

PANAMA

Plant Protection Products And Nutrients Authorisation Management



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2 Agenda

- Introduction
- Panama - Home page
- Enterprise Account
- Applications for fertilisers
- Applications for plant protection products
- Features for consultants
- Security



3 What is PANAMA ?

On-line submission of applications for

- Fertilisers
- Plant Protection Products
- GEP and products for experimental purposes



4 Why PANAMA ?

Advantages

- 1 integrated tool for the management of all applications
- 1 database containing all data
- => easier for treatment

- Smoother communication with external experts, inspection, authorisation holder, users, ...

- More transparency during treatment of application



5 PANAMA Home Page

Menu

Create applications for new products

Portfolio

Consult existing applications and documents
Create applications for existing products = "second versions"

Account:

Management of Enterprise data



6 Account - Enterprise mgt

Enterprise data:

Link with national register of enterprises
("only once principle")
Data specific for Panama

Contact persons

Invoice address

Producer / production site

Storage room

Delegations to consultant



7 Application / Product

Application status:

- "Draft"
 - "Introduced" / "Committee" / ...
 - "Finalised"
- > decision: authorised / not authorised / ...

For one product, many applications
All applications ("versions") are saved



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Applications for fertilisers



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9 Fertiliser - Contact Info

Tab Contact data

- Headquarter of the authorisation holder
- Contact person
- Invoice address
- Communication language
- Authorisation language



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10 Fertiliser - Application details (1)

Application Info:

- Mutual recognition
- Application context -> defines expected documents
- Mixed with PPP + info



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11 Fertiliser - Application details (2)

Product info:

- Proposed type designation
- Commercial name
- Classification
- Responsible enterprise (responsible for authorisation)
- Producer / production site
- Product of animal origin
- Estimated volume that will be sold
- Package
- Formulation type

Comment



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12 Fertiliser - Documents

-> list of expected documents / information to be submitted
(depending on application type and context)

- Upload documents
Add comments (if needed)



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13 Fertiliser - Possible actions in "Draft"

Save / Save and Close / Cancel
 Print -> temporary PDF-report

Submit =>

- Validations
- Status "Draft" => "Introduced"
- Creation of PDF-report

!!! No more modifications possible in FO
 (but BO can modify the application)



14 Fertilisers - Portfolio

- Products -> Create 2nd version
- Draft dossiers -> Applications not yet submitted
- Introduced dossiers -> Submission report
- Finalised dossiers -> Authorisation + other documents



15 Fertiliser - Application types

Application types for fertilisers in PANAMA:

- Derogation / duplicate derogation / sludge
- Application for new product
- + 2nd version (renewal)
- + Translation

Certificate



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Applications for Plant Protection Products



17 PPP - Contact Info

Tab Contact data

- Headquarter of the authorisation holder
- Contact person
- Invoice address
- Communication language
- Authorisation language



18 PPP - Application

- Details about the application
- Comments for each question
- General comments on application



19 PPP - Product

- Nature of the product
- Contains fertilisers + information
- Commercial name of the product
- User group
- Formulation type
- Comment
- Production sites



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20 PPP - Composition (1)

Add active substance / safener / synergist

Search and select component known in PANAMA
OR create new component

Data about:

- Chemical nature
- Content in formulation
- Sources and purity



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21 PPP - Composition (2)

Add co-formulant

Search and select co-formulant known in PANAMA
OR create new co-formulant

Data about:

- Role in formulation
- Content in formulation
- Sources

Create groups of equivalent co-formulants



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22 PPP - Labelling

Sections:

- CLP (no DSD / DPD in PANAMA)
- European PPP legislation
- National / Other legislation
- Comments

Mandatory phrase(s) (for user group)
Add / delete others

Edit / View instructions



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23 PPP - Packaging

Type / material / volume(s)

Per volume:

- Water soluble bags / tablets / measuring device
- National conditions if for non-prof use
- National conditions if large packaging for prof use

Stability studies

National conditions if for non-prof use



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24 PPP - Usage

Crop

conditions of use / mitigation measures / warnings

+ pest(s)

