

CADDY Forum (formerly Joint CADDY Steering Group)

CADDY Application Guide

How to Use the CADDY Format Specification to File
a Pesticide Registration Dossier on Electronic Media

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Acknowledgments

This document references other standards like TIFF, ISO standards and others. We would like to thank all those who have worked on these standards.

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1 Introduction

1.1 About this Application Guide

This document describes the application of CADDY, an electronic dossier interchange and archiving format for pesticide registration application documents. CADDY stands for **C**omputer **A**ided **D**ossier and **D**ata supply. The Application Guide has to be seen in the overall context of the CADDY standardization work.

The purpose of this document is to create a common understanding between regulatory authorities and industry on how to use CADDY and what to expect from CADDY.

It should:

- Enable regulatory staff in industry to file an electronic submission on CADDY CD-ROM sets
- Present information for regulatory authorities on handling CADDY CD-ROM sets

CADDY consists of a number of different building blocks:

- **The CADDY Format Specification:** this document describes the technical details of how a paper dossier should be represented on a series of CD-ROMs. The CADDY format specification is especially important for IT-experts who wish to generate software for the compilation of CADDY dossiers, or the review of such dossiers;
- **CADDY Compilation Software:** This is computer software that can create CADDY dossiers, using either electronic documents, or hard copy as a source. Compilation software is commercially available, or can be created by IT-experts on the basis of the CADDY format specifications;
- **CADDY Conformity Test Software (CTSW):** this freely available software can be used to check if CADDY dossiers, created with any form of compilation software, are fully compliant with the CADDY format specification;
- **CADDY Retrieval Software (RSW):** A retrieval software for CADDY dossiers is freely available from the internet; this software allows users to browse dossiers, find specific reports and underlying electronic files, create and share annotations during the review of dossiers, and communicate with other evaluators by creating and using both internal and external hyperlinks

The document was prepared on behalf of:

- The European Commission
- Regulatory Authorities of the European Union Member States
- European Crop Protection Association (ECPA)

Strategic Goal of the CADDY Project

Representatives from regulatory authorities and industry expressed their strategic goal in the following statement:

CADDY has to facilitate

- the provision of dossiers for pesticides to regulatory authorities,
 - the long-term archiving of such dossiers,
 - the accessibility of information contained in such dossiers
 - and the examination and assessment of dossiers by regulatory authorities
- in a cost-effective manner using electronic media.

1.2 Scope of the Application Guide

This Application Guide is intended to be a technical and practical guide both for producers and receivers of CADDY CD-ROM sets. The Application Guide often references the CADDY Format Specification [1] for specific technical details. A certain level of competence in information technology is assumed of the readers of these documents. Although regulatory authorities may choose to include herein supplemental guidance necessary to facilitate dealing with CADDY, the Application Guide is not intended to replace any existing guidance or requirements set forth by any authority. Nor is it intended to provide step-by-step instructions on dealing with the creation, management, and review of CADDY CD-ROM sets or dossiers. Rather, this document recommends ways of implementing the CADDY standard in an organization. The parties involved in developing CADDY support these recommendations. The Application Guide is dynamic and developments in the regulatory process will be reflected in future versions of the Application Guide.

1.3 The CADDY Submission Process

A CADDY CD-ROM submission begins its life cycle when study reports are generated. Most study reports and regulatory summaries are created using computer technology normally using a word processor. Additional applications such as spreadsheets or databases are also used. Since these reports are available in their native electronic format, it makes sense – where possible - to keep them in the electronic form for submission and bypass the paper stage altogether. Rather than first printing reports and regulatory summaries to paper and then scanning the paper to create CADDY compliant TIFF-pages, these CADDY- pages can be generated directly from the source document through a soft-scan process, which is described later in this document. The CADDY pages are then written to CD-ROM, along with ASCII text indexing information to facilitate organization and retrieval. Details on the indexing information are provided later in this document and in the CADDY Format Specification [1].

It is strongly advised that whenever original electronic versions are available of any report included in a dossier, this electronic version, or another electronic rendition of it, is attached to the CADDY pages of the document. This can be done in the form of the so-called CCFs (CADDY Controlled Files). If word processing files are available, it is advised that in addition to the original file (e.g. in WinWord format), a PDF-version is created and added. As the current Retrieval Software (Version 2.x) allows the user to decide if he wants to work by default with the CADDY-TIFF-pages, or with any other file-type (as long as that is available), the use of one file-type (such as PDF) is strongly advised.

Once the CADDY CD-ROM set has been finalized, it is submitted to the appropriate regulatory authorities where the CADDY Retrieval Software is used to view the study reports, extract information from the submission for re-use in the review process. Some regulatory authorities have found it convenient to store the entire CADDY submission on their own in-house network, thus eliminating the need to manage the distribution of CD-ROM sets to the individual reviewers. Information on how to achieve this is described later in this document. Companies may wish to obtain copies of the Retrieval Software so that they can confirm for themselves that their CADDY CD-ROM sets are properly fully functional and to facilitate internal accessibility of dossiers.

Some regulatory authorities will choose to accept CADDY submissions only, or a mix of paper and CADDY submissions. CADDY is designed to facilitate document exchange between applicants and regulatory authorities as well as between regulatory authorities. The CADDY standard is completely open and is not tied to any specific submission structure, e.g. EU, EPA, and OECD etc. Submissions in CADDY format can be used by anyone, irrespective of the submission structure specified by the regulatory authorities. That is, though the contents of CD-ROM sets may differ from submission to submission, the technical format of the CD-ROM set is uniform and, thus, usable by all authorities accepting CADDY CD-ROM sets.

1.4 The Future of CADDY

Version 1 of CADDY was designed to encompass only the essential elements for making electronic data submission a reality. As with first versions of most software, desirable enhancements and features not yet developed then become obvious through their absence. A number of ideas for future versions of CADDY have surfaced over the past 4 years since the introduction of CADDY, have been discussed, agreed and prioritized by the CADDY Forum and many have already been implemented in the latest versions of the CADDY standard and the Retrieval Software.

Whereas the first version of the CADDY Retrieval Software was conceived as a 16-bit stand alone application, the latest version is a 32-bit application and now includes additional features requested by the users, such as true network functionality and multi-user support, the capability of importing and exporting annotations and the possibility to create hyperlinks both within a submission as well as to additional files (CADDY Controlled Files) included with the submission. This has taken CADDY far beyond the original scope of being primarily an electronic archiving tool and has opened up completely new possibilities for regulatory authorities to work with electronic submissions.

US and Canada participated in the definition of the initial CADDY standard. However, due to differences in the review approach between the EU (top down evaluation) and North America (bottom-up evaluation) it became obvious that the requirements for electronic submission tools were equally different. Although different technological solutions have been chosen, dialogue is continuing at the OECD level to ensure future convergence rather than divergence of electronic submission tools.

More recently, an additional standard – CADDY-xml – has been developed and published (see CADDY website). This will allow a better integration with the internal information system of regulatory authorities and will provide the ability to view dossiers without installing additional software.

CADDY-xml is aligned with future developments at OECD level, which go in the direction of xml-based submission templates, and will facilitate broader exchange of regulatory dossiers also in regions and countries where CADDY is not used.

1.5 CADDY Project Management Office (PMO)

In the organization of the CADDY project, the responsibilities are clearly established. ECPA is the focal point for CADDY support. Therefore ECPA will register new and existing CADDY users, and host the access to the CADDY e-mail helpdesk. Within ECPA the Data Transfer Working Group (DTWG) is responsible for the day-to-day running of the project. The DTWG works in close collaboration with the CADDY Forum, the Regulatory Authorities within the European Union, and all other authorities that take an interest in CADDY developments.

The CADDY Project Management Office (PMO) is run by Hewlett-Packard (HP), under ECPA's guidance. Within that role, HP is responsible for further software development, helpdesk response, web site maintenance and many other "behind-the-scene" activities.

1.5.1 CADDY Support

Registered users of the CADDY RSW can obtain free email support by writing an email to caddy_support@ecpa.eu.

1.5.2 CADDY Website

Actual information on CADDY can be obtained from the CADDY website on <http://caddy.ecpa.eu>. The website always contains the latest news and developments on CADDY. It also offers all the free downloadable software (Retrieval Software, Conformity Test Software) and documents (the CADDY format specification, this application guide, the brochure, etc.) and CADDY training materials, which can be used for either self-training, or for organizing a group training in the use of the retrieval software. For any questions about CADDY, the Retrieval Software or any other document or software, the website provides the actual contact information.

2 CADDY Users and their Requirements

2.1 Authority Reviewers

The success of CADDY largely depends upon acceptance by the users and the incorporation of CADDY-format data reviewing into their daily work. To this end, the reviewers should be as comfortable as possible using the software. Ensuring reviewer comfort with CADDY consists of several things. First, the reviewer must be comfortable in the actual use of the software. This means the software must be properly installed; must provide ready access to the data to be evaluated; and the reviewer must have sufficient training to effectively use the system. Secondly, the reviewer must be physically comfortable, since reviewing documents onscreen is very different from reviewing paper documents.

Authorities should ensure that appropriate internal work processes in the organization are established to support the reviewing process with CADDY CD-ROM sets. Access to the documents on CDs should be as simple as access to paper studies; there should be no additional burden placed on reviewers. A good implementation plan for CADDY within the organization should be developed as soon as possible. Look at current methods and how studies are routed around the organization. Try to align the routing of CADDY submissions with the way the process currently works. This will help prevent reviewers from being overwhelmed by both a new reviewing paradigm and new workflow processes within the organization.

Additionally, there might be reviewers who prefer to spread out sheets of paper in front of them and conduct their evaluations that way. Rather than alienate these reviewers from the new system, try to accommodate them and at the same time, demonstrate the options available while doing online reviews. High-speed printers should be available as a fallback solution. Show these reviewers that perhaps only part of a study may need to be printed for review, while other parts might more easily be reviewed onscreen. Give them time to overcome any initial hesitation, the learning curve, and to discover for themselves the benefits of reviewing electronically. Also recognize that there are times when reviewing may be better done using paper. Most important, but too often overlooked, is the matter of ergonomics. For the CADDY system to be successful, reviewers must be physically comfortable while using the system. In fact, the risk of physical injury is much higher among workers who spend long periods of time using a computer without regard for the physical effects of this type of work. Hence, ergonomics is not to be ignored in determining reviewer needs. Of particular importance to a reviewer will be a large monitor. The reviewer's monitor should be large enough so that a full page, or even two pages side-by-side, can be read at once without having to scroll or zoom. The monitor should also have a high refresh rate. The higher the refresh rate, the less the monitor flickers at higher resolutions and the easier it is on the eyes. Ambient lighting is a similar consideration. Many offices are equipped with fluorescent lighting. However, these types of lights flicker as well, and can cause eyestrain. A better choice might be halogen lighting. It provides constant, soft light and is easier on the eyes. Halogen desk and floor lamps can be obtained quite cheaply.

