

# EU-CEG USER GUIDE

### THE EU COMMON ENTRY GATE



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### 1 INTRODUCTION

Under the Tobacco Products Directive (2014/40/EU)

(<a href="http://ec.europa.eu/health/tobacco/docs/dir\_201440\_en.pdf">http://ec.europa.eu/health/tobacco/docs/dir\_201440\_en.pdf</a>) manufacturers and importers of **tobacco products, e-cigarettes** and **refill containers** have to submit key information to the authorities in the Member States in which they plan to market any new or modified products, no later than six months before marketing.

This includes information on:

- ingredients
- emissions
- toxicological data

The IT tool for providing this information is the EU Common Entry Gate (EU-CEG).

### **Other products**

In some EU countries, EU-CEG can be also used to provide information on other products, such as:

- herbal smoking products
- nicotine-free e-cigarettes

### 1.1 Information requirements

The information manufacturers and importers need to provide is set out in two implementing decisions:

- → tobacco products implementing decision (<a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL</a> 2015 312 R 0003)
- e-cigarettes and refill containers implementing decision (<a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015D2183">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015D2183</a>)

### 1.2 About EU-CEG

**EU-CEG** it is an IT tool designed to ensure uniform reporting of information on tobacco products and notification of information on electronic cigarettes and refill containers.

Its aim is to reduce administrative burden for companies and regulators, and make it easier to compare data. The tool was developed by the European Commission, working closely with Member States and industry stakeholders. It became operational in May 2016.

### 2 EVERYTHING YOU NEED TO KNOW TO GET STARTED WITH EU-CEG

EU-CEG is only accessible for companies with a *Submitter ID*. Therefore, before any submission can take place, a submitter must obtain the ID.

### 2.1 How to know if you need a submitter ID



### 2.2 How to register for a *submitter ID*

If you don't have an EU Login account yet, first create one, as explained in Chapter 3.1.

### Following steps:

- → <u>Download the registration form</u>
- Fill in the form
- → Submit the form (follow the instructions on the form).



**NOTE:** Fill in the form in with as much detail as possible (including the optional fields) and attach any official documents (e.g. company registration/incorporation certificate, utility bill, tax return).

Once we receive your completed form, we will start the process of assigning your submitter ID.



Consider that this is only one part of the process. After receiving the *Submitter ID* you will receive also the *Party Identifier* (as explained in 3.3.2 Party Identifier). Both steps can take several days, especially during busy periods, so please be patient.

Before we issue your submitter ID, we may need to ask you for some extra information. We also reserve the right to revoke a submitter ID if necessary.

### 2.3 Technical options for submitting data

Once you have your submitter ID, you have two options for submitting product information to EU Member States via the EU-CEG:

- **STANDALONE SOLUTION** for companies with a small IT infrastructure
- → SYSTEM TO SYSTEM SOLUTION for companies with a large IT infrastructure and many products

You have to select one of the two options in the field "Intended submission tool".

### 2.3.1 Standalone registration process

The "standalone" registration process means that for the registration you will use a computer programme for the reporting. Specifically, an **XML generator** that allows you to create your notification in the form of one or more XML files, which must be uploaded to EU-CEG later.



**NOTE**: The Commission provides a free XML generator called "XML Creator Tool", but the use of this client is optional. You can use any other software application and upload your files into the system, subject to their conformity with the XSD file and the *Data dictionary business rules* published in the **CIRCABC** online library.

To submit your data using this option, you have to follow two steps:

- 1. run the XML creator on your local computer.
- 2. **upload** the created XML file(s) to EU-CEG, via eTrustEx, an open-source platform for the secure exchange of data.



**NOTE:** The uploading process requires an <u>EU Login (ECAS) account</u> for authentication purposes.

You can find more information about the standalone registration process in *chapter 3* and, about eTrustEx, in *chapter 5*.

### 2.3.2 System-to-system solution

"System-to-system" means that you setup your own infrastructure in order to provide data for the reporting directly to the EU-CEG system.

This option uses the AS4 protocol for document exchange. The Commission offers a reference implementation of the AS4 access point called "Domibus" (<a href="https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/Domibus">https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/Domibus</a>), which is part of *eDelivery* in the CEF programme. Domibus is an open-source software, but stakeholders are free to choose any other AS4 compliant access point if they wish so.

For more information about the "system-to-system" option, contact the EU-CEG IT Support at <a href="mailto:SANTE-EUCEG-ITSUPPORT@ec.europa.eu">SANTE-EUCEG-ITSUPPORT@ec.europa.eu</a>

### 2.4 Privacy statement

To find out how we use and protect your **personal data**, please read our privacy statement (https://ec.europa.eu/health/sites/health/files/euceg/docs/privacy statement en.pdf).

### 3 STANDALONE REGISTRATION PROCESS – STEP BY STEP

This section will guide you through the standalone registration process.

### 3.1 Step 1: EU LOGIN (ECAS) account

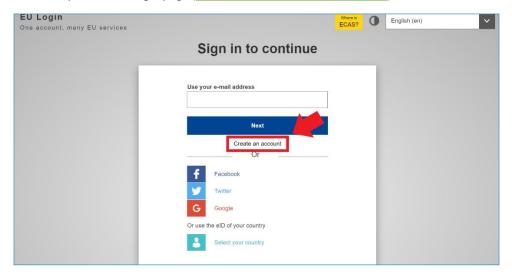


**NOTE:** If you already have an EU Login (formerly ECAS) account, you can jump directly to <a href="Step 2">Step 2</a>: PDF <a href="PDE">Registration Form</a>.

This also applies if you have created an ECAS account before the ECAS system changed to EU login, since your ECAS credentials remains the same for EU Login

To create your EU Login account:

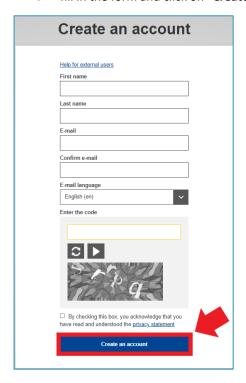
→ open the EU Login page (<a href="https://webgate.ec.europa.eu/cas/">https://webgate.ec.europa.eu/cas/</a>) and click on "Create an account":





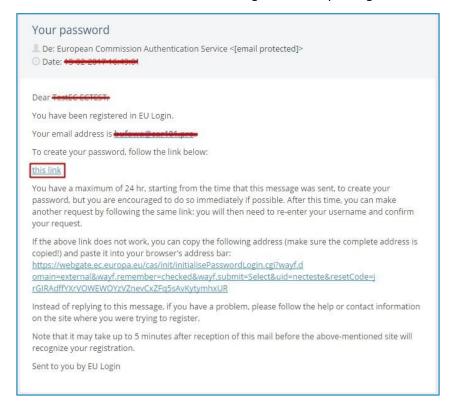
**NOTE:** Logging in through the social media platform will not let you enter the application. To access EU-CEG you have to create an EU Login, following the instructions described here.

ill in the form and click on "Create an account":

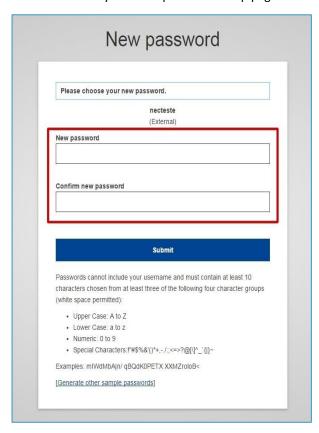


A trigger email will be sent to the email address that you have provided in the form;

iclick on the link in the email message to confirm your registration:

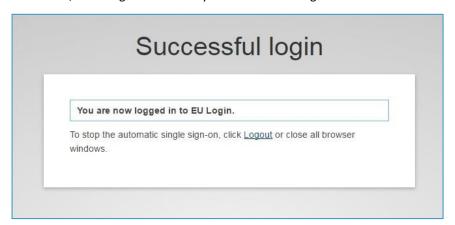


The link will lead you to the password setup page:



