

FAO GM Foods Platform user guide

Sharing information on safety assessments of genetically modified (GM) food



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Abstract

The Food and Agriculture Organization of the United Nations (FAO) maintains the "FAO GM Foods Platform", available at http://fao.org/gm-platform/, a simple, easy-to-access, global online resource that shares information on food safety assessments of genetically modified (GM) plants. This user guide provides an easy reference for the Platform's users so that they can effectively share their GM food safety assessment data in accordance with the relevant Codex Alimentarius guidelines. This user guide aims to ensure that user data remains up to date and provides global benefits, particularly in the case of low level presence situations. There are four types of FAO Foods Platform users: 1) Visitors, 2) Registered Users (Focal Points), 3) Content Administrator, and 4) IT manager. This user guide particularly targets Registered Users so that they can review, upload and use the relevant data on GM food safety assessments.

Keywords

Food safety, genetically modified organisms; GMO; GM food; GM feed; risk analysis; risk assessment; risk management; risk communication; database; information system; trade; low level presence; adventitious presence; Codex Alimentarius; FAO; guideline; regulatory framework

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Acronyms

FAO Food and Agriculture Organization of the United Nations

GM Genetically modified IT Information technology

MB Megabyte

OECD Organisation for Economic Co-operation and Development

URL Universal (or uniform) resource locator

1 Introduction

The Food and Agriculture Organization of the United Nations (FAO) GM Foods Platform is a simple online platform for sharing information on safety assessments of foods derived from recombinant-DNA plants, and is authorized in accordance with the Codex Alimentarius "Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants (CAC/GL 45-2003, annex III adopted in 2008)". FAO GM Foods Platform also facilitates the effective utilization of food safety assessment in situations of low level presence of recombinant-DNA (r-DNA) plant materials in food.

The FAO GM Foods Platform is freely accessible to anyone. However, only officially nominated country Focal Points can upload relevant data or edit their country information. Focal Points are nominated by the respective countries through their Codex Contact Points. Once a nomination is received using an FAO standard nomination form, the Focal Point is provided with a user name and a temporary password and can begin sharing data and information on the Platform. Focal points are fully responsible for the information they upload on the Platform and the uploaded entries are subject to a format check by FAO before they appear online.

2 Scope and objectives

This user guide is the reference document for all Platform users, and provides the necessary instructions to navigate the FAO GM Foods Platform and to upload information on it.

3 User levels

There are four levels of FAO GM Foods Platform users:

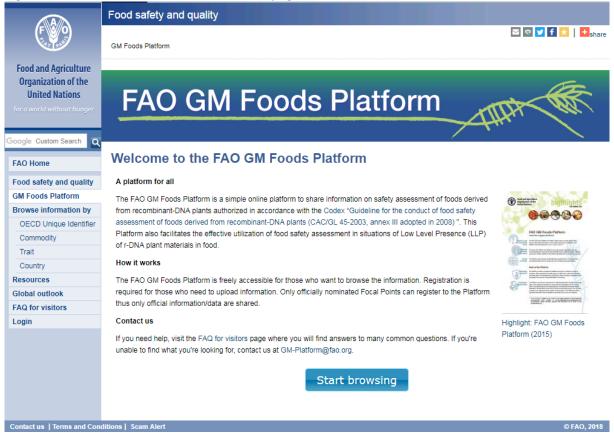
- 1) **Visitor**: A Visitor is a non-registered Platform user who can read all of the information on the FAO GM Foods Platform. Neither log-on nor permission is required. A Visitor cannot, however, add or edit information on the Platform.
- 2) **Registered User**: A Registered User is a registered national Focal Point who has been officially nominated by his or her respective country through its Codex Contact Point. A Registered User can upload and edit national information on the Platform but a log-on is required to do so.
- 3) Content Administrator: A Content Administrator can do all that the Registered User can do and, in addition, can approve the format of the submitted records to be published. Content Administrators are FAO food safety officers or consultants, and one of them is the overall manager of the FAO GM Foods Platform.
- 4) Information Technology (IT) Manager: An IT Manager can do all that the Content Administrator can do. An IT Manager will also maintain the Platform's IT functions. IT Managers are IT Division officers of FAO.

4 FAO GM Foods Platform – home page

The home page of the FAO GM Foods Platform (http://fao.org/gm-platform/) contains two main sections (Figure 1):

- The main navigation menu on the left.
- A central area where a short description of the website is given. The central area also contains
 a "Start browsing" button at the bottom of the page. Pressing this button will automatically
 direct users to the page under "Browse information by OECD Unique Identifier". All Platform
 users can browse information without logging in.

Figure 1. The FAO GM Foods Platform home page



The main navigation menu on the left side contains links to seven pages:

- FAO Home: FAO's home page
- Food safety and quality: FAO Food Safety and Quality homepage
- ➤ **GM Foods Platform**: Homepage of the Platform
- > Browse information by: There are four options for browsing information on the Platform:
 - 1) by OECD Unique Identifier;
 - 2) by Commodity;
 - 3) by Trait; and
 - 4) by Country.
 - Resources: Useful and relevant documents and websites are listed in this section. Resources include Platform-related materials, Codex documents on the topic, other relevant documents from national, regional and international sources, training tools, and other relevant links.
 - ➤ **Global outlook**: Current status of the Platform, including the list of participating countries, data statistics in various formats such as maps, bar graphs and pie charts. These outlooks reflect the real-time data shared by the Focal Points.
 - **FAQs for visitors**: Frequently-asked questions about the Platform for visitors.
 - **Login**: Link to login to the Platform.

5 How to browse information

On the left side of the navigation menu, the "Browse information by" page provides four submenus: Browse information by: 1) OECD Unique Identifier, 2) Commodity, 3) Trait and 4) Country. Each submenu allows users to browse information using their preferred criteria.

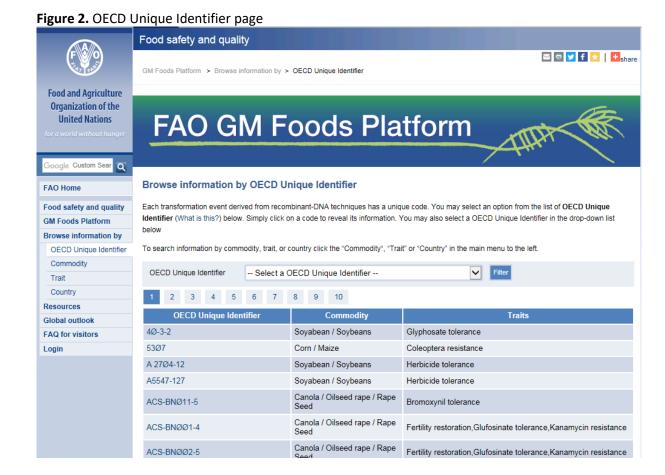
5.1 Browse by OECD unique identifier

The FAO GM Foods Platform uses the Organisation for Economic Co-operation and Development (OECD) Unique Identification system for transgenic plants. The OECD Unique Identifier is a code of a fixed length of nine alphanumeric digits for a transformation event derived from r-DNA techniques. It is composed of three elements separated by dashes:

- two or three alphanumerical digits to designate the applicant;
- five or six alphanumerical digits to designate the "transformation event"; and
- one numerical digit as verification.

Consult the "Revised 2006: OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants" for more information.

By clicking on the "OECD Unique Identifier" submenu, a page with the list of OECD Unique Identifiers appears (Figure 2). All OECD Unique Identifiers are listed in alphabetical order. Clicking on a code will open an individual page with detailed information about that particular Unique Identifier. See section 5.4 for navigation instructions on the individual detailed page.