Another item to look at is the reviewer's workstation. A comfortable, adjustable seat with lumbar support, arm rests, and wheels are important to keep the reviewer comfortable. Ergonomically designed keyboards and mice are also worth evaluating, as well as various types of support pads used along with these devices. Angled or adjustable footrest platforms are another way to help prevent physical strain to the reviewer. Finally, do not overlook the desk itself. Furniture in most offices was not designed with computers in mind. An ergonomically designed desk will allow for adjustable placement of the monitor, the height of the desk; it will allow for proper adjustable placement of the keyboard and mouse; and the desk should allow for enough workspace that the computer is not in the way when not in use.

2.2 Authority Regulatory Administrators

Regulatory Administrators are those who handle administrative procedures regarding the receipt and review of scientific data within an authority. As such, they will also benefit from having access to CADDY CD-ROM sets. A Regulatory Administrator's role might be to coordinate with companies the submission of the dossier and to coordinate within his own organization the tracking and scientific review of the information contained within the dossier. To these ends, training in and knowledge of CADDY would be of benefit. In addition, there may be times when a Regulatory Administrator might wish to access information on a CADDY dossier for various purposes. It would, therefore, be useful for Regulatory Administrators to have access to the CADDY Retrieval Software.

2.3 Industry Regulatory Specialists and IT Specialists

Industry Regulatory specialists are those who are responsible for the compilation of registration dossiers. In that, they aim at producing dossiers that comply with existing guidelines and that are easy for Regulatory Authorities to work with.

Standardized Retrieval Software, which can be used by the Regulatory Authorities for working with the CADDY submissions, has been developed and continuously improved by the CADDY project teams since 1998. This was possible because every CADDY CD-ROM set complies with the same technical specifications. On the other hand it was decided not to create a common CADDY compilation software since the starting point will not be the same for everyone and applicants should have the freedom to produce the CADDY submissions in the way that fits best into their IT environment. In some cases, dossiers will be compiled directly from paper, scanning the pages and storing them in the correct way as CADDY CD-ROM sets. On the other hand, most larger companies now have document management systems (e.g. based on DOCUMENTUM) in place to manage their regulatory documents and each of these systems has its own specific architecture and configuration. Therefore, every company is responsible for producing its own CADDY compilation/creation software (also called "compilation software"). In addition, there are several independent service companies that offer the compilation of a CADDY submission as a service to their customers.

Since the compilation of a submission is a long-term activity, starting a year or more before the planned submission date, the compilation software needs to support a process that might best be described as an "emerging submission" process. It should allow the regulatory personnel in charge of creating the submission to start with an empty submission structure representing the desired submission format and then gradually fill this submission with reports, regulatory summaries and risk assessment as well as any other required documents as these become available. This process will allow an overview of the state of progress and completion of the submission at any time and will allow sufficient time for quality and technical consistency checking activities over the creation period of the submission, so that these activities will not need to be done under time pressure at the last minute. While the process of compiling a submission is a long-term process, the last steps in completing the dossier are typically hectic, as the last bits and pieces of the dossier tend to become available only at the very last moment. Therefore, the final steps in the compilation process (the actual production of the CD-ROMs) should not become a bottleneck for meeting deadlines.

2.3.1 Paper versus CD-ROM

During the first years of the introduction of CADDY, some regulatory authorities have rapidly adopted the new technology while others preferred to receive paper copies of dossiers alongside the CD-ROMs. These paper copies, by definition, must be identical to the CD-ROM sets. There are two ways of achieving this objective. The first option – is to first build a paper version of the dossier and concurrently compile the CADDY version. This approach is both tedious and tricky, as it may be difficult to guarantee the two versions (paper and CD-ROM) are identical. The other alternative is easier: to build the dossier in an electronic document management system (either an in-house system or compilation software such as IABG's PlantOS) and once the dossier is finished, to prepare a paper and an electronic submission from the same dataset. Obviously this requires some extra time after production of the CD-ROM. High-speed printing facilities are now available where the difference between printing and photocopying speed become marginal.

2.3.2 European Considerations: Submission of Summary Dossiers

For the compilation of EU dossiers, some additional comments can be made. On the EU website documents are available ([H2] and [H3]) that describe the number of copies of full dossiers and of summary-dossiers required in each Member State for new and existing active substances, respectively. Because of the dynamics of the review process the exact number of copies required should always be confirmed with the Rapporteur Member State. Regarding the distribution of the files over the different CD-ROMs of the set, it is advisable to ensure that the summary dossier and the package of individual study reports can still be separated.

A more or less standard complete CADDY dossier would thus look as follows:

- 1 CD-ROM for the confidential data (Document J)

- 1 or more CD-ROMs for the individual study reports (Documents K-II and K-III)

- The last CD-ROM should contain documents A-I, the Tier 1 to 3 summaries, the completeness checks and the index files.

If organized like this, the last volume will contain all the elements required for the submission of a summary dossier and can be used stand-alone, where appropriate.

Although the CADDY Format Specification [1] allows storage of pages on any volume in a CD-ROM set, it is clear that a document should not be split across two volumes. Also, it is advisable that entire sections of a dossier be kept together on one volume because it would be convenient for a reviewer if he or she does not have to swap discs often.

2.3.3 Dossier Updates

When a dossier needs to be updated (e.g. when requested by the Rapporteur Member State or for subsequent submissions), there are several possibilities: One option is to reduce the number of supplemental volumes that need to be produced by placing all additional data, plus the updated index files on one volume. This replaces the previous index volume of a CD-ROM set. The same applies for "repairing" study reports. For example, if, in the original submission, certain pages of a report were missing, it is possible to place only the missing pages on the new index volume of a set. However, a reviewer who is browsing through a report would have to swap discs every time he comes across a "new" page. Therefore, the entire report should be placed on the new index volume.

However, when the above described strategy of keeping the (European) summary dossier separated from the rest of the dossier is followed, there is always the option of storing new reports or "repaired" reports on the last of the "reports discs," if that disc has space available. This means that for updating a complete dossier, two new volumes are required: one with the new study reports, and a new index volume. Which of the options to be used, depends on the submitting company's strategy. For the receiving regulatory authorities, it makes little or no difference in updating their existing dossiers.

2.3.4 Compilation Software Requirements

As described above, the process of compiling an electronic dossier will over time replace the current process of compiling submission from paper masters. The compilation software must therefore feel "natural" to industry Regulatory Specialists. It must allow them to choose the format of the dossier they wish to compile starting with an "empty" dossier of the correct structure, and work with it over an extended period of time. During the process they must be able to create and print overviews of the status of their dossier, check the number of volumes required, and to manage the storage of data (what will be stored on what disc). The compilation software must enable them to keep track of the history of dossiers when updates are created. It must allow the user to start with a certain version of a dossier if he wants to create a new or different dossier. It must allow the user, without assistance from IT-staff, to "burn" his CADDY CD-ROM set once his dossier is finalized. And it must enable him to organize the printing of an entire dossier, either in-house, or using an external supplier of high-speed printing services, with an absolute minimum of additional work after the printing.

3 Authority Requirements

3.1 General

A CD-ROM set consists of enough individual CD-ROMs necessary to provide the information contained in the dossier. If, however, a submitter provides authorities with an update version of a dossier without prior submission of the first version, it might be possible to submit only, for example, volumes 1, 2 and 4 if all the information of volume 3 is included on volume 4 except for modified pages.

3.1.1 Delivery of CD-ROM Sets

Submission of CD-ROM sets to the authorities should be done using appropriate freight carrier. The submitter should get information on the number of CD-ROM sets required to be sent to the respective authorities either from the relevant documents (see below) or by contacting the authorities to ensure the provision of the correct number of CD-ROM sets.

The addresses of respective authorities, as well as the name of a contact person, are listed and updated in separate documents, some of which are cited in this document within the sections specific to national requirements. The required number of CD-ROM sets containing dossiers or supplements are also listed in separate documents and also cited in the more country-specific sections of this document.

For security reasons it is recommended that authorities acknowledge their receipt of CD-ROM sets.

3.1.2 Distribution of CD-ROM Sets

The distribution of CD-ROM sets within the authorities will be organized by the authorities themselves according to their organizational needs and computer systems, taking into account whether the systems are networked or stand-alone PCs.

On stand-alone PCs, it is necessary to distribute the CD-ROM set, or at least the CD-ROM containing the index files (index volume) to any PC on which the dossier has to be installed. Systems using storage and provision of the data on shared network drives or in jukeboxes do not need to have any CD-ROM present at PC-site during the installation of the submitted dossier or supplement. It is sufficient if the index volume is accessible through the network.

When distributing the CD-ROMs within the authorities, special attention should be paid to security aspects. It should be kept in mind that not only the volumes containing the confidential information but also the other CD-ROMs contain large amounts of dossier data on a very small sized storage medium. Refer to the chapter on „Security Aspects“ for more information regarding this subject.

3.1.3 Usage of CD-ROM Sets

Requirements for access to and usage of the CD-ROM sets may vary depending on the authorities' set-ups. Both local CD-ROM drives and shared systems such as networks or jukeboxes may access CD-ROM sets.

In general, every CD-ROM set submitted, be it the initial dossier or a supplement, must be registered by the CADDY Retrieval Software on the PC. Only then can the data on the CD-ROM set be accessed from that PC. This is true regardless of whether the CD-ROM sets will be accessed locally or remotely for review. For the registration of CD-ROM sets, the index volume of the set must either be in the local CD-ROM drive or be accessible through the shared system.

When using the CADDY Retrieval Software on stand-alone PCs the CD-ROM set must be physically available to the user. The Retrieval Software requests the user to insert specific volumes into the drive,

depending on the study being reviewed and its placement on the volumes of the CD-ROM set. It is advisable to keep the complete CD-ROM set available except the specially labeled confidential volume. In the case of supplemental submissions, it is sufficient to have available only the submitted CD-ROMs if the access will be limited only to the newly submitted data. Otherwise, the other volumes of former submissions containing any data (except the previous index volume) must be available. The index files of the newly submitted supplement will replace the index files of former versions.

To access the submitted data in shared systems, no CD-ROM has to be present at PC workstation since there is no need to insert any discs into the CD-ROM drive for data access. However, all data from the CD-ROMs must be accessible via the network.

Currently, the CADDY system allows storing the information from the CD-ROMs on hard disks shared within a network (e.g. a shared drive on a network server). For network access of the data, the contents of the individual volumes in a CD-ROM set must be copied to separate subdirectories for each single CD-ROM, which are accessible from any PC with respective network access.

CD-ROM jukeboxes can be used if a separate jukebox server providing network-like access is used. In this case, special software on the server regulates the access to the various discs in the jukebox.