- choose and confirm your password
- click on "Submit"
- click on "Proceed" to log in with your account

Once done, a message will confirm your access to EU login:



### 3.2 Step 2: PDF Registration Form

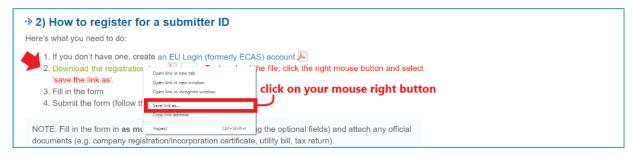
### 3.2.1 How to download and fill in the registration form

The **PDF Registration Form** is avail on the EU-CEG website, <u>point 2.2 of the "Step by step quide"</u>, but you can download it also from:

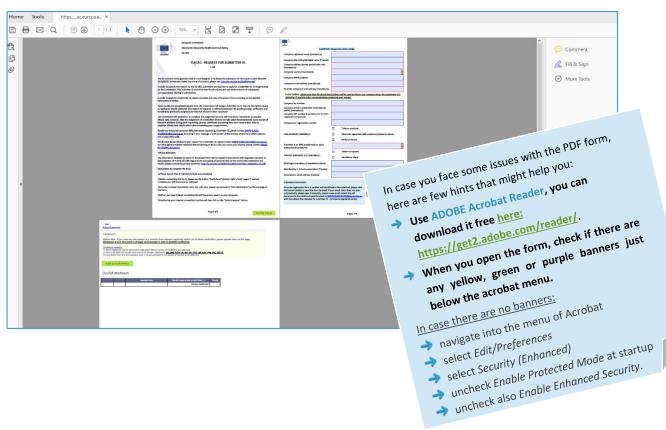
https://ec.europa.eu/health/sites/health/files/euceg/docs/submitterid\_registrationform\_en.pdf.

→ Download the file in your computer

To download the file, right click on the mouse and select "Save link as":



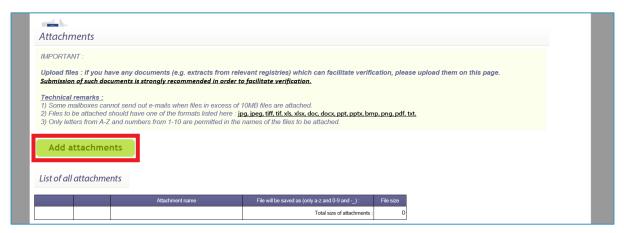
→ Open the form from the saved location with the *Adobe Reader* software and fill it in with your company information:





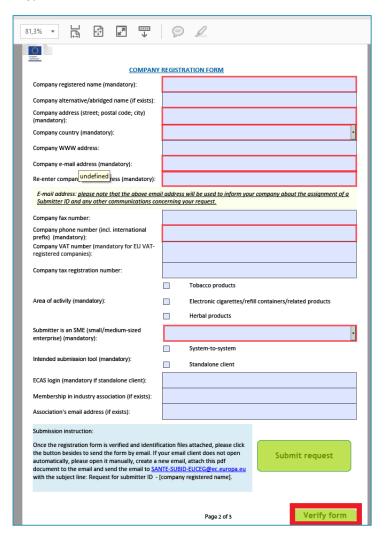
**TIP:** Fill in the form in as much details as possible (including the optional fields) and attach any official documents (e.g. company registration/incorporation certificate, utility bill, tax return).

→ Add such documents on the last page of the form by clicking on "Add attachments":



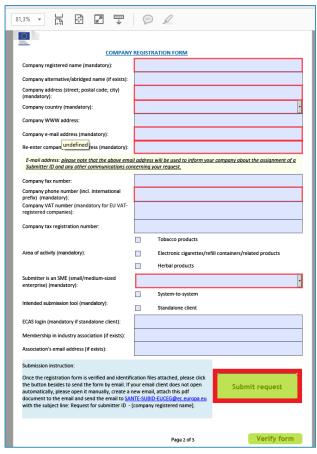
When you have completed the PDF registration form, save it on your computer.

Before you submit the form, you must click on "**Verify form**" make sure that all the mandatory fields have been filled:



If the verification reports error(s), you will need to follow the instruction given to correct your form.

→ Verify that your internet connection is active and then click on "Submit request":



This action will make your email client to open a new email to <u>SANTE-SUBID-EUCEG@ec.europa.eu</u> with a subject filled and your registration form attached. At this point, you can simply send the email without adding anything else.



**NOTE:** If your email client does not open automatically, you will have to create a new email, attach your PDF registration form and send the email to <a href="mailto-sant-subid-EUCEG@ec.europa.eu">SANTE-SUBID-EUCEG@ec.europa.eu</a> with the subject line: **Request for submitter ID - [company registered].** 



**TIP**: If you have documents such as extracts from trade register, it can facilitate the validation, please attach them to the PDF registration form. The transmission of such documents is strongly recommended.

Some mailboxes cannot send emails when attachments exceed **10 MB**.

The files to be attached must be in the following format:

jpg, jpeg, tiff, tif, doc, xls, xlsx, ppt, pptx, docx, png, bmp, pdf, txt.

Only letters from **A** to **Z** and numbers from **1** to **10** are allowed in the names of the files to be attached.

### 3.3 Step 3: Submitter ID and Party Identifier

### 3.3.1 Submitter ID

After sending your registration form to <u>SANTE-SUBID-EUCEG@ec.europa.eu</u>, the process of validation for the assignment of your submitter ID starts.

The Commission reserves the right to revert to applicants should additional information be required, to withhold Submitter IDs pending further verification and to withdraw previously assigned Submitter IDs, should it deem necessary.

The Commission will endeavour to complete the assignment process within as short a timeframe as possible.



Please consider, however, that the assignment of a Submitter ID does not take place instantaneously upon receipt of the form and that during peak requesting periods, additional processing time up to several days may be required.

At the end of the process, you will receive an email confirming your Submitter ID or explaining why it was not assigned or withdrawn.



**NOTE:** The Submitter ID is used for submitting products information on EU-CEG as it is linked to your company and **not to access eTrustEx**. As explained in the email, to access eTrustEx you will need to receive a *Party Identifier* (please see the next Chapter here below).

### 3.3.2 Party Identifier

After a couple days that you have received your Submitter ID, you will receive your Party Identifier.



Please consider that the party identifier attribution process can take several days, especially during busy periods.

In the meanwhile, you can already start creating your XML files by following the instructions that you can find in <a href="Chapter 4.2">Chapter 4.2</a>

Once your party identifier has been issued, you will receive a confirmation email with further information, such as the link to eTrustEx, where you will have to upload your XML submission files.

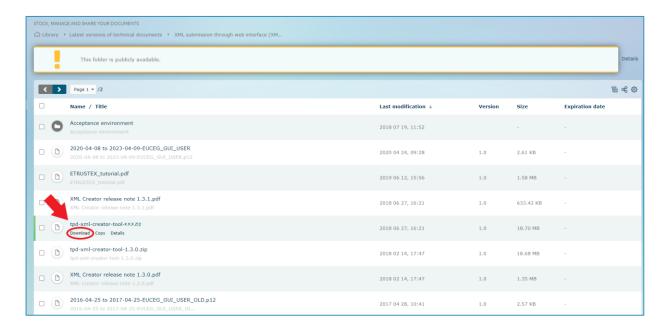
### 4 THE XML CREATOR TOOL

As mentioned before, the EU-CEG system requires you to submit the data of your products via XML files.

We strongly recommend that you use the XML Creator tool put at your disposal by the European Commission, as no support is provided on custom-made solutions.