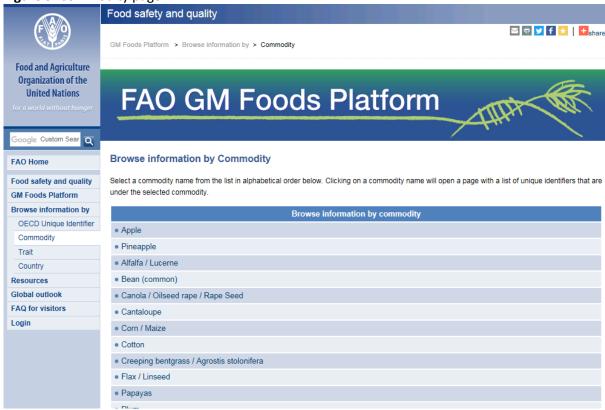


3

5.2 Browse by commodity

By clicking on the "Commodity" submenu, a page with an alphabetical list of Commodity names appears (Figure 3).

Figure 3. Commodity page



When a Commodity name is selected, a page opens with a list of OECD Unique Identifiers of the selected Commodity (Figure 4).

Figure 4. Commodity details

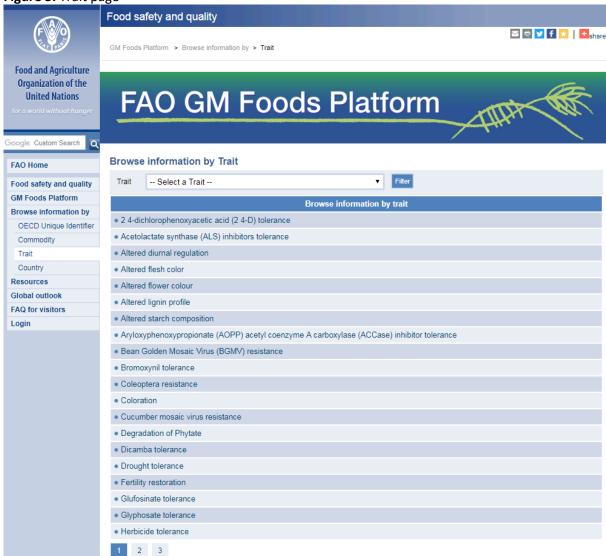


Clicking on one Unique Identifier code opens an individual page with detailed information about the OECD Unique Identifier. See section 5.4 for navigation instructions on the individual detailed page.

5.3 Browse by trait

By clicking on the "Trait" submenu, a page with an alphabetical list of Traits appears (Figure 5).

Figure 5. Trait page



Clicking on one of the Traits (see red arrow) opens a page that lists OECD Unique Identifiers that contain this Trait (Figure 6).

Figure 6. Trait details



Clicking on one Unique Identifier code opens an individual page with detailed information on this OECD Unique Identifier. See section 5.4 for navigation instructions on the individual detailed page.

5.4 Browse by country

By clicking on the "Country" submenu, a page with the list of the six Codex region names appears (Figure 7). When a region is selected, a list of the counties in this region appears. Note that this list shows only the names of countries that have already registered to the Platform; therefore, if a certain country is not listed, it does not necessarily mean that it does not have food safety assessments on r-DNA plants.

Figure 7. Browse information by Country



By clicking on a country name from the list (see the red arrow), you will be taken to the selected "Country page" that shows information on safety assessments conducted on r-DNA-derived foods in the selected country (Figure 8).

Figure 8. Country page (Example: Australia)

Browse information by Country > Australia

| 1 2 3 4 | 5 6 7 | 8 9 10 | | |
|--|---|--|--|--------------------------|
| OECD Unique lo | dentifier | Commodity | Traits | Latest entry uploaded on |
| ACS-BNØ11-5 | | Canola / Oilseed rape / Rape Seed | Bromoxynil tolerance | 14/06/2013 |
| ACS-BNØØ1-4 | | Canola / Oilseed rape / Rape Seed | Fertility restoration,Glufosinate tolerance,Kanamycin resistance | 13/06/2013 |
| ACS-BNØØ2-5 | | Canola / Oilseed rape / Rape Seed | Fertility restoration,Glufosinate tolerance,Kanamycin resistance | 13/06/2013 |
| ACS-BNØØ3-6 | | Canola / Oilseed rape / Rape Seed | Fertility restoration, Glufosinate tolerance | 13/06/2013 |
| ACS-BNØØ4-7 | | Canola / Oilseed rape / Rape Seed | Glufosinate tolerance,Kanamycin resistance,Male sterility | 13/06/2013 |
| ACS-BNØØ5-8 | | Canola / Oilseed rape / Rape Seed | Glufosinate tolerance, Male sterility | 13/06/2013 |
| ACS-BNØØ7-1 | | Canola / Oilseed rape / Rape Seed | Glufosinate tolerance | 13/06/2013 |
| ACS-BNØØ8-2 | | Canola / Oilseed rape / Rape Seed | Glufosinate tolerance | 13/06/2013 |
| ACS-GHØØ1-3 | | Cotton | Glufosinate tolerance | 14/06/2013 |
| ACS-GMØØ5-3 | | Soyabean / Soybeans | Glufosinate tolerance | 14/06/2013 |
| 1 2 3 4 | 5 6 7 | 8 9 10 | | |
| | | Focal Point Informatio | n | |
| E-mail: | janet.gorst@food | dstandards.gov.au | | |
| Country: | Australia | | | |
| Organization/agency name (Full name): | Food Standards Australia New Zealand | | | |
| Contact person name: | Janet Gorst | | | |
| Website: | http://www.foodstandards.gov.au | | | |
| Physical full address: | Boeing Building, | 55 Blackall Street, Barton ACT 2600, Austr | alia | |
| Phone number: | +61 2 6271 2266 | | | |
| Fax number: | +61 2 6271 2278 | | | |
| Country introduction | | | | |
| Summary: Food Standards Australia New Zealand (FSANZ) is the regulatory agency responsible for the development of food standards in Australia and New Zealand. The main office (approximately 115 staff) is located in Canberra (in the Australian Capital Territory) and the smaller New Zealand office (approximately 10 staff) is located in Wellington on the North Island. | | | | |
| | | Framework | | |
| Regulatory framework: | My country has a regulatory framework that requires the competent authority to conduct safety assessment of GM food. | | | |
| Structure for GM food safety assessment: | My country has competent authority, agency, organization, ministry, department, committee, commission or a system/mechanism that is tasked to conduct or review GM food safety assessment. | | | |
| Supplemental information: | the Application Handbook). Following the last public consultation, an Approval Report is prepared and is considered by the FSANZ Board who make a decision about whether the requested variation to the Code should be approved or not. The Board's decision is then passed on to the Legislative and Governance Forum on Food Regulation (the Forum), a committee comprising senior government Ministers from Australia and NZ. This Committee has approximately 2 months to review the Board's decision. If the Board's approval is accepted by the Forum, the approval is then gazetted and becomes law. | | | |
| Contact details of the competent authority(s) responsible for the safety assessment and the product applicant: | Food Standards Australia New Zealand (FSANZ) (http://www.foodstandards.gov.au) | | | |

On the top page, there is a list of uploaded information by Country. Following the list of information, there is a space for country information and contact information.

Users can further click on an OECD Unique Identifier to open an individual detailed page about that OECD Unique Identifier. See section 5.5 for navigation instructions on the individual detailed page.

5.5 Individual detailed page for a OECD Unique Identifier

For all of the above four pages (i.e. OECD Unique Identifier, Commodity, Trait or Country), clicking on an OECD Unique Identifier opens an individual detailed page (Figure 9).



Each individual page has basic information about the OECD Unique Identifier, including Commodity and Traits. The list of countries that have uploaded information about the concerned OECD Unique Identifier follows.

Under each country's name, there is a table that includes information on:

- ➤ Name of product applicant
- Summary of application
- > Date of authorization
- Scope of authorization
- Links to information on the same product in other databases maintained by relevant international organizations, as appropriate
- Summary of the safety assessment
- Where to obtain detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation
- Relevant links to documents and information prepared by the competent authority responsible for the safety assessment (Figure 9)
- Authorization expiration date.

