SANCO/6895/2009 rev 3

12 October 2023

Technical guidelines on the presentation and evaluation of plant protection product dossiers in the format of a (draft) Registration Report

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Revision History

When	What
20 March 2015	• Cover sheet is adapted, - The numbering is aligned according to the numbering of the DAR (SANCO/12592/2012), • The content is aligned with guidance document SANCO/12580/2012 rev. 3.1 (reference lists) and Regulation (EU) No 284/2013 (data requirements), • New document B.0 containing general information has been added, • A summary should be added at beginning of each part and study evaluation in the appendix, • An overview on the data gaps should be included in the summary in the beginning of each section, • The presentation of the different GAPs has been streamlined.
7 October 2016 (rev. 1)	Part B6 (Mammalian Toxicology) is updated according to the latest guidance on exposure assessment of operators, workers, bystanders and residents
26 January 2018 (rev. 2.2)	• Update of the guidance to the dRR template • Advice on applications referring to Article 34
12 October 2023	- Updated to include new draft Registration Reports for plant protection products containing active substances which are micro-organisms, which reflect the new data requirements for plant protection products and the uniform principles amended by the Reg (EU) 2022/1440 and the Reg (EU) 2022/1441, respectively.

Background

Aim of this guideline

1. This guideline describes in detail the structure and content of updated draft registration reports (dRR) for plant protection products containing either chemical active substances (Annex 1) or micro-organisms (Annex 2), following revisions based on experience of use and regulatory developments. It provides advice to applicants to help them prepare submissions for authorisation of plant protection products. It also advises MS on their role in assessing and completing the documentation necessary to support EU authorisation procedures, in accordance with article 39(1)b of Reg. (EC) No 1107/2009[1].

2. This version updates the version from January 2018 of this Guidance document. For details of the transition between the two templates, see Annex 1 and Annex 2.

3. The Annex 1 of this guidance refers to additional information concerning dRRs for chemical plant protection products.

4. The Annex 2 of this guidance refers to additional information concerning dRRs for plant protection products containing an active substance which is a micro-organism.

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

For which type of applications should the dRR format be used?

5. The dRR should **clearly and concisely** present an assessment for a **plant protection product**, according to the Uniform Principles Regulation EU No 546/2011[2] (including amendments by Regulation (EU) No 2022/1441[3]) and Product Data Requirement Regulation EU No 284/2013[4] (including amendments by Regulation (EU) No 2022/1440[5]). This assessment will be based on EU agreed end-points for the active substance(s), product data evaluation and appropriate risk assessment relevant to the uses of the product.

6. The use of the format of the revised dRR is a requirement for the reporting and exchange of information on plant protection products and is compatible with the 'work-sharing' processes for the:
   - zonal approach to **new product** assessment and amendment thereof (see Guidance Document on zonal evaluation and mutual recognition for procedures SANCO 13169/2010);
   - **renewal** of existing product authorisations, in accordance with Article 43 of Reg. (EC) No 1107/2009 – see Guidance Document on renewal SANCO 2010/13170;
   - voluntary work-sharing (VWS) for **re-registration** of existing product authorisations, in accordance with Article 80(5)b Reg. (EC) No 1107/2009 – see Guidance Document on re-registration SANCO 10796/2003 and Guidance Document on intra and inter zonal work-sharing SANCO/6896/2009 for procedures. Note: procedures for VWS will be phased out in due course.

   In each case, the Zonal Rapporteur Member State (zRMS) evaluates a core assessment, which should then be used by other MS as a basis for their national assessments.

7. Whilst it is not a requirement to use the dRR format for mutual recognition applications, or other product applications handled at the national level, the use of the dRR format (national sections of the documents) is recommended when making these submissions.

[2] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

[3] Commission Regulation (EU) 2022/1441 of 31 August 2022 amending Regulation (EU) No 546/2011 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms (OJ L 227, 1.9.2022, p. 70).

[4] Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

[5] Commission Regulation (EU) 2022/1440 of 31 August 2022 amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for plant protection products containing micro-organisms (OJ L 227, 1.9.2022, p. 38).

8. The dRR format is not required for submissions relating to administrative-type changes, emergency authorisations under neither Article 53 nor Article 45 withdrawal requests. It is intended to present technical evaluations and national risk management decisions.

