Environmental Risk Management and Decision Making

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Department 2

Risk assessment and risk management in the authorisation procedure

Legal stipulations
Defining the level of protection and safeguards

Type of application

Properties of products and active substances

Risk assessment:
Describing possible risks in the environment

Risk management:
Deducing necessary risk mitigation measures

Risks acceptable

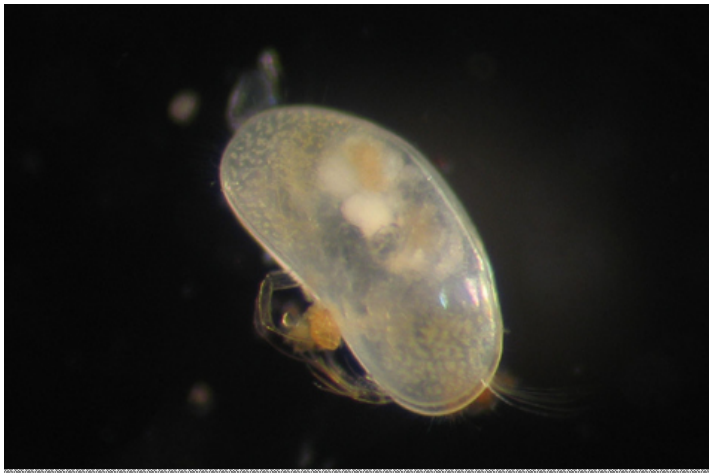
Risks not acceptable

Can be authorised if used correctly and for the intended purpose

Cannot be authorised

Groundwater - important aspects

Niphargus aquilex



Mixtacandona laisi

- Protection of groundwater as the most important resource for supplying drinking water
- In the context of authorising plant protection products: protection of groundwater in its entirety, irrespective of its use
- Protection of groundwater as a habitat for non-target organisms and a source of new surface water

Assessment in the authorisation procedure

Statutory prerequisite for authorisation (PflSchG):

no harmful effects on groundwater through using a plant protection product

- Deemed a subject of absolute protection for human health (no benefit analysis intended as far as the plant protection product use is concerned)
- Input from active substances or relevant metabolites into groundwater in concentrations of > 0.1 µg not acceptable (limit value from Drinking Water Directive)
- Assessment on the basis of predicted leachate concentrations (computer simulations, lysimeter studies, field leaching studies)

Protection of wild plants and animals

No unacceptable effects on the environment due to the use of plant protection products (German Plant Protection Act)

Maintaining the diversity of animal and plant species (non-target organisms) in agrarian landscapes

Prerequisite:

- Minimising impact on populations on treated areas
- Maintaining populations on adjacent untreated areas / water bodies
- Ensuring recolonisation and recovery on treated areas
- Reduction of active substance input into adjacent areas/water bodies

Basic principles of risk assessment

Exposure: concentrations / residues which can be expected in the environment

Toxicity: the effects a certain active substance can have on organisms

Exposure

(Predicted Environmental Concentration (PEC)):

e.g. in / on soil, in groundwater and surface water, on plants and insects as food for non-target organisms

Toxicity

Impact on organisms, e.g.:

lethal effects

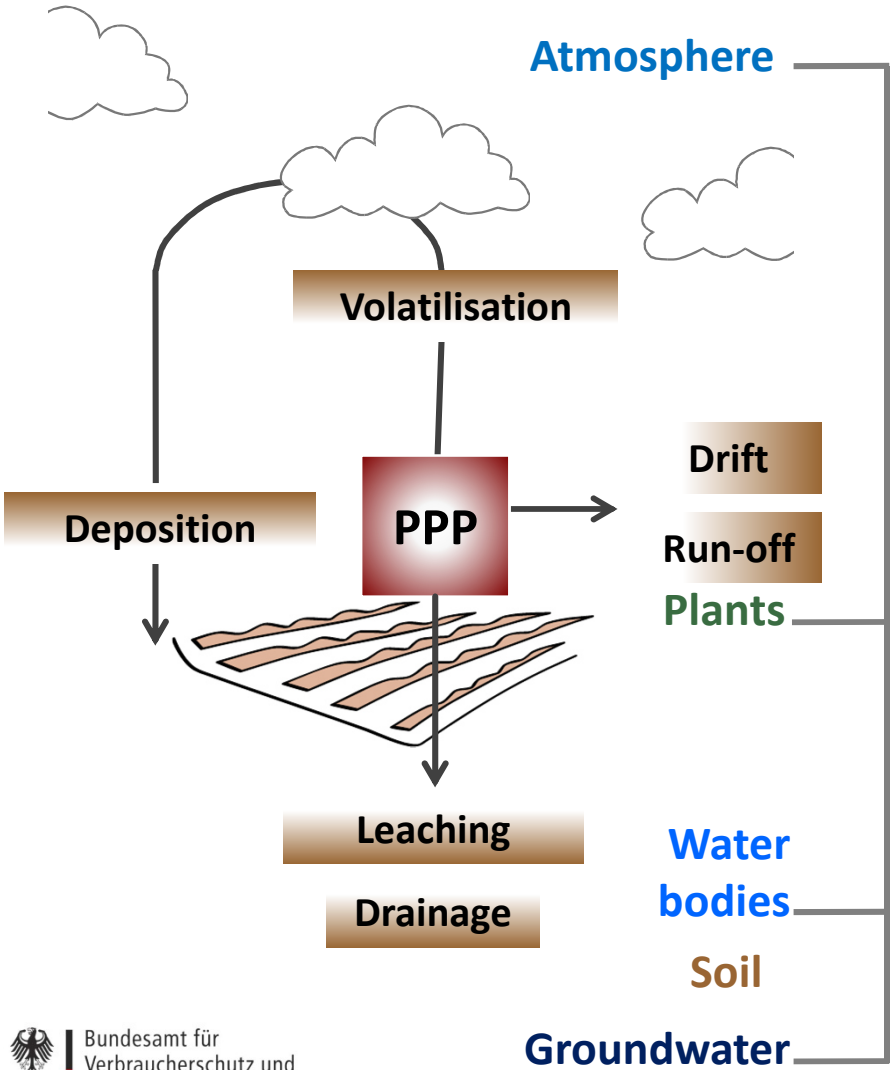
(mortality)

sublethal effects

(e.g. impact on offspring)

