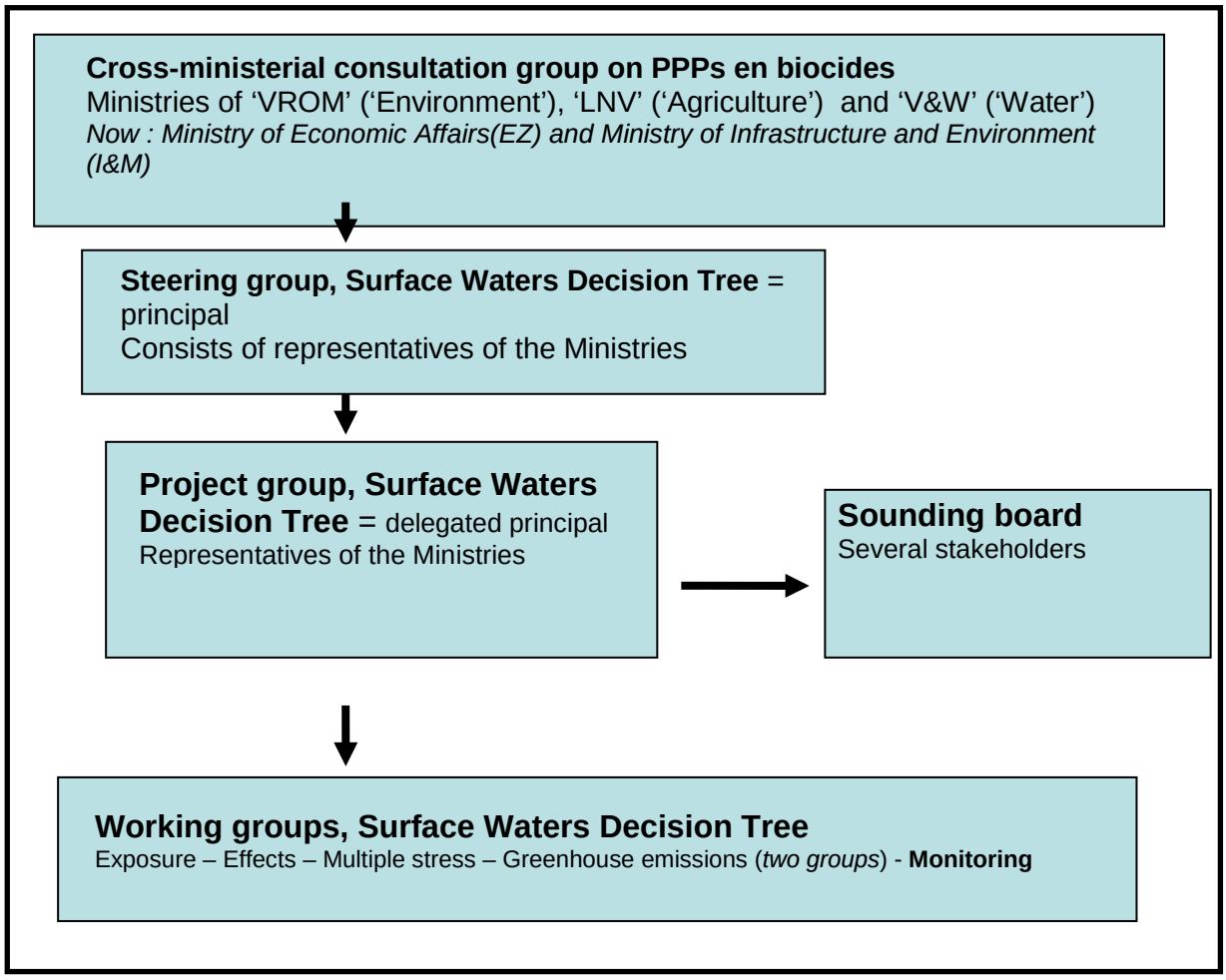


Figure 1.1. Organisation of the 'Surface Waters Decision Tree' project.

1.2 Reading guide

In this report the Monitoring working group proposes a procedure for the use of monitoring results in the authorisation procedure.
The three main steps of the procedure are described in the following chapters:

1. Chapter 2: Identification and ranking of problematic substances.
2. Chapter 3: Protocol for causal analysis and its background and the Emission Reduction Plan.
3. Chapter 4: Feedback procedure

The protocol for the analysis of causes of quality standard exceedances is described in detail. This document also visualises the main principles and policy choices underlying the described procedures and protocol.

In developing the causal analysis protocol, the Monitoring working group took as its point of departure a 'prototype' (De Werd and Merkelbach, 2006), which was then iteratively elaborated while working through realistic cases. The results of these case studies are not reported in this document. Besides this 'prototype', the methodology was further developed within a framework set by policy decisions,

communicated by the Surface waters decision tree Project group. Policy decisions, taken as boundary conditions, are specified as such in the following chapters. The main principles communicated by the project group as boundary conditions to be applied are given below.

Boundary conditions *for the methodology as a whole:*

- *Transparency*
- *Optimal support of the involved stakeholders*
- *Authorisation holders are given the opportunity to solve water quality problems*

Appendix I provides an explanation of the abbreviations in the main text and a glossary of specialist terms.

2 Identification and ranking of problematic substances

This chapter describes the proposed procedure for identifying and ranking 'problematic' substances based on monitoring data. Section 2.1 describes the procedure itself. Sections 2.2 (Water quality standards), 2.3 (Substance categories in the WFD) and 2.4 (Monitoring by Dutch water authorities) provide the background information necessary. Section 2.5 describes the Pesticides Atlas: the instrument used for processing, analysing and visualising monitoring results, which is also used for the identification of problematic substances.

For most PPPs and relevant metabolites several water quality standards have been derived. The outcome of the procedure for identifying problematic substances strongly depends on which of these standards are used and how and where they are applied. Exceedance of water quality standards in WFD water bodies may lead to a review of the authorisation by the Ctgb and in the worst case a negative authorisation decision.

Boundary conditions and policy decisions *for identifying and ranking problematic substances:*

Choice of water quality standards
- If available, the EQS applies. For substances for which no EQSs have been derived, the MPC applies.
- Monitoring results of metabolites are treated equally to data concerning active ingredients of PPPs.

Consequences in relation to measuring location
- Only EQS exceedances in WFD water bodies, including edge of field ditches in WFD water bodies, may have consequences for authorisation.
- Quality standard exceedances at WFD reporting locations have a higher priority than exceedance at other locations.
- Quality standard exceedances in WFD water bodies have a higher priority than outside WFD water bodies.
- Quality standard exceedances outside WFD water bodies should be taken into account in the feedback to the authorisation holder and the registration authority Ctgb. On their own, such exceedances cannot lead to mandatory adjustment of authorisations.
- Edge of field ditch monitoring results are not included in the ranking.

Consequences in relation to substance categories
- Quality standard exceedances by WFD priority substances have the highest priority.
- AA-EQS exceedance and MAC-EQS exceedances are weighed equally.

2.1 Procedure for identification and ranking of problematic substances

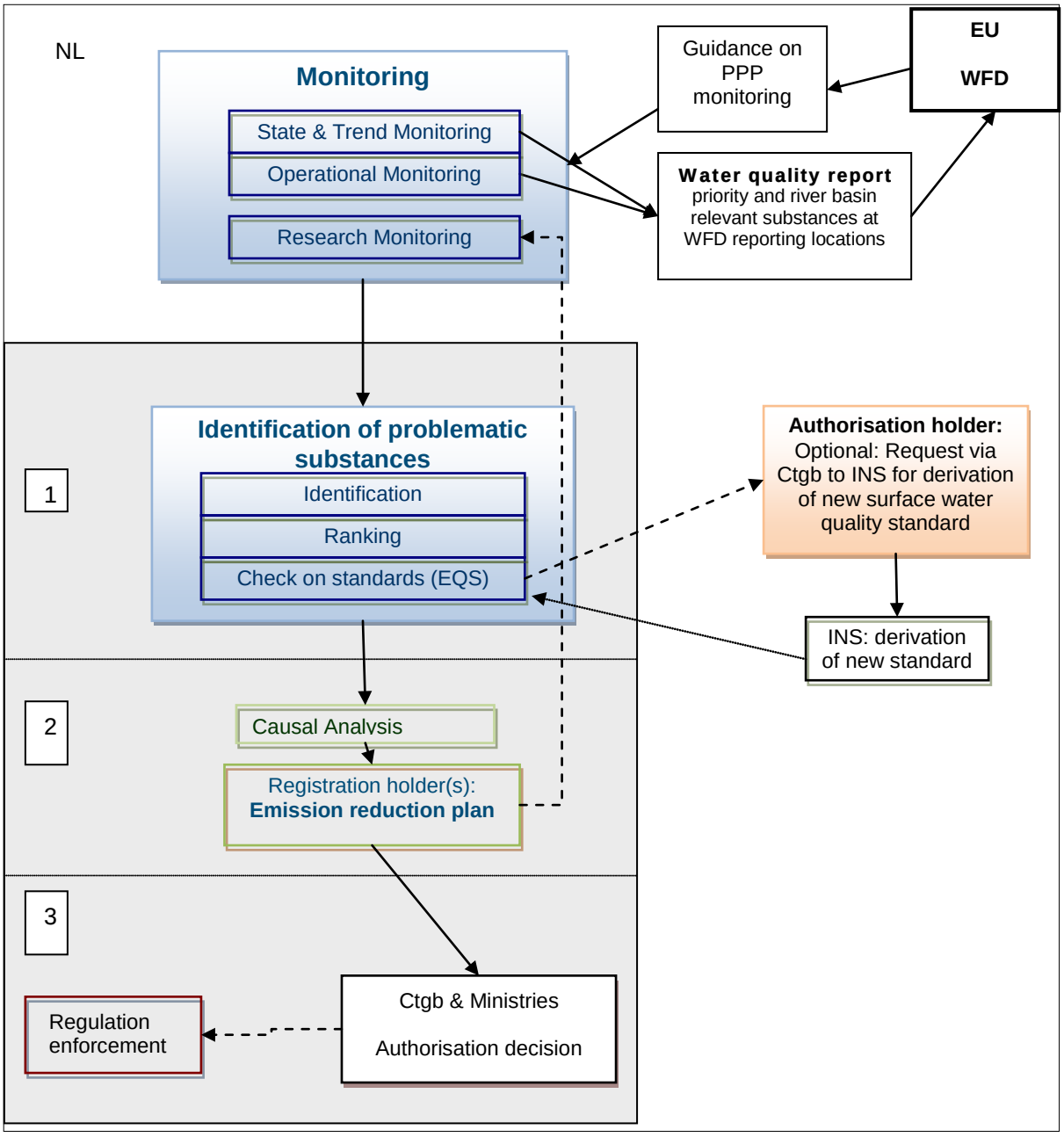


Figure 2.1. Identification of problematic substances and feedback to monitoring, as part of the procedure for the use of monitoring results in the authorisation procedure. The grey box represents the procedure for feedback of monitoring results to the authorisation holder and registration authority. The white box represents the Dutch national context and the connection to the EU and Water Framework Directive (WFD). Dotted arrows indicate optional steps. A causal analysis and ERP does not always lead to an authorisation decision.

Figure 2.1 shows the main steps of the identification of problematic substances within the procedure for feedback of monitoring results in the authorisation procedure. All the types of monitoring described in the WFD Monitoring guidance document (Rijkswaterstaat, 2009) are applied in the identification and ranking of problematic substances. In a later phase of the feedback procedure the need may arise for more, or adjusted, monitoring. This may imply feedback to the monitoring itself: 'Research Monitoring'. Quality standard exceedances may sometimes be resolved by adjusting the quality standard based on new or supplementary information on the effects of the substance. The procedure for feedback of monitoring results provides scope for adjusting the quality standard. For this reason the figure includes a loop to derivation of new standards, with a link back to the process of problematic substance identification.

2.1.1 Processing of monitoring data

Based on monitoring data, problematic substances in surface water are identified and listed in a ranking based on several characteristics of the exceedance. This ranking can be used to support objective prioritising of follow-up actions (chapter 4).

The frequency of identification of problematic substances is contingent on the frequency with which the Pesticide Atlas is updated with new monitoring results. This is generally once a year.

Measurements with results equal to or below the limit of reporting ánd at the same time a limit of reporting higher than the water quality standard, are not included in the calculation of percentages of measurements and measuring points made for the substance ranking.

Ditch classification in the Netherlands

There is no data base that classifies Dutch ditches as 'edge of field ditch' or 'not an edge of field ditch'. Water boards have classified ditches in an A, B and C category. Category A and B ditches generally have a water transportation function in the catchment area, whereas Category C ditches normally have a drainage function for a limited number of fields only. Category A ditches are owned and maintained by water boards, whereas Category B ditches are owned by others who have the legal task for ditch maintenance (cleaning). For Category C ditches, there is no such legal arrangement because the state of these small ditches does not affect the surface water system. Ditches categorised as class C are assumed to be edge of field ditches. If no A, B, C classification is available, a ditch is assumed to be an edge of field ditch, when it is classified at the topographical map as < 3 m wide. The consequences of the classification are stated in the text box with boundary conditions above.

1. First, all substances exceeding quality standard in WFD water bodies are selected as being 'problematic'. This is done once a year, based on the three most recent years available in the Pesticides Atlas. This also holds for substances for which a causal analysis, emission reduction plan or authorisation review is on-going. For these substances no new causal analysis can be requested for the same authorisation(s).

2. Substances defined as WFD priority (hazardous) substances by the EU are then marked as such and placed at the top of the list. For the EU these substances have the highest priority with respect to emission reduction, and any exceedance of standards must be reported to the EU accordingly. For these substances, EQSs have been defined that are valid for all water bodies. These quality standards are included in the so called 'Besluit Kwaliteitseisen en Monitoring Water' (BKMW). The BKMW describes the Dutch implementation of the WFD, amongst other aspects, with regard to the chemical water quality standards. As of 2012, isoproturon was the only priority substance registered as a PPP in the Netherlands besides one registration for a priority substance for coating of seeds for export.

3. All other substances are given points, based on:
   a) *location*
   b) *degree of exceedance*
   c) *number of locations with exceedance*
   d) *percentage of locations with exceedance.*

Each of these will now be discussed. More background on the scoring method is provided in Appendix II.

a) Location

For each monitoring location: determine whether an EQS (or MPC if no EQS is available) has been exceeded during the period concerned. At each location, points are awarded based on the type of location according to Table 2.1. If both the AA-EQS and MAC-EQS have been exceeded at a particular location, points are awarded only once.

Table 2.1. Points given for quality standard exceedance according to type of monitoring location.

	WFD reporting locations in WFD water bodies	Remaining locations in WFD water bodies	Locations outside WFD water bodies, except edge of field ditches
EQS (AA and/or MAC) or MPC	4	2	1

WFD reporting locations are scored highest because the water quality at these locations is reported to the EU. For water bodies not defined as WFD water bodies the same quality standards apply. The WFD quality standards (MPC and EQSs) are not used for feedback to PPP authorisation of water quality in edge of field ditches outside WFD water bodies. The monitoring data from these locations can be used in the causal analysis of exceedance and to help prioritise observed problematic substances.

b) Degree of exceedance

At locations where quality standards are exceeded, the degree of exceedance may lead to extra points being given.

Table 2.2. Extra points given for degree of exceedance.
X is the ratio of measured concentration to quality standard

Degree of exceedance	*extra points*
$1 \leq x \leq 2$	0
$2 < x \leq 4$	1
$4 < x \leq 13$	2
$x > 13$	3

If both the AA and MAC EQS have been exceeded, only the highest degree of exceedance is taken into account. The classes of exceedance are based on quartiles of the total collection of standard exceedances for the substances on the list: for example, 25% of the quality standard exceedances is more than 13x the standard. This is then the highest quartile.

At each location the points awarded for location type and degree of exceedance are now combined, as is done in Table 2.3

Table 2.3. Score derived from combining scores for location type (1-4 points) and degree of exceedance (0-3 points).

	Degree of exceedance of EQS or MPC (points)			
Location type (points)	1≤x≤2 (0)	2<x≤4 (1)	4<x≤13 (2)	x>13 (3)
WFD water body, Reporting location (4)	4	5	6	7
WFD water body, remaining locations (2)	2	3	4	5
Remaining locations outside WFD water bodies, except edge of field ditches (1)	1	2	3	4

c) Number of locations with exceedance
For each substance, the scores emerging from the previous step are summed for all monitoring locations with exceedances, to reflect the number of locations in exceedance in the overall ranking.

d) Percentage of locations with exceedance
Finally, each of these summed scores is multiplied by the percentage of locations in exceedance, in order to reduce the influence of the relative number of monitoring locations of one substance compared with another on the outcome of the ranking.

4. All substances given at least one point are now ranked in tabular form according to the scores emerging from the previous step. This table also visualises:

- whether it has an authorisation in the Netherlands (at the moment the table is filled out)
- the type of substance (PPP, B (biocide), …)
- whether it is a parent, metabolite or both*
- whether it is a current WFD priority substance
- the number of locations in exceedance relative to the number of monitoring locations
- the quality standard(s) in force
- the percentage and number of quality standard exceedances per quality standard relative to the number of monitoring locations.

A metabolite may have more than one parent. These may not all be PPP or biocides.
In the procedure only monitoring data are used that can be sensibly compared with water quality standards: 1) measured concentrations are higher than the detection limit or 2) measured concentrations are equal (or lower) than the limit of reporting and the limit of reporting is lower than the relevant water quality standards.

Exceptions
If quality standards are exceeded as a result of reported accidents, this does not constitute a reason for a mandatory review of authorisation. The final step in the identification of problematic substances is therefore to check with the inspection authorities and with regional water authorities whether any serious accidents have been reported that may have led to one or more of the quality standard exceedances extracted from the Pesticides Atlas. If such is the case, this is reported along with the table showing the problematic substances identified.

Table 2.4. Example of a table showing water quality standard exceedances for plant protection products. n = number of monitoring locations with exceedance; n-tot = total number of monitoring locations for this substance in WFD water bodies.

substance							AA-EQS and/or MAC-EQS or MPC exceedances			AA-EQS			MAC-EQS			MPC		
											Exceedances			Exceedances			Exceedances	
no.	name	authorization	type	parent compound / metabolite	prior subst	pnts awarded	perc	n	n-tot	quality standard (ug/l)	perc	n	quality standard (ug/l)	perc	n	quality standard (ug/l)	perc	n
121	Substance 1	yes	PPP	parent	1	191	2.10	30	1429	0.3	1.61	23	1	1.89	27			
6	Substance 2	no	B	parent	1	23	0.63	9	1433	0.2	0.63	9	1.8	0.28	4			
Etc	Etc.	yes	PPP+B	parent	1	17	0.77	8	1040	0.03	0.58	6	0.1	0.58	6			
		unknown	Etc	parent	1	4	0.34	2	590	0.1			0.6	0.34	2			
		yes		parent	2	9449	15.75	200	1270	0.067	14.57	185	0.2	13.07	166			
		unknown		metabolite	2	7610	45.57	36	79							0.0024	45.57	36

[p] WFD Priority substance; [MPC] Maximum Permissible Concentration; no EQS available for this substance.

2.1.2 Check on laboratory methods

Before the list of problematic substances is finalised, it must be checked whether it contains any substances for which there is a realistic chance that the concentrations reported in the Pesticides Atlas are not due (solely) to the parent substance of concern. This is particularly relevant for isomers and esters. Moreover, it is not always clear whether metabolites have been distinguished from parent substance or competing parent substances. This may depend on the applied conservation and analysis methods, which may vary across laboratories.

A table of substances for which the above considerations apply will be incorporated in the Pesticides Atlas and will be updated on a yearly basis before the list of substances exceeding quality standard is renewed. If a problematic substance appears in this table, an assessment is made of whether it can be ascertained that only the parent substance has been reported. If this is not feasible, it is described what this implies for the picture of quality standard exceedances for the substance in question. This check is carried out under the direction of the Ministry of Infrastructure and Environment, in consultation with the authorisation holder. No causal analysis can be requested before this check on the conservation and analytical methods employed has been carried out and reported.

2.1.3 Derivation of new quality standards

As new scientific information becomes available, this can be used to reassess current water quality standards. If such reassessment leads to a numerically higher quality standard that eliminates the problematic quality standard exceedances, the substance may no longer be considered problematic for aquatic systems. In such cases the derivation of a new quality standard can be interpreted as a measure to meet the WFD goals.

A rule of thumb is applied to check whether there is a realistic chance that an update of the environmental quality standard may lead to a new standard with which the substance should no longer be seen as a problematic substance. This may be the case when the quality standard used for risk assessment has been established using a safety factor. The rule of thumb evaluates whether the EQS is more than a factor 10 lower than the regulatory acceptable concentration (RAC) for chronic exposure for the most sensitive aquatic organism: AA-EQS < 0.1 RAC or MAC-EQS < 0.1 RAC (Figure 2.2). Registration holders are informed by the Ctgb when this condition holds for their PPP(s) on part of the list of problematic substances for which a causal analysis will be demanded. The Ctgb needs to verify whether the authorisation holder intends to request derivation of a new quality standard before the authorisation holders can be asked for a causal analysis. If this is indeed the intention, the Ctgb consults the authorisation holder on the type of additional data to be delivered and the time required to have this data available. Based on this information, the Ctgb then establishes a deadline for supplying this data and filing the request for quality standard review. If by that date no request has been filed, the procedure of feedback of monitoring results can be continued by starting Part 2 of the procedure: the causal analysis.

When no RAC is available, it is assumed to be equal to the EQS (MAC-EQS or MPC if no EQS has been derived).

Besides the situation described above, an authorisation holder can always request a review of a quality standard based on additional information. However, if the quality standard for risk assessment is not at least 10 times higher than the AA-EQS or MAC-EQS, the feedback process may be continued with the causal analysis during the process of quality standard review.