9. The dRR should not be used to submit/assess technical equivalence assessments – instead a Technical Equivalence report should be prepared by the RMS, in accordance with the template provided in SANCO 10597/2003 (for plant protection products containing chemical active substances), or SANCO/12823/2012 (for PPPs containing micro-organisms) If a technical equivalence assessment is to be conducted as part of an application for authorisation (as per Article 38 Regulation 1107/2009), Part C of the dRR should highlight this.

High level aims of the dRR/RR documentation.

10. As for the original dRR format, the dRR is first presented as an applicant 'assessment', which is then checked, modified, and agreed by the MS conducting the assessment. Whilst the draft Registration Report 'starts' as a company submission, the completed Registration Report (RR) represents the finalised MS assessment, which may then be used to support following zonal and mutual recognition applications. The document thus 'evolves' from company submission to MS assessment. However, the authorship of the different parts should be clear and traceable.

11. The documentation should be clear (detailing the basis of the Uniform Principles assessment) and concise (avoiding superfluous information and unnecessary duplication of text and information), and covering only relevant uses (i.e. using the risk envelope approach, see point 15) and assessments as well as study summaries for all studies evaluated. The dRR should only support the present application.

12. The narrative should be factual, and the risk assessment section (section B) should not anticipate the final risk management decision (authorisation to be granted or not) which should be provided by MS in Part A.

13. The revised dRR templates provide some examples of clear presentation (using tables etc.). Applicants should note that it may not be necessary to present all the information in each table and each subsection. In some sections the proposed approach may not be appropriate. Where the suggested presentation is unnecessary or unsuitable the proposed format should be replaced ensuring that all product data

relevant for the evaluation is presented in a transparent manner. Where information has been evaluated elsewhere in the report it should be referred to rather than repeated.

14. In general, there should be one dRR prepared for each product, although special rules apply to products with zonal and interzonal uses (see section on interzonal uses). This one product/one dRR rule may not apply when considering amendments to dRR e.g. adding new crops to an already authorised product (see section on amending dRRs).

15. The dRR uses the 'risk envelope' approach in order to minimise the number of separate assessments to be presented/assessed. Section B0 of the dRR should present an overview of all the uses supported by the assessment but each part of the risk assessment (Part B) should only consider and evaluate those uses that form the critical use pattern. The remaining uses falling within the risk envelope of the critical uses. For more details on presenting assessments in the dRR please see the section on 'risk envelope'.

16. Whilst it is intended that the dRR is a 'standalone' assessment for a product and its uses, it is acceptable to refer to other assessments when relevant robust summaries of previous assessments are provided in the dRR. Reference should be limited to information from appropriate EU assessments e.g. sanitised DARs/DRARs (available on the EFSA website), EFSA conclusions (also available on EFSA website), other EU documentation (from EU Pesticides Database) and historical registration reports (available to MS via CIRCABC).

17. It is not necessary to copy the detail of those previous assessments into the dRR, instead provide a summary of the previous assessment and any relevant outcomes. For example;
    - if a formulation dermal absorption study is assessed in the RAR, then there is no need to duplicate that assessment in the product dRR. Instead reference should be made to the previous assessment and a brief summary provided, and the end-points derived from that study should be used in the risk assessment for the new product.
    - If a mesocosm study has been fully assessed in another product submission (assessed by another MS), there is no need to duplicate that assessment for the new product submission. Instead full reference should be made to the earlier product assessment and a brief summary provided. The end-points derived from that previous study should be used in the risk assessment for the new product.

18. When referring to previous assessments (either from a DAR or EFSA conclusion or

reasoned opinion, or another product RR), it is important to demonstrate through robust summaries that those assessments were conducted to appropriate standards (i.e. that Art 36 1 is respected and that appropriate Guidance Documents were used at the time of application); and that they apply to the new product/use (i.e. they represent the risk envelope, or an appropriate extrapolation); and that the previous assessment has been through EU peer review or commenting.

19. Note when making submissions for a 'group' of similar products at the same time (such as required for re-registration and renewal of authorisation), it is appropriate and desirable for the applicant to use the principle of risk envelope and cross referencing between dRRs to reduce the amount of assessments required. However, the principles laid down in paragraphs 16 and 18 should be applied.

