



Joint CADDY-xml Steering Group presents

CADDY-xml Version 1.1.0 proposal 5

**An XML-based Interchange Format
for Pesticides Registration Applications**

ECPA DTWG

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1 About the CADDY-xml Specification

1.1 Background

This document describes CADDY-xml, an electronic dossier interchange and archiving format for modifications of plant protection products. CADDY stands for **Computer Aided Dossier and Data supply** and was introduced in 1996. The CADDY-xml standard is an extension of the current CADDY 2.0 specification and is intended to support the demand for standardized data-exchange through the **[XML]** format between the applicant and the national competent authority. CADDY-xml is additionally designed to adequately support the product specific lifecycle.

Compared to CADDY, CADDY-xml is extended by a lifecycle management mechanism, helping notifiers and authorities to reduce costs and shorten the evaluation time.

1.2 Reading of this Specification

The specification has been written with various modes of presentation in mind. In case of a discrepancy, the online electronic version is considered the authoritative version of the document.

This document uses the terms **must**, **must not**, **required**, **shall**, **shall not**, **recommended**, **should**, **should not**, **may**, and **optional** in accord with **[RFC 2119]**.

1.3 How the Specification is Organized

The specification is organized into the following chapters:

Chapters 1 and 2

The introduction outlines the design principles and includes a brief tutorial on CADDY-xml. The second chapter gives an overview of general considerations to take into account for the submission of a CADDY-xml dossier.

Chapters 3 to 6

CADDY-xml reference manual. These chapters describe the XML elements directory structure and more **[XHTML]**.

Appendices

The appendices contain normative references for CADDY-xml, information on references, and other useful information.



1.4 Documentation Conventions

The following typographical conventions are used to present technical material in this document.

Official terms are defined in the following manner: [Definition: You can find most **terms** in chapter 6.4 References]. Links to **terms** may be specially highlighted where necessary.

The XML representations of various elements within CADDY-xml are presented using the syntax for Abstract Modules in XHTML Modularization.

Examples are set off typographically:

Example: Example item

`Example Item`

References to external documents appear as follows: **[REF]** with links to the references section of this document.

Sample Reference

Reference - linked to from above.

The following typesetting convention is used for non-normative commentary:

Note:

A gentle explanation to readers.

1.5 Remarks for Version 1.1.0

This version of the CADDY-xml specification stands for its own. It will be as much compatible with former versions as possible but is it not kept downward compatible to keep it lean. Changes are only made where there are helpful for the overall usage but may result in conflicts. See 1.1 for details of the changes.

2 Introduction to CADDY-xml

2.1 Overview

CADDY-xml is based on CADDY 2.0 but introduces some differences. Primarily the exchange format is XML based. In general CADDY-xml supports everything needed to submit electronic dossiers to authorities. It maintains general information, a table of contents, confidential, and non-confidential documents, report information and hyperlink information. Additionally, a CADDY-xml based dossier can be instantly viewed with a common web-browser supported by Acrobat Reader.

This standard is flexible to accommodate to different dossier structures such as OECD and EU based standards.

A CADDY-xml submission consists out of a well defined directory structure and an XML file that describes the meta-information of the submission. The XML-file can be thought of as the backbone of the dossier. It references every document that is included within the directory structure.

In a nutshell CADDY-xml is composed of product information, a table of content and a list of documents.

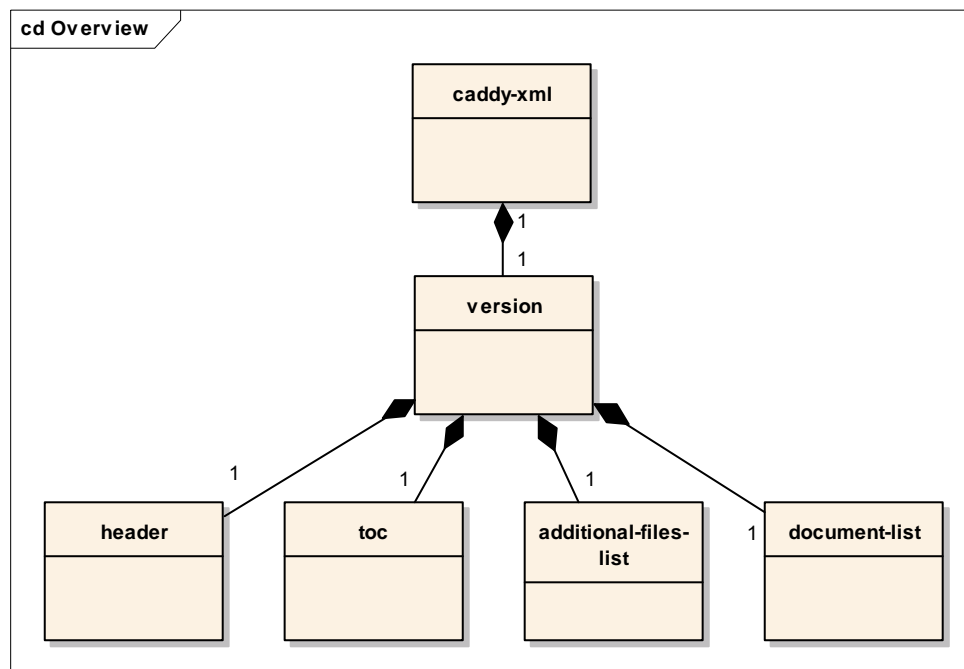


Figure 1: XML-Backbone Overview

The product information, called header, provides a summary describing the product. It consists of optional dossier-related attributes, product, active substance, concentration and company information. The table of contents lists the chapters hence the logical structure of the documents. Any table of

contents item has its numbering-scheme and name. A version history list gives information about all the changes made compared to the former submission version. A list of documents and reports that contains references to the files and to optional report data or attached files is an additional component of the CADDY-xml specification. See Figure 1: XML-Backbone Overview.

The element “version-history-list” was removed in CADDY-xml specification 1.1.0. The information stored there can be seen as duplicate as information can be rebuilt via document-list. Removal of version-history-list as a separate element eliminates the potential risk of having inconsistencies in submissions.

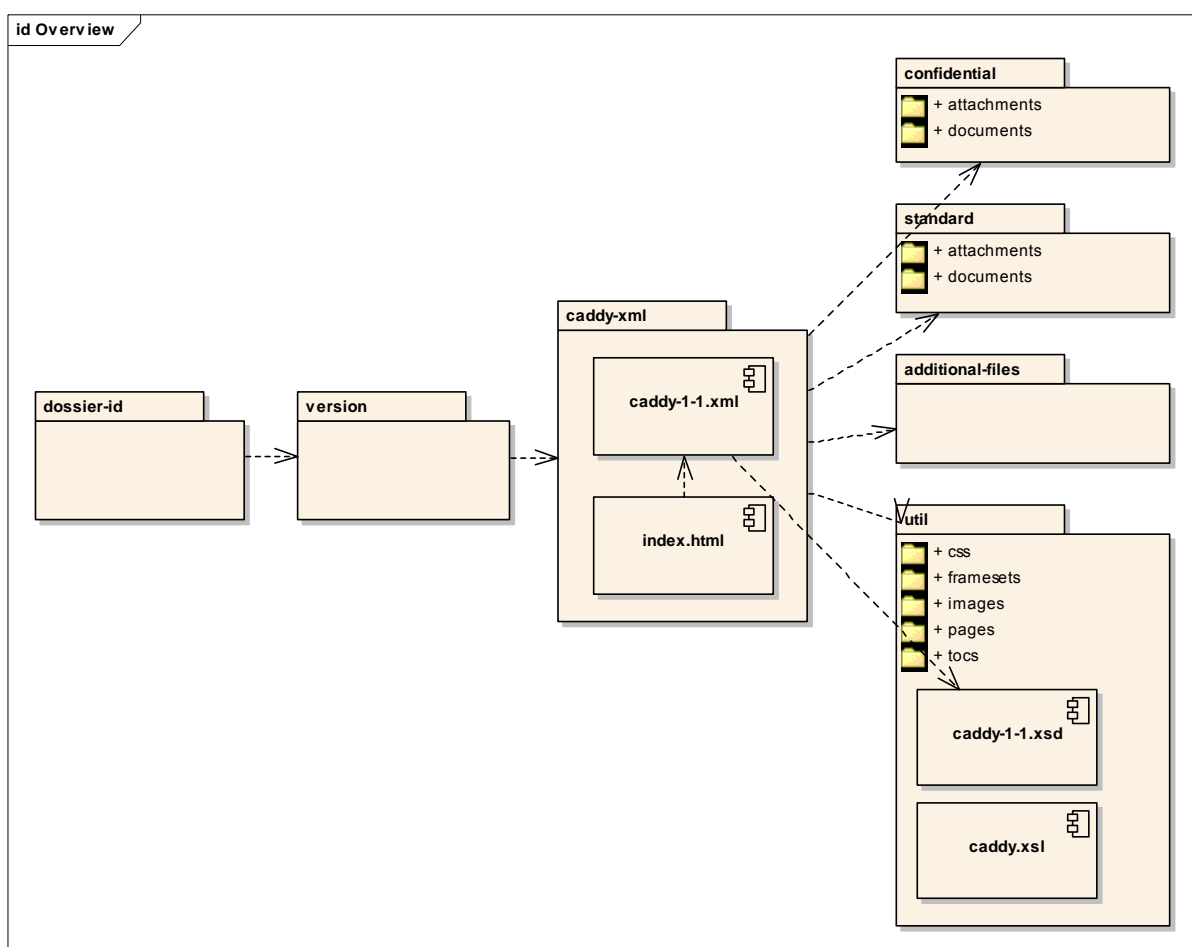


Figure 2: File-System Organization

In general, a dossier contains the XML backbone-file combining all information mentioned above and the submitted documents. The files are organized in a file-system directory structure allowing the differentiation between confidential and standard documents. The entry point for each submission is either the **caddy.xml** or the **index.html** file. The latter allows a direct access to the web based representation of the dossier. See Figure 2: File-System Organization



Documents in the CADDY 2.0 standard are page-based TIFF-standard files representing each page. CADDY-xml is document-based where the preferred file format is PDF. Using PDF as a document format allows viewing of CADDY-xml dossiers without separate viewing software; a compatible web-browser is sufficient. On the other hand, replacing, deleting, or replacing single pages or appending pages cannot be done transparently. Each of these actions will result in a replaced document. Hence a reviewer may not be able to see the changes instantly. Therefore, in CADDY-xml each document has a status and when there is a change there is a comment representing the changes made to the document. Additionally, the version number where the document was introduced is also noted, so recent changes can be identified easily.

2.2 Matching the concepts of CADDY 2.0 with CADDY-xml

This document describes CADDY-xml. The design of CADDY-xml combines the advantages of recent XML technology in addition to the achievements of the CADDY 2.0 standard. Based on the new technologies which are addressed by CADDY-xml new concepts and terminologies have been introduced which are different from the well known CADDY 2.0 concepts and terminologies.

The content within a CADDY 2.0 submission is based on single based TIFF pages which are referenced within a submission specific table of content. CADDY-xml is not referencing single TIFF pages anymore. The smallest entity containing submission specific content is called a *document* within CADDY-xml. Thus CADDY-xml does not concentrate anymore on the well ordered referencing of single pages but on the referencing of *documents*.

Within CADDY 2.0, the information of the submissions structure as well as additional dossier data is organized in terms of a set of indexing files. Based on the achievements of XML technology, the entire structural representation of a submission and additional dossier data is now represented within the XML backbone.

As an enhancement from CADDY 1.1 to CADDY 2.0, CCFs (CADDY Controlled Files) have been introduced. Within the CADDY-xml standard the concept of CCFs is from now covered by *attachments*.

3 General Considerations

This chapter discusses the various aspects of the CADDY-xml in detail. The focus is set to the explanation of the CADDY-xml aspects. The following chapter is meant to be a reference showing all the details.

3.1 The XML-Backbone

As previously mentioned the XML-backbone represents a file that stores all relevant data of the dossier, except the documents and attached files. This file is placed in the root directory of each version of a dossier (See [XML]). The file format is XML, a widely used and well understood standard for data-exchange.

Each version of a dossier is represented with a separate XML-backbone file that covers all information of the version. This allows viewing the current version without reference to previous versions.

The XML-backbone file contains the following groups of information:

3.1.1 Definition

Any XML file has a definition file that defines its structure. This structure is defined using the [XML Schema] definition language. This file also defines the rules for CADDY-xml. Hence each XML file must reference the XML definition file. This reference is one of the first instructions.

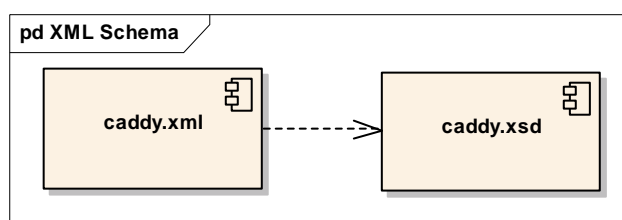


Figure 3: XML Schema

3.1.2 Specification Version

To allow the CADDY-xml standard to evolve a specification version stored in the topmost element allows a mapping of the correct XSD-version used for validation and structure enforcement independently from the delivered XSD-file.

This specification version is introduced with the CADDY-xml standard version 1.1.0. If no specification version is given the former CADDY-xml version 1.0.1 is assumed as the default.

Having a specification version allows that the different CADDY-xml versions may not be up or downward compatible to keep the standard lean.

3.1.3 Version

The central element in CADDY-xml is the version. The version groups all other information. A submission uses a version numbering scheme that allows distinguishing between major and minor versions. By definition a submission with a minor version equal to zero must contain all documents. A submission with a minor version above zero must contain at least all changed documents.

3.1.4 Header

A header groups the information for a dossier version. These are title, authority, company, product information, active substances and their concentration. Versioning of the header information allows determining changed values.

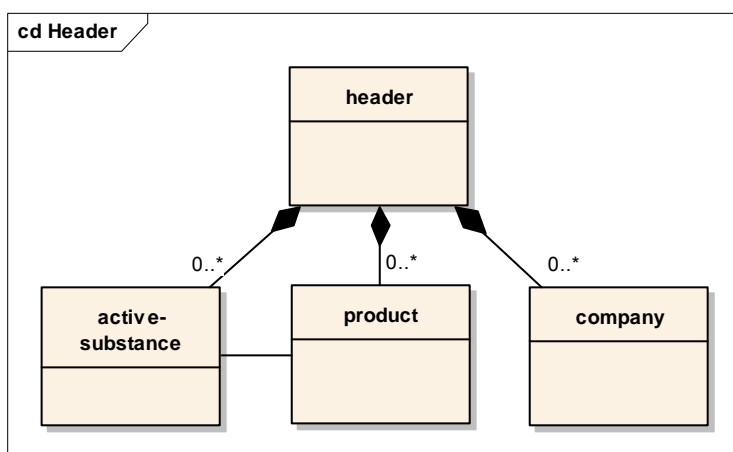


Figure 4: Header

3.1.5 Table of Contents

The table of contents describes the structure of the submitted dossier. Basically any hierarchical structure can be expressed within CADDY-xml.

