MARKETING AUTHORISATION APPLICATION FOR NEW PLANT PROTECTION PRODUCTS VIA THE MUTUAL RECOGNITION PROCEDURE AS SPECIFIED UNDER REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

This guidance is intended to provide specific details with regard to the possibility of adopting marketing authorisation for plant protection products from other EU Member States and to clarify the criteria and requirements stipulated under Regulation (EC) No 1107/2009 of the European Parliament and of the Council, which are therefore binding for the Czech State Phytosanitary Administration and for applicants seeking the marketing authorisation of a product via this means.

The main difference between marketing authorisation proceedings for a product via mutual recognition of marketing authorisation from another EU Member State and the existing legislation (Directive 91/414/EEC) and Regulation No 1107/2009 applicable as from 14 June 2011, is the time within which Member States are required to deal with this type of application. Whereas previously the processing time was governed by national legislation and could vary across the European Union, a uniform time limit of 120 days has now been set.

Another important difference is that applicants are not now strictly required to demonstrate comparability of conditions. Instead it is up to the registration authority, which is required to provide grounds to the European Commission for refusal of marketing authorisation from a Member State belonging to the same zone, with respect to reasons involving specific agricultural conditions and plant protection conditions or environmental conditions, including climatic conditions and cases where there is justified cause to believe that the plant protection product poses an unacceptable risk to human or animal health or to the environment.

A third important difference is that applicants are now entitled to apply to official or scientific bodies involved in agricultural activities or professional agricultural organisations for mutual recognition of a product.

Despite these significant differences, the majority of the requirements and criteria remain largely unchanged. To avoid rejection due to non-compliance with certain conditions, we are submitting a list of requirements and criteria, with explanatory notes on certain points. We would also like to provide applicants with instruction on how to deal with applications for mutual recognition.

1. List of requirements and criteria compliant with Regulation No 1107/2009

A) Criteria for applications for mutual recognition of marketing authorisation (Article 40 of Regulation No 1107/2009)

I. The authorisation was granted by a Member State belonging to the same zone

N.B.: The Czech Republic is in the "Central" zone. The zones for marketing authorisation of plant protection products (hereinafter referred to as "PPPs") are defined in Appendix I to Regulation No 1107/2009. Central zone: Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia and United Kingdom.

II. The authorisation was granted by a Member State belonging to a different zone

N.B.: The State Phytosanitary Administration ("SPA") can also grant marketing authorisation for a plant protection product which has been granted marketing authorisation in a state belonging to a different zone. In this case as well as SPA will assess the specific agricultural conditions and plant protection conditions, environmental conditions, including climatic conditions and acceptability of the risk to human or animal health or the environment. If marketing authorisation is granted for such a product in the Czech Republic, the marketing authorisation must not be used for mutual recognition in a third country in the Central zone. Exceptions include applications for use in greenhouses or post-harvest treatment or for treatment of empty rooms or containers used for storing plants or plant products or for seed treatment.

B) Requirements for supporting documentation (Article 42 of Regulation No 1107/2009)

I. Application in Czech or Slovak

II. A copy of the authorisation granted by the reference Member State and the translation of the authorisation into Czech

III. A complete or summary dossier for the product (at the request of the SPA)

N.B.: The SPA will always require a complete dossier for the product. It is not the SPA´s intention to evaluate the documentation submitted – it has already been evaluated by the reference Member State. In more complex cases, however, we may inspect the documentation for clarification. The dossier will be primarily used for cases of subsequent applications, e.g. changes to marketing authorisation, when the evaluation will be based on the original dossier.

IV. An assessment report of the reference Member State containing information on the evaluation of the PPP

N.B.: The assessment report is an important supporting document for devising risk management for the PPP. If the assessment report is not in Czech, Slovak or English, it must be translated into one of those languages. The applicant is responsible for arranging the translation of the assessment report at their own expense. Evaluation of the product specified in the report must comply with the "Uniform Principles for Evaluation /and Authorisation of Plant Protection Products/", i.e. can be performed during the period of validity of Regulation No 1107/2009 and Directive 91/414/EEC. If the evaluation is not performed in accordance with the above principles, the product cannot be authorised in the Czech Republic by the mutual recognition procedure (only possible for evaluation performed during the period of validity of Directive 91/414/EEC). In general terms this applies for cases when the re-evaluation of the products has not yet taken place in accordance with the classification guideline for the active substance ("re-registration", Step II) or a certain part of the evaluation is missing from the assessment report and the risk management cannot be determined on the basis of data otherwise available. If the assessment report contains the shortcomings referred to above and risk management cannot be devised marketing authorisation for the product cannot be granted in the Czech Republic.

Applicants are advised to check the quality and completeness of the assessment report with the SPA employees responsible, prior to submitting their application.

