

Explanatory notes on the alignment of formatting of the dRR templates

1) dRR Templates with and without “report.dot file”

- The dRR templates can be used with or without a connection to the format template report.dot. Therefore, two zip files are being distributed, one which contains only the dRR templates and a second zip file, in which in addition to the templates for the sections of the dRR, a “report.dot” file is included.

In the second zip file, the dRR templates are connected to the report.dot file (see A 3.1 of Help for Report.dot), thereby making several macros (e.g. Insert Table label) available, which allow for a less time-consuming editing. A help information (file Help-for-Report.dot.pdf attached) provides more information on the “Report.dot” and assistance on using the available macros. The report.dot file includes an electronic signature, so that only digitally signed macros need to be activated in the safety settings.

2) Explanations on changes and use of dRR templates

- Specific paragraph formats (names starting with “Rep”) were created, which include all relevant styles for Headings, Subheadings, texts (Standard + Tables), Bullet points, etc. For realizing proper work with the document, the appropriate format style should be assigned to text passages copied in the document (see also Point 2.5 of Help for Report.dot).
- The texts in turquoise (for applicant) and grey (for zRMS only) boxes, which provide general information on and support for completing the templates, were aligned with regard to format and content. They generally should be deleted completely; however, if applicants/ zRMS want to use parts of the text, they may be copied or another format can simply be ascribed (Rep Standard).
- Title pages were aligned between all dRR templates, including now the latest agreements on inclusion of product name(s) and (regarding a comment of COM) on clarification of the dRR template version (= for chemical active substances, not microorganism → phrase “Chemical active substance”). As agreed in the 2nd meeting of the dRR working group, the appropriate detail can be selected from the information given in the cover page to identify the version of the document (e.g. Core assessment / National Addendum).
- Headers were aligned. In addition to the proposal of the 2nd meeting, information on dRR template version (Template for chemical PPP and date) as well as page numbers were included. As a consequence a footer is no longer needed. A frame is used for text on the right to allow for automatic adaption when inserting pages with landscape format.
- Numbering is aligned starting with the respective number of the section (without any prefix) in the main part of the document. In the appendices, the prefix “A” is used to clearly differentiate between the two parts. Since table labels refer to the 2nd list level (Rep Heading 2), it is not possible to include tables under the 1st level heading with appropriate numbering. Therefore, in particular cases an additional subheading had to be included (see also Point 2.1.2 of Help for Report.dot).
- Tables were aligned with regard to format and labels. Almost all tables were given a label to allow precise reference during commenting. Table footnotes were aligned as far as possible.

- Automatic references to headings and tables were included when referred to in the text, which allows much faster navigation to the referenced table/ chapter. To assure that all tables/ figures and references are correct, it is recommended to run the function “Refresh / All fields” before a document is officially sent out (see also Point 2.2.1 of Help for Report.dot).
- Reference lists were included according to latest discussion on PAI (March 2015). It was noted that reference lists should correspond to the formatting given in the GD on preparing lists of tests and study reports according to Article 60 of Reg (EC) No 1107/2009. Thus, the previous column “relied on (Y,N,Add)” was deleted and separate tables were included for the different options on how the studies were used (also including a category for studies already evaluated at EU-peer review).
- The headers of the studies in the Appendices and commenting boxes were aligned. In sections where vertebrate studies may be reported, an additional line was added in the header for the justification in case a duplicate for a vertebrate study is provided.

3) Open issues

During alignment of formatting some differences between the sections were identified that have not been adjusted, since changes would have clearly influenced the structure or may have had an impact on the content. Therefore such changes should not be made without prior agreement with the subgroup. These points are listed as follows and may be considered during the next revision of the templates.

- Summaries and Conclusions were kept at the places foreseen by the subgroup, although it would be appreciated if they were consistently inserted at the beginning. This may not be appropriate, however, in some single sections (e.g. Section B.0).
- The list on data gaps (in the chapter Conclusion) was not added in all sections, since it may not be necessary in some sections (e.g. Section B.10). If it is considered helpful for any section (in which it is not included up to now), it may be added during a revision of the dRR templates, subsequent to the first experiences when working with the templates.
- Grey text shading or grey boxes (indicating editing only by zRMS) were used in the summary and conclusion as foreseen by the subgroup or where it was clear that the specific part should only be completed by zRMS.
- In most sections, text highlighted in yellow indicates example text that should be changed as specified. In some sections of the dRR, text highlighted in yellow indicates a text form field, in which text needs to be replaced completely. Text form fields may be time-saving when editing the document; however, it would have been quite time-consuming to include them in the templates. Since it was not always clear whether yellow text needed to be replaced or amended, the formatting was kept as was foreseen by the subgroup.

If questions concerning the formatting occur, please contact:

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In case of questions on the content of the templates please contact the BVL being the coordinating agency for the templates revised in April 2015 (200@bvl.bund.de).