GUIDELINE

for providing monitoring data and to carry out monitoring studies for plant protection products with high-risk potential for groundwater and surface water

The guideline is in accordance with § 5 par. 10 letters j) Decree of the Ministry of Agriculture and Rural Development of the Slovak Republic No. 485/2011 Coll. which establishes the details of plant protection products as amended, in accordance with § 4 of Act no. 364/2004 Coll., on water and on the amendment of Slovak National Council Act No. 372/1990 Coll. on offenses as amended (Water Act) and in accordance with document SANCO/13144/2010, version 1, 13 June 2009 ASSESSMENT OF THE POTENTIAL FOR THE MOVEMENT OF ACTIVE SUBSTANCES AND THEIR METABOLITES IN GROUNDWATER IN THE EU/ Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU, where the monitoring is specified in point 9 APPROACHES TO THE USE OF GROUNDWATER MONITORING DATA IN TIER 4 (the highest tier demonstrating safe use even without previous tiers 1-3).

Within the framework of the national authorization of plant protection products, following the risk assessment in Tier 1 to Tier 3, in the case of increased concerns about the pollution of groundwater and surface water by the active substance or its metabolites by using the plant protection product, as one of the measures to prevent the risk for groundwater and surface water, the provision of data from the targeted monitoring of the pesticide substance is required for the purpose of real verification and demonstration of the safe use of the product in the Slovak Republic in relation to the protection of water sources used for drinking purposes, or potentially used.

Increased concern for the presence of the active substance or its relevant metabolites in groundwater at concentrations exceeding 0,1µg/l may be indicated:

- for the purpose of their authorization or renewal of authorization or amendment of authorization, or
- during risk assessment in tier 1 for the purpose of approval or renewal of approval of the active substance at the EU level.

Reliable demonstration of the safe use of plant protection products in terms of their risk to drinking water will be demonstrated by the monitoring of the active substance and its metabolites in groundwaters or surface waters.

Monitoring studies are defined as: Studies in which groundwater samples are taken from several locations in regions or countries and subsequently analyzed for determined concentrations of active substances or their metabolites (SANCO/13144/2010).

For existing active substances and their metabolites, monitoring results obtained within the framework can be used:
(A) large-scale retrospective study
(B) small-scale retrospective study
(C) small-scale prospective study

The sources of groundwater and surface water monitoring data are:
1. Determined monitoring studies conducted in response to specific requests (State basic and operational monitoring)
2. Targeted proactive monitoring studies (targeted monitoring)
3. Data from monitoring provided by a third-party organization (e.g. research organizations, water company, etc.)

At the EU level, but also in the Slovak Republic, it is unlikely that monitoring data will be available for new active substances before the decision on their approval and inclusion in Annex I of Executive Regulation (EU) No. 540/2011. Monitoring data will therefore only be available to assess the existing risks of active substances in the process of renewing their approval. Approval criteria of the active substance is that within the EU there is a so-called "safe use".

Representativeness of monitoring:
The representativeness of the monitoring must correspond to its purpose and the data from the monitoring must be in the required range and of the required quality.

According to SANCO, the requirements for the scope and quality of monitoring are:
From the point of view of risk to groundwater, in order for an active substance to be approved at EU level, 90% of analyzes obtained from at least 50 locations (defined as a single well or a group of boreholes at the same location) must meet the requirement of a concentration in groundwater < 0, 1 μg/l.

Quality criteria
1. The data are from areas where the active substance have been used for a long time and are still being used at the time of sampling.
2. Soils in the studied area should be hydrologically connected with groundwater.
3. Sample analysis and technical documentation must correspond to currently available technology.
4. Contamination of the borehole must be excluded.
5. Groundwater pumping should be adequate so that the water level does not fall below the monitored level of the aquifer
6. The quantification limit of the analytical method should be lower than 0.1 μg/l.

At the national level, it is required to assess the aim of groundwater protection and scientifically determine whether the aim is being achieved.

