

User Reference Guide – E-cigarettes Submissions – Update 25/2/2022

This is a Tips, Troubleshooting and FAQ guide for users that wish to make submissions to notify E-cigarette products in Great Britain via MHRA Submissions.

Tips & Troubleshooting for efficiently submitting notifications

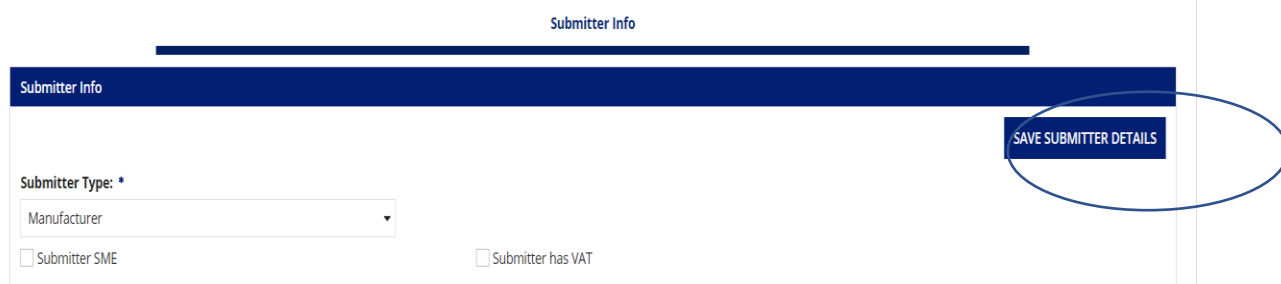
- We would recommend you manually submit your first notification and use this as a template for further notifications which can then be easily edited.
- Use Bulk Submissions for uploading XMLs generated by the EU portal TPD XML Creator Tool (minus documents).
- You will be unable to view your migrated notifications from the EU Portal. However, they will be on our system so you will be able to seamlessly upload your new submission type for that notification.
- Please note if there is a warning that a Type1 does not exist for this notification then you will need to submit the Type1 before submitting any other notification types. If you are unable to upload the required Type 1 use the support tile to raise a request for upload. You will need to supply the original Type 1 to IT services.
- When editing an existing submission and clicking Save Submitter Details you will return to the Homepage. You will need to wait 5 minutes before you can reopen the submission from the Edit Submissions (this will ensure data is refreshed and fully populated).
- Whilst making a submission on MHRA submission portal if you find the portal is providing an option to generate new submitter ID instead of pre-populating your EU submitter ID then instead of progressing with the submission please report this to MHRA via the 'Help and Support' tile on MHRA submission portal.
- Once you have validated the submitter ID assigned by MHRA submission portal and it is in line with your EU submitter ID then you will have an option to raise a request to update your company display name. A request can be raised via the 'Help and Support' tile.
NOTE- Company name displayed on the MHRA submission portal is also used in the extract published on our MHRA gov website.

Frequently asked questions

How do we add documents with a Bulk Submission? Please note that when making a bulk submission you will be required to manually add documents and CLP Stot Description to required fields after submitting the bulk upload.

Why do I sometimes lose my submission progress? We would like to stress the importance of selecting “save” after completing each tab. This not only ensures that your current progress won’t be lost but also makes sure that any documents you upload will appear under “Refer Docs” for ease of reference when uploading documents in future. Each tab has a save function as evidenced below:

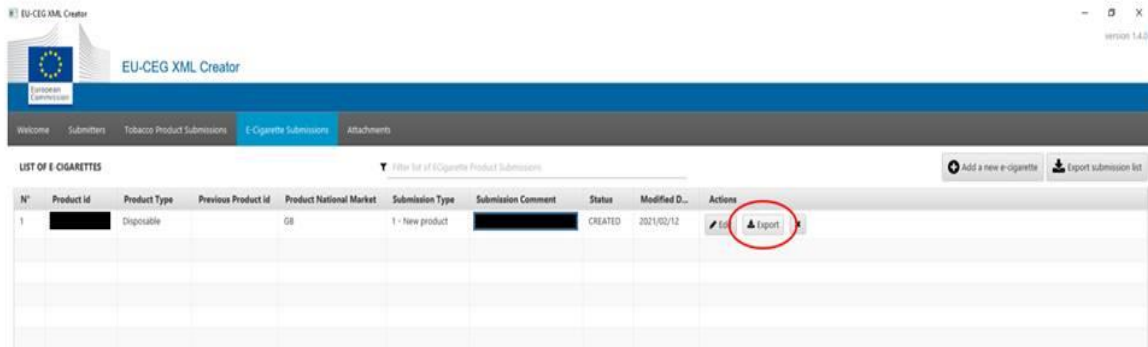
Please ensure that you have saved all the tabs. If not, the unsaved changes will be lost on submission.