List of allowed pest + create other

Application stage / rate / other information

Precautions succeeding crops

Overview tables allow to copy



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25 PPP - Documents

- > list of expected documents / information to be submitted (depending on application type)
- Upload documents
 - Add comments (if needed)
 - Allowed and recommended to send study reports on CD-rom
- Submit reports



26 PPP - Possible actions in "Draft"

Save / Save and Close / Cancel
Print -> temporary PDF-report

Submit =>

- Validations
- Status "Draft" => "Introduced"
- Creation of PDF-report

!!! No more modifications possible in FO (except when BO reopens the application)



27 PPP - Portfolio

Products: Will allow to create 2nd version

Draft dossiers: Applications not yet submitted

Introduced dossiers

- Introduced: Submission report(s)+ send additional info
- Re-opened: Submission report(s) + send additional info + edit
- Waiting: Submission report(s) + send additional info

Finalised dossiers: documents (ao authorisation)



28 PPP - Application types

Application types for PPP in PANAMA:

Zonal application for authorisation
Application for mutual recognition

- + 2nd versions
- + "Derived" versions
- + ...



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Features for consultants



30 Consultants - Types of delegation

Two types of delegation:

- 1) Delegation for creating new products
 - => create applications for new products
 - > access via Menu
- 2) Product specific delegation
 - => can create applications for existing product
 - > access via Portfolio



31 Consultants - Principles (1)

Main principles for delegations:

- Created manually and for each product separately
Except for new products created automatically
- Specific delegation is always created by auth. holder
Can not be passed on to other consultant
- Stopped manually
- Can be stopped at all times - stop one / more / all product(s)



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32 Consultants - Principles (2)

- For one product more than one consultant possible
- Consultant sees (only) own applications
- Different consultants can create different applications for the same product at the same time
- Authorisation holder sees all his applications
(also all applications created by consultant)



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33 Consultants - Principles (3)

- Enterprise can be authorisation holder and consultant at the same time
- All enterprises have similar screens and features in FO



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34 Consultants - Communication

Features to ensure communication:

Authorisation holder:

- has access to all his applications (incl. created by consultant)
- can indicate to receive a copy of all mails and letters sent to contact person
- will get a warning when application is finalised
(to remind that a derogation is not stopped automatically)



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35 Consultants - access levels PPP

Access levels for PPP "2nd version":

- Full access
 - No access to composition
 - Producer / Production site of product hidden
 - All details with regards to component hidden
 - Limited access to composition
 - Producer / Production site product hidden
 - Sources and purity of components hidden
- > For application for new product all details must be encoded



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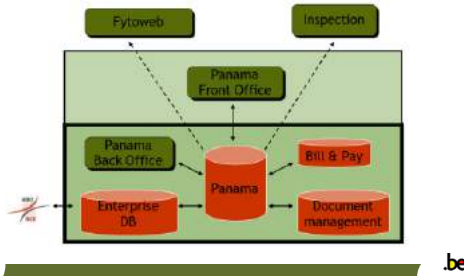
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Security



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37 Structure



38 Security

- HTTP-S
- Login:
 - FO/Extranet: Classical e-mail based login account
- Management of login accounts
 - FPS:
 - at crucial points (create "local admin"-accounts)
 - in case of emergency
 - Company (normally)

39 Data protection

- Have access to applications encoded in PANAMA:
- BO-users: dossier managers, experts, ...
 - All users of the enterprise that is authorisation holder
 - All users of the enterprise that acts as consultant
 BUT only as long as a delegation is given
 and only applications created by consultant

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Coming soon ...

41 Modular approach - Provisional timing

- 1) Partial production fertilisers summer 2014
 PANAMA / current DB used in parallel for a few new products
- 2) Full production fertilisers BO + fytoweb search fertilisers
 BO: summer 2015 / FO: 1 to 2 months later
- 3) Full production for pesticides and GEP: BO + fytoweb search
 BO: winter 2015 -2016 / FO: 1 to 2 months later

TESTING

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Thank you for your attention