CADDY-xml may reference a Standard TOC (See 3.2). Such Standard TOCs are defined in extra XML files which can be used by validators to check the structure of the submitted table of contents. A reference to a Standard TOC is optional but may be mandatory for some regulatory authorities.

A table of contents element consists of a unique ID, a structuring number (e.g. Annex point) and heading title (e.g. section title). A table of contents element may contain other table of contents elements as a child.

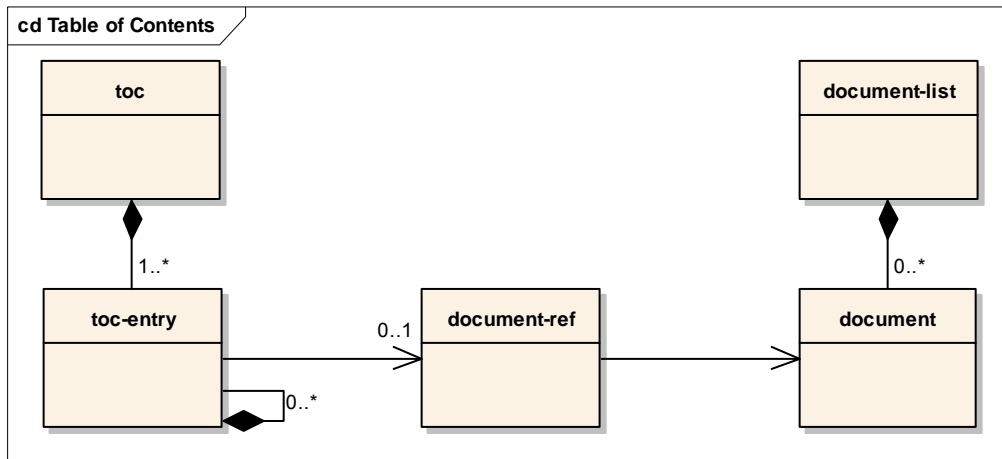


Figure 5: Table of Content

Each table of contents element may also have a reference to one document. From several table of contents elements CADDY-xml allows to reference to the same document.

To allow a better control about an empty document reference a table of content element can optionally flagged as 'intentionally left blank'. Such a TOC entry explicitly must not have a document reference and shall be treated as "not missing" by validators or viewers. Instead these programs shall generate an empty "Intentionally left blank" page showing the optional comment.

3.1.6 Documents

The XML-Backbone maintains a list of documents. This list is separated from the table of content to support one document in different table of content sections. For archiving reasons the document must be a PDF or an XML document. Documents cannot be included in an XML file, so the location within the file system is also noted in the XML-backbone. See Figure 6: Document List

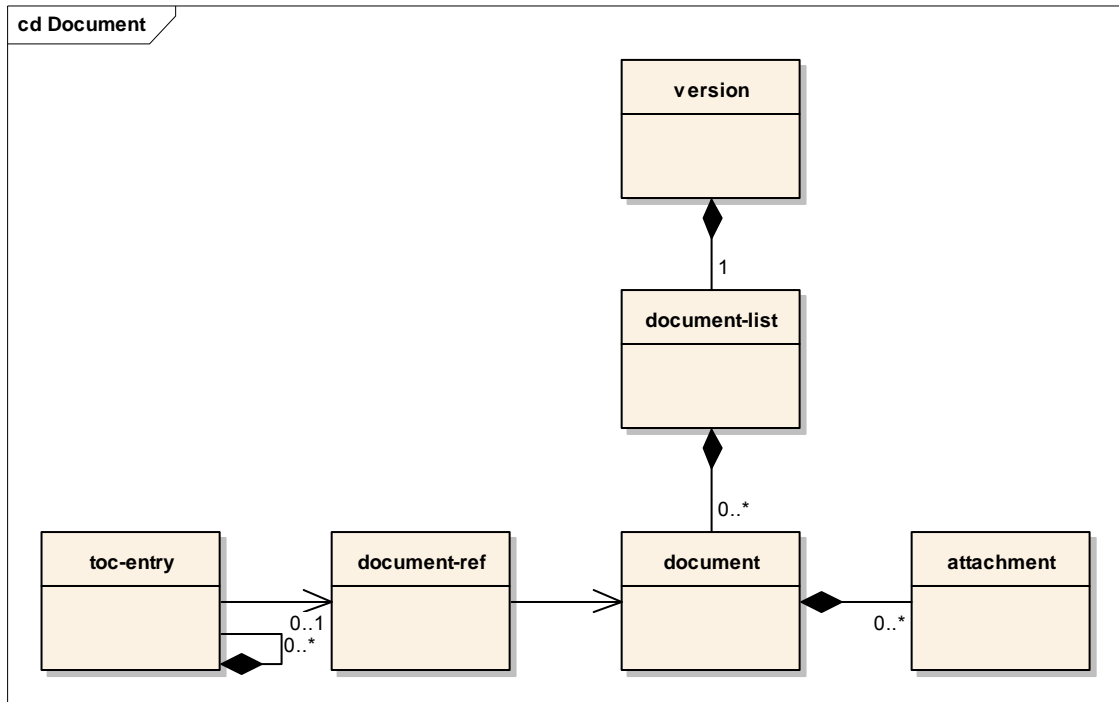


Figure 6: Document List

For document lifecycle reasons and for review purposes the document has states and a version number representing the dossier version it was introduced.

CADDY-xml introduces a document operation. The document operation introduced by the [eCTD] standard gives the opportunity to support reviewers with an assignment of the intention of this document. Supported operations are **new**, **deleted** and **replaced**. To explicate the operation an optional comment should be filled out.

Access to documents can be controlled via the confidential attribute that must be either set to be true or false. Confidential files are stored separately from standard files. See 3.4

To ensure data integrity referred to in section 3.5, a checksum exists that gives each document a unique identifier. The checksum algorithm that must be used is the MD5 code. [RFC 1321] This will identify that the document is the same.

The directory structure for documents is defined in section 3.4. For file formats or names, refer to 3.8.

Optionally a document can be described in a formal way using report data, referencing several attributes like authors, document date, title, owner, and the flags GLP, published and data protection.



3.1.7 Attachments

Documents may refer to additional files that are called attachments in CADDY-xml (CADDY 2.0 refers to these files as CADDY controlled files). These files are meant for several purposes. An optional comment can be defined. The purpose values are defined in section 3.8.2.

Each attachment file can be uniquely associated to one document. The access to attachments is controlled via the confidential flag of the according document. Hence confidential documents imply confidential attachments.

The directory structure for attachments is defined in section 3.4. For file formats or names refer to 3.8.2.

3.1.8 Additional Files

Submissions based on CADDY 1.1 and CADDY 2.0 may reference additional files to the submission for review purposes. CADDY-xml may also contain a helper directory called “additional files”. This directory can be seen as transfer container to submit files which do not belong to specific documents and must not be treated as attachments.

3.1.9 Hyperlinks

Each table of content entry may contain hyperlinks guiding reviewers through the submission. A hyperlink is defined having a source and a destination. Compared to e.g. web-pages having the hyperlink within the document (implicit), CADDY-xml uses explicit hyperlinks. Due to this definition, CADDY-xml doesn't store hyperlinks within a document. Changes to the dossier table of contents do not enforce replacing of documents, like with implicit hyperlinks.

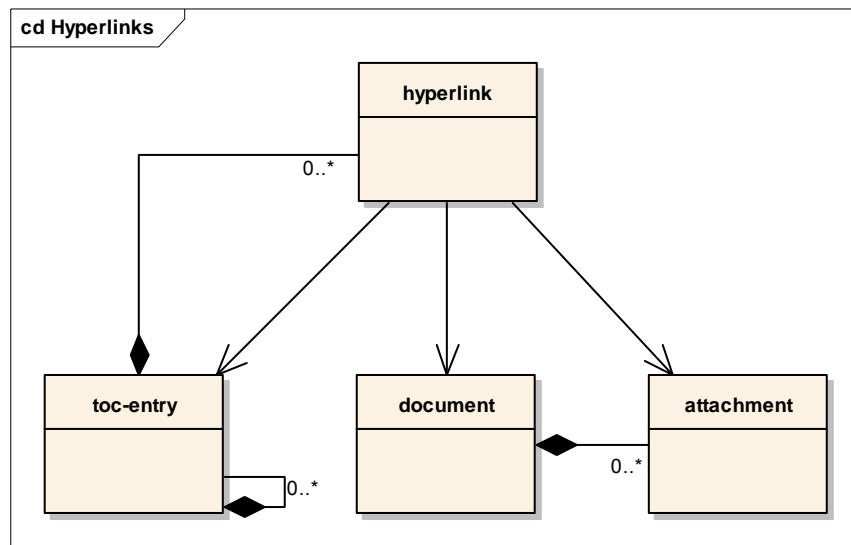


Figure 7: Hyperlinks

Explicitly representing hyperlinks implies a definition of the source. The source can be either the table of content entry itself, a specific document or an attachment. If the source is noted to be a document, the hyperlink must be described additionally with a page number and a rectangular region placed on that page. Each hyperlink must have a title describing the target. Often a section name in the bookmark structure is sufficient. See Figure 7: Hyperlinks.

The destination of a hyperlink can be another table of content entry, a document, or an attachment. Having defined a document as the destination, the precise position can be defined either by a named destination or by a page. Default is the first page of the document. See [Adobe-Ref]

Example:

Opens a document at the bookmark "named_destination".

```
prodlist.pdf#namedest=named_destination
```

Opens a document on page 12.

```
prodlist.pdf#page=12
```

3.2 Standard Table of Contents

Introduced with CADDY-xml specification 1.1.0 a Standard Table of Contents (Standard TOC) allows the definition of official table of contents structures. The CADDY-xml files should reference such a Standard TOC and must then define a table of content which is compliant with the structure the Standard TOC defines. To ensure remaining flexibility the Standard TOC shall define table of content elements as extensible where appropriate and define restrictions for document references.

3.2.1 Definition

Like CADDY-xml a Standard TOC has a definition file that defines its structure. This structure is defined using the [XML Schema] definition language.

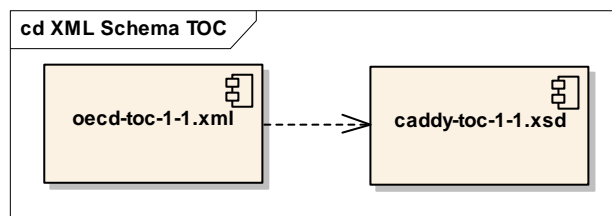


Figure 8: XML Schema

3.2.2 Specification Version

To allow the Standard TOC to evolve it must have a specification version stored in the topmost element. This allows a mapping of the correct XSD-version used for validation and structure enforcement.

Having a specification version the different CADDY-xml Standard TOC versions may not be upward or downward compatible to keep the standard lean.

3.2.3 Table of Contents

The table of contents elements describe a structure for a Standard TOC. It consists of a structuring number (e.g. Annex point) and heading title (e.g. section title) but has no Id as there is no relation to other elements. A table of contents element may contain other table of content elements as a child.

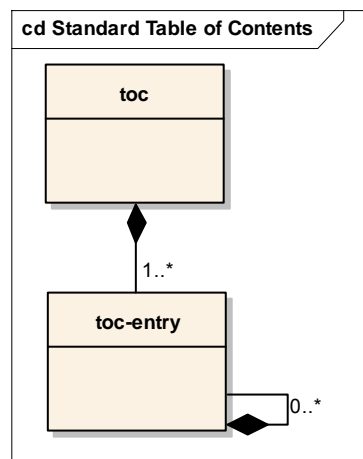


Figure 9: Standard Table of Content



To allow a definition of slightly flexible structures each table of content for a Standard TOC can be defined as extensible which allows additional table of content elements. Furthermore the occurrence of documents in the dossier must be specified for each table of content entry. Document references shall be marked as **required** (mandatory), **allowed** (optional) or **prohibited** (not allowed at all).

3.2.4 Validation of Authenticity

Standard TOCs will be made available by ECPA. To ensure integrity these files are secured by a checksum which is stored in a separate file distributed together with the actual Standard TOC file. The checksum will be generated from the unchanged content of the file and is based on MD5 [RFC 1321]. The result will be stored in an extra file (without line wraps) using the same name but with the extension “.md5” instead of “.xml”.

3.2.5 Directories and Filenames

A Standard TOC may be distributed in the CADDY.xml directory structure with the directory ‘tocs’. As validators shall use the official versions of Standard TOCs the file will usually not be referenced. Transmitting the used valid Standard TOC only allows a convenient inspection (via a compatible Web browser) of the used standard.

The filename of a Standard TOC should have the TOC version number within the filename e.g.:
OECD-CADDY-xml-TOC-01-00.xml.

3.2.6 Validity and Distribution of Standard TOCs

Standard TOCs are downloadable from the official ECPA website. Download can be located via the following URL: http://caddy.ecpa.eu/format_specification.html#Downloads.

All official supported Standard TOCs will be made available via this page. At the date of this specification the following downloads are available:

TOC Name	TOC Version	Specifcaton Version	URL
OECD-CADDY-xml-TOC-01.00	01.00	01.01.00	http://caddy.ecpa.eu/download/OECD-CADDY-xml-TOC-01-00.zip

A Standard TOC version must be treated effective (i.e. allowed for usage) as long as the correct date is between the “validFrom” and “validTo” dates specified in the header. An attribute “substituteVersion” will allow a replacement of a previous effective version. Such a replacement should be recognized and the new Standard TOC should be used instead of the previous one. Only an effective Standard TOC



version can replace a previous version. As long as the new version is not effective the replacement is only a hint for the future of the Standard TOC.

3.3 Version Handling of Submissions

The CADDY-xml standard supports two modes to submit a dossier: complete and incremental. Complete submissions must contain all documents, incremental only those that have been changed from the former version. To simplify the creation of review software and to deal with removed or modified hyperlinks the TOC structure must always be included completely.

Deleted files will not be part of the TOC structure any more. Hyperlinks defined in previous submissions of such effected toc entries shall be removed.

Due to processes that are well defined between submitter and authority, the first submission evolves with the help of a rapporteur country. During this evolvement only the minor part of the version number will be advanced and only the newly added or changed files will be transferred.