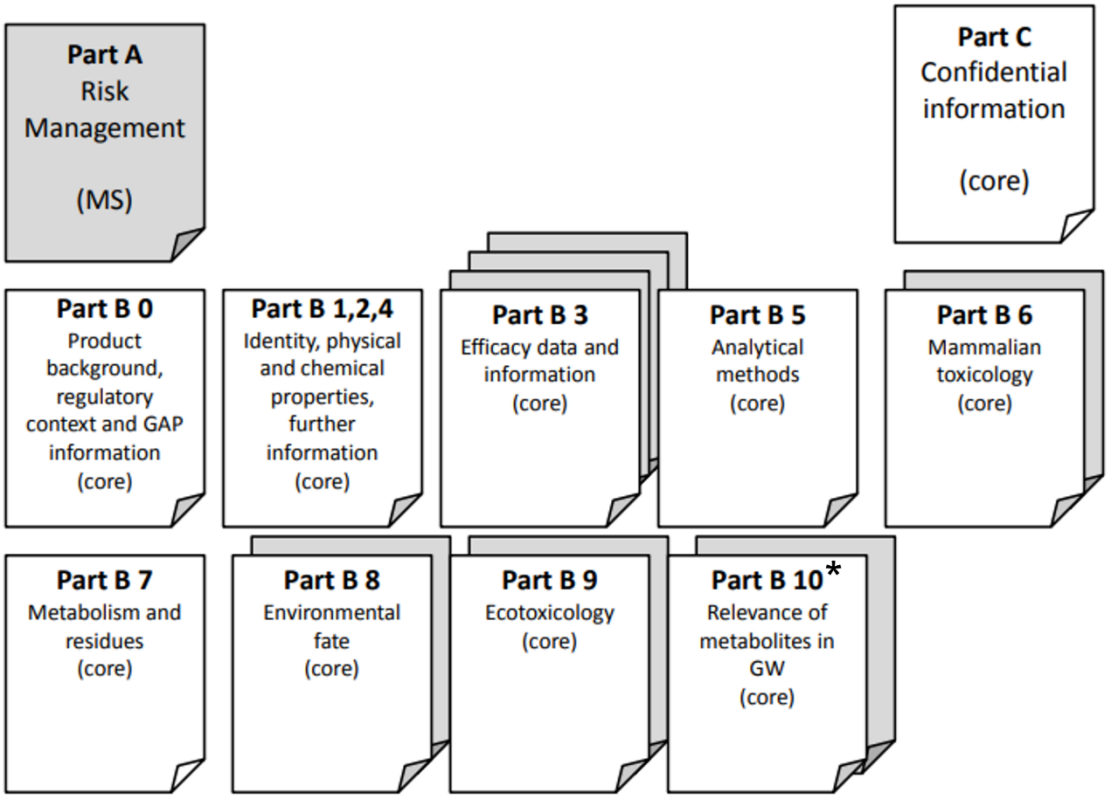
Structure of revised dRR

20. As with the original dRR, the revised dRR is split into 3 main sections:
    - Part A –risk management (national)
    - Part B –data evaluation and risk assessment (core and national addenda)[6]
    - Part C – confidential information (core)

21. Part B is split further into 'subject' sections, and may be further divided into core assessments (to be assessed by the zonal RMS) and national addenda (covering MS specific national requirements).

22. A diagram of the structure of the revised dRR (including core and national Part B assessments) is given below. White documents represent core documentation, grey documents represent national documents:

[6] Please note that section B10 is not necessary for dRR templates concerning plant protection products which contains micro-organisms. This is due to the fact that the assessment of metabolites of concern produced by micro-organisms is covered by the Guidance SANCO/2020/12258.



* Applicable only for chemical PPP

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

23. The core dRR should be prepared (and assessed) in English, to allow for the exchange of assessments between MS, and to allow mutual recognition. Ideally the national sections should also be produced in English, although national language is required for some parts (e.g. labels and authorisation documents).

24. In general, the product/use assessment should be evaluated to Uniform Principles (in accordance with Regulation (EU) No 546/2011, including amendments by Regulation (EU) No 2022/1441). The assessment should be to *current* technical guidance (noting the guidance documents cited within the templates are not exhaustive) at the time of application. Where relevant zonal guidance documents should be followed. The assessment should use EU-agreed active substance end-points and end-points from relevant formulation studies.

25. The applicant should complete all sections of the template (A, B and C), with the exception of the grey boxes (for MS use only). If the section is not relevant (e.g. the complete section B7 for a non-edible crop use) then the section can be omitted but this should be justified and highlighted in section B0. If a subsection is not relevant to the product/use (e.g. bird assessment for an indoor use) then it can be omitted but this should be justified and highlighted in the relevant subsection.