### 4.1 Run the XML Creator tool

Go to the CIRCABC public site (<a href="https://circabc.europa.eu/ui/group/a4c7629c-0054-41d6-96e7-19c7c9da0a80/library/b3141f3c-f8be-413f-b2a8-6c9f44b82cae">https://circabc.europa.eu/ui/group/a4c7629c-0054-41d6-96e7-19c7c9da0a80/library/b3141f3c-f8be-413f-b2a8-6c9f44b82cae</a>) to download the latest version of XML Creator. From the Library<sup>1</sup>, hover your mouse over "tpd-xml-creator-tool-x.x.x.zip" where x.x.x, from now on, means the latest version/number of the XML Creator, and click "Download" which will appear below the file name:



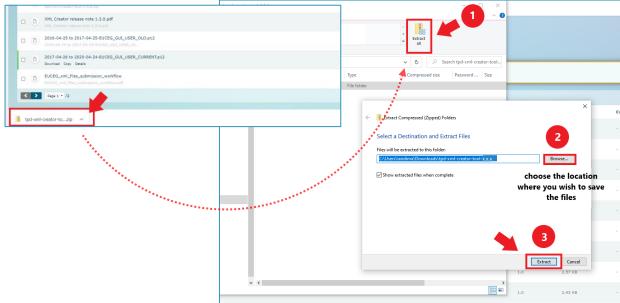


**NOTE**: To run this JavaFX application, it is required to have a Java SE Runtime Environment 8 (JRE 1.8) installed on your computer. You can download the latest JRE on the following link:

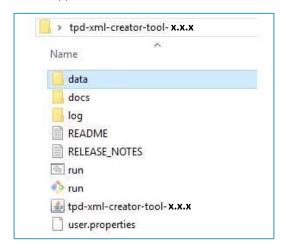
https://java.com/en/download/windows xpi.jsp

<sup>&</sup>lt;sup>1</sup> The actual file structure may differ from the example below

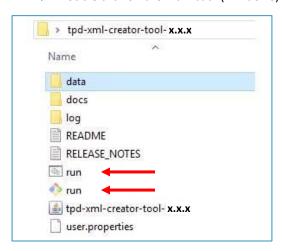
→ Follow the procedure to extract (unzip) application zip package and save it to your chosen location:



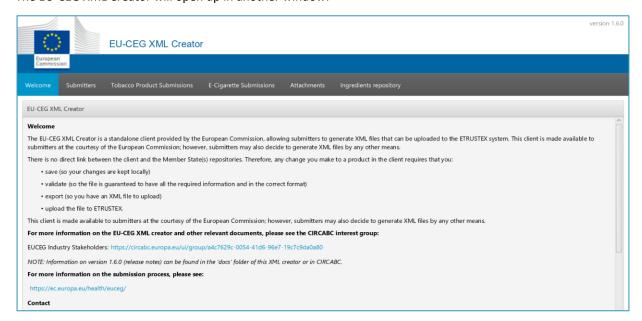
The unzipped folder will look like this:



→ Double click on the "run.bat" (Windows) or "run.sh" (MacOs) according to your Operating System:



### The EU-CEG XML Creator will open up in another window:





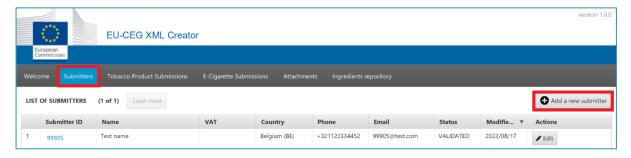
Making <u>any</u> changes to the folder structure and/or its content can have major consequences including loss of data. Therefore, <u>do not move or rename any folders or file and do not make manual changes to the content of the XML files</u>.

### 4.2 Practical use of the XML Creator Tool

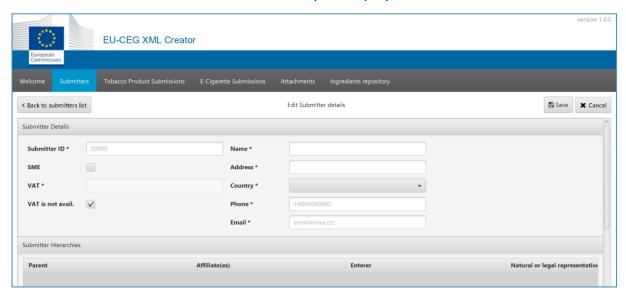
### 4.2.1 Create your submitter ID XML file

The first step is to create your submitter ID XML file. The initial information should, in principle, correspond with the information in your Submitter ID application. The submitter ID XML file may be updated to reflect possible modifications over time.

In the top navigation menu of the EU-CEG XML Creator, click on "Submitters", then on "Add a new submitter":



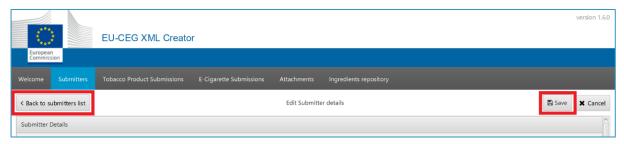
Fill in the different fields with information about your company:



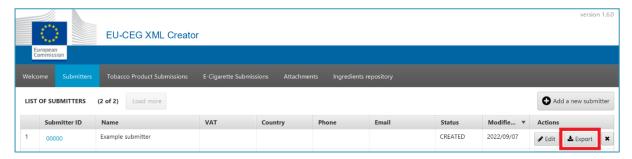
This information will allow the concerned Member States to identify your products.

Once you have provided the requested data, click "Save" in the top right corner of the window.

Then click on "< Back to the submitters list" to go back to the previous page:



Back to the main page, click on "Export" to generate the file:

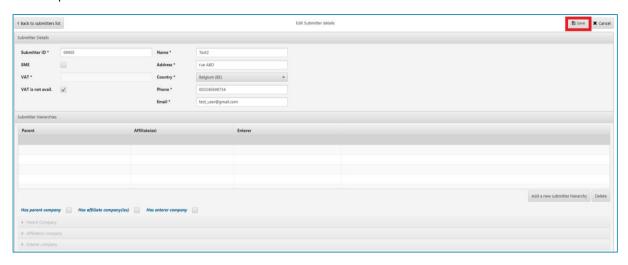


In case the contact details of your company change, you can update your information by clicking on "Edit" in the "List of Submitters" page:



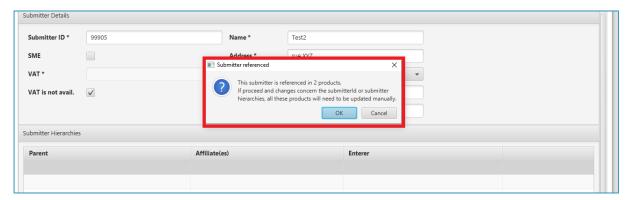
The "Submitter Details" page will open again.

→ Update the information and click on "Save":



A dialogue box will warn you that if your changes concern the submitter ID or the submitter hierarchies, the referenced products linked to them will need to be updated manually.

→ Click "OK" and go back to the "List of Submitters":



Back to the main page, click on "Export" to regenerate the file:





NOTE: The XML Creator is a local tool that is designed to help you create the XML submission files (submitter, product, attachments).

There is no direct link between the tool and the Member State(s) repositories.

Therefore, any change you make to a file in the tool requires that you:

- 1. Save (so your changes are kept locally),
- 2. (in case of a Product) Validate (so the file is guaranteed to have all the required information and in the correct format),
- 3. Export (so you have an XML file to upload)
- 4. **Upload** the file to eTrustEx (see Chapter 5).

Now, you can insert your products in the system.