A. *CRITERIA FOR PREVENTIVE MEASURE REQUEST "PROVIDING OF MONITORING DATA"*

Request	Criteria
Monitoring of active substance/ toxicologically relevant metabolite in surface water	1. Modeling of the potential environmental concentration of the active substance and toxicologically relevant metabolite in surface water PECsw > 0.1 µg/l in at least one of the models relevant for SR 2. Restriction of use of PHO[1] to PHO[5] (except PHO[3]) 3. Restriction of frequency of use to 1x in 2 or 1x in 3 years
Monitoring is required if criterion 1 is met and criterion 2 or 3 is met at the same time	

Monitoring of active substance/ toxicologically relevant metabolite in groundwater	1. Modeling of the potential environmental concentration of the active substance and toxicologically relevant metabolite in groundwater PECgw > 0.075 µg/l in at least one of the models relevant for SR 2. Restriction of use of PHO[1] to PHO[5] 3. Restriction of frequency of use to 1x in 2 or 1x in 3 years
Monitoring is required if criterion 1 is met and criterion 2 or 3 is met at the same time	

Monitoring of toxicologically irrelevant metabolite in groundwater	1. Modeling of the potential environmental concentration of irrelevant metabolite in groundwater PECgw > 3 µg/l in at least one of the models relevant for SR 2. Restriction of use of PHO[1] to PHO[5] 3. Restriction of frequency of use to 1x in 2 or 1x in 3 years
Monitoring is required if criterion 1 is met and criterion 2 or 3 is met at the same time	

B. *CRITERIA FOR MEASURE "MONITORING"*

The national monitoring quality criteria are based on the recommendations of document SANCO/13144/2010 in point 9.5.

Demonstration of safe use by monitoring is required only in the case of significant use of the plant protection product/products with the present risky active substance in the Slovak Republic.

"Significant use" is considered if the annual consumption of the product/products in the Slovak Republic in the current year exceeded 1000 kg (> 1 ton per year) of the main substance, which may be the subject of monitoring for the relevant period (at least the last 3 years).

Explanation: *The subject relevant period is considered to be the period (years) from the issuance of the authorization decision with the condition of monitoring to the specified deadline for the submission of monitoring results.*

1. ***Exclusion criterion***

In case that the annual consumption of a product/products with a specific active substance in the Slovak Republic in the relevant period is lower than 1,000 kg of active substance per year, it is not necessary to submit the monitoring results in accordance with the requirement stated in the decision.

The holder of the authorization will prove this fact with a certificate issued by the Department of Plant Protection of the Central Control and Testing Institute of Agriculture in Bratislava, based on the consumption of the relevant risk active substances in the Slovak Republic in the relevant period.

Explanation of exclusion criterion
With the confirmation, the holder of the registration will provide information on the total annual sales of the subject product with a given active substance, including calculation to the given active substance, for which monitoring was required, respectively monitoring of its metabolite was required.In case that the company has authorized other products for usage with this active substance, the company will also specify the amount of active substance in these products applied in the given year / individual years. The Central Control and Testing Institute of Agriculture will verify the facts of the company in the reported data and check whether the total consumption of this substance in the Slovak Republic is not doubled. Unless such use is considered as "not significant". If so and the usage is more than 2 times higher, the applicant informs about this fact. But it is not necessary in such a case for a company that really markets a small amount of PPP with a given A.S. to monitor compulsorily.

The Central Control and Testing Institute of Agriculture can also verify which other products with the same A.S. (of other applicants/registration holders) are being used in a given period and whether they have a monitoring obligation and can notify the applicant about it. Thus, it is not necessary for a company that really markets a small amount of PPP with a given A.S. to monitor compulsorily. However, if the amount is high and other companies also use higher amounts, it is auspicious to know about each other and possibly participate in monitoring.

2. ***Exclusion criterion***

For plant protection products authorized for non-professional users, due to the scope of use, monitoring is irrelevant and not required.