In the event of problems with obtaining an assessment report from the registration authority in the reference Member State, the future applicant can ask the SPA for assistance in obtaining the report. In such cases the SPA will contact the authority in the reference Member State and ask for provision of the assessment report.

If the assessment report is not drawn up in one of the languages specified above, the SPA will submit it to the applicant to arrange translation. Marketing authorisation will be refused in the event of failure to submit an assessment report from the reference Member State in the language required.

C) Further information to be submitted

I. Label proposal in Czech or Slovak

II. MSDS in Czech or Slovak

III. Copy of label in original language and in translation into Czech

IV. Copy of evaluation from equivalence assessment in case that the source or manufacturing process is different from the source or manufacturing assessed within EU review process

V. Comparability of conditions

N.B.: It is not obligatory but highly recommended.

VI. Technical specifications for the product in accordance with the FAO/WHO Manual

VII. Letter of Access for the active substance, plant protection product

N.B.: Where relevant. The owner is different as the applicant.
LoA should be an original or an officially approved copy.
The requirement is not applicable for applicants who apply on grounds of public interest (official or scientific bodies involved in agricultural activities or professional agricultural organisations).

VIII. Prove of public interest

N.B.: Where relevant.

IX. A formal statement that the composition of PPP is identical to that authorised by the reference MS

X. Analytical method for determination of active substance in PPP; analytical method for determination of impurities in PPP (if identified)

XI. Statement confirming that the product packing is made of the same material in which the 2-year storage study was conducted (or the specification of what containers the product is to be distributed in).

XII. Filled in the „Form for Checking Mutual Recognition Applications form Completeness"

D) Cases where the SPA is not required to authorise the product under the same conditions as in the reference Member State or is not required to authorise a plant protection product at all (Article 41 of Regulation No 1107/2009)

I. Other requirements (in view of the situation in the Czech Republic) – grounds for this situation must be submitted to the Commission

N.B.: Other conditions are taken to refer to conditions with respect to unacceptable risks to human health, animal health and the environment. If the SPA is not able to devise its own risk management from an assessment provide to the SPA by another Member State, this essentially constitutes a case of "other conditions". The difference to previous practice in accordance with Directive 91/414/EEC is that in the case of "other conditions", it is the SPA which provides the reasons as to why the conditions are different.

II. If the product contains a substance which candidate for substitution

N.B.: The SPA will decide whether a product is to be granted marketing authorisation in the Czech Republic on the basis of comparative assessment as specified under Article 50

III. The product being applied for has been granted marketing authorisation under Article 30 (provisional authorisation)

N.B.: This applies for marketing authorisation for a product containing an active substance which has not yet been approved or where the European approval process has not yet been completed. Similarly can be approved PPP in accordance with Article 8 of the Directive 91/414/EEC.

IV. The product contains a substance approved in accordance with Article 4(7) (approval for a limited period necessary to control a serious danger to plant health)

N.B.: The SPA will only grant marketing authorisation for products serving to control a serious danger to plant health. Otherwise the SPA will refuse marketing authorisation.

E) Specific conditions in the Czech Republic

For the evaluation of EFATE (fate and behaviour in the environment), a situation arises for the majority of applications whereby the SPA will be required to calculate the PEC (Predicted Environmental Concentration) for surface water or groundwater due to the establishment of protection zones and buffer zones. The said calculations require some time to process, especially for more complex cases or where accumulation of mutual recognition applications make it impossible, for time-related reasons, to perform a calculation over the course of evaluation of the application itself, thereby threatening a conflict with the deadline stipulated under Regulation No 1107/2009 for dealing with the application.

The resulting values of the active substance or active substances in surface waters, as defined in the assessment of the EFATE area, are then used to determine the TER (Toxicity Exposure Ratio) for ecotoxicological evaluation. As in the previous case, evaluation of the risk to aquatic organisms may also require a varying length of time, depending on how serious the impact is of these substances on the representatives of aquatic organisms evaluated and what measures are required to reduce the risk to such organisms.

Other requirements in accordance with national conditions in the Czech Republic relate to the area of evaluation of physical/chemical properties and analytical methods. If the information is not contained in the dossier, we will ask for submission of full composition of the formulation (doc J), Analytical method for determination of active substance in PPP, analytical method for determination of impurities in PPP (if identified), recommendations for storage of flammable liquids, technical specifications for the product in accordance with the FAO/WHO Manual and a statement confirming that the product packing is made of the same material in which the 2-year storage study was conducted.

