

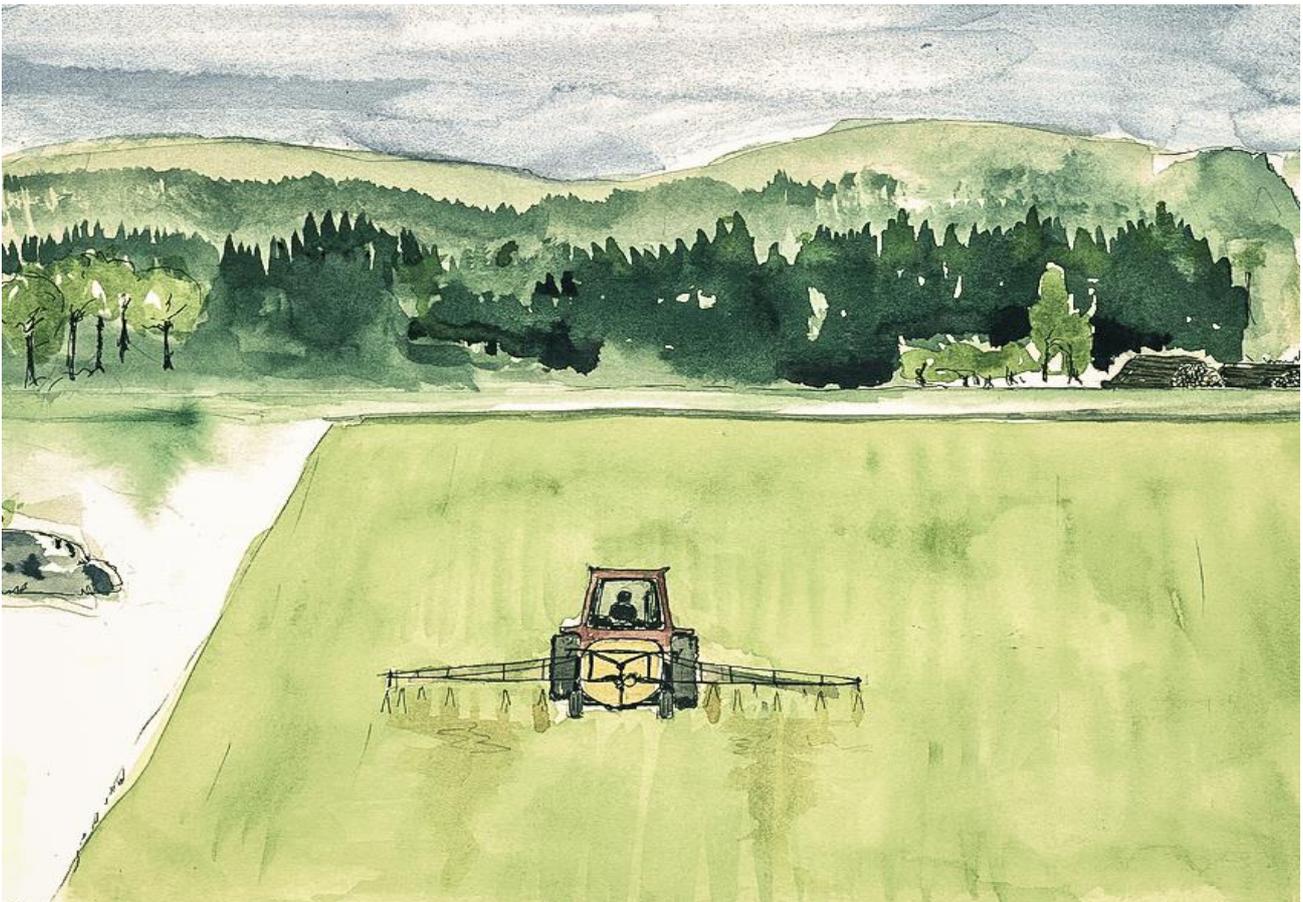


SWEDISH ENVIRONMENTAL
PROTECTION AGENCY

Swedish Agency
for Marine and
Water Management

Permits for the use of pesticides in water protection areas

Guidelines to the permit authorisation procedure



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Preface

Since the 1990s there have been major changes in the regulations relating to pesticides in terms of both the approval of pesticides and provisions regulating their use. These changes have resulted in the phasing out of a number of pesticides with inappropriate properties, but the handling of pesticides has also been improved. The approval process has also undergone change. Nowadays, the requirement for base data for approval of a substance for use is considerably more extensive than before. Many of the substances that have proven to pose a risk to human health or the environment are no longer approved, or dosages and application areas have been restricted.

However, surveys show that pesticide residues are nevertheless still present in both groundwater and surface water. The pesticide residues found in groundwater are mainly older, now prohibited substances; but as far as surface water is concerned, the findings are dominated by approved plant protection products used primarily in agriculture. The fact that groundwater findings are still dominated by residues of old non-selective herbicides that have been prohibited for several decades indicates the importance of striving to achieve sustainable use of pesticides, as their effects in the environment may otherwise be serious and long term. It is particularly important to carry out risk assessments and, if necessary, restrict the use of pesticides in water protection areas.

Use of pesticides in water protection areas is currently regulated by means of local water protection regulations established pursuant to Chapter 7, Section 22 of the Environmental Code and – as regards pesticides that constitute plant protection products – by means of the general permit requirement for all water protection areas in Chapter 6, Section 1 of Swedish Environmental Protection Agency regulations (NFS 2015:2) on application and certain other handling of plant protection products. The purpose of the permit requirement is to maintain raw water that is free of pesticide residues, thereby safeguarding water resources for future generations.

As there is a certain degree of overlap in the responsibilities for guidelines in respect of the Swedish Agency for Marine and Water Management and the Swedish Environmental Protection Agency with regard to the use of pesticides in water protection areas, the authorities have devised the following guidelines together.

The content of these guidelines replaces the Swedish Environmental Protection Agency's general recommendations (NFS 2000:7) for the permit authorisation procedure in accordance with Section 14 of SNFS 1997:2 concerning the use of chemical pesticides in water protection areas, plus, where relevant, the Swedish Environmental Protection Agency's general recommendations (97:3) on the application of Swedish Environmental Protection Agency regulations on the application of chemical pesticides, both of which ceased to apply on 1 November 2015.

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SUMMARY	9
GLOSSARY OF TERMS	10
AUTHORITIES AND THEIR RESPONSIBILITIES	11
PURPOSE AND TARGET GROUP	13
SCOPE.....	13
WATER PROTECTION AREAS	13
Water protection regulations.....	14
RULES FOR THE USE OF PESTICIDES	17
The general permit requirement in respect of water protection areas	17
The meaning of the general permit requirement	18
Changes in relation to previous rules	19
PROCESSING OF PERMIT CASES	20
Regulatory framework.....	20
The authority's enquiry responsibility.....	20
Information in applications.....	21
A. Administrative details	21
B. Information on the site.....	22
C. Information on the plant protection product and its use	24
D. Data from simulation in a model tool	25
Risk assessment.....	25
The term "chemical-intensive cultivation"	26
Description of MACRO-DB decision support.....	27
Simulation according to MACRO-DB	28
Step 1.....	28
Step 2	29
How can the results from MACRO-DB be used?	29
Factors that are not considered in model simulations with MACRO-DB.....	31
Use of plant protection products in areas other than agricultural land and horticulture.....	32
Golf courses	33
Greenhouses	34
Other land.....	34

DECISION.....	37
Decision to issue a permit.....	37
Permit duration	37
Conditions.....	37
Examples of conditions.....	38
Decision to reject an application	42
Amendment of the permit	43
Appeals	43

Summary

These guidelines can be used by both supervisory authorities and operators with regard to applications for the use of pesticides in water protection areas. The guidelines deal with both the permit authorisation procedure in accordance with the water protection regulations established pursuant to Chapter 7, Section 22 of the Environmental Code and in accordance with Chapter 6 of *Swedish Environmental Protection Agency regulations (NFS 2015:2) on application and certain other handling of plant protection products*.

The guidelines have been defined so that they relate to the permit authorisation procedure for chemical plant protection products with emphasis on the queries arising with regard to agricultural handling of plant protection products. However, use of chemical plant protection products in other fields is also discussed in the guidelines to a certain extent.

The overall purpose of these guidelines is to maintain good raw water quality in our water catchments, free of pesticide residues. The guidelines also aim to pave the way for simpler, more consistent handling of permit applications for the use of pesticides in water protection areas.

The guidelines begin with general information on the regulations with regard to water protection areas and regulations for the use of pesticides. Guidelines on the handling of permit cases, from the receipt of an application to a decision being made, are then provided. The information that should be included in the processing of permit cases, the risk assessment that has to be carried out by the authority, what decisions on permit cases should include and how they should be formulated are all important elements in the handling of permit cases described in these guidelines.

Glossary of terms

Catchment area is the total land and water area upstream of a certain point in a lake, waterway or sea area towards which all runoff takes place. If only the land area is referred to, this is known as the drainage area instead. The catchment area for surface water is defined by elevated ridges (watersheds), where runoff caused by precipitation and meltwater flows in different directions. The drainage area for a groundwater reservoir is instead defined by the groundwater divide.

Pesticides can be either plant protection products or biocidal products.

Pest control threshold relates to the number of pests per unit (e.g. stem, plant or area) required for control to be justified in financial terms. Use of pest control thresholds is also an important element in a needs-based control strategy so as not to overuse chemical pesticides and control pests for preventive purposes. However, pest control thresholds are not available for all pests. More information is available on the Swedish Board of Agriculture website.

Biocidal product is a product designed to destroy, render harmless, prevent, prevent the effects of or otherwise control harmful organisms by means other than physical or mechanical impact.¹ Wood preservatives, mosquito repellent, rat poison and antifouling paints for water vessels are examples of biocidal products.

