Joint Action on Tobacco Control (JATC)
Agreement n°: 761297— JATC — HP-JA-03-2016

D5.3 – Technical solution for securely accessing and processing public non confidential data

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Table of Contents

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Background information

The purpose of this procedure is to establish a guideline for requesting, sharing and handling data from the EU Common Entry Gate (EU CEG) within the Joint Action on Tobacco Control (JATC). This procedure only concerns the data of those Member States that have signed the legal agreement of non-disclosure and other obligations concerning product information exchange between Member States participating in the JATC and the non-participating Member States.

This procedure also sets out the legal and technical framework of data sharing.

Legal responsibility and data sharing[1]

Any handling, sharing and downloading of EU CEG data must be done in a secure manner in accordance with i) the legal agreement of non-disclosure and other obligations concerning product information exchange between Member States participating in the JATC and non-participating Member States, ii) Section 10 of the JATC Consortium Agreement (Annex A) and iii) the national service level agreements on the storage of data on tobacco products, on novel tobacco products, on electronic cigarettes and refill containers and on herbal products for smoking.

Any person handling EU CEG data is responsible for the correct and secure handling of the data, thereby also in the case of a breach or if the data is mishandled. The data must not be disclosed to a third party, i.e. any natural or legal person that does not form part of the relevant competent authority responsible for participating in the JATC in each of the Member State, or a JATC partner.

However, a Party should not be liable if:

1) The data was publicly available at the time it was disclosed or has become publicly available since;

2) The data was disclosed with prior approval by a relevant competent authority responsible for participating in the JATC;[1]

3) The data becomes known to the Receiving Party by other means than the Disclosing Party;

4) The data is disclosed pursuant to the order or requirement of a court, administrative agency, or another governmental body.

If a Member State wishes to leave the JATC or no longer share the national EU CEG data, it is possible to have the national data destroyed or returned. The Recipients of the data is required to return to the Disclosing

[1] For the full legal framework and set of obligations of sharing EU CEG data in JATC, please refer to legal documents mentioned in the section.

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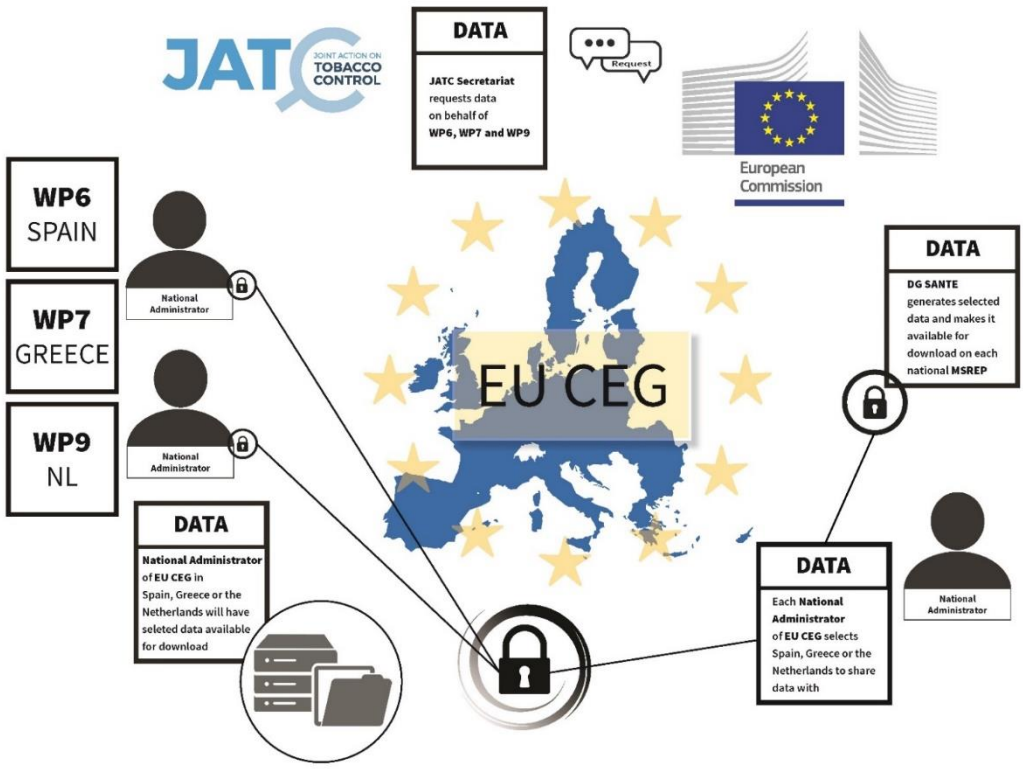
Party, or destroy, on request all confidential information that has been disclosed to the Recipients including all copies thereof and to delete all information stored in a machine-readable form to the extent practically possible. The Recipients may keep a copy to the extent it is required to keep, archive or store such confidential information because of compliance with applicable laws and regulations or for the proof of on-going obligations provided that the Recipients comply with the confidentiality obligations herein contained with respect to such copy for as long as the copy is retained. In accordance with the Consortium Agreement, this is possible for a period of 4 years after the end of the JATC project.

