Final Technical Report

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We would like to acknowledge the partners of the Joint Action on Tobacco Control (JATC). We dedicate this project and report to the EU population who bravely face the tobacco epidemic and to those who have lost loved ones from it.

1. Explanation and overview of the activities

Within the current report we provide an 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 TPD throughout the 28 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 JA 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) in JATC, and through seven specific objectives that are presented in detail throughout this current report.

1.1. Objectives

The specific objectives of JATC are:

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

In general, the work done during the reporting period corresponds to the finalisation of all the above-mentioned objectives and the essential progress was reached for all of them. This report covers the 2nd and final reporting period (RP2-from 16/04/2019 to 15/12/2020), during which the specific objectives were addressed through the collaborative action of partners within the JATC Consortium. The results and update of those actions are presented in this current final report.

1.2 Explanation of the activities and results per Work Package (WP)

This section provides a detailed presentation of the work performed in each WP, the main results and other important aspects of the WP progress completed within RP2, that complete the work that was initiated in RP1.

Work Package 1: Coordination (Months 1-38)
(Lead Beneficiary: HCS)

Objective 1: To support the overall management of the project
(Lead: HCS; Participants: all Consortium parties; M1-38)

Task 1.1: To develop and implement a Consortium Agreement

The Consortium Agreement, which was developed and signed by all partners in RP1, concerns the responsibilities of parties, liability towards each other, governance structure, financial provisions, results, access rights and non-disclosure of information. In RP2, the Consortium Agreement continued to be implemented and referred to.

Task 1.2: To monitor and guide the progress of individual WPs

HCS continued to monitor and guide the progress of individual WPs throughout the duration of RP2. Regular communication via email, teleconferences and in-person meetings were maintained between individual WPs, to be further described in Objective 4. The project timeline was continually monitored, and partners of specific WPs were sent reminders and check-ins to ensure progress with achieving milestones and deliverables.

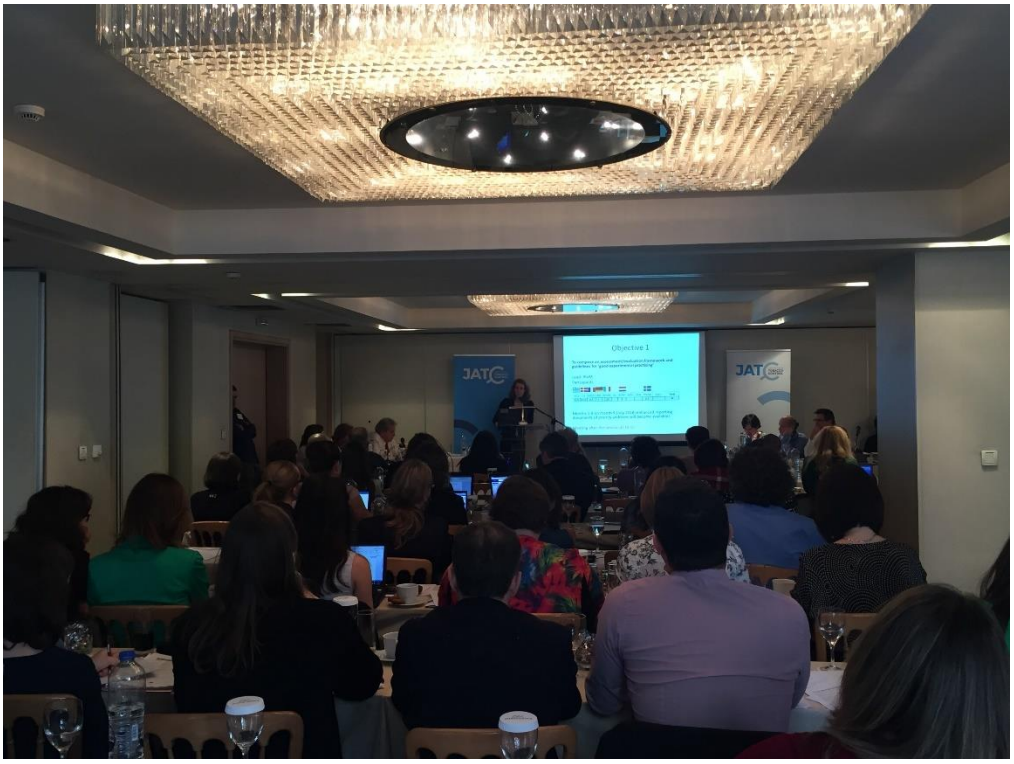
Task 1.3: To stimulate the integrated progress of the work by fostering collaboration between individual WPs, linking up with third parties and networks and stimulating the use of additional data sources or innovative methodologies

During RP2, integrated progress of the work was fostered. Two complete Consortium Meetings were organized during RP2 to foster collaboration between individual WPs and between different teams within the JATC Consortium. The dissemination of JATC results was also promoted by linking up with different networks, while collaboration and synergy between other EU projects was encouraged by organizing Consortium meetings concurrently with meetings of other groups – such as the EU MS expert groups, to allow for discussion and collaboration during the session breaks in between.