Dosage key makes it possible to adapt the dose when controlling various pests on the basis of the conditions in place in the location where control is taking place. Use of dosage keys is an important element in a needs-based pest control strategy so as not to use a higher dose of plant protection products than required by the situation. Dosage keys are not available for all types of plant protection product. More information is available on the Swedish Board of Agriculture website.

Plant protection products, which may be chemical or biological, are mainly used to protect plants and plant products for agricultural, forestry and horticultural purposes. They may provide protection against pests, fungal attack or competing plants.

¹ Regulation (EC) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

Authorities and their responsibilities

As far as pesticides are concerned, there are a number of central authorities that share responsibility for providing supervisory guidance. Operational supervision is mainly implemented by the municipalities. Below is a brief description of the primary responsibilities of each authority. List in alphabetical order.

Arbetsmiljöverket, the **Swedish Work Environment Authority**, makes decisions on regulations relating to safety in the work environment when handling and using chemical pesticides. The Swedish Work Environment Authority also holds regular courses for operators.

Havs- och vattenmyndigheten, the **Swedish Agency for Marine and Water Management**, has been responsible since 1 July 2011 for coordination of water work (seawater and freshwater) and long-term planning of the sea environment. The authority holds central responsibility for guidelines relating to setting up and administering water protection areas, with associated regulations in accordance with Chapter 7 of the Environmental Code. The authority is also the supervisory guidance authority for issues relating to water protection areas and protection of groundwater.

Jordbruksverket, the **Swedish Board of Agriculture**, is responsible for training and issuing the permits required for professional use of plant protection products. The Swedish Board of Agriculture is also responsible for supervisory guidance on the use of plant protection products in agriculture and horticulture.

The Swedish Board of Agriculture makes decisions on regulations relating to authorisation for the use of plant protection products, integrated plant protection, documentation requirements (spray record) and mandatory function testing of spraying equipment.

The Swedish Board of Agriculture organisation includes regional plant protection centres that provide advisors and growers with information and recommendations for adapting chemical pest control to needs and reducing its risks.

The Swedish Board of Agriculture is involved in projects such as Focus on Nutrients and Focus on Pesticide Use, which aim to distribute information and provide recommendations to reduce the occurrence of plant protection product residues in the environment.

Kemikalieinspektionen, the **Swedish Chemicals Agency**, examines applications for permits to sell and use pesticides, known as product approval in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. The terms and conditions applicable to the use of the product are provided in connection with a product approval. All approved pesticides are included in the database known as the pesticides register.

The Swedish Chemicals Agency is responsible for operational supervision of primary suppliers of pesticides and supervisory guidance for Sweden's municipalities concerning the control of pesticide distributors.

The Swedish Chemicals Agency is responsible for providing information and support and cooperating with companies, authorities and other relevant parties with regard to pesticides. The authority compiles annual statistics of pesticide quantities sold.

Kommuner, Swedish **municipalities**, are mainly responsible for supervising the use of pesticides. The municipality is able to set up water protection areas and issue regulations for these pursuant to Chapter 7, Sections 21 and 22 of the Environmental Code, and also to grant exemptions and examine applications for permits based on such water protection regulations. The municipal authority that fulfils the tasks of the municipality in respect of protection of the environment and health is also the examining authority for permit applications in

accordance with Chapter 6, Section 1 of NFS 2015:2. The municipality is also a supervisory authority for the water protection areas set up by the municipality, as well as the water protection areas where the county administrative board has transferred operational supervision to the municipality. Operational supervision is exercised by the environment and health administration or equivalent in the municipality in question.

Livsmedelsverket, the **National Food Administration** runs a programme for monitoring pesticide residues in food. The National Food Administration also issues regulations concerning requirements relating to the production and provision of drinking water. *National Food Administration regulations (SLVFS 2001:30) concerning drinking water* specifies requirements for producers and providers of drinking water to investigate the occurrence of pesticides. These regulations also include limits for the occurrence of pesticides in water that is ready to drink. The limit for individual pesticides is 0.1 µg/l, and 0.5 µg/l for the total level. A limit of 0.030 µg/l is applied for certain substances (aldrin, dieldrin, heptachlor and heptachlor epoxide).

Länsstyrelserna, the **county administrative boards**, train farmers, commercial growers of garden plants, etc. on the use of plant protection products and issues factual evidence and permits to use class 2L and 1L plant protection products. The county administrative board is able to set up water protection areas and issue regulations for these pursuant to Chapter 7, Sections 21 and 22 of the Environmental Code, and also to grant exemptions and examine applications for permits based on such water regulations. The county administrative board is also a supervisory authority for the water protection areas set up by the county administrative board, and is also responsible for supervisory guidance for municipalities carrying out operational supervision.

Naturvårdsverket, the **Swedish Environmental Protection Agency**, issues regulations on the application of plant protection products in the external environment and holds indicative responsibility for supervision in accordance with the Environmental Code. According to the Environmental Management Ordinance (2011:13), the Swedish Environmental Protection Agency is responsible for supervisory guidance for all use of plant protection products except in agriculture and horticulture. This involves supervisory guidance responsibility for use of plant protection products on golf courses and railway embankments and in domestic gardens, for example.

Skogsstyrelsen, the **Swedish Forest Agency**, is responsible for supervisory guidance for issues relating to forestry and to make decisions on the application of certain provisions in the Pesticides Ordinance concerning the use of plant protection products in forestry.

Purpose and target group

These guidelines aim to:

- help provide effective protection of water catchments
- describe the regulations that include permit requirements for the use of pesticides in water protection areas
- help ensure simpler, more consistent handling of permit applications, and
- provide examples of conditions that may be required for the issuing of a permit.

The primary target group for these guidelines is the authorities examining applications for permits for the use of pesticides, but also other related parties as regards the use of pesticides in water protection areas.

Scope

These guidelines are only relevant to permitting aspects of chemical plant protection products, with emphasis on agricultural applications.

Issues relating to the use of biological plant protection products or biocidal products are not covered.

Please refer to *Swedish Environmental Protection Agency regulations (NFS 2015:3) on application of certain biocidal products* and the Swedish Environmental Protection Agency guidelines for guidance and for more information relating to these aspects.

Exemptions from prohibitions in local Water Protection Regulations are outside the scope of this document

Water protection areas

Chapter 7, sections 21 and 22 of the Environmental Code include provisions relating to the setting-up of water protection areas. According to Chapter 7, Section 21 of the Environmental Code, an area of land or water may be declared by the county administrative board or municipality as a water protection area in order to protect a groundwater or surface water supply that is used or may be assumed to be used for water catchment. Chapter 7, Section 22 of the Environmental Code states that the county administrative board or municipality must provide notification of such regulations on restrictions on the right to possess properties needed to fulfil the purpose of the area.

According to Chapter 7, Section 25 of the Environmental Code, the restrictions reported within the area must not go further than required to fulfil the purpose of the protection of the area. The restrictions reported within a water protection area generally take the form of prohibitions or requirements for special permits.

According to the preamble to currently applicable provisions, the water protection area with associated provisions must be so far-reaching that the *raw water* can be used for its purpose *following a normal treatment procedure* (Government bill 1997/98:45 II p. 93 f). This means that these levels of pesticide residues in the raw water must be kept close to nil so that there is no need to install special treatment stages at the waterworks in order to separate pesticide residues when producing drinking water.

The limit for individual pesticides in *drinking water* is 0.10 µg/l and for pesticides – total (the sum of all pesticides detected and quantified in a sample) 0.50 µg/l. A limit of 0.030 µg/l is applied for certain substances (aldrin, dieldrin, heptachlor and heptachlor epoxide). These limits can be found in National Food Administration regulations (SLVFS 2001:30) on drinking water.

The limits for pesticides in drinking water are not based on any risk to health, but are based on the perception that it is unacceptable to have pesticide residues in drinking water. The level was established within the EU as early as 1980 and was based on the levels that the laboratories were capable of analysing at the time². However, analysis technology has developed greatly since then, and the detection limits for most substances have fallen considerably. However, the National Food Administration is of the opinion that the limits specified ensure a good safety margin for human health.

0.1 µg/l = 1 g active substance in 10 million litres of water

Water protection regulations

As indicated above, the starting point for assessment of the need for restrictions is the water catchment's need for protection. This need is concretised in respect of individuals by developing water protection regulations.

Water protection regulations involve restrictions on land use, i.e. they can be formulated as prohibitions or as requirements for specific permits for certain types of activity or action.

Prohibitions may be one alternative if:

- The overall effect of the use of pesticides, e.g. as a consequence of certain land use in an area, is unacceptably high.
- The consequences of an activity are deemed to be serious and the knowledge base does not allow the risks to be reduced sufficiently by specifying requirements for protective measures or other precautions.

² Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption, Annex 1, section D, point 55.

Support for introducing a prohibition on all use of plant protection products within certain zones within a water protection area may, for example, include:

So much of the drainage area being cultivated conventionally that the overall diffuse load on the water catchment is unacceptable despite the fact that handling at each individual agricultural unit takes place in the best conceivable way.

The risk of accidents must be eliminated fully.

The above conditions, either in combination or individually, may constitute reasons for introducing zones where the use of plant protection products is prohibited in the water protection regulations. Implementing a prohibition of this kind will achieve a greater safety margin to prevent the water catchment being affected by plant protection products.

If the risks are so great that a permit should generally not be issued within a primary zone, for example, a prohibition on the use of plant protection products must be introduced in the water protection regulations. If the requirements for a permit apply in areas where circumstances would instead justify a prohibition on the use of plant protection products, the examining authority will instead have to examine each case on the basis of the criteria in each individual case. For a permit application to be rejected, it is necessary for the risk assessment in the case in question to be capable of forming a basis for rejection. Rejecting an application by stating that the substance should never be handled within a protected zone should never take place. In this situation, the restriction level should justify a prohibition instead of a permit requirement.

