

Documentation for the Central Format Template Report.dot

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1 Introduction

The central format template Report.dot was developed at the Federal Institute for Risk Assessment (BfR) in Germany. Its macros provide functions that can be used for the creation or modification of empty Word-templates as well as for completion of a (draft) Registration Report ((d)RR) in the zonal authorization process or a draft assessment report (DAR) in the active substance approval process. The template was designed so that the general core can be adjusted for the specific needs of an authority or applicant.

This template was first used in Germany in the AIR-3 programme for the completion of the DARs. Since the dRR templates have been formatted by Germany, Report.dot will be used for the first time at EU level.

All Word documents based on Report.dot can be used with or without a connection to this template (for information on connection with Report.dot see A 2.1). In principle, all the functions described hereafter can also be performed via the internal Word functions, but the use of these macros is advantageous in that complex functions can be performed similarly by all authors with reduced time expenditure.

This documentation describes only a basic (minimal) function set. An interesting set of other functions exists

- to create and manage sub-chapters for a parallel edition
- to replace known paragraph formats into “Rep” styles according to a matching table
- for connection to a local document management system (DMS)

and could be enabled by your local administrator.

The central template was developed with Word 2003 and then adapted for Word 2010. The optimization in Word 2010 is still pending.

This documentation is aimed at users of the format template and was written with Report.dot as its template. Those interested in the technical background should refer to Appendix 1.

The following symbols are used throughout the document:

Rule	Example
Keyboard shortcuts in MS-Word <>	<strg><g>
Important advice for the user	Attention
Further tips that are not necessary for comprehension	<i>Remark</i>

2 The “Report” menu

If a Word document (assessment report) is connected to Report.dot, the additional toolbar “Assessment Report”¹ is visible. This toolbar contains a menu providing macros specialized for the completion of the assessment.

If the following minimal toolbar is visible² when opening a document that is to be used for an assessment, it is properly connected to the template Report.dot. If this is not the case, please refer to the remarks in A 2.1.



¹ A term independent of any specific procedure was deliberately chosen.

² It may be that your administrator has enabled further functions.

In the following text all functions will be described in the order of appearance in the minimal toolbar.

Attention: Please note that changes to the text created with macros are often not fully reversible. Therefore it is recommended to previously save the document.

Remarks:

- In Word 2010 the toolbar for Report.dot is found under “Add-Ins”.
- An overview of the functions of the menu is presented in tabular form in Appendix 1.
- The menu can be augmented by an authority and / or applicant. This is described in A 2.2.
- If the macros are too slow, the work should be completed on a local hard drive.

2.1 Insert

2.1.1 Landscape Page

This function enables the insertion of pages in a different orientation, e.g. landscape pages separated by two section breaks from the surrounding sections in portrait orientation. The headers and footers from the previous sections are retained.

2.1.2 Table Label und Figure Label

The menu points “Insert / Table Label” or “Insert / Figure Label” generate headings for tables and figures (for the structure of the numbering see A 3.2 and for the referral to these labels in the text see 2.1.3). The cursor should be positioned above the table or below the figure before giving the desired command.

Remarks:

- *Labels of tables and figures in the main document refer to the 2nd list level (Rep Heading 2 and to the 1st list level for the Appendix. If there is no 2nd list level in the main document, it will result in error indication.*
- *Therefore it is not possible to insert tables and figures under the 1st list level in the main document.*



2.1.3 Reference to Headings and Labels

This function allows cross referencing of all headings and labels (see A 3.3)

2.1.4 Table of Contents

Position the cursor where the table of contents should be inserted and activate this function (Insert / Table of Contents). This function can also be used to update the table of content by positioning the cursor in the existing one.

Remarks:

- *The format of the table of contents was set via the format template “Rep Table of Contents”.*
- *If the text already has a table of contents, it will be overwritten by the new one.*
- *The table of content includes all headings up to the 4th list level.*

2.2 Refresh

2.2.1 All Fields

All fields including heading numbers, figure and table labels and cross references will be updated.

2.2.2 Pagination and Language

This function formats the page numbers and headers and eventually erases footers in all sections of the Word document. The language of the entire text will be set to “English UK” with automatic syllable division.

2.3 Delete

2.3.1 Hidden Text

This function frees up all hidden text either in a selected section or the entire document. It is recommended to run this function before a document is officially sent out.

2.3.2 Links

If applicants or authorities are using links from the Word document into their own document management system (DMS), these links could be converted into normal text in a selected section or the entire document”.

Attention: This function deletes all links including hyperlinks to external websites (e.g. EFSA Conclusion).