3.1.4 Archiving of CD-ROM Sets

Storage of the CD-ROMs for purposes of archiving should be at dry conditions at ambient room temperature out of direct sunlight and at a stable temperature. Storage in darkness is preferable to avoid UV-radiation and to prolong the life of the CD-ROMs, which is believed to be about 70-100 years.

3.2 EU Considerations

3.2.1 Purpose of Use of CADDY

In the European Community, CADDY is intended primarily for submission of dossiers concerning the evaluation of active substances and the authorization and the placement of plant protection products on the market according to Council Directive 91/414/EEC of 15 July 1991 and its amendments.

This Directive concerns the authorization of plant protection products containing active substances existing prior to 25 July 1993 as well as new active substances to be introduced to the market after this date. It lays down the requirements on necessary information to be submitted to the authorities for the evaluation process. The approved substances will be listed in Annex I of the Directive. The requirements for the dossier to be submitted for the inclusion of an active substance or the authorization of a plant protection product are laid down in Annex II and Annex III, respectively.

Guidelines and criteria for the preparation and presentation of dossiers for inclusion of active substances in Annex I are given by the Commission document 1663/VI/94 [3]. This document gives detailed information on the content and examples of the layout of the complete dossier and of the summary dossier (the latter containing only summarizing and supporting information without individual test or study reports).

3.2.2 Requirements on the Content of the CD-ROM Sets

The CD-ROM set should be compiled based on the currently provided paper copy of the dossier, which should follow the recommendations of document 1663/VI/94 [3]. I.e. the content of the supporting documentation (documents A to J, and O) as well as the tier summaries (documents L-II & L-III, M-II & M-III and N) should be included as image files. Furthermore, all studies submitted should be included on the CD-ROM sets as image files. Thus, the documents stored on the CD-ROM sets should be identical to the paper copy of the dossier.

In addition to the dossiers submitted to the authorities on CD-ROM, the submitter must submit a signed statement to indicate that the paper copy and the copy on the CD-ROM set are identical.

Basically, the data on the CD-ROM can be arranged freely on the CD-ROM provided the requirements of the latest version of the CADDY Format Specification [1] are followed. However, one restriction is the use of a standardized Table of Contents (TOC). The length of entries in the TOC is limited to a maximum size of 70 characters. This may limit the display of titles in the TOC. This limitation in the CADDY Retrieval Software is a compromise allowing for display of the TOC and a page viewer window side-by-side. To facilitate the navigation within the TOC, the use of the standardized TOC is mandatory. The structure of the standardized TOC for the current EU formatting guideline and the OECD formatting guideline can be found in the Appendices B and C to this Application Guide. These standardized TOC conforms to the current and future requirements of the Directive 91/414/EEC and will ensure and facilitate the proper access of the documents.

3.2.3 Additional Information on CD-ROM

For the process of evaluating dossiers within the European Community, electronic versions of summary dossier information (documents L-II, L-III, M-II, M-III and N) are necessary. These are to be submitted to the authorities alongside the paper copies of the dossier.

- When compiling CADDY version 1 dossiers, the word processor files of the documents L, M and N should be included on the CD-ROM in a separate sub directory named „FILES“ in the root directory of any volume per the CADDY Format Specification [1]. However, as there is no standardization of the content of this sub directory, the submitter of a CD-ROM set and the authorities are recommended to devise a mutual agreement on the word processor format prior to submission. Generally, it is advisable to use a widely used word processing format such as Microsoft Word, WordPerfect or others to make the data accessible to as many authorities as possible.
- In the case of CADDY version 2 dossiers, files should be stored as CCF (CADDY Controlled Files) linked to the table of content following the CADDY Format Specification rev. 2.0.

3.2.4 Number of CD-ROM Sets Requested by EU Member States

The Commission and the EU Member State authorities will request various numbers of different dossiers. The respective guidance documents on the DG SANCO webpage describe the number of copies of full dossiers and of summary-dossiers required in each Member State for new and existing active substances, respectively. Because of the dynamics of the review process the exact number of copies required should always be confirmed with the Rapporteur Member State. Regarding the distribution of the files over the different CD-ROMs of the set, it is advisable to ensure that the summary dossier and the package of individual study reports can still be separated.

3.2.5 Contact Points for CD-ROM Submissions

A list of contact points within EU Member States for the submission of dossiers on new substances or for the re-evaluation program of existing active substances is provided in Commission document [SANCO/3065/2001](#) [4]. This document lists respective addresses to which dossiers including copies on CD-ROM should be sent.

3.3 OECD Considerations

Work is underway to improve the harmonization of technical and regulatory aspects of pesticide registration among various countries and the pesticide industry. Many government and private organizations have been working closely for several years to foster this harmonization. These efforts by government and industry are expected to make more efficient use of limited resources and deliver more timely and informed decisions.

One of the most significant initiatives to facilitate harmonization among countries was the development and use of common formats for the submission of information by registrants to support new registrations and for documenting science and regulatory decisions by government agencies that review these submissions. These guidelines were completed in 2000 and adopted by the OECD in 2001. The objective is that OECD member states will now gain experience with this new format over a period of five years. The current EU formatting guidelines will be replaced by the new OECD version by 31 December 2004. Accordingly, CADDY submissions will need to follow the OECD structure and numbering and a standard OECD TOC is presented in document CADDY Standardized Table of Content (download from the CADDY-Website on page [CADDY Application Guide](#) [5]).

4 How to Put a Dossier on CD-ROM

The objective of this chapter is to provide general recommendations on the following subjects:

- How to generate the dossier pages in the CADDY-specified format
- How to generate the index files which are to be included in the CADDY CD-ROM along with the dossier pages
- How to store the submission relevant information on CD-ROMs

The figure below gives an overview of the general approach covered by this chapter:

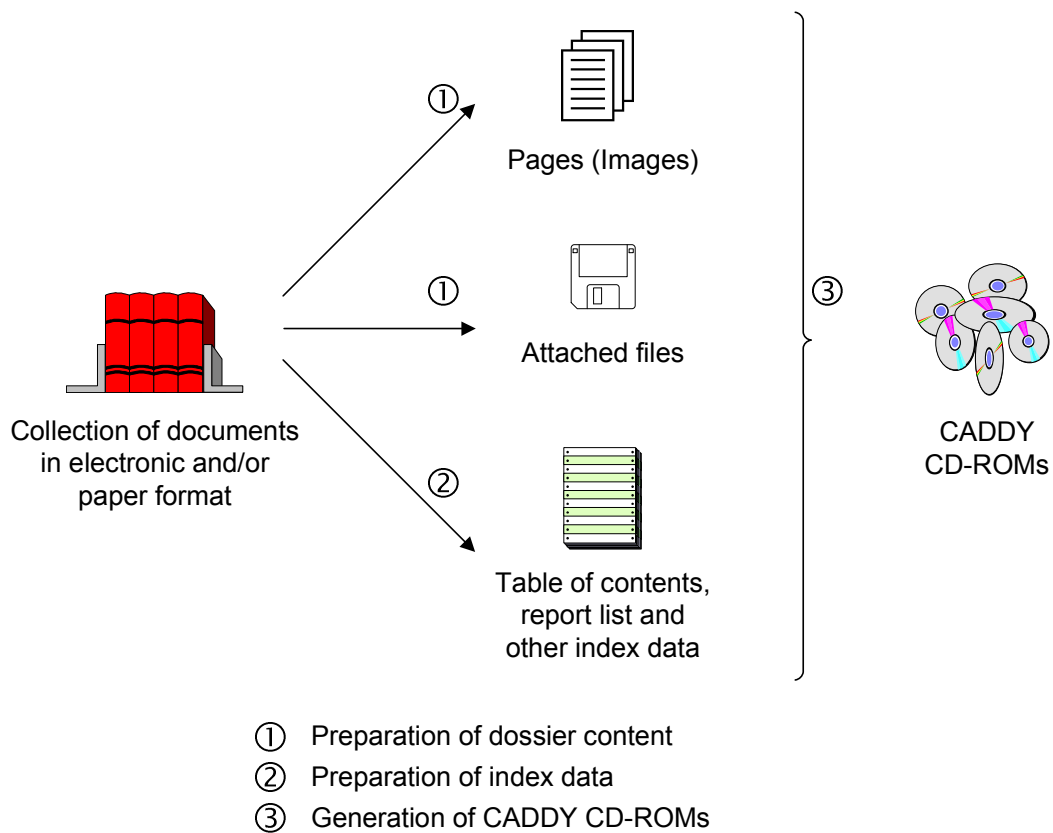


Figure 4-1 Preparation of dossiers

There are many different possibilities to generate a CADDY submission. In this Application Guide, a sequence of steps is suggested based on the assumption that all documents that will be included in the submission are already available:

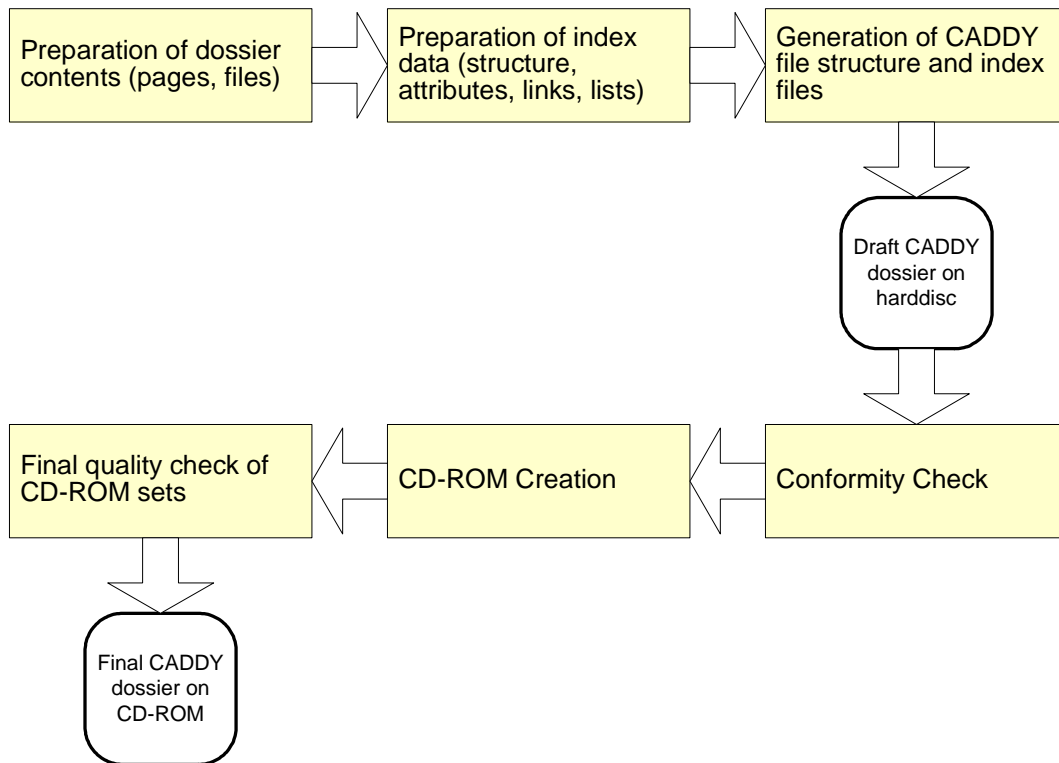


Figure 4-2 Steps for the production of CADDY submissions

In addition to the basic steps for generating the electronic dossier, the necessary quality aspect is covered also. The final product of the process is a set of CADDY conform CD-ROMs that can be submitted to authorities.

