



Information for EMTOC users

Voluntary 2010 submission in NL, DE and BE

Tasks of EMTOC Trust Centre, hosted by RIVM

- Issue of smart cards, PIN, EMTOC login ID, password
- Ingredient list update
- Emergencies, problem solving with smart cards (loss)
- Help desk for submission of data and problems with entry EMTOC system
- Changes of contact details EMTOC users

Application procedure

Documents (DOC) mentioned can be downloaded from the EMTOC page on the website

To apply for access to and use of the EMTOC system:

- Read the EMTOC Instructions (**DOC**) and the EMTOC Terms of Use (**DOC**);
- Sign the EMTOC User Agreement form (is also the application form) form (**DOC**);
- Send the completed and duly signed EMTOC User Agreement form to the regulator of Belgium (BE), Netherlands (NL) or Germany (DE). For address(es): see EMTOC List of Regulators (**DOC**).
- Transfer the fee of €200 ** per MS to the bank account of the EMTOC Trust Centre:
Royal Bank Scotland, ABN AMRO N.V., G. Mahlerlaan 10, NL 1081 PP Amsterdam
IBAN: NL58RBOS0569998921. BIC/SWIFT code: RBOSNL2A.

Account holder is RIVM (clearly mark on transfer sheet: "EMTOC").

- The Regulator of NL, BE or DE verifies your authenticity, approves (Y/N) the application and informs EMTOC Trust Centre.

Following approval and receipt of the fee transferred, you will receive from the EMTOC Trust Centre:

- Sending 1. Personal smart card and one password for EMTOC system by registered mail.
- Sending 2. User ID name and Smart Card PIN by E-mail.

Sending 2 will follow only after your confirmation by e-mail [emtoc.trustcentre@rivm.nl] of receipt of sending 1 to the EMTOC Trust centre. You will need only one smart card to enter EMTOC, but one ID + password for each MS, where you wish to upload data.

Start up

Software for Smart card to be downloaded at http://www.rivm.nl/emtoc-ca/Classic_Client_32_User_setup.msi

After the first login into the EMTOC system the password has to be changed. After three failed attempts to enter the PIN in the Card Reader, the Smart Card is blocked and has to be send back to the regulator.

Fee for deblocking of Smart Cards:	50 €
Fee for replacement of Smart Cards (loss):	500 €
Validity of smart card certificate:	12 months

Contact details of the Trust Centre

Institution	RIVM – GBO, P.O. Box 1, 3720 BA Bilthoven, The Netherlands
Telephone	(+) 0031-30-274-2196
FAX	(+) 0031-30-274-4446
Email	emtoc.trustcentre@rivm.nl
Availability	8 hours / 5 days
Website of Trust Centre	www.tabakinfo.nl
Location EMTOC database	Federal Ministry of Health (BMG), Vienna, Austria
Website of EMTOC (training)	https://www.emtoc.eu/training/manufacturers
Website of EMTOC (submission)	https://www.emtoc.eu/manufacturers

The approved Third Party that has access to all data for evaluation purposes: European Commission, DG SANCO, Unit C6 (T. Peetso), Rue Froissart 101, 1049 Brussels, Belgium.

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GENERAL INFO

1. BACKGROUNDS EMTOC

1.1 Principles EMTOC system

1. EMTOC (Electronic Model TOBacco Control) is a web-based data system, which enables submission of tobacco ingredient data by tobacco companies to national authorities i.e. the regulators.
2. EMTOC is based on the harmonised template of the European Commission (Practical Guide) [LINK](#).
3. EMTOC is fully supported by the European Commission.
4. European countries participating in EMTOC (14 partners) are NL, DE, DK, UK, CH, PO, RO, BU, BE, NO, SE, FI, HU, and AU. ES and FR are candidate members. Each MS has one part in the EMTOC system, which is fully separated from the other parts. **To date, only NL, BE and DE allow voluntary upload via EMTOC in 2010; others partners may follow soon.**
5. The EMTOC system enables a safe transfer of these partly confidential data uploaded by tobacco companies via the web. Every users of EMTOC will receive the 'EMTOC Instruction', which clearly describes the safety procedures during transfer and download. According to the Instructions, it is strongly advocated not to download data. If data are downloaded, they must be destroyed immediately after use or stored in an encrypted form (Truecrypt).
6. To enter the EMTOC system a smart card has to be used. The smart card is a personal card. Users have to purchase a suitable card reader, like the Gemalto PC Pinpad Reader (product no: HWP113026 B) (proposed).
7. The present version of the EMTOC-system comprises 14 separated shelves; one shelf for each EMTOC partner. As the shelves are strictly separated from each other, the regulator of member state (MS) A has only access to the data submitted to MS A.
8. Tobacco companies have only access to the data they have submitted themselves i.e. company X has only access to the data of company X, not to those of company Y.
9. Within EMTOC, tobacco companies may selectively submit to MSs i.e. participation to EMTOC does not imply that the data submission must occur to all EMTOC partners.