At the bottom right corner of each table, there is a blue button labelled "View Country Profile". Clicking the button allows users to view, in a popup window, the country contact information as well as the Country Profile, including relevant GM food safety assessment-related policies (Figure 10).

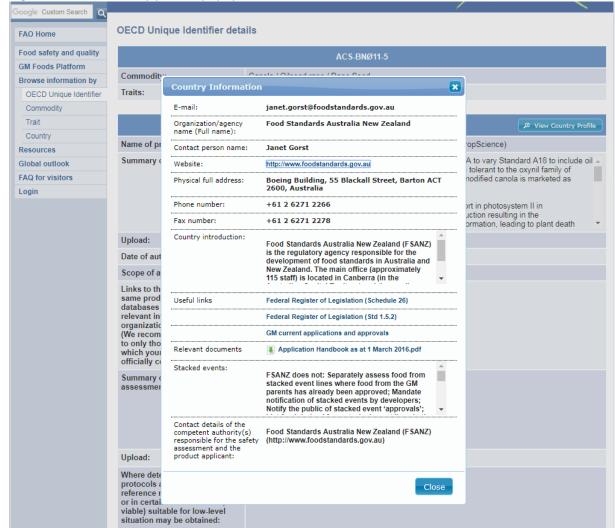


Figure 10. View country profile, popup window

6 How to register to the FAO GM Foods Platform (first time)

One Focal Point per Codex Member Country is officially nominated by the respective country through its Codex Contact Point. The nominated Focal Point is then invited to become a Registered User of the Platform. A Registered User is able to upload relevant national data and information to the Platform.

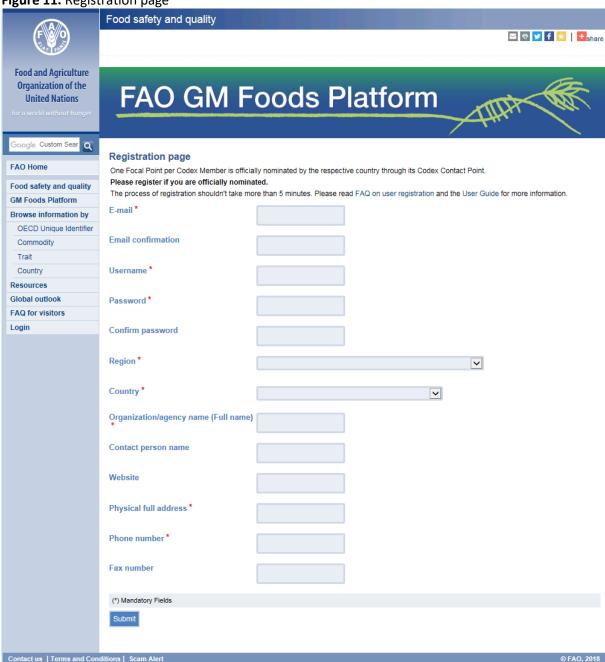
6.1 General mechanism to become a registered user

- 1) Once an official nomination has been received by FAO (at GM-Platform@fao.org), the Content Administrator will send an email message to the nominated Focal Point, with a direct link to the registration page (Figure 11).
- 2) The nominated Focal Point will use the link to register with the Platform. See below (section 6.1) for step-by-step instructions for completing the registration form. This process should take only five minutes.
- 3) Once the form has been submitted, the Content Administrator will review the form and grant the nominee access to the Platform.
- 4) The Focal Point will be informed of the approval and become a Registered User.
- 5) If you believe that you should be a Registered User for the Platform, it is strongly recommended that you to contact your country's national Codex Contact Point and request that they officially nominate you as a Focal Point for this Platform. In principle, one Focal Point per Codex member

must be officially nominated by the respective country through its Codex Contact Point. If necessary, a country could nominate an alternative Focal Point to be a Registered User, and who would use the same account as the Focal Point.

- 6.2 Step-by-step instructions for completing the registration form
- 1) To register, click on the link provided by email from FAO. You will then be taken to the registration page (Figure 11).

Figure 11. Registration page



2) At the top of the registration page, there is a link to "FAQs on user registration" that contains answers to commonly-asked user registration questions and a link to the user guide. It is recommended that you read the FAQs before you begin filling out the form. The FAQs are also available in Annex 2of the present document.

- 3) A red asterisk (*) indicates a mandatory field. In case of errors, validation messages will appear, notifying you of the missing field(s) or incorrect format(s).
- 4) After you provide your work email address (mandatory), the system will ask you to confirm the email you entered.
- 5) Set your username (mandatory). It is recommended that you use your country name as a username (e.g., if you are from Australia, use "Australia" or "australia", rather than your name). Although this is only a recommendation, it becomes useful if, for example, a national Focal Point changes within a government; then, only the contact information needs to be changed, but not the username.
- 6) Set your password (mandatory). Keep both the username and password safe. The system will ask you to enter and confirm a password of choice.
- 7) Select your Codex region from the dropdown list (mandatory).
- 8) Select your country from the dropdown list (mandatory). For the European Union Focal Point, choose "European Union" from the list.
- 9) Provide the full name of your organization or agency, followed by an acronym in parentheses if applicable. Then, if applicable, provide the full name of the department, section or unit responsible for the safety assessment. Ensure that the name of your organization appears correctly in the form (mandatory).
- 10) Provide the name of a contact person (optional, but strongly recommended).
- 11) Provide the website address of your organization (optional).
- 12) Provide the full physical business address of your organization, and ensure it appears correctly in the form (mandatory).
- 13) Provide your work phone number (mandatory).
- 14) Provide your fax number (optional).

Once all fields are filled out, click "Submit" to complete the registration process. Afterward, you will receive an email receipt of your account registration request. Once your account is verified by the FAO Content Administrator, you will receive a confirmation email.

7 How to login to the Platform

7.1 General login

The steps for all Registered Users to follow to login to the FAO GM Foods Platform are as follows:

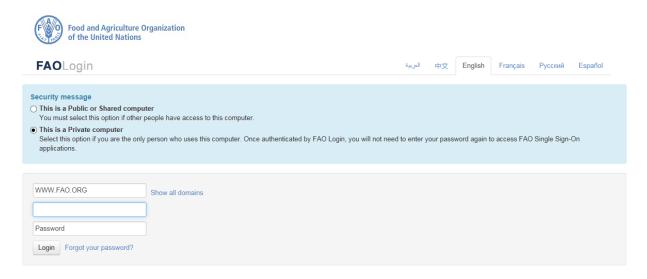
- 1) Click "Login" at the bottom of the left menu (Figure 12).
- 2) Click "Click here to login" under "User login"

Figure 12. FAO GM Foods Platform login page

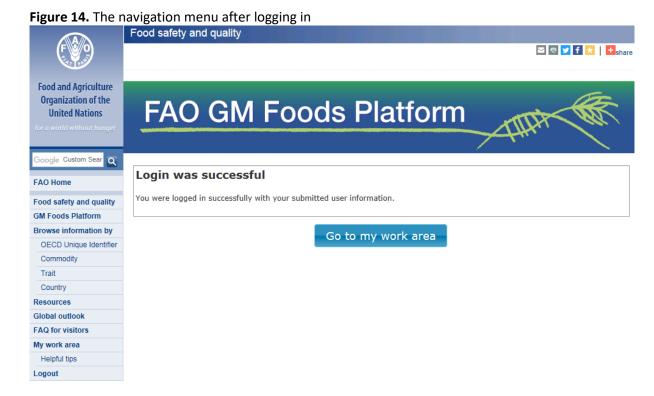


3) Insert your username and password on the login page (Figure 13). Keep <u>WWW.FAO.ORG</u> in the first field (domain name) and click the "Login" button.

Figure 13. FAO login page



4) You are now logged in. You will notice that the left side of the navigation menu now contains new menu items. You will also see a blue button stating "Go to my work area" in the central area (Figure 14).



