



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL  
Directorate E - Safety of the food chain  
E3 - Chemicals,contaminants,pesticides

SANCO/6895/2009 rev 1

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**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**

This document has been conceived as a guidance document of the Commission Services, which was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Annex II, III and VI of Council Directive 91/414/EEC, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

## **Aim of this guideline**

This guideline describes in detail the structure and content of the draft registration report (dRR), a new format for applicant submissions for plant protection products containing substances included in annex I. It also describes how MS should evaluate these submissions.

For such submissions, until now the same presentation requirements were used as prescribed by Working document 1663/VI/94 “Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in annex I of Directive 91/414/EEC (Article 5.3 and 8.2)”, which was modified by the introduction of the OECD formatting system by the document Sanco/10518/2005 “Guideline developed within the Standing Committee on the Food Chain and Animal Health on the preparation and presentation of complete dossier for the inclusion of active substances in annex I of Directive 91/414/EEC (Article 5.3 and 8.2)”. However, these guidelines were developed for submissions supporting annex I inclusion of active substances. This new guidance was specifically developed for national applications for plant protection products containing annex I included active substances.

Guidance document Sanco/10796/2003 (on the format for registration reports for the assessment of plant protection products following inclusion of an active substance in annex I of Council directive 91/414/EEC) described a ‘skeleton’ format for the evaluation of product applications by the MS. This new guidance document develops the structure of that registration report further.

## **Aim of the dRR**

The dRR presents the *same information* as required under the historical Annex III dossier format – including e.g. proposed labels, MRL information, data summaries and risk assessment. However, it is drafted in the format of a ‘MS evaluation’ (registration report) to minimise any repetition of work required to ‘convert’ the dossier to an evaluation. In addition to the dRR, the applicants would still be required to provide the actual studies (doc K of the above mentioned guidelines) which are referenced and summarised in the dRR.

The dRR is compatible with the

- zonal approach to product assessment (as will be imposed by the new Regulation to replace Directive 91/414/EEC) and
- current work sharing for re-registration between MS as referred to in Guidance document of plant protection products following inclusion of an existing active substance in Annex I to Council Directive 91/414/EEC (Doc SANCO/10796/2003).
- Draft guidance on intra and inter-zonal work-sharing (SANCO/6896/2009)

In each case, the lead MS in each zone evaluates a core assessment, which can then be used by other MS in the zone as a basis for their national assessments.

The dRR uses the 'risk envelope' approach. The core data evaluation and risk assessment in each zone covers *all* uses required across the zone. When using the dRR, the applicant proposes which uses in the zone reflect the 'worst case' assessment in each technical area – this is then checked by the MS evaluator. For details on the zonal approach to product assessment and risk envelopes, see the new guidance document SANCO/6896/2009 on a process for intra & inter zonal worksharing 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.

### **When should the dRR be used?**

The dRR is the format that the applicants should use for all product submissions, for both new products or re-registration of existing products. Whilst the dRR was primarily drafted to reflect 'conventional' plant protection products, it may be modified as required to reflect the Uniform Principles for biological plant protection products.

If an applicant submits a dRR then the competent authority should accept this submission format (if complete). From 2 October 2009 (date the current guidance document was noted by the Standing Committee on the Food Chain and Animal Health). All submissions submitted one year after the noting of this guidance document should be submitted in dRR format.

