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Biotechnology and GMOs

GMOREGEX User Guide

A. Rana, F. Foscarini, M. Canonico

Institute for Health and Consumer Protection
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The mission of the Institute for Health and Consumer Protection is to provide scientific support to the development and implementation of EU policies related to health and consumer protection.

The Institute for Health and Consumer Protection carries out research to improve the understanding of potential health risks posed by chemical, physical and biological agents from various sources to which consumers are exposed.

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GMOREGEX User Guide
(Project Final Report – 2006)

A. Rana, F. Foscarini and M. Canonico

Abbreviations /Acronyms

Term	Definition
AEP	Authorised External Party
AIA	Advance Informed Agreement procedure
AR	Assessment Report
BCH	Biosafety Clearing House
CA	Competent Authority
COM	Commission
CPB	Cartagena Protocol on Biosafety
DAO	Data Access Objects
EC	European Commission
EC-BCH	European Commission Biosafety Clearing House
EIS	Enterprise Information System
EJB	Enterprise Java Beans
EU	European Union
GMO	Genetically Modified Organism
GMOREGEX	GMO REGistration and EXchange
HTML	Hyper Text Mark-Up Language
HTTP	Hyper Text Transfer Protocol
HTTPS	Hyper Text Transfer Protocol Secure
ID	IDentifier
J2EE	Java 2 Platform Enterprise Ediction
J2SE	Java 2 platform Standard Edition
JRE	Jave Runtime Enviroment
JSP	Java Server Page
LCA	Lead Competent Authority
LMO	Living Modified Organism
MS	Member State
MVC	Model View Controller
PDF	Portable Document Format
SDK	Software Development kit
SNIF	Summary Notification Information Format
SOAP	Simple Object Access Protocol
URL	Uniform Resource Locator
XML	eXtended Markup Language
XSLT	eXtensible Stylesheet Language Transformations

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References

The reference documents are listed in Table 1.

Reference	Document
[DIR.2001/18]	DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
[REG.1946/2003]	REGULATION (EC) No 1946/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 July 2003 on transboundary movements of genetically modified organisms
[REG.65/2004]	COMMISSION REGULATION (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms
[SNIF.PARTB]	Summary notification information format for Part B releases - 2002/813/EC
[SNIF.PARTC]	Summary notification information format for Part C releases - 2002/812/EC
[J2EE]	Designing Enterprise Applications with the J2EE Platform, Second Edition http://java.sun.com/blueprints/guidelines/designing_enterprise_applications_2e/DEA2eTOC.html
[GIP]	GMOREGEX Global Implementation Plan
[PR]	GMOREGEX Preparatory Report

Table 1: Reference documents

1. Introduction

This document contains the user manual for the GMOREGEX application. It describes in detail the user functionalities provided by the system to the four different types of users for which the system has been implemented, i.e. the generic (non authenticated) user, the Member States National Competent Authorities user, the Commission user and finally a special type of authenticated user that can add comments or observations to GMO notifications based on the authorisation granted by the Competent Authorities and the Commission users.

The **GMOREGEX system** is a web-based application that enables the electronic support of the GMO notification and authorisation process as defined in Directive 2001/18/EC [DIR.2001/18]. As specified in the Preparatory Report [PR] and in the Global Implementation Plan [GIP], the system has been developed to support the management of document exchange, information dissemination and events tracking related to the authorisation process for the deliberate release of new GMOs for experimental purposes (Part B notifications and associated SNIFs - [SNIF.PARTB]) or for marketing purposes (Part C releases and associated SNIFs and reports - [SNIF.PARTC]). The processes followed in the system are in accordance to "**DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC"** and follow the technical specifications and indications contained in the Preparatory Report [PR] and in the Global Implementation Plan [GIP]

This manual is designed to familiarize users with the **GMOREGEX system** and provide a reference of the system's functionalities and use. The **GMOREGEX system** includes also the implementation of the GMO Register which supports the storage of information and related documentation of authorised GMOs in the EU, as well as the dissemination of public information to the general public according to the provisions of Art. 31.2 of [DIR.2001/18]. The GMOREGEX system includes also a component that implements the information submission to the Biosafety Clearing House (BCH) in support of the Cartagena Protocol on Biosafety – Regulation (EC) No. 1946/2003 [REG.1946/2003].

The **GMOREGEX system** supports the following five roles:

- Commission user (COM)
- Competent Authority (CA) user (this role includes both " LEAD CA" and "Non LEAD CA", a CA is given the role of "LEAD CA" for all notifications that are created by users associated to it)
- Authorised External Party (AEP)
- Anonymous user (Guest)

In addition, and administrator role is defined for administration and management of the system:

- System administrator (Admin)

From a functional viewpoint, the **GMOREGEX** system supports the following high-level functionalities:

- Creation of a new notification (Part B and Part C)

- Management of the lifecycle associated to a new GMO notification (i.e. circulation and publication of information, gathering, sending, collecting and circulation of comments, etc.)
- Dissemination/publication of public information associated to an authorised GMO
- Submission of information to the BCH Central Portal and publication to a EU-based BCH interface
- Reporting
- Advanced search facilities

The current document is partially based on the documentation generated within the project on the implementation of the system carried out with the collaboration of an external contractor.

2. Software architecture

As already identified in the [GIP], the architecture of the GMOREGEX system is based on the J2EE standard [Java 2 Platform Enterprise Edition] for developing component-based multi-tier enterprise applications, using the J2SE environment, delivered in the form of a Software Development Kit (SDK) and an associated Java Runtime Environment (JRE).
A multi-tier architecture is a client-server architecture in which an application is executed by more than one distinct software agent.
As a J2EE multi-tier application, the system is divided in three main tiers:

- **Presentation (Web) tier:** Tomcat (Servlet, JSP container) is used for preparation and delivery of a rich user interface, supporting advanced searching and retrieving functionality.
- **Business tier:** JBOSS, the premier Open Source J2EE Application Server play host to the application Business Components implemented as Enterprise Java Beans (EJB's), following the J2EE standard.
- **Enterprise Information System (EIS) tier:** Oracle database is utilised as the primary storage repository.

In the current release the interface of the application is provided in English but the architecture allows for easy extendibility to support other languages.

Figure 1 below provides a high-level visual representation of the software architecture.

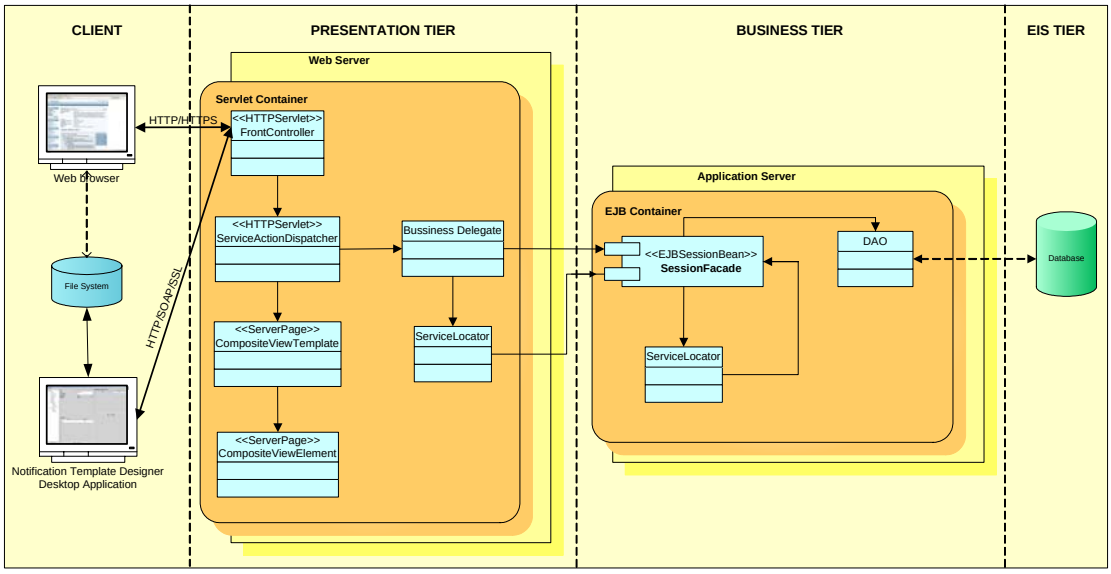


Figure 1: GMOREGEX software architecture

The business logic, which contains all the code necessary to execute the functions associated to the process of management of GMO notifications, resides in the business tier of the application, separated from the data and presentation tiers. This way, the application core components can be managed and deployed separately from the user interface and databases, accommodating high maintainability and re-usability.

Clients (e.g. end-users or external systems) will communicate with the application via the presentation tier utilising the following protocols:HTTPS and SOAP.

2.1. Presentation Tier

The Presentation Tier, situated between the client (thin client, web browser, etc) and the Business Tier, is responsible for processing client requests and generating appropriate responses.
In order to provide the required functionality while ensuring system maintainability and reusability, the Presentation Tier is implemented utilising standard [J2EE] patterns.

2.2. Business Tier

The Business Tier, the second tier in the 3-tier Enterprise Application model, plays host to the components implementing the application business logic. The Business Tier is responsible for executing business activities requested by the Presentation Tier and returning the relevant results to the Presentation Tier.
In effect, the Business Tier acts as a middleman between the Presentation Tier and the application data repository (Model), appropriately manipulating the application data according to requests from the Presentation Tier and returning the relevant results. The Presentation layer then updates the appropriate views.
The Business Tie is implemented utilising standard [J2EE] patterns.

2.3. Enterprise Information System (EIS) Tier

The Enterprise Information System (EIS) Tier plays host to external Enterprise applications, in this case the Oracle 10g database and the Oracle Workflow engine, which the Business Tier must interoperate with.

3. User Interface Principles

The **GMOREGEX** interface utilises specific components consistently, across all functionalities of the application. The interface components available for all user roles supported by the **GMOREGEX** system are explained in more detail in the following sections in order to further improve users' comprehension of the navigability and semantics of the overall interface.

In these sections we will often refer to **"non authenticated users"** and **"authenticated users"**. The first category identifies all users for which no authentication is required in order to access the functionalities being described, while the second category identifies all users in the roles which require explicit authentication in order to perform the actions being described.

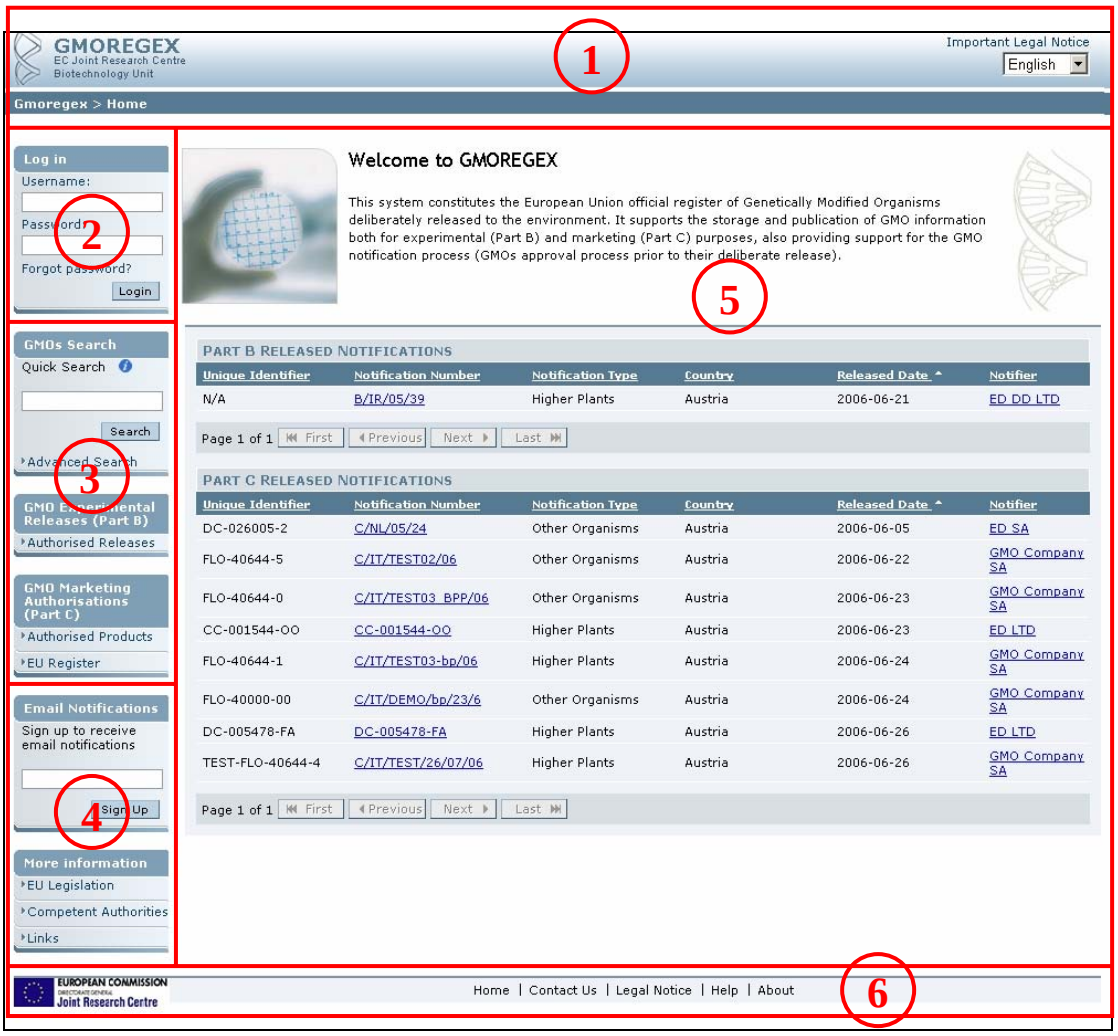


Figure 2: Interface components of GMOREGEX default homepage for Anonymous User

Figure 2 shows the interface components of the Home Page available for the non-authenticated users, which are described in detail in Table 1.

#	Interface Component Name	Purpose
1	Header	Presents the "corporate identity" of the GMOREGEX system through a banner and logo. Additionally, the "Header" component provides functionality to users to select their preferred language, and displays the path of the current page[1]. The "Header" component is included in all web-pages, and has the functionality and dimensions of the Europa banner[2].
2	Log in	Supports the functionality for users to log in the application when anonymous, or to log out when authenticated. Furthermore, when a user is authenticated, the "Log in" component allows the user to view his/her tasks and preferences according to his/her user role. This component is included in all web-pages of the application (with the exception of pop-ups).
3	Main menu	Facilitates the navigation among the various parts of the application. It allows users to view lists of GMOs and notifications, separated in Part B and Part C. Furthermore, it allows users to execute searches, e.g. quick search and advanced search of Notifications/GMOs., as well as, to view non-GMO related information, for instance details associated to Competent Authorities. If logged in, users will see, in the "Main menu" component additional functionalities depending on their role within the system. This component is included in all web-pages of the application
4	Secondary functionalities	Facilitates secondary functionalities of the application, including interfaces for support of the email newsletter subscription functionality.
5	Main content area	Presents the main content of the application, including GMOs, Notifications, Competent Authorities, etc. A more detailed description of the details of the Notification/ GMOs web-page is given in the following chapters.
6	Footer	Similarly to the "Header" component, the "Footer" is included in all web-pages of the application, providing links to useful web-pages of the application.

Table 2: Graphical User Interface components of all web-pages of the GMOREGEX system

[1] The system has been implemented in order to allow multi-language support. However, currently the interface is available only in English.
[2] http://europa.eu.int/comm/ipg/rule4/rule4_en.htm#banner

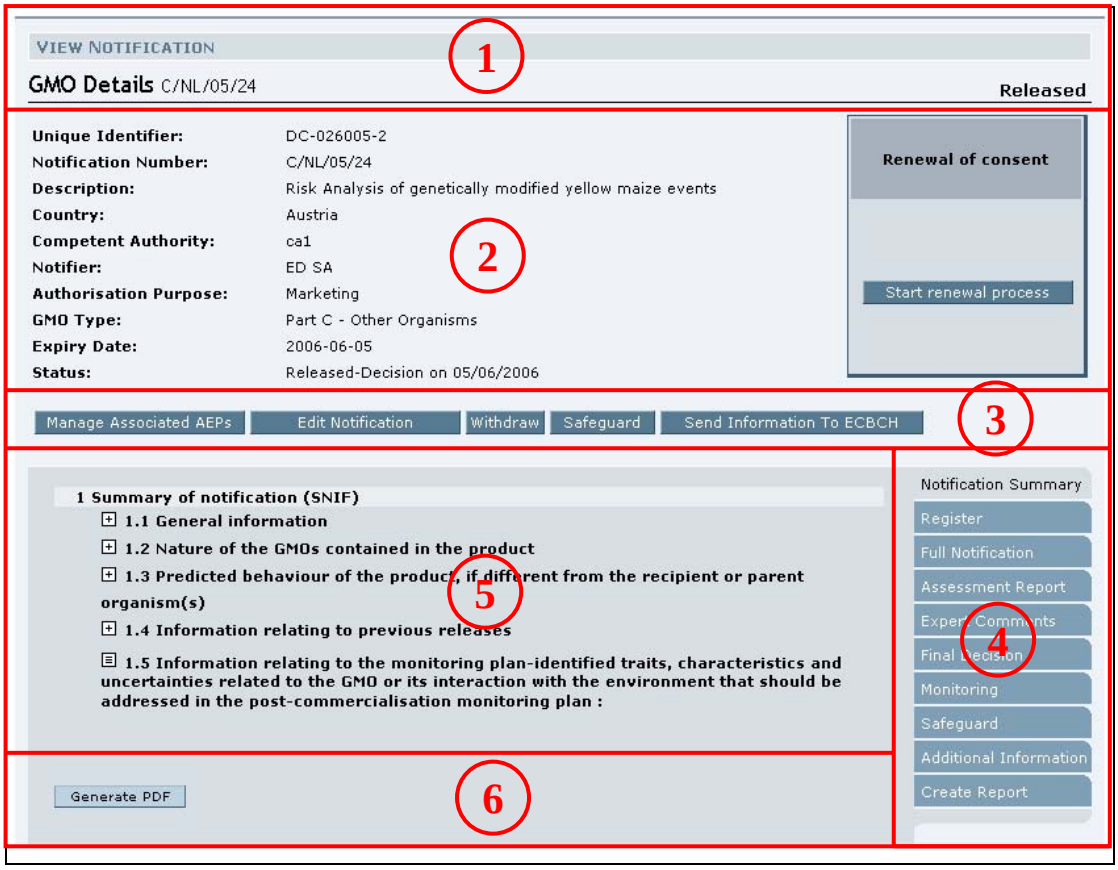


Figure 3: Interface components of the View Notification/GMOs Details (Released Status – Part C notification) of the GMOREGEX system for CA User

Figure 3 shows the page that is displayed to authenticated users (Competent Authorities in this case) when they display the details of a Part C Notification. The upper part of the window contains high level information about the notification, while the lower part contains the details about the notification contents. The interface components are described in more detail in Table 2.

#	Interface Component Name	Purpose
1	GMO Status and ID	Presents the status of the GMO notification and its identification number. If the GMO is approved, then the left-hand side area indicates "GMO Details (#)" and the right-hand side area states "Released". If the authorisation process has not been completed yet, then the left-hand side reads "Notification Details (#)" and the right-hand side area states the current status of the notification.
2	GMO Overview	Provides core information for a Notification/GMO, including the Unique Identifier, Notification Number, Project, Country, Competent Authority (CA), Notifier, Authorisation Purpose (marketing or experimentation), GMO Type (high-plant or other) and Status. Depending on the type of notification, an additional area might appear which presents information related to the "renewal of consent".
3	GMO Operations	Provides functionality for performing operations on the Notification/GMO. For instance, such operations may involve withdrawing a notification from the notification process, etc. The operations available to a user depend on the user's role.
4	Tabs	Facilitates the grouping of information of a Notification/GMO into virtual folders. The Notification/GMO information is segmented into the following tabs: **Notification summary:** contains the SNIF **Register:** contains the register data (Part C notifications only) **Full Notification:** contains mechanisms for viewing/exporting the full notification dossier of a GMO **Assessment report :** contains the Assessment report for Part C notifications and for new notifications based on the "renewal of consent" process **Expert comments:** contains comments from Authorised External Parties (AEPs), for instance an ethics committee **Public comments:** contains comments received from the general public **Monitoring**: upload monitoring documents **Final Decision:** functionality to add final decision to a Notification/GMO **Safeguard:** contains documents related to the safeguard clause of a notification **Additional Information:** provides the Lead Competent Authority (LCA), CA and COM users with the facilities to exchange information **Create Report:** allows users to generate reports about the status of a notification Each user, depending on his/her role, will be presented with all and/or a subset of the above tabs. Furthermore, the number of options available to users will depend on the type and status of a Notification/GMO. (e.g. the "Notification Summary" will be available to the general public only when it is published by the Commission, and the Safeguard tab will only appear for Part C notifications while the option *expert comments* and *public comments* will be displayed only if comments are uploaded.

5	Selected Tab Details	Presents the details of the selected tab. This will take the form of: **Lists:** provide information in a tabular format. **Submission forms:** allows user to submit information to the system. For instance, when a user of the general public accesses the "Public comments" tab, a submission form will allow the user to submit a comment for a Notification (only during time-period, as defined by [DIR.2001/18]) **Tree-structure display forms:** allows users to view the details of a data item. This display mechanism is used for SNIFs and ARs, as these items are long and have complex structures. Through this mechanism, users will be provided with the facility to fully expand a Tree-structure display form and view the full details of a SNIF or AR, or navigate directly to a specific item in the form
6	Selected Tab Operations	Similarly to the "GMO Operations" component, the "Selected Tab Operations" component allows users to perform operations for a selected tab. For instance, in the SNIF tab, users that have the appropriate access rights, may initiate the operation for circulating the SNIF amongst CAs, or publishing the SNIF to the general public

Table 3: INTERFACE components of the View Notification/GMOs Details (Released Status – Part C notification) of the GMOREGEX system for CA User

4. General Functionalities

This chapter covers the general functionalities of the application that are accessible both from the non authenticated and authenticated users.
These functionalities are search, view and creation of notifications.
This chapter provides details on functionalities available for non-authenticated users and then integrates them with the functionalities available for authenticated users. Namely:

- Generic (non-authenticated) users
  - Homepage
  - Quick Search Notifications/GMOs
  - Advanced Search Notifications/GMOs
  - Export Document in PDF
  - View CAs and related notifications
  - View Notifiers and related notifications
  - View Notifications/GMOs Details
- Authenticated users
  - Login-Logout
  - User Account Activation
  - Create Summary Reports
  - View My Tasks
  - Advanced Notifier Search

Tasks that can be executed by non authenticated users can be also executed by authenticated users during their session.

4.1. Generic (non-authenticated) users

This section describes the functionalities that the GMOREGEX system provides to generic users.
These functionalities are mainly associated to search and view of notifications.

4.1.1. Homepage

Non-authenticated users (the general public), that may access the “information dissemination” component of the GMOREGEX system, are presented with the default homepage of the **GMOREGEX** system. The main body of the page displays two lists: Part B Released Notifications and Part C Released Notifications, respectively.

Figure 4 shows the central part of the homepage, without the navigation menus.

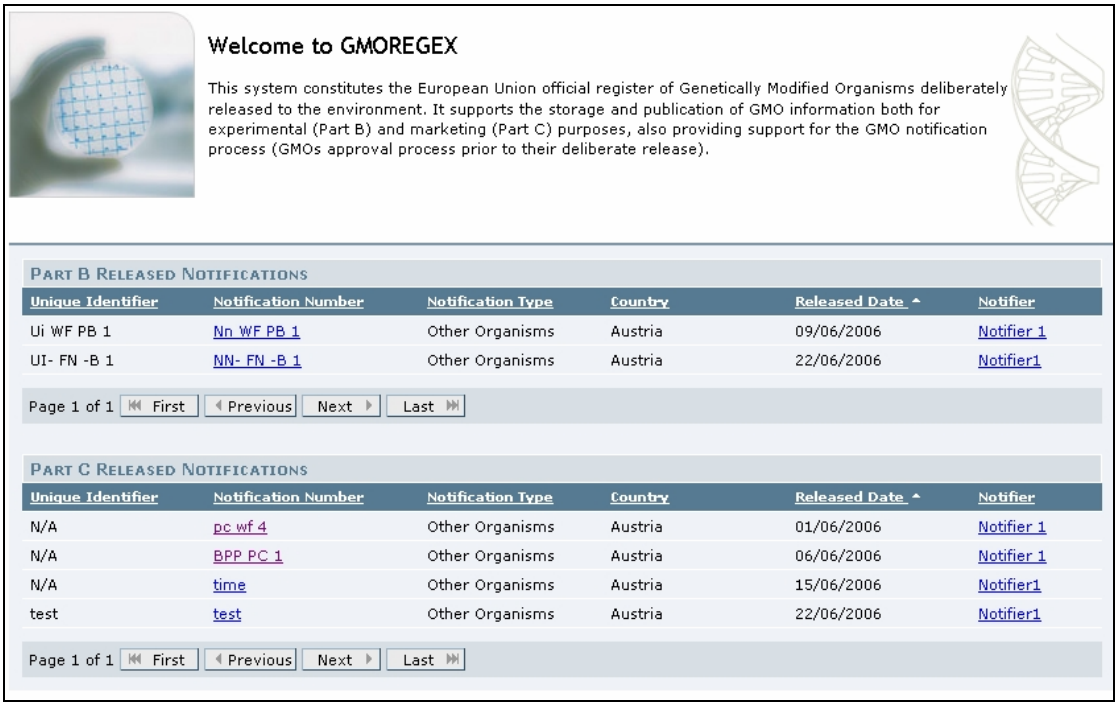


Figure 4: Default Homepage screen

4.1.2. Quick Search Notifications/GMOs

Users may execute a **quick search** of Notifications/GMOs by entering a search term in the *GMOs Search* menu item. The **quick search** performs the search action by searching for the terms specified by users in the following fields: ***unique id***, ***notification number*** or ***project name*** (Figure 5.)

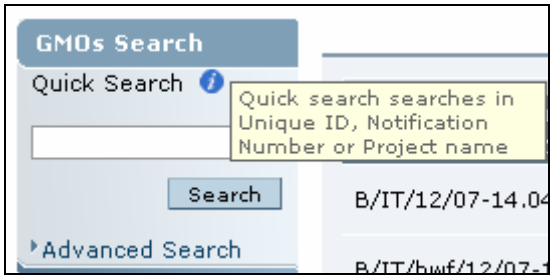


Figure 5: GMOs Search

When the user clicks on the **Search** button the system executes the query and forwards the user to the *Search Notification Results* screen. An example is shown in Figure 5.
Please note that the information shown in these snapshot has been inserted in the system for test purposes only and must not be intended as real data in the system.
The results page shows a row for each entry in the system that matches the search criteria. Additional detail on the Notification can be retrieved by clicking on the Notification number link. The page displays a summary only of the available information which includes:

- Unique ID as defined in [REG.65/2004]
- Notifcation Number
- Notification Type[3]

[3] More details about the Notification Types can be found in section 6.2.2.

- Date of creation
- Status of the dossier
- Notifier
- Lead CA

Unique ID	Notification Number	Notification Type	Date Created	Status	Notifier	Lead CA
B/IT/12/07-14.04	B/IT/12/07-14.04	Part B - Other Organisms Simple	12/07/2006 14:05:56	Released	GMO Company SA	Competent Authority 1
B/IT/bwf/12/07-15.14	B/IT/bwf/12/07-15.14	Part B - Other Organisms	12/07/2006 15:15:05	Released	GMO Company SA	Competent Authority 1
C/IT/OOs/bpf/12/07-15.51	C/IT/OOs/bpf/12/07-15.51	Part C - Other Organisms Simple	12/07/2006 15:53:24	Released	GMO Company SA	Competent Authority 2
C/IT/OOs/12/07-16.09	C/IT/OOs/12/07-16.09	Part C - Other Organisms Simple	12/07/2006 16:10:13	Released	GMO Company SA	Competent Authority 2
UI 130706/WF B1	NN 130706/WF B1	Part B - Other Organisms	13/07/2006 11:07:57	Released	ED Notifier	ED CA
UI 130706/WF C1	NN 130706/WF C1	Part C - Higher Plants Simple	13/07/2006 11:58:25	Running	ED Notifier	ED CA
C/IT/OPs/13/07-15.52-IUT	C/IT/OPs/13/07-15.52-IUT	Part C - Higher Plants Simple	13/07/2006 15:54:15	Running	GMO Company SA	Competent Authority 1
C/IT/bwp/13/07-17.40-UNECBCHtest	C/IT/bwp/13/07-17.40-UNECBCHtest	Part C - Other Organisms Simple	13/07/2006 17:41:16	Released	GMO Company SA	Competent Authority 1

Page 1 of 1 First Previous Next Last

Figure 6: Notification Search Results

4.1.3. Advanced Search Notifications/GMOs

Users may perform an **advanced search** for Notifications/GMOs by clicking on the *Advanced Search* link in the *GMOs Search* menu item.

Figure 7: GMOs Search

In this case a form is displayed to allow users to search for Notifications/GMOs by specifying a value for each of the following fields:

- Date Created
- Status
- Company Name (Notifier)
- Lead CA Name

Users have the option to select additional search fields by clicking the button marked by the plus sign: + , and/or remove search fields by clicking on the button marked by the minus sign: -

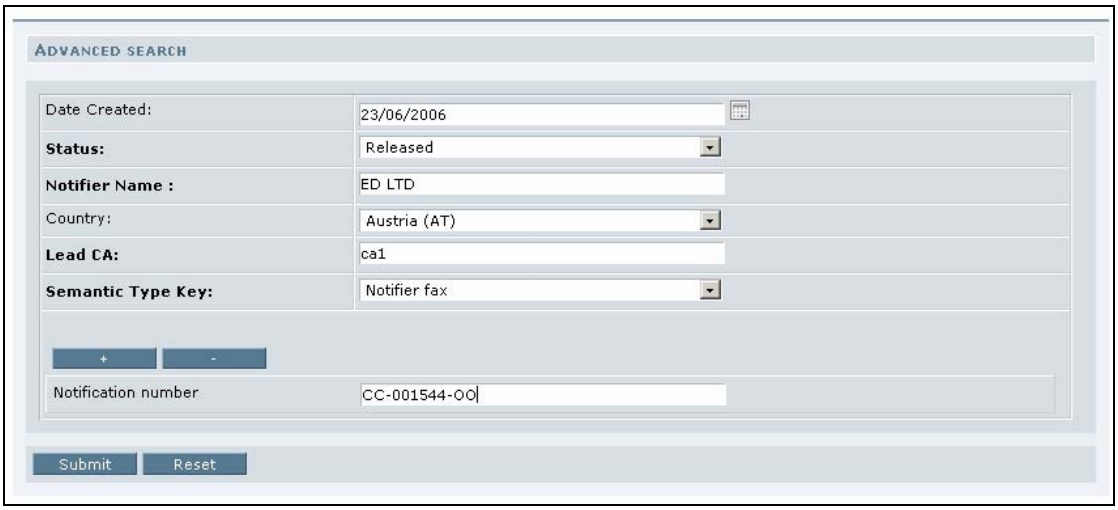


Figure 8: Advanced Notification Data to Search form

The system executes a database query, based on the search criteria introduced by the user, and displays the results in the ***Search Notifications Results*** screen. All criteria must match in a notification for that to be displayed. Security and confidentiality are also taken into account when executing a search in the database (e.g. if a user does not have access to the SNIF of a notification because it is not yet circulated, or if the value of one of the selected fields is confidential in a particular notification, then that notification will not be included in the search results). Criteria set are case insensitive.

Figure 8 shows the search results for the criteria specified in figure 7.

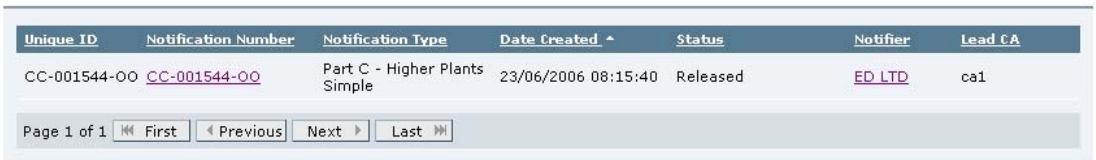


Figure 9: Notification Search Results

4.1.4. Export Document in PDF

A user may export information associated to a notification to Portable Document Format (PDF) when viewing a Notification/GMOs details, by clicking on the on **Generate PDF** button: Generate PDF

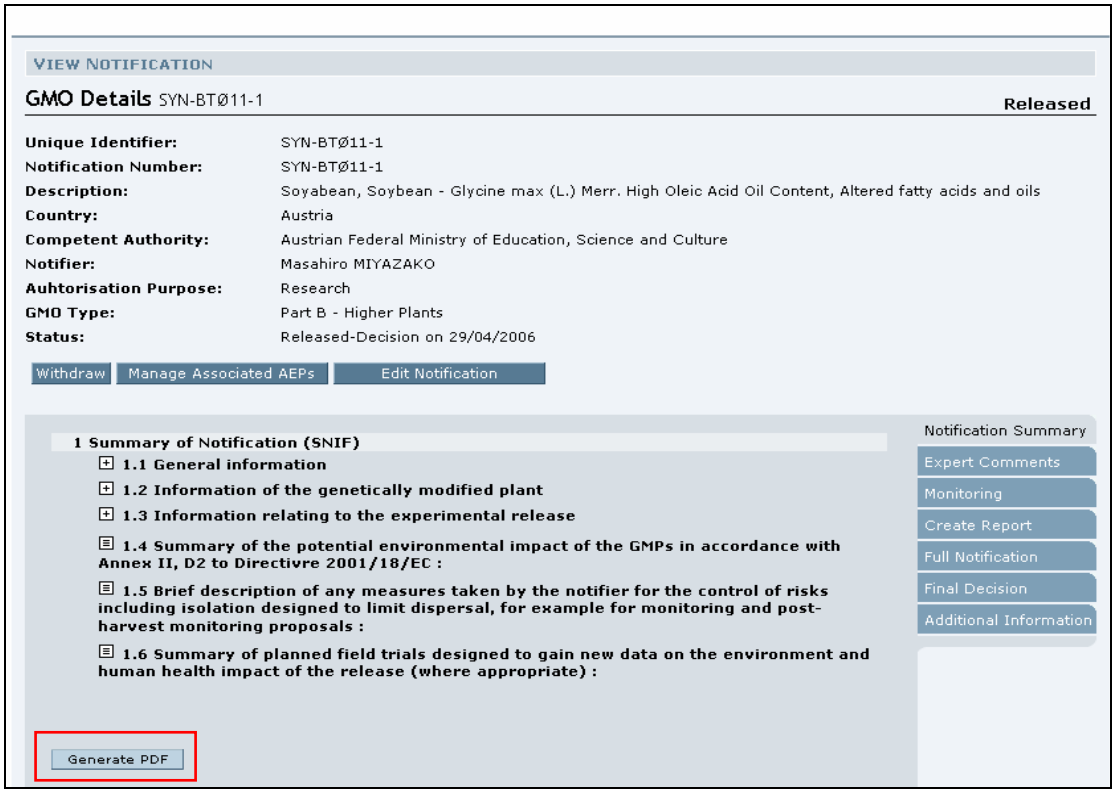
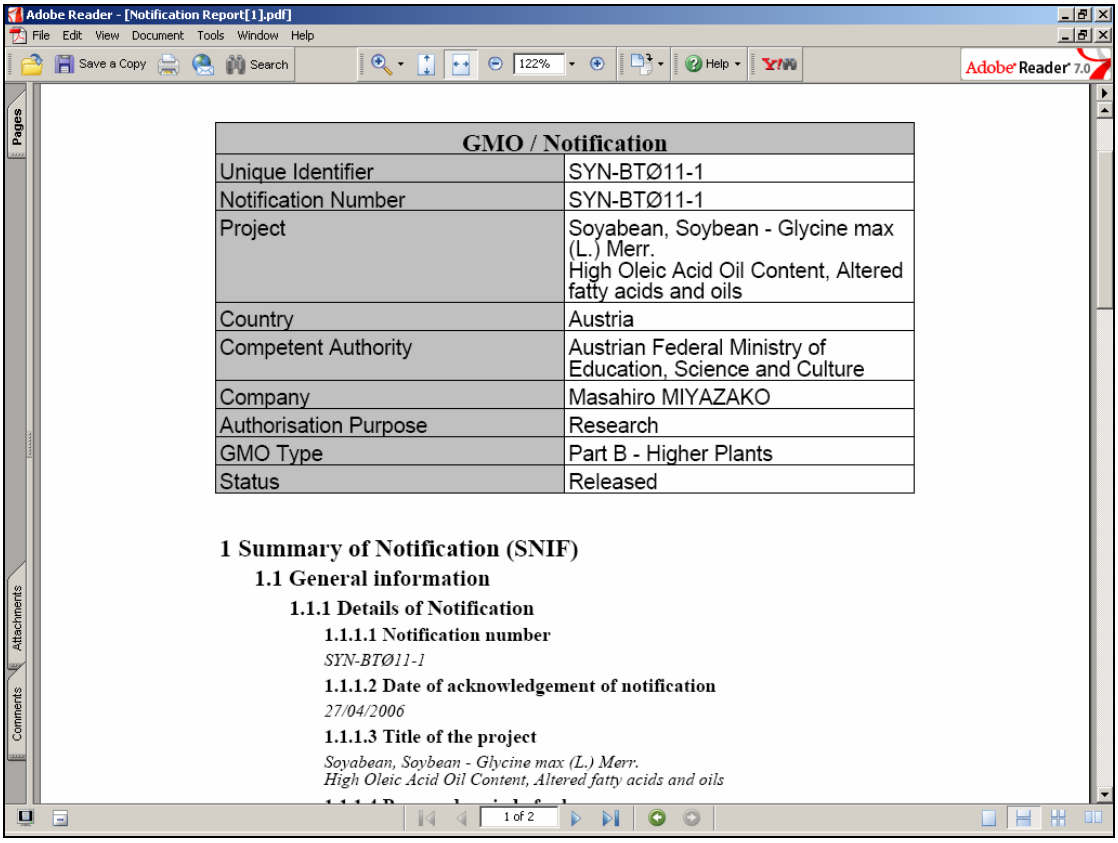


Figure 10: View Notification/GMO details

The system will create the document in PDF format containing the information available for each section of the notification indicating where fields or components are confidential.
The user can select whether to save the document and view it in an appropriate reader application (e.g. Acrobat Reader), or display it in a new browser window (if the appropriate plug-in to the browser is available):



GMO / Notification	
Unique Identifier	SYN-BTØ11-1
Notification Number	SYN-BTØ11-1
Project	Soyabean, Soybean - Glycine max (L.) Merr. High Oleic Acid Oil Content, Altered fatty acids and oils
Country	Austria
Competent Authority	Austrian Federal Ministry of Education, Science and Culture
Company	Masahiro MIYAZAKO
Authorisation Purpose	Research
GMO Type	Part B - Higher Plants
Status	Released

1 Summary of Notification (SNIF)

1.1 General information

1.1.1 Details of Notification

1.1.1.1 Notification number

SYN-BTØ11-1

1.1.1.2 Date of acknowledgement of notification

27/04/2006

1.1.1.3 Title of the project

Soyabean, Soybean - Glycine max (L.) Merr.
High Oleic Acid Oil Content, Altered fatty acids and oils

Figure 11: Export Notification/GMO in PDF

4.1.5. View CAs and related notifications

A user may visualise a list of all registered Competent Authorities (CAs) in the system by clicking on the appropriate link shown in the figure below:

Figure 12: View Competent Authorities

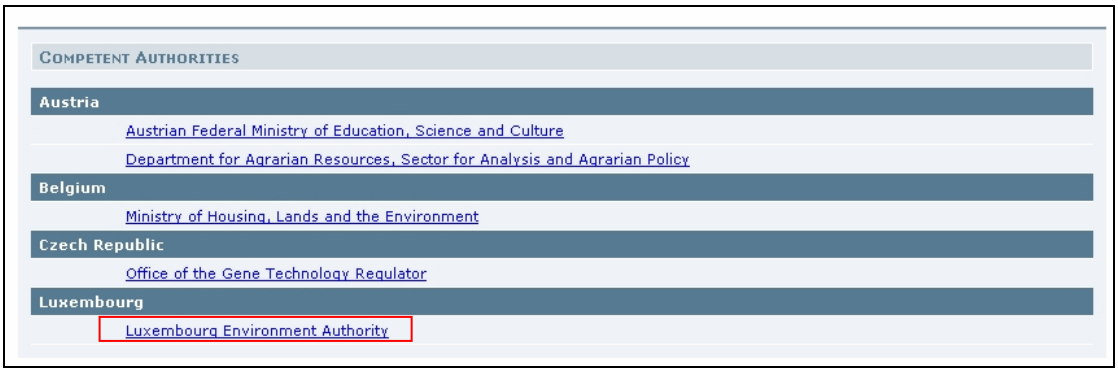
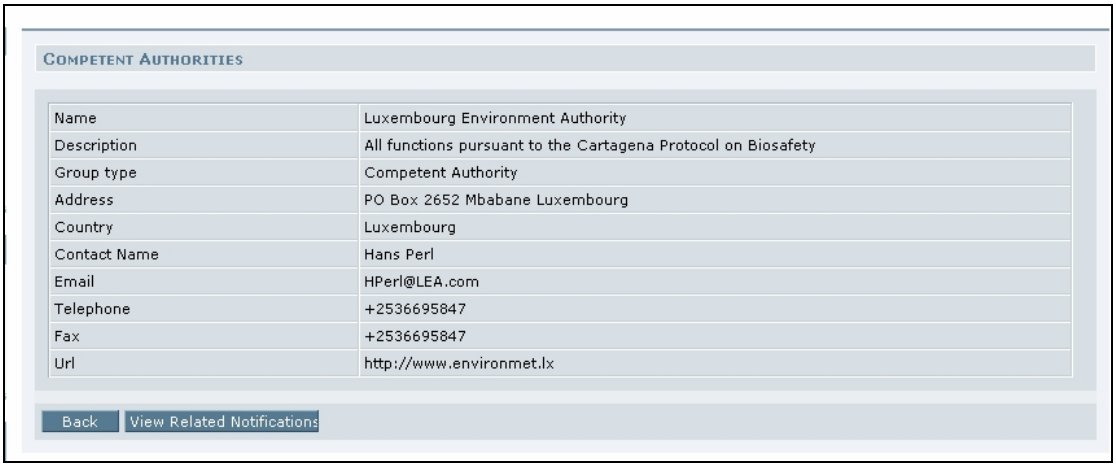


Figure 13: List of Competent Authorities

Additionally, a user may click on CA name and the system will display details for the selected competent authority.



COMPETENT AUTHORITIES

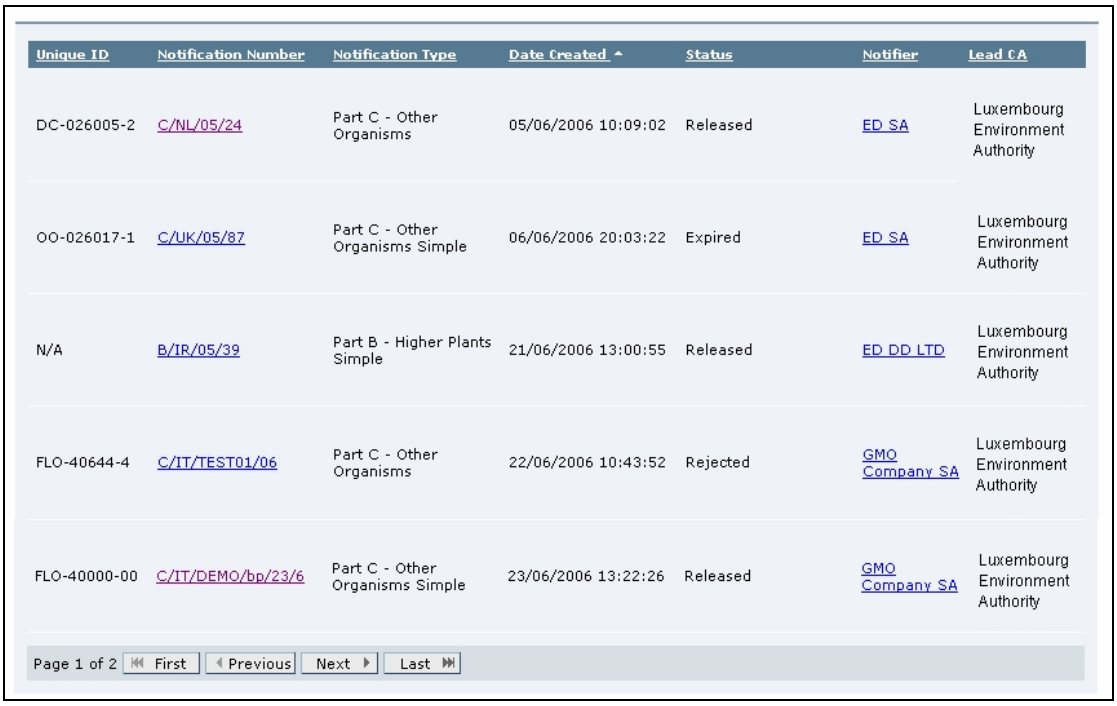
Name	Luxembourg Environment Authority
Description	All functions pursuant to the Cartagena Protocol on Biosafety
Group type	Competent Authority
Address	PO Box 2652 Mbabane Luxembourg
Country	Luxembourg
Contact Name	Hans Perl
Email	HPerl@LEA.com
Telephone	+2536695847
Fax	+2536695847
Url	http://www.environmet.lx

Back | View Related Notifications

Figure 14: Competent Authority details

By clicking on View Related Notifications button 

, the user may view all notification for which that particular competent authority is Lead CA.



Unique ID	Notification Number	Notification Type	Date Created	Status	Notifier	Lead CA
DC-026005-2	C/NL/05/24	Part C - Other Organisms	05/06/2006 10:09:02	Released	ED SA	Luxembourg Environment Authority
OO-026017-1	C/UK/05/87	Part C - Other Organisms Simple	06/06/2006 20:03:22	Expired	ED SA	Luxembourg Environment Authority
N/A	B/IR/05/39	Part B - Higher Plants Simple	21/06/2006 13:00:55	Released	ED DD LTD	Luxembourg Environment Authority
FLO-40644-4	C/IT/TEST01/06	Part C - Other Organisms	22/06/2006 10:43:52	Rejected	GMO Company SA	Luxembourg Environment Authority
FLO-40000-00	C/IT/DEMO/bp/23/6	Part C - Other Organisms Simple	23/06/2006 13:22:26	Released	GMO Company SA	Luxembourg Environment Authority

Page 1 of 2 | First | Previous | Next | Last

Figure 15: View Related Notifications

4.1.6. View Notifiers and related notifications

Users may click on the link displaying Notifier (Figure 15, page 29) to view details about a Notifier.