7.2 What if I forget my password?

If you cannot remember your password, send an email to GM-Platform@fao.org and you will be provided with a temporary one within three working days. Once you have received your new password:

- 1. Login to your country profile;
- 2. Verify that your credentials are working correctly;
- 3. Inform <u>GM-Platform@fao.org</u> if you could successfully login. If your login has failed, inform <u>GM-Platform@fao.org</u>, who will liaise with the FAO IT department and contact you back once the problem is solved.

7.3 How do I change my password?

To change your password, go to "My work area", click on the "Your account information" blue tab at the top right, click "Edit profile" at the bottom, then change your password and click "Submit changes".

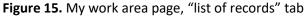
8 How to edit information and upload data to the Platform

8.1 My work area

Once you have logged in (section 7), click the blue button that says "Go to my work area". This will take you to a designated space for your country, entitled "My work area". You can also get to this page by simply clicking "My work area" from the left side of the navigation menu.

The "My work area" page contains four main sections in blue tabs at the top (Figure 15).

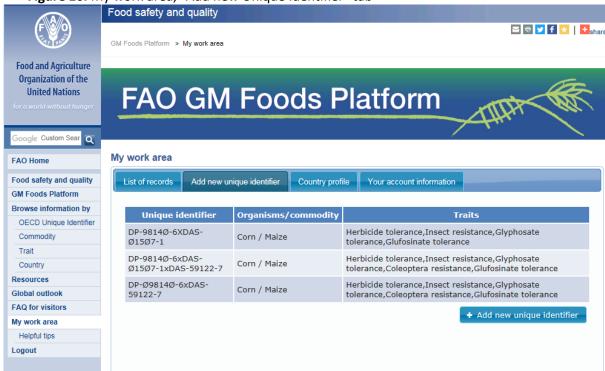
List of records. This tab is automatically selected when "My work area" has been clicked. This page shows a list of submitted records by your country, and has a button to "Add new record", which takes you to the form to create a new record (section 8.3).





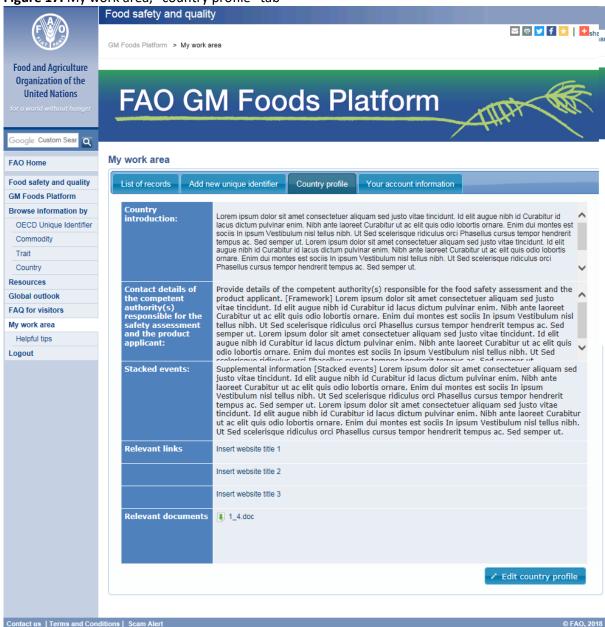
Add new Unique Identifier. The space under this tab provides a list of OECD Unique Identifiers submitted by you (Figure 16). This page also has a button to "Add new Unique Identifier", which takes you to the form to create a new Unique Identifier (section 8.5).

Figure 16. My work area, "Add new Unique Identifier" tab



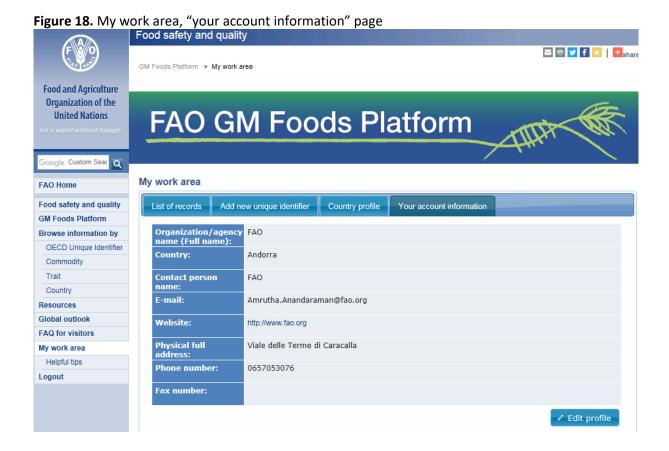
➤ **Country Profile.** The space under this tab provides a link for the respective country so that the country information can be edited (Figure 17). The page shows also a button which takes you to the form that you can use to edit your country profile (section 8.6).

Figure 17. My work area, "country profile" tab



Your account information. The space under this tab provides a link for the Registered User to edit his/her account information (Figure 18). The page shows a button which brings you to the form that you can use to update your account information (section 8.7).

In principle, all information must be submitted in one of FAO's official languages (English, French, Spanish, Arabic, Chinese or Russian). However, note that during the Platform's development process, many countries strongly recommended using English in order to avoid any confusion due to possible mistranslations.



8.2 I am new to the Platform. What should I do first?

The first time you login to the Platform, most of the above sections will be empty or the information is possibly outdated. Before you start uploading information to the Platform, it is recommended that you first make sure to update your account information (section 8.7) and complete the Country Profile section (section 8.6).

It is also recommended that you browse through the form to create a new record by clicking the "Your submitted records" tab, then clicking the "Add new record" button. You will see necessary items you might like to prepare offline. See section 8.3 for more details.

8.3 How to upload records with safety assessment information

When you have all the required information available (see above paragraph), you are ready to start uploading the information to the Platform following the step-by-step instructions below.

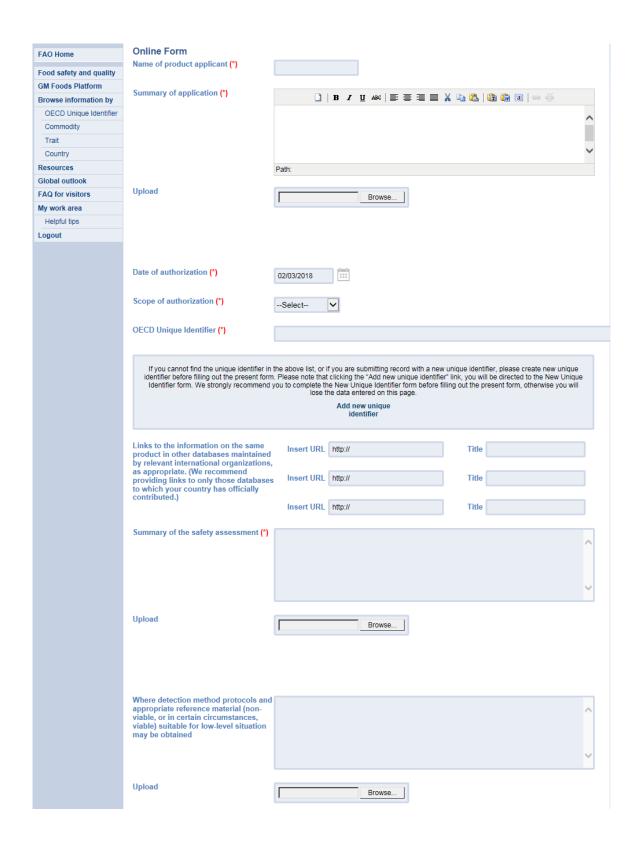
- 1) Make sure you have logged in (section 7).
- 2) Click "My work area" from the left navigation menu (or a button saying "Go to my work area" on the screen immediately after you login).
- 3) Make sure you are looking at the page under the "List of records" tab.
- 4) Click the blue "Add new record" button.

