

Manual for applicants

This manual contains instructions on the structure and format of dossiers for plant protection product applications other than administrative applications. These include the following types of application:

- NLKUG: Application for national extension in the Netherlands of an existing authorisation with minor uses only
- NLRG: Application for zonal renewal of plant protection product authorisation with the Netherlands as the Member State concerned
- NLTG: Application for zonal authorisation of a plant protection product with Netherlands as the Member State concerned
- NLWERGZ: Application for national authorisation of a plant protection product via mutual recognition
- NLWG: Application for national amendment of the legal instructions for use (WG) of the Netherlands-specific requirements for a plant protection product
- NLWTG: Application for zonal amendment of a plant protection product authorisation with the Netherlands as the Member State concerned
- ZRG: Application for zonal renewal of plant protection product authorisation with the Netherlands as rapporteur
- ZTG: Application for zonal authorisation of a plant protection product with the Netherlands as rapporteur
- ZTG-LR: Application for zonal authorisation of a plant protection product based on low-risk substances with the Netherlands as rapporteur
- ZWTG: Application for zonal amendment of a plant protection product authorisation with the Netherlands as rapporteur
- ZWTG-LR: Application for zonal amendment of a plant protection product authorisation based on low-risk substances with the Netherlands as rapporteur

The new file format will go into effect on 1 May 2024 and will be mandatory from 1 July 2024. Please note! Failure to comply may result in your application not being accepted.

Alternatively, it will also remain possible to submit an application using the CADDY format.

If you have any questions on this topic, please contact the Ctgb Service Desk: servicedesk@ctgb.nl

General administrative requirements

1. Folder structure:
 - a. No changes should be made regarding the order, naming or structure of folders
 - b. All documents should be saved in the existing folders (except for the spreadsheet 'Meta-data_Ctgb_Document_Submission' described below)
 - c. Not all folders may be needed for your application. These folders may be left empty.
2. Documents:
 - a. Naming:
 - i. File names must be unique; multiple documents with the same title may not be submitted
 - ii. File names must be shorter than 256 characters, file extension included
 - iii. File names must **not** contain the following characters: " * : < > ? / \ |
 - iv. Do not use leading and trailing spaces in file names
 - b. Files should be submitted in in Open format (ODT) but preferably as Microsoft Word, Microsoft Excel, PDF (Acrobat)
3. Fill in the spreadsheet 'Meta-data_Ctgb_Document_Submission' with descriptive data of the submitted documents:
 - a. The naming, order and structure of the columns must not be changed
 - b. A distinction is made between study reports and other documents. Study reports require different descriptive data than other documents. Orange-coloured columns are compulsory for each document.
 - c. **The file name that is entered in column A must be identical to the name of the document itself**
4. In the dossier, place the spreadsheet 'Meta-data_Ctgb_Document_Submission' outside the folders at the same level as the *Registration and Risk Assessment and Study Reports* and *(public) Literature* folders

Folder structure and Meta-data

The folder structure is broadly based on that of CADDY-xml from CropLife ([link](#)). The full completed folder structure is shown in Annex 1.

At the top level a separation is made between the documents for the Registration and Risk Assessment on the one hand and Study Reports and (public) Literature on the other.

1 Registration and Risk Assessment

The main folder for application and risk assessment follows the format of a zonal dossier:

Part A - Risk Management

Part B - Data evaluation and Risk Assessment, the risk assessment with sub folders B0 to B10

Part C - Confidential Information

Part D - Additional Documentation, with the sub folders MSDS, LoA, WG GAP, Application Form, Statements and Cover Letter

Part E - Other*, with the sub folders Model Input-Output, Original Authorisation (in the case of a WERG), Comparative Assessment and Non-assignable (not assignable to any of the other parts)

* applicants are allowed to add their own folders within the sub folders of Part E. However, this is **not** allowed in any other folders within the folder structure.

2 Study Reports and (public) Literature

A distinction is made between studies based on an active substance or a metabolite (the KCA folder) and studies based on a product (the KCP folder). Literature should be placed in the (public) Literature folder.

These three folders each have a number of sub folders corresponding to a component or aspect (folder Section 1 to 12).

Meta-data

Meta-data is data about the documents you submit.

The meta-data should be submitted in the spreadsheet 'Meta-data_Ctgb_Document_Submission' developed specially for this purpose. The first column contains the unique name of the file that is located in one of the folders within the folder structure described above, so that the file and its meta-data can be linked. The meta-data for the Registration and Risk Assessment section is quite limited; the meta-data for the Study Reports and (public) Literature section is more extensive.