On the other hand it may be favourable to submit complete dossiers as one version instead of submitting all versions. With creation of a new major version all files will be placed in the same version directory, regardless in with version they were originally submitted. Multiple times replaced files will only be submitted in their last version but deleted files will not be included in a submission. To allow a simple recognition of deleted files, the former document element shall be kept in the document-list with the filename of the last submission.

CADDY-xml defines to use incremental submissions for subversion unequal zero and complete submissions if the subversion is zero.

See Appendix (section 6.3) for a sample dossier which demonstrates the different aspects of versioning.

3.4 Directory Structure and Volume Handling

The submission of a CADDY-xml dossier may be transferred to the authorities on any kind of electronic media agreed upon with the agency. The authority is responsible to copy the submission into the file system or into an appropriate CADDY-xml review system. All confidential documents are placed in a separate folder and can be separated from the standard documents.

The root folder of a submission must be named with the unique dossier ID. See 4.18.9. It is recommended to submit all documents of a CADDY-xml version with one media. If it is distributed over more than one media the directory structure on all media must be the same and the 'utils' and 'tocs' directory as well as the 'caddy.xml' file must be placed within the version directory of the first media.

A submission may reference documents or attachments from previous versions. To support this all versions of a dossier must be placed within the same folder. The folder name must be the same as the version attribute of the submission.

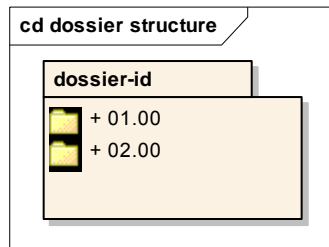


Figure 10: Dossier Structure

The folder for each version must contain the file system structure outlined in Figure 11: Version Structure. The 'standard' and 'confidential' folders host the reports and attachments. The 'additional-files' folder contains the files that are meant to support the whole dossier. The 'utils' folder contains the style sheet, the XML schema file, and additional files used for the HTML presentation of the dossier.

All filenames and paths are restricted to a maximum summarized length of 250 characters. It is highly recommended to not have a length of more than 200 characters to allow the storage of dossiers in an existing directory and still not override the total path length of 256 characters to allow an access in filesystems which restrict the length of filenames and/or paths.

Furthermore a directory must not have more than 500 files in total. Depending on the affected directory such files need to be put into additional subdirectories instead.

For the 'documents' and the 'attachments' directories (also their sub- directories), the names of the additional subdirectories must consist of 3 numeric characters starting from '000' and continuing consecutively. The extra directory level may be used from the beginning even if less than 500 files are included.

For the 'additional-files' directory or the supporting directory of XML files (See 3.8.1) the additional subdirectories may use an individual naming but need to respect the length restriction from above for the resulting complete file path.

The following filenames have to be used:

Filename	Path	Description
caddy.xml	version	The XML backbone file containing the information of the submission version.
caddy-1-1.xsd	version/utils	The XML Schema definition file that validates the submission and its structure.
caddy-1-1.xsl	version/utils	The style sheet that is used to present the submission within a web browser.
caddy-toc-1-1.xsd	version/utils/tocs	The XML Schema definition file that validates a Standard TOC for a submission. (Optional)
caddy-toc-1-1.xsl	version/utils/tocs	The style sheet that is used to present a Standard TOC within a web browser. (Optional)

For the filenames that must be used for documents, attachments or additional files refer to section 3.8 which describes the nomenclature in detail.

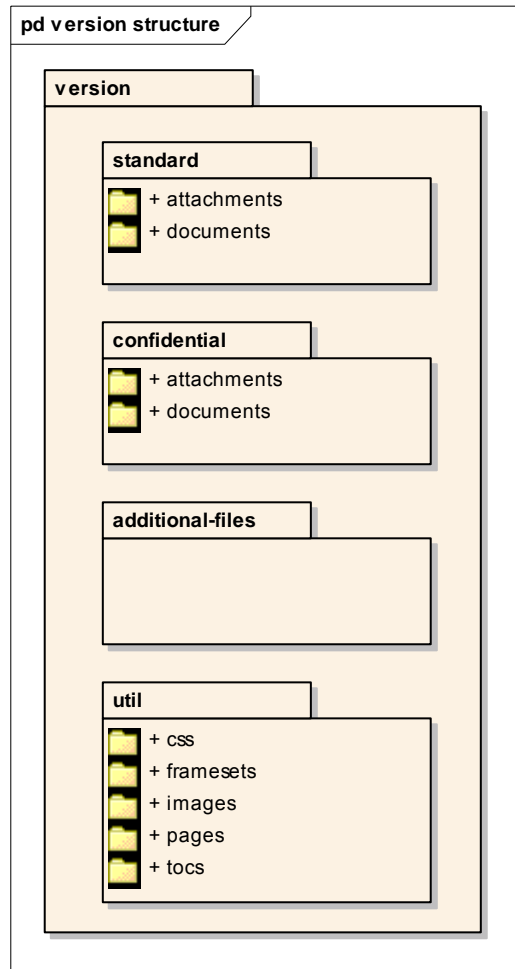


Figure 11: Version Structure

3.5 Document Integrity

Documents, attachments and additional files are protected with checksums. The intention of this checksum is to verify the uniqueness of a file. The algorithm used for the checksum generation is described in [RFC 1321]. Its purpose is to identify the content of a file to be unique. Any change within a file will result in a different checksum. This allows the submitter and authorities to protect from unintentionally changed files.

3.6 Document Status

CADDY-xml defines states that allow identifying the changes that have been made to a document.



Operation	Description
new	If a document is newly added to a submission
deleted	If a document has been deleted
replaced	If a document has been replaced by another document

3.7 File References

The references to files within the submission is done with the xlink:href attribute, see [XLink]. The URL that is used for reference must contain a relative path including the submission version where the document was submitted last. This is independent to the attributes addedVersion or changedVersion. The relative path always starts from the submission version directory where the 'caddy.xml' file is placed.

Examples:

Document A (ID=idd0001) has been changed in version 1.1 but document B (ID=idd0002) is unchanged. Relative paths (without specification of access protocol i.e. file:// or http://) shall be used to allow that CADDY-xml dossiers can be viewed on web servers as well as on local storage.

Version 1.0:

```
<... xlink:href="../../../01.00/standard/documents/idd0001.pdf" .../>  
<... xlink:href="../../../01.00/standard/documents/idd0002.pdf" .../>
```

Version 1.1:

```
<... xlink:href="../../../01.01/standard/documents/idd0001.pdf" .../>  
<... xlink:href="../../../01.00/standard/documents/idd0002.pdf" .../>
```

Version 1.2:

```
<... xlink:href="../../../01.01/standard/documents/idd0001.pdf" .../>  
<... xlink:href="../../../01.00/standard/documents/idd0002.pdf" .../>
```

Version 2.0: (Keep in mind that major versions are always submitted completely)

```
<... xlink:href="../../../02.00/standard/documents/idd0001.pdf" .../>  
<... xlink:href="../../../02.00/standard/documents/idd0002.pdf" .../>
```

3.8 Common File Formats

This chapter defines the constraints that submitted CADDY-xml files must conform to. CADDY-xml distinguishes between three kinds of documents or files. The first are the original documents that are referenced directly from the table of content. The second are attachments that come with an original



document for several reasons. The third are the dossier related additional files which do not belong a single original document.

3.8.1 Original Documents

The original document that is submitted must follow certain rules to improve readability and compatibility across different platforms. These files must be either in PDF format or in XML format.

PDF Documents:

To achieve a normative, readable, reproducible and usable form for PDF documents several features of the PDF standard must be used in a well defined manner. Additionally the graphics resolution of the contained graphics must be restricted to a feasible size to reduce the dossier size and to enforce fast access to the documents.

In general the PDF files in this section must be conform to **[ISO-19005-1]** , also known as PDF/A, which restricts PDF in a way that it is optimized for exchange and reproducibility of the content. Compliance with PDF/A-1b is required. CADDY-xml restricts also the use of hyperlinks. The following table will show such restrictions. For the complete list please refer to **[ISO-19005-1]** .

Type	Description
Trailer:ID	Required
Trailer:Encrypt	Prohibited
Page	CADDY-xml does not limit the format of the individual pages but the page restrictions mentioned in [ISO-19005-1] must be covered.
Resources, Font, FontDescriptor	Especially the [ISO-19005-1] restriction that every font used for text must be embedded within the PDF file.
Actions	Prohibited
JavaScripts	Prohibited
Annotations	Within PDF, hyperlinks are annotations. Although [ISO-19005-1] does allow hyperlinks, in CADDY-xml external hyperlinks (GoToR) are prohibited.
Image Resolution	The image resolution must not exceed 300 dpi.

XML Documents:

XML files that are referenced directly from the table of contents must be restricted in a way that the content is displayed with the help of an XML-Style sheet. Submitted XML files must have a style sheet that transforms the XML content to **[XHTML]** which will be viewed by the reviewer.

Often these style sheets use supporting files like images. Hence, restrictions for all the files are defined. The XML file, the style sheet and all additional files must be placed in a subfolder named with the ID attribute of the document. Within this folder subfolders may be used, if necessary (See 3.4 for length restrictions).

E.g.: Document with ID 'id012130123' with its style sheet that references two picture files.

01.00/standard/documents/id012130123/report.xml



01.00/standard/documents/id012130123/stylesheet.xml

01.00/standard/documents/id012130123/picture1.jpeg

01.00/standard/documents/id012130123/picture2.jpeg

Filenames:

The file of an original document must be placed into the 'documents' folder. To achieve uniqueness for filenames these must be named as the ID attribute of the document (See 4.13). Additionally the filename must contain only lowercase characters, numbers, hyphens or underscore characters. It can be expressed with the following regular expression ([a-z] | [0-9] | [-] | [])*.

E.g.: id000001.pdf or id012130123.xml

3.8.2 Attachments

Attachments within CADDY-xml are stored in the attachments subfolder either of the confidential or standard folder. The attachments of a document are grouped within a subfolder that is named after the ID attribute of the document and follows the above mentioned restrictions of the filename. Within this folder the files do not have limitations for their filenames unless they do not exceed the allowed total path length (See 3.4). Filenames should prevent the use of special characters outside of the valid characters for Original Documents (see 3.8.1). Mutual agreements between submitter and receiver should be used to define less restrictive rules if necessary.

Example: Document A (ID=idd0001) has three attachments

01.00/standard/documents/idd0001.pdf

01.00/standard/attachments/idd0001/attachment_number_1.xls

01.00/standard/attachments/idd0001/attachment_number_1.doc

01.00/standard/attachments/idd0001/attachment_number_1.xpt

The attachment must be classified with a type which can be one of the following:

Type	Description
rendition	This attachment is a rendition of the document
appendix	This attachment is an appendix
figure	This attachment is a descriptive figure
photo	This attachment is a descriptive photo
sas-table	This attachment is a SAS file containing the original data
oecd-data	This attachment is a collection of oecd conform XML report description files
zip-file	This attachment is a general ZIP file
other	This attachment does not conform to other types. The comment attribute must be used to describe the attachment type.



3.8.3 Additional Files

Additional files that are dossier related are stored in a folder within the root directory of a submission version. This folder must be named 'additional-files'. Within this folder the files do not have limitations for their filenames unless they do not exceed the allowed total path length (see 3.4). Filenames should prevent the use of special characters outside of the valid characters for Original Documents (see 3.8.1). Mutual agreements between submitter and receiver shall be used to less restrictive rules if necessary.

3.9 CADDY-xml in a Web-Browser

CADDY-xml is defined to have a HTML preview of the 'caddy.xml' file. This is done through the help of a file named 'index.html'. This file is placed within each submission version within the same folder as the 'caddy.xml' file. The HTML pages allow the user to review the complete submission: dossier information, table of contents, report-data, documents, and hyperlinks.

The HTML file is generated through the help of a style sheet directly via the web-browser. A CADDY-xml submission must contain this style sheet and the according files, but slight modifications for the appearance are allowed. For details refer to 6.2.

Only specific web-browsers must be supported for such a preview (See following table). Other programs may work as well, but may have restriction or implications in display and navigation.

Program	Version
Microsoft Internet Explorer (MSIE)	6.0 or higher
Mozilla Firefox for MS Windows	1.5 or higher

4 The CADDY-xml Core Elements

This chapter describes all elements and their associations in detail. Figure 12 gives an overview of the hierarchical structure of the CADDY-xml structure. All elements within this section are XML-elements that are placed within one file.

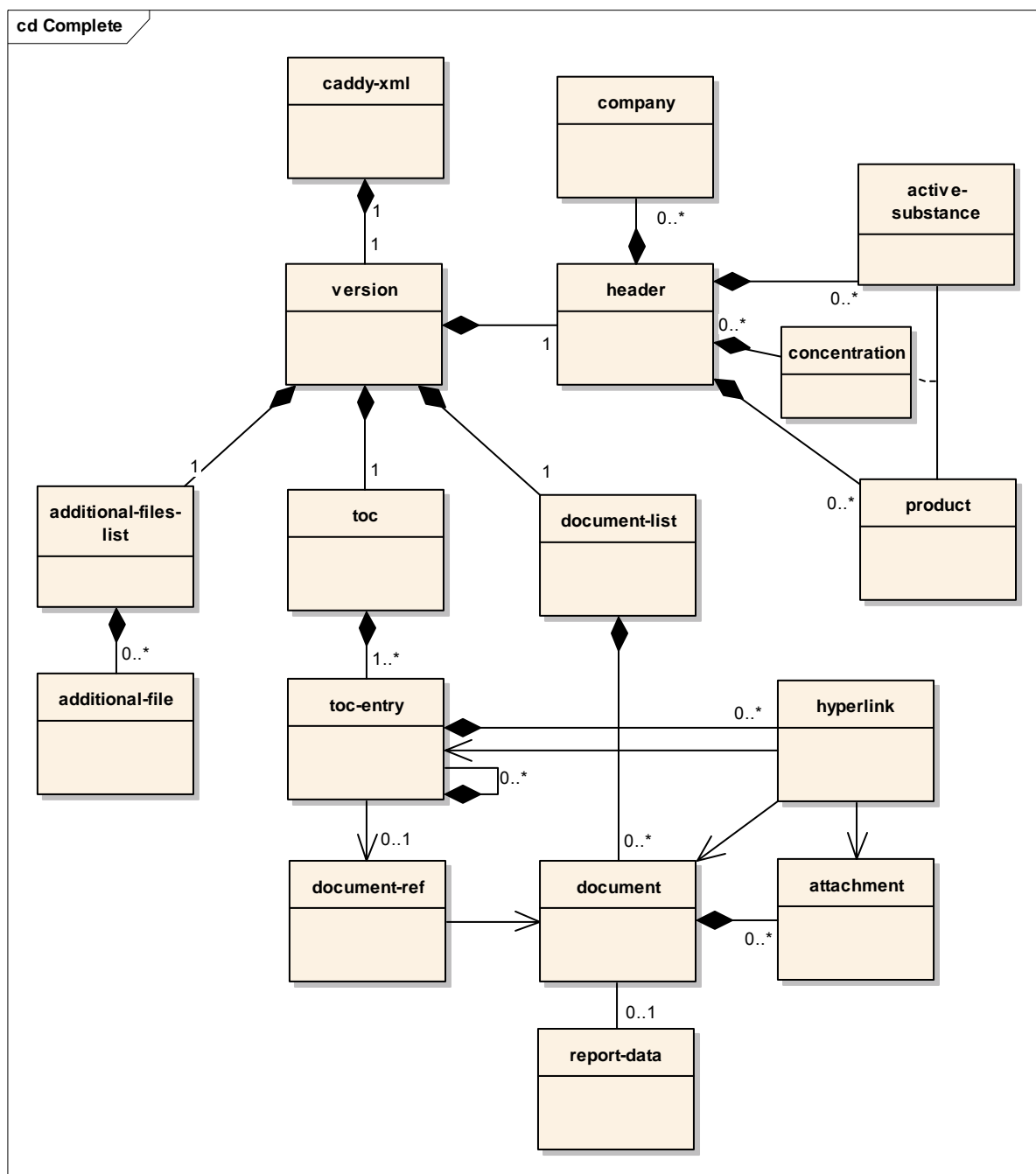


Figure 12: Overview CADDY-xml Elements



4.1 The caddy-xml Element

This element is the root element of all CADDY-xml files. The caddy-xml element must have exactly one child, the version element. It does not have attributes.