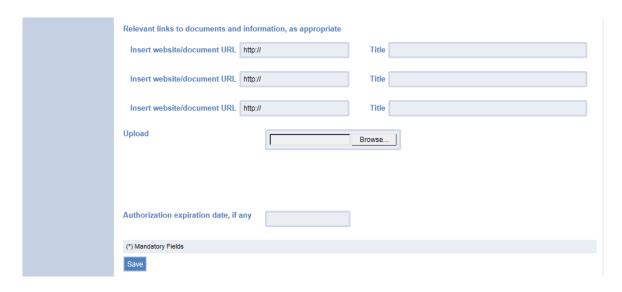
- 5) A form consisting of ten fields appears¹ (Figure 19).
- 6) The form should be completed and submitted in a single session (timeout: 24 hours) as it is not possible to save a partially completed form online. If you log out without submitting your work, the information entered will be lost. It is, therefore, recommended that you prepare your record offline and transfer the relevant sections on the online form after completion.

Figure 19. Online form

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¹ The form has been created according to the items listed in the Codex Plant Guideline (CAC/GL 45-2003, Annex 3).





The following instructions explain the different steps involved in completing the form:

- 1) Provide the name of product applicant
- 2) Provide the summary of the application

The goal of the "summary of application" field is to provide only summarized information — and not the entire application — as part of the request for authorization. While in principle the attachments can be in any of the FAO's official languages (English, French, Spanish, Arabic, Chinese or Russian), it is strongly recommended that the summary of application is written in English to guarantee the accessibility of the information to all users.

NOTES:

- There is no set length for the summary field.
- ➤ If you prefer to upload a document with the application or a document of the summary instead of cutting and pasting paragraphs in the text box upload the document, and then the summary text field will become an optional field.
- You can upload up to three files to an entry by clicking on the "Browse" button besides the box that says "Upload".
- > Acceptable file formats are: portable document format (pdf) and Microsoft Word (doc or docx).
- > The maximum file size is set to 40MB.
- > Important: Name your files properly before you upload the file, as the link will appear with the clickable file name. It is recommended that you name your document with a descriptive filename and, if there is enough space, your country name.
- If you want to remove an uploaded file, "check" the checkbox beside the file, and then you will be able to delete it from the list.

In principle, all records must be in one of FAO's official languages (English, French, Spanish, Arabic, Chinese or Russian). However, during the Platform development process, many countries strongly recommended using English in order to avoid any confusion due to possible mistakes in translation.

- 3) Select the date of authorization from the calendar.
- 4) Select the scope of authorization from the dropdown list.
- 5) Select the OECD Unique Identifier from the dropdown list.

If you cannot find the OECD Unique Identifier in the provided list, or if you are submitting a record with a new Unique Identifier, it is recommended that you create a new Unique Identifier before filling out the main form, otherwise you will lose the entered data. See section 8.4 for additional instructions in how to create a new Unique Identifier.

- 6) Provide links to the information on the same product in other databases maintained by relevant international organizations, as appropriate. First, enter the title of the website, and then insert the corresponding URL (starting with http://) next to the title to create a hyperlink.
- 7) Provide a summary of the safety assessment, which should be consistent with the framework of food safety assessments of the Codex Plant Guideline, including:
 - a. A description of the r-DNA plant and the host plant and its use as a food.
 - b. A description of the donor organism(s).
 - c. Information on naturally occurring toxins and allergens.
 - d. A description of genetic modification.
 - e. A characterization of the genetic modification(s).
 - f. For all expressed substances in the r-DNA plant the information to be provided should include the gene product(s) (e.g., protein or untranslated RNA), the function of the gene product(s), the phenotypic description of the new Trait(s), and the concentration of the expressed substance in the edible portions of the r-DNA plant.
 - g. Analyses of key toxicants and allergens are important in certain types of foods derived from r-DNA plants (e.g., those that are commonly consumed whole and undiluted such as potatoes, tomatoes, and papaya).
 - h. Safety assessment of the possible toxicity and the allergenicity (proteins) of newly expressed substances.

The goal of the summary of the safety assessment field is to provide only summarized information and not the entire safety assessment submitted as part of the request for authorization. While in principle the attachments can be in any of the FAO's official languages (English, French, Spanish, Arabic, Chinese or Russian), it is strongly recommended that the summary of the safety assessment is written in English to guarantee the accessibility of the information to all users.

NOTES:

- > There is no set length for the summary field.
- ➤ If you prefer to upload a document of the safety assessment or a document of the summary instead of cutting and pasting paragraphs in the text box upload the document so that the summary text field becomes an optional field. Uploading additional documents that contain detailed information on the safety assessment is also acceptable.
- You can upload up to three files to an entry by clicking on the "Browse" button besides the box that says "Upload".
- Acceptable file formats are: portable document format (pdf) and Microsoft Word (doc or docx).
- The maximum file size is set to 40MB.
- Important: Name your files properly before you upload the file, as the link will appear with the clickable file name so we recommend you to name your document with a descriptive filename and, if enough space, your country name.
- If you want to remove an uploaded file, "check" the check-box beside the file then you will be able to delete it from the list.

In principle, all records must be in one of FAO's official languages (English, French, Spanish, Arabic, Chinese or Russian). However, during the Platform development process, many countries strongly recommended using English in order to avoid any confusion due to possible mistranslations.

- 8) If applicable, provide details on where the detection method protocols and appropriate reference materials may be obtained. State what guidelines the detection methodology follows. You can upload up to three files by clicking on the "Browse" button besides the box that says "Upload".
- 9) If you want to share complimentary information related to the conclusions of the safety assessment in accordance with the Codex Plant Guidelines, first enter the title of the webpage, then insert the corresponding URL (starting with http://) next to the title to the page in order to create a hyperlink. If you want to share any related documents, up to three files can be uploaded by clicking on the "Browse" button besides the box that says "Upload".
- 10) Once you have finished filling in all mandatory fields, review the contents you have inserted, then click "Save" to submit your information. In case of errors, validation messages will appear, notifying you of missing field(s) or incorrect format(s).

Note that your information will not become available online immediately after you have submitted the information. After clicking the "Save" button, you will receive an email receipt of your submission. The format of all the entries will be reviewed by the FAO Content Administrator before the information becomes available online. FAO is not responsible for the content of your submitted information. Your submitted records will be locked while in this review process and you will not be able to edit your record. Once your record has been reviewed and placed online, another email will be sent to you to confirm this. You can check the status of your record on the "My work area" page, under the "Your submitted records" tab.

Remember to "Logout" from the Platform when you finish uploading information. See section 10 for further information.

8.4 How to edit/update a posted record

If you want to edit or update the information on the Platform, go to the "My work area" page and select the "List of records" tab (Figure 20). You can edit the information of posted records by clicking the edit icon depicting a yellow pencil () at the right side of the entry.

Figure 20. List of records



Once you have finished editing and updating, press the "Save" button to re-submit the record. Note that the information will not become available online immediately after you have submitted the information. After clicking the "Save" button, you will receive an email receipt of your submission. The format of all the entries will be reviewed by the FAO Content Administrator once again before the information becomes available online. FAO is not responsible for the content of your submitted information. Your re-submitted records will be locked again while in this review process and you will not be able to edit your record. Once your record has been reviewed and made available online, another email will be send to you to confirm this. You can check the status of your record on the "My work area" page, under the "List of records" tab.

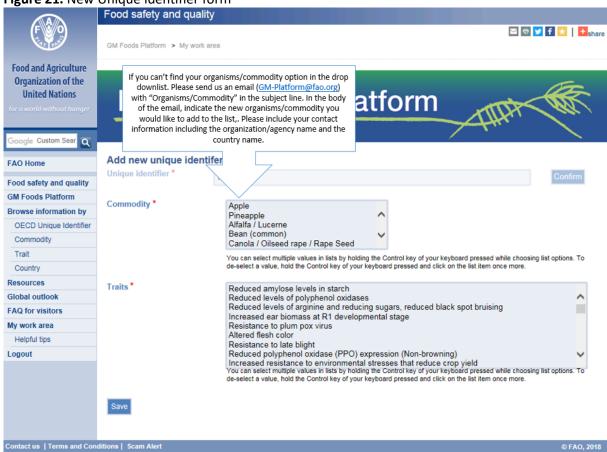
8.5 How to add a new unique identifier to the dropdown list

If you cannot find the OECD Unique Identifier of the information you would like to submit in the dropdown list, or if you are submitting a record with a new Unique Identifier, first add a new Unique Identifier to our database before filling out the record form (section 8.2), otherwise you will lose the data.