Biological efficacy is an important part of every product evaluation. As mentioned above, it is not up to the applicant to demonstrate comparability of conditions. However it is highly recommended to the applicant provides a brief evaluation and comparison of the conditions under which the product is used in the reference Member State and under which it will be used in the Czech Republic. This applies in particular in cases of mutual recognition of marketing authorisation from a Member State belonging to a zone other than the Central zone. It should also be noted that “conditions “ are not only meant to refer to climatic conditions, which comparability in many cases is taken to mean. “Conditions” are to be understood to refer, first and foremost, to agricultural conditions, forestry conditions, plant protection practice, including ecology and occurrence of pest organisms and possible protection methods.
An important condition for mutual recognition is also the performance of efficacy tests at certified sites pursuant to the conditions of good experimental practice (GEP). The SPA will not grant marketing authorisation by the mutual recognition procedure where marketing authorisation is based on testing performed without applying GEP.

There is also one purely technical issue among the special requirements for the Czech Republic. Two institutions are involved in the marketing authorisation of plant protection products. The Czech State Phytosanitary Administration grants or refuses marketing authorisation for plant protection products

and also evaluates the specialist areas of ecotoxicology, fate and behaviour in the environment, physical/chemical properties and biological efficacy. The second institution involved is the Czech Ministry of Health, which issues toxicological assessments. The Czech National Institute of Public Health conducts expert evaluation of toxicology, operator exposure and residues on behalf of the Czech Ministry of Health. To ensure that marketing authorisation applications for plant protection products are dealt with duly and properly, they must be submitted to all the institutions. Below can be found a brief summary of what needs to be sent to the respective institutions and the contact details of those institutions:

Státní rostlinolékařská správa
(Czech State Phytosanitary Administration)
Zemědělská 1a
613 00 Brno
The following need to be sent: marketing authorisation application for the plant protection product with all the appendices; a complete dossier for the product, active substance and, where applicable, safeners and synergists;

Ministerstvo zdravotnictví
(Czech Ministry of Health)
MUDr. Adriena Hammerová
Palackého nám. 4
128 01 Prague 2
The following needs to be sent: application for toxicological assessment.

Státní zdravotní ústav
(Czech National Institute of Public Health)
MUDr. Miroslava Hornychová
Centrum hygieny práce a pracovního lékařství
(Centre for Hygiene and Occupational Medicine)
Šrobárova 48
100 42 Prague 10
Tel.: + 420 267 082 625
The following needs to be sent: application for performance of a toxicological assessment and complete dossier for a product and active substance (substances). For further details about application and requirements for data submission please contact directly Czech National Institute of Public Health.

F) Data protection

One of the areas often neglected by applicants is data protection, which is regulated in detail under Article 59 of Regulation (EC) No 1107/2009. The period of data protection is ten years (the most common case), starting from the data of first authorisation in the Czech Republic. The data covered by data protection includes the dossier for the product, the active substance and, where applicable, the safener or synergist. Applicants seeding marketing authorisation via mutual recognition from another Member State must have access to the data that was submitted for the said marketing

authorisation. This means that the applicant must either be the owner of the data or the period of data protection must have expired. Another possibility is when the applicant has received approval for use of the data from its owner. Even in the event of public interest, the SPA cannot permit uses based on data which comes under the provisions of Article 59 of Regulation No 1107/2009. This would amount to a breach of the law.

G) Mutual recognition based on grounds of public interest

Official or scientific bodies involved in agricultural activities or professional agricultural organisations may apply, with the consent of the authorisation holder, for an authorisation of a plant protection product where such a product is not authorised in the Czech Republic. In such a case the applicant must prove that the use of the product is on ground of public interest. SPA may accept application also without content of the applicant holder.

As an exception from above mentioned requirements the applicant for mutual recognition of a product based on ground of public interest is not obliged to submit Letter of Access for active substance and/or plant protection product. The further requirements should be fulfilled.

For applications based on ground of public interest the regulation is issued which entitles the applicant to import the plant protection product from abroad a use it. This product must not be used for commercial purposes (sold atc.)

H) Procedure (Article 42 of Regulation No 1107/2009)

The SPA is required to decide on applications for mutual recognition of a product within 120 days. In the event that the SPA determines, during assessment, that any of the above requirements have not been met and it is therefore impossible to determine risk management for the marketing authorisation required, the application for mutual recognition will be rejected.

Prior to submission of the application the applicant is entitled to contact an SPA representative to discuss problematic areas with regard to the application and its acceptability in view of the set requirements at a joint meeting or meetings. This procedure is recommended by the SPA and prevents problems arising following submission of an application applying the mutual recognition procedure in view of the time limits for processing applications.

2. Meeting the prospective applicant

Prior to submission of the actual marketing authorisation application for the PPP, the applicant is entitled to request a meeting with a representative of the SPA.