It is possible that a new quality standard is derived after the initiation of a causal analysis for the substance. A quality standard based on new file information or new scientific insight may overrule the quality standards on which the identification of problematic substances is normally based. The authorisation holder may check whether the substance still constitutes a problematic substance based on the new quality

standard(s). The authorisation holder informs the Ctgb of the outcome. The Ctgb checks the information and decides whether or not the need for a causal analysis is to be cancelled. A causal analysis can be canceled if the substance is no longer be considered to be a problematic substance, or if it is assigned a lower priority due to a new, numerically higher water quality standard.

If a causal analysis is initiated or continued, it is directed towards the exceedances based on the most recent quality standards.

If a substance is in the process of quality standard review, it is marked as such in the list of problematic substances. In addition, substances for which a causal analysis or emission reduction plan is ongoing, or has been carried out, are marked as such in this list.

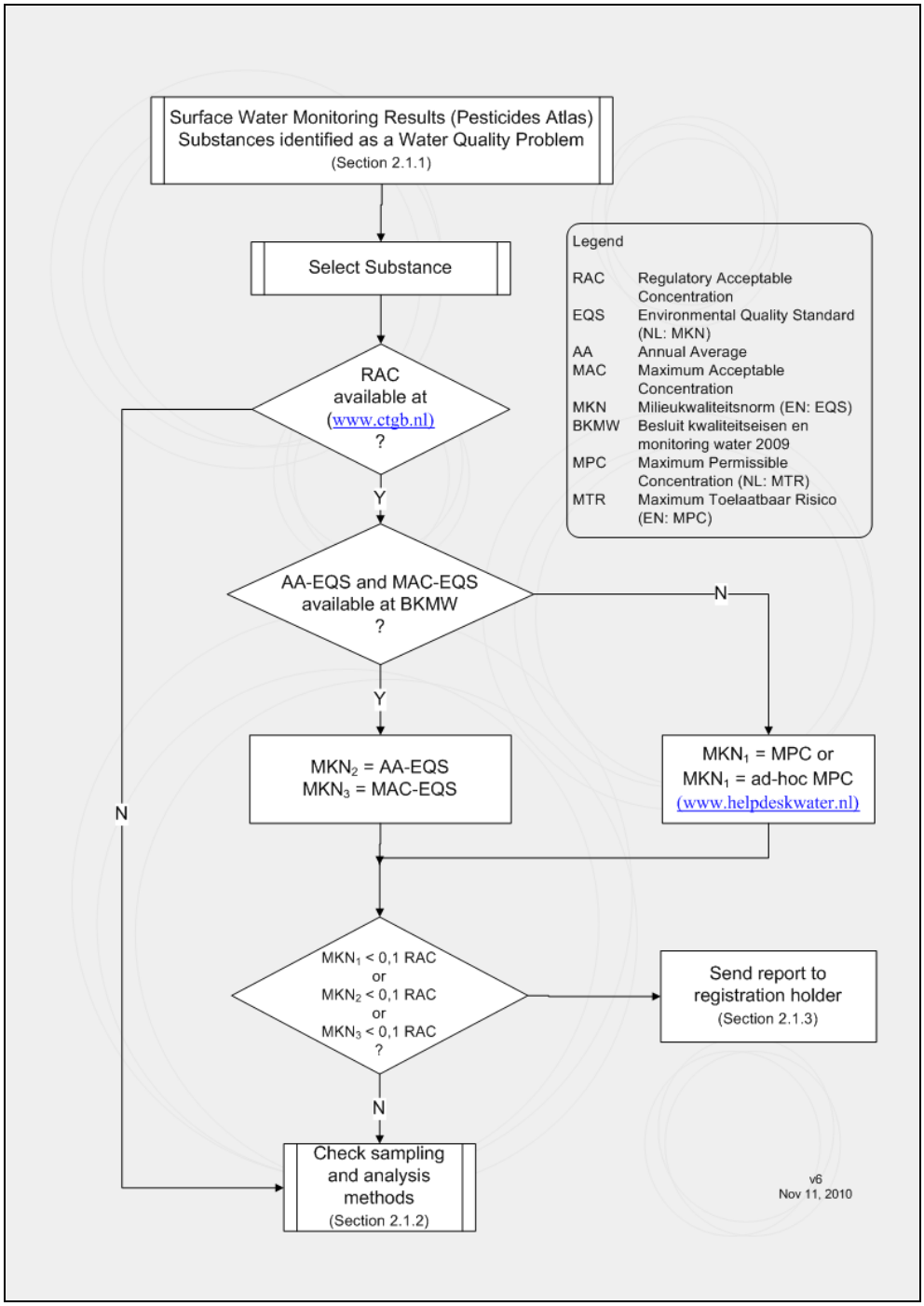


Figure 2.2. Schematic representation of the procedure for identifying substances for which quality standard review may be relevant, as part of Step 1.

2.2 Water quality standards

With the implementation of the WFD, European water quality standards came into force for a series of priority substances. For non-priority substances, new quality standards have been derived to meet the demands of the WFD. These new standards, the Environmental Quality Standards (EQS), replace the current surface water quality standard MPC ('MTR'), used by Dutch water authorities. The EQS consists of two components: the AA-EQS (Annual Average) and MAC-EQS (Maximum Allowable Concentration).

The Environmental Quality Standards are defined as follows:

- The **MAC-EQS** is the maximum peak concentration required to protect against possible effects of short-term exposure. The MAC-EQS is compared with the maximum of all individual measurements at a given location within a year.
- The **AA-EQS** is the average concentration over a year (or relevant period within a year) required to protect the aquatic ecosystem against long-term chronic effects. The AA-EQS is compared with the average concentration at a given location in the course of a year (or relevant period within a year).

The comparison of the EQS with the measurement is an important difference compared to the application of the MPC, where the comparison is with the 90 percentile concentration.
Since not all MPCs can be replaced by the new EQS standards instantly, in the period up to 2015 the MPC will be applied for those substances for which no EQS standards are available.

For identification of problematic substances, the water quality standards laid down in two regulations apply: the Decree on Quality Standards for Water Monitoring, 2009 (In Dutch: *Besluit kwaliteitseisen monitoring water,* 2009) and the underlying Ministerial Regulation on WFD monitoring. These are described further in Section 2.3 and will be referred to as the 'BKMW' and the 'WFD Monitoring Regulation'. For the substances in the BKMW, EQS standards have been derived. If the substance is not in the BKMW, the quality standard to be applied (EQS or MPC) is derived from the water quality standard database at www.helpdeskwater.nl. It is plausible that for future identification of nationally relevant substances and river basin district relevant substances (Section 2.3) the same water quality standards (EQS) will apply as for identification of problematic substances in the context of authorisation. An overlap between the WFD substance categories and the problematic substances for authorisation can thus be anticipated.

More information on the water quality standards and their application in line with the WFD can be found in Appendix I and the instruction 'Richtlijn Monitoring Oppervlaktewater en Protocol Toetsen & Beoordelen' (Rijkswaterstaat, 2009), the 'BKMW' and the 'Regeling monitoring KRW' via www.helpdeskwater.nl (all in the Dutch language). The derivation of EQS standards in the BKMW and the 'WFD Monitoring Regulation' are part of the implementation of WFD and have no direct relation with individual decisions on such issues as permits or PPP authorisations. For the feedback of monitoring results to the authorisation holder and registration authority, the Monitoring working group uses only the numerical values from these documents.

2.3 Substance categories in the Water Framework Directive

With the method described in Section 2.1 a new category of substances emerges. Under the WFD three main categories of substances in surface water are already defined:

1. Priority substances / Priority hazardous substances
2. River basin district relevant substances
3. Nationally relevant substances

The ranking of substances according to Section 2.1 takes into account whether a substance is a WFD

priority substance. In this section the WFD substance categories are defined.

The substances in question and their respective quality standards are listed in the BKMW and the WFD Monitoring Regulation. The first of these is anchored in the legal provisions for implementation of the WFD in the Netherlands. The substances and quality standards in the WFD Monitoring Regulation can be updated up to twice a year. More information on these regulations is available at www.helpdeskwater.nl.

1. Priority substances have been defined at the EU level. Within this category only isoproturon is registered for agricultural use as a PPP in the Netherlands (2012), Chloorpyrifos is a priority substance as well, but allowed for coating of seeds that are to be exported only. Priority substances and their quality standards are included in the BKMW.

2. River basin district relevant substances are substances that are not expected to meet the water quality standard of the WFD within that district in 2015 (2021, 2027, etc.). These substances and their water quality standards are included in the WFD Monitoring Regulation. In April 2010 this category overlaps with the substances listed in 2005 (76/464-EC Directive on dangerous substances in surface waters, 2005), except for chlorotoluron.

3. The category 'Nationally relevant substances' is elaborated by individual EU member states and is based mainly on presence in national surface waters, not necessarily on quality standard exceedances. In the Netherlands this category comprises the substances listed in 76/464-EC (around 50 plant protection products), augmented with the active ingredients of PPPs derived from the Midterm Evaluation of the Plant Protection Policy of the Netherlands (Linden *et al.*, 2006) and the substance selection made in the multi-stakeholder project 'Schone Bronnen'. The water quality standards of these substances are described in the WFD Monitoring Regulation.

2.4 Monitoring by Dutch water authorities

Types of monitoring

The WFD sets minimum requirements for the monitoring of surface water quality. Based on these, national guidelines have been drawn up for water quality monitoring programmes (Rijkswaterstaat, 2009). These cover monitoring locations, monitoring frequency, (categories of) substances to be monitored and the quality standards to be applied. They also state which monitoring results must be reported to the EU. In 2009 the monitoring practices of none of the Netherlands' regional water authorities satisfied the minimum requirements of the WFD. On the other hand, various water authorities monitored more frequently or at more locations than required under WFD guidelines. The Dutch Ministry of Infrastructure and Environment is currently working on a national PPP monitoring framework to obtain more consistent monitoring data over years, and more similarity in monitoring between regions.

The WFD distinguishes three types of monitoring. The minimum monitoring frequency depends on the type of monitoring and the substance category concerned (Table 2.5):

Table 2.5. Minimum monitoring frequency in the WFD guidelines for PPPs in surface water.

Type of WFD monitoring	Cycle: measured per … year(s)	Substance group	Frequency in a measuring year	Number of measuring points (2007-2009)
State & Trend	6	Priority substances	≥12	105
		Other relevant substances	≥4	
Operational	1	Priority substances	≥12	303
		Other relevant substances	≥4	
Research Monitoring	-	*As relevant*	*Not specified*	*Not specified*

State & Trend Monitoring is used to monitor the status and trends of surface water quality over periods of several years. For this purpose 105 monitoring sites are employed in the period 2007-2009.

Operational Monitoring for the WFD is applied at 303 locations in the period 2007-2009 to gain more insight into water quality trends in water bodies that are at risk with respect to WFD targets. Not all locations are used in every year. The second goal of Operational Monitoring is to assess the effect of water quality improvement measures. Operational Monitoring over shorter periods can provide a more detailed picture of water quality at a regional or local level compared to State & Trend Monitoring, which has a lower frequency and intensity and is used to inform the EU.

Measurements made as part of Research Monitoring can improve insight into the applications and emission pathways giving rise to exceedance of quality standards. Schomaker & Knoben (2007) provide guidance on application of Research Monitoring to plant protection products. Key elements of this type of monitoring include measurement timing and location in relation to land use patterns and application periods.

Monitoring locations

In the process of implementing the WFD, 724 so-called 'WFD water bodies' have been defined. In a number of these water bodies, measuring locations have been assigned which are used for the purpose of EU-reporting of water quality. The Netherlands has 100-120 of these WFD reporting locations. These represent a minority of Dutch water bodies. If water quality at EU-reporting locations fails to comply with WFD standards, remedial action needs to be taken.

WFD water bodies are generally larger water bodies, not including edge of field ditches. Water authorities monitored PPPs at 713 measuring points in 2009, of which 314 were in WFD water bodies. This means that not all measuring points in WFD water bodies are WFD reporting points. These numbers also show that a relevant part of the monitoring takes place outside WFD water bodies. In the monitoring programmes of regional water authorities, edge of field ditches are not commonly monitored.

Table 2.6. Number of measuring points in surface water in the period 2007-2009 categorised by type of waterbody (topographical, 1-23) and the categories: a) WFD reporting points in a WFD waterbody, b) other measuring points in a WFD waterbody and c) measuring points outside WFD waterbodies. WFD = Water framework directive. The table is in Dutch. WFD waterbody = KRW waterlichaam (KRW WL).

watertype code	watertype	a KRW-meetpunten binnen KRW-WL	b overige meetpunten binnen KRW-WL	c overige meetpunten buiten KRW-WL	total
ZEE	Noordzee	1	0	0	1
KBS	Beschermd kustwater	3	9	0	12
OTY	Overgangswater	7	8	1	16
MBR	Brakke wateren	28	38	2	68
MGD	Grote meren	19	25	4	48
MMD	Matig grote diepe meren	8	3	0	11
MMO	Matig grote ondiepe meren	7	6	0	13
MKO	Kleine ondiepe plassen	1	2	19	22
MKV	Kleine ondiepe veenplassen	2	1	2	5
RRS	Snel stromende rivier	1	1	0	2
RRV	Rivier	12	11	1	24
MKA	Kanalen en vaarten	83	62	2	147
RMB	Middenloop of benedenloop	16	11	0	27
RBS	Snel stromende wateren (beken)	10	4	4	18
RBL	Langzaam stromende wateren (beken)	78	50	9	137
MWR	Water in rivierengebied	2	2	0	4
MVN	Vennen	0	0	3	3
	subtotal 1-18	278	233	47	558
MSL_T_S	Sloten_TOP10_smal*	19	2	275	296
MSL_T_B	Sloten_TOP10_breed*	4	3	92	99
MSL_T_G	Greppels_TOP10*	7		37	44
	subtotal 21-23	30	5	404	439
	total	308	238	451	997

*no. 21: small ditch = < 3 m (code 601 TCN), no. 22 wide ditch 3-6 m (code 602) and no. 23: 'greppel' (ditch which does not contain water the whole year, code 600)

2.5 The Pesticides Atlas

Water authorities (such as water boards) apply a range of strategies for monitoring PPPs in surface water. Some regions select the substances and monitoring locations partly on the basis of expected use and emission risks in their region, whilst in other regions broad packages of substances are measured regularly at numerous locations. The monitoring frequency, number of monitoring points and analysis techniques employed vary across regions and measuring points.

Water authorities pass on their raw monitoring data to the Pesticides Atlas. They are requested to send a complete overview of their monitoring results of pesticides in surface water. The quality of these data is then thoroughly checked for input errors, handling of detection limits, quantification limits and reporting limits and unknown codes (e.g. new substances) before they are included in the Pesticide Altlas. The most recent protocol used for the data check is available through CML in Leiden. Next the data are converted to maps and graphs and finally presented on the website www.bestrijdingsmiddelenatlas.nl. This website contains the (downloadable) converted data of pesticide concentrations for individual years as well as the metadata (number of measurements, number of substances monitored, etc.). The maps provide a visualisation of the exceedance of different types of quality standards. Information on exact locations and dates of measurements, based on several quality standard of pesticides can be extracted from the Atlas and be used as input for the causal analysis of exceedances. Once a year a ranked list of 'problematic' substances is drawn up., A list of quality standard exceeding substances at measuring points in WFD water bodies is then added, as described in Section 2.1, for the purpose of feedback of monitoring results to the authorisation holder and registration authority.

3 Protocol for causal analysis and its background

This chapter describes the design and background of the procedure for analysing plausible causes of quality standard exceedances and how to apply it. The question when (for which substance and in which authorisation procedures) to apply it, is answered in chapter 4. Appendix III contains the actual Protocol for causal analysis, including a framework showing the respective phases and topics covered.

In developing this procedure the Monitoring working group took as its point of departure a 'prototype' (De Werd and Merkelbach, 2006), which was then iteratively elaborated while working through realistic cases.

An introduction and broad overview of the methodology is provided in Section 3.1, along with the most relevant background information. In Sections 3.2 to 3.5 the design and background of the procedure itself are described in more detail.

In section 3.2 the 'protocol manager' is introduced, and in section 3.3 the phases and main principles of the Protocol are explained. The most relevant instruments employed in the analysis are described in sections 3.4 to 3.5. These instruments are the Crop Protection Sharepoint (CPS), the Dutch Environmental Risk Indicator for Plant Protection Products (NMI 3; Section 3.6) and the Pesticides Atlas (BMA).

3.1 Introduction to the causal analysis protocol

The causal analysis protocol is used to identify plausible causes of exceedance of quality standards for the active substances of PPPs and/or metabolites in surface water in a thorough and transparent manner. Plausible causes of quality standard exceedance are determined by answering the following questions.

1. Substance properties:
    - Based on substance properties, which emission pathways to surface water are most relevant for the substance?

2. Dutch authorisation:
    - Based on authorisation and Good Agricultural Practice (GAP), what applications and emission pathways are likely to play a role in emissions to surface water?
    - Are there product-specific restrictions that influence the risk of a certain emission pathway?

3. Agricultural use data:
    - What are the relevant product applications, application methods, application periods and regions with relatively intensive use?
    - What are the implications for the emission patterns (spatial variation, pathways)?

4. Emission pathways:
    - Are there emission pathways that are likely to be relevant but are not included in the calculated emission indicators (NMI)? *('emission indicator' is explained in the Glossary)*
    - According to the expected emissions (calculated emission indicators + interpretation of expert information), what are the most relevant emission pathways to surface water?
    - What are the consequences of the relevant emission pathways for the temporal pattern of substance concentrations within a year?
    - Are the relevant emission pathways a consequence of an application that does not comply with GAP?

5. Surface water monitoring results:
    - How does the temporal pattern of water quality standard exceedance over a year compare with application periods in relevant crops?
    - Do the spatial distribution and temporal pattern of exceedances imply a correlation with certain crops, application methods and/or emission pathways?
    - How does the spatial distribution of quality standard exceedance compare with the spatial distribution of calculated emission indicators? What does this imply for the relevance of the various applications and emission pathways?

6. Comparison of calculated emission indicators (NMI) and monitoring data:
    - Visual: how does the spatial distribution of exceedance of quality standards in monitoring data compare with the calculated emission indicators? What does this imply for the relevance of the various applications and emission pathways?
    - Calculated: how does the spatial distribution of exceedance of quality standards in monitoring data correlate with the land use (crop maps) and PPP application statistics?

The final step of the causal analysis is to interpret the answers and arrive at an overall conclusion regarding plausible causes and non-application of Good Agricultural Practice.

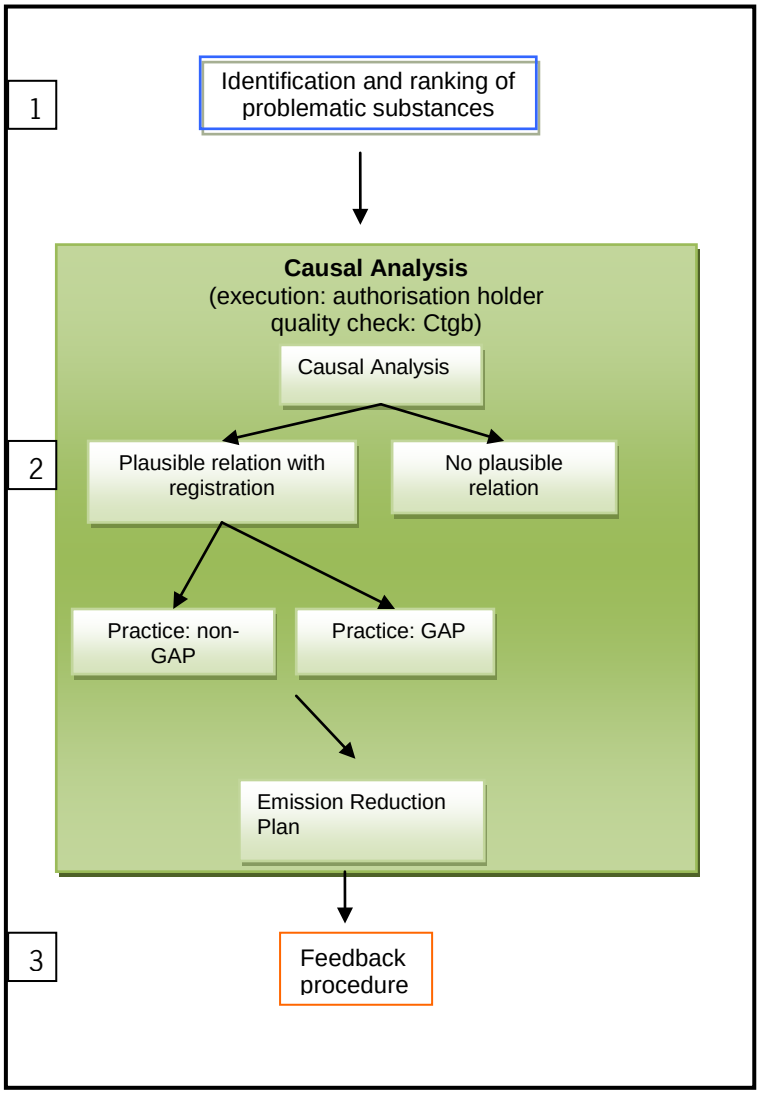


Figure 3.1. Step 2: the causal analysis and Emission Reduction Plan in the green box.

3.2 Application for metabolites

In case the protocol needs to be applied because a PPP metabolite exceeds the water quality standard, the substance properties and emissions to surface water are included for both the parent(s) and the metabolite. If for both the parent and metabolite(s) a causal analysis is requested, one combined causal analysis is sufficient. The information on substance properties, emission to surface water and monitoring results needs to be included for both the parent and the metabolite. If a comparison of calculated emission indicators and measured concentrations is carried out in Phase 1, this is also applied for the parent, as well as the metabolite.

3.3 The protocol manager

The protocol manager is responsible for the process, documentation and reporting of the causal analysis. He or she is also responsible for interpreting the data and arranging expert input, as well as for formulating conclusions and recommendations. It is the protocol manager's responsibility to ensure that appropriate experts and expertise are involved throughout the process.

The protocol manager is appointed by the authorisation holder, who in all cases bears ultimate responsibility for execution of the causal analysis. The protocol manager is not necessarily employed by the company. If several authorisation holders cooperate in the analysis, they may together appoint one protocol manager. The causal analysis will comprise part of the information filed with the Ctgb for authorisation. The Ctgb will execute a check on the process and outcome of the analysis. The protocol manager is allowed to act as one of the experts when expert consultation is carried out (described in 3.4)

3.4 Phases of the causal analysis protocol

Before the causal analysis is started, the history of the substance is checked. If a causal analysis or formal emission reduction plan is already ongoing (as recorded in the list of problematic substances), the progress is checked by the responsible authorities. Based on the timeline of the Emission Reduction Plan and the progress made, further actions are defined. This procedure is specified in further detail in the feedback procedure described in Chapter 4.

The causal analysis protocol guides the protocol manager through a maximum of five phases, shown in Figure 3.2 along with the document(s) to be delivered after each phase. The protocol combines fact-finding (Phases 1 and 3) with expert consultation. The aim here is to make optimum use of available knowledge, not only from national databases and models, but also from regional expertise and expertise that has not (yet) been incorporated in national models and instruments. The analysis starts on a national, more general scale (Phases 1 and 2), covering all regions and crops, and may go into more detail at a later stage (Phases 3 and 4) if this is expected to yield relevant additional information.

The protocol manager may decide to combine several of the documents listed in Figure 3.2 into a single document. This is acceptable as long as it is clear from the documents which phases have been completed and what the individual phases have delivered in the process of causal analysis.

3.4.1 Phase 1: Inventory of basic information, national scale

In Phase 1 a factsheet is prepared, based on readily available, high-quality, standard information sources. In Phase 1 the fact-finding is carried out on a national scale: the information sources cover a wide variety of PPPs and crops and encompass the whole country. The substance properties retrieved from the standard database (CtgBase) are checked in this phase, and if available replaced by more recent substance property data. At this stage, however, there is no need for a detailed investigation of authorisation dossiers and information on the backgrounds of national-scale datasets. The use of high-quality, standard sources results in a standardised factsheet. The result of Phase 1 serves as input for Phase 2.

In Phase 1 of the causal analysis, product authorisations are checked for any recent changes in restrictions on the label that influence emissions. Extra restrictions are an indication as to which emission pathways might play an important role.

The procedure is applicable to active ingredients and metabolites of PPPs, not to biocides, pharmaceuticals and (chemical) substances with other types of use. Even though the causal analysis focuses on the use of substances as PPPs, information on relevant non-agricultural use and other possible sources of surface water contamination should be mentioned in the factsheet if available. Although these are not analysed any further under the causal analysis protocol, they may be relevant for establishing specific mitigation measures.

If it can be concluded that it is implausible that agricultural use of the substance as a PPP (Ctgb category 'L' = 'Gewasbeschermingsmiddelen') is responsible for the majority of quality standard exceedances, the Causal Analysis can continue with Phase 5 of the Protocol, the final conclusions.

Phase 1 is concluded by ascertaining whether all the requested data have indeed been collected and whether they contain any contradictions. Missing data and contradictions are specified in the conclusions of

the factsheet.

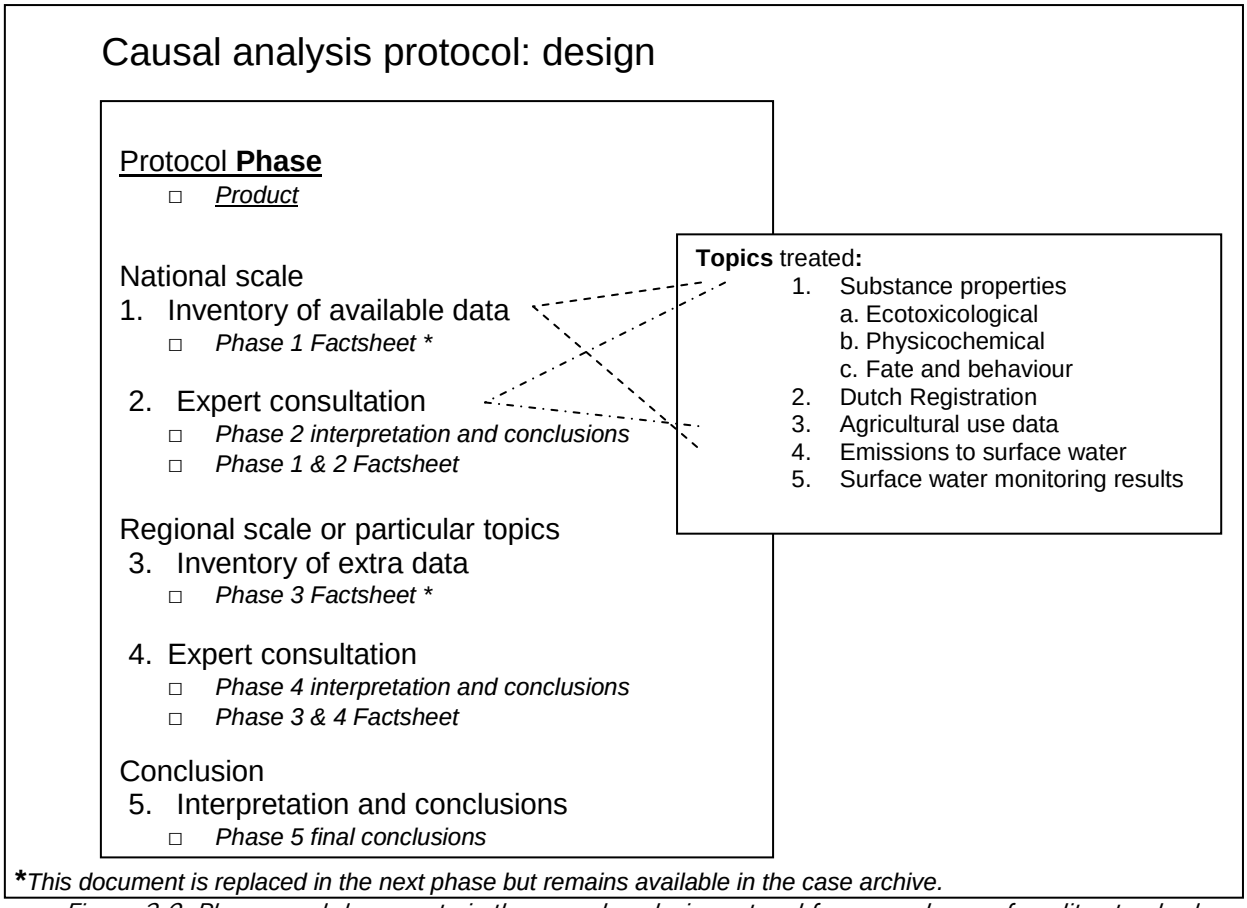


Figure 3.2. Phases and documents in the causal analysis protocol for exceedance of quality standards.

3.4.2 Phase 2: Expert consultation and interpretation, national scale

A phase of fact-finding (Phases 1 and 3) is always followed by expert consultation. Phase 1 is followed by expert consultation in Phase 2, and Phase 3 is followed by Phase 4. The goal of Phases 2 and 4 is to interpret the facts collected and reported in the previous phase and to establish whether these factsheet data require any adjustment or amendment by experts.

The expert consultation in Phases 2 and 4 consists of interaction with a potentially large number of experts working for a variety of research organisations and other stakeholders. The protocol manager decides which organisations are contacted for which question(s). For each combination of question and expertise, at least one, and if possible more organisations are contacted. For each organisation a contact person selects one or more experts within their organisation. These are approached by the contact person within that organisation to respond to the questions. If possible, the contacted organisations should represent a balance between governmental and independent research organisations on the one hand, and agribusiness on the other. Protocol managers are requested not to restrict the number of experts involved too much. The listings of organisations and contact persons in Appendix VI can be updated on request of the protocol manager.

Questions for experts are categorised per topic (Figure 3.2). To ensure the entire Phase 1 Factsheet is duly studied by experts in Phase 2, all the predefined questions (as described below) are used in all cases. Questions should not be defined in a way that they direct experts towards certain applications, emission pathways, etc.. whilst other emission routes may get no or less attention from the experts. Each question is labelled with specific expertise's (Table 3.1). Questions, expertise's and organisations with their expertise's

and contact persons are listed in Appendix VI. If further analysis is required in Phases 3 and 4, the protocol manager may define new questions for a new round of expert consultation.

A methodology for systematic comparison between spatial patterns of measured concentrations and predicted concentrations has been developed by Alterra and CML (appendix VIII). When applied in Phase 1 or 3, questions which are specific for the causal analysis may be added by the protocol manager in Phase 2 or 4. These questions must then help experts to find plausible causes for mismatches between measurements and calculated emission indicators in certain water board areas. The systemic comparison is an optional step in the causal analysis protocol.

In expert consultation, an expert is always asked to support his or her answers with references or other information source(s). This may be expert knowledge/expert judgement, but preferably the expert refers to publicly accessible documents. Experts have access to each other's contributions and can react on them. In this way the Crop Protection Sharepoint can serve as a platform for discussion among experts. The protocol manager uses the results of the expert consultation to improve the factsheet and for the purpose of interpretation and conclusions.

Table 3.1. Fields of expertise relevant for expert consultation in the causal analysis.

1.	Available PPPs and crop protection
2.	Crop protection advice
3.	Environmental risks of PPPs
4.	Surface water quality research and analysis methods
5.	Surface water quantity research and water management
6.	Authorisation
7.	Fulfilment of restrictions on application of PPPs (enforcement)
8.	Processing of monitoring results
9.	Data collection and horticultural and agricultural analysis
10.	(Geo)statistics

Background to the predefined questions per topic

Substance characteristics
For mobile substances in particular, new data on substance characteristics may become available in the near future. These may indicate a higher leaching potential than assumed up till now and/or different distributions of emission pathways. For calculating predicted emissions, the first choice should be to adopt the most recent methods, parameters and data on substance characteristics, as used by the Ctgb. However, experts may also present new relevant information that has not yet been integrated into the Ctgb methodology. The protocol manager may decide to use this new information to calculate emissions using alternative scenarios. Information on the water analysis method from the registration files is included. In this way experts can better respond to the question about the water analysis methods applied to obtain the monitoring results in the Pesticides' Atlas.

Dutch authorisation
Authorised use can be derived from the product labels and the extra information in the Good Agricultural Practice (GAP) table applied by the Ctgb and integrated into the Phase 1 Factsheet. Exact information on authorised use in the past can be difficult to locate, especially when it concerns special and older authorisations.

Agricultural use data
In practice, agricultural use may differ from the use that has been authorised. This may entail a different application frequency or spray interval, but more relevant still are deviations from authorised use, involving application in crops without authorisation (illegal use) or use of application methods that are not part of authorised use. Such practices may lead to unexpected emission patterns. In addition, the expert consultation may yield information on the market share of different products, which may vary in authorised

use and application advice and therefore vary predicted emissions. In expert consultation on this topic, it is not only deviations from authorised use that are noted. On the basis of the experts' response a more detailed and robustly supported overview of actual use in practice is made. This leads to estimations or calculations of predicted emissions that are more detailed and/or better supported.

Emissions to surface water
Based on expert input, the protocol manager may specify and apply additional or refined emission scenarios, for example using adjusted values for substance properties, application parameters and/or emission factors. Another possibility is a national scenario that excludes a specific area or application from the calculations.

Surface water monitoring results
Depending on the outcome of Phase 1, additional information on the monitoring results may be relevant. This may relate to:

- more detailed information on e.g. the temporal course of substance concentrations
- differences between regions in numbers of measurements and exceedances.

If an expert brings up monitoring results which are not in the Pesticides Atlas, this expert is requested to provide due information on the origin of the new data.

Phase 2 interpretation and conclusions of the causal analysis protocol

The protocol manager makes transparent how the expert responses are to be used in the further process. He or she may decide to discuss the findings obtained and to consult more experts, in order to arrive at robust interpretation and conclusions. In this case the authorisation holder(s) of the substance are invited to be represented at this discussion.

As a follow-up, the protocol manager may opt to take the following actions:

Regarding the source information in the factsheet:

- Adjust or add to the source information in the factsheet.
- Add qualitative remarks to specific topics in the factsheet.
- Recalculate the predicted emissions using adjusted input data.

Regarding interpretation of the collected information:

- Use the information to interpret the data in the factsheet, draw conclusions and make recommendations for the next phase of the Protocol.

Regarding the protocol:

- If relevant, the protocol manager may make a recommendation to modify the protocol for use in subsequent cases.

Conflicting information

In the event of conflicting information, missing information or striking regional differences in variables of influence on expected emission levels, the protocol manager may opt to add pertinent remarks.

Information from different experts may be mutually conflicting or conflict with the information in the Phase 1 Factsheet. If the protocol manager is able to judge and duly support which information is most valuable or best-supported, the rest of the Protocol is followed using this superior information.

If the protocol manager cannot establish which information is best, all the information sources should be used in the further process of causal analysis. If the conflicting information concerns variables that are used to calculate emissions or emission indicators, the causal analysis is continued with more scenarios. If the uncertainty concerns multiple variables, the protocol manager may decide to continue the process with a minimum, maximum and average emission scenario. To gain an indication of which scenario is most realistic, the protocol manager can compare the calculated emission indicators with monitoring data.

The interpretation and conclusions of Phase 2 are documented in a new document: '*Substance name*: Phase 2 Interpretation and Conclusion.

For each topic (Figure 3.2) the most relevant findings are described, followed by the conclusions on that topic in relation to establishing relevant applications and emission pathways. Based on these conclusions per topic, the protocol manager then draws the main conclusions for Phase 2 with respect to the applications and emission pathways that are to be deemed the most plausible cause of the water quality problem.

The protocol manager does not need to prove a causal relationship, but if possible he or she should seek to answer the following questions concerning the regions and/or seasons of concern;

- What product application(s) have a plausible relation with the exceedance of quality standards?
- What emission pathway(s) have a plausible relation with the exceedance of quality standards?
- Is it possible to rank emission pathways according to their contribution to the exceedance of quality standards?
- What sources and applications can be excluded from the list of possible causes of quality standard exceedances?

Protocol continuation after Phase 2

It is not always necessary to work through all the phases of the Protocol. If a more detailed analysis is considered not necessary or expected not to add relevant information after Phase 2, for example, then Phases 3 and 4 can be skipped. Figure 3.4, showing the Protocol phases and topics, indicates this optional short-cut.

The protocol manager uses the following decision tree to decide whether Phases 3 and 4 are to be included in the causal analysis (cf. Figure 3.3):

> A: Are there unexplained striking differences between the distribution of the expected emissions and the measured exceedance of quality standards between regions? Yes?: -> D. No? -> B
>
> B: Are there unexplained striking differences between the distribution in time of the expected emissions and the measured exceedances of quality standards Yes?: -> D. No? -> C
>
> C: Is there a plausible relation between applications in certain crops, related emission pathways and the measured exceedances of quality standards? Yes?: -> Phase 5. No? -> D
>
> D: Is it anticipated that further analysis of one or more of the topics studied in Phase 2 will improve insight into the cause of the exceedance of quality standards? Yes?: Continue with Phases 3 & 4.

No: continue with Phase 5.

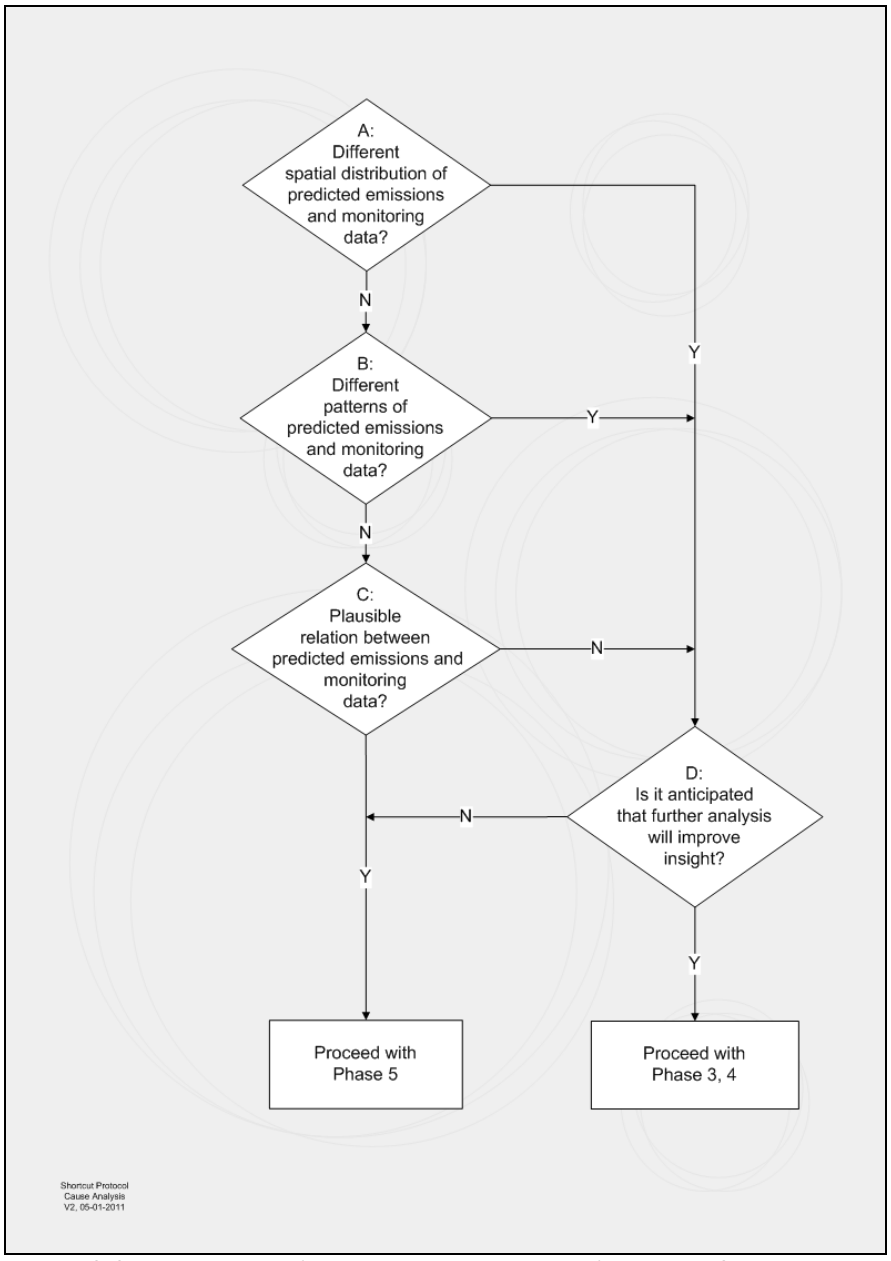


Figure 3.3. Decision tree for Protocol continuation after Phase 2.

Phases and topics in the Protocol for Causal Analysis	
Protocol Phase	
1.	Inventory of available data at national scale
2.	Expert consultation (national scale)
3.	Inventory of additional data (regional scale or particular topics)
4.	Expert consultations (regional scale or particular topics)
5.	Interpretation and conclusions
Topics treated	
1.	Substance properties
2.	Dutch Registration
3.	Agricultural use data
4.	Emissions to surface water
5.	Surface water monitoring results

Dashed line: Shortcut Phase 2 → 5 *(see text)*

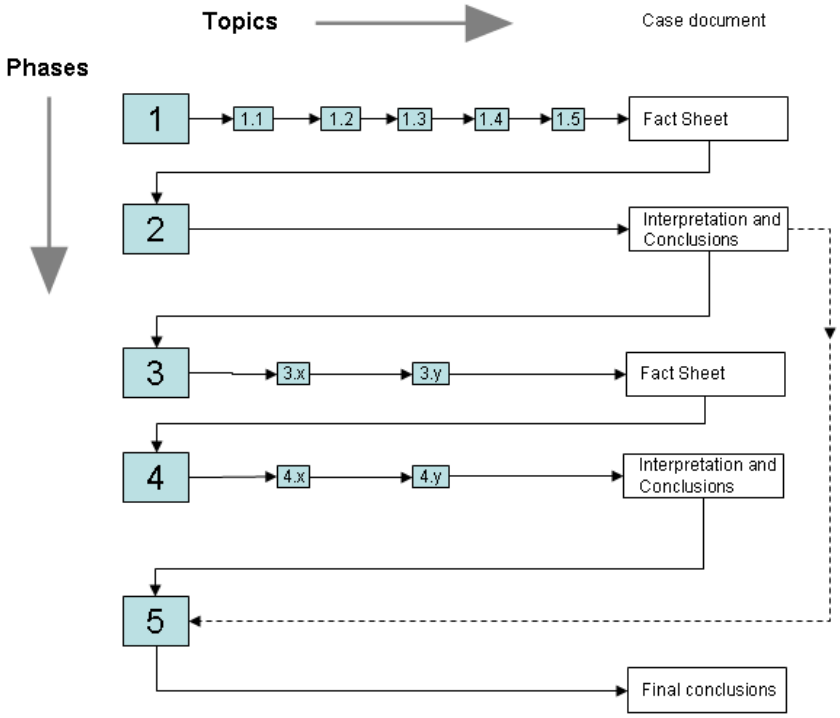


Figure 3.4. Phases and topics of the causal analysis protocol.

3.4.3 Phase 3: Inventory of extra data, regional scale or particular topics

The aim of Phase 3 of the Protocol is to gather more information on topics of interest emerging from Phases 1 and 2. This additional step is only carried out if relevant extra or superior information is expected to be available. Superior information should substantiate the plausible causes of exceedance of quality standards.

In contrast to Phase 1, the topics and sources to be consulted in Phase 3 are selected on a case-by-case basis (per substance). The results of Phase 3 are documented in a 'Phase 3 Factsheet'. Phase 3 is always followed by Phase 4.

In Phase 1 standard sources were consulted on the following topics:

1. Substance properties
2. Dutch authorisation
3. Agricultural use data
4. Emissions to surface water
5. Surface water monitoring results

Now, in Phase 3, the protocol manager decides which of these topics require more in-depth analysis, for example:

- an analysis of the relevance of a certain emission route in a particular water board district
- an analysis of a particular physico-chemical characteristic of the substance
- a further analysis of the application technique in practice
- an analysis of the monitoring results in a water board district
- a more detailed analysis of the agricultural use in a certain crop and/or area (dosage, time of application, etc.).

The protocol manager makes use of public available information like databases and literature, but may also consult organisations or experts for specific supplementary information in the context of Phase 3.

3.4.4 Phase 4: Expert consultation, regional scale or particular topics

Phase 4 is similar to Phase 2, but now concerns the additional information collected in Phase 3. In Phase 3 the protocol manager may already have consulted one or more experts to acquire more detailed information on particular topics. In Phase 4 the findings of Phase 3 are none-the-less presented to a wider range of experts in order to broaden the basis and optimise the quality of analysis.
The protocol manager decides which questions are to be presented to which organisations. For the more specific or area-bound questions characterising Phase 4, contact persons may well opt to contact or refer to other experts compared with Phase 2.

To the extent that the list of experts and organisations permits, the same constraints apply as in Phase 2:

- Per question, at least two experts are contacted and have replied. If, in Phase 3, information has been retrieved from one or more experts, the two experts just mentioned must differ from these if, and as available.
- Per question, at least one governmental or independent research organisation and one commercial organisation (e.g. authorisation holder) are contacted and have replied. This is not necessary for questions on monitoring results.

The protocol manager can decide during this process to continue fact-finding and further expert consultation depending on what information is still lacking and the time available until the causal analysis needs to be filed with the Ctgb.

As in earlier phases, the complete process of fact-finding and expert consultation is documented and made visible through the Crop Protection Sharepoint (CPS).

3.4.5 Phase 5: Final conclusions and recommendations

In Phase 5 the overall conclusion is drawn. In this conclusion the applications and emission pathways that have a plausible relation with the exceedance of quality standards are specified as far as possible. The conclusion may also be that no plausible causes have been found, or that only part of the quality standard exceedance can be explained.

The final conclusions are based on the emission per surface unit treated crop or field and thus not directly influenced by differences in the total amount applied in specific crops.

Conclusions are drawn with respect to the following questions:

There is **a plausible relation** between **the application of substance** …. **in crop(s)** …. and the exceedance of quality standards in the period …. in the surface water in the area(s) …. / in The Netherlands.

There is **no plausible relation** between **the application of substance** …. **in crop(s)** …. and the exceedance of quality standards in the period …. in the surface water in the area(s) …. / in The Netherlands.

There is **a plausible relation** between specific **emission routes** following the application of substance …. in crop(s) …. and the exceedance of quality standards in the period …. in the surface water in the area(s) …. / in The Netherlands.

These conclusions are presented in a table showing, per crop and, if possible, emission pathway, whether there is a plausible relation with the observed quality standard exceedances. An example is given in Table 3.2.

Table 3.2. Example of an overview of plausible causes of quality standard exceedance in the time frame 2003-2006 for a herbicide. The plausible causes are based on the emission per surface unit of area treated. Consequently, the conclusions are independent of the total area treated. The example case is based on emissions calculated with the Dutch Environmental Risk Indicator for Plant Protection Products NMI 2. In the current version NMI 3, the emission pathway "drainage" replaces the emission pathway "lateral leaching".

Time frame: 2003-2006			Emission route					
Crop on which the substance is applied*	Authorisation	Percentage of national use of metribuzin*	Diffuse sources				Point sources (from farmyards and buildings, from greenhouses)	
			spray drift	atmospheric deposition	lateral leaching***	run-off	open field crops	covered crops
Table / crisp potatoes	Yes	71	Plausible cause main cause of exceedances in spring and summer	Not a plausible cause	plausible cause main cause of exceedances in autumn and winter	not investigated	Cannot be excluded Sprayer cleaning (internal and external) possibly relevant in application period and autumn	No applications
Starch potatoes	Yes	22	Plausible cause exceedances in spring and summer		Plausible cause exceedances in autumn and winter			
Seed potatoes	No	1	Plausible cause		Plausible cause			
Asparagus	Yes	4	Plausible cause		Plausible cause Multi-annual crop: increases the risk			
Grass seed	No	-**	Plausible cause		Plausible cause Application in autumn increases the risk			
Carrots	No	-	Application in this time frame is negligible (information from authorisation holder)					
Grassland	No	-	Not plausible that this application occurs in practice; no further analysis carried out					
Strawberries	No	-	Not plausible that this application occurs in practice; no further analysis carried out					

* Sources: 'CBS pesticides questionnaire 2004' and LEI ('Bedrijveninformatienet')

** Supplementary information from authorisation holder: approx. 1% of use is in grass seed cultivation.

*** Preferential flow and discharge through pipe drains have not been analysed

If no plausible relation is established, a distinction is made between two situations:

- The investigations led to the conclusion that there is no plausible relation, or a plausible relation can neither be confirmed nor denied.
- The relation was not investigated

The conclusions table also specifies distribution of use of the substance of concern over the various different crops.

GAP – Non-GAP

During the causal analysis information is collected on the role of incorrect or illegal (non-GAP) application of the substance of concern. If this information is well-supported, a short paragraph is added to the conclusions concerning the expected contribution of non-GAP to the quality standard exceedances.

Recommendations

Based on the outcome so far, the protocol manager may draw up recommendations:

- for reducing exceedance of quality standards, based on the outcome of the Protocol
- for improving the Protocol for subsequent cases.

Checklist

To validate that the causal analysis protocol has been correctly and fully applied, the protocol manager uses the protocol (Appendix III) as a checklist and checks all bullets that have been completed. This checklist can also be used by the Ctgb to check on the correct application of the protocol.

3.5 The Crop Protection Sharepoint (CPS)

Based on the tables in Appendix III, more than 50 different combinations of organisations and expertise may be relevant in Phase 2 of the causal analysis. This large number of potential expert contributions and the interaction with and between experts needs to be managed in a way that ensures a standardised and transparent process. To this end the Crop Protection Sharepoint (CPS) has been developed. This is an online location where documents and other files can be stored and interaction with and among experts can be managed in a transparent manner. The Crop Protection Sharepoint (in the Dutch language), can be accessed at www.gewasbeschermingsplatform.nl.

The Sharepoint can be used to:

- organise and process the interaction with and between experts in an efficient manner
- file and retrieve data, from current and closed cases (using a digital library)
- ensure transparency of the procedure and conclusion of each case for experts and optionally also for stakeholders involved

CPS User Manuals are available at the Crop Protection Sharepoint for registered users.

Transparency

The transparency required of the causal analysis process means that only non-confidential information can be used. All the information used in the course of the analysis will be accessible to all the organisations and experts involved in the analysis, and use of non-public information is only possible if the provider of that information grants permission for use in the case documentation. The protocol manager should ensure that the organisations contacted for expert consultation are made aware of this need for transparency.

Case archive

The documents 'Phase 1 Factsheet' and 'Phase 3 Factsheet' (Figure 1) are replaced during the process by a 'Phase 1&2 Factsheet' and a 'Phase 3&4 Factsheet'. However, all the case documents remain accessible in the Crop Protection Sharepoint archive for the experts and contact persons involved.

Changes in the Crop Protection Share point that have consequences for running and future causal analyses can only be realised with permission from the responsible authorities. Minor incidental deviation for a specific causal analysis can be carried through without permission of the authorities. The protocol manager is responsible for notifying these incidental deviations towards the registration authority.

3.6 The Dutch Environmental Risk Indicator for Plant Protection Products (NMI 3)

In Protocol Phase 1 information is collected about the agricultural use of pesticides and the resulting emission patterns. Such information at national scale is currently available from the Dutch Environmental Risk Indicator for Plant Protection Products: NMI 3.

The NMI 3 was developed to support the end evaluation of the crop protection policy of the Dutch Government (EDG-2010). The concepts and the methodology of the NMI 3 are described in (Kruijne et al., 2011ab). The NMI 3 includes modules for calculating emission to surface water resulting from atmospheric deposition, spray drift, drainage flow, point sources, discharge from greenhouses with soilless cultivation, and from greenhouses with soil bound cultivation (Figure 3.5).

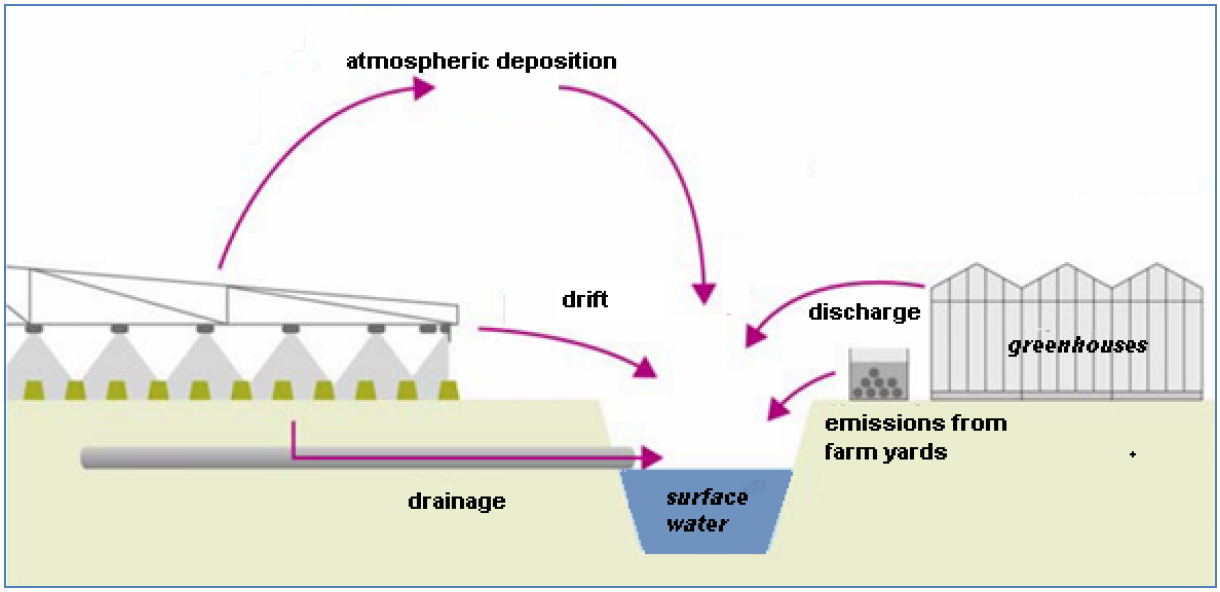


Figure 3.5: Emission pathways in the Dutch Environmental Risk Indicator for Plant Protection Products (NMI 3). (Figure adapted from Van der Linden et al., 2012)

The NMI 3 is comprised of a number of simple modules, i.e. compared to the more refined tools for specific types of application which may be used in registration. The NMI 3 combines a wide range of information about pesticide usage, emission factors, the geographical distribution of crops, surface water, soil and climate properties, and substance properties. The application type determines the emission pathways considered (Appendix VII).

The primary goal of the NMI 3 is to produce trend lines of the overall, annual-based emissions towards surface water and the corresponding aquatic risk. The results can also be used for ranking, for comparing applications of similar type, and for visualisation of spatial patterns in calculated emission indicators. The surface water compartment is defined in the model as the watercourse adjacent to the field treated.

The NMI substance database contains physico-chemical, fate and ecotoxicological parameters of plant

protection products and metabolites, derived from EU and Dutch authorisation dossiers (Ctgbase). Pesticide usage is described in terms of national average applications. These applications are prepared from farm/crop based survey data and from additional information on the implementation of drift reducing measures and on the use restrictions prescribed by the Dutch registration authority Ctgb. The resulting national average applications in the model differ from real applications according to the product label, with respect to the rate applied. The whole of national average applications in a particular model crop cannot be compared with common crop protection activities at individual farms, because all crop locations in the model are treated (at an adjusted rate) with any substance applied at one or more of the farms represented in the survey.

The use of national average applications and relatively simple emission models implies that the calculated exposure concentration cannot be directly compared with a safe concentration (e,g. the AA-EQS). For this reason, only the emission indicators are included in the Fact Sheet. Exposure concentrations are not included in the Fact Sheet. Some of the emission models in the NMI 3 are derived from tools which were developed for use in registration, whereas other models are based on simple worst case scenarios. Comparison of emissions (loads) over different application types, calculated using dissimilar models, may result in misleading conclusions about the relative importance of these application types. The best option in such cases is to combine these results with the other topics addressed in the Fact Sheet and with the expert consultation in Phase 2. Crop maps and compound properties used in the NMI 3 are available at http://www.pesticidemodels.eu/nmi/home.

The NMI 3 can also be used with alternative use data or with values for substance properties reported in the most recent registration dossier.

3.7 Application of the Pesticides Atlas

In Chapter 2 the Pesticides Atlas (www.bestrijdingsmiddelenatlas.nl) was briefly characterised. All the monitoring data registered in this Atlas can be used as input in the causal analysis. The following products are available:

- List of problematic substances (Chapter 2).
- Maps per year for the period under investigation showing observed exceedances of water quality standard(s). This enables identification not only of regions with no, or, frequent exceedances, but also of regions in which the pesticide under investigation has been measured and those in which there has been insufficient monitoring.
- Diagrams per year for the period under investigation showing the frequencies of classes of exceedances.
- Diagrams per year for the period under investigation showing the frequencies of quality standard exceedances per month; this comprises absolute as well relative (%) frequencies.
- Tables per two years for the period under investigation showing significant correlations between land use type and concentration or quality standard exceedances.

More detailed information can be extracted from the Pesticides Atlas on request, for example tables of frequencies of quality standard exceedances per month in different regions (e.g. water board districts), or more detailed information about the measurements.

4 Feedback procedure

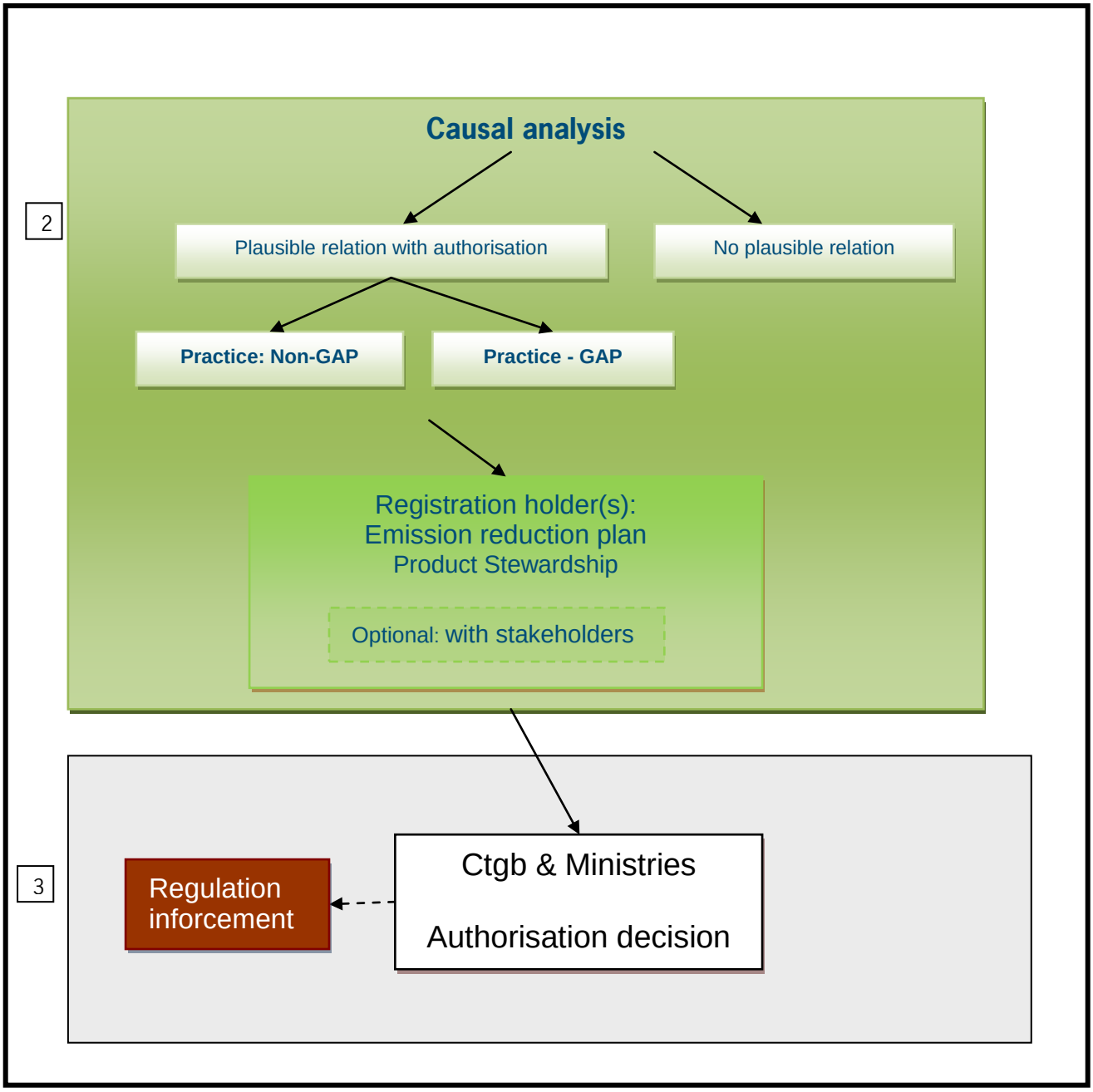


Fig. 4.1 Feedback procedure (3) in the grey box. Dotted arrows indicate actions that are not necessary in all cases. The feedback to regulation enforcement may take place via the authorisation holder(s) or based on the authorisation decision published by the Ctgb. A causal analysis does not always result in an authorisation decision.

This chapter, Feedback procedure, describes the role of the causal analysis and Emission Reduction Plan (ERP) in authorisation procedures and which feedback takes place between the stakeholders involved. The set-up of the causal analysis has been explained in the previous chapter. The boundary conditions set by the Decision Tree Water Project group are described separately in the textbox below.

Policy decisions / boundary conditions

Consequences for authorisations
The possible consequences of the outcome of the causal analysis for a specific authorisation depend on whether a plausible relation has been found between an authorisation (application according to GAP) and the standard exceedances. In case of a plausible relation, the Ctgb may decide not to prolong the existing authorisation or decide negative on a new authorisation request if the authorisation holder does not submit an appropriate emission reduction plan (ERP).
If there is no such a plausible relation, the Ctgb cannot make an autonomic negative authorisation decision in consequence of monitoring data.

Problematic substances
The number of substances for which a causal analysis is requested is a political choice. The project group has decided to work with a non-limitative list of problematic substances. If a regular re-authorisation request concerns a substance on this list, a causal analysis and emission reduction plan are required. For the problematic substances with the highest ranking a causal analysis and emission reduction plan are requested independent of the regular authorisation period.
The Monitoring working group proposes that the conditions for requesting such an analysis are reconsidered as soon as a better empirical picture of the workload for the Ctgb and the authorisation holder(s) is obtained. One option is to request a causal analysis in situation A (4.1.1.) only for those substances scoring a minimum number of points according to the ranking method described in Section 2.1.

Duration ERP and monitoring of results
There is no preset (maximum) period after which the results of the an emission reduction plan should be visible. The authorisation holder includes in her plan what effect on the exceedances is expected and within which time. The Ctgb judges whether the ERP fits well with the outcome of the causal analysis and whether the described reduction of standard exceedances and the time at which they occur are realistic.
The responsible ministries (of Economic affairs and of Infrastructure and the Environment) decide whether the suggested timeframe and the expected emission reduction are acceptable.

On a yearly basis, the authorisation holder informs the ministries and Ctgb about the progress of the implementation of emission reduction plan and reduction of exceedances. If insufficient progress is observed, it may be necessary to adjust the ERP. Again the ministries decide whether the proposed actions are expected to be sufficient.

4.1.1 Causal analysis and ERP in the draft registration report

For substances identified as problematic, the Ctgb may decide that a causal analysis is required. The outcome of the causal analysis is always used by the authorisation holder(s) to formulate an emission reduction plan (ERP).
The causal analysis protocol is applicable for substances with (expected) relevant use as a PPP. Such an analysis may be requested in two types of situation:

Situation A:
Regular re-authorisation: an authorisation holder files for a prolongation of an existing authorisation. The request for a causal analysis applies for all substances identified as problematic substances.

Situation B:
For the most problematic substances:

I. Interim review of existing authorisations, independent of the regular authorisation period.
II. New authorisation requests (table 4.1) for substances already on the market as a PPP.

Criteria for identifying the most problematic substances are to be set by the ministries.

The need to execute the causal analysis in situation B-II, for new authorisations (table 4.1) depends on

1) The estimated risk of breaching the quality standard
2) The availability of a causal analysis and ERP for this substance

ad 1) If the risk is estimated to be lower than for the existing authorisations, the use of this protocol is not needed. Ctgb assesses this estimation of the applicant with the decision scheme in Figure 4.2. If the risk is estimated to be comparable or higher, step 2 applies:

ad 2) Since situation B applies, a causal analysis and ERP are requested for existing authorisations. If the causal analysis and ERP are available, they need to be integrated in the draft registration report for new authorisation requests of this substance. Under the PPP Directive 1107/2009 it is foreseen (personal communication Ctgb and Nefyto, see also EU/1141/2010), that a pre-submission meeting with the registration authority of the zonal reporting member state (zRMS) is held before submitting the draft registration report.
If the Netherlands is the zRMS, the following procedure is proposed: during the pre-submission meeting the completeness of the dossier is assessed. If this meeting is held and no causal analysis and ERP are available at this particular moment, the authorisation request will be submitted and the procedure will be followed without these documents. If later, at the time of the authorisation decision, the causal analysis and ERP have become available, the integration of these documents in the draft registration report will be requested as an additional question for information by the registration authority.
In case no pre-submission meeting takes place, the availability of a causal analysis and ERP will be checked by the registration authority at the time of the authorisation decision.
If another member state is zRMS, and the Dutch registration authority receives an authorisation request, the Netherlands is a so called 'concerned Member State' (cMS). In this case there is no such pre-submission meeting foreseen in the Netherlands. The registration authority will then check as part of the completeness check for the national addendum, if a causal analysis and ERP should be part of the dossier.

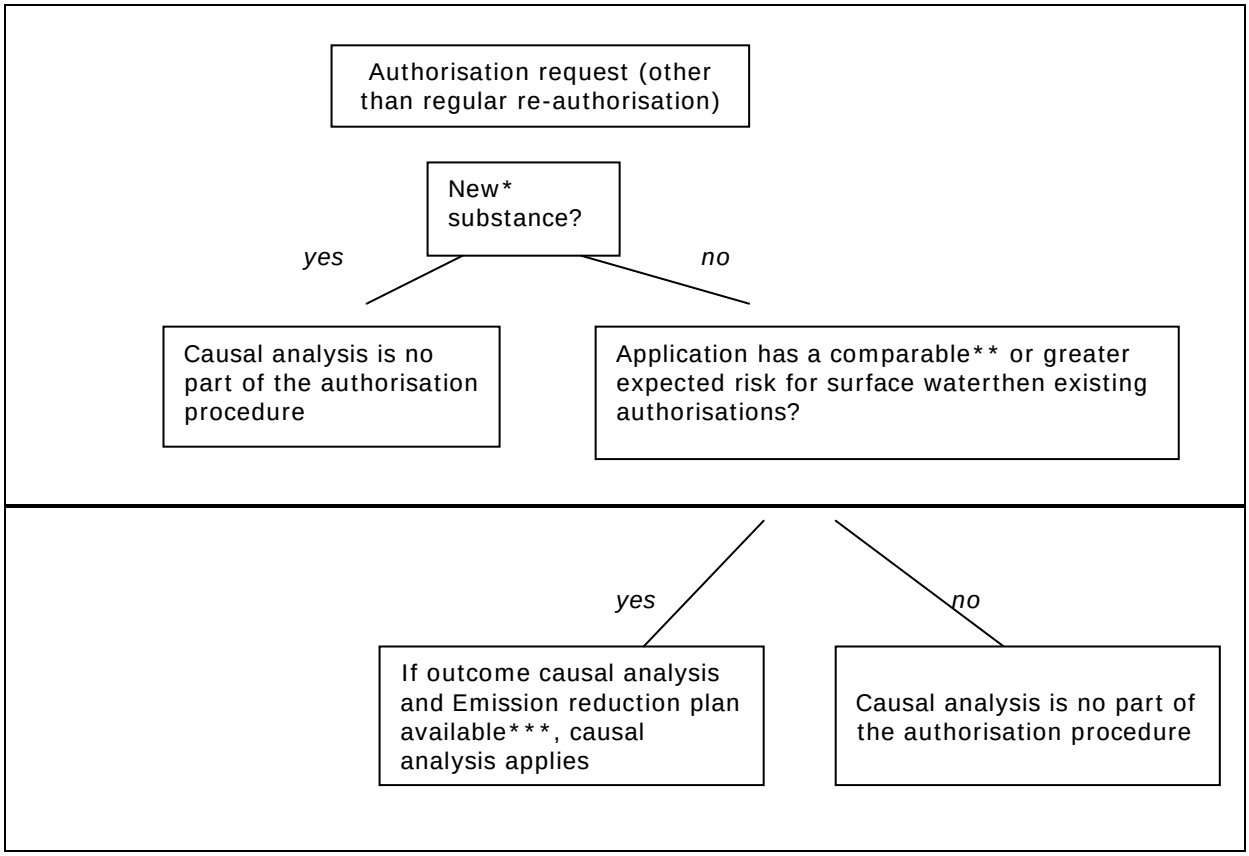


Figure 4.2. Decision scheme for the application of the protocol for causal analysis for authorisation requests for substances in 'Situation B'. This does not include the regular re-authorisation.
** Not authorised as a PPP*
*** Comparable crop and application method*
**** At the time of filing the request. If available later (at latest at the moment of the authorisation decision, an additional request to apply the outcomes may be filed by the authorisation authority.*

The above scheme applies for the authorisation requests that can be found in table 3.1. For a so called 'Dringend Vereiste Toelating (DVT) the protocol will not be applied, as this implies an authorisation with urgency for one year or season.

Code)	**Beschrijving type aanvraag**
TG	Toelatingsaanvraag (nieuw middel, kan van bestaande stof zijn maar kan ook een nieuwe stof zijn)
TVG	Aanvraag voorlopige toelating (stof nog niet geplaatst in EU)
UG	Uitbreidingsaanvraag van reeds toegelaten middel
VUG	Vereenvoudigde uitbreiding (= uitbreiding naar vergelijkbaar gebruik)
WGGAG	Aanvraag tot wijziging gebruiksvoorschrift

WERG	wederzijdse erkenning (hierbij dient Ctgb de beoordeling van andere lidstaat over te nemen, wel mogen een aantal aspecten waaronder risico aquatische organismen NL specifiek worden beoordeeld)

Table 4.1 Categories of authorisation requests (in Dutch)

Update problematic substances

The authorisation holders of substances for which situation B-I applies, are requested by the authorisation authority to submit a causal analysis and ERP. In case of (re-)authorisation requests (situation A and B-II) it is the applicant's responsibility to verify with the list of problematic substances whether a causal analysis and ERP need to be included in the draft registration report.
As described in chapter 2, the list of problematic substances is updated once a year and valid starting January 1st of every year. To determine the necessity of a causal analysis and ERP for regular re-authorisations (situation A) and new authorisation requests of already registered substances (situation B-II) the list of problematic substances valid at the date of the pre-submission meeting applies. In case there is no pre-submission meeting, the list valid at the date of submission applies.

PPP only

The Protocol is not used for analysis when use of the substance (or its parent substance in case of a metabolite) as a plant protection product (Ctgb substance category 'L' = 'Gewasbeschermingsmiddelen') is not permitted and/or clearly not causing the quality standard exceedances. If use as a PPP is not relevant, but the authorisation holder has information on the use and emission of the substance anyway, this information is reported to the Ctgb.

4.1.2 Emission reduction plan: set up

The ERP can consist of different types of measures and involve several stakeholders. In case the causal analysis shows that it is plausible that application according to GAP resulted in exceedances of the water quality standards, there will be a proposal for a change in the GAP. This means that the authorisation holder suggests an adjustment of the authorisation.
If it is plausible that non-GAP use resulted in these exceedances, other so called Product Stewardship measures will be proposed. If there is no plausible cause found, further research to reveal the causes of the standard exceedances can be proposed. In case the water quality standards are not reached in the following years, emission reduction will be necessary to reach the WFD goals.

4.1.3 Authorisation decision

The causal analysis and ERP are sent to the registration authority (Ctgb) and involved ministries. The Ctgb has to assess the completeness and quality of the causal analysis and justification of the proposed actions described in the ERP. Representatives of the ministries of Economic affairs and Infrastructure and Environment will decide whether the time frame for actions and water quality improvement are acceptable. The Ctgb may decide negatively on the authorisation request in case the absence of a causal analysis and/or the ERP not being accepted as justified in consideration of the causal analysis. In case of a plausible relation with an authorisation (application according to GAP), the expected effectiveness of the ERP has consequences for the authorisation decision. If the Ctgb judges that the ERP cannot be expected to reduce the quality standard exceedances sufficiently in the described timeframe, the Ctgb may decide negatively on a re-authorisation request (situation A) or a request for a new authorisation for a problematic substance (situation B-II).
If applicable, the main conclusions of the causal analysis and the essence of the ERP will be used in registration report Part A (Risk management - national assessment) to underpin the authorisation decision. This section is available as an appendix to the decision on the Ctgb website and will be the information source for all involved parties, ministries, agricultural inspection services (Nederlandse Voedsel en Warenautoriteit, NVWA), water authorities, non-governmental organizations (NGOs), etc.. Details of the

causal analysis and ERP will be included in the underlying risk assessment (Part B.5) of the registration report.

No authorisation decision
If a causal analysis and ERP concern an existing authorisation they do not always result in an authorisation decision: if there is no plausible relation with a specific authorisation for which situation B-1 applies, this authorisation can remain unchanged without a formal authorisation decision.

4.1.4 Effectiveness of the emission reduction plan

The effectiveness of an emission reduction plan is judged based on the water quality monitoring data and the yearly update of the list of problematic substances. The protocol manager informs the ministries and Ctgb of the progress made every year. If necessary, the ERP is adjusted and elongated until the standard exceedances are solved.
The Ctgb can derive from the substance labelling in the list of problematic substances, what the status of the substance is in case situation A or B applies for the same substance in a later year. Has a causal analysis been carried out and has an ERP been initiated and if so, what are the starting and end date? Based on this information the Ctgb determines in cooperation with the involved ministries whether the effect of the ERP should be visible in the monitoring results yet and if there is need for a renewed ERP (see 'boundary conditions' for more details).

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Milieukwaliteitsnormen voor oppervlaktewater: www.wateremissies.nl

Bestrijdingsmiddelenatlas: www.bestrijdingsmiddelenatlas.nl

NMI 3: http://www.pesticidemodels.eu/home

Normen
- http://www.helpdeskwater.nl/emissiebeheer/normen_voor_het/normen_zoeksysteem/
- http://www.rivm.nl/rvs/normen/

Besluit kwaliteitseisen monitoring water, Regeling monitoring KRW:
- http://www.helpdeskwater.nl/
- http://www.wetten.nl

Appendix I: Abbreviations and Glossary

Abbreviations

AA-EQS: Annual Average - Environmental Quality Standard
BMA: Bestrijdingsmiddelenatlas
BKMW: Besluit kwaliteitseisen en monitoring water 2009
CBS: Centraal Bureau voor de Statistiek
CML: Centrum Milieuwetenschappen Leiden
CPS: Crop Protection Sharepoint
Ctgb: College voor de toelating van gewasbeschermingsmiddelen en biociden
DVT: Dringend vereiste toelating
EDG: Evaluatie Duurzame Gewasbeschermings
EL&I: Economie, Landbouw & Innovatie
EQS: Environmental Quality Standard (NL: MKN)
ERP: Emission reduction plan
GAP: Good Agricultural Practice
I&M: Infrastructuur en milieu
KRW: Kaderrichtlijn Water (EN: WFD)
KRW-WL: Kaderrichtlijn Water – Waterlichaam (EN: WFD waterbody)
LEI: Landbouw Economisch Instituut
MAC-EQS: Maximum Acceptable Concentration – Environmental Quality Standard
MKN: Milieukwaliteitsnorm (EN: EQS)
MPC: Maximum Permissible Concentration (NL: MTR)
MTR: Maximaal Toelaatbaar Risico (EN: MPC)
NGO's: Non Governmental organizations
NMI: Nationale Milieu-indicator (Dutch Environmental Risk Indicator for Plant Protection Products)
NVWA: Nederlandse Voedsel en Warenautoriteit
PPP: Plant protection product
RAC: Regulatory Acceptable Concentration
WFD: Water Framework Directive (NL: KRW)
INS: (Inter-)nationale Normen Stoffen
zRMS: zonal reporting member state

Glossary

Term	Definition	Source
Environmental Quality Standard (EQS)	the concentration of a particular pollutant or group of pollutants in water, sediment or biota which should not be exceeded in order to protect human health and the environment.	EN: WFD 2000/60/EC, Art. 2(35) http://ec.europa.eu/environment/water/water-framework/index_en.html
AA-EQS	annual average concentration (AA-EQS) to protect against the occurrence of prolonged exposure	EN: draft EQS guidance NL: Nota van toelichting bij het ontwerp-Besluit Kwaliteitseisen en monitoring water http://www.kaderrichtlijnwater.nl/publicaties/juridische/?ActItmIdt=18374
MAC-EQS	maximum acceptable concentration (MAC-EQS) to protect against possible effects from short-term concentration peaks	EN: draft EQS guidance NL: Nota van toelichting bij het ontwerp-Besluit Kwaliteitseisen en monitoring water http://www.kaderrichtlijnwater.nl/publicaties/juridische/?ActItmIdt=18374
Maximum Permissible Concentration (MPC)	In Dutch pollutant policy (VROM, 2004) the MPC is defined as the scientifically-based standard indicating the concentration in an environmental compartment at which no effect to be rated as negative is to be expected for ecosystems;	Brochure (Inter)nationale normen stoffen (VROM, 2004): http://www.vrom.nl/pagina.html?id=2706&sp=2&dn=w015 KRW-guidance Lepper, 2005
Regulatory Acceptable Concentration (RAC).	The Regulatory Acceptable Concentration (RAC) is the effects assessment endpoint, expressed in terms of a permissible concentration in the environment, which is used directly in the risk assessment by comparing it with the appropriate field exposure estimate (e.g. PEC_{max}).	ELINK
assessment factor	Numerical adjustment used to extrapolate from experimentally determined (dose-response) relationships to estimate the agent exposure at which an adverse effect is unlikely to occur. See also: safety factor and uncertainty factor	Risk assessment of chemicals: an introduction. 2nd edition 2007. C.J. Van Leeuwen and T. Vermeire, eds. Dordrecht, Netherlands, Springer.

Correlation *(correlatie)*

A statistical measure of association between two variables, e.g. land-use and concentration of a pesticide in surface waters.

Emission indicator

Annual load to surface water adjacent to the crop treated (kg). The emission indicator applies to the national scale and is calculated with the model NMI 3 based on national average usage data.

Exemption *(Vrijstelling)*

Regulation through which a not authorised application of a PPP was permitted for a year or season. This regulation was ended by 1-1-2008.

Detection limit *(LOD - detectielimiet)*

The lowest concentration of a pesticide that can be measured with a certain physicochemical technique, usually approximately 1/3 of the LOQ.

Limit of quantification LOQ *(kwantificeringslimiet)*

The lowest concentration of a pesticide that can be measured with a specified certainty.

Limit of reporting LOR *(rapportagegrens)*

The lowest concentration of a pesticide that is (to be) reported. The LOR is equal to or larger than the LOQ

Measured *(gemeten)*

Results of measurements may be below, above or equal to the detection limit.

Measurement *(meting)*

Carried out at one monitoring site *(meetpunt)* at one date/time.

Measurement observed or above the detection limit (*aangetoond*)

Result of measurement is positive; the pesticide has been found in a measurable amount.

Measurement below detection limit *(niet aangetoond)*

A pesticide has been measured, but since results are below the detection limit, it is uncertain whether the pesticide is present and, if present, at what concentration.

Monitoring site *(Meetpunt)*

A single site of which the geographical coordinates have been documented and on which monitoring of pesticides is taken place regularly.

Significant *(idem)*

In relation to statistics, used for an association between variables or difference between groups that cannot be ascribed to chance alone given an accepted level of error (often 5%).

Appendix II: Rating quality standard exceedances: background

This document provides background on the procedure for identifying 'problematic compounds', Part 1 of the methodology for feedback of monitoring results to the approval process.

To support this procedure, the exceedances of standards reported in the Pesticides Atlas 2003-2008 have been analysed (Table 1) to obtain the number and percentage of standard-exceeding substances, the number and percentage of standard-exceeding monitoring sites and measurements, and the distribution, average and maximum of exceedances. The standard taken for this purpose was the maximum tolerable concentration (MTR). The degree of standard exceedance is calculated as concentration divided by MTR. Calculations on standard exceedance can only be performed on testable observations.[1]

In this procedure a substance's score is determined by three criteria:

- per monitoring site:
    - type of water/monitoring site (A)
    - degree of standard exceedance (B)
- % of standard-exceeding monitoring sites (C).

The substance's score is ultimately calculated as C*Σ(A+B).
For criteria B and C, category bounds (Tables 2 and 4) and weights per category (Table 3 and 5) have also been elaborated.

There is a number of options for the category bounds: subdivision into categories or continuous values, with or without transformation. Van der Hulst and Kalf's original proposal has also been included in the tables. Based on their proposal, a final recommendation has been made (final row in Tables 2, 3, 4 and 5), which is summarized below and is as close as possible to the original proposal. In doing so, the weighting has been simplified as far as possible, making the minimum score equal to 1.

There are many (satisfactory) options; the working group has opted for the following.

	B. Degree of exceedance X and (weighting) of EQS or MTR			
A. Type of water (weighting)	1≤x≤2 (0)	2<x≤4 (1)	4<x≤13 (2)	x>13 (3)
Other waters (1)	1	2	3	4
WFD water body Other mon. sites (2)	2	3	4	5
WFD water body Reporting sites (4)	4	5	6	7

N.B. Monitoring sites on minor ditches outside the water bodies falling under the Water Framework Directive (WFD) have been provisionally omitted.

[1] A testable observation is a measurement that exceeds the limit of reporting, or the LOR is lower than the standard. In the case of a non-testable observation, a measurement is <LOR threshold is higher than the standard.

For criterion C we have opted for the percentage of standard-exceeding monitoring sites.

Example calculation:

	Degree of MAC exceedance	Degree of AA exceedance	Number of sites
Location 1: WFD monitoring site, 2009 only	4 and 2 and 1	3	6
Location 2: non-WFD water-body, 2009 only	20 and 2 and 1.5	2	4
Location 3: WFD water body, non-WFD mon. site, 2007	1.3 and 1.1	1.8	2
Location 3, 2009	12	4	4

AA = annual average standard, MAC = maximum concentration standard

The EDG procedure
As part of the evaluation of the sustainability of crop protection in the Netherlands the so-called SNO calculation method is used to determine the sum (S) of standard exceedances (in Dutch: NO) across all substances. Here, the degree of standard exceedance is calculated somewhat differently: NO = (concentration/standard) – 1 and ≥0. At a concentration exactly equal to the standard, NO is thus equal to 0. The exceedances thus calculated are summed across all monitoring sites and all substances. Another difference is that calculations are based on the 90% percentile as well as the NR (negligible risk) level and the MTR (Maximum Tolerable Risk).

Table 1. General information for the period 2003-2008 on number and percentage of standard-exceeding substances, monitoring sites and measurements and on degree of standard exceedance (including the log-transformed standard exceedance; the values presented have been reconverted following calculation). Standard employed: MTR. The data have been broken down per year and per standard-exceeding substance (average and maximum). No. = number; st.-exg. = standard-exceeding; st. exc. = standard exceedance; comp. = compounds; mon. sites = monitoring sites; meas. = measurements; av. = average; max. = maximum.

	'03	'04	'05	'06	'07	'08	'03-'08
No. of st.-exg. compounds	85	59	77	77	99	92	166
No. of testable compounds	211	233	255	339	390	386	433
Total no. of compounds	226	265	291	427	484	477	509
% of st.-exg. compounds	40.3	25.3	30.2	22.7	25.4	23.8	38.3
No. of st.-exg. mon. sites	283	186	258	235	378	334	783
No. of testable mon. sites	592	448	567	575	618	678	1356
% of st.-exg. mon. sites	47.8	41.5	45.5	40.9	61.2	49.3	57.7
Av. no. of st.-exg. mon. sites/st.-exg. comp.	11.1	7.7	6.5	6.8	9.6	8.6	8.5
Max . no. of st.-exg. mon. sites/st.-exg. comp.	72	76	84	123	208	172	208
Av. % of st.-exg. mon. sites/st.-exg. comp.	43.7	32.1	39.8	22.9	28.1	28.7	32.4
Max. % of st.-exg. mon. sites/st.-exg. comp.	100	100	100	100	100	100	100
No. of st.-exg. meas.	1971	886	890	1012	1709	1589	8057
No. of testable meas.	113998	79164	122355	157816	207350	212687	893370
% of st.-exg. meas.	1.73	1.12	0.73	0.64	0.82	0.75	0.90
Average st. exc.	36.1	119.1	248.2	32.6	40.3	66.4	76.7
Maximum st. exc.	1660	11250	37500	2923	4154	11571	37500
Average log st. exc.	7.5	8.1	6.0	5.5	5.5	5.7	6.3
Av. of av. st. exc./st.-exg. comp.	32.5	121.9	458.2	41.0	77.4	65.4	126.9
Max. of av. st. exc./st.-exg. comp.	333	2625	26125	1500	3300	1348	26125
Av. of av. log st. exc./st.-exg. comp.	7.0	7.2	8.7	5.2	5.4	6.8	6.5
Max. of av. log st. exc./st.-exg. comp.	333	1361	23519	1500	3300	1096	23519
Av. of max. st. exc./st.-exg. comp.	107	434	1162	117	175	302	365
Av. of max. log st. exc./st.-exg. comp.	21.1	23.4	21.9	12.7	15.1	17.7	17.9

Table 2. Options for standard exceedance categories. Standard employed: MTR. With quartiles observations are divided into groups of (approx.) 25%. With'quarter ranges'1/4 of a range is taken for each category bound.

	categ. 1	categ. 2	categ. 3	categ. 4
Standard exceedance				
(1) Quartile	1-1.9	1.9-4.0	4.0-13.1	>13.1
	25%	25%	25%	25%
(2) Quarter range	1-9,000	9,000-19,000	19,000-28,000	>28,000
	99.85%	0.11%	0.02%	0.02%
Hulst-Kalf	1-2	2-3	3-5	>5
	26.5	14.0	15.6	43.9
Logarithm of standard exceedance				
(3) Quarter range	1-30	30-1,000	1,000-30,000	>30,000
	84.0	15.0	1.04	0.02
(4) Simple A	1-100	100-1,000	1,000-10,000	>10,000
	92.3	6.64	0.92	0.14
(5) Simple B	1-10	10-100	100-1.000	>1.000
	69.3	23.0	6.64	1.06
No category bounds (6)				
Proposal	1-2	2-4	4-13	>13

Table 3. Options for weighting standard exceedances. Standard employed: MTR. Weights calculated on basis of average category values relative to average value of first category, here set to 1.

			categ. 1		categ. 2		categ. 3		categ. 4
Simple			1		2		3		4
Weighted	(1)	1		2		6		1300	
		(2)	1		3		5		7
		(3)	1		70		2000		2200
		(4)	1		11		110		1100
		(5)	1		11		110		1100
	Hulst-Kalf	1		3		5		7	
	log	(3 etc.)	1		2		3		4
No categ. bounds		(6)	x NO of x log(NO)						
Proposal			0		1		2		3

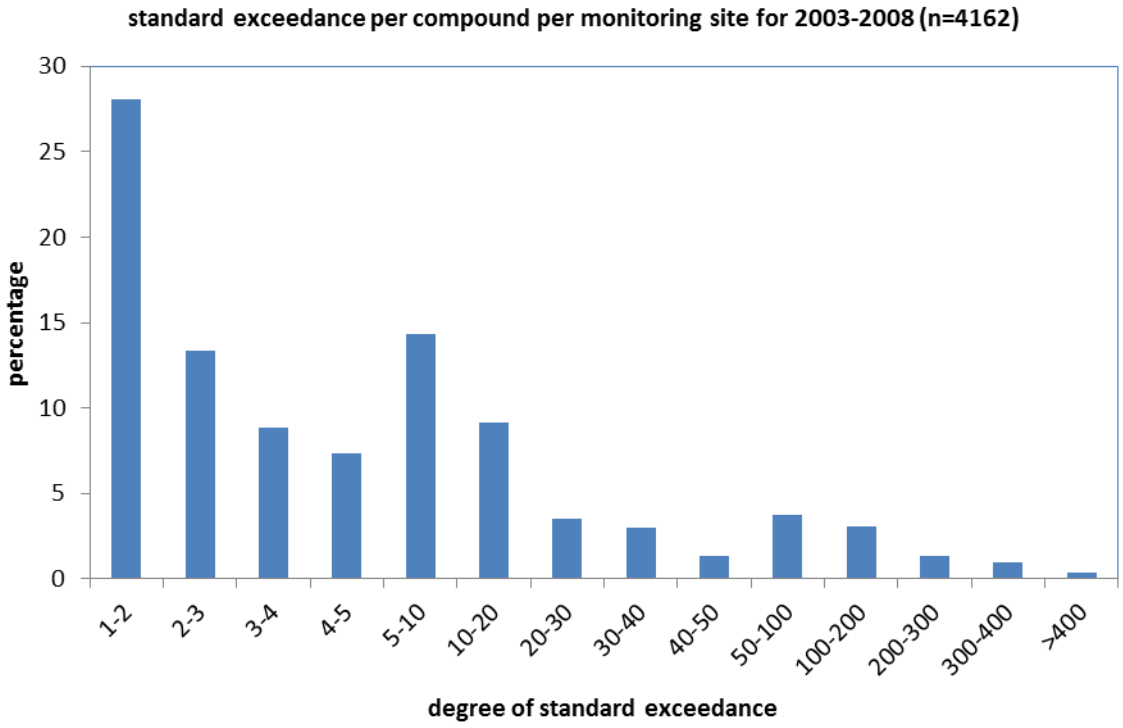
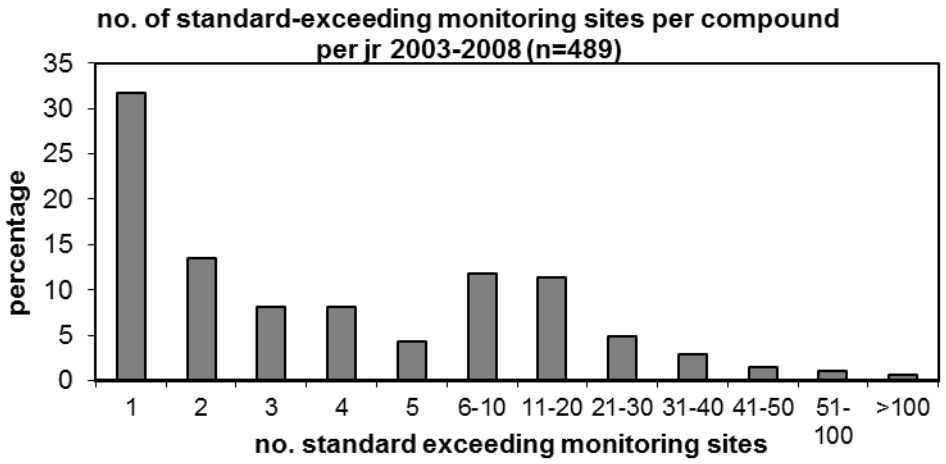


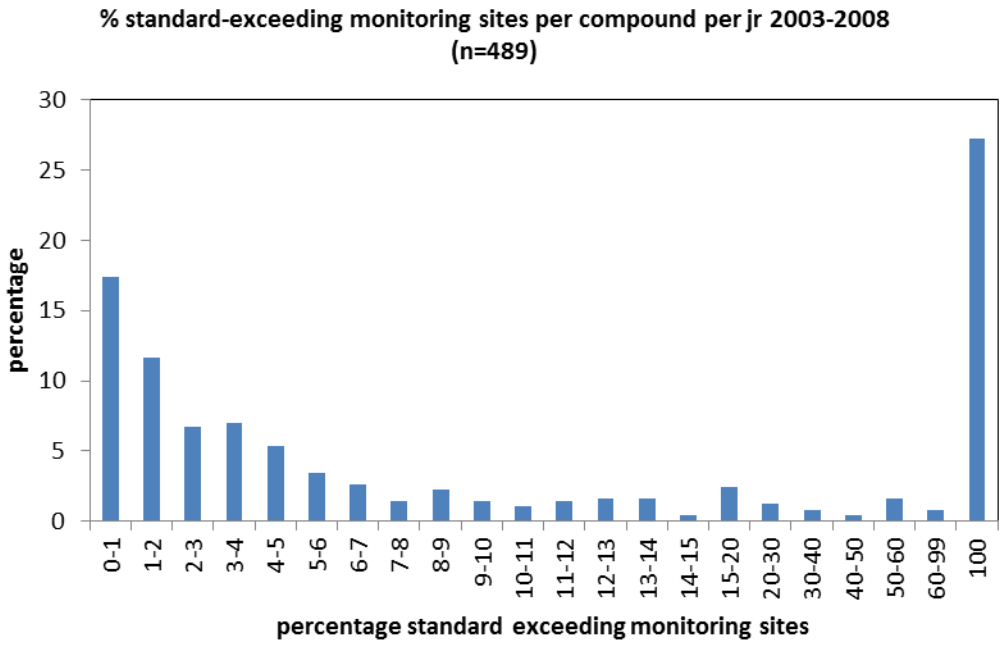
Table 4. Options for category bounds for number of percentage of standard-exceeding monitoring sites. Standard employed: MTR. See also Table 2.

		categ. 1	categ. 2	categ. 3	categ. 4
Number					
	(1) Quartile	1	2-3	4-9	>9
		32%	21%	22%	25%
	(2) Quarter range	1-50	50-100	100-150	>150
		98%	1%	<1%	<1%
	(3) log ¼ range	1-3	4-15	15-55	>55
		53%	32%	13%	2%
Percentage					
	(4) Quartile	0-1.6	1.6-5.7	5.7-100	100
		25%	25%	21%	27%
	(5) Quarter range	0-25	25-50	50-75	75-100
		69%	1.6%	2.2%	28%
	(6) log % range	0-3	3-10	10-30	>30
		35.7%	33.1%	11.2%	31%
	Hulst-Kalf 0-1	1-2	2-4	>4	
		17%	12%	14%	64%
No cat. bounds (7)					
Proposed percentage		0-2	2-6	6-100	100
		29%	23%	22%	27%

Table 5. Options for weights for number or percentage of standard-exceeding monitoring sites. Standard employed: MTR. See also Table 3.

		categ. 1	categ. 2	categ. 3	categ. 4
Simple		1	2	3	4
Weighted (1)	1	3	7	109	
	(2)	1	3	5	7
	(3)	1	4	15	66
	(4)	1	5	66	125
	(5)	1	3	5	7
	(6)	1	4	13	43
	H-Kalf	1	3	5	7
No categ. bounds	(7)	1) no weighting, or 2) x number, or 3) x percentage (0-100%)			
Proposal		1	2	3	4


no. of standard-exceeding monitoring sites per compound per jr 2003-2008 (n=489)
percentage
35
30
25
20
15
10
5
0
1
2
3
4
5
6-10
11-20
21-30
31-40
41-50
51-100
>100
no. standard exceeding monitoring sites


% standard-exceeding monitoring sites per compound per jr 2003-2008 (n=489)
percentage
30
25
20
15
10
5
0
0-1
1-2
2-3
3-4
4-5
5-6
6-7
7-8
8-9
9-10
10-11
11-12
12-13
13-14
14-15
15-20
20-30
30-40
40-50
50-60
60-99
100
percentage standard exceeding monitoring sites

Appendix III: Protocol for Causal Analysis of surface water quality standard exceedance

Introduction

This appendix describes the protocol to be used when a Causal Analysis is requested by the Ctgb as part of the information required for (re-)authorisation or interim review of an existing authorisation. The background of this Protocol is described in more detail in Chapter 3 of this report.

Before a causal analysis is started, the authorisation holder may check if there is reason to derive a new EQS. Also, for substances for which there is a potential risk that the substances of interest and related substances (for example isomers and esters) are not distinguished, a check on the applied method of analysis may be carried out. This is described in chapter 2, as final steps in the identification and ranking of substances.

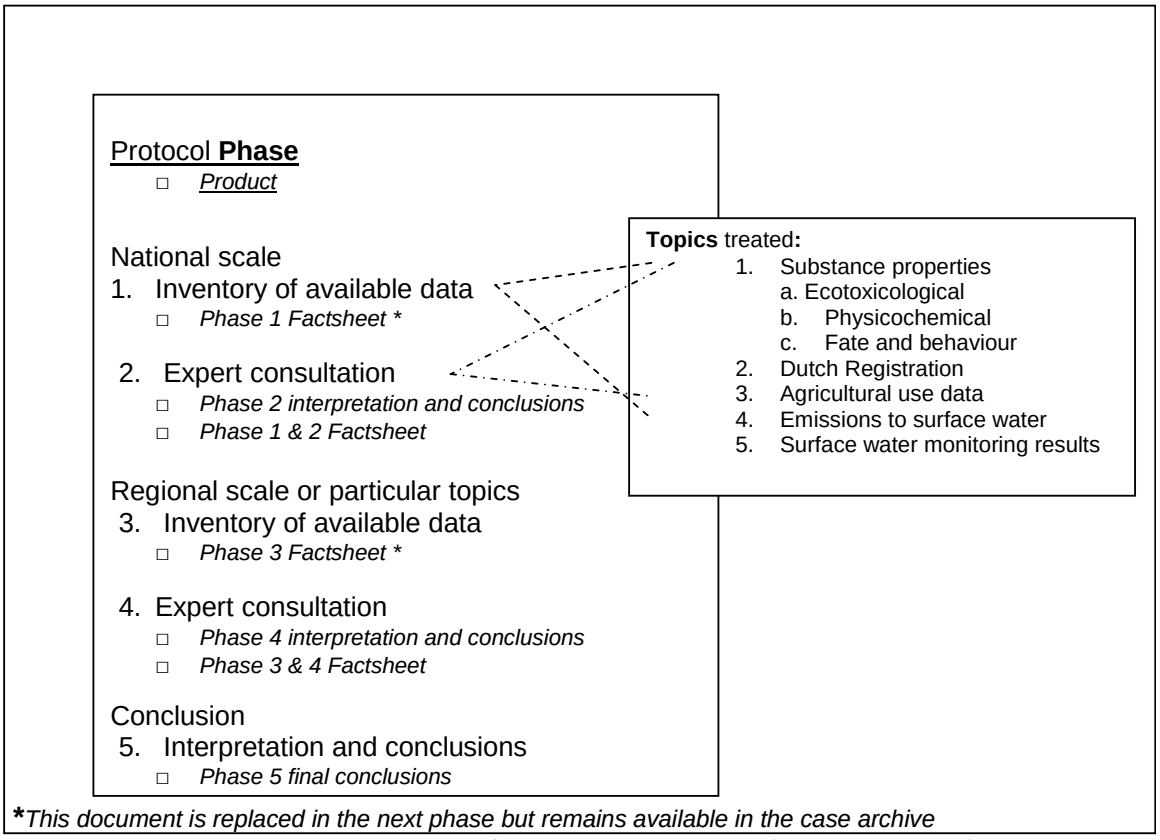


Figure III-1. Phases and documents in the Causal Analysis Protocol for exceedance of quality standards.

Templates are available for all standard documents ('products' in Figure III-1). The paragraphs and chapters in the templates correspond with the chapter and paragraph numbering in this protocol. Factsheets are to be made available in Dutch. Other case documentation can be written in Dutch and/or English language, depending on the preference of the protocol manager or the authorisation holder.

It is not always necessary to work through all the phases of the Protocol. For example, if a more detailed analysis proves unnecessary or is not expected to add any relevant information after Phase 2, then Phases 3 and 4 are skipped. Figure III-1 shows the phases and delivered products. Figure III-2 shows the optional shortcut.

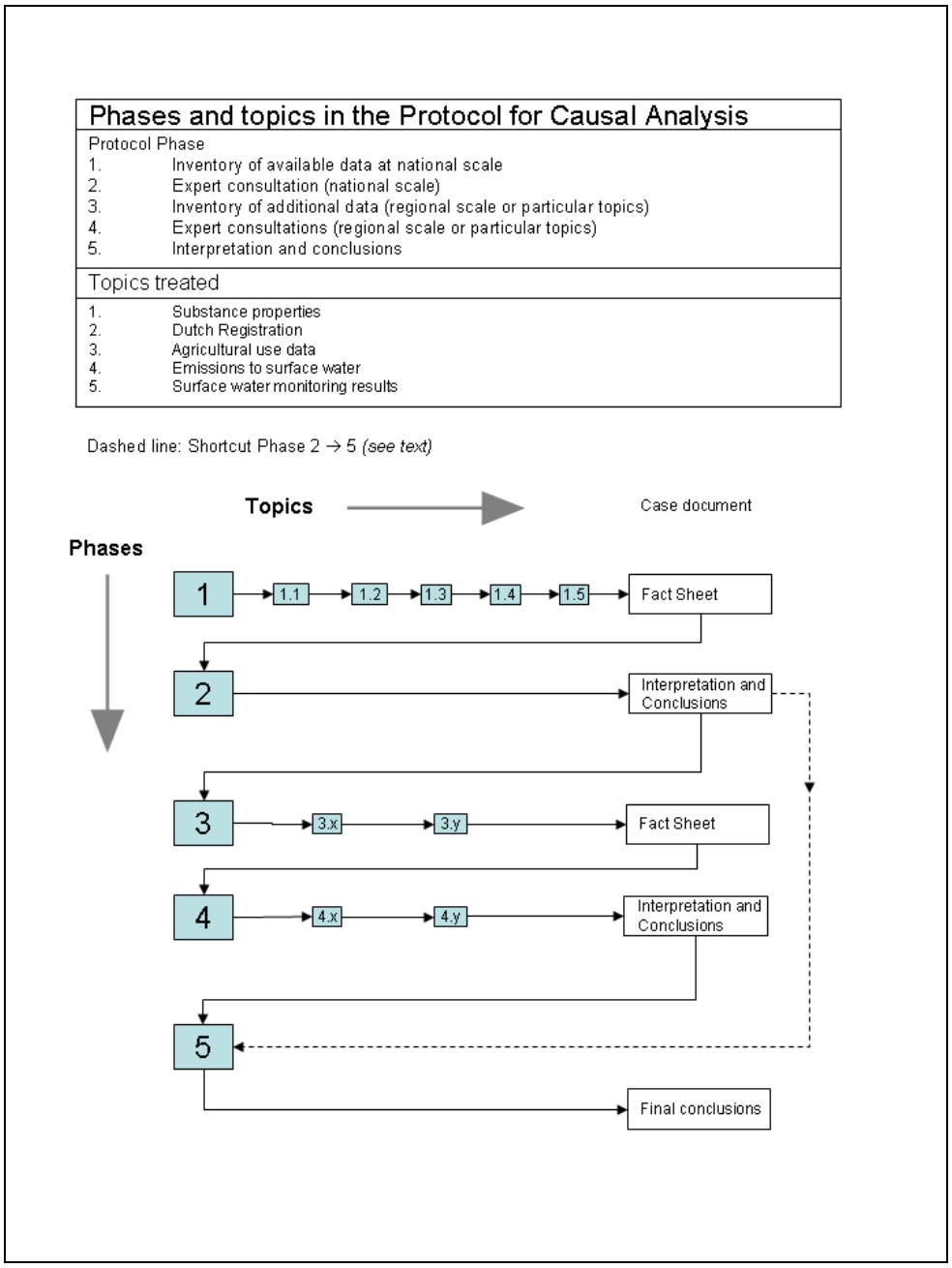


Figure III-2. Phases and subjects of the for Causal Analysis Protocol.

Part of the protocol below, refers to the Crop Protection Sharepoint (CPS). Use the protocol in combination with the CPS quick guides and the hints, given online while using the CPS.

Protocol initiation

A Causal Analysis may be carried out in co-operation with other authorisation holders that have authorisations for the same substance. In the case of regular re-authorisation or interim review of a substance, all authorisation holders may have had a request for a Causal Analysis.

- ☐ When applicable, decide on co-operation with other authorisation holders.
- ☐ Identify a protocol manager: one person with overall responsibility for carrying out the Causal Analysis.
- ☐ If it is the first Causal Analysis for this protocol manager, request the administrator of the Crop Protection Sharepoint (CPS, www.gewasbeschermingsplatform.nl/cms) for a CPS account.
- ☐ Login and go to 'Active analyses' and start a 'causal analysis' for this new Causal Analysis at the CPS using the 'wizard'. Include the substance name in the title.

Phase 1: Inventory of basic information, national scale

Phase 1 of the Causal Analysis is based on readily available, standard information sources. At this stage, there is no need for a detailed investigation of authorisation dossiers and information on the backgrounds of national-scale datasets. The result of Phase 1 serves as input for Phase 2. To prepare a standardised factsheet it is necessary to use only the sources listed below. Additional information from other sources can be added in Phase 2.

☐ Prepare the Phase 1 Factsheet (template available)

Phase 1 Factsheet consists of:

1. Introduction
   - ☐ Problematic substance and monitoring period
   - ☐ In case the substance is a metabolite: parent compounds (active ingredient of PPP)
   - ☐ Documentation overview and reading guide

2. Substance properties

Summary

Data in case the problematic substance is a metabolite:
- ☐ Ad 1: Both for the metabolite and the parent(s)
- ☐ Ad 2-6: Only for the metabolite
- ☐ Ad 7

Data:

2.1 Water quality standards

1. The lowest values of the toxicity for acute and chronic exposure (EC50) for fish, algae and daphnia.

2. The water quality standard that has been applied in the risk assessment for

authorisation.

3. The protocol manager is expected to use the most recent data available for emission calculations. Relevant data present in the NMI-database are send to the Ctgb, requesting a check on the availability of more recent data (endpoints). In case it is decided to use more recent endpoints calculation of the emission indicators, these newer data are listed in the table with substance characteristics used for the calculation. The old data remain visible by applying the 'strike through' font on the data from the NMI-database.
4. If available: The Environmental Quality Standards (EQS): the Annual Average (AA-EQS) and the Maximum Allowable Concentration (MAC-EQS);
5. In case no EQS is derived: the MPC* as a quality standard for chronic exposure and its legal status.

The most recent legal environmental quality standard is marked and made recognisable as such. New quality standards that have been derived but do not yet have legal status are also included.

6. Derivation of the surface water quality standards (methodology and assessment factors).
7. The difference between the water quality standard (EQS; MPC if no EQS is available) and the quality standard for chronic - and peak exposure used in the risk assessment.

2.2 Physico-chemical properties

8. Substance codes and physico-chemical properties and fate properties: average K_{om} in case of normal sorption behaviour, or $K_{om,basic}$, $K_{om,acid}$ and pK_a in case of pH-dependent sorption behaviour, geometric mean DegT50 for surface water and for soil, saturated vapour pressure, solubility in water, molar weight, formation fraction in case of metabolite, and more *(table with specifications available in template)*

2.3 Water analysis methods

9. Water analysis method(s), described in the registration file(s) for the substance.

2.4 Fate and behaviour

10. Describe the consequences of the physical chemical characteristics for the fate and behaviour of the substance in the environment. The values defining the substance properties are classified as high, average or low according to Appendix V.

Definitions of the various water quality standards are provided in the glossary (Appendix I).

Sources:

1,7: Substance database NMI 3 according to EDG-2010 (Alterra) or a more recent database if available (median values) and Ctgb (check on more recent data (endpoints).
2 CtgBase (Ctgb)
3: BKMW and MR Monitoring (www.overheid.nl); if not listed in BKMW or MR Monitoring: 'normen zoeksysteem' via www.helpdeskwater.nl
4, 5: 8: Registration file(s) of the substance9: To standardise the classification, the definitions given in Appendix V are used (extracted from RIVM report 679101022 (1995)): Manual for summarising and evaluating the environmental aspects of pesticides. Dutch authorisation

In case the problematic substance is a metabolite: all known parents are to be included. Data are given from the present, back to five years before the first year of the monitoring that led

to inclusion in the most recent list of problematic substances.

3. Authorised use

Summary

3.1 Products and applications

Data:

Overview of which products with the substance of interest as active ingredient have and have had an authorisation and for which crops. Include:

1. Authorisation number, license owner and expiry date (for sale and for use).
2. Authorised applications in combination with crop or crop group
3. Per product: restrictions of influence on the expected emission

Extra note:

□ **Latest restrictions indicate emission pathways**

If the most recent authorisations contain extra emission-reducing measures compared with older versions, this should be specified in an extra note. Extra restrictions provide an indication of emission pathways that may play a key role.

3.2 Exemptions

4. Exemptions for application not included in the regular authorisation

3.3 Label instructions

5. Legal usage prescription; period of application, number of applications, etc.
6. Users guide; period of application, number of applications, etc.

3.4 Good Agricultural Practice

7. GAP table per product

3.5 Substance category and non-agricultural use

8. Substance category
9. Non-agricultural use in the relevant period

Sources:

The Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) is the standard source of information on this subject:
1, 2, 3: Public online Ctgb database and
4: Ctgb or authorisation holder. Check www.overheid.nl (search for exemptions, 'vrijstellingen' in Dutch) if data from 2007 and earlier are needed.
5,6,7,8,9: Ctgb database Make sure to provide (a hyperlink to) a readable table. Sometimes the available tables have too small a font to be readable.

4. Agricultural use data

In case the problematic substance is a metabolite: all known parents with an agricultural use present in de NMI database are to be included.
The minimum set of data to be used are the most recent agricultural use data of the CBS for all crops, (grassland not available) and data of the LEI for grassland. Recent changes in the authorisation may be reason for the protocol manager to include additional LEI information of relevant years in the factsheet Phase 1 (LEI data are available per year) and/or more than one year

of CBS data (available for 2008; 2012 expected to be available at [1] in 2014). If this extra information is used, the protocol manager explains in the factsheet why these additional data are included.
In case LEI data are included it is recommended that all three years of the monitoring period are included + one year before the monitoring period of interest.

Summary of the main applications (crop and application method)

Data:

1. Usage according to farm survey statistics (Statistics Netherlands / CBS) and LEI (grassland only for the year of the CBS questionnaire or –optional- all crops for the measuring period + 1 year before):
   a. Usage per crop group (percentage of total amount applied).
   b. *Optional:* usage per crop and application method (percentage of total amount applied).
   c. Time distribution of usage per crop (per month)
   d. Sample statistics (number of growers applying the substance, and sample size).
   e. Average dosage per ha per year at farms where the active ingredient is applied.
2. Mention relevant, non-agricultural use and other possible sources of surface water contamination if information is available.

To obtain a standardised factsheet please include the following tables in the factsheet. (these can be generated by Alterra):

- TABEL 4.0: Landsdekkend gemiddeld volume verbruik per sector (CBS/LEI) TABEL 4.1a: Verdeling van het landsdekkend gemiddeld volume verbruik per gewas (CBS/LEI)
- TABEL 4.1a: Verdeling van het landsdekkend gemiddeld volume verbruik per gewas – zie Appendix VII (CBS/LEI, expertise van gewasbeschermingsdeskundigen)
- TABEL 4.1b: Verdeling van het landsdekkend gemiddeld volume verbruik per gewas en per soort toepassing – combinatie van toepassingsmethode en behandeld object – zie Appendix VII (CBS/LEI, expertise van gewasbeschermingsdeskundigen)
- TABEL 4.2: Procentuele verdeling op maand/kwartaalbasis van het jaargemiddeld verbruik per gewas (CBS/LEI, expertise van gewasbeschermingsdeskundigen)
- TABEL 4.3: Steekproefomvang en aantal steekproefbedrijven met gebruik (CBS)

Optional:

- TABEL 4.4: Gebruik per sector/gewasgroep per jaar volgens het Bedrijfsinformatienet (BIN van LEI-WUR)

□ **Short-cut:** Is the major use agricultural or non-agricultural? If it is implausible that agricultural use of the substance as a PPP (Ctgb category 'L' = 'Gewasbeschermingsmiddelen') is responsible for the majority of the quality standard exceedances, skip the remaining topics and continue with the final conclusions (Phase 5).

□ **Check data for consistency:** data from different sources (e.g. LEI and CBS) should be checked for any significant differences. State in the factsheet whether significant differences occur.

□ **Include the following standard note** in the Phase 1 Factsheet: 'Illegal use is expected

not be present in the CBS or LEI data'. Illegal use is addressed in Phase 2 of the analysis.

Sources:

1: Statistics Netherlands (CBS) questionnaires (dataset(s) closest in time to the relevant monitoring period) and LEI-Wageningen UR; Company Information Network (BIN). In contrast to the CBS databases, BIN contains annual use data in agricultural crops, including grassland. Both BIN and CBS data are based on farm surveys and thus give an indication of substance usage.

2: Kempenaar et al., 2009, or more recent sources.

5. Emissions to surface water

The emission indicators in this section are calculated based on substance properties which should be included in Section 2 and based on use data which should be included in Section 4 of the fact sheet. In case the problematic substance is a metabolite: Separate emission indicators for all known parents and for the metabolite

Summary of calculated emissions to surface water.

5.1 Emission indicators calculated with the NMI 3

Data:

1. Total emission of the active substance per crop (group) to the environmental compartments surface water, groundwater, and air (kg a.i. a^{-1}).
2. Total emission to surface water per crop (group) and per emission pathway (kg a^{-1}) per year.
3. Crop maps (add in appendix; also available on the internet)
4. Maps showing emission to surface water (per emission pathway and total, for all crops together (add in appendix).

To obtain a standardised factsheet please include the following tables in the factsheet (these can be generated by Alterra):

- TABEL 5.1: Verbruik en berekende indicatoren per sector voor de totale emissie naar oppervlaktewater, grondwater en lucht (NMI3, CBS)
- TABEL 5.2: Berekende emissie indicatoren per sector voor de hoeveelheid emissie naar oppervlaktewater (NMI3, CBS)
- TABEL 5.2b: Berekende emissie indicatoren voor de kasteelt naar oppervlaktewater per soort toepassing, inclusief toelichting (NMI3, CBS)
- TABEL 5.3: Verbruik en berekende indicatoren per gewas voor de totale emissie naar oppervlaktewater, grondwater en lucht (NMI3, CBS)
- TABEL 5.4: Berekende emissie indicatoren per gewas voor de hoeveelheid emissie naar oppervlaktewater (NMI3, CBS)

Sources:

1, 2, 4: Nationale Milieu Indicator (NMI 3) (Alterra, RIVM).

3: www.pesticidemodels.eu/nmi

5: List of endpoints in most recent registration or evaluation files

5.2 Exposure concentrations calculated for authorisation

5. Optional: include PEC_{SW} values for relevant applications calculated for the authorisation dossier and explain what these values imply. PEC_{sw} = predicted environmental concentraties for surface water adjacent to the treated field

Sources: the most recent available authorisation dossier for the substance

6. Surface water monitoring results

In case the problematic substance is a metabolite: include only the monitoring results for the metabolite.

Summary of presence, spatial and temporal distribution of exceedances of the water quality standard for the period under investigation. This information is based on the water quality standards used for the most recent update of the list of problematic substances. If new quality standards have been derived, these can be applied if agreed upon by the Ctgb.

Data:
1. Map: exceedances of the water quality standard in different classes in Dutch surface waters.
2. Figure: histogram with frequencies of classes of exceedances.
3. Figure: histogram with frequencies of exceedances per month for the whole of the Netherlands.
4. Figure: number of measurements with exceedance of the quality standard per month.
5. Correlation between land use (crop) and concentrations.
6. Correlation between land use (crop) and exceedances of the quality standard.

Sources:
1-6: Pesticides Atlas (BMA). Consultation with the Institute of Environmental Sciences (CML) or the Waterdienst (part of Rijkswaterstaat).

7. Phase 1 conclusions

Include the following conclusions:
- The information required for Phase 1 of the Causal Analysis Protocol has / has not been fully collected. *If not complete: list what is missing, and why.*
- Significant contradictions in the delivered data have / have not been observed. *If contradictions have been observed: list them.*

□ Start Phase 1 at the CPS ('Basisinformatie verzamelen')

□ Upload Phase 1 Factsheet to the CPS

Irrespective of completeness or presence of contradictions, Phase 1 is always followed by Phase 2

Phase 2: Expert consultation and interpretation

Start Phase 2 at the Crop Protection Sharepoint ('Experts raadplegen en analyse')

- □ Close Phase 1 at the CPS
- □ Start Phase 2 at the CPS
- □ Upload documents relevant for the experts: at least the Phase 1 Factsheet
- □ Apply all predefined questions to ensure that the complete factsheet is judged / complemented by experts (questions listed in Appendix VI)
- □ Select organisations (use the list in Appendix VI)
    - o For each question, at least one and if possible two experts are contacted and reply (one per organisation).
    - o For each question, at least one governmental or independent research organisation and one commercial organisation (e.g. authorisation holder) are contacted and reply. This is not necessary for questions on monitoring results
- □ Contact the organisations with the desired expertise to select experts.

  Experts selected by the contact persons of the organisations in the CPS environment, will receive a request to answer questions for this causal analysis online.

During this period experts can respond to the questions and to each other:

- □ Check frequently (at least once a week) whether experts have been assigned by the contact persons and whether the experts have answered the questions.
- □ Check the expert responses: if unclear or incomplete, request additional information. If no response at the closing date of the response period, remind and if necessary contact the expert personally.

Now fill the template for 'Interpretation and conclusions Phase 2'

- □ Prepare an overview of the expert responses.
- □ Define and document what actions should follow on from the expert responses, e.g.:

  With respect to the factsheet:
    - o Correct the facts presented in the factsheet.
    - o Add a qualitative remark to specific information in the factsheet.

  With respect to the conclusions of Phase 2:
    - o Apply in interpretations and conclusions.
    - o Further analysis (may be) necessary in next phase.

  With respect to the Causal Analysis Protocol:
    - o Recommend improvements.

- □ Update the Phase 1&2 Factsheet (template available)
- □ Finalise the document 'Interpretation and conclusions Phase 2':

  For each topic treated in the factsheet, describe what can be concluded from the information in the Phase 1&2 Factsheet and expert responses with respect to relevant applications and emission pathways. It is very important that the reasoning process, that has led the protocol manager to a conclusion, is well described in this document. This

normally includes weighing and funnelling of pieces of information. Describing this reasoning is necessary for the reader to understand and judge how the available information from the factsheet and experts responses has been used. If applicable, the protocol manager should make clear why certain pieces of information in the fact sheet or contributions from the experts are not taken into account.

Substance properties:

- Based on substance properties, which emission pathways to surface water are most relevant for the substance?

Dutch authorisation:

- Based on the authorisation and Good Agricultural Practice, what applications and emission pathways are likely to play a relevant role in the emission to surface water?
- Are there product-specific restrictions that influence the risk of a certain emission pathway?

Agricultural use data:

- What are the relevant product applications, application methods, application periods and regions with relatively intensive use?
- What are the implications for the emission patterns (spatial variation, pathways)?

Emission pathways:

- Are there emission pathways that are likely to be relevant, but are not included?
- According to the expected emissions (calculated emission indicators + interpretation of expert information), what are the most relevant emission pathways to surface water?
- What are the consequences of the relevant emission pathways for the temporal pattern of substance concentrations within a year?
- Are the relevant emission pathways caused by an application that does not comply with Good Agricultural Practice (GAP)?

Surface water monitoring results:

- How is the course of exceedances of the water quality standard within a year, compared with application periods in the relevant crops?
- Do the spatial distribution and time course of the exceedances imply a correlation with certain crops, application methods and/or emission pathways?

Comparison of calculated emission indicators (NMI) and monitoring data:

- How does the spatial and (if possible) temporal distribution of exceedance of quality standards in monitoring data compare with calculated emissions, land use and PPP application statistics? What does this imply for the relevance of the different applications and emission routes?

Conflicting information

In the event of conflicting information, missing information or striking regional differences in variables of influence on expected emission levels, this should be duly noted by the protocol manager. Information from different experts may be mutually conflicting or conflict with the information in the Phase 1 Factsheet. If the protocol manager is able to judge and duly support which information is most valuable or best-supported, the rest of the protocol is run using this superior information. If the protocol manager cannot establish which information is best, all the information sources should be used in the further Causal Analysis. If the conflicting information concerns variables that are used to calculate emissions, the Causal Analysis can be continued with

two or more scenarios. If the uncertainty concerns multiple variables, the protocol manager may decide to continue the process with a minimum, maximum and average scenario for certain emissions. To gain an indication of which scenario is most realistic, the protocol manager can compare the emissions calculated with the different scenario's with the monitoring data.

□ Draw an overall conclusion based on the gathered information and add this to the draft document.

Answer, as far as possible, the following questions:

- What product application(s) have a plausible relation with the exceedance of quality standards?
- What emission pathway(s) have a plausible relation with the exceedance of quality standards?
- Is it possible to rank the emission pathways by contribution to the exceedance of quality standards?

□ Conclude whether it is useful to gather more information on one or more topics in Phase 3 & 4:

Use the following decision tree:

A: Are there unexplained striking differences between the distribution of the expected emissions and the measured exceedance of quality standards between regions? Yes?: -> D. No? -> B

B: Are there unexplained striking differences between the distribution in time of the expected emissions and the measured exceedances of quality standards Yes?: -> D. No? -> C

C: Is there a plausible relation between applications in certain crops, related emission pathways and the measured exceedances of quality standards? Yes?: -> Phase 5. No? -> D

D: Is it anticipated that further analysis of one or more of the topics studied in Phase 2 will improve insight into the cause of the exceedance of quality standards? Yes?: Continue with Phase 3 & 4. No: continue with Phase 5.

□ Upload Factsheet phase 2 and the document 'Interpretation and conclusions, phase 2' to the CPS.

Optional:

- Notify experts (manually) that they can respond (suggestion: within one week).
- Document and upload the responses
- Process the responses if relevant
- Upload the final version of 'Interpretation and conclusions, phase 2' to the CPS and notify the organisations and experts involved.

□ Close phase 2 at the CPS. Involved experts will be notified automatically that Phase 2 has been closed and that the final documents of phase 2 are available at the CPS.

If relevant: Phase 3 and Phase 4

Phase 3: Inventory of extra data, regional scale or particular topic

Phase 3 can be implemented in causal analyses where it is deemed relevant to gather or create more detailed or region-specific information on one or more of the topics analysed in Phases 1 and 2. The result of Phase 3 is always checked by expert consultation in Phase 4. In contrast to Phase 1, the topics and sources to be consulted in Phase 3 are selected on a case-by-case basis (per substance). The results of Phase 3 are documented in a 'Phase 3 Factsheet'.

- □ Compose the Phase 3 Factsheet (template available)
  - o Specify the questions to be answered in Phases 3 & 4 (based on the conclusions of Phase 2).
  - o Gather relevant information.
  - o Compile the information gathered into an additional factsheet: the Phase 3 Factsheet.
  - o Conclude in this Factsheet:
    - The necessary information for Phase 3 of the Causal Analysis Protocol has / has not been fully collected. *If not: specify the missing information.*
    - Significant contradictions in the delivered data have / have not been observed. *If so, list the contradictions.*

- □ Start Phase 3 at the CPS ('Nadere analyse')
- □ Upload the Phase 3 Factsheet and (optional) supporting documents to the CPS.

Phase 4: Expert Consultation

- □ Start Phase 4 at the CPS
- □ Upload relevant documents, at least the Phase 3 Factsheet.
- □ Compose new questions in the CPS for Phase 3 of this causal analysis.
- □ Select organisations:
  - o For each question, at least two experts (one per organisation) are contacted and have replied.
  - o For each question, at least one governmental or independent research organisation and one commercial organisation (e.g. authorisation holder) are contacted and have replied. This is not necessary for questions on monitoring results.

- □ Select organisations (use the list in Appendix VI)
  - o For each question, at least one and if possible two experts are contacted and reply (one per organisation).
  - o For each question, at least one governmental or independent research organisation and one commercial organisation (e.g. authorisation holder) are contacted and reply. This is not necessary for questions on monitoring results
- □ Contact the organisations with the desired expertise to select experts.

Experts selected by the contact persons of the organisations in the CPS environment, will receive a request to answer questions for this causal analysis online.

During this period experts can respond to the questions and to each other:

□ Check frequently (at least once a week) whether experts have been assigned by the contact persons and whether the experts have answered the questions.

□ Check the expert responses: if unclear or incomplete, request additional information. If no response at the closing date of the response period, remind and if necessary contact the expert personally.

□ Now fill the template for 'Interpretation and conclusions Phase 4'

□ Prepare an overview of the expert responses.

□ Define and document what actions should follow on from the expert responses, e.g.:

With respect to the Phase 3 factsheet:
- Correct the facts presented in the factsheet.
- Add a qualitative remark to specific information in the factsheet.

With respect to the conclusions of Phase 4:
- Apply in interpretations and conclusions.
- Further analysis (may be) necessary in next phase.

With respect to the Causal Analysis Protocol:
- Recommend improvements.

□ Compose the Phase 3 & 4 Factsheet (template available)

□ Finalise the document 'Interpretation and conclusions Phase 4':

For each topic treated in the factsheet, describe what can be concluded from the information in the Phase 3&4 Factsheet and expert responses with respect to relevant applications and emission pathways in addition to prior conclusions in Phase 2.
It is very important that the reasoning process, that has led the protocol manager to a conclusion, is well described in this document. This normally includes weighing and funnelling of pieces of information. Describing this reasoning is necessary to understand and judge how the available information from the factsheet and experts responses has been used.

Answer, as far as possible, the following questions:
- What product application(s) have a plausible relation with the exceedance of quality standards?
- What emission pathway(s) have a plausible relation with the exceedance of quality standards?
- Is it possible to rank the emission pathways by contribution to the exceedance of quality standards?

Conflicting information
See textbox 'conflicting information' *in Phase 2*.

□ Upload the Phase 3 & 4 Factsheet and the document 'Interpretation and

conclusions, phase 4' to the CPS.

Optional

- Notify experts that they can respond (suggestion: within one week).
- Document and upload the responses
- Process the responses if relevant

□ Upload the final version of 'Phase 4 Interpretation and conclusions' to the CPS

□ Close Phase 4. Experts involved in Phase 4, via the CPS, will receive a notification that the 'further analysis' has been finished and that the documents are available through the CPS.

Phase 4 is always followed by Phase 5: the final phase of the causal analysis.

Phase 5: Conclusions and recommendations

□ Initiate Phase 5 at the Crop Protection Sharepoint

□ Prepare a new document: substance name – ' Final Conclusions, Phase 5' (template available)

□ Draw the final conclusions:

The conclusions are specified per area, region, crop, etc., to the extent that this is feasible and likely to be relevant for mitigation measures. These conclusions take the following form:

- There is a plausible relation between the application of substance …. in crop(s) …. and the exceedance of quality standards in the period …. in the surface water in the area(s) …. / in The Netherlands.

- There is no plausible relation between the application of substance …. in crop(s) …. and the exceedance of quality standards in the period …. in the surface water in the area(s) …. / in The Netherlands.

- There is a plausible relation between specific emission routes following the application of substance …. in crop(s) …. and the exceedance of quality standards in the period …. in the surface water in the area(s) …. / in The Netherlands.

□ Present the final conclusions in a table (table III-1):

This table shows for each crop and, if possible, emission route, whether a plausible relation with the observed quality standard exceedance has been found. An example of this standardised table is included below. All crops for which the substance has an authorisation are included. In the case of usage in crops without authorisation, these crops are also included in the table.

If no plausible relation has been found, a distinction is made between 'relevance unknown / not investigated' and 'plausibly non-relevant'. The table also specifies the distribution of substance

usage over the various different crops.

□ Report what can be concluded regarding the contribution of applications not according to Good Agricultural Practice (non-GAP) to the quality standard exceedance.

Optional:

□ define recommendations:
  - o on improving the understanding of the emission pathways or patterns for the substance of interest
  - o on improving the Causal Analysis Protocol.

□ Upload the document with the final conclusions to the CPS.

□ Conclude Phase 5 at the CPS.

□ Experts involved in Phase 2 and/or Phase 4 of this causal analysis receive a notification that the causal analysis has been finalised and that documents can be found on the CPS.

Table III-1. Example of an overview of plausible causes of quality standard exceedance in the time frame 2003-2006 for a herbicide. The plausible causes are based on the emission per surface unit of area treated. Consequently, the conclusions are independent of the total area treated. The example case is based on emissions calculated with the Dutch Environmental Risk Indicator for Plant Protection Products NMI 2. In the current version NMI 3, the emission pathway "drainage" replaces the emission pathway "lateral leaching".

Time frame: 2003-2006			Emission route					
Crop on which the substance is applied*	Authorisation	Percentage of national use of metribuzin*	Diffuse sources				Point sources (from farmyards and buildings, from greenhouses)	
			spray drift	atmospheric deposition	lateral leaching***	run-off	open field crops	covered crops
Table / crisp potatoes	Yes	71	Plausible cause main cause of exceedances in spring and summer	Not a plausible cause	plausible cause main cause of exceedances in autumn and winter	not investigated	Cannot be excluded Sprayer cleaning (internal and external) possibly relevant in application period and autumn	No applications
Starch potatoes	Yes	22	Plausible cause exceedances in spring and summer		Plausible cause exceedances in autumn and winter			
Seed potatoes	No	1	Plausible cause		Plausible cause			
Asparagus	Yes	4	Plausible cause		Plausible cause Multi-annual crop: increases the risk			
Grass seed	No	-**	Plausible cause		Plausible cause Application in autumn increases the risk			
Carrots	No	-	Application in this time frame is negligible (information from authorisation holder)					
Grassland	No	-	Not plausible that this application occurs in practice; no further analysis carried out					
Strawberries	No	-	Not plausible that this application occurs in practice; no further analysis carried out					

* Sources: 'CBS pesticides questionnaire 2004' and LEI ('Bedrijveninformatienet')

** Supplementary information from authorisation holder: approx. 1% of use is in grass seed cultivation.

*** Preferential flow and discharge through pipe drains have not been analysed

Appendix IV: Crop definitions

Separate document

Appendix V: Classification of substance properties

Classification of data on physico-chemical properties, environmental behaviour and ecotoxicology

Remarks:
The tables in this Appendix contain indicative qualifications, derived for typically Dutch conditions. These qualifications are used in want of internationally agreed qualifications. For several aspects qualifications are lacking. It was out of the remit of the working group to establish such missing qualifications.

Physical properties

*** Solubility (S) at 20-25 °C**

Classification		S [mg/l]			
Nederlands	English				
zeer slecht oplosbaar	very slightly soluble	<	0.1		
slecht oplosbaar	slightly soluble		0.1	-	10
matig oplosbaar	moderately soluble		10	-	1000
goed oplosbaar	readily soluble			≥	1000

*** Vapour pressure (P) at 20-25 °C**

Classification		P [Pa]			
Nederlands	English				
weinig vluchtig	very slightly volatile	<	0.0001		
enigszins vluchtig	slightly volatile		0.0001	–	0.01
matig vluchtig	moderately volatile		0.01	–	1
vluchtig	volatile		1	–	100
zeer vluchtig	highly volatile			≥	100

*** Volatility from water (Henry's Law Constant, dimensionless) at 20 ºC**

Classification (Lyman, 1982)		H [-]			
Nederlands	English				
weinig vluchtig	very slightly volatile	<	0.00001		
matig vluchtig	moderately volatile		0.00001	–	0.03
zeer vluchtig	highly volatile			>	0.03

Transformation and mobility in soil

*** DT50 at 20 ºC, pF = 2, top soil**

Classification		DT50 [d]			
Nederlands	English				
zeer slecht afbreekbaar	very slightly degradable			>	180
slecht afbreekbaar	slightly degradable		60	–	180
redelijk afbreekbaar	fairly degradable		20	–	60
goed afbreekbaar	readily degradable			<	20

*** Mobility at 20 ºC**

Classification		R_f			$K_{s/l}$ [dm^3/kg]				K_{om} [dm^3/kg]			
Nederlands	English											
zeer weinig mobiel	immobile	0	–	0.09			>	2.6			>	100
weinig mobiel	slightly mobile	0.10	–	0.34		0.53	–	2.6		20	–	100
matig mobiel	moderately mobile	0.35	–	0.64		0.15	–	0.53		5	–	20
mobiel	mobile	0.65	–	0.89		0.03	–	0.15		1	–	5
zeer mobiel	highly mobile	0.90	–	1.00	<	0.03			<	1		

Transformation in water

*** Transformation water/sediment system DT50sys at 20 ºC (whole system)**

Classification		DT_{50} [d]			
Nederlands	English				
zeer slecht afbreekbaar	very slightly degradable			>	180
slecht afbreekbaar	slightly degradable		60	–	180
redelijk afbreekbaar	fairly degradable		20	–	60
goed afbreekbaar	readily degradable	<	20		

*** Hydrolysis DT50 at 20 ºC, pH 7**

Classification		DT_{50} [d]			
Nederlands	English				
slecht hydrolyserend	slightly hydrolysing			>	30[2]
matig hydrolyserend	moderately hydrolysing		10	–	30
redelijk hydrolyserend	fairly hydrolysing		4	–	10
goed hydrolyserend	readily hydrolysing		1	–	4
zeer goed hydrolyserend	very rapidly hydrolysing	<	1		

*** Phototransformation in water DT50 (continuous light regime)**

Classification		DT_{50} [d]			
Nederlands	English				
weinig afbreekbaar	slightly degradable			>	30[3]
matig afbreekbaar	moderately degradable		10	–	30
redelijk afbreekbaar	fairly degradable		4	–	10
goed afbreekbaar	readily degradable		1	–	4
zeer goed afbreekbaar	very rapidly degradable	<	1		

[2] When a preliminary test was performed, in which < 10% of the pesticide was hydrolysed at 50 °C within five days, then the pesticide is considered hydrolytically stable. No main test need to be performed, and the extrapolated DT_{50} (20 °C) is > 500 days

[3] When a preliminary test was performed, in which < 10% of the pesticide was photolysed at 20 - 25 °C within 30 days, then the pesticide is considered photolytically stable

Toxicity

* **Aquatic organisms, acute: algae (96-h EC50), Daphnia (48-h LC50) and fish (96-h LC50)**

RIVM/SEC-classification		EU-classification	E(L)C_{50} [mg/l]			
Nederlands	English					
zeer weinig giftig	very slightly toxic	harmful			>	100
weinig giftig	slightly toxic	harmful		10	–	100
matig giftig	moderately toxic	toxic		1	–	10
zeer giftig	highly toxic	very toxic	<	1		

* **Aquatic organisms, chronic**

Classification		NOEC [mg/l]			
Nederlands	English				
zeer weinig giftig	very slightly toxic			>	1
weinig giftig	slightly toxic		0.1	–	1
matig giftig	moderately toxic		0.01	–	0.1
zeer giftig	highly toxic	<	0.01		

* **Birds, acute oral**

Classification		LD_{50} [mg/kg bw]			
Nederlands	English				
weinig giftig	slightly toxic			>	500
matig giftig	moderately toxic		50	–	500
giftig	toxic		5	–	50
zeer giftig	highly toxic	<	5		

* **Earthworms, soil test**

Classification		LC50 [mg/kg dry soil]			
Nederlands	English				
zeer weinig giftig	very slightly toxic			>	1000
weinig giftig	slightly toxic		100	–	1000
matig giftig	moderately toxic		10	–	100
giftig	toxic		1	–	10
zeer giftig	highly toxic	<	1		

* **Bees, contact and oral**

Classification		LD50 [µg/bee]			
Nederlands	English				
zeer weinig giftig	very slightly toxic			>	100
weinig giftig	slightly toxic		10	–	100
matig giftig	moderately toxic		1	–	10
giftig	toxic		0,1	–	1
zeer giftig	highly toxic	<	0,1		

*** Other beneficial insects, mites, and spiders, laboratory testing (bees excluded)**

Classification		Reduction in beneficial capacity [%]			
Nederlands	English				
onschadelijk	harmless	<	30		
weinig schadelijk	slightly harmful		30	–	79
matig schadelijk	moderately harmful		80	–	99
schadelijk	harmful			>	99

Bioconcentration

Classification		BCF_{wo}*			
Nederlands	English				
weinig concentrerend	slightly concentrating	<	100		
matig concentrerend	moderately concentrating		100	–	1000
sterk concentrerend	highly concentrating			>	1000

* wo = whole organism

Risk for algae (growth inhibition), crustaceans and fish (both chronic effects)

Classification		PEC/NOEC			
Nederlands	English				
verwaarloosbaar	negligible	<	0.1		
aanwezig	present		0.1	–	1
groot	large			>	1

Risk for acute effects for algae, crustaceans and fish (mortality)

Classification		PEC/L(E)C50			
Nederlands	English				
verwaarloosbaar	negligible	<	0.01		
klein	small		0.01	–	0.1
aanwezig	present		0.1	–	1
groot	large		1	–	10
zeer groot	very large			>	10

Reference

B.J.W.G. Mensink, M. Montforts, L. Wijkhuizen-Maslankiewicz, H. Tibosch, J.B.H.J. Linders. Manual for Summarising and Evaluating the Environmental Aspects of Pesticides. RIVM Report no. 679101022, Bilthoven, The Netherlands, July 1995, 135 pp.

J.B.H.J. Linders, J.W. Jansma, B.J.W.G. Mensink, K. Otermann. Pesticides: Benefaction or Pandora's Box? A synopsis of the Environmental Aspects of 243 Pesticides.. RIVM Report no. 679101014, Bilthoven, The Netherlands, March 1994, 214 pp.

Appendix VI: Expert consultation

Table III-1: Fields of expertise

1. Available PPPs and crop protection
2. Crop protection advice
3. Environmental risks of PPPs
4. Water quality research and analysis methods
5. Water quantity research and water management
6. Authorisation
7. Fulfilment of restrictions on application of PPPs (enforcement)
8. Processing of monitoring results
9. Collection and analysis of horti- and agricultural data
10. (Geo)statistics

Table III-2: Questions and expertise for expert consultation

Questions to be used in Phase 2 and optional for Phase 4

Subject (see also Phase 1)	nr.	Question (in Dutch)	Expertise (Table 1)
1	1	Welke gegevens zijn gebruikt bij het afleiden van de waterkwaliteitsnormen (AA- en MAC-EQS; MTR indien EQS ontbreekt) en is er daarbij een assessment factor gebruikt?	3
1	2	Op welke gegevens over het afbraak- en sorptiegedrag van de werkzame stof is het toelatingsbesluit gebaseerd?	3
1	3	Zijn er sinds het toelatingsbesluit aanvullende inzichten ten aanzien van het afbraak- en sorptiegedrag van de werkzame stof? Ten aanzien van andere stofeigenschappen?	3
2	1	Zijn er aanvullende gegevens over de toegelaten toepassingen voor deze stof. Welke?	1, 6
3	1	Zijn er betere of aanvullende data beschikbaar over de hoeveelheid verbruik in verschillende gewassen of de verdeling van het gebruik over gewassen? Zo ja, geven die een afwijkend beeld vergeleken met de informatie in de factsheet? In welk opzicht?	1, 2, 9
3	2	Is er betere of aanvullende informatie over de verdeling van het verbruik binnen een jaar beschikbaar? Zo ja, geeft die informatie een afwijkend beeld vergeleken met de informatie in de factsheet? In welk opzicht?	1, 2, 9
3	3	Is er informatie over de verdeling van het verbruik van de actieve stof per teelt over de verschillende producten (merknamen / formuleringen) beschikbaar?	1, 2, 9
3	4	Verschilt de toepassing in de praktijk duidelijk van die volgens de gebruiksaanwijzing en het wettelijk gebruiksvoorschrift op het etiket en de GAP tabel? Zo ja, op welke aspecten? Denk aan toedieningswijze en restricties met gevolgen voor de emissie, tijdstip toepassing in het jaar, frequentie per jaar, gewassen waarop het toegepast wordt, etc. Zijn er gegevens over de implementatiegraad van verplichte emissiereducerende maatregelen of restricties? Bij gebruik op gewassen zonder toelating: heeft u informatie over de omvang van deze toepassing?	1, 2, 7, 9
4	1	Zijn er betere gegevens beschikbaar over de emissieroutes die in de factsheet staan? Zo ja, welke? Of zijn er relevante emissieroutes die niet in het factsheet vermeld worden? Zo ja welke routes en wat is er over bekend?	1, 2, 3, 7, 8
4	2	Zijn er mogelijke bronnen/emissies, die niet aan de locatie van de teelt zijn gebonden (zoals bijvoorbeeld behandeling van plantgoed, bolontsmetting, bewaarruimten, natte sortering of spoelen van geoogst product, etc.?	1, 2, 3, 7, 8, 9
4	3	Zijn er betere of aanvullende gegevens over het grondgebruik (lokatie van de teelten waarin de stof wordt gebruikt) beschikbaar?	1, 2, 9, 10
5	1	Zijn er verschillen tussen regio's in de spreiding van metingen binnen het jaar? (alle metingen, dan wel de normoverschrijdende metingen) Zo ja, welke?	4, 5, 8, 10
5	2	Zijn er verschillen tussen regio's v.w.b. het type oppervlaktewater waar de stof is gemeten? (alle metingen, dan wel de normoverschrijdende metingen) Zo ja, welke?	4, 5, 8, 10
5	3	Zijn er redenen om aan te nemen dat overschrijdingen (mede) veroorzaakt worden door inlaat van water van buiten Nederland? Zo ja, op welke locaties?	4, 8
5	4	**Monsterneming:** welke methode van bemonstering is gebruikt (bijv. eenmalig bulkmonster, samengesteld monster in ruimte of tijd, debietproportioneel monster, ... , absorptie aan een absorbens) ?	4
5	5	**Conservering:** is een conservering van het monster toegepast (bijv. aanzuren, toevoegen van adsorbens, toevoegen van extractiemiddel, ...) ? en wat waren de omstandigheden tijdens transport en opslag	4

5	6	**Analyse:** Welk lab heeft de analyses gedaan? Welke extractiemethode is gebruikt? Welke analysemethode is gebruikt? Is deze methode gericht op het gehele molecule of een deel daarvan? Zijn er bevestigingsmethoden toegepast?	4
5	7	Zijn er verschillen tussen of bijzonderheden met betrekking tot beschikbare analysemethoden in relatie tot de stof, die het landelijke beeld van de overschrijdingen kunnen beïnvloeden? Zo ja, welke verschillen of bijzonderheden en wat zijn de mogelijke gevolgen?	4

Table III-3: Organisations and their expertise*

Organisatie		Expertise										Opmerking / specialisatie
1	DLV Plant	1	2	3								
2	Gbm leverancier bijv. Agrifirm / etc	1	2	3								
3	Toelatinghouder bijv. Bayer Crop Science, BASF	1	2	3	4		6	7				4: water analyse technieken
4	Waterdienst			3		5	6		8			8: met name voor rijkswateren
5	KWR Watercycle Research Institute (voorheen onderdeel KIWA)				4							4: water analyse technieken
6	RIVM			3	4		6					
7	NVWA (organisatieonderdeel dat voorheen AID was)							7				
8	Waterschappen, Platform Landbouwemissies			3	4	5		7	8			8: lokale en regionale wateren
9	Ctgb			3			6					
10	Centrum voor Milieuwetenschappen (CML)			3	4				8		10	Niet meer data dan in de standaardbronnen toegepast voor de Factsheet Fase 1
11	Alterra			3	4	5					10	Niet meer data dan in de standaardbronnen toegepast voor de Factsheet Fase 1
12	PPO/WUR-Glastuinbouw	1	2	3								3: emissieroutes
13	Centrum voor landbouw en milieu			3								
14	Plant research internaltional (PRI)		2	3								2: toepassingstechnieken, gebruik op verhardingen en in openbare ruimtes 3:emissie routes
15	LEI									9		
16	CBS									9	10	
17	PBL									9	10	
18	LTO / LTO Noord (Land- en Tuinbouw)	1										
19	LTO Groei-service (Tuinbouw)	1										
20	KAVB (Bloembollen en bolbloemen)	1										Verwijst door naar PPO
22	NFO (Fruitteelt)	1										
23	NVWA (organisatieonderdeel dat voorheen PD was)	1	2	3			6					

*Momentopname 2010. Deze kan bij gebruik door de protocolhouder ge-update worden

Table III-4: Overview organisations and contacts (2010)

Organisatie	**Contact**
DLV Plant	Dhr. Jacob Dogterom
Gbm leverancier	Via Agrodis: Dhr. Conno de Ruijter
Toelatinghouder bijv. Bayer Crop Science, BASF.	Branche or product manager of the authorisation holder
Toelatinghouder bijv. Bayer Crop Science, BASF.	Registration manager of the authorisation holder
Waterdienst	Dhr. Dennis Kalf
KWR Watercycle Research Institute (voorheen onderdeel KIWA)	
RIVM	Dhr. Ton vd Linden
NVWA (organisatieonderdeel voorheen AID)	Dhr. Jan Ooijman (Oost-NL) Dhr. Rien van Diessen (West NL, glastuinbouw)
NVWA (organisatieonderdeel voorheen PD)	Mevr. Johanneke Wingelaar
Waterschappen, Platform Landbouwemissies	Specialists land- en tuinbouwemissies; (via) Dhr. Wim van der Hulst of Dhr. Rien Klippel
Ctgb	Mevr. Corine van Griethuysen
Centrum voor Milieu-wetenschappen (CML)	Dhr. Wil Tamis
Alterra	Dhr. Roel Kruijne
PPO/WUR-Glastuinbouw	Gewas- of gewasbeschermingsspecialisten PPO en WUR Glastuinbouw (via) Dhr. Rik de Werd
CLM	Mevr. Erna van der Wal
PRI	Dhr. Jan van de Zande
LEI	Dhr. Jakob Jager
CBS	Dhr. Rob Vijftigschild
PBL	Dhr. Hans Visser
LTO / LTO Noord (Land- en Tuinbouw)	Dhr. Jaap van Wenum
LTO Groei-service (Tuinbouw)	Dhr. Harmen Hummelen
KAVB (Bloembollen en bolbloemen)	Dhr. Paul Vanderbosch
NFO (Fruitteelt)	Dhr. Jaco van Bruchem

Appendix VII: Application types, emission pathways and exposure concentrations (NMI 3)

Introduction

The emission models built into the Dutch environmental risk indicator for plant protection products NMI 3 are assumed to cover the major agricultural applications in terms of usage, crop area and possible emission routes. Most of these models are derived from recently developed scenarios and tools intended for use in Dutch and/or European registration, e.g. the exposure assessment for aquatic organisms resulting from spray drift and drainage (Zande et al., 2012, Tiktak et al., 2012), and the exposure assessment for soilless cultivation in greenhouses (Vermeulen et al., 2010). Other emission models are based on simple worst case assumptions.

The applications in the NMI 3 Usage database are assumed to approach GAP. Non-agricultural use and illegal use are not included. In lack of emission factors for losses from farm yards, the number of point sources included in the model is limited (See below). For similar reasons, emission by run-off from arable fields is not considered in the model.

Application types and emission pathways

In the NMI 3, application types are defined by the combination of object treated and application method. The application type determines which emission indicators are calculated. Each application in the usage database belongs to one of the categories shown in Table VII-1. The application method may refer to the object treated (soil, crop, plant material, or harvested products), the location (arable field, greenhouse, farm yard, or storage building), the equipment and the formulation of the product. Table VII-1 shows the emission pathways to surface water calculated for applications to arable crops, applications at the farm yard, and applications to covered crops, respectively.

Applications to field crops

For field spraying applications (1, 2), atmospheric deposition, spray drift and drainage flow are calculated. Because the emission factors for atmospheric deposition and spray drift do not apply to spraying with a knapsack (3), only drainage flow is considered for this application type. In case of soil incorporation, soil injection, and granular application methods (4), emission to surface water is assumed equal to zero. (For this application type 4, emissions to other environmental compartments are calculated). For seed treatment in arable crops (5) no emission factors are available.

Applications at the farm yard

Treatment of plant material (6) and harvested products in storage buildings (7) may lead to run-off from the farm yard or losses by discharge of condensation water. This kind of losses is referred to as point source emissions.

Applications to covered crops

Different application methods in greenhouse crops with soilless cultivation (8, 9, 10) may lead to discharge of water and dissolved substances, whereas applications in greenhouse crops rooting in soil (11) may lead to emission by drainage flow (leaching) and by discharge. Finally, applications in mushrooms cultivation may lead to discharge of condensation water collected inside cultivation buildings (12).

Results for metabolites can only be obtained for applications with a field sprayer boom (1). In standard NMI 3 output, results for the parent compound and metabolites present in the Compound database are lumped together. In cases for the protocol for causal analysis, results for the parent compound and metabolites can be printed to separate output files, if necessary.

Table VII-1: Emission pathways to surface water and application types (i.e. combinations of object treated and application method) in the model NMI 3. Field applications (1-5), losses from farm yards (6-7) and applications in covered crops (8-12) explained in the text.

Application method and object treated	Emission pathway to surface water					
	Atmos-pheric deposition	Spray drift	Drainage flow	Leaching	Point sources	Discharge from green-houses
Spraying with field sprayer boom (1)	X	X	X			
Spraying followed by soil incorporation (2)	X	X	X			
Local field spraying (knapsack) (3)			X			
Soil incorporation, soil injection, and granular application (4)						
Seed treatment in arable crops (5)	No emission factor available					
Treatment in storage buildings (6)					X	
Treatment at farm yards (7)					X	
Application along with the recirculated nutrient solution (8)						X
Spraying, fogging or fumigating greenhouse crops; soilless cultivation with roots shielded (9)						X
Spraying, fogging or fumigating greenhouse pot plants standing on flooding tables (10)						X
Spraying, fogging or fumigating greenhouse crops rooting in soil (11)				X	X	
Application in mushroom cultivation buildings (12)					X	

Exposure concentrations

For each application the emission indicator is converted into short-term and long-term exposure concentrations in the field ditch. This is shown in Figure VII-1 for a spraying application in a field crop which consists of four different spray drift events at 7-day interval. The long-term exposure concentration is calculated as the maximum, 21-days time-weighted average (the red line in figure VII-1). In case the application results in emissions by drainage too, the maximum exposure concentrations are calculated for spray drift and for drainage separately. Next, the maximum concentration of these two emission pathways is selected. Emissions from spray drift and atmospheric deposition are lumped together, because both entries occur at application time. Emissions from drainage are assumed to take place at different time. The procedure explained here is used in a similar way for the emission pattern resulting from other application types.

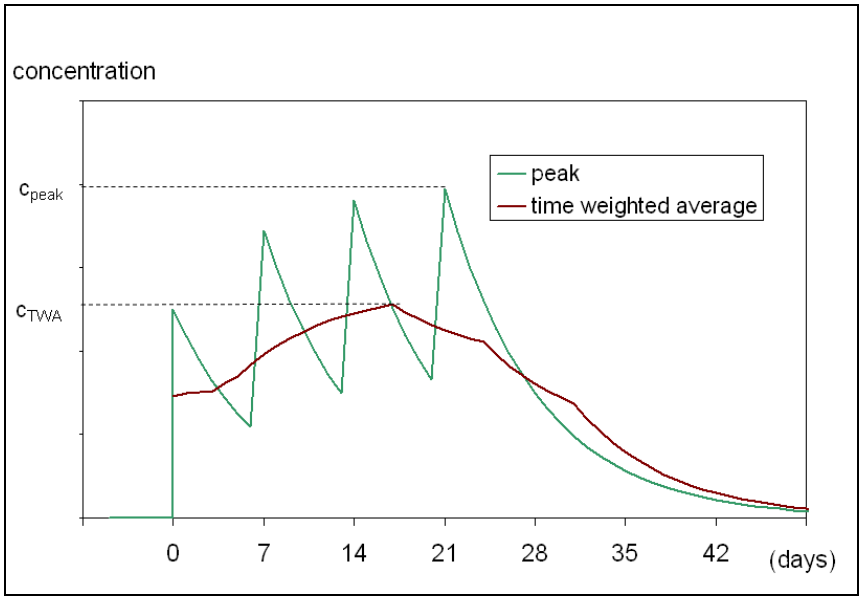


Figure VII-1. Example of exposure concentrations in a field ditch due to spray drift resulting from a multiple application. The short-term exposure concentration is the highest peak concentration. The NMI 3 accounts for dissipation from the water body by degradation and by volatilisation assuming standing water conditions.

References

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Appendix VIII: Comparing distributions of measured and predicted concentrations

Separate document