



Joint Action on Tobacco Control (JATC)

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WP5 – D5.2

“Defined legal aspects of accessing other MS data
in the JATC project”

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Background

Under the European Union (EU) Tobacco Products Directive (2014/40/EU) (TPD), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information to the European Commission (EC) and Member States (MS) on products which they intend to place on the EU market. The submitting information includes, but is not limited to, ingredients, emissions and toxicological data, with the specific parameters defined in the Annexes to Commission Implementing Decision (EU) 2015/2186 for tobacco products and Commission Implementing Decision (EU) 2015/2183 for e-cigarettes and refill containers. Such data is necessary for the EC and EU MS to carry out their regulatory responsibilities of monitoring the tobacco product landscape in Europe and assessing the attractiveness, addictiveness, toxicity, and health risks associated with the consumption of tobacco products, with the overall objective of ensuring protection for human health of the EU population.

The EU Common Entry Gate (EU-CEG) is an Information Technology (IT) tool developed to provide a common format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonized reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate tobacco products on the EU market. As such, the EC has worked closely with both EU MS and industry stakeholders to develop EU-CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximise the system's utility and output.

While the EU-CEG IT-system is owned by the EC (system owner), each EU MS own their data in the EU-CEG (information owner). According to the TPD, EU MS shall ensure that the EC and other EU MS have access to the Information submitted via the EU-CEG for the purpose of applying the Directive. However, data sharing has not yet been done regarding any data, so there is no predefined way to access EU MS data. It is within this context that this legal document has been prepared.

The aim of Work Package 5 (WP5) in the Joint Action on Tobacco Control (JATC) is to provide the framework for the accessibility of the data submitted through the EU-CEG, including in light of the application of TPD Art. 5, p 4 and TPD Art. 5, p.7 according to which *“Member States shall store the information electronically and shall ensure that the Commission and other Member States have access to that information for the purposes of applying this Directive.”*

In Task 2.1 of WP5, the JATC is to define the technical and legal requirements for the transfer and handling of data that has been submitted via the EU-CEG for the purposes of JATC and within the context of TPD Art. 5 (6-7) and TPD Art. 20(7). This Deliverable 5.2 covers the legal requirements for sharing EU-CEG data within the JATC and does not cover the technical or IT requirements for the sharing of the data which is the purpose of Deliverable 5.3.

Within this context, the Danish legal firm Horten Advokatpartnerselskab was subcontracted to work with The Danish Safety Technology Authority (SIK) to produce the legal document *“AGREEMENT CONCERNING NON-DISCLOSURE AND OTHER OBLIGATIONS BETWEEN MEMBER STATES PARTICIPATING IN THE JOINT ACTION ON TOBACCO CONTROL”* which is presented in the Annex of this Deliverable 5.2.

ANNEX

AGREEMENT CONCERNING NON-DISCLOSURE AND OTHER OBLIGATIONS

BETWEEN MEMBER STATES PARTICIPATING IN THE JOINT ACTION ON TOBACCO CONTROL

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1. BACKGROUND

- 1.1. The Tobacco Product Directive (2014/40/EU)¹ (hereinafter referred to as "**the Directive**") governs how tobacco products, novel tobacco products, e-cigarettes and refill containers are to be manufactured, produced and presented in the European Union.
- 1.2. Under the Directive, Member States shall require manufacturers and importers of tobacco products, novel tobacco products, e-cigarettes and refill containers to submit to their competent authority information on the ingredients used in the manufacture of the tobacco products, the emissions from these products and other key information² (hereinafter referred to as "**the Information**").
- 1.3. The IT tool for providing the Information is called the EU Common Entry Gate. The common electronic format for the submission of Information is set out in Commission Implementing Decision (EU) 2015/2186 for tobacco products and Commission Implementing Decision (EU) 2015/2183 for electronic cigarettes and refill containers.
- 1.4. Member States shall ensure that the European Commission and other Member States have access to the Information for the purpose of applying the Directive. In this regard, Member States and the European Commission shall ensure that trade secrets and other confidential information are treated in a confidential matter. In addition, Member States shall ensure that certain key aspects of the Information are made publicly available on a website.
- 1.5. The purpose of the reporting obligations is to enable Member States and the European Commission to assess the attractiveness, addictiveness and toxicity of tobacco products and the health risks associated with the consumption of tobacco products, novel tobacco products, e-cigarettes and refill containers.
- 1.6. The Joint Action on Tobacco Control (hereinafter referred to as the "**JATC**") is a collaborative action between the European Commission and Member States with the purpose of supporting the implementation of the Directive. The relationship among the parties participating in the JATC is governed by the Consortium Agreement Version 30 April 2018 (hereinafter referred to as the "**Consortium Agreement**").
- 1.7. The purpose of this Agreement is to compliment the confidentiality provisions set out in section 10 of the Consortium Agreement and in this regard, to facilitate the access and exchange of the Information between Member States participating in the JATC (hereinafter referred to individually as a "**Party**" and collectively as "**the Parties**").
- 1.8. This Agreement should also be open to Member States not participating in the JATC and should provide the basis for further exchange of information between Member States after the conclusion of the JATC.
- 1.9. The Information accessed and exchanged within the JATC will specifically be used to assess and evaluate tobacco products, e-cigarettes and the priority additives subject to enhanced reporting obligations under the Directive. This assessment is carried out by three work packages within JATC.
- 1.10. This Agreement is without prejudice to any rights and obligations applying to the Parties pursuant to the Directive and the Consortium Agreement, in specifically section 10 of the Consortium Agreement on non-disclosure of information.