Relationship between toxicity and exposure also known as TER (Toxicity Exposure Ratio)

Calculating the PEC for estimating exposure



Exposure Concentrations / residues which can be expected in the environment

Exposure paths via water, soil, atmosphere and / or plants e.g. through contact, feeding or the food chain taken into consideration

PEC predicted environmental concentration

Influenced by:

- Product use pattern
  Application method, crop, growth stage, application rate
- Fate and behaviour of the active substance in the environment

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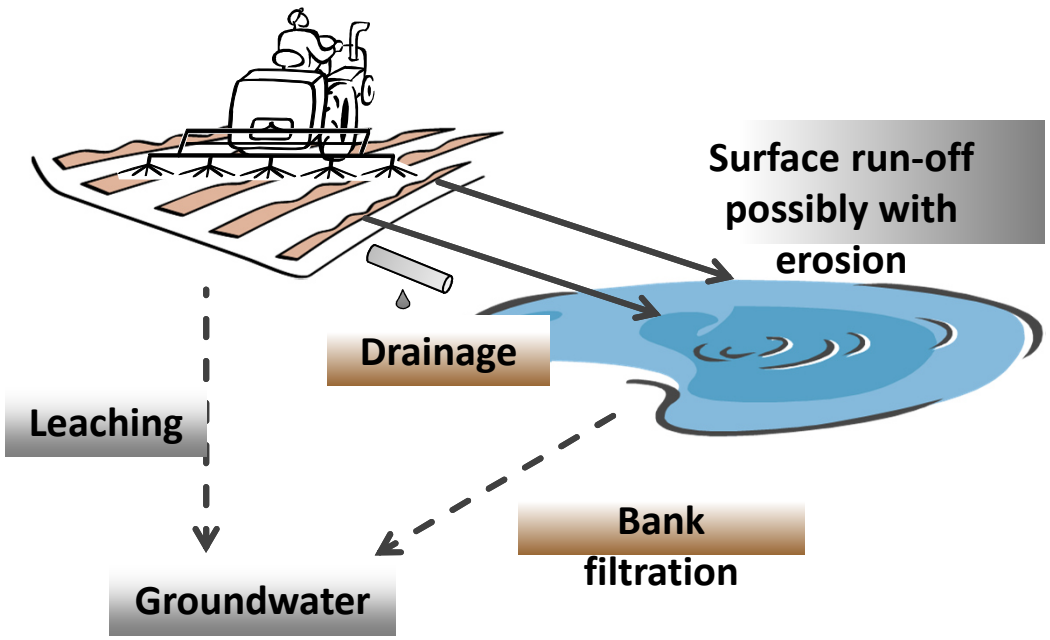
Estimation of input due to leaching and bank filtration from surface water



- Significant input parameters:
  - Application rate
  - Interception by the crop (crop growth stage)
  - Degradation (DT_{50}) and adsorption (Koc value) in soil
  - Timing of application
- Calculations (computer models PELMO/PEARL and EXPOSIT)
- Leaching study (e.g. lysimeter study)

Standard ecotoxicological studies

Studies on ecotoxicological impact are performed with representative species from different organism groups:

- laboratory trials which can be standardised well
- often artificial substrate
- species which can be bred easily
- individuals in the same age category
- well standardised exposure

- The risk assessment must also cover species which have not been examined and extrapolation to outdoor conditions.
- A safety factor is therefore taken into consideration (target value) for the intended protection level.

Further ecotoxicological studies

Tests under more realistic conditions may become necessary if unacceptable effects are expected on the basis of a standard risk assessment.

Ecological water analyses

- Higher tier test systems in the laboratory
  - examination of further species
  - make exposure more realistic
- Outdoor studies
  - examination of biocoenoses with many species
  - realistic exposure and environmental influences
  - recovery of populations is recorded

The safety factor (target value) may possibly be reduced due to greater certainty in predicting risks.

