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Biotechnology and GMOs

# GMO Register User Guide

A. Rana and F. Foscarini

## Institute for Health and Consumer Protection
## 2007

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# GMO Register – User Guide

**A. Rana and F. Foscarini**

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# 1 INTRODUCTION

According to Article 31(2) of Directive 2001/18/EC [DIR.2001/18], the Commission is to establish one or several register(s), for the purpose of recording the information on genetic modifications in GMOs specified in Section A, point 7 of Annex IV to that Directive.

The information to be stored in this register is listed in Commission Decision 2004/204/EC of 23rd February [COM.2004/204] laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council [COM.2004/204].

In response to the aforementioned legislation requirements, DG ENV and DG JRC initiated the GMO Register project, with an objective to put in place the GMO Register system as a web-based application that supports the effective dissemination of GMO information to the general public, MS Competent Authorities (CA), and other interested parties. Furthermore, this system will take into account analogous requirements, in terms of data fields, from legislation related to international agreements (i.e. the Cartagena Protocol on biosafety) in order to help in the effective submission of GMO information to the Biosafety Clearing House.

This document contains the high level description of the functionalities implemented in the GMO Register system, as well as its User Guide. Its purpose is to provide guidance on the use of the system.

Additional documentation on the structure or functionalities of the system are available in the Functional Specification Document [GMOR.FSD.2005], in the System Design Document [GMOR.SDD.2005] and in the System Description document (in this final report).

## 1.1 Scope of the Project

Scope of the project is to implement a GMO register according to the requirements of [COM.2004/204] taking advantage of the experience acquired in the development of the systems that have already been implemented and are operational in the B&GMO Unit of the JRC.

The purpose of the project is to implement the Commission GMO Register as defined in Article 31(2) and further described in Annex IV of [COM.2004/204]. Such register must record and make publicly available, when not confidential, the information on GMOs products authorized in the EU, including information on genetic modifications. The types of information that must be recorded in the register are described at a high level of detail in [COM.2004/204] laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in [DIR.2001/18].

## 1.2 Scope of the document

The purpose of this document is to provide the User Guide for the GMO Register application. The functional specifications identified three possible roles in using the system. User guidelines are provided in this document for all the identified roles, i.e. Anonymous user, authenticated user, administrator.

## 1.3 Document structure

This document contains the following chapters:

**Chapter 1 – Introduction:** provides an introduction to the project, its scope and scope of the system. Additionally, abbreviations used throughout the document and reference documents are listed.
**Chapter 2 – High Level Functionality:** presents an overview of the functionality to be supported by the GMO Register system.

**Chapter 3 – Elements of the Graphical User Interface:** presents the elements of the Graphical User Interface, i.e. the components that are available in each screen of the application and their meaning.

**Chapter 4 – Public View of the Register:** contains the user guide for the public view of the register explaining how to use the functionalities associated to the non-authenticated (anonymous) user (list and search).

**Chapter 5 – Restricted View of the Register:** contains the user guide for the restricted view of the register explaining how to use the functionalities associated to the authenticated user (add, modify) and management of the system (administrator).

**Chapter 6 – System Requirements:** presents the system requirements and the platforms on which the system has been tested.

## 1.4 Abbreviations/Acronyms

| *Term* | *Definition* |
|---|---|
| BCH | Biosafety Clearing House |
| CA | Competent Authority |
| CSS | Cascading Style Sheets |
| DTD | Data Type Definition |
| EC | European Commission |
| ERD | Entity-Relationship Diagram |
| GMO | Genetically Modified Organism |
| GUI | Graphical User Interface |
| HTTPS | Hyper Text Transfer Protocol Secure sockets |
| IT | Information Technology |
| JRC | Joint Research Centre |
| MS | Member State |
| SQL | Structured Query Language |
| UML | Unified Modelling Language |
| XHTML | eXtended HyperText Markup Language |
| XML | eXtensible Markup Language |

## 1.5 Reference Documents

The reference documents are listed in Table 1.1

| *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 organism and replacing Council Directive 90/220/EEC. |
| [COM.2004/204] | Commission Decision 2004/204/EC of 23rd February 2004 laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council |
| [GMOR.FSD.2005] | GMO Register – Functional Specification Document (GMO Register Intermediate Report), JRC/TN N.EUR 22263EN |
| [GMOR.SDD.2005] | GMO Register – System Design Document (GMO Register Intermediate Report), JRC/TN N. EUR 22263EN |

*Table 1: Reference Documents*

# 2 HIGH-LEVEL FUNCTIONALITY

The scope of the GMO Register project is to implement an Information Technology (IT) system, capable to support the storage of information and related documentation of authorised GMOs in EU, and disseminate non-confidential information to the general public.

The GMO Register system is a standard Web-based and easy-to-use application that allows non-technical users to easily create, manage, and publish content.

The core functionality of the GMO Register system ensures the storage and online publication of information related to authorised GMOs. It is expected that information to be stored within the system will be submitted by Competent Authorities (CA).

In summary, the following functionalities are supported by the GMO Register system:

- Entering register data
- Receiving register data
- Registering the data related to GMOs authorised under Directive 2001/18/EC
- Making the data available for browsing, listing, and searching for all users, based on their access rights
- Entering data in compliance, as far as possible, with the Biosafety Clearing House specifications and with the detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in [COM.2004/204]

The GMO Register system supports the following actor types:

- Authenticated users (Commission user and Competent Authority (CA) user)
- Anonymous user (general public)
- System administrator

## 2.1 Data exchange

In order to enter data into the register, two mechanisms have been implemented: a web-based graphical user interface that allows authenticated users to enter data into the system and a data upload mechanism based on the use of standard formats.

An XML schema has been defined to describe an entry in the Register. Users can upload an entry by providing the data structured according to this format.

Describing the GMO Register data using an XML syntax has the following advantages:

- Automatic parsing of the message and upload into a database;
- "Export as" XML function to be associated to existing database allows creating of the data collection in a step;
- The use of a formal Schema allows automatic validation of the data (e.g. to verify that mandatory fields are all present and have a valid data type, etc.);
- Data can be extracted from an existing database or added through an ad-hoc data entry interface;

The data collection formatted according to the specified schema can be either transmitted over a (secure) network or burned on a CD and sent via mail;

The following steps have been followed in defining an XML Schema for the GMO Register:

- Identify the data items that are required
- Identify the relationships among the data items (e.g. relationship between a GMO event and a notification or between a GMO event and a detection method, etc.)
- Define a formal data model for representing the entities (groups of data items associated to a unique object or concept) – use ERD or UML
- Define a hierarchical representation of the data model suitable for formal description using XML
- Define the XML DTD (or Schema) for the XML message

The XML schema is available in [GMOR.FSD.2005] and is also attached to this document as an annex.