2.3.3 Animation

This function deletes animated text from the entire document. It is recommended to run this function before a document is officially sent out.

2.3.4 Colours

This function deletes all character colours and text shadings from the entire document (except table and cell shadings).

Attention: This function is to be used with caution when revisions are marked with colour.

2.4 Rep Manage Templates

The following menu points refer mostly to steps taken during the compilation of chapter templates. Assessors will not normally need to use these.

2.4.1 Refresh Styles from Template

With this function it is possible to

- Assume newly defined formats from the central template into the current Word document.
- Reset all formats to the original specifications of Report.dot.

Remark: Such action may be necessary if the central template has been further developed by a central template editor and certain formats cannot be activated via the toolbar. In this case it is recommended to update paragraph formats.



2.4.2 Delete not used Styles

This function deletes all unused user-specific styles in the document from the list of available styles (see also 2.5).

2.5 Rep Styles

This menu point, together with the menu point “Rep Table Styles” (see 2.6) shows all important functions for the formatting of paragraphs and tables. The definition of the paragraph and character formats can be found in Appendix 3.

Remark: The Assessment Reports should be formatted only by paragraph formats with names starting with “Rep”. Additional paragraph format styles imported via copy and paste into the Word document should be replaced by the Assessment Report specific “Rep” formats and could be then deleted as not used styles.

2.5.1 Rep Standard Rep Label

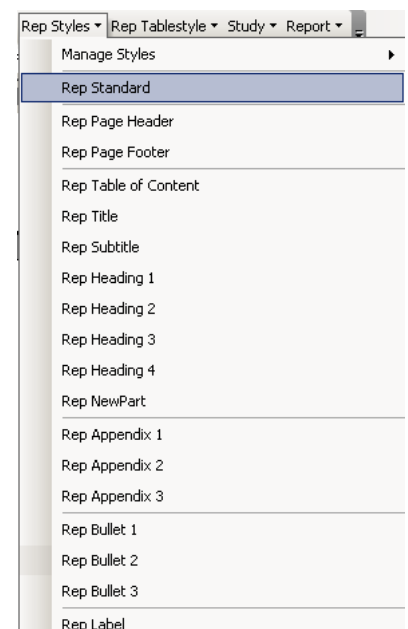
The defined “Rep” paragraph formats can be found under the Microsoft Word functions. In addition, the standard “Rep” format can be found in the Assessment Report toolbar under the menu point “Rep Styles”. This function puts marked passages into the chosen format.

Attention: The following paragraph formats will be erased when Rep Standard is chosen:

- Indentations
- Tabs

Selected sections can be formatted with a character format in addition to the paragraph format. These character formats remain intact even when passages are reformatted with Rep Standard. Examples for character formats are:

- Font style and size
- Bold, italic, subscript, superscript
- Background colour, hidden text



If it is desired that the character format is returned to the basic format, see 2.5.2. Use caution in new text passages, especially in tables.

In tables, Rep Table should be used, rather than Rep Standard.

2.5.2 Reset Fonts to Rep Template

A selected text passage is returned to the standard format with this function. This is equivalent to the Word shortcut key combination <ctrl><spacebar> (Remove character formatting), but this function is not very well known.

Attention: With this function all character formats will be deleted.

2.6 Rep Table Styles

All actions for the formatting of a table are found under this heading.

2.6.1 Rep Table Rep Table Small Bold

The basic “Rep” paragraph formats needed for tables can all be found under this menu point.



2.6.2 Reset to Table Format

This function is meant to support the standardization of the formatting of various tables.

Test ^α	Concentrat ^α e ^α	Spray- dilution ^α (dilutio n ^α factor) ^α	Formulation ^α in study ^α	Acceptability ^α of study ^α	Justification ^α provided on representativ ity of study formulation ^α for current product ^α	Acceptability ^α of justification ^α	Referenc e ^α
In- vivo ^α (rat) ^α	xxx-% ^α	xxx-% ^α	Product code/name ^α	Yes /- No /- Supplementa ry ^α	Yes (see Annex 2.11) /- Not required ^α	Justification accepted /- Endpoint can be used for current product /- Justification not accepted Endpoint cannot be used for current product ^α	Author, year ^α

Figure 2.6-1: Example for a table needing formatting

Position the cursor in the table or mark the table, then go to the menu point Reset to Table Format.