The screenshot shows a web form titled "Submitter Info". At the top, there is a blue header bar with the text "Submitter Info" and a "SAVE SUBMITTER DETAILS" button on the right, which is circled in blue. Below the header, the form contains a "Submitter Type: *" dropdown menu with "Manufacturer" selected. There are also two checkboxes: "Submitter SME" and "Submitter has VAT", both of which are currently unchecked.

Why am I unable to view submissions made on EUCEG Portal? Please note that notifications which have been migrated from the EUCEG Portal to the MHRA Portal prior to January 1st 2021 will not be viewable on your end. All historic notifications are available for the MHRA to carry out regulatory functions. The submissions will be viewable within your profile after XML updates are made.

Why am I unable to upload an XML? When uploading XML files to the MHRA submission portal be aware that you may encounter errors if you are using a save file from the EU XML creator. If you wish to upload EU generated XML files, please use the ETRUSTEX export XML file. The MHRA Portal will only recognise the 'Export' file of the XML which is a condensed file type. This will not work with the 'Data' file which is the file used to make changes to the product notification in the EU-CEG XML Creator:



How do I submit Annual Sales Data? As in previous years the MHRA will be continuing to accept annual sales for the whole of the UK (Great Britain and Northern Ireland). Submitters can upload this information to the MHRA Portal in the Product Presentation tab as per below:

The screenshot shows a form for uploading annual sales data. It starts with a section for 'Unit Packet Picture File' containing an 'UPLOAD' button and a 'Drop files here' area, followed by a 'REFER DOCS' button. Below this is a table with three columns: 'Product Sale Volume', 'Product Mode Of Sales', and 'Product Sale Volume Year'. The 'Product Mode Of Sales' column has an 'UPLOAD' button and a 'Drop file here' area. To the right of the 'Product Sale Volume Year' column is a '+' sign. Below the table is another 'REFER DOCS' button. At the bottom of the form are two buttons: 'ADD PRESENTATION' and 'BACK'.

Additionally, you can request a copy of our annual sales template for email submissions if you prefer. Annual sales notifications should be submitted to the MHRA by May 20th, the report should cover the whole of the preceding year.

Please note that failure to provide this information to the relevant competent authority is an offence.

My business is based outside of the UK, can I still submit products for Great Britain? Great Britain no longer recognises authorised representatives and responsible persons based in the EU.

For the purposes of submission, the account can be set up/operated by a business in any part of the world. However, there is a specific field where the submitter must provide details of the responsible person based in the UK. This would usually be a legal representative, importer, local office or other suitable representative for the purposes of legal responsibility in GB. This can be entered at the Submitter Info page as per below:

Submitter Info

Submitter Info

SAVE SUBMITTER DETAILS

Submitter Type: *

--- Select a Type ---

Submitter SME Submitter has VAT

Country: *

--- Select a Country ---

Address: *

Phone: * Email: *

Submitter Has Parent Company

Submitter Has Affiliate Company

Submitter Appoints Enterer

SAVE SUBMITTER DETAILS

As a submitter you are required to provide this information to the MHRA via the GB Submission Portal. This information should be added to the “Affiliate Company” field in Submitter Information for each product notification. Failure to provide this information may constitute an offence under the Regulations and will significantly delay the publication of affected product notifications.

Note: ‘Affiliate company’ is your GB-based responsible person/entity as required under the regulations.”

When you click on **Submitter Has Affiliate Company** an **ADD** box will appear which you will need to select. Upon doing so the below fields will become available to enter the relevant details after which you should then select **SAVE AFFILIATE DETAILS**. In the event you need to add more than one you have the option of again selecting **ADD** and repeating the process.

I don’t have a submitter ID, what do I do? At the beginning of the submission process you will find that the Submitter ID will be auto populated if previous submissions have been made. In the event one does not exist please select the Generate Submitter ID tab at which point a unique MHRA submitter ID number will be generated for you. If you are sure you have an existing MHRA account and relevant submitter number, do not auto generate a new ID. Please proceed to the support tile and provide your company information for review.

