

Layman report

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Acronym:
JATC

Title:
Joint Action on Tobacco Control

Authors:
JATC Consortium

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1. Explanation and overview of the activities

Within the current document we provide a high level overview of the actions that took place as a Consortium to address the research aim of the Joint Action on Tobacco Control (HP-JA-2016 JATC).

The main aim of JATC is to provide support for the implementation of the Tobacco Products Directive (TPD) throughout the 28 European Union Member States (EU MS). The TPD is a complex legislative document with the aim to support the functioning of the internal market of tobacco products in the EU as also ensuring the preservation of a high level of European public health. Through the provisions of the TPD, both tobacco products and e-cigarettes are regulated. This Joint Action is a collaborative action between the European Commission and the EU MS to implement an action-oriented initiative based on evidence-based tobacco control policies and implementation at the national, regional or European level. Thus, our main aim is addressed through integrated research-oriented work packages (WP), and through seven specific objectives that are presented in detail throughout this current report.

1.1. Objectives

The specific objectives of JATC were:

1. To enhance the ease of access to the data collected through the EU Common Entry Gate (EU-CEG);
2. To monitor and provide support to the tasks of tobacco and e-cigarette product regulation;
3. To assist EU MS networking and collaborations between laboratories for tobacco evaluation;
4. To support EU MS in the process of monitoring and updating priority additives;
5. To ensure appropriate coordination and evaluation of the project;
6. To support the dissemination of information to the public, regulators and researchers;
7. To integrate the JATC results into national policies.

PARTICIPANTS

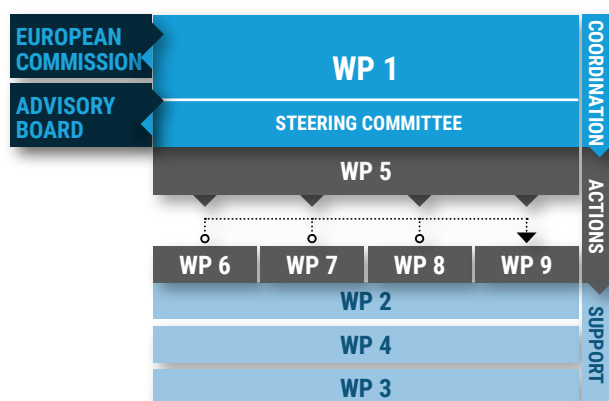
1 HCS	Greece	16 MOH-IT	Italy
2 AGES	Austria	17 HI	Latvia
3 BHTC	Belgium	18 NTAKD	Lithuania
4 NCPHA	Bulgaria	19 NVSPL	Lithuania
5 MoH-CY	Cyprus	20 DEH	Malta
6 SIK	Denmark	21 RIVM	The Netherlands
7 TA	Estonia	22 NIPH	Norway
8 ANSES	France	23 NOMA	Norway
9 BfR	Germany	24 MS-DGS	Portugal
10 APTL-CERTH	Greece	25 BATUT-IPHS	Serbia
11 SU-(SE)	Hungary	26 NZLOH	Slovenia
12 DOHI	Iceland	27 ICO & IDIBELL*	Spain
13 HSE	Ireland	28 CSJA & AGAPA*& FPS*	Spain
14 IRCCS-IRFMN	Italy	29 UK-DH	UK
15 ISS	Italy	30 HTS	Greece

*. Affiliated Partners

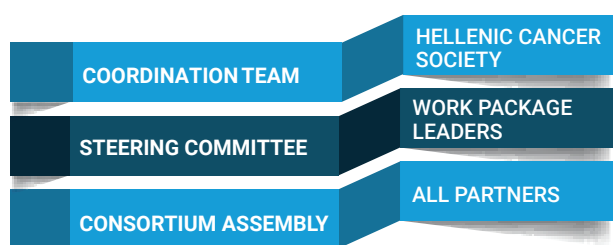
COORDINATION TEAM

Project Coordinator	Prof. Panagiotis Behrakis
Project Associate Coordinators	Prof. Constantine Vardavas Dr. Anna Tzortzi
Project Manager	Dimitris Kagkos
Project Secretariat	Penelope Stambouli