1.2 Legal principles

1. The submission of tobacco ingredient data has been described in EU Directive 2001/37, which amongst others states that the data may be submitted in any form (on paper, as electronic file sent by regular mail or via EMTOC). As such, the use of EMTOC is facultative i.e. Reporting parties are not obliged to use EMTOC (except in AT).
2. The EMTOC-system has been created by a consortium of 13 EU member states plus CH. Of the total budget required to realise the EMTOC system, 60% was funded by EAHC (former PHEA), and 40% by the partners.
3. The only users of EMTOC are: (1) the regulators of the consortium, (2) the European Commission and (3) representatives of tobacco companies and importers, which have been identified and approved by the regulators. Others have no access to the EMTOC database.
4. Regulators are public officers. As such, and regulated by national legislation, regulators must maintain the confidentiality of submitted data. Only the European Commission is entitled to receive a copy of the submitted data.
5. According to the Directive ingredients in amounts > 0.1% w/w are not confidential. Therefore two lists have to be submitted by the reporter. The non-confidential list for the public will be disseminated to the public by the regulator. Confidential data remain confidential and are only accessible to the regulator and the European Commission.
6. Trust centre. The trust centre works on behalf of and under the responsibility of the consortium. The main task of the trust centre is to give user's access to EMTOC (issue of smart cards + PIN, userID name, and password). RIVM also functions as 'data base administrator', whose task it is to update the EMTOC tobacco ingredient list, including that of competitively sensitive ingredients.

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7. Before access to EMTOC is granted, all users, including the regulators, have to sign the User agreement, which expresses that the user has been informed about the conditions as described in the Terms of Use and the Instructions and will proceed to comply with them accordingly.

2. EMTOC IN PRACTICE

1. The EMTOC system has three modes of upload.
 - 1.1. Manually on line (after login)
 - 1.2. Bulk upload via xml
 - 1.3. Filling the data in the excel2xml tool. Tool will create an xml-file suitable for bulk upload. Data are (1) described in an Excel template, (2) converted by the tool to xml-format, and (3) the file in xml-format can be uploaded in the EMTOC system.
2. EMTOC database is hosted by the Ministry of Health (BMG) in Vienna, Austria.
3. RIVM functions as Trust centre (assigned by all partners of EMTOC).
4. Registration procedure for tobacco companies. The company (producers and importers) applies to participate to EMTOC at regulator of the member state where upload of tobacco ingredient data is wished. The regulator approves (Y/N) the application and sends a list with accepted users to the Trust centre with the data required. For every accepted user the trust centre creates (a) one smart card + PIN code, (b) a user name and a login password.
5. Using Smart card and PIN the User has internet access to EMTOC server. Login to EMTOC-system (login name and password) and upload the data to the EMTOC data system.
6. Every MS defined his own reporting time frame.
7. After the submission deadline, the regulator reports back to the RP about the data submitted.
8. The submission of toxicological data is still in development. Only summaries of documents about toxicity of ingredients can currently be uploaded as zipped PDF file.

3. INFORMATION TO BE UPLOADED

- a) Information about the company (address data) [Online]
- b) A duly signed document testifying that the data submitted are correct [PDF]
- c) Test laboratory certificate [PDF]
- d) Ingredients list for public [xml]
- e) Ingredients list for authorities (confidential) [xml]
- f) Summary of toxicological data (tick-box) [xml]
- g) Toxicological data sheets [PDF]

Remark: All files have to be packed (compressed as ZIP) before upload

4. FINANCIALS

A financial contribution, based on real costs, has to be paid by the reporting party (RP) to maintain the EMTOC system. For the 2010 submission the fee for each RP is €200 per member state, where data are uploaded by the RP. Note that certain MS do not ask a fee.

5. AVAILABLE DOCUMENTATION

Once you have entered (logged in) the EMTOC database, you may download the following documentation, which is available on the main page (will also be available on EMTOC website LINK):

- a. User manual EMTOC system, which contains information about system requirements, and how to use the web portal for up- and downloads.
- b. EMTOC Instructions, containing safety procedures
- c. Manual local software (excel2xml tool, Truecrypt, smart cards)
- d. Integral ingredient list
- e. XML-schemes for bulk upload
- f. Information to EMTOC users
- g. The excel2xml tool is freely available

Software for smart card will be made available freely on EMTOC website.

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