26. Part A is a national document, which as well as summarising the core assessment, should demonstrate how that assessment impacts upon the proposed national authorisation, particularly with regard to specific risk mitigation requirements, national labelling requirements etc.

27. Part C is a core document which contains confidential information/data. If the applicant claims confidentiality for information other than 'normally defined' in Art 63(2) of Reg. (EC) No 1107/2009, they must provide verifiable evidence to show that the disclosure of the information might undermine their commercial interests, or the protection of privacy and the integrity of the individual.

28. Since the core dossier covers all uses in the zone, applicants should consider carefully which uses represent the risk envelope in each area of assessment, and justify their choices in the relevant sections of the dRR, including provision of the critical GAP (cGAP) in each section (or subsection) of Part B. Note critical GAPs are not relevant for efficacy section where all GAPs are considered.

29. The applicant must ensure that the GAP tables, assessment, national labels and all parts of the dRR are consistent with one another.

30. In order to prevent unnecessary duplication, the dRR should refer to other available EU assessments where available (See paragraph 16). There is no need to re-submit or re-assess data/information that has been assessed previously at an EU level.

31. The applicant should refer to the relevant assessment (DAR, registration report, technical equivalence report), and provide a brief summary of that assessment. They should demonstrate that they have considered the relevance of any previous assessment to the new one; the impact of any changes to technical guidance since the previous assessment was conducted; and whether the previous assessment was peer reviewed/commented upon.

32. Active substance data evaluation may be presented in a dRR, but this should only be necessary if the data were not assessed during approval/renewal of approval and only if they are required to refine product risk assessments to allow an acceptable use – see SANCO 10328/2004 on the evaluation of new active substance data post approval. Note that active substance data that are also product data (e.g. analytical methods, residue data) are an exception. The respective studies should address the specific data point in the dRR and the results (e.g. level of residue) should be given.

Reference to EU documents should be included as foreseen in the dRR template. The applicant should make it clear in the dRR that active substance data are provided and justify why they are needed.

33. The applicants should highlight which test guidelines have been used for each study provided, and justify their approach if they deviate from those outlined in Commission Communications for chemical active substances/plant protection products[7], and Commission Communications for microbial active substances/plant protection products containing micro-organisms[8].

34. Similarly, applicants should highlight which technical guidance (Guidance Document) has been followed in preparing the assessment. In general, current guidance at time of application should be used. Applicants must justify any deviations from this approach. Where new SANCO/EFSA guidance is noted but not fully implemented, the applicant may choose to use the new approach to assessment in advance of it becoming a requirement, although MS cannot insist upon this.

    Detailed study evaluation (e.g. evaluation of a mesocosm study) should be placed in the relevant Part B *appendix*. A study summary should appear in the relevant section Part B/C, and the end-points derived from that study should be used in any risk assessment (which is also included in the relevant Part B section - not in the appendix). Where available the appropriate standard OECD study format has to be followed.

35. Applicants should refrain from making statements such as 'this use is safe' or 'this product is harmless', and instead should use factual statements such as 'This assessment demonstrates an acceptable risk'.

36. Applicants should note that MS may require additional information to be provided with the submission (e.g. application forms, covering letters, national language labels).

37. The dRR template is compatible with CADDY, CADDY XML, although it is not a requirement to submit the information/dossier in this electronic format in all MS.

Which information should be included in the *core* assessment, and which in the national addenda?

[7] As of 27 June 2023: 2013/C 95/01 and 2013/C 95/02.
[8] As of 27 June 2023: 2023/C 202/03 and 2023/C 202/02.

38. In general *all* data evaluation and risk assessment should be included in the core assessment. All uses of the zRMS and cMS should be considered in the core assessment. The applicants should try to optimise the information presented in the core assessment, since this will then reduce the amount of additional work required at individual MS level. Whilst there is no specific list of 'core requirements', they are essentially the data requirements, according to Uniform Principles and current technical guidance (all of which are harmonised across the EU). EU agreed methodologies must be used in the core dRR (unless zonal guidance documents state otherwise). Where there is no harmonised approach for a specific assessment, applicants may discuss their submission with the zRMS (ideally at a pre-submission meeting), to determine how to present the core assessment in the most appropriate way.

