of the product samples that was taken in distribution chain, or for analysis of samples of treated crops or samples of food.

➲ *Risk assessment for environmental components*

The assessment is focused on determination of risk for soil, water and air. It includes the ways of dissociation of active substances and metabolites, mobility and remaining in the environment and through mathematic models it also involves estimations of active substance amount in soil, water and air during certain period of time after the application of plant protection product. In case the application does not fulfil the safety criteria, the result of the assessment might be for example a restriction of the application close to the source of drink water or a restriction of the application within certain period, e.g. one year and more.

Foto: Ing. Kristina Hutařová, ÚKZÚZ

➲ *Risks for non-target organisms*

The assessment follows up the outputs of risk assessment for environment. The assessment is focused on organisms living in soil or in water, on non-target arthropods, bees and other pollinators, also on terrestrial vertebrates including birds and non-target plants. The safety standards are not fulfilled such plant protection product might be labelled as dangerous for endangered organisms, protective distances from surface water and from edge of treated lands might be determined, the plant protection product may not even be authorized.

Foto: Ing. Mgr. Miloslava Navrátilová, Ph.D., ÚKZÚZ

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Other activities

➲ *Certification of GEP*

The Division of PPPs certifies the eligibility of testing organizations for testing of plant protection products in compliance with Good Experimental Practice and supervises the activities of testing organizations. Only the results gained by testing organizations with the GEP Certification can be used as documentation for assessment of biological efficacy in the authorization procedure of a plant protection product in the Czech Republic or in other Member States of the European Union.

➲ *Statistic of consumption of PPPs*

According to the Regulation (EC) No 1185/2009 about statistic of pesticides ÚKZÚZ process (in cooperation with Czech Statistic Office) the statistic of active substances contained in plant protection products, which are placed on the market and are used by professional users of PPPs. Data of the consumption of PPPs are publiced on our webside **www.ukzuz.cz.**

➲ *Competenc for use of PPPs*

For ensuring safe use of PPPs, every person needs to have a certificate of competenc for use of PPPs. ÚKZÚZ grent certifikat of 1st and 2nd degree, the term is to pass special exam. Date of this exames are regularly puliced on our webside.

Foto: Ing. Ivana Minářová, ÚKZÚZ

Contacts:

ÚKZÚZ: **Hroznová 2**
656 06 Brno
www.ukzuz.cz

Division of Plant Protection Products: **Zemědělská 1a**
613 00 Brno
tel.: 545 110 438
fax: 545 211 078
pripravky@ukzuz.cz

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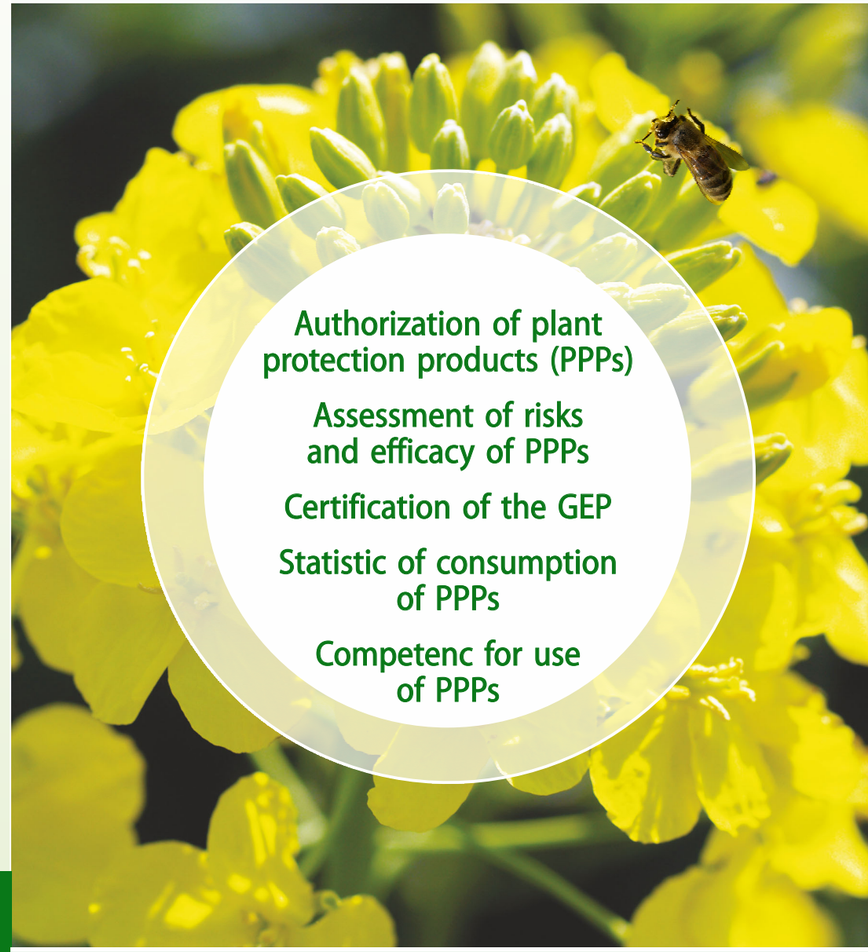
CENTRAL INSTITUTE FOR SUPERVISING AND TESTING IN AGRICULTURE

PLANT PROTECTION PRODUCTS



PLANT PROTECTION PRODUCTS

Introduction

Harmful organisms have caused great amounts of losses on the crop yields and even affected the quality of the products since the beginning of growing agricultural crops, vegetable and fruit. The growers naturally tried to fight against the negative influences of these organisms.

