



EMTOC TERMS OF USE

version 1.5

DEFINITIONS

Within the context of these Terms of Use, the definitions described in the EMTOC Instruction are to be used. However, when a definition is listed below this definition will prevail.

- EMTOC:** See EMTOC Instruction;
- EMTOC application form:** Form, to be duly signed by the User, which expresses full agreement with the EMTOC Instruction and the Terms of Use;
- Data:** All data transmitted through the EMTOC-system on behalf of the Reporting Party;
- Importer:** See EMTOC Instruction;
- Manufacturer:** See EMTOC Instruction;
- Regulator:** This is the Member State's authority or designated institution, under national legislation, to which reporting on tobacco product ingredients is to be addressed, and which is subsequently authorised to access or disclose non-confidential data. The Regulator is, by virtue of the relevant national implementing directive 2001-37-EC, designated to supervise on the reporting on tobacco product ingredients and receive, archive and process the reports;
- Reporting Party:** This term covers any natural or legal person who is registered with the REGULATOR for ingredient reporting. This is in general the tobacco MANUFACTURER or the IMPORTER. It may also be a person to whom the reporting duty has been assigned. The Reporting Party is subject to the statutory reporting obligations pursuant to the (laws implementing into national legislation) EC directive 2001-37 and/or officers or legal entities to whom such Importer or Manufacturer has assigned its reporting obligations;
- Sending Party:** As the context requires the Reporting Party (in case of uploads) or the Regulator (in case of making available reports);
- Sensitive Information:** All information which is (i) classified as confidential and /or (ii) for which the confidential nature is apparent from its content. For the avoidance of doubt, all Data processed through the EMTOC System, except for the general public in accordance with Table 3 of the European Commission's Practical Guide on 'Reporting on tobacco product ingredients', shall be considered

Sensitive Information. Sensitive INFORMATION comprises trade secrets as well as confidential toxicological data. The requirements of handling sensitive INFORMATION have been described in the EMTOC Instruction. In addition, the regulations about personal data protection have to be respected;

Smart card: See EMTOC Instruction;

Trust Centre: The party that has been appointed by the member states that participate in the EMTOC project to manage the EMTOC system (*inter alia* on behalf of the Regulators taking care of the issuance of certificates user ID's and passwords), the management of User accounts, and helpdesk services;

User: Natural person authorised to use the system in a role listed under Section 6 of the EMTOC Instruction. The User, affiliated to a Reporting Party, has been authorised by this Reporting Party to sign the User agreement and to fulfill the obligations of the Reporting Party mentioned above. Authorisation is granted exclusively to a specific person and must not be transferred to another person. Only REPORTING PARTIES are allowed in own responsibility to share one USER access and SMART CARD between authorised persons (responsible person and his deputy). The User, granted access by the Regulator to use EMTOC, is filed and accepted by the Trust Centre;

1. GENERAL

- 1.1 The EMTOC-system may only be used by authorized Users who have accepted these Terms of Use. If you are not an authorized User and / or do not agree to the EMTOC Instruction and these Terms of Use, you must stop (attempting to) use or access the EMTOC-system.
- 1.2 By using the EMTOC-system and/or signing the EMTOC Application form the User accepts the EMTOC Instruction and the Terms of Use set out hereunder.
- 1.3 It is understood and accepted that the Trust Centre is an auxiliary person of its Regulator and that the Trust Centre can use subcontractors in the performance of its duties.
- 1.4 The Regulator is allowed to download data that have been submitted to the Regulator through the EMTOC system only according to the EMTOC Instruction. The tasks that are performed by the Trust Centre for and on behalf of the Regulators (as set out below) form part of the data exchange, storage and security process that has been set out in the EMTOC Instruction. In case of inconsistencies or conflicts between the language in the EMTOC Instruction and these Terms of Use, the latter shall prevail.