4.1.1 Child Elements

Elementname	Mandatory	Min	Max	Definition	Description
version	yes	1	1	4.2	Must include this element that describes the submission in detail.

4.1.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
xmlVersion	No	xmlVersionNumber	4.18.1	The version number of the used CADDY-xml specification. It is composed of a two digit major, a two digit minor and a two digit review version number separated by single dots. (e.g. 01.00.01 or 01.01.00). If this attribute is missing the default used is CADDY-xml version 1.0.1

4.1.3 Definition

```
<xs:element name="caddy-xml" type="caddy-xml-type"/>
<xs:complexType name="caddy-xml-type">
  <xs:sequence>
    <xs:element ref="version"/>
  </xs:sequence>
  <xs:attribute name="xmlVersion" type="xmlVersionNumber"
    use="optional"/>
</xs:complexType>
```

4.1.4 Example

```
<?xml version="1.0" encoding="ISO-8859-15"?>
<caddy-xml xmlVersion="01.01.00"
  xmlns:xsi=http://www.w3.org/2001/XMLSchema-instance
  xsi:noNamespaceSchemaLocation="caddy-1-1.xsd"
  xmlns:xlink="http://www.w3.org/1999/xlink" >
  <submission version="01.00">
  </submission>
</caddy-xml>
```



4.2 The version Element

This element is the root of a submission. It is defined to have a header element, a toc element, and a document-list element as children. It has a version attribute that has to be unique over the whole lifecycle of the submission. The version is composed of a two digit mayor and a two digit minor version number separated with a dot. E.g. 01.00 or 01.02

4.2.1 Child Elements

Elementname	Mandatory	Min	Max	Definition	Description
header	yes	1	1	4.3	Must include this element that describes the submission in detail.
toc	yes	1	1	4.8	Must include this element that manages the table of content of the submission.
document-list	yes	1	1	4.12	Must include this element that maintains a list of documents/reports.
additional-files-list	yes	1	1	4.16	Must include this element which maintains a list of additional files.

4.2.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
version	yes	versionNumber	4.18.2	The version number of this submission. It is composed of a two digit major and a two digit minor version number separated with a dot. E.g. 01.00 or 01.02
masterDate	yes	xs:date	[XML Schema]	Day of mastering the electronic CADDY-xml version of the dossier (CADDY compilation date)
issueDate	no	xs:date	[XML Schema]	Issue date of the original dossier.

4.2.3 Definition

```
<xs:element name="version" type="version-type"/>
<xs:complexType name="version-type">
  <xs:sequence>
    <xs:element ref="header"/>
    <xs:element ref="toc"/>
    <xs:element ref="document-list"/>
    <xs:element ref="additional-file-list"/>
  </xs:sequence>
  <xs:attribute name="version" type="versionNumber" use="required"/>
  <xs:attribute name="masterDate" type="xs:date" use="required"/>
  <xs:attribute name="issueDate" type="xs:date" use="optional"/>
</xs:complexType>
```



4.2.4 Example

```
<version version="01.00" masterDate="2001-02-01">
  <header .../>
  <toc/>
  <document-list/>
  <additional-file-list/>
</version>
```

4.3 The header Element

This element describes the global attributes of the version. The header may also have elements for company, product, active-substance, and concentration.

4.3.1 Child Elements

Element Name	Mandatory	Min	Max	Definition	Description
company	no	0	*	4.4	May include elements that describe the submitting company in detail.
product	no	0	*	4.5	May include elements that describe the submission's product in detail.
active-substance	no	0	*	4.6	May include elements that describe the submission's active substance in detail.
concentration	no	0	*	4.7	May include elements that describe the concentration of an active substance within a product.

4.3.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
id	yes	xs:ID	[XML Schema]	A unique number unchanged over the whole lifecycle of the dossier. If a new version introduces changes in header attributes it must have a new id.
dossierTitle	yes	string250	4.18.3	Dossier title
dossierSubtitle	no	string250	4.18.3	Dossier subtitle
uniqueDossierID	yes	dossierID	4.18.9	Companies unique dossier id. See 4.18.9
authority	yes	string100	4.18.3	Authority (e.g. EEC)
guideline	yes	string100	4.18.3	Requirement / official guideline
regulation	yes	string100	4.18.3	Regulation (e.g. 3600/92)
rporteur	yes	IndISO2	4.18.4	European rapporteur member state (alpha-2 code [ISO 3166-1-alpha-2])



changedVersion	no	versionNumber	4.18.2	Represents the version number of the last change to this element.
----------------	----	---------------	--------	---

4.3.3 Definition

```
<xs:element name="header" type="header-type" />
<xs:complexType name="header-type">
  <xs:sequence>
    <xs:element ref="company" minOccurs="0" maxOccurs="unbounded" />
    <xs:element ref="product" minOccurs="0" maxOccurs="unbounded" />
    <xs:element ref="active-substance" minOccurs="0"
      maxOccurs="unbounded" />
    <xs:element ref="concentration" minOccurs="0"
      maxOccurs="unbounded" />
  </xs:sequence>
  <xs:attribute name="id" type="xs:ID" use="required" />
  <xs:attribute name="dossierTitle" type="string250" use="required" />
  <xs:attribute name="dossierSubtitle" type="string250"
    use="optional" />
  <xs:attribute name="uniqueDossierID" type="dossierID"
    use="required" />
  <xs:attribute name="authority" type="string100" use="required" />
  <xs:attribute name="guideline" type="string100" use="required" />
  <xs:attribute name="regulation" type="string100" use="required" />
  <xs:attribute name="rapporteur" type="lndISO2" use="required" />
  <xs:attribute name="changedVersion" type="versionNumber"
    use="optional" />
</xs:complexType>
```

4.3.4 Example

```
<header id="IDH00001"
  dossierTitle="CADDY Version 2 Demonstration Dossier"
  dossierSubtitle="Test dossier for CADDY-xml"
  uniqueDossierID="DOEGB001"
  authority="EU Commission"
  guideline="1663/VI/94, rev. 8"
  regulation="91/414/EEC"
  rapporteur="ch">
  <company .../>
  <product .../>
  <active-substance .../>
  <concentration .../>
</header>
```

4.4 The company Element

This element describes the company making the submission.

4.4.1 Child Elements

There are no child elements for this element.



4.4.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
id	yes	xs:ID	[XML Schema]	A unique number unchanged over the whole lifecycle of the dossier. If a new version introduces changes in company attributes it must have a new id.
name	yes	string100	4.18.3	Company name
code	yes	companyCode	4.18.5	3-digit EU company code or 6-letter US company ID
country	yes	string100	4.18.3	Country name of the company's location
countryCode	yes	lndISO2	4.18.4	Companie's state (alpha-2 code [ISO 3166-1-alpha-2])
changedVersion	no	versionNumber	4.18.2	Represents the version number of the last change to this element.

4.4.3 Definition

```
<xs:element name="company" type="company-type" />
<xs:complexType name="company-type">
  <xs:attribute name="id" type="xs:ID" use="required"/>
  <xs:attribute name="name" type="string100" use="required"/>
  <xs:attribute name="code" type="companyCode" use="required"/>
  <xs:attribute name="country" type="string100" use="required"/>
  <xs:attribute name="countryCode" type="lndISO2" use="required"/>
  <xs:attribute name="changedVersion" type="versionNumber"
    use="optional" />
</xs:complexType>
```

4.4.4 Example

```
<company id="IDC0001"
  name="Company-Name"
  code="123456"
  country="Germany"
  countryCode="de" />
```

4.5 The product Element

This element describes each product of the submission.

4.5.1 Child Elements

There are no child elements for this element.

4.5.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
-----------	-----------	------	------------	-------------



id	yes	xs:ID	[XML Schema]	A unique number unchanged over the whole lifecycle of the dossier. If a new version introduces changes in product attributes it must have a new id.
name	yes	string250	4.18.3	Product name
formulation	yes	string10	4.18.3	Formulation type according to GIFAP rules
annex	yes	xs:boolean	[XML Schema]	True, if covered by European annex III dossier
changedVersion	no	versionNumber	4.18.2	Represents the version number of the last change to this element.

4.5.3 Definition

```
<xs:element name="product" type="product-type" />
<xs:complexType name="product-type">
  <xs:attribute name="id" type="xs:ID" use="required" />
  <xs:attribute name="name" type="string250" use="required" />
  <xs:attribute name="formulation" type="string10" use="required" />
  <xs:attribute name="annex" type="xs:boolean" use="required" />
  <xs:attribute name="changedVersion" type="versionNumber"
    use="optional" />
</xs:complexType>
```

4.5.4 Example

```
<product id="IDP0001"
  name="Product-Name"
  formulation="FOR"
  annex="true" />
```

4.6 The active-substance Element

This element describes each active substance of the submission.

4.6.1 Child Elements

There are no child elements for this element.

4.6.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
id	yes	xs:ID	[XML Schema]	A unique number unchanged over the whole lifecycle of the dossier. If a new version introduces changes in active substance attributes it must have a new id.
name	yes	string250	4.18.3	Substance name
cipac	no	string10	4.18.3	Cipac number
cas	no	string100	4.18.3	CAS code



annex	yes	xs:boolean	[XML Schema]	True, if covered by European annex II dossier
changedVersion	no	versionNumber	4.18.2	Represents the version number of the last change to this element.

4.6.3 Definition

```
<xs:element name="active-substance" type="active-substance-type"/>
<xs:complexType name="active-substance-type">
  <xs:attribute name="id" type="xs:ID" use="required"/>
  <xs:attribute name="name" type="string250" use="required"/>
  <xs:attribute name="cipac" type="string10" use="optional"/>
  <xs:attribute name="cas" type="string100" use="optional"/>
  <xs:attribute name="annex" type="xs:boolean" use="required"/>
  <xs:attribute name="changedVersion" type="versionNumber"
    use="optional"/>
</xs:complexType>
```

4.6.4 Example

```
<active-substance id="IDS0001"
  name="Substance"
  cipac="CIPA"
  cas="CAS-Code"
  annex="true" />
```

4.7 The concentration Element

This element describes the concentrations of active substances within a product.

4.7.1 Child Elements

There are no child elements for this element.

4.7.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
id	yes	xs:ID	[XML Schema]	A unique number over the whole lifecycle of the submission. If a new submission introduces changes in the concentration attribute it must have a new id.
concentration	yes	string100	4.18.3	Total concentration containing units (e.g. 15 g/m)
productId	yes	xs:IDREF	[XML Schema]	Reference to a product id
substancelid	yes	xs:IDREF	[XML Schema]	Reference to a substance id
changedVersion	no	versionNumber	4.18.2	Represents the version number of the last change to this element.



4.7.3 Definition

```
<xs:element name="concentration" type="concentration-type"/>
<xs:complexType name="concentration-type">
  <xs:attribute name="id" type="xs:ID" use="required"/>
  <xs:attribute name="concentration" type="string100" use="required"/>
  <xs:attribute name="productId" type="xs:IDREF" use="required"/>
  <xs:attribute name="substanceId" type="xs:IDREF" use="required"/>
  <xs:attribute name="changedVersion" type="versionNumber"
    use="optional"/>
</xs:complexType>
```

4.7.4 Example

```
<concentration id="IDR001"
  concentration="15mg/l"
  productId="IDP0001"
  substanceId="IDS0001"/>
```

4.8 The toc Element

A toc element groups all table of content relevant elements. It must have a least one toc-entry element as child. An optional reference to a Standard TOC allows validators to check the structure of the toc children (See 3.2 for details).

4.8.1 Child Elements

Elementname	Mandatory	Min	Max	Definition	Description
toc-entry	yes	1	*	4.9	Must include at least one toc-entry element

4.8.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
standardTocID	no	xs:ID	[XML Schema]	A reference to a Standard TOC from ECPA to allow validators to check the nested structure.
xlink:href	no	xlink:href	[XLink]	References the Standard TOC within the 'toc' subdirectory.

4.8.3 Definition

```
<xs:element name="toc" type="toc-type"/>
<xs:complexType name="toc-type">
  <xs:sequence>
    <xs:element ref="toc-entry" maxOccurs="unbounded"/>
  </xs:sequence>
  <xs:attribute name="standardTocID" type="xs:ID" use="optional"/>
  <xs:attribute ref="xlink:href" use="required"/>
</xs:complexType>
```



</xs:complexType>

4.8.4 Example

```
<toc standardTocID="Sample-OECD-CADDY-xml-TOC"
  xlink:href="utils/tocs/sample-oecd-toc.xml">
  <toc-entry .../>
</toc>
```

4.9 The toc-entry Element

Each entry within a table of content is represented by a toc-entry element. A table of content entry may be a section or a document. In case of a section, it may contain additional table of content elements. In case of a document, a table of content entry must contain a document-ref element.