The first three steps have to be done using dossier compilation software that is able to prepare CADDY dossiers. In this, CADDY is a format like PDF that can also not be written manually by an end user. Instead, PDF writer software is required to produce the PDF files from various sources. In contrast to PDF writer software, dossier compilation software is highly specialized software that supports the generation and maintenance of dossiers. The production of the CADDY output requires only a module like a printing module that outputs the final dossier in a specific format.

When not otherwise stated, the recommendations provided in this chapter apply to any CADDY submission or CD-ROM set following the CADDY Format Specification [1] and are generic to all countries supporting CADDY.

The process itself is not dependent on the CADDY version. For CADDY 1.1 some of the minor steps (like preparation of CCFs or hyperlinks) can simply be omitted.

4.1 Preparation of dossier contents (pages, files)

The content of the dossier is represented twofold: One representation is a page by page representation of the whole dossier on the basis of a reliable long-term image format. This representation is called CADDY pages. In addition, parts of the dossier or the whole dossier itself can be represented in other electronic formats. This representation is called CADDY controlled files. The big advantage of this concept is, that the CADDY page representation fulfils the requirement of technology independent reliability and readability and the CADDY controlled file representation fulfils the requirement to support a maximum flexibility in the usage of the dossier information, if the accessing computer is properly equipped with the correct software releases in order to cope with the supplied electronic formats.

4.1.1 Page files (CADDY TIFFs)

There are several electronic formats that may represent dossier contents (document pages) within IT-systems. The TIFF format is reliable, easy to use and well known by most IT users. Standard scanning software packages are able to generate TIFF files and many programs to view these files are available on the market. Because of its wide support and simplicity, this format was chosen for CADDY to reliably represent the dossier pages. It has also a very important advantage, which is long-term availability. Even if, in the future, there were no software available on the market to directly view TIFF images, it is such a simple format that it would be easily possible to develop a program to read the existing CADDY images with limited amount of resources.

Based on the format of the original document, there are two alternatives to generate TIFF images:

- If the document is available in paper only, the paper document has to be scanned and stored as images of the pages. In a second step, a more computer oriented, character based representation can be produced by a process called OCR (optical character recognition). In general OCR requires additional resources and an additional quality assurance mechanism.
- If documents are already electronically available, the original software should generate the images of the pages directly. For example a word processor might use a plug-in or some similar tool or output driver to create the TIFF files. This mechanism is called soft scan.

Scan Paper Documents

Documents in paper format can be scanned in order to produce TIFF images. A scanner and corresponding software are necessary in order to generate the images. Several companies offer scanning equipment and software commercially. When selecting the equipment and software, make sure that the CADDY requirements (ex. TIFF tags and size) as described in the CADDY Format Specification [1] are supported.

Soft Scan Electronic Documents

Documents available electronically (such as Microsoft Word, WordPerfect, PDF, Excel, PostScript or another format) can be directly converted to TIFF. This conversion process is called soft scan. Specific software is required and can be obtained on the market from different suppliers. When selecting such software, make sure that the CADDY requirements (ex. TIFF tags and size) as outlined in the CADDY Format Specification [1] are supported.

Documents Received from External Sources

One possible way to obtain the required TIFF images is to ask external partners, such as sub-contractors, to provide documents in TIFF format.

CADDY TIFF Limitations

The particular TIFF format specified by CADDY has some limitations due to compatibility issues of the TIFF format. These limitations are specified in detail in the CADDY Format Specification [1]. The most important of these limitations are mentioned below:

Only DIN-A4 and US Letter page formats are supported. DIN-A4 and US Letter pages can be freely mixed in one CADDY dossier. However, pages may be scanned using one of these formats and viewed and printed using the other. For this purpose, the CADDY Retrieval Software allows to scale the pages for viewing and printing and to avoid cutting the borders of the pages.

Colors and grey areas are not supported. Only black and white images are supported. This can lead to loss of important information such as when the relevant phenomena are shown in color pictures or graphs. In these cases it is possible to provide the pictures, graphs, etc. in their original format, cross-referenced with the corresponding reports in the CADDY submission. Another alternative is to provide high-resolution color scans of such images. For this purpose, CADDY provides the concept of CADDY Controlled Files where any additional information can be provided in electronic format.

Remarks:

Soft scan products require careful testing. Some products may not support all the features provided by common text processing tools and may cause problems when converting documents containing tables, indentation, and dual orientation (portrait and landscape) in the same document.

As an alternative to soft scan, if the product selected does not perform properly on a specific document type, the electronic document can be printed and scanned.

Check to ensure the TIFF files correspond to the CADDY Format Specification [1] as soon as the files are produced. Problems not detected before the submission is generated may cost valuable time and possibly delay the submission.

Normally it is enough to check just a couple TIFF files to see if the scanning software & hardware produce files that meet the CADDY Format Specification [1]. In certain cases, the same software may generate different TIFF variations depending on internal control mechanisms. So unless it can be guaranteed that it is not the case with the product selected, the only way to be sure that the images are CADDY compliant, is to check all produced TIFF files.

4.1.2 CADDY Controlled files

CADDY controlled files (CCF) files are controlled attachments to the dossier that can have any format. These files are controlled regarding the version control mechanism of CADDY. Their content or format is not limited by CADDY. CADDY controlled files allow additions of renditions (alternative electronic format) of reports or to add data elements like tables or pictures in native format.

Documents available electronically (such as Microsoft Word, WordPerfect, PDF, Excel, PostScript or another format) can be directly used as CCFs.

4.2 Preparation of index data (structure, attributes, links, lists)

The CADDY Retrieval Software relies on index data to find and retrieve documents from the CD-ROM sets. The following suggestions will help to easily generate index data:

Index data can be generated using standard database programs. This allows easy handling and last minute corrections before the index files are finally generated using an export routine (as described below). Companies should ensure that the final index files generated meet the CADDY Format Specification [1] requirements.

4.2.1 Page table and CCF table

First, assign each document to a volume. Then generate the page table containing one entry for each page in the submission. All pages of a confidential document have to be marked as confidential.

Although CADDY supports the use of a pagination field that allows the user of the Retrieval Software to directly access any desired page within a document by typing in a page number, it may not be possible for the companies' systems to support this feature. For this reason, a sequential number starting with one for each document can be used instead.

The CCF table is produced by generating one entry for each controlled file that should be included within the CADDY submission.

4.2.2 Table of contents and report list

Table of Contents (TOC)

Each document that is part of the submission must have at least one entry in the TOC. If a document appears more than once in the table of contents it has to be inserted more than once in the CADDY dossier (electronic copies instead of electronic references!).

Generate the TOC table according to the requirements of the authority you will send your submission to. It is important to note that the field allocated to the text entry of each item in the TOC is limited to a maximum of 70 characters. This means that the titles of the documents that are longer than 70 characters must be abbreviated to fit this length.

Reports List

For each study report entry in the Table of Contents, an entry must be included in the Reports List. Reports with multiple entries in the TOC need the same number of entries in the Reports List.

4.2.3 Version history and volume list

Volume List

This table stores the access information for the volumes. Every volume entry corresponds to a volume. Only the attribute "vol_necessary", that informs the user if he needs this volume for retrieval, may be updated in a new dossier version.

Version History

This table contains a version history. The information stored in this table can be used to keep track of supplemental volumes and dossier versions. For each version of the dossier that is created, an additional line has to be added to the Version History.

4.2.4 Dossier header attributes

1. Generate the header companies, header products, header active substances and the header attribute set tables.
2. Generate the product - substance table.

4.2.5 Change table

This table is not produced for the first version of the dossier. It might only be necessary for version 2 and subsequent versions depending on the changes made to create a new version.

This table will contain one entry for each page, CCF or report deleted or for modifications made in the attributes of existing reports. In order to get the information necessary to generate this table, compare the entries in the Page Tables, CCF tables and Report Lists for the current and previous submissions.

4.2.6 Hyperlinks

CADDY Hyperlinks, stored on CD-ROM are dossier internal hyperlinks from an area (x-Coordinate, y-Coordinate, width, height) on a source page to either a location (x, y) on a target page, a table of contents entry or a controlled file. A submitter of a CADDY dossier will provide these links. The hyperlink table stores the hyperlinks inside the dossier. It contains a list of all hyperlinks within the current dossier version.

Document internal hyperlinks, hyperlinks within a WinWord document for example, can be converted to CADDY hyperlinks by the appropriate software. Hyperlinks between documents might be added.

4.2.7 Additional Remarks

- The tables DD Tables and DD Columns relate to the version of the CADDY Format Specification [1] followed and are used for backward compatibility. For the same version of the Format Specification, these tables are not changed (beside column tab_rowcount) and are therefore equal for all dossiers.
- For pesticide registrations, except for the Reports List and the Changes History Table, all other tables are mandatory. In case of a dossier containing no reports but only summary documents, the Reports List table is not necessary. The Changes History is only required for dossier supplements.

4.3 Generation of CADDY file structure and index files

After the information has been completely prepared, the CADDY directory structure and the index files have to be created.

4.3.1 Generation of directory structure

The directory structure to be created is described in the CADDY Format Specification [1]. Directory branches below the directories PAGES, CCF, INDEX and FILES have to be created. This can be done on hard disk first. After the files have been added the full volume content can be copied to CD.

4.3.2 Copy pages and controlled files

Export CADDY Pages to the PAGES directory

Before the files are copied to the target media (e.g. a CD-ROM or other intermediate media), it is recommended that the complete submission is stored in a temporary place (e.g. magnetic storage) for a final quality and completeness check. A submission with 50,000 pages may require a significant amount of storage (up to 3 GB) even using CCITT Group 4 compression. See the CADDY Format Specification [1] for the supported compression types.

Image files have to be named according to the CADDY Format Specification [1].

Copy each document page to the volume it has been assigned to. Confidential pages must be stored on a confidential volume. All pages of confidential documents should be marked as confidential.

The copying process may take up to several hours, depending on the size of the submission and the speed of the I/O devices used. In case of interruptions, make sure that the process is resumed at the correct place and no pages are missed or duplicated by mistake.

Export CADDY Controlled Files to the CCF directory

CADDY controlled files supplemental to the CADDY submission can be copied into the CCF directory branch of a volume.

Controlled files have to be named according to the CADDY Format Specification [1].