39. The national addenda should only be used to present assessments or data required at a national level, e.g. a drain-flow assessment should be presented to a MS via a national addendum. MS should make available details of those national requirements.

How will MS evaluate the dRR?

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

41. The assessment part of the dRR templates should reflect the zRMS evaluation. Commenting boxes should be used for the detailed study evaluation in the Appendices. Additional MS comments boxes may be added where required.

42. If the MS assessor chooses, they may amend the text/assessment provided by the applicant (making it clear they have done so). If it is efficient to do so, they may present new assessments deleting (or striking through) the applicants assessment. However where significant re-drafting is required, the assessor can ask the applicant to provide re-drafted text for insertion.
43. Part A should be amended to reflect any changes in the assessment in Part B.

44. MS should make it clear which data have been used to support the authorisation, by updating the data lists accordingly.

45. ZRMS should place the finalised RR on CIRCABC using the appropriate naming convention.

GAP tables

46. All GAP tables should be presented in the standard format provided, noting that the different sections of the dRR represent different information:
    a. Part B0 = **all intended** GAPs across the zone (listed by MS).
    b. Part A = **national** GAPs
    c. **Critical GAPs** relevant to the zonal/national assessment (and representing the risk envelope for that section) should appear in each relevant Part B section [B.6 (mammalian toxicology), B.7 (metabolism and residues), B.8 (fate) and B.9 (ecotoxicology)]. CGAPs listed in sections from Part B should retain the numbering from part B.0.

47. Regarding Article 43 applications, in accordance with SANCO 2010/13170 on renewal of authorisation, it should be noted that there should be no new/changed GAP, except if the GAP has to be changed (because of changed end points). This should be clearly indicated by the applicant

Data lists

48. Part A and each section of Part B of the dRR (including national addenda) have 4 reference lists of tests and studies as Appendix. Two lists need to be filled by the applicant ("All studies required to address the data points in the dRR and not previously evaluated at EU level" & "All studies required to address the data points in the dRR and already evaluated at EU level"). Each reference should only appear in one of the two lists. All 4 reference lists need to be considered by the zRMS (i.e. the first two lists and "Data not relied on" & "Data not submitted but relied on"). Such data lists should be prepared in the format as required in SANCO 12580/2012. If additional data are submitted during the evaluation, they should be added to the lists in the dRR. An updated data list should be supplied by the applicant. Note that the applicant must also indicate in the list in part A (provided separately for each country in the zonal/interzonal application) for which studies protection was claimed, as necessary to meet the requirements of Art 60 (2 b).

Risk envelope

49. Of the multiple GAPs throughout MS, the applicant should select uses which represent the critical GAP in each section of risk assessment and subsection of the dRR. The assessment for that critical GAP then establishes the 'risk envelope' for the other uses required in all MS. This can significantly reduce the number of separate use assessments required.

50. It should be noted that the selection of the critical GAP can be different depending

on the type of assessment. For example the critical GAP for operator exposure may be different to the critical GAP for bystander exposure. It is important therefore that applicants justify their selection of uses to assess in each compartment of the risk assessment.

51. The MS assessing the dRR will check that the proposed critical GAP is appropriate to form the risk envelope, before checking whether the assessment complies with the UPs. If necessary the MS may ask the applicant to amend its dRR to amend the critical GAP.

52. Full details on the use of the risk envelope approach can be found in SANCO 11244/2011 Guidance document on risk envelope

53. Although there is no scope to use the risk envelope approach for the efficacy assessment similar principles can be applied by demonstrating comparability of effects to an existing product.

Special cases Application of Article 34

54. Some applicants may cite access to third party data, or data out of protection. In either case, those data can often not be supplied by the applicant, and it will not always be possible to present an assessment based upon those data. In addition to showing that its product is safe, the applicant should use the dRR format to describe how its product/GAP has comparable effects to the plant protection product to which they refer. It is *this comparison* of formulation type/GAP/claims that MS will consider. More information about the evaluation is provided in the Guidance Document on Zonal Assessment and Mutual Recognition.

55. Where possible applicants should submit or refer to a complete list of tests and studies that support the application. The studies should be sufficient to address each data point and applicants need to demonstrate access in accordance with Article 59, 61 or 62 of Reg. (EC) No 1107/2009 or expiration of data protection for all studies.