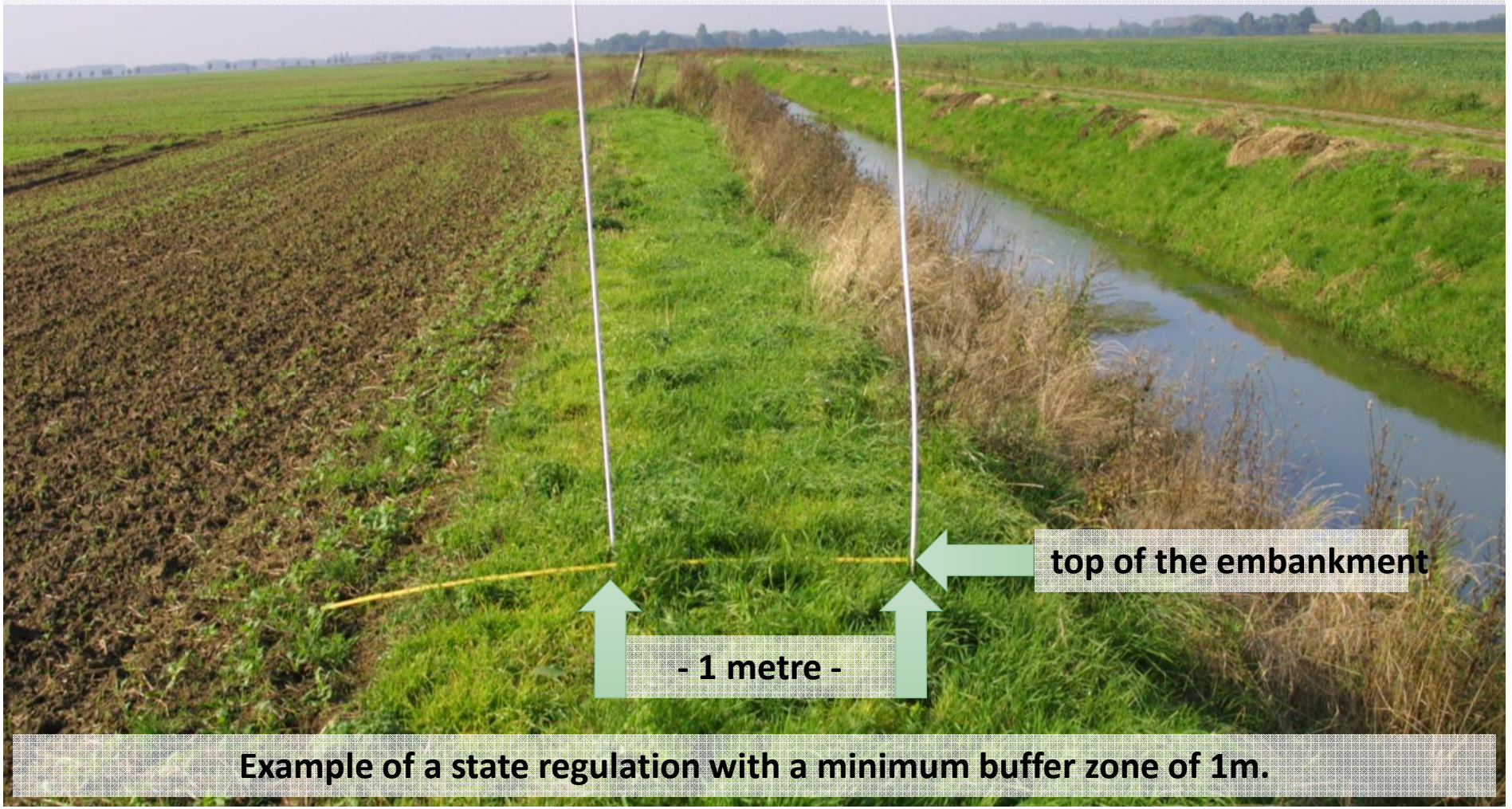
If the required TER is not achieved, the expected exposure of non-target organisms must be reduced by additional risk mitigation measures in order to allow authorisation.

risk mitigation measures stipulated at the time of authorisation, e.g.

- use of drift reducing application methods
  (e.g. mitigation categories 50%, 75%, 90%)
- maintaining buffer zones (to adjacent water bodies or ecotones such as hedges)
- limiting application rates (e.g. reducing number of treatments, modify timing of application)
- stipulating an upper limit for active substances which must not be exceeded by other products containing the active substance

Example for calculating minimum buffer zones

The buffer zone to be kept to water is measured from the top of the embankment.



Example of a state regulation with a minimum buffer zone of 1m.

Risk management to protect groundwater

If the predicted concentration in groundwater exceeds the limit value, authorisation is only possible if the expected concentration is reduced by additional risk mitigation measures.

Possible risk management measures for the purpose of authorisation:

- Exclusion of applications on certain types of soil (e.g. sand)
- Application only under conditions which favour degradation in soil and keep leaching low (e.g. use only in spring instead of autumn)
- Restricting the dosage of the active substance (e.g. reducing the number of treatments, limiting the period of application)
- Determining the maximum amount of active substance per year which may be applied to a surface (taking into consideration all products containing the active substance)

Examples for groundwater risk management

Conditions of use which govern the timing of application, e.g.:

No use between 1 September and 1 March

No use on drained surfaces between 1 June and 1 March

Prohibit use on certain soils, e.g.:

No use on soils with an organic carbon content (C_{org}) of less than 1 %

No use on soil consisting of pure sand, slightly silty sand and slightly clayey sand

No use on soils with an average clay content > 30 %

Conclusions

- Harmful effects on ground water and unacceptable effects on non-target life must be precluded
- Risk assessment for ground water, birds and mammals, honey bees, non-target arthropods and plants, soil organisms are always conducted
- Often risk mitigation measures are set when authorising products
- Work on EU-wide harmonisation is in progress (e. g. MAgPIE-Workshop)

Thank you for your attention!

Example risk management: input into surface water by drift II

Calculation of the active substance concentration in water

active substance dosage: **1 × 1000 g/ha**
drift scenario: **field crops (cereals)**
relevant toxicity: **6 µg/L (NOEC, water-flea)**
relevant TER: **10**

