APPLICATION FOR MARKETING AUTHORISATION FOR A NEW PLANT PROTECTION PRODUCT IN ACCORDANCE WITH REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL – THE CZECH REPUBLIC IS CONCERNED MEMBER STATE

This document is intended to follow on from previous SPA reports regarding the marketing authorisation of plant protection products and to provide clear information to applicants wishing to apply for marketing authorisation for a new plant protection product in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, in cases where the Czech Republic is not acting as the zonal rapporteur Member State.

One of the main changes from current practice in marketing authorisation proceedings for plant protection products is that the dossier submitted with the application for marketing authorisation is not evaluated by all the Member States in which the application is filed, but only by one of them. The applicant is entitled to propose the evaluating Member State responsible for evaluation of the application. The other Member States affected will not take any action until the Member State evaluating the application has completed the said evaluation. The findings of the evaluation are then sent to the other Member States, which either grant or refuse marketing authorisation in accordance with the findings of the evaluating Member State.

Although this represents an undeniable step towards uniform evaluation of applications for marketing authorisation of plant protection products, there are still areas specific to individual Member States which will be resolved at national level. In the case of zonal evaluation these will be resolved in the form of national amendments to the main dossier, which will then be evaluated by the various national authorities. Although this process looks simple at first glance, there are many hidden difficulties and consequently we are presenting applicants with a brief overview of the requirements and instructions on how to deal with applications where the Czech Republic is as a concerned Member State.

1. Applications must contain the following information (Article 33 of Regulation)

Even if the Czech Republic is not the zonal rapporteur Member State, the application must contain all the information specified in Article 33 of Regulation. A detailed explanation and description of each requirement can be found in the document issued by the State Phytosanitary Administration ("SPA") dated 29.08.2011. The only difference in the requirements as regards the information submitted relates to the sample of the plant protection product and the analytical standards of its components (Article 33(6)). In cases where the Czech Republic is not the zonal rapporteur Member State, no product samples or product component standards will be required.

2. Meeting the prospective applicant

Prior to submission of the application the applicant is entitled to contact an SPA representative to discuss problematic areas with regard to the application, issues relating to future marketing authorisation proceedings for PPPs, etc. at a joint meeting or meetings. In cases where the Czech Republic is not acting as the rapporteur Member State these meetings are not an important factor, but they may be useful in proceedings where evaluation of national amendments is anticipated.

Contact details for individuals responsible:
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3. Submission of applications

There is 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 both 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. How the SPA will proceed following receipt of the application

Article 33 of Regulation No 1107/2009 reads as follows: "An applicant (…) shall apply for an authorisation (…) to each Member State where the plant protection product is intended to be placed on the market". Article 33 does not, however, say anything about the time interval in which the said applications are to be submitted. It is left up to the Member States to decide how to proceed with applications. SPA is generally obliged to accept applications whenever submitted. This also applies in the case of marketing authorisation applications for plant protection products where the Czech Republic is not acting as the rapporteur Member State. Late submission, however, may have an impact on the final outcome of the proceedings.

National amendments requiring evaluation by the SPA have already been mentioned. These amendments are primarily in the form of data relating to evaluation of efficacy. Specific national requirements relating to evaluation of the product´s impact on the environment must also be mentioned. In most cases the PEC (Predicted Environmental Concentration) is converted for surface or groundwater due to the stipulation of buffer zones and distances. This data is then used to determine the TER (Toxicity Exposure Ratio) for evaluation of the product´s impact on non-target aquatic organisms. The ZRMS can also arrive at the conclusion that marketing authorisation can only be granted for the product subject to compliance with specific mitigation measures, which are not applied, however, in the Czech Republic. Subsequently, as a result of the short time-limits for processing applications and limited options for resolving situations arising, the SPA may decide to refuse a specific indication or even an entire application.

For the above reasons it is best if the marketing authorisation application is submitted to the SPA at roughly the same time as it is submitted to the zonal rapporteur Member State and no later than three weeks from when submitted in the ZRMS.
When describing the next action to be taken by the SPA, this Article focuses primarily on the procedures that will differ compared to cases where the Czech Republic is acting as the ZRMS. First and foremost, there will be differences in the checking of formal completeness of the dossier. The SPA will perform this checking but the checking will only apply to national amendments (where applicable). Requirements relating to the dossier for the active substance and the product will be checked by the ZRMS.

Applicants will be notified of shortcomings and asked to submit additional information with regard to the application. The deadline for submission of additional information is to be set at 4 ½ months

from submission of the application in the ZRMS. If the application submitted remains incomplete even then, applicants will be notified of this fact, together with the possible consequences that might result from incomplete information (data submitted after that deadline will not be taken into account). Applicants will also be notified where the SPA´s requirements have been met.

As a rule the other Member States, including the ZRMS, will not be informed of the SPA´s requirements, because these will be purely specific national requirements.
As soon as the SPA has access to the evaluation report from the ZRMS, it will complete evaluation of the national amendments and specific areas.

5. Issuing a decision granting or refusing marketing authorisation for a product

This stage should follow immediately after a decision is issued in the ZRMS and should not take longer than 120 days.
The SPA will compile a decision proposal for and send it to applicant to comments.
A decision incorporating the applicant´s comments on the decision proposal will be issued during the final stage of the proceedings.

6. Comments by the SPA with respect to the DRR

The Czech Republic, the other Member States and the applicant will have an opportunity to comment on the draft report regarding the evaluation conducted by the ZRMS. The observations submitted by the SPA and the Czech National Institute of Public Health will focus primarily on areas that might in some way affect the stipulation of risk management in the Czech Republic. In the event that the results of the evaluation performed indicate possible restrictions by the SPA, the applicant will be contacted and the SPA and the applicant will jointly search for ways to resolve the situation.

7. 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.