The screenshot shows a web form titled 'Home' in the top navigation bar. The form contains several fields: 'Submission Type' (dropdown), 'Company' (dropdown), 'Submitter ID' (text input), 'Product Previous ID(EC ID)' (text input), and 'Product ID(EC ID)' (text input). Below the 'Submitter ID' field, there is a blue button labeled 'GENERATE SUBMITTER ID' which is circled in red. To the right of this button, the 'Submission Date' is displayed as '29 Oct 2020'. Below the 'Submitter ID' field, there is a text area for 'Submission General Comment' and a 'Territory' field. A 'BACK' button is located in the bottom right corner of the form area.

What should I do in the event of a change of ownership ?

If your company ownership has changed and you require a new 5-digit MHRA company number for the MHRA Submissions Portal please raise a request via the [Reference Data Team](#)

Please be sure to include as much of the information below as possible in your email:

- Full legal entity/company name (no abbreviations, trading styles or short names please)
- Headquarters address
- Bill To/Invoicing address (If different from the Headquarters address.)
- Invoicing email address

What do I do if I think there has been a mistake in my publication status or a previously withdrawn product has not been republished? If you believe the publication status of your product is incorrect, please contact the notification team at tpdnotifications@mhra.gov.uk

How can I get my submission assessed more quickly? Submitted notifications can only be reviewed for compliance after payment has been made.

Why is it taking so long to publish my products? A product should be submitted six months prior to intended supply. If the product notification is published by the MHRA before the end of this period it can be made available. Since launching the integrated publication system the average time for the publication of compliant submissions is 3 weeks. The length of time taken for a product to achieve publication status will be impacted by the quality of the original submission and the taken to complete any corrective actions required by the MHRA.

Failure to achieve timely publication status is often due to a combination of the reasons below:

- Submitter has failed to carry out required corrective actions in relation to any data requirements (common examples – missing tox data, no responsible person provided)
- Submitter has failed to notify the MHRA of corrective action, no re-assessment can take place until they have responded
- Submitter has not paid the fee, in which case no assessment has been carried out (this includes partially paid invoices and payments without required information – invoice ref, MHRA account number etc)
- Submitter has set up their account incorrectly on MHRA submissions
- Submitter has failed to follow published guidance requiring IT intervention prior to further submissions taking place

You will be informed in writing when any of these issues affect your submissions.

It is essential to follow all published guidance which can be found in the “Submission Guidance” tile within MHRA Submission and on our main web page.

Please note: It is in your best interests to ensure your notifications are complete and meet regulatory requirements upon submission. Incomplete submissions will receive an email titled “Checking of Notifications” in which we outline any issues which need to be addressed. These ECIDs are placed on hold pending a response from the submitter confirming corrective action has been taken. This in effect means your submissions will be placed at the back of a queue of ECIDs requiring reassessment, which in turn will likely mean a significant delay irrespective of how fast corrective action has been taken. Products which are on hold will be reassessed in order, hence requests for immediate reassessment and publication cannot be accepted. The TPD Notifications Team will notify you when reassessment is complete and the ECIDs will then appear in the next update of the Published Lists (assuming corrective actions suffice).

Submissions will also not be reviewed for updates until the MHRA have been informed of corrective actions in writing. To ensure your corrections are reviewed you must respond directly to the “Checking of Notifications” email you have received from the TPD Notifications Team. Do not use this email to raise further enquires not related to the specific corrective actions at hand. If you require assistance on a different matter (including product submissions not referenced in our original communication) you must outline this issue in a separate email.

How can I provide notification toxicology data if none is available? From March 2022 all submitters will be required to provide evidence of safety assessments carried out in respect of ingredients where no published data is available. Validation will not be successful until this information has been provided. Further review of this data will be carried out by assessors for suitability with MHRA requirements.

Although the requirements for the provision of toxicology data for ingredients remain the same, the mandatory fields have changed. When using the MHRA submission portal, uploaded documents are now mandatory for each aspect of toxicology data (CMR, cardiopulmonary etc). Whilst there might not be relevant data for each field, the system still requires an upload. If there is no available data for one aspect of the toxicology requirements, then details of searches performed (including details of the search terms and databases used) can be uploaded. Searches should be wide ranging, looking for data from multiple sources. Information from published studies which showed no harmful effect is valid.

Where no toxicity studies or information can be found for any of the required aspects, the suitability of the ingredient for use in a product should be questioned. Producers are required to ensure their products can be considered safe and safety cannot be assumed in the absence of available data. Producers should carry out their own safety assessment where no information is available. Toxicology uploads with vague statements about lack of data/studies and no evidence of assessment will not be accepted, nor will placeholder documents.

Please note: Deleting ingredients from submission data in an attempt to circumvent this requirement is an offence and may lead to the permanent removal of products and/or the submission account.