



## Benefits

- Content can be dragged & dropped from any repository (DMS, Sharepoint, desktop or fileshare) to your electronic submission
- Full archiving capability allows quick access to the lifecycle of old dossiers
- PDF, XML or paper based submissions supported in one tool
- Required reference lists can be created with a single click
- Internal validation forces users to comply with regulatory requirements
- Significant effort reduction in preparation of supplementals and amendments
- Configuration flexibility to meet individual business needs
- Worldwide management of dossiers
- Long term strategy to incorporate new regulatory requirements



## Product Information PlantOS™ 3

### PlantOS 3 – register plant protection products the easy way

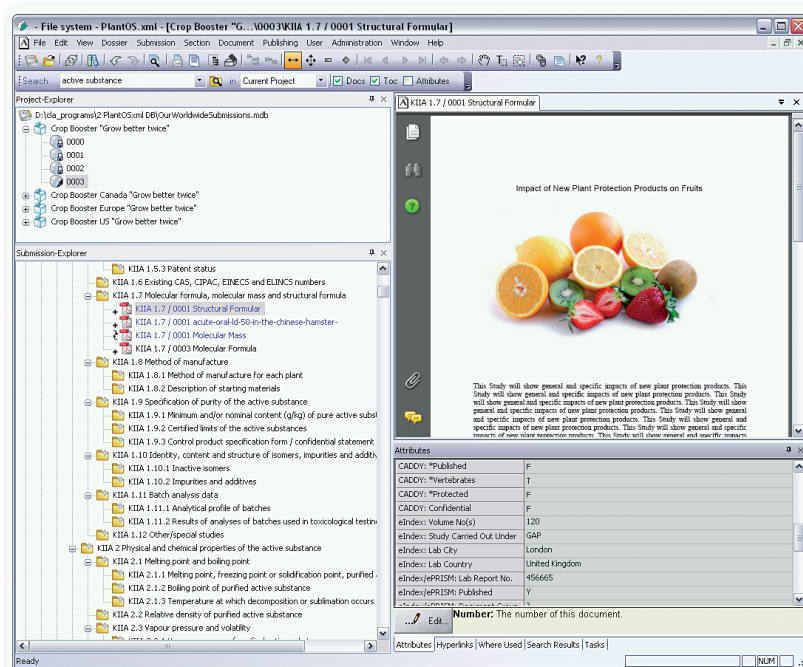
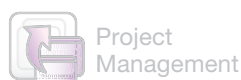
Today the crop sciences industry has to use data from different registration procedures and multiple standards to meet the requirements of global regulatory authorities. In the future a common worldwide standard for submitting pesticide registration application documents could facilitate a much better way of interchanging dossiers between companies and authorities.

- e-PRISM (USA)
- e-Index (CAN)
- CADDY.xml (EU)

In addition, due to a free configurable submission tree and a universal PDF output that supports paper output for all standards, other regulatory standards can be supported as well.

EXTEDO PlantOS 3 is an off-the-shelf solution that manages the assembly and compilation of electronic dossiers. The following digital standards for regulatory affairs in Crop Science are supported and can be exported from one single data collection (based on the OECD CADDY table of content).

EXTEDO is committed to add support for additional regulatory standards to PlantOS 3 as soon they are officially released and will support the change towards a next generation of electronic submission standards on an OECD level.



*Intuitive User Interface*

## Streamline the regulatory workflow for extra gains

Submission management is an essential function for bringing crop products to market. Its contribution to company profit goals can vary. Push-backs, physical limitations or authority decisions can substantially affect overall company targets.

## Functional Overview

PlantOS 3 has been designed as a client/server architecture. It requires Adobe Standard or Adobe Professional being installed for all submission creators. It can be implemented stand-alone or in combination with a Document Management System. The users front-end can be a desktop installation or embedded into a terminal server setup. In an enterprise setup the usage of MS SQL or Oracle is supported.

In order to meet different customer requirements and continuous changes within the regulatory field, PlantOS 3 is designed as a highly configurable system. The main elements of all digital submissions are file folders, PDF-files and additional XML files.

PlantOS 3 allows you to work on a submission with other employees and to reuse existing content from other submissions. PlantOS 3 also helps you produce a higher quality submission which reduces the risk of having issues with a regulatory authority.

PlantOS 3 can be installed quickly and requires minimal administration. Bulk registrations on state (US) or country level (EU) are supported with a powerful copy dossier/submission functionality. Full text search in documents, variables and table of contents allows users to quickly navigate to specific documents.

Version history: The first implementation of PlantOS was based on a TIFF handling process for CADDY output only. A technology change towards PDF and multiple outputs has been successfully done with PlantOS.xml. Further development of PlantOS.xml now results in the 3rd generation of PlantOS software: PlantOS 3.

### Available Modules

- **PlantOS DMS Connector:**  
Enables integration with leading document management systems
- **PlantOS Viewer:**  
Easy to use client for non-regulatory employees

## About us

EXTEDO is the key software and service solutions provider in the field of Regulatory Information Management. The complete EXTEDOsuite is unique in all that it covers within eRegulatory Affairs:

- Product Registration Planning & Tracking
- Submission Management (eCTD, CTD; NeeS, CADDY, ePRISM, eIndex, eNTA, vNeeS)
- Pharmacovigilance Management (SUSAR, ICSR, PSUR, E2B)
- Labeling Management and
- Document Management

We provide configurable off-the-shelf products, as well as customized and integrated solutions. EXTEDO also provides EURS is Yours, the validation, review and approval software solution for the EMA and more than 25 Regulatory Authorities worldwide.

Today we serve more than 700 customers in 57 countries ranging from small companies with less than 25 employees to large multinational organizations. EXTEDO operates in the following areas of life sciences: pharmaceutical, biotech and biopharma, generics, homeopathics, medical devices, healthcare, and public sector.

EXTEDO is recognized as one of the worldwide leaders in each of our areas of operation.

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