



## CADDY-xml

Update on E-submissions in the  
European Union

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## CADDY Background

The original CADDY format specification was developed in 1995 when study reports used for the preparation of submissions existed primarily in paper form in an archive or as paper scans in an electronic archive. The original strategic goal was defined as follows:

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

in a cost-effective manner using electronic media.

These objectives have largely been achieved in Europe, with number of submitted paper dossiers distributed to EU member states significantly reduced

## CADDY-xml: why?

- Document management technologies have evolved considerably and XML-based web technologies have become standard.
- Applicants are increasingly producing and storing study reports in native electronic formats
- PDF/A has emerged as an ISO standard and is thus a suitable alternative to TIFF for long-term storage of documents
- The uptake of CADDY has been limited to agrochemicals in Europe, with other regulatory programs and regions pursuing a different approach based on PDF.
- The CADDY standard needs further development to make it useful as a tool for dossier and data exchange in the context of global work sharing
- In addition, there is a clear trend towards more structured data submission based on OECD templates which needs to be appropriately supported by modern technology.

For this reason, the ECPA DTWG worked with the EU Commission and some EU member states to further develop CADDY on the basis of PDF and xml.

## What is CADDY-xml?

- CADDY-*xml* is based on the CADDY 2.0 format, but introduces some important differences by providing the general information, a table of contents, confidential and non-confidential documents, report information and hyperlink information in an XML framework.
- The TIFF-files are replaced by PDF/A versions of the documents, which can be either image-based or text-based. Additionally, a CADDY-*xml* based dossier can be instantly viewed with a common web-browser supported by Acrobat Reader. This standard is flexible to accommodate different dossier structures such as OECD, EU or any other standard.
- Within this setup XML-representation can be thought of as the backbone of the dossier. It references every document that is included within the directory structure.

## Current Status

- The CADDY-*xml* Specification version 1.0.1 has been finalized in June 2005 and agreed in the [CADDY Forum](#).
- A conversion software that transforms CADDY 1.1 and CADDY 2 dossiers into CADDY-*xml* dossiers is currently in the final stages of development and will become available in the fourth quarter 2005. It will then be made available on the CADDY website for download.
- With these tools (specification and conversion software), applicants and reviewing authorities are able to create and exchange self-contained dossiers
- The foundation for further developments to support and facilitate work-sharing has been created.
- A demo CADDY-xml dossier is available

## Will CADDY 2.0 continue to be supported?

- CADDY 1.1 and 2.0 format compliant dossiers remain the European submission standard and will continue to be supported.
- This means that authorities can continue to use already submitted CADDY 1.1 and CADDY 2.0 dossiers without modification. While maintenance of the CADDY Retrieval Software will continue, it is not planned to develop further functionality.
- It is expected that future work-sharing needs will require more sophisticated review tools. The XML format lays the foundation for such future developments.

## Where to find more information

Additional information on CADDY-xml can be found at:

<http://caddy.ecpa.be/>