4.9.1 Child Elements

Element Name	Mandatory	Min	Max	Definition	Description
document-ref	no	0	1	4.10	If this element describes a document this element must be used to reference the document.
toc-entry	no	0	*	4.9	If this element represents a section it may have these elements representing subsections.
hyperlink	no	0	*	4.11	Hyperlinks that are associated with this element.

4.9.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
id	yes	xs:ID	[XML Schema]	A unique number over the whole lifecycle of the submission. If a new submission introduces changes in header attributes it must have a new id.
number	yes	string100	4.18.3	Hierarchical number of the section or document
title	yes	string100	4.18.3	Title of the document or section
intentionallyLeftBlank	no	xs:boolean	[XML Schema]	If this is set to 'true' the document-ref is explicitly not defined for this node. Default is 'false'



intentionallyLeftBlankComment	no	string250	[XML Schema]	A comment available for the viewers in case of the flag 'intentionallyLeftBlank' is 'true'. Comments in case of intentionallyLeftBlank is 'false' are not allowed.
-------------------------------	----	-----------	---------------------	--

4.9.3 Definition

```
<xs:element name="toc-entry" type="toc-entry-type"/>
<xs:complexType name="toc-entry-type">
  <xs:sequence>
    <xs:choice>
      <xs:element ref="document-ref" minOccurs="0"
        maxOccurs="1"/>
      <xs:element ref="toc-entry" minOccurs="0"
        maxOccurs="unbounded"/>
    </xs:choice>
    <xs:element ref="hyperlink" minOccurs="0"
      maxOccurs="unbounded"/>
  </xs:sequence>
  <xs:attribute name="id" type="xs:ID" use="required"/>
  <xs:attribute name="number" type="string100" use="required"/>
  <xs:attribute name="title" type="string100" use="required"/>
  <xs:attribute name="intentionallyLeftBlank" type="xs:boolean"
    use="optional"/>
  <xs:attribute name="intentionallyLeftBlankComment" type="string250"
    use="optional"/>
</xs:complexType>
```

4.9.4 Example

The following table of content:

- 1 Section**
- 1.1 Document**
- 2 Section**
- 2.1 Section**
- 2.1.1 Document**
- 2.2 Document**

is represented by:

```
<toc>
  <toc-entry id="ID00001" number="1" title="Section">
    <toc-entry id="ID00002" number="1.1" title="Document">
      <document-ref docId="IDD00001"/>
      <hyperlink id="IDH0001" sourceType="toc-entry" targetId="ID00006"/>
    </toc-entry>
  </toc-entry>
  <toc-entry id="ID00003" number="2" title="Section">
    <toc-entry id="ID00004" number="2.1" title="Section">
      <toc-entry id="ID00005" number="2.1.1" title="Document">
        <document-ref docId="IDD00001"/>
      </toc-entry>
    </toc-entry>
  </toc-entry>
```



```
<toc-entry id="ID00006" number="2.2" title="Document">
  <document-ref docId="IDD00001"/>
</toc-entry>
</toc>
```

4.10 The document-ref Element

This element describes a reference from a table of content entry to a document (4.13) that is placed within the document list (4.12).

4.10.1 Child Elements

There are no child elements for this element.

4.10.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
docId	yes	xs:IDREF	[XML Schema]	A unique number over the whole lifecycle of the submission that refers to a document Id within the document list.
targetPage	no	xs:Integer	[XML Schema]	This attribute allows to open the document on the specified page.

4.10.3 Definition

```
<xs:element name="document-ref" type="document-ref-type"/>
<xs:complexType name="document-ref-type">
  <xs:attribute name="docId" type="xs:IDREF" use="required"/>
  <xs:attribute name="targetPage" type="xs:integer" use="optional"/>
</xs:complexType>
```

4.10.4 Example

In the following example the document-ref element refers to the document named "Document Title 1" through the Id (IDD00001).

```
<toc>
  ...
  <toc-entry id="ID00001" number="1" title="Document">
    <document-ref docId="IDD00001"/>
  </toc-entry>
  ...
</toc>
<document-list>
  <document id="IDD00001"
    title="Document Title 1" .../>
  ...
</document-list>
```



4.11 The hyperlink Element

This element describes a hyperlink. Hyperlinks are defined through a source and target description. They may either point to and from table of content entries, documents, or attachments. This is represented by the source and target type, respectively.

For the coordinate system the following definition is made: The positive x axis extends horizontally to the right and the positive y axis vertically upward, as in standard mathematical practice. This is in accordance to the former CADDY 1.1 and CADDY 2.0 standard.

4.11.1 Child Elements

There are no child elements for this element.

4.11.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
id	yes	xs:ID	[XML Schema]	A unique number unchanged over the whole lifecycle of the dossier. If a new version introduces changes in the concentration attribute it must have a new id.
title	no	xlink:title	[XLink]	Optional description of the hyperlink. E.g. a section name.
targetType	yes	hyperlinkType	4.18.6	Describes the destination type of a hyperlink.
sourceType	yes	hyperlinkType	4.18.6	Describes the source type of a hyperlink.
targetId	yes	xs:IDREF	[XML Schema]	References the table of content id of the target or the attachment. It has to be valid for any targetType, not only for the type "table of content". For the types document and toc-entry it references the table of content entry containing the target. For attachments it references the attachment id.
sourcePage	no	xs:integer	[XML Schema]	Source page. Only valid if sourceType is document.
sourceX	no	xs:decimal	[XML Schema]	x-coordinate of source on source page [mm]. Only valid if sourceType is document.
sourceY	no	xs:decimal	[XML Schema]	y-coordinate of source on source page [mm]. Only valid if sourceType is document.
sourceW	no	xs:decimal	[XML Schema]	width of source on source page [mm]. Only valid if sourceType is document.
sourceH	no	xs:decimal	[XML Schema]	height of source on source page [mm]. Only valid if sourceType is document.
targetPage	no	xs:integer	[XML Schema]	Target page. Only valid if targetType is document. Definition will be overridden if targetDestination is given.



targetX	no	xs:decimal	[XML Schema]	x-coordinate of target on target page [mm]. Only valid if targetType is document. Definition will be overridden if targetDestination is given.
targetY	no	xs:decimal	[XML Schema]	x-coordinate of target on target page [mm]. Only valid if targetType is document. Definition will be overridden if targetDestination is given.
targetDestination	no	String250	4.18.3	named destination. Only valid if targetType is document. Definition overrides targetPage, targetX and targetY.

4.11.3 Definition

```
<xs:element name="hyperlink" type="hyperlink-type"/>
<xs:complexType name="hyperlink-type">
  <xs:attribute name="id" type="xs:ID" use="required"/>
  <xs:attribute name="title" type="xlink:title" use="optional"/>
  <xs:attribute name="sourceType" type="hyperlinkType" use="required"/>
  <xs:attribute name="targetType" type="hyperlinkType" use="required"/>
  <xs:attribute name="targetId" type="xs:IDREF" use="required"/>
  <xs:attribute name="sourcePage" type="xs:integer" use="optional"/>
  <xs:attribute name="sourceX" type="xs:decimal" use="optional"/>
  <xs:attribute name="sourceY" type="xs:decimal" use="optional"/>
  <xs:attribute name="sourceW" type="xs:decimal" use="optional"/>
  <xs:attribute name="sourceH" type="xs:decimal" use="optional"/>
  <xs:attribute name="targetPage" type="xs:integer" use="optional"/>
  <xs:attribute name="targetX" type="xs:decimal" use="optional"/>
  <xs:attribute name="targetY" type="xs:decimal" use="optional"/>
  <xs:attribute name="targetDestination" type="string250"
    use="optional"/>
</xs:complexType>
```

4.11.4 Example

The following example implements two hyperlinks. The first (IDHL0001) points from this table of content entry to the table of content entry with the id ID000001. The second hyperlink is placed on page 2 in the lower left corner (10mm,10mm,10mmx10mm) and points to the named destination 'Summary' of a document with IDD00002.

```
<toc-entry id="ID000005" number="D 1" title="Intended uses ...">
  <document-ref docId="IDD00001"/>
  <hyperlink id="IDHL0001"
    sourceType="toc-entry"
    targetType="toc-entry"
    targetId="ID000001"/>
  <hyperlink id="IDHL0002"
    sourceType="document"
    targetType="document"
    targetId="IDD00002"
    sourcePage="2"
    sourceX="10.0"
    sourceY="10.0"/>
```



```

    sourceW="10.0"
    sourceH="10.0"
    targetDestination="Summary" />
</toc-entry>
    
```

4.12 The document-list Element

The document-list element groups all documents within this submission. It must have at least one document element as child.

4.12.1 Child Elements

Element name	Mandatory	Min	Max	Definition	Description
document	yes	1	*	4.13	Must include at least one document element

4.12.2 Attributes

There are no attributes for this element.

4.12.3 Definition

```

<xs:element name="document-list" type="document-list-type"/>
<xs:complexType name="document-list-type">
  <xs:sequence>
    <xs:element ref="document" maxOccurs="unbounded"/>
  </xs:sequence>
</xs:complexType>
    
```

4.12.4 Example

```

<document-list>
  <document id="IDD00001" title="Document Title 1" .../>
  <document id="IDD00002" title="Document Title 2" .../>
  <document id="IDD00003" title="Document Title 3" .../>
</document-list>
    
```

4.13 The document Element

This element represents a document. A document must be referenced by at least one table of content entry. A document itself may contain a report data attribute set and/or attachments.

4.13.1 Child Elements

Element Name	Mandatory	Min	Max	Definition	Description
report-data	no	0	1	4.14	May contain a more descriptive set of attributes.



attachment	no	0	*	4.15	May contain attachment elements.
------------	----	---	---	------	----------------------------------

4.13.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
id	yes	xs:ID	[XML Schema]	A unique number unchanged over the whole lifecycle of the dossier. One id identifies one document over its whole lifecycle.
title	yes	string250	[XML Schema]	Title of the document / report
xlink:href	yes	xlink:href	[XLink]	Reference to the file location of the document.
confidential	yes	xs:boolean	[XML Schema]	If true it marks the document and its attachments as confidential.
operation	yes	changeOperation	4.18.7	The operation valid for this version of the document. See also 3.6
addedVersion	yes	versionNumber	4.18.2	This version number represents the number where this document was initially added to the submission.
changedVersion	no	versionNumber	4.18.2	Represents the version number of the last change to this element.
checksum	yes	md5	4.18.8	Hold a md5 checksum that uniquely identifies this document. See 3.5

4.13.3 Definition

```
<xs:element name="document" type="document-type"/>
<xs:complexType name="document-type">
  <xs:sequence>
    <xs:element ref="report-data" minOccurs="0" maxOccurs="1"/>
    <xs:element ref="attachment" minOccurs="0"
      maxOccurs="unbounded"/>
  </xs:sequence>
  <xs:attribute name="id" type="xs:ID" use="required"/>
  <xs:attribute name="title" type="string250" use="required"/>
  <xs:attribute ref="xlink:href" use="required"/>
  <xs:attribute name="confidential" type="xs:boolean" use="required"/>
  <xs:attribute name="operation" type="changeOperation"
    use="required"/>
  <xs:attribute name="addedVersion" type="versionNumber"
    use="required"/>
  <xs:attribute name="changedVersion" type="versionNumber"
    use="optional"/>
  <xs:attribute name="checksum" type="md5" use="required"/>
</xs:complexType>
```

4.13.4 Example

A document newly added to the submission version 1.0. It is not confidential and is stored in the file system in file './standard/documents/idd00001.pdf':

```
<document id="IDD00001"
```



```

title="Document Title 1"
confidential="false"
operation="new"
xlink:href="../../../01.00/standard/documents/idd00001.pdf"
addedVersion="01.00"
checksum="2d9238e6dfffd389a80b208d68e4a1ef0">
<report-data .../>
<attachment .../>
</document>
    
```

A replaced document changed in version 2.0. It is not confidential and is stored in the file system in file

'./standard/documents/idd00001.pdf':

```

<document id="IDD00001"
title="Document Title 1"
confidential="false"
operation="replaced"
xlink:href="../../../02.00/standard/documents/idd00001.pdf"
addedVersion="01.00"
changedVersion="02.00"
checksum="2d9238e6dfffd389a80b208d68e4a1ef1">
<report-data .../>
<attachment .../>
</document>
    
```

4.14 The report-data Element

The report data element stores a set of attributes describing a document.

4.14.1 Child Elements

There are no child elements for this element.

4.14.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
id	yes	xs:ID	[XML Schema]	A unique number unchanged over the whole lifecycle of the dossier. If a new version introduces changes in the report data attributes it must have a new id.
dossierFilenumber	no	string100	4.18.3	Dossier file number (for EU) / MRID (for US and Canada)
companyFilenumber	no	string100	4.18.3	Company file number



date	yes	xs:date	[XML Schema]	date of document. If validMonth and validDay is true, then date contains the effective date of the report. If validDay = false and validMonth = true, then the day of the month is unknown and date should only be displayed by the software without a day. For sorting and consistency reasons the date field will contain the first day of the month. If validDay and validMonth = false, then the month of the year is unknown and date should only be displayed by the software as a year. For sorting and consistency reasons the date field will contain the first January of the year. The combination validDay = true and validMonth = false is ignored.
validMonth	yes	xs:boolean	[XML Schema]	Is day of report date applicable? for explanation see field date
validDay	yes	xs:boolean	[XML Schema]	Is month of report date applicable? for explanation see field date
title	no	string250	4.18.3	Title of document
authors	no	string250	4.18.3	Authors of document
source	no	string250	4.18.3	Source of document
owners	no	string250	4.18.3	Owners of report at submission date
testFacility	no	string250	4.18.3	Test facility
glp	yes	xs:boolean	[XML Schema]	Is report GLP conform ?
published	yes	xs:boolean	[XML Schema]	Was report published ?
vertebrates	yes	xs:boolean	[XML Schema]	Test on vertebrates ?
protect	yes	xs:boolean	[XML Schema]	Data protection claimed ?
changedVersion	no	versionNumber	4.18.2	Represents the version number of the last change to this element.