## 2.2 User types supported by the system

Table 2.1 describes the user types to be supported by the GMO Register system, their access rights and their primary actions.

| *User Role* | *Type* | *Access Rights* | *Primary actions* |
|---|---|---|---|
| Authority User | Authenticated | Limited access to GMO Register entries | Submits data related to an approved GMO |
| COM User | Authenticated | Limited access to GMO Register entries | Checks/modifies data related to a register entry |
| General Public (Anonymous) | Non Authenticated | Read-only access to “public set” of data | Obtains access to public information |
| Administrator user | Authenticated | Full access to the system | Administers and maintains system, manages user roles and organisations, access rights and system parameters |

*Table 2: User types supported by the GMO Register system*

# 3 ELEMENTS OF THE GRAPHICAL USER INTERFACE

In order to preserve consistency, the GMO Register GUI utilises specific GUI components, to be available to users in a consistent manner for all functionalities of the application. Figure 3.1 depicts the GUI components available in all web-pages of the application.


**Illustration 3.1: GUI components of all web-pages of the GMO Register system**

| # | *GUI Component Name* | *Purpose* |
|---|---|---|
| 1 | Header | Presents the “corporate identity” of the GMO Register through a logo and eventually a banner. The “Header” component is included in all web-pages in case future requirements necessitate its use. |
| 2 | User information | Supports the functionality to users to log in the application when anonymous, or log out when authenticated. Furthermore, when a user is authenticated, the “Log in” component allows the user to view his/her preferences. This component is included in all web-pages of the application |
| 3 | Main menu | Facilitates the navigation amongst the various web-pages of the application. Depending on the access rights of an authenticated user, the “Main menu” component may present additional functionalities to the user (e.g. administrative functions). This component is included in all web-pages of the application |
| 4 | Secondary functionalities | Facilitates secondary functionalities of the application. This area includes the GUI for support of the newsletter subscription and quick search functionalities. Depending on the access rights of an authenticated user additional secondary functionalities are also included in this GUI component (e.g. administrative tasks). This component is included in all web-pages of the application |
| 5 | Main content area | Present the main content of a web-page. |
| 6 | Footer | Similarly to the “Header” component, the “Footer” is included in all web-pages of the application, providing additional information about the web site (e.g. the copyright). |
| 7 | Validators | Contain all the validations that are passed by the current web-page (e.g. Valid XHTML 1.0 Strict, Valid CSS) |

**Table 3: GUI components of all web-pages of the GMO Register**

# 4 PUBLIC VIEW OF THE REGISTER

The public view of the system shows the information that are publicly available.

No authentication is necessary to access to this part of the system.


*Illustration 4.1: Public view*

## 4.1 Introduction

The public view represents the component of the system that is available to all user roles.

Without authenticating themselves, users in all user roles can access this portion of the system and perform basic search and list functionalities.

## 4.2 How to list all entries in the register

The simplest way to retrieve information about the entries in the GMO Register is by listing them using the panel on the left side.

By clicking on the menu items provided in the left menu under the "View Authorised products" label, the user will be presented with the list of all the entries in the system in the main view of the window (fig. 4.2)[1].

The list of the entries in the register can be ordered according to seven possible criteria:

1. by the name of the Applicant who has received an authorisation for the GMO described in that specific entry;
2. by the UniqueID associated to the GMO described in that specific entry;
3. by the intended use for which the authorisation has been granted (BCH code);
4. by the name of the organism;
5. by the introduced trait (BCH code);
6. by year in which the authorization has been granted;
7. by Member State which received the initial submission (Lead CA).

The following figures show the results of the operation described above for list criteria 1, 2 and 4.

[1] The data shown in these figures is fake data that has been used for test purposes only.

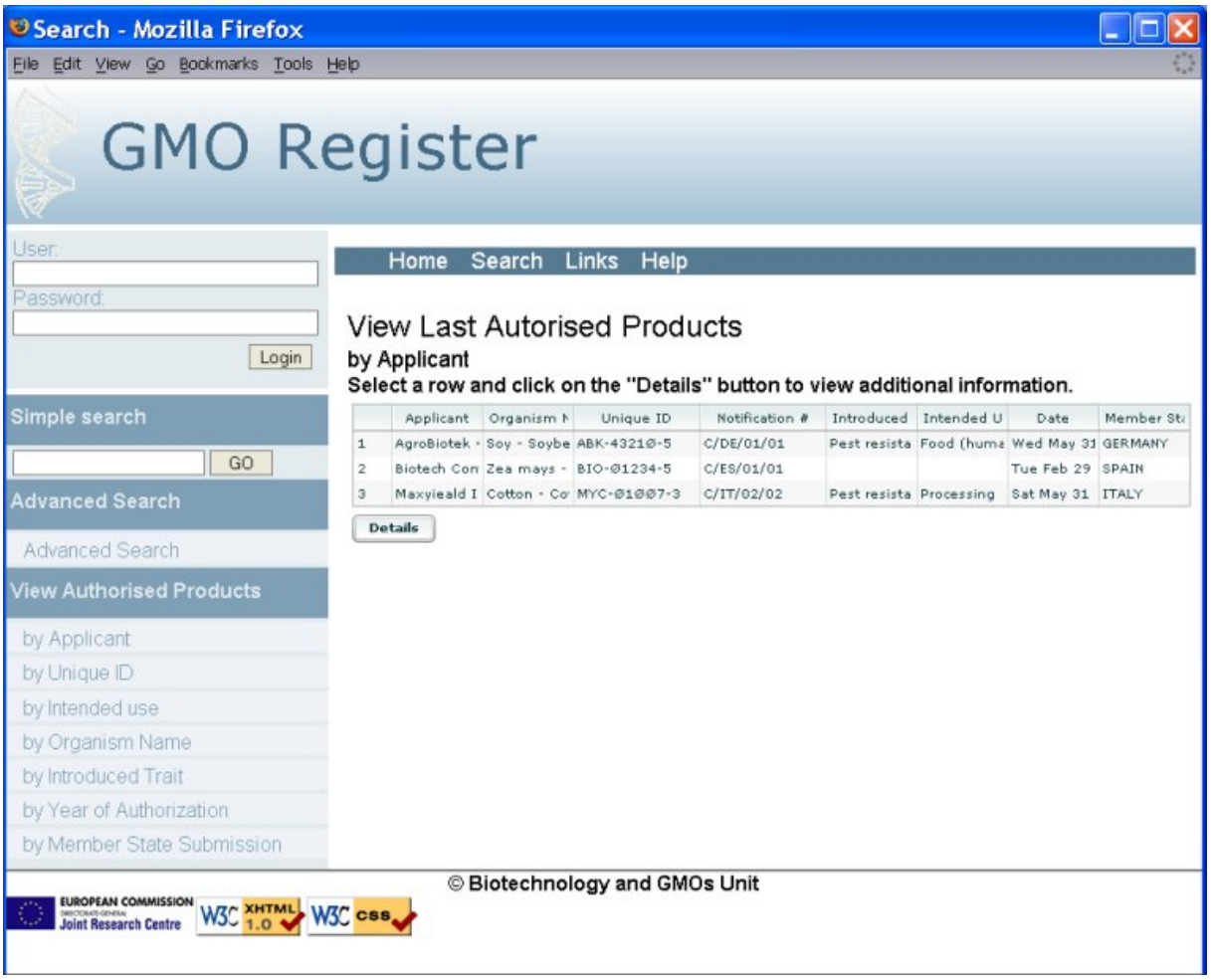


*Illustration 4.2: View authorised products ordered by Applicant name*

The results of the list operation are shown in a table where only a summary of the information available for each entry in the register is provided.