Introducing a permit requirement may be one option if it is possible to use conditions relating to protective measures and precautions to considerably improve handling or reduce the adverse effects of an activity or action.

Swedish Environmental Protection Agency general recommendations NFS (2003:16) on water protection areas and the Handbook with general guidelines for Water protection areas (2010:5) include recommendations stating that a prohibition should be prescribed for the handling of chemical pesticides within primary protection zones and that permit requirements should be prescribed for the handling of chemical pesticides in secondary protection zones.

Example of how a water protection regulation established pursuant to Chapter 7, Section 22 of the Environmental Code may be formulated

Primary protection zone

Outdoor application of chemical pesticides is prohibited.

Secondary protection zone

Chemical pesticides may only be handled for commercial purposes when a permit has been issued by the municipal authority.

Remarks

All use of chemical pesticides outdoors is prohibited within the primary protection zone in this particular water protection area. This prohibition includes both commercial use and use by private households.

The regulation has been restricted in the secondary protection zone to requirements for permits, relating only to commercial handling of chemical pesticides.

The term chemical pesticides is frequently used in the water protection regulations in water protection areas set up pursuant to Chapter 7 of the Environmental Code or previous legislation. In the case of the permit authorisation procedure pursuant to water protection regulations, a check should therefore be carried out to see how the permit requirement has been defined in the water protection regulations, i.e. which types of pesticide are covered by the permit requirement.

It is also important to note which authority will examine any permits in accordance with local water protection regulations, as the examining authority may be either the municipality or the county administrative board.

The general permit requirement in Chapter 6, Section 1 of *Swedish Environmental Protection Agency regulations (NFS 2015:2) on application and certain other handling of plant protection products* is applicable only to plant protection products. This differs from the requirements in accordance with the Swedish Environmental Protection Agency's now repealed regulations SNFS 1997:2, which related to the use of chemical pesticides.

Rules for the use of pesticides

A number of changes in respect of pesticides have taken place within the EU in recent years.

Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (the EU Plant Protection Product Ordinance) has been in force since June 2011. Regulation (EC) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (the EU Biocide Ordinance) came into force in September 2013.

Use of pesticides is regulated in Directive 2009/128/EC of the European Parliament and of the Council to achieve the sustainable use of pesticides (the Pesticides Directive). This directive, which is currently applicable only to plant protection products, came into force in November 2011.

This directive is intended as a complement to the EU Plant Protection Product Ordinance. Reducing the risks and consequences of the use of pesticides in respect of human health and the environment is an important purpose of the directive. The directive also aims to prevent contamination of surface water and groundwater and restrict the use of pesticides in particularly sensitive environments.

As a consequence of the amended EC regulations in respect of pesticides, the government adopted a new ordinance (2014:425) on pesticides (the Pesticides Ordinance) on 28 May 2014, and this came into force on 15 July 2014. The Pesticides Ordinance gathers together rules relating to the use of plant protection products and biocidal products, including provisions that enact the Pesticides Directive in Swedish law. The provisions in the Pesticides Ordinance follow the division in EU law, which means separate rules for plant protection products and biocidal products.

The general permit requirement in respect of water protection areas

The Swedish Environmental Protection Agency has been authorised in the Pesticides Ordinance to make decisions on more detailed regulations on buffer zones, safeguard zones and precautionary measures to protect human health and the environment.

Pursuant to relevant authorisations, the Swedish Environmental Protection Agency announced *Regulations (NFS 2015:2) on application and certain other handling of plant protection products* on 11 June 2015. These regulations come into force as of 1 November 2015 and replace, together with the *Regulations (NFS 2015:3) on application of certain biocidal products*, the previously applicable *Regulations (SNFS 1997:2) on application of chemical pesticides* with associated guidelines in the form of the *General recommendations 97:3 and NFS 2000:7*.

The Swedish Environmental Protection Agency regulations NFS 2015:2 include provisions on permit requirements for commercial use of plant protection products within the abstraction zone and primary and secondary protection zones within water protection areas.

Chapter 6, NFS 2015:2 Permit for use in water protection areas

Section 1 Use of plant protection products outdoors within the parts of a water protection area that are designated as abstraction zone, primary (inner) protection zone and secondary (outer) protection zone is prohibited without a special permit from the municipal authority.

If a water protection area has not been divided into zones, the prohibition on use without a permit in accordance with the first paragraph is applicable throughout the entire water protection area.

Section 2 The provision in Section 1 is not applicable to spot treatments or similar use and that are of such limited extent that there is no risk of harm to human health or the environment.

The provision in Section 1 is not applicable to water protection areas that have been set up after 1 January 2018 or water protection areas for which regulations for the protection of the area have been amended after 1 January 2018.

According to Chapter 2, Section 36, second paragraph of the Ordinance (2014:425) on pesticides, the provision in Section 1 is not applicable to water protection areas or parts of a water protection area that are subject to regulations announced pursuant to Chapter 7, Section 22 of the Environmental Code prohibiting the use of plant protection products.

The meaning of the general permit requirement

- The permit authorisation procedure means that the criteria for the issuing of a permit must always be assessed in each individual case.
- A permit may be combined with conditions relating to protective measures and precautions.
- The fact that an assessment must always be made on the basis of the existing circumstances in the case in question does not exclude the fact that there may be aggravating circumstances which mean that the municipal authority should generally be restrictive in granting a permit. This is applicable to the use of plant protection products on permeable surfaces, for example. In these cases, permits should only be issued if conditions relating to protective measures or precautions ensure that there is no risk of harm to the environment or humans.
- The general permit requirement for the use of plant protection products in water protection areas according to NFS 2015:2 involves a relatively rough tool as regards assessment of the need for protection in individual water protection areas. In some cases, the general permit requirement may constitute insufficient protection within certain parts of water protection areas, and in this case the municipality should act to ensure that the need for protection is instead met by introducing a prohibition on the use of plant protection agents in the water protection regulations.
- The fact that an assessment of the need for protection should take place at a local level is also one of the reasons as to why there is an intention to phase out the general permit requirement as of 2018.

The general permit requirements within primary zones

The general requirement for a permit can never be equated with a prohibition in certain parts of water protection areas. Under certain circumstances, a prohibition on the application of plant protection products should be introduced to the water protection regulations instead. This may, for example, be the case if the examining authority comes to the conclusion that a permit should generally not be issued:

- Within a certain subarea within the water protection area, e.g. a primary zone, or
- If the conditions are such that cumulative effects of conventional cultivation are deemed to be too great or too difficult to assess during individual permit authorisation procedures.

Changes in relation to previous rules

The provisions on permit requirements according to Chapter 6 of NFS 2015:2 correspond to an extent to the rules previously applicable according to Section 14 of SNFS 1997:2; that is to say, that permits are required for commercially used plant protection products within water protection areas. However, there are a number of significant differences that it may be worth highlighting in particular:

- The present provisions apply only to plant protection products and not to pesticides in general, as was previously the case.
- The general permit requirement for the use of plant protection products in water protection areas according to NFS 2015:2 is not applicable with regard to water protection areas that have been set up after 1 January 2018 or with regard to water protection areas for which the protection regulations have been amended after 1 January 2018. Therefore, for water protection areas set up or amended after 1 January 2018, an assessment needs to be carried out at a local level of whether there is a need for a permit requirement for the use of plant protection products. If it is then concluded that the use of plant protection products needs to be examined separately, provisions have to be introduced to the protection regulations for the water protection area in question. This regulation is in line with the objectives whereby the use of plant protection products in the long term only should be regulated in water protection regulations as this scheme will lead to more appropriate and needs-based protection for the water catchments that are or will be used for drinking water supply.
- A third important difference is the fact that the general permit requirement is currently only applicable within primary (inner) and secondary (outer) zones within water protection areas and not, as previously, throughout entire water protection areas. However, an exception to this basic rule is applicable if the water protection area comprises only one zone, in that case, the general permit requirement is applicable to the entire water protection area.

Processing of permit cases

Regulatory framework

As specified above, permit cases can be initiated either due to provisions relating to permit requirements in water protection regulations, or due to the general permit requirements in Chapter 6, Section 1 of NFS 2015:2. When a permit application is received, it may be appropriate to observe the following:

- If a permit case is to be examined on the basis of provisions in water protection regulations, it is important when processing the case to work on the basis of the restriction defined in the water protection regulations. For example, the permit requirement in accordance with the water protection regulations may include all types of pesticide, i.e. both plant protection products and biocidal products. Moreover, permit requirements in accordance with water protection regulations may also apply to non-commercial use or indoor use, and in this case are also applicable in the case of use in greenhouses. Therefore, checks should always be made of how the permit requirement has been defined in the water protection regulations.
- It is frequently the case that the permit requirements in accordance with the water protection regulations completely or partly overlap the general permit requirement according to Chapter 6, Section 1 of NFS 2015:2. In these cases, there is a formal requirement to examine permit applications in accordance with both sets of regulations. In these situations, it is particularly important to note which authority is obliged to examine the permit in accordance with local water protection regulations, as this is sometimes an authority other than the municipal authority. As both sets of regulations are applicable in parallel, there may be occasions on which the regulations involve examinations by different authorities.
- If a prohibition on the use of plant protection products has been introduced to the water protection regulations, the general permit requirement in Chapter 6, Section 1 of NFS 2015:2 is not applicable. This means that it is not possible to apply pursuant to NFS 2015:2 for a permit for the use of plant protection products in parts of a water protection area where the use of pesticides is prohibited, as is also indicated by Chapter 2, Section 36, second paragraph of the Pesticides Ordinance.

The authority's enquiry responsibility

For the authority to be able to make a well-founded decision, the operator is required to provide sufficient information on the handling of plant protection products. The operator is always responsible for showing that they can be used at no risk to the environment: see Chapter 2, Section 1 of the Environmental Code.