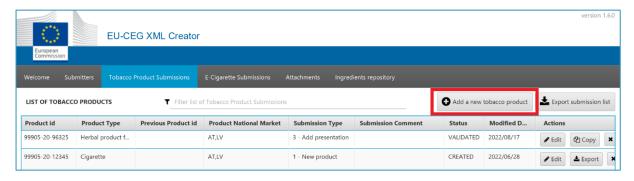
Start selecting either the tab "Tobacco Product Submissions" or "E- Cigarette Submissions", according to your type of business:



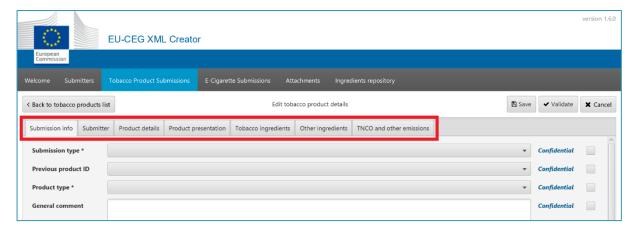
Once the proper tab is selected, you will be able to start the creation of your product files by clicking on "Add a new tobacco product" or "Add a new e-cigarette" and, subsequently, filling in the different fields with your products information.

### 4.2.2 Example - Add a new tobacco product

Click on "Add a new tobacco product":



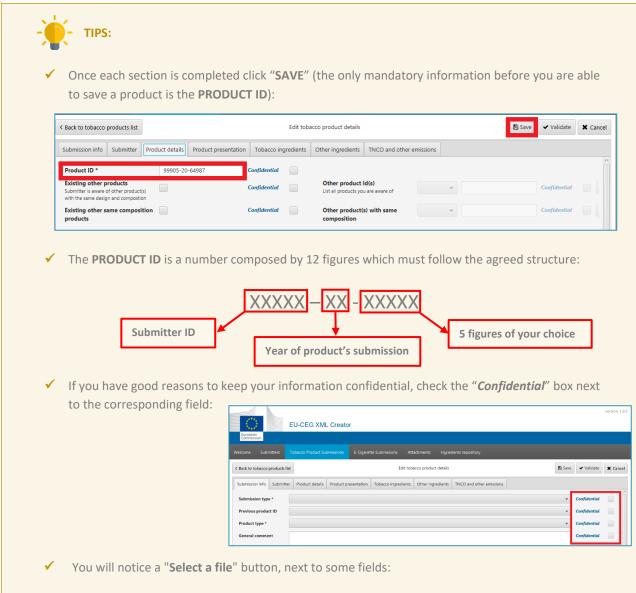
### The form that opens up includes several sections:



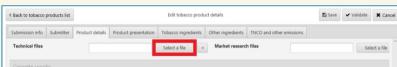
**2.** Fill in all the fields in each section with your products information. You can move from one section to another by clicking on the relevant tabs.



**NOTE:** All the fields marked with the asterisk (\*) are mandatory



The data expected in these fields is an attachment loaded in the XML Creator tool (see Chapter 4.3)



✓ If you wish to add more files, click on the "+" button. In case you want to remove it, just click on the "-" button:



✓ "Product Presentation"



One product can have multiple presentations. If this is the case, when you re-upload the product you have to make sure to keep always all the presentations, even if no changes were made to a specific presentation.

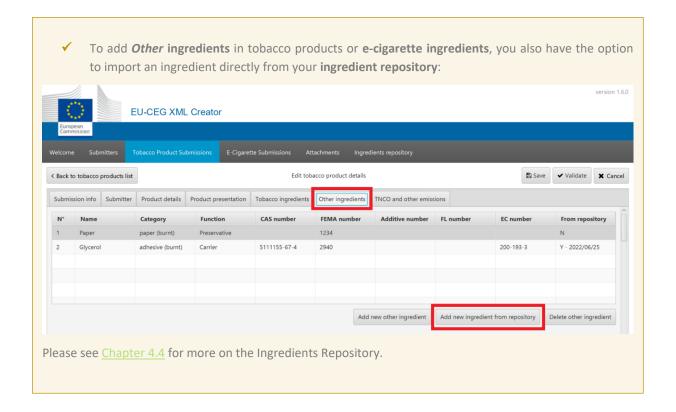
This is particular important because if a product with more than one presentation is uploaded again, without some of its presentations, this will be interpreted by the system as an (incorrect) product withdrawal and will move the product to the inactive list, for the countries where it was removed.

✓ In the two sections related to the ingredients, to add more ingredients to your list, click on "Add new ingredients". Similarly, if you wish to remove specific ingredients, after selecting them from the list, click on "Delete ingredient":



✓ Once you have provided your data, click on "Save" and then on "Validate":

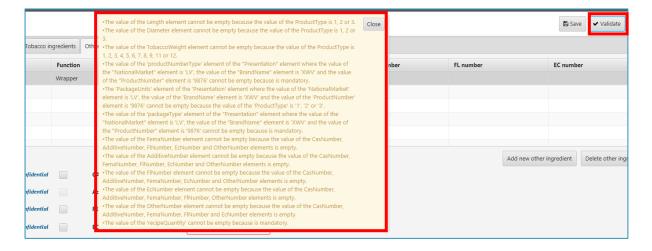




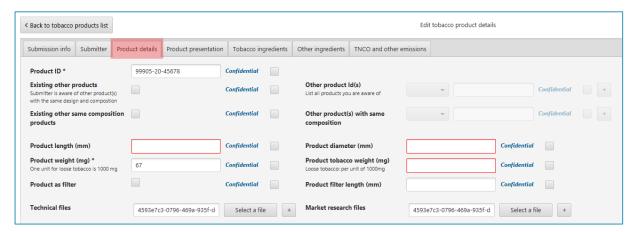
### 4.2.3 How to handle validation errors

The validation of your file is a necessary step before you can export your XML file as it verifies that you have provided every mandatory information, in the right format. However, what happens if this is not the case?

If something is wrong in your form, after clicking on "Validate", a pop up window will appear showing you the list of all the errors encountered:



The fields that contain errors or missing data will be highlighted by a red frame:





**NOTE:** The red frames will only show if you are on the tab where the errors are. If an error shows up and you do not see any red frames, it means that the error is on a different tab. Browse through the tabs and click "**Validate**" on each of them to highlight missing data/errors.

### [ 4.2.4 Validate and Export

After you have fixed all the errors and all the red fields have disappeared, save and validate your product again. If everything is correct, a pop up message will confirm validation:

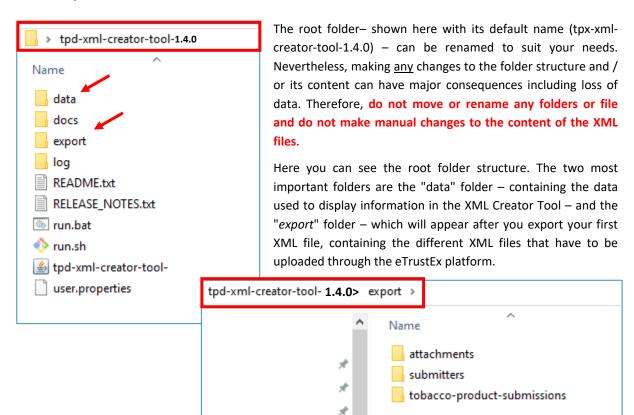
- After your product submission is validated, go back to the "Tobacco Product Submission" page.
- Here, select the appropriate row from the list and click on "Export":





**NOTE:** The procedure is the same for e-cigarette products.

As long as these instructions are followed, the XML Creator will create and save your XML files in a folder named "Export", located inside the root folder of the creator tool:





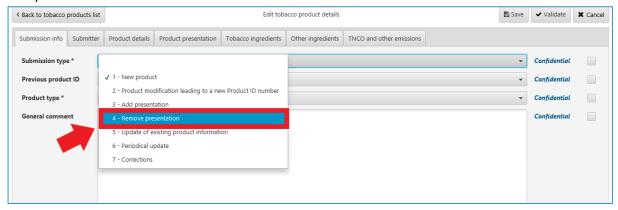
### 1 4.2.5 Withdraw a product

To withdraw a product ("make it inactive"), you need to make a submission to indicate the withdrawal of your product for that specific market ("presentation").

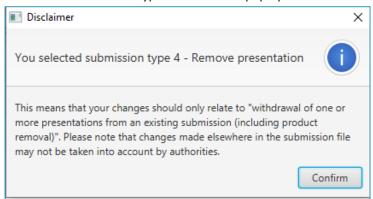
You will find here the steps that you need to follow to withdraw a product from one market.