¹ Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2000/37/EC.

² See Article 5 (Reporting of ingredients and emissions) and Article 6 (Priority list of additives and enhanced reporting obligations).

2. EXCHANGE OF INFORMATION

- 2.1. The Parties are entitled to access and exchange the Information. Any exchange of Information must be limited to what is necessary in relation to the objectives of the JATC in the context of the application of the Directive and the purpose of the specific exchange.
- 2.2. The Parties undertake to ensure that the Information is treated in a confidential, safe and secure manner.
- 2.3. The Parties undertake not to exchange any Information containing personal data and to process all personal data in accordance with the obligations set out in Regulation 2016/679 on data protection³ and any national regulation on data protection applicable to the Party.
- 2.4. Information may be used by a receiving Party only for the purpose of applying the Directive and in furtherance of or in relation to the objectives of the JATC and the purpose of the specific exchange.
- 2.5. The receiving Party must not disclose the Information 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 States, a JATC partner or a JATC subcontractor. The receiving Party is liable for any unlawful disclosure of information to a third party.
- 2.6. Notwithstanding the above, the receiving Party shall not have liability to the disclosing Party if the receiving Party can prove that the Information:
 - a) was publicly available at the time it was disclosed or has become publicly available through no fault of the receiving Party;
 - b) is disclosed with the prior approval of the disclosing Party;
 - c) becomes known to the receiving Party, without restriction, from a source other than the disclosing Party without breach of this Agreement by the receiving Party;
 - d) is disclosed pursuant to the order or requirement of a court, administrative agency, other governmental body or applicable laws or regulations, provided, however, that the receiving Party provides prompt notice of such court order or requirement to the disclosing Party.
- 2.7. Each Party shall promptly advise the other Party in writing of any unauthorised disclosure, misappropriation or misuse of the Information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

3. AMENDMENTS TO THE AGREEMENT

- 3.1. Any Party wishing to propose an amendment to the Agreement shall forward such proposal to the Danish Safety Technology Authority, which will notify the JATC Steering Committee. The JATC Steering Committee has sole competence to decide whether the procedure for amendment as described in section 3.2 and 3.3 shall be initiated. The JATC Steering Committee must make such decision within 60 days after receiving the proposal.

³ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

- 3.2. Any term of this Agreement may be amended only on the initiative of the JATC Steering Committee after a prior written notice of 30 days, in so far as, within the 30 days, no Party objects to the amendment.
- 3.3. If a Party does not object to the amendment within 30 days, either orally or in writing to the JATC Steering Committee, the Party will be considered as having consented to the amendment.
- 3.4. Any amendment must be in writing, signed by an authorized representative of the JATC Steering Committee.
- 3.5. Any amendment effected in accordance with this section shall be binding upon the Parties.

4. WITHDRAWAL FROM THE AGREEMENT

- 4.1. A Party may at any time withdraw from the Agreement. A withdrawal must be in writing, forwarded to the Danish Safety Technology Authority, which will notify the JATC Steering Committee.
- 4.2. Without prejudice to the rights and obligations of the Parties pursuant to the Directive and the Consortium Agreement, after having withdrawn from the Agreement, the former Party is no longer entitled to require the remaining Parties to exchange the Information as set out in section 2.1.
- 4.3. Without prejudice to the rights and obligations of the Parties pursuant to the Directive and the Consortium Agreement, after having withdrawn from the Agreement, the former Party's obligations as set out in section 2.2-2.6 shall remain in effect.

5. DURATION OF CONTRACT AND SIGNATURE

- 5.1. This Agreement will apply to the Parties that at any given time have signed the Agreement and have not withdrawn from the Agreement as set out in section 4. The Agreement continues until the end of the JATC.
- 5.2. This Agreement must be signed by all Member States wishing to facilitate the access and exchange of Information to the JATC.
- 5.3. This Agreement can be signed by either the legal representative of the Member State or the National Administrator of the EU Common Entry Gate.

6. SIGNING

- 6.1. Member States participating in the JATC accept this Agreement by signing:

Date / legal representative of