Namely, these summary information include:

- **Applicant**
- **Organism Name**
- **UniqueID**
- **Notification Number**
- **Introduced Trait**
- **Intended use**
- **Date of approval**
- **Member State (LCA)**

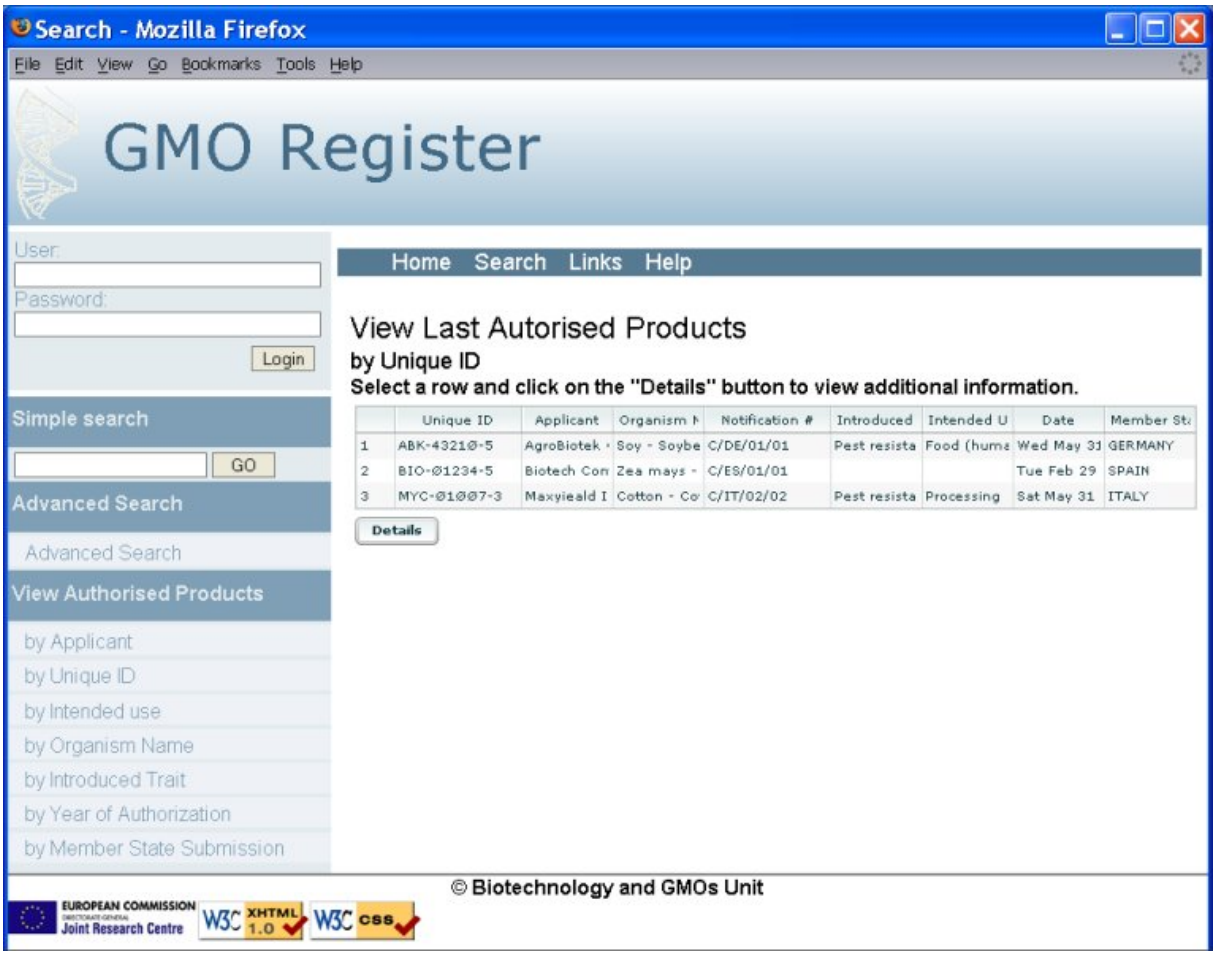


*Illustration 4.3: View authorised products ordered by UniqueID*

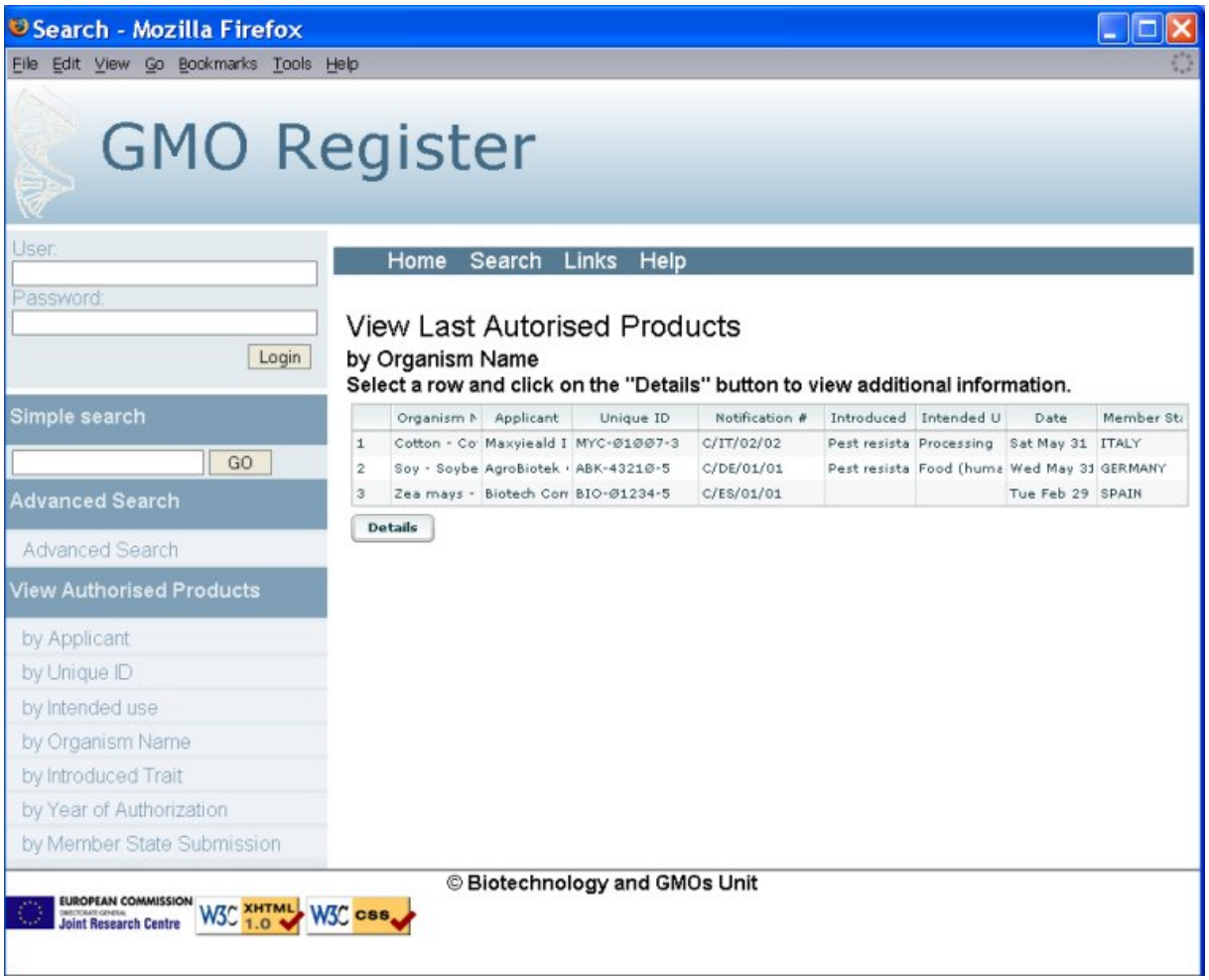


*Illustration 4.4: View authorised products ordered by Organism Name*

In order to view the details available for a register entry, the user must select an entry and click on the “Details” button.

When this operation is performed a new page is displayed in the main content area (Fig 4.5). This page contains the five sections into which the information related to a GMO register entry is grouped.

These are:

- **Details concerning the Notifier and responsible person**
- **General information concerning the GMO**
- **Information on the insert**
- **Information concerning the identification and detection method**
- **Information on lodging, storage and supply of samples**

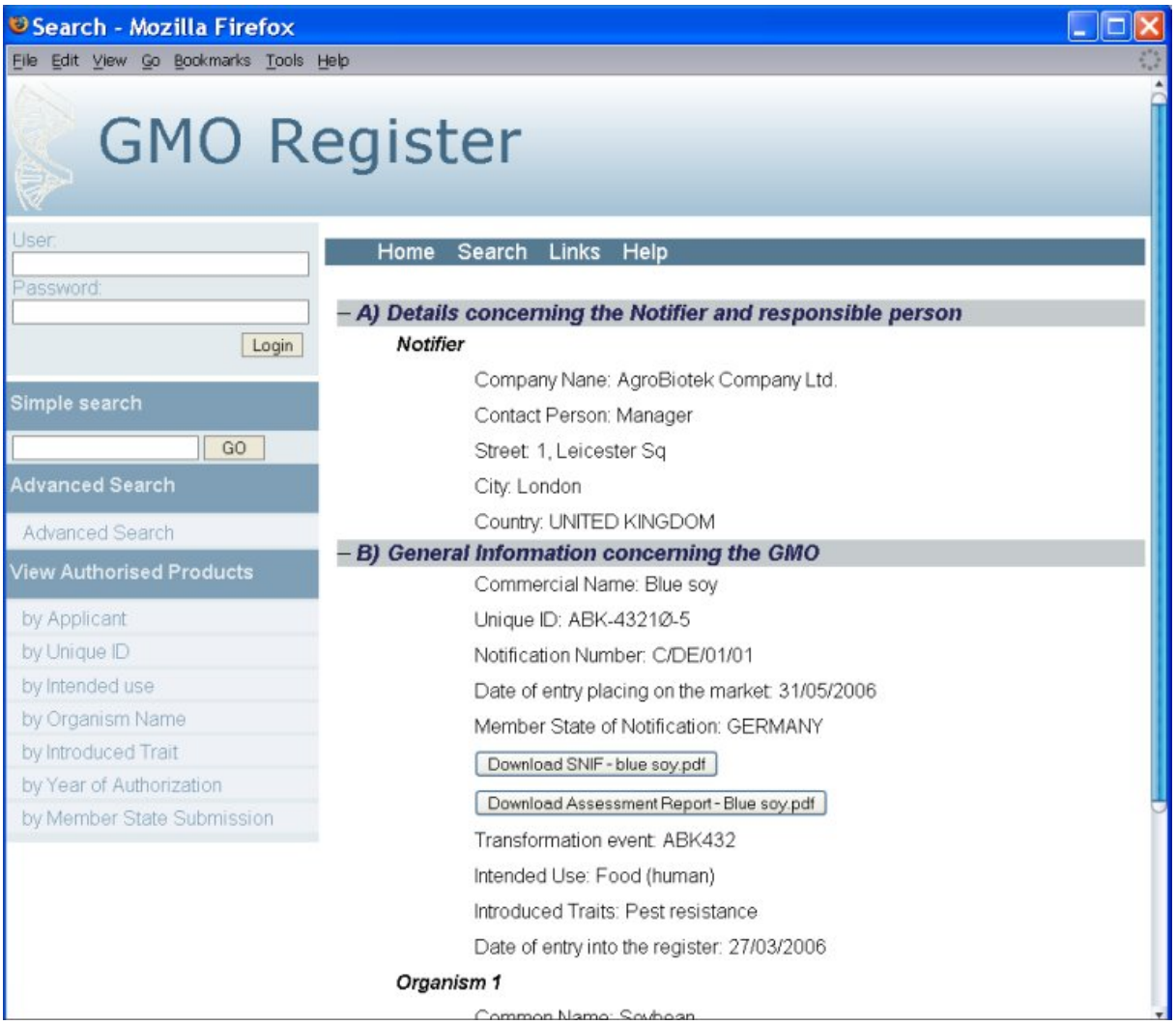


*Illustration 4.5: Register Entry details*

Each of these sections can be expanded to display the details of the information contained in each of them. When they are expanded, the "+" sign beside the name of the section is changed into a "-" indicating that the section has been expanded and that the information that follows belongs to that specific section. If the "+" signs changes into a "-" sign and no information appears below the label of the section, it means that no information is available for that section.

These sections and their contents are based on the data items described in chapter 4 of the Functional Specifications [GMOR.FSD.2005].

Users are given the option to download the content of the entry as a PDF file which is generated on the fly by the system with the information contained in all the sections.

## 4.3 How to search for a specific entry

The system provides two types of search mechanisms:

- simple search
- advanced search

The **Simple Search** can be started by specifying a search term in the input field under the label "Simple Search" in the left menu.

The term specified in the input field is searched in the "Country", "Organism name", "UniqueID", "Intended use" and "Introduced trait" sections of the database and the results are displayed in a table in the main content window.

Details about the entry can be displayed as described in the section above on listing entries.

The **Advanced Search** is activated by selecting this option on the left menu bar. A form which details all fields in the database is provided in the main content area. Users can specify values for each input field and search for all or for any of the selected parameters.

