

## **Environmental risk assessment of plant protection products**

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**Abstract.** Plant protection products (PPP's) are hazardous chemicals that are intentionally spread into the environment. In order to protect human and animal health and the environment the risk assessment has to be performed before the authorisation of PPP's. Risk assessment is based on the general principles and requirements laid down in the European Council Directive 91/414/EEC (concerning the placing of plant protection products on the market), international guidelines and Estonian legislation. This paper describes ecotoxicological and environmental risk assessment, the use of mathematical models and feasible risk mitigation measures to assure acceptable risk of PPP's under the proposed conditions of use in Estonia.

**Key words:** plant protection products, risk assessment, ecotoxicology, environmental fate and behaviour, risk management

### **INTRODUCTION**

The competent authority for authorisation of PPP's in Estonia is Estonian Plant Production Inspectorate, Plant Protection Department. Authorisation consists of processing the application, evaluation and risk assessment and implementation of feasible risk mitigation measures of PPP's. The department is also responsible for supervision of the use of PPP's.

#### **Environmental risk assessment and management of PPP's in Estonia**

##### 1. Environmental fate and behaviour

During the authorisation of PPP's the fate and behaviour of pesticides, their active substances and/or relevant metabolites in the environment is assessed. To assess the exposure into environment PEC values (predicted environmental concentrations) in soil, surface water, sediment, ground water and air under the proposed conditions of use are calculated. In European Union (EU) a tiered approach is taken for assessing the risks – first tier studies present more conservative results whereas the outcome from higher tier risk assessment presents a realistic worst-case situation. The assessment follows the procedures approved for EU. There are no specific requirements for risk assessment in Estonia.

##### 1.1 Soil

The PEC values for soil and accumulation possibility are assessed with MS Excel spreadsheets that consider application rate, interception value, degradation time in soil, the rate order for degradation and interval between applications. If the active substance

or its metabolite(s) show accumulation tendency, no authorisation will be granted or application will only be allowed in every other year.

### 1.2 Surface water and sediment

The PEC values for surface water and sediment are assessed with Step1&2 in FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use). The main entry to surface water bodies is considered to occur via spray drift as runoff and drainage are not relevant due to the landscape of Estonia. Therefore Step3 values are usually not calculated. If the calculated PEC values exceed the values fixed in EU and Estonia no authorisation will be granted or no treatment buffer zones are assigned to certain crops.

### 1.3 Groundwater

For calculation of PEC values in groundwater, the leaching behaviour of the active substance and relevant metabolites have to be assessed. Estonia uses in tier 1 calculations FOCUS defined scenario Jokioinen (a combination of weather, soil and cropping data) in model PEARL (Pesticide Emission Assessment at Regional and Local scales) that is a one-dimensional numerical model of pesticide behaviour in the soil-plant system. This model allows estimating the possibility for an active substance and/or its relevant metabolite(s) to reach into the target depth in FOCUS of 1 m. If the calculated PEC values for ground water exceed the limit value fixed in EU level or in Estonian legislation, lysimeter studies that characterize the leaching behaviour of an active substance and relevant metabolites in realistic conditions have to be submitted to perform tier 2 risk assessment. If there is no safe use indicated for groundwater, no authorisation will be granted.

## 2. Ecotoxicology

The main purpose of ecotoxicological risk assessment before the authorisation of PPP's is to identify risks and impacts on non-target organisms and where necessary to work out risk mitigation measures. There are different methods to assess risks to the non-target organisms. Annex VI of directive 91/414 establish the trigger values which are followed.

### 2.1 Birds and mammals

The most common species whose toxicity data is used in risk assessment are bobwhite quail, japanese quail, mallard duck and rat or mouse.

Birds and mammals can be exposed mainly via diet, but there is also possibility for dermal and inhalation exposure. Exposure should be expressed as daily dose for all time scales (acute, short-term and long-term). Basically the estimated daily uptake of a compound depends on different aspects: food intake ratio of indicator species, body weight, concentration factor of compound in fresh diet, avoidance factor, fraction of diet obtained in treated area and fraction of food type in diet.

The standard risk assessment is based on toxicity/exposure ratio (TER) values. The acute and short-term TER is the ratio between LD50 from the acute or short-term test and exposure value. The long-term TER is the ratio between the NOEC from the reproduction test and exposure value.