2 REGISTRATION OF USERS AND ENROLLMENT

- 2.1 Access is requested by the Reporting Party for the User specified in the application form <http://www.rivm.nl/tabakinfo/emtoc>.
- a. Request for access by a Reporting Party. The request is made through the management or authorized representative of the Reporting Party; in the EMTOC User Agreement the person(s) is (are) identified who have been appointed by the Reporting Party to use the EMTOC system on its behalf. The Terms of Use (this form) and the EMTOC Instruction is part of the User Agreement (available online by the Trust Centre <http://www.rivm.nl/tabakinfo/emtoc>. The User Agreement is to be printed out, signed and sent to the Regulator.
 - b. The Regulator verifies the User's identity, and the other information provided in the application form including but not limited to the User's signature and acceptance of the Terms of Use.
 - c. The Reporting Party is obliged to pay the administrative costs to the Trust Centre (not applicable in all member states; inquire at the Regulator of the member state).
 - d. The Regulator requests the Trust Centre to create a user profile, passing on the application form and indicating the User's role.
 - e. After receipt of the application form and the registration fee, the Trust Centre sets up access for the User specified in the application form in accordance with the information provided by the Regulator.
 - f. The Trust Centre sends the User a smart card, the assigned password of the EMTOC system, and the address for the online portal by registered mail.
 - g. Upon confirmation of receipt of the smart card and password, the Trust Centre sends the User the Smart Card PIN and the user ID of the EMTOC system by E-mail, so as to permit access.
 - h. The Trust Centre informs the Regulator that access has been granted.
- 2.2 User accounts are personal, may only be used by the person listed in the relevant application form. User accounts, passwords et cetera may not be transferred to another person.
- 2.3 After a User's account has been activated he/she shall be entitled to use the EMTOC-system for transmitting files to the EMTOC-system (uploading) and retrieving reports (downloading) via the online portal in accordance with his role, using equipment that meets or exceeds the requirements set out in Annex 1.
- 2.4 In the case of (suspected) misuse of the EMTOC-system: e.g. three failed attempts to enter the EMTOC password or Smart Card Pin, the Users access will be (temporarily) blocked. A new access will be established after verification of the reasons.
- 2.5 In the case of a lost Smart Card, the account of the User concerned shall be blocked and access shall be denied within 24 hours of notification of such loss to the Trust Centre. A new access and Smart Card will be reissued as described above sub 2.1. The Trust Centre will charge the costs plus a penalty fee for the replacement of the Smart Card.

3. FEES & COSTS

- 3.1 The fees for the use of the EMTOC-system (the administrative costs mentioned in 2.1c) will be calculated each year on the basis of the exploitation costs and will be divided among the Reporting Parties according to a formula set out by the Trust Centre. The amount of the administrative costs and the penalty fee for loss of smart cards will be published on the EMTOC website and may be amended by the Trust Centre from time to time.

4. ACCESS AND USE OF THE EMTOC-SYSTEM

- 4.1 Any access to the EMTOC-system is subject to the following procedure:
- a. User must insert its Smart Card in the card reader, with the entry of the appropriate PIN;
 - b. If the correct credentials have been entered, the User's web browser and the EMTOC system shall exchange the relevant certificates via https (for the avoidance of doubt, no intervention of User is required as this is an automated process;
 - c. User must enter its user ID and secret password in order to login on the EMTOC system via the secure connection.
- 4.2 All Data to be uploaded to the EMTOC-system shall be prepared and delivered by the Reporting Party in accordance with the conditions set out in Annex 1 or otherwise determined by the Trust Centre. The Reporting Party shall remain responsible for the security and data integrity of any Data uploaded to the EMTOC-system until the moment such Information is captured in the EMTOC-system, and is responsible for any (mis)use by any person using the access means made available to it.
- Within the meaning of this Article 4.2, "captured" means actual receipt of the Information at the physical (back-end) connection of the EMTOC equipment to the Internet.
- 4.3 The Reporting Party agrees and acknowledges that the Trust Centre may change the requirements for use in Annex 1, giving notice to users.
- 4.4 Transport and transmission of any Data, in whatever manner, shall at all times occur at the Sending Party's responsibility, even if they have been facilitated, carried out or arranged by the Trust Centre.
- 4.5 The Trust Centre provides the help desk function for Users of EMTOC i.e. technical assistance in data submission via EMTOC (problem solving and answering questions in relation to filling the templates of the EMTOC).
- 4.6 Regulators, identified by the Trust Centre, shall only use the EMTOC system according to the principles set out in the EMTOC Instruction.

5. OBLIGATIONS OF THE REPORTING PARTY

- 5.1 The Reporting Party shall check the correctness of the Data transmitted in the automatically generated reports.