Task 1.4: To organize, chair and take minutes of the Steering Committee meetings and Consortium Meetings

Within the current reporting period 4 Consortium meetings were held within which the partners collectively presented and discussed upcoming activities, new information and planning of actions to be performed within JATC. Within these meetings, all researchers from each participating partner were allowed to join so as to collectively increase coherence between the large pool of researchers. Time was allowed also for questions and for networking between the members of the Consortium. Consortium meetings took place on:

- Kick-off meeting: Athens 12-13.12.2017
- 1st Consortium meeting: Brussels 6-8.2.2019
- 2nd Consortium meeting: Brussels 4-6.2.2020
- Final meeting: Online 4.12.2020



1st Meeting, Athens Greece

2nd Meeting, Brussels, Belgium

3rd Meeting, Brussels, Belgium

In order to closely monitor the research activities of the project and allow for strategic high level planning, the Steering Committee met **18** times, both in person and via teleconference during the current reporting period. This was done to ensure a closer monitoring of partner activities. All teleconferences have been implemented via the go-to-meeting digital platform with a quorum of the WP leaders. All meeting minutes have been circulated to all SC members and have been finalized after their comments and approval.During these meetings, high level planning and decisions were taken with regard to actions that would increase the scientific output of JATC research. Steering Committee meetings took place on:

- ✓ Pre-kick off meeting: Athens 11.12.2017
- ✓ 1st 9.11.2017
- ✓ 2nd 23.11.2017
- ✓ 3rd 5.12.2017
- ✓ 4th 26.2.2018
- ✓ 5th 25.5.2018
- ✓ 6th 22.11.2018
- ✓ 7th 15.1.2019
- ✓ 8th 4.4.2019
- ✓ 9th 25.9.2019
- ✓ 10th 29.10.2019
- ✓ 11th 9.12.2019
- ✓ 12th 14.1.2020
- ✓ 13th 13.2.2020
- ✓ 14th 7.5.2020
- ✓ 15th 24.6.2020
- ✓ 16th 4.9.2020
- ✓ 17th 30.10.2020
- ✓ 18th 25.11.2020

Objective 2: To coordinate financial management
(Lead: HCS; Participants: all Consortium parties; M1-38)
Task 2.1: To communicate rules for financial administration and management and ensure their implementation by all partners
In RP2, HCS continued to communicate rules for financial administrative and management, ensuring that this topic was an agenda item at all Consortium and Steering Committee Meetings. HCS further provided additional support on financial administrative to teams with less experience and capacity within this area. Requests for internal timesheets and costs continued to be made at six-month periodic intervals, so as to ensure close financial monitoring. In addition to the above the HCS repeatedly followed up with each partner with regards to budget expenditure and budget absorption throughout the project so as to ensure that each partner is aware of the status quo of budget use.

Task 2.2: To prepare interim and final financial reports for CHAFEA and acquire all information and documents needed for this task, including but not limited to the collection of internal reports from members of the Consortium and WP leaders
HCS continued to coordinate the acquisition of necessary information and documents for the preparation and submission of the financial reports for CHAFEA. These are submitted as part of the current Final report. During the period of the Grant Agreement (GA) amendments we were in permanent contact with the EU Project Officers coordinating the progress of the amendment preparation.

Task 2.3: To adapt, if necessary, financial planning and aspects of the project activities based on the progress of the project, the completion of milestones and deliverables and partner engagement
Within RP2, close monitoring of the project expenses continued to be implemented in order to allow for an assessment of the need to alter financial spending as related to the performed activities as noted above in Task 2.1

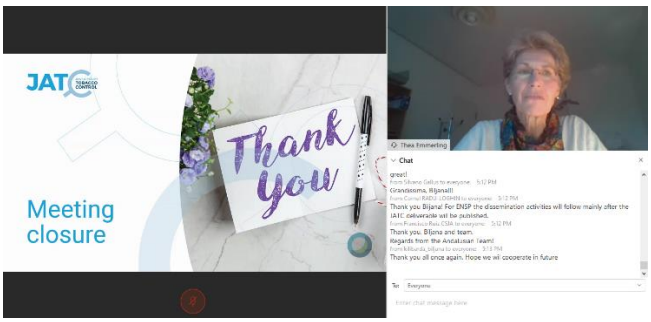
Objective 3: To support communication activities
(Lead: HCS; Participants: all Consortium parties; M1-38)
Task 3.1: Together with the leader of WP2, prepare a structure for external communication
HCS, in collaboration with the WP2 leader, during RP2, continued to follow the dissemination strategy and plan created during RP1. Furthermore, HCS continued to implement the dissemination and external communication plan that had been introduced by its external subcontractor in RP1, to support the WP2 lead in their activities. This led to the development of a number of dissemination activities presented in the WP2 presentation.