VIEW NOTIFIER DETAILS

Company Name:	ED DD LTD
Contact Name:	PB BP
Address :	El Venizelou 665
Telephone:	
Fax:	
Email:	
Country:	Austria

View Notifications

Figure 16: View Related Notifier

To view all notification related to a selected Notifier, users can click on View Notifications button View Notifications

Unique ID	Notification Number	Notification Type	Date Created	Status	Notifier	Lead CA
N/A	B/IR/05/39	Part B - Higher Plants Simple	21/06/2006 13:00:55	Released	ED DD LTD	Department for Agrarian Resources, Sector for Analysis and Agrarian Policy

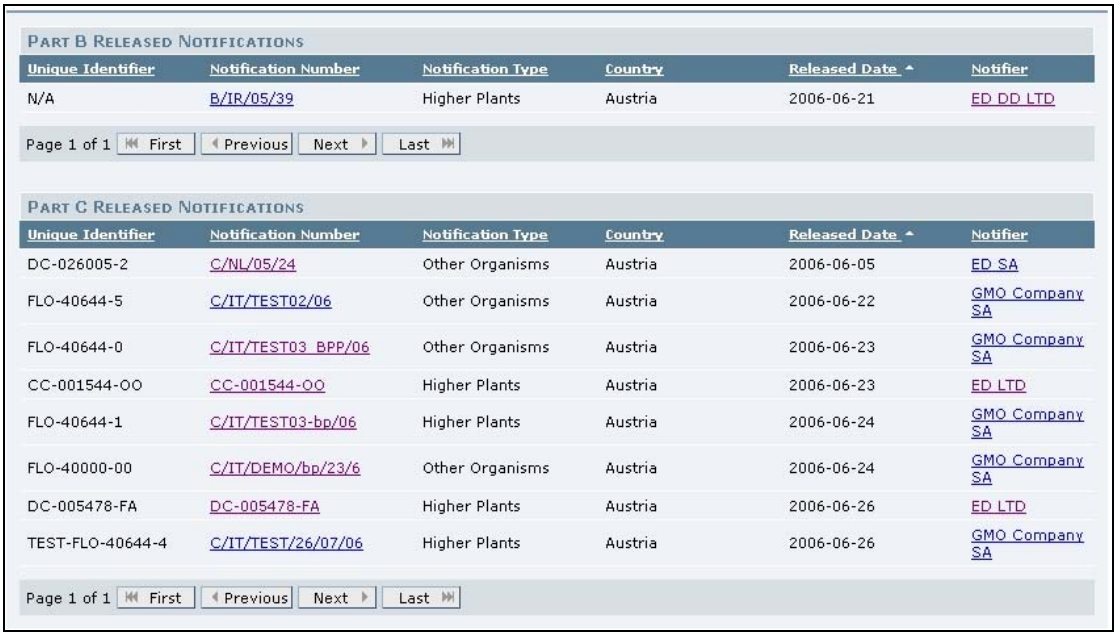
Page 1 of 1 First Previous Next Last

Figure 17: View Related Notifications

4.1.7. View Notifications/GMOs Details

The details of a specific Notification/GMO for Part B and Part C Released Notifications are displayed in the homepage of the **GMOREGEX** system in tabular format (Figure 18).

The buttons ***First***, ***Previous***, ***Next*** and ***Last*** allow users to navigate in the set of Part B and Part C Released Notifications. ***First*** button displays the first page of the results, ***Previous*** button shows the previous page, ***Next*** button displays next page, while ***Last*** button shows the last page.
In order to view the details of a particular notification (Figure 19), users may click on the *Short Textual Description* of a Notification/GMO (e.g. the link that contains the notification number of the Notification/GMO).



PART B RELEASED NOTIFICATIONS

Unique Identifier	Notification Number	Notification Type	Country	Released Date	Notifier
N/A	B/IR/05/39	Higher Plants	Austria	2006-06-21	ED DD LTD

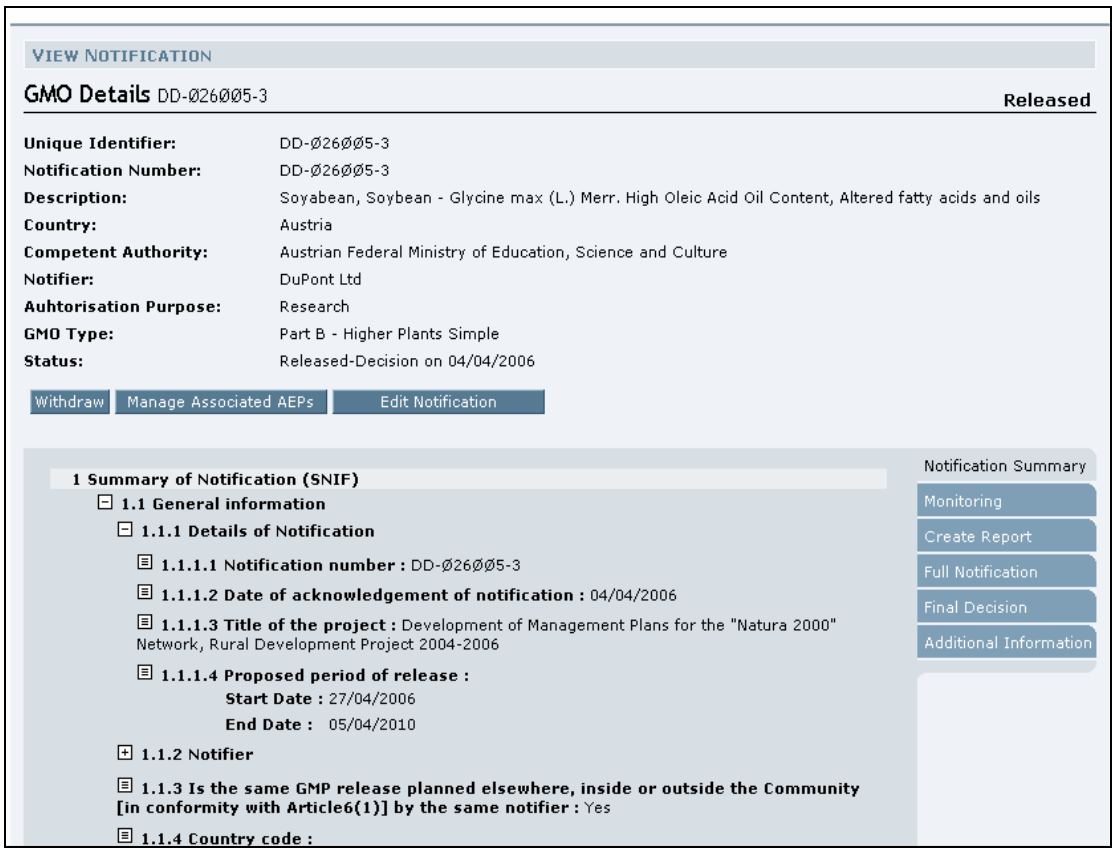
Page 1 of 1 First Previous Next Last

PART C RELEASED NOTIFICATIONS

Unique Identifier	Notification Number	Notification Type	Country	Released Date	Notifier
DC-026005-2	C/NL/05/24	Other Organisms	Austria	2006-06-05	ED SA
FLO-40644-5	C/IT/TEST02/06	Other Organisms	Austria	2006-06-22	GMO Company SA
FLO-40644-0	C/IT/TEST03_BPP/06	Other Organisms	Austria	2006-06-23	GMO Company SA
CC-001544-OO	CC-001544-OO	Higher Plants	Austria	2006-06-23	ED LTD
FLO-40644-1	C/IT/TEST03-bp/06	Higher Plants	Austria	2006-06-24	GMO Company SA
FLO-40000-00	C/IT/DEMO/bp/23/6	Other Organisms	Austria	2006-06-24	GMO Company SA
DC-005478-FA	DC-005478-FA	Higher Plants	Austria	2006-06-26	ED LTD
TEST-FLO-40644-4	C/IT/TEST/26/07/06	Higher Plants	Austria	2006-06-26	GMO Company SA

Page 1 of 1 First Previous Next Last

Figure 18: Part B and Part C Notifications – synoptic information



VIEW NOTIFICATION

GMO Details DD-Ø26ØØ5-3 **Released**

Unique Identifier: DD-Ø26ØØ5-3
Notification Number: DD-Ø26ØØ5-3
Description: Soyabean, Soybean - Glycine max (L.) Merr. High Oleic Acid Oil Content, Altered fatty acids and oils
Country: Austria
Competent Authority: Austrian Federal Ministry of Education, Science and Culture
Notifier: DuPont Ltd
Auhtorisation Purpose: Research
GMO Type: Part B - Higher Plants Simple
Status: Released-Decision on 04/04/2006

Withdraw | Manage Associated AEPs | Edit Notification

1 Summary of Notification (SNIF)
- **1.1 General information**
  - **1.1.1 Details of Notification**
    - **1.1.1.1 Notification number :** DD-Ø26ØØ5-3
    - **1.1.1.2 Date of acknowledgement of notification :** 04/04/2006
    - **1.1.1.3 Title of the project :** Development of Management Plans for the "Natura 2000" Network, Rural Development Project 2004-2006
    - **1.1.1.4 Proposed period of release :**
      Start Date : 27/04/2006
      End Date : 05/04/2010
  - **1.1.2 Notifier**
  - **1.1.3 Is the same GMP release planned elsewhere, inside or outside the Community [in conformity with Article6(1)] by the same notifier :** *Yes*
  - **1.1.4 Country code :**

Notification Summary
Monitoring
Create Report
Full Notification
Final Decision
Additional Information

Figure 19: View Notification Details

4.2. Authenticated users

This section describes the functionalities that the GMOREGEX system provides to authenticated users, i.e. to users associated to the roles of "Competent Authorities", "Commission" and "Authorised External Party".
These functionalities are related to creation and management of notifications and circulation/publication of associated documents and comments.

4.2.1. Login-Logout

Registered users of the **GMOREGEX** system may login in to the system by providing their *Username* and *Password* in the login module of the **GMOREGEX** default homepage.
Once valid user credentials have been entered, the user can proceed by clicking on the **Login** button**.**

Figure 20: Login Credentials

Following a successful login, the system authenticates the user and displays the user's homepage that allows her/him to view information pertaining to his/her user role and to perform activities in the system.

To logout user should click on **Logout** button.

Figure 21: Logout

4.2.2. User Account Activation

When a user logs into the system for the first time, she/he is required by the system to activate her/his user account according to the information contained in the ***User Registration Email*** that is sent automatically by the system to their email address. Users receive a transaction number that they are required to enter the first time they log-in into the system. This is a security measure which is intended to verify that the user accessing the system is indeed the one for whom the account has been created.

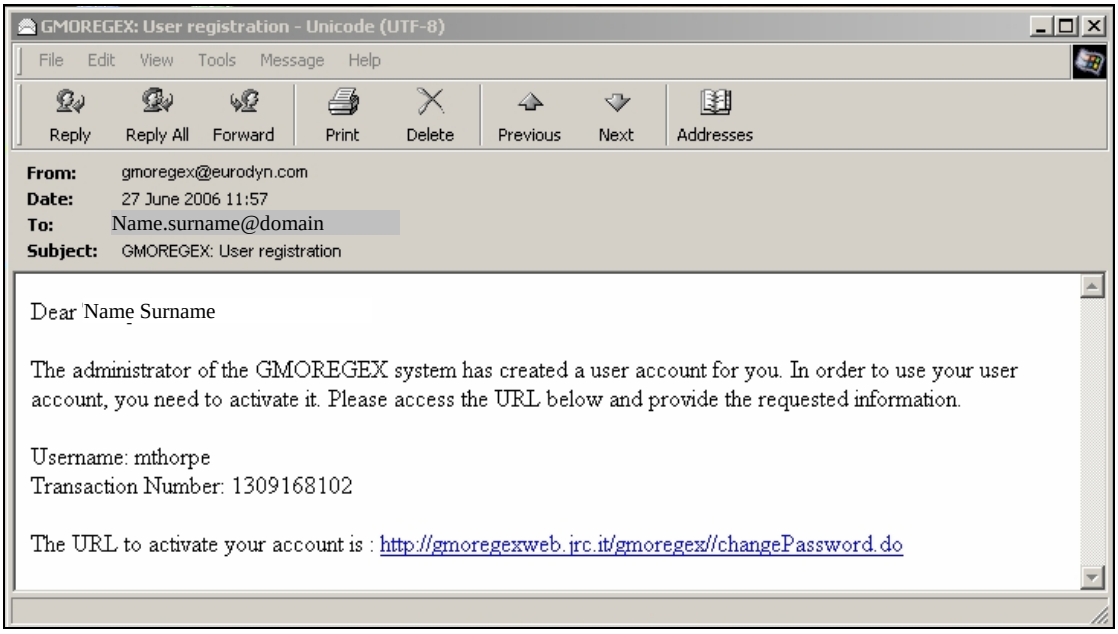


Figure 22: User Registration Email

By accessing the *URL* provided in the body of the email, the user may proceed with login to the system and to initiate his/her account activation process.
The user enters his/her user credentials composed of their username and password.

Figure 23: User Registration Email Login Credentials

The system forwards the user to the *User Account Activation* screen prompting user to enter his/her transaction number in the form below.
The following message is displayed in order to indicate to the user that the account requires activation before the user gains registered access to the **GMOREGEX** system.

Figure 24: User Account Activation Message

The *User Account Activation* screen contains a form comprising the following fields:

- **Password** (for the security reasons, user should contact system administrator to provide her/him with password. The password is case-sensitive.)
- **New Password** (user should change password by his/her will)
- **Re-enter new Password** (confirmation of new password value)
- **Transaction Number** (sent in the email)

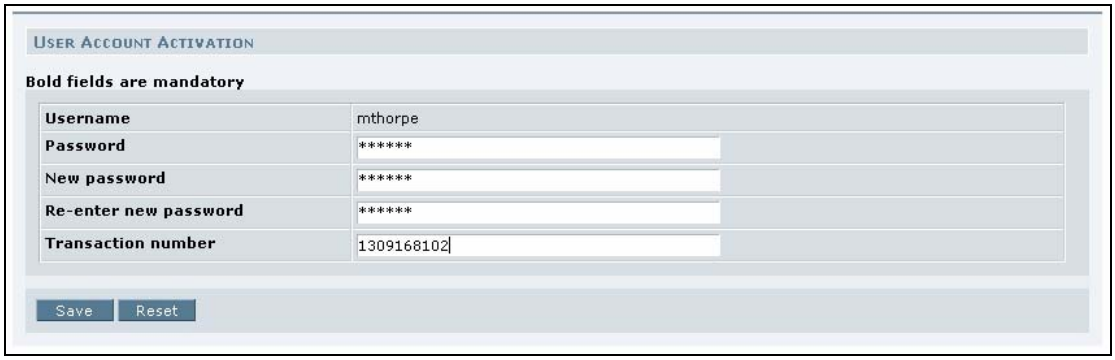


Figure 25: User Account Activation screen

Once a user has filled in the above fields correctly, she/he may click on the **Save** button for the system to activate his/her user account. The system confirms that the account has been successfully activated as indicated by the confirmation screen below:

Figure 26: Successful User Account Activation screen of Confirmation

The user clicks the **OK** button, as indicated above**,** and the system forwards the user to the default homepage corresponding to his/her user role.

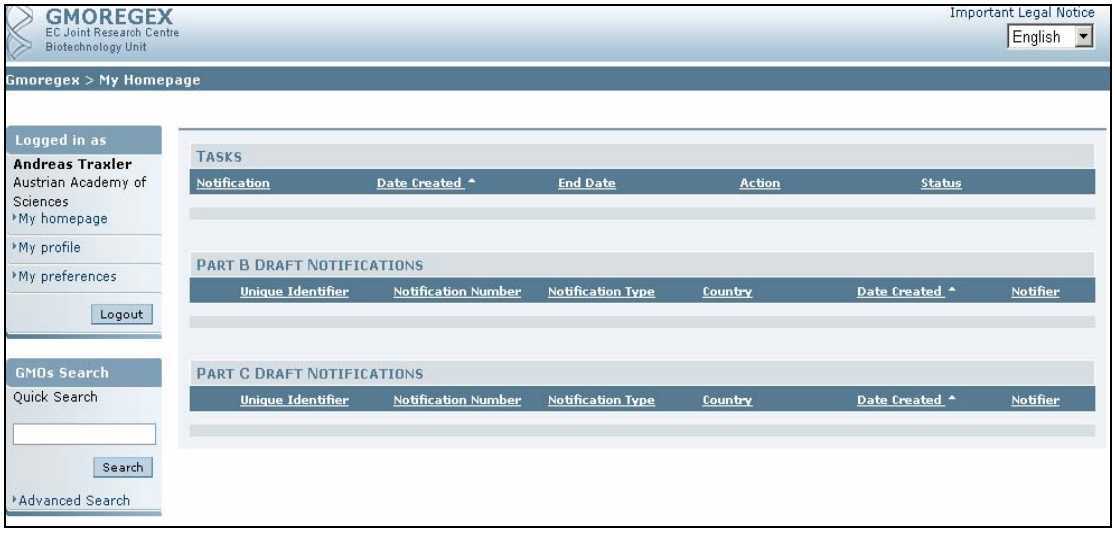


Figure 27: CA User Default Homepage following User Account Activation

4.2.3. Create Summary Reports

The Create Summary Report functionality is available for COM Users, who may create summary reports by clicking on the *Create Summary Reports* link located in the main menu.

Figure 28: Create Summary Reports links for Commission User

When this functionality is activated, the system forwards the user to the *Notifications Reports Criteria* screen.

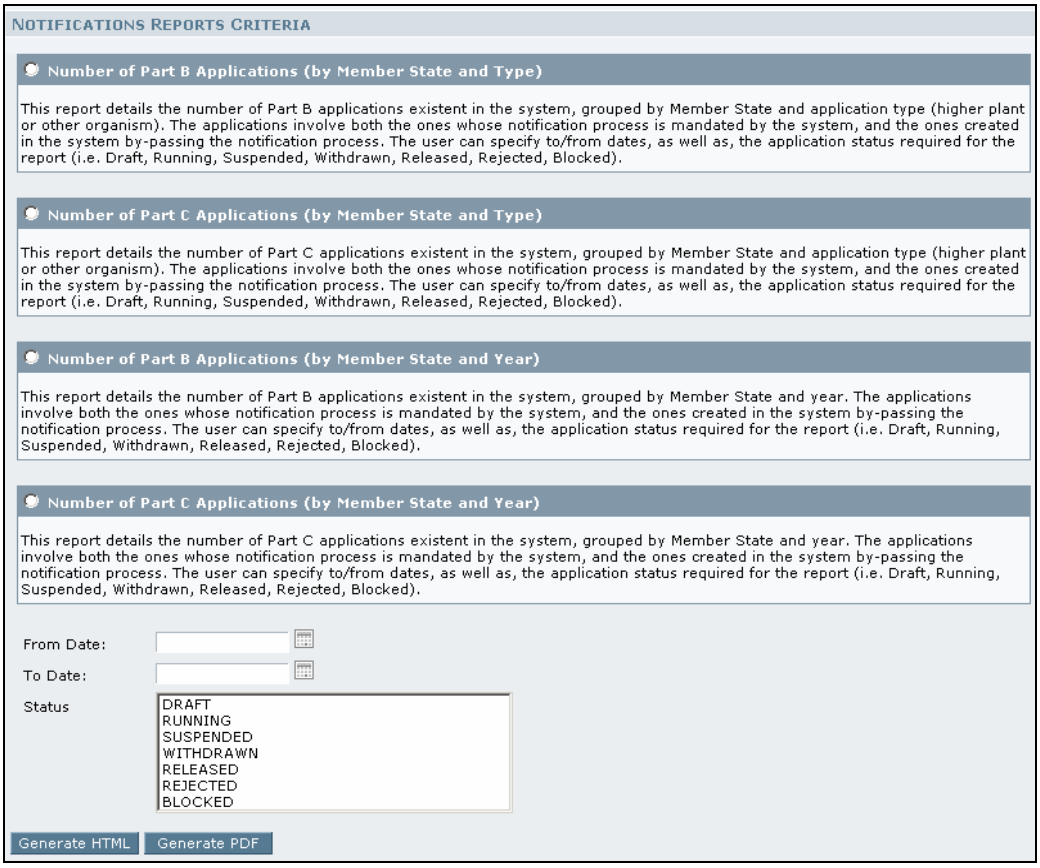


Figure 29: Notifications Reports Criteria screen

The user can select the type of report she/he wishes to generate, the status criterion, and date-range for the report and in which format to generate the report in. If the user does not set status and date-range criteria, the system will consider all available statuses and will set no date-range criteria in the query.

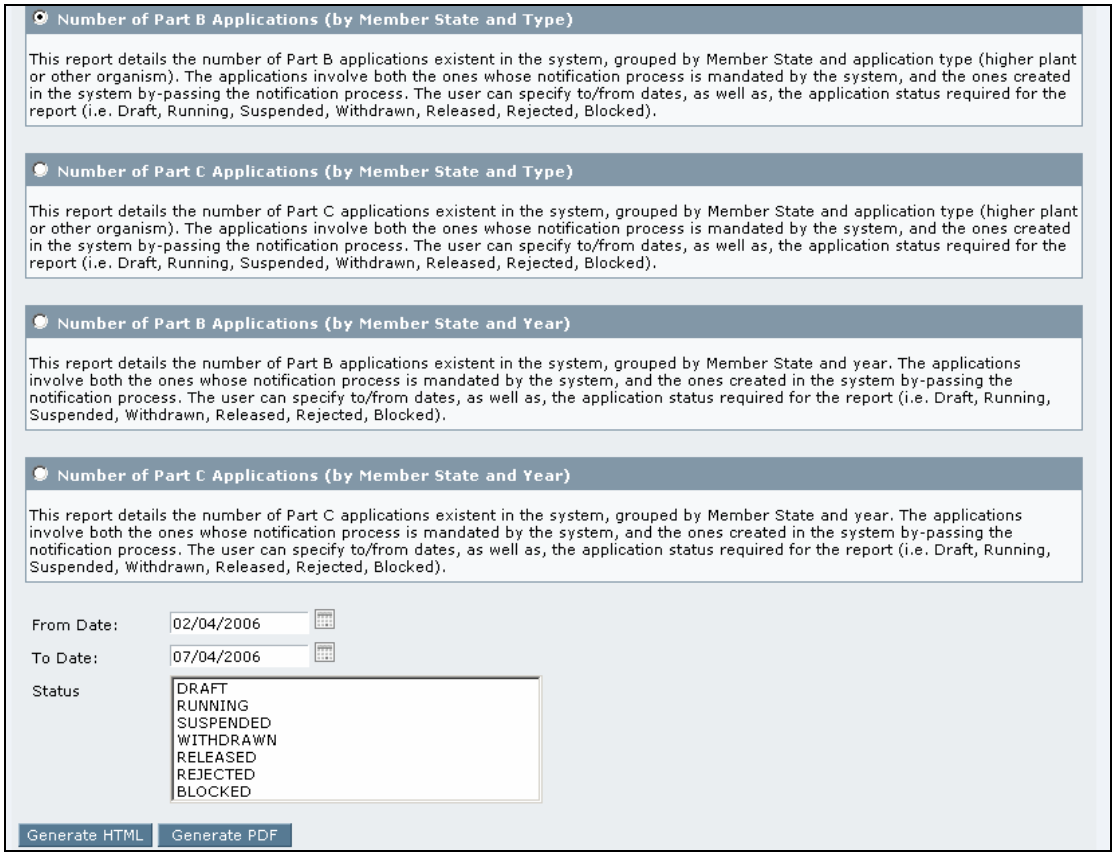


Figure 30: Completed Notifications Reports Criteria screen

The user may select to *Create a Summary Report in HTML* and click on the **Generate HTML** button: Generate HTML.
The system generates the report according to the user defined criteria and forwards the user to the following page:

NUMBER OF PART B APPLICATIONS (BY MEMBER STATE AND YEAR)

From Date: 02/04/2006 To Date: 07/04/2006
Status DRAFT, RUNNING, SUSPENDED, WITHDRAWN, RELEASED, REJECTED, BLOCKED

Year	Member State	
	AT	EU
2006	12	12
Total	12	12

Back

Figure 31: Notifications Report in HTML

The user may select to *Create a Summary Report in PDF* and click on the **Generate PDF** button: Generate PDF.
The system will prompt the user with the following pop-up window for selecting to open, save, or cancel the export of the file.

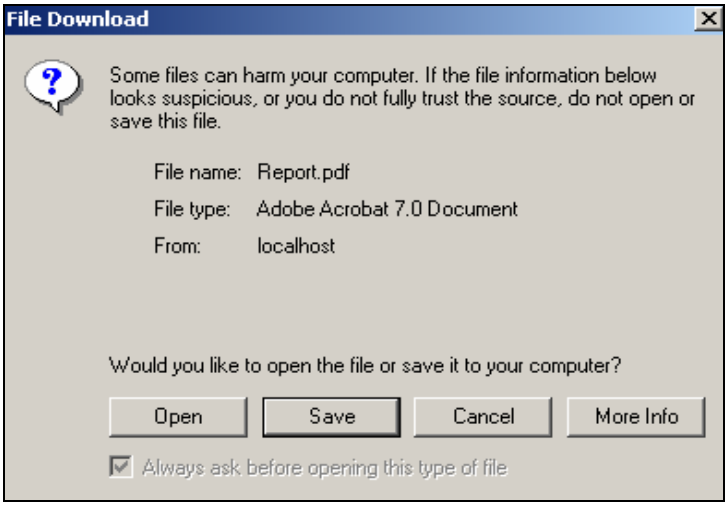
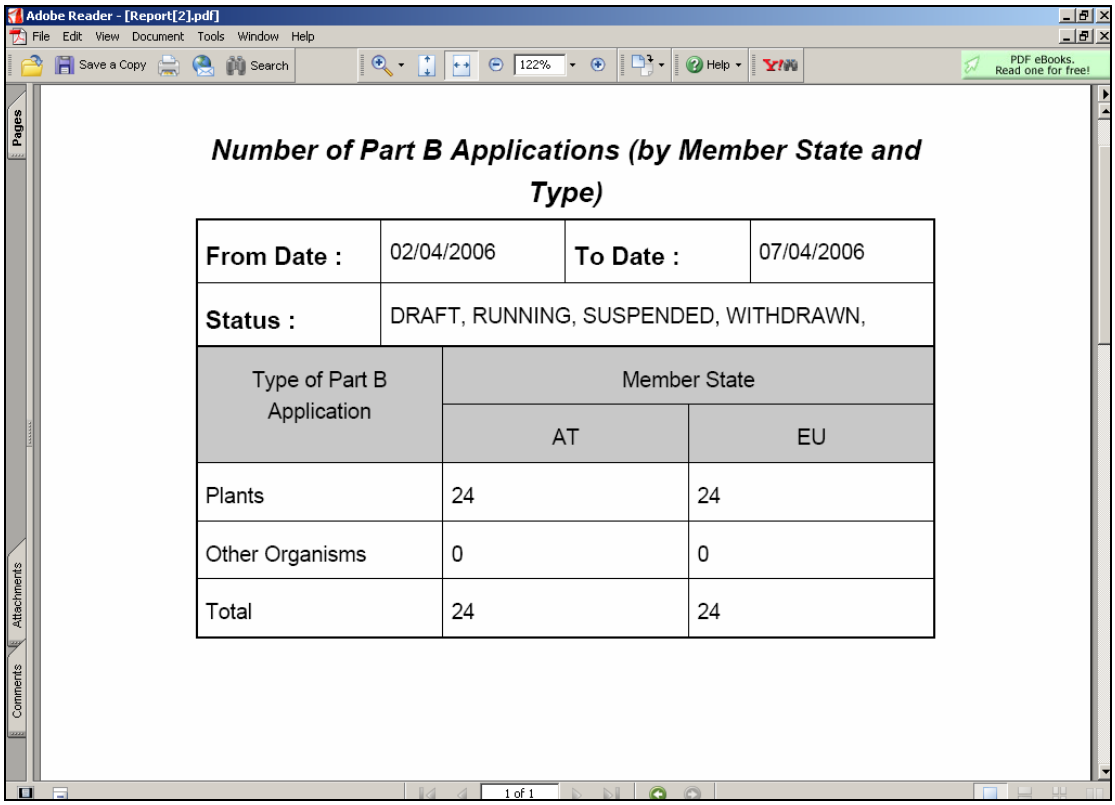


Figure 32: Pop-up window for Create Summary Reports in PDF format

The user may click on either the **Open** button or the **Save** button and the system will generate the report in PDF format as follows:



Number of Part B Applications (by Member State and Type)

From Date :	02/04/2006	**To Date :**	07/04/2006
Status :	DRAFT, RUNNING, SUSPENDED, WITHDRAWN,		

Type of Part B Application	Member State	
	AT	EU
Plants	24	24
Other Organisms	0	0
Total	24	24

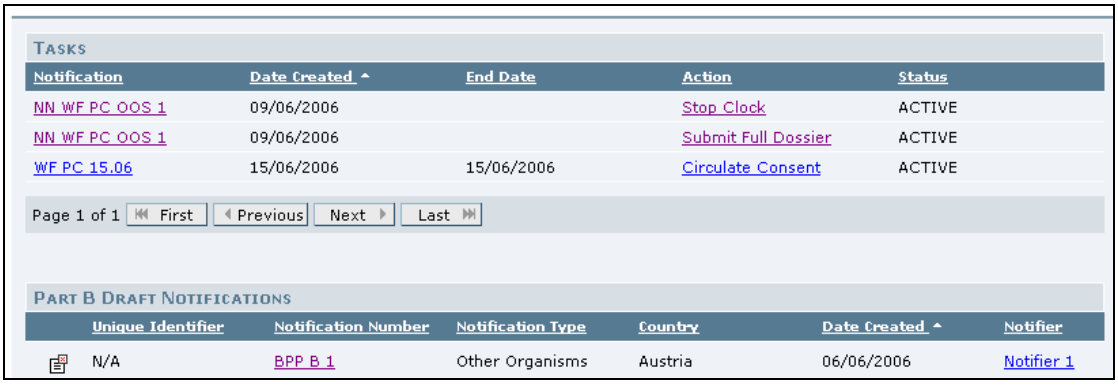
Figure 33: Notifications Report in PDF

4.2.4. View My Tasks

COM and CA users may view the tasks associated to their role and to all pending Notifications in their homepage which is either displayed when they log in or accessible by clicking on the *My Homepage* link on the left menu.

Figure 34: *My Homepage* link

Figure 35 shows an example of a list of active tasks for a user as it is displayed in her/his homepage or after clicking on the My Homepage link.



TASKS

Notification	Date Created	End Date	Action	Status
NN WF PC OOS 1	09/06/2006		Stop Clock	ACTIVE
NN WF PC OOS 1	09/06/2006		Submit Full Dossier	ACTIVE
WF PC 15.06	15/06/2006	15/06/2006	Circulate Consent	ACTIVE

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PART B DRAFT NOTIFICATIONS

Unique Identifier	Notification Number	Notification Type	Country	Date Created	Notifier
N/A	BPP B 1	Other Organisms	Austria	06/06/2006	Notifier 1

Figure 35: Active Tasks

4.2.5. Advanced Notifier Search

This functionality allows authenticated users to find detailed and historical information about notifiers. In fact, in order to be able to associate a notification to a company even in cases where companies change names or merge, the system supports the creation of multiple versions of a notifier and links all these versions together “knowing” that they are all related. Thus, although the application allows CAs to create notifications based on the new details of a notifier (as received in the paper-based notification received outside the context of this system), previous notifications created by the same notifier with out of date information are not modified but still associated to the same entity. Therefore, when a new notifier is created for a new notification, the application automatically locates notifiers with similar information stored in the system and prompts users to propose association. In this manner it is possible to search for notifiers and locate submitted notifications using both the old and current information.

In order to access this functionality, the user must click on the *Advanced Notifier Search* link from the menu to access the search page of the application.

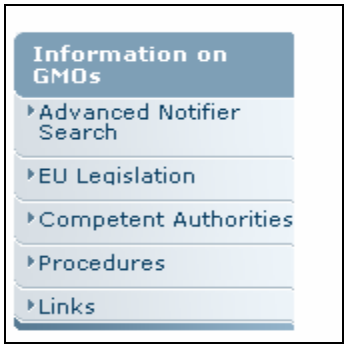


Figure 36: Advanced Notifier Search link

The user enters a company name as a search terms and clicks on the **Submit** button.

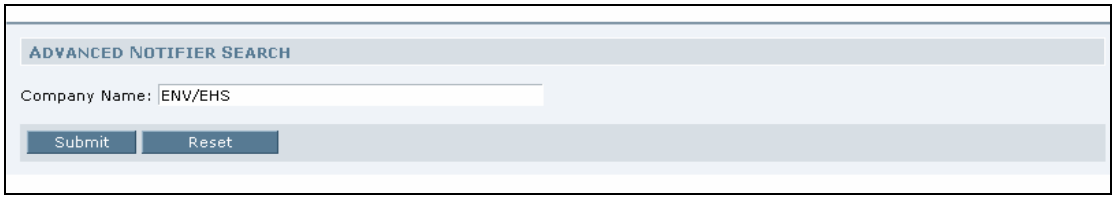
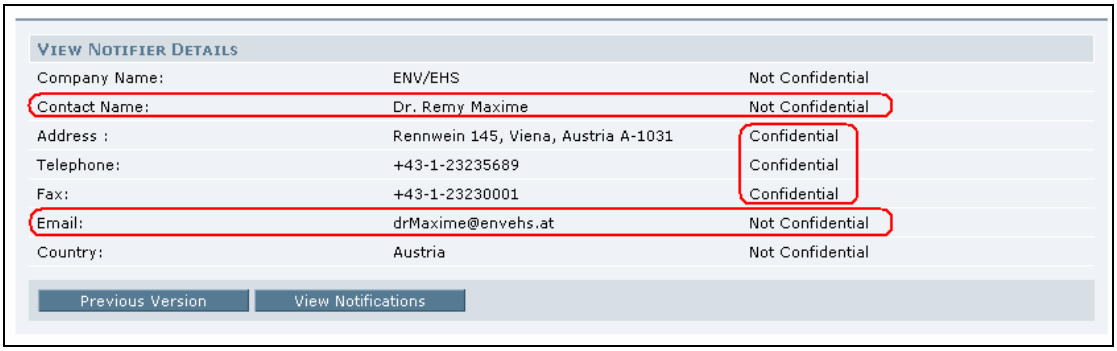


Figure 37: Advanced Notifier Search

The system returns Notifiers matching the search term entered previously. The user may click on the link of a notifier version from the list returned by the search. Each list consists of two columns each of which may maintains a list of company names that match the initial search term and its' corresponding latest version, if one exists in the system.

Figure 38: Advanced Notifier Search Results

The user may further proceed by clicking on the Notifier name, which will present the user with details pertaining to the Notifier's version and the functionality to navigate to previous and/or latest versions further of the particular notifier, if any, via the **Previous Version** and **Next Version** buttons.

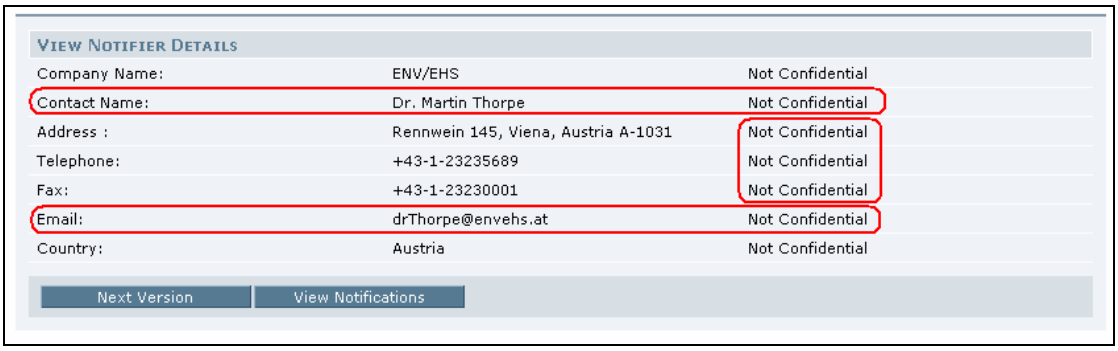


VIEW NOTIFIER DETAILS

Company Name:	ENV/EHS	Not Confidential
Contact Name:	Dr. Remy Maxime	Not Confidential
Address :	Rennwein 145, Viena, Austria A-1031	Confidential
Telephone:	+43-1-23235689	Confidential
Fax:	+43-1-23230001	Confidential
Email:	drMaxime@envehs.at	Not Confidential
Country:	Austria	Not Confidential

Previous Version | View Notifications

Figure 39: View Latest Version of Notifier Details



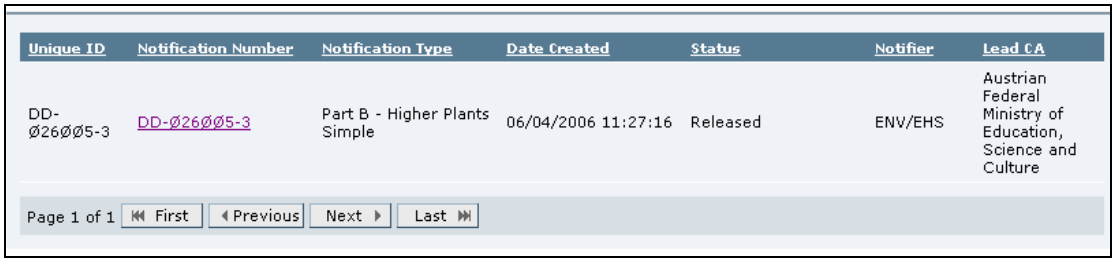
VIEW NOTIFIER DETAILS

Company Name:	ENV/EHS	Not Confidential
Contact Name:	Dr. Martin Thorpe	Not Confidential
Address :	Rennwein 145, Viena, Austria A-1031	Not Confidential
Telephone:	+43-1-23235689	Not Confidential
Fax:	+43-1-23230001	Not Confidential
Email:	drThorpe@envehs.at	Not Confidential
Country:	Austria	Not Confidential

Next Version | View Notifications

Figure 40: View Previous Version of Notifier Details

The user may also click on the **View Notification Details** button in order to view the Notifications corresponding to the particular Notifier version, as displayed in the following screen:



Unique ID	Notification Number	Notification Type	Date Created	Status	Notifier	Lead CA
DD-Ø26ØØ5-3	DD-Ø26ØØ5-3	Part B - Higher Plants Simple	06/04/2006 11:27:16	Released	ENV/EHS	Austrian Federal Ministry of Education, Science and Culture

Page 1 of 1 | First | Previous | Next | Last

Figure 41: View Notifications by Notifier following an Advanced Notifier Search

5. Notifications

This chapter covers the more specific functionalities available to authenticated users during the lifecycle of a notification. It includes description of how to create and work with a notification during the authorisation process.

The structure of the chapter is the following:

- Manage a notification
  - Create Notification
  - Create Notifiers
  - Edit Notification/GMO
  - Withdraw Notification/GMO
  - Create Report on a Notification/GMO
  - Associate AEP with a Notification/GMO
  - Disassociate AEP with a Notification/GMO
  - Additional Information
- Bypass Workflow Procedure
  - By pass process - Part B notification
  - By pass process - Part C notification
- Part B / Part C process notifications
  - Submit Document
  - Circulate Document
  - Publish Document
  - Request Full Dossier of a Notification
  - Stop clock (Request Additional Information)
  - Resume Clock
  - Submit Final Decision on a Notification
  - Deadlines

5.1. Manage a notification

This section describes the functionalities that the GMOREGEX system provides to authenticated users during the whole lifecycle of a notification.
These functionalities are mainly associated with the creation, modification and withdrawal of a notification and the management of notifiers and AEP.

5.1.1. Create Notification

Users in the "CA User" role may create a new Notification by clicking on the *Create Notification* link from the menu. They can select either **GMO Experimental Releases Part B** or **GMO Marketing Authorisations Part C**.
For the newly created notification, the CA associated to this user will assume in the system the role of Lead CA (LCA).

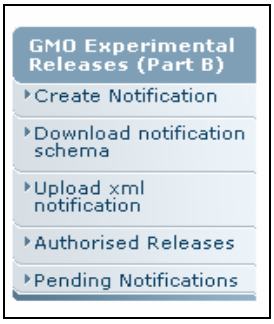


Figure 42: Create Notification Link for GMO Experimental Releases Part B

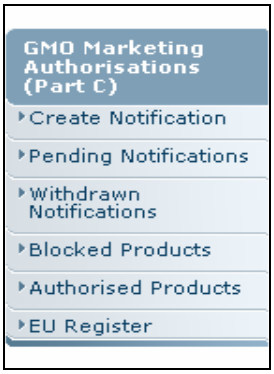


Figure 43: Create Notification Link for GMO Marketing Authorisations Part C

After selecting the type of notification, users are given the possibility to select the type of process that will be activated and the type of notification structure that will be created.

The menu labelled ***"Notification type"*** specifies the types of notification structures that are available, depending on the type of procedure selected (i.e. Experimental Releases-Part B or Marketing Authorisations-Part C).
Available values in the current version[4] of GMOREGEX are:

- Part B – Higher Plants
- Part B – Higher Plants simple
- Part B – Other Organisms
- Part B – Other Organisms simple
- Part C – Higher Plants
- Part C – Higher Plants simple
- Part C – Other Organisms
- Part C – Other Organisms simple

The menu labelled ***"Select Workflow Type"*** allows users to create a new notification in the system and insert the associated information without activating the tracking system that will manage the life cycle of an authorisation. In this way it is possible, for instance, to insert in the system the information associated to notifications for which the authorisation process has already been completed. In this case, the user is lead through a number of steps that lead to the insertion of all the information including the SNIF, the Assessment Report and the final decision in a single session.

[4] This list is configurable by defining and uploading in the system new structures for the notification dossier

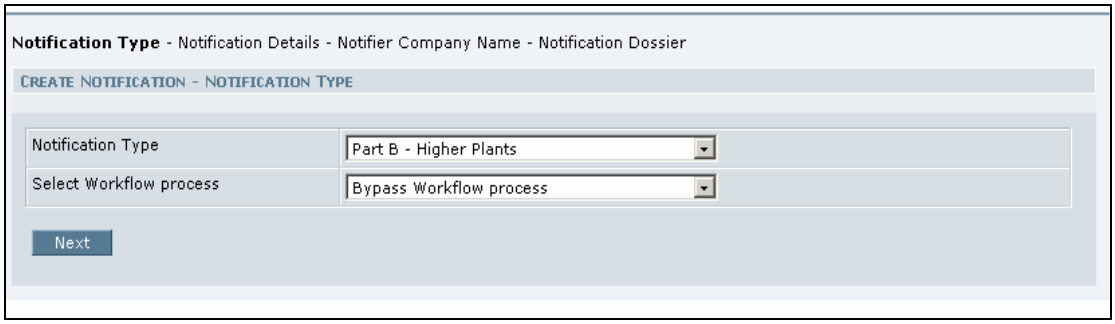


Figure 44: Notification Type and Workflow Process

Mandatory fields for each form are highlighted in bold. In order to proceed, the user must populate all mandatory fields. The user is then required to provide notification details that consist of the following:

- Unique Identifier (Unique ID)
- Notification Number
- Description
- Notification Acknowledgement Date

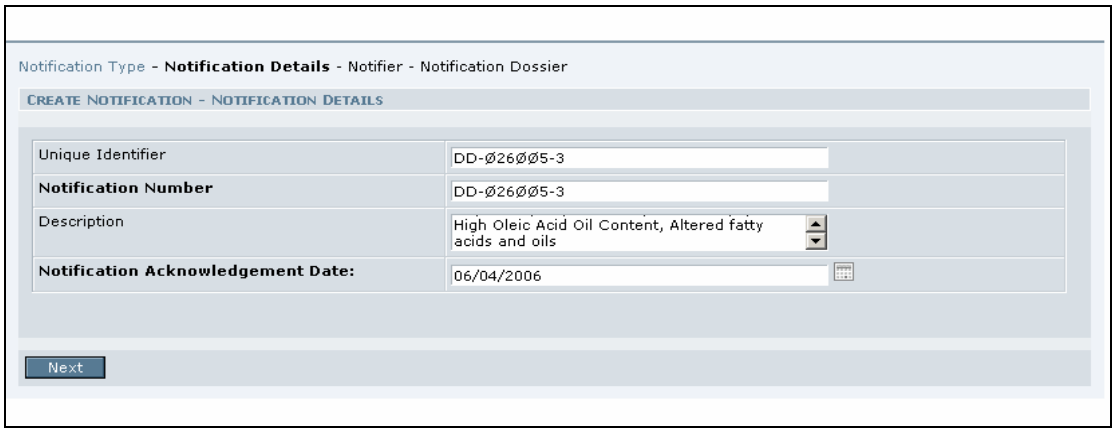


Figure 45: Notification Details

Then, the user is required to complete the Create Notifier form:

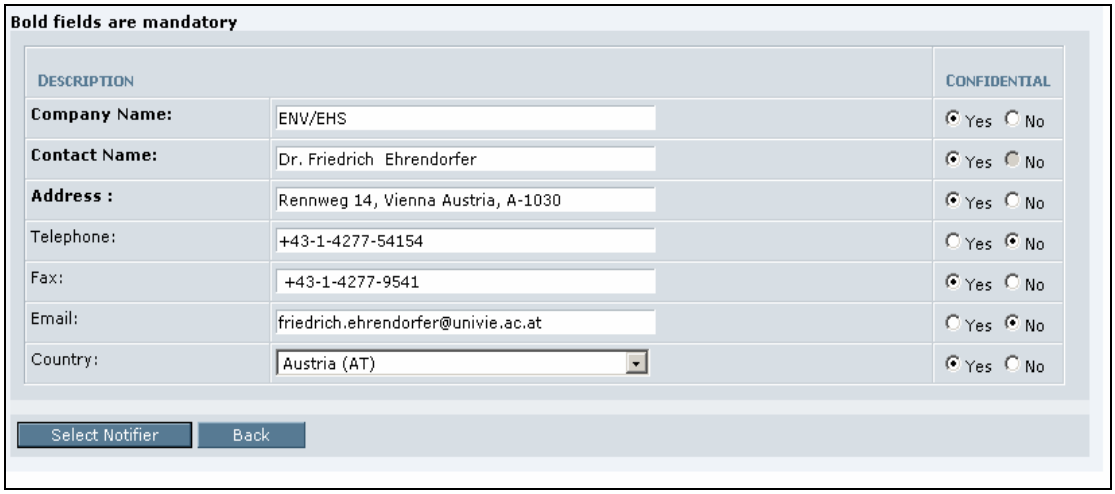


Figure 46: Notifier Details

Following this, the user must provide information for the Notification Dossier, making sure that all mandatory fields are filled in.

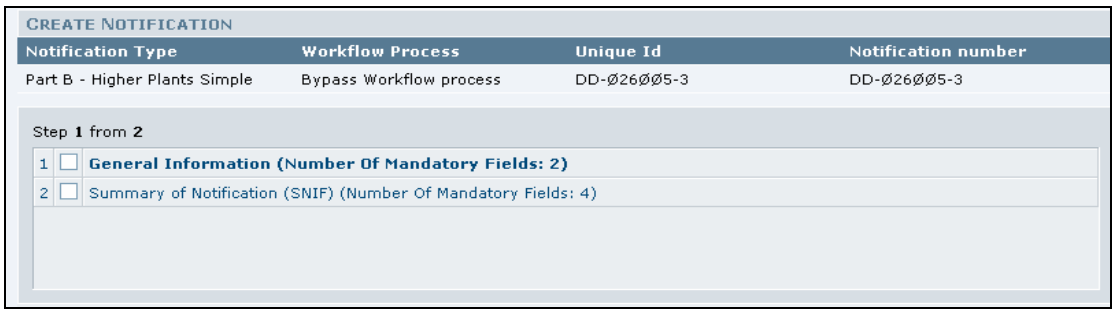


Figure 47: Create Notification Step 1

At each step of the *Create Notification* Process the status of each step is indicated by a black checkbox.
When a step is completed, related checkboxes are marked with an ☒ icon.