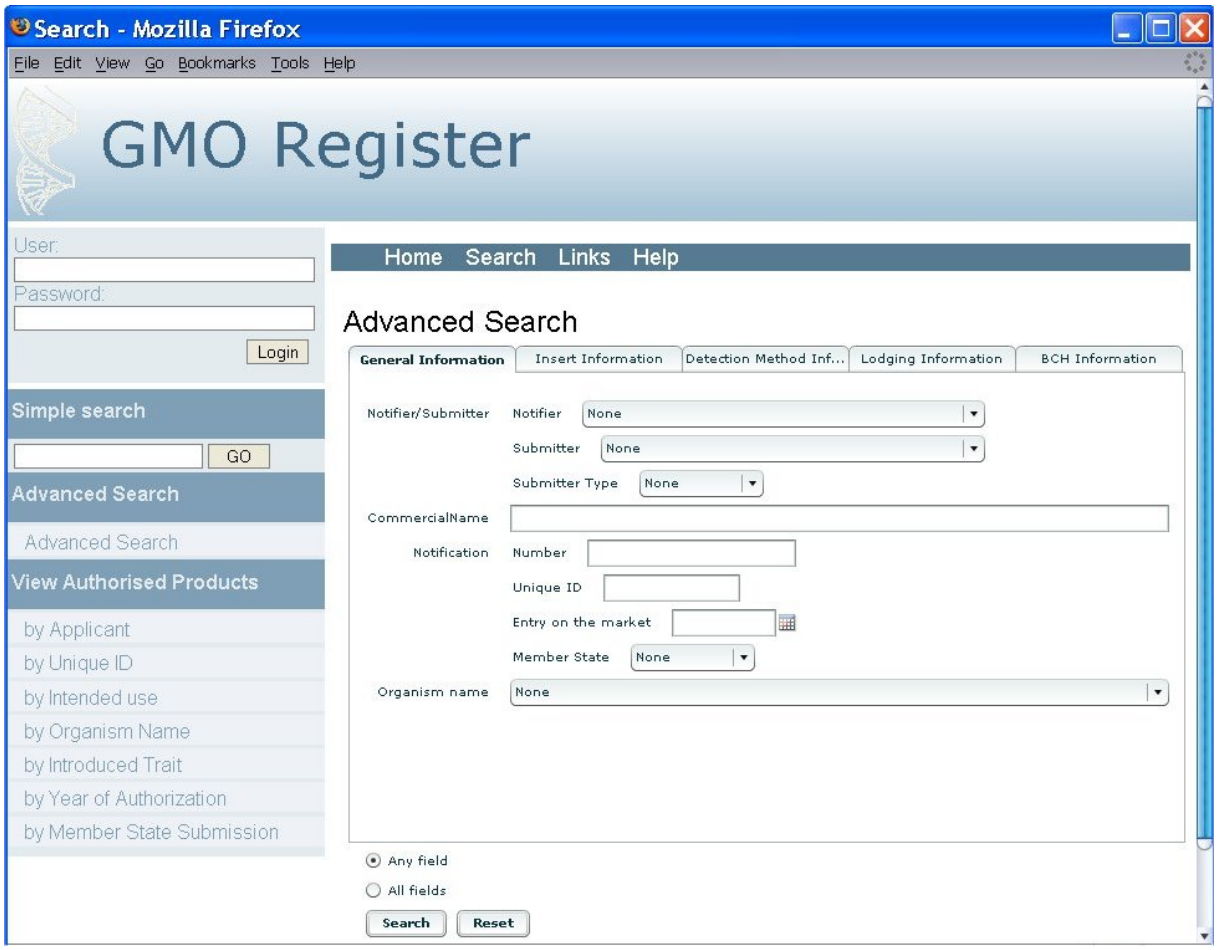


*Illustration 4.6: Advanced Search window*

# 5 RESTRICTED VIEW OF THE REGISTER

The restricted view of the register is available for authenticated users only, i.e. for Competent Authority, Commission users and administrator.

This view can be accessed only by specifying username and password in the login input fields on the top part of the left menu.

When the login function is activated, the communication protocol between the client (browser) and the server is switched to HTTPS and thus secured.

## 5.1 Authenticated (Authority/COM) User

When a user logs in, the environment in figure 5.1 is displayed.


*Illustration 5.1: Authenticated user login page*

An additional item is available in the upper menu bar ("**Authority/COM**"), by selecting this menu item, a new menu is displayed in the left part of the window. This new menu provides access to the functionalities available for the authenticated users.

On top of the left menu, authenticated users can access the information associated to their profile and, if necessary, modify them. This functionality provides also the possibility for authenticate users to modify their password.


*Illustration 5.2: Authenticate User: My Profile*

The left menu for authenticated users (authority/COM) provides the following section:

1. Register
2. Contacts
3. Organisms
4. Techniques
5. Recipient/Donors

6. Controlled Vocabulary
7. Simple Search

Sections 2, 3, 4, 5 provide the same functionalities, i.e.:

- add
- manage
- delete

These functionalities are used to create components of a Register Entry. A component of the Register Entry must be created before it can be used in a register entry. A component can be deleted only if it has not been yet used in a register entry, otherwise it can only be modified. This is not allowed in order to avoid inconsistencies in the database.

