APPLICATION FOR AUTHORISATION OF A NEW PLANT PROTECTION PRODUCT IN COMPLIANCE WITH REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL – WITH THE CZECH REPUBLIC ACTING AS THE ZONAL RAPPORTEUR MEMBER STATE

Due to the marketing authorisation process for new plant protection products undergoing some fundamental changes with the introduction of new regulations, this report aims to lay down the State Phytosanitary Administration´s ("SPA) standard approach for accepting applications for new plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and to give detailed and understandable instructions for applicants seeking marketing authorisation of products in cases where the Czech Republic is proposed by the applicant as the zonal rapporteur Member State (hereinafter referred to as "the ZRMS").

The main change compared to existing practice for the authorisation of plant protection products in accordance with Regulation (EC) No 1107/2009 applicable from 14 June 2011 is the zonal approach to assessment. This means that a marketing authorisation application for a product submitted at a given time in, for example, five Member States in the Central zone (1) will be assessed by only one of those Member States, while the other Member States wait until the Member State evaluating the application has completed its evaluation. The findings of the evaluation are then submitted to the concerned Member States, who either grant or refuse marketing authorisation based on the ZRMS´s findings. If the rapporteur Member State grants marketing authorisation, the other Member States can still reach a different decision and reject the application, but only if, as a result of specific agricultural or environmental conditions, there are well-founded reasons to suggest that the product continues to present an unacceptable risk to human or animal health, or the environment, and that this risk cannot be regulated through the implementation of national risk-mitigation measures. In such situations the applicant and the European Commission must be informed.

The second important change concerns the time-limits for processing applications for new products, which have been made uniform for all the EU Member States. The time-limit for evaluation and publication of evaluation findings in a ZRMS has been set at twelve months.
A maximum time-limit has also been set for the applicant to provide additional information. This is now six months.
On the basis of the ZRMS´s findings, the other Member States are required to grant or refuse the marketing authorisation application within 120 days.
Despite these important changes, many things remain unchanged. For the most part, these are for applications based on summary documentation about the product and the active substance, and the criteria for evaluation thereof.

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 instructions on how to precede applications for plant protection products approval where the Czech Republic is acting as ZRMS.

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1. <u>The application must include the following information (Article 33)</u>

- a list of intended uses in each zone and the Member States where the applicant has made or intends to make an application;
- a proposal as to which Member State the applicant expects to evaluate the application in the zone concerned. In the case of an application for use in greenhouses, as postharvest treatment, for treatment of empty storage rooms and for seed treatment, only one Member State shall be proposed, which evaluates the application taking account of all zones. In this case the applicant shall send the summary or complete dossier to other Member States on request;

  <u>Note</u>: Initial contact with the Member State, which the applicant proposes as the rapporteur Member State should be made sufficiently in advance of submitting the application itself. Above all, it is important to ensure that the selected state is willing to act as the evaluating Member State, and to verify its labour and time resources available.
- a copy of any authorisations already granted for that plant protection product in a Member State;

  <u>Note:</u> For SPA is not necessary to submit the authorisations. It is enough to mention this products in application for new product approval.

- a copy of any conclusion of the Member State assessing equivalence

  <u>Note:</u> To be submitted if the product contains an active substance, safeners or synergist, from a different source than originally approved.

1.1 The application shall be accompanied by the following:

- for the plant protection product concerned, a complete and a summary dossier for each point of the data requirements of the plant protection product;

  <u>Note:</u> Annex III studies and draft Registration Report (dRR) in compliance with SANCO 6895/2009.
- for each active substance, safener and synergist contained in the plant protection product, a complete and a summary dossier for each point of the data requirements of the active substance, safener and synergist;

  <u>Note:</u> Annex II studies (dossier for the active substance). By 14th December 2014, a regulation will be enacted stipulating the data requirements for safeners and synergists. Until then the said requirements will not be enforced.

- for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;

- the reasons why the test and study reports necessary for first authorisation or for amendments to the conditions of the authorisation;

- a copy of the application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;
  Note: Will apply in cases where an MRL has not yet been set for certain uses (crops) or where the product contains an active substance which has not been approved (provisional authorisation, Article 30 of the Regulation).

Note: Applicants may be exempt from the obligation to submit study reports and tests as specified under 1.1. Applicants are exempt if they demonstrate that they have been granted access as specified under Article 59 (Data protection and data sharing), Article 61 (General rules on avoidance of duplicative testing), or Article 62 (Sharing of tests and studies involving vertebrate animals), or the period of data protection has expired. Even in that case, however, the following information must still be provided as a minimum:

- *all data necessary for evaluation of the plant protection product, including its complete composition, as well as a declaration that no unacceptable co-formulants have been used;*
- *information necessary for the identification of the active substance, and safener or synergist, if approved, including evidence that these substances were obtained from the same source;*
- *data required to prove that the effects of the plant protection product are comparable to the plant protection product detailed in the study referred to.*

1.2 Additional information relating to the application

- request for certain information, including certain parts of the dossier, to be kept confidential;
  Note: This is not a compulsory part of the application, but the applicant has this option (cf. Article 63 of Regulation (EC) No 1107/2009). Confidential information in the dossier must be separate from the other information and a list of tests and studies must be attached. The SPA evaluates the justification of the confidentiality request, and makes amendments if required. In the event that a request arises for such information to be made public, The SPA is governed by the information obtained.