Typical files that may be included in this directory are the editable versions of the dossier summaries. Confidential files have to be copied into the CCF directory of the confidential volume.

4.3.3 Export of index files

Index information is typically generated with commercial database applications such as Microsoft Access or ORACLE. It needs to be converted to the general index file format specified by the CADDY Format Specification [1]. Ensure that the software used supports conversion to the required format. If not, use a commercial software package to perform that task or your company may develop its own program to perform this task.

Remarks:

Normally the rows in relational tables are not ordered. The order of rows must be defined by application specific rules. Make sure that the rows of the tables are not re-ordered when exporting the indexes from a database program to the CADDY format.

4.3.4 Generation of label files

Generate a volume label for each volume (CD-ROM) in the CADDY submission. The labels contain volume-related information, like volume type and identification, as well as the applying company (registrant) and active ingredient. Refer to the CADDY Format Specification [1] for detailed information about the volume label.

4.3.5 Additional files

Files supplemental to the CADDY submission can be copied into the FILES directory of any volume. These files are not directly supported by the CADDY Format Specification [1] and the contents of this

directory will depend on an agreement between the applying company and the receiving authority. Typical files that may be included in this directory are the editable versions of the dossier summaries. Confidential files have to be copied into the FILES directory of the confidential volume.

4.4 Conformity Check

It is recommended to make a conformity check of the CADDY dossier before the CD-ROM sets are produced. This can be already done after a CADDY dossier is produced on the hard disc. There are two steps. The first step is mandatory!

Check the submission using the CADDY Conformity Test Software. This software will be provided as part of the CADDY project and will check the conformity of the submission to the CADDY Format Specification [1]. The current version can be downloaded from the CADDY web site <http://caddy.ecpa.eu>.

Also check the submission using the CADDY Retrieval Software. This is the software that will be used by the authorities to review the submission. By doing this check, it can easily be verified that the submission can be loaded and read using the Retrieval Software. Also the quality and readability of the images can be verified.

The second step is not sufficient to verify the CADDY compliance of a submission, because the current Retrieval Software is not using all possible features of CADDY and will be enhanced in the future.

The final quality check of the produced CD-ROMs should also be done using the CADDY Conformity Test Software

Remarks:

Although it is the intention to make the conformity check as complete as possible, no guarantee can be given that this software will be able to find all possible errors in a submission.

Beside the tests recommended above, which mainly focus on technical aspects, other types of mistakes are possible, as listed below, which cannot be detected by those tests:

Make sure that the CD's are labeled correctly and that the confidential CD is marked as such.

Make sure that the file names and file name extensions are written correctly as specified (lower case / upper case)

Completely missing documents such as no entry in the TOC, or in the Reports List, and no scanned pages available

Wrong dossier attributes

Additional files i.e., the „FILES“ directory is optional and will not be checked, so make sure that any additional files needed are available

Make sure that the TIFF-files are TIFF 6.0 compatible. (This is determined by the TIFF generation program.)

Remember that CADDY is just a standard to transfer electronic information to the authorities.

The quality and completeness of the submission are the responsibility of the applicant.

4.5 CD-ROM Creation

The following approaches can be used to generate the CD-ROMs:

In-house generation of all CD-ROM copies. For this purpose a CD-ROM writer (also called CD-ROM burner) and the corresponding software are needed. This

equipment allows storing information on a CD-ROM. Low cost CD-ROM burners are commercially available. With this equipment, the necessary CD-ROM's can be generated internally.

In-house generation of the master CD-ROM. Same as described above, except that instead of generating internally all copies needed, just generate one set of CD-ROMs and order the necessary number of copies from a specialized company. This may save time and internal resources since the process of burning CD-ROMs can be very time consuming.

Generate a master on other media than CD-ROM. Copy the submission volumes to the target media (e.g. a tape or removable hard drive) and contract a specialized company to generate the necessary CD-ROM copies from it. The target media to be used will depend on the specific needs of the applying company and the limitations of the company contracted to generate the CD-ROM copies.

Remarks:

Make sure that the CD's are ISO 9660 compatible. (This is determined by the CD burning program.)

When selecting an external company to generate copies of CD-ROMs, make an evaluation of different suppliers. Large price and service differences are not uncommon.

4.6 Final quality check of CD-ROM sets

Before submitting a CADDY dossier to the authorities, it must be finally checked that the CD-ROM sets prepared are physically readable and 100% compliant to the CADDY Format Specification [1].

It is recommended to use the CADDY Conformity Test Software in order to check the final CD-ROM sets. In addition, the readability of the pages can be checked by using the latest CADDY Retrieval Software.

To check the readability of the index files by the CADDY Retrieval Software is not sufficient!

Not all CADDY features are used by the current version of this software and it has no compliance check built-in. The readability of the dossier cannot be guaranteed for future versions of this software, if the dossier is not 100% CADDY compliant.

5 Handling of Supplements

After initial submission of a CD-ROM set containing the first version of a dossier, it may become necessary to submit further data. These subsequent submissions are regarded as subsequent versions of the dossier and are intended to complete the dossier with data that were not in the former version(s) or to modify previously submitted data.

When submitting substitute data, such as replacing a single page of a study report that contains some errors, all pages of this document or report, including the unchanged pages, should be copied to the new supplemental volume. However, unchanged documents should not be included in the new volume, as the newly submitted information will be labeled as „modified“. As required in the CADDY Format Specification [1], a supplement must contain the full set of current index files in order to rebuild the dossier database. This means the last volume of a supplement must contain a complete Reports List besides the Table of Contents. In some cases no reports are submitted at all, such as in summary dossiers submitted to European authorities. These contain no test or study reports from the very first version on and do not need a Reports List when supplemented.

As the supplementary submissions do not contain the complete data package of the dossier, they must be used together with the former version(s). Nevertheless, if all the data of a single volume is contained in a subsequently submitted version, the formerly submitted volume will no longer be used for data access. Information on the relevance of any single volume is indicated in the Volume List.

When receiving supplements substituting particular pages of the dossier, annotations might have been attached to the respective pages of the former version during the evaluation process with the Retrieval Software. These annotations must be transferred to the respective page of the new version, which will be done automatically by the Retrieval Software during the registration of the supplemental dossier for unchanged pages. However, in the case of modified pages - as they will have modified internal page numbers (UPIDs) - any annotations to the old pages will not be transferred to the newly submitted page.

5.1 Registration Requirements

If several documents and/or reports have to be supplied subsequently, it is advisable to submit these documents/reports in one single submission in order to reduce the number of versions to be distributed to the authorities. Details on summarizing should be mutually agreed upon between submitter and authority.

Minor changes can be transmitted by paper for informational purposes only, provided they will be included in the next supplement.

However, if the data to be submitted indicate potentially dangerous effects on human or animal health or groundwater or the environment, the submitter of the data must submit these data immediately without waiting for any outstanding data.

5.2 How to Handle Supplements

Regarding delivery, distribution, and usage, supplements should be treated like regular first-time submissions. The number of CD-ROM sets to be sent to the authorities, as well as respective contact points, are the same as for first-time submissions, as referenced above.

- Regulatory authorities receiving supplements need to update all PCs having an old version of a dossier with the new supplement. Distribution of the CD-ROMs depends on how the data is accessed in the organization (stand-alone or shared systems). In the case of stand-alone systems, it is necessary to provide the supplementary set to any relevant PC site to rebuild the database of the respective dossier. In systems with shared data access within a network environment, the CD-ROM set needs only to be added to the former submission (i.e. copied to the server hard drive or inserted into the jukebox). In this system, the updating procedure can be accomplished by network access to the index files of the supplement. After updating the database, the handling of the CD-ROM set depends on the data access within the authority as outlined previously (see Authority Requirements).

5.3 Supplemental dossier creation

The creation of supplemental CADDY dossiers is primarily the same as the creation of a first CADDY version of a dossier. In addition, some further aspects have to be considered:

All documents modified and the complete set of index tables must be available in the supplemental volume.

If confidential documents were modified, a confidential CD-ROM will also be needed.

If a document used more than once in a submission is modified, then this document must be available in the supplemental submission as many times as it is used.

Note that for each page, the UPID is constant over all versions of the submission. For this reason UPIDs of pages dropped cannot be re-used for pages added in future versions of the submission. The UPID can be generated sequentially, following the CADDY Format Specification [1]. This number is not related to the location of the page inside a document and there is no need to skip numbers just to allow for the insertion of supplemental pages in between.

6 Index Attributes

6.1 Introduction

The content of the index files defines the structure of the dossier and provides the meta data for the elements of the dossier to allow navigating and searching through the dossier to find the required information. Therefore, every CADDY dossier on CD-ROM is accompanied by a set of index files that is converted to a relational database by the Retrieval Software, which allows the user, to find what he is looking for. The database allows the user to create search-queries, to browse through reports, and to find specific pages.

In order to make the CADDY dossier so accessible, it is necessary for the database to be "filled" by the industry registration experts during compilation of the dossier. The CADDY Format Specification [1] provides the design and the structure of the index files comprising the database. This design is, for reasons of conformity, rigid, and cannot easily be modified. In future versions of the CADDY Format Specification [1] it is possible that new elements will be added, but it is necessary for old dossiers to remain readable by future versions of the Retrieval Software.

Although the structure of the index database is rigid, the contents of many of the attributes are open to interpretation. To prevent any misunderstanding of submitted dossiers, such as if evaluators expect to find information in certain fields different from what the producer of the dossier has entered, this Application Guide provides instructions on how to deal with the database.

6.2 Structure

This chapter simply follows the listing of the tables of the index database as provided in the CADDY Format Specification [1].

Many of the fields in the index database are for "internal use", i.e. for use by the Retrieval Software. The information contained within those fields is never visible to the user, whether they are the compilers of a dossier (using their own specific compilation software), or evaluators working with the Retrieval Software. The compilation software will automatically create this type of information. IT-specialists, those responsible for the creation of the compilation software, will have to deal with these fields. It should be noted that there are many ways of dealing with those fields. How these fields are filled depends on the writer of the compilation software. The important thing is compliance with the CADDY Format Specification [1]. Internal fields are mentioned below with the remark "*internal field*", without further explanation. This Chapter is aimed at the regulatory experts, both from industry and regulatory authorities. It explains what information should be stored in the database fields.