Task 3.2: To develop and operate a structure for internal communication, aimed specifically to monitor the progress of each WP and to stimulate collaboration between WPs
Within RP2, close communication with Consortium members was maintained, with additional close communication with WP leaders, to stimulate the work within and between different WPs. This is further outlined below.

Objective 4: To provide scientific support to individual WPs
(Lead: HCS; Participants: all Consortium parties; M1-38)
Task 4.1: To provide timely scientific advice on the plans, progress and outcomes of each WP
In RP2, HCS provided significant scientific support to individual WPs that extended beyond the level of monitoring progress. In addition to regular email communication and phone calls, formal teleconferences and in-person meetings were coordinated between HCS and individual WPs to provide scientific advice and support, especially within the context of Steering Committee meetings. As already referred to in Task 1.4, **18** Steering Committee meetings took place in which important decisions were made for both days to day activities as also strategic development of the JATC.

Task 4.2: Undertake any other action that may benefit the work in WPs, such as organizing special workshops of common research interests
During RP2, the frequency of Consortium-wide conference calls was increased in order to keep partners engaged and foster collaboration across WPs. Furthermore, given the diverse background of JATC partners, the Coordinating team encouraged the collaboration between groups for information-sharing and capacity building, to facilitate the exchange of information and communication across individual WP members.

Objective 5: To communicate and report to the EC
(Lead: HCS; Participants: all Consortium parties; M1-38)
Task 5.1: To invite representatives of the EC to attend the project meetings and dissemination events
Representation from DG SANTE and CHAFEA was invited to all steering committee members to allow for a close integration between the implementing organisations and the EC. The presence of EC representatives was valuable and provided critical feedback and broader insight. Furthermore, DG SANTE and CHAFEA representatives welcomed the participants of the JATC Final Conference on December 4th 2020 -allowing for a further integration between the beneficiaries and the EC.



Task 5.2: To prepare an interim report and one final report to the EC
During RP2 a Grant Agreement (GA) amendment was made, during which were in permanent contact with the EU Project Officers coordinating the progress of the amendment preparation. In RP2, the current final report to the EC was also prepared.

Work Package 2: Dissemination (Months 1-38)
(Lead Beneficiary: BATUT - IANPH)

Objective 1: To disseminate, as widely as possible, the policy recommendations of the project to the target audiences identified in section 3 of the current JATC proposal

(Lead: BATUT, Participants: HCS, MOHCY, SE, LSMU, external contractor; M1-38)

Task 1.1: To create a dissemination plan for the development and reporting of dissemination activities (M6). This dissemination plan will include detailed information of whom will be contacted and include all the methods needed to perform the dissemination activities of the JATC

The dissemination plan that was created in RP1 was maintained to outline the activities taking place within the dissemination WP of the JATC. This plan continued to be used as a guide for the implementation of dissemination actions.

Task 1.2: Project website/social media development and maintenance

In RP2, the JATC dynamic website, which was launched in RP1, continued to be updated with recent news regarding the project work advances. The project website includes sufficient information for the general public, researchers and regulators to be informed of the impact and progress of the project. Website development was assigned to an external subcontractor who worked under the guidance of HCS and BATUT. Detailed information on the website is provides in Section 3.7

Task 1.3: To produce digital leaflets, scientific manuscripts, policy reports and conference abstracts that would disseminate the findings and recommendations of the project

This activity is integrated throughout the entire proposal and all research WPs. It aims to disseminate information to the public, stakeholders and policymakers in English, in a digital format, in order to promote health literacy in this field. 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.

Objective 2: To set up a network of interested policy makers, professionals and other stakeholders at an EU level and to maintain communication and dissemination with this network
(Lead: BATUT, Participants: all WP partners; M2-38)
Task 2.1: Network development and upkeep
In order to ensure that the project findings reach the relevant end users, a stakeholder analysis was performed in RP1 to identify and build partnerships with regulators, professionals and other stakeholders involved in tobacco control, public health policy and practice. During RP2, the network of interested policymakers, professionals and other stakeholders was continuously developed and updated. This network has been provided with the information produced through the JATC to be able to maximize its outreach. This task had direct feedback from and has provided feedback to WP4, to ensure issues of sustainability and national implementation through the use of this network.

Objective 3: To organize a final project conference
Task 3.1: To organize a final project conference
Due to the COVID-19 pandemic, a face to face in person conference was impossible and hence a virtual final conference was implemented. On the 4th December 2020 a virtual final conference took place within the course of a full day. Following introductions from the coordinating team and the European Commission, each WP presented their main take home points and work performed during the past years. The Final meeting was also made available to the members of the expert subgroup of tobacco ingredients.