Follow the step-by-step instructions below.

- 1) Make sure you have logged in (section 9).
- 2) Click "My work area" from the left side of the navigation menu (or a button that says "Go to my work area" on the screen immediately after logging in).
- 3) Click the blue "Add new Unique Identifier" tab on the top (see Figure 16).
- 4) Click on the blue "Add new Unique Identifier" button.
- 5) You will be directed to the new Unique Identifier form (Figure 21).

Figure 21. New Unique Identifier form



- 6) Enter the Unique Identifier code in the top field labelled "Unique identifier". (Make sure to check with the developer of the product as to what identifier to use. The developer should set the Unique Identifier in accordance with the OECD document entitled "Revised 2006: OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants". See the Resources section of the Platform to download the document.)
- 7) Select the related Commodity from the dropdown list.

NOTE: If you cannot find the Commodity you are searching for in the dropdown list, send an email to: GM-Platform@fao.org. In the email, write "Commodity" in the subject line. In the body of the email, indicate the new Commodity you would like to add to the list. Include your contact information, along with the name of your organization or agency and the country name.

8) Select the related Traits from the dropdown list. You can select multiple values in the list by holding down the Control key of your keyboard while choosing list options. To de-select a value, hold the Control key of your keyboard and click on the list item once more.

NOTE: If you cannot find the Traits you are searching for in the dropdown list, send an email to: GM-Platform@fao.org. In the email, write "Traits" in the subject line. In the body of the email, indicate the new Trait(s) you would like to add to the list. Include your contact information along with the name of your organization or agency and the country name.

- 9) Review your entry and click "Save" to finish creating the code.
- 10) Once you have finished this process, the new Unique Identifier you have created will be available to choose from in the dropdown list on the record submission form (see Figure 19). Note that the

Unique Identifier you have added will be visible only to you until the main record (see Figure 19) is submitted to FAO and published.

8.6 How to enter and update my country profile

In order to edit your "Country Profile", follow the steps below.

- 1) Make sure you have logged in (section 7).
- 2) Click "My work area" from the left navigation menu (or a button that says "Go to my work area" on the screen immediately after logging in).
- 3) Click the blue "Country Profile" tab at the top.
- 4) Click on the blue "Edit Country Profile" button.
- 5) You will be directed to the Country Profile Form (Figure 22).

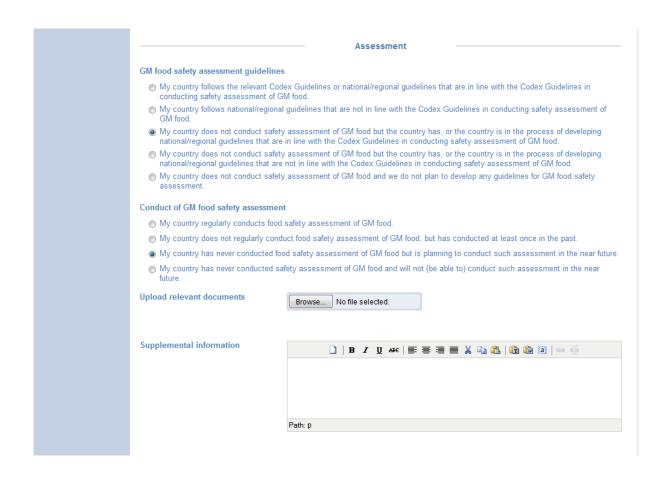
The "Country Profile" is visible when a Visitor browses the entry your country has submitted (see Figure 8). The Country Profile is also visible from the popup menu from the individual detailed page for a Unique Identifier once a Visitor clicks the button labelled "View Country Profile" (see Figure 11). The "Country Profile" page (see Figure 17) offers a space for countries to provide information about GM food safety assessments in their countries.

You will see that the "Country Profile" page is separated into the following sections:

- ➤ **Country introduction.** Countries are invited to provide any relevant country information on GM food safety assessments. There is a space to explain any of the country's specific schemes or mechanisms for safety assessments and/or systems to review or authorize product applications.
- Frame work. Check the box with the description that explains your country's regulatory framework and structure for GM food safety assessments. If there are relevant documents, countries can upload these. Provide supplemental information and provide details of the competent authority(s) responsible for the food safety assessment and product application.
- Assessment. Check the box for the applicable description of your country's situation regarding GM food safety assessment. If there are relevant documents, these can be uploaded. Provide supplemental information.
- > Stacked events. Check the box with the description that explains your country's regulation on stacked events. Upload relevant documents. If your country prefers, a short description of existing national policies, regulations, mechanisms or approaches in assessing "stacked" events can be provided in this space.
- Production and trade. Check the box on GM food/feed production, GM food/feed imports according to your country.
- ➤ Others: Check the box on low level presence (LLP) and adventitious presence (AP) incidents and labelling requirements.
- **Relevant links.** Include links to national documents, databases or websites.
- ▶ Other relevant documents. Include other various documents that the country would like to share.

Remember to "Logout" from the Platform when you finish uploading information. See section 10 for further information.





Some of the fields on the "Country Profile" form are used to collect responses in order to develop the "global outlook" page, which is the overall statistics generated from responses. Therefore, inserting relevant information and selecting appropriate options from the fields in the "Country Profile" are important for helping maintain the most accurate and official statistics on the Platform. See section 8 for more details about the global outlook.

Once you have finished entering your information, press the "Submit changes" button to save the information. You can edit and update your "Country Profile" page any time. Your saved information will not be reviewed by FAO, and the changes you make will be immediately reflected in the Platform.

Remember to "Logout" from the Platform when you finish uploading information. See section 12 for further information.

8.7 How to check and update my registered account information

In order to edit your account information, follow the steps below.

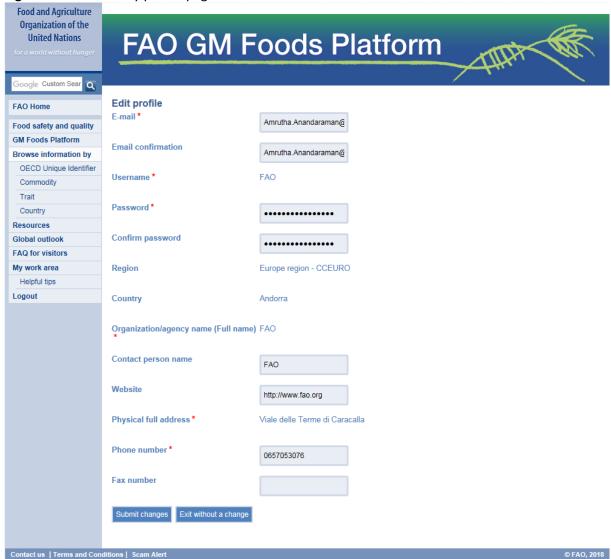
- 1) Make sure you have logged in (section 7).
- 2) Click "My work area" from the left navigation menu (or a button that says "Go to my work area" on the screen immediately after logging in).
- 3) Click the blue "Your account information" tab at the top.
- 4) Click on the blue "Edit profile" button (see Figure 18).
- 5) You will then be directed to the Edit profile form (Figure 23).