Nevertheless, it is also possible to make multiple withdrawals at once by repeating the steps for each market, before uploading the product to eTrustEx.

Edit the product where you want to notify a withdrawal and choose "Submission type 4" - Remove presentation:



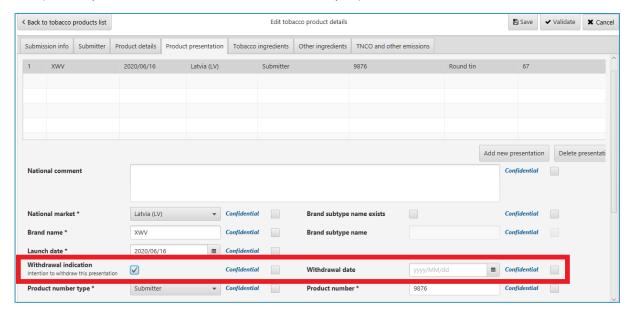
The relevant submission type disclaimer will pop-up:



- Click on "Confirm" to proceed;
- Go to the "Product Presentation" and select the specific presentation that you wish to withdraw:



Check the box "Withdrawal indication - Intention to withdraw this presentation" and insert the withdrawal date (it is also possible to indicate a withdrawal date in the past):



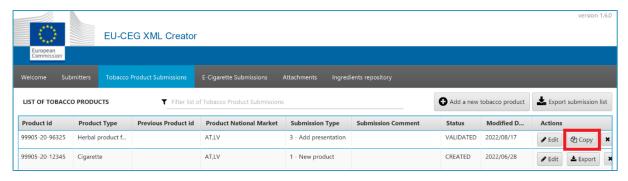
- Save and validate the product.
- To complete the withdrawal you need to export and upload your submission through eTrustEx



**NOTE:** If the product is being presented in more than one market, the other markets should be kept in the submission. Simply deleting a market and uploading the submission file will move the product to the inactive list for those markets.

### 4.2.6 Copy an existing product

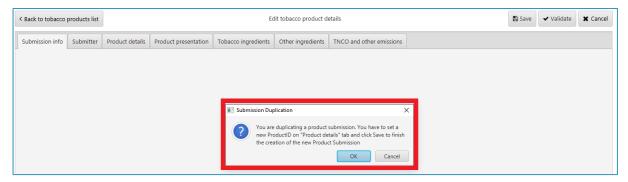
After you have exported your product, back on the "List of Products" you will notice that the "Export" button has been replaced by a "Copy" button:



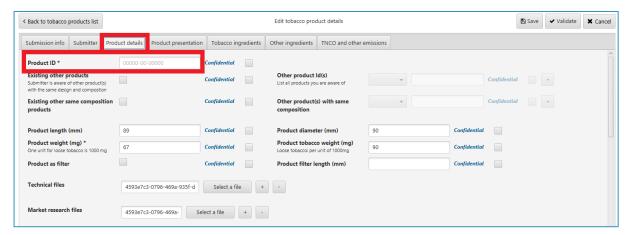
You can use this option to add to your list products that have similar characteristics (e.g. same composition but different flavouring), without having to fill every single field again. However, please make sure that you **review** all the information before submitting your product.

Click on "Copy"

A dialogue box will inform you that you are duplicating a product submission and you have to set a *new product ID* under "**Product details**" and click "**Save**" to finish the creation of the new product submission:



- Click "OK" to proceed. This will bring you to the "Submission info" tab of the copied product.
- → Go to "Product Details" and insert a new product ID and save it:

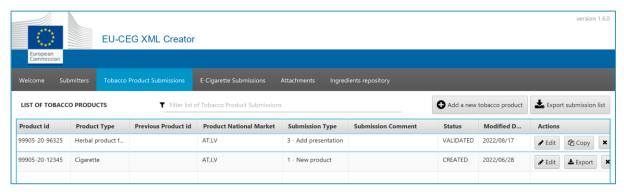


Thange the information about the new product where needed, browsing through the different sections and filling in the fields as explained in <a href="Chapter 4.2.2">Chapter 4.2.2</a>.

### [ 4.2.7 Export your product list to Excel

Once you have added all your products, you can export the list of your submitted products to an Excel format.

→ Go to your list of products (tobacco or e-cigarettes):



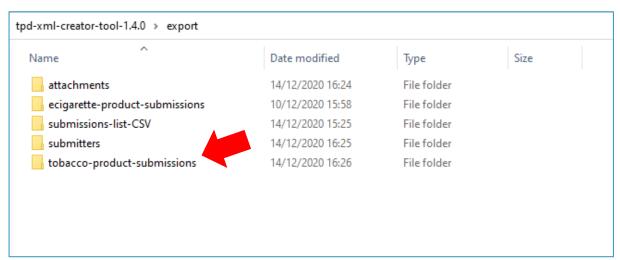
Click on "Export submission list":



A confirmation message will inform you that your product submission list has been successfully exported:



You will find the file (csv format) in the XML Creator Tool export folder:



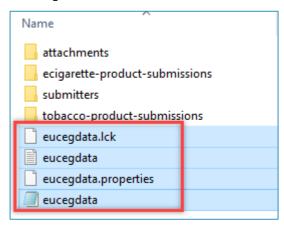


### Restore a deleted submission

When you delete a submission, the XML file will be moved to data> recycled> tobacco-product-submissions or to data> recycled> ecigarette-product-submissions.

If you want to restore this submission:

- close the tool,
- copy the file back in data> tobacco-product-submissions or data> ecigarette-product-submissions folder,
- once the file has been restored, you need to force a rebuild of the local database by deleting the four following files from the data folder:



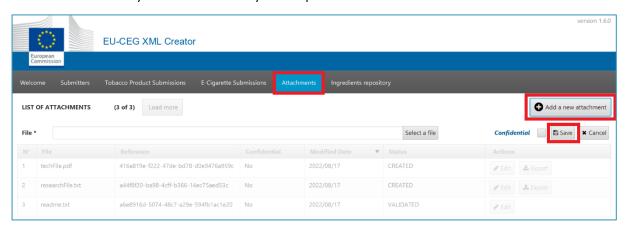
restart the tool.

The restored file will appear back in the list pf products.

### Add your attachments to the XML Creator Tool

From the "Attachments" page, you can create attachments and load them in the XML Creator Tool. "Attachment" refers to any document providing some specific information about your product that you wish to add in your product submission, e.g. the description of the measurements methods used to assess emissions.

- Click on the "Attachments" tab in the top navigation menu and then on "Add a new attachment".
- Select the file that you wish to add from your computer and click on "Save":



Your files will be added to the list of attachments and you will be able to use them within your product submission(s).

### 4.4 Manage your ingredients repository

From the tab "Ingredients repository" you can create your own database of ingredients (e-cigarettes only) or *Other* ingredients (tobacco products only) and use it to easily add ingredients to a product, thus avoiding repetitive actions when dealing with multiple products and multiple ingredients.

