CZECH REPUBLIC
State Phytosanitary Administration
Plant Protection Products Section

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Zonal evaluation of applications for plant protection products in the Czech Republic

version 1/12/2010

Introduction and background

Two EU Guidance Documents have been noted which outline the process for intra and inter-zonal work-sharing and the submission format of such applications to **all** MS that apply at the EU level. These are available on the Commission website:

- Guidance document on a process for intra & inter-zonal work-sharing to facilitate the registration and re-registration of plant protection products following inclusion of an active substance in Annex I of council directive 91/414/EEC (SANCO/6896/2009).
- Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report (SANCO/6895/2009).

The purpose of this information sheet is to highlight that the Czech Republic follows the procedures as foreseen by these new guidance documents noting the following key issues:

- The procedures in SANCO/6896/2009 apply from 02 October 2010 and require notification of your intention to apply at least six months before application submission to enable MS to determine the workload and allocate the ZRMS. This procedure should be followed from now on.
- You can use the dRR submission format detailed in SANCO6895/2009 from now, but there is no need to retrospectively submit a dRR for applications prepared with the old style registration report or Annex III dossier format. From 02 October 2010 the dRR submission format will be a requirement for all MS.

What information do I need to submit in the Czech Republic?

The draft Registration Report (dRR) presents the same information as the traditional Annex III dossier and as a result you are no longer required to submit an Annex III dossier to the Czech Republic if your application includes a dRR. You are still required to provide the actual studies (doc K) which are referenced and summarised in the dRR. If you wish you can provide this in caddy format, placing the dRR where docs M and N would normally be, and part C of the dRR where doc J would be. There is no equivalent to doc O in the dRR, but this is not a requirement for a product submission in the UK.

Therefore, when submitting an application to the Czech Republic you should submit the following documentation:

- a covering letter
- a completed application form
- draft Registration Report Part A, detailing the risk management (and draft label) pertinent to the Czech Republic
- draft Registration Report Part B, detailing the core assessment and any national assessment
- draft registration report Part C
- data underlying the core assessment (and national assessment if required)
- a valid letter of authorisation to third party data, where necessary
- any previous relevant correspondence

More details concerning the presentation of these data are given in the presentation schemes for the concerned types of application (annex III, annex II and III, mutual recognition).

Please note you are advised to contact each MS separately to confirm their precise national submission requirements.

Background

Zonal re-registration has been developed to facilitate the evaluation of the large number of product re-registration applications expected in the next few years in all Member States (MS). It is an initiative developed on a voluntary basis between competent authorities of MS in all three zones (Southern, Central and Northern) and is similar to the zonal authorisation procedure included in the new regulation to replace 91/414/EC.

In summary, the process is as follows:

- the applicant submits to all MS where they wish to gain/maintain authorisation (the 'concerned' MS),
- one lead MS in each zone - the zonal RMS (ZRMS) - will complete the evaluation of a core assessment on behalf of and in advance of assessment by other MS in the zone,

- the ZRMS will then make this assessment available to all other MS. Other MS then complete their national assessments based on the ZRMS core assessment.

This guideline outlines a procedure for the submission and assessment of zonal applications in the Czech Republic

What does the core assessment look like?

The core assessment by the ZRMS will be used by other MS in the zone as a basis for national regulatory decisions. The core assessment must reflect a Uniform Principle assessment for a product and its uses, and should cover all the uses required in the zone (see section on risk envelope below). Assessments must be supported by appropriate Annex III data, or access to the same.

What is the risk envelope approach and how shall it be used in the context of zonal submissions?

The risk envelope is a concept which exploits the idea that within a group of products and uses, there will be certain uses which represent the worst-case situation in each area of assessment. The assessment of this worst-case product/use will cover all other situations where the GAP is less critical or the same. This is applicable to all sections except efficacy and residues for which assessment will be based on individual crops (although even in these areas, there may be some scope for extrapolation).

By establishing the risk envelope, it is possible to minimise the number of individual product/use assessments that need to be completed. The concept of risk envelope can be applied:

- **within products** (e.g. use on apples at 2N rate will cover use on pears at N rate in certain risk assessment areas)
- **within a group of products** (e.g. use of 'Product 100EC' will cover use of 'Product 50 EC' where the in-use rates are the same)
- **across the zone** (e.g. the use of Product X on cereals at 100g/ha in DE will cover the use of Product X on cereals at 80 g/ha in UK in some areas of the risk assessment)

Note however that limitations of this approach are possible due to data protection, differences in composition or specific scenarios of the applicable guidance (e.g. the new guidance document for birds and mammals).

Applicants should propose the use which establishes the zonal risk envelope in each area of the assessment (whilst also highlighting all the uses authorised/required within the zone). Assessors will consider the proposal to establish the risk envelope as part of their assessment.

What types of products can be evaluated through this procedure?

The procedure can be used to obtain authorisation for new products or to re-register existing products (or a combination of the two - e.g. an existing product re-registered in the ZRMS may then be launched as a new product in another MS). These procedures can be applied to products

containing new and/or existing active substances. The only pre-requisite should be that all active substances in the product are included on Annex I.

Note that according to Article 80 paragraph 5b of the Regulation 1107/2009 to replace 91/414/EC, re-registration of existing products will continue in accordance with the Directive's provisions. It should be noted however that when the Regulation 1107/2009 applies (14/06/2011) applications for new products will be assessed by the zonal procedure.

Can these principles be applied *between* the zones?

Yes. There are some areas of the assessment which clearly apply to all MS, irrespective of the zone (e.g. physical chemical properties and formulation toxicity). There are also some types of uses (e.g. greenhouses, products to be applied in storage areas) where the same assessment will apply across the whole EU. If you think this is the case, you should highlight this possibility prior to/at submission.