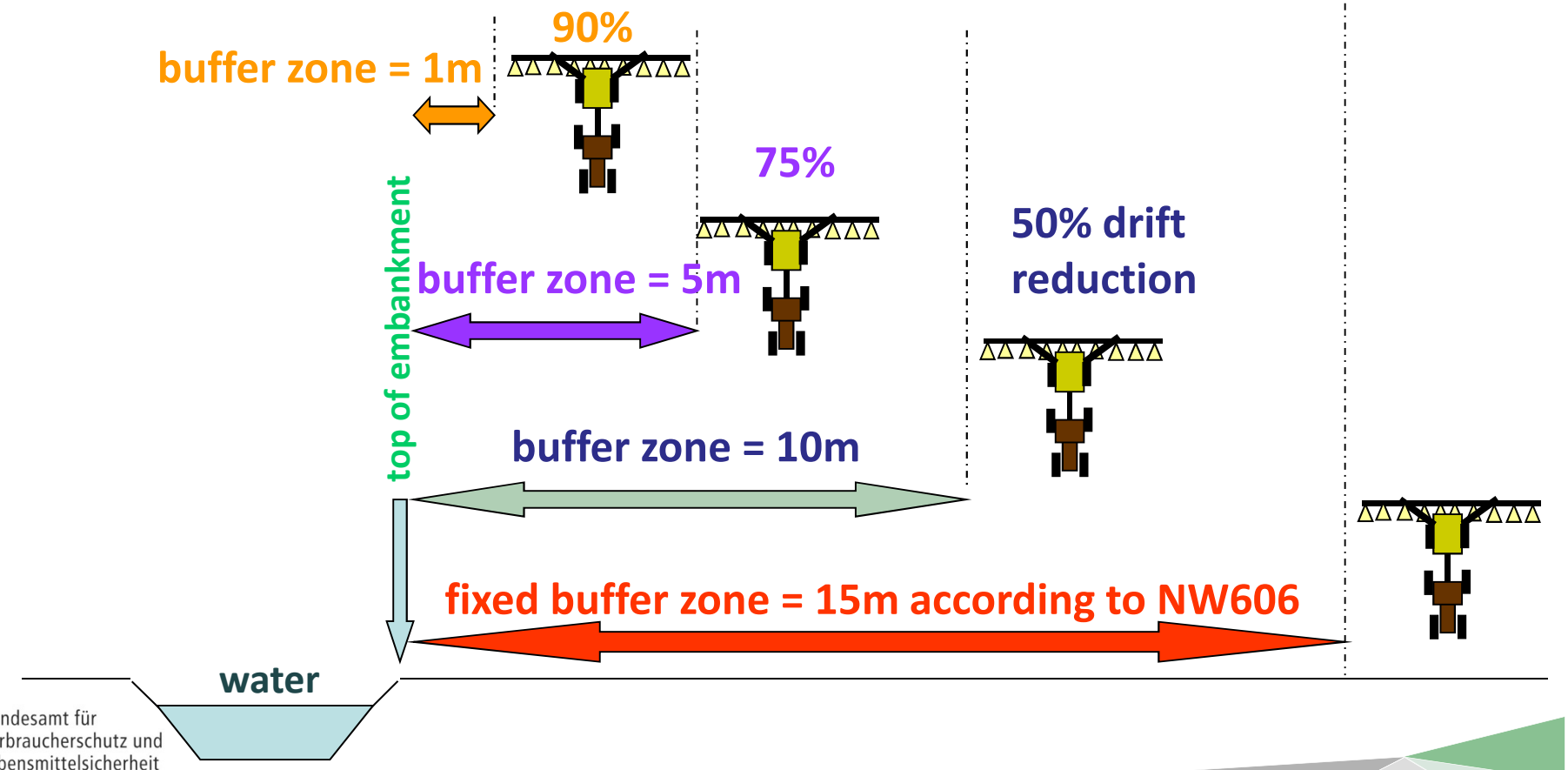
buffer zone	input through drift	PEC	TER values depending on drift reduction			
[m]	[%]	[µg/L]	no reduction	50% min.	75% min.	90% min.
1	2.77	9.23	0.6	1.3	2.6	6.5
5	0.57	1.90	3.2	6.3	13	32
10	0.29	0.97	6.2	12		
15	0.20	0.67	9.0			
20	0.15	0.50	12			

- A buffer zone of 20m should be kept to surface water (condition of application) without drift reduction.
- If drift reducing technology is applied, the buffer zone can be reduced to 10m (at 50% drift reduction) or 5m (at 75% and 90% drift reduction) (condition of application).

Example of a condition of application for drift reduction

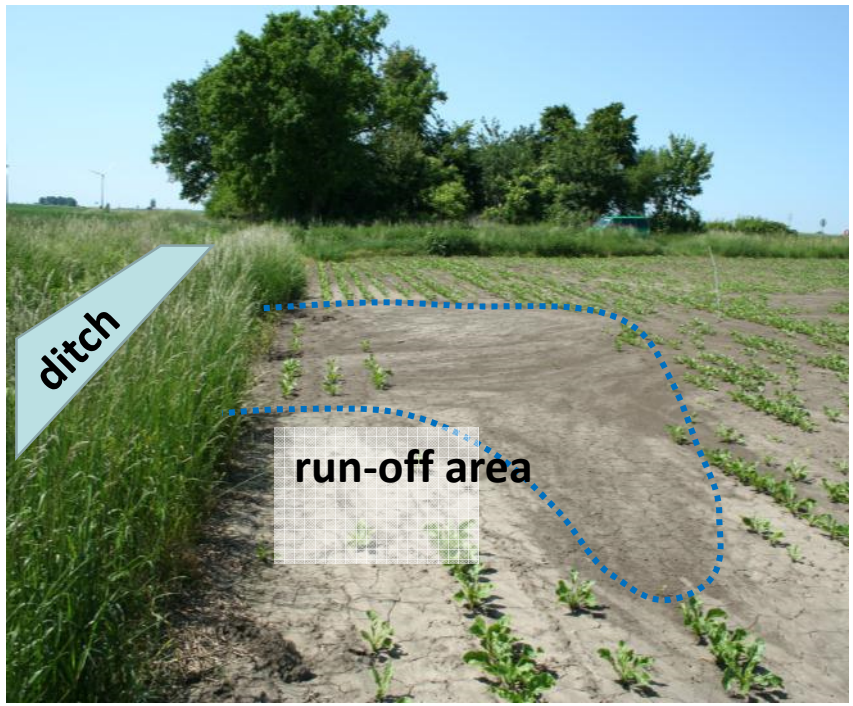
Condition of application NW605 and NW606