56. In addition to the robust summaries of the previous assessments, MS can use the following text or similar to explain their general approach to assessment:
    - Product A is identical to Product B. The proposed use/s is/are identical. Product B has been authorised following an assessment conducted to Uniform Principles using the relevant agreed Guidance Documents along with additional MS-specific requirements. Product A therefore poses no additional risks to human health or the environment above those of Product B and can be authorised.
    - Product A is not identical to Product B. However, the [formulation] [pack]

[proposed use/s] difference has been carefully considered in detail. The evaluator's expert judgement is that these two products are essentially similar. Product B has been authorised following an assessment conducted to Uniform Principles using the relevant agreed Guidance Documents along with additional [MS name]-specific requirements. Product A poses no additional risks to human health or the environment above those of Product B and can be authorised.

Amending Registration Reports

57. Where an applicant wishes to amend the authorisation of a product already on the market, applying Article 33 of Reg. (EC) No 1107/2009, they need to supply data and assessment only in those areas relevant to the modification applied for. The applicant should refer to the previous assessment (as per paragraph 15) and only provide documentation relevant to the new use. The dRR submitted should be titled "extension/amendment of use on …." on the cover page of the new dRR template.

Extension of authorisation for minor use

58. It is considered impractical for applicants (such as grower groups etc.) to use the dRR format when making submissions for extensions of authorisations for minor use relating to Article 51 of Reg. (EC) No 1107/2009.

59. Where an authorisation holder applies for an extension of authorisation for minor use, they may make their submission as part of a complete dRR, as an amendment as referred to in paragraph 57 above. When combined in a 'conventional dRR', the applicant must highlight which uses are considered minor in nature (noting this may differ between MS).

Interzonal applications

60. If a product has both zonal and interzonal uses (e.g. outdoor and protected), then two separate processes must be followed (e.g. zonal and interzonal commenting) for each type of use with the exception of home garden uses (home garden uses are to be regarded zonal even if indoor uses are applied for). To facilitate these processes, two separate dRRs must be submitted, one covering the product specific information and the outdoor use data/assessment; and another cross referencing the product specific data and detailing the protected use data/assessment. The zRMS and izRMS are to ensure there is no duplication of assessment for the zonally independent areas.

1. The revised dRR format should be used for applications for product authorisations submitted after 1 July 2018 (to ensure that the product data requirements are fully addressed in accordance with Regulation (EU) No 284/2013). Revised dRR templates for chemical plant protection products are available with[9] or without[10] report.dot.

2. The original dRR format *may* be acceptable after this date (e.g. for AIR Art 43 renewal, where the 'old' data requirements will apply) however this should be agreed with all affected MS before submission.

How is the revised dRR template different to the original template?

3. Whilst the broad structure and aim of the dRR is unchanged, there have been a number of modifications to the original template structure:
   a. Each section has a standardised cover-sheet, allowing easy identification of the product assessment
   b. Sections are now numbered in line with the sections of the DAR (according to SANCO/12592/2012). Efficacy is now section B3 (noting sections B1, 2 and 4 remain combined in one document). Residues is in section B7.
   c. New document B0 was introduced for general information about the product and active substance(s) e.g. information on authorisations and products in each MS, MRLs, and conditions of approval for active substances where this information is relevant. It should include the overview table for all GAPs of the zRMS and the cMS.
   d. Better alignment with other Regulations and Guidance documents was introduced, e.g. data requirements in accordance with Reg. (EU) No 284/2013, study lists in accordance with SANCO 12580/2012.
   e. Full study evaluation appears as an *appendix* to the relevant section of Part B, the main section should only include a summary of that evaluation (with the exception of the efficacy section, where full trials data evaluation will be available in the Biological Assessment Dossier (BAD) not in Part B Section 3).
   f. Data lists appear as an appendix to the relevant section (and formatted as per SANCO 12580/2012 - see section on Data lists)
   g. Clarification was made of GAPs via separate, clear tables, with each GAP line numbered to allow cross-reference between the sections – see the section on GAP tables.

4. The templates provide advice to the applicant (blue highlighted text). Yellow

[9] https://food.ec.europa.eu/document/512167b2-af43-416a-9819-41978a1eea8b_en
[10] https://food.ec.europa.eu/document/3f862900-1bb9-4f25-b9aa-bc056cc084f5_en

highlighted text indicates elements of text that should be modified by the applicant. Grey highlighted text should only be inserted by the MS conducting the assessment.