4.14.3 Definition

```

<xs:element name="report-data" type="report-data-type" />
<xs:complexType name="report-data-type">
  <xs:attribute name="id" type="xs:ID" use="required" />
  <xs:attribute name="dossierFilenumber" type="string100"
  use="optional" />
  <xs:attribute name="companyFilenumber" type="string100"
  use="optional" />
  <xs:attribute name="date" type="xs:date" use="required" />
  <xs:attribute name="validMonth" type="xs:boolean" use="required" />
  <xs:attribute name="validDay" type="xs:boolean" use="required" />
  <xs:attribute name="title" type="string250" use="optional" />
  <xs:attribute name="authors" type=" string250" use="optional" />

```



```

<xs:attribute name="source" type=" string250" use="optional"/>
<xs:attribute name="owners" type=" string250" use="optional"/>
<xs:attribute name="testFacility" type=" string250" use="optional"/>
<xs:attribute name="glp" type="xs:boolean" use="required"/>
<xs:attribute name="published" type="xs:boolean" use="required"/>
<xs:attribute name="vertebrates" type="xs:boolean" use="required"/>
<xs:attribute name="protect" type="xs:boolean" use="required"/>
<xs:attribute name="changedVersion" type="versionNumber"
use="optional"/>
</xs:complexType>
    
```

4.14.4 Example

```

<report-data id="IDR00001"
dossierFilenummer="D/00001"
companyFilenummer="I/00001"
date="2001-02-01"
validMonth="true"
validDay="true"
title="Title of the document"
authors="Smith et. al."
source="Source"
owners="Owner"
testFacility="Testfacility"
glp="true"
published="true"
vertebrates="true"
protect="true"/>
    
```

4.15 The attachment Element

The attachment element stores a reference to an attachment file in the file system. The attachmentType describes the function in respect of the document of this file.

4.15.1 Child Elements

There are no child elements for this element.

4.15.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
id	yes	xs:ID	[XML Schema]	A unique number over the whole lifecycle of the submission. If a new submission introduces changes in the attachment attributes it must have a new id.
attachmentType	yes	attachmentType	4.18.10	Classifies the attachment file.
title	yes	string250	4.18.3	Describes the attachment file.
xlink:href	yes	xlink:href	[XLink]	References the attachment file in the file system.



addedVersion	yes	versionNumber	4.18.2	The version number where this attachment was added.
checksum	yes	md5	4.18.8	An unique md5 identifier for the attachment file.
changedVersion	no	versionNumber	4.18.2	Represents the version number of the last change to this element.
comment	no	string250	4.18.3	Comment describing the function of this attachment.

4.15.3 Definition

```
<xs:element name="attachment" type="attachment-type" />
<xs:complexType name="attachment-type">
  <xs:attribute name="id" type="xs:ID" use="required" />
  <xs:attribute name="attachmentType" type="attachmentType"
  use="required" />
  <xs:attribute name="title" type="string250" use="required" />
  <xs:attribute ref="xlink:href" use="required" />
  <xs:attribute name="addedVersion" type="versionNumber"
  use="required" />
  <xs:attribute name="checksum" type="md5" use="required" />
  <xs:attribute name="changedVersion" type="versionNumber"
  use="optional" />
  <xs:attribute name="comment" type="string250" use="optional" />
</xs:complexType>
```

4.15.4 Example

```
<attachment id="IDA00001"
  attachmentType="rendition"
  title="Rendition of the document"
  xlink:href=" ../01.00/standard/attachments/idd00001/rendition.pdf "
  addedVersion="01.00"
  checksum="2d9238e6dfffd389a80b208d68e4a1ef0" />
```

4.16 The additional-file-list Element

An additional file list element groups all additional file elements. For details refer to section 3.1.8.

4.16.1 Child Elements

Elementname	Mandatory	Min	Max	Definition	Description
additional-file	no	0	*	4.17	May include additional file elements

4.16.2 Attributes

There are no attributes for this element.



4.16.3 Definition

```
<xs:element name="additional-files-list"
type="additional-files-list-type"/>
<xs:complexType name="additional-files-list-type">
  <xs:sequence>
    <xs:element ref="additional-file" minOccurs="0"
      maxOccurs="unbounded"/>
  </xs:sequence>
</xs:complexType>
```

4.16.4 Example

```
<additional-files-list>
  <additional-file id="IDAV0001"
    comment="Standard CADDY Logo"
    xlink:href=" ../01.00/additional-files/CADDY-Logo.gif"
    addedVersion="01.00"
    checksum="6e93076f8b0b79938eb8ab7019cf2249"/>
</additional-files-list>
```

4.17 The additional-file Element

This element represents an additional file that does not belong to a specific table of content element.
 For details refer to section 3.1.8.

4.17.1 Child Elements

This element has no child elements.

4.17.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
id	yes	xs:ID	[XML Schema]	A unique number over the whole lifecycle of the submission. One id always belongs to one additional file and its whole lifecycle.
comment	yes	string250	4.18.3	Any text describing the additional file.
xlink:href	yes	xlink:href	[XLink]	Reference to the file location of the document.
addedVersion	yes	versionNumber	4.18.2	This version number represents the number where this document was initially added to the submission.
changedVersion	no	versionNumber	4.18.2	Represents the version number of the last change to this element.
checksum	yes	md5	4.18.8	Hold a md5 checksum that uniquely identifies this document. See 3.5



4.17.3 Definition

```
<xs:element name="additional-file" type="additional-file-type"/>
<xs:complexType name="additional-file-type">
  <xs:attribute name="id" type="xs:ID" use="required"/>
  <xs:attribute name="comment" type="string250" use="required"/>
  <xs:attribute ref="xlink:href" use="required"/>
  <xs:attribute name="addedVersion" type="versionNumber"
  use="required"/>
  <xs:attribute name="changedVersion" type="versionNumber"
  use="optional"/>
  <xs:attribute name="checksum" type="md5" use="required"/>
</xs:complexType>
```

4.17.4 Example

```
<additional-files-list>
  <additional-file id="IDAV0001"
  comment="Standard CADDY Logo"
  xlink:href=" ../01.00/additional-files/CADDY-Logo.gif "
  addedVersion="01.00"
  checksum="6e93076f8b0b79938eb8ab7019cf2249" />
</additional-files-list>
```

4.18 CADDY-xml Types

CADDY-xml introduces a list of CADDY-xml specific types.

4.18.1 The xmlVersionNumber Type

This type represents a CADDY-xml version number of a valid and effective specification version. It consists of two digit numbers for version (major version), subversion (minor version) and review. These version components are separated by single dots. E.g. "01.01.00" for version 1.1.0.

4.18.1.1 Definition

```
<xs:simpleType name='xmlVersionNumber'>
  <xs:annotation>Version number: six digits</xs:annotation>
  <xs:restriction base='xs:string'>
    <xs:pattern value='\d{2}.\d{2}.\d{2}' />
  </xs:restriction>
</xs:simpleType>
```

4.18.2 The versionNumber Type

This type represents a CADDY-xml submission version number that consists of a two digit number for version (major version) and subversion (minor version). These versions are separated by a dot. E.g.



“01.00” for version 1.0, or “02.01” for version 2.1. Major versions start with 01 and minor versions start with 00. Both must be consecutive.

4.18.2.1 Definition

```
<xs:simpleType name='versionNumber'>
  <xs:annotation>Version number: four digits</xs:annotation>
  <xs:restriction base='xs:string'>
    <xs:pattern value='\d{2}.\d{2}' />
  </xs:restriction>
</xs:simpleType>
```

4.18.3 The Restricted String Types

There are several string types defined within CADDY-xml. These are aimed to restrict the length of a string. E.g. string250 restrict a string to the length of 250 characters.

CADDY-xml defines the following string types: string10, string100, and string250.

4.18.3.1 Definition

Real types use the actual length of the string instead of XX:

```
<xs:simpleType name='stringXX'>
  <xs:restriction base='xs:string'>
    <xs:minLength value='1' />
    <xs:maxLength value='XX' />
  </xs:restriction>
</xs:simpleType>
```

4.18.4 The IndISO2 Type

This type is used for the [ISO 3166-1-alpha-2] two alpha country code.

4.18.4.1 Definition

```
<xs:simpleType name='IndISO2'>
  <xs:restriction base='xs:string'>
    <xs:pattern value='[a-z][a-z]' />
    <xs:maxLength value='2' />
  </xs:restriction>
</xs:simpleType>
```

4.18.5 The companyCode Type

This type represents the company code. It must either be the 3-digit EU company code or a 6-letter US company id.

4.18.5.1 Definition

```
<xs:simpleType name='companyCode'>
  <xs:restriction base='xs:string'>
```



```
        <xs:minLength value='3' />
        <xs:maxLength value='6' />
    </xs:restriction>
</xs:simpleType>
```

4.18.6 The hyperlinkType Type

This type is used to represent the source or target type of a hyperlink. It is either a toc-entry, a document or an attachment.

4.18.6.1 Definition

```
<xs:simpleType name='hyperlinkType'>
    <xs:restriction base='xs:string'>
        <xs:enumeration value="toc-entry" />
        <xs:enumeration value="document" />
        <xs:enumeration value="attachment" />
    </xs:restriction>
</xs:simpleType>
```

4.18.7 The changeOperation Type

This type represents the operations that can be done for documents.

Operation	Description
new	If a document is newly added to a submission
deleted	If a document has been deleted
replaced	If a document has been replaced by another document

4.18.7.1 Definition

```
<xs:simpleType name='changeOperation'>
    <xs:restriction base='xs:string'>
        <xs:enumeration value="new" />
        <xs:enumeration value="deleted" />
        <xs:enumeration value="replaced" />
    </xs:restriction>
</xs:simpleType>
```

4.18.8 The md5 Type

This type represents the md5 checksum specified in [RFC 1321]. A md5 checksum is a string that contains 32 hexadecimal characters.

4.18.8.1 Definition

```
<xs:simpleType name='md5'>
    <xs:annotation>MD5 Checksum</xs:annotation>
    <xs:restriction base='xs:string'>
        <xs:pattern value='[a-f,A-F,0-9]{32}' />
    </xs:restriction>
</xs:simpleType>
```



4.18.9 The dossierID Type

To identify a dossier, every dossier will get an unique dossier ID, which is built using the following three subparts:

[dossierID] ::= [notifying company shortcode] [country shortcode] [current dossier number]

[notifying company shortcode] ::= Notifying company or in case of a task force the leading company
(short form with 3 characters, only capital letters are allowed.)

[country shortcode] ::= Country code of the notifying company (short form with 2 characters)
(ISO 3166 - Alpha-2-code, only capital letters are allowed.)

[current dossier number] ::= Current number of dossier generated by the notifying company
(padded with leading zeros to 5 characters)

This ensures, that the notifying company is able to guarantee the uniqueness of the dossierID (formally known as “Volume Set IDs”) of its submissions.

Example: DOEGB00001

4.18.9.1 Definition

```
<xs:simpleType name='dossierID'>
  <xs:restriction base='xs:string'>
    <xs:pattern value='[A-Z,0-9]{10}' />
  </xs:restriction>
</xs:simpleType>
```

4.18.10 The attachmentType Type

This type classifies an attachment. See an overview of the various attachment categories in chapter 3.1.7.

4.18.10.1 Definition

```
<xs:simpleType name='attachmentType'>
  <xs:restriction base='xs:string'>
    <xs:enumeration value="rendition" />
    <xs:enumeration value="appendix" />
    <xs:enumeration value="figure" />
    <xs:enumeration value="photo" />
    <xs:enumeration value="sas-table" />
    <xs:enumeration value="oecd-data" />
    <xs:enumeration value="zip-file" />
    <xs:enumeration value="other" />
  </xs:restriction>
</xs:simpleType>
```

5 The CADDY-xml Standard TOC Definitions

This chapter describes all elements and their associations of a CADDY-xml Standard TOC in detail. The following figure gives an overview of the hierarchical structure of the Standard TOC structure. All elements within this section are XML-elements that are placed within one file.

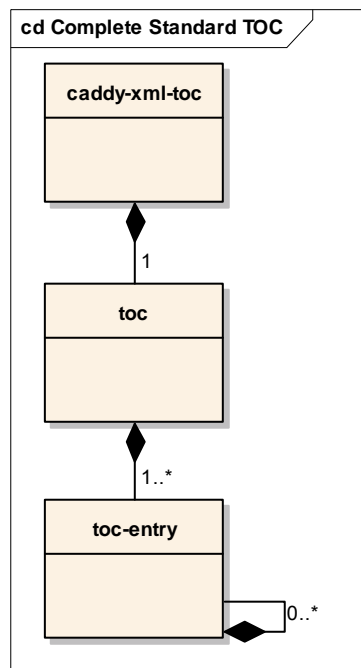


Figure 13: Overview CADDY-xml Standard TOC Elements

Note: All types of the following attributes definitions references the CADDY-xml types wherever appropriate. Only attribute types not already defined earlier are introduced in section 5.4.

5.1 The caddy-xml-toc Element

This element is the root element of all CADDY-xml Standard TOC files. The caddy-xml-toc element must have exactly one child, the toc element.

5.1.1 Child Elements

Element name	Mandatory	Min	Max	Definition	Description
Toc	yes	1	1	5.2	Must include this element that describes the toc in detail.



5.1.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
xmlVersion	yes	xmlVersionNumber	4.18.1	The version number of the used CADDY-xml specification. It is composed of a two digit major, a two digit minor and a two digit review version number separated by single dots (e.g. 01.00.01 or 01.01.00).
Id	yes	xs:ID	[XML Schema]	A unique number unchanged over the whole lifecycle of the TOC and its different versions.
Title	yes	string250	4.18.3	A title for the TOC.
tocVersion	yes	versionNumber	4.18.2	The version number of this TOC. It is composed of a two digit major and a two digit minor version number separated with a dot. E.g. 01.00 or 01.02
originator	yes	string100	4.18.3	Organisation which created this TOC.
author	no	string100	4.18.3	Responsible person for this TOC.
issueDate	yes	xs:date	[XML Schema]	Issue data of the TOC
validFrom	yes	xs:date	[XML Schema]	The earliest date from which this TOC can be treated as valid.
validTo	no	xs:date	[XML Schema]	The latest date till this TOC can be treated as valid.
substitutesVersion	no	versionNumber	4.18.2	A previous version which will be substituted by this version. New Versions shall always set this field even if it is defined optional.