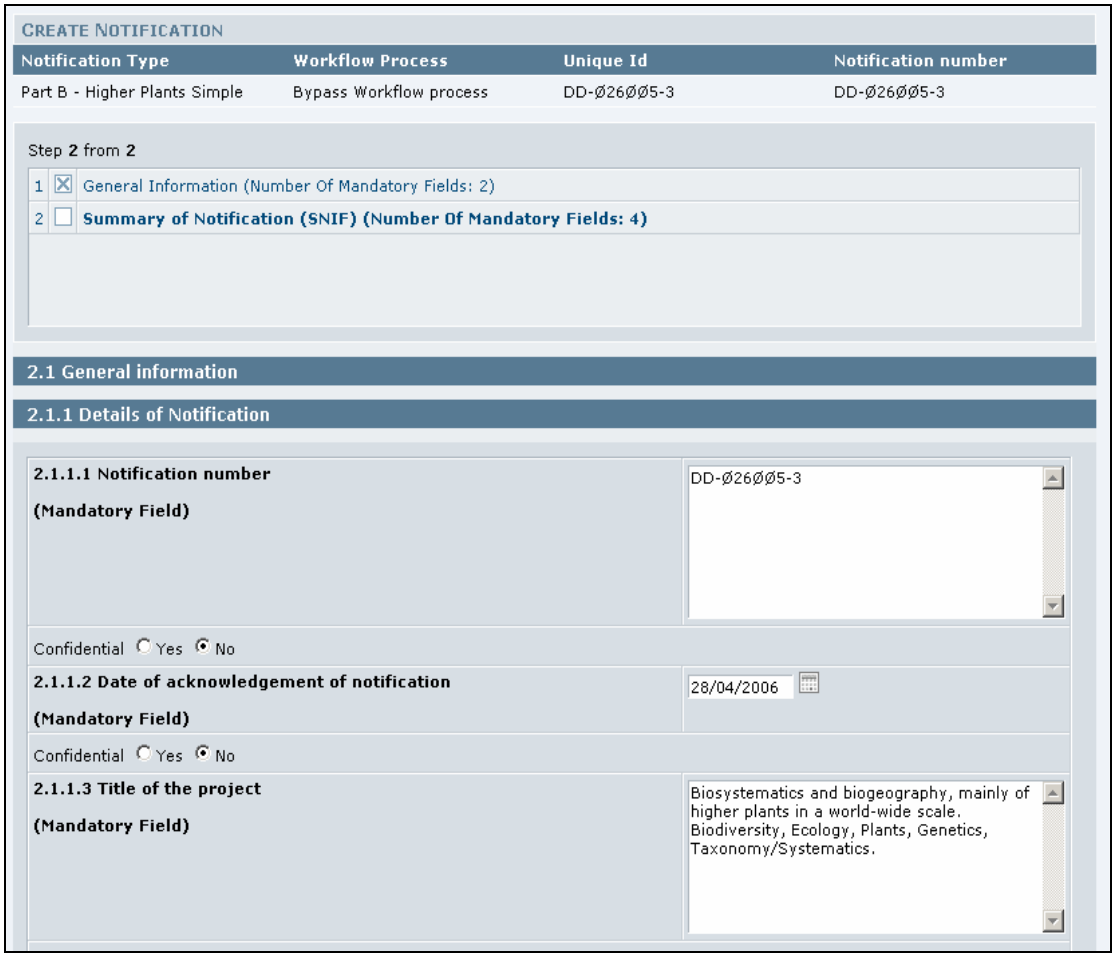


Figure 48: Step 2 in Create Notification form

When all information for the Notification Dossier are provided, the user can click on the **Create Notification** button Create Notification

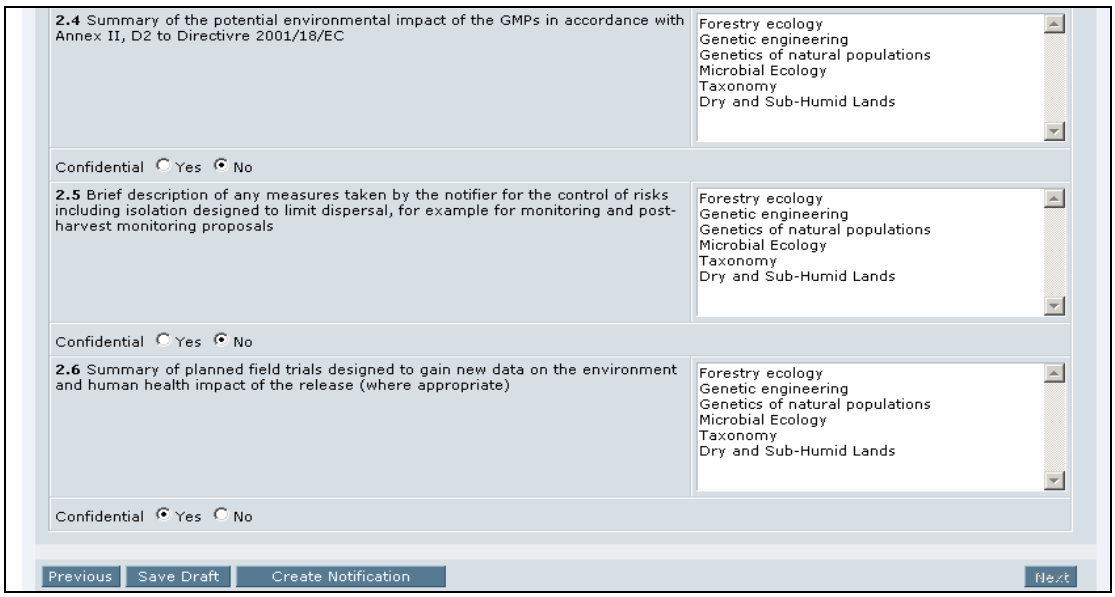


Figure 49: Final Step in Create Notification form

The system performs validation of the form, and prompts the user if some of the mandatory fields are not populated.
Furthermore, if there are sections in the Notification Dossier that are not visited at least once by the user, the system will also not permit the user to create notification (even if that section is not marked as containing mandatory fields).
One of the steps in the population of the notification dossier is the SNIF.
As some fields in the SNIF are also required for the Register, the system pre-populates those fields in Register for which a value has already been provided when completing the SNIF. In this way, the user does not have to fill in all fields of Register, but only those for which a corresponding field in the SNIF does not exist. This is shown in Figure 51.

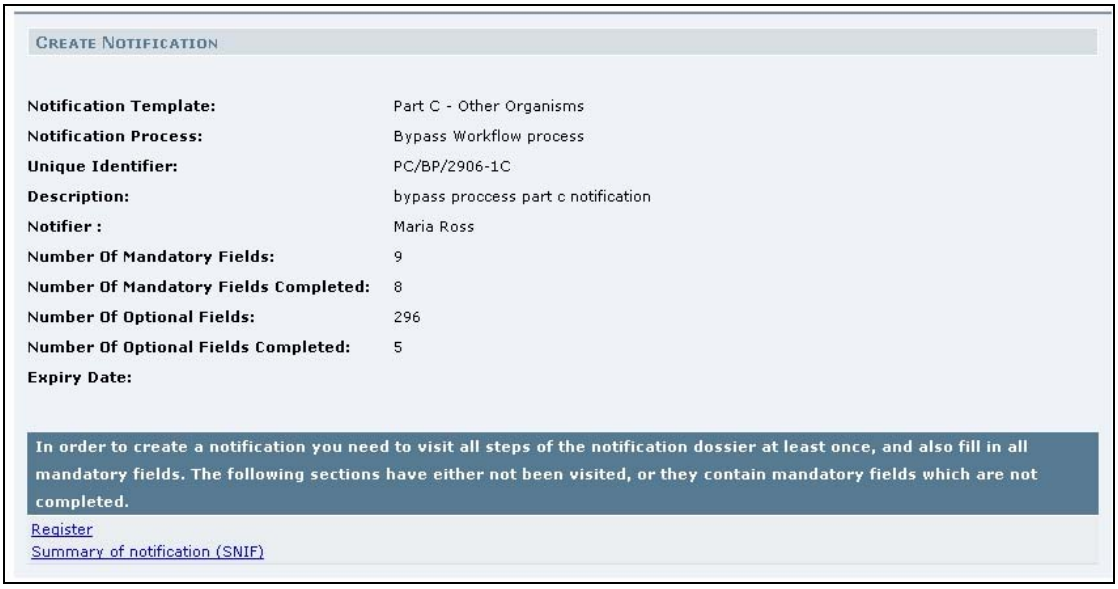


Figure 50: Summary page – user has not completed all mandatory fields

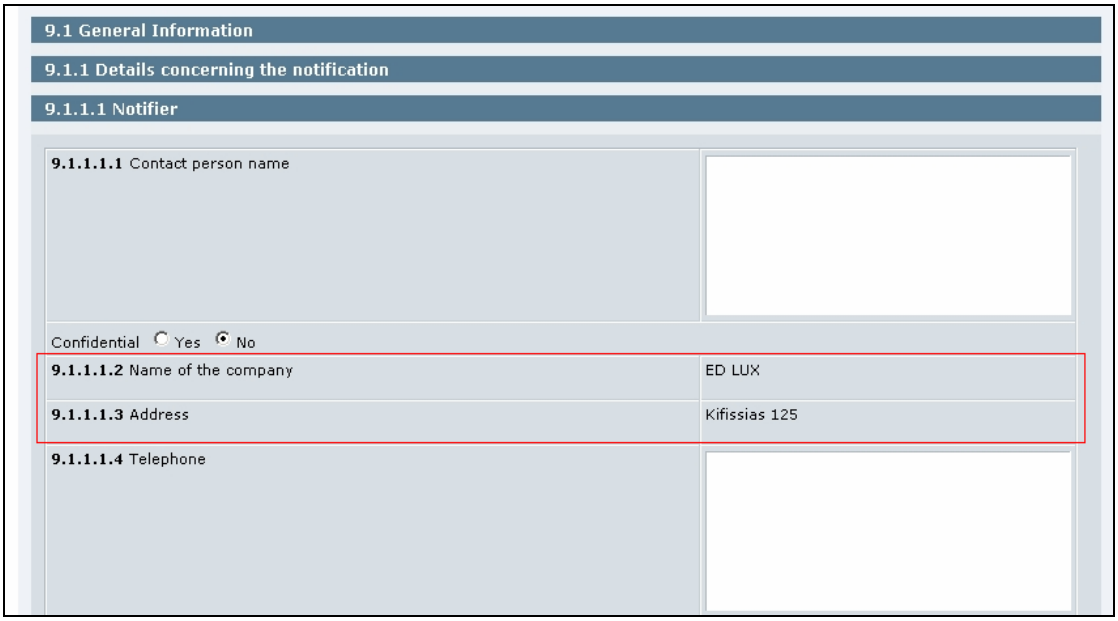


Figure 51: Example of pre-populated fields in the Register of Part C notification

After completing all steps the notification creation process, the user will be presented with the ***Summary Page*** of the Notification and asked to provide confirmation, as shown in figure 52.

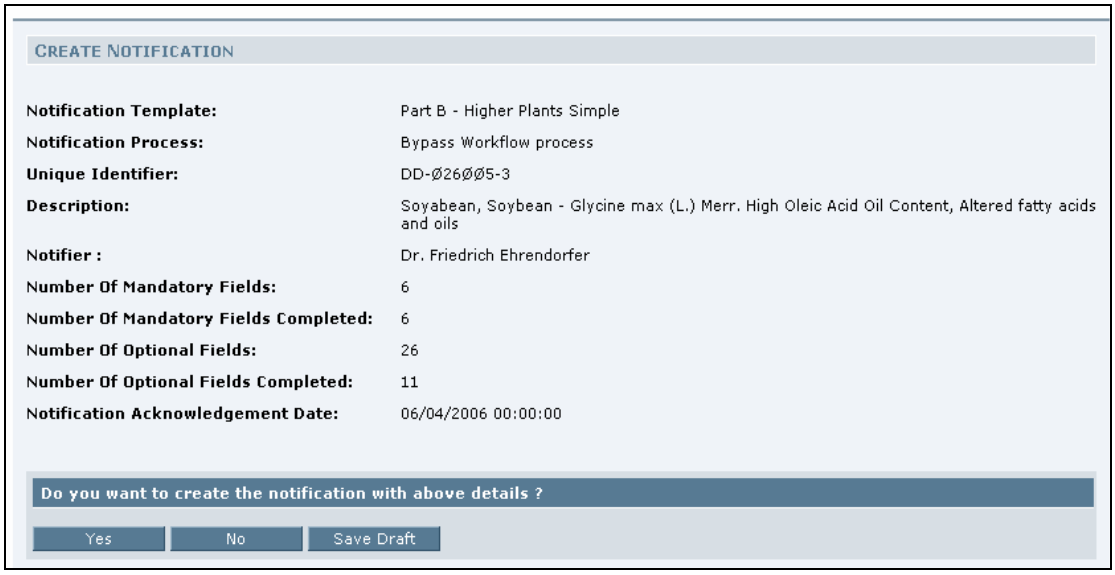


Figure 52: Summary Page

Following an affirmative answer by the user, the system will create the necessary data structures in the database and store the Notification information in the system in the system.

When the option not to activate the workflow is selected (***Bypass Workflow Procedure)***, the system displays the screen shown in figure 53 which provides the possibility to upload the final documentation associated to the notification.

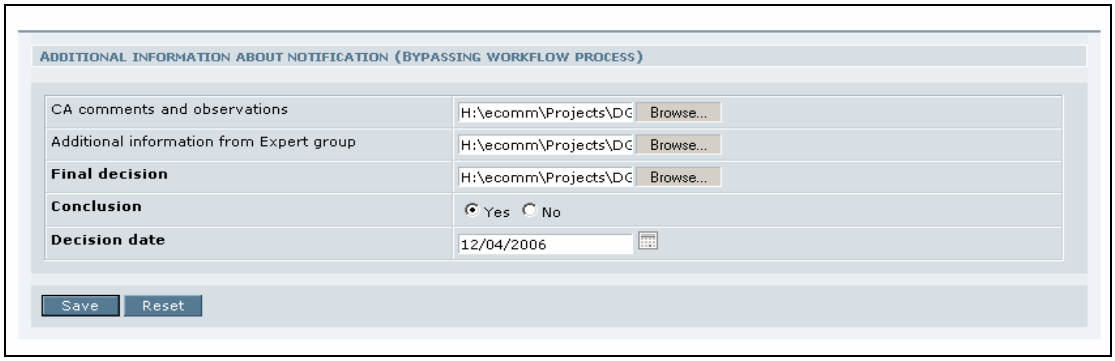


Figure 53: Additional Information about Notification (Bypassing Workflow Process) Screen

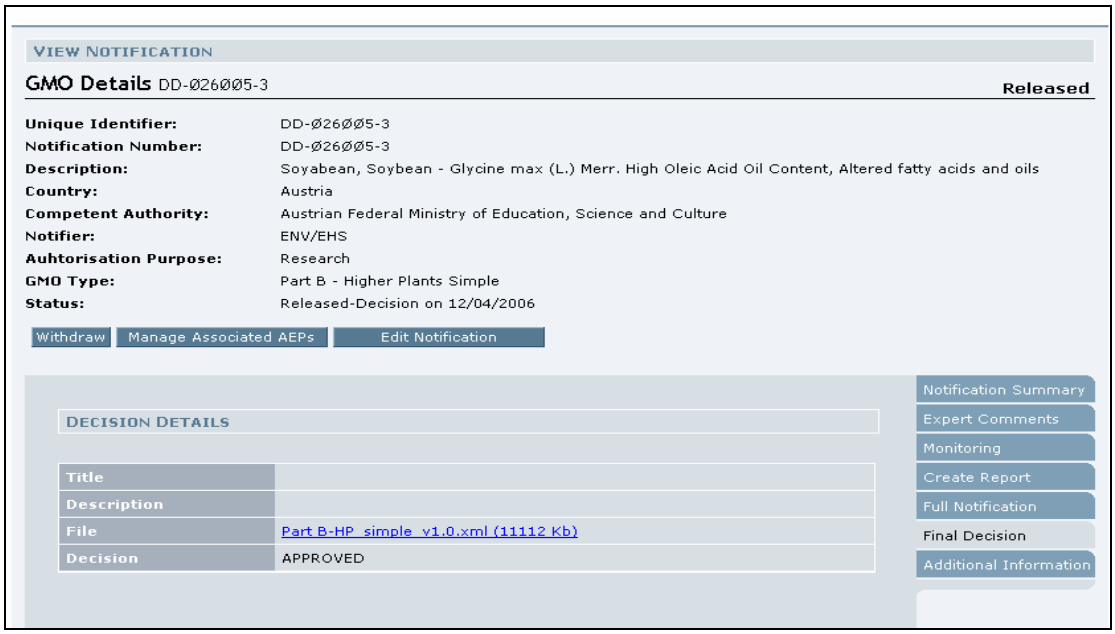


Figure 54: View Notification Details

5.1.2. Create Notifiers

One of the first steps in the creation of a new notification is to create the Notifier. The screen that is displayed to users is shown in figure 55.

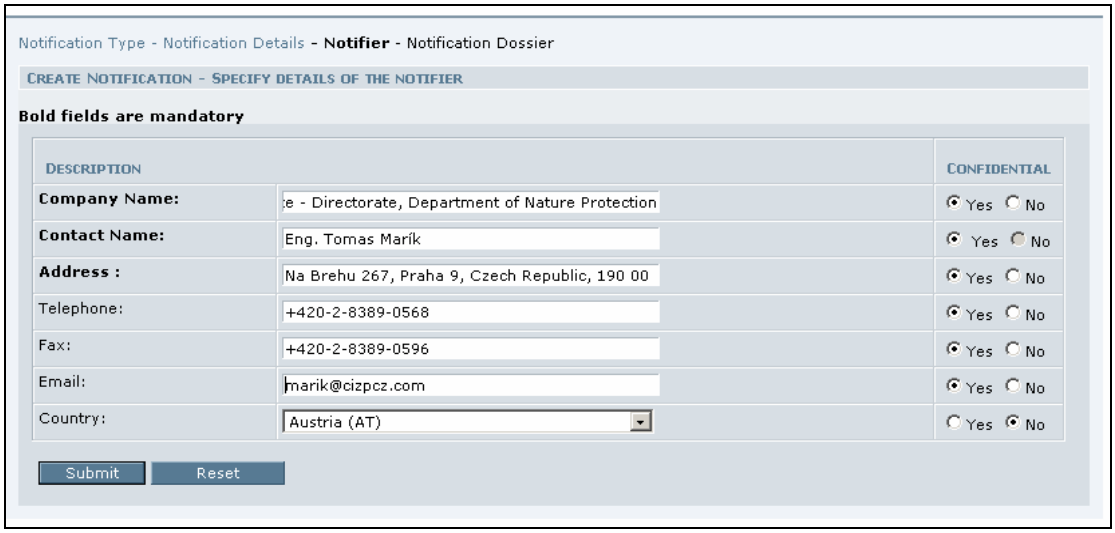


Figure 55: Create Notifier form

Once the user clicks on the **Submit** button, the system executes a database query, based on the data entered by the user, in order to check if the information provided as associated to a notifier entered for a previously submitted notification. The basis for "similarity" is a similar **company name**, **contact name** or **address**.
If the search returns a positive result, then the system displays the list of matching items in tabular format so that the user can select to associate the new notifier to an existing entry. Otherwise a new notifier is created and the system proceeds with the create notification process.

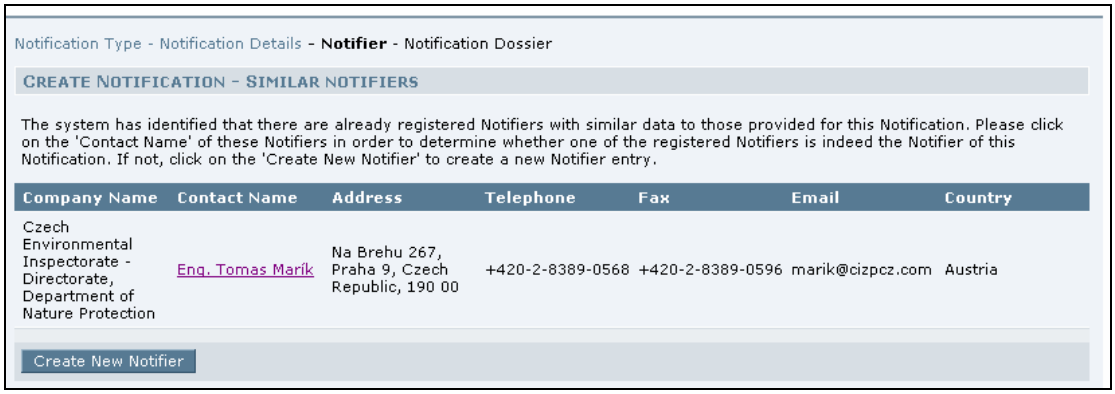


Figure 56: Notifier Search Results

The user may click on the **Create New Notifier button**: Create New Notifier. The system will store the new notifier in the data repository and forward the user to appropriate page in order for her/him to proceed with the Create Notification Process. If an existing notifier needs to be used, the user must click on the Contact Name and click on "select notifier" in the next screen.

5.1.3. Edit Notification/GMO

A LCA or COM user, depending on the stage in the authorisation process, may edit the details of a Notification/GMO when viewing a Notification/GMO by clicking on the **Edit Notification** button: Edit Notification

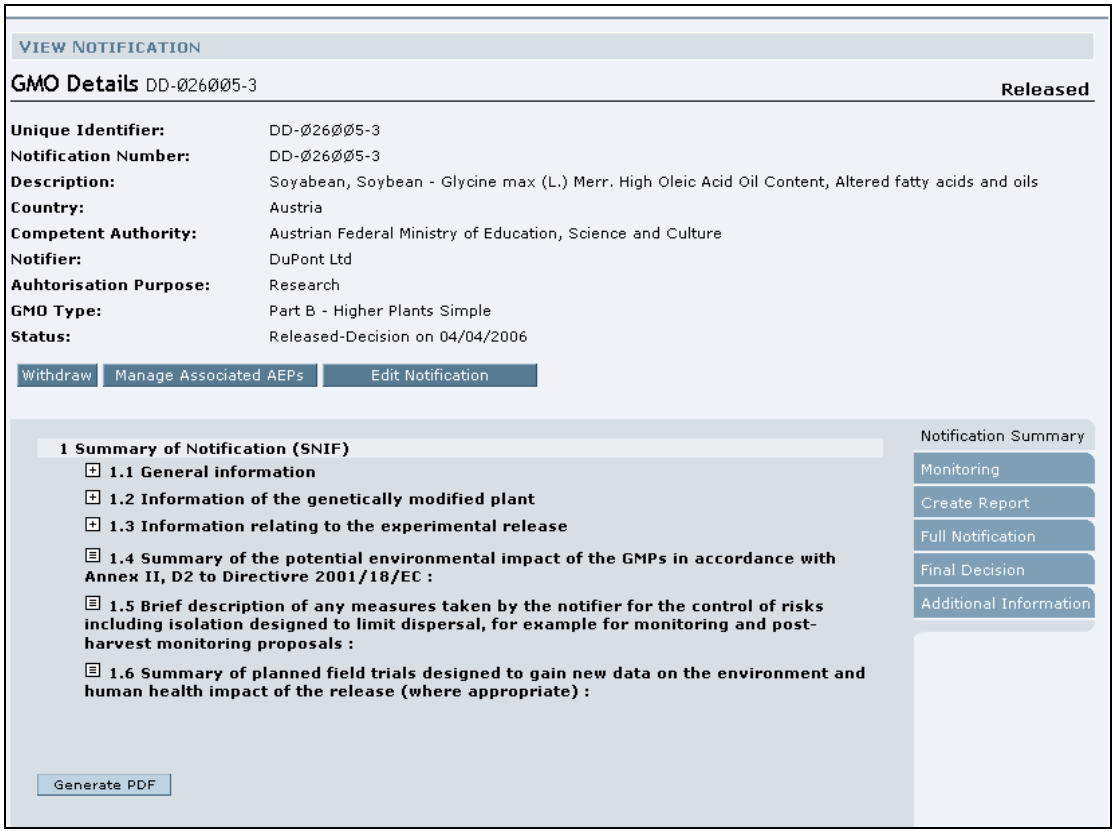


Figure 57: View Notification Details

The system will present to the user the details of the Notification/GMO that can be edited. The user may edit the Notification, following the same steps that are followed in the process of creating a notification. The only difference between creating and editing a notification, is that in the first case the user has to select a Notification Template and the Notification process to be followed, while in the second case the template and process cannot be edited.

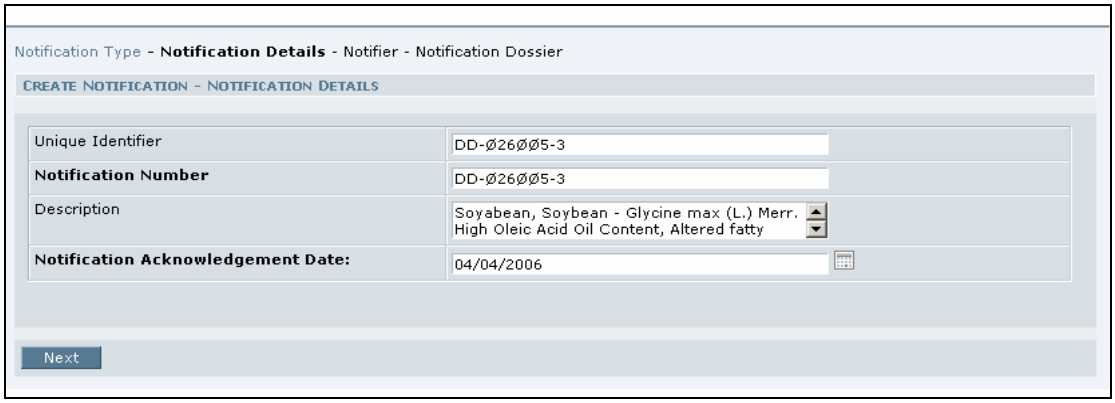


Figure 58: Edit details of Notification Details

Once the user has made the required changes, she/he may submit them and the system will update the database record with the modified data.

5.1.4. Withdraw Notification/GMO

A LCA user may withdraw a specific Notification (on behalf of the notifier) when viewing a Notification/GMO by clicking on the **Withdraw** button: Withdraw

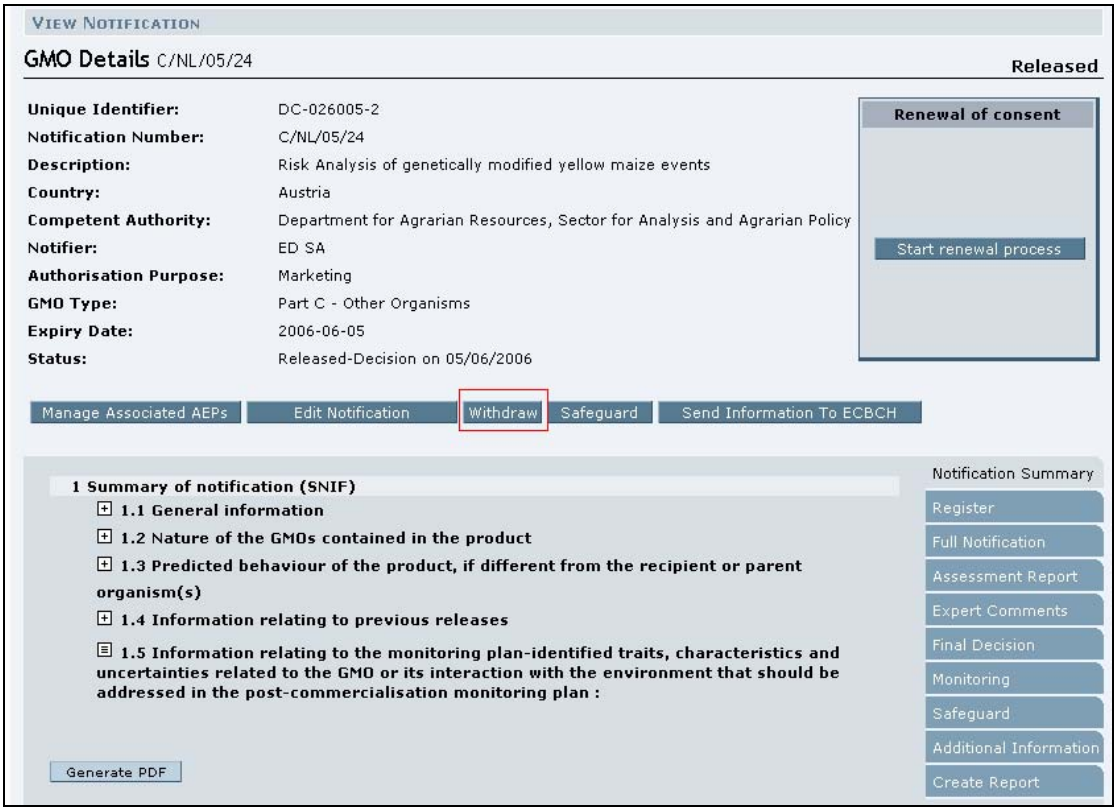


Figure 59: View Notification Details

Next, the user is required to confirm the withdrawal of the Notification/GMO.

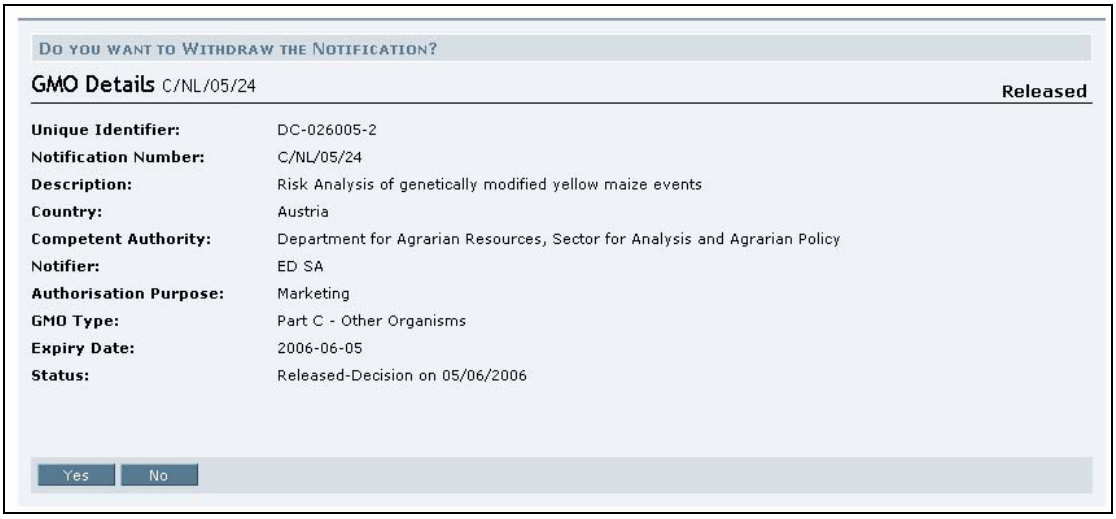


Figure 60: User confirmation screen for "Withdraw Notification" action

The system generates a message indicating that the “Withdraw Notification” operation is complete.

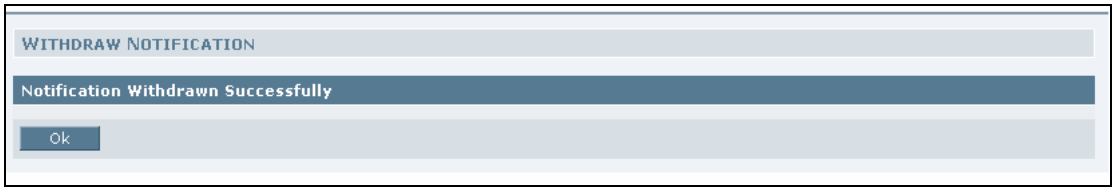


Figure 61: System confirmation screen for “Withdraw Notification” action

Following the successful withdrawal of the Notification, the system will remove all relevant data from the system. The withdrawal of a notification can be performed both for “running” notifications and “released” notifications.

5.1.5. Create Report on a Notification/GMO

A LCA or COM user may create a report on a specific Notification/GMO while viewing its details by clicking on the *Create Report* tab.

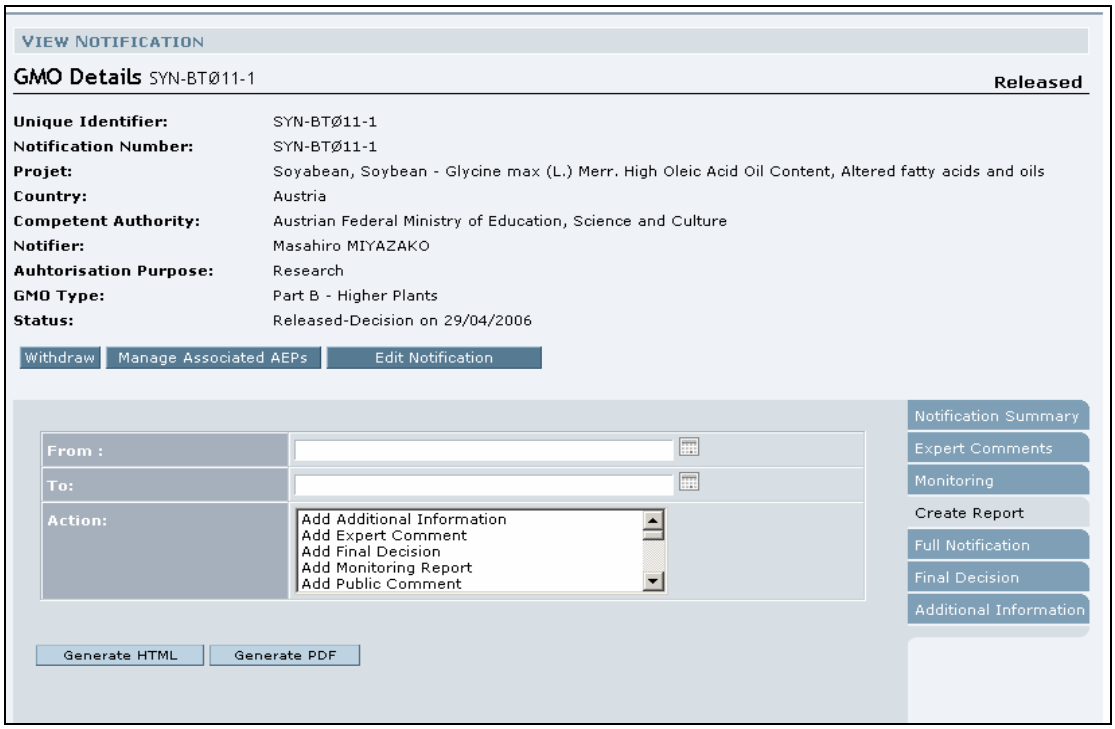


Figure 62: View Notification Details

Users may select filtering criteria and/or the data-range covered by the report. In case no criteria are set, the system will display all history information related to a notification.

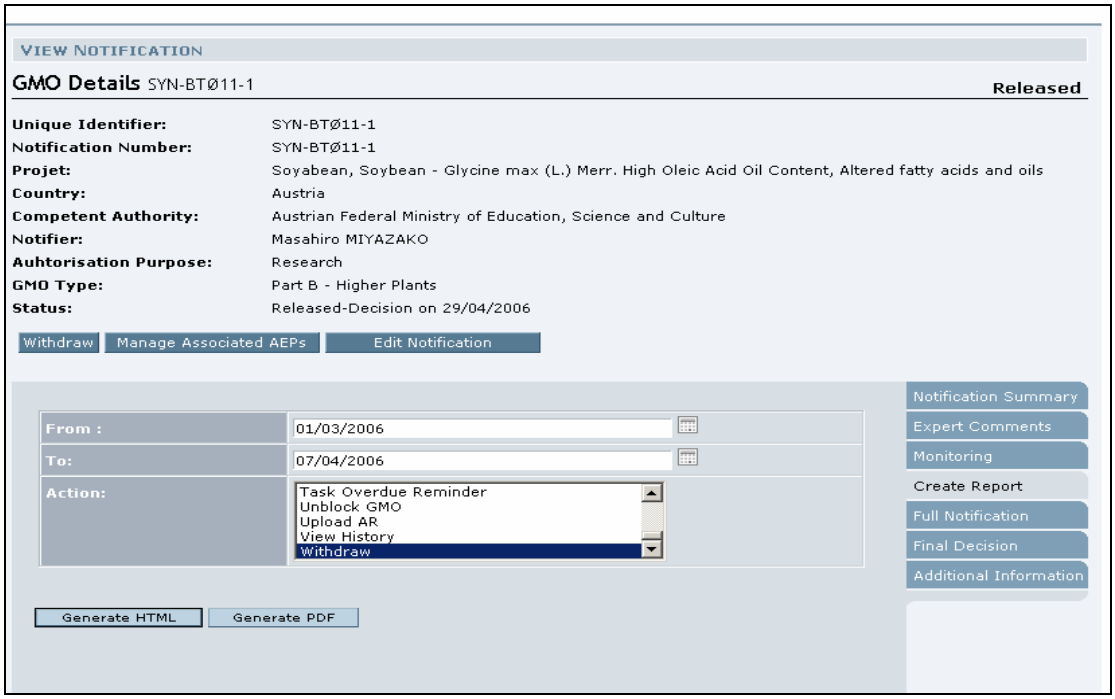


Figure 63: Select Criteria from Create Report section

The system provides exporting facilities in either HTML or PDF format. Users may select the format by clicking on the **Generate HTML** or **Generate PDF** buttons.

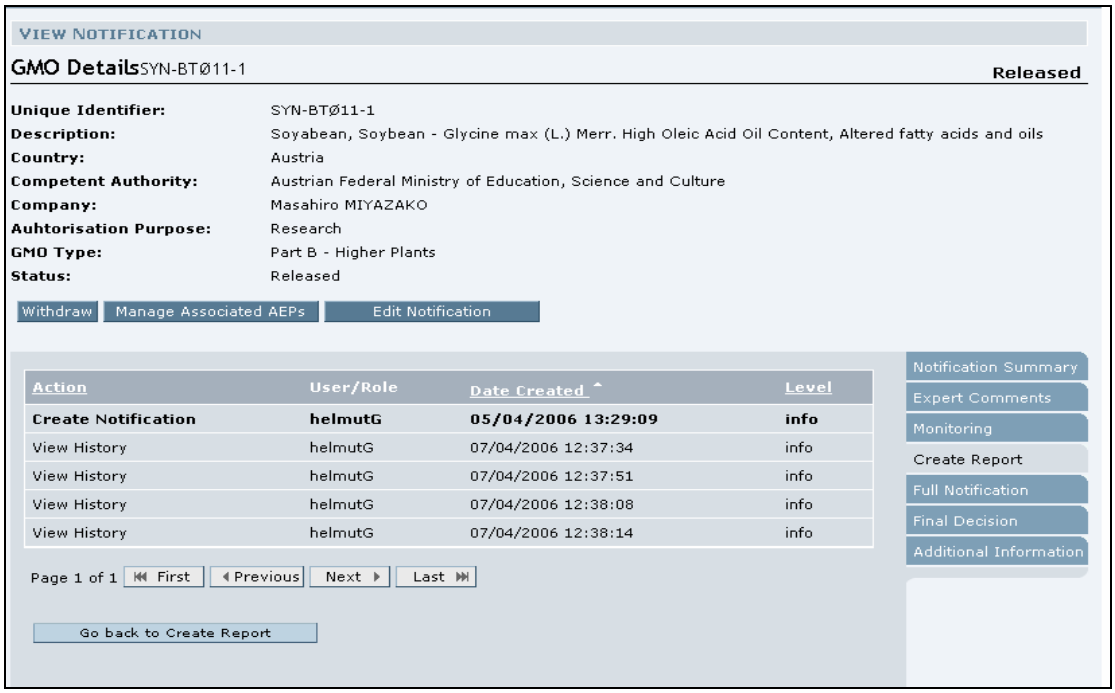
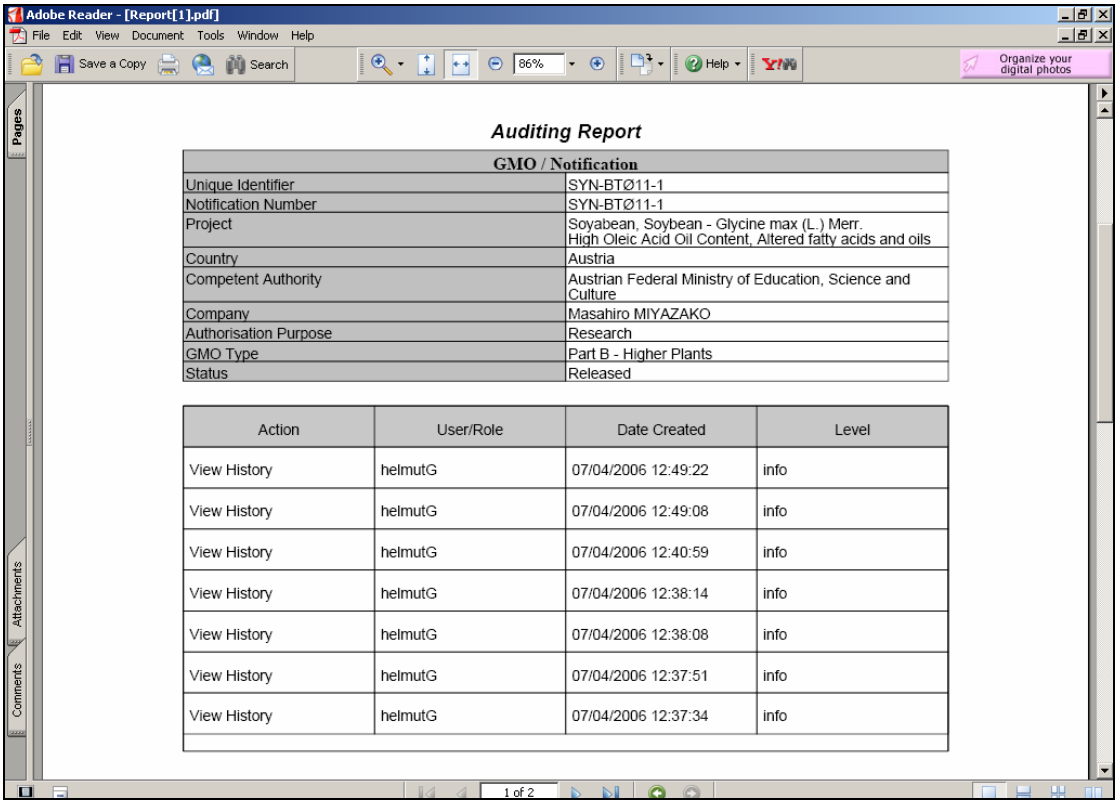


Figure 64: Generate Report in HTML



Adobe Reader - [Report[1].pdf]

Auditing Report

GMO / Notification	
Unique Identifier	SYN-BTØ11-1
Notification Number	SYN-BTØ11-1
Project	Soyabean, Soybean - Glycine max (L.) Merr. High Oleic Acid Oil Content, Altered fatty acids and oils
Country	Austria
Competent Authority	Austrian Federal Ministry of Education, Science and Culture
Company	Masahiro MIYAZAKO
Authorisation Purpose	Research
GMO Type	Part B - Higher Plants
Status	Released

Action	User/Role	Date Created	Level
View History	helmutG	07/04/2006 12:49:22	info
View History	helmutG	07/04/2006 12:49:08	info
View History	helmutG	07/04/2006 12:40:59	info
View History	helmutG	07/04/2006 12:38:14	info
View History	helmutG	07/04/2006 12:38:08	info
View History	helmutG	07/04/2006 12:37:51	info
View History	helmutG	07/04/2006 12:37:34	info

Figure 65: Generate Report in PDF

5.1.6. Associate AEP with a Notification/GMO

A LCA or COM user may associate an Authorised External Party (AEP) with a specific Notification. This functionality allows the integration of comments/observations from authorised parties such as scientific or ethical committees. This function is available in the page where details about a Notification/GMO are displayed by clicking on the button **Manage Associated AEPs:**

Figure 66: View Notification Details (Manage Associated AEPs)

The following screen appears allowing the user to search for an AEP.

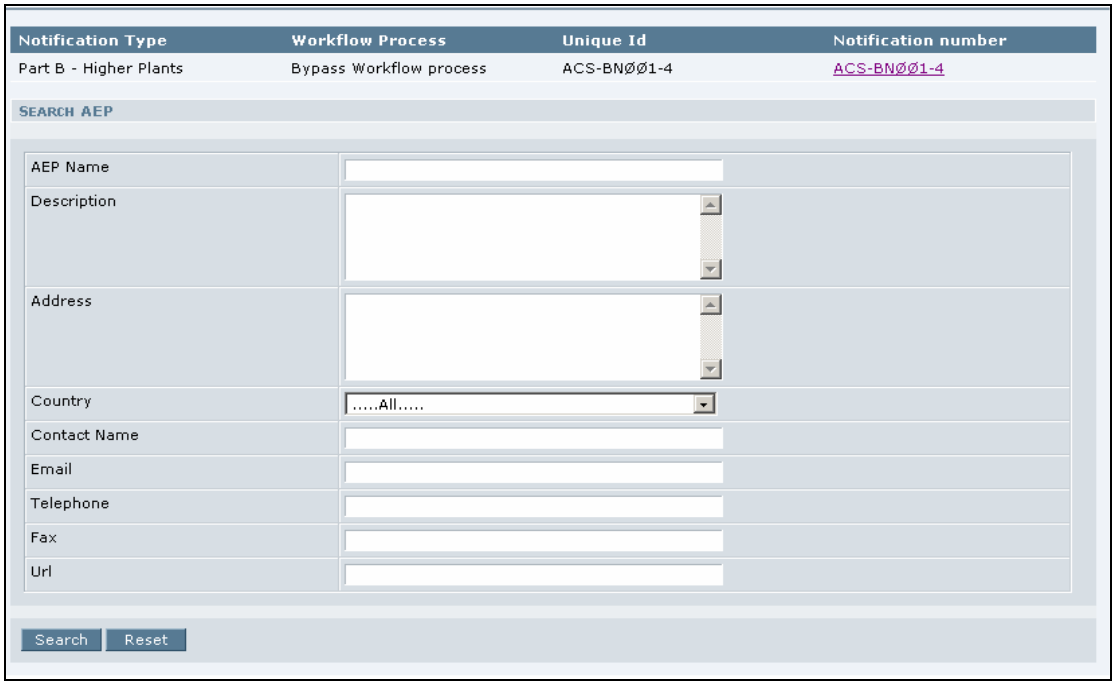


Figure 67: Search AEPs screen during Manage Associated Process

The system executes the query and presents the user with the results of the search. The user may select the AEP to associate with the particular Notification/GMO.

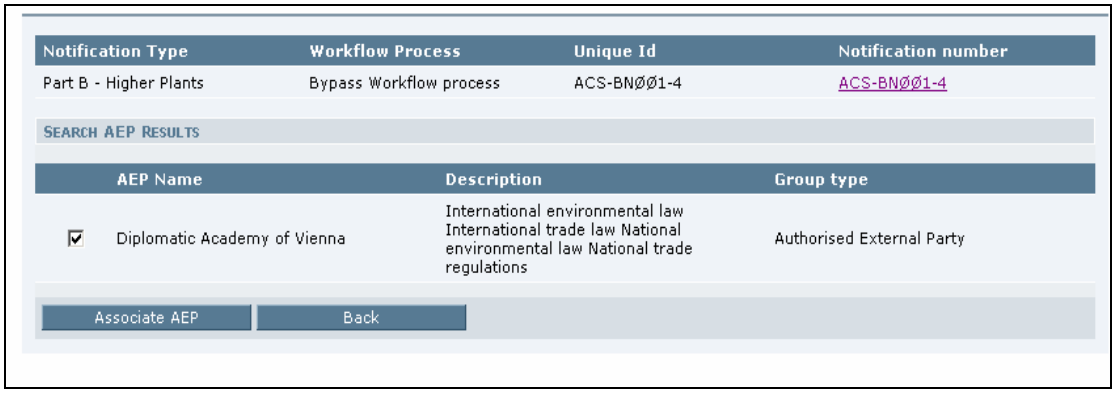


Figure 68: Manage Associated Screen

Once the user selects an AEP by clicking on the appropriate checkbox as indicated by the above screen, she/he may click on the button **Associate AEP**. The system associates the particular AEP and displays the following screen.
This functionality allows external parties (e.g. EFSA or the Scientific Committee) to upload observations or comments to a particular notification. External parties users will have to login into the application providing valid access information (i.e. Username and Password).