PROJECT MANAGEMENT STRUCTURE



ORGANIZATIONAL STRUCTURE



WORK PACKAGES 1-9

01 HCS	<u>Coordination</u> Hellenic Cancer Society	05 SIK	<u>Common Entry Gate (CEG) data extraction and handling</u> HCS, AGES, BHTC, NCPHA, TA, ANSES, MoH IT, NTAKD, NOMA, MS-DGS, NLZOH, CSJA, UK-DH
02 BATUT	<u>Dissemination</u> HCS, MoH CY, SE	06 ICO	<u>Tobacco Product Evaluation</u> HCS, AGES, BHTC, SIK, ANSES, BfR, APTL-CERTH, HSE, IRCCS - IRFMN, ISS, MoH IT, NTAKD, RIVM, NIPH, MS - DGS, NZLOH, CSJA, UK-DH, HTS
03 AGES	<u>Evaluation</u> HCS	07 HCS	<u>E-Cigarette Product Evaluation</u> AGES, BHTC, ANSES, BfR, APTL-CERTH, DOHI, HSE, IRCCS-IRFMN, ISS, MoH IT, HI, NTAKD, RIVM, NIPH, NOMA, MS-DGS, ICO, CSJA, UK-DH, HTS
04 ISS	<u>Integration into National Policies & Sustainability</u> HCS, NCPHA, TA, ANSES, BfR, SE, HSE, IRCCS-IRFMN, NTAKD, CSJA	08 IRFMN	<u>Laboratory Verification, Collaboration & Analyses</u> HCS, AGES, BfR, APTL-CERTH, NVSPL, RIVM, NLZOH, CSJA, HTS
		09 RIVM	<u>Additives Subject to Enhanced Reporting Obligations</u> HCS, SIK, ANSES, BfR, IRCCS-IRFMN, ISS, NIPH, CSJA

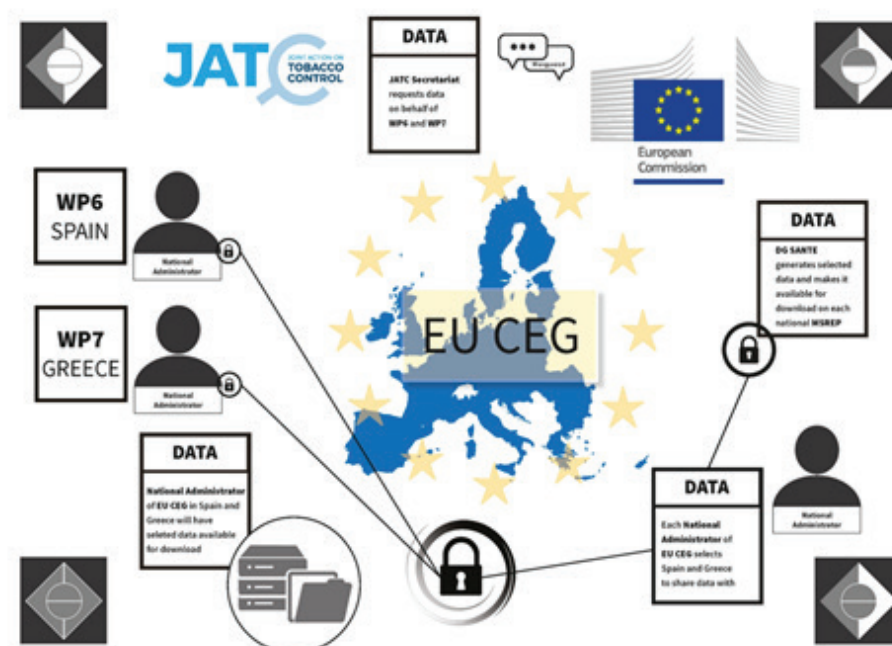
2. Project Key Results and Visibility

2.1 Major results and key findings

Major results of the JATC are a collective work of all JATC partners, across multiple WPs and from combined work of many European organisations. In bullet point form the major results of the JATC are as follows:

Data sharing across EU-MS

Within the JATC a standard operating procedure (SOP) for data sharing was finalized which was subsequently discussed with EU MS via their expert groups and national regulators and a final data sharing agreement was created. This document set out the rules and regulations for the sharing of data between EU MS, within the context of the JATC. This data sharing agreement is a legal agreement that was produced for both JATC partners and non-JATC partners and sets out the legal aspects of sharing and handling data for JATC partners and non-JATC partners. This paved the way for the actual sharing of EU-CEG data across EU MS. A total of 19 EU MS and Norway had signed the data sharing agreement and 15 EU MS were able to share data with other EU MS within the context of the JATC. Building on the experiences and knowledge gained through the sharing of data between JATC members, a permanent mechanism to share data among member states was proposed (building on the already developed solution), and the prepared legal framework was made available to all EU MS to adjust according to their needs.



To identify the variables that should be considered as public, within the information submitted via the EU common entry gate (EU-CEG) and to facilitate making this information available to the general public

This part of the objective was reached through the completion of D5.1 “Report on the principles to distinguish what data is public non confidential and confidential data”. The report was circulated among member states, it was also presented on the Expert Group meeting in October 2019, Brussels. The report assessed each variable within EU-CEG in order to classify if the variable is

- 1) public (Data which are to be fully disclosed to the public).
- 2) Conditionally Public Data (Data which are conditionally public based on specific criteria i.e. a threshold in ingredient quantity).
- 3) Confidential Data (Data which are to be regarded as trade secrets and not to be disclosed to the public).