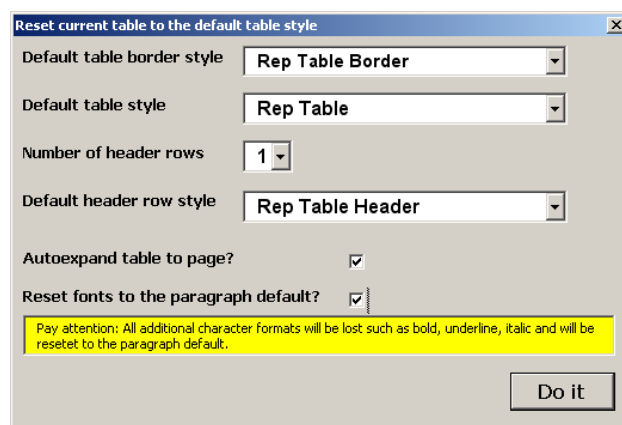
Various options for the formatting of the table can now be chosen.

The basic format is provided in “Rep Table Border”.

It can be chosen between two formats for the contents, and the amount of rows belonging to the table header can be determined.

For table headers with combined cells every row should be included.

The last option allows the cell contents to be formatted according to the basic paragraph format (default).



Test ²	Concentrations ²	Spray-dilution ² (dilution factor) ²	Formulation in study ²	Acceptability of study ²	Justification provided on representativity of study-formulation for current product ²	Acceptability of justification ²	Reference ²
In-vivo (rat) ²	xxxx % ²	xxxx % ²	Product code/name ²	Yes / No / Supplementary ²	Yes (see Annex 2.11) / Not required ²	Justification accepted: Endpoint can be used for current product / Justification not accepted: Endpoint cannot be used for current product. ²	Author, year ²

Figure 2.6-2: After running the function “Reset to Table Format”

Remark: Cells previously formatted with a “Rep Table” style, e.g. “Rep Table Small Bold”, will retain this format. Only those formats not beginning with “Rep Table” will be changed.

2.7 Help

2.7.1 User Help

Here this documentation on Report.dot will be opened, if the administrator has set the necessary parameters described in Section A 2.2.

2.7.2 Menu Version Info

The parameters set by the administrator are shown here (see A 2.2).

Appendix 1 The Report.dot Menu

Table A 1: The Minimal Toolbar

Insert 2.1	Refresh 2.2	Delete 2.3	Rep Manage Template 2.4	Rep Styles 2.5	Rep Table Styles 2.6	User Help 2.7
Landscape Page	All Fields	Hidden Text	Refresh Styles from Template	Rep Standard	Rep Table	User Help
Table Label	Pagination and Language	Links	Delete not used Styles	Rep Page Header	Rep Table Bold	Menu Version Info
Figure Label		Animation		Rep Page Footer	Rep Table Foot-note	
Reference to Headings and Labels		Colors		Rep Table of Content	Rep Table Header	
Table of Content				Rep Supertitle	Rep Table Header Small	
				Rep Table Small	
				Rep Label	Rep Table Small Bold	
				Reset Fonts to Rep Template	Reset to Table Format	

Appendix 2 Administration of Report.dot

A 2.1 Where is Report.dot located and how do documents access it?

The core Report.dot template should be saved in the template directory, whereby the workgroup template directory (read only) is recommended.

If a Word text is sent to another valuation entity, the locally existing version of Report.dot will automatically be used if a central format template with the same name exists there in one of the following directories (Word 2003):

- The actual working file location
- User templates file location
- Workgroup templates file location

There is not yet enough experience to give a full guideline for managing the different Word template directories for other Word versions.

Attention: Changes in the core Report.dot affect all Word documents that are connected to this template. The changes will take place at different times:

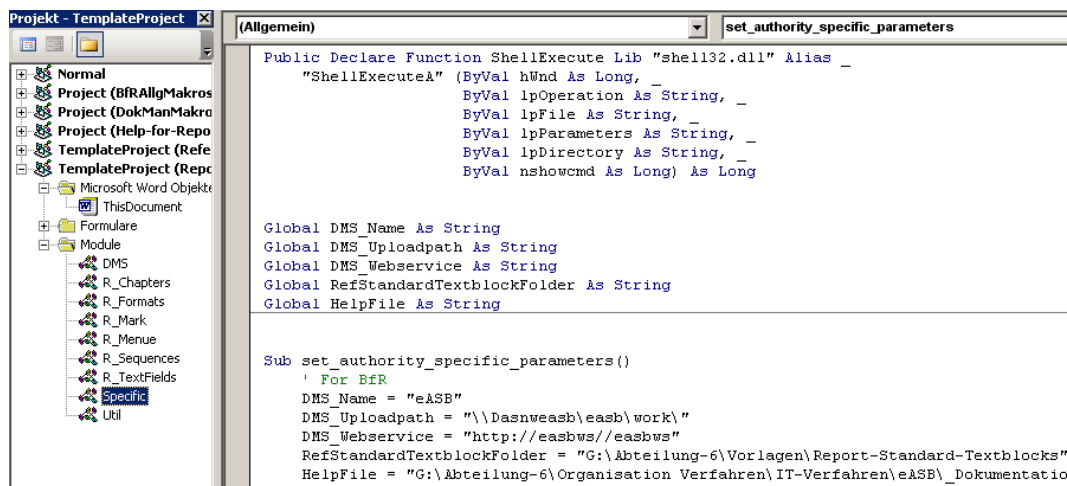
- The administration-specific toolbar is visible immediately.
- Macros are carried out according to the parameters locally set in the macros.
- “Refresh Styles from Template” activates the format changes to the template in the text.