Work Package 3: Evaluation of the action (Months 1-38)
(Lead Beneficiary: AGES)

Objective 1: To create an evaluation plan, that will describe the criteria, methods, activities and timeline for project evaluation, as well as the procedures and tools for the project's quality assurance
(Lead: AGES, Participants: all WP partners; M1-4)

Task 1.1: To define the process, output and outcome indicators
The 88 processes, 85 output and 38 outcome indicators to track the progress of the project quantitatively from month 1 to month 38 were maintained in RP2. The Logical Evaluation Framework (LogFrame) includes all these indicators, highlights the planned and actual delivery dates in case of deliverables and milestones, and aligns them to the corresponding WP. The source for the definition of the indicators is the Grant Agreement that was used to generate a LogFrame, which was then circulated and approved by WP leaders.

Task 1.2: To finalize instruments for WP3 data collection
Four instruments for primary data collection were developed during RP1 to monitor the project's progress and outcome, as well as the quality of project implementation:
- ✓ Topic guides for interviews on the initial project context (outcome evaluation)
- ✓ Topic guides for focus groups on the final project context (outcome evaluation)
- ✓ Quality Questionnaire on project progress (quality assurance)
- ✓ Quality Questionnaire on meetings and teleconferences (quality assurance)

Two instruments for secondary data collection were also defined to monitor the project's outputs and outcome:
- ✓ LogFrame Matrix (output evaluation)
- ✓ Basic Needs Assessment questionnaire (deliverable 7.1.) (outcome evaluation)

Task 1.3: To prepare and obtain approval of the evaluation plan from the steering committee
The evaluation plan, including communication and reporting plan, were developed and approved by the Steering Committee during RP1. The main purpose of Evaluation is to optimize the implementation of JATC and to ensure that it meets all objectives envisaged. The plan is designed to ensure a joined learning process for all stakeholders involved by generating useful information and knowledge to improve the project and the outcomes and outputs. To this end, it seeks to: a) measure the extent to which the project objectives have been achieved, b) measure if the outcomes of JATC meet the needs of the project´s target groups and c) optimize the processes used to ensure that the project activities are implemented as intended.

Objective 2: To implement the evaluation plan throughout the duration of the project
(Lead: AGES, Participants: all WP partners; M4-38)
Task 2.1: To implement the evaluation plan
The recipients of the evaluation results are the project partners of the JATC. Throughout the project period, but in particular, towards the project´s end, the evaluation results have been a useful guide to

making decisions about further steps after the end of the project. More particularly, findings from the evaluation shall contribute to further improve the implementation of the TPDII in all EU MS.

Recommendations for future projects have been presented at the final meeting (RP2) and are listed in detail in the final evaluation report.

Task 2.2: To collect and analyse qualitative and quantitative WP3 evaluation data

✓ Qualitative data:

- Semi-structured expert interviews/administered with web-conferences (RP1)

A comprehensive perspective on the starting environment was gained by conducting 10 interviews with EU regulators and EU-CEG experts during RP1. The findings have been used to assist work package leaders of the JATC in the improvement of their work and to evaluate the outcome of joint action by comparing them with focus group results at the end of the project.

- Focus group / open questionnaire (RP2)

A focus group of five was held and an open questionnaire was disseminated to 66 EU-Regulators and Experts to get an overview over outcomes which have started to unfold during the project period and will start to unfold in the period after the project end. The findings were compared with the findings of the starting environment and recommendations have been given for further actions.

✓ Quantitative data: surveys with discrete scale and open-ended questions/administered with an online survey tool

In RP1, the Quality Questionnaire on the project's progress and procedures was administered four times (April, August and December 2018, April 2019). The data were analysed, and the results were disseminated to the steering committee. Four more rounds were planned to be dispatched. The Quality Questionnaire on meetings and teleconferences was administered four times (December 2017, March and October 2018, March 2019). Data sets were analysed, and corresponding results were reported to WP5 leader and WP1 leader.

In RP2, the Quality Questionnaire on the project's progress and procedures was administered eight times. The data was analysed, and the results were disseminated to the steering committee. General findings were included in the final evaluation report and presented at the final conference. The Quality Questionnaire on meetings and teleconferences was administered five times (December 2017, March and October 2018, March 2019, February 2020). Data sets were analysed, and corresponding results were reported to WP5 leader and WP1 leader. This on-demand-service was provided as often as requested.

✓ Quantitative data: logical evaluation matrix (LogFrame)/administered with email correspondence and the project's portal

The LogFrame was developed during RP1 in cooperation with WP leaders. The first findings on the indicators were reported in the interim evaluation report. The monitoring of the indicator was an ongoing process. Subsequent findings were included in the final evaluation report.

In RP2, the process was ongoing. The LogFrame matrix can be found in Annex I of the final evaluation report.