Here are the main actions you can perform from the "Ingredients repository" tab:

### → View

Click on "Ingredients repository" on the top navigation menu to view your complete ingredient repository:



IMPORTANT: Please remember that this list only contains ingredients that you have added in the repository and not all ingredients that you have separately added in your products. To see the full list of a tobacco product's *Other ingredients*, refer to the product's "Other ingredients" tab under "Tobacco Product Submissions", as shown below (similarly, for an e-cigarette submission, refer to the product's "Ingredients"):

Version 1.60

Welcome Submitters Tobacco Product Submissions E-Cigarette Submissions Attachments Ingredients repository

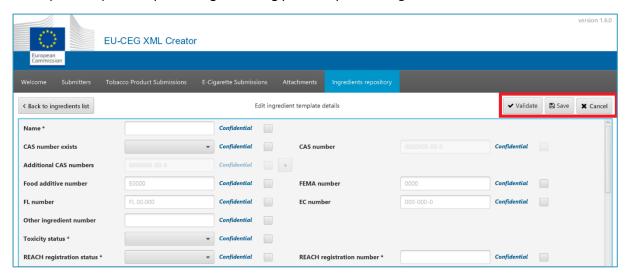
Back to tobacco products list		Edit tobacco product details						Save	<b>✓</b> Validate	* Cano
ubmis	sion info Submitter	Product details	Product presentation	Tobacco ingredients	Other ingredients	TNCO and other emiss	ions			
N°	Name	Category	Function	CAS number	FEMA number	Additive number	FL number	EC number	From repos	itory
1	Propylene	paper (burnt)	Carrier	568151-22-1					N	
2	Glycerol	tobacco (burnt)	Addictive Enhancer	5111155-67-5	2940			200-193-3	Y - 2022/08/	17
					Add r	new other ingredient	Add new ingredie	nt from repository	Delete other ing	redient

### Add new ingredient

1. Click on "Add a new ingredient" to create a new entry in your ingredient repository:



- 2. Fill in the relevant fields for the specific ingredient.
- 3. Complete the process by validating and saving your newly created ingredient:



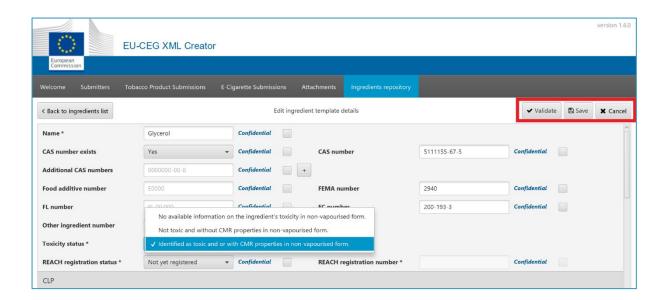
### View and edit ingredient details

1. Click on "Edit" next to the ingredient of your choice to view its details:



Under "Modified date" you can see your most recent update of the ingredient.

2. Once inside the ingredient's details table, make any modifications as necessary and complete the process by clicking on "Validate" and then "Save":





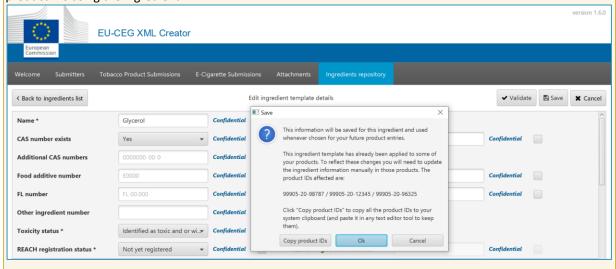
**NOTE**: To add an ingredient from the repository in a product submission it must be under "Validated" status, otherwise the ingredient can only be viewed as "Created" in the repository.



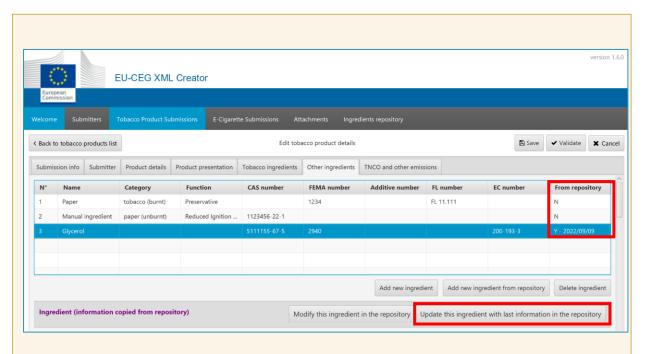
#### TIPS:

When you modify a repository ingredient, it is only updated in the repository for future use, but **not** automatically in the products containing this ingredient.

When updating a repository ingredient that is used in products, a dialogue box will provide you with all the product IDs using the ingredient:

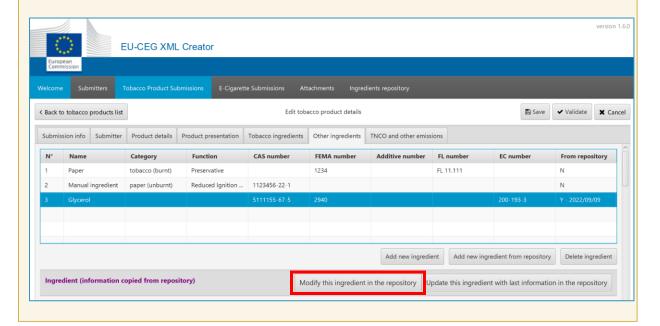


You may choose to update it manually in each of the products separately, in which you wish to reflect the modification. To do this update, select the ingredient inside the correct product and click "Update the ingredient with the last information in the repository":



The column **"From repository"** shows whether the ingredient was added from the repository and if so, its latest update in the repository.

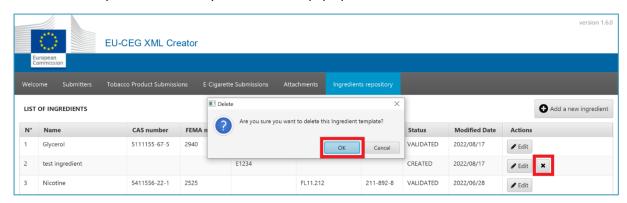
You can modify an ingredient, added from the repository, inside a specific **product submission**, affecting **only** the specific product by clicking **"Modify the ingredient in the repository"**. This action will allow you to update the ingredient fields both in the current product as well as in the repository entry for future use:

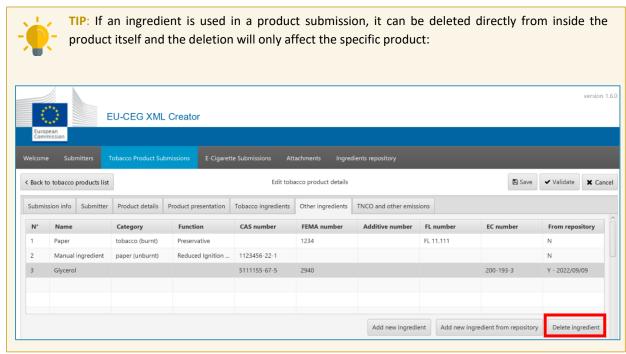


### Delete an ingredient

It is possible to delete an ingredient inside the repository only in case it is **not** used in any product.

Click on the "x" symbol and confirm your action in the pop-up window:

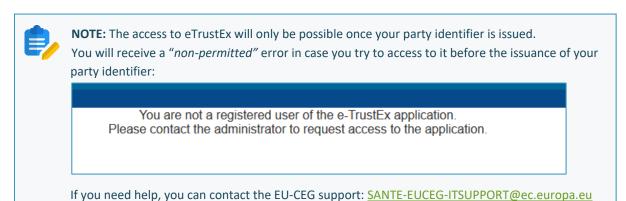




### 5 eTrustEx

After you have created the XML file, you have to submit it to the EU-CEG system using eTrustEx.

→ Go to eTrustEx - <a href="https://euceg.ec.europa.eu/etrustex/">https://euceg.ec.europa.eu/etrustex/</a>
If you are not logged into your EU Login account, you will need to insert your EU login credentials:



Once connected to EU login, you will be automatically redirected to the eTrustEx website.

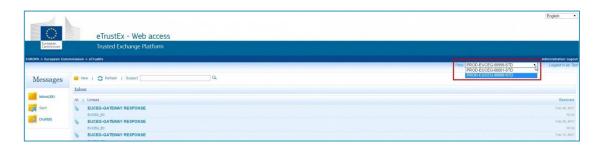
The first page of eTrustEx is your **Inbox**, here is where you will receive your responses on each file upload attempt:



You are able to see the Party Identifier and the username you are using on the top right corner of the page:



**NOTE:** If you have several Party Identifier registered to your account (if third party, for example) **please verify on which Party Identifier you are connected before submitting anything.** You will be able to switch from Party Identifier by clicking on the Party Identifier itself and the list will appear:



### 5.1 Submit your product information

To successfully submit a product, the data has to be sent through different XML files, which have to be uploaded in a specific order, and through separate messages in eTrustEx.