The status for providing the results of the monitoring of the subject active substance and its metabolites will be determined by the date of submission of the documentation for the purpose of renewing the authorization of the plant protection product. In case that the time frame for re-evaluation is unknown or very short, the Central Control and Testing Institute of Agriculture may set another time frame for the submission of documentation, but no sooner than 5 years after the decision was issued.

C. *MONITORING STUDY / REPORT*

The submitted monitoring report may contain monitoring results:

1. Own purposeful monitoring from the sources of the authorization holder

2. National monitoring (in the state monitoring network SHI, WRI)

3. Monitoring in the member states of the central zone (in case of seed treatment in the entire EU)

4. Monitoring of other organizations in the Slovak Republic (e.g. monitoring of water management companies, research organizations, etc.)

Recommendation: Before the implementation of the own (prospective) monitoring study, it is necessary to create a purposeful monitoring program, within which the conditions for demonstrating the safe use of the product should be processed, taking into account the "worst case" conditions of use.

It is required to provide data from the monitoring of the active substance or its metabolites / or groups of active substances and their metabolites in water (groundwater and surface water):

1. *Monitoring can be carried out in the Slovak Republic or in one of the member states of the central zone of the EU (preference for states neighboring the Slovak Republic – Czech Republic, Austria, Hungary, Poland). In case of providing monitoring results from another EU member state, its representativeness will be considered in terms of comparability of climate-geographical and soil-hydrogeological conditions.*
2. *Both existing (retrospective studies) and new targeted monitoring studies that meet the quality criteria listed in points 4–7 and in part D can be used.*
3. *The implementation of water monitoring should also include vulnerable areas (at least 50% of the total number of objects) and sensitive areas in terms of use and its risk (at least 25% of the total number of objects)*
4. *Monitoring should be carried out at the observation points of agriculturally used places where the mixture with the given active substance or its metabolite is used (prospectively)/used (retrospectively) (minimum 80% of the total number of objects). In the case of retrospective monitoring studies, a minimum of 2 years of consumption/use analysis is required. We recommend optimally using 5–10 years.*

   In the case of monitoring of new active substances, the monitoring locations should be concentrated on the areas with the greatest potential impact (worst case).
5. *Monitoring must provide data from areas where the product/active substance has been used for at least 5 years and is still being used, or where it was currently being used at the time of sampling (sampling).*
6. *By selecting monitoring objects, contamination of the observation object by other anthropogenic activities must be excluded.*
   Recommendation: Observation objects should be located on agriculturally cultivated land, or in places of proven application of products - depending on its main use (e.g. railways, canals...). Or near them in the direction of groundwater flow.
7. *Monitoring should include all significantly represented soil types. Recommendation: Take into account the prevailing types of soil that are listed in the Atlas of Soils of the Slovak Republic and are located in areas with important hydrogeological collectors (hydraulic connection with groundwater).*

Collection and analysis of samples:

Sampling and sample analysis, including the development of a monitoring program and technical documentation, must be provided and carried out by accredited organizations and must correspond to the latest currently available techniques. The analysis of the samples must be carried out during the entire monitoring period by the same accredited analytical method with a limit of quantification of the analytical method less than 0.1 µg/l.

Groundwater sampling is performed according to STN ISO 5667-11 for groundwater sampling and according to STN EN ISO 5667-1: 2007 for surface water sampling.

Recommendation: In addition to classic point sampling, it is also advisable to carry out sampling using a combined method - classic point sampling in combination with passive sampling (at least on 10% of monitoring objects). In addition, it is recommended to provide at least 1% of control samples.

Recommendation: At least the value of the limit of determination should reach less than 50% of the limit value (i.e. in the case of the quality standard for pesticides, the value of 0.05 µg / l).