Task 2.3: To create progress reports on the evaluation process

The following reports were developed and delivered during RP1:

- One report on the evaluation approach to the consortium at the Kick-off meeting;
- One report on the results of the interviews on the initial project context to the steering committee via email;
- One report on the pretest of quantitative data collection instruments to steering committee via mail;
- Four reports on the results of the Quality Questionnaire on progress report to the steering committee via email;
- Four reports on the results of the Quality Questionnaire on meeting and teleconferences to the steering committee via email;
- One report as a preview for the interim evaluation report to the consortium at the interim consortium meeting;
- One interim evaluation report to the steering committee via mail;
- One SWOT analysis, in addition to the interim evaluation report to the steering committee via mail.

Future reports included the results of the Quality Questionnaires, the results of the focus groups on the final project context, the preview for the final evaluation and the final evaluation itself. Additional reports would be generated upon request by the project team.

The following reports have been developed and delivered in RP2:

- Four reports on the results of the Quality Questionnaire on progress report to the steering committee via email;
- One reports on the results of the Quality Questionnaire on meeting and teleconferences to the steering committee via email;
- One final evaluation report to the steering committee via mail.

Task 2.4: To develop the final evaluation report

The final evaluation report was developed and delivered during RP2 in line with the evaluation approach and in the manner of the interim evaluation report. Findings from output measurement (LogFrame matrix), outcome measurement (interviews, focus groups, final open questionnaire) and quality assurance (quality questionnaires) were interpreted. Results partly built upon each other, which was accordingly referred to in the interpretation. Further detail on the evaluation report of the JATC is provided further below.

Work Package 4: Integration into national policies and sustainability (Months 1-38) (Lead Beneficiary: MOH-CY)

Objective 1: To map the capacity building and knowledge needs for the effective and efficient application of the TPD across the 28 EU MS and EEA where applicable

(Lead MOH-CY, Participants, all WP partners; Months 1-12, 24-38)

Task 1.1: To help the EU MS understand their gaps (Months 1-12)

This task was executed during RP1 to help EU MS understand their gaps through facilitating capacity building and knowledge needs within the context of JATC. This task led to the development of the common needs questionnaire that had been incorporated in M13. This questionnaire was developed by representatives of all WPs in JATC through the context of an in-person meeting at the Kick-Off of the JATC and multiple teleconferences. The current questionnaire aimed to collect through one common portal feedback from CA on critical issues of the TPD and related to components that the JATC addresses or national policy issues which could be addressed within the remit of JATC.

This questionnaire was sent out digitally (SurveyMonkey) to be completed by the CA, primarily those involved with EU-CEG monitoring and tobacco/e-cigarette product regulation, however as the different chapters cover different issues, respondents were requested to skip questions that the respondents regarded as non-relevant to their current activities. Furthermore, additional skip questions were introduced to avoid unnecessary burden for respondents when covering irrelevant questions. However, all respondents had to read all the questions before they could finish the survey to ensure that they could view and potentially respond to all questions.

In total, 25 CAs responded to the survey performed during the summer months of 2018 (CAs are either the competent authority or the person responsible for EU-CEG data handling), with the responses being anonymous.

Task 1.2: To map tobacco control funding across the EU MS, including submission fees to the EU-CEG or fees for the implementation of TPD Art7(13) and TPD Art20(2) through a survey to EU MS regulators and competent authorities (Months 1-9, Months 24-30).

During RP1, a dedicated questionnaire was developed by the WP4 team members, aiming to map the TPD funding and sustainability activities as well as the in-house and cross border regulatory, scientific and technical capacity resources available to regulators and needed to ensure the uptake of the JATC outcomes and the maintenance of the mechanisms set up as part of JATC. This questionnaire aimed to collect information regarding both Tasks 1.2 and 1.3. Domains of this questionnaire included information about the types of fees collected under the TPD, the products for which fees are collected, the frequency of payment, the usage of collected fees and also the bodies representing the industry for policies and legislation and the nature of the bodies responsible for vaping/tobacco policy. This was shared with stakeholders towards the end of RP1.

Task 1.3: To identify and map in-house and cross border regulatory, scientific and technical capacity resources available to regulators that are needed to ensure the uptake of the outcomes of the Joint Action and the maintenance of the mechanisms set up as part of the JATC (Months 1-9, Months 24-30).

This task was performed through the above-described questionnaire in order to identify and map in-house and cross border regulatory, scientific and technical capacity resources, such as labs, experts, websites, available to regulators in Member States.