For all documents in the main folder Registration and Risk Assessment, please enter the following document data in the spreadsheet:

Document Name	File name
Main Folder Name	Name of the main folder (e.g. Part D)
Sub Folder Name	Name of sub folder (e.g. MSDS)
Company Filenumber	Applicant's document number

For all documents in the main folder Study Reports and (public) Literature, please enter the following document data in the spreadsheet:

Document Name	Name of file (study report or article)*
Annex Point	Annex Point of the study (e.g. Data point, first column on reference list Part A)
Authors	Authors (surnames, separated by commas)
Date Report	Date of publication (dd-mm-yyyy)
Title Study	Title of the study or article
Test Facility	Name of the test facility where the study was conducted
Dossier Filenumber	Report number of the test facility
Company Filenumber	Applicant's report number
Sponsor	Sponsor of the study
GLP / GEP	GLP / GEP/ N/A
Published	Public (Yes/No)
Confidential	Confidential (Yes/No)
Vertebrate Study	Vertebrate study (Yes/No)
Protect	Data protection claimed (Yes/No)
Company Name	Legal owner of the report

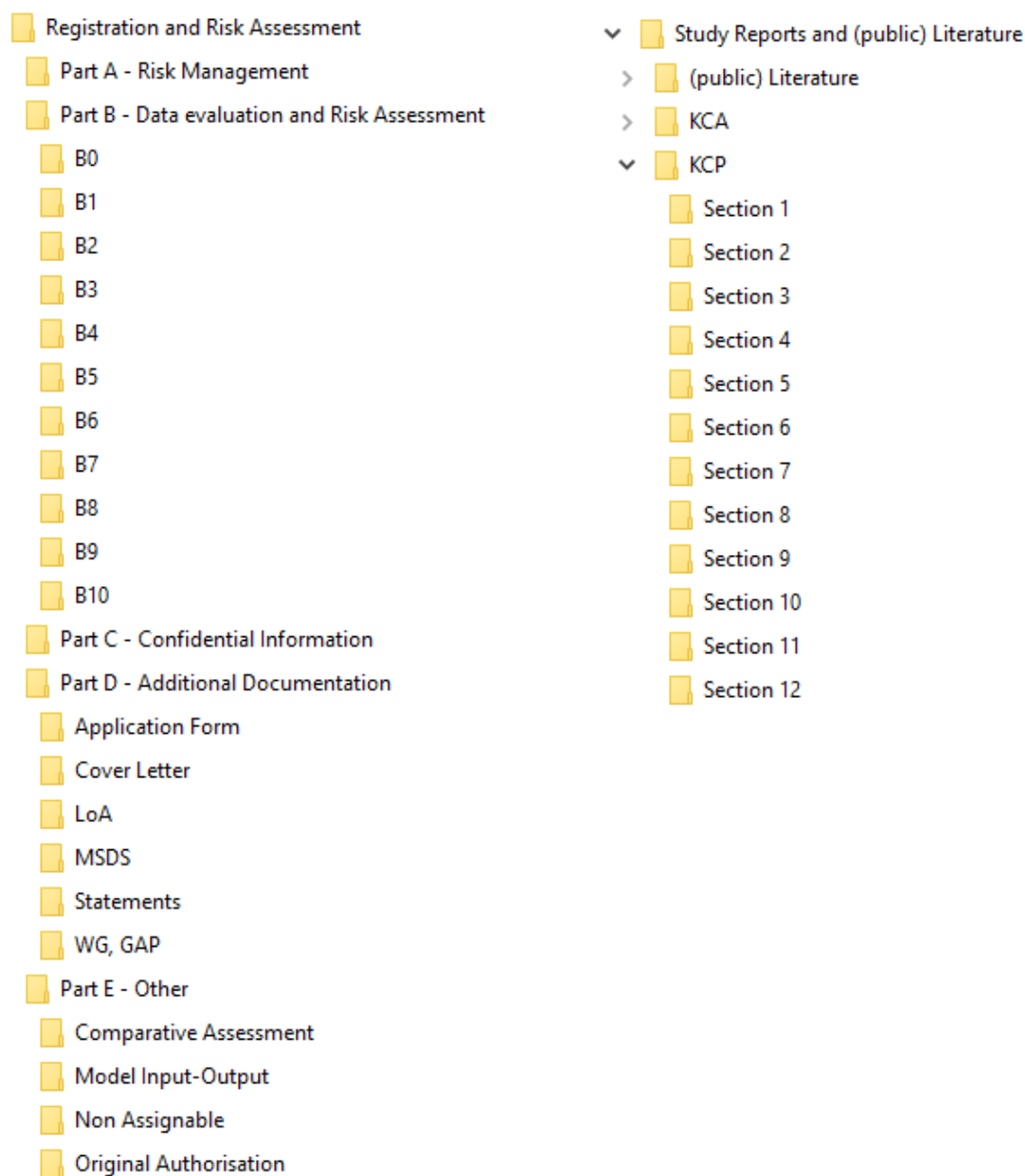
* The recognition of a document depends on clear and consistent naming. The Ctgb is aware that you have your own naming system. Linking each individual file with its associated document data (meta-data) improves document recognition. Nevertheless, we would like to use this opportunity to stress the importance of a name that is understandable to Ctgb, i.e. the name should refer clearly to the contents of a file.

Note:

The reference list may also be used to fill in the Excel-file with the necessary meta-data regarding study reports, as the majority of the required meta-data is noted in the reference list.

By exporting the reference list from Word to Excel, it is possible to transfer the data in each column per row to the meta-data columns in the Excel-file using the [DEEL](#) (page in Dutch) functionality in Excel.

Annex 1 New folder structure*



* The sub folders (public) Literature and KCA in the main folder Study Reports and (public) Literature also contain the underlying folders Section 1 to Section 12 as shown under the sub folder KCP