However, the authority is always responsible for ensuring that the decision data is sufficiently extensive. In other words, the authority is responsible for the enquiry and has to ensure that necessary data is submitted. The authority's enquiry responsibility generally extends further in cases involving intervention

in order to protect the environment or human health; for example when ordering an injunction to take measures. However, as regards permit cases, the authority is also responsible for leading the process and ensuring that sufficient data is submitted.

If there is insufficient data in a permit application, the authority can fulfil this responsibility by ordering supplementary data to be submitted, for example. Some support with regard to what should be included in application is available to the authority in section 23 of the Ordinance (1998:1252) on area protection and Chapter 7, Section 1 of NFS 2015:2.

Information in applications

Applications for permits for the use of plant protection products in water protection areas should include the information specified in chapter 7, section 1 of NFS 2015:2 as a minimum.

Chapter 7 of NFS 2015:2 Permits and notifications

Section 1 Applications for permits to use plant protection products according to Chapter 2, Section 40 of the Ordinance (2014:425) on pesticides or a notification relating to use of plant protection products other than use in woodland according to Chapter 2, Section 41 of the Ordinance (2014:425) on pesticides must include

1. a map or other description of the location and area of the application area,
2. contact details for the party that will be applying plant protection products and, where appropriate, the party on behalf of which the application of the products is being carried out,
3. the purpose of the application,
4. the name and registration of the number of the plant protection product, providing information on the active substance,
5. a description of the application method,
6. the dosage to be used, and
7. the estimated point in time or period of the application.

Further information is often required to be able to perform a sufficiently well-founded risk assessment. Given this fact, information that is normally needed to examine an application for a permit can be divided as follows:

- A. Administrative details
- B. Information on the site
- C. Information on the plant protection product and its use
- D. Data from simulation in a model tool

A. Administrative details

The administrative details that generally need to be submitted with permit applications are specified below.

Applicant	The operator utilising the land where plant protection products are to be applied is the party that should generally apply for a permit. This is normally an agricultural or horticultural company if the product is to be used on agricultural land. Anyone farming the land normally has an overview of and responsibility for the entire operation and therefore also has the best knowledge of plant cultivation, soil and ground conditions and the presence of sensitive areas. It is often also appropriate, from a standpoint relating to right of disposition, for the party farming the land to also apply for the permit.
Information on the applicant	Contact details plus information on the company registration number or personal ID number are the items of information that need to be submitted.
Information on the party that intends to distribute the product	It is not unusual for the party submitting an application for a permit to be someone other than the party actually applying the product. According to <i>Swedish Board of Agriculture regulations (SJVFS 2015:49) on documentation requirements for commercial users of plant protection products</i> , the party commercially using plant protection products must document who is applying plant protection products in a certain location. If an application is submitted for a number of years – for an entire crop rotation, for example – it may be difficult in practice, at the time of submitting the application, to provide contact details for the party that will be applying the product in each individual case as several different parties may be involved. In these cases, it should suffice if the applicant is able to submit contact details retrospectively, at the request of the authority, for the party that applied the product.

B. Information on the site

To be able to assess the risk of accidental application of plant protection products in a specific location, information is required on the plots of land on which plant protection products are to be used. The details that generally need to be submitted for a permit application to be processed are specified below. Which information is required in each individual case may vary and is decided by the permit authority following consideration of plausibility.

Map of the management unit, specifically indicating the location where plant protection products will be stored and the location where replenishment and cleaning will take place.	It is a good idea to include information on the storage location for products and how the product will be stored, e.g. in a locked area with an option for clearing up any spillages. Information on the location where replenishment and cleaning will take place is also needed as a basis for a decision. Chapter 5, section 1 of NFS 2015:2 states that plant protection products used for commercial application must be stored in an embanked area or embanked container offering the opportunity to collect leaks or spillages. Provisions for replenishment and cleaning are discussed in Chapter 4 of NFS 2015:2.
Map of relevant arable field plots	Relevant plots of land should be marked on a map, and the protection zones in the water protection area in which the plots are located should be specified.
Information on open waterways	In water protection areas for surface water catchments, it is important to include all open waterways such as ditches and small streams in the map information. Other sensitive locations such as individual wells should also be included in the map.
Drainage conditions	Drainage conditions in a specific location are of major significance to how plant protection products can be spread in the environment to groundwater or surface water.
Texture	The texture indicates the size distribution of the individual soil particles in the various parts of the soil profile. The texture is of significance to the properties of the soil with regard to structure, specific area, plasticity, cohesion, etc.
Structure of the soil profile	The structure of the soil profile from ground level down to deeper layers of soil is of crucial significance to the risk of unintentional pollution of plant protection products. It is important to remember that the results from any model simulation tools, such as MACRO-DB (see a later section in the guidelines for a more detailed description of this tool), can never be better than the data input into the tool. The soil

	<p>profile can roughly be divided into three layers that are of significance to how a substance moves through the layers of soil.</p> <p>The parent material, i.e. unaffected mineral soil or bedrock. Located beneath the subsoil, so deeply that it is largely unaffected by biological activity.</p> <p>The subsoil is located beneath the topsoil, and its thickness varies. There is a certain amount of biological activity, as well as roots and wormholes, in the subsoil. Roughly, the subsoil can be found at a depth of -30 cm to 2 m beneath the surface of the soil.</p> <p>The topsoil layer, the farmed part of the soil profile with the greatest biological activity. Can be found from the surface down to depths of approximately 25–30 cm.</p>
<p>Information on the parent material</p>	<p>It is necessary to input information on the original parent material so as to be able to carry out reliable model tool simulations (e.g. MACRO-DB). The easiest thing to do is enter the details found in soil maps from the Geological Survey of Sweden (SGU), available to download for free from the SGU website. However, it should be noted that these maps are rough and that glaciofluvial deposits, for example, are often of exaggerated size compared with reality. This may mean that there are probably farmed plots located in areas where SGU soil types indicate greater vulnerability than is actually the case. If there is any disagreement between the authority and the operator concerning the vulnerability of a specific location, and the operator is of the opinion that the criteria are more favourable than indicated by SGU's soil maps, the operator must demonstrate what criteria are applicable in the location by means of representative soil sampling. The parent material then has to be analysed by means of an appropriate number of soil samples to a depth of 2 m below the soil surface. The appropriate number of points varies depending on the location: the prime concern is to ensure that a representative view of the area is provided. It should be pointed out that the parent material does not change over time. Therefore, soil sampling of the parent material does not need to be repeated if it has already been carried out.</p>
<p>Information on the subsoil</p>	<p>In the majority of cases, the percentage content of clay, silt and sand in the subsoil is the same as in the topsoil, which means that sampling the topsoil is sufficient in order to obtain the information needed for model tool simulations (e.g. MACRO-DB). If the operator suspects that the texture of the subsoil differs from the texture of the topsoil in a manner that would be beneficial to the operator, it is up to the operator to demonstrate these conditions by sampling the soil. The samples in this case should be selected to provide a representative view of the conditions at the location. The content of clay, silt and sand does not change over time, so soil sampling does not need to be repeated if it has already been carried out.</p>
<p>Information on the topsoil layer</p>	<p>Information on the percentage content of clay, silt and sand in the topsoil needs to be produced, along with information on organic matter content.</p> <p>The content of clay, silt and sand does not change over time, and therefore sampling does not need to be repeated if it has already been carried out.</p> <p>The organic matter content in the topsoil layer changes depending on the management emphasis. Therefore, sampling the organic matter content in the topsoil layer needs to be repeated at regular intervals. The organic matter content in the topsoil is always checked when the farmer maps the land. If the organic matter content is known, the value can be converted to a percentage of organic carbon. The Swedish Board of Agriculture has published recommendations via Markkarteringsrådet (the Land Mapping Council) on how land mapping should be carried out: regularity, the appropriate number of samples per surface unit and which analyses should be carried out as standard.³ The Swedish Agency for Marine and Water Management and the Swedish Environmental Protection Agency are of the opinion that it is appropriate to comply with these recommendations in respect of regularity and sampling frequency in order to check the organic matter content in the topsoil layer.</p>

³ Markkarteringsrådets rekommendationer för Markkartering av åkermark, Jordbruksinformation 19.

C. Information on the plant protection product and its use

To be able to carry out an assessment of the need for use of plant protection products, information on the use and selection of plant protection products is needed. Information is also needed on how the operator has observed the principles of integrated plant protection and the product selection principle according to the specifications of Chapter 2, Sections 31–34 of the Pesticides Ordinance and Swedish Board of Agriculture regulations and general recommendations (2014:42) on integrated plant protection. The information that generally needs to be specified on plant protection products and planned use is indicated below. Which information is required in each individual case may vary and is decided by the permit authority following consideration of plausibility.

Principles of integrated plant protection and the product selection principle	<p>Chapter 2, section 31 of the Pesticides Ordinance indicates that there must be compliance with the principles of integrated plant protection when using plant protection products. The Swedish Board of Agriculture has issued regulations and general recommendations (2014:42) that indicate in greater detail how the principles of integrated plant protection should be applied.</p> <p>Chapter 2, sections 33 and 34 of the Pesticides Ordinance also include provisions on method and product selection as regards plant protection products.</p> <p>The regulations on integrated plant protection must be applied for all commercial use of plant protection products and include the fact that the party considering use of plant protection products must primarily use preventive methods to suppress pests, weeds and other factors that may justify plant protection measures. Furthermore, non-chemical pest control methods must always be used in the first instance.</p> <p>The application should specify how the principles of integrated plant protection have been taken into account. One way of doing this is to describe the crop rotation that the operator is planning to use. Furthermore, how the planned use relates to the requirements for method and product selection according to the Pesticides Ordinance should be indicated where appropriate. If a number of plant protection products are available for the same application and purpose, the application should indicate the reasons for the choice of product or products to which the application refers.</p>
Which plant protection product is to be used	The name and registration of the number of the plant protection product should be indicated, providing information on the active substance, A copy of the safety data sheet should be enclosed with the application.
Dosage	The dosage used for treatment is of major significance as regards the concentration that may occur in groundwater or surface water.
Application equipment	The application should indicate what application equipment the operator is intending to use for the treatment.
Crop	The crop or crops to which pest control relates should be specified in the application.
Frequency of recurring treatments	How frequently an area is planned to be treated with a plant protection product should be specified as this is of major significance to the concentration that may occur in the water resource.