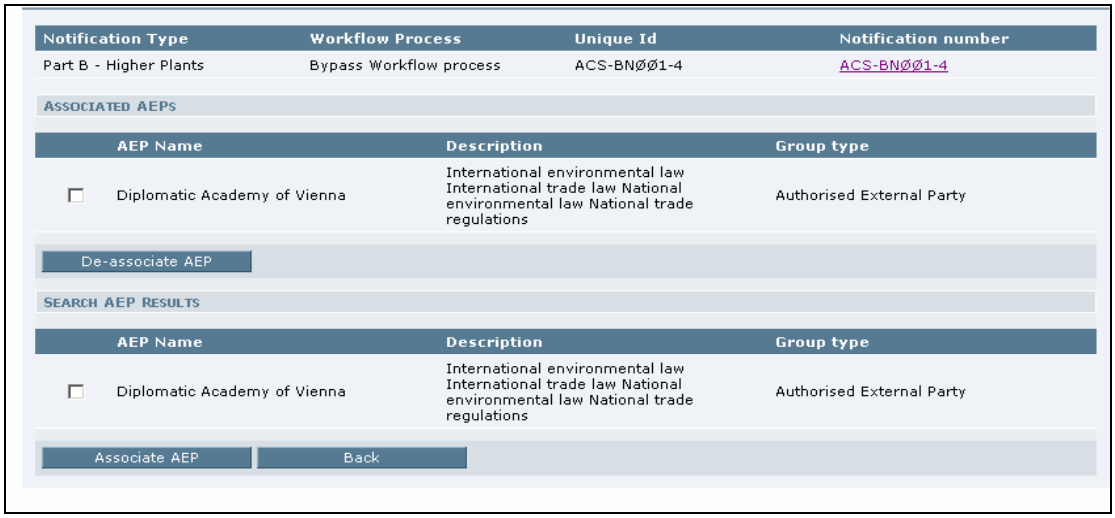


Figure 69: Manage Associated Screen with Associated AEPs

5.1.7. Disassociate AEP with a Notification/GMO

A LCA or COM user may disassociate an AEP from a specific Notification while viewing the details of a Notification/GMO by clicking on the button **Manage Associated AEPs:**

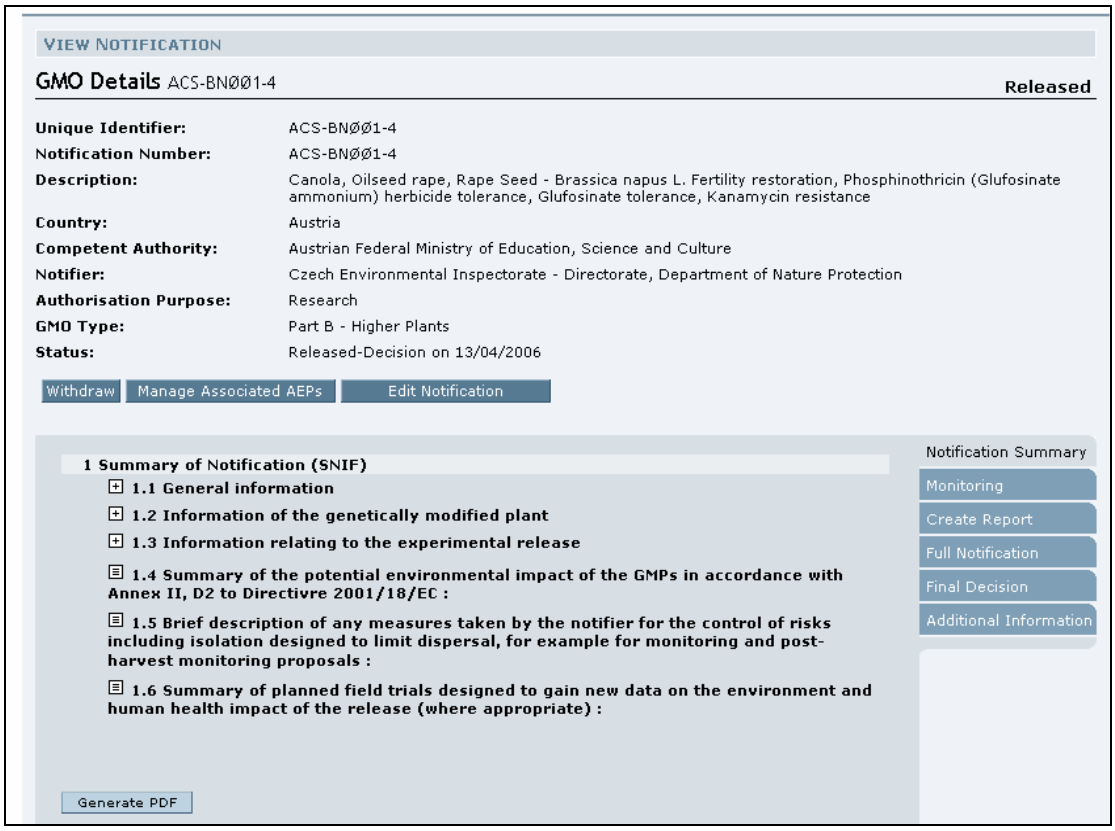


Figure 70: View Notification Details (Manage Associated AEPs)

The system displays the following screen comprised of a section that indicates associated AEPs with the particular Notification and the search AEP screen.

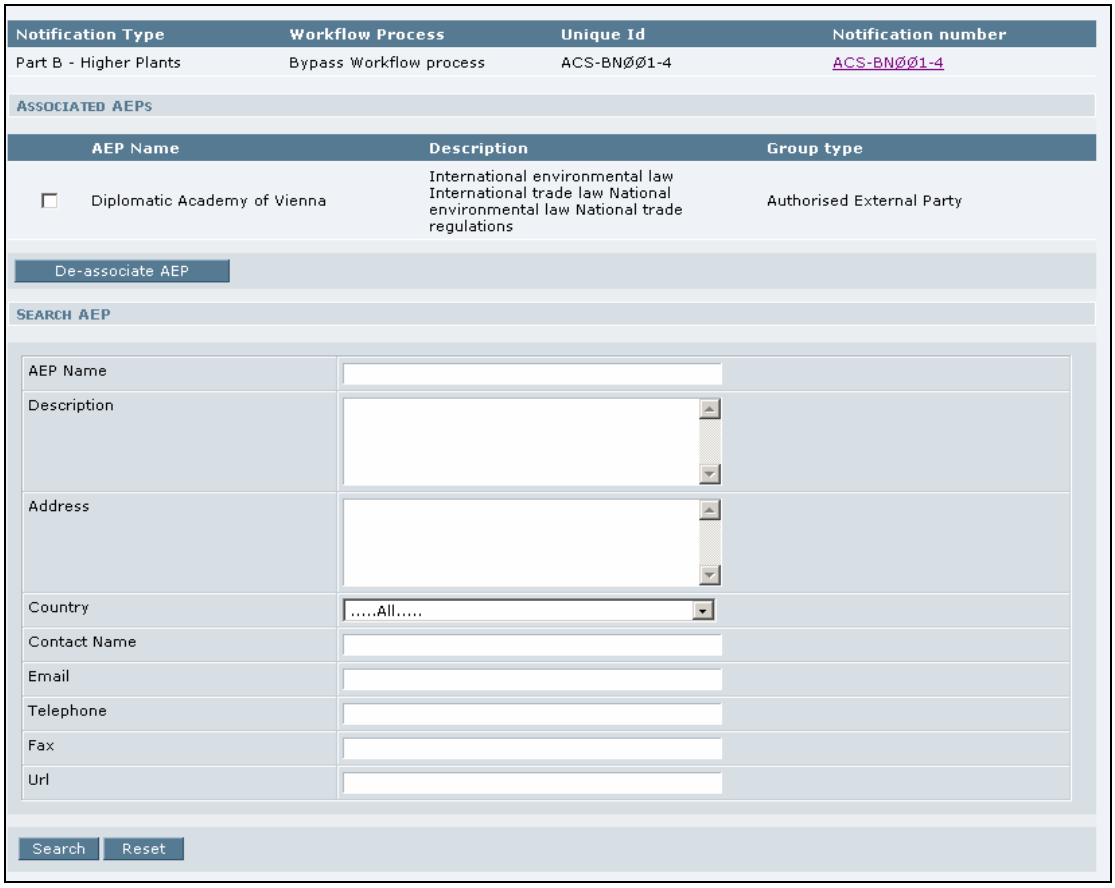


Figure 71: Disassociate AEP screen

The user may select the AEP to be disassociated by checking the checkbox next to the name of the AEP and proceed by clicking on the button **De-associate AEP**

The system disassociates the AEP as indicated by the final screen.

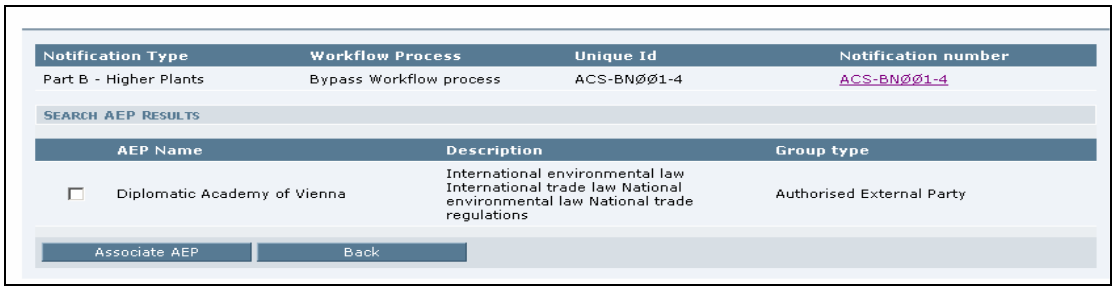


Figure 72: Search AEP Results screen following an AEP Disassociation screen

At this point, the AEP will no longer be able to attach comments/observations to the notification.

5.1.8. Additional Information

LCA, CA and COM users may upload additional information and documents for a particular Notification which can in this way be shared by all parties involved in the authorisation process. This can be achieved by clicking on the ***Additional Information*** tab while viewing the details of that particular Notification/GMO.

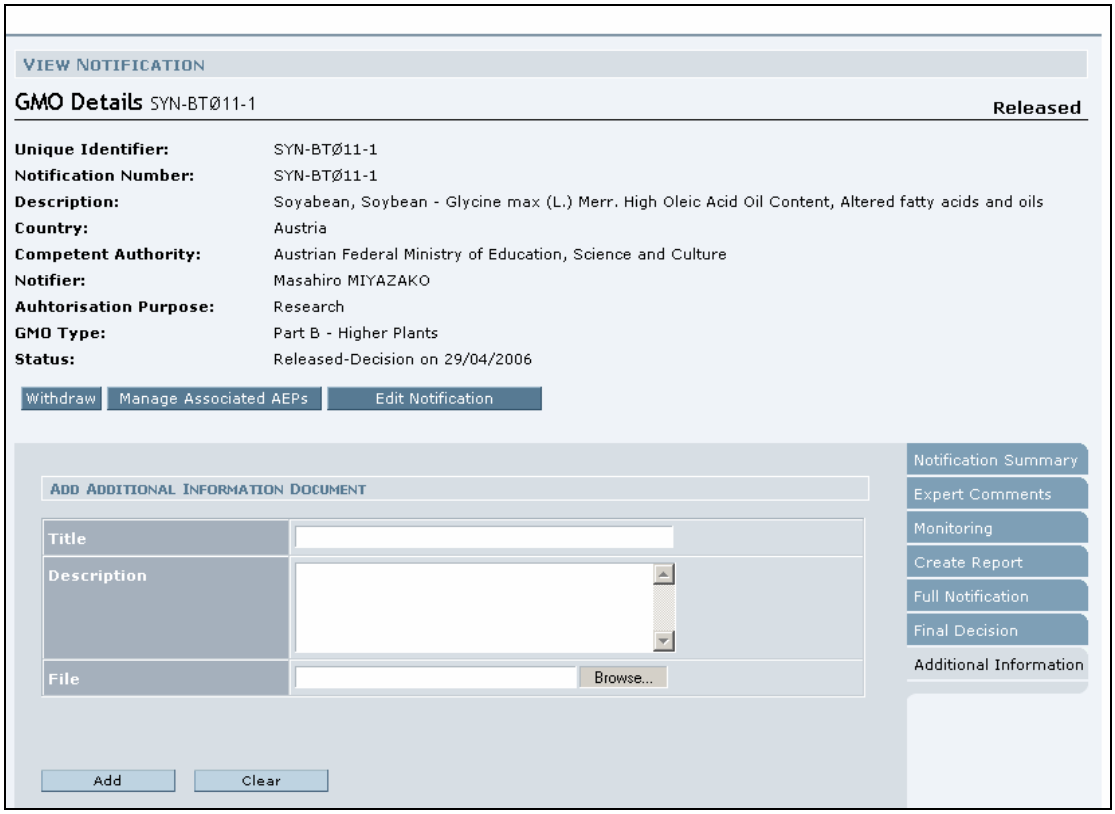


Figure 73: Additional Information Screen

In order to upload a document into the system, a user must specify some metadata on the document itself, namely the document title and a description, in addition to the document itself. Either Title or Description must be provided.

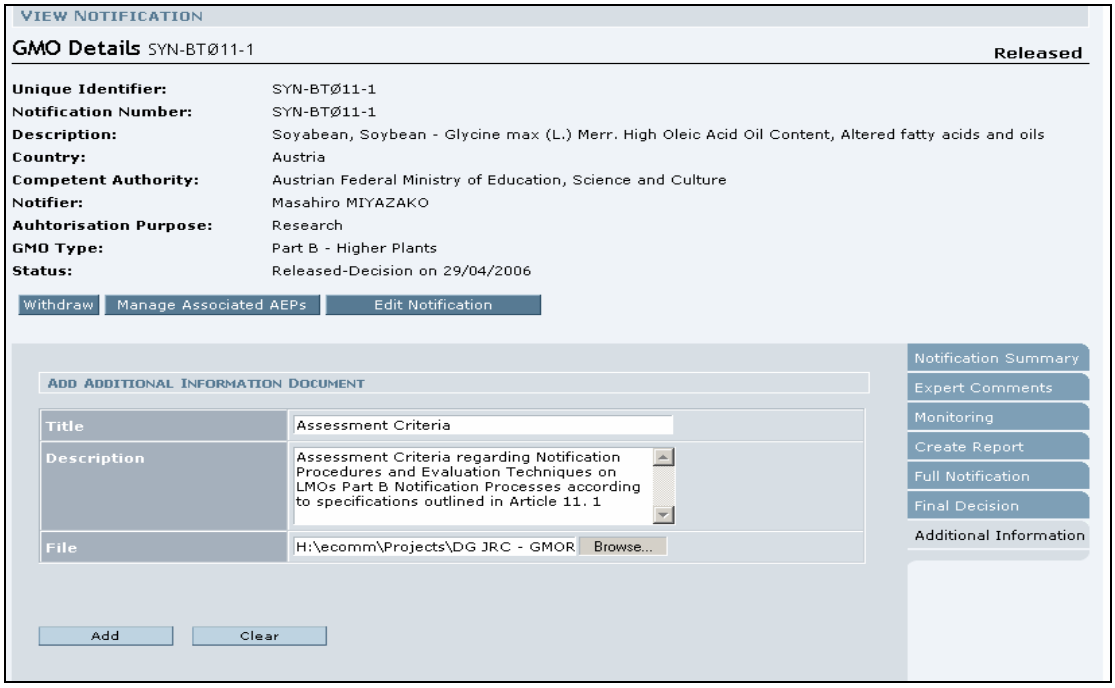


Figure 74: Upload Document in Additional Information Screen

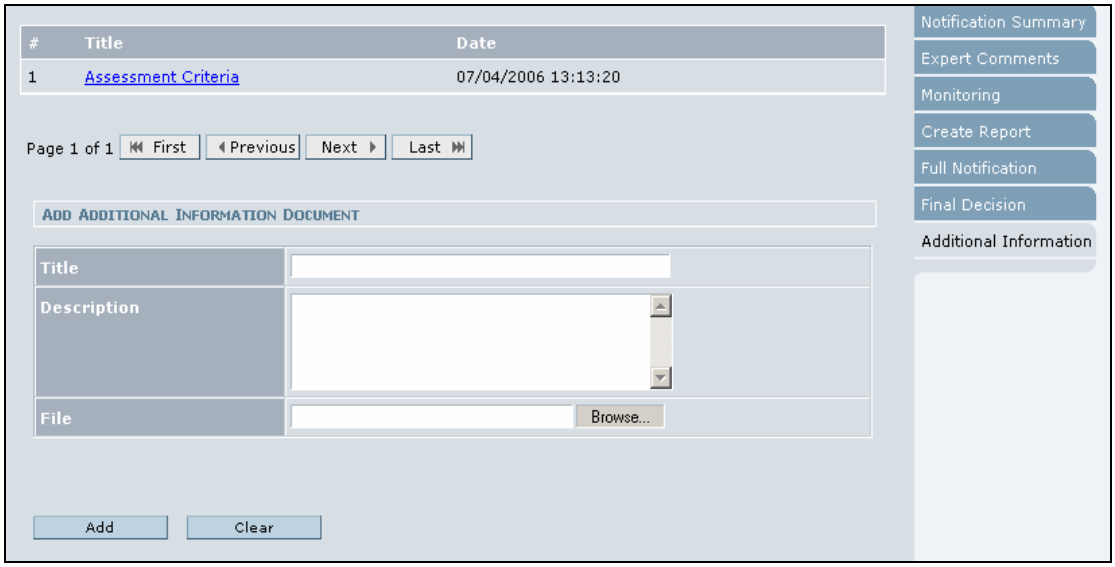


Figure 75: Additional Information Screen following the Successful Upload of Document

5.2. Bypass Workflow Procedure

The Bypass Workflow procedure has been implemented in the system to allow for insertion of information related to authorisation application for which the workflow process is not available for some reason. These could be related to notification whose process is already completed or also, possibly, to notifications that are submitted outside the authorisation process according to [DIR.2001/18]. In this procedure, the documents that would be submitted in the system as a result of the actions required by the workflow, are submitted without any intervention from the workflow.
Therefore, the last step for creating notifications using the bypass process (section 5.1.1 Create Notification) requires users to provide the documents that would normally be produced and uploaded in the system if the full workflow Part B or Part C process was followed. To this end, this last step is a page called ***Additional information about notification***. Mandatory documents for this page are highlighted in bold.

For both Part B and Part C, the mandatory document is the Final Decision, while the user must specify whether the conclusion of the process is positive (**Yes**) or negative (**No**). In the first case the notification will acquire the status **Released**, while in the second case it will acquire the status **Rejected.** Furthermore, the Decision date must be provided.

5.2.1. By pass process - Part B notification

When using the "Bypass workflow process" for Part B notifications, in addition to uploading information on the notification and on the SNIF, users may optionally upload CA comments and information from Experts groups.

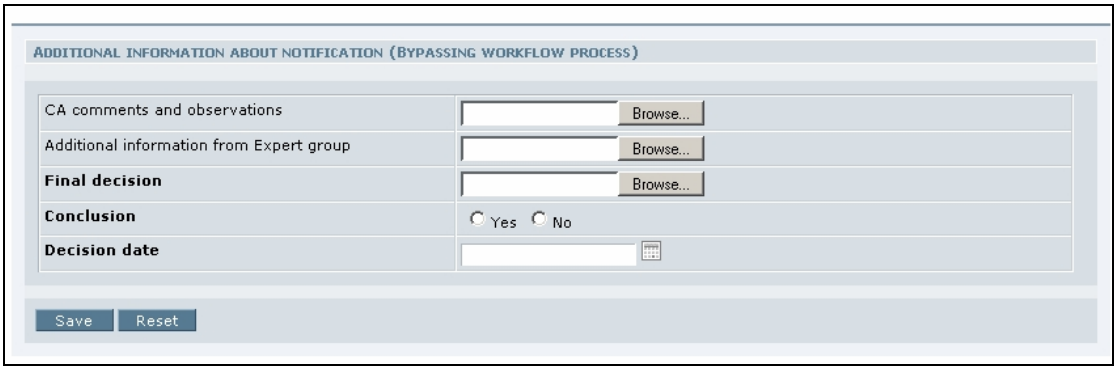


Figure 76: Additional Information Screen following the Successful Create Notification of Part B

5.2.2. By pass process - Part C notification

When using the "Bypass workflow process" for Part C notifications, users must provide the Assessment Report document and Assessment Report Conclusion (**Yes** for Positive, and **No** for Negative), the text of the final decision, the date of the decision as well as the expiry date of the authorisation and must indicate whether the decision was favourable or not. All other fields in the page are optional. As in other cases, mandatory fields are marked in bold (fig. 77).

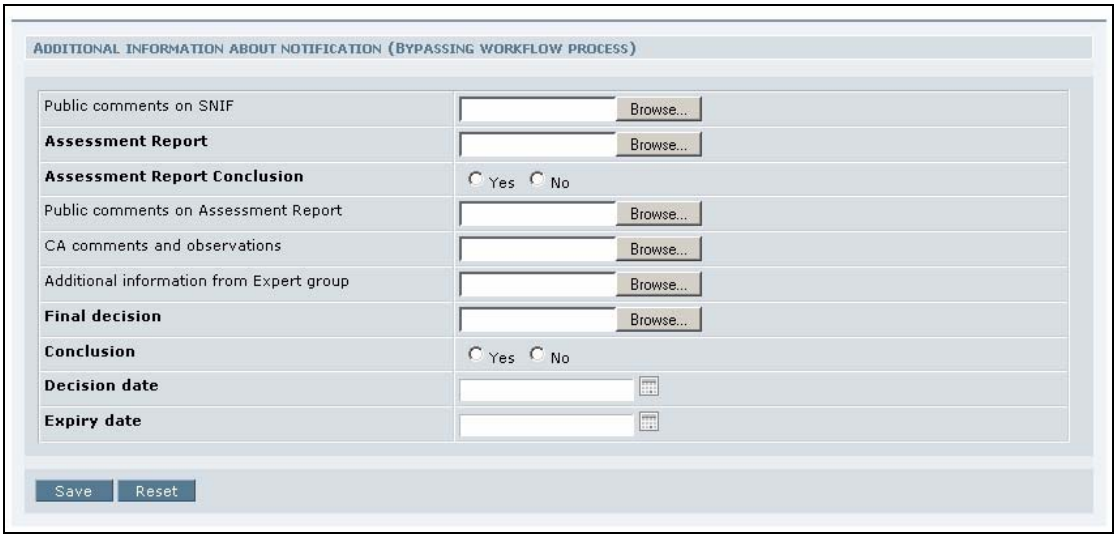


Figure 77: Additional Information Screen following the Successful Create Notification of Part B

5.3. Part B / Part C process notifications

All operations described in section 5.1 of this document are available only when the notification process is in the appropriate state, and the application is accessed by the appropriate authorised users (i.e. the SNIF can be submitted to the COM only by the LCA and only when foreseen in the workflow process). In this section we will describe the workflow process and, when necessary, we will refer to the operations already described in section 5.1.

In order to better describe the functions associated to the workflow management, figures 78 and 79 provide a graphical representation of the authorisation process for part B and Part C notifications respectively given in UML Activity Diagrams format which show actions, roles that execute actions and timing between actions.

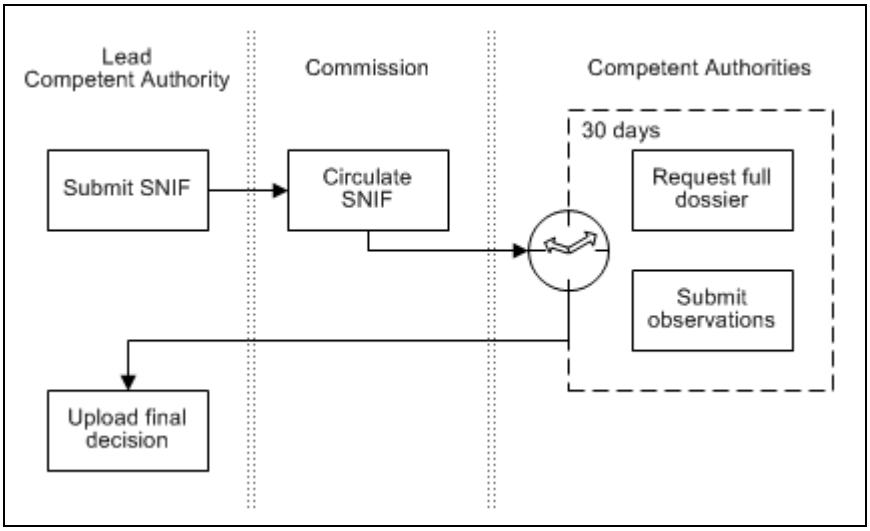


Figure 78: Example of Part B WorkFlow Diagram

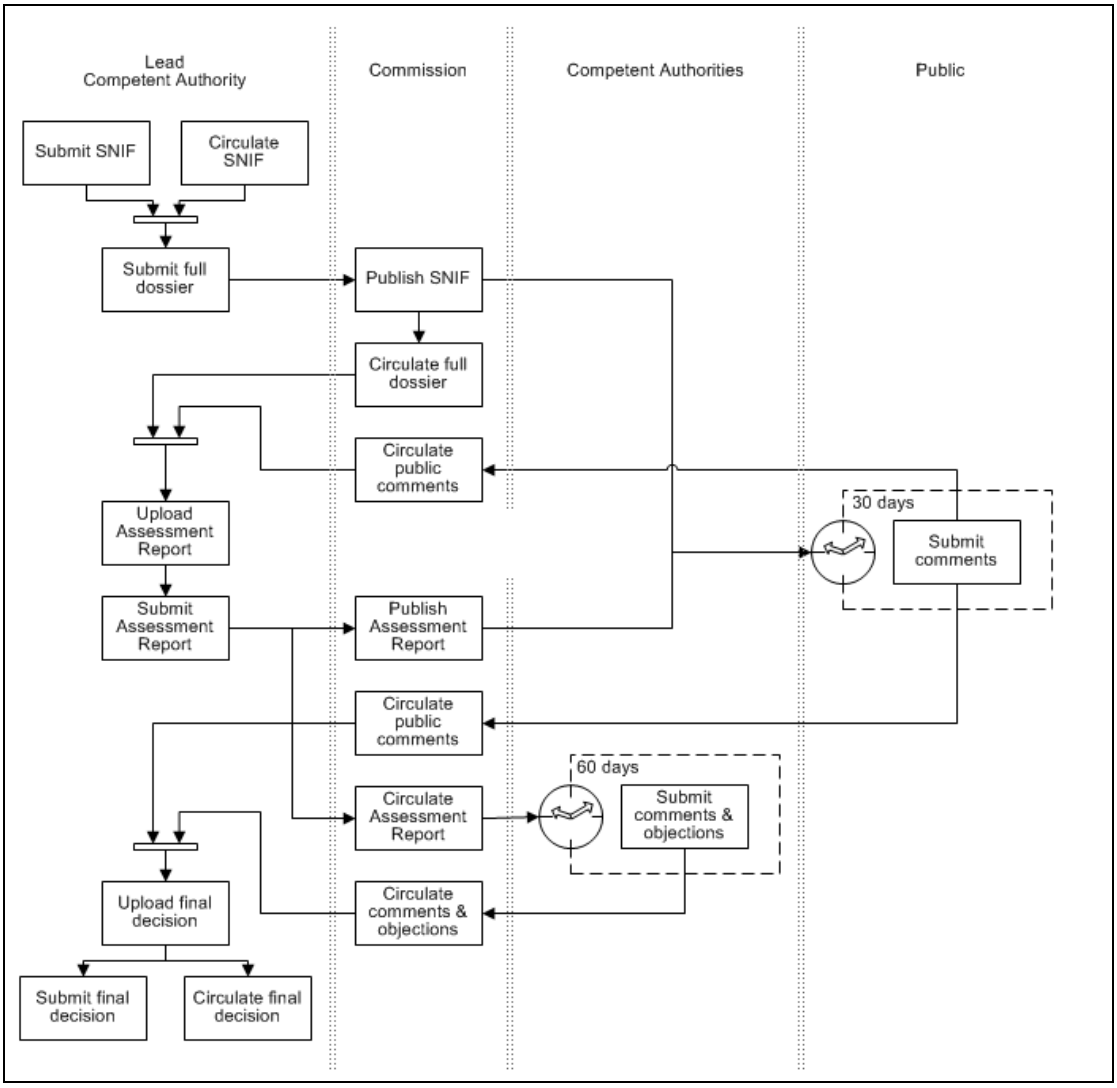


Figure 79: Example of Part C WorkFlow Diagram

5.3.1. Submit Document

The "Submit document" function is available for different types of documents and allows users to submit a document to the next actor in the authorisation process.
This function is made available at the bottom of the page containing information on the notification only when it is viewed by users who are allowed to perform that function on that specific notification.

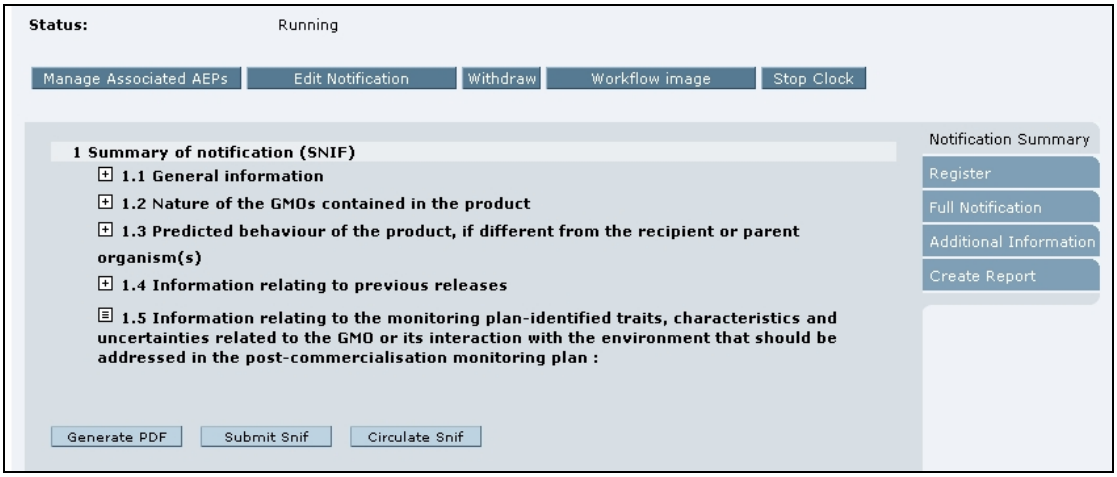
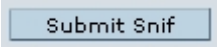


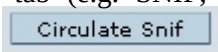
Figure 80: Submit Document (Submit SNIF)

Once the user clicks on the **Submit** button, 

the user has to confirm the action. Once this action is confirmed, the document becomes available to the next actor in the process.

5.3.2. Circulate Document

The "Circulate document" function is available for different types of documents and allows users to circulate a document to a set of actors who are allowed to view it in a particular step in the authorisation process.
This function will be made available at the bottom of the page containing information on the notification only when it is viewed by users who are allowed to perform that function on that specific notification.

A user may circulate a specific document (SNIF, AR, Comment) related to a Notification/GMO among all CAs by clicking on the appropriate tab (e.g. SNIF, AR, Comment) and then proceed by clicking on the **Circulate** button(e.g 

)

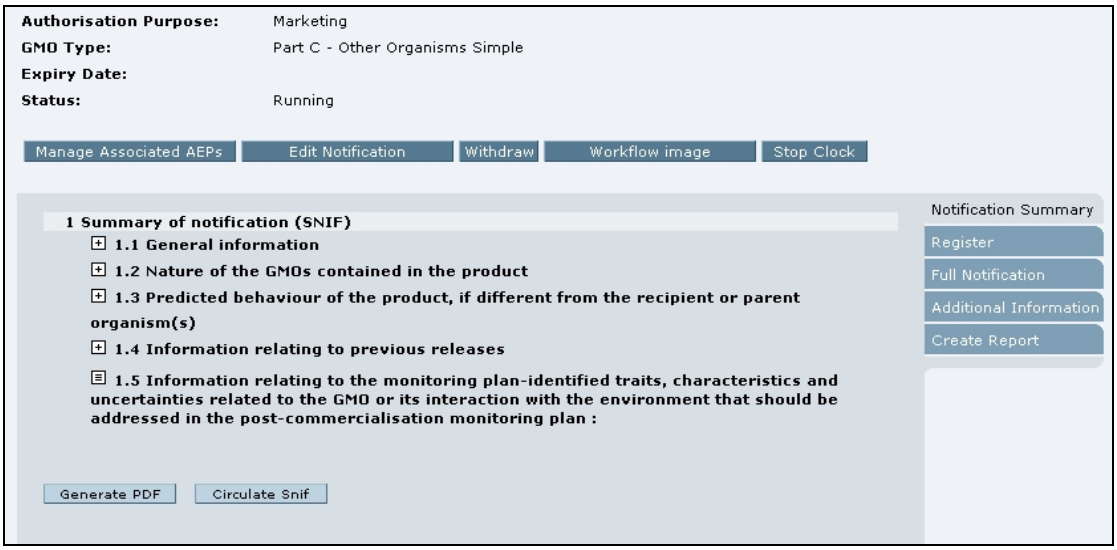


Figure 81: View Notification Details – Circulate SNIF

Subsequently, the user is prompted with confirmation page.

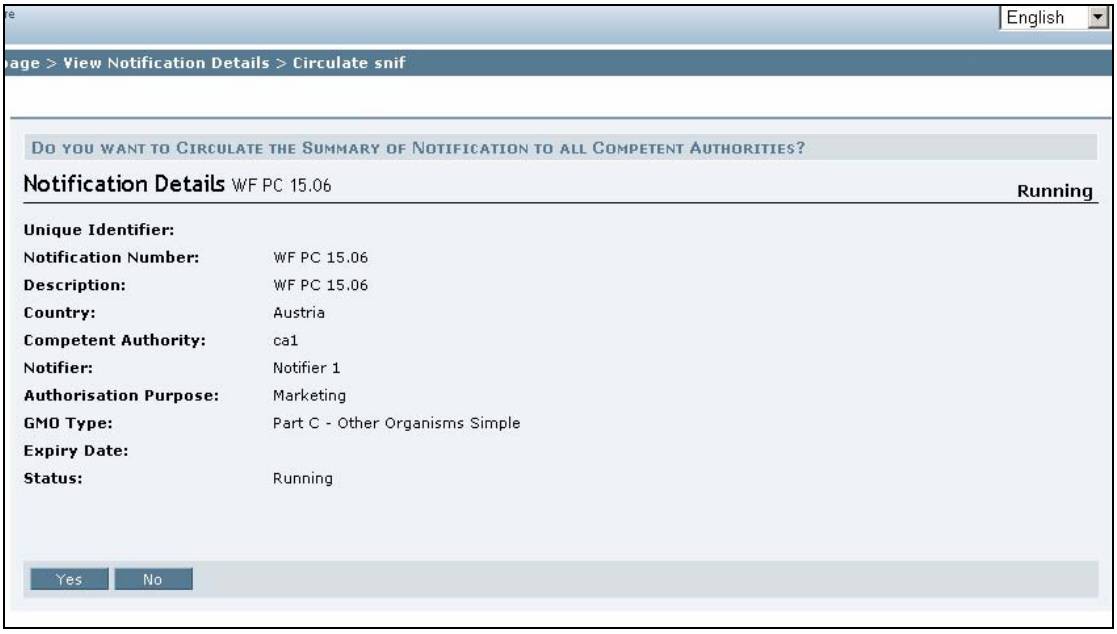


Figure 148: Confirmation page

The particular document becomes visible to all CAs.

5.3.3. Publish Document

The "Publish comment" function allows COM users to publish a specific document (SNIF or AR) related to a Notification, i.e. make it available to the general public. Publication is done by clicking on the appropriate tab (e.g. SNIF) when viewing a Notification/GMO that has reached the appropriate stage in the authorisation process. The possibility to publish a document is also shown in the task list of the home page of a COM user when the notification has reached the appropriate stage.

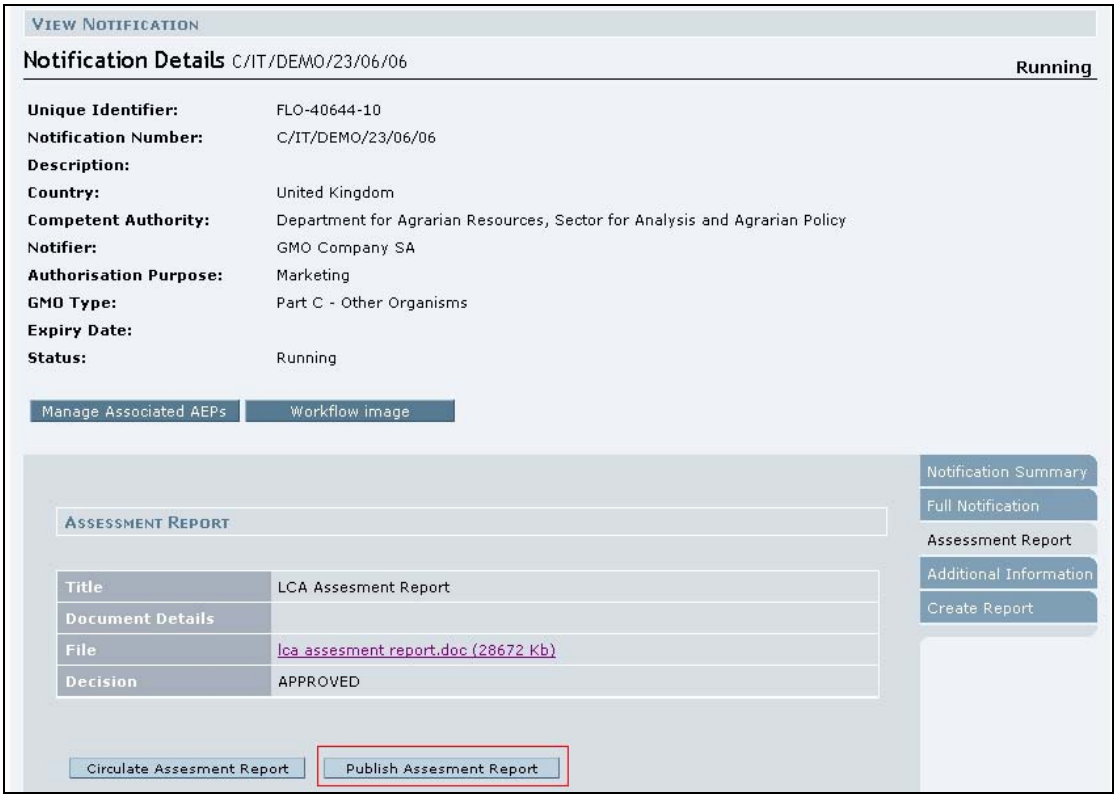


Figure 82: Publish document

Once the action is confirmed by the user, the document becomes available to the general public.

5.3.4. Request Full Dossier of a Notification

The user may request the full dossier of a Part B Notification when viewing a Notification/GMO by selecting **Request Full Dossier** task and in addition button **Request Full Dossier**.

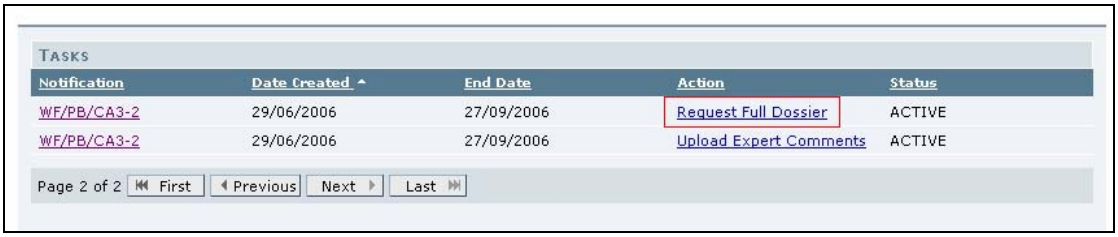


Figure 83: Task page – Request full Dossier

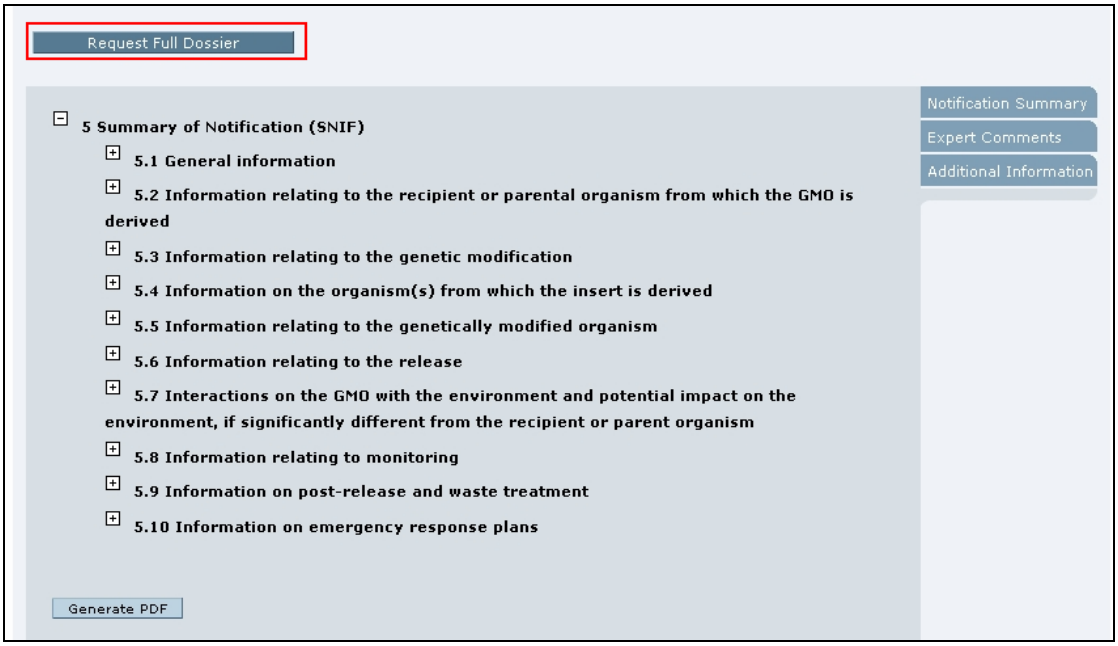


Figure 84: SNIF page – Request Full Dossier

Figure 85: Confirmation page – Request Full Dossier

The system will then send an email to the CA which is responsible for that particular dossier, to inform it that another CA wishes to receive the full notification dossier for the notification identified in the message.

5.3.5. Stop clock (Request Additional Information)

A user may stop the clock of a Notification process in order to request additional information from the notifier, or when waiting for an action from an external party. The option to stop the clock is available in the page where the notification information is displayed and only if the process is in a state where the clock can be stopped.

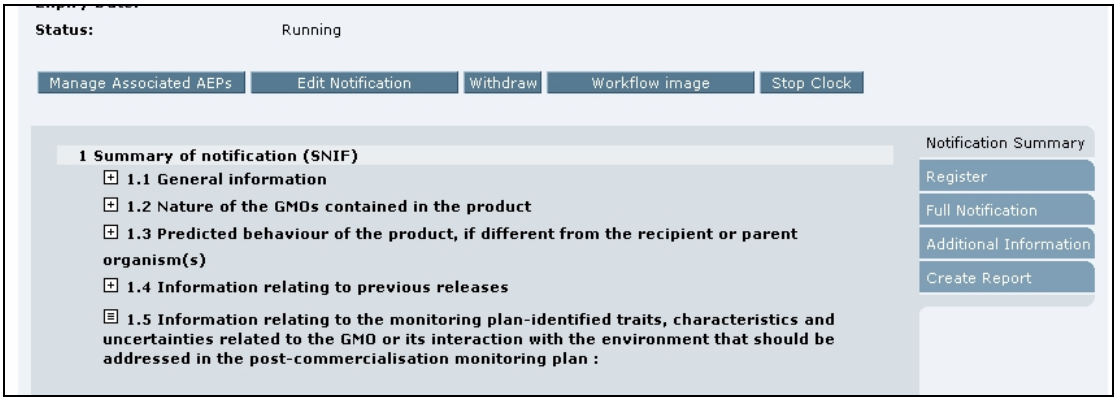
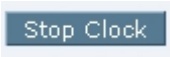


Figure 86: View Notification Details (Stop Clock)

The clock can be stopped by clicking on the 

button.

The system confirms that the clock has been stopped.

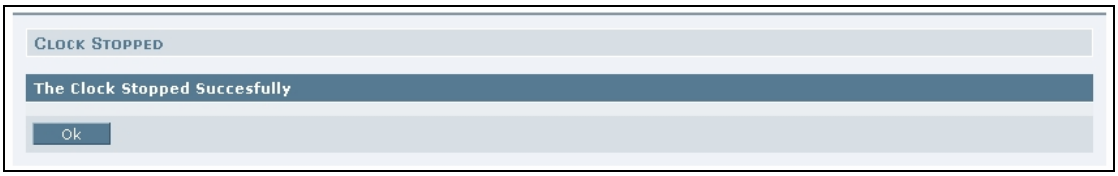


Figure 87: Stop Clock - Confirmation

When the clock is stopped, Notification enters the SUSPENDED status and the only active task for LCA is Resume Clock (5.3.6 Resume Clock):

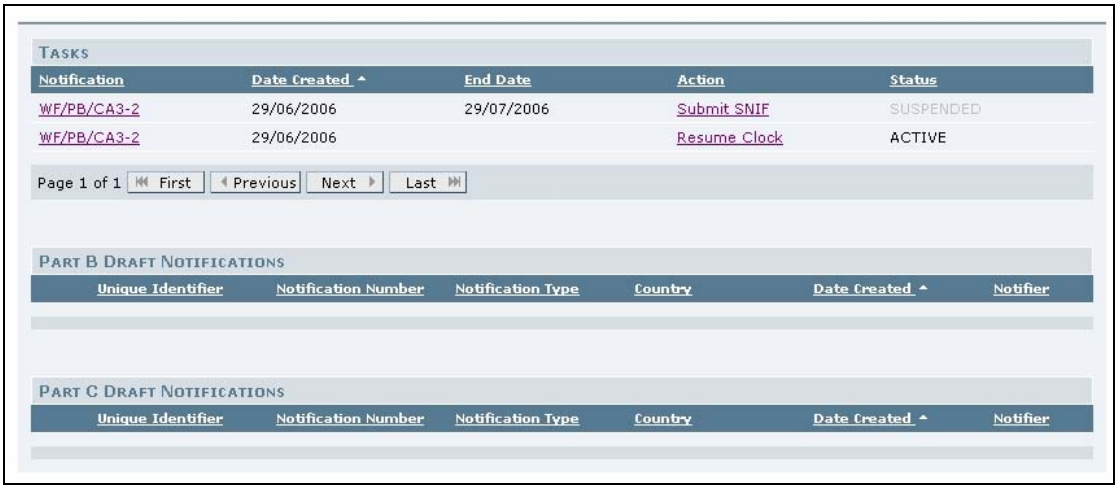


Figure 88: Clock stopped, notification SUSPENDED

5.3.6. Resume Clock

An authorized user may restart the clock (*Resume Clock*) for a Notification process that has been stopped with the stop clock function. The option to resume the clock is available in the page that displays the information details about a notification.

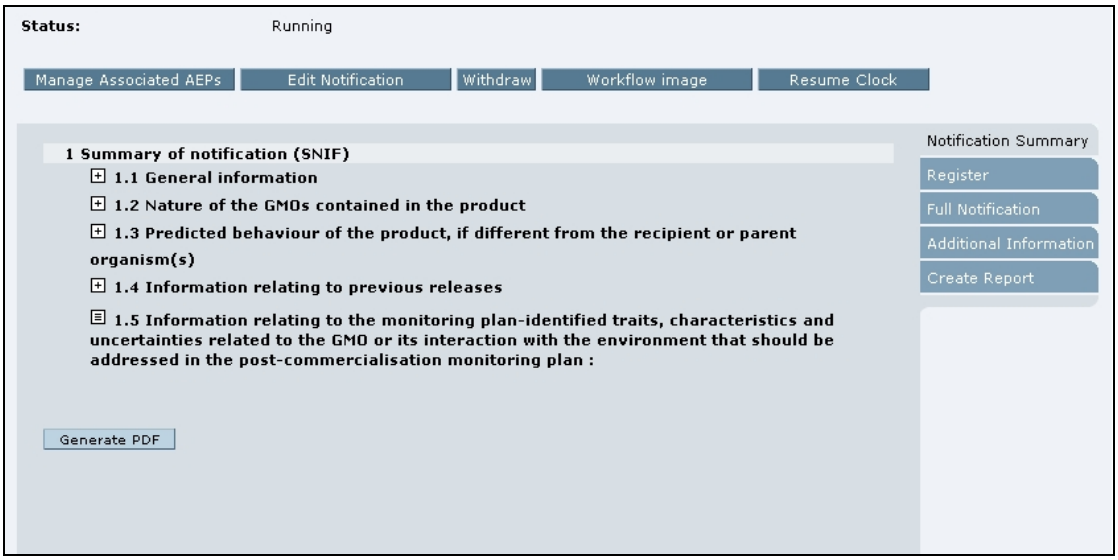
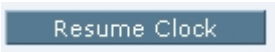


Figure 89: View Notification Details – Resume Clock

The user may click on the 

button.