6.2.1 Table dh_ver: version history

field name	field description
ver_UVER	Version number. <i>Internal field</i> generated by the compilation software.
ver_master_date	This field represents the day of mastering the CADDY version of a dossier (the compilation date). It is not the dossier issue date (see below). This field is added to enable the tracing of possible discrepancies between a paper and an electronic version of a dossier.
ver_idxvol_UVOL	<i>internal field</i> , to be generated by the compilation software.
ver_stdv	<i>internal field</i>
ver_attrib_UHID	<i>internal field</i>
ver_issue_date	Issue date of the original dossier. Contrary to what is indicated in the CADDY Format Specification [1], this is NOT the submission date. It is the date on which creation of the dossier was finalized. This date is important because it is the "closing" date of the dossier creation. Reports issued after this date, but before submission of the dossier, cannot be expected to be part of the dossier.
ver_chg_rep	<i>internal field</i>
ver_chg_has	<i>internal field</i>
ver_chg_toc	<i>internal field</i>
ver_chg_pag	<i>internal field</i>
ver_chg_ccf	<i>internal field</i>
ver_chg_lnk	<i>internal field</i>

6.2.2 Table dh_vol: volume list

field name	field description
vol_UVOL	<i>internal field</i> , to be generated by the compilation software.
vol_name	<i>internal field</i>
vol_pages	<i>internal field</i>
vol_index	<i>internal field</i>
vol_confidential	<i>internal field</i>
vol_necessary	<i>internal field</i>

6.2.3 Table dc_rep: report list

field name	field description
rep_order	<i>internal field</i>
rep_URID	<i>internal field</i>
rep_tocnode_UNID	<i>internal field</i>
rep_doss_fn	The contents of this field depend on the type of submission: <ul style="list-style-type: none"> • For submissions of active substance dossiers in the EU (for inclusion in Annex I of Directive 91/414), this field contains the Dossier File Number. • For submissions in the US, this field contains the MRID.

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rep_comp_fn	A free text field (max 20 characters) to identify the internal company file-number for the report. There are no requirements for this field: its purpose is for notifiers/submitters of dossiers to identify study reports using their own internal coding system.
rep_date	Issue date of the report. The system allows for incomplete dates, e.g. "April 1992" or even "1978". Because computer-systems can only function with valid date-formats, these dates will internally be stored as "01 April 1992" and "01 January 1978"; the next two fields r_valid_day and r_valid_month will indicate whether the indicated day and month are to be ignored by the system or not. Identifying the issue-date for a specific study report is not always obvious: often the date is indicated on the title page, but frequently study reports do not carry a specific "report date." In the case of GLP studies, it is advised to select the date of signature of the Study Director as the issue date.
rep_valid_day	see above
rep_valid_month	see above
rep_title	Report title (240 characters)
rep_authors	Author(s). To be entered in the standardized format: <i>Author1, Initial.Initial., Author2, Initial.Initial., Author3, Initial.Initial. or Author1, Initial.Initial., et al.</i> Examples: <i>Weber, H., Klein, O., Bornatsch, W.</i> <i>Ullman, L., Sacher, R., et al.</i>
rep_source	Source of the document. This field does not contain the name of the testing facility (see below). The source of the study report is often identified within that report as the study sponsor. The sponsor of the report is not necessarily also the owner of the report on the date of submission. It is quite possible that the source of the report (company X) has merged with another company, or has sold its interest in a specific active substance to another company, who is now owner and submitter of the report. Also, a report may be generated by one company, but can be the property of a task force now.
rep_owners	Owners of the document/report at the date of submission. Owner can be a company, a group of companies (e.g. a task force) or a person. This field is not mandatory.
rep_test_facility	The name of the test facility, where the study was carried out.
rep_confidential	Boolean field (i.e. a Yes or No field). This field indicates if the study report is confidential or not. (For EU submissions: if this field contains a YES, the report belongs to the so-called Document J). NB: The confidentiality of specific study reports must always be indicated in the dossier documentation, accompanying letters, etc. The information contained within this field provides helpful information to the reviewer/regulator, but it can never be regarded as a statement of (non-) confidentiality by the notifier/submitter.
rep_glp	Boolean field (i.e. a Yes or No field). This field indicates whether the study was carried out under GLP (Good Laboratory Practices).
rep_published	Boolean field (i.e. a Yes or No field). This field indicates if the study report was published.
rep_vertebrates	Boolean field (i.e. a Yes or No field). This field indicates if the study contains tests on vertebrate animals.
rep_protect	Boolean field (i.e. a Yes or No field). This field indicates if the notifier/submitter claims Data Protection for this study report. NB: as explained above for the field r_confidential , the information contained

	within this field provides helpful information to the reviewer/regulator. However Data Protection claims must be indicated in the dossier/submission itself.
rep_added_UVER	<i>internal field</i>
rep_changed_UVER	<i>internal field</i>

6.2.4 Table dc_toc: table of contents

All fields in the “**table of contents**” are *internal fields*, and will be generated or provided by the compilation software.

In the Appendices, a standardized Table of Contents for European submissions is provided. An electronic copy of this Table of Contents is available through the contact points indicated in the Introduction section of this Application Guide.

field name	field description
toc_UNID	<i>internal field</i>
toc_report_URID	<i>internal field</i>
toc_parent_UNID	<i>internal field</i>
toc_level	<i>internal field</i>
toc_page_UPID	<i>internal field</i>
toc_h_number	<i>internal field</i>
toc_text	<i>internal field</i>

6.2.5 Table dc_pag: page table

All fields in the “**page table**” are *internal fields*, and will be generated by the compilation software, except for pag_pagination.

field name	field description
pag_UPID	<i>internal field</i>
pag_curvol_UVOL	<i>internal field</i>
pag_orgvol_UVOL	<i>internal field</i>
pag_confidential	<i>internal field</i>
pag_pagination	This field has to contain the pagination string that is visible on the paper version of the dossier.
pag_added_UVER	<i>internal fields</i>

6.2.6 Table dc_Ink: hyperlinks

field name	field description
Ink_ULID	<i>internal field</i>
Ink_link_title	title for display purposes
Ink_source_UPID	<i>internal field</i>
Ink_source_x	<i>internal field</i>
Ink_source_y	<i>internal field</i>
Ink_source_w	<i>internal field</i>

Ink_source_h	<i>internal field</i>
Ink_target_type	<i>internal field</i>
Ink_target_UxID	<i>internal field</i>
Ink_target_x	<i>internal field</i>
Ink_target_y	<i>internal field</i>

6.2.7 Table dc_ccf: controlled files

field name	field description
ccf_UFID	<i>internal field</i>
ccf_curvol_UVOL	<i>internal field</i>
ccf_orgvol_UVOL	<i>internal field</i>
ccf_page_UPID	<i>internal field</i>
ccf_confidential	<i>internal field</i>
ccf_title	title string which is shown (printed) on the virtual directory [index]
ccf_extension	original file extension
ccf_added_UVER	<i>internal field</i>

6.2.8 Table dh_has: header attribute set

field name	field description
has_UHID	<i>internal field</i>
has_title	Title of the dossier
has_sub_title	Subtitle of the dossier
has_authority	This field refers to the authority to which the dossier is originally submitted. In the case of European submissions, this should be "EU, DG VI", not the name of the Member State where the dossier is first submitted.
has_guideline	This field refers to the guideline or requirement used for the formatting of the dossier (e.g. for a European submission: "1663/VI/94, rev. 7.2")
has_regulation	Reference to the legislation, act, regulation or directive under which the submission is made (e.g. "3600/92" or "91/414")
has_rapporteur	2-letter ISO code for the US, Canada, or European Rapporteur Member State. In case of a submission of a new active substance for which no European Rapporteur Member State has been selected yet, use the code for the Member State where the first submission is made.

6.2.9 Table dh_asu: header active substances

field name	field description
asu_UASU	<i>internal field</i>
asu_UHID	<i>internal field</i>
asu_substance	Name of the active substance. Not chemical name, but (preferably) ISO name. If no name is available yet, a company-code is acceptable and may be replaced in subsequent versions of the dossier with the name, or as soon as the name is available.
asu_cipac	CIPAC code for the active substance.

asu_cas	CAS number for the active substance.
asu_annex	Boolean field (i.e. a Yes or No field). If a dossier contains dossier information on a formulated product that contains more active substances than the "key" active substance of the dossier, the names of these additional active substances are also covered in the index. This field indicates if a dossier in this submission covers the active substance.

6.2.10 Table dh_rps: relation product substance

field name	field description
rps_UPRO	Link with the product (<i>internal field</i>).
rps_UASU	Link with the active substance (<i>internal field</i>).
rps_concentration	Concentration of the above active substance in the above product, with units (e.g. "250 g/l", or "10 % w/w")

6.2.11 Table dh_pro: header products

field name	field description
pro_UPRO	<i>internal field</i>
pro_UHID	<i>internal field</i>
pro_name	Commercial name of the product. If a product is marketed under several commercial names within the territory for which the submission is made, a key name has to be entered.
pro_formulation	Formulation type following GIFAP rules (e.g. WG, EC, WP, SC, etc.)
pro_annex	Boolean field (i.e. a Yes or No field). It is possible to provide a listing of available formulated products containing the key active substance of the underlying submission. This field indicates if this submission contains a (European Annex III) dossier on the formulated product, in addition to the active substance dossier.

6.2.12 Table dh_com: header companies

field name	field description
com_UCOM	<i>internal field</i>
com_UHID	<i>internal field</i>
com_name	Company name of the submitting company.
com_code	3-digit EU company code or 6-letter US company ID.
com_country	Country where the company is located.
com_country_code	2-letter ISO code of the country.

6.2.13 Table da_chg: changes history

All fields in the “changes history” are *internal fields*, and will have to be generated by the compilation software.

field name	field description
chg_type	<i>internal field</i>
chg_UxID	<i>internal field</i>
chg_ver_UVER	<i>internal field</i>

6.2.14 Table dd_tab: data dictionary tables

All fields in “**dd tables**” are *internal fields*, and will have to be generated by the compilation software.

field name	field description
tab_name	<i>internal field</i>
tab_version	<i>internal field</i>
tab_rowcount	<i>internal field</i>

6.2.15 Table dd_col: data dictionary columns

All fields in “**dd columns**” are *internal fields*, and will have to be generated by the compilation software.

field name	field description
col_tab_name	<i>internal field</i>
col_name	<i>internal field</i>
col_type	<i>internal field</i>
col_value_min	<i>internal field</i>
col_value_max	<i>internal field</i>

7 Security Aspects

Recommendations Relating to Security Aspects of CADDY CD-ROM sets

The registration dossier for an active substance or a plant protection product represents a considerable investment by the data producer and, therefore, constitutes commercially sensitive proprietary data, some of which is also confidential (Document J). Taking this into consideration, regulatory authorities in most OECD countries have introduced appropriate rules and regulations regarding the protection of registration data for plant protection products. For example a period of time may be established during which the registration data submitted by the data owner must not be used in support of the registration of other applicants without prior consent from the data owner. For instance, in the US registration data is protected for 10 years and is subject to compensation for another 5 years. In the EU, data for new active substances is protected for 10 years while additional data for existing active substances is protected for 5 years. On the other hand, it must be recognized that in many parts of the world the concept of intellectual property and the data protection standards do not reach the same level as those of the EU and the US. As with registration dossiers in paper form, it is therefore advisable to ensure that adequate measures are taken to avoid misappropriation and misuse.