Fixed minimum buffer zones to water must be kept when applying the product; variable buffer zones are possible when drift reducing nozzle systems are used (buffer zone means untreated verge)



Example risk management: input into surface water by run-off I

Input through run-off and drainage in adjacent surface water



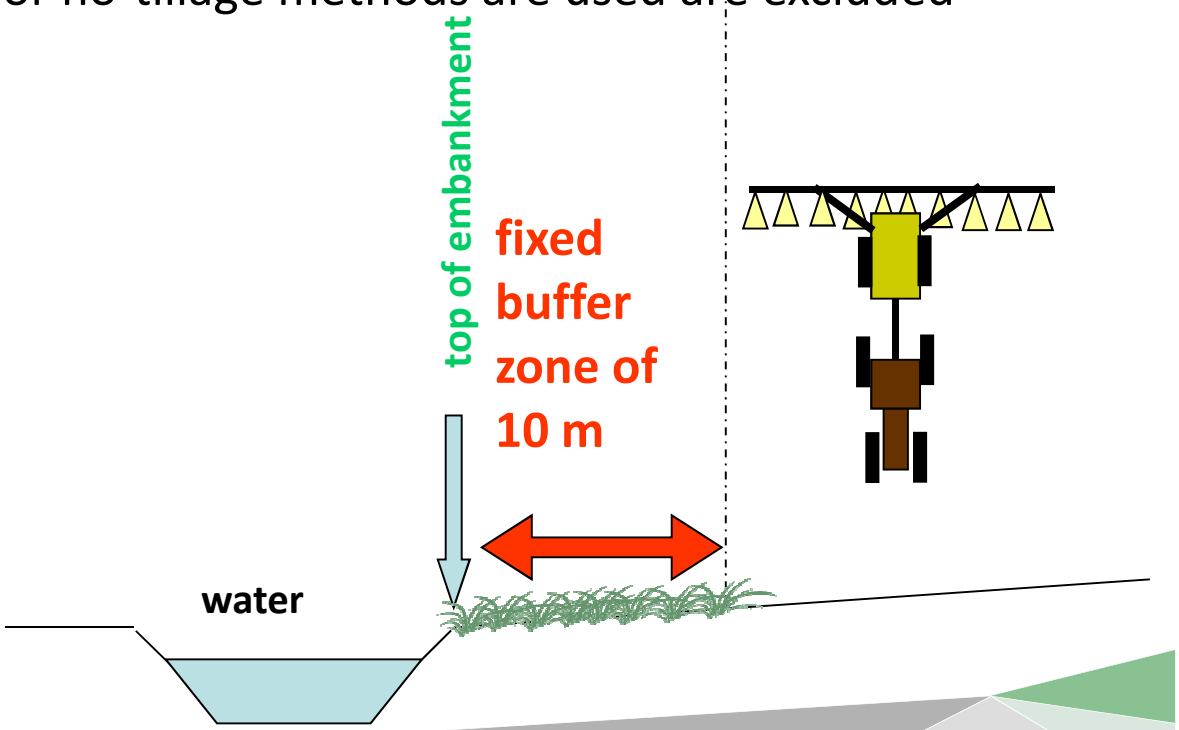
- lowest NOEC from laboratory studies with aquatic organisms: **6.0 µg/l**
- the acceptable active substance concentration of **0.6 µg/l** results when safety factor 10 is used
- model water: shallow ditch (30 cm deep) directly adjacent to the treated field
- calculation of the active substance concentration in water based on dosage

Example of a condition of use for reducing run-off input

Condition of use NW 701

There must be a buffer zone of at least 10 m in width under plant cover when applying a plant protection product if there is a risk of input through surface run-off from a treated area with an incline of ≥ 2 % leading to water.

Surfaces where conservation or no-tillage methods are used are excluded from this condition of use.



Module 5: Environmental risk assessment and risk management

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Protection of Groundwater

01 Groundwater - important aspects

02 Assessment in the authorisation procedure

03 Estimation of groundwater exposure

04 Metabolites in groundwater

05 Risk management to protect groundwater

06 Examples of groundwater risk management

07 Appropriate use of products by the operator for the specific site

Index Module 5

Environmental risk assessment and risk management

Index Module 7

Protection of Surface Water and Aquatic Organisms

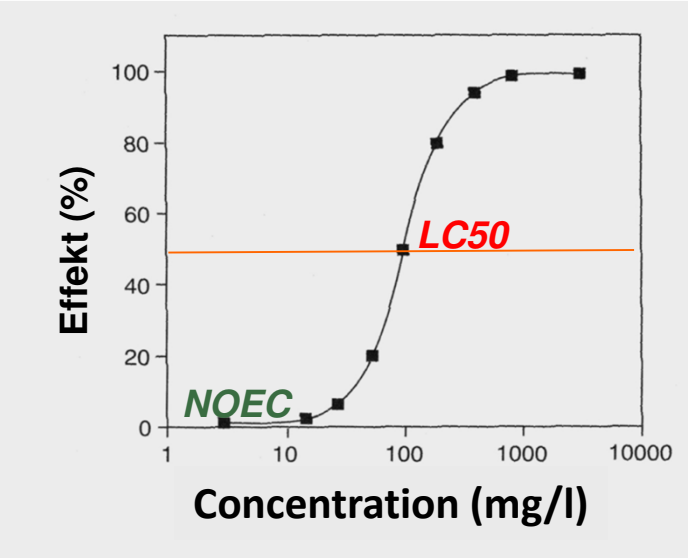
Index Module 8
Protection of Terrestrial Organisms