Can I select the Czech Republic as the ZRMS?

Yes you can! If you wish the Czech Republic to act as ZRMS please contact us at the earliest opportunity to discuss this (ideally at least 6 months before the Step 2 re-registration submission deadline or the intended submission date for a new product). We will require details of the products and uses you are intending to support in the central zone, and which MS they are/will be approved in. In considering your request we will need to take into account a number of factors including who was the original RMS for Annex I inclusion, the relevance/importance of the products in the Czech Republic, the deadline for submission and resource availability, and also the fact if an MRL needs to be set or a technical equivalence of the active substance needs to be evaluated.

The choice of the ZRMS for new products will be discussed on European/Zonal level in the so called Zonal Steering Committee. If the Czech Republic is finally selected as ZRMS, confirmation will follow about 4 months prior to the intended submission date. From then on, the applicant is expected to stay in close contact with the Czech authorities, especially concerning the intended submission date. A monthly update of the submission date is expected and, in the month prior to submission, a weekly update. This will allow careful planning and keeping the resources available, as the Czech Republic will give first priority to zonal applications.

What do I submit to the Czech Republic if they are ZRMS?

If the Czech Republic agrees to act as the ZRMS your applications should be made by the Step 2 submission deadline. The core dossier should be submitted in draft registration report (dRR) format detailing all the intended uses across the zone and identifying the uses that establish the risk envelope for the zone in each area of the assessment. We will evaluate the core dossier and any the Czech Republic specific issues and make the RR available to other MS to use as the basis for their own national regulatory decisions. The same is valid for new product applications.

What is the detailed format of the draft RR?

The templates for the draft Registration Report have been laid down in the European Guidance Document Sanco/6895/2009 on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report.

You will note that when supplied with the data (doc K of the traditional dossier), the draft RR contains all of the information previously required in the summary dossier, but in a format that better represents the final evaluation document.

The draft RR also reflects the zonal assessment procedure, allowing separation of the core assessment and national addenda. It still maintains the familiar three part structure:

- Part A risk management (national),
- Part B risk assessment (core) and addenda (national)
- Part C confidential information

Where we agree to act as ZRMS, we would prefer applicants to use the latest version of the draft RR in their submission. To help you complete the draft RR templates, guidance documents have also been prepared, which highlight:

- the type of information that should be presented and the level of detail required
- the type of assessment that should be conducted in each area (referring to EU Guidance documents where appropriate)
- that the risk envelope approach should be used where possible
- that reference can be made to other assessments (DAR and MRL)

The templates and guidance documents can be found on the Commission website or on the Czech website www.srs.cz under “Plant Protection Products”.

Registration Report Section	Blank template	Guidance document - Core Assessment	Guidance document - National Addenda
Part A	dRR part A - template blank	dRR part A - with guidance	Not required as country specific document (except if the Czech Republic is not the ZRMS).
Part B, Section 1 - Identity, Phys Chem Props	dRR part B Section 1 - template blank	dRR part B Section 1 - with guidance	Not required as all data can be considered as core data (if required an addenda can be produced using the blank template).

Part B, Section 2 - Analytical methods	dRR part B Section 2 - template blank	dRR part B Section 2 - with guidance	Not required as all data can be considered as core data (if required an addenda can be produced using the blank template).
Part B, Section 3 - Mammalian toxicology	dRR part B Section 3 - template blank	dRR part B Section 3 - with guidance- both UK POEM and German OPEX assessment to before seen by applicant	Not required as all data can be considered as core data (if required an addenda can be produced using the blank template).
Part B, Section 4 - Metabolism and residues	dRR part B Section 4 - template blank	dRR part B Section 4 - with guidance	Not required as all data can be considered as core data (if required an addenda can be produced using the blank template).
Part B, Section 5 - Environmental fate	dRR part B Section 5 - template blank	dRR part B Section 5 - with guidance – all FOCUS scenario's covering the whole zone to be foreseen by applicant	Not required as all data can be considered as core data (if required an addenda can be produced using the blank template).
Part B, Section 6 - Ecotox studies	dRR part B Section 6 - template blank	dRR part B Section 6 - with guidance	Not required as all data can be considered as core data (if required an addenda can be produced using the blank template).
Part B, Section 7 - Efficacy	dRR part B Section 7 - template blank	dRR part B Section 7 - with guidance	

Part C - confidential	dRR part C - template blank	dRR part C - with guidance	Not required as all data can be considered as core data (if required an addenda can be produced using the blank template).

Do I have to submit to all MS at the same time?

Most MS will require a complete dossier to be submitted by the Step 2 deadline, but it is recommended to check this with all concerned MS. Some MS prefer to wait until the core assessment by the ZRMS is available.

What are the costs and timelines?

Applications will be streamed as fast track applications with a 1 year target for processing. Charging is the same as for a normal application for (re-)registration.

Compatibility with Regulation 1107/2009

The dRR has been designed so that it is compatible with the zonal approach to product assessment according to Regulation 1107/2009. A guidance document detailing the process of zonal evaluation, authorisation and mutual recognition under Regulation 1107/2009 is in preparation and will apply to product assessments made or due to be made after the date of application of the Regulation (14 June 2011). This document is being prepared by the Commission following consultation with MS and industry and will be published on the Commission website in due course. Wherever possible, the process for intra and inter-zonal work-sharing has been aligned with the new regulation to allow a smooth transition between the two processes.

Contact information

If you have any questions relating to this information sheet, please contact Martin Prokop (telephone +420 545 110 464 or e-mail martin.prokop@srs.cz).