Security aspects of CADDY CD-ROM sets were addressed repeatedly by the CADDY working group members, but it was concluded that techniques such as encryption, passwords, etc., should not be used, since it was felt that these would make the system less user-friendly and might compromise the acceptance of CADDY. Adequate security provisions must, therefore, be taken at the operational level. The following measures can be envisaged:

By the applicant:

Applicants are encouraged to keep lists of recipients of the CD-ROM sets.

The use of serial numbers or other appropriate means of identifying a specific set of CD-ROMs should be considered, at least on the label.

Personal delivery should be considered, where appropriate.

By the receiving party:

The receiving party should confirm receipt of the CD-ROM sets.

CD-ROM sets may not be copied by the receiving party except to hard drives for network use. Where required, additional CD-ROM sets should be requested from the applicant.

Making the CD-ROM sets available via a network only can be expected to significantly reduce the risk of misuse. Access to the network drives has to be restricted to the users who need access to the information of the dossier for the review process.

Where individual CD-ROM sets are used at the workplace, they should be locked away safely after use. Authority personnel should be made aware of the commercial sensitivity of the information on the CD-ROM sets.

The applicant must be informed if a CD-ROM set is lost.

CD-ROM sets may be returned to the applicant if they are no longer used. This applies to both CD-ROMs that have been completely replaced by supplementary submissions as well as to full sets that will not be used for archiving purposes. A confirmation of receipt by the applying company is recommended.

8 Hardware and Software Technology Recommendations

The CADDY standard is independent from any hardware technology aside from CD-ROM technology. Therefore, special hardware for CADDY is not needed. In order to use CADDY, it is necessary to use three different types of software:

- CADDY Compilation Software (or production software)
- CADDY Conformity Test Software
- CADDY Retrieval Software

8.1 CADDY Compilation Software

Software of this type has to be used in order to produce a CD-ROM. This can be done by an existing in-house system that was enhanced by a CADDY output module or by a stand-alone application for dossier compilation that produces CADDY output (such as PlantOS from IABG or Core Dossier from Liquent). The industry is responsible for the creation of this software. If such a software package is not available, the CD-ROM can be produced manually by using standard database software (like ORACLE, MS-ACCESS and others), simple text processors (like MS-EDIT, MS-NOTEPAD and others) and imaging software (like WANG, IMAGE BASIC and others). Manual production of a CD-ROM requires expert IT knowledge, involves a lot of work and is not generally recommended.

8.2 CADDY Conformity Test Software

In order to use CADDY dossiers for exchange and archiving purposes, conformity to the CADDY format must be ensured. For this, a conformity test tool is needed. The conformity test software can report deviations from the CADDY format specification for a given dossier version on CD-ROM.

CADDY Conformity Test Software scans CADDY CD sets for many conditions. For a description of the CADDY format see the CADDY Format Specification [1] that is part of the distribution package. The CADDY Conformity Test knowledge base comprises over 100 known bugs and other problems.

The CADDY Conformity Test Software is available as freeware on the CADDY web site <http://caddy.ecpa.eu>.

The CADDY Conformity Test Software does not have any special hardware requirements. The minimum configuration defined for the Retrieval Software can be seen as sufficient.

8.3 CADDY Retrieval Software

Standard CADDY Retrieval Software was originally specified by the Joint CADDY Steering Group and was implemented in 1997. Subsequent versions with enhanced user functionality were implemented in recent years and the development of further versions will continue.

If the functionality of the standard package is not sufficient (e.g. it seems necessary for an authority to include dossier tracking of incoming dossiers or enhanced reviewer support), it is possible to create alternative software packages for reviewing dossiers.

The performance of today's standard PC is sufficient to fulfill the requirements for the CADDY Retrieval Software.

Independent of CADDY, for any office environment it is advisable to buy ergonomic computer systems. To optimize the purchase of new workstations the professional advice of IT experts is recommended.

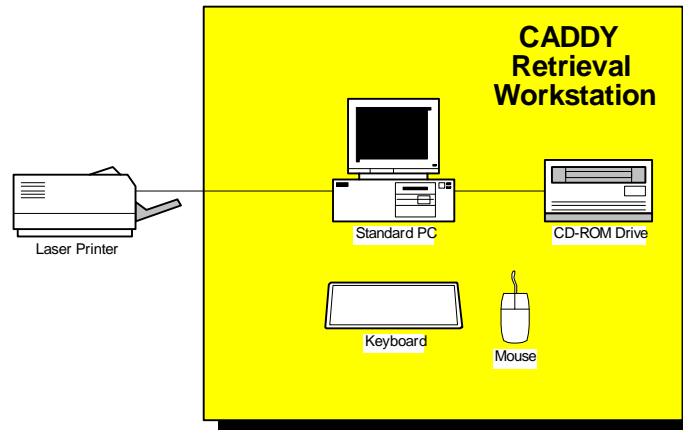


Figure 8-1 CADDY Retrieval Software on local workstation

Standard PC with Keyboard and Mouse

There is no special requirement on the PC. In general, it is preferable to use a fast computer because this makes working for a reviewer much more comfortable.

Monitor

Monitor resolution, size, refresh rate, and display quality will be some of the most important ergonomic factors of an office system. This applies to CADDY too. The CADDY functionality will not be limited if a small monitor is used, but a larger monitor (19" – 21" CRT, 17" –19" LCD) will be more suitable for sustained use.

CD-ROM Drive

Any standard CD-ROM drive will do the job. A fast CD-ROM will give faster image access, but even the slowest CD-ROMs may already be fast enough for some users.

Laser Printer

Any standard Windows printer will do the job. A fast printer will give more comfort to the reviewer. A resolution of 300 dpi is enough for use with CADDY. Lower resolutions will cause quality loss of the printout. Also, other printer types like inkjet printers, matrix printers and others can be used, if quality and speed of the printout meets the requirements of the reviewer.

8.4 More Complex Office System Environments

Currently, the CADDY system allows for storage of the information of the CD-ROMs on hard disks shared within a network (e.g. hard disk on a network server). For network access of the data, the data have to be copied to separate subdirectories for each single CD-ROM, which are accessible from any PC with respective network access.

CD-ROM jukeboxes can be used if a separate jukebox server providing a network-like access is used. In this case, a special program on the server regulates the access to the various disks in the jukebox.

Local Area Networks (LAN)

The CADDY system can be used within a local area network (LAN) environment forming part of an integrated system for data exchange and access. Regulatory authorities will need to consider how best to implement CADDY in a networked facility. Suggestions for the most common situations are provided in the CADDY installation guide that is available for download on the CADDY web site <http://caddy.ecpa.eu>.

It is possible to use a CD-ROM jukebox to enable many users to access dossiers without changing discs in their local CD-ROM drives. A network printer with fast printing options can be used to print efficiently whole studies without having a local printer.

Local area network resources can be used for CADDY without any limitation, because the CADDY format on CD-ROM is hardware independent.

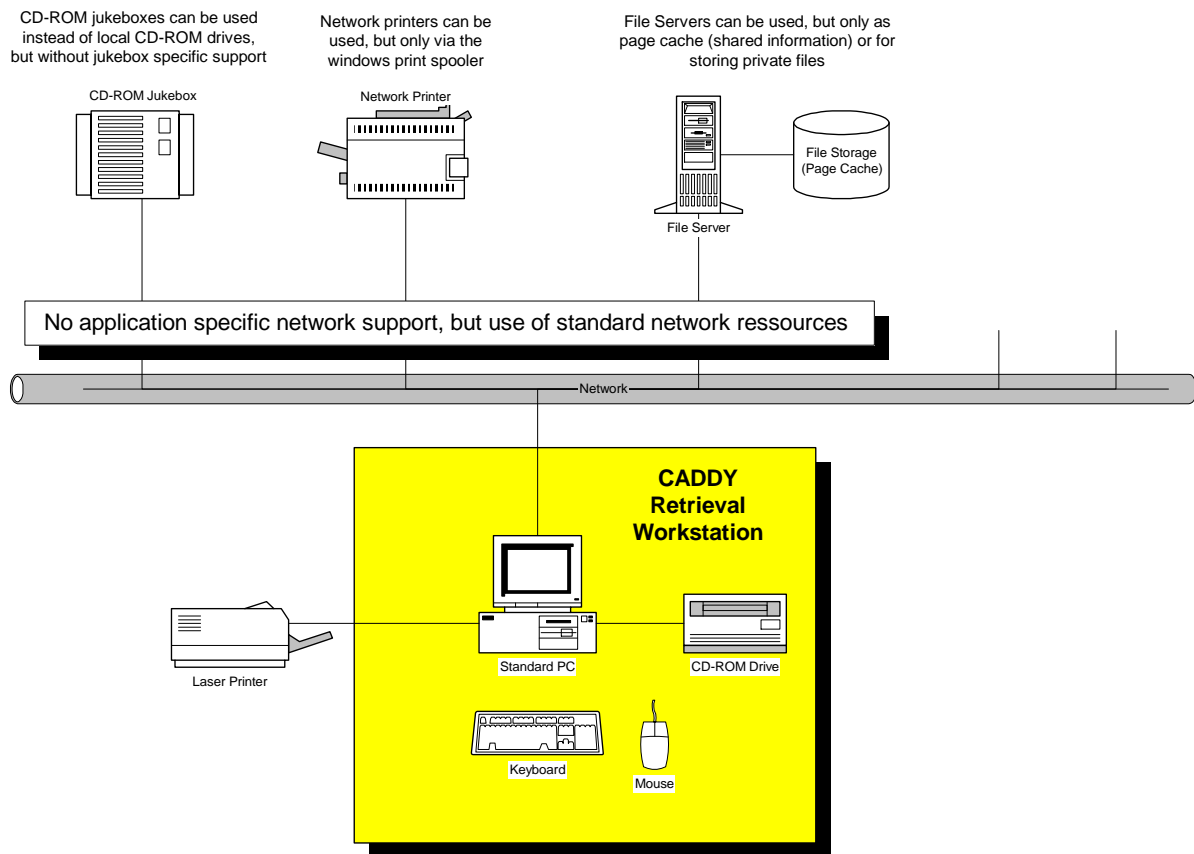


Figure 8-2 CADDY Retrieval Software in network environments

9 References

- [1] Document Interchange Format For Pesticides Registration Applications
Format Specification CADDY 2.0 / June 19, 2002
Joint CADDY Steering Group
(Download from the CADDY website at <http://caddy.ecpa.eu>)

- [1a] Document Interchange Format For Pesticides Registration Applications
Format Specification CADDY 1.1 / September 23, 1997
including Addendum to CADDY 1.1 Format Specification as of February 24, 1998
Joint EU / US / Canada CADDY Steering Group
(Download from the CADDY website at <http://caddy.ecpa.eu>)

- [2] CADDY Information Brochure:
Turning the Key To Electronic Submissions For Plant Protection Product Registration
Joint CADDY Steering Group, (March 1998)
(Download from the CADDY website at <http://caddy.ecpa.eu>)

- [3] Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers for the
Inclusion of Active Substances in Annex I of Directive 91/4141/EEC,
Commission Document 1663/VI/94, Rev. 8, April 22, 1998
http://europa.eu.int/comm/food/fs/ph_ps/pro/wrkdoc/1663_en.zip

- [4] Guideline developed within the Standing Committee on Plant Health concerning instructions for
industry on dossier submission,
Commission Document Sanco/3989/2001 Rev. 2, December 6, 2001
http://europa.eu.int/comm/food/fs/ph_ps/pro/wrkdoc/submission_instructions_en.pdf

- [5] CADDY Standardized Table of Content:
Document that describes the standardized structure of the CADDY Table of Content of CADDY
Plant Protection dossiers.
(Download from the CADDY website at <http://caddy.ecpa.eu>)

9.1 Useful Web Links

For the following web links be sure to get the latest version of the document.