Remember the conditions for use

Some plant protection products are associated with special conditions for use, e.g. requirements to set up an untreated, vegetated buffer strip in order to protect against contamination due to surface runoff or erosion. Conditions for use of another type specify requirements for the use of special drift-reducing equipment when applying the product. There are also restrictions on the number of treatments permitted per season for certain products.

More information on which plant protection products are approved in Sweden and the conditions for use applicable to these can be found in the Swedish Chemicals Agency's pesticides register. There must always be compliance with the conditions for use, regardless of whether the product is being used inside or outside a water protection area. The Swedish Chemicals Agency is the authority that is able to answer questions on the properties of individual substances and conditions for use for plant protection products.

D. Data from simulation in a model tool

This data is mainly relevant as regards assessing applications for the use of plant protection products on agricultural land and in horticulture.

Results from model simulations

A number of municipalities that have chosen to use model simulation tools (e.g. MACRO-DB) in their handling choose to request complete simulations from applicants. This is in accordance with the requirement that states that the operator bears the burden of proof, to indicate that the process can be executed with no risk of affecting the water catchment. In these cases, the background data that forms the basis for the calculations must also be stated as well, together with the complete results, in order to facilitate checks by means of random samples, for example.

Points to remember in particular

When simulations are executed in MACRO-DB for a specific treatment in a specific location, the time of the treatment must be specified, precise to within two weeks. The results of the simulations may be used entirely or partly as a basis for a decision on a permit to be made by the permit authority. It is important to remember that a permit is based specifically on the criteria indicated in the application, such as the specified time of the treatment. If the applicant would like greater flexibility in order to adapt pest control on the basis of variations in growth season, for example, the applicant should consider providing in the application simulations for a number of possible treatment occasions during a season. This makes it possible for the permit authority to issue a permit that is valid for a longer period of time. There are both practical and environmental advantages to creating greater flexibility in this regard by allowing pest control thresholds and dosage keys to control the treatment throughout the period of the permit, insofar as such aspects are of relevance in the case in question.

Requiring decision data in the form of simulations in MACRO-DB is reasonable

In a verdict given by the Land and Environment Court at Vänersborg District Court, it was found that a municipal authority was entitled to demand data in the form of calculations in MACRO-DB in the event of an application for a permit for commercial use of plant protection products within a secondary protection zone (see the verdict of the Land and Environment Court at Vänersborg District Court, dated 19 March 2015, case no. M 768-14).

Risk assessment

The release of plant protection products onto the market is currently regulated by Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. The

Swedish Chemicals Agency approves products for use in Sweden. A number of different reasonable “worst-case scenarios” – i.e. the combination of soil conditions and climate in these scenarios must correspond to the 90th percentile for Swedish conditions – are simulated when assessing the risk of accidental spreading to surface water and groundwater. However, this also means that there may be a risk of leakage involving higher levels than calculated over 10% of the area. As things stand at present, no knowledge or methods are available to permit identification at a general level of the areas where the risk of leakage is elevated. Therefore, location-specific risk assessments within water protection areas are justified.

In the Swedish Chemicals Agency’s examination for release onto the market, the simulated levels for groundwater are compared with 0.1 µg/l. This is equivalent to the EQS for drinking water for individual substances in pesticides according to National Food Administrations regulations. For surface water, on the other hand, the levels are compared with levels that are not expected to have a harmful impact on aquatic organisms. These levels may vary widely between different active substances, and it is possible that products may be approved that are at risk of leaching out at levels above 0.10 µg/l, provided that they are not particularly toxic to aquatic organisms.

In the 1990s, the Swedish Chemicals Agency produced a list of volatile substances that constituted a particularly major risk of accidental spreading to groundwater in permeable soils. The first stage of the assessment involved using what is known as the GUS method⁴ to classify the mobility of the substances on the basis of the half-life of the parameters and the ability to bond to soil particles (adsorption capability). This list merely showed substances that were risk of leaching out into groundwater, and it was retracted in 2011 due to the fact that the Swedish Chemicals Agency did not have the opportunity to keep it up to date.

The risk of unintentional pollution of the surrounding area is due to many different factors. Climate and ground conditions in the location in question are of major significance and cannot be covered by a general list. The dosage and frequency of use of plant protection products are also crucial to the risks. There are opportunities at present to carry out more detailed location-specific assessments of the risk of accidental application of plant protection products. The properties of plant protection products are an important factor in these assessments, but other factors such as geological and hydrological information about the location are also of significance.

The term “chemical-intensive cultivation”

The Swedish Environmental Protection Agency’s general recommendations NFS 2000:7, which were valid until 1 November 2015, stated that chemical-intensive crops – i.e. crops treated with chemical plant protection products more than six times throughout their growth period – are always inappropriate to cultivate within water protection areas. Given the knowledge that is available nowadays, this position must be revalued. Surveys show that the total amount

⁴ Gustafson, D.I. (1989) Groundwater ubiquity scores: a simple method for assessing pesticide leachability, *Environmental toxicology and chemistry*, Vol. 8, pp. 339-357, 1989.

of plant protection product used within the area is what controls the risk of affecting the raw water, rather than the number of treatments applied to individual crops. An analysis carried out by the Swedish University of Agricultural Sciences shows a link between the total amount of plant protection product used in a runoff area and the frequency of findings above 0.10 µg/l in surface water⁵. However, high frequencies of findings of some substances were prominent despite less use of plant protection products (e.g. bentazon), which shows that the inherent properties are also of significance. However, the assessment must always take into account the fact that a large number of treatments increases the risk of accidents during replenishment, cleaning and transport. Therefore, assessment of whether a specific cultivation policy is problematic must be assessed in each individual case, factors to be taken into account include the number of treatment instances and the size of the areas to be treated.

Description of MACRO-DB decision support

For it to be possible to really be able to assess the elevated risk of unintentional spread of plant protection products in a specific location, it is necessary nowadays to perform model calculations which also take into account geological and hydrological conditions at the location in question. This can be done using model simulation tools. The decision support tool MACRO-DB is in common use. This model is primarily adapted for simulation in the event of application of plant protection products on agricultural land and in horticulture.

The macro model is a basic model that generalises knowledge of the processes that govern the distribution of chemical pesticides in the environment. Various risk assessment tools have been developed on the basis of the macro model, including the following:

- MACROinFOCUS, which is used for risk assessment when registering chemical pesticides in Sweden and the EU.
- MACRO-DB, which is used during the permit authorisation procedure and advisory services at field and farm level.

As things stand at present, MACRO-DB is the only model simulation tool that can be used free of charge by operators and the municipalities of Sweden in order to perform qualified assessments of the risk of accidental application of plant protection products in a specific location. It is conceivable that more tools will be developed over time. As there is currently no similarly available tool for assessing the risk of accidental application, other than by using MACRO-DB, the guidelines largely focus on what details need to be obtained to allow calculations to be performed or reviewed in MACRO-DB. The variables that differ from location to location and that thus determine the risk of accidental application of plant protection products in a specific location provide the data needed by the model.

⁵ Boye, K., Gönczi, M. and Kreuger, J. 2013. Grödornas relativa bidrag till förekomst av växtskyddsmedel i ytvatten – Resultat från nationella miljöövervakningen av växtskyddsmedel 2002–2011. CKB report 2013:3. Swedish University of Agricultural Sciences.

The Land and Environment Court has concluded that the risk assessment based on calculations in MACRO-DB is acceptable when examining permits to use plant protection products within water protection areas (see the verdict of the Land and Environment Court at Vänersborg District Court, dated 19 March 2015, case no. M 768-14).

In the grounds for the judgement, the court specified the following: "The MACRO-DB simulation model constitutes a tool for facilitating the permit authorisation procedure and reducing the risk of leakage of plant protection products in water protection areas, provided that the outcome of the calculations can be handled in a reasonable and due fashion."

Simulation according to MACRO-DB

MACRO-DB simulates the risk of unintentional spread of plant protection products to groundwater and surface water. Simulations can be performed in two stages, as described briefly below.

The tool can be accessed via the website of the Centre for Chemical Pesticides (CKB) at the Swedish University of Agricultural Sciences. This tool is constantly being developed, so the description is kept general. For further information, please see the CKB website, which provides detailed instructions on the tool and how it is used.

Step 1

Step 1 involves a quick, simple risk assessment corresponding to "worst-case scenarios" and is based on the results from a large number of MACRO-DB simulations performed in advance. The user specifies the product, dosage, time of spraying, how frequently the product is used (e.g. every year, every two years, every three years, etc.) and whether the product is to be distributed at a surface water catchment, groundwater catchment or both. There is also an opportunity to take into account dilution as a consequence of how much arable land there is in the drainage area. As step 1 comprises a large number of different "worst-case scenarios" that are multiplied during simulation, the results constitute a very strong worst-case scenario with an estimated safety margin of > 99%.

Notification from the simulations is provided immediately in the form of brief text explanations of the results from the simulations.

Results following calculations in MACRO-DB step 1

The results from MACRO-DB stage 1 are displayed as one of the following options:

1. The simulations show that there is a negligible risk of the product being capable of being transported to groundwater and/or surface water at levels above 0.1 µg/l.
2. The results from the simulation show that there could be instances when the product can be transported to groundwater and/or surface water at levels above 0.1 µg/l. Continue to stage 2.