The system confirms that the clock is resumed.

Figure 90: Resume Clock – Confirmation

5.3.7. Submit Final Decision on a Notification

The function to submit the final decision in the system is available when the authorisation process has been completed. This function becomes available in the list of tasks for the LCA in their home page ("*My homepage*", tasks section, "**Upload Final Decision**" task).

Figure 91: Tasks page – Upload Final Decision

The user is then forwarded to the appropriate web-page in which she/he may select a type of decision (Approve/Reject) and upload a file containing the full decision (conditions, justification etc).
Again, metadata about the decision file is required. Either the "Title" field and at least one field between "Description" and "File" must be filled in.

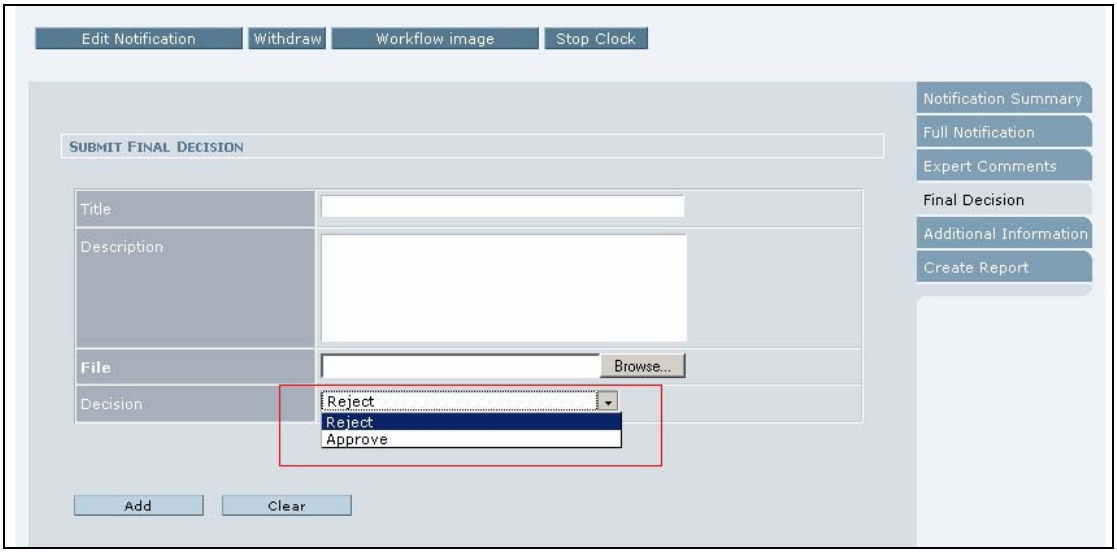


Figure 92: Upload Final Decision

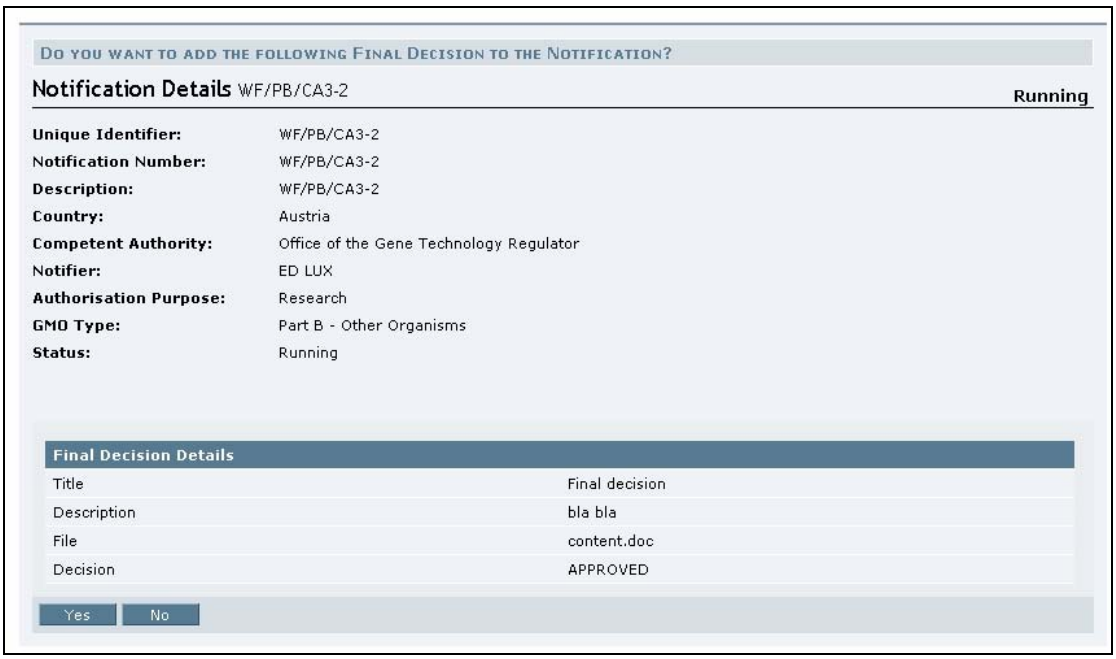


Figure 93: Confirm Upload Final Decision

Once the action is confirmed by the LCA user, the Decision Details page will be displayed.

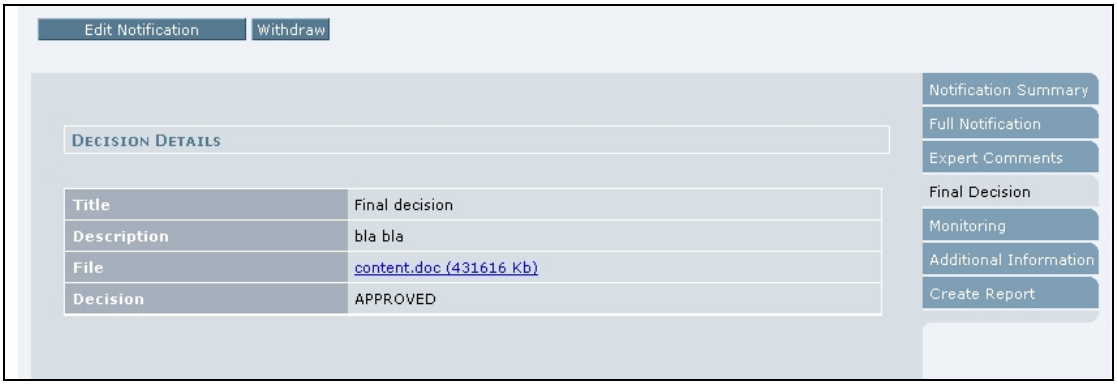


Figure 94: Final Decision details

5.3.8. Deadlines

According to [DIR.2001/18], some of the tasks, such as Submit Public / Expert Comments, can be performed only during pre-defined time periods. Also a number of tasks must be completed within predefined deadlines (e.g. the SNIF for a [SNIF.PARTB] must be circulated by the COM to all CAs within 30 days).

Five days before deadlines are reached, users who are affected by the deadline will receive an email with a reminder that the indicated task will be overdue soon and an action is expected from their side.

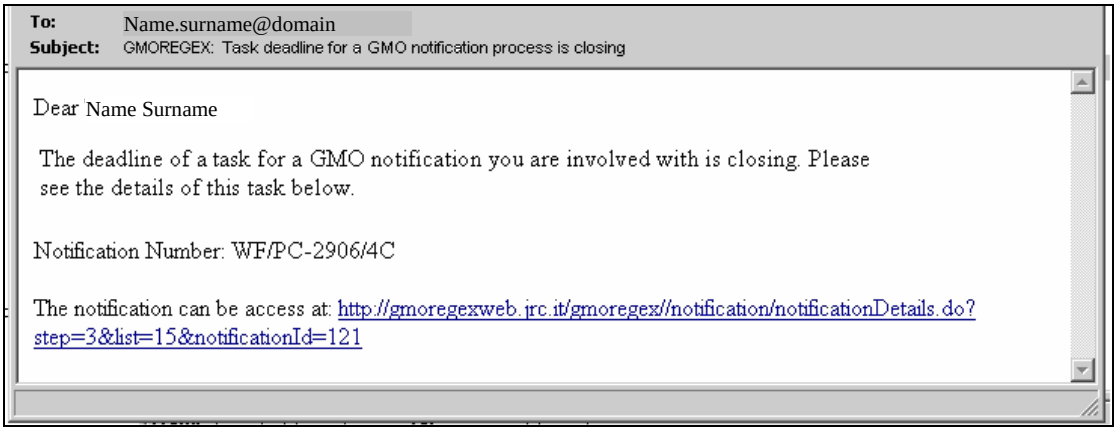


Figure 95: Task deadline reminder email

When a deadline is reached, another email will be sent by the system to all related users to inform them that either a task is overdue (e.g. circulation of the SNIF) or the submission period for comments is over.

Figure 96: Task ended email

5.4. Renewal

Released Notifications of Part C can be renewed. In the system, this is managed by creating a new notification which will be "linked" to the previous one.
The renewal process is detailed in Article 17 of [DIR.2001/18].

To start the renewal process, the user may click on **Start Renewal process** button which becomes available for notifications in "Released" status.

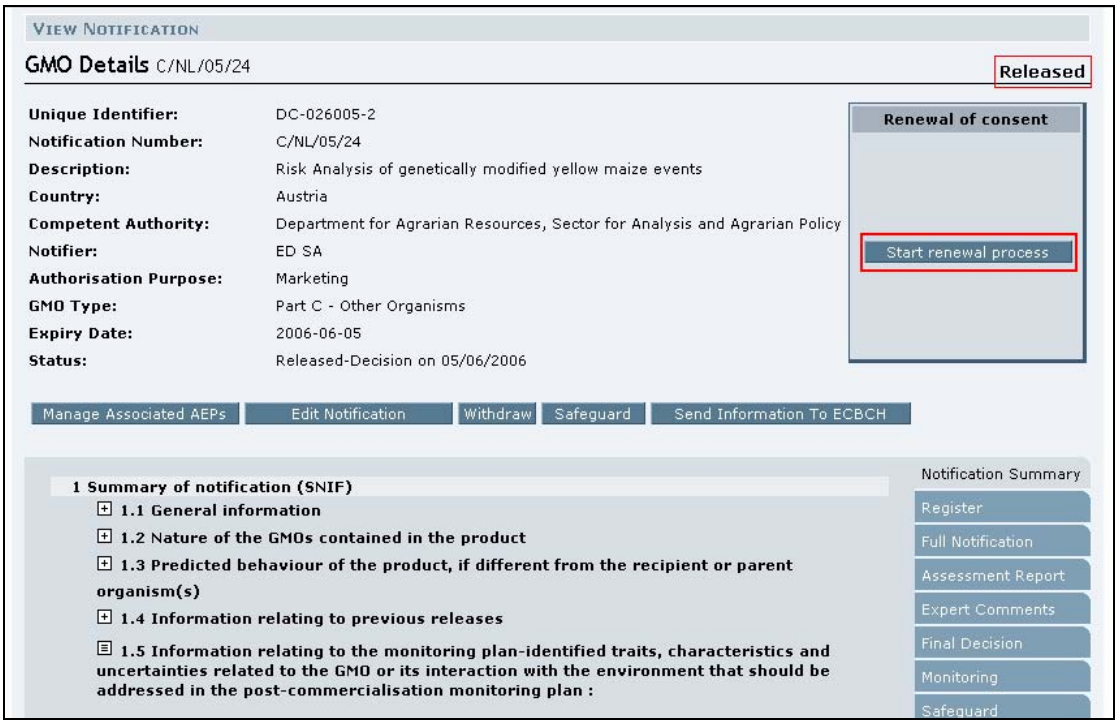


Figure 97: Start renewal process

The "Old" notification remains in Released status, whilst the new notification can be visualised by clicking on the link in the **Renewal of Consent** section of view notification page, shown in the figure below.

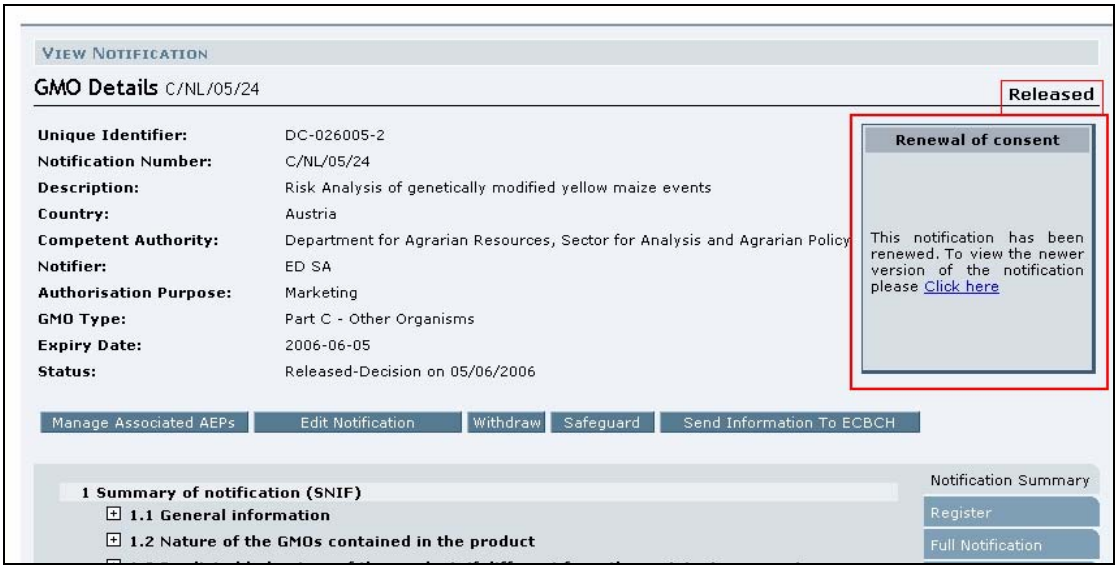


Figure 98: "Old" notification

The user may view the "Old notification" when visualising the new notification by clicking on the appropriate link in the section **Renewal of Consent**.

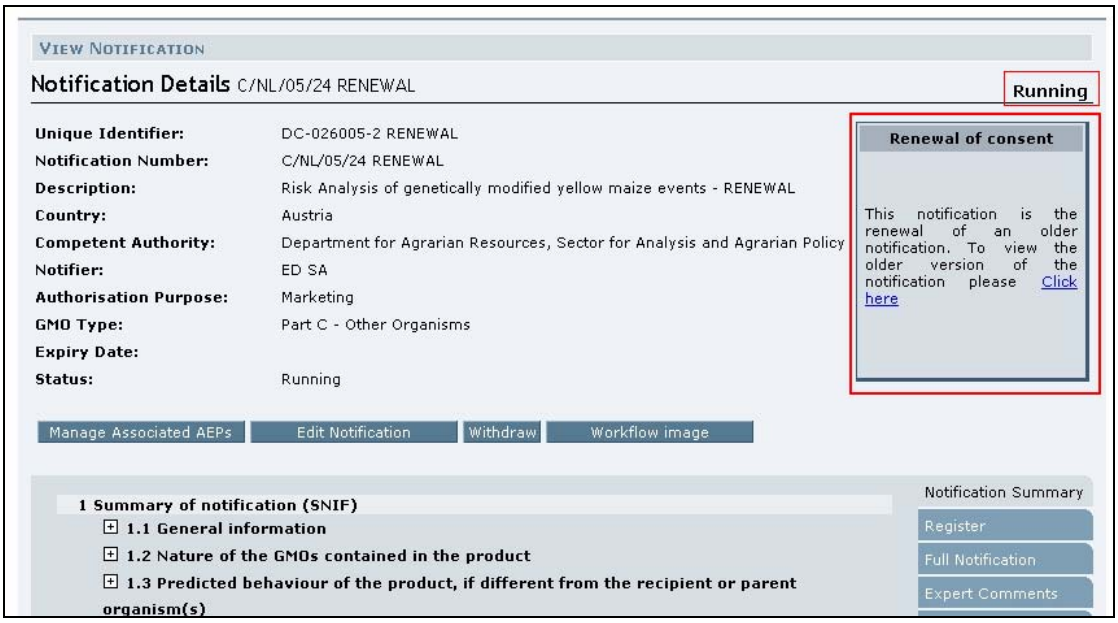


Figure 99: "Renewal" notification

The process followed in the new notification is similar to a simplified Part C process, as detailed in[DIR.2001/18]. Once the renewal of consent is granted for a notification, the "old notification" status is set to Expired, while the "new notification" status is set to Released.

If a Part C notification is not renewed and its expiry date is reached, then the status of the notification will be automatically changed from Released to Expired.

6. Scenarios Examples

The following sections provide examples of scenarios that illustrate how Part B and Part C Notification procedure can be carried out. The procedures are followed showing how users in different roles perform actions during the process and how these actions are triggered by events that occur as the process evolves.

6.1. Part B Notification

This section provides the description of the scenario for [SNIF.PARTB].

6.1.1. Actions invoked in the Procedure and roles involved

The procedure of a [SNIF.PARTB] is divided in different steps. The following schema is a step-by-step representation of this procedure and each step will be explained in detail in next chapter.

Steps	Action	GMOREGEX User invoked
1	Login as LCA User[5]	LCA User
2	Select "Create Notification" in "GMO Experimental Release (Part B)"	LCA User
3	Choose the desired workflow procedure for the notification	LCA User
4	Fill mandatory fields about the notification details	LCA User
5	Choose the Notifier or create a new Notifier for the notification	LCA User
6	Fill Notification pages (according to the selected notification type in Step 3, the Notification pages may be slightly different)	LCA User
7	Save the notification as Draft or Submit the notification	LCA User
8	After submitting the notification, the user is driven to the homepage	LCA User
9	Wait for the system to update the database	LCA User
10	Reload the homepage to see in the "Tasks" section that a new action has been added. The LCA user will also receive a e-mail in which the new task is described	LCA User
11	Select the "Submit SNIF" link in the "Task" area in order to start the [SNIF.PARTB] procedure	LCA User
12	After following SUBMIT SNIF link, the LCA User will be lead to "View Notification Details" page., here press the "Submit SNIF" button	LCA User

[5] Although this is not the terminology currently used for Part B procedures, we have labeled the CA that manages the [SNIF.PARTB] as "LCA" in order to distinguish its role from the role of the CA in the other Member States.

13	Confirm sending the SNIF to the Commission. After this submission, the LCA User has to wait because the next step is to be performed by the Commission User.	LCA User
14	The Commission User receives an e-mail in which she/he is informed that he has a new task to accomplish. Log in the system and check the “Task” area in the homepage.	Commission User
15	Click on “Publish SNIF” to make the SNIF available to all CAs	Commission User
16	After this operation, the application will send an e-mail to all CA informing that a new task has been set in their homepage “Tasks” section	Application
17	The application will now wait until the defined time to submit comments is overdue. Close to timeout, the application will send an e-mail as a reminder that a task is close to timeout.	Application
18	Other CA Users, after login, will be able to see in their homepage “Task” section that a new task has been added by the application	CA User
19	Following the link, the CA User will be able to send Comments and/or request the Full Dossier	CA User
20	If the CA User send comments or request the full dossier, the application will send an e-mail to all invoked user	Application
21	After going again to the homepage, the LCA User will see, if any, all Comments sent by the other CA	LCA User
22	The application will wait for the ending of the defined period for this task. When the timeline approach, the application will send reminder e-mail	Application
23	At the end of the time defined for this task, the LCA will be able to upload the Final Decision	LCA User

Table 4: Part B notification procedure – actions and users

6.1.2. Action description

The user logs in the application providing valid username and password.

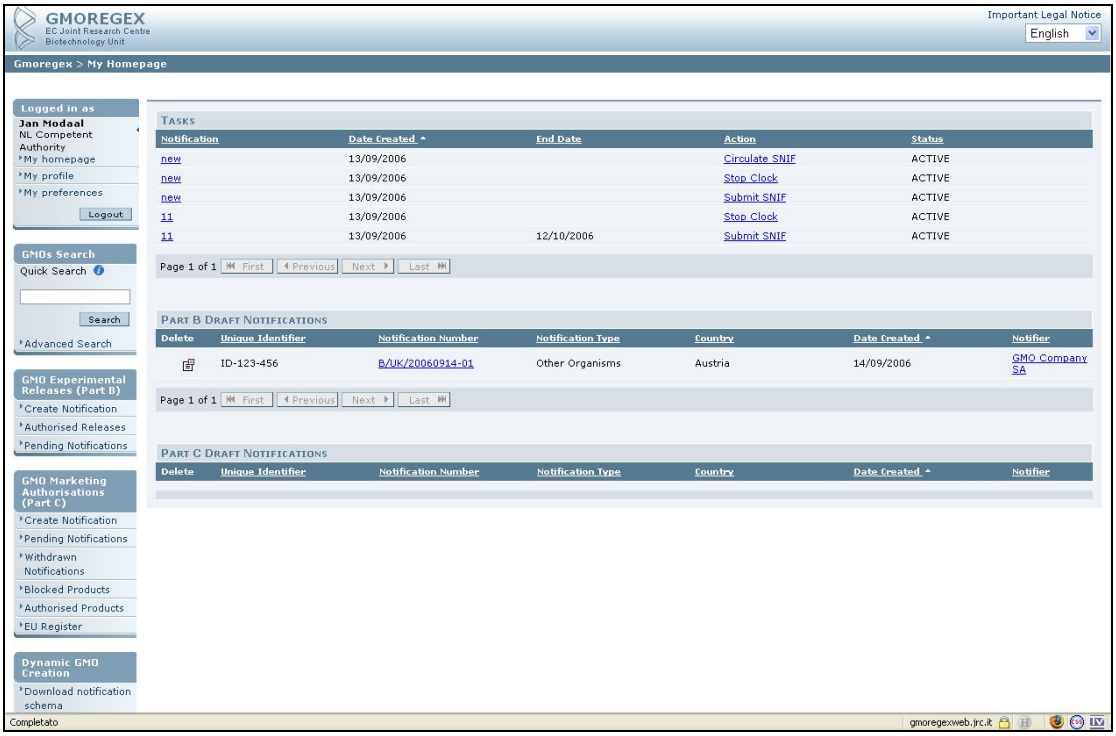


Figure 100: homepage with active tasks

After successful login, the user must click on the ***"Create Notification"*** link in **"GMO Experimental Release (Part B)"** section in left menu.

Figure 101: Link to select to start a Part B Notification procedure

After this action, the main part of the page will change. In this new part of the application, the LCA User will be asked to define the type of notification she/he is going to create, and the type of workflow procedure desired (i.e. with or without the workflow).

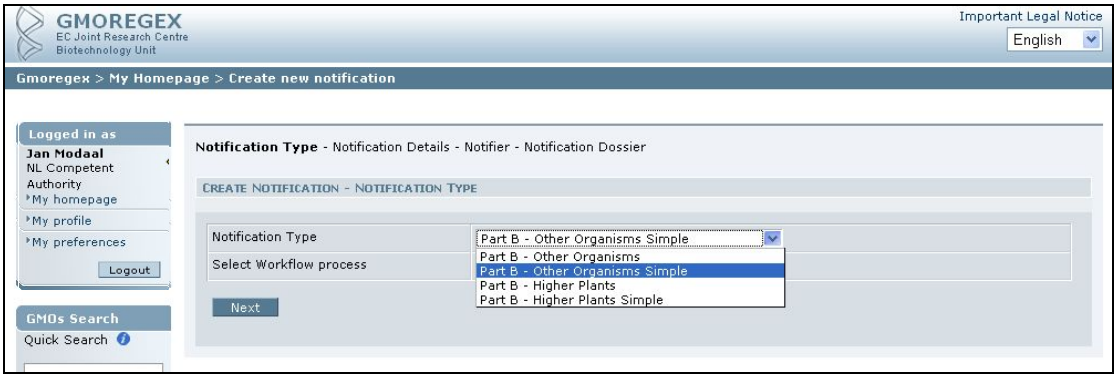


Figure 102 – Part B Notification Type Selection Option

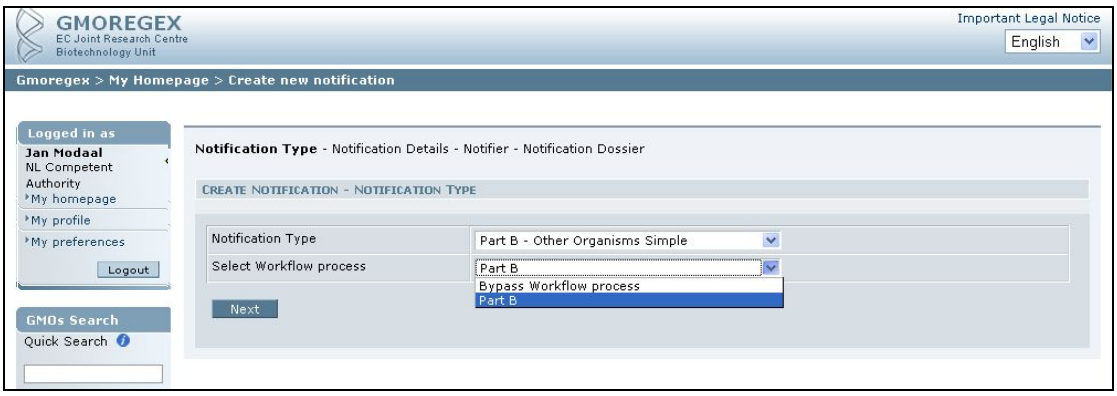


Figure 103 - Part B Select Workflow Procedure Option

After defining this information, the LCA User has to press the ***next*** button in order to proceeds to next step.

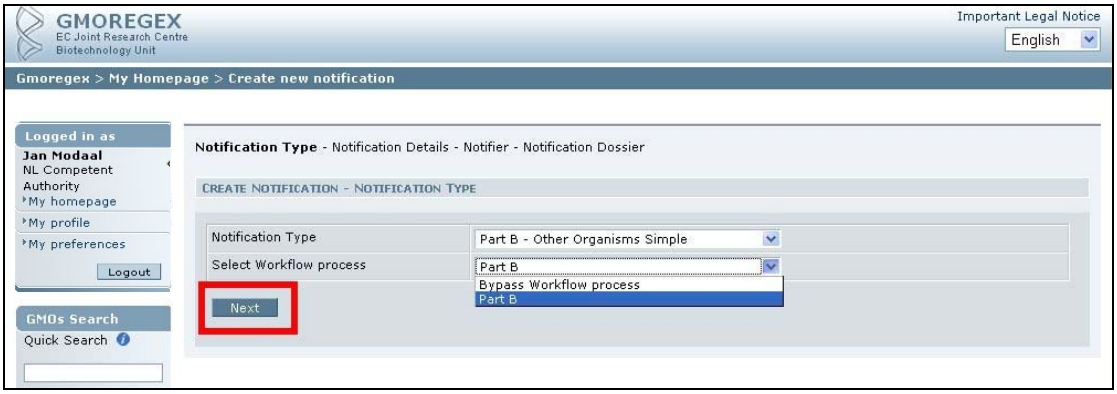


Figure 104 - Proceed to Notification information

The following step concerns the basic information about the Notification itself.

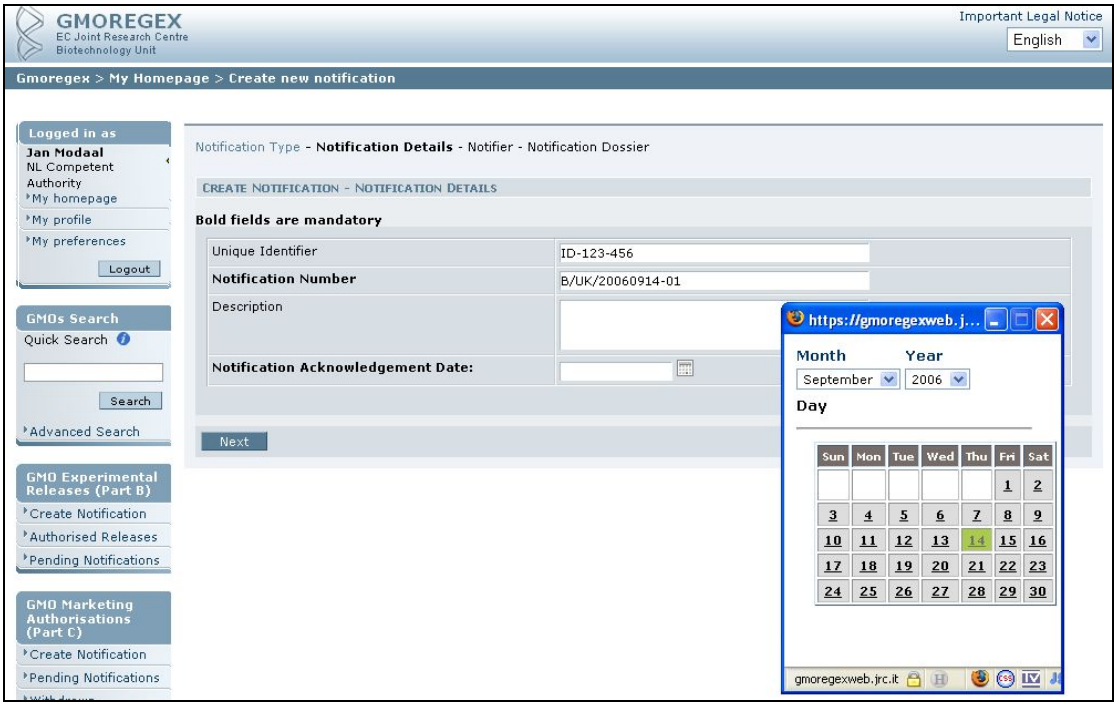


Figure 105 - Part B notification Details page

Here the LCA User can add information about the notification she/he is creating. Please notice that some information is mandatory. Mandatory fields are marked in bold.
After this step has been completed and the "Next" button has been clicked, the LCA User has to fill fields about the notifier.
Also in this case, mandatory fields are marked in bold.

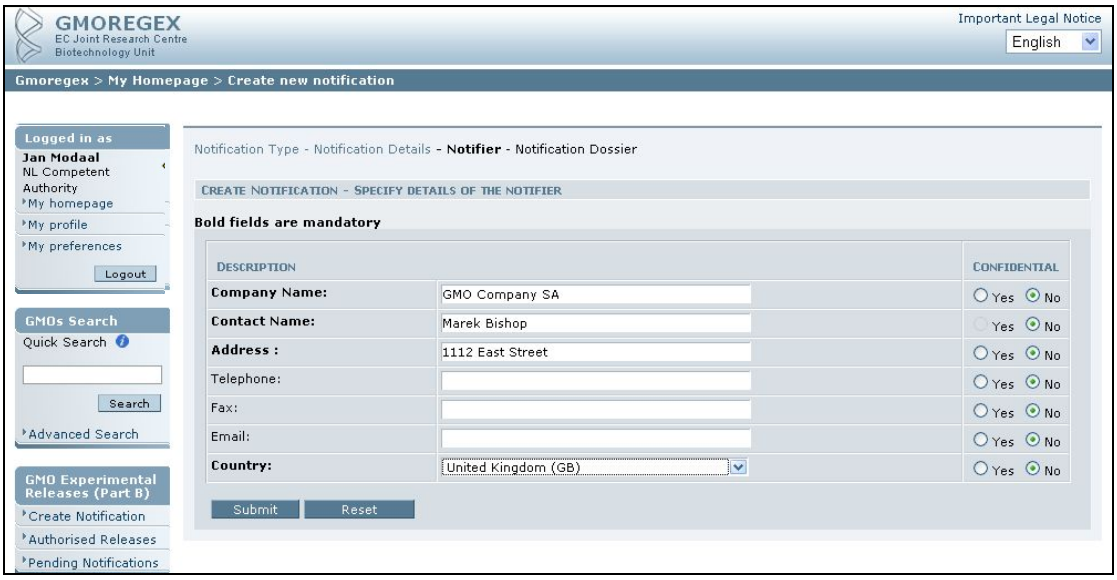


Figure 106 - Notifier Details Page

To proceed further, the LCA User has to click the "**Submit**" button, after filling in all mandatory fields.
If a similar Notifier exists in the application, the LCA User will be taken to a page in which she/he can choose one of the existing Notifier or create a new one.

Figure 107 - Choose existing Notifier or create a new one

In this example, the database already contains data about a Notifier that has similar information. The application asks the LCA User if she/he wants to create a new Notifier, and if so, the ***"Create New Notifier"*** button, highlighted in figure and marked with number 1, has to be clicked.
Otherwise, if the LCA User wants to use an existing Notifier, she/he will need to select the contact name of the Notifier, highlighted and marked with number 2 in the figure.
If the LCA User selects an existing Notifier, the application will show the Notifier data, so that the LCA User will be able to modify the data, if necessary. In case of modification of some data, these will be saved for further use.

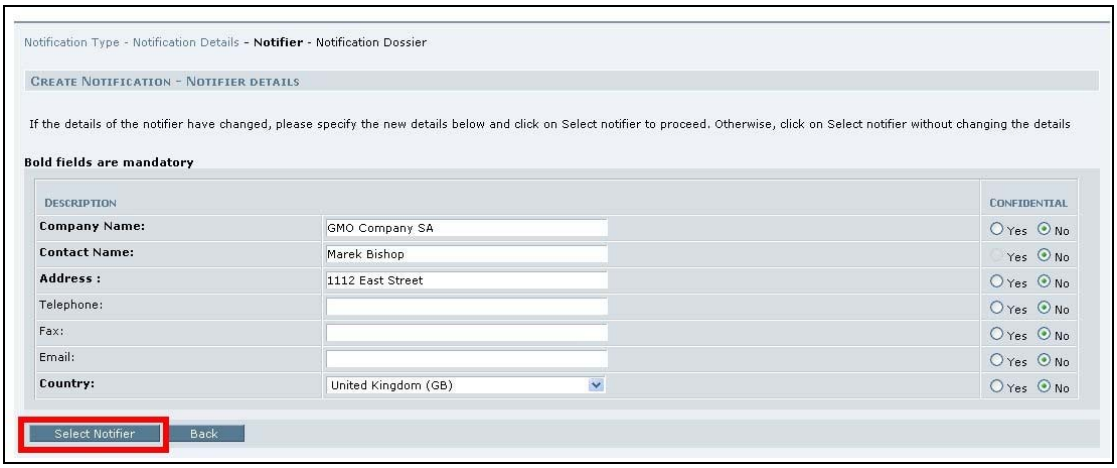


Figure 108 - Confirmation of Notifier

After controlling that the data shown by the application are correct, the user can proceed by clicking on the ***"Select Notifier"*** button, highlighted in figure.
The next step is filling the **Full Dossier** and **SNIF** with required information.
Remember that the fields that the LCA User will see depend on the type of Notification that has been selected at the very beginning of the procedure.
In this example, we are using a **"Part B - Other Plant Simple"** Notification Procedure. That means that the fields shown in this example are those defined for this particular procedure.

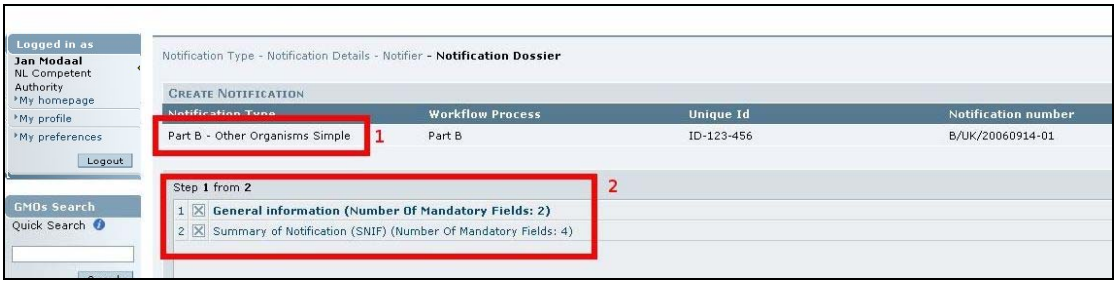


Figure 109 - Step for a Specific Part B Notification Procedure

The Notification Procedure we are following is also visible in the **"Create New Notification"** page, as shown in figure, marked with number 1.
The steps required for this procedure are highlighted in the figure above, marked by number 2. In all cases, the number or mandatory fields to be filled to succeed in creating the procedure are marked in bold. As you can see in figure, the Step in which we are, **"General information (Number of Mandatory Fields: 2)"**, is marked in bold and defines also the number of mandatory fields. These fields are marked in bold, and in the next figure, they are identified by number 1 and 2

Figure 110 - Mandatory fields

To proceed to the next step, the LCA User can operate in two different ways:

1. Select the following step in the "Step" section of the page
2. Select the Next button on the lower right angle of the page

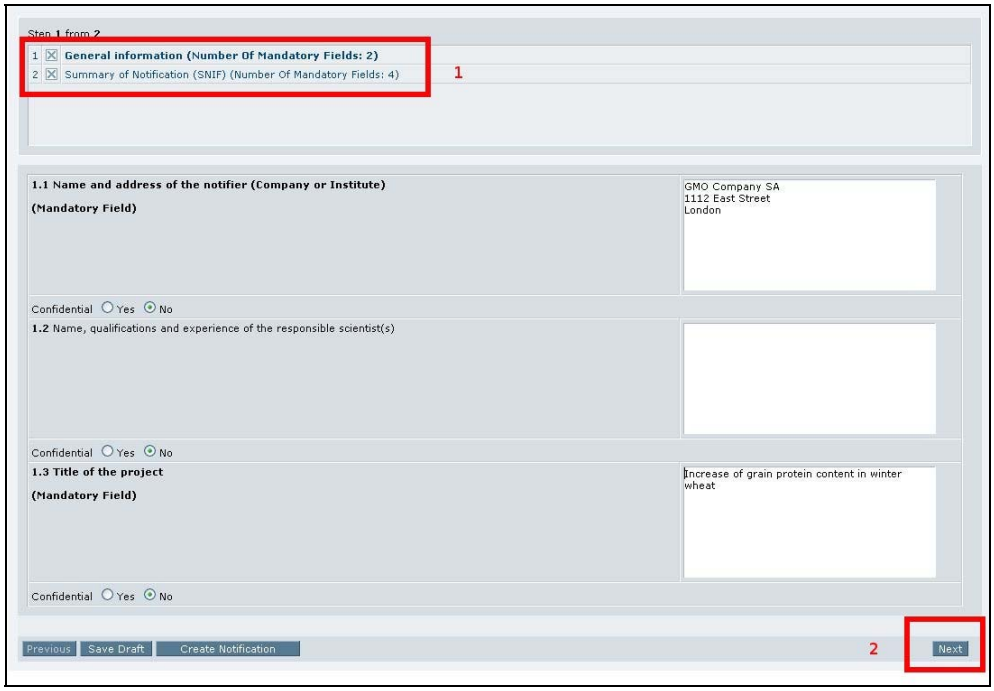


Figure 111 - Steps completed and Next button disabled

The LCA User has to fill in all mandatory fields in all steps in which the Notification Procedure he have selected is divided.
When the latest step is reached, the ***"Next"*** button is disabled and the ***"Create Notification"*** and the ***"Save Draft"*** button are enabled identifying the next action that can be executed.

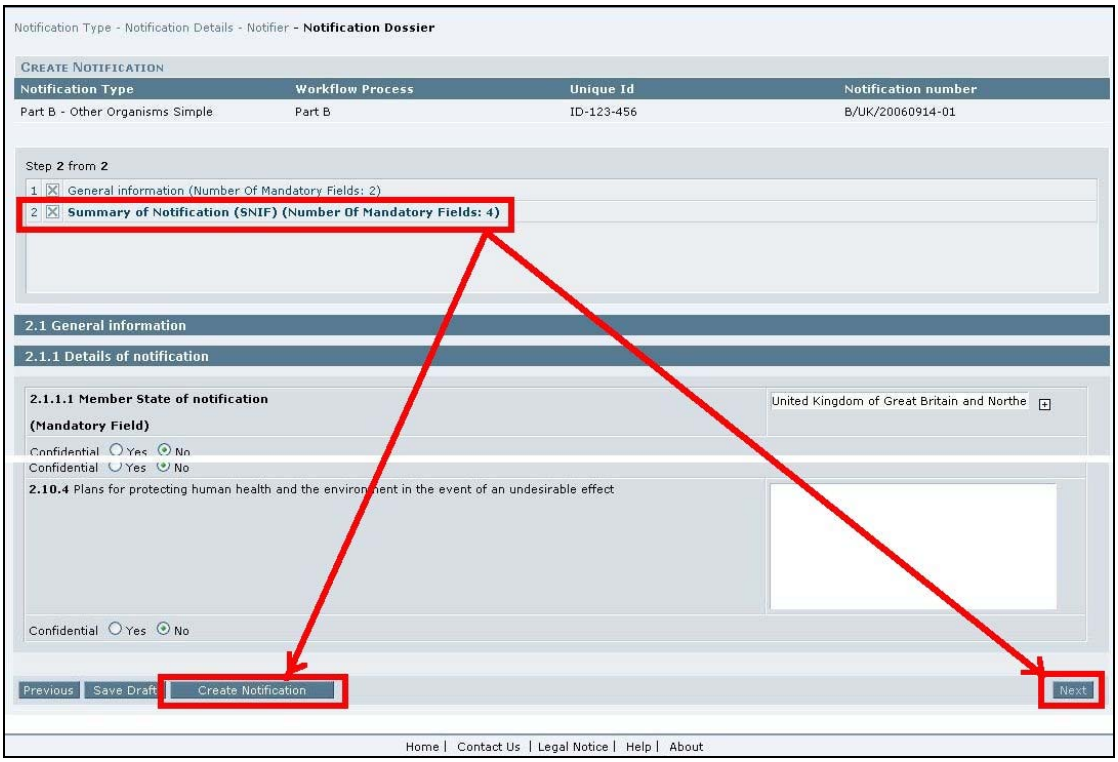


Figure 112 - Create Notification and next button

If the LCA User presses the ***"Save Draft"*** button, the procedure will save the data the "Draft" area of the home page. The LCA User will be able to call back this procedure at a later stage and to complete it.
Otherwise, if the ***"Submit Notification"*** button is clicked, the LCA User will be taken to another page in which a summary of the notification just completed will be displayed.
This is the last chance for the LCA User to decide if the Notification Procedure has to start or if the notification is still in a Draft status.

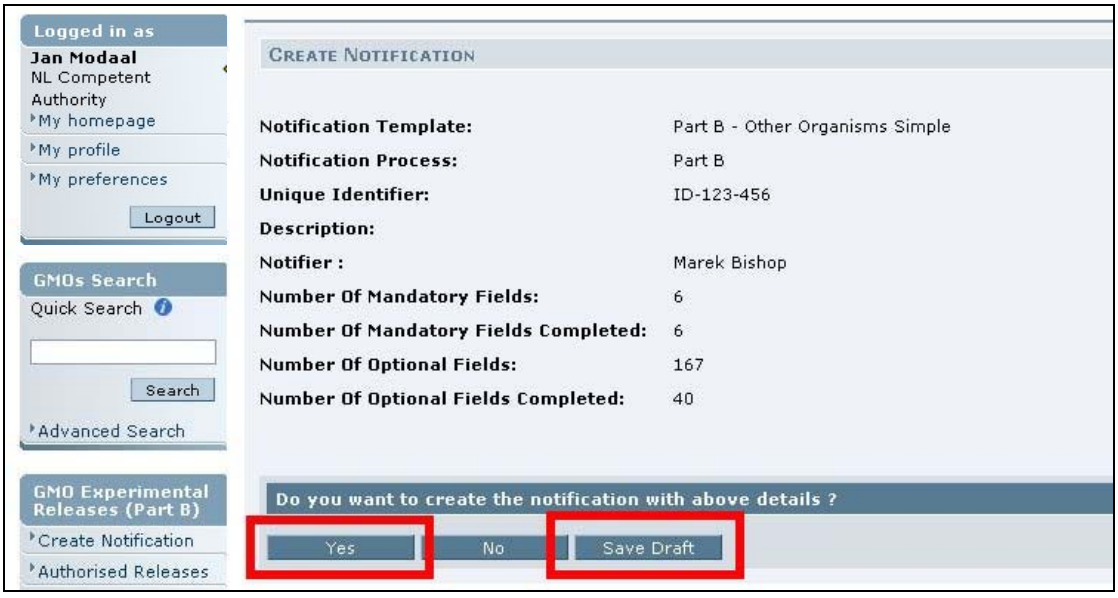


Figure 113 - Start the Create Notification procedure or Save Draft option

Clicking the ***"Yes"*** button, the LCA User starts the Notification procedure. Once this is done, the **"Homepage"** is displayed again. The application needs five or ten minutes to activate the procedure. The LCA User should refresh the home page from time to time, clicking on the **"My homepage"** link.

Figure 114 - My homepage link in left Menu

In order to display the Homepage, the "reload" button of the browser ***should not*** be used, because it does not start the necessary processes to reload the correct page.
The **"My homepage"** button should be clicked instead in order to have the application display the correct status.

After reloading the system by clicking on the **"My homepage"** link, the application will show the new tasks related to the Notification just created, as shown in the next figure.
Two new tasks have been added for the LCA User:

1. Stop Clock
2. Submit SNIF

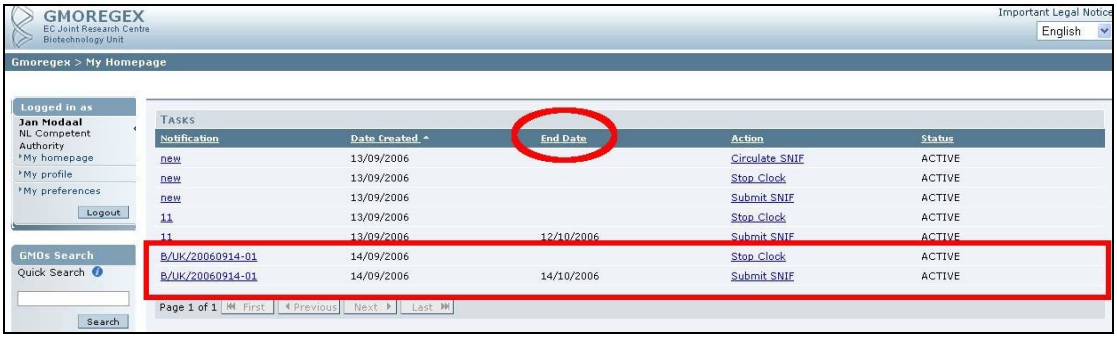


Figure 115 - Task in the LCA User Homepage and timeline

The **"Submit SNIF"** procedure has an end date, as defined in [DIR.2001/18]. So the LCA User has 30 days to complete this task.
If the LCA User decides that the SNIF can be submitted to the Commission, she/he can select the **"Submit SNIF"** link. This will take the user to a **"Notification Summary"** page, in which the **"Submit SNIF"** button is present.