- [H1] Contact Points in the Member States and the European Commission,
Commission Document SANCO/3065/2001, Rev. 27, July 1, 2003
http://europa.eu.int/comm/food/fs/ph_ps/pro/contactpoints_adress0307.xls

- [H2] Existing active substances: Number of dossiers to be submitted
July 1,2003 (50KB)
http://europa.eu.int/comm/food/fs/ph_ps/pro/eva/existing/number_dossiers.pdf

- [H3] Evaluation of new active substances: Number of dossiers to be submitted
July 1,2003 (52KB)
http://europa.eu.int/comm/food/fs/ph_ps/pro/eva/newactive/nb_dossiers_en.pdf

10 Glossary

CD-ROM set

A set of CD-ROMs containing all the individual CD-ROMs, which are part of a submission. Each submission (first time or supplemental) represents a separate CD-ROM set.

Full Dossier

Expression used for European dossiers. A "full dossier" is the complete dossier containing all study reports, summary dossiers (see below), and additional documents. The format of this type of dossier is provided in the EU working document 1663/VI/94 [3]

I/O devices

Hardware components within the PC that regulate the data flow between hardware components (e.g. hard drive and CD-ROM recorder)

OECD

Organization for Economic Cooperation and Development

Summary Dossier

Expression used for European dossiers. A Summary dossier (under the current formatting guideline, see above under "Full dossier") contains three levels of summaries, ranging from detailed summaries for each study report to an executive summary of the entire dossier.

Table Of Contents (TOC)

The Table Of Contents (TOC) is a window that displays a hierarchical organized list of chapters.

TIFF Files

TIFF (Tag Image File Format) is an accepted industry standard file format that describes the storage format for raster images. Because of the flexibility and richness of TIFF, there is no „standard“ TIFF file. The subset used for CADDY submissions is described within the CADDY Format Specification [1].

Unique Page ID (UPID)

Every page in a dossier has a unique page ID (UPID), which serves as a system key for internal use only.

Unique File ID (UFID)

Every CCF in a dossier has a unique file ID (UFID), which serves as a system key for internal use only.

11 Appendix A Index File Examples

European Example

Additional line breaks were inserted where necessary to show the full entry in this document.

The example below should demonstrate the contents of the CADDY index files. The example is not binding and will not overwrite rules given in the CADDY Format Specification [1].

dh_ver

```
1|4/16/1999|3|2|1|8/1/1997|0|0|0|0|0|0
2|4/17/1999|4|2|2|10/1/1997|0|1|0|1|0|0
3|4/18/1999|5|2|2|12/1/1997|1|0|1|1|0|0
4|5/18/2002|6|3|2|5/18/2002|0|0|0|0|1|1
5|6/17/2002|7|3|2|6/17/2002|0|0|0|0|1|0
```

dh_vol

```
1|CAYBE004-001|6000|0|0|1
2|CAYBE004-002|12|0|1|1
3|CAYBE004-003|3921|1|0|1
4|CAYBE004-004|53|1|0|0
5|CAYBE004-005|57|1|0|1
6|CAYBE004-006|0|1|0|1
7|CAYBE004-007|0|1|0|1
```

dc_rep

...

```
19|73|KIIA 2.7 /01|PC22464|9/30/1989|1|1|Solubility of CADDYTEST in representative organic
solvents|Thorn, J.|Caddy Inc.|Caddy Inc.|Caddy Inc., department,
laboratory|0|1|0|0|1|1|0
20|75|KIIA 2.8 /01|PC54233|12/3/1988|1|1|Partition coefficient of CADDYTEST|Thorn, J.|Caddy
Inc.|Caddy Inc.|Caddy Inc., department, laboratory|0|1|0|0|1|1|0
21|78|KIIA 2.9.1 /01|PC59849|8/7/1991|1|1|Hydrolysis of CADDYTEST in sterile aqueous buffer
solutions|Brumhard, B.|Caddy Inc.|Caddy Inc.|Caddy Inc., department,
laboratory|0|1|0|0|1|1|0
```

...

dc_toc

...

```
26|0|18|5|48|KIIA 1.8|Method of manufacture (synthesis pathway) of the active substance
27|0|18|5|51|KIIA 1.9|Specification of purity of the active substance in (g/kg)
28|0|18|5|54|KIIA 1.10|Identity of inactive isomers, impurities and additives
29|0|18|5|0|KIIA 1.11|Analytical profile of batches
```

...

dc_pag

...

1449|3|3|0|613|1

1450|3|3|0|614|1

1451|3|3|0|615|1

1452|3|3|0|616|1

1453|3|3|0|617|1

...

dc_ccf

...

1|6|6|69|0|CCF01 PDF Document|pdf|4

2|6|6|72|0|CCF02 Word Document|doc|4

3|6|6|75|0|CCF03 Excel Document|xls|4

4|6|6|81|0|CCF04 1/3 Word Document|doc|4

5|6|6|82|0|CCF05 2/3 PDF Document|pdf|4

...

dc_ink

...

1|Test Page Link|69|100|100|100|50|P|72|100|100

2|Test TOC Link|70|100|200|100|50|N|44|100|100

3|Test CCF Link|71|100|300|100|50|F|3|100|100

4|Test Page Link|72|10|10|1040|1475|P|2|398|708

5|Test TOC Link|72|1050|1485|1040|1475|N|44|100|100

6|Test CCF Link|73|10|10|2090|2960|F|3|100|100

...

da_chg

...

P|9022|1

P|9023|1

P|9024|1

...

dh_has

1|Imaginary Active Substance for Use in the CADDY Beta Test||EEC|91/110|1000/92|BE

2|Imaginary Active Substance|Sub\|title|EEC|91/110|1000/92|BE

dh_asu

1|1|CADDYTEST|1234|123456-37-5|1

2|2|CADDYTEST|0000|123456-37-5|1

dh_rps

1|1|15 ml/l

2|2|15 ml/l

3|2|150 ppm

dh_pro

1|1|SC400|WP|1

2|2|SC400|WP|1

3|2|Nihililit|EC|1

dh_com

1|1|CaddyCorp|CAY|Belgium|BE

2|2|CaddyCorp|CAY|Belgium|BE

3|2|Nihilinc|NIC|United Kingdom|GB

dd_tab

dh_ver | 3 | 5
dh_vol | 2 | 7
dc_rep | 2 | 179
dc_toc | 2 | 652
dc_pag | 2 | 9918
dc_ccf | 3 | 9
dc_lnk | 3 | 6
da_chg | 2 | 24
dh_has | 2 | 2
dh_com | 2 | 3
dh_asu | 2 | 2
dh_pro | 2 | 3
dh_rps | 2 | 3
dd_tab | 2 | 15
dd_col | 2 | 122

dd_col

...
dc_rep | rep_order | integer | 1 | 9999
dc_rep | URID | integer | 1 | 9999
dc_rep | r_tocnode_UNID | integer | 1 | 99999999
dc_rep | r_doss_fn | text | 0 | 20
dc_rep | r_comp_fn | text | 0 | 20
dc_rep | r_date | date | 0 | 1
dc_rep | r_valid_day | boolean | 0 | 1
dc_rep | r_valid_month | boolean | 0 | 1
dc_rep | r_title | text | 0 | 240
dc_rep | r_authors | text | 0 | 120
...

12 Appendix B European Standard TOC

The Standardized European Table of Contents is proposed for CADDY dossiers prepared according to the current EU formatting guidelines (document 1663/VI/94 rev 8 dated 22 April 1998 [3]). The CADDY dossier is an exact representation of the paper dossier and therefore the structure follows the presentation of the dossier required in the formatting guide.

This proposed Standardized European Table of Contents was agreed by a working group consisting of representatives from Member States and ECPA in 1998 and has not been changed, except that the words "and reference lists" were added to the description of items "Document LIIA" and "Document LIIIA1" to clarify where the reference lists should be linked in.

Three comment should be made regarding the design chosen for the Standardized European Table of Contents and its use in practice:

The table of contents was designed to be the index to the summary documents and study reports contained in the CADDY dossier. It thus follows that the numbering through the K-document will show gaps, since not all data points will have a study report or a summary document linked to them and would always be empty. For instance, the KIIA-document starts with KIIA 1.8 - Method of manufacture of the active substance, as this is the first Annex point which actually contains a document/report. Data points KIIA 1.1-1.7 are simply paragraphs within the Tier II (MII) , Section 1, Annex II rather than individual documents or reports and thus would always be empty. Following the same logic, the numbering in KIIIA1 starts at KIIIA1 - Detailed composition of the product.

The suggested table of contents provides a minimum structure to be used in the CADDY submission. It may be appropriate to add further subpoints, depending on the number and type of reports provided in the dossier.

For a full submission (Annex II plus one or more Annex IIIs) items in the table of contents containing no study reports should be left empty rather than deleted. However, where only an Annex III is submitted, the respective KIIA, LIIA and MIIA entries can be removed if not needed.

For the Standardized European Table of Contents please refer to the document "CADDY Standardized Table of Content" which is available on the CADDY web site <http://caddy.ecpa.eu>.

13 Appendix C OECD Standard TOC

The European Commission has now decided to replace the Rev. 8 dossier format with the OECD dossier format, which also requires an adaptation of the table of contents of the CADDY. A Commission Working group including EU Member States and representatives of ECPA met several times to define the technical details of this format switch. Based on past experience with CADDY dossiers and to maximize the usefulness to Member States, the OECD-style table of content is much more detailed than the previous Rev. 8 one. It covers all OECD Annex points and it should therefore not be necessary to add additional annex points. Also, the Commission Working Group recommended that annex points, which do not contain documents, should be left empty and not be removed.

The CADDY specification requires that headings do not exceed a length of 70 characters and therefore some headings had to be shortened.

For the Standardized OECD Table of Contents please refer to the document "CADDY Standardized Table of Content" which is available on the CADDY web site <http://caddy.ecpa.eu>.