



Explanatory memorandum on the background of the proposed policy decree:

Policy decree on implementation of Article 44 of Regulation (EC) No. 1107/2009 regarding structural exceedances of the authorisation criterion in surface water

Core concept of this memorandum

Compared to current practice, the proposed policy decree places additional specifications on including surface water monitoring data in the authorisation process for plant protection products. It concerns an operational method for dealing with plant protection products based on substances that structurally exceed the authorisation standard in surface water. The proposal involves two steps:

1. Identifying substances that *structurally* exceed the authorisation standard. This is done on the basis of an evaluation (annual or otherwise) of monitoring data in the Pesticide Atlas using a decision tree that is defined in the policy decree.
2. The re-assessment of products based on structural exceedances under Article 44 Regulation (EC) 1107/2009. In this step, only emissions to surface water are recalculated based on the latest methodologies (calculation models for emissions to surface water). If warranted by the reassessment, the authorisation – after consultation with the authorisation holder in accordance with Article 44 Regulation (EC) 1107/2009 – will be amended or withdrawn where necessary.

The operational method in the proposed policy decree on reassessing existing authorisations under Article 44 Regulation (EC) 1107/2009 also tightens the processing of pending applications, particularly regarding applications for minor uses.

Background

Monitoring data in surface water show that *structural* exceedances of the authorisation criteria have been observed for a number of active substances from plant protection products^{1 2}. Exceedances can have many causes, such as the unauthorised/incorrect use of such products. It is also possible that certain exceedances are caused by regular use that is in compliance with the legal conditions for use.

¹ Please note that this memorandum does not involve monitoring data from groundwater, which are included in the Groundwater Atlas.

² This memorandum does not concern Water Framework Directive (WFD) standards. WFD standards and authorisation standards may differ. For details on WFD standards, see the Ctgb advice to LNV on exceeding WFD standards in relation to authorisation policy; [Stand van zaken moties en toezeggingen op het gebied van gewasbescherming - voorjaar 2024](#), annex.

When renewing product authorisations under Article 43 of Regulation (EC) 1107/2009, the estimated emissions are tightened in many cases. This is because the Ctgb uses the latest methodologies, such as the GEM model for greenhouses (from 2016) or the WDC (Wageningen Drift Calculator) for unprotected cultivation (from 2022). As a result, renewals of plant protection products according to Article 43 based on substances that exceed the authorisation standard often require changes to the authorisation.

When structural exceedances of the authorisation standards occur in surface water, it is desirable for the Ctgb to also have an effective operational method *in the interim* to deal with this problem in order to prevent exceedances due to the authorised use of plant protection products as much as possible.

Legal framework

Article 44 of Regulation (EC) 1107/2009 allows the Ctgb to review the authorisations of plant protection products and to intervene where necessary. The proposed process used for exceedances of authorisation standards in surface water has two steps:

1) Identify 'substances that structurally exceed the authorisation standard':

Article 44, first clause: "Member States may review an authorisation at any time where there are indications that a requirement referred to in Article 29³ is no longer satisfied".

The Ctgb considers 'structurally exceeding the authorisation standard' in surface water as a possible indication that the requirements referred to in Article 29 are no longer satisfied. Later in this memorandum, a standardised decision tree is provided that enables to carefully distinguish 'substances that structurally exceed the authorisation standard' from substances with incidental exceedances.

2) Reassess products and intervene in the authorisations if necessary:

After identifying 'substances that structurally exceed the authorisation standard', the Ctgb, according to Article 44, first clause, "may review an authorisation at any time" of products based on these substances. This means that the Ctgb can carry out an interim reassessment of products based on substances that have been identified as structurally exceeding the authorisation standard. Article 44 third clause under a) Regulation (EC) 1107/2009 states: "The Member State shall withdraw or amend the authorisation, as appropriate where the requirements referred to in Article 29 are not or are no longer satisfied." Under Article 44 the Ctgb can therefore amend or withdraw the authorisation of plant protection products based on substances that structurally exceed the authorisation standard if the interim reassessment shows that the surface water authorisation standard is not or is no longer satisfied.

³ Article 29, first clause, introductory wording and section e in conjunction with Article 4, third paragraph, introductory wording and section e)

Elaboration of Step 1

Criteria for substances that structurally exceed the authorisation standard

The [Pesticide Atlas](#)^{4, 5} is a digital application that provides a national picture of active substances in relation to various standards in surface water based on measurement data from regional water authorities, including the authorisation criterion for plant protection products. The authorisation standards used by the Ctgb are derived in accordance with prevailing European regulations and guidelines. In some cases, authorisation standards may differ per product, for example due to information from more recent assessments. The most stringent relevant authorisation standard is included in the Pesticide Atlas as the 'authorisation criterion'.