D. RECOMMENDATIONS AND REQUIREMENTS FOR FULFILLING THE CONDITION OF PROVING THE SAFE USE OF THE PRODUCT IN THE SR IN THE CASE OF IMPLEMENTING YOUR OWN PURPOSE MONITORING (prospective small-scale study)

1. *Duration of monitoring at least 2 years.*
   Recommendation: To increase reliability and representativeness, we consider at least a 3-year monitoring study.

2. *Sampling frequency 1-4 times a year, or a combination with continuous concentration monitoring. Recommendation: We consider the frequency of 2 times a year to be optimal, reliable and representative for most hydrogeological collectors, while one of the sample collections should be carried out after the date of application of the product. In the case of karst areas and areas with high permeability, we recommend increasing the frequency to 4 times per year.*

   In the case of a frequency of 2 x a year, it is appropriate to add continuous monitoring of the concentration (passive sampling) to at least 5% of the monitoring sites.

3. *The number of monitoring locations requires at least 50 locations / monitoring objects.*

If monitoring of the active substance and its metabolites is required only in groundwater:
Recommendation: We consider 100 groundwater monitoring objects to be optimal for monitoring in the Slovak Republic, while at least 10% (i.e. 10 objects) of them should include the second aquifer horizon, from the point of view of evaluating the possibility of pollution penetration to depth.

If monitoring of the active substance and its metabolites is required only in surface water:
Recommendation: We consider 20 monitored profiles to be optimal for monitoring in the Slovak Republic, but all orders of surface flows from the largest to the smallest (flow of the 1^{st} to 5^{th} order) must be adequately represented.

If monitoring of the active substance and its metabolites in both groundwater and surface water is required:
Recommendation: We consider 100 groundwater monitoring objects to be optimal for monitoring in the Slovak Republic, while at least 10% of them should also include the second aquifer horizon, from the point of view of evaluating the possibility of pollution penetration to depth, as well as monitoring in at least 25 profiles on surface flows, while at least on 5% of the profiles, the hydraulic connection of GW and SW should be taken into account.

4. **Condition for confirmation of safe use:**

a) **At least 90% of the analyses of the monitoring study for the active substance and toxicologically relevant metabolite meet the quality standard - concentration of the active substance or toxicologically relevant metabolite in water < 0.1 µg/l, or for toxicologically irrelevant metabolites concentration < 0.75 µg/l in groundwater.**

b) **In at least 90% of the objects of the monitoring study for the active substance and toxicologically relevant metabolite, it meets the quality standard - the concentration of the active substance or toxicologically relevant metabolite in water < 0.1 µg/l, or for toxicologically irrelevant metabolites concentration < 0.75 µg/l in groundwater.**

c) **In at least 75% of objects, the documented concentration value was lower than the difference between the quality standard and the limit of determination / 2.**

E. CONCLUSION – EVALUATION OF PROVIDED DATA FROM MONITORING STUDIES

IF ALL REQUIREMENTS ARE MET, the safe use of the plant protection product is confirmed/proven and the condition is met. Subsequently, as part of the renewal of the authorization of the product in the Slovak Republic, the condition of monitoring will be canceled / possibly other restrictions on use may be adjusted according to the results.

IN THE CASE OF FAILURE TO FULFILL any of the requirements, within the framework of the renewal of the authorization of the plant protection product, the measures may be tightened, or in case of inadequacy of the study or unreliability of the monitoring study, the monitoring requirement may be extended for another period, under the same conditions as were requested (see above).

IN THE CASE OF FAILURE TO FULFILL THE REQUIREMENTS AND A HIGH RATE OF SURFACE OR GROUNDWATER POLLUTION DEMONSTRATED BY MONITORING - i.e. exceeding the criteria and limits specified in part D 4 in more than 25% of the samples, the safe use of the plant protection product was not proven by monitoring and the indicated high and unacceptable risk was confirmed. The use of the preparation may cause a water quality deterioration and therefore its authorization/use will be canceled/resp. not renewed.

This guideline come into force from January 1, 2022

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On: August 27, 2021
Revision after comments 11/11/2021/ 30/11/2021
Updated July 26, 2024