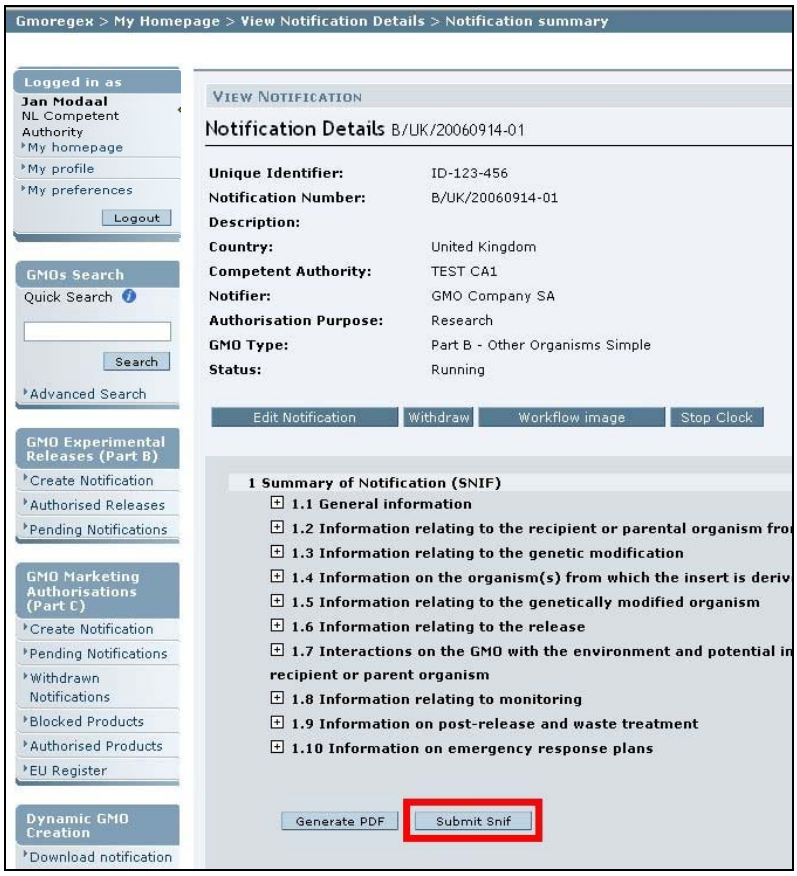


Figure 116 - Submit SNIF button

If pressed, this button will take to another page, where the application shows a summary of the Notification and asks the LCA User confirmation to send the SNIF to the Commission, as highlighted in the figure.

Figure 117 - Submit SNIF to Commission

Please note that the status of the notification can be always seen in the upper right corner of the page (highlighted in the figure). After submitting the SNIF to the Commission, a confirmation page appears. The LCA User Home Page, will now show only one task that can be done on the previously created Notification.

Figure 118 - Tasks available after submitting SNIF

Selecting the notification Number, the LCA User will be taken to the **"View Notification"** page. In this page, clicking on the **"Workflow"** button, the LCA User will be able to see where in the workflow is the Notification procedure.

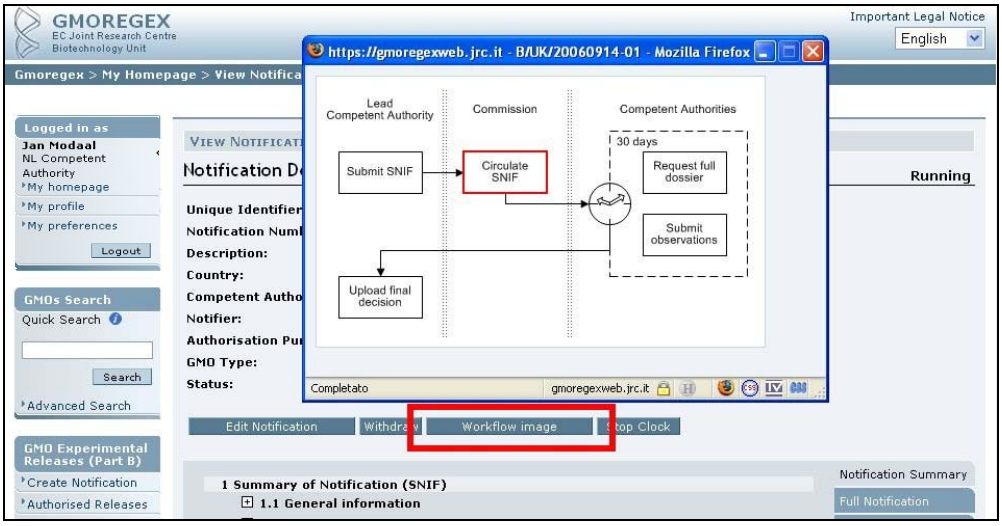
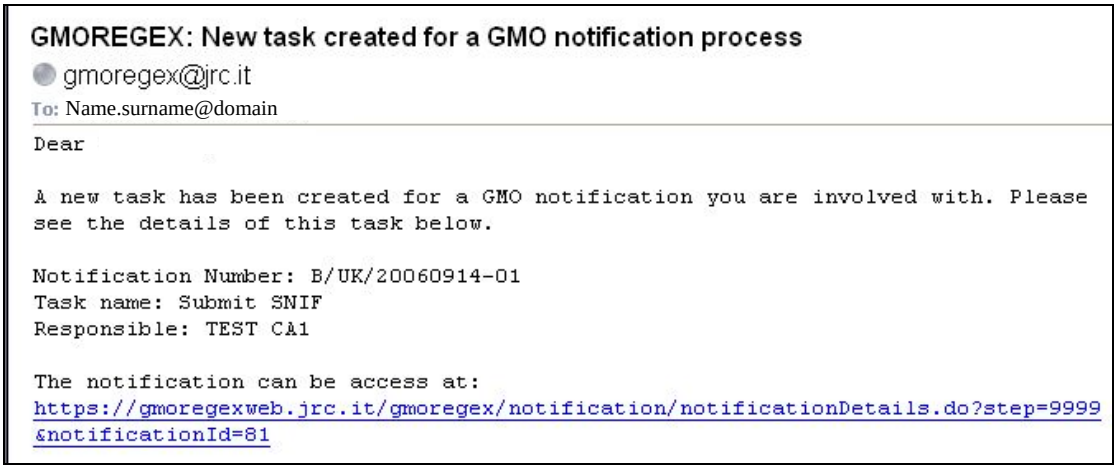


Figure 119 - Workflow button and workflow example

In this case, the next step is a task for the Commission User, as can be seen in the figure. During this operation, e-mails are sent by the application to other CAs and to Commission User.



GMOREGEX: New task created for a GMO notification process

gmoregex@jrc.it

To: Name.surname@domain

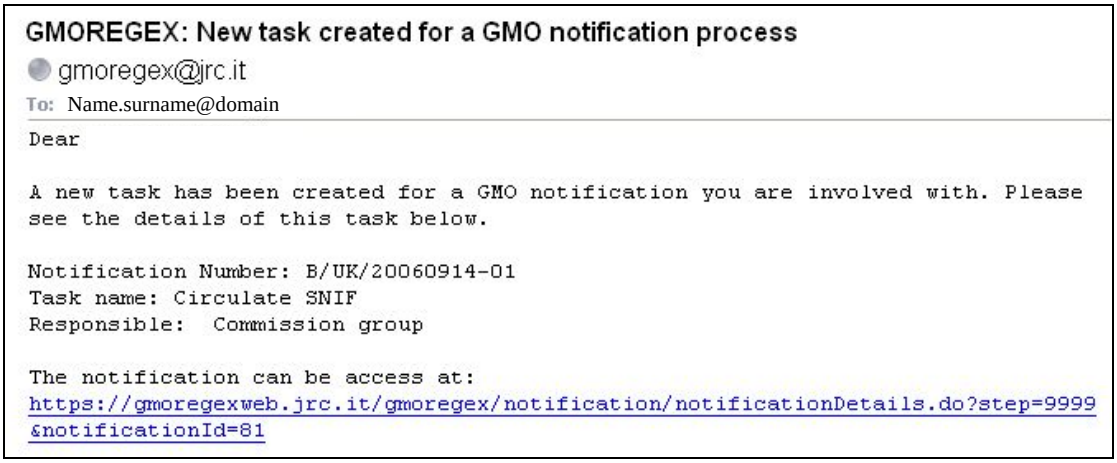
Dear

A new task has been created for a GMO notification you are involved with. Please see the details of this task below.

Notification Number: B/UK/20060914-01
Task name: Submit SNIF
Responsible: TEST CA1

The notification can be access at:
https://gmoregexweb.jrc.it/gmoregex/notification/notificationDetails.do?step=9999&notificationId=81

Figure 120 - Example of task notification e-mail



GMOREGEX: New task created for a GMO notification process

gmoregex@jrc.it

To: Name.surname@domain

Dear

A new task has been created for a GMO notification you are involved with. Please see the details of this task below.

Notification Number: B/UK/20060914-01
Task name: Circulate SNIF
Responsible: Commission group

The notification can be access at:
https://gmoregexweb.jrc.it/gmoregex/notification/notificationDetails.do?step=9999&notificationId=81

Figure 121 - Example of task notification e-mail

Emails indicate which is the action that has to be performed and who is the responsible actor for this action.
Now the Commission User has to login to perform the next action in the process.

Figure 122 - Commission User Task section example

After logging in, the Commission User will see his/her homepage. In the **"Task"** part of the page the actions to be performed are displayed.
In this example, the Commission User has only one task to perform, which is related to the Notification created before. This action has a timeline, as can be seen in the Figure.
Following the **"Circulate SNIF"** link, that describes the action to be performed, the Commission User will be taken to the **"Notification Summary"** page.

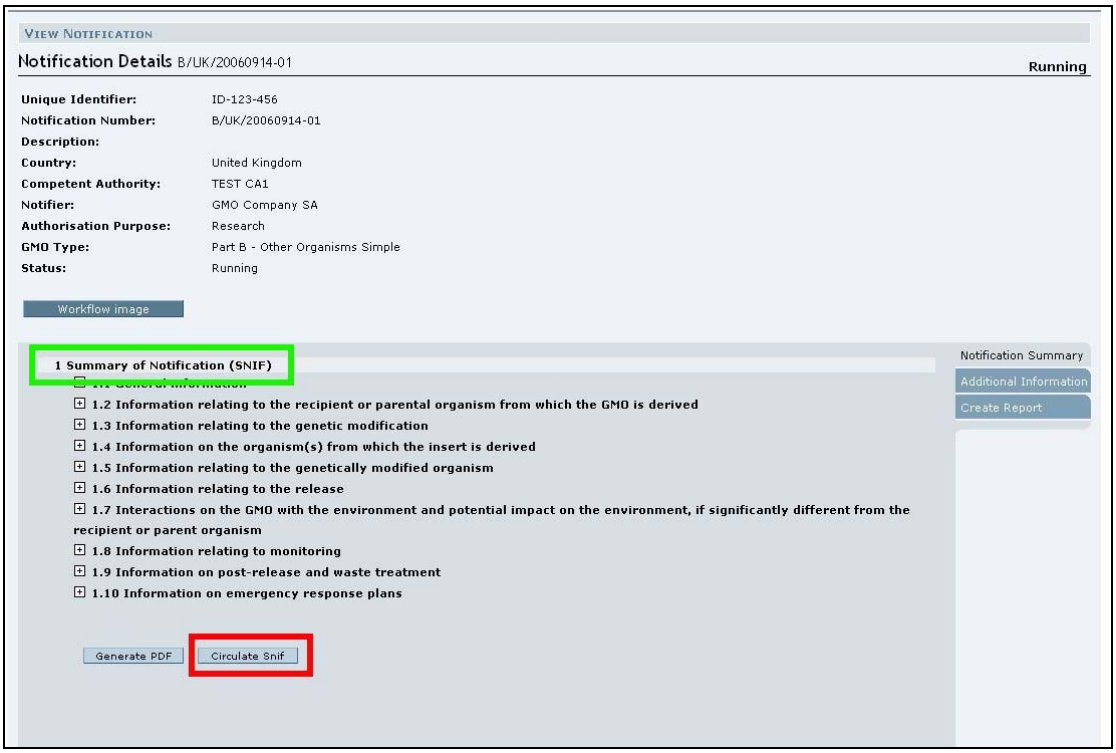


Figure 123 - Commission User has to circulate SNIF

In this page, the Commission User will be able to see the SNIF (highlighted in green) and to **"Circulate SNIF"** among all the CA registered to the application.
Clicking on the **"Circulate SNIF"** button, the Commission User will be taken to the **"Circulate SNIF"** page.

Figure 124 - Confirmation request to Circulate SNIF

Clicking on the **"Yes"** button, the Commission User will circulate the SNIF to all CAs for comments.
Also in this case, a confirmation page will appear, and e-mails will be sent from the application to all the CA users registered in the application.

Figure 125 - Confirmation that SNIF has been successfully circulated

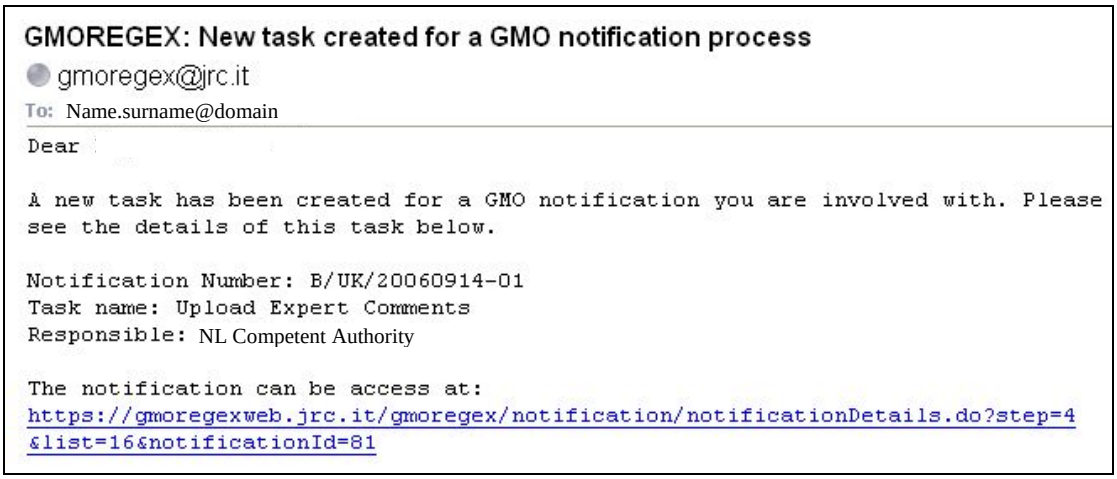
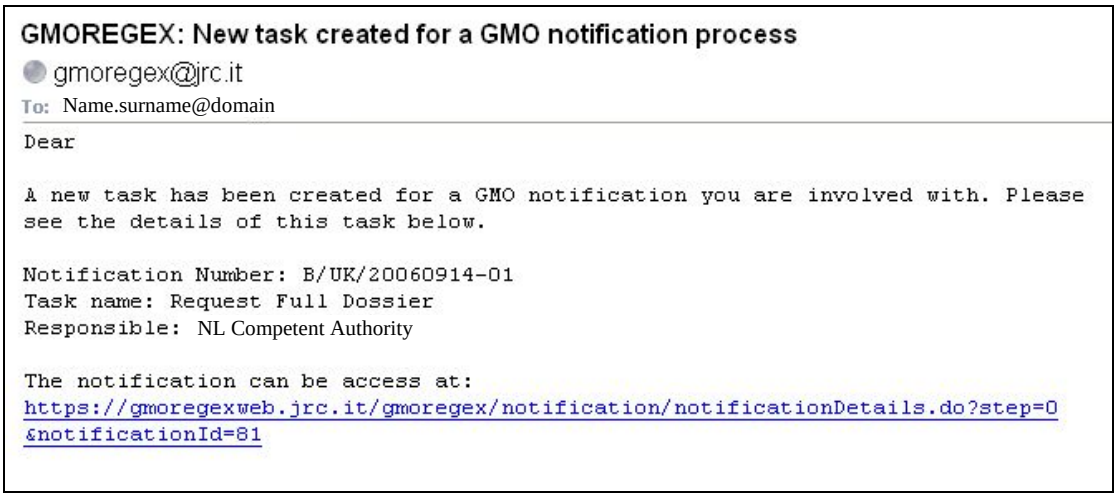


Figure 126 - Task notidication e-mail: Upload Comments


GMOREGEX: New task created for a GMO notification process
gmoregex@jrc.it
To: Name.surname@domain

Dear

A new task has been created for a GMO notification you are involved with. Please see the details of this task below.

Notification Number: B/UK/20060914-01
Task name: Request Full Dossier
Responsible: NL Competent Authority

The notification can be access at:
https://gmoregexweb.jrc.it/gmoregex/notification/notificationDetails.do?step=0&notificationId=81

Figure 127 - Task notification e-mail: Request Full Dossier

In the next step, all actors are involved. All the CAs can Upload Comments to the Notification and can also Request the full dossier.
Also the Commission User homepage will change not showing the task to circulate the SNIF.

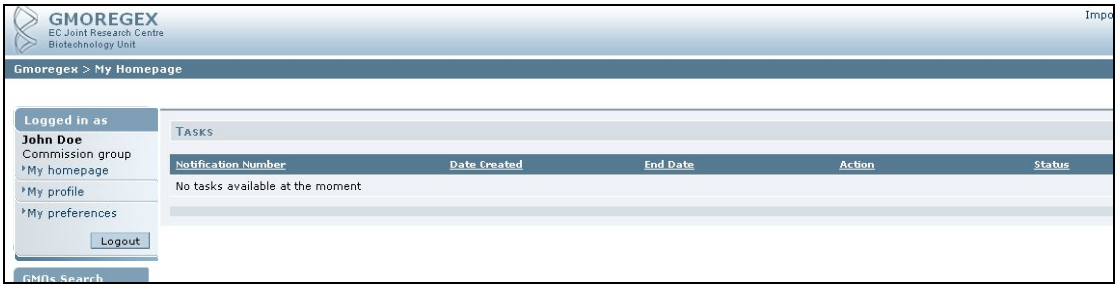


Figure 128 - Commission User has no other task to accomplish

The actions related to the Notification are no longer available.
On the other hand, new tasks have been added to CA users homepages.

Figure 129 - No-LCA User available tasks

In the homepage of a CA user which is not the LCA, two new tasks will be added, as specified in the mail that the system sent before.
The CA User may

1. Request the Full Dossier
2. Submit Experts Comments to the notification

If the CA User selects the **"Request Full Dossier"** link, she/he will be taken to the **"Full Notification"** page, in which the complete SNIF can be seen (highlighted in green in the

figure) and the ***Full Dossier*** can be requested to the LCA using the related button (highlighted in red in the figure).

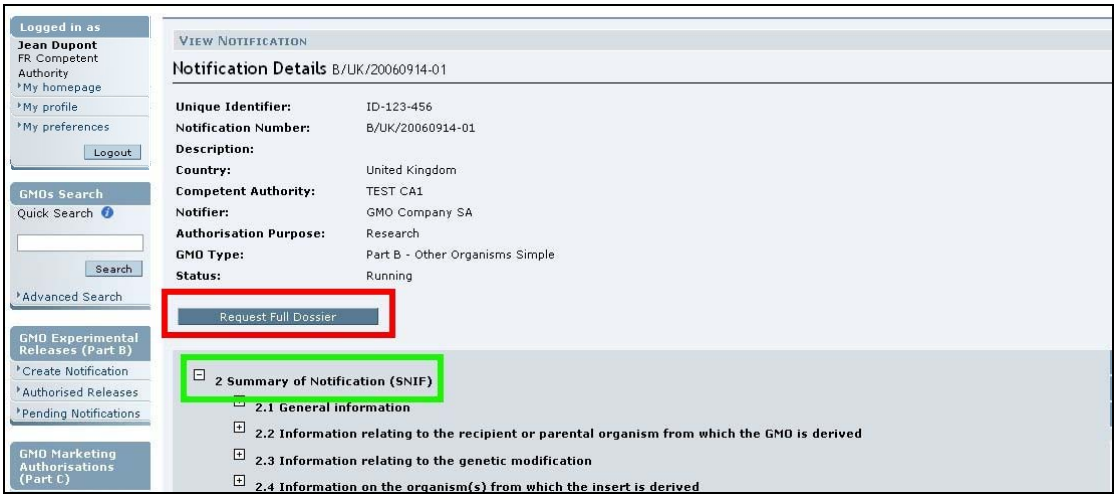


Figure 130 - No-LCA User can request Full Dossier and see the SNIF

If the **"Request Full Dossier"** button is selected, an e-mail will be sent to the LCA and to the Commission, specifying which CA asked for the Full Dossier.

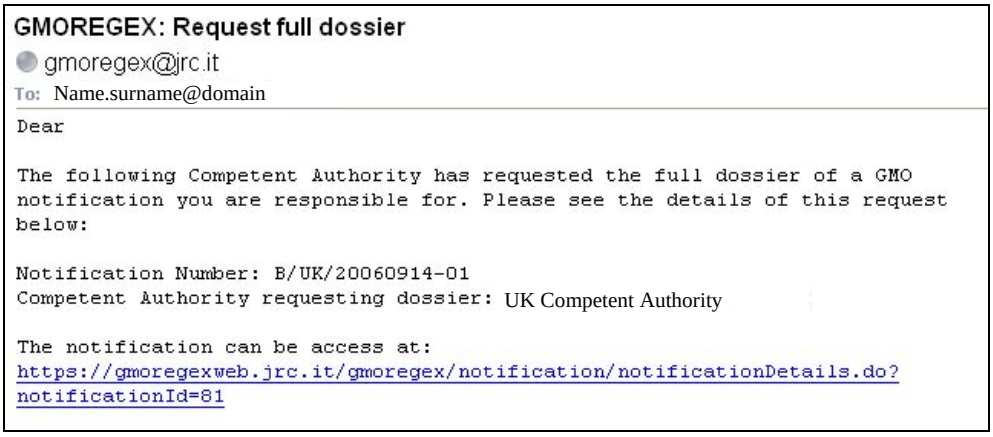


Figure 131 - LCA User receives a request for Full Dossier by another CA

A confirmation page will also been shown to confirm that the request was successfully completed.

Figure 132 - Confirmation screen after requesting a Full Dossier

The CA can also Upload Expert Comments. To perform this action, it is necessary to follow the link present in the CA homepage, as shown before for the "Request Full Dossier".

In this case, the CA User will be taken to a page in which it is possible to upload a document and/or to add a comment.

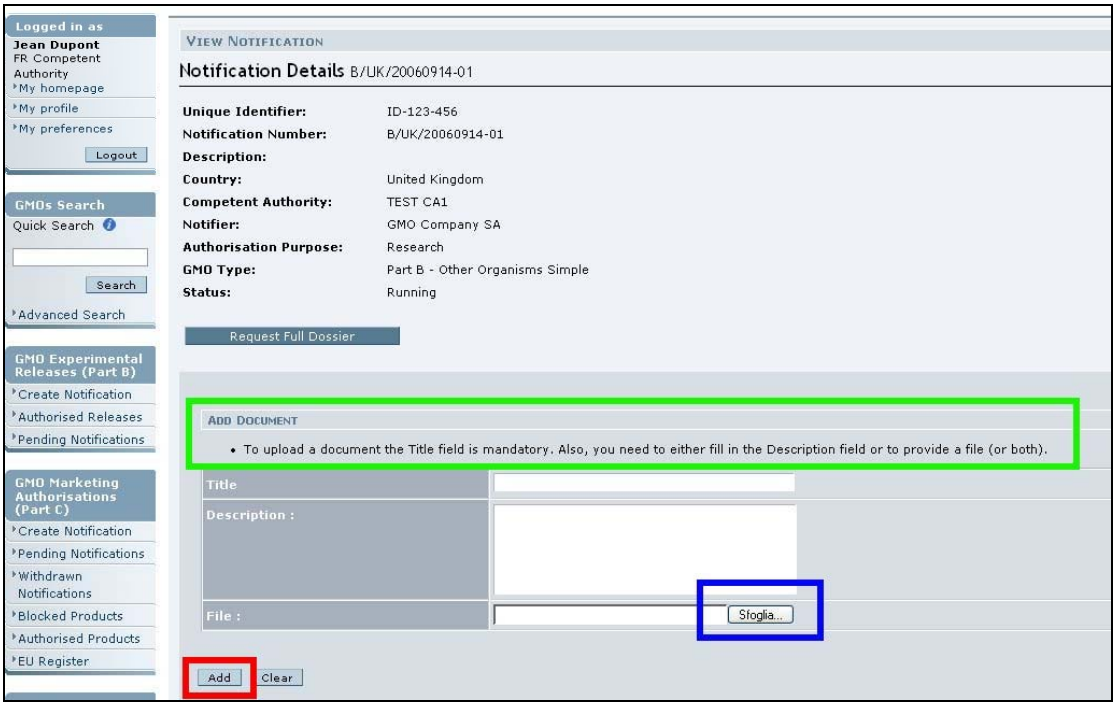


Figure 133 - Sending Expert Comments on a Notification

As specified in the instructions (highlighted in green in the figure) the CA User has to define the **"Title"** of the Expert Comment and has to fill in the "**Description Field"** and/or choose a File to upload, using the **"Choose"** button (highlighted in blue).
Only when at least two fields have been filled, the CA User can send this comment to the Commission, clicking the **"Add"** button.

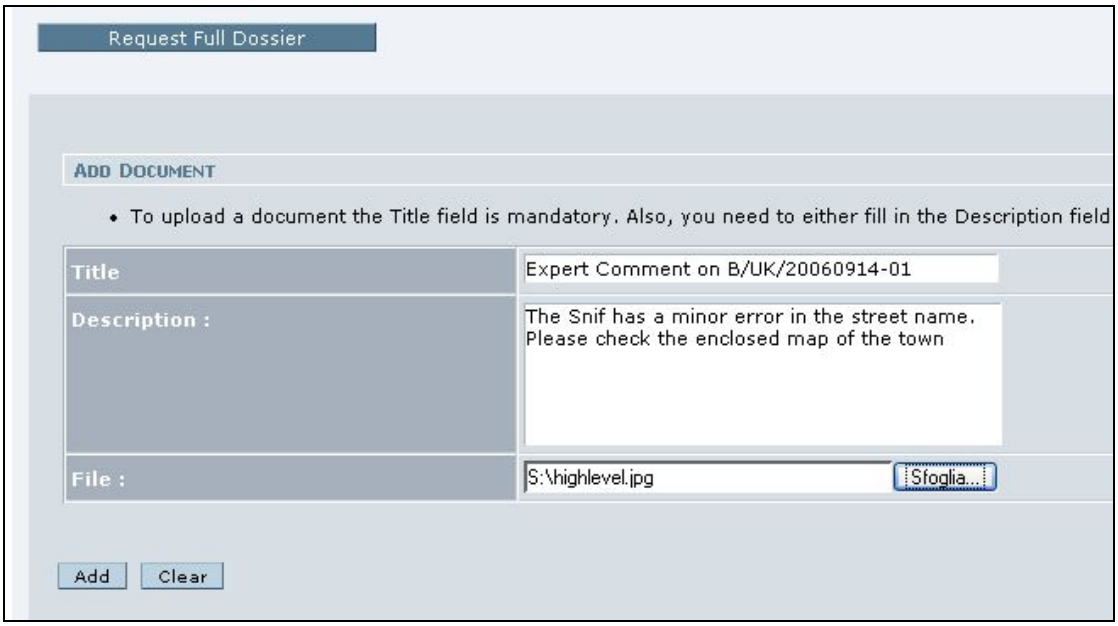


Figure 134 - Example of filled fields while Sending Comments

A confirmation page will appear, and a confirmation e-mail will be sent by the application.

Figure 135 - Comments sent to the Commission

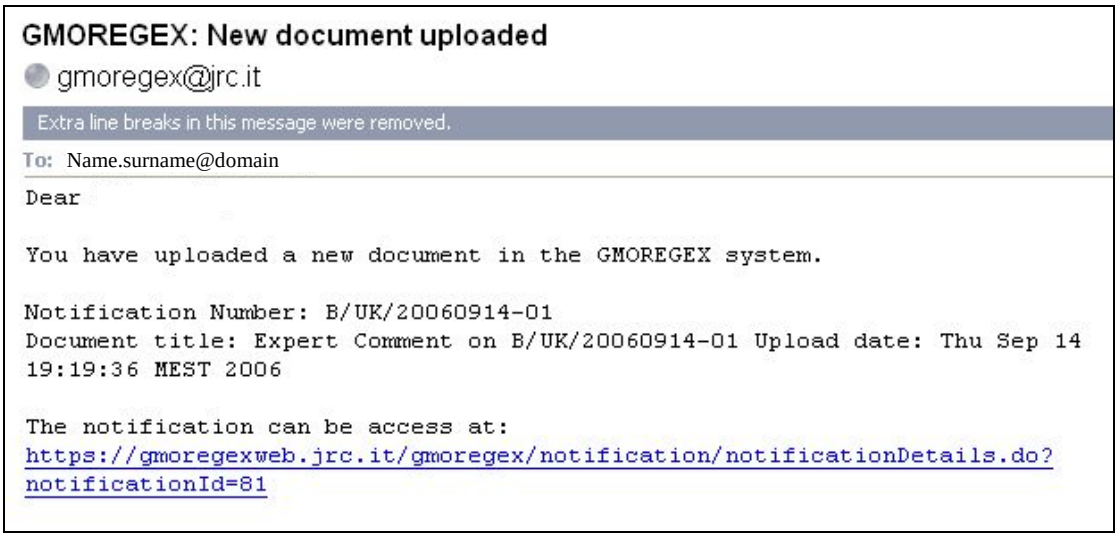


Figure 136 - Confirmation via e-mail of the comments upload

The workflow will wait for 30 days for requests and comments, as can be seen in the diagram below.

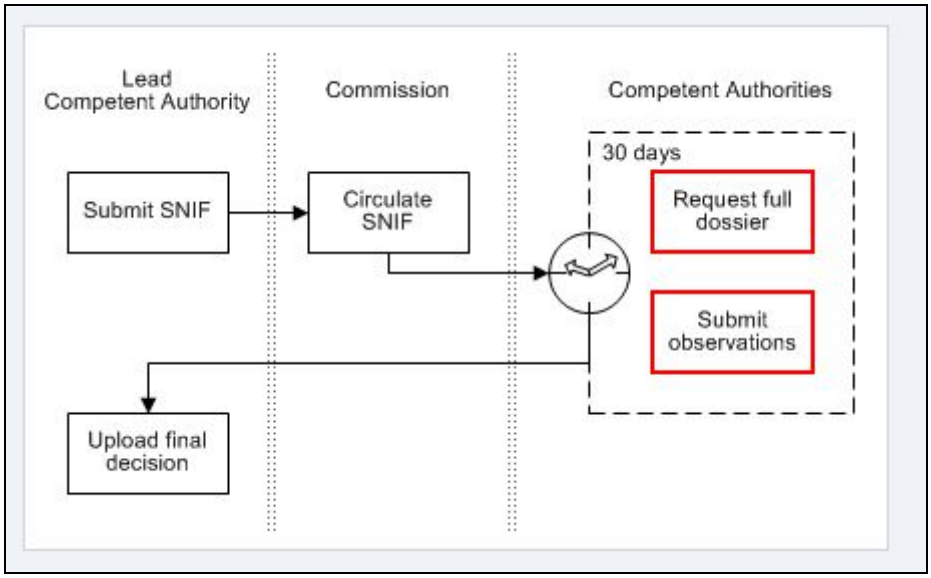


Figure 137 - Next step in the notification

Before this period expires, the application will send a reminder to all actors of the procedure, i.e. CA Users and Commission User.

The next action has to be performed by the LCA User that has to upload the final decision into the system.

Figure 138 - LCA has to Upload Final Decision

Following the highlighted link in the homepage, the LCA User will see the **"Upload final decision"** page, in which she/he will be able to send the information about the final decision.
The figure shows the mandatory fields highlighted in green.
A file for the final decision can be uploaded using the **"Choose"** button. Please notice that the default value for the decision is **"Reject",** so please pay attention to this field before submitting the decision using the highlighted **"Add"** button.
A confirmation page, with a summary of the previously inserted data, will be shown for final confirmation.

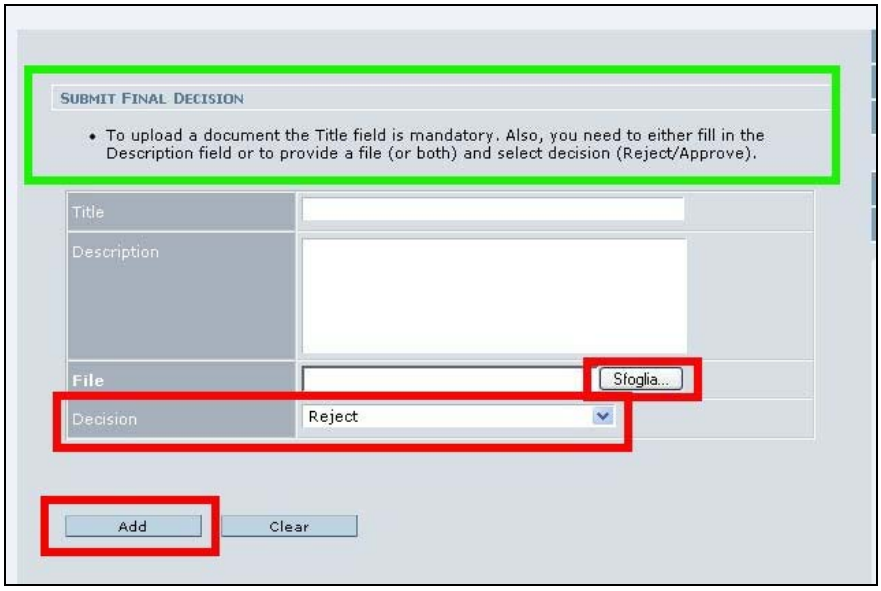


Figure 139 - Upload Final Decision

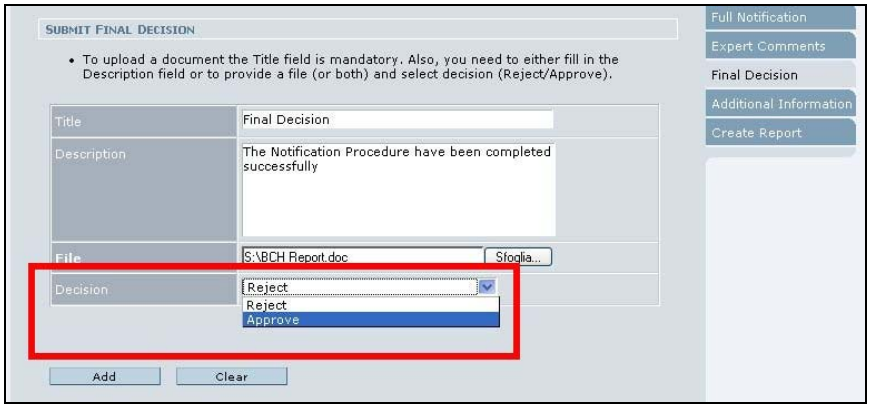


Figure 140 - Pay attention on "Decision" default value

Figure 141 - Confirmation of Final Decision

Once this operation is completed, the newly completed notification will be visible also by non-authenticated users in the home page (if the decision is positive).
Otherwise, all users may perform a search and see that the notification have been completed and the release status.

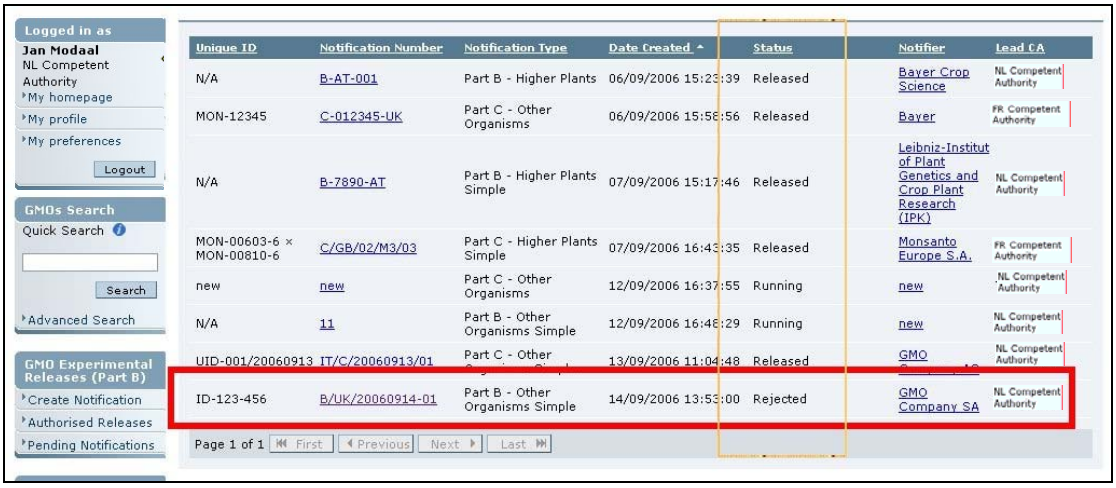


Figure 142 - Search result: notification status and basic information

6.2. Part C Notification

This section provides the description of the scenario for [SNIF.PARTC].

6.2.1. Action and user invoked in this Procedure

The procedure of [SNIF.PARTC] is divided in different steps. The following schema is a representation of this procedure and each step will be explained in detail in next chapters.

Steps	Action	GMOREGEX User invoked
1	Login as LCA User	LCA User
2	Select "Create Notification" in "GMO Marketing Authorization (Part C)"	LCA User
3	Choose the desired workflow procedure for the notification	LCA User
4	Fill mandatory fields about the notification details	LCA User
5	Choose the Notifier or create a new Notifier for the notification	LCA User
6	Fill Notification pages (according to the selected notification type in Step 3, the Notification pages may be slightly different)	LCA User
7	Save the notification as Draft or submit the notification	LCA User
8	After submitting the notification, the user is driven to the homepage	LCA User
9	Wait for the system to upload the database.	LCA User
10	Reload the homepage to see in the "Tasks" section that a new action has been added. The LCA user will also receive a e-mail in which the new task is described	LCA User
11	Select the "Submit SNIF" link in the "Task" area in order to start the [SNIF.PARTC] procedure	LCA User
12	After following SUBMIT SNIF link, the LCA User will be lead to "View Notification Details" page., here press the "Submit SNIF" button	LCA User
13	Confirm sending the SNIF to the Commission. In the same page there is the "Circulate SNIF" button, used to circulate SNIF among the CAs.	LCA User
14	The LCA User Complete the procedure by submitting the Full Dossier (a new task appear in the "Task" area of his/her homepage)	LCA User
15	Following this link, the LCA User will be lead in a page in which the "Submit full Dossier" action can be performed. After this submission, the LCA User has to wait because the next step is to be performed by the Commission User.	LCA User
16	The Commission User receives an e-mail in which she/he is informed that he has a new task to execute. Log in the system and check the "Task" area in the homepage.	Commission User

17	Click on "Publish SNIF" to make the SNIF available to all CAs	Commission User
18	The Commission User receives an e-mail in which she/he is informed that he has a new task to accomplish. Log in the system and check the "Task" area in the homepage.	Commission User
19	Click on "Publish Full Dossier" to make the Full Dossier available to all CAs	Commission User
20	After this operation, the application will send an e-mail to all CAs advising that a new task has been set in their homepage "Task" section	Application
21	The application will now wait until the defined time to submit comments is overdue. Close to timeout, the application will send an e-mail as a reminder that a task is close to timeout.	Application
22	Public User may submit Comments to the published SNIF. Public Users will have to submit their own e-mail address. They will receive a "Transaction Number" to be authorized to submit a Comment	Public Users
23	The Application will send an e-mail to all Actors whenever a Public Comment has been submitted	Application
24	At the end of the time defined for this task, the Commission User receives an e-mail in which she/he is informed that he has a new task to accomplish. Log in the system and check the "Task" area in the homepage	Commission User
25	Click on "Submit Public Comments" to make the Public Comments available to all CAs	Commission User
26	The LCA User receives an e-mail in which she/he is informed that he has a new task to accomplish. Log in the system and check the "Task" area in the homepage.	LCA User
27	Click on "Upload AR" to upload the AR to the application Click on "Submit AR" to make the AR available to the Commission	LCA User
28	The Commission User receives an e-mail in which she/he is informed that he has a new task to accomplish. Log in the system and check the "Task" area in the homepage.	Commission User
29	Click on "Circulate Assessment Report" to make the AR available to all CAs	Commission User
30	Click on "Publish Assessment Report" to make the AR available to Public Users	Commission User
31	Public User may submit Comments to the published AR. Public Users will have to submit their own e-mail address. They will receive a "Transaction Number" to be authorized to submit a Comment	Public Users
32	The application will send an e-mail to all CAs informing that a new task has been set in their homepage "Task" section	CA Users
33	At the end of the time defined for this task, the LCA will be able to send the Public Comment to the Commission	LCA User

34	The Commission User has to login in the application to circulate public Comments to the CAs.	Commission User
35	The LCA will be able to upload the Final Decision.	LCA User
36	The LCA will be able to Submit and Circulate Consent	LCA User
37	The Notification Procedure has finished. Public user will be able to see the notification in the application homepage (if the Notification has been approved)	Public Users

Table 5: Part C notification procedure – actions and users

6.2.2. Action description

The LCA User has to login in the application providing valid username and password.

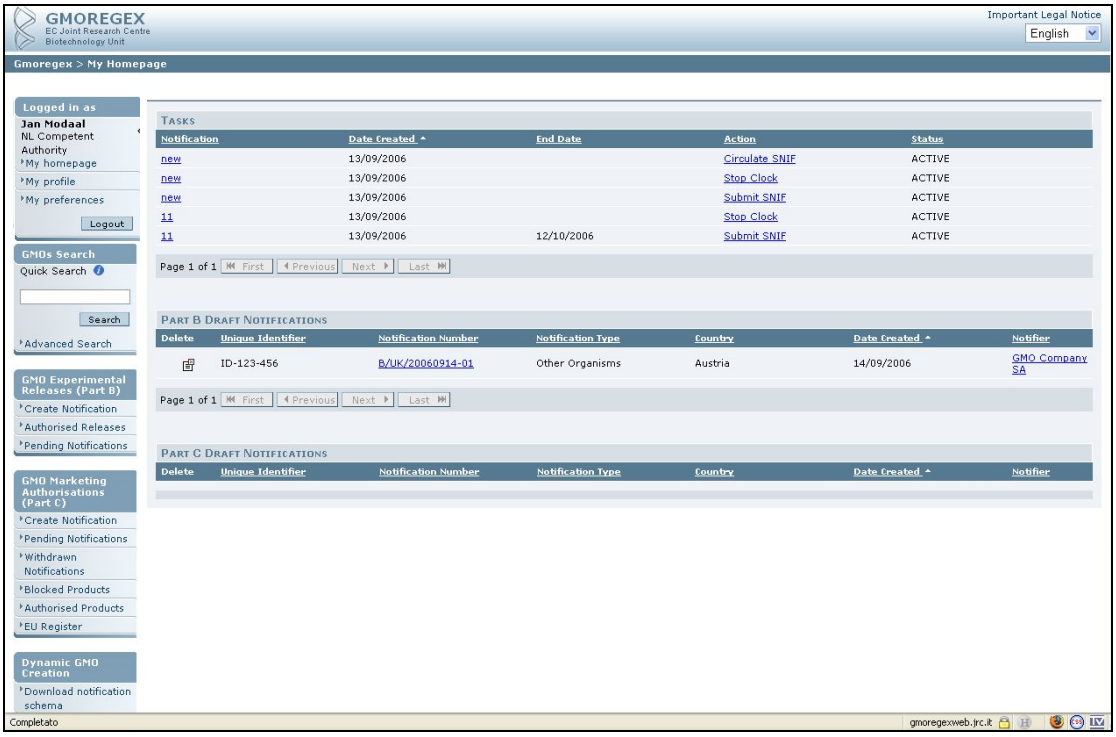


Figure 143: homepage with active tasks

After successful login, the LCA user has to click on the "**Create Notification**" link in "**GMO Marketing Authorization (Part C)**" section in left menu.

Figure 144: Link to select to start a Part C Notification procedure

After this action, the core part of the page will change. In this new part of the application, the LCA User will be asked to define the type of notification she/he is going to create, and the type of workflow procedure desired.

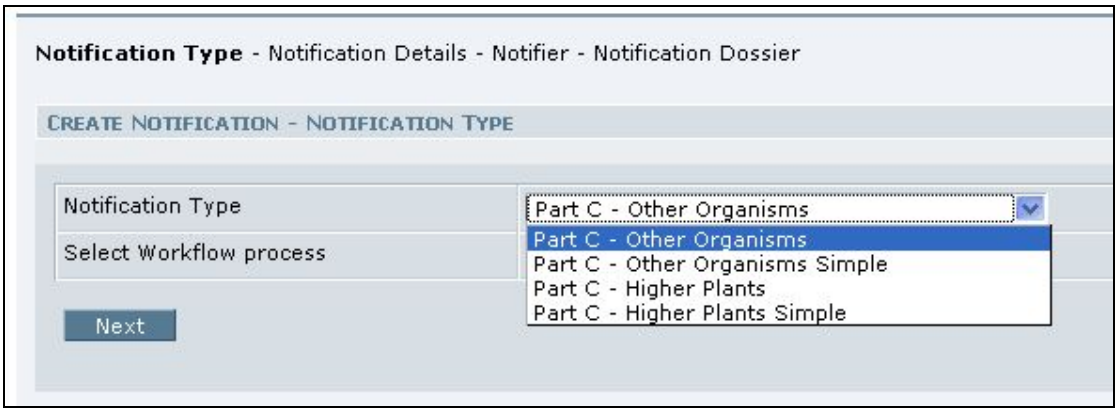


Figure 145 - Part C Notification types available

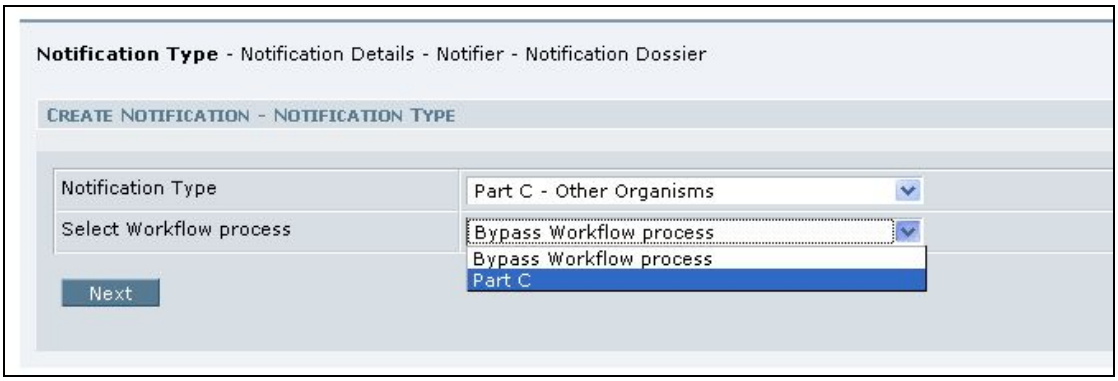


Figure 146 - Part C Workflow types available

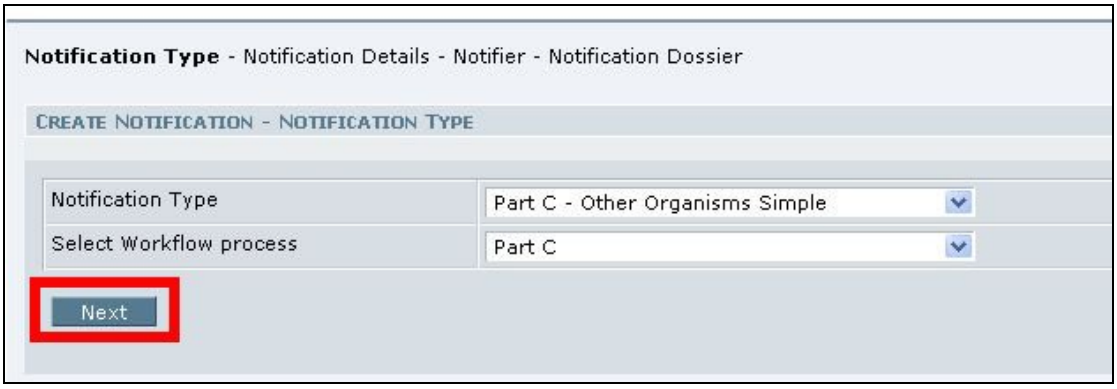


Figure 147 - Part C notification: first step

After defining this information, the LCA User has to press the next button in order to proceed to the next step.
The following step concerns the basic information about the Notification itself.
The Notification Dossier description page is similar to the [SNIF.PARTB] page previously described. Mandatory fields are marked in bold.