The Ctgb defines exceedances of the authorisation criterion for surface water in the Pesticide Atlas as 'structural' when exceedances occur frequently over multiple years and at multiple monitoring points. If significant correlations of exceedances with certain crops can be shown in the Pesticides Atlas, this may be an additional indication that exceedances are related to specific authorised uses of plant protection products.

The criteria used by the Ctgb for 'structural exceedance' are explained below.

When exceedances of authorisation criterion occur in the Pesticides Atlas in the last three available calendar years, this is considered an indication of structural exceedances:

The Pesticides Atlas includes a list of substances with the most severe exceedances, based on an exceedance index. The Ctgb uses this index as a starting point to define the concept of 'frequent exceedances'. The exceedances index is an indication of the magnitude of the exceedance and consists of a combination of the frequency (the number of sites with exceedances compared to the total number of monitored sites) and level of exceedances, i.e. the severity of the exceedances. For this purpose, the Pesticides Atlas distinguishes two classes: 1 to 5 times above the standard and more than 5 times above the standard. As an alternative to the index, selection could be based on the percentage of sites where the authorisation standard is exceeded. The Ctgb has decided to use the exceedances index because it also takes the level of exceedance into account.

Substances with the highest values (≥ 0.1) are regarded as substances structurally exceeding authorisation standards. This is based on analogy with a *spatial* 90th percentile. European and national assessment methodologies for estimating exposure in surface water use the *overall* 90th percentile as a realistic worst case⁶. The Pesticides Atlas already uses the *temporal* 90th percentile for reviewing the authorisation standard per site. Of the measurements taken in a single calendar year, the 90th percentile concentration is compared with the authorisation standard. There is no further scientific interpretation of the *overall* 90th percentile for monitoring data, but this approximates it as closely as possible.

At an index value of 0.1, it may concern 10% of sites where the standard is exceeded. However, it may also involve less than 10% of sites, with a higher level of standard exceedance. In the absence of a clearly defined protection target, a pragmatic interpretation of the spatial 90th percentile is used here for the time being.

Substances with a lower index value (≥ 0.01) are considered to be structurally exceeding the authorisation standard when there are additional indications of structural exceedance, e.g. when

⁴ Vijver M.G., Zelfde M. van 't, Tamis W.L.M., Musters C.J.M. & Snoo G.R. de (2008), Spatial and temporal analysis of pesticides concentrations in surface water: pesticides atlas, Journal of Environmental Science and Health part B 43: 665-674.

⁵ The Pesticides Atlas is published by the Centre for Environmental Sciences Leiden and funded by the Ministry of Infrastructure and Water Management, in collaboration with Rijkswaterstaat WVL, UvW, RIVM and Ctgb.

⁶ FOCUS groundwater scenarios in the EU review of active substances - the report of the work of the groundwater scenarios workgroup of FOCUS (Forum for the Co-ordination of pesticide fate models and their Use), version 1 of November 2000. EC Document Reference Sanco/321/2000 rev.2.

FOCUS surface water scenarios in the EU Evaluation Process under 91/414/EEC, report of the FOCUS working group on surface water scenarios. EC Document Reference Sanco/4802/2001-rev.2.

there is a correlation of exceedances with authorised uses (indicating a plausible link) or a high proportion of 'non-verifiable' monitoring sites. Water boards sometimes use an analytical method that cannot measure the substance in question at concentrations corresponding to the authorisation standard. With a high percentage of non-verifiable measurements, a significant correlation with land use may be present but not statistically demonstrable. The higher the percentage of 'non-verifiable' monitoring points, the less reliable the monitoring results are. When more than a quarter of the sites are 'non-verifiable', an excessive impact on the outcome of the correlations is expected. Therefore, for substances that are 'non-verifiable' at more than a quarter of the monitoring points, it is assumed that a significant correlation with the authorised land use of plant protection products could exist, even if significant correlations with land use are absent in the Pesticides Atlas.

For substances for which the exceedance index value is <0.01 , it is assumed for now that the (incidental) exceedances are not due to the authorisation. These substances are therefore not identified as structurally exceeding the authorisation standards.

A key criterion for structural exceedances is that there must be a minimum number of exceedances, which would exclude incidental exceedances. The latter could be due to incorrect use, for example, and not to the authorisation conditions themselves. The number of monitoring points in the Netherlands varies by substance. Consequently, the value of the exceedance index alone cannot be relied upon. In practice, the number of monitoring points is around 500 for many substances; the minimum is 1% of this (by analogy with an exceedance index value of 0.01). For a substance to be considered structurally exceeding an authorisation standard, exceedances must be measured at a minimum of five monitoring points (averaged over three years).