5.1.3 Definition

```

<xs:element name="caddy-xml-toc" type="caddy-xml-toc-type"/>
<xs:complexType name="caddy-xml-toc-type">
  <xs:sequence>
    <xs:element ref="toc"/>
  </xs:sequence>
  <xs:attribute name="xmlVersion" type="xmlVersionNumber"
  use="required"/>
  <xs:attribute name="id" type="xs:ID" use="required"/>
  <xs:attribute name="title" type="string250" use="required"/>
  <xs:attribute name="tocVersion" type="versionNumber"
  use="required"/>
  <xs:attribute name="originator" type="string100" use="required"/>
  <xs:attribute name="author" type="string100" use="optional"/>
  <xs:attribute name="issueDate" type="xs:date" use="required"/>
  <xs:attribute name="validFrom" type="xs:date" use="required"/>
  <xs:attribute name="validTo" type="xs:date" use="optional"/>
  <xs:attribute name="subsitutesVersion" type="versionNumber"
  use="optional"/>
</xs:complexType>

```



5.1.4 Example

```
<caddy-xml-toc
  xmlns:xsi=http://www.w3.org/2001/XMLSchema-instance
  xsi:noNamespaceSchemaLocation="caddy-toc-1-1.xsd"
  xmlns:xlink=http://www.w3.org/1999/xlink
  xmlVersion="01.01.00"
  id="Sample-OECD-CADDY-xml-TOC"
  title="Sample OECD CADDY.xml TOC"
  tocVersion="01.00"
  originator="ECPA"
  author="Andreas Wastl"
  issueDate="2007-07-06"
  validFrom="2007-07-06">
```

5.2 The toc Element

A toc element groups all Standard TOC relevant elements. It must have at least one toc-entry element as child.

5.2.1 Child Elements

Element name	Mandatory	Min	Max	Definition	Description
toc-entry	yes	1	*	5.3	Must include at least one toc-entry element

5.2.2 Attributes

There are no attributes for this element.

5.2.3 Definition

```
<xs:element name="toc" type="toc-type"/>
<xs:complexType name="toc-type">
  <xs:sequence>
    <xs:element ref="toc-entry" maxOccurs="unbounded"/>
  </xs:sequence>
</xs:complexType>
```

5.2.4 Example

```
<toc>
  <toc-entry .../>
</toc>
```



5.3 The toc-entry Element

Each entry within a Standard TOC is represented by a toc-entry element. A table of content entry may contain additional table of content elements to build up a tree structure.

5.3.1 Child Elements

Element Name	Mandatory	Min	Max	Definition	Description
toc-entry	no	0	*	4.10	Further subsections of this toc-entry or a placeholder for a document.

5.3.2 Attributes

Fieldname	Mandatory	Type	Definition	Description
number	yes	string100	4.18.3	Hierarchical number of the section or document
title	yes	string100	4.18.3	Title of the document or section
extensible	yes	xs:boolean	[XML Schema]	If this is set to either 'true' the toc may have extra sub levels starting from this entry.
documentRef	yes	documentRefType	[XML Schema]	Guideline for the occurrence of a document reference in the submission toc. Either 'allowed', 'required' or 'prohibited'.

5.3.3 Definition

```
<xs:element name="toc-entry" type="toc-entry-type"/>
<xs:complexType name="toc-entry-type">
  <xs:sequence>
    <xs:element ref="toc-entry" minOccurs="0"
      maxOccurs="unbounded"/>
  </xs:sequence>
  <xs:attribute name="number" type="string100" use="required"/>
  <xs:attribute name="title" type="string100" use="required"/>
  <xs:attribute name="extensible" type="xs:boolean" use="required"/>
  <xs:attribute name="documentRef" type="documentRefType"
    use="required"/>
</xs:complexType>
```

5.3.4 Example

The following Standard TOC :

- 1 Section**
- 2 Section** (no documents allowed, not extensible)
 - 2.1 Section**
 - 2.2 Section**
 - 2.2.1 Document** (document required, not extensible)



is represented by:

```
<toc>
  <toc-entry number="1" title="Section"
    extensible="true" document-ref="allowed">
  </toc-entry>
  <toc-entry number="2" title="Section"
    extensible="false" document-ref="prohibited">
    <toc-entry number="2.1" title="Section"
      extensible="true" document-ref="allowed">
    </toc-entry>
    <toc-entry number="2.2" title="Section"
      extensible="true" document-ref="allowed">
      <toc-entry number="2.2.1" title="Document"
        extensible="false" document-ref="required">
      </toc-entry>
    </toc-entry>
  </toc-entry>
</toc>
```

5.4 CADDY-xml Standard TOC Types

CADDY-xml Standard TOCs introduces an extra list of CADDY-xml specific types.

5.4.1 The documentRef Type

This type represents the different document reference enforcements within a Standard TOC.

5.4.1.1 Definition

```
<xs:simpleType name='documentRefType'>
  <xs:annotation>Gives an enumeration of the valid document references
  </xs:annotation>
  <xs:restriction base='xs:string'>
    <xs:enumeration value="allowed"/>
    <xs:enumeration value="required"/>
    <xs:enumeration value="prohibited"/>
  </xs:restriction>
</xs:simpleType>
```



6 Appendices

This chapter contains the appendices

6.1 XML Definition

The XML definition is not part of this document and only available online.

Refer to ECPA CADDY-xml internet page: http://caddy.ecpa.eu/caddy_xml.html

6.2 XSL Transformation

The XSLT transformation is not part of this document and only available online.

A version can be displayed within a browser using one of the 'index.html' within its version folder. JavaScript will be used to deliver the necessary dynamic updates resulting from mouse clicks. Formatting is done with browser's built-in XSLT processors (available in common browsers, e.g. Microsoft Internet Explorer, Mozilla Firefox).

The appearance is designed to be customizable to a certain extent. Basic knowledge of web development techniques is required. Experience with Cascading Style Sheets (CSS) is necessary.

6.2.1 Directory-Structure

All supporting files are placed within the directory 'utils' (at the same level as the 'caddy.xml' file). Special sub-directories exist to structure the different types of these files:

Directory	File	Description
utils		Base directory for further sub-directories and supporting files for XML No changes must be applied here.
	caddy-1-1.xsd	XML Schema for caddy.xml
	caddy-1-1.xsl	XSL to transform caddy.xml to HTML
	xlink.xsd	XML Schema for XLink used within caddy-1-1.xsd
	top.js	JavaScript for all interactive updates during browser usage
utils/css		Directory with CSS-files. Changes and customization possible. (See 6.2.3)
	general.css	Global CSS used within all frames except the tree view
	tree.css	CSS used within tree view
utils/framesets		Directory with HTML-files for frameset definitions. No changes must be applied here.
	docdetails.html	Frameset for document details (content and hyperlinks)
	docnode.html	Frameset for document (tabs and document details)
	dossnode.html	Frameset for dossier details (tabs and information)
	secnode.html	Frameset for section details (information and hyperlinks)
	treenode.html	Frameset for content area (navigation and main area)



utils/images		Directory with images. Changes and customization possible. (See 6.2.2)
utils/pages		Directory with HTML-files for default frame content. No changes must be applied here.
	banner.html	Banner-page to display top images and caddy (company) logo
	blank.html	Empty-page used as default content
	doccontent.html	Page used for document content display
	doctabs.html	Page used for action-tabs during document display
	dossdetails.html	Page used for dossier information display
	dosstabs.html	Page used for action-tabs during dossier information display
	hl.html	Page used for hyperlink display
	sec.html	Page used for section display

6.2.2 Customisation of Images

The following images are referred by the default HTML pages and can be exchanged. The standard size should be reused whenever possible. Size limitations must be followed.

File	Standard Size	Size Limitation	Description
banner-background.gif	1600*88	Height=88	Background for top frame. Width of banner should support high resolutions
logo.gif	98*68	Height<80	Transparent CADDY logo used on right side of banner. Width of image should be limited to leave space for version title and subtitle.
document.gif	20*20	Height≤20 Width≤20	Icon of Document in folder Standard. Image should have 1 pixel border and should be defined as transparent
document-locked.gif	20*20	Height≤20 Width≤20	Document in folder Confidential. Image should have 1 pixel border and should be defined as transparent
empty.gif	9*9	Height≤20 Width≤20	Empty image of same size as collapse.gif and expand.gif. Used for none-expandable sections. Image should have 1 pixel border and should be defined as transparent
section.gif	20*20	Height≤20 Width≤20	Icon for CADDY section. Image should have 1 pixel border and should be defined as transparent
collapse.gif	9*9	Height≤20 Width≤20	Icon for collapse button to close section. Image should have 1 pixel border and should be defined as transparent
expand.gif	9*9	Height≤20 Width≤20	Icon for expand button to open section. Image should have 1 pixel border and should be defined as transparent
tab-background.gif	16*15	Height≤20 Width≤20	Background for action buttons. Image should have 1 pixel border and should be defined as transparent



6.2.3 Customisation of the Appearance

The appearance (or branding) i.e. colours, font-sizes and font-styles of the browser preview can be changed via CSS classes. The following classes will be used by the default HTML-pages and HTML-framesets. Changes may be applied there. All other existing CSS classes must not be changed. New classes may be defined.

CSS-class	Definition	Description
body	both	Default settings for colours (background and foreground) and fonts
TD	both	Font and alignment of table cells
TH	both	Font and alignment of table headers
P	both	Font and alignment of paragraphs
.frameless	both	Class to define the borders of frames to completely or mostly frameless
.trigger	both	Class for clickable tree entries and action tabs
.link	general.css	Class for hyperlinks
.title	general.css	Class for version title in banner frame
.subtitle	general.css	Class for version sub-title in banner frame
.branch	tree.css	Class for indent width of tree



6.3 Versioning Example

6.3.1 Introduction

This section illustrates versioning within CADDY-xml with a small sample dossier consisting of three submissions 01.00, 01.01 and 02.00. Each submission has different document operations which cover the different actions during the dossier lifecycle.

6.3.2 Table of Content

The following outline of a table of content shows the locations where documents are located:

1 Section	(initially added in submission 01.00)
1.1 Document A*	
1.2 Document B*	
1.3 Document C*	
1.4 Document D*	
2 Section	(initially added in submission 01.01)
2.1 Document KK*	
2.2 Document LL*	
2.3 Document MM*	
3 Section	(initially added in submission 02.00)
3.1 Document SSS	
3.2 Document TTT	
3.3 Document UUU	

Due to incremental build-up and delete operations the above structure will not really exist in any of the submissions completely. It is only an outline for all documents which are part of the Table of Content over all submissions. The different submissions will only have subsets of this structure.

6.3.3 Submission 01.00

The initial submission is always a major submission and can only have documents with the operation “new”.

6.3.3.1 Operations

The following documents will be newly added:

- Document A
- Document B (with report-data)
- Document C
- Document D

The following hyperlinks exist:

- Document-Link from Document A (page 1) to Document B (page 1)



- Document-Link from Document B (page 1) to Document C (page 1)
- Document-Link from Document C (page 1) to Document D (page 1)

6.3.3.2 XML Snippet

The following XML fragment shows the relevant parts concerning versioning and does not contain all mandatory attributes and elements:

```
<caddy-xml ...>
...
<toc>
  <!-- Submission 01.00 TOC -->
  <toc-entry id="IDT001" number="1" title="Section">
    <toc-entry id="IDT011" number="1.1" title="Document A*">
      <document-ref docId="IDD001"/>
      <hyperlink targetType="document" targetPage="1" title="A to B"
        id="IDHL001" sourceType="document" sourcePage="1" targetId="IDT012"/>
    </toc-entry>
    <toc-entry id=" IDT012" number="1.2" title="Document B*">
      <document-ref docId="IDD002"/>
      <hyperlink targetType="document" targetPage="1" title="B to C"
        id="IDHL002" sourceType="document" sourcePage="1" targetId="IDT013"/>
    </toc-entry>
    <toc-entry id=" IDT013" number="1.3" title="Document C*">
      <document-ref docId="IDD003"/>
      <hyperlink targetType="document" targetPage="1" title="C to D"
        id="IDHL003" sourceType="document" sourcePage="1" targetId="IDT014"/>
    </toc-entry>
    <toc-entry id=" IDT014" number="1.4" title="Document D*">
      <document-ref docId="IDD004"/>
    </toc-entry>
  </toc-entry>
</toc>
...
</toc>
<document-list>
  <document id="IDD001" title="Document A" operation="new"
    xlink:href="../01.00/standard/documents/idd001/idd001.pdf"
    addedVersion="01.00" .../>
  <document id="IDD002" title="Document B" operation="new"
    xlink:href="../01.00/standard/documents/idd002/idd002.pdf"
    addedVersion="01.00" ...>
    <report-data id="IDR001" validDay="true" protect="true"
      date="2005-03-15" published="true" vertebrates="true"
      validMonth="true" glp="true" title="Report Data Title Original"/>
  </document>
  <document id="IDD003" title="Document C" operation="new"
    xlink:href="../01.00/standard/documents/idd003/idd003.pdf"
    addedVersion="01.00" .../>
  <document id="IDD004" title="Document D" operation="new"
    xlink:href="../01.00/standard/documents/idd004/idd004.pdf"
    addedVersion="01.00" .../>
</document-list>
...

```



</caddy-xml>

6.3.4 Submission 01.01

The first follow-up submission contains some variation in the files and hyperlinks:

6.3.4.1 Operations

The following documents will be newly added:

- Document KK
- Document LL
- Document MM

The following documents will be replaced:

- Document A will become Document AA
- Document C will become Document CC
- The report-data of Document B

The following documents will be deleted:

- Document D

The following hyperlinks will be added to the already existing ones

- Document KK to Document LL
- Document LL to Document MM

Note: Hyperlinks which point to not longer existing documents will be removed from the table of contents.