The risk is acceptable for birds and mammals when acute and short-term TER is higher than 10 and long-term TER is higher than 5. If concern is raised, *i.e.* a TER is less than the appropriate trigger value, then a refined risk assessment must be conducted.

## 2.2 Aquatic organisms

To assess risks on aquatic life there are different organisms whose toxicity data (acute and chronic toxicity) used in risk assessment. Toxicity data for the following organisms is always required: waterflea (representative of invertebrates, usually *Daphnia magna*), fish (representative of vertebrates, usually rainbow trout), algae (representative of plants, usually green algae).

To assess exposure there are different scenarios available. In the worst case scenario it is assumed that water body is a static ditch of 30 cm depth and PPPs application rate is maximum season`s usage applied as a single dose. It is also assumed that in application time there is always spray drift from sprayer. In the worst case scenario it is assumed that the distance between sprayer and water body is 1 m for row crops (spray drift 2.77% from PPPs application rate) and 3 m for tall crops.

The risk is acceptable when acute TER is higher than 100 and chronic TER is higher than 10. If as a result of this initial assessment concern is raised, *i.e.* the resulting TER is less than the trigger values, then a higher tier risk assessment is needed. In higher tier risk assessment there is a need for data from more complicated studies (microcosm or mesocosm studies).

In certain instances (TER values are below trigger values and there is no data from higher tier studies or results from higher tier studies show that there is still a risk) it may be necessary to have a buffer zone restriction included into the authorisation conditions and added to the label to protect aquatic life.

## 2.3 Honeybees

To assess risk to bees there is a need for oral and contact toxicity data. Risk assessment is based on the calculation of hazard quotients (HQ):

$$\text{HQ} = \text{maximum PPPs application rate/toxicity} = (\text{g/ha})/(\mu\text{g/bee})$$

Risk is acceptable when HQ values are below 50. Where the hazard quotient is greater than 50, further testing may be required (field studies, bee brood feeding test).

If a risk to bees is identified then the product is labelled appropriately: To protect bees and other pollinating insects do not apply to crop plants when in flower/Do not use where bees are actively foraging.

## 2.4 Arthropods other than bees

To assess risk to other arthropods there is a need for information on toxicity, infectiveness and pathogenicity. The most common species whose toxicity data is used in risk assessment are two sensitive standard species, a parasitoid and a predatory mite (*Aphidius rhopalosiphi* and *Typhlodromus pyri*).

Risk is acceptable when less than 30% of the test organisms are affected in lethal or sublethal laboratory tests conducted at the maximum proposed application rate.

Where a risk is identified, it may be necessary for the product to be labelled with special safety precautions.

## 2.5 Earthworms

To assess risk to earthworms there is a need for information on acute and reproduction toxicity. The most common test organisms are compost worms (*Eisenia fetida*).

The standard risk assessment is based on TER values. The acute TER is the ratio between the LC50 from the acute test and the PEC. The long-term TER is the ratio between the NOEC from the reproduction test and the PEC. The PEC estimate is based

on the assumption that the total dose/unit area is mixed into the upper 5 cm of the soil and a soil density of 1.5 g/cm<sup>3</sup>.

Risk is acceptable when acute TER is higher than 10 and long-term TER is higher than 5. Where the TER is below the Annex VI trigger, higher tier testing *e.g.* a field trial, may be required.

#### 2.6 Soil non-target micro-organisms

Risk to the soil non-target micro-organisms is acceptable if the nitrogen or carbon mineralization processes in laboratory studies are affected less than 25 % after 100 days.

#### 2.7 Non-target plants

Non-target plants are plants located outside the treatment area. They can be exposed via spray drift. To identify risks at least 6 species from different taxa must be tested at the highest nominal application rate of PPPs. Where a risk to non-target plants is identified an appropriate advisory warning may be added to the product label.

## **CONCLUSIONS**

Plant protection products (PPP's) are hazardous chemicals that are intentionally spread into the environment. During the authorisation of PPP's in Estonia environmental fate and behaviour and ecotoxicological properties of pesticides, their active substances and/or relevant metabolites are assessed by Estonian Plant Production Inspectorate, Plant Protection Department. In order to protect human and animal health and the environment certain authorisation conditions (risk mitigation measures and safety precautions) for plant protection products that are indicated on the product label have to be followed.