- List of studies submitted with application and indicated protection of relevant studies;
- Technical specifications for the product in accordance with the FAO/WHO Manual;
- Label proposal in Czech or Slovak;
- MSDS in Czech or Slovak;
- GAP table for each zone in which the application is supposed;

- Written consent of PPPs approval holder which are supposed to be use as partners in Tank-mix combinations;
  Note: Only in case that such combination is asked.

- a sample of the plant protection product and analytical standards of its ingredients.
  Note: if the Czech Republic is the zonal rapporteur Member State, SPA will require a sample of the plant protection product and analytical standard/s of active substance/s and relevant impurity/is if they are present.

As specified above, the rapporteur Member State has 12 months from the receipt of the application to evaluate the information submitted and issue a decision. The applicant also has a limited period (6 months) to submit any additional information. In the first few months after Regulation (EC) No 1107/2009 becomes applicable especially, these facts will pose a significant

work load on both parties. For this reason, the Member States have agreed to allow applicants to consult with selected Member States with regard to their applications before actual submission thereof.

If you choose the Czech Republic as the zonal rapporteur Member State, you will also have an opportunity, prior to submission of the application, to contact an SPA representative and 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 during the application evaluation procedure in view of the time-limits set. It is up to the applicant to choose whether to make use of the procedure offered.

2. Meeting with a potential 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:
Lucie Váňová; Tel.: +420 545 110 478; E-mail: lucie.vanova@ukzuz.cz
Jana Ondráčková; Tel. : +420 545 110 470; E-mail: jana.ondrackova@ukzuz.cz

First meeting (contact):
The very first contact by applicants should be made by email or telephone, stating their intention to submit an application and to appoint the Czech Republic as the zonal rapporteur Member State (ZRMS). Upon first contact applicants should provide the SPA as a minimum with basic information about the forthcoming application and the plant protection product. Applicants can use the "Notification form for zonal application" for this purpose, which has been compiled by theMember States. This form can be found on the SPA website or the European Commission website.We also recomment contact responsible persons from Czech National Institute of Public Health (CNIPH) (see contact details below) and discuss the prospective application also there.

The SPA and CNIPH starts with an internal review of the applicant´s proposal and also notifies the other Member States of the applicant´s intention. In the future this will be performed via a pan-European database of plant protection products. Currently it is performed by notifying the presiding Member State, which duly enters the relevant information into the collective zonal evaluation table. If no objections to the appointment of the Czech Republic are raised by any of the Member States within one week, direct preparations for the application can begin.

Preparations can begin with a face-to-face meeting at co-ordination level, with the participation of the Department Manager or Section Head.

Purpose of meeting: to discuss general issues associated with the application (expected course of proceedings, interest in a pre-submission meeting (or other meetings), requirements with respect to information submitted with the application, anticipated date of submission of the application, etc.).

Note: Initial contact, in which applicants express their intention to submit an application and appoint the Czech Republic as the rapporteur Member State, can be performed by e-mail or telephone. A face-to-face meeting may not

be necessary if the applicant is already sufficiently familiar with the zonal assessment process and the other formalities for submission of an application.

Pre-submission meeting

Purpose of meeting: to discuss whether the required documentation prepared for the submission of the marketing authorisation application is complete.

The list of areas 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 send the SPA all the documents available to the applicant as supporting documentation for the marketing authorisation application (see the requirements and criteria as stipulated under Regulation (EC) No 1107/2009) in advance (at least 4-6 weeks 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 to the applicant to submit the application.

The actual recommendation that the applicant can submit the application to the SPA does not automatically mean that no further requirements will be introduced during the evaluation process or that the application will be approved, because whether or not the application and accompanying complete and summary dossier satisfy all the requirements and whether or not thefindings of the resulting assessment lead to the marketing authorisation requested can only be determined through detailed evaluation and assessment. The aim is to minimise data gaps which could crop up in the evaluation process and which are obvious and easy to determine.

The applicant is required to compile a record of the meeting and the document is to be approved by all those in attendance at the end of the meeting.

It is not necessary for all meetings to go ahead. 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 meeting or even no meetings at all, without this jeopardising the course or outcome of the evaluation of the application.

3. Submission of applications

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 you will find a brief summary of what needs to be sent to the respective institutions and the contact details for those institutions:

Ústřední kontrolní a zkušební ústav zemědělský
(Central Institute for Supervising and Testing in Agriculture)
Hroznová 2, 656 06 Brno
The following needs to be sent: marketing authorisation application for the plant protection product with all the annexes; a complete dossier for the product, active substance and, where applicable, safeners and synergists+ all supplementary documentation and information associated with the application, irrespective of which part of the evaluation they relate to.

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.