Objective 2: To develop a series of "how to" guides and an online repository for a sustainable long term educational intervention and to organise internal and external meetings/training seminars including stakeholder NGOs, researchers and regulators (Lead ISS; Participants: all WP partners; Months 1-38)
Task 2.1: To develop a series of "how-to" guides for regulators including but not limited to aspects related to EU-CEG data handling, data extraction, product evaluation, product compliance. They may be provided directly through the EU-CEG or through an independent platform. Directly related to sustainability, up to 5 "how-to" guides will be created and uploaded, each one may contain one or more areas of interest to regulators
Proposals on guidance documents to be prepared were collected in February 2020 during the JATC Interim Meeting. Priorities were given to a selection of guidance documents approved, according on what was more needed and feasible.

Most of the partners prepared their own guidance documents, while a few others were given the task by the WP leader. Drafts of the eight produced guidance documents were circulated among the partners, with 4 or 5 rounds of critical review and comments for each guidance (depending on the type of guidance) on average. Each guidance document indicates the main author and the reviewers who worked on it (some of the partners were exclusively reviewers and some documents had also external reviewers).
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 guidance documents written by the WP4 partners are the following:

1. *Guidance to reporting system of e-cig adverse effect* by Istituto Superiore di Sanità (ISS), Italy (guidance related to WP7);
2. *Guidance to checklist for e-cig compliance to TPD* by Terviseamet (TA), Estonia (guidance related to WP 7);
3. *Guidance to recommendations for treating E-cig and HTP dependence cigarettes* by Semmelweis University (SU), Hungary (guidance related to WP 7);
4. *Certain legislative aspects of national measures to implement TPD with regards to e-cigarettes and heated tobacco products cigarettes* by Semmelweis University (SU), Hungary (guidance related to TPD);
5. *The Tobacco Data Lake: An IT system to monitor and perform economic analyses of tobacco and nicotine products* by Semmelweis University (SU), Hungary;
6. *General guidance on mapping actors in the field of electronic cigarettes* by Semmelweis University (SU), Hungary This is the only guidance that is not final yet (related to WP7);
7. *Laboratory analysis related to tobacco and nicotine products* by Istituto di Ricerche Farmacologiche Mario Negri (IRFMN), Italy (related to WP8);
8. *Guidance document on how to clean and handle EU-CEG data* by Hellenic Cancer Society (HCS), Greece (related to WP5, 6 and 7).

Deliverable D4.2 reports all the guidance documents and indicates possible and feasible paths related to the tasks of JATC vertical WPs and the TPD. The paths of activities are described in each guidance

document and may be promoted and possibly implemented at national or at European level, post the JATC.
The Sustainability paragraph, at the end of each guidance document, describes the possibilities of getting resources to conduct the activities for the implementation of TPD.

Task 2.2: To develop and continuously update an online repository of the designed "how-to" guides so to aid future regulator training, enhance homogeneity and support sustainability in training. The platform will be continuously fed with reports created from vertical WPs of the JATC and also with dissemination material released through WP2, too make sure that the 28 EU MS commit themselves to the maintenance of the keeping the how-to guides and information up to date after JATC period ends (M24-M38)
This task will be completed by uploading of the guidance documents produced in task 2.1 on the JATC website, once Deliverable D4.2 is approved and possibly through publication in *Tobacco Prevention and Cessation*, the official ENSP journal.

Task 2.3: To organise external joint meetings between tobacco control stakeholder NGOs, researchers and regulators so as to engage them in future activities and enhance TPD implementation and monitoring. Meetings may be in person or via distance webinar communication. Researchers and NGO's would also be trained on the existence and potential use of the publicly available data released from WP5 so as to enhance the likelihood that more people would be working on the wealth of data after the JATC has been completed (M24-M38)
The guidance documents were presented at the final meeting of JATC on December 4 2020, with the participations of the JATC partners and other researchers and stakeholders. Each MS can further disseminate the documents to CAs, stakeholders and other and interested parties, referencing either the deliverables or the produced peer reviewed manuscripts.

Task 2.4: To organise internal joint action training seminars for regulators so as to enhance TPD implementation and monitoring. Meetings may be in person or via distance webinar communication. The rationale here is that by improving the regulators knowledge they would be able to use the EU-CEG better. These training seminars then directly would increase the possibility that the same tasks are performed after the JATC has concluded.
These trainings were performed not as separate dedicated webinars/seminars but within the context of presenting JATC results to the expert subgroups on tobacco policy within the framework of such meetings. This synergy allowed for greater integration of JATC activities with EU MS representatives.

Summary of the WP4 deliverables and milestones: Overall, WP4 deliverables and milestones were completed and submitted timely.

Work Package 5: Common Entry Gate data extraction and handling (Months 1-38) (Lead Beneficiary: SIK)

Objective 1: 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 (Participants: all WP partners; Months 1-38)

Task 1.1: To identify the variables that should be considered as public and not confidential, within the common formats for the notification of tobacco products and e-cigarettes published through implementing acts 2015/2186 and 2015/2183 and within the context of TPD Art5(4) (Months 1-6, Lead, HCS)

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.