- 5.2 The Reporting Party shall inform the Regulator about changes of address or a change of User.
- 5.3 The Reporting Party shall inform the Trust Centre immediately in cases where abuse of the system or compromise of the user ID is suspected or in case of loss of password and/or Smart Card.
- 5.4 The Reporting Party guarantees that the EMTOC-system will not be used for any other purpose than uploading the data it is obliged to provide to the Regulator and/or generating reports and/or other purposes specifically determined by the Regulator. In particular the Reporting Party shall not use the EMTOC system for the exchange of illegal files or files with illegal content and take all possible measures to prevent misuse by third parties. Within the meaning of this clause Illegal content is understood to include:
- a Content containing software viruses or other program code which is designed to damage the functionality of the computer software, hardware or telecommunication hardware or software;
 - b Content which infringes the (property) rights of third parties such as copyright, trademark rights and patent right;
 - c Content which contains trade secrets of third parties and/or other Sensitive Information to which the Reporting Party is not entitled.

6. LIABILITY

- 6.1 The Reporting Party is fully responsible for the transfer of data from the Reporting Party to the Member State(s). The Regulator i.e. the Member State is legally liable for loss of or integrity problems with the Data that has been submitted to that Member State in the exact same manner as would be the case in the event of loss of data that was reported in a way other than via EMTOC. The Reporting Party acknowledges and accepts that the Trust Centre (in its capacity of operator of the EMTOC system and auxiliary person of the Regulator) shall in no event be liable for any damages or loss, in connection with the use of the EMTOC-system, if the Trust Centre has met the requirements of the EMTOC Instruction.
- 6.2 The Regulator shall not be liable for damages resulting from the (unauthorized) use of the EMTOC-system, nor for loss of data or damage to Data during the transfer thereof by or on behalf of the Reporting Party. For the avoidance of doubt, the management and administration of the Data after their transfer does not fall within the scope of the EMTOC service, and hence the Terms of Use do not constitute (nor disclaim) liabilities or other legal obligations in respect thereof. Notwithstanding anything in the foregoing, however, nothing in these Terms of Use shall constitute, or be construed as, a waiver of any claim or right that the Reporting Party may have against the Regulator, including, but not limited to claims regarding the Member States' or European Community's liability for their officials.
- 6.3 The Reporting Party shall not be excused for any failure to fulfil its statutory reporting obligations as a result of uploaded data not being received by the Regulator.

- 6.4 The Trust Centre grants access to a User to the data of a Member State only if the User was authorised by the Regulator of the Member State for having access to the data according to the specified role as defined in the EMTOC Instructions.
- 6.5 The Trust Centre will grant access to the EMTOC-system to users in the role of the European Commission to all data submitted to the EU Member States.
- 6.6 The Trust Centre shall not be liable to any User for any loss, cost, damage or expense sustained in task of the Trust Centre, except in the event of wilful misconduct or gross negligence.

7. DATA PRIVACY AND CONFIDENTIALITY

- 7.1 The Reporting Party shall only use Data downloaded from the EMTOC-system for the verification of its report and other statutory permitted purposes. The Reporting Party shall not use and immediately delete any data which are not destined for the Reporting Party, notify the Trust Centre of reception of such Data and confirm deletion thereof.
- 7.2 Any personal Data exchanged through the EMTOC-system shall be processed in accordance with applicable data protection law.

8. ARBITRATION

Unless the parties mutually agree that a dispute should be resolved before Dutch courts, any dispute in connection with use of the EMTOC system shall be finally settled by arbitration under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The seat of the proceedings shall be Utrecht and they shall be conducted in the English language.

ANNEX 1 REQUIRED TECHNICAL EQUIPMENT

- PC with MS Windows
- Gemalto Card Reader
- Installed Driver for the Card Reader
- Installed encryption software TrueCrypt for data downloads by Users other than Reporting Parties
- Access to the world wide web (WWW)
- Internet browser MS Internet Explorer

Furthermore it is necessary to have received from the Trust Centre after approved application:

- Smart card with PIN
- UserID and password for EMTOC system
- Client software for smart card reader

FILE SPECIFICATION

The following files can be found on and downloaded from the website of Trust Centre:

<http://www.rivm.nl/tabakinfo/emtoc>

1. General information about EMTOC has been described in 'Information for EMTOC users'.
2. The 'EMTOC Instruction', prescribing the EMTOC safety procedures.
3. The 'EMTOC_User_Agreement form' to apply for access to EMTOC.
4. The 'EMTOC User manual' describes the technical requirements and specifications for the use of EMTOC.
5. The manual 'Smart card' explains the use of smart cards.
6. The Excel2xml tool contains a help file which gives information about the tool and how to install the Tool.