Because of increasing agricultural production it was necessary to increase also the efficacy of protective measures. There was search of new chemical preparations in order to decrease the losses caused by harmful organisms. It was found out gradually that the preparations might have had also a lot of negative effects on the environment, treated plants and human health.

Authorization of plant protection products

The authorization process has two stages, the first is the approval of the active substance by European Commission and the second is the authorization of the plant protection product by a particular Member State. The plant protection product must be authorized before it can be sold and used in the Czech Republic. The regulatory authority for authorization in the Czech Republic is the Central Institute for Supervising and Testing in Agriculture (ÚKZÚZ), Section of Agricultural Inputs (SZV), Division of Plant Protection Products (OPOR). Currently in the European Union there is neither a common or central institute for plant protection products affairs, nor a common authorization. The applicant is entitled to use so called mutual recognition, in case the plant protection product has already been authorized in another Member State. Nevertheless in this case it is still necessary to submit the application to the Central Institute for Supervising and Testing in Agriculture. The results of the assessment from the particular Member State are then used as basis for the decision.

Currently Division of Plant Protection Products is processing approximately 1000 applications for authorization or applications for a change in the plant protection product authorization and auxiliary products for plants protection.

➲ *Assessment of active substances*

Firstly the active substance of the plant protection product (i.e. chemical substance or microorganism which causes the effect) must be authorized by the European Commission. The Member States do the assessment for the European Commission and they are called the Zonal RMS (Zonal Reporting Member State). Reporter prepares the evaluation report and sends it to EFSA. EFSA is responsible for the process of its review by all Member States and after the review prepares the conclusions, which are basis for the decision of the Commission. The application for assessment must be submitted to the relevant authority in one of the Member States. The Division of Plant Protection Products usually evaluates between 2 and 4 active substances a year as the Zonal RMS.

➲ *The examination for authorization of plant protection products*

Before the plant protection product is authorized it has to be proved that its application is safe and efficient. The applicant proves the safety of the application by prescribed studies. He is obliged to select laboratories certified according the OECD standards. The applicant has to prove the safety of the application, it is the basic rule. If the required studies do not prove the safety of the application (or if the studies are not submitted) the plant protection product is regarded as dangerous and cannot be authorized. Ministry of Health of the Czech Republic is entitled to assess the effects of applications of the plant protection products on human health.

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Foto: Markéta Vodáková, ÚKZÚZ

The decision on potential authorization has to take into account the effects of the plant protection products on the environment, human health and agricultural production, and it also has to reflect the national legislation of the particular country. The Division of Plant Protection Products conducts approximately 40 assessments a year as the zonal RMS and comments on about 70 reports on assessment of plant protection products.

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Foto: Ing. Hana Wolfová

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Minor uses

The costs of preparing documents for individual uses in OECD Member States and in EU Member States have been increasing constantly. Therefore the applicants consider for which products the costs spent on the required studies are compensated by the profits. A lot of crops produced in minor range are omitted and possible protection is restricted. EU regulations enable research institutes, growing associations or individual growers to initiate the authorizations of plant protection products for these crops. The Division of Plant Protection Products focuses on this field as well and the Division issues approximately 30–40 authorizations per year in cooperation with growing associations and research institutes.

Currently there is acting in this field also the Minor Uses Coordination Facility in Paris, which mediates information on minor uses within EU. See: **http://www.eumuda.eu.**

Expert assessments

➲ *Efficacy of PPP and its influence on treated crop*

The applicant submits studies on efficacy of its PPP and the Division of PPPs assesses whether the efficacy of the product against the target pest is sufficient. The Division also assesses if the use of the product can harm treated crops, surrounding plants, subsequent crops, quality and the amount of yield, propagating material of the treated plant and processability of crops (for example the influence on wine or beer fermentation) etc. The result of the assessment might be a modification of the proposed dosage, a change in dates of applications or in numbers of applications, or a notification sent to the grower about the side effects.

➲ *Composition of the product, physical and chemical properties and analytic methods*

The experts of the Division of PPPs assess if the applicant stated correctly the identification of particular substances in the PPP and evaluate its properties. If they corresponds to the type of formulation and to the purpose, for which is the PPP intended to be used. Evaluators are dealing with the classification of the PPP based on its physical and chemical properties and recommends proper labeling. They also evaluate the compatibility of proposed packaging materials with the PPP. The conclusions of evaluations are used for risk assessment, for laboratory analysis