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COMPARATIVE ASSESSMENT OF PLANT PROTECITON PRODUCTS IN CR

A) Introduction

Regulation (EC) No 1107/2009 introduced a lot of new elements, essentially influencing the whole process of placing plant protection products on the market. One of the important changes (next to the zonal approach to applications for authorization of new plant protection products, or renewal of products already authorized) is the concept of comparative assessmentof the products containing substances to be substituted. The term „substance to be substituted"is new on the European level and was brought out in the above stated regulation.

On 11 March 2015 the European Commission issued in compliance with Article 80 Paragraph 7 of Regulation (EC) No 1107/2009 the Implementing Regulation (EU) No 2015/408 establishing a list of candidates for substitution. Criteria for inclusion in the list are defined under Point 4 of the Annex II to the Regulation (ES) No 1107/2009 and the Commission strictly followed these criteria when creating the above mentioned list of candidates for substitution.

The list in the implementing regulation contains in total 77 substances from all of the most important groups of pesticides used in the agriculture (herbicides, fungicides, insecticides, rodenticides). In April 2015 there were 54 active substances enlisted contained in more than 300 plant protection products authorized for use in Czech Republic.

The basis of the comparative assessment is a process in which the uses of plant protection products containing the candidate for substitution are compared to possible alternatives. The result of such assessment is a conclusion on the possibility or impossibility to substitute the plant protection product with a more suitable alternative. According to Regulation (EC) No 1107/2009 Member States shall not authorize or shall restrict the use of a plant protection product containing candidate for substitution for use on a particular crop where the comparative assessment demonstrates that:

1. *for the uses specified in the application an authorised plant protection product, or a non-chemical control or prevention method, already exists which is significantly safer for human or animal health or the environment;*
2. *the substitution by plant protection products or non-chemical control or prevention methods referred to in point (a) does not present significant economic or practical disadvantage;*
3. *the chemical diversity of the active substances, where relevant, or methods and practices of crop management and pest prevention are adequate to minimise the occurrence of resistance in the target organism; and*
4. *the consequences on minor use authorisations are taken into account.*

These basic requirements for comparative assessment are further elaborated by additional conditions stated in Annex IV of Regulation (EC) No 1107/2009. The only possibility not to conduct comparative assessment is if a new product is concerned and when „*it is necessary to acquire experience first through using that product in practice*." Such authorizations shall be granted once for a period not exceeding five years.

The institution responsible for placing plant protection products on the market in Czech Republic is the Central Institute for Supervising and Testing in Agriculture (CISTA), therefore comparative assessment is one of CISTA's competences.

The aim of this article, considering that comparative assessment is a completely new issue resulting in a number of questions and concerns for the possible loss of a number of frequently used products, is to answer some of the most urgent questions and make the public acquainted with the procedure to be followed by CISTA.

B) Frequently asked questions

When will the comparative assessment start?

Pursuant to Commission Implementing Regulation (EU) No 2015/408 the assessment will be conducted for all plant protection products, or their uses, for which the application will be submitted to CISTA after 31 July 2015. Types of applications concerned are: application for authorization of a new plant protection product, application for renewal of authorization of plant protection product and application for extension of use of plant protection product (new use), regardless of the Czech Republic being the Rapporteur Member State or not. In case of applications for extension of use, only the newly requested use will be subject of comparative assessment.

Applications submitted before 1 August 2015 will not be subject of comparative assessment.

Does comparative assessment concern minor uses as well?

Minor uses are not going to be subject of comparative assessment.

How to submit information for comparative assessment?

If plant protection product contains a substance approved as candidate for substitution, it is required to submit all necessary information together with the application for authorization, for renewal of authorization or for extension of use (new crop). Information should besubmitted in form of a national addendum to the draft registration report (DRR). Only reasonable argumentation shall be provided. We would like to inform you at this point that letters from farmers requesting to keep a particular product on the market will have a minimum value from the comparative assessment point of view and will have no influence on the final decision.

Are there any examles or forms available?

All the forms and examples on how to fill them are available on CISTA‘s webpage. There is also the possibility to use examples given in the Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009; SANCO/11507/2013 rev. 12 issued by the European Commission.

How will comparative assessment be completed if the product is authorized for minor uses?

The eventual effect of comparative assessment on minor uses is considered when assessing the possibility to substitute the product with respect to agronomic conditions. The authorization holder of a plant protection product containing substance approved as candidate for substitution should submit a list of minor uses authorized for the product (if the plant protection product in question has been already authorized). The possible effect on the particular minor use if the plant protection product or one of its main uses would be substituted should be discussed. Apart from the agronomical risks, consideration should be given to economic indicators as well – for example marketability of the plant protection product should one of the main uses be revoked. It is recommended to present the possible alternatives for the particular minor use.

Concerning new plant protection products, an analysis of the possible future minor uses of the plant protection product should be given, unless the minor uses are already part of the submission.

What happens if CISTA concludes that the use (product) can be substituted?

If CISTA concludes that a substitution for any of the uses of the product is appropriate (there are acceptable alternatives available) a withdrawal or amendment of the decision on authorization will be proposed. This will take effect three years after the decision to withdraw or amend the authorization or at the end of the approval period of the substance approved as candidate for substitution expires where that period ends earlier.

There will be an opportunity to provide further information to CISTA in the three-year period in order to change the decision on comparative assessment. This might happen for example when there is a need to extend the authorization for a minor use.