The "Your account information" page (see Figure 18) summarizes your registered account details. This page shows the following items of your account:

> Email

- Organization or agency name (full name)
- Region
- Country
- Contact person's name
- Website
- Full physical address
- Phone number
- > Fax number

Figure 23. Edit country profile page



6) You will be able to edit and update the following fields: email, password, contact person's name, telephone number, and fax number. Changes are recorded only after the "Submit changes" button is clicked. You will receive a notification email that you have successfully changed your account information.

Note:

On "your account information" page you will not be able to manually change your organization/agency name and the physical full address. If there was an update of these

information, contact <u>GM-Platform@fao.org</u> with the updated information. FAO will change it accordingly to your instructions and get back to you for your confirmation.

Remember to "Logout" from the Platform, when you finish editing or updating information. See Section 12 for further information.

Note:

If you do not make any changes to the form, click the "Exit without a change" button to leave the page.

8.8 How to create a link to the Platform from your national relevant website

You can create a link between your national website that conduct a work relevant to the Platform and the Platform: this will increase the discoverability of both websites on search engines as search algorithms will value the link as a proof of reliability and trustworthiness. To create a link:

- 1. Identify the website in your country that you want to create a link from;
- 2. Contact GM-Platform@fao.org to receive all possible linking options;
- 3. Once the link is created, inform GM-Platform@fao.org;
- 4. If the link was created according to the linking options guidelines, FAO will link back the national website you have identified at "resources" page under the dropdown menu of "biotechnology-related websites".

9 Global outlook

The global outlook page (Figure 24) shows statistical data based on Focal Point inputs to their Country Profile (Figure 22). Focal Point responses automatically reflect the results on statistical data into "Platform statistics" and "Data syntheses of regulatory frameworks" in two different formats: bar graphs and pie charts.

The first category, "Platform statistics", is generated with data on:

- leading countries in data sharing;
- registration status by region;
- > number of records by Commodity; and
- number of records by Trait.

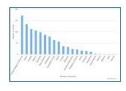
The second category, "Data syntheses of regulatory frameworks", generates 12 statistical datasets:

- 1) Presence of national GM food-related regulatory framework
- 2) Existence of national structure of GM food/feed safety assessment
- 3) Use of GM food safety assessment guidelines
- 4) Extent of country experience with GM food safety assessments
- 5) Approaches to the regulation of stacked events
- 6) Global GM Food/Feed production
- 7) Approaches to manage GM Food/Feed imports
- 8) Experience with LLP and AP situation
- 9) GM Food/Feed labelling requirements

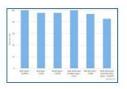
Figure 24. Global outlook page

Global outlook

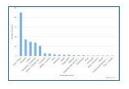
Platform statistics



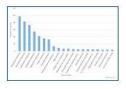
Leading countries in data sharing



Registration status by region



Number of records by commodity



Number of records by trait

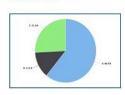
Data syntheses of the regulatory frameworks



Presence of national GM Food related Regulatory Framework



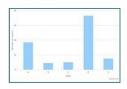
Extent of country experience with GM Food safety assessment



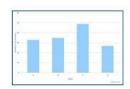
Approaches to manage GM Food/Feed imports



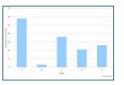
Existence of National structure for GM food/feed safety assessment



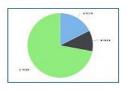
Approaches to the regulation of stacked events



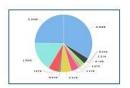
Experience with LLP and AP situations



Use of GM food safety assessment guidelines



Global GM Food/Feed production



GM Food/Feed labelling requirements

10 Resources page

On the left menu you will find the "resources" section. By clicking on it, you will be re-directed to a page displaying several drop-down menus.

Under "Resources for the FAO GM Foods Platform users", a link and/or a downloadable PDF is available with the latest resources available for users. These include:

- 1. The latest version of the Platform user guide;
- 2. Platform banners for link creations;

Under "FAO links and documents, including training tools", you will find links and/or downloadable PDF files including:

- 1. Meeting reports;
- 2. Tools for trainers;

- 3. FAO Websites closely connected with the Platform;
- 4. Codex document on the Platform.

Under "Biotechnology-related websites", you will find a list of links that will re-direct you to country-specific websites that conduct a work relevant to the Platform. This list only displays websites from those countries that have created a link to the Platform. If you don't see a website from your country, contact GM-Platform@fao.org to receive instructions on how to proceed, or refer to section 8.8: Other databases are linked under "Databases on safety assessment of foods derived from r-DNA plants".

Figure 25. Resources page



11 Helpful tips

You will notice there is a submenu under "My work area" on the left side of the navigation menu, called "Helpful tips". Clicking this link will take you to the page that contains some useful tips and FAQs for first-time users (Annex I) when filling out online forms (Figure 25).

Figure 26. Helpful tips page

Helpful tips

We recommend that you take a few minutes to read through the User Guide before filling in the on-line form. The submission process is simple and will probably take between ten and twenty minutes to complete.

- Step one: Read carefully the form and make sure you can provide the required information and documents.
- Step two: Fill out all necessary blanks, typing your answers in the response boxes and uploading your files. You can upload up to 3 files at a time. Acceptable file formats are: Portable Document Format (.pdf) and Microsoft Word (.doc, .docx).
- Step three: Check your answers
- Step four: Click on 'Save' button.

The form consists of 10 fields, according to the items listed in the Codex Plant Guideline (CAC/GL 45-2003, Annex 3). A red asterisk (*) indicates a mandatory field. The following fields are optional: 1) Links to the information on the same product in other databases maintained by relevant international organizations, as appropriate; 2) Where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation may be obtained; 3) Relevant links to documents and information prepared by the competent authority responsible for the safety assessment; 4) Authorization expiration date.

- > The form should be completed and submitted in a single session as it is not possible to save a partially completed form online.
- If you log out without submitting your work, the information entered will be lost.
- It is therefore recommended that you prepare your responses offline, where appropriate, cut and paste them into the relevant sections during the single section.
- You will be able to view your complete form only by clicking the 'Save' button.
- If you have missed out information or you have incorrectly filled in some parts of the submitted form , please contact us.
- Records are locked while in an approval process and you will not be able to make any changes to it.
- After you submit your form, you will be sent an acknowledgement e-mail shortly to confirm that your information and files have been safely processed.
- Once your record is submitted, the administrator has to approve it for publication.
- If you click on "My work area", in the left-hand side menu, you will see your uploaded file(s) and information and their status.

If you have any questions about the form filling process please contact us at GM-Platform@fao.org.

The below set of frequently asked questions (FAQ for uploaders) provides brief guidelines to answering.

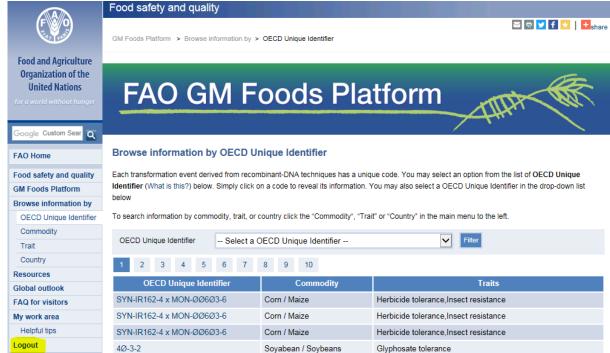
- ▶ 1. What information do I need to provide in the summary of the application?
- > 2. What information do I need to include in the summary of the safety assessment?
- > 3. What other information needs to be addressed regarding the product?
- > 4. Is there a maximum (or recommended) length for the summary field?
- ▶ 5. What files format and versions would be accepted?
- lacksquare 6. Is there any limit to the number of files that can be uploaded?
- 7. Can I provide hyperlinks instead of uploading files or providing text?
- > 8. What language(s) should I use to submit data and information to the Platform?
- 9. What do I provide in the field "Relevant links to documents and information prepared by the competent authority responsible for the safety assessment"?
- ▶ 10. Can I save a partially completed form?
- ▶ 11. Who is the administrator of FAO GM Foods Platform?
- ▶ 12. What is the role of the administrator?
- 13. Who is responsible for the correctness of the information on safety assessment of foods submitted by countries and published on the Platform?
- ▶ 14. Will FAO be responsible for maintaining links to other databases?