**Step one:** send the "submitter details" XML file. This will "register" your company details in the system. It has to be sent <u>only once</u> unless you need to update company information (address, phone, etc.).

**Step two:** send the attachment XML file(s) if you have added attachment file(s) to your product submission.

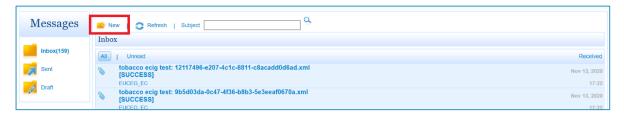
**Step three:** send the product XML file (tobacco product or e-cigarette):



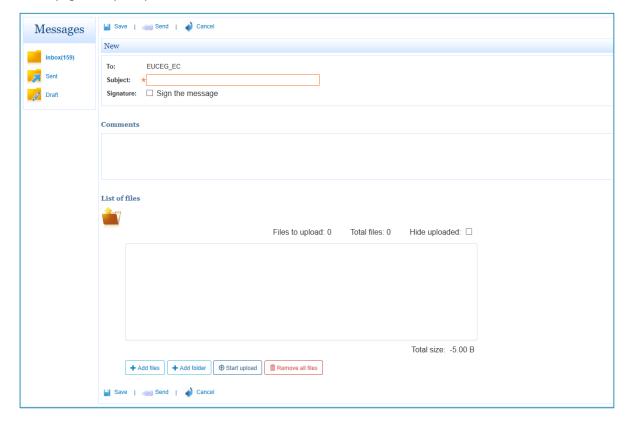
**NOTE:** Failure to respect this workflow will return an error that will be visible in the eTrustEx inbox.

### 5.2 How to upload and send an XML document

From your "Inbox" in eTrustEx, click on "New":



### A new page will open up:



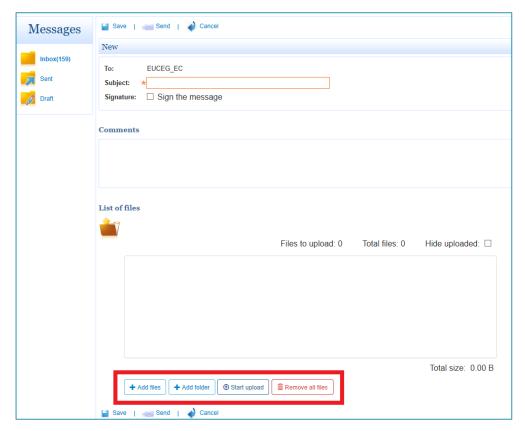
Four buttons at the bottom of the page are available, allowing you to:

Add files: to add the XML files one by one.

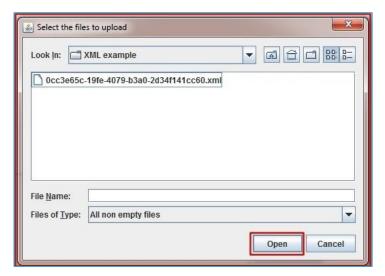
Add folders: to add an entire folder containing several XML documents.

**Start upload**: to complete the upload of the files.

Remove all: to remove all the loaded XML documents.

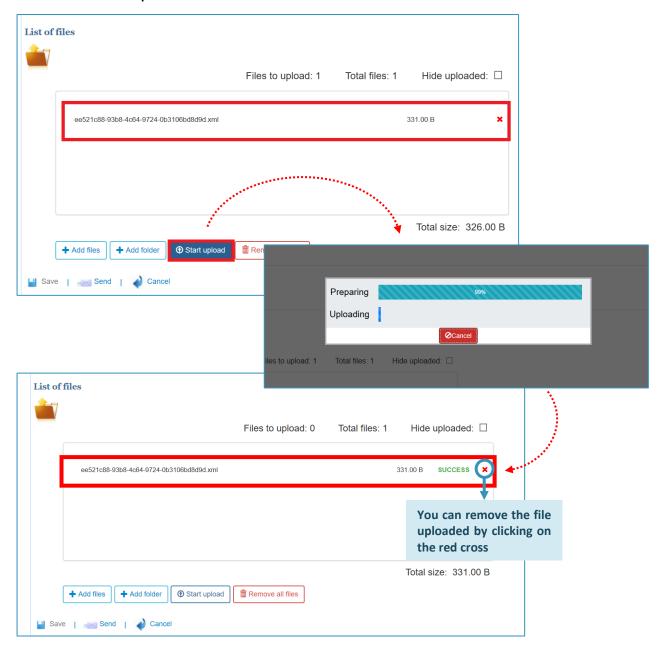


- Click on "Add files" or "Add folder"
- → Select a document / folder and click on "**Open**":



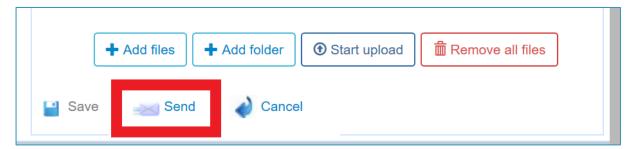
The file is added to the files list (but not uploaded yet).

Click on "Start upload":



After the documents have been uploaded, you can add other files or documents.

Once the XML's documents are loaded into the box, click "Send" at the bottom of the page to send your XML file directly to the EU-CEG System:



For each file that you send, you will receive a response in your inbox with the details of your submission:



- Check the response provided by the system in your inbox:
  - if the response is **[SUCCESS]** it means that the file has been uploaded successfully and it should therefore reach the relevant Member State(s), based on the presentations contained in the product submission;
  - if the response is **[ERROR]**, your file <u>will not reach the Member State(s)</u>. If this happens, you need to check the error message, make the necessary adjustments in your submission, and upload the file again. If you have troubles understanding the error message and / or how to fix it, you can contact the support by email at <a href="mailto:SANTE-EUCEG-ITSUPPORT@ec.europa.eu">SANTE-EUCEG-ITSUPPORT@ec.europa.eu</a>



**NOTE:** Please be aware that simply uploading an attachment in eTrustEx, will not make it visible to the Member State(s). The newly uploaded attachment must be referenced in the product submission, which must then be uploaded again.

### 5.3 Some common errors and how to fix them

Most commonly, when an error shows up, it is due to an empty mandatory field or a field that does not follow the business rule (for example the product ID). However, some errors can also appear later on in the process when you upload your (valid) files through the eTrustEx platform.

Here's a list of some common errors and their solutions:

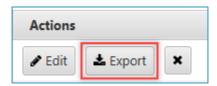
### <Message>XSD validation failed.</Message>

This error comes up when the uploaded files are coming from the "data" folder of the XML creator tool, which do not have the correct structure.

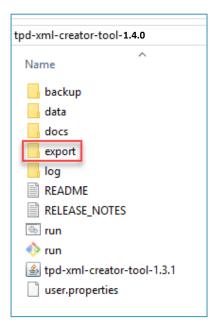
You MUST upload the XML files that are located in the "export" folder of the XML creator tool and not those located in the "data" folder.

Follow the instructions described below:

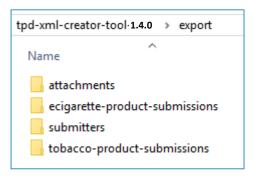
once your XML is validated by the tool, click on export:



You will notice that a new folder called export has been created on the XML creator tool root folder:



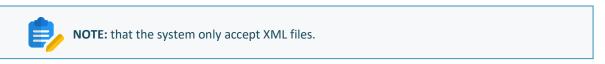
Here, you will find the XML files with the correct XSD structure that you can then upload on eTrustEx.