Who will be responsible for data sharing in your Member State?

In each Member State, the National Administrator of EU CEG should be in charge of sharing the data with JATC. If the competent national authority does not participate in JATC, we suggest that the participating JATC partner establishes communication with the National Administrator of EU CEG (competent authority) in order to clarify questions in relation to the JATC. All users authorized to access the Member States Reporting Tool (MS REP) in each participating Member States will have access to the generated data[22].

Procedure for sharing data – in six steps



[2] Disclaimer:
Currently, MSREP application does not differentiate user rights and therefore the data can be shared by any MSREP user at national level. WP5 has proposed that the ability to share data within MS REP should be restricted, so that only few responsible persons in the participating Member States can share the EU CEG data.

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1. Selecting the data

The leaders of work package (WP) 6, 7 and 9 send a "selected data request form" to the JATC Secretariat at jatc@researchlab.gr. The selected data request form is a clearly defined list of which specific variables from EU CEG WP6, WP7 and WP9 need at each time point in order to conduct their research. The form includes information on what is the research hypothesis, what are the objectives of this research, what specific data variables are needed and who will be handling the data after receipt. The data selection request form is provided in Annex B.

Only the variables defined as above and following an explicit approval of the source Member State will be shared for each research hypothesis.

2. Requesting the data from DG Sante

The JATC Secretariat sends an official request, accompanied by the selected data request form to DG Sante at SANTE-B2-TOBACCO-CONTROL@ec.europa.eu, on behalf of JATC to generate the selected data files.

Each National Administrator of EU CEG in all Member States that data will be requested from will be notified via the above email from the JATC Secretariat.

3. DG Sante generates the data

DG Sante validates the request and generates the requested data set within MS REP for each individual Member State specified in the request. Once generated, the data will be available for download on each national MS REP (you will see the newly created national data file for your EU MS). These data reports will be visible in a specific box under "Report Repository" in MS REP. The format of the data will be structured, i.e. XML, CSV.

At this point data as requested has been compiled into a file. However, it has not been shared with other Member States.

4. National Administrators of EU CEG selects EU MS to share data with in MS REP

The National Administrator of EU CEG in each country selects the Member States the national data should be shared with, within MS REP. Based on the selected data request form, either Spain, Greece and/or the Netherlands should be selected as per the request, as WP6, WP7 and WP9 research teams are located in those EU MS.

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5. Data is ready for download in MS REP for Spain, Greece and the Netherlands

MS REP users in Spain, Greece and the Netherlands (depending on the request) will now have the selected data available for download on their national MS REP.

WP6, WP7 and WP9 leaders can now access the data themselves through their MS REP user access.

6. Handling of data after it is downloaded

Confidential data are safeguarded by the application of various levels of both physical and electronic security measures that are routinely used when handling patient-level data, as per the routine practice of both the WP6 and WP7 leads.

- ✓ Researchers will receive only subsets of the data, consisting of the sample groups and variables required for their particular analyses.
- ✓ Data are stripped of identifiers that could permit a direct relationship to be established between data holdings and specific people. Identifiers such as name, telephone specific geographic location, etc. are not to be requested.
- ✓ The actual TP-ID will be separated from the original dataset. The TP-ID will be replaced by another code, random and unrelated to the TP-ID. The file linking the original TP-ID and the randomly generated ID code will be stored at a separate location of the original file. These two files will not be on the same computer.
- ✓ Once downloaded onto a computer the data sets will be stored in a password-protected location on the computer
- ✓ The data set file itself will be password protected.
- ✓ The computer will be password protected.
- ✓ The computer will be stored in a locked location under alarm surveillance
- ✓ The computer will have no access to the internet and will have its LAN and WIFI access disabled.
- ✓ Upon expiration of the timeframe of analysis (in Annex B) the data must be deleted.