Figure 148 - Part C Notification: Notification details

The following step is used to define the Notifier. As in the [SNIF.PARTB], the LCA User can select an existing Notifier or create a new one.

Figure 149 - Notifier specification

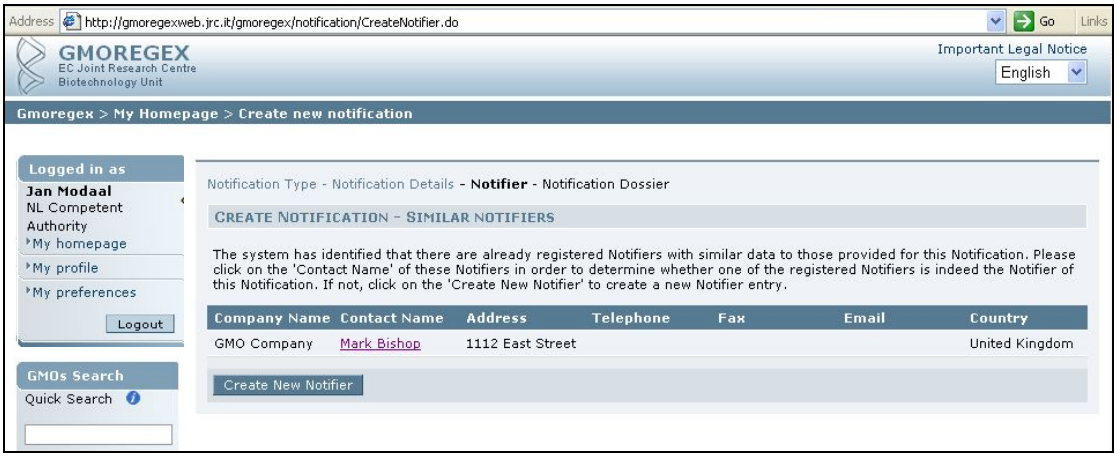


Figure 150 - Choose existing notifier or create a new one

Also in this case, if the LCA User inserts some data which are similar to data which also belong to an existing notifier, the application will ask the LCA User if she/he want to create a new Notifier or to use an existing one.
If the LCA User chooses to use an existing Notifier, a page proposing the Notifier details is shown for further confirmation.

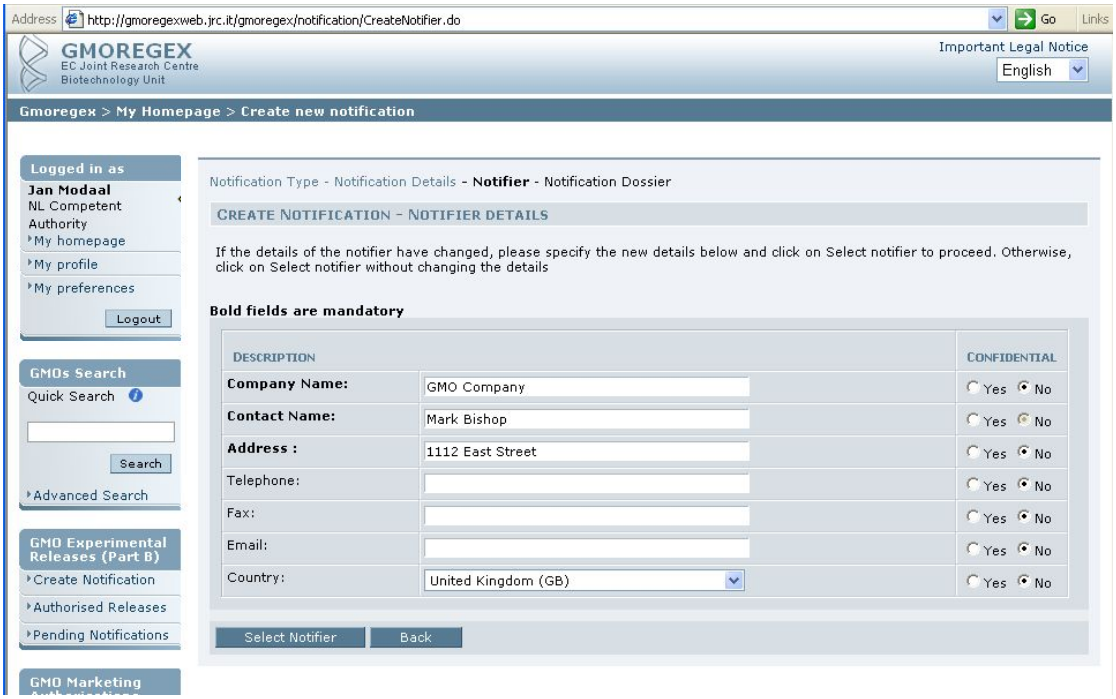


Figure 151 - Selection of an existing notifier

The next step is to fill in the information for the Full Dossier and the SNIF. Also in this case, the number and the type of the fields that will be shown by the application depend on the Notification Method chosen in the first step of the Notification Procedure.

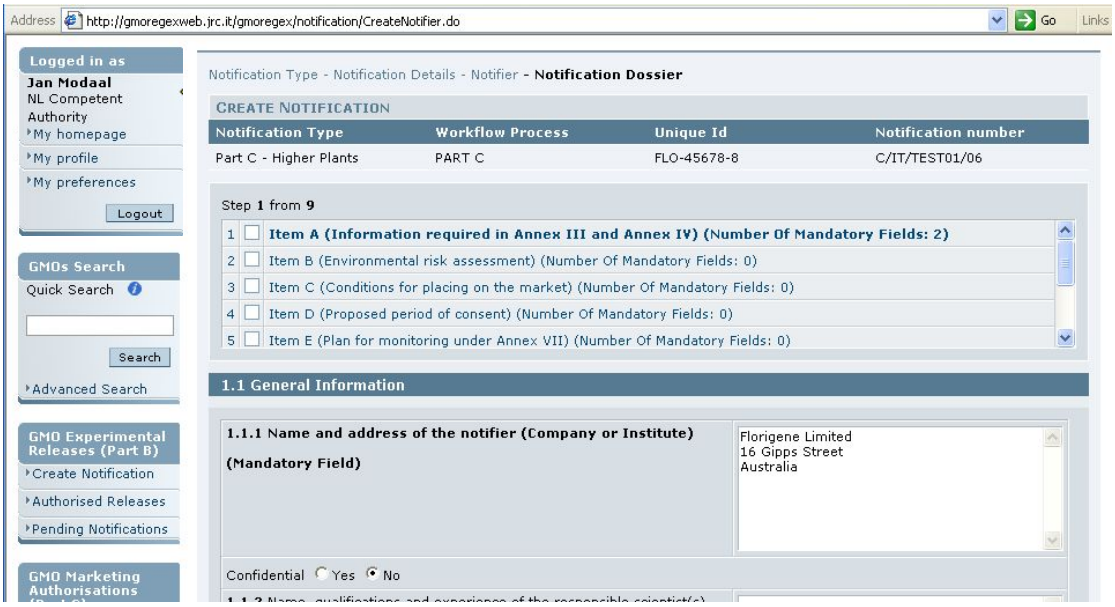


Figure 152 - Notification Steps

For each step in which the Notification Procedure has been divided, the number of mandatory fields is shown in the “Step” part of the page. For each step, the mandatory fields are marked in bold.
Some fields have to be filled in by choosing their value from a **Controlled Vocabulary** lists.

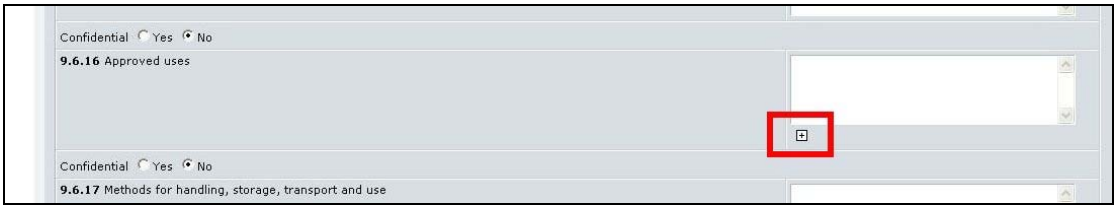


Figure 153 - Controlled vocabulary button

Controlled Vocabulary fields can be recognized by a plus icon, as highlighted in the figure, that have to be clicked in order to display the allowed values.

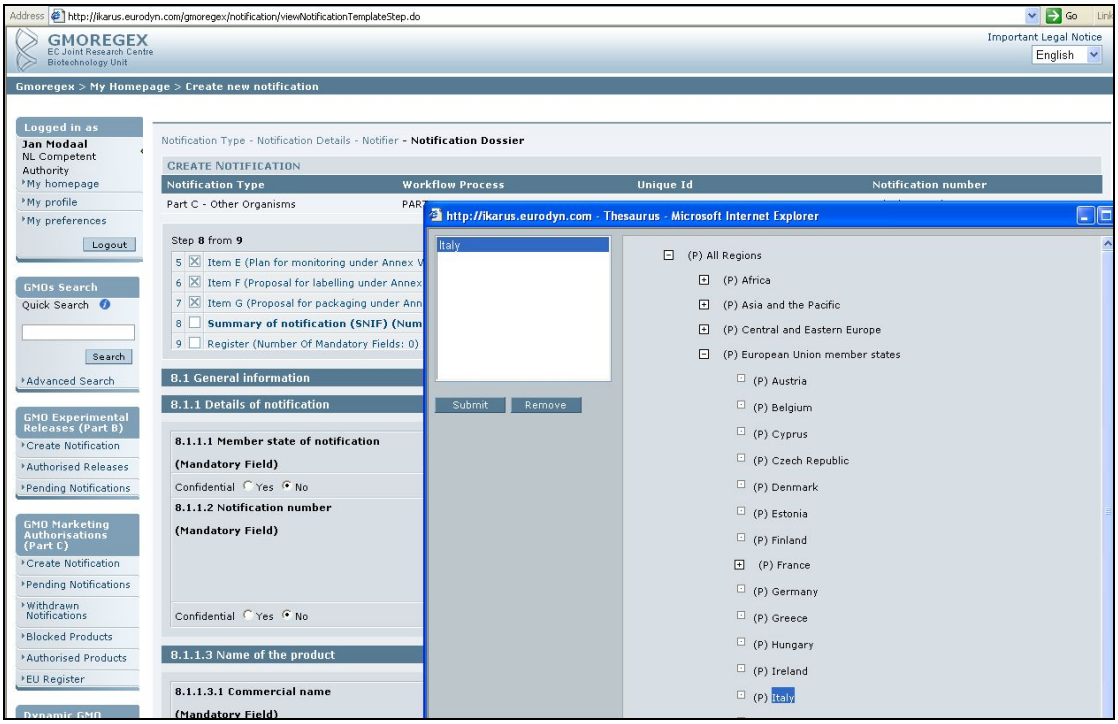


Figure 154 - Example of controlled vocabulary

In the figure above, the controlled vocabulary list for “Member State of notification” is shown.

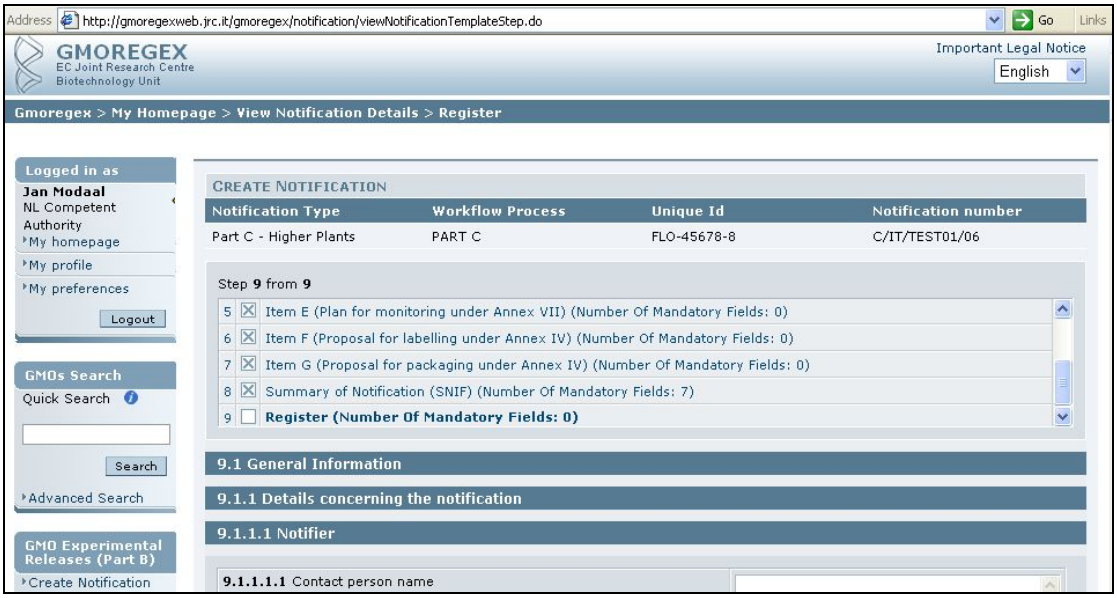


Figure 155 - Part C: last step

After each step has been passed through, and all mandatory fields have been filled, the LCA User can press the "Create Notification" button in order to see a confirmation screen and send the notification to the Commission. Otherwise, the notification can be saved as Draft, in other to be completed lately.

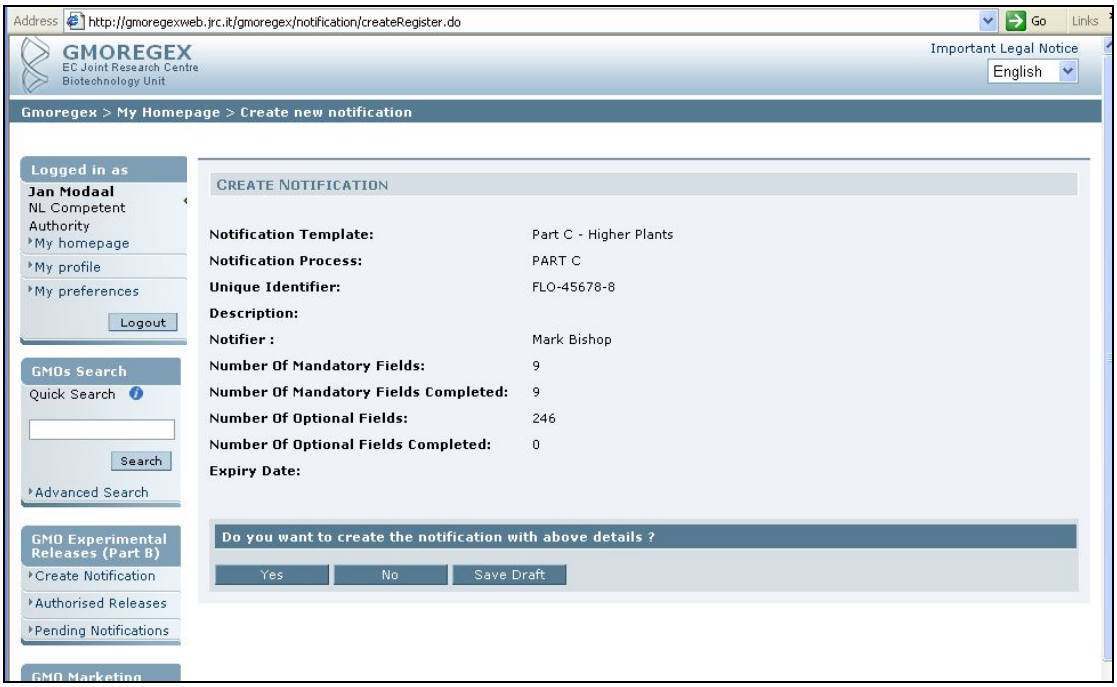


Figure 156 - Confirmation of Create Notification

The next step for the LCA User will be to submit the SNIF to the Commission. In the LCA User home page new tasks have been added.

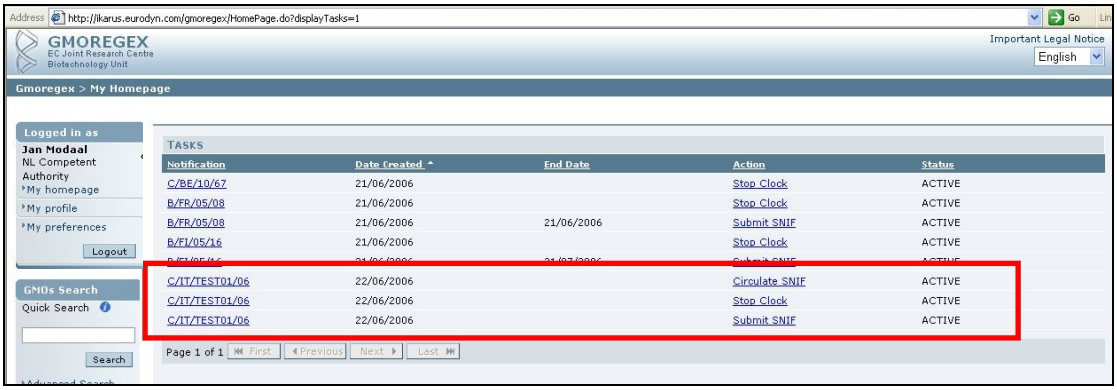


Figure 157 - Action to be performed by LCA as soon as the notification has been created

Following the "Circulate SNIF" link, the LCA User will be able to Submit and Circulate SNIF, using the buttons in the bottom part of the page.

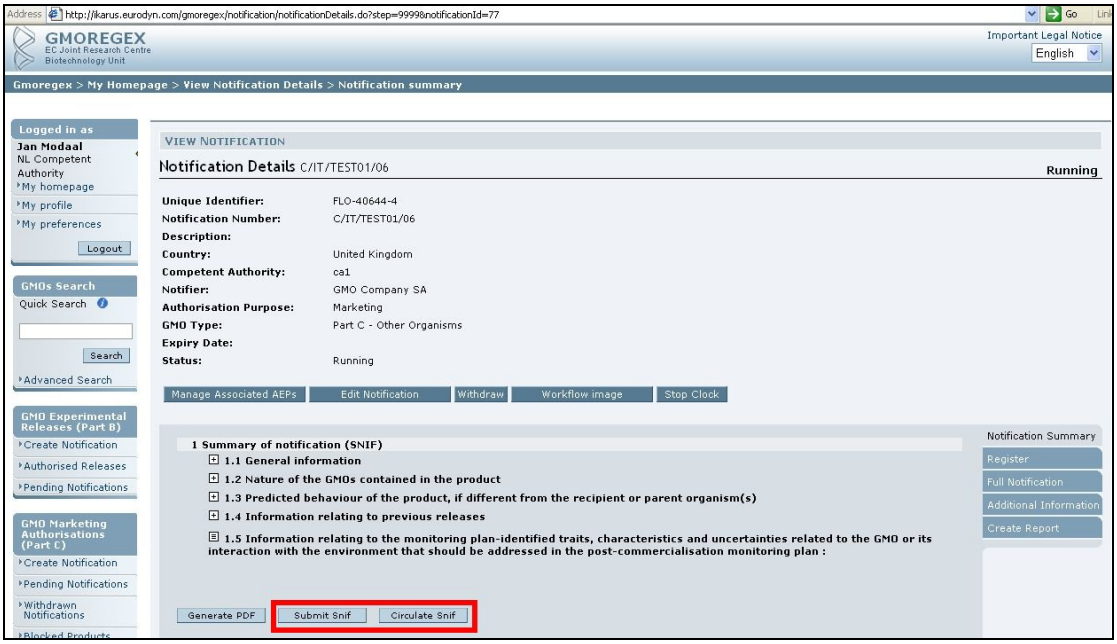


Figure 158 - Submit SNIF and Circulate SNIF buttons

In both cases, a confirmation screen will be displayed. Both operations (Submit SNIF and Circulate SNIF) have to be completed before proceeding to the next step.

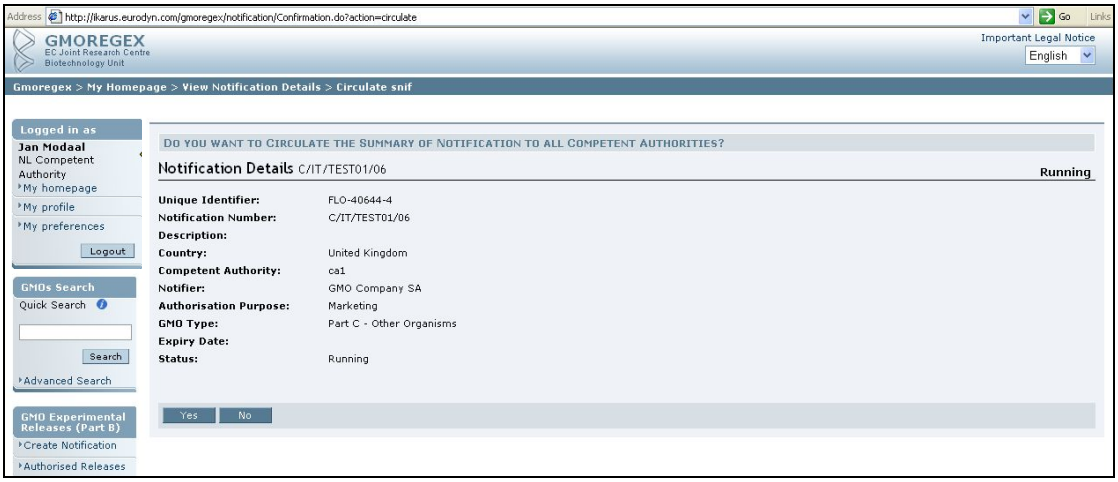


Figure 159 - Circulate SNIF confirmation page

Figure 160 - SNIF successfully circulated

After completing one of the steps, the "Notification Page" details will not show the button related to the task just completed.

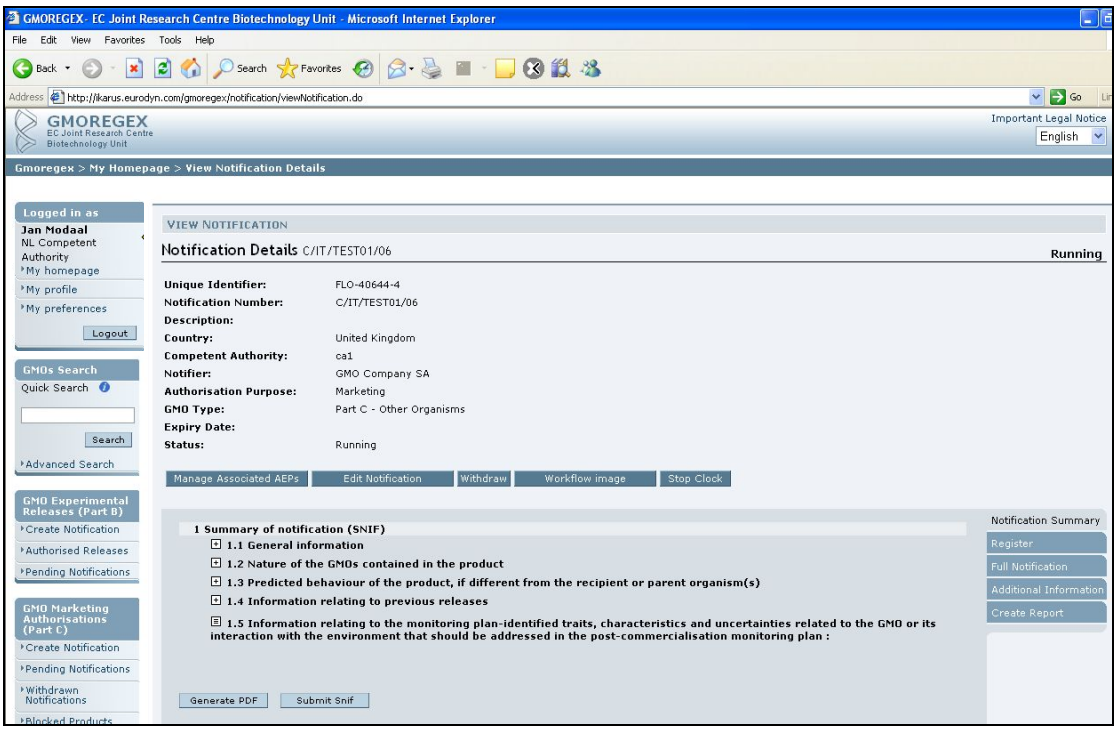


Figure 161 - In View Notification page is shown the other task to be performed

Figure 162 - Send SNIF to Commission confirmation Page

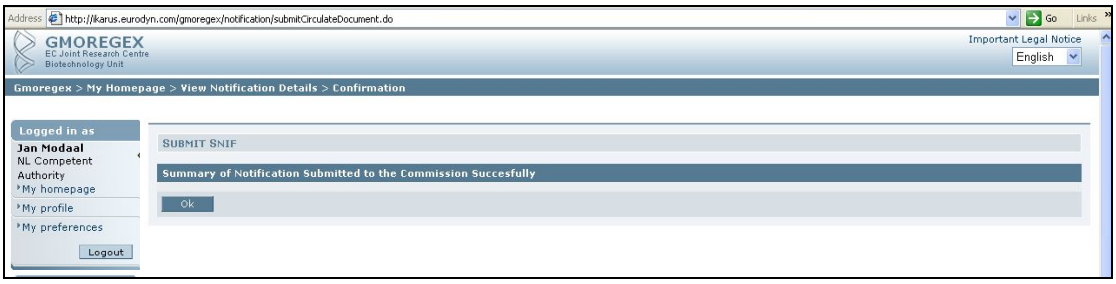


Figure 163 - SNIF successfully sent to the Commission

After completing these two steps, in the LCA User homepage a new task will be displayed, as highlighted in the figure.

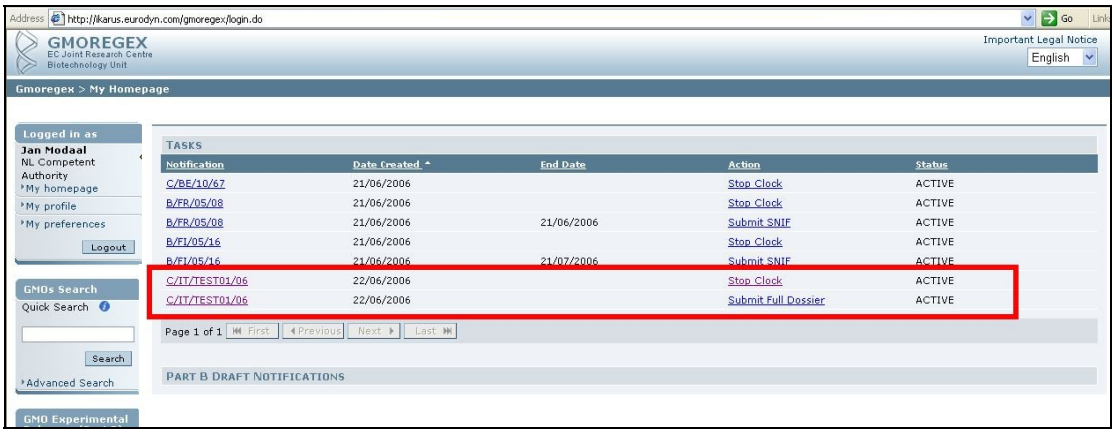


Figure 164 - Next action to be performed by LCA

The LCA User has to submit the Full Dossier. The procedure is similar to the previous ones. The LCA User has to follow the link added in his/her home page. This will lead the user in a page in which she/he will see a summary of the notification.

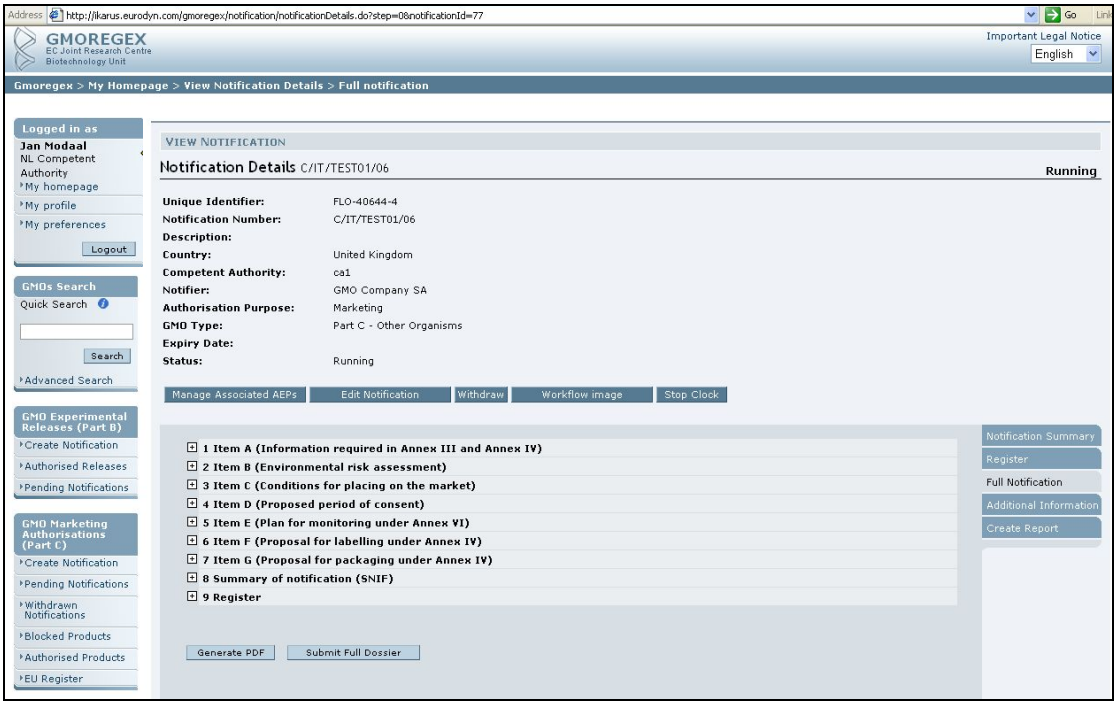


Figure 165 - Submit Full Dossier page

Selecting the "**Submit Full Dossier**" button, the Full Dossier will be submitted to the Commission.

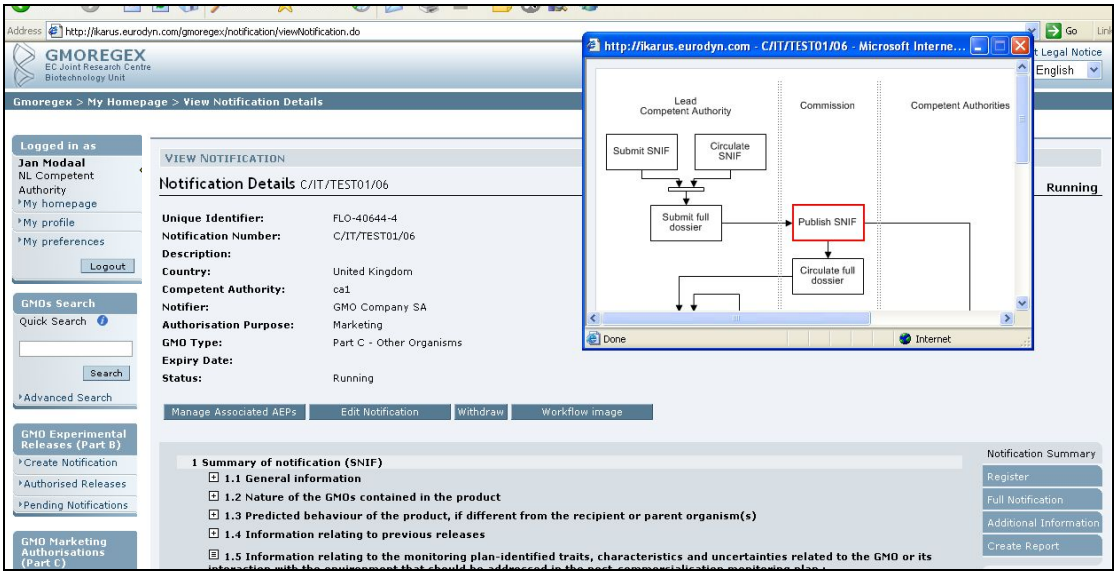


Figure 166 - Next step is to be done by the Commission User

In Notification Details page, the application gives the option to display an image representing the workflow and the current step in the process for the current notification. As shown in the above Figure, the Commission User is involved in the next action for this particular notification.
The Commission User will receive an e-mail to inform her/him that a new task has been added. After logging in, the Commission user will see a new task in his/her homepage.

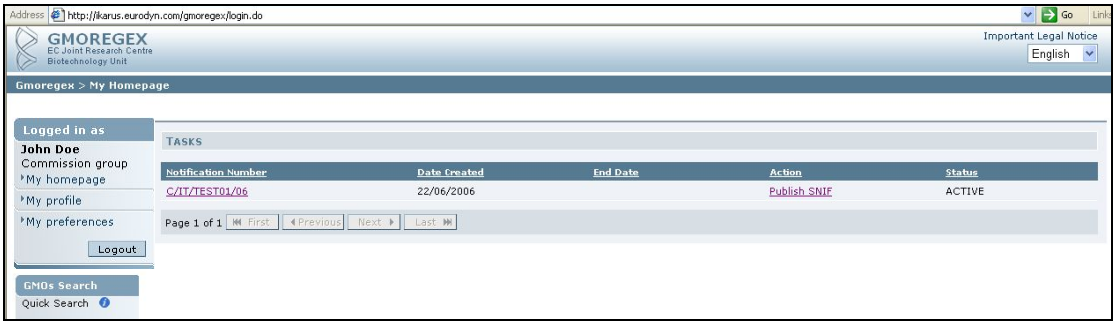


Figure 167 - Commission User Task

In order to perform the required action, the Commission User will have to follow the link displayed in the homepage. This will lead the Commission User in the page where the "**Publish SNIF**" action can be performed by selecting the relative button.
The application will show the Commission User a summary of the notification. After confirming, the Commission User will be taken to a page in which the confirmation of the success of the action performed is shown.

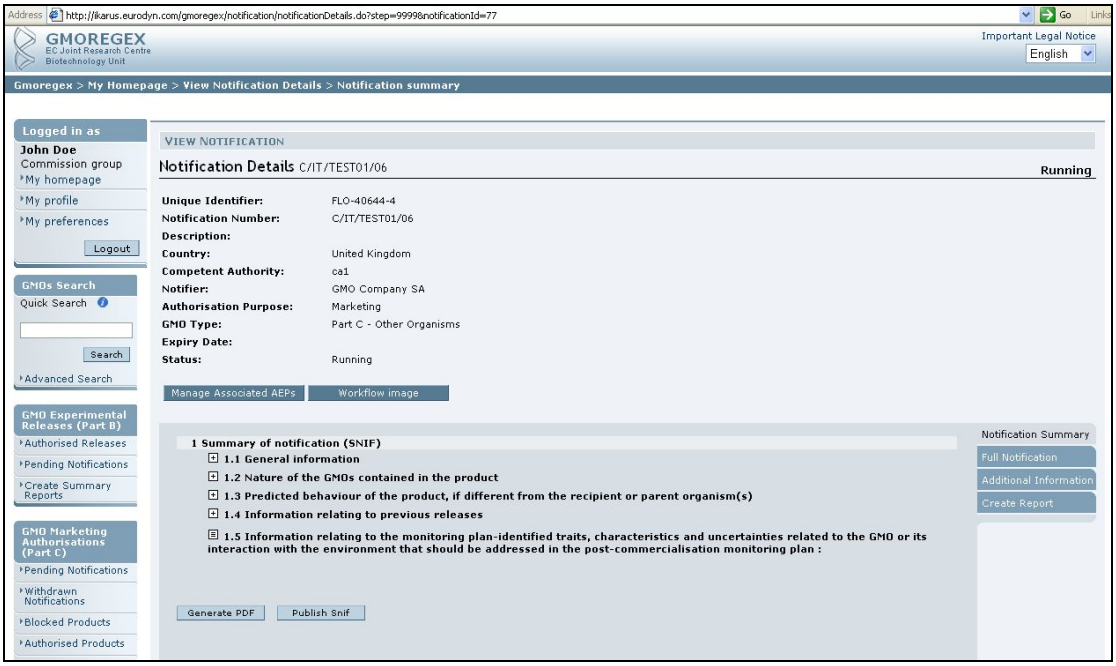


Figure 168 - Commission User has to Publish the SNIF

The next step is the circulation of Full Dossier. The actions are similar: the Commission User will have to confirm the action to circulate the Full Dossier to all registered CAs.

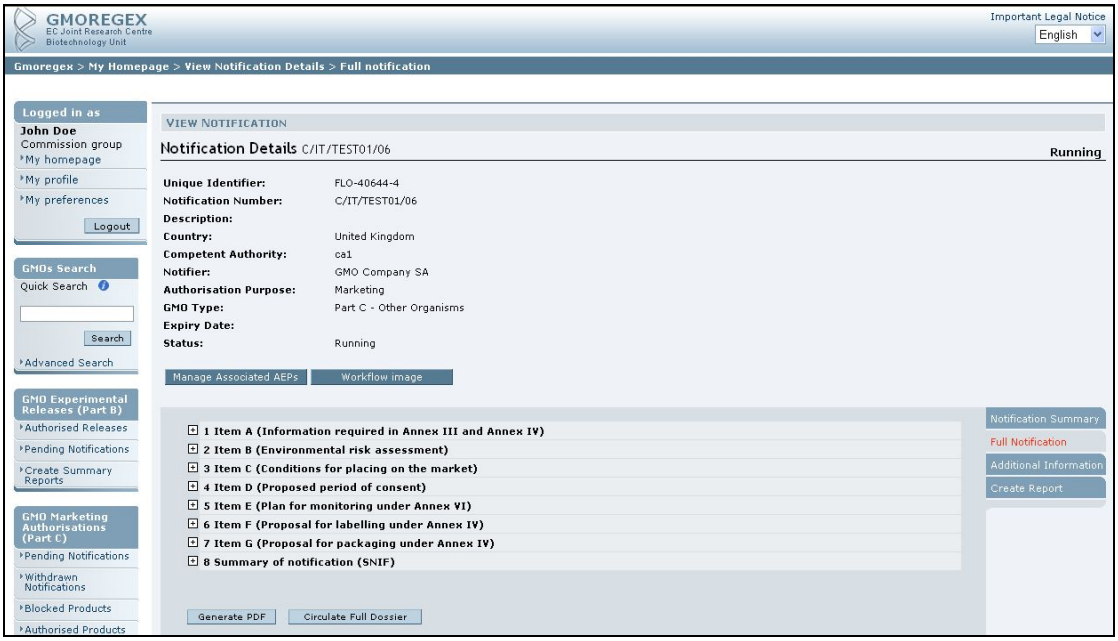


Figure 169 - Circulate Full Dossier Confirmation Page

Figure 170 - Circulate Full Notification Confirmation Page

Going back to the Notification Details page, the Commission User will be able to see the next step in the notification procedure.

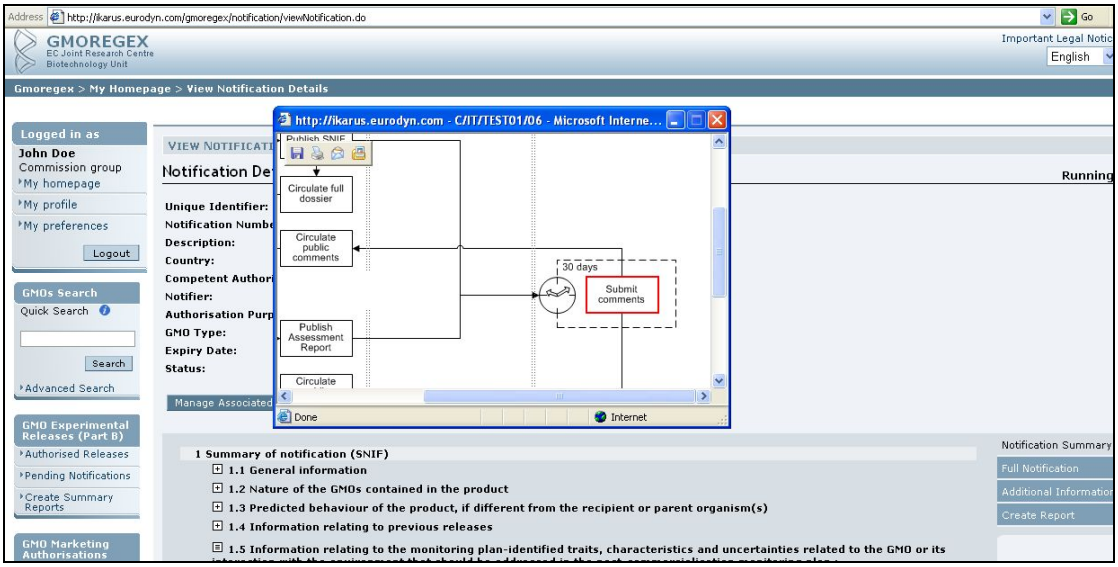


Figure 171 - Next Step in notification procedure

During this 30 days period, the SNIF will be available both for Public Users and for CA. Both of them can submit Comments.
When the period for submitting comments is overdue, the Commission user will receive an e-mail to remind her/him that a new task has been added in his/her "Task" in the Homepage.

Figure 172 - Commission User next action

After logging in, the Commission User will see a new task related to this ongoing notification, the task is related to the Circulation of Public Comments (if any) to all CAs.
This action can be performed following the "Circulate Public Comments" link.
In the Notification Details page, the Commission User will see the Public Comments (if any) and the "**Circulate Public Comments**" button.

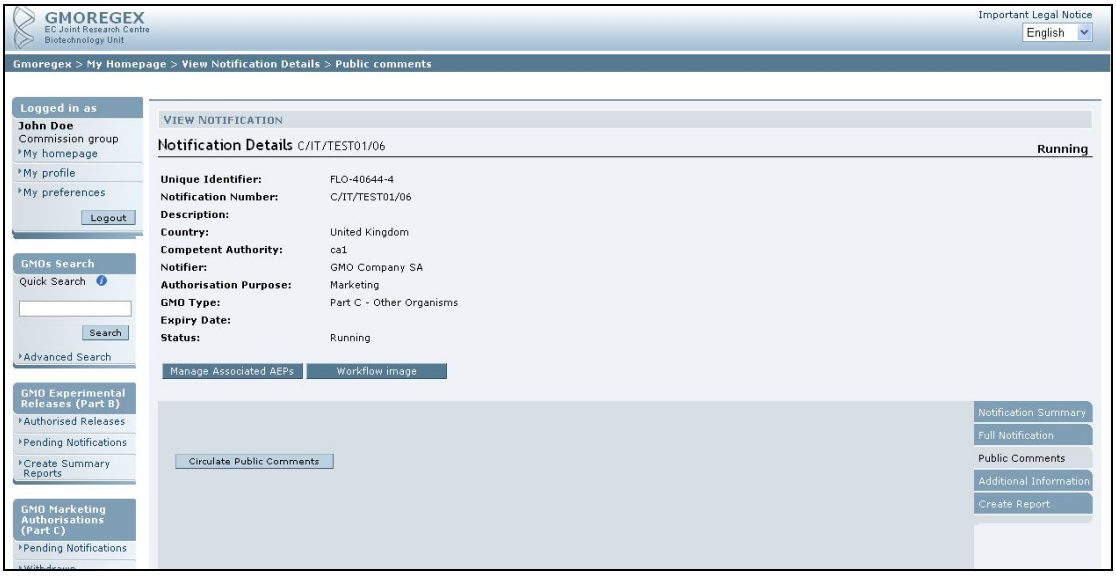


Figure 173 - Commission User can Circulate Public Comments

This will lead the Commission User in a three step procedure, where she/he will see the Notification Details.

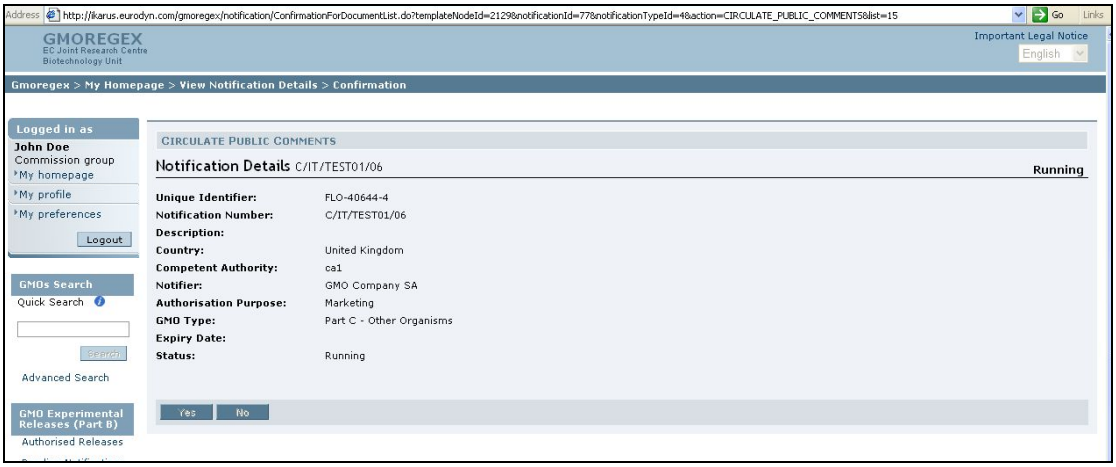


Figure 174 - Confirmation Page to send public comments

Figure 175 - Public Comments sent successfully

The next step is a LCA User action. The application informs the LCA User about the new task by sending an e-mail.

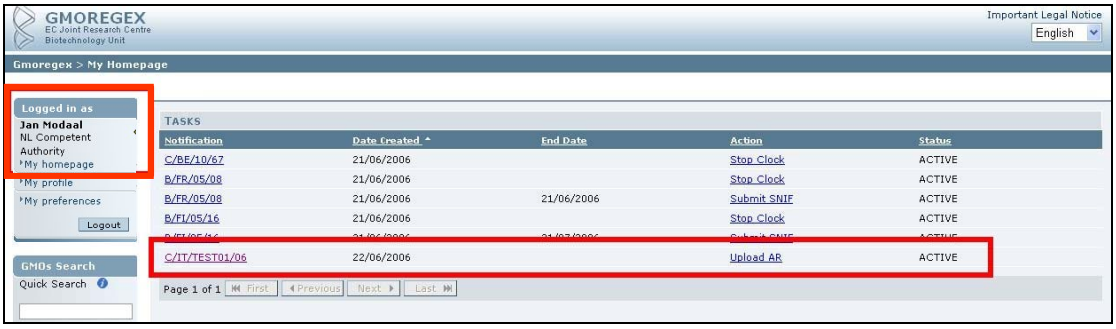


Figure 176 - LCA User tasks: Upload AR

The action for the LCA User is to upload the Assessment Report.
Following the link displayed, the LCA User will be taken to the "Assessment Report" page.