12 How to log out from the Platform

Remember to "Logout" from the Platform when you finish uploading information. To log out, follow the steps below.

- 1) Click "Logout" from the navigation menu on the left.
- 2) Your login status page appears (Figure 26).

Figure 27. Where to find the "Logout" link



- 1) Click the "Logout" button.
- 2) You are now logged off from the Platform. You will be directed to the login form (see Figure 12).

Annex 1. Frequently asked questions (FAQs) for visitors

What is the basis of the safety assessment information shared on this Platform?

The safety assessment information shared on the FAO GM Foods Platform should be based on the principles and guidelines developed by the Codex Alimentarius Commission. Many international expert consultations carried out by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have contributed to the development of these principles and guidelines. See "Resources" section for more information.

How does the Platform work?

The FAO GM Foods Platform is freely accessible to those who want to browse the information. Registration is required for those who need to upload information. Only officially nominated Focal Points can register to the Platform. One Focal Point per Codex member is officially nominated by the respective country through its Codex Contact Point. The nominated Focal Point is then invited to register to the Platform. Once his or her registration has been approved, the Focal Point can begin uploading the relevant national data and information to the Platform. All entries are reviewed by FAO before they appear online. See "Resources" section for more information.

What is an OECD Unique Identifier?

The FAO GM Foods Platform applies the OECD's unique identification system for transgenic plants. The Unique Identifier is a code of a fixed length of nine alphanumeric digits for a transformation event derived from recombinant DNA techniques. It is composed of three elements separated by dashes: two or three alphanumerical digits to designate the applicant; five or six alphanumerical digits to designate the "transformation event"; and one numerical digit as a verification. Consult "revised 2006: OECD guidance for the designation of a Unique Identifier for transgenic plants" for more information.

Where can I find information about the procedure for safety assessment of GM plants? Refer to the Codex Plant Guideline entitled "Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants (CAC/GL 45-2003, annex III adopted in 2008)".

Does the FAO GM Foods Platform also cover feed?

This Platform is established for Codex members to share information on safety assessment of foods derived from recombinant-DNA plants authorized in accordance with the Codex Plant Guideline. However, countries have the opportunity to indicate feed-related authorization information.

- I would like to provide a comment or suggest a change to the Platform. How do I proceed? Comments can be sent to: GM-Platform@fao.org. However, if you are suggesting a change to the Platform, the suggestion should be submitted through your (closest) national Focal Point in order to have consensus by all Codex members. Discuss your suggestion with your country's Codex Contact Point to seek a way to obtain consensus among Codex members (not observers).
- Who is responsible for the accuracy of the information on safety assessments of foods submitted by countries and published on the Platform?

Focal Points who have been nominated by Codex Contact Points are responsible for the accuracy of the records that they submit. FAO checks the format of the submitted records.

- ➤ How do I navigate the Platform to see the data and information I am looking for? Consult the User Guide, which is available online. If you have other specific technical questions, contact: GM-Platform@fao.org.
- Who can upload the information to the FAO GM Foods Platform?
 Only officially nominated Focal Points can upload information to the Platform, after the FAO Content Administrator grants the nominee access.

Annex 2. Frequently asked questions (FAQs) on user registration

What name do I provide when registering?

Provide the full name of your organization or agency with the acronym in parentheses if applicable, the full name of your department, section or unit responsible for the safety assessment. Ensure that the name of your organization appears correctly in the form.

➤ What address do I provide?

Provide your full physical business address of the organization and your work email address in the registration form, as this will be used as the primary means of communication with FAO. Ensure it appears correctly in the form.

Who can upload information to the Platform?

The information and data shared on the Platform will be uploaded only by the Codex-nominated Focal Points from national authorities (government agencies).

Who should I contact if I need help with my registration?

If you experience problems with registration, contact: GM-Platform@fao.org

Annex 3. Helpful tips for uploading information

➤ What information do I need to provide in the summary of the application? Provide an explanatory summary regarding product details, including the name of the product, its scientific name, the country of authorization, date of authorization, the scope of authorization and other details about the product and the organization. Refer to the Codex Plant Guideline for more details. Note that the intent of the summary of application field is to provide only summarized information, so do not submit an entire application.

What information do I need to include in the summary of the safety assessment?

Provide a summary of the safety assessment, which should be consistent with the framework of food safety assessment of the Codex Plant Guideline including:

- a. A description of the r-DNA plant and the host plant and its use as a food.
- b. A description of the donor organism(s).
- c. Information on naturally occurring toxins and allergens.
- d. A description of the genetic modification.
- e. A characterization of the genetic modification(s).
- f. For any expressed substances in the r-DNA plant, the information to be provided should include the gene product(s); for example, protein or an untranslated RNA, gene product(s)' function, a phenotypic description of the new Trait(s), and the concentration of the expressed substance in the edible portions of the r-DNA plant.
- g. Analyses of key toxicants and allergens are important in certain cases of foods from r-DNA plants (e.g., those that are commonly consumed whole and undiluted such as potatoes, tomatoes, and papaya).
- h. Safety assessment of the possible toxicity and the allergenicity (proteins) of newly expressed substances. See the Resources section to check available documents for more information.

Note that the intent of the summary of application field is to provide only summary information and not the entire application submitted as part of the request for authorization.

What other information needs to be addressed regarding the product?

Provide details of any detection method protocols, together with reference materials relevant to detection of the product. State whether the detection methodology follows the Codex Plant Guideline or follows some other recognized standard protocol.

> Is there a maximum (or recommended) length for the summary field?

There is no set length for the summary field, although it should not be excessively long. If an attachment is provided, the summary text field can be left empty.

What file format and versions are accepted?

Acceptable file formats are portable document format (pdf) and Microsoft Word (doc or docx). Files should not exceed 40MB in size.

➤ Is there a limit to the number of files that can be uploaded?

Yes. You may select up to three files for each form item.

Can I provide hyperlinks instead of uploading files or providing text?

Provide a short text summary together with the URL in the summary text box or upload files. This will prevent the Platform from having broken links.

➤ What language(s) should I use to submit data and information to the Platform? In principle, all the records must be in one of FAO's official languages (English, French, Spanish, Arabic, Chinese or Russian). However, during the Platform development process, many countries strongly recommended the use of English, in order to avoid any confusion due to possible mistakes in translation.

➤ What should I provide in the field "Relevant links to documents and information prepared by the competent authority responsible for the safety assessment"?

If applicable, provide a link (URL) to your national decision document, relevant data uploaded to other databases, public notification documents available on your websites, and other information.

Can I save a partially completed form?

No. It is not possible to save a partially completed form. Make sure that all of the information is available before uploading a new record. It may be useful to prepare the information in an offline document, and then cut and paste into the relevant fields.

Who is the administrator of FAO GM Foods Platform?

FAO's Food Safety and Quality Unit in the Agriculture and Consumer Protection Department is responsible for the FAO GM Foods Platform. For more information, contact: GM-Platform@fao.org

What is the role of the administrator?

The FAO GM Foods Platform administrator is responsible for maintaining the website. The administrator's duties include regulating and managing the access rights of users; approving submitted records; ensuring that the web servers, hardware and software are operating correctly; generating and revising web pages; and replying to user comments.

Who is responsible for the accuracy of the information on safety assessments of foods submitted by countries and published on the Platform?

The FAO Content Administrator checks the format of submitted records. All the Platform Focal Points who have been nominated by the Codex Contact Points are responsible for the accuracy of the records they submit.

➤ Will FAO be responsible for maintaining links to other databases?

FAO will check and update the Resources section but not the individual Country pages. Country information should be edited and maintained by the nominated Focal Point.

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