6.3.4.2 XML Snippet

The following XML fragment shows the interesting parts concerning versioning and does not contain all mandatory attributes and elements:

```
<caddy-xml ...>
...
<toc>
  <!-- Submission 01.00 TOC -->
  <toc-entry id="IDT001" number="1" title="Section">
    <toc-entry id="IDT011" number="1.1" title="Document A*">
      <document-ref docId="IDD001"/>
      <hyperlink targetType="document" targetPage="1" title="A to B"
        id="IDHL001" sourceType="document" sourcePage="1" targetId="IDT012"/>
    </toc-entry>
  </toc-entry>
</toc>
</caddy-xml ...>
```



```
<toc-entry id=" IDT012" number="1.2" title="Document B*">
  <document-ref docId="IDD002"/>
  <hyperlink targetType="document" targetPage="1" title="B to C"
    id="IDHL002" sourceType="document" sourcePage="1" targetId="IDT013"/>
</toc-entry>
<toc-entry id=" IDT013" number="1.3" title="Document C*">
  <document-ref docId="IDD003"/>
</toc-entry>
</toc-entry>
<!-- Submission 01.01 TOC -->
<toc-entry id="IDT002" number="2" title="Section">
  <toc-entry id="IDT021" number="2.1" title="Document KK*">
    <document-ref docId="IDD005"/>
    <hyperlink targetType="document" targetPage="1" title="KK to LL"
      id="IDHL004" sourceType="document" sourcePage="1" targetId="IDT022"/>
  </toc-entry>
  <toc-entry id=" IDT022" number="2.2" title="Document LL*">
    <document-ref docId="IDD006"/>
    <hyperlink targetType="document" targetPage="1" title="LL to MM"
      id="IDHL005" sourceType="document" sourcePage="1" targetId="IDT023"/>
  </toc-entry>
  <toc-entry id=" IDT023" number="2.3" title="Document MM*">
    <document-ref docId="IDD007"/>
  </toc-entry>
</toc-entry>
</toc>
...
</toc>
<document-list>
  <!-- Submission 01.00 Files -->
  <document id="IDD001" title="Document AA" operation="replaced"
    xlink:href=" ../01.01/standard/documents/idd001/idd001.pdf "
    addedVersion="01.00" changedVersion="01.01" .../>
  <document id="IDD002" title="Document B" operation="new"
    xlink:href=" ../01.00/standard/documents/idd002/idd002.pdf "
    addedVersion="01.00" ...>
    <report-data id="IDR001" validDay="true" protect="true"
      date="2005-03-15" published="true" vertebrates="true"
      validMonth="true" glp="true" title="Report Data Title Changed"/>
  </document>
  <document id="IDD003" title="Document CC" operation="replaced"
    xlink:href=" ../01.01/standard/documents/idd003/idd003.pdf "
    addedVersion="01.00" changedVersion="01.01" .../>
  <document id="IDD004" title="Document D" operation="deleted"
    xlink:href=" ../01.00/standard/documents/idd004/idd004.pdf "
    addedVersion="01.00" changedVersion="01.01" .../>
  <!-- Submission 01.01 Files -->
  <document id="IDD005" title="Document KK" operation="new"
    xlink:href=" ../01.01/standard/documents/idd005/idd005.pdf "
    addedVersion="01.01" .../>
  <document id="IDD006" title="Document LL" operation="new"
    xlink:href=" ../01.01/standard/documents/idd006/idd006.pdf "
    addedVersion="01.01" .../>
  <document id="IDD007" title="Document MM" operation="new"
    xlink:href=" ../01.01/standard/documents/idd007/idd007.pdf "
    addedVersion="01.01" .../>
</document-list>
```



```
...  
</caddy-xml>
```

6.3.5 Submission 02.00

This submission will be again a complete submission but also introduces some changes:

6.3.5.1 Operations

The following documents will be newly added:

- Document SSS
- Document TTT
- Document UUU

The following documents will be replaced:

- Document AA will become Document AAA
- Document LL will become Document LLL

The following documents will be deleted:

- Document CC
- Document MM

The following hyperlinks will be added to the already existing ones:

- Document SSS to Document TTT
- Document TTT to Document UUU

Note: Hyperlinks which point to not longer existing documents will be removed from the table of contents.

6.3.5.2 XML Snippet

The following XML fragment shows the interesting parts concerning versioning and does not contain all mandatory attributes and elements:

```
<caddy-xml ...>  
...  
<toc>  
  <!-- Submission 01.00 TOC -->  
  <toc-entry id="IDT001" number="1" title="Section">  
    <toc-entry id="IDT011" number="1.1" title="Document A*">  
      <document-ref docId="IDD001"/>  
      <hyperlink targetType="document" targetPage="1" title="A to B"  
        id="IDHL001" sourceType="document" sourcePage="1" targetId="IDT012"/>  
    </toc-entry>  
  </toc-entry>  
</toc>
```



```
</toc-entry>
<toc-entry id=" IDT012" number="1.2" title="Document B*">
  <document-ref docId="IDD002"/>
</toc-entry>
</toc-entry>
<!-- Submission 01.01 TOC -->
<toc-entry id="IDT002" number="2" title="Section">
  <toc-entry id="IDT021" number="2.1" title="Document KK*">
    <document-ref docId="IDD005"/>
    <hyperlink targetType="document" targetPage="1" title="KK to LL"
      id="IDHL004" sourceType="document" sourcePage="1" targetId="IDT022"/>
  </toc-entry>
  <toc-entry id=" IDT022" number="2.2" title="Document LL*">
    <document-ref docId="IDD006"/>
  </toc-entry>
</toc-entry>
<!-- Submission 02.00 TOC -->
<toc-entry id="IDT003" number="3" title="Section">
  <toc-entry id="IDT031" number="3.1" title="Document SSS">
    <document-ref docId="IDD008"/>
    <hyperlink targetType="document" targetPage="1" title="SSS to TTT"
      id="IDHL004" sourceType="document" sourcePage="1" targetId="IDT032"/>
  </toc-entry>
  <toc-entry id=" IDT032" number="3.2" title="Document TTT">
    <document-ref docId="IDD009"/>
    <hyperlink targetType="document" targetPage="1" title="TTT to UUU"
      id="IDHL005" sourceType="document" sourcePage="1" targetId="IDT033"/>
  </toc-entry>
  <toc-entry id=" IDT033" number="3.3" title="Document UUU">
    <document-ref docId="IDD010"/>
  </toc-entry>
</toc-entry>
</toc>
...
</toc>
<document-list>
<!-- Submission 01.00 Files -->
<document id="IDD001" title="Document AAA" operation="replaced"
  xlink:href=" ../02.00/standard/documents/idd001/idd001.pdf"
  addedVersion="01.00" changedVersion="02.00" .../>
<document id="IDD002" title="Document B" operation="new"
  xlink:href=" ../02.00/standard/documents/idd002/idd002.pdf"
  addedVersion="01.00" ...>
  <report-data id="IDR001" validDay="true" protect="true"
    date="2005-03-15" published="true" vertebrates="true"
    validMonth="true" glp="true" title="Report Data Title Changed"/>
</document>
<document id="IDD003" title="Document CC" operation="deleted"
  xlink:href=" ../01.01/standard/documents/idd003/idd003.pdf"
  addedVersion="01.00" changedVersion="02.00" .../>
<document id="IDD004" title="Document D" operation="deleted"
  xlink:href=" ../01.00/standard/documents/idd004/idd004.pdf"
  addedVersion="01.00" changedVersion="01.01" .../>
<!-- Submission 01.01 Files -->
<document id="IDD005" title="Document KK" operation="new"
  xlink:href=" ../02.00/standard/documents/idd005/idd005.pdf"
  addedVersion="01.01" .../>
```



```
<document id="IDD006" title="Document LLL" operation="replaced"
  xlink:href="../../../02.00/standard/documents/idd006/idd006.pdf"
  addedVersion="01.01" changedVersion="02.00" .../>
<document id="IDD007" title="Document MM" operation="deleted"
  xlink:href="../../../02.00/standard/documents/idd007/idd007.pdf"
  addedVersion="01.01" changedVersion="02.00" .../>
<!-- Submission 02.00 Files -->
<document id="IDD008" title="Document SSS" operation="new"
  xlink:href="../../../02.00/standard/documents/idd008/idd008.pdf"
  addedVersion="02.00" .../>
<document id="IDD009" title="Document TTT" operation="new"
  xlink:href="../../../02.00/standard/documents/idd009/idd009.pdf"
  addedVersion="02.00" .../>
<document id="IDD010" title="Document UUU" operation="new"
  xlink:href="../../../02.00/standard/documents/idd010/idd010.pdf"
  addedVersion="02.00" .../>
</document-list>
...
</caddy-xml>
```

6.4 References

6.4.1 Normative References

[eCTD]

ICH eCTD IWG, *Electronic Common Technical Document Specification V 3.2*, ICH M2 EWG, 2004

(See <http://www.ich.org>)

[ISO 3166-1-alpha-2]

ISO 1366-1:1997: *Codes for the representation of names of countries and their subdivisions -- Part 1: Country codes -- Alpha-2*, ISO, 1997

[ISO-19005-1]

ISO-19005-1:2004: *Document management – Electronic document file format for long-term preservation - Part 1: Use of PDF 1.4 (PDF/A-1)*, ISO, 2004

[RFC 1321]

RFC 1321: The MD5 Message-Digest Algorithm

(See <http://www.ietf.org/rfc/rfc1321.txt>)

[RFC 2119]

RFC 2119: Key words for use in RFCs to Indicate Requirement Levels , S. Bradner, 1997.

(See <http://www.ietf.org/rfc/rfc2119.txt>)

[URL]

RFC 1738, Uniform Resource Locators (URL). Internet Engineering Task Force.

(See <http://www.ietf.org/rfc/rfc1738.txt>)

[XHTML]

M. Altheim, et al. *Modularization of XHTML*, 2001. W3C

(See <http://www.w3.org/TR/xhtml1-modularization/>).

[XML]

Tim Bray, Jean Paoli, C.M. Sperberg-McQueen, and Eve Maler, editors. *Extensible Markup Language (XML) 1.0 (Second Edition)*. World Wide Web Consortium, 2000.

(See <http://www.w3.org/TR/2000/REC-xml-20001006.>)

[XLink]



Steve DeRose, Eve Maler, David Orchard, and Ben Trafford, editors. *XML Linking Language (XLink)*. World Wide Web Consortium, 2000.

(See <http://www.w3.org/TR/xlink>.)

[XML Schema]

David C. Fallside, Priscilla Walmsley - Second Edition, editors. *XML Schema Part 0: Primer Second Edition*, World Wide Web Consortium, 2004.

(See <http://www.w3.org/TR/xmlschema-0/>)

[XSLT]

James Clark , editor. *World Wide Web Consortium. XSL Transformations (XSLT). W3C Recommendation.*, World Wide Web Consortium, 1999

(See <http://www.w3.org/TR/xslt>)

6.4.2 Informative References

[Adobe-Ref]

How to link from an HTML page to a specific page in PDF file , Adobe, 2005.

(See <http://www.adobe.com/support/techdocs/315385.html>)



6.5 Version History

The following table gives an overview of the existing versions of this specification.

Version	Date	Author	Status
1.0	29/04/2005	Oliver Bojahr	Initial version
1.0.1	19/07/2005	Oliver Bojahr	<ul style="list-style-type: none"> - version-history-list must not have entries for the initial submission. MinOccurrence of version-history set to "0". - Complex types have the suffix "-type" to allow import with JAXB
1.1.0	03/07/2006	Oliver Bojahr	<ul style="list-style-type: none"> - unique dossier ID added to section 4.3 and 4.20.8 - master and issue dates added to version in section 4.2 - string types reduced - set header attributes as optional - dossier id as root folder of dossier - Section 5.1: CADDY-xml definition replaced by reference
1.1.0 prop. 3	06/07/2007	Andreas Wastl	<ul style="list-style-type: none"> - Old section 3.1.4 "Version History" and all references to version-history in texts or images removed - New section "Specification Version" (3.1.2) introduced - "Table of contents" (3.1.5): Reference to Standard TOC and "intentionally left blank" introduced - "Documents" (3.1.6): Reference numbers (sections) corrected - "Attachments" (3.1.73.1.6): Reference numbers (sections) corrected - "Additional files description" (3.1.8): Text slightly enhanced - New section "Standard Table of Contents" (3.2) introduced. - "Version Handling of submission" (3.3): Enforcement of complete TOC structure for complete and incremental submissions introduced - "Directory Structure and Volume Handling" (3.4): Recommendation for max. 200 chars for paths and restriction to 500 files per directory; Standard TOC xsd/xsl file added. - "File References" (3.7): Prefix "file://" removed to have consistent examples - "Common file formats" 3.8: Used naming for files adapted to match used section titles of 3.8.x; directory structure of XML files changed; filename restrictions softened; missing "oecd-data" added - "CADDY-xml in a Web-Browser" (3.9): Restriction to MSIE 6.0+ and Mozilla Firefox 1.5+ introduced - <caddy-xml> (4.1.x): Attribute 'xmlVersion' introduced - <version> (4.2.x): Missing 'additional-file-list' child added - <header> (4.3.x): Sequence of child elements in definition and



Version	Date	Author	Status
			<p>example adapted to sequence of description table</p> <ul style="list-style-type: none"> - <active-substance> (4.6.x): Attribute length for 'cas' in definition corrected; sequence of attributes in example adapted - <concentration> (4.7.x): Mandatory flag in attribute table for attribute 'productId' and 'substancelid' changed to 'true' to match definition - <toc-entry> (4.8.x): Reference to Standard TOC introduced - <toc-entry> (4.9.x): New attributes 'intentionallyLeftBlank' and 'intentionallyLeftBlankComment' introduced; Example shortened - <hyperlink> (4.11.x): Reference to CADDY standard; attribute 'targetDestination' introduced; attribute 'title' in attributes table and definition corrected; changed example with 'targetDestination' - <document> (4.13.x): Duplicate attribute 'changedVersion' from definition removed; prefix "file://" removed within example <report-data> (4.14.2): Name of attribute 'dossierFileNumber' in attribute table corrected - <attachment> (4.15.2): Attribute type for 'addedVersion' corrected to 'VersionNumber'; example corrected, "file://" removed - Old section 4.16 'The version-history-list Element' removed - Old section 4.17 'The version-history Element' removed - <additional-file-list> (4.16.x): Attribute sequence in example changed - <additional-file> (4.17.x): Attribute sequence in example changed - New section 'The xmlVersionNumber Type' (4.18.1) inserted - Old section 4.20.10 "The elementType Type" removed - New chapter 5 "The CADDY-xml Standard TOC Definitions" introduced - "Customisation of Images" (6.2.2): New size for tab-background.gif - Overall: Formatting of XML code - Overall: Slight changes in wording or removal of spelling or grammar mistakes
1.1.0 prop. 4	12/11/2007	Andreas Wastl	<ul style="list-style-type: none"> - Overall replacement of ecpa.be with ecpa.eu - "Hyperlinks" (3.1.9): Prefix "file://" removed to have consistent examples - Version Handling of Submissions (3.3): Hyperlink handling for deleted toc entries; No more inclusion of deleted files in major submissions, only document references. - File References (3.7): Use of service part of URL (file:// or http://) stated as forbidden.



Version	Date	Author	Status
			<ul style="list-style-type: none"> - Original Files (3.8.1): Only compliance with PDF/A-1b required - Attachments (3.8.2) / Additional Files (3.8.3): Recommended restriction of allowed characters and necessary agreement between sender and receiver. - CADDY-xml in a Web-Browser (3.9): Restriction to support of Firefox for MS Windows - Example (4.1.4): Use of ISO-8859-15 (as this supports some characters which are missing in ISO-8859-1. - <toc-entry> (4.9.2): IntentionallyLeftBlankComment only allowed for intentionallyLeftBlank 'true' - Versioning Example (6.3.x.2): Adaption to changes within 3.3.
1.1.0 prop. 5	28/01/2008	Andreas Wastl	<ul style="list-style-type: none"> - Attributes (4.11.2): Accidentally deleted sourceType added again. - The dossier Type (4.18.9): Mixture of "volume set ID" and "dossierID" corrected and clarified. - Original Documents (3.8.1): Typo "documents" corrected.