Task 1.2: To outline the requirements (legal/technical, etc.) for making the information identified through Task 1.1, available to the general public through collaboration with the competent authorities (Months 6-30, Lead, SIK)

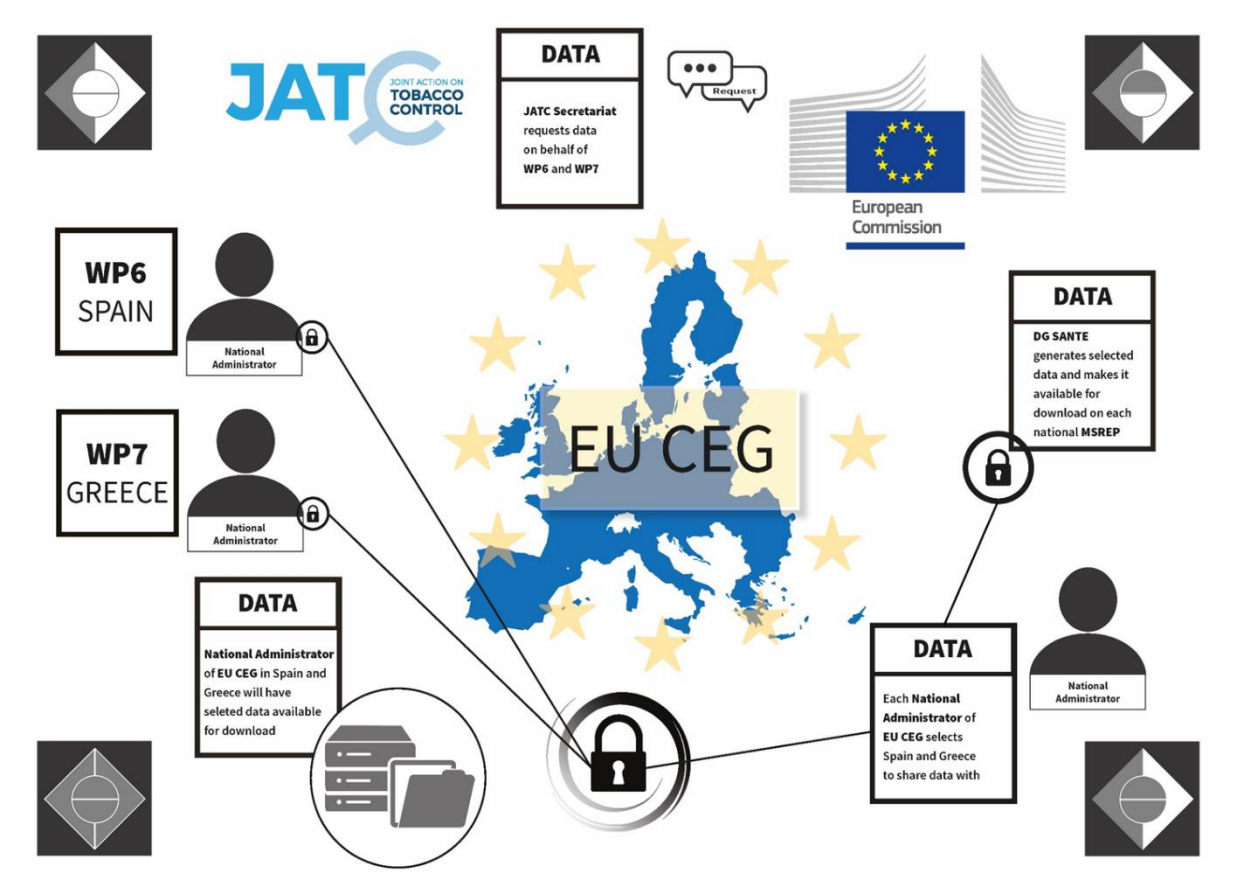
This deliverable on providing a technical solution for publishing public and non-confidential data was due on April 15th, 2019. The task was initially delayed as it required the finalization of deliverable D5.1 in order to specify which data should be published and hence was strategically moved to RP2. This task was solved through several deliverables building on the classification in D5.1, as the D.5.1 report had already set out which data was to be made public. This main objective here was to clarify the needs of member states and to suggest a possible centralized IT-solution for making the EU-CEG data identified in 5.1 available to the public. The key delivery in this matter was the 5.4 report *"Technical solution for public non confidential data"*. The report was drafted on the basis of EU MS inputs and in cooperation with the Commission. The main points collected from member states for the publication tool was: Support from MS for a common solution; Must be web-based; Report generator requested as a feature; Should be updated frquently; Publication must happen in a common format. The report was delivered in November 2020.