Each variable was followed by a justification for the classification.

Assessment of tobacco products design and ingredients:

In EU-CEG data base there are twelve tobacco products classified as follows: chewing, cigars, cigarettes, cigarillos, herbal, oral, other, nasal, novel tobacco products (NTP), pipes, roll-your-own (RYO) and waterpipes – this data was shared within the JATC and we were able to perform a comprehensive assessment of this data across 12 EU MS. A mapping of ingredients and product design was performed – the first time across multiple EU MS.

Assessment of e-cigarette product design

Within the JATC, data across 13 EU MS were assessed with regards to e-liquids. These analyses allowed for the outlining of technical design factors, nicotine content, compliance to the TPD as also a detailed assessment of ingredients from both a quantitative and qualitative perspective. In total over 1,000 unique CAS numbers were identified and a pattern of the most frequent ingredients and flavours was noted across the EU MS.

E-cigarette reporting sheet

Previous work through an assessment of 8 EU MS Poison Centers and their reported events related to e-cigarettes in 2018-2019 indicated that the lack of a harmonised reporting format was a major weakness in creating an evidence base across the EU. Within the JATC we supported the EU MS in the development of a format for the reporting of information on suspected adverse effects on human health. Two reporting sheets were created. One for adverse events by poison centers and one for economic operators.

E-cigarette compliance checklist

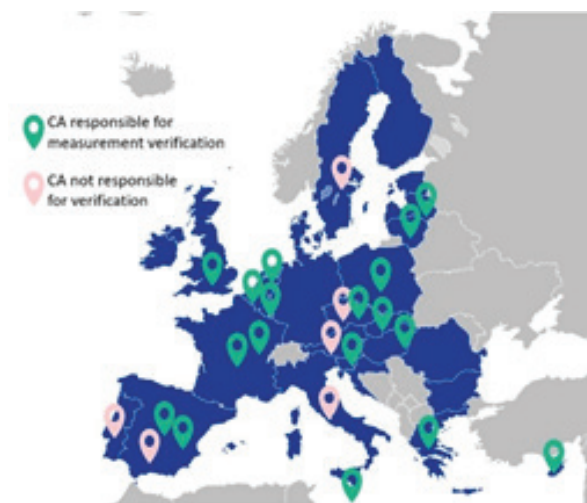
Within the JATC we created a checklist that would aid monitoring of e-cigarette product compliance to the TPD Under TPD Art20(1) and including but not limited to Art20(3-4) and implementing act 2016/586. The checklist that was created was “all embracing” meaning that it can be used for all types of businesses (manufacturers, importers, retailers); it can be used by surveillance institutions depending on their delegated functions (scopes of activity); it includes main requirements for product that is placed on the market in order to be fully compliant and is intended to be filled in electronically.

SOP for laboratory analyses

The JATC developed a Standard Operating Procedure was developed for measuring analytes in e-liquids. This SOP was implemented in order to collect original analytical data and information about laboratory measurement across labs in Europe. Samples sent to 27 EU and TobLabNet laboratories indicated that the independent laboratories showed a good instrumental capacity, although few laboratories had mass spectrometry analytical capacity. Results indicated that laboratories are able to work on new methods, to adapt the new SOP, and their analytical quality is excellent.

EU laboratory collaboration:

The JATC was the occasion to start developing communication with other large international initiatives, including GoToLab and WHO TobLabNet. In addition to enhancing these communications, an active network of EU independent laboratories has been created. The SOP that was developed and implemented across laboratories was an opportunity to collaborate, to discuss about methods, samples, training samples and validation samples. The general impression is that there is a need for a European network of laboratories, to share new methods for new analytical challenges coming from new products facing the market. This network showed that EU collaboration is possible, as well as collaboration with international networks, TobLabNet, and Universities.



Peer review of priority additives

The new Tobacco Products Directive (TPD) 2014/40/EU strengthens the rules regarding the reporting and composition of tobacco products. In addition to tighten the obligations of manufacturers to report on ingredients contained in tobacco products in general, enhanced reporting obligations apply to 15 priority additives added to cigarettes and roll-your-own (RYO) tobacco by May 2016. For these priority additives, studies were carried out by the industry. In the JATC we created an independent review panel comprised of experts from different fields, for the assessment of the documents. All experts signed the Conflict of Interest form and acquired access to the enhanced reporting documents on priority additives. Consequently, a comprehensive deliverable was created, including a description of the main outcomes of the review, the review process and strategies, methodological issues and limitations encountered in the industry reports and individual reports for each of the additives.

