Proposal for options for specifying the groundwater protection goal at national level within the EU

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Prepared by a number of participants of the 7th EU Modelling Workshop held in Vienna 21-23 October 2014.

Introduction

The Uniform Principles state that the concentration of parent substances and relevant metabolites in groundwater intended for the production of drinking water should not exceed 0.1 µg/L. In the EU decision making process also a limit is set to the concentration of non-relevant metabolites in groundwater intended for the production of drinking water. As described by EFSA (2010), such a general protection goal is not sufficient for decision making. For designing an appropriate risk assessment scheme definition of a specific protection goal is needed. Note that this specific protection goal applies to the whole risk assessment scheme, so the tiered approach of the risk assessment scheme should be consistent with the specified goal.

The Uniform Principles do not define 'groundwater' in further detail and concentrations in groundwater vary in space and time. So the specific groundwater protection goal has to define (i) the type of groundwater in which the concentration has to be assessed, (ii) the spatio-temporal dimensions of this concentration and (iii) the decision criteria. Thus the following questions need to be answered:

1. What type of concentration should be considered ?
Examples: (i) the concentration in the soil pore water passing 1 m depth (as is done in the FOCUS groundwater scenarios), (ii) the concentration in the upper meter or decimeter of the water saturated zone below treated fields, (iii) the concentration in the upper meter of the water-saturated zone below treated fields but not considering water-saturated zones shallower than 1 m, (iv) the concentration in water flowing out of drainpipes below treated fields without considering the depth of this drainpipe, (v) the concentration in groundwater at 10 m depth below the soil surface in the area of use of the substance, (vi) the concentration in water pumped from a drinking-water abstraction well in the area of use of the substance.

2. What should be the spatial units considered ? [The spatial unit defines also the areas or elements over which concentrations can be averaged.]
Examples: (i) one square metre of an agricultural field, (ii) the whole agricultural field, (iii) one drainpipe from such a field, (iv) all drainpipes from such a field, (v) a single drinking-water abstraction well, (vi) all drinking-water abstraction wells from a drinking-water pumping station.

3. What spatial statistical population of these units should be considered?

Examples (assuming that the spatial unit is an agricultural field): (i) all treated fields in the area of use, (ii) only those treated fields in the area of use that generate percolation water that can potentially be used for drinking water purposes (so e.g. excluding fields in areas with brackish groundwater or in areas that generate no percolation water), (iii) all fields in the area of use (in which case the fraction of the crop area treated with the substance would become part of the risk assessment).

4. What temporal statistical population of concentrations should be considered?
Examples: (i) annual maximum of daily or monthly concentrations, (ii) yearly average concentrations (as in FOCUS).

5. What value of the percentile should be used and how should it be determined from the resulting combined spatio-temporal statistical population?
Examples: (i) overall 90^{th} percentile, based on combining a 80^{th} percentile in space with an 80^{th} percentile in time, (ii) spatial 90^{th} percentile combined with 50^{th} percentile (median) in time, (iii) overall 100^{th} percentile so maximum in space and maximum in time.

So the answers to these questions describe the construction of the relevant spatio-temporal statistical population of concentrations and the decision-making criterion that is applied to this population of concentrations.

The options for the specific groundwater protection goal

The options for the specific groundwater protection goal intend to cover the full range that could be considered relevant by risk managers, so going from a very strict protection goal option (nr 1) to almost the least strict protection goal option (nr 7).

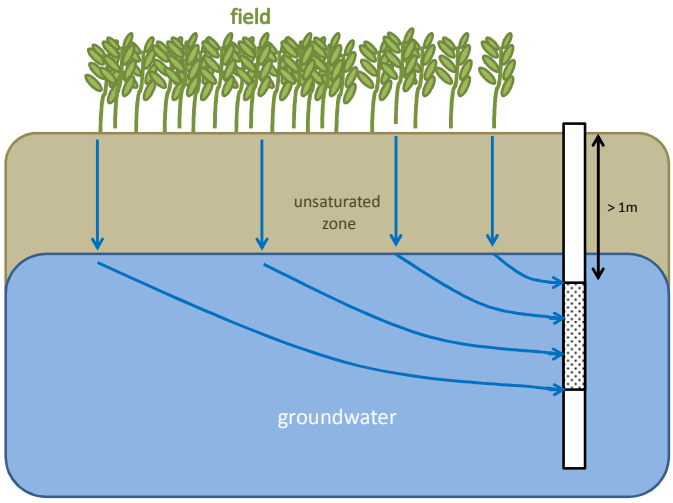
It is the intention that Member States express their preference for these options. Member States have also the possibility to express their preference for an option but specifying other percentile values than those offered for this option. Member States are given the possibility to define their own options as long as these are based on answers to the five questions described above.

It is assumed that appropriate quality criteria are applied to the sampling and measurement method, so avoiding false positives (e.g. resulting from contamination of wells) and false negatives (e.g. resulting of sampling of groundwater below treated fields at the border of the field but in the upstream direction of groundwater flow).