5. Unlike the previous templates, there is no separate 'guidance' for most sections of the template. The exception is the efficacy section, guidance for which can be found in Annex 3.

6. In most sections and subsections, the templates provide suggested formatting such as tables and 'standard' text. As noted in paragraph 11, applicants and MS should only use these tables/text if they are *relevant* to the assessment and are considered to be the best way of demonstrating the Uniform Principles assessment. Applicants and MS assessors should avoid unnecessary duplication of information, or provision of unnecessary information.

Annex 2: additional information concerning dRRs for plant protection products containing an active substance which is a micro-organism

1. New Regulations are applicable from 21 November 2022 onwards, on data requirements for plant protection products containing micro-organisms, and uniform principles for assessing them[11]:
   - Commission Regulation (EU) 2022/1440, amending Regulation (EU) No 284/2013[12] as regards the information to be submitted for plant protection products and the specific data requirements for plant protection products containing micro-organisms;
   - Commission Regulation (EU) 2022/1441, amending Regulation (EU) No 546/2011[13] as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms.

2. It is then appropriate to align the current structure of the draft registration reports (dRR) for plant protection products which contain micro-organisms as active substances, with the revised data requirements and uniform principles.

3. Please note that as regards metabolites of concern produced by micro-organisms, the relevant dRR template considers the worst case in which the metabolites of concern must be taken into account in the risk assessment. Therefore, the dRR template includes the assessment of both the micro-organism(s) and metabolite(s) of concern in the same dRR. Where the suggested presentation is unnecessary (i.e. absence of metabolites of concern), the proposed format should be adapted (e.g. it could be deleted).

4. Please note that as regards the employment of a weight of evidence approach in the risk assessment of micro-organisms, a dedicated section has been introduced in the new dRR template, part B.1,B.2, B.4 (see introduction). This will allow to include the most relevant information (e.g., on the biology, mode of action etc.) to justify the employment of the weight of evidence approach in the different areas of the risk assessment. Information is coming from the EU dossier and should not be reassessed.

5. Applicability of the dRR templates.

   - Before 21 November 2024,
     - for applications for authorisations submitted in accordance with Regulation (EU) No 284/2013 as it stood before being amended by Regulation (EU) 2022/1440, the former templates of the dRR[14] are

[11] https://food.ec.europa.eu/plants/pesticides/micro-organisms_en
[12] https://eur-lex.europa.eu/eli/reg/2013/284/2022-11-21
[13] https://eur-lex.europa.eu/eli/reg/2011/546/2022-11-21
[14] https://food.ec.europa.eu/document/40e60b5e-0859-406b-9d6c-993213fc7c65_en

applicable[15];

- for applications for authorisations submitted in accordance with Regulation (EU) No 284/2013 as amended by Regulation (EU) 2022/1440, the new templates of the dRR[16] are applicable.

- As from 21 November 2024, for all the applications for authorisations only the new templates of the dRR apply.

[15] Please see Article 2 of Regulation (EU) 2022/1440 for more information on transitional measures. https://eur-lex.europa.eu/eli/reg/2022/1440/oj

[16] https://food.ec.europa.eu/document/906e9c6f-45aa-499b-93be-4ac37844e329_en

Annex 3: Technical guidance for applicants in preparing a concise efficacy summary

Under Regulation (EC) No 1107/2009 and (EU) No 284/2013 (Section 6: Efficacy data), efficacy data must be provided. The data submitted are presented in an "Efficacy Package", composed of 3 documents:

- A **dRR (draft registration report, part B Section 3 Efficacy**): It is a document prepared by the applicant and written in accordance with the Guidance Document SANCO/6895/2009[17] and following all relevant EPPO PP standards. The purpose of this dRR for the Efficacy assessment is to provide an appropriate critical concise summary of the Biological Assessment Dossier (BAD), so that the zonal rapporteur member state (zRMS) can determine how the proposed uses(s) are supported, and whether each data requirement has been appropriately addressed (either by data or a justified reasoned case). The dRR should have sufficient detail such that the (z)RMS can largely refer to this document during the assessment, and use this as the basis of the final Registration Report (RR). dRR and RR should be standalone documents.