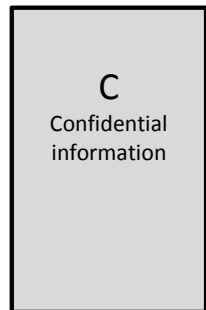
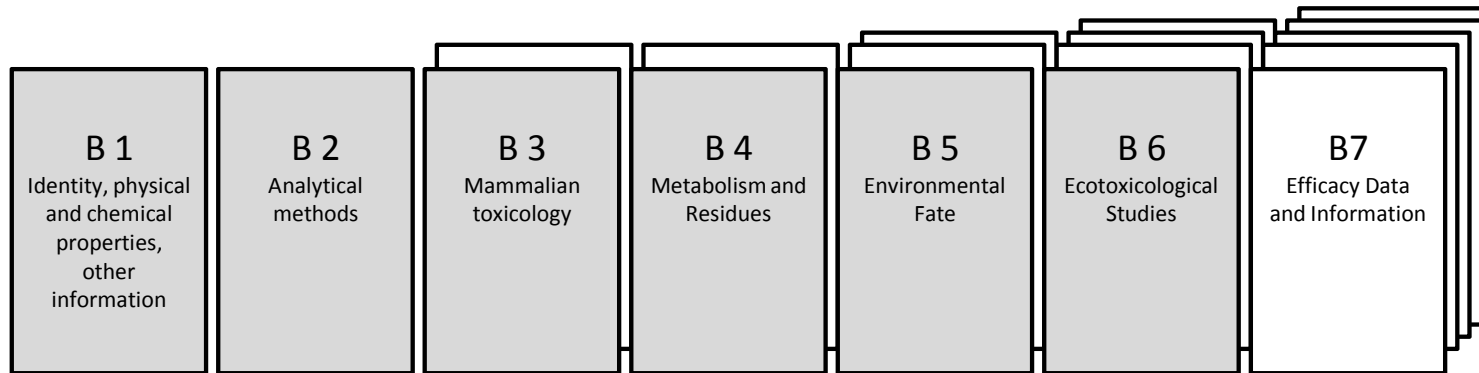
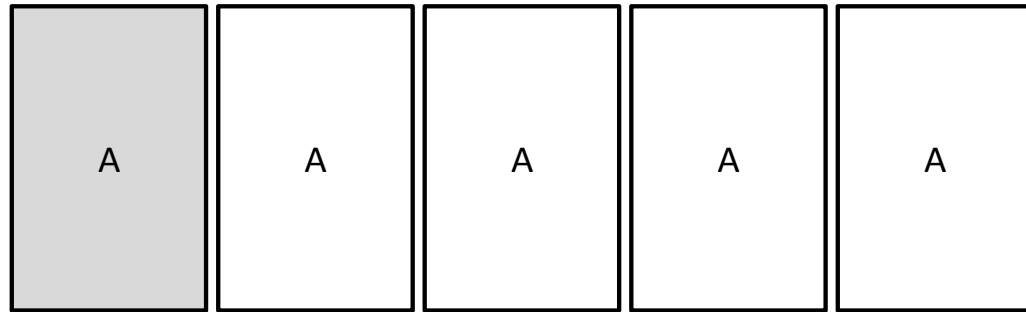
### **Structure**

The dRR is split into 3 main sections:

- Part A –risk management
- Part B –data evaluation and risk assessment
- Part C – confidential information

Part B is split further into specialist sections, and may be further divided into core assessments (to be assessed by the zonal RMS) and national addenda (covering each MSs specific national requirements). You will note that the numbering in the document follows OECD dossier format.

A diagram of the structure of the dRR (including core and national assessments) is given below:



key



National – produced for/by each MS



Core – produced for/by zonal RMS & used by other MS

Appended to this guidance document (and available on the europa website as Word versions) are blank templates for each section of the dRR. With each section of the template, there is an associated guidance document which explains the type and level of assessment that is required (including examples of text that may be used). In the template guidance documents the coloured text relate to following information:

- Text in blue provides general information/support.
- Text in red has been taken from the new registration report templates. The text summarises the minimum information that should be provided in each section.
- Text in black is example text that could be inserted by the notifier/authorities. The text/tables are not fixed and should be adapted by the notifier / authorities to suit the product being evaluated.

This template is a starting point – it is anticipated that with use, regulators and industry will be able to feed back ‘best practice’ which can then be incorporated into future versions of the document. There will be a review of this template on a regular basis, to allow this feedback to be incorporated in the template structure.

### **How to prepare the dRR – a summary of applicant requirements.**

The dRR should be prepared (and assessed) in English language, to allow for exchange of assessments between MS, and to allow mutual recognition.

The dRR is compatible with caddy format, and guidance will be available soon on how to prepare caddy dRR submissions.

Since the core dossier covers all uses in the zone, applicants should consider carefully which uses represent the risk envelope in each technical area, and justify their choices in the relevant sections of the dRR.