Outline

- Set of Slides for communication with users, advisers, ...
- Protection Goals
- Overview of Risk Assessment Schemes
- Risk Mitigation Measures
- Conclusions

Toxicity - calculating impact

Example of a concentration-effect-relationship



Various parameters are examined depending on the species
(e.g. mortality, reproduction, weight, behaviour)

Acute and longer-term test parameters

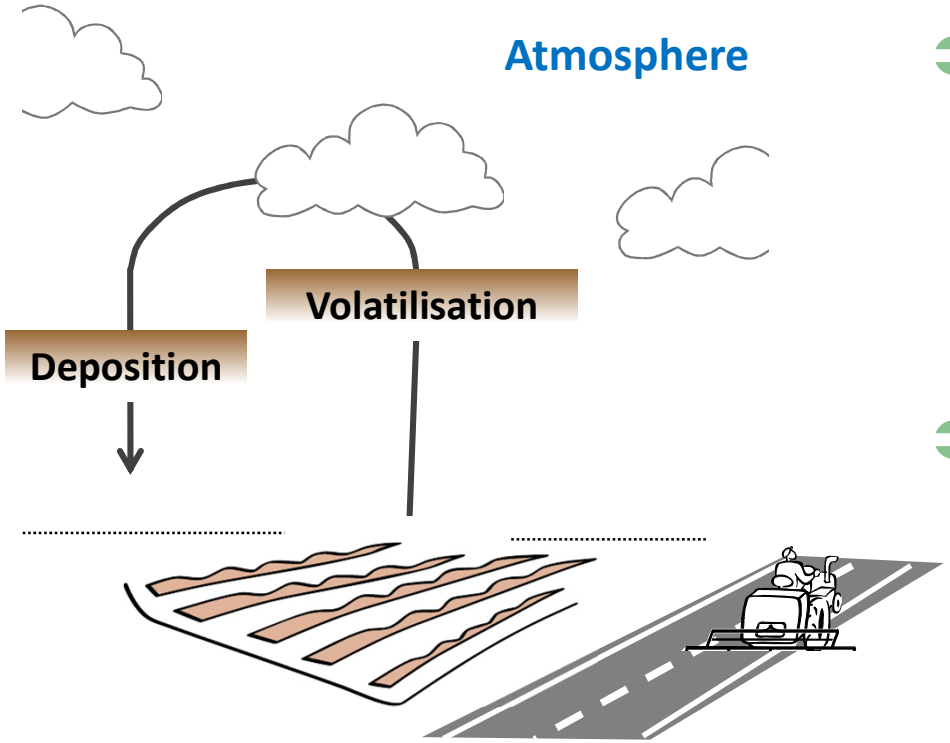
LC50 = Lethal Concentration 50%
Active substance concentration at which 50% of the test organisms die

EC50 = Effect Concentration 50%
Active substance concentration at which 50% of the test organisms are affected adversely

NOEC = No Observed Effect Concentration
Highest concentration examined without an impact on test organisms

Estimation of exposure due to volatilisation

Estimation of input due to volatilisation and deposition



- Significant input parameters:
  - Vapour pressure
  - Application rate
  - Type of crop (leaf surface)
- Distance-related calculation (computer model EVA) with tabulated deposition values (based on volatilisation trials in a wind tunnel)

The toxicity value relevant for assessment is considered in relation to the expected exposure (Toxicity-Exposure-Ratio, TER)

$$\frac{\text{EC50/NOEC}}{\text{PEC}} = \text{TER} \geq \text{target value}$$

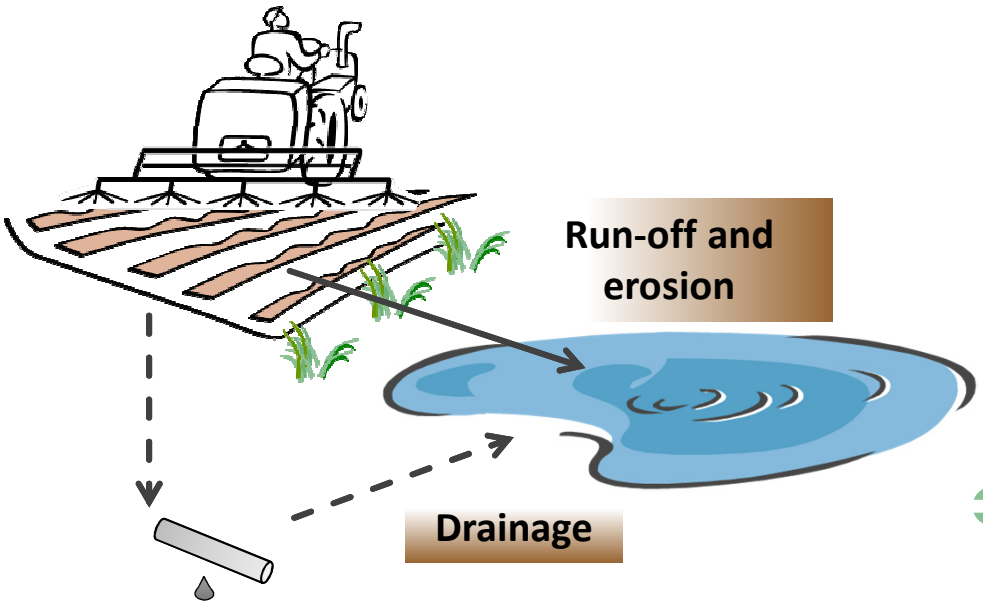
The higher the TER, the lower the risk
(the values for expected environmental concentration and toxicity are wide apart).