A 2.2 Building of the menu

If Report.dot is started via “Open” (rather than double click) the Visual Basic Editor can be started with <Alt><F11>.

The following authority-specific parameters can be defined with the macro “set_authority_specific_parameters” in the “Specific” module:

- DMS_Name Name of the Document Management System
- DMS_Uploadpath Index for the uploading into the DMS
- DMS_Webservice Web service for the DMS
- RefStandardTextblockFolder Index for the insertion of study templates
- HelpFile Name of the help file



An administrator can adjust the module “R_Menu” for further specific needs of the authority / applicant. This can take place via comments on menu points.

If the macro “R_menu.Create_Assessment_Report_Menu()” is started, a new version of the toolbar “Assessment Report” will be formed with the defined authority-specific parameters. This toolbar should then be put at the final position where it should be visible for the user.

Remark: The connection of the BfR specific Document Management System is already realized. The connection to other authority specific Document Management System would be possible with own VBA code but is much more complex than the adaptation of the menu.

Appendix 3 Specific Settings

A 3.1 Rep-Formats

The benefit of Report.dot is the standardization of the styles used. All format names begin with Rep as a synonym for report. If this name is used for the format, the cross-effects will be minimized when copying from other texts. The range of formats is shown in the following figure:

Figure A 1: Collection of Rep Formats

Formatierung löschen	Appendix 1 Rep Appendix 1	A 1.1 Rep Appendix 2
A 1.1.1 Rep Appendix 3	A 1.1.1.1 Rep Appendix 4	A 1.1.1.1.1 Rep Appendix 5
A 1.1.1.1.1.1 Rep Appendix 6	• Rep Bullet 1	o Rep Bullet 2
• Rep Bullet 3	Rep Editor Note	Rep Editor Notes
Rep Editor Notes MS	Rep Label	Rep NewPart
Rep Page Footer	Rep Page Header	Rep Standard
Rep Subtitle	Rep Subtitle Bold	Rep Supertitle
Rep Table	Rep Table Bold	Rep Table Border
Rep Table Footnote	Rep Table Header	Rep Table Header Small
Rep Table of Content	Rep Table Small	Rep Table Small Bold
Rep Textoption	Rep Title	Rep Title Bold
Prefix.1 Überschrift 1,Rep H1	Prefix.1.1 Überschrift 2,Rep Headin	Prefix.1.1.1 Überschrift 3,Rep Head
Prefix.1.1.1.1 Überschrift 4,Rep He:	Untertitel	Verzeichnis 1
Verzeichnis 2	Verzeichnis 3	Verzeichnis 4

A 3.2 Table and Figure Labels

Tables and figure labels are positioned above the objects with the format “Rep Label”.

If the table or figure is in the main body of the text (rather than in the Appendix) the title will consist of the following components:

- Type (Table or figure)
- Non-breaking space
- Chapter heading of the 2nd level
- Hyphen
- Continuing number for tables and figures (counts from the beginning in every chapter of the 2nd level)

Attention: Tables and figures in the main text body can only be in chapters of the 2nd list level (or higher). Furthermore, the type is a fixed part of the label at the time of insertion.

For example: Table 2.10-1.

For labels in the Appendix:

- Type (Table or figure)
- Non-breaking space

- Chapter prefix (A)
- Non-breaking space
- Continuing number for tables and figures within the entire appendix

For example: Table A 2

A 3.3 Cross references

Within a document cross references are possible to the following:

- Chapter headings
- Table and figure headings
- Cross references to chapter headings include the complete chapter number, while those to tables and figures to the complete title.

Examples:

see 2.3.1

see Table A 1

see Figure 2.6-1