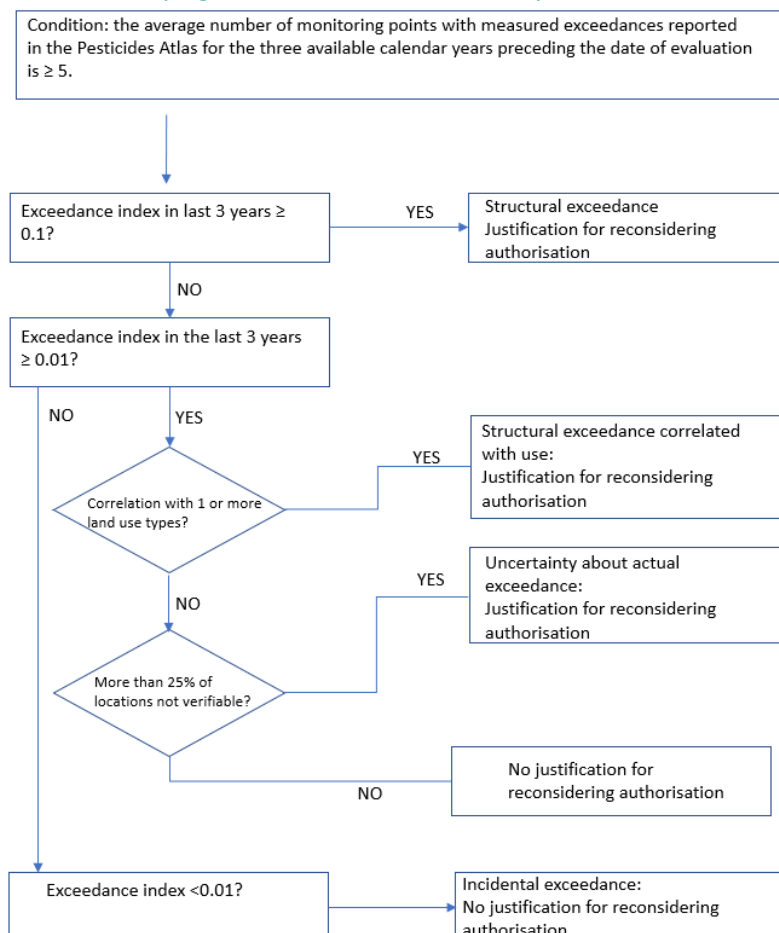
This leads to the following proposal for a decision tree for identifying 'substances that structurally exceed the authorisation standard' (see also Flowchart 1):

Decision tree: Structural exceedances of the surface water authorisation criterion

The Ctgb considers an active substance/metabolite for which the authorisation criterion is exceeded in surface water to be a structurally exceeding substance when the monitoring results for this substance meet each of the following criteria:

- a) The exceedance index in the list of substances with the most severe exceedances as reported in the Pesticides Atlas in relation to the authorisation criterion has a value of:
 - ≥ 0.1 in each of the three available calendar years preceding the date of evaluation
 - or
 - $\geq 0,01$ in each of the three available calendar years preceding the date of evaluation, where at least one of the following criteria is also met:
 - a significant correlation of exceedances with one or more authorised land use types is present
 - $\geq 25\%$ of the monitoring points are non-verifiable.
- b) As reported in the Pesticides Atlas, the average number of monitoring points that have shown exceedances during the 3 available calendar years preceding the date of evaluation is ≥ 5 .

Flowchart: Identifying substances that structurally exceed the authorisation standard



Elaboration of Step 2

Reassessment of plant protection products based on 'substances that structurally exceed the authorisation standard'

If the intervention in the authorisation of plant protection products due to substances that structurally exceed the authorisation standard were to be based only on monitoring data, it would not be entirely clear that the exceedances can be attributed to the authorisation. However, the necessary burden of proof for intervention in the authorisation under Article 44 Regulation (EC) 1107/2009 can be provided through a reassessment based on the latest assessment framework. The assessment framework used by the Ctgb for assessing the risk of plant protection products is not static, but evolves over time. New knowledge and methodologies/calculation models are becoming available, enabling increasingly adequate estimates of, among other things, the exposure of aquatic organisms in surface water to active substances and/or metabolites from plant protection products. In the case of substances that structurally exceed the authorisation standard, a reassessment of the aspect exposure to surface water may reveal whether it is necessary to amend or withdraw an authorisation under Article 44.