According to legal authorisation criteria, the TER must at least achieve a target value which depends on

- Organism group (e.g. aquatic organisms, birds etc.)
- Toxicity value from acute or longer-term tests

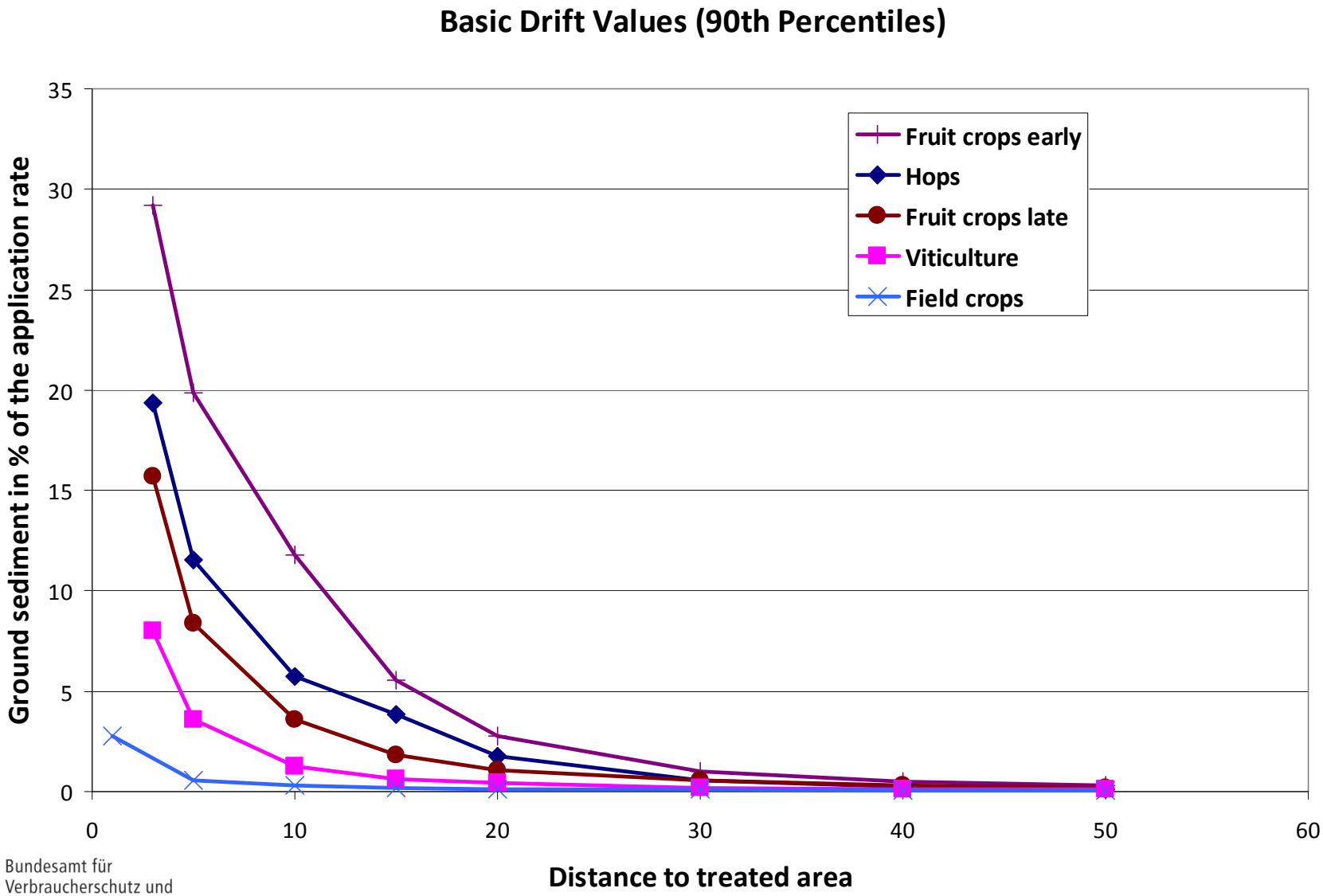
Estimation of exposure due to run-off and drainage

Estimation of input due to run-off and drainage



- Significant input parameters:
  - Application rate
  - Interception by the crop (crop growth stage)
  - Timing of application
  - Degradation (DT_{50}) and adsorption (Koc value) in soil
- Calculations (computer model EXPOSIT)

Basic drift values



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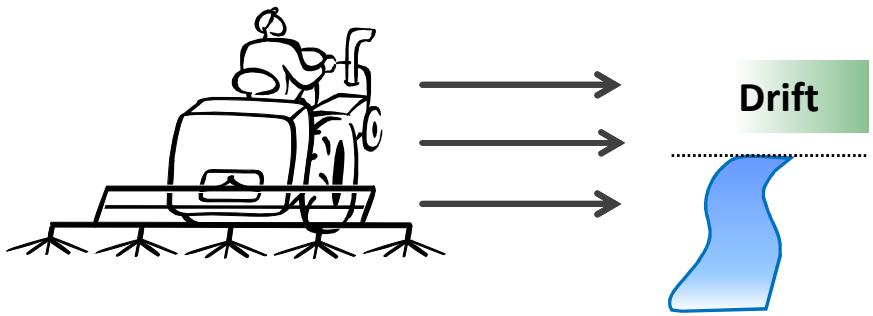
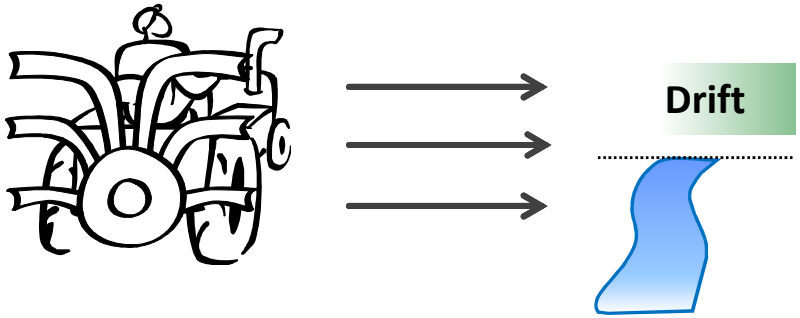
Calculating input due to drift (spray-drift)