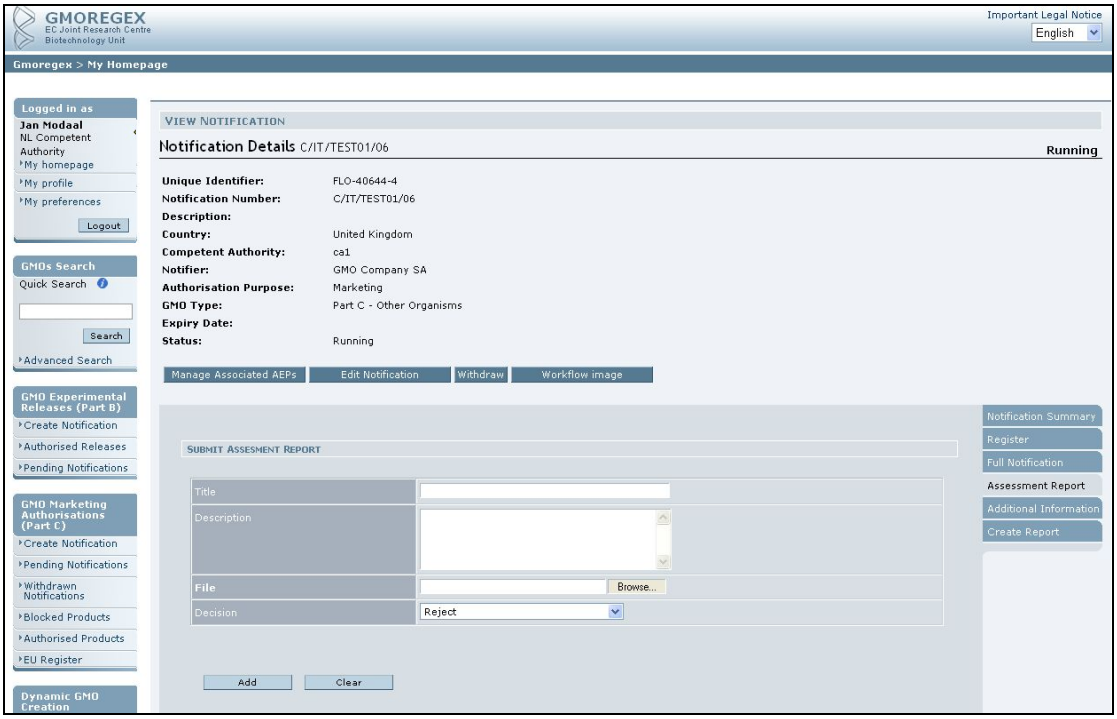


Figure 177 - LCA User has to upload Assessment Report information

The LCA User has to fill the fields with the appropriate information. Please note that the default value for "Decision" is "Reject".
After uploading the AR to the application, the LCA User has to submit the AR to the Commission. In order to execute the "submit assessment report" action, a new task is added by the application in the LCA User homepage.
Following this link, LCA User will see a summary of the running procedure and send the AR to the Commission.

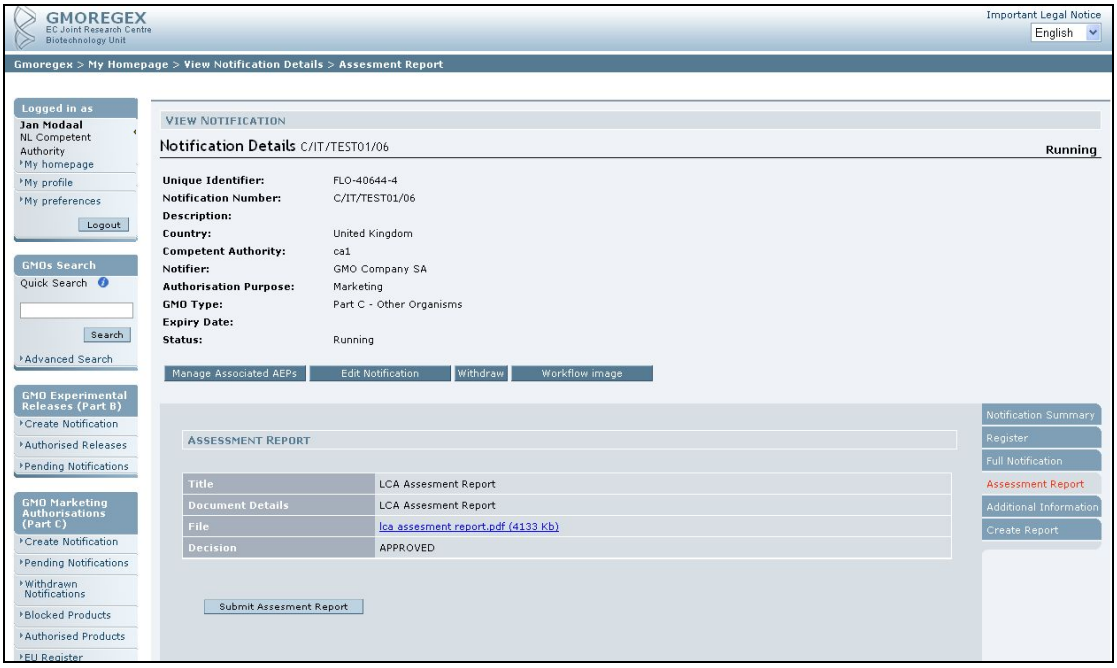


Figure 178 - Summary of Assessment Report information and submit AR to Commission button

As usual, a confirmation page will be shown to the LCA User, for further confirmation of the operation.

Figure 179 - Confirmation of submitting AR to Commission

The next action is a Commission User Task.
After logging in, the Commission User will see that two new tasks have been added to his/her homepage.

Figure 180 - Commission tasks: publish and circulate AR

Both tasks have to be accomplished before proceeding in the notification procedure.

The "Circulate Assessment Report" is used to send the AR to all CAs, so that they can add "Expert Comments".

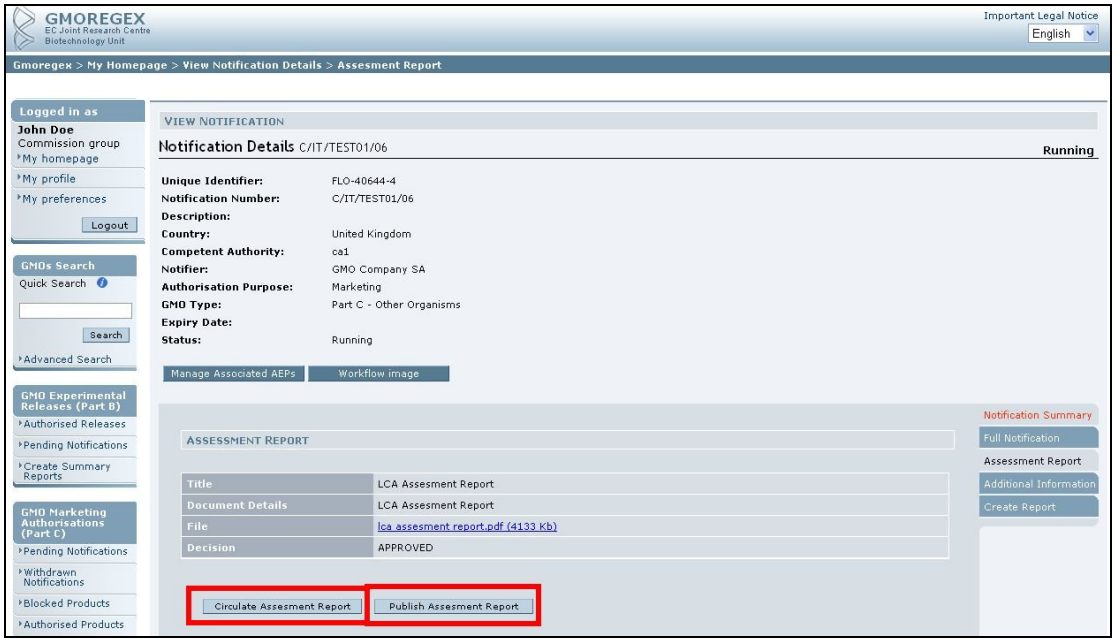


Figure 181 - Commission User: task related to AR

The "Publish Assessment Report" action is related to General Public. Through this operation, Commission User will publish AR to General Public, so that comments can be added by Guest users.

Figure 182 - Circulate AR confirmation page

Both actions have to be performed in the same way. After selecting the desired action, the Commission User will see a small summary of the notification and the AR details.
A confirmation screen will also appear when the procedure is nearly finished, to confirm the action.

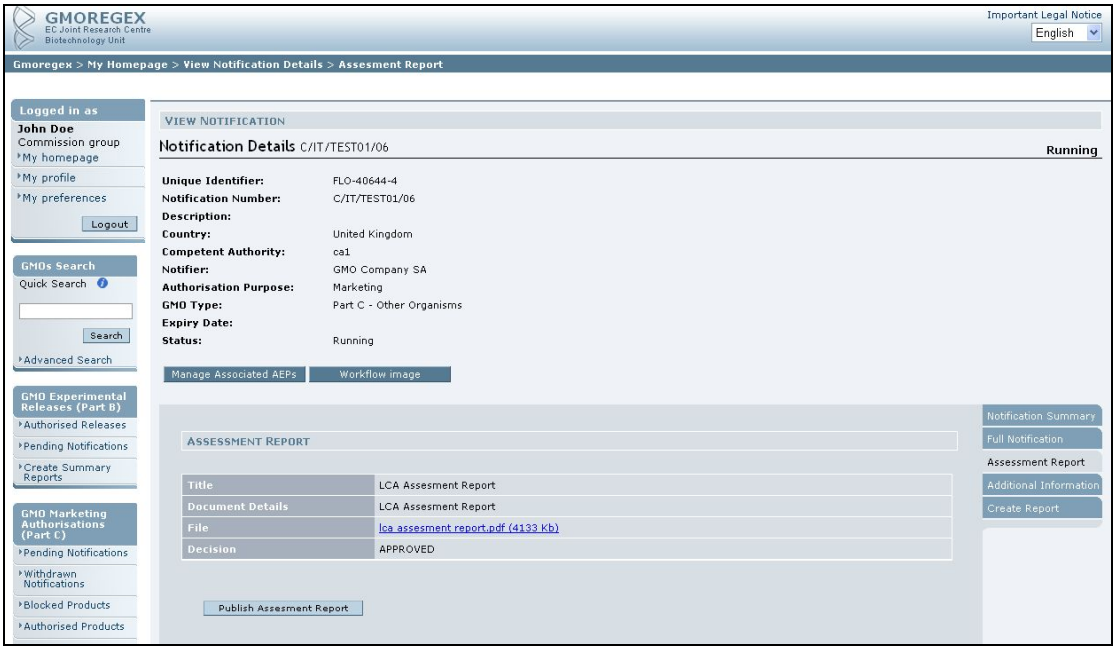


Figure 183 - Commission User can Publish AR

Figure 184 - Confirmation of circulating AR

After these actions have been performed, all CAs can Submit Comments to the AR using a link that will be added by the application in their "Tasks" section in the Homepage.

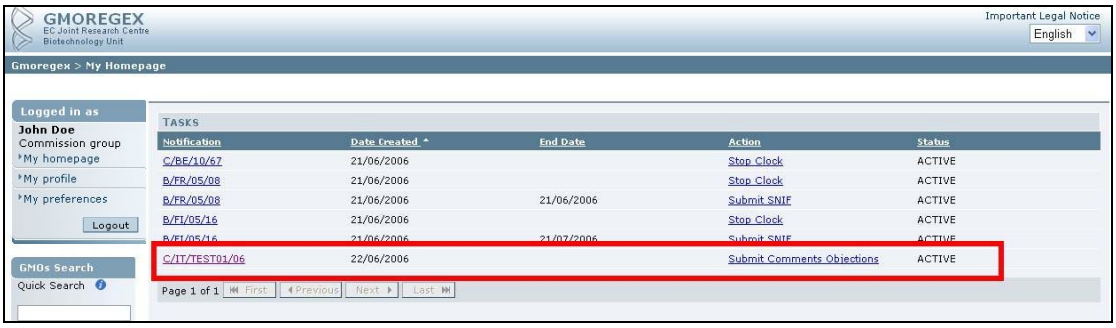


Figure 185 - CA User can Submit Comments

In order to submit a comment, a CA user can follow the link. In the opened page, the CA User will be able to add a Comment and to send this comment to the Commission.
Please notice that a file can be uploaded too.
The "Title" field is mandatory. And moreover, at least one of the two other fields, "Description" or "File", has to be filled.

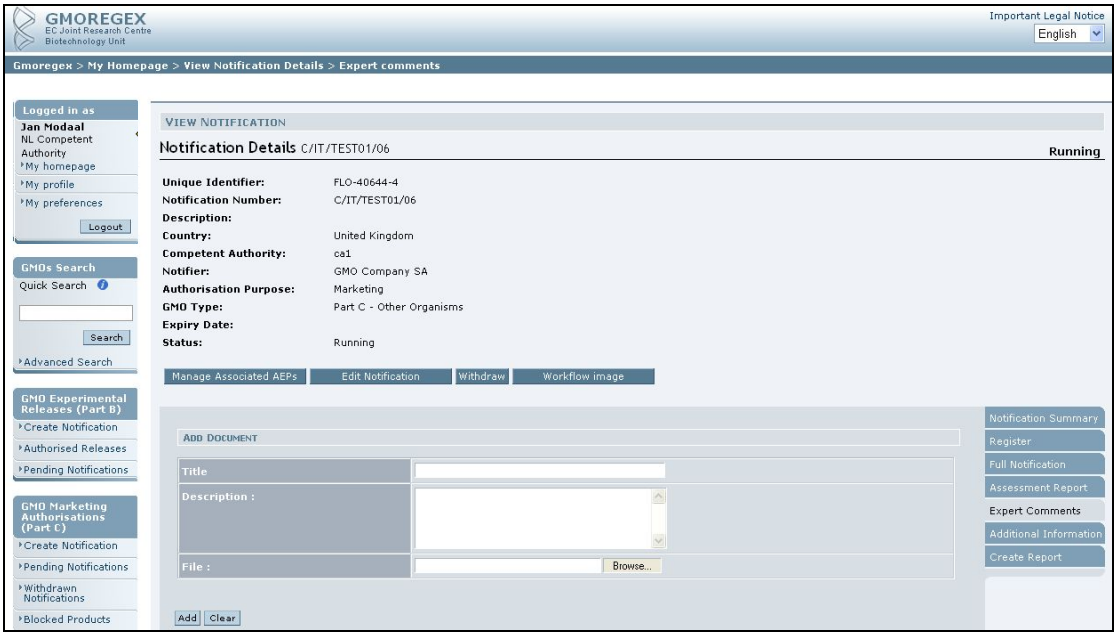


Figure 186 - Send Comments page

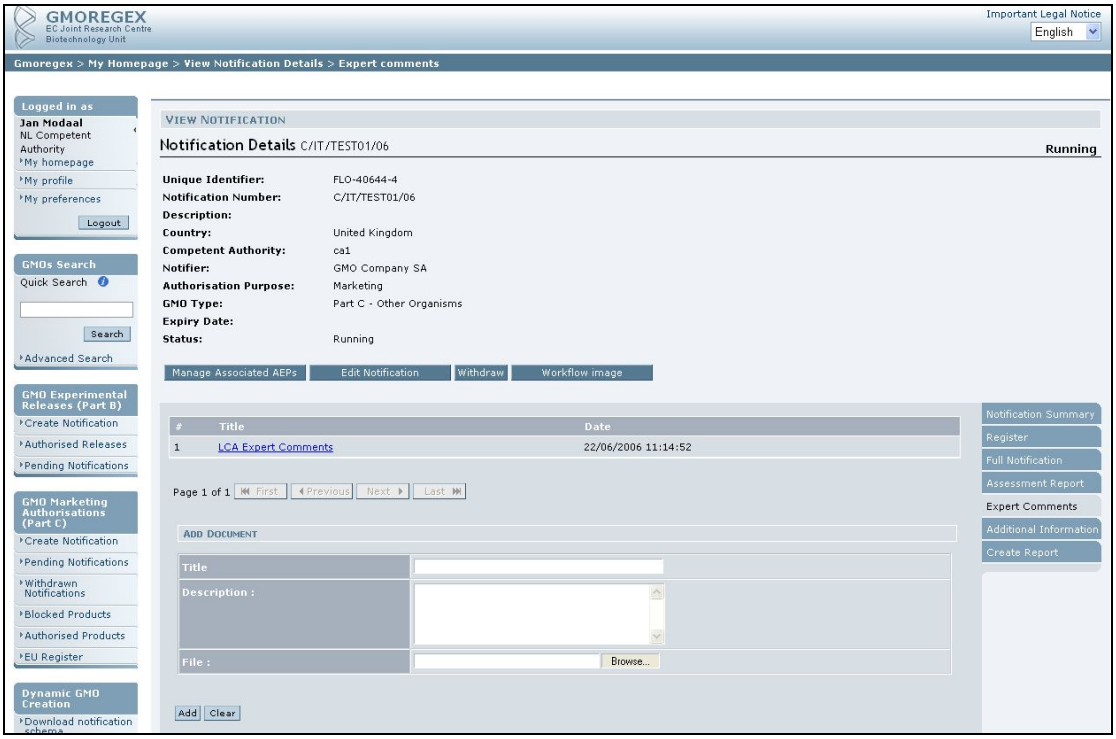


Figure 187 - Comments page

Now the application will wait for the defined period of 60 days, so that all CA may add comments to the notification, if they wish.

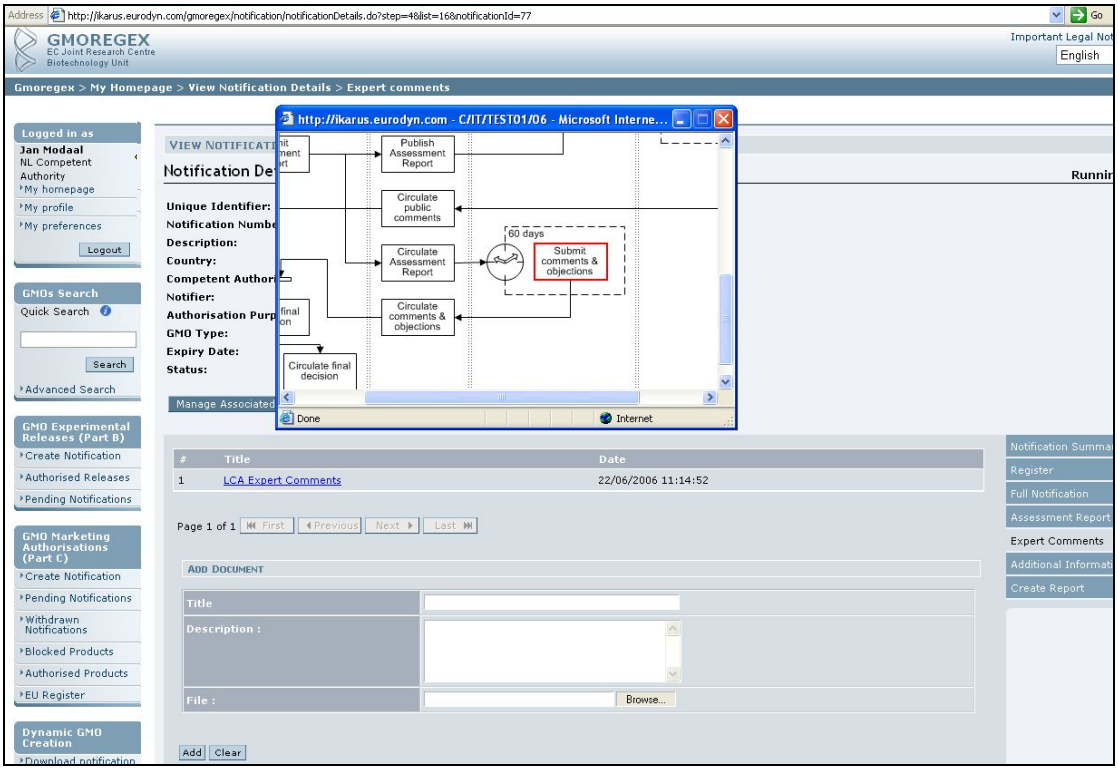


Figure 188 - Workflow page showing next step

When the 60 days period is about to expire, the application will sent a message, to all actors involved in this step to remind them that the submit comment period is about to end.
When this period is overdue, the Commission User will have a new task added in his/her "Tasks" section in his/her homepage, as can be seen in the Figure.

Figure 189 - Commission User has to Circulate Comments

Commission User will have to Circulate CA Comments among all CAs.

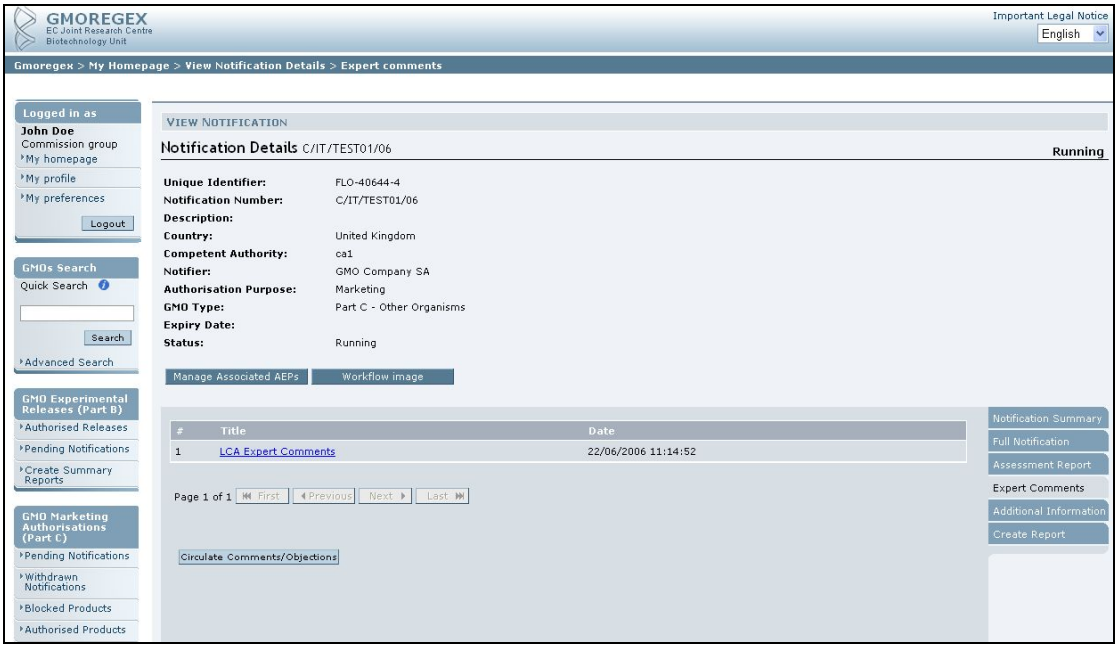


Figure 190 - Circulate Comments

Figure 191 - Circulate Comments confirmation page

After this action has been completed, the application will allow the General Public to see the Assessment Report and to send Comments to the Commission.
When the Public Comments period is overdue, the Commission User will be able to see the Public Comments and to Circulate these comments among all registered CAs.

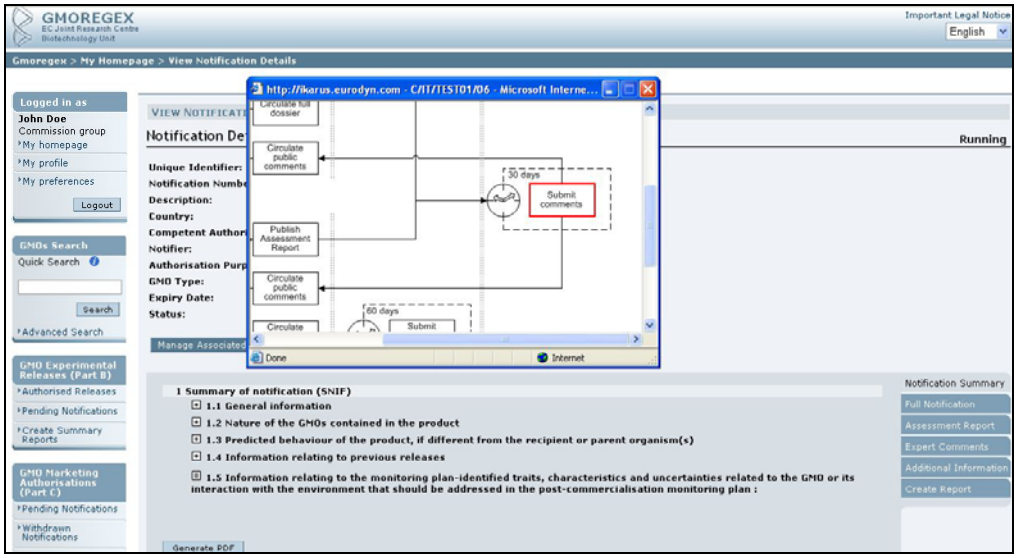


Figure 192 - Next step seen in the Workflow

The “Circulate Public Comments” task will appear in Commission User Homepage.

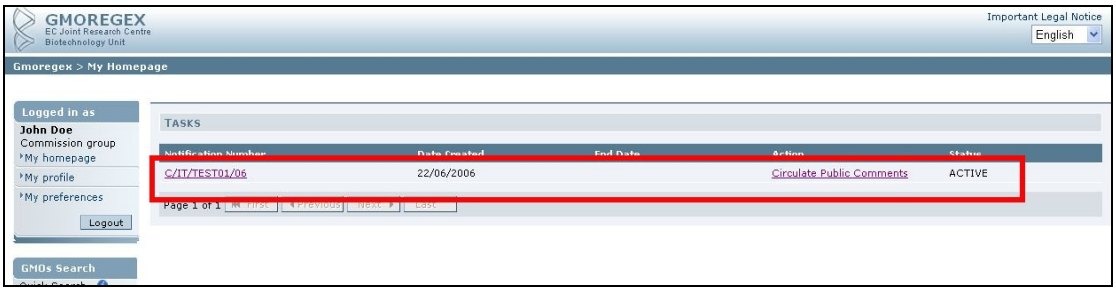


Figure 193 - Circulate Public Comments Commission User Page

The Commission User has to complete this action, even if no Comments have been submitted by General Public.

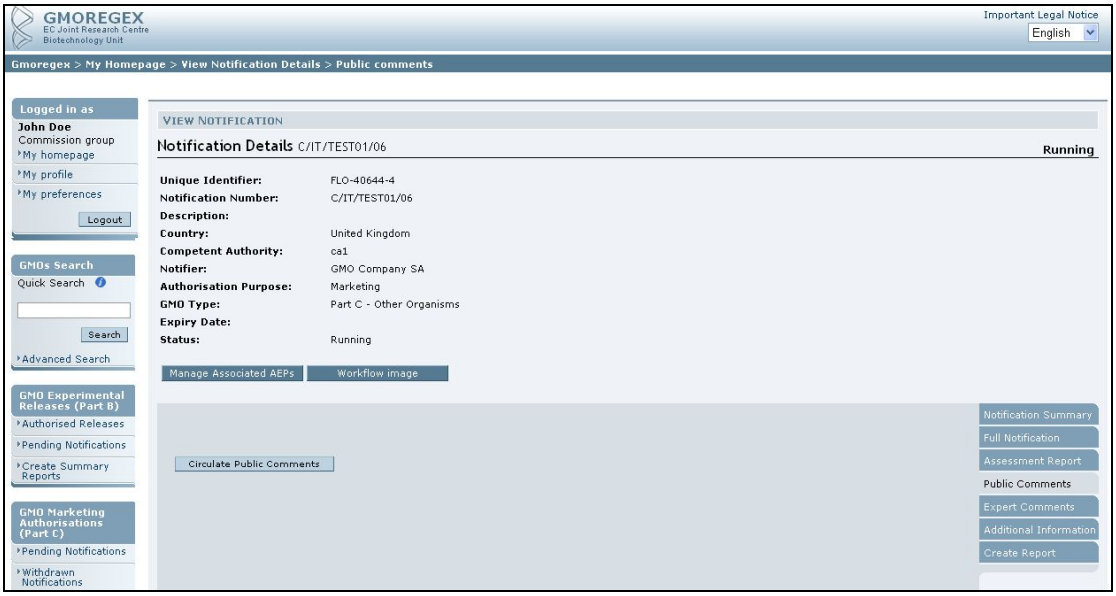


Figure 194 - Circulate Public Comments

Figure 195 - Circulate Public Comments confirmation page

After this action, the CAs will receive an e-mail to be informed that Public Comments have been circulated.
LCA User has the last task to accomplish.
After logging in the system, LCA User will see two new tasks added in his/her homepage.

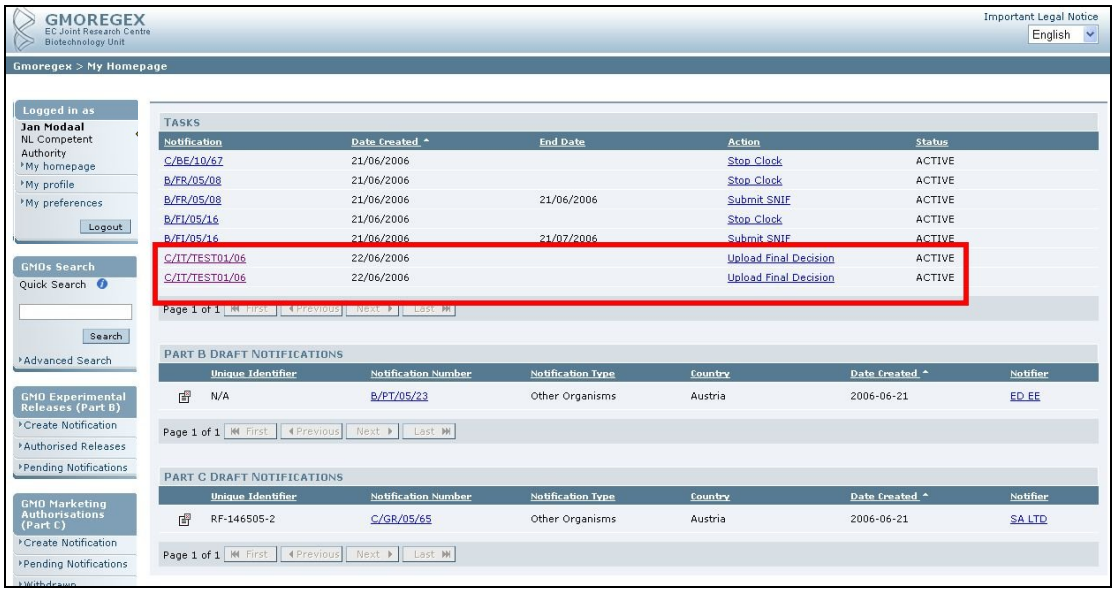


Figure 196 - LCA User Final Decision Task

The LCA User has to Upload Final Decision to the application. This task can be accomplished following the link that is displayed in the LCA User homepage.
Please note that the default value for “Decision” is “Reject”.
Again, all fields are mandatory and have to be filled in. It is also possible to upload a file containing the text of the Decision.
After that, the LCA User has still to Submit and Circulate Consent among CAs.
This action will be shown in the “Tasks” section of LCA User homepage, as soon as previous action has been completed.

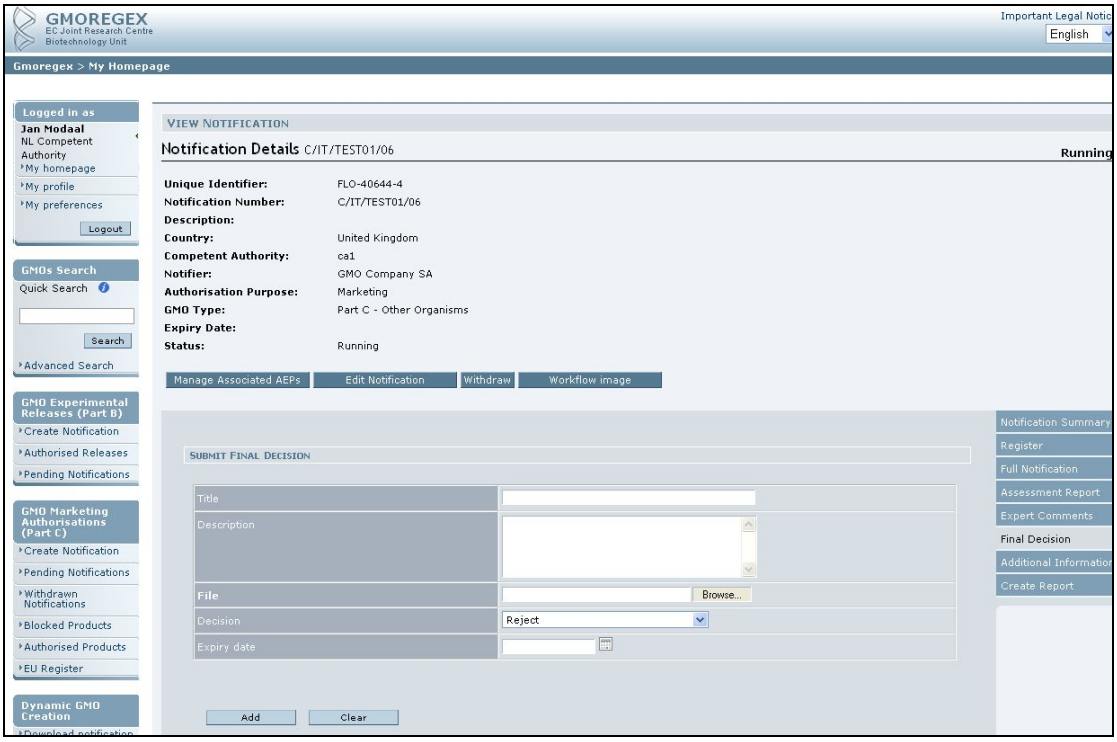


Figure 197 - Upload Final Decision page

Figure 198 - Upload Final decision confirmation page

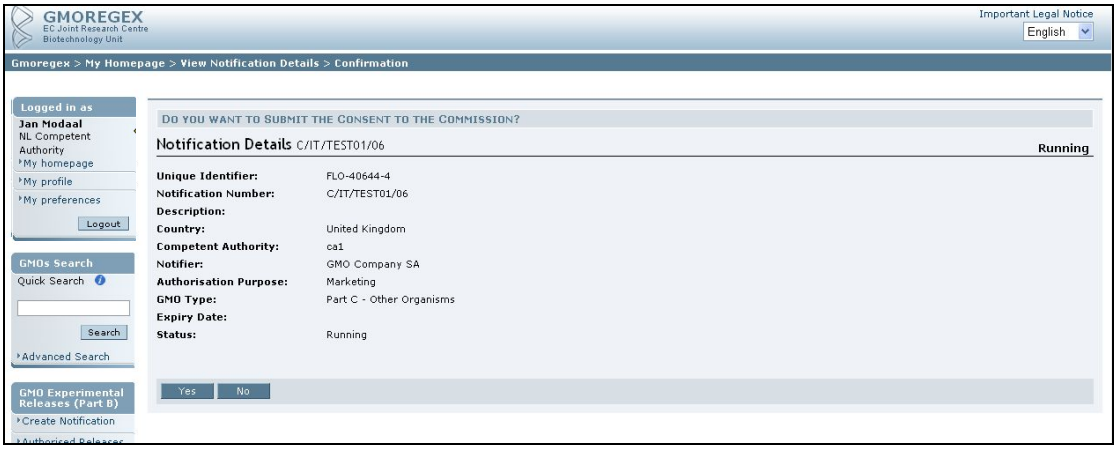


Figure 199 - Submit Final Decision to Commission

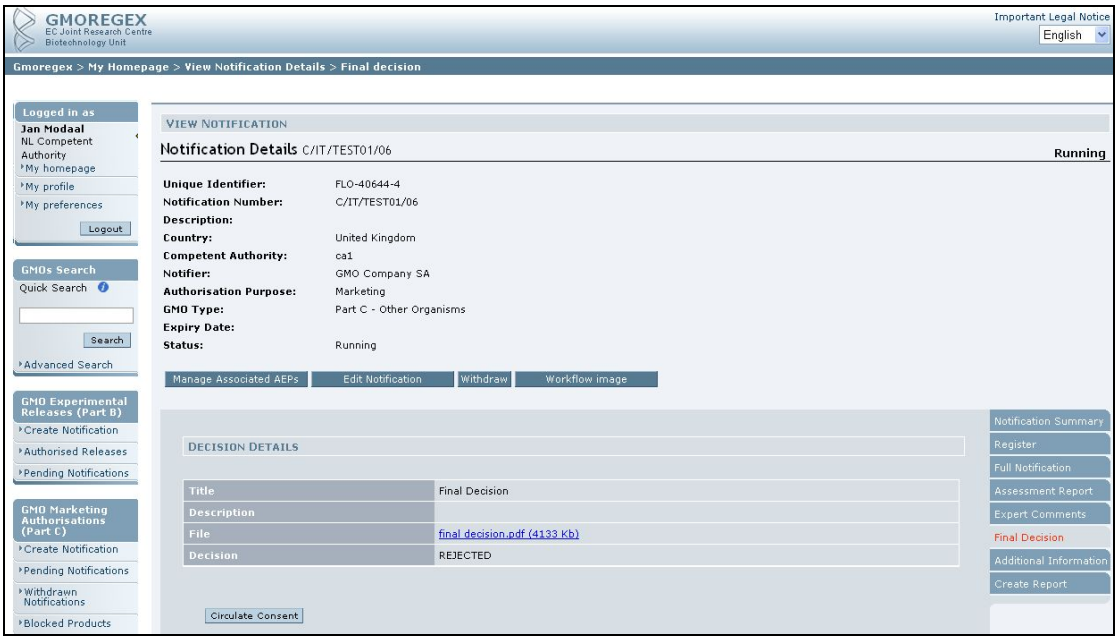


Figure 200 - Final Decision Uploaded

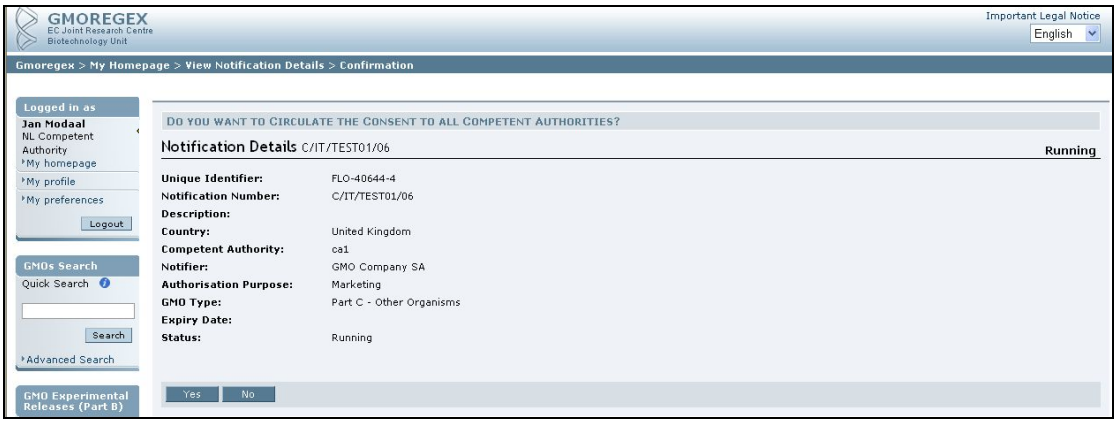


Figure 201 - Circulate Final Decision to all CA

Figure 202 - Part C notification completed

6.2.3. Connection to EC BCH and UN BCH

Once a [SNIF.PARTC] has successfully completed its authorization procedure, the LCA User may decide to send information to EC-BCH, according to [REG.1946/2003].
The LCA User has to login in the application providing valid username and password.
Once logged in, the LCA User has to retrieve from the database the information on the notification she/he want to submit to EC-BCH. To do that, she/he can make a search using the "GMOs Search" section of left menu.

Figure 203 - Search Section

The LCA User may decide to insert in the search field data that can be used to recognize the Notification she/he is looking for, or she/he can leave that field empty, so the search will return all notification that have been saved in the system, regardless their status.
The figure shows the search result for the test system.
The LCA User can send to EC-BCH only [SNIF.PARTC] whose status is "Released" and only the ones that have been managed by the same Competent Authority.
In the figure, the [SNIF.PARTC] that can be sent to EC-BCH by the selected user are highlighted in red.

The notification highlighted in blue has a “Released” status, but it was managed by another Competent Authority (NL Competent Authority), so, user Jean Dupont, who belongs to “FR Competent Authority” Competent Authority, cannot send this Notification to EC-BCH.

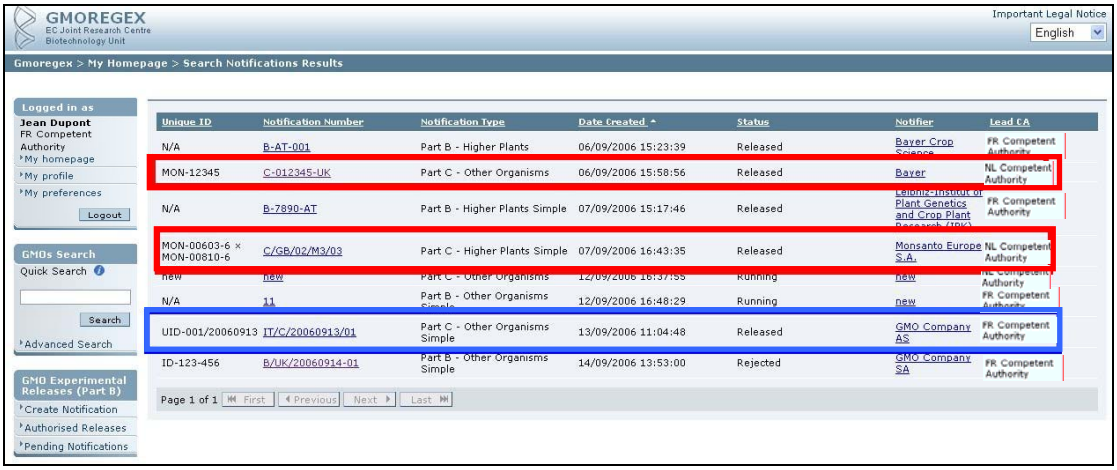


Figure 204 - Available part C Notifications

The LCA User has to select the desired notification, by selecting the “Notification Number”.

Figure 205 - Send Information to ECBCH Button

In the “View Notification” page, the LCA User will see the “Send Information to ECBCH” button. Once pressed, the procedure to send this notification to EC-BCH starts.
Once the sending procedure is finished, the LCA User task is completed.
The EC-BCH User will have to login into the EC-BCH portal by selecting the “Management Centre” link in EC-BCH Homepage.

Figure 206 - Managment Center link in ECBCH Page

Figure 207 - ECBCH Login screen

After providing valid access parameters, the user will be lead in the Management centre page. In this page, the "Update ECBCH" button will activate an automatic procedure used to update the EC-BCH application with the information previously sent through the **GMOREGEX** application.

Figure 208 - Update ECBCH Button

When the operation ends, a summary screen will be shown to the user.

Figure 209 - ECBCH Update screen

This page is divided into two parts. The top of the page displays the information regarding newly added or modified CAs, according to the data sent from **GMOREGEX**.
The bottom part shows information about the Notification.
In this example, the procedure has updated one CA with some information and has created a new Notification.
The success of the update operation can be seen both in the page displayed to the authenticated user and in the public page, as shown in the following figures.

Figure 210 - Logged user homepage

Figure 211 - Anonymous user homepage

After this operation, the LCA User can upload data to UN-BHC, as defined in [REG.1946/2003].
In order to be able to upload the data to UN-BCH, the EC-BCH User has first to find the desired Notification.
This can be done through a search.

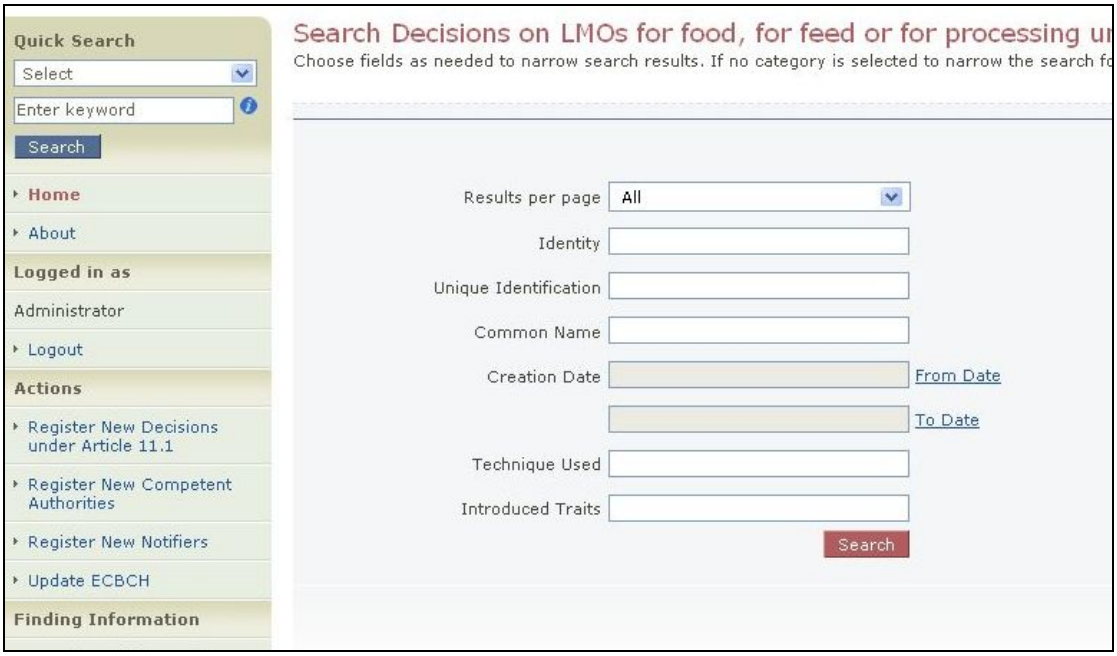


Figure 212 - ECBCH Search Screen

Once the EC-BCH finds the notification she/he want to submit to UN-BCH by clicking on the "**more details**" link, the details of the notification will be displayed as well as the "**Send to UN-BCH**" link, as shown in next figures.
Once pressed, the EC-BCH User only has to wait for the confirmation page.

Figure 213 - More Details link in search result page

Figure 214 - Send to UNBCH link in decision page

Figure 215 - Data successfully sent to UNBCH

European Commission

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Abstract

This document contains the user manual for the GMOREGEX application. It describes in detail the user functionalities provided by the system to the four different types of users for which the system has been implemented, i.e. the generic (non authenticated) user, the Member States National Competent Authorities user, the Commission user and finally a special type of authenticated user that can add comments or observations to GMO notifications based on the authorisation granted by the Competent Authorities and the Commission users.
The GMOREGEX system is a web-based application that enables the electronic support of the GMO notification and authorisation process as defined in Directive 2001/18/EC
[DIR.2001/18]. As specified in the Preparatory Report [PR] and in the Global Implementation Plan [GIP], the system has been developed to support the management of document exchange, information dissemination and events tracking related to the authorisation process for the deliberate release of new GMOs for experimental purposes (Part B notifications and associated SNIFs - [SNIF.PARTB]) or for marketing purposes (Part C releases and associated SNIFs and reports - [SNIF.PARTC]). The processes followed in the system are in accordance to "DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC" and follow the technical specifications and indications contained in the Preparatory Report [PR] and in the Global Implementation Plan [GIP].
This manual is designed to familiarize users with the GMOREGEX system and provide a reference of the system's functionalities and use. The GMOREGEX system includes also the implementation of the GMO Register which supports the storage of information and related documentation of authorised GMOs in the EU, as well as the dissemination of public information to the general public according to the provisions of Art. 31.2 of [DIR.2001/18].
The GMOREGEX system includes also a component that implements the information submission to the Biosafety Clearing House (BCH) in support of the Cartagena Protocol on Biosafety - Regulation (EC) No. 1946/2003 [REG.1946/2003].
The GMOREGEX system supports the following five roles:
- Commission user (COM)
- Competent Authority (CA) user (this role includes both "LEAD CA" and "Non LEAD CA", a CA is given the role of "LEAD CA" for all notifications that are created by users associated to it)
- Authorised External Party (AEP)
- Anonymous user (Guest)

In addition, and administrator role is defined for administration and management of the system:
- System administrator (Admin)

From a functional viewpoint, the GMOREGEX system supports the following high-level functionalities:
- Creation of a new notification (Part B and Part C)
- Management of the lifecycle associated to a new GMO notification (i.e. circulation and publication of information, gathering, sending, collecting and circulation of comments, etc.)
- Dissemination/publication of public information associated to an authorised GMO
- Submission of information to the BCH Central Portal and publication to a EU-based BCH interface
- Reporting
- Advanced search facilities

The current document is partially based on the documentation generated within the project on the implementation of the system carried out with the collaboration of an external contractor.

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