Option 1

Type of concentration	Concentration in the upper decimeter of the water-saturated zone of a treated field (including output from tile drains)
Spatial unit	1 m^2 of treated fields
Spatial statistical population of units	All 1-m^2 units of treated fields in the area of use of the substance
Temporal statistical population of concentrations	Daily values
Percentile	100^{th} both in space and time
Consequences for risk assessment	The concentration in water percolating to groundwater may not exceed the limit below any square meter of any treated field at any time. Even groundwater collected from shallow depths in rainy winter periods (e.g. between 30 and 40 cm depth) is considered relevant. Measurements in drainwater concentrations are considered relevant because they may contain groundwater from the top decimeter of the water-saturated zone or stem from percolation water traveling along preferential flowpaths towards the drainpipes. Any measured value above the limit will lead to unacceptable risk. The procedure used in the current FOCUS groundwater scenarios (or any higher tier option mentioned therein like lysimeters or field leaching studies) is not considered acceptable at national level. This option will discourage companies to perform higher tier and/or monitoring studies because any exceedance will lead to unacceptable risk.
Impact on product registrations	More than 90% of the pesticides currently registered at EU level are expected to fail this specific protection goal.

Option 2

Type of concentration	Concentration in the upper portion of groundwater originating from below treated fields but excluding groundwater shallower than 1 m below the soil surface 
Spatial unit	Treated fields, so order of 1 ha
Spatial statistical population of units	Treated fields in the area of use of the substance
Temporal statistical population of concentrations	Annual average concentrations (as in FOCUS)
Percentile	90th overall, using the concept of an 80th percentile in time combined with an 80th percentile in space
Consequences for risk assessment	Concentrations in shallow groundwater below treated fields can at some times and places exceed the limit as long as the defined temporal and spatial averages are below. Concentration measurements in groundwater sampling wells from a single field have to be averaged and concentrations measured in groundwater in the same year have to be averaged. Note that this approach implies that concentrations at some times and places can exceed the regulatory concentrations as long as the temporal and spatial averages are below.

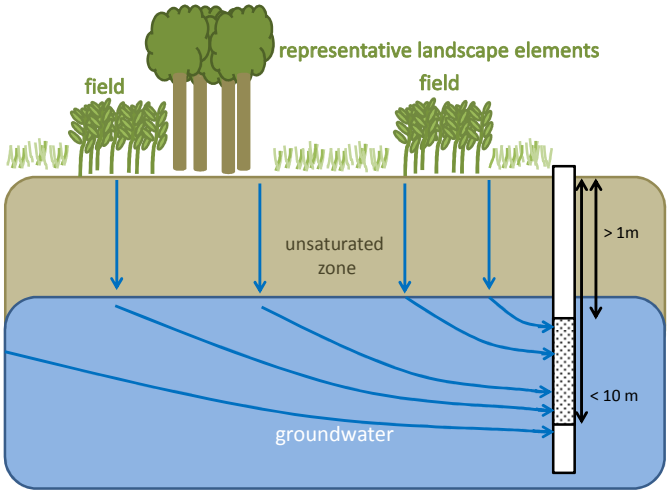
	Monitoring could be carried out by taking a groundwater sample from the top 1.5 to 3 mof the groundwater. This protection goal may imply that results of higher tier leaching experiments, modelling exercises or groundwater monitoring studies cannot be used as a higher tier option in leaching assessments. Findings (even below the LOQ) in public groundwater monitoring networks may have to be recalculated to the relevant type of concentration (see above "upper meter of groundwater below treated fields").
Impact on product registrations	Only products passing lower tier modelling assessments will obtain registrations. Will probably be difficult to conduct adequate monitoring studies for products previously passing modelling assessments, but no longer passing due to increased conservatism. Any finding in public monitoring studies, from which normal leaching cannot be excluded, is likely to lead to a loss of registration. General monitoring results will not be able to be used to demonstrate absence of leaching to ground water.

Option 3

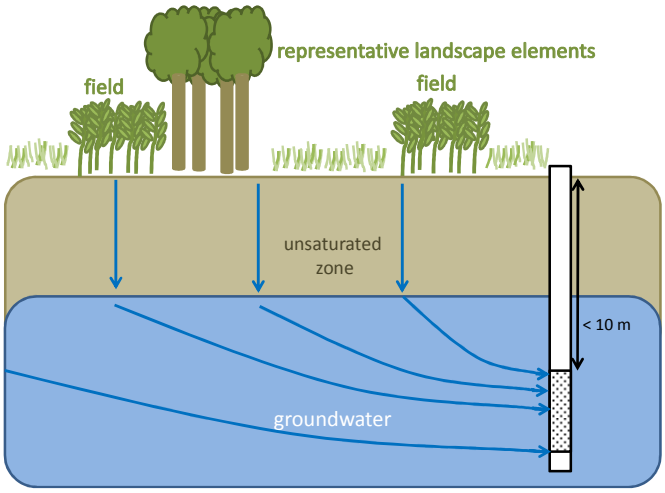
As option 2 except:

Spatial statistical population of units	Treated fields in the area of use of the substance that generate percolation water that potentially can be used for production of drinking water (so e.g. excluding areas with brackish groundwater and areas with impermeable layers preventing recharge to aquifers)
Consequences for risk assessment	Same as option 2 except areas that will never be used for production of drinking water are excluded.