Remarks

It can be clarified that the results of the simulation in stage 1 are based on a limit of 0.10 µg/l for levels in groundwater and surface water, which means in practice that a boundary is drawn at a level of 0.095 µg/l. If the results exceed 0.095 µg/l for any of the soil that is simulated, the user is encouraged to proceed to stage 2.

Step 2

In other words, step 2 is completed if the results from step 1 show that there could be occasions where the plant protection product could be transported to groundwater and surface water at levels above 0.095 µg/l. Step 2 involves more realistic simulations with MACRO-DB under the conditions prevailing in the area in question, based on available information on soil type, crops, etc.

The user of the model tool defines a simulation by making selections relating to soil (parent material, texture class and mull level class), active substance, crop, climate zone and spraying operations. A MACRO simulation is defined on the basis of the choices made by the user.

An average concentration at the bottom of the simulated profile (2 m depth) is reported for use in the assessment of the risk of transport of plant protection product to groundwater. Losses to surface water are simulated as an average concentration in the drainage pipe out from the edge of the field.

The simulated concentrations are based on the assumption that the entire drainage area is treated with the plant protection product in the manner specified in MACRO-DB. As it is very rare for a product to be used over the entire area that drains to a water catchment, it is possible to carry out a simple dilution calculation which takes into account the proportion of arable land in the *catchment area* and the treatment frequency. Note that a water protection area is frequently smaller than the catchment area and that information about the catchment area has to be produced separately. The result achieved after the dilution calculation is a simulated average concentration in the water catchment.

As the calculation is based on the notion that all arable land is treated, there is generally a safety margin in this result as well. This is because it is not common for all arable land to be treated with the same plant protection products or active substances.

Results following calculations in MACRO-DB step 2

The results from MACRO-DB step 2 are displayed as one of the following options, depending on whether a groundwater catchment or a surface water catchment is involved.

1. 1 Example of calculation results for groundwater

Simulated average concentration from the soil profile (µg/l): 0.097

Percentage of agricultural land in the catchment area (%): 50

Treatment frequency: Every year

Estimated average concentration in the groundwater reservoir (µg/l): 0.049

2. 2 Example of calculation results for surface water

Simulated average concentration in drainage water, field edges (µg/l): 0.0042

Percentage of agricultural land in the catchment area (%): 75

Treatment frequency: Every 3 years

Estimated average concentration in surface water (µg/l): 0.0011

How can the results from MACRO-DB be used?

The results from model simulations in MACRO-DB do not constitute complete data when assessing an application. As indicated below, a range of circum-

stances are not covered by the model simulation. During the permit authorisation procedure, therefore, it is important to carry out an overall assessment of all relevant data, of which the results from MACRO-DB form part.

The results from MACRO-DB indicate the risk of certain use of plant protection products causing unintentional spread of plant protection products to groundwater and surface water, specified in $\mu\text{g}/\text{l}$. As described above, MACRO-DB works on the basis of a limit of $0.10 \mu\text{g}/\text{l}$ for groundwater and surface water levels. This is equivalent to the limit for drinking water for individual pesticidal substances according to National Food Administration regulations. As also discussed above, the results from MACRO-DB include a high safety margin as it is based on assumptions on the basis of “worst-case scenarios”. In many cases, therefore, the results from MACRO-DB overestimate the risks. The actual concentration that may conceivably occur in the water catchment will therefore in many cases probably be considerably lower than the tool indicates.

During the permit authorisation procedure, it is important to bear in mind that the level of $0.10 \mu\text{g}/\text{l}$ with regard to individual pesticidal substances in drinking water as specified in the National Food Administration regulations constitutes a limit value.

Of course, it should be pointed out that this limit relates to drinking water and not raw water. However, as we described at the outset in the section entitled Water protection areas, the purpose of setting up a water protection area and prescribing certain restrictions on the use of the land is to maintain sufficiently good raw water quality so that it is not necessary to install new and costly treatment stages in order to produce drinking water. To fulfil the purpose of the water protection area, therefore, it is relevant to note the limit when examining individual permit application cases as well.

Permits should therefore not be issued if there is any risk of the limit being exceeded. It is also important to note that the objective is for pesticide residues in raw water should be considerably lower than that, and they should only be present at levels close to zero.

As MACRO-DB works on the basis of a groundwater and surface water level limit of $0.10 \mu\text{g}/\text{l}$ and is also based on assumptions in “worst-case scenarios”, the results provide a suitable starting point for assessing whether or not a permit should be issued following an application. However, it is important to bear in mind that there may be circumstances in individual cases that affect the risk assessment and that are not covered by the model simulation in MACRO-DB.

Results from MACRO-DB during the permit authorisation procedure

Results from step 1

When the results from the step 1 simulations show that there is a negligible risk of the product being capable of being transported to groundwater and/or surface water at levels above 0.1 µg/l and there are no other aggravating circumstances, it should be possible to issue a permit in combination with conditions required in the case in question.

Results from step 2

If the results from the step 1 simulations show instead that there could be occasions when the product may be transported to groundwater and/or surface water at levels above 0.1 µg/l, you should progress to step 2 and perform calculations on the basis of the circumstances in the location.

1. Example of calculation results for groundwater – outcome below limit

Simulated average concentration from the soil profile (µg/l): 0.097

Percentage of agricultural land in the catchment area (%): 50

Treatment frequency: Every 1 year

Estimated average concentration in the groundwater reservoir (µg/l): 0.049

In this case, it should be possible to issue a permit in combination with the terms required in the case in question, Provided that there are no other aggravating circumstances that argue against the possibility of issuing a permit.

2. Example of calculation results for groundwater – outcome above limit

Simulated average concentration from the soil profile (µg/l): 0.109

Percentage of agricultural land in the catchment area (%): 100

Treatment frequency: Every 1 year

Estimated average concentration in the groundwater reservoir (µg/l): 0.109

In this case, the results from the calculations in step 2 show instead that usage would result in an estimated average concentration of 0.109 µg/l in the groundwater catchment, i.e. above the limit. A permit should not be issued for this usage.

Plausibility assessments

There may be circumstances that are not taken into account in the model simulation in MACRO-DB which indicate that the risk is actually considerably lower than indicated by the results from MACRO-DB. In these cases, the permit authority should perform a plausibility assessment of the calculation results on the basis of other circumstances. This may, for example, relate to certain special crops grown in very small areas within the water protection area and where the starting point of the calculations – i.e. the fact that treatment takes place over the entire section of agricultural land within the water protection area – must be viewed as so unrealistic that it should not be applied.

Factors that are not considered in model simulations with MACRO-DB

The calculation results obtained following a MACRO simulation must also be assessed in relation to other parameters. This includes a number of factors that are not included in the model.

- MACRO-DB simulates the transport of pesticides from normal use and does not take into account incorrect use, e.g. spillage during replenishment and cleaning of spraying equipment, or accidents. Therefore, supplementary protective measures have to be implemented in order to minimise the risk of accidental application during handling of this kind.
- The application routes of spray drift, surface runoff and erosion, as well as particle-borne transport through the drainage pipes, are currently

(version 4) not included in the tool. This is of significance to spreading to open waterways, for example. Therefore, supplementary protective measures have to be implemented in order to minimise the risk of accidental application as a consequence of this. However, when it comes to risk assessment for groundwater, no importance should be attached to not including particle-borne transport via drainage pipes in the tool.

- MACRO-DB has been developed with the assumption that no breakdown products will leach into groundwater or surface water in higher concentrations than the parent substance. If the active substance has a half-life of two days or less, a relevant metabolite is simulated instead of the parent substance.
- MACRO-DB does not take into account cumulative effects such as other spraying measures within the drainage area. It is generally difficult to take cumulative effects fully into account in risk assessments in individual cases. If so much of the drainage area is cultivated conventionally that it is deemed difficult to achieve acceptable minimisation of risk by means of examinations at individual management units, whether to introduce a prohibition on the use of plant protection products should be considered (see the section entitled Water protection regulations).

Special considerations regarding glyphosate

MACRO-DB cannot be used at present to assess the risk of transporting glyphosate to surface water. At present, there is no other method for modelling the risk with regard to how this substance is transported to surface water. However, the model is a reliable way of assessing the risk of transporting glyphosate to groundwater.

At present, glyphosate is the single most commonly sold substance in Sweden. Glyphosate and its breakdown product AMPA are substances that are measured at levels above 0.10 µg/l in surface water. In this context, it may be pointed out that concentrations above 0.10 µg/l have only been found to date in smaller watercourses in areas where intensive farming takes place.

Unintentional spread to surface water mainly takes place via rapid transport routes such as flows in macropores to drainage pipes, spray drift, and also via erosion and surface runoff. Dilution and turnover are natural protection mechanisms for surface water, as are breakdown and immobilisation in sediment. For a surface water catchment, therefore, the distance between the location for application of plant protection products and the location for intake of raw water is of major significance to the risk scenario.

As we currently do not know how the spread of glyphosate to surface water could be restricted effectively, the precautionary principle should be applied; which means that the authority issuing the permit should be restrictive with its issuing of permits for the use of glyphosate within primary protection zones as regards water protection areas for surface water catchments.

Use of plant protection products in areas other than agricultural land and horticulture

A permit case may relate to the use of plant protection products in areas other than agricultural land and horticulture. It may, for example, relate to the use of

plant protection products on industrial estates, railway embankments, golf courses, etc.

Swedish Board of Agriculture regulations on integrated plant protection must be applied with regard to all commercial use of plant protection products and so are also applicable in these areas. Furthermore, it is also important in these areas to ensure that the plant protection product that the operator is intending to use is also approved for the application in question. Model simulation tools (e.g. MACRO-DB) are frequently not adapted for the use of plant protection products in areas other than agricultural land and horticulture, which is why risk assessment should generally be based on other data. However, the information that should be included in the application is mainly what is specified in sections A–C in the section entitled “Information in applications” that appeared earlier in these guidelines. Further guidelines for the permit authorisation procedure for use of plant protection products in areas other than agricultural land and horticulture are provided below.