In order to prevent unnecessary duplication, the dRR should refer to other available EU assessments where possible – e.g the Uniform Principles (UP) assessment for the representative product/uses reported in the Draft Assessment Report, or a UP assessment for a similar product which establishes the risk envelope, or a technical equivalence report which establishes an equivalent source of active substance. There is no need to re-submit or re-assess data that has been assessed previously at an EU level – one should simply refer to the relevant assessment (DAR, registration report, technical equivalence report). However, the referenced documents should be readily available, or made available to the assessors.

It may be necessary to include Annex II (active substance) data evaluation in a dRR, but it should be noted that this should only be necessary if the data were not assessed in the

review and if they are required to refine product risk assessments to allow an acceptable use – see SANCO guidance doc 10328/2004 on the evaluation of new Annex II data post annex I inclusion of an active substance. The applicant should make it clear that Annex II data are provided and justify why they are needed.

The applicants should highlight which tests and guidance documents have been used in their assessment and where they deviate from any standard approaches they should fully explain their reasoning.

The applicant should complete all sections of the document Parts A-C. If a particular area of an assessment is not relevant then this should be stated and justified. The applicant can use the comment boxes to propose their conclusions (although these should be ratified by the MS assessor).

The applicant should present his assessment with sufficient detail to ensure that the proposed assessment is clear, explaining all his reasoning. The exact level of the detail will depend on the type of assessment – where appropriate the standard OECD study format has to be followed. A more complex higher tier risk assessment will require more explanation than a simple one. Any comments/amendments made by the MS should also be clear.

The guidance documents provided with the templates are not exhaustive – they should be considered as suggestions as to how to approach the assessment and complete the dRR text. The applicants may tailor their submissions as required, but should ensure that the assessment reflects the evaluation standards for product assessments i.e. those outlined by the Uniform Principles in Annex VI of Directive 91/414/EEC.

MS may require additional information to be provided with the submission (e.g. application forms). However where an acceptable dRR is provided, MS should not ask for ‘conventional Annex III dossiers’ in addition.

### **Which information should be included in the core assessment?**

In general *all* data evaluation and *some* risk assessment should be included in the core assessment. The applicants should try and optimise the information in the core assessment, since this will then reduce the amount of additional work required at the MS level.

Where a technical SANCO guidance document is available, this should be followed as part of the core assessment. The applicants should describe which version of the guidance has been followed to allow identification of the methods used. Where new SANCO/EFSA guidance is produced, the applicant may incorporate this as part of the core assessment.

The national addenda should be used to present any assessments or data required at a national level, e.g. drain-flow assessments should be presented to the UK, the Dutch model should be used for operator exposure in the Netherlands. MS should consider developing specific guidance to allow for preparation of national addenda.

The templates for the Part B national addenda are identical in structure to the core templates. Optional header pages for the core and national addenda appear in the template.

### **How will MS evaluate the dRR?**

Whilst the dRR is a submission format for industry to use, it should be noted that at the end of the process this document will 'become' the registration report (core and national), thus the MS should ensure that all of the information provided is correct and compliant with the UPs.

All text prepared by the applicant will be checked by the MS assessor.

All study report assessments have an associated comment box (shaded in grey), in which applicants can propose outcomes of the study, summarise end-points, and MS evaluators can record their conclusions. For example, the applicant may propose in their submission that 'The study is acceptable' but this may be overwritten by the MS who may conclude 'The study is acceptable, however because of x, the agreed end-point is y'. If necessary the MS may ask the applicant to amend the study summary, or they may do so themselves.

Comment boxes are not provided for risk assessments. The applicant should prepare a risk assessment in each area, but the MS should check this to ensure it is fully compliant with requirements/guidelines. If necessary the MS may ask the applicant to amend the risk assessment (or they may do so themselves if it is efficient to do so) to ensure it reflects a fully correct UP assessment.

MS should highlight at the end of each risk assessment area that a suitable UP assessment was conducted, and that on this basis no harm to [e.g. operators/bystanders/consumers/environment/wildlife] is anticipated if the product is used in accordance with the proposed uses. They should refrain from making statements such as 'this use is safe' or 'this product is harmless'.

## Appendices

dRR part A – template blank

dRR part A – with guidance

dRR part B section 1 – template blank

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dRR part C – with guidance