Option 4

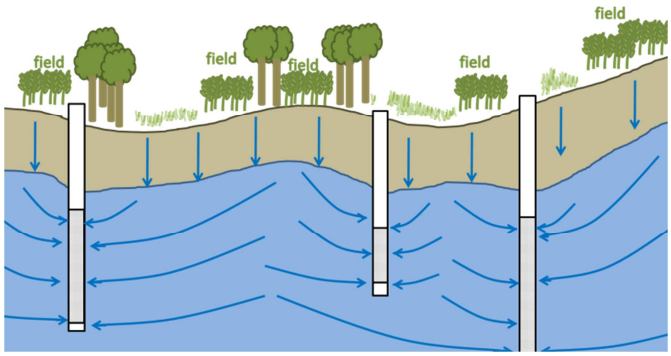
Type of concentration	Concentration in groundwater not influenced by infiltrating surface water at less than 10 m below the soil surface but excluding groundwater shallower than 1 m below the soil surface 
Spatial unit	Groundwater sampling wells with filters not deeper than 10 m below the soil surface
Spatial statistical population of units	All such wells in the area of use of the substance
Temporal statistical population of concentrations	Annual average concentrations (as in FOCUS)
Percentile	90^{th} percentile in space combined with the median (50^{th} percentile) of the annual average concentrations
Consequences for risk assessment	Similar to option 2 since samples from shallow groundwater are included as part of this option.
Impact on product registrations	Similar to option 2 except that conduct of monitoring studies will be easier.

Option 5

Type of concentration	Concentration in groundwater not influenced by infiltrating surface water at 10 m below the soil surface (this may be considered as representing a typical depth below which ground water is abstracted by wells of public waterworks). 
Spatial unit	Groundwater sampling wells with filters at least 10 m below the soil surface
Spatial statistical population of units	All such wells in the area of use of the substance excluding areas that will never be used for production of drinking water
Temporal statistical population of concentrations	Annual average concentrations (as in FOCUS)
Percentile	90th percentile in space combined with the median (50th percentile) of the annual average concentrations
Consequences for risk assessment	It is considered acceptable that concentrations in percolation water from treated fields are considerably higher than the criterion because the groundwater at 10 m depth can be lower for a number of reasons. One of the most important is degradation in either the soil or ground water below one meter. If well screens are relatively long (for example 3 m or more) the samples can represent recharge water from beneath treated fields (perhaps from different fields and years) and untreated areas.

Impact on product registrations	Will be possible to conduct monitoring programs to support registration of products previously registered but do not pass current modelling assessments due to increased conservatism. Will be able to register those products that degrade at an adequate rate in soil and water below 1 m.

Option 6

Type of concentration	Concentration in raw water of a drinking-water pumping station using groundwater not influenced by surface water (no bank filtration) 
Spatial unit	Whole catchment area of a drinking-water pumping station, so average concentrations from all drinking-water wells
Spatial statistical population of units	All catchment areas of drinking-water pumping stations in the area of use of the substance
Temporal statistical population of concentrations	Daily or weekly concentrations
Percentile	95th percentile meaning that only exceptional exceedances of the guideline concentration are considered acceptable
Consequences for risk assessment	Same as option 5 with the additional consideration that the points of measurement are wells used to provide drinking water .
Impact on product registrations	Similar to option 5.

Option 7

Type of concentration	Concentration in raw water of a drinking-water pumping station using groundwater not influenced by surface water (no bank filtration) but not older than 50 years (this age limitation is needed to avoid that too much dilution is included in the assessment)
Spatial unit	Whole capture zone of a drinking-water pumping station, so average concentrations from all drinking-water wells
Spatial statistical population of units	All capture zones of potential drinking-water pumping stations in the area of use of the substance; in this context potential means that also capture zones of drinking water pumping stations are considered that do not yet exist but may be created in future; it means also that areas with e.g. brackish water are excluded from this statistical population because no drinking-water pumping stations will be created there.
Temporal statistical population of concentrations	Daily or weekly concentrations
Percentile	95^{th} percentile meaning that only exceptional exceedances of the guideline concentration are considered acceptable; since water is originating from a relatively large capture zone, the temporal fluctuations of the concentrations are expected to be small so that the temporal statistics are not so important.
Consequences for risk assessment	Same as option 5 with the additional consideration that the points of measurement are wells used to provide drinking water.
Impact on product registrations	Similar to option 5.

Reference

EFSA, 2010. Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). EFSA Journal 2010 8(10): 1821, 55 pp.