### <Message>Invalid XML document.</Message>

This error can occur if:

- Your XML file is not a real XML file (e.g. a file with the .doc, .jpeg, etc. extension changed in .xml).
- You have created the XML file yourself, without the XML creator tool, and some tags are missing.
- You have manually edited the XML file created by the XML creator tool and left a mistake.



The validity of the XML is determined by the XSD structure we have set up. You can find the concerned XSD in the CIRCABC online library.

<Message>The value of the 'SubmissionType' element cannot be '1' because a submission already exists for this product.</message> (duplicate submissions)

This error states that your submission already exists in the EUCEG system and the system does not accept duplicate submissions. In other words, you cannot use submission type 1 for a product that was already registered.

Therefore, if this is a new product, you need to change the product ID and submit it again with the same submission type.

If you are trying to notify an update for an existing product, you must resubmit the product and use the appropriate submission type according to the data dictionary below:

Value	Name
1	Notification of information on a new product (new EC-ID).
2	Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).
3	Addition of product presentation (e.g. national market) to an existing product submission.
4	Removal of product presentation, including product withdrawal, from an existing product submission.
5	Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.
6	Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients.
7	Correction of clerical/administrative errors in existing product submission.

# <Message>The Submitter with the submitterID 'XXXXX' is not registered yet in the EUCEG system.</Message>

This error is related to the **submission workflow**: it occurred because you have submitted your product XML file(s) before your submitter ID and / or your attachment XML file(s).

As a reminder, this is the submission workflow:

- 1. Submitter ID XML File (this file has to be uploaded only once, unless you need to change details about your company)
- 2. Attachments XML File(s) if there are any (once the attachment is uploaded, it can be used in the product file and doesn't have to be uploaded again unless you update the attachment in the xml creator)
- 3. Product XML File(s)

Each type of document should be sent through a separate message in eTrustEx following the above sequence (making sure a [SUCCESS] response is returned on each step before moving on to the next one).

# <Message>The 'MethodsFile' element with attachmentID '35981765-3431-43ae-b733-f8df06a53f6a' does not exist.</Message>

In this example it's the 'Method file' but it could be any attachment.

Just like in the previous example, also in this case, the error is again "workflow related". This means that you have sent the product before uploading that specific attachment (the *Method file*, in this case), so you did not follow the workflow. To fix the error, repeat the submission procedure uploading the XML files in the correct order.

As you can see, the error messages are self-explanatory which in turn, makes errors easy to solve but in case you need some additional help, you can always reach out to the EU-CEG support by email at <a href="mailto:SANTE-EUCEG-ITSUPPORT@ec.europa.eu">SANTE-EUCEG-ITSUPPORT@ec.europa.eu</a> (please make sure to provide your submitter ID and send a screenshot of the error message).

### 5.4 Add a new user in your Organisation

You need a local Party Administrator to administer users on behalf of your Organisation.

The first local Party Administrator of your Organisation (**you**) is set-up by the Commission. Once this person has been granted access, you will be able to administer users independently from the services of the Commission.



NOTE: It is recommended to setup a "back up" administrator

When adding users you have to assign them a "role". The role will define what usage rights they will have in the application.

### There are two types of role available:

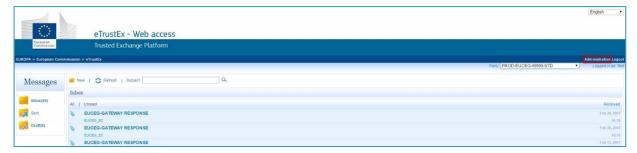
Operator: this role allows you upload files and view the response messages of your party (or parties).

**Administrator:** this role grants you "Operator" rights but also the ability to grant Operator and Party Administrator roles to other users for your party (or parties) in the system.



**NOTE:** The new user will need to have an EU Login account to have the ability to be added on the organization

Click on "Administration" next to "Logout", at the top right corner of eTrustEx web page:



You will be redirected to the Administration page. Here you can see the configured users of your organization (only you, by default).

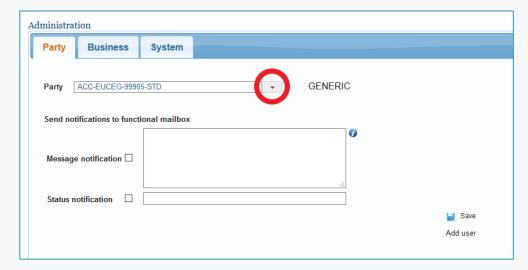


### NOTE:

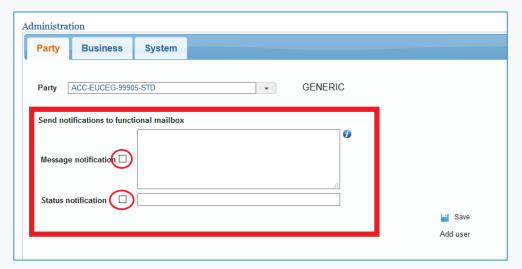
- It is possible for a Party Administrator to have access to multiple parties.

If this is the case for you, open the dropdown list to display the list of all your administered parties.

Otherwise, you will only see your single party already displayed:

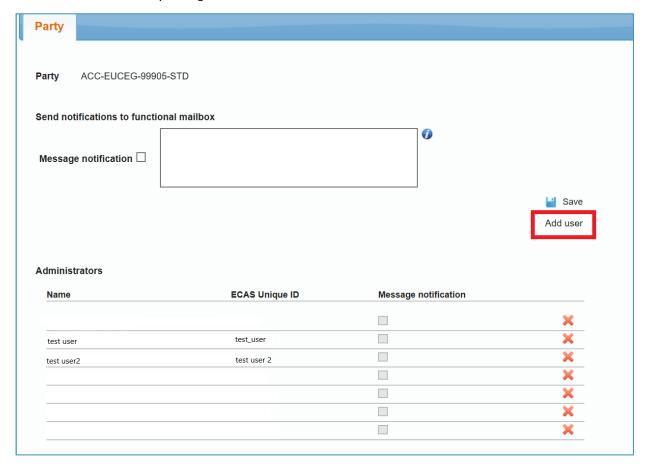


- If you have another functional mailbox, you can add it in the fields highlighted below. When a new message arrives, a notification is sent to this mail address:



You can choose if you want to receive a notification only when a submission is done (message) or when your profile (status) change, or you can choose both options. **The checkbox needs to be activated.** 

To add a new user in your organization click on "Add user":



A pop-up window will appear.

- 1. Type the full name of the user
- 2. Enter the ECAS (EU Login) Unique ID (UID: "Unique identifier at the Commission") as provided by the user



**NOTE:** the user must provide you the UID and not their login username, the UID can be find on their EU Login account details page and generally starts with the letter "n\*\*\*\*\*\*"

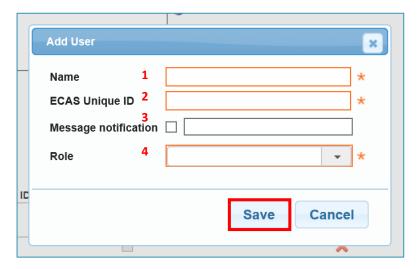
- 3. Optionally, you can enter an email address. **This is only** if the user wishes to receive a notification email when a product has been submitted or the status has been changed. You can choose both options. If this is the case, select the checkbox to activate the email features
- **4.** Enter a role for the new user:

**Operator:** this role will allow you to view messages for the selected party.

Administrator: this role will allow you to view messages and administer the users of the selected party.

→ Click on "Save" to confirm the new user.

The user will be added in your organization, any changes to the roles will be activated at the next login for that user.



### 5.4.1 Additional actions

#### Edit user:

Click on the name.

A popup window will open the form, where you can modify the values of the selected user.

### Delete user:

Click on the icon to the right of the user.

A popup window appears to confirm the delete.

→ Click on "Remove" to confirm the delete of the user



**NOTE:** Make sure to keep at least one "Administrator" otherwise you will not be able to access to eTrustEx and you will have to contact the support team that will restore the administrator used in the registration form.