Objective 2: To define and complete the technical and legal aspects necessary for data transfer and handling and subsequently request the data from the EU-CEG for the purpose of the JATC and with regards to sales/market data from each EU MS (Lead SIK, Participants: HCS, BHTC, NCPA, SIK, TA, ANSES, MOHIT, NTAKD, NOMA, MS, NLZOH, CSJA, UK-DOH, Months 1-38)

Task 2.1: To define the technical and legal requirements for the transfer and handling of data that has been submitted via the CEG for use within the Joint Action and for use after the Joint Action, within the context of TPD Art5(6-7) and TPD Art20(7) (Lead SIK, Months 1-38)

The technical solution and procedure for securely accessing and processing EU CEG data in JATC were due on January 15th, 2019. A standard operating procedure (SOP) for data sharing was finalized and uploaded to the JATC participant portal on March 18th, 2019. Within the context of WP5, it is also important to note that we created a data sharing agreement 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 has been 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 is the biggest achievement of WP5 so far as it paves the way for the actual sharing of data. A total of 19 EU MS and Norway had signed the data sharing agreement and were in the position to share data with other JATC members in WP6 and WP7.

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). The mechanism is now available to all member states, and the prepared legal framework is made available to all member states to adjust according to their needs. A Standard Operation Procedure has also been provided to EU MS in case they wish to share EU-CEG data.



Task 2.2-Task 2.3: To collect the list of variables that are requested by WP6-9 and to request and obtain access to the data belonging to each participating EU MS as submitted via the EU- CEG and *create individual datasets that will include only the variables needed for each specific objective within WP6, WP7, WP8 and WP9 and forward these datasets to the relevant task leaders* (Lead SIK, Months 6-30)
Within the context of RP1, WP5 partners created and shared a "data sharing protocol" which outlines the steps to practically share data between EU MS. This also included a "data request form" that was used for requesting data from EU MS. In total during RP2, 13 EU MS shared EU-CEG data. This data sharing allowed for the data analyses of WP6 and WP7 to commence (Described in those WPs)

Objective 3: To enhance utility and propose improvements to the EU-CEG, including on the basis of feedback from EU MS regulators(Lead SIK; Participants, AGES, MOH-IT, NTAKD, NOMA, CSJA, DGS, HCS, NLZOH; Months 3-38)
Task 3.1: To perform an active data collection process from EU MS regulators, on aspects that may enhance the utility of the reporting formats and the EU-CEG. The overall aim is to support the use of data by MS regulators including through suggesting potential improvements/alterations based on the feedback so as to improve the utility of the CEG (Lead: SIK; Months 3-38)
The relevant report was prepared by the UK in close correspondence with WP5 partners, was finalized and uploaded to the JATC participant portal during RP1. It provided an overview of actions that could potentially improve the utility of the reporting formats and the EU-CEG. The report prepared by UK (D5.6) was followed by another report (D5.7) building on the findings made in D5.6. Many of the improvements identified in both D5.6 and D5.7 was already implemented (with help from the EU Commission) before the end of the JATC, for instance the ability to flag obsolete products and distinguish between public and confidential data (D5.1). The D5.7 report was delivered in November 2020. The report is based on inputs from member states. The main conclusion was that the report identified a need for further education (webinars etc.) of member states, as many of the requested features by member states was already available in EU-CEG.

Work Package 6: Tobacco product evaluation (Months 1-38)
(Lead Beneficiary: ICO)

Objective 1: To perform a needs assessment of EU regulators with regards to tobacco product evaluation through EU-CEG

(Lead ICO; Participants: HCS, BHTC, SIK, ANSES, BfR, CERTH, HTS, HSE, IRFMN, IS, MOHIT, NTAKD, RIVM, NIPH, MS, NLZOH, ICO, CSJA, UK-DOH; Months 1-6)

Task 1.1: To perform a qualitative needs assessment of EU regulators, so as to flag issues of importance to EU MS (Month 6)

Under Task 1.1, in collaboration with other WPs, the needs assessment questionnaire was developed during RP1. Its mature version was circulated among the WP6 Partners for their review and final comments, which was of importance as a few WP6 Partners are also national-level stakeholders of the Project. Even though a delay of Task 1.1 "Qualitative needs assessment of EU regulators" occurred due to an extended discussion among the partners and the decision to prepare a common questionnaire for all relevant WPs; this delay did not affect the completion of the next objectives of WP6. The extended review of the questionnaire enabled to sharpen the focus of it and allowed a comprehensive discussion of the questionnaire among the partners. The questionnaire was sent to the regulators and the EU-MS. They responded accordingly by July 2018.

When the needs assessment was finalized, WP6 team started working on the data analysis plan and main questions justifying the data analysis plan. Both documents were shared with WP6 partners for their feedback. Overall, 19 partners were approached, of which 7 responded (37% response rate). Additionally, the data analysis plan was pilot tested to ensure that the main indicators would comply with different phases of analysis. The final document on the analysis plan was consolidated, shared among the WP6 Partners and presented during the JATC session within the 4