Contact details for individuals responsible:

Martin Prokop, Tel.: +420 545 110 464, E-mail: martin.prokop@srs.cz

Jana Ondráčková, Tel.: +420 545 110 470, E-mail: jana.ondrackova@srs.cz

First meeting (contact)

Meeting at coordination level, with the participation of the Head of Coordination department or Head of coordination Division. Purpose of meeting: to discuss general issues associated with the application (expected course of proceeding, interest in a pre-submission meeting (or other

meetings), documentation requirements – generally anticipated date of submission of the application, etc.).

Second meeting (pre-submission meeting)

Purpose of meeting: to discuss whether the required documentation prepared for the submission of the application for mutual recognition of the product is complete. The list of areas or issues for discussion must be sent in advance to the contact individuals, at the same time as sending the request for a meeting. In order to ensure that the purpose of this second meeting is fulfilled, the potential applicant must sent the SPA all the documents available to the applicant as supporting documentation for the application for marketing authorisation via mutual recognition (see the requirements and criteria as stipulated under Regulation No 1107/2009) in advance (at least 14 days before the meeting). For the SPA to be able to provide the most accurate recommendations possible, the applicant must submit the final version of the documentation and information, including the GAP table, for the purposes of the meeting.

The SPA will then evaluate the documentation and advise the applicant at the meeting on the next steps to take to comply with the requirements specified in the regulations. In an ideal scenario, the SPA will then recommend the applicant to submit the application.

The actual recommendation that the applicant can submit the application to the SPA does not automatically mean that the application will be approved, because whether or not the application and accompanying dossier satisfy all the requirements can only be determined through detailed evaluation and assessment. However, the meeting will minimise the possibility of the application being rejected.

It is not necessary to adhere to the proposed number of meetings before submitting an application. It is up to the applicant as to what form of help or assistance the applicant requires from the SPA. Applicants with prior experience in the submission of marketing authorisation applications for plant protection products will require one meet or even no meetings at all, without this jeopardising the course or outcome of the evaluation of the application.

3. How else the SPA can assist applicants seeking mutual recognition of marketing authorisation

The main way in which the SPA can help is through the provision of certain documentation or information to which the applicant does not have access.

Documentation which the SPA can help applicants to obtain:

I. A copy of the authorisation granted by the reference Member State;
II. A complete or summary dossier for the product (active substance, safener, synergist);
III. An assessment report from the reference Member State.

The SPA can assist applicants with obtaining all the above documentation through direct contact with reference Member State. In the case of the complete or summary dossier for the product, however, the applicant must be the owner of the studies or have consent from the holders of the ownership rights to the said studies. If this is not the case, the SPA is not entitled to use such studies, because this would be in breach of the requirements of Regulation No 1107/2009 on data protection. The SPA

cannot, however, influence the quality of the data obtained and the reference Member State´s willingness to respond to the application.

4. How the SPA will proceed following receipt of the application

As soon as the SPA receives a marketing authorisation application for a plant protection product via mutual recognition of marketing authorisation, notification is sent to the applicant that the application has been received and that the evaluation is to be performed.
Once the evaluation has been performed, the case coordinator compiles the decision proposal and a summary of costs for evaluation[1] for which the applicant is required to pay the SPA. These documents will then be sent to the applicant to comment. Following approval of the supporting documentation used as a basis for the decision and the statement detailing specialist tasks performed, the SPA will issue a decision on the matter.

Determination of missing data during evaluation

If the SPA determines, during evaluation, that there are shortcomings in the supporting documentation submitted, despite preliminary completeness checking being done, the SPA will contact the applicant and request submission of missing information. The deadline of 7 days from receipt of the request will be given to the applicant to submit such information. The applicant will be informed in the request to provide additional information that if they do not submit the required documentation within the set deadline, the evaluation of the application will be performed on the basis of the documentation submitted, therefore with the risk of rejection.

Comments on the decision proposal

The applicant has an opportunity to comments on the decision proposal. The applicant´s comments will be included into the final decision. In case that some of the applicant´s comments are not accepted the appropriate reasoning is stated.
The SPA will not take the applicant´s comments into account if they relate to the risk management set, which result from SPA approved procedures or from valid legislation. The applicant will be informed of the reasons for not-compliance in the reasons given for the decision on the matter, in unaltered form, corresponding to the version of decision proposal.

5. Charges relating to filing an application for mutual recognition of marketing authorisation

Administrative fee: CZK 5000 – must be paid to the SPA´s bank account within fifteen days from delivery of confirmation of receipt of the application.

Payment for specialist tasks: CZK 72 300 – must be paid on the basis of an invoice received[2] following the issue of a decision on the matter.

[1] In the revised version of Act No 326/2004 Coll., on Phytosanitary Care, evaluation of a product without compensation is proposed in substantiated public interest cases. In such cases the statement detailing specialist tasks will not be sent.

[2] In the event of an application for mutual recognition of a product in the public interest, only the administrative fee is paid; this type of application is exempt from payment for specialist tasks.