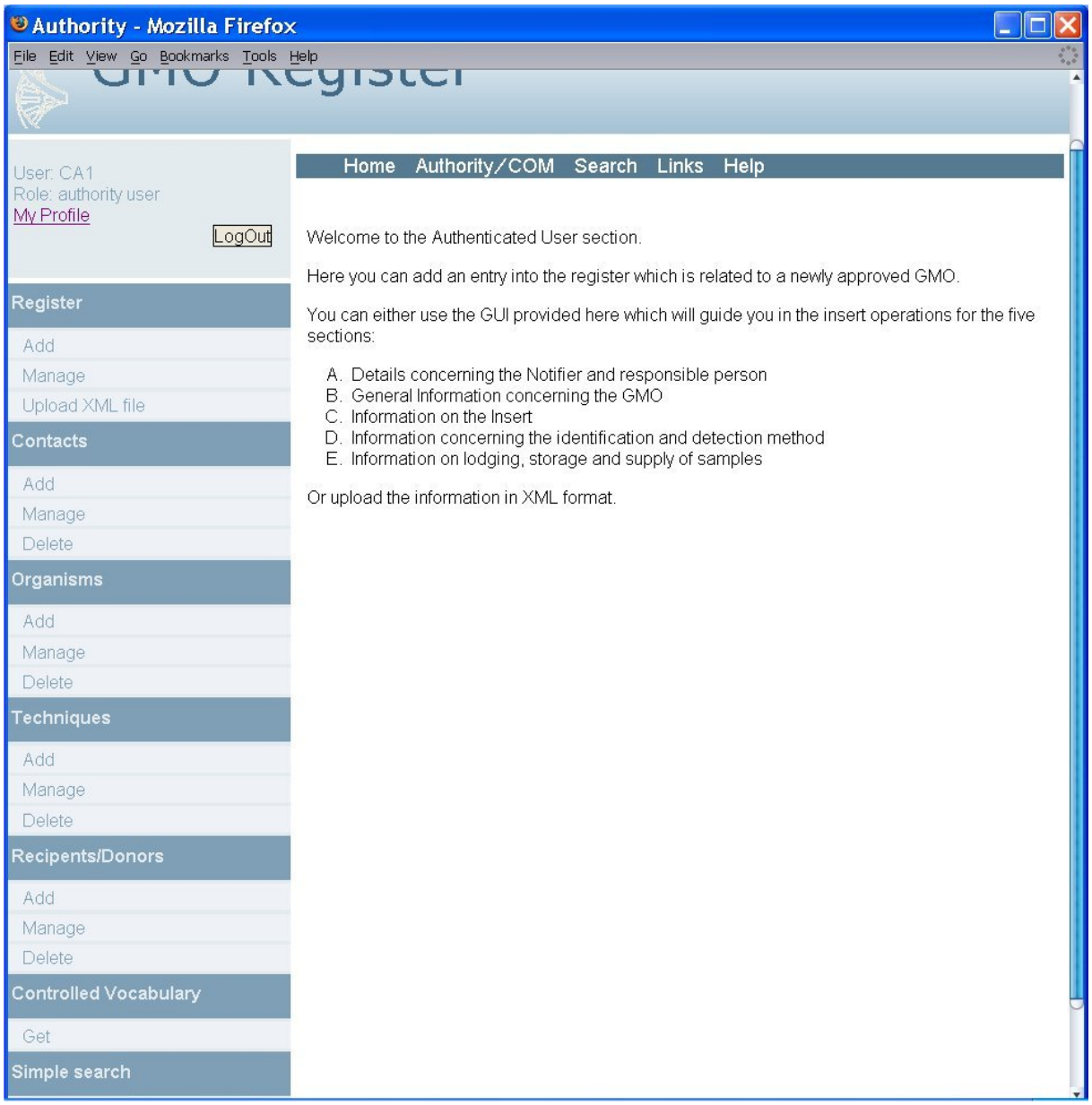


*Illustration 5.3: Authenticated User menu*

### 5.1.1 How to search for a specific entry

By clicking on the "Search" item in the top menu bar, users can change the menu on the left and access the menu that is available in the non authenticated mode. From this menu, they can select the Simple Search or the Advanced Search functionalities in the same way as described in section 4 of this document.

### 5.1.2 How to list all entries in the register

By clicking on the "Search" item in the top menu bar, users can change the menu on the left and access the menu that is available in the non authenticated mode. From this menu, they can select the functionalities associated to the menu item "View Authorised Products" in the same way as described in section 4 of this document.

### 5.1.3 How to insert a new entry into the Register

Before inserting a new entry in the register, the following components must be already available:

- Notifier
- Organism
- Transformation techniques (for BCH data items only)
- Recipient/Donors (for BCH data items only)

These components will be available in the respective drop-down menus when a new register entry is created. "Transformation techniques" and "Recipient/Donors" are components that are useful in completing the data fields for a BCH submission. They are not strictly required for a GMO Register entry (see [GMOR.FSD.2005]).

After creating these components, a new Register entry is created by selecting "Add" in the section "Register" in the left menu.

Tabs in the main content area allow users to insert data for each section of a register entry. Ad-hoc tabs are provided for additional information on BCH items and to upload Assessment Reports or SNIF files (files cannot be larger than 15 MB).

Information about the Detection Method can be given in text form or a URL to a place where further details can be obtained can also be specified. Users can indicate the type of information provided at the indicated URL in the field "URL Description".

Users can upload files associated to the register entry they are creating. When doing so, they must select the file by clicking on the "Choose" button and locate the file, then in order to update the file

onto the system, they must click on the “Upload” button. An indication will be given by the system that the file has been uploaded.

Users can save register entries as drafts, if additional information need to be added in a second time or if parts of it need to be modified. Register entries saved as draft are not visible in the public view.

An entry should not be saved as draft until all tabs have been completed.

When a register entry is complete, users can publish the entry which will become visible also in the public view.

The following figures illustrate the add entry functionality. The data shown in these figures is fake data that has been used for test purposes only.