Identification of flagged additives for further assessment

The JATC provided EU MS and researchers with a list of selected additives that should be considered for further assessment using independent literature. The selection of additives was performed in four parts: Part 1 based on the SCENIHR evaluation from 2016. Part 2 based on an evaluation of EU-CEG data from cigarettes, provided by WP 6. Part 3 is as well based on the evaluation of EU-CEG data from cigarettes, provided by WP6. This evaluation covered Netherlands, France, Belgium, Denmark, and Czech Republic and focused on CMR properties explicitly mentioned in the EU-CEG data set.

Development of a series of “how to” guides

A series of eight guides were created, to facilitate and support EU MS activities on tobacco product regulation. Some of the documents are more general, giving orientation and advice on some topics, while others are more practical, outlining more specifically a step-by-step process. The following guidance documents were developed:

- ✓ Guidance to reporting system of e-cig adverse effects
- ✓ Guidance to checklist for e-cig compliance to TPD
- ✓ Guidance to recommendations for treating E-cig and HTP dependence cigarettes
- ✓ Certain legislative aspects of national measures to implement TPD with regards to e-cigarettes and heated tobacco products cigarettes
- ✓ The Tobacco Data Lake: An IT system to monitor and perform economic analyses of tobacco and nicotine products
- ✓ General guidance on mapping actors in the field of electronic cigarettes
- ✓ Laboratory analysis related to tobacco and nicotine products
- ✓ Guidance document on how to clean and handle EU-CEG data

2.2. Project visibility and dissemination

The aim of the dissemination activities were to maximize the impact of the JATC and ensure that the project's outcomes in supporting the implementation of TPD throughout EU MS were made available to the target groups, mainly EU and national Regulators, international and national tobacco control stakeholders, researchers, and the general public. Dissemination actions were led by JATC partners but also supported by the European Network For Smoking and Tobacco Prevention (ENSP). Each partner played an important role in the dissemination activities and contributed to the representation of JATC to the scientific community, as demonstrated by the extensive dissemination activities that took place throughout the project. Dissemination strengths included the multiple channels engaged, the discreet target audiences and the impact the JATC dissemination activities had on the end-users – EU MS regulators. More dissemination opportunities were planned within the third year of the project, within the form of major events, participation in international conferences and the final

public policy event to take place in the European Parliament – however the implementation of these activities was severely impacted by the declaration of COVID-19 as a pandemic by the WHO in early 2020.

Dissemination takes place both through traditional, but also digital media, so as to ensure a broader outreach to appropriate target audiences.

- ✓ Digital and printed leaflets: During RP2, the JATC project leaflet that had been designed in RP1 was also used at external dissemination events including conferences.
- ✓ Digital Newsletter: Annual newsletters continued to be released so as to briefly describe the JATC activities and maintain interest among the stakeholders. Three annual newsletters has been prepared so as to briefly describe the JATC activities and maintain interest among the stakeholders. More than 5000 recipients were reached per newsletter with opening rate higher than 30% .
- ✓ Conference abstracts in peer-reviewed journals:
 - Joint Action on Tobacco Control Consortium. The EU Joint Action on Tobacco Control. Tobacco Prevention & Cessation. 2019;5(Supplement):A1. doi:10.18332/tpc/105211;
 - Vardavas CI, Behrakis P, Tzortzi A, Kilibarda B. Ensuring sustainability and dissemination of TPD and JATC activities in Europe. Tobacco Induced Diseases. 2018;16(3):12. doi:10.18332/tid/95251
- ✓ Presence at the national and international conferences:
 - JATC Kick off event in the Zappeio Megaro, Athens during December 11-13, 2017
 - 3rd ENSP-CNPT SRP International Conference on Tobacco Control in Madrid 2018 (the conference was attended by 450 participants from 44 countries)
 - 14th Annual Conference of the International Society for the Prevention of Tobacco Induced Diseases in Izmir 2018 (300+ participants from 100+institutions)
 - 4th ENSP-SRP International Conference on Tobacco Control in Bucharest 2019 (attended by 400 European and International attendees from 50 countries)
 - Participation at the EU Health Program High Level Conference in Brussels, September 30th 2019
 - 8th ECToH in February 2020, Berlin, Germany (representatives of the JATC Consortium at the JATC stand provided detailed information and answered visitor's questions on the JATC outputs and their importance for tobacco control in Europe).
 - 2 Interim meetings with the members of the expert subgroup on ingredients
 - JATC meetings with JRC and WP8 meetings with TobLabNet
 - JATC Final Conference on December 4th 2020.
- ✓ During all ENSP conferences, leaflets with general information about JATC were distributed to all participants, while the JATC one-pager was inserted into the abstract books and a special session within each conference was dedicated to the JATC.

