CHAPTER 1 - SUBMITTING NOTIFICATIONS ON THE EUROPEAN COMMON ENTRY GATE

SUBMISSION OF NOTIFICATIONS FOR NORTHERN IRELAND UNDER ARTICLE 20 OF DIRECTIVE 2014/40/EU

**IMPORTANT NOTICE**  
The new release of the **XML Creator 1.4.0** complemented with a release note and a new comprehensive user guide are available for download in the CIRCABC online library for both [Tobacco](https://circabc.europa.eu/ui/group/3c46204a-2d6c-4c28-b12c-0520b8316e1a/library/8aa40522-a9bd-4912-8c76-a535554b5cd6?p=1&n=10&sort=modified_DESC) and [E-Cigarette](https://circabc.europa.eu/ui/group/a4c7629c-0054-41d6-96e7-19c7c9da0a80/library/b3141f3c-f8be-413f-b2a8-6c9f44b82cae?p=1&n=10&sort=modified_DESC) stakeholders group. **All valid XML files generated with previous versions of the tool remain fully compatible until further notice**.

**Submissions to the United Kingdom in respect of Northern Ireland market**

As of 1st of January 2021:

* The reporting by the manufacturers of products for UK and (UK Travel Retail) main island (Great Britain) market will no longer be done via the European Union system EU-CEG
* The reporting of products for the Northern Ireland area will continue to be done via EU-CEG

For data integrity reasons, the code “GB” will be maintained at XML level but as of 1st of January 2021 will only be linked to Northern Ireland market in the EU-CEG context. In the new release of the **XML Creator Tool (1.4.0)** for the National Markets selection, the label shown as "United Kingdom" **will be changed to "United Kingdom in respect of Northern Ireland" while internal GB code will be kept**.

Applying for a Submitter ID and ECAS account

Notifications have to be submitted to MHRA through a European Common Entry Gate (EU-CEG) notification portal made available by the European Commission.

1. Create an [ECAS account](https://webgate.ec.europa.eu/cas/wayf?loginRequestId=ECAS_LR-21723079-0mO1Gig6at8PBf8vSY2n1oUJnf9HYLhbvkVyoNvTlnkB69ivYg1Hkn5TyrId4tYYPoG88doLTVcvrZvaoynNpm-Jj71zxYb8yrdaMmFt4gSYi-5dNULQGlUEnYvmsXlu1gzzL38AUrzukRKdfOsoNiHSgy&caller=%2Fcas%2Flogin)
2. Apply for a [submitter ID number](http://ec.europa.eu/health/euceg/step_by_step/index_en.htm)
3. Guidance on the EU-CEG and how to complete these steps has been made available [by the European Commission](http://ec.europa.eu/health/euceg/step_by_step/index_en.htm)

Submitting a notification

Once you have an ECAS account and Submitter ID number, you can continue with the application process. The European Commission have published some guidance to help you with this. You can find this guidance by following the steps below:

1. Ensure you have a [ECAS account](https://webgate.ec.europa.eu/cas/wayf?loginRequestId=ECAS_LR-21723079-0mO1Gig6at8PBf8vSY2n1oUJnf9HYLhbvkVyoNvTlnkB69ivYg1Hkn5TyrId4tYYPoG88doLTVcvrZvaoynNpm-Jj71zxYb8yrdaMmFt4gSYi-5dNULQGlUEnYvmsXlu1gzzL38AUrzukRKdfOsoNiHSgy&caller=%2Fcas%2Flogin)
2. Go to the [EU-CEG website](http://ec.europa.eu/health/euceg/introduction_en)
3. In the tabs at the top select [‘Downloads’](http://ec.europa.eu/health/euceg/download_en)
4. Click the link that says [‘e-cigarettes and refills’](https://circabc.europa.eu/w/browse/7dedde5d-b276-40f6-8d21-ccf98df87d46). You will need an ECAS account to access this page. If you cannot see the information below, you will need to create an [ECAS account](https://webgate.ec.europa.eu/cas/wayf?loginRequestId=ECAS_LR-21723079-0mO1Gig6at8PBf8vSY2n1oUJnf9HYLhbvkVyoNvTlnkB69ivYg1Hkn5TyrId4tYYPoG88doLTVcvrZvaoynNpm-Jj71zxYb8yrdaMmFt4gSYi-5dNULQGlUEnYvmsXlu1gzzL38AUrzukRKdfOsoNiHSgy&caller=%2Fcas%2Flogin), log in, and start again from step 2
5. You have now accessed the CIRCABC (Communication and Information Resource Centre for Administrations, Businesses and Citizens). Click ‘latest version of technical documents’
6. Unless you have an AS4 Access point, you will need to click ‘XML Submission through web interface’ (if you do not know whether you have an AS4 Access point, or are not sure what one is, we recommend you use the web-interface option)
7. On this page you will find:

The ETRUSTEX tutorial.pdf, which contains all the necessary information regarding how to:

* + submit your XML through the web interface;
  + read the encrypted messages sent by EU-CEG; and
  + manage user accounts in the XML upload system (E-trustex)

A keystore (EUCEG\_GUI\_USER) to decrypt the messages received by the EUCEG system. (The ETRUSTEX tutorial gives you the information about how to use this keystore)

* + How to install the XML creator tool procedure (procedure to install the TDP XML creator tool.pdf)
  + The XML creator system (tpd-xml-creator-tool-**1.4.0**.zip)

Unless you wish to use a bespoke XML file creator, the Commission have provided one that is free for you to use. To access it, download the tpd-xml-creator-tool-**1.4.0**.zip and run the file named the tpd-xml-creator-tool-**1.4.0**.jar

Once you have created your XML files using the tool, you can upload them to the portal by following the instructions in ETRUSTEX tutorial.pdf.

Please note MHRA does not run the notification portal or XML creator, and the steps above are for guidance only. If you have any difficulties, please contact the portal’s technical team directly via the email addresses below:

EU-CEG Contacts

* Should you encounter technical difficulties, please contact [SANTE-EUCEG-ITSUPPORT@ec.europa.eu](mailto:SANTE-EUCEG-ITSUPPORT@ec.europa.eu) (including in your message a ‘print screen’ of the window where the problem appears)
* Should you encounter difficulties in obtaining a submitter ID, please contact [SANTE-SUBID-EUCEG@ec.europa.eu](mailto:SANTE-SUBID-EUCEG@ec.europa.eu).
* For other general matters related to the functioning of the EU-CEG, but not to your request, please contact [SANTE-EU-CEG@ec.europa.eu](mailto:SANTE-EU-CEG@ec.europa.eu).

**MHRA March 2022**