Golf courses

If there is any uncertainty as to whether pest control on golf courses within water protection areas could potentially have an adverse impact on groundwater or surface water catchments, the precautionary principle should be applied. This means that permits should only be issued if this is consistent with conditions relating to protective measures and precautions that prevent the risk of accidental application of plant protection products.

It should also be noted that distribution of plant protection products on golf courses is subject to a permit requirement according to Chapter 2, Section 40, Clause 5 of the Pesticides Ordinance.

Fairways and rough

Model simulation tools (e.g. MACRO-DB) can be used to assess the risk of unintentional spread from fairways and rough to groundwater, but not for assessment of accidental spreading to surface water. This is because drainage on golf courses is often structured differently to drainage on agricultural land.

MACRO-DB when assessing risks for unintentional spread on golf courses

When using MACRO-DB to assess the risk of accidental spreading of plant protection products from fairways to groundwater, grassy banks are specified as crops and otherwise the same procedure is applied as for agricultural land.

As there is no reliable tool available for simulating the risk of accidental spreading of plant protection products to surface water, assessments need to be carried out in each individual case. The structure of the drainage on site should be clarified in order to ensure that any accidental application of plant protection products has no significant impact on adjacent surface water catchment. For example, on many golf courses the drained water is diverted to some kind of watering system.

The examining authority should be restrictive with the issuing of permits for the use of glyphosate within primary zones as regards water protection areas for surface water catchments.

Greens and tees

There is no reliable tool for simulating the risk of unintentional spread of plant protection products to surface water when using plant protection products on greens and tees. When assessing the risk of spreading to surface water, drainage at the location is a factor of major significance. Just as for fairways and rough, the structure of the drainage on site should be clarified in order to ensure that any accidental application of plant protection products has no significant impact on adjacent surface water catchment.

It is possible to use model simulation tools (e.g. MACRO-DB) to assess the risk of accidental spreading from greens and tees to groundwater, even if the usage is probably a small proportion of the total load on the ground water catchment as small areas are being treated. Nevertheless, the examining authority has the opportunity to request results from model simulations as a basis for its decision following consideration of plausibility. Other factors that are not taken into account in model simulations with MACRO-DB are specified in previous sections in these guidelines.

MACRO-DB when assessing risks for unintentional spread on golf courses

The topmost layer (approximately 30 cm) on a green is frequently specially constructed so that water drains away quickly. Specify Coarse (class 1) texture for the topsoil. The mull level should be measured in situ, but this is usually fairly low on greens. The same procedure as for agricultural land is used for parent material and texture for the subsoil. Tees are processed as either fairways or greens, depending on whether or not they consist of landscaped land.

Greenhouses

Water protection regulations specify requirements for permits when using plant protection products in greenhouses.

For a permit to be issued, requirements should be defined indicating that the activities taking place within a greenhouse have a closed, recirculating water system. However, one alternative to a recirculating system is to use a system for collecting and treating the water that contains plant protection products. Requirements should also be defined for review at least once a year of the system used in order to prevent the risk of accidental application.

See also the specification below concerning permeable surfaces.

Other land

For the areas below, far-reaching requirements should be defined for operators to demonstrate that all conceivable alternatives to the use of plant protection products, such as thermal or physical treatment, are disproportionate. This means that the operators should be able to describe which alternative methods have been considered and justify the choice of chemical pest control. This should be indicated by the information about the plant protection product and its use which, according to the guidelines, should be included in an application. The assessment of when alternative methods are unreasonable should be based on the type of surface on which pest control is to take place, and the type of pest to be controlled. In general, there are more non-chemical methods available for

controlling weeds on a gravel surface than for controlling fungal attacks on lawns, for example, and this should be taken into account in the assessment. Any permits issued should also be of single-use nature. This means that permits extending over a number of years should not be issued, and that permits should be restricted to a small number of treatments over a limited period. If larger areas are to be treated, permits should be conditional upon requirements for follow-up of effects on the surrounding area.

In general, it can be stated that the degradation time and the risk of unintentional spread increase if a product is used on land with properties that are different to the properties of biologically active agricultural land. Therefore, the permit authority should be restrictive with the issuing of permits for such areas.

It should also be noted that as regards commercial use of plant protection products during planning and construction work, permits are required according to Chapter 2, Section 40, Clause 6 of the Pesticides Ordinance.

Industrial estates

As industrial states often comprise hard surfaces where there is a major risk of surface runoff to surrounding environment, examining authority should be restrictive with the issuing of permits. Permits should only be issued for use of plant protection products if the extent of the application and the choice of application method present a low risk of unintentional spread. Furthermore, permits should be combined with conditions relating to protective measures and precautions that prevent the risk of accidental application of plant protection products during other handling.

It should also be noted that application of plant protection products on asphalt or concrete surfaces or other hard materials is subject to a permit requirement according to Chapter 2, Section 40, Clause 8 of the Pesticides Ordinance.

Permeable surfaces

As regards applications for distribution of plant protection products on road areas, gravel surfaces and other very permeable surfaces, the examining authority should be restrictive with the issuing of permits. Permits should only be issued for use of plant protection products if the extent of the application and the choice of application method present a low risk of contamination. Furthermore, permits should be linked with conditions relating to protective measures and precautions that prevent the risk of accidental application of plant protection products during other handling.

It should also be noted that application of plant protection products on permeable surfaces is subject to a permit requirement according to Chapter 2, Section 40, Clause 7 of the Pesticides Ordinance.

Railway embankments

As regards railway embankments, the permit authority should also be restrictive with the issuing of permits as this usually involves very permeable surfaces with soil poor in mull.

Permits should only be issued for use of plant protection products if the extent of the application and the choice of application method present a low risk of contamination. Far-reaching requirements should be defined for operators to demonstrate that all conceivable pest control alternatives are unreasonable.

Woodland

Woodland is frequently permeable in nature, which is why the permit authority should be restrictive with the issuing of permits in woodland within water protection areas.

Decision

Applications for permits should generally conclude with a decision to issue a permit or a decision to reject or turn down the application entirely or in certain parts. A decision to issue a permit may be combined with conditions according to Chapter 16, Section 2 of the Environmental Code.

The decision should indicate the legal grounds for the decision. Both provisions should be specified if a permit requirement is applicable according to Swedish Environmental Protection Agency regulations and water protection regulations.

The permit authority may combine a decision to issue a permit with an order relating to protective measures or prohibiting the use of certain plant protection products. This should be avoided, as the applicable rules can easily become unclear.

If an application cannot be granted in its entirety, a permit should be granted for the plant protection products that can be approved and the application should be rejected for the plant protection products that are not deemed suitable to handle within the water protection area.

Decision to issue a permit

Permit duration

For practical reasons, permits can be issued for a longer period to operators who repeatedly need to use plant protection products in their operations. A crop rotation cycle may provide a good starting point for the validity of a permit.

Conditions

Decisions to issue permits are generally linked with relevant conditions relating to protective measures and precautions for usage and other handling. The general rules of consideration found in Chapter 2 of the Environmental Code are applicable when assessing which conditions are needed in each individual case. This also means that the examining authority has to perform a plausibility assessment according to Chapter 2, Section 7 of the Environmental Code so that unreasonable requirements are not defined. Conditions must be appropriate and proportionate when it is necessary to prevent, impede or counteract adverse impact on the water catchment due to usage of plant protection products. If there are several alternative protective measures that are compliant with the purpose of protecting the water catchment, requirements that are least far-reaching for the applicant should be selected.

To summarise, it may be stated that the requirements for consideration must be environmentally justified without being financially unreasonable. It is important for the conditions to be stated clearly and also justified in the decision.

In some cases, property owners may be entitled to compensation if conditions would significantly impede ongoing land use and this relates to a decision pursuant to regulations according to Chapter 7, Section 22 of the Environmen-

tal Code. This is indicated in Chapter 31, Section 4, Clause 5 of the Environmental Code. Claims for such compensation are examined separately, normally by a Land and Environment Court following a case being brought by the party wishing to receive compensation.

The section below entitled “Examples of conditions” describes risk-reducing measures and suggestions for appropriate conditions linked with these.

Suggested decision wording when permits are issued:

The Environmental and Public Health Committee issues A.A. with a permit to use/distribute/handle plant protection products within the secondary zones of the XX water protection area at property Y. This permit is valid for the following plant protection products:

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The following conditions are applicable for this permit:

See also the section entitled Examples of conditions, below

a)
b)

The permit is time-limited and will be valid until [specify date].

Legal basis: Chapter 6, Section 1 of Swedish Environmental Protection Agency regulations on distribution and certain other handling of plant protection products, section 3 of water protection regulations in decisions on water protection areas for the XX water catchment

Examples of conditions

A few examples of conditions that can be used in decisions relating to permits are provided below.

Preventive measures relating to cultivation technology

A decision to issue a permit should include preventive measures relating to cultivation technology and non-chemical pest control methods, aiming primarily to restrict usage and other handling (fewer treatments and lower doses). Requirements should be formulated so that they comply as far as possible with the provisions in Chapter 2, Sections 31–34 of the Pesticides Ordinance, as well as Swedish Board of Agriculture regulations and general recommendations (2014:42) on integrated plant protection.

Conditions for minimising the use of plant protection products

Pest control thresholds and dosage keys must control the extent of the use of plant protection products.

Dilution, mixing and replenishment of plant protection products

One important risk reducing measure is to ensure that the party using plant protection products undertakes all precautions possible when handling such products. This involves ensuring that dilution, mixing and replenishment of plant protection products and cleaning equipment used for application of plant protection products all take place in safe locations. This is regulated to an extent in NFS 2015:2, and information on this is included in the mandatory authorisation training courses for the use of plant protection products. However,

conditions for such handling may need to be defined for both surface water and groundwater catchments within water protection areas.