If the plant protection product is no longer authorized – after the three-years period is over - a new application for an authorization according to article 33 of the Regulation(EC) No 1107/2009 has to be submitted.

Will CISTA conduct so called optional comparative assessment?

CISTA does not intend to use the optional comparative assessment in the next couple of years.

Use of guidance or comparative assessment of other Member States

Comparative assessment of plant protection products takes place on a national level of Member States. There might be different guidance in each Member State; different forms might be used taking into account specific national conditions. To be able to minimize the effort to produce dossier for comparative assessment, CISTA will accept documents elaborated for other Member States in the zone, if the information included in these documents is relevant to the situation in the Czech Republic and if the documents are in English, Slovak or Czech language.

C) Basic instructions to follow when obtaining and submitting information for comparative assessment

The process of comparative assessment can be divided to three steps starting with more simple and rather straightforward to more complex and difficult-to-define facts.

1. Is it possible to make use of derogation in Article 50(3) of Regulation (EC) No 1107/2009

The derogation concerns new plant protection products, where „*it is necessary to acquire experience first through using that product in practice*." Such plant protection products can be authorized for a period not exceeding 5 years without providing comparative assessment. It also covers renewal of authorization of a product which has not been on the market longer than 5 years.

Examples where the derogation from comparative assessment can be used are listed below:

- Plant protection product contains an active substance which is new (not yet used) in the Czech Republic.
- A new use of an active substance on a crop or against a pest (in that case only this particular use is covered by the derogation, not the whole plant protection product)
- Plant protection product contains a new combination of active substances not yet used in the Czech Republic.
- There is a significant advance in the formulation type of the plant protection product and its use is expected to improve some of the parameters in crop protection (efficacy, safety etc.). A thorough argumentation and demonstration of evidence is needed.

If a plant protection product fulfils requirements for the derogation no further comparative assessment is needed. Submission of conclusive evidence in favour of granting the derogation is sufficient.

2. Assessment of possible substitution from agronomic perspective

If the derogation in Article 50(3) of Regulation (EC) No 1107/2009 cannot be used the comparative assessment has to be conducted. For practical reasons it is recommended to start with agronomic conditions considering the uses of the product to be substituted. When completing this part, the EPPO guidance has to be followed (Guidance on comparative assessment, PP 1/271; Bulletin OEPP/EPPO Bulletin 41, 256-259). This guidance covers the definition of use of the plant protection product to be substituted; defining alternatives, which may be used; comparative assessment of all efficacy and crop safety aspects; assessment of resistance occurrence and practical or economical disadvantages, including minor uses.

When selecting alternative uses, not all the alternatives found have to be used. It is possible to group the alternatives using the same parameters – for example the same active substance, dose rate, formulation etc.

After defining the uses of product and possible alternatives, it is not binding to follow the order given by EPPO guidance for comparative assessment. Based on experience with the useof the plant protection product, with regard to its characteristics, it is possible to approach the point (points) crucial for the final decision – for example assessment of the risk of occurrence of resistance or potential consequences on minor uses etc.

As soon as the point is reached in the comparative assessment concluding that the plant protection product cannot be substituted, the comparative assessment can be closed without any further assessment ensuring the final decision is made the fastest way with minimum effort. Comparative assessment should not only concern recent aspects of crop protection but also those relevant for future. This means that some perspective of future use of the plant protection product should be considered as well. For example development of new active substances or on contrary loss of active substances available on the market with relation to therisk of occurrence of resistance or the possibilities of use of the plant protection product on minor crops.

3. Assessment of substitution from human or animal health or environmental perspective

If a decision has not been reached, when assessing the agronomic aspects, the assessment of risks for human health, animal health and environment has to be provided. The steps to be followed are described in the European Commission guidance (Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009; SANCO/11507/2013).

The procedure can differ based on the plant protection product characteristics. It seems logical to start with comparing the specific criteria that resulted in an active substance being defined as candidate for substitution. For example if the substance has been defined as candidate for substitution due to high bioaccumulation, the comparison of influence on environment should

be carried out in first place. If the substance is candidate for substitution due to AOEL value, the comparative assessment should start with comparing the risks to human health.

If the first step shows that there are more suitable alternatives, the next step is to compare other areas of potential risks. If the alternative proves to be less suitable in those areas andthat there are restrictions associated with it, which may be even stricter that those assigned to the product to be substituted, the substitution should not take place. For example product „A"is considerably safer than product „B" when comparing the AOEL value (active substance in product „B" is candidate for substitution and has been defined as such due to significantly lower AOEL value). In this case it has to be established that product „A" does not constitute higher risk to the environment. If the product „A" is safer from the human health point of view but it can only be applied using large buffer zones with regard to the environment and non-target organisms (i.e. it will pose more risks in this area than product „B") this substitution will not be possible.

The final decision on substitution with a suitable alternative from the human health, animal health and environmental perspective is a complex of discrete options and there is no uniform approach for reaching it. When deciding, CISTA will follow the European Commission guidance taking into account all the argumentation submitted by the applicant.

From what has been written above it is clear that comparative assessment is a complicated process which can have many forms. Starting with the simple ones, where the assessment ends at the beginning by establishing that the product is a new one and experience has to be acquired first through using that product in practice though to situations where it is necessary to assess particular areas of influence of the product and its alternatives on environment and human and animal health. Only the experience with practical use of comparative assessment will show to what extent and how effectively we will be able to tackle this task.

D) <u>Annexes:</u>

1. Template – CZ National addendum to the draft registration report for purpose of comparative assessment.