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Step by step overview of the process

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ANNEX A

SECTION 10 OF THE CONSORTIUM AGREEMENT VERSION 30 APRIL 2018

NON-DISCLOSURE OF INFORMATION

10.1. All information in whatever form or mode of communication, which is disclosed by a Party (the "Disclosing Party") to any other Party (the "Recipient") in connection with the Project during its implementation and which has been explicitly marked as "confidential" at the time of disclosure, or when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the Disclosing Party, is "Confidential Information".

10.2. The Recipients hereby undertake in addition and without prejudice to any commitment on non-disclosure under the Grant Agreement, for a period of 4 years after the end of the Project:

- not to use Confidential Information otherwise than for the purpose for which it was disclosed;
- not to disclose Confidential Information without the prior written consent by the Disclosing Party;
- to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
- to return to the Disclosing Party, or destroy, on request all Confidential Information that has been disclosed to the Recipients including all copies thereof and to delete all information stored in a machine readable form to the extent practically possible. The Recipients may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations provided that the Recipients comply with the confidentiality obligations herein contained with respect to such copy for as long as the copy is retained.

10.3. The Recipients shall be responsible for the fulfilment of the above obligations on the part of their employees or third parties involved in the Project and shall ensure that they remain so obliged, as far as reasonably possible, during and after the end of the Project and/or after the termination of the contractual relationship with the employee or third party.

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10.4. The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

- the Confidential Information has become or becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
- the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;
- the Confidential Information is communicated to the Recipient without any obligation of confidentiality by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidentiality to the Disclosing Party;
- the disclosure or communication of the Confidential Information is foreseen by provisions of the Grant Agreement;
- the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party;
- the Confidential Information was already known to the Recipient prior to disclosure, or
- the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Section 10.7 hereunder.

10.5. The Recipient shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the Project as with its own confidential and/or proprietary information, but in no case less than reasonable care.

10.6. Each Party shall promptly advise the other Party in writing of any unauthorised disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

10.7. If any Party becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, to the extent reasonably practical, it shall to the extent it is lawfully able to do so, prior to any such disclosure

- notify the Disclosing Party, and
- comply with the Disclosing Party's reasonable instructions to protect the confidentiality of the information.

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ANNEX B

DATA REQUEST FORM

A. Requesting WP	
B. Contact details • **Name of the contact person** • **Mail address** • **E-mail address** • **Telephone number**	
C. Data[3] requested: Please indicate which data from the MS REP you are requesting based on Commission Implementing Decision 2015/2186 or 2015/2183 (add lines as necessary)	
Section	**Variables**
D. The above-mentioned data ("the Data") is intended only for use in agreed upon research activities. Describe the research hypothesis for which you are requesting Data ("the Research").	
Research Description:	
E. Period of Implementation and target dissemination outcome	
F. Who will be handling the data	
Name/Position	**Role**
G. Declaration	
The Data are provided to the entity requesting the Data, hereinafter referred to as "the Receiving Party", exclusively and solely for use in the Research described in section D above ("the Research"). The Receiving Party shall not use and shall require any person having access to the Data not to use, the Data for any purpose other than the Research. The Receiving Party will ensure that the Data will only come into the possession and control of those who are engaged in the above-mentioned Research under the supervision of the Receiving Party and who have accepted the same obligations and restrictions in respect of the Data. In case the Receiving Party would like to use the Data for other research purposes, a new Data Request Form should be submitted. Other than explicitly provided herein, this Data Request Form will not be construed as conveying to the Receiving Party any rights or title to the Data. The Receiving Party will treat the Data as strictly confidential and will disclose such Data only to persons who have a need to know for performing the Research and are bound by the same	

[3] The data request form should be complemented with an .xls sheet clearly outlining the requested output structure so as to aid data extraction and analysis

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obligations and restrictions as contained herein. The Receiving Party will ensure that the Data will be retained in appropriately secure means.
Agreed and accepted by the Principal Investigator responsible for the Research Signature: Date: Name: Title: Name of entity (the Requesting Party):

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