Conditions for dilution, mixing and replenishment of plant protection products

In water protection areas, dilution, mixing and replenishment of plant protection products, as well as external cleaning of equipment used for distribution of plant protection products, should take place on a biobed or machine cleaning area or solid manure storage attached to a collection tank or slurry storage or another corresponding safe location.

Spray drift

The provisions in Chapter 3, Section 2 of NFS 2015:2 indicate that anyone applying plant protection products outdoors for commercial purposes must always determine and maintain a buffer zone to water catchments, lakes and waterways and the surrounding land. Buffer zones must be adapted according to distribution conditions in the local area, which is why particular attention must be paid to a number of parameters in order to limit the risk of spray drift.

One way of taking into account the parameters referred to in Chapter 3, Section 2 of NFS 2015:2 and thereby restricting the spray drift risks during application is to follow the steps in *Hjälpreda vid bestämning av anpassade skyddsavstånd* [*Helper to determine proper safety distances adapted to local conditions*] from the Focus on Pesticide Use campaign. There are two versions of the “helper” available; one for use of agricultural boom sprayers and one for use of fan sprayers when growing fruit. Spray drift is an important application route, primarily to surface water.

Conditions for preventing spray drift

An adapted buffer strip must be determined using “*Helper to determine proper safety distances adapted to local conditions*” (*Hjälpreda vid bestämning av anpassade skyddsavstånd*) when using an agricultural boom sprayer or a fan sprayer when growing fruit.

Surface runoff and erosion

There are further routes for spreading to surface water in the form of surface runoff and erosion. A knowledge synthesis issued by the Swedish University of Agricultural Sciences indicates that despite limited scientific data, it is thought that only a small proportion of agricultural land in Sweden is subject to surface runoff to a significant extent during the growth season.⁶ Farmland in Sweden is deemed to be at lower risk of surface runoff and erosion than farmland in many other European countries, due to slopes that are less steep, a more well-developed structure and a higher infiltration capacity, as well as extensive drainage. This is also indicated by the Swedish University of Agricultural Sciences’ review of the surface runoff scenario (R1) used by the Swedish Chemicals Agency when registering plant protection products.

⁶ Boye, K., Jarvis, N., Moeys, J., Gönczi, M. & Kreuger, J. 2012. Ytavrinning av växtskyddsmedel i Sverige och lämpliga motåtgärder – en kunskapssammanställning med fokus på skyddszoner. CKB report 2012:1. Swedish University of Agricultural Sciences.

To an extent, the risk of accidental application as a consequence of surface runoff and erosion has been dealt with at a general level. In part, this takes place in Swedish Environmental Protection Agency regulations (NFS 2015:2) that include requirements for buffer zones to sensitive environments such as ditches, lakes and waterways when using plant protection products. The Swedish Chemicals Agency also assesses the risk of surface runoff and erosion when approving new plant protection products. Approval conditions with specific requirements for protective measures are established for certain plant protection products, e.g. setting up an untreated, vegetated 10-metre buffer strip along all waterways. However, this assessment merely considers the risk of active substances being transported to surface water at higher levels than are acceptable with regard to influence on aquatic organisms. There is a great deal of variation in what levels are harmful to aquatic organisms, and for some substances this may be considerably higher than 0.1 µg/l.

Conditions for prevention of surface runoff and erosion

Plant protection products must not be applied when it is raining or snowing. Nor may plant protection products be applied if there is any risk of extensive precipitation on the day following application. Conditions as required according to the above, together with the regulations in NFS 2015:2 and conditions for use for certain plant protection products, are deemed to be sufficient to protect the majority of surface water catchments from contamination with plant protection products via surface runoff or erosion.

Function testing of application equipment

It is important for the sprayer to be kept in good condition so that it sprays the correct dosage. Correct functioning of the sprayer is also a prerequisite to enable compliance with the special conditions for use specified for certain plant protection products. After 26 November 2016, all pesticide application equipment used commercially for application of plant protection products must be approved by the Swedish Board of Agriculture. The pesticide application equipment has to have undergone function testing for it to be approved. The requirement for mandatory function testing is now applicable throughout the EU. According to the rules, sprayers must undergo function testing at least every three years.

The Swedish Board of Agriculture is responsible for devising provisions and instructions on how these function tests are to be implemented.

Function testing of application equipment

It has been common for special requirements to be defined in permits for the use of plant protection products in water protection areas, concerning the implementation of function testing of application equipment. One common requirement is for the sprayer to be tested every two years. As of November 2016, carrying out regular function test is mandatory.

Therefore, there is no reason to prescribe requirements for special function tests in permits within water protection areas. However, it is expedient to notify applicants of the requirement in the legislation.

Dealing with accidents

What to do in the event of an accident is discussed in the authorisation training courses offered at regular intervals. Moreover, the Focus on Pesticide Use campaign has worked on producing recommendations and instructions on what individuals should do in the event of an accident. Chapter 9, sections 1–4 of NFS 2015:2 also indicate the obligations of any party handling plant protection products as regards giving notification of contamination as a consequence of an accident.

In water protection areas, special requirements should be defined for the production of an action plan describing how any accidents should be handled.

Conditions relating to requirements for an action plan in the event of accidents

An action plan must be in place that clearly describes what to do in the event of accidents in connection with application when plant protection products have leached out or may be feared to have leached out.

Storage of plant protection products when they are not in use

It has been common to define special requirements for the plant protection product labelling, storing within embankments and protection against precipitation when they are stored within water protection areas. Chapter 5, Section 1 of NFS 2015:2 now includes special requirements on how plant protection products should be stored when they are not in use.

Storage of plant protection products when they are not in use

As there is now a requirement for plant protection products used commercially to be stored in an embanked area or embanked container offering the opportunity for collection, there is no reason to define further requirements in conditions for decisions on issuing permits for the use of plant protection products within water protection areas. Applicants should be notified of this requirement in the permit decision.

Follow-up

When an application for a permit has been submitted to the examining authority, this is largely a matter of carrying out a qualified assessment of how the operation will be implemented over the forthcoming permit period. Certain criteria may be amended during the permit period, and the permit application may, for example, include risk assessments of a number of plant protection products that ultimately are not used as there is no need for them. The number of treatments will probably vary from year to year, too. It is important to gain a fair overview of which substances are used within the water protection area, how frequently they are used and when treatments take place so that the monitoring programme for water catchment can be adapted to these circumstances. It is therefore reasonable for the permit authority to require annual follow-up and description of how pest control has been carried out in the activities. Preferably, this is done by regularly requesting copies of the information to be documented by the party applying plant protection products according to Swedish Board of Agriculture regulations (SJVFS 2015:49) concerning documentation requirements for commercial users of plant protection products. The contents

of this documentation also provide useful information prior to inspection of activities and as a basis prior to licensing new permit authorisation procedure.

Conditions relating to follow-up

A copy of the documentation required according to Chapter 2, Section 56 of the Ordinance (2014:425) on pesticides and Swedish Board of Agriculture regulations (SJVFS 2015:49) on documentation requirements for commercial users of plant protection products must be submitted annually to the supervisory authority. This documentation must be received by the supervisory authority by [specify date].

Decision to reject an application

Permits must not be issued if there is insufficient decision data to be able to assess the use of the products and which conditions may need to be prescribed.

The operator must be given the opportunity to supplement the case with the information or investigation that is missing, and this party must be notified of the fact that it will not be possible to issue a permit unless there is compliance with the authority's request. If there is no compliance with this request, the case may be closed with a decision to reject or dismiss the application.

In some cases, it may also be necessary to reject an application concerning use of products in a certain location or use of a certain substance. See the section entitled Risk assessment above with regard to assessment of whether permits should be issued for applications or whether they should be rejected entirely or in part. In this case, it is important for any decision to reject the application to be justified carefully and for the operator to be notified of the opportunity to appeal.

In some cases, property owners may be entitled to compensation if a decision would significantly impede ongoing land use and this relates to a decision pursuant to regulations according to Chapter 7, Section 22 of the Environmental Code. This is indicated in Chapter 31, Section 4, Clause 5 of the Environmental Code. Claims for such compensation are examined separately, normally by a Land and Environment Court following a case being brought by the party wishing to receive compensation.

Suggested decision wording when applications are rejected:

The environmental board reject the application for the use/application/handling of plant protection products within the primary zones of the XX water protection area, concerning the following plant protection products:

-
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Legal basis: Chapter 6, Section 1 of Swedish Environmental Protection Agency regulations on application and certain other handling of plant protection products, and section 3 of water protection regulations in decisions on water protection areas for the XX water catchment

It is possible to appeal against this decision; see the appendix.

Points to remember

An application may conclude with a decision which issues a permit for the use of some of the plant protection products applied for, while others are turned down. It is important for the decision to be formulated so that the authority's reasons are clearly indicated in the various sections. Instructions must also be included on how to appeal against the decision, and the period for appeals.

Amendment of the permit

An operator may return halfway through a cultivation season and request rapid amendment or addition to a permit decision already granted. This is often due to an acute need to control pests, fungal attacks or competing plants using plant protection products that are not covered by the permit already issued.

There is no alternative examination or registration procedure in the general regulations that could be applied in the case of urgent matters. This means that of the authorisation procedure for supplements or other amendments to a permit is formally required.

The authority is always required to deal with matters as promptly as possible, but it is also important for the applicant to understand that sufficient time is needed to allow the authority to handle the case duly and correctly before making a decision.

Appeals

It is possible for a party to appeal against any decision made against that party, as is indicated by Section 22 of the Administrative Procedure Act (1986:223). In other words, applicants may appeal against decisions to reject applications. Even if a permit is issued, the conditions decided upon by the authority may result in dissatisfaction and the operator may wish to appeal against that element.

The authority must always provide information on how to appeal against the decision.