- Significant input parameters:
  - Type of crop (field and tall growing crops)
  - Drift reducing methods for various reduction categories
  - Application rate/number of treatments
- Result: tabulated basic drift values, calculation with computer model EVA

Risk mitigation for soil organisms

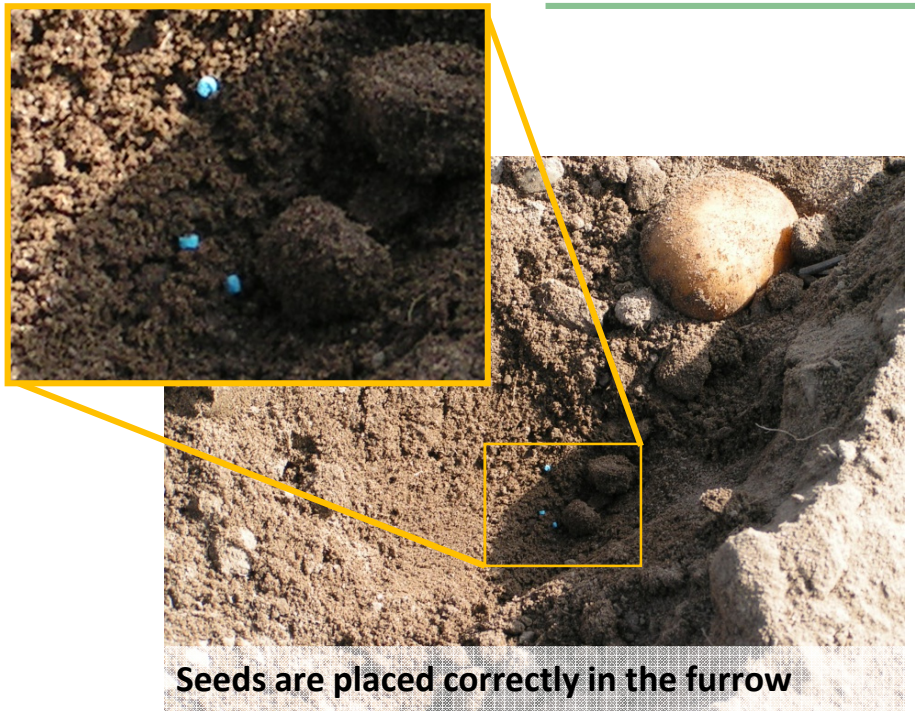
Reducing exposure by limiting the active substance dose per hectare and year

Examples of conditions of application

- The product is classified as harmful for earthworm populations, therefore only apply this and comparable products once every 3 years on the field.

- The maximum application rate of 3000g pure copper per hectare and year (for hop growing: 4000g pure copper per hectare and year) for the same area - even in combination with other plant protection products containing copper - must not be exceeded.

Risk mitigation for vertebrates



Seeds are placed correctly in the furrow

Objective: reducing exposure

- difficult to put into practice for spray applications (e.g. if possible treatment should take place at times when areas are not attractive)
- in the case of seed and granulate treatments, for example, ensure that the treated seeds or granules are not left exposed

Examples of conditions of application

On packaging containing dressed seeds, the following label is required:

- "Sweep up and remove spilled seeds immediately."
- "This product is poisonous for small mammals. For this reason, do not leave seeds exposed. Switch off the dosing equipment on time before lifting out the shares to prevent trickling afterwards."

Example of risk management for insects and plants in ecotones

50, 75 or 90% drift reduction in 20m strips bordering the field

and/or

5m buffer zone to ecotones from a width of 3m onwards

- exceptions to the rule in areas where there are sufficient margins (ecotones) (see 'index of regional proportions of ecotones')

- as a rule, adjacent paths, roads and public places and adjacent cultivated areas are not affected by restrictions

General and specific aims with regard to biological diversity

General aims:

Protection of habitats and protection of wild animals, plants, fungi and microorganisms.

Sustainable use of wild and cultivated species and their genetic diversity.

Specific targets defined in the national strategy on biological diversity (2007):

- Biodiversity in agrarian ecosystems shall increase considerably by the year 2020. By 2015, populations of the majority of species (in particular wild species) which are typical of cultivated landscapes used for agrarian purposes shall be secured and begin to increase again.
- By 2015 the percentage of agrarian biotope areas valuable for nature conservation (grassland and fruit tree meadows of high quality) shall increase by at least 10% compared to 2005. In 2010, the share of virtually undisturbed landscape elements (e.g. hedges, boundaries, field shrubs, small bodies of water) in agrarian areas shall be at least 5%.

Biodiversity and plant protection measures

- up to present, direct effects on biodiversity are taken into account at authorisation
- indirect effects through impact on important food sources and structures on cultivated areas in particular for protected species have not been considered up to now
- the use of plant protection products must not lead to a deterioration of the maintenance condition of local populations of protected species
- integrated plant protection on cultivated areas important

Maintaining and encouraging biodiversity

- create flower strips, windows for skylarks, etc.
- less intensive use on parts of agriculturally cultivated areas (e.g. poorly accessible / low yield)
- apply for agri-environmental measures and contract-based nature conservation
- grassland preservation / extensification
- support / create ecotones