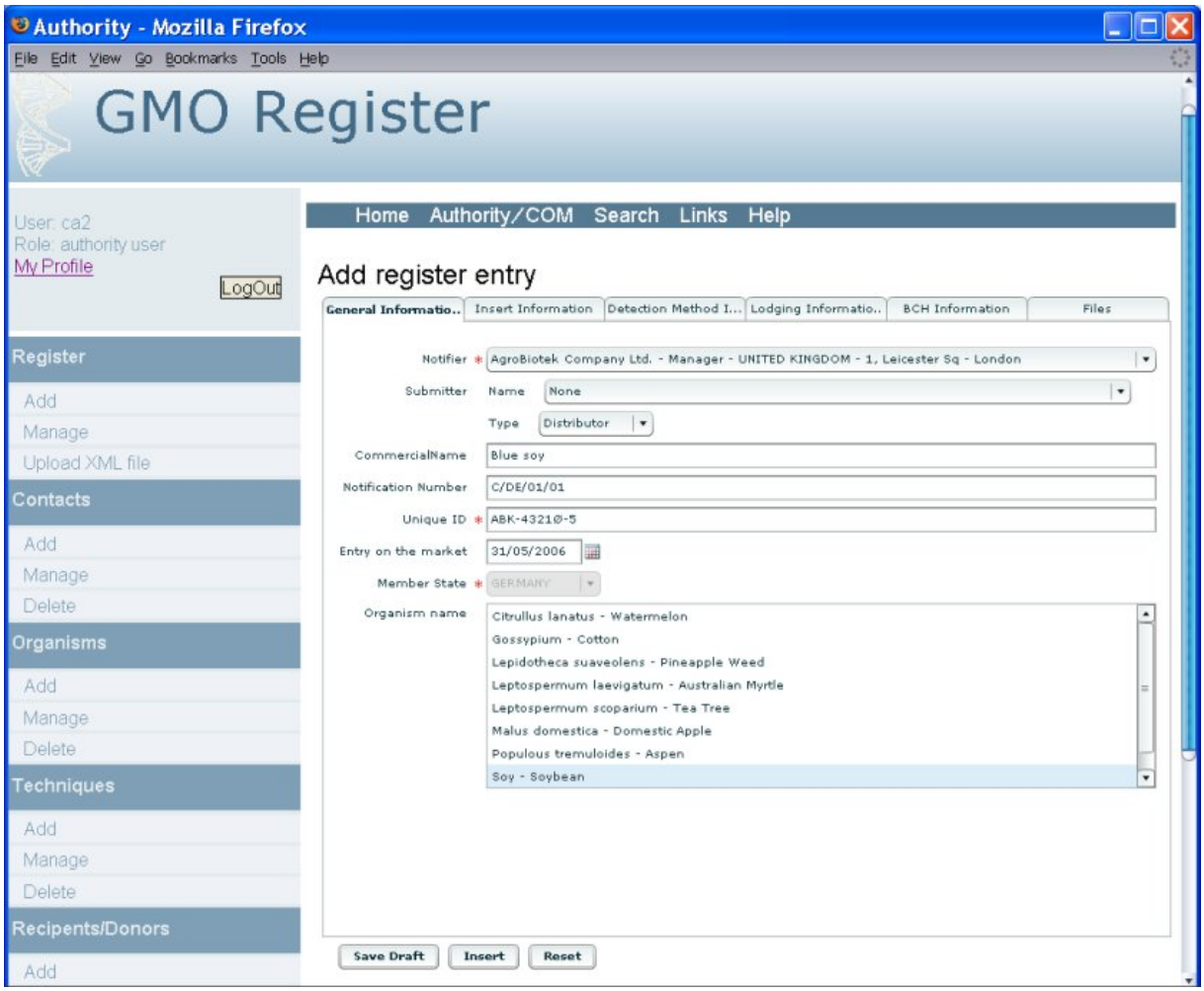


*Illustration 5.4: Add Register Entry - General Information*

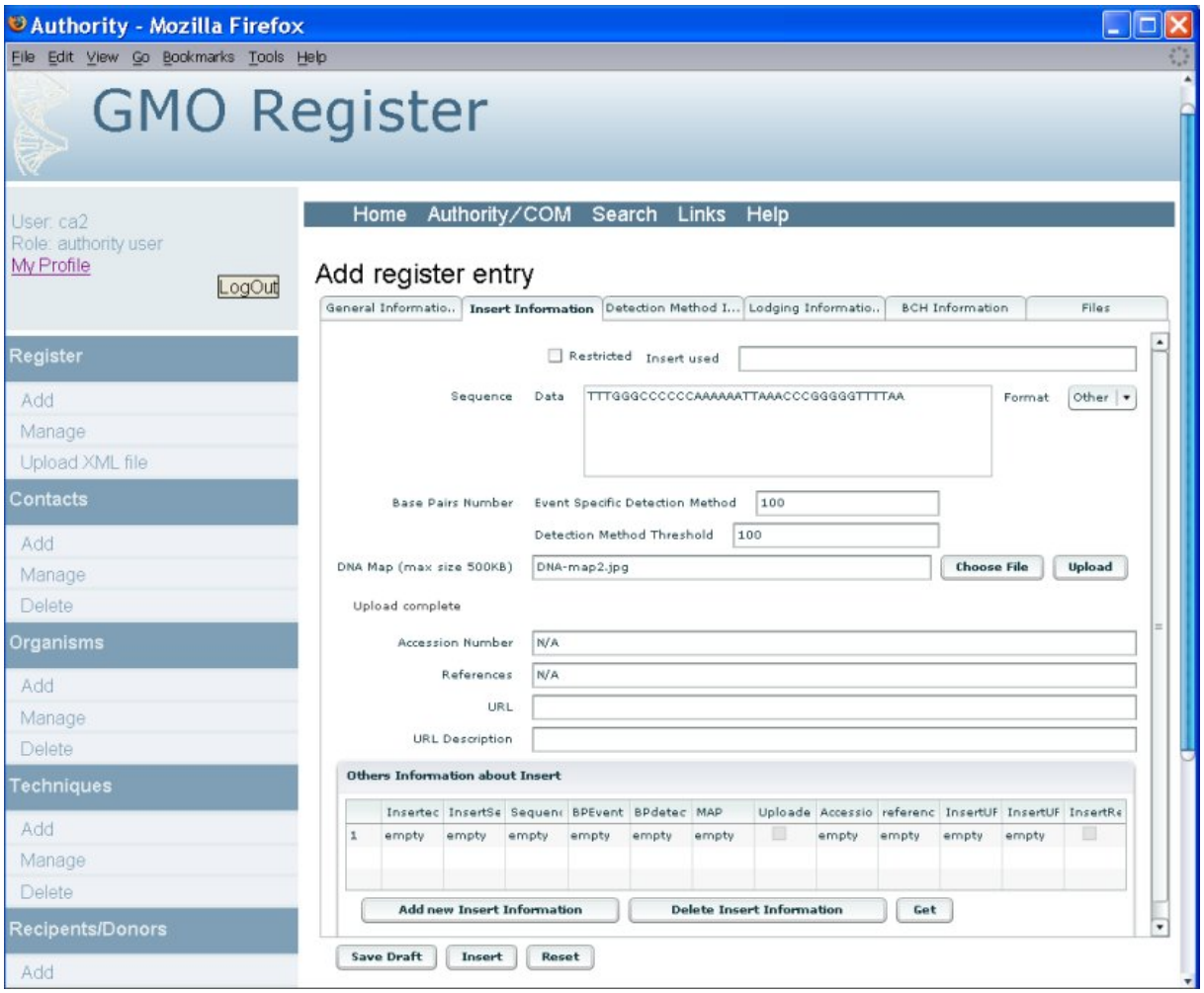


*Illustration 5.5: Add Register Entry - Insert information*


*Illustration 5.6: Add Register Entry - Detection Method information*


*Illustration 5.7: Add Register Entry - Information on lodging*

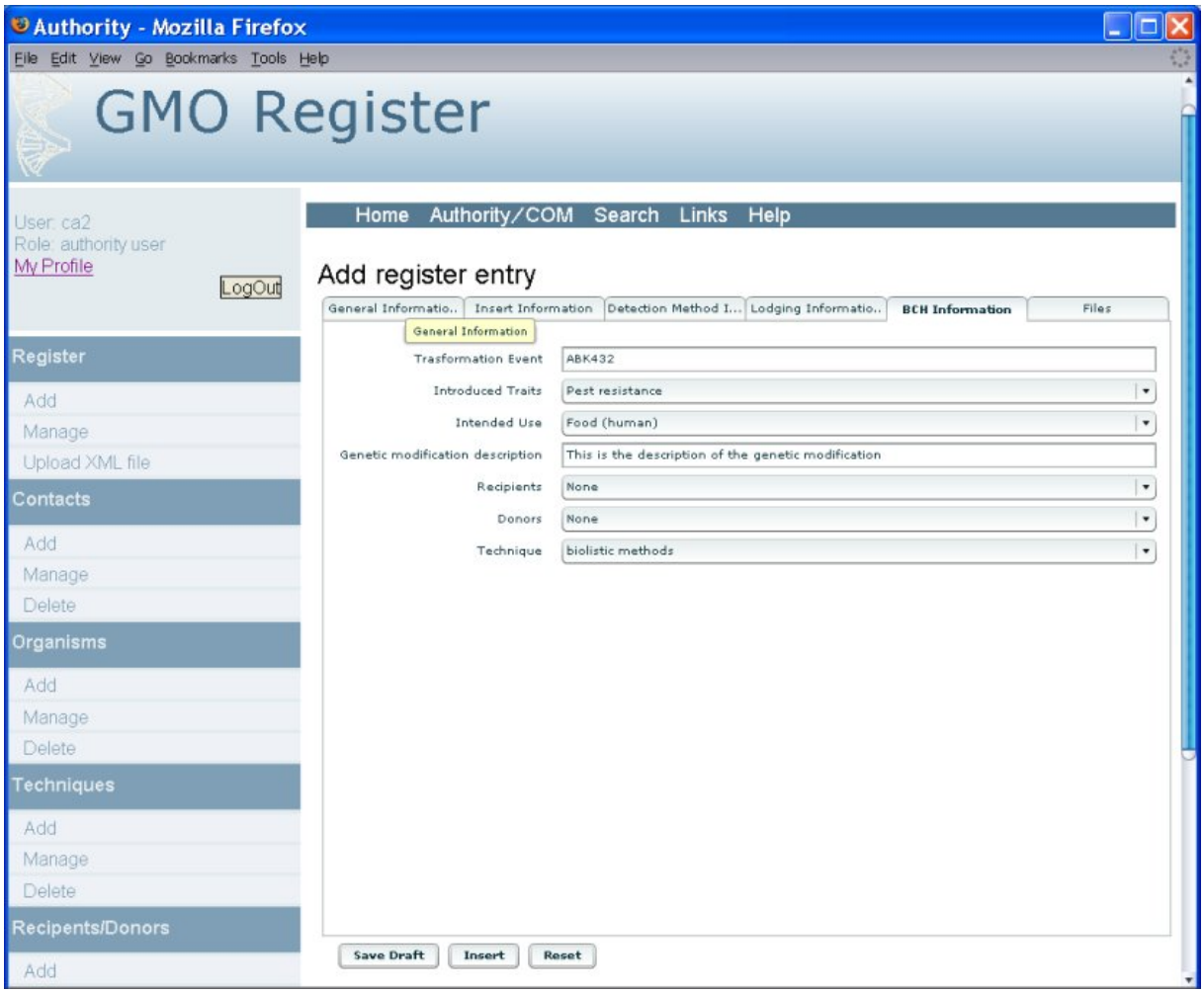


*Illustration 5.8: Add Register Entry - BCH information*

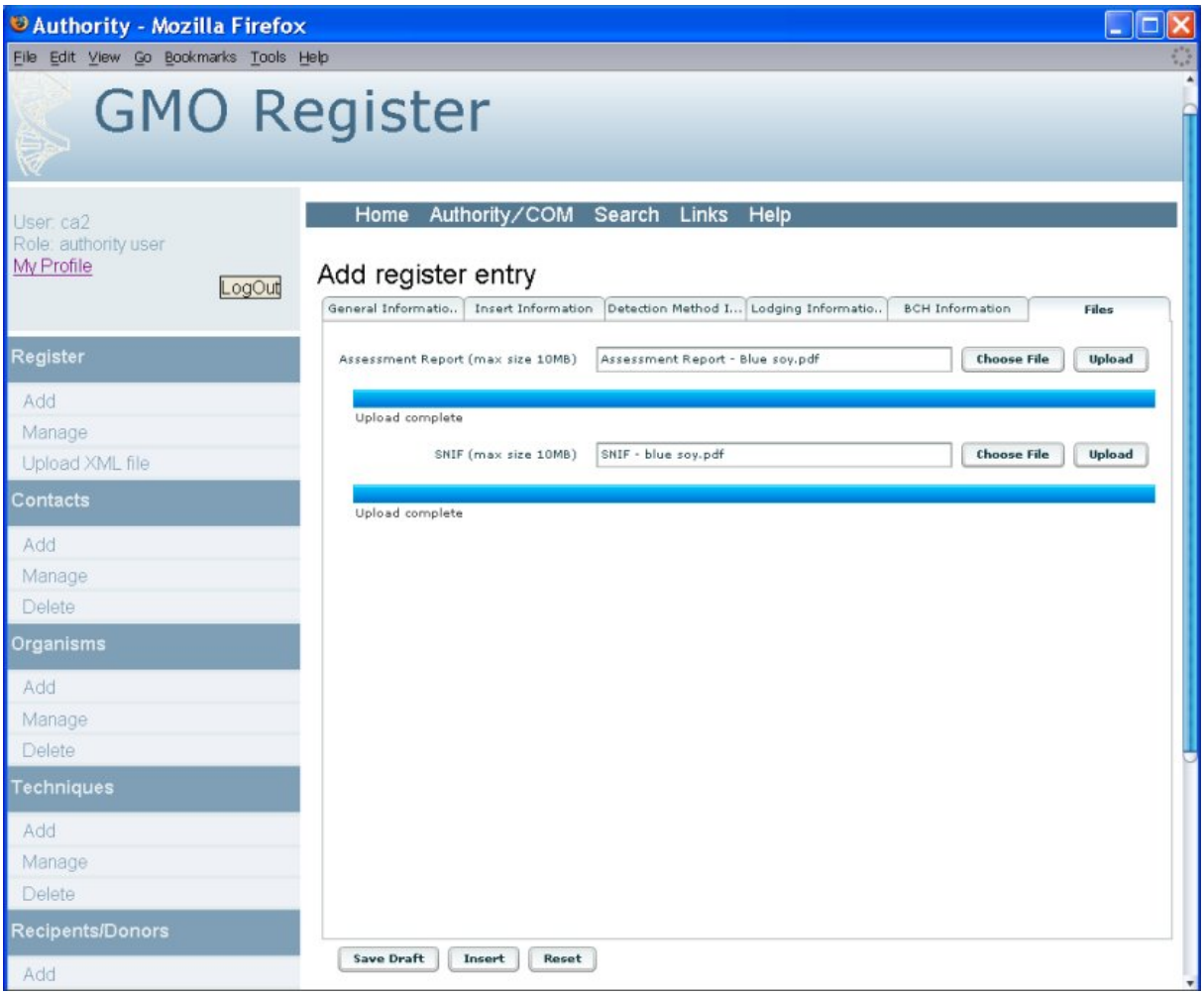


*Illustration 5.9: Add Register Entry - Files*

### 5.1.4 How to modify an entry in the Register

In order to modify an entry, authenticated users must select the “Manage” option and specify the “UniqueID” of the entry that they want to modify.

## 5.2 Administrator

When an administrator logs in, the environment in figure 5.10 is displayed.


*Illustration 5.10: Admin login page*

An additional item is available in the upper menu bar (“Administrator”), by selecting this menu item, a new menu is displayed in the left part of the window. This new menu provides access to the functionalities available for the administrator.

On top of the left menu, administrators can access the information associated to their profile and, if necessary, modify them. This functionality provides also the possibility for administrators to modify their password.

The left menu for administrators provide the necessary functionalities to add new users and to modify the data associated to existing users.

Administrators can also directly query the database using the SQL language.

### 5.2.1 How to create a new user account or edit an existing one

Administrators can create a new user by selecting the "Add user" option or can modify data associated to an existing one by selecting the "Manage user" option and specifying the login name of the user whose profile needs to be modified.


*Illustration 5.11: Admin Add User*

The item "Manage users" is used to change the profile associated to a user or to disable an account. A similar screen is presented to the administrator as the one in fig. 5.5.

# 6 SYSTEM REQUIREMENTS

On the client side the system requirements are:

- A web browser
  - Mozilla Firefox 1.0.x and above
  - MS Internet Explorer 6.x and above
- Macromedia Flash Player (at least version 8 is required for authenticated users)

The system has been tested on the following platforms:

Windows XP

- Mozilla Firefox 1.5.x
- Macromedia Flash Player 8
- MS IE 6.x

Linux (SuSE 10)

- Mozilla Firefox 1.0.x
- Konqueror 3.4.2

MacOSX

- Mozilla Firefox 1.5.x
- Safari 1.2

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Abstract

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This document contains the high level description of the functionalities implemented in the GMO Register application, as well as its User Guide. Its purpose is to provide guidance on the use of the system to end users.

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