4. <u>How will the SPA proceed following receipt of the application</u>

Applicants seeking marketing authorisation are required to submit their applications in Czech, using the model available on the SPA website. They must also submit, at the same time, applications in the other countries where the product is to be marketed. Applicants must determine from the various registration authorities what timescale is permitted in the other Member States for submission of the application.

Along with application the applicant must submit all the documentation specified under Article 33 of Regulation (EC) No 1107/2009, including any national amendments (see above).

As soon as the SPA receives the application, the applicant is notified that it has been received and is set to be evaluated.

Checking the formal completeness if the application

Even if preliminary meetings have been held, the SPA will check the formal completeness of the application. The SPA will base this check on the information and documentation presented to it during the period prior to submission of the application and upon submission of the application. The formal completeness check will be carried out within six weeks of submission of the application and the applicant will be informed of the outcome.

In the event that the application does not contain all the information required, the applicant will receive a request to submit the missing information within a given time-limit. Along with the request for the submission of additional information, the applicant will also receive a decision on suspension of proceedings for the period stated in the request for the submission of additional information. The maximum suspension of proceedings is for six months. The concerned countries where marketing authorisation for the plant protection product is also being sought will also be notifies of the suspension in proceedings.

As soon as the applicant provides the additional information specified in the attachment to the request for the submission of additional information, the SPA will once again check the completeness thereof and, assuming the requirements have been met, resume evaluation of the product. The applicant and the concerned Member States will be informed of the resumption of proceedings.

If the additional information supplied is still insufficient, the applicant will be sent notification regarding completeness of data, stating which requirements from the previous request for the submission of additional information have been met and what information is still outstanding.

Should the applicant fail to provide the requested information within the set time-limit, the SPA is entitled to extend suspension of the proceedings. This is again performed through sending notification regarding completeness of data, in which the SPA refers to the previous decision on suspension of proceedings and indicates the remaining requirements outstanding. The suspension in the proceedings can, however, only by extended for up to six months, the total maximum duration for suspension in the proceedings.

If the required information has not been provided after a 6-month suspension in the proceedings, the SPA will send the applicant notification informing them that the application will be evaluated on the basis of the information received to date, and that any additional information will be disregarded. In exceptional cases proceedings may be terminated due to inadmissibility of the application, as specified under Article 37(1) of Regulation (EC) No 1107/2009. The concerned Member State will also be informed of this.

The above procedure will also be applied if missing information is identified during the actual evaluation of the plant protection product. The SPA will stipulate requirements for additional information within 5 months from submission of the application. This period may be extended in line with duration of the suspension in proceedings as defined under Regulation (EC) No 1107/2009.

Evaluation of the plant protection product

In accordance with the EU´s procedure specified in SANCO/13169/2010 Rev. 5, the SPA has a maximum of eight month´s to produce its draft report on evaluation of the marketing authorisation application for the plant protection product. This period can be extended by the

duration of the suspension in the proceedings. After eight months the SPA sends its draft report on the evaluation to the other Member States for observations (Part B – Assessment, Part C – Sensitive Data). The draft Registration Report is also sent to the applicant for comment (Part B – Assessment, Part C – Confidential Information). The Member States and the applicant have six weeks to send their comments, to be submitted in the prescribed format using the "reporting table" sent with the draft Registration Report.
After the six weeks are up, the SPA processes the other Member States´ comments and incorporates any amendments to the evaluation report highlighted by those comments. The SPA records in the reporting table which observations were incorporated, and which were not.

Evaluation findings

On the basis of the evaluation report, the SPA compiles the decision proposal, which it sends to the applicant for comments, together with a costs overview. Applicants have ten days to comment on decision proposal. One of the components of the decision proposal is a summary of how the SPA dealt with the applicant´s comments to the evaluation report. Due grounds are provided if the SPA does not accept any of the applicant´s comments.
The coordinator incorporates any observations into the decision granting or refusing marketing authorisation for the plant protection product.
The final step in the evaluation of the marketing authorisation application is the decision to grant or refuse marketing authorisation, based on the findings from evaluation of the product. The decision to grant or refuse marketing authorisation is notified to the applicant and the partner Member States.

5. Charges associated with the submission of marketing authorisation applications for plant protection products with regard to marketing and use

Administrative fee:

CZK 6000 (active substance not approved – provisional authorisation)
CZK 5000 (active substance approved)
The administrative fee must be paid to the SPA´s bank account within fifteen days from receipt of confirmation of receipt of the application.

Payment for the specialist tasks:

CZK 417 200

Active substance not approved. This is provisional authorisation, not for a low-risk substance. CZK 55600 is deductible for each partial evaluation if the study does not required evaluation.

CZK 278 100

Active substance approved, not for a low-risk substance. CZK 39 000 is deductible for each partial evaluation if the study does not require evaluation.

CZK 264 300

Active substance approved, not for a low-risk substance. CZK 39 000 is deductible for each partial evaluation if the study does not require evaluation.

Payment for specialist tasks must be paid on the basis of an invoice received following the issue of a decision on the matter.