- A **BAD (under the dRR chaptering)** is a detailed summary: The data within the BAD should address the specific Efficacy data requirements detailed in EU Regulation and the relevant Guidance Document on the Efficacy Composition of Core Dossiers and National Addenda[18]. As for the dRR, applicants must also refer to all relevant EPPO PP standards. The BAD is classified as a 'K document' (non-public document).

- **Annex**: Trials / study reports, trial series report (summaries), published papers, etc. They also belong to the "K document" (non-public document).

Efficacy follows the layout of the requirements in "Section 6: Efficacy" of the data requirements in regulation 284/2013.

Where no data is provided for a chapter or a requirement, this should be explained / justified in the context of the product type, the type of demand, etc.

Zonal submissions are usually made to one of three **EU regulatory zones**. The dRR and the BAD must be adapted to each zone and not be a single all-encompassing dossier for the entire EU. Exceptions to this are for those uses, where the EU is considered as one regulatory zone (e.g. protected crops, products for stored produce, seed treatments).

Where there are particular National Requirements that may require further information and/or data, these could be addressed in accompanying National Addenda. This is explained more fully in Guidance Document SANCO 10055/2013, which describes the composition of

[17] SANCO/6895/2009: 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.

[18] Guidance Document on the Efficacy Composition of Core Dossier and National Addenda Submitted to Support the Authorisation of Plant Protection Products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on Placing of Plant Protection Products on the Market

the Efficacy core dossier and any accompanying National Addenda. Only limited additional data should be included in National addenda; the bulk of data / information should be presented in the core dossier. This guidance document should be referred to when drafting the dRR Section 3.

This guidance developed in this template is for applicants to define the necessary information for a dRR concise summary, allowing its transformation into a RR - Registration Report, after an evaluation by a (z)RMS. The RR is a final concise document, fully under the responsibility of the zRMS and possibly available to the public (depending on individual MS policies on release of information).

The relationship between the BAD, the dRR and the RR (Part B Section 3) is illustrated in Figure 1.

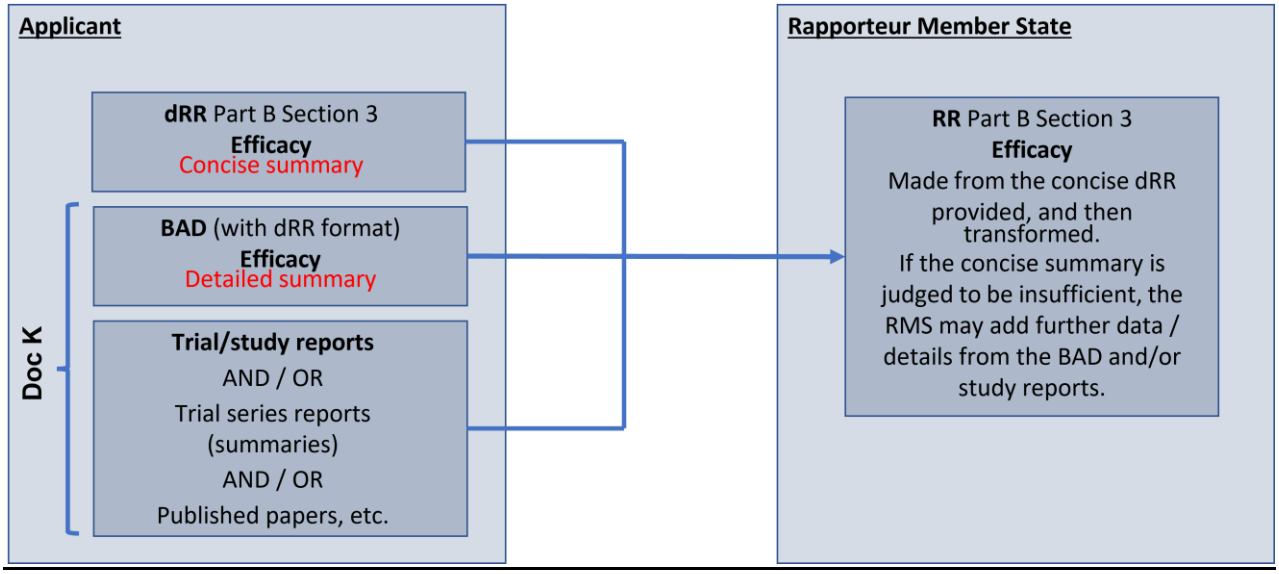


Figure 1. Relationship between the BAD, the dRR and the RR (Part B Section 3).