In the case of plant protection products based on substances that structurally exceed the authorisation standards, however, consideration is first given to whether an interim reassessment is desirable. After the authorisation of a product, new insights and/or methodologies for the aspect of emissions to surface water should have become available in the current assessment framework. Products for non-professional use are not expected to contribute significantly to structural exceedances and reassessment is generally not necessary for these products. There may also be procedural reasons not to do an interim reassessment, for example when the product is already being reassessed under Article 43 or when the active substance in the product is expected to lose its approval within short.

In an interim reassessment based on Article 44 Regulation (EC) 1107/2009, only the aspect of emissions to surface water is reassessed, as this can be used to estimate whether an exceedance of the authorisation criterion, as shown in the Pesticides Atlas, can be expected. For substances from plant protection products with an exceedance index ≥ 0.1 in each of the last three years, all authorised uses where emissions to surface water may occur are reassessed, and for substances with an index value of 0.01 to 0.1, this is done only for those authorised uses that correlate with exceedances of the authorisation standard in surface water. For 'non-verifiable' substances, all authorised uses are examined and correlations with concentrations from the Pesticides Atlas are used. The re-estimated emissions to surface water are compared with the authorisation standard for the product in question, based on studies with aquatic organisms. If the reassessment indicates an unacceptable risk to aquatic organisms, after consultation with the authorisation holder in accordance with Article 44 of Regulation (EC) 1107/2009, the authorisation must be amended.

Impact on workload and assortment of authorised products

Based on an initial analysis of the monitoring results from 2020, 2021 and 2022, the proposed decision tree has identified eight substances that structurally exceed the authorisation standard, which are used in about 40 products. However, when monitoring data for 2023 are included, this may lead to different results. One area of concern is the capacity required at the Ctgb to reassess products containing substances that structurally exceed the authorisation standard. To ensure that the required capacity remains manageable, a phased approach could be taken at the start of this operational method, with, for example, the three highest-risk substances being reassessed every year. The substances identified in the first year can then be reassessed within two or three years. A smaller workload is expected after the start-up year. This is because only products with problematic (structurally exceeding) substances that are identified after the start-up year will need to be reassessed.

As new knowledge and/or improved methodology for calculating the exposure in surface water has recently become available (such as GEM or the WDC), updating the assessment of products provides realistic options for tightening the authorisations. Thus, the reassessment is expected to have an impact on the authorisation of products based on substances that structurally exceed the authorisation standards. The impact on the available assortment of authorised products also depends on what measures will be needed, which can range from requiring additional drift-reducing measures, restricting the dosage or frequency of use, eliminating certain uses to withdrawing the authorisation entirely. The exact scope of these measures will only become clear after the reassessment.

Advantages and limitations

With the proposed operational method, all products based on a substance that structurally exceeds the authorisation standard will be addressed at the same time. As a result, the intervention can be expected to have a maximum impact.

Since some exceedances in surface water are not related to the authorisation of plant protection products but to other causes such as incorrect use (incidental), weather conditions or because the substance in question is also authorised as a biocide or veterinary medicine, the proposed methodology cannot provide a solution for all exceedances of authorisation standards. The proposed operational method can only address those exceedances – as shown by the assessment methodology – that are related to the authorised use of plant protection products.

If the reassessment shows that amendment of the authorisation of plant protection products is not required, the Ctgb will communicate this to the enforcing authorities (e.g. ILT, NVWA, the Dutch Water Authorities) and the Ministry of Infrastructure and the Environment. The causes of the exceedances must then be addressed by other means.

Impact on procedure for applications for authorisation

The Ctgb uses monitoring data from the Pesticides Atlas in the current operational method for each new application for authorisation or renewal. This only has an effect in a few cases because applicants for new authorisations can often substantiate that exceedances observed in monitoring are not caused by the use of the new product. For previously authorised products that have uses for which a correlation of exceedances with land use has been shown, no action is taken at that time. The operational method described in this memorandum and policy decree regarding the reassessment of existing authorisations under Article 44 Regulation (EC) 1107/2009 concerns a tightening of the existing operational method for assessing applications for new authorisations or renewals. Especially in applications for minor uses based on substances that structurally exceed the authorisation standard, for which due to the 'risk envelope' approach, the assessment framework of the original authorisation is used. To avoid the need to intervene immediately after authorisation on the basis of Article 44 of Regulation (EC) 1107/2009, the most up-to-date assessment framework as described in the *Evaluation Manual* on the Ctgb website will always be used to estimate emissions to surface water in applications for the authorisation and renewal of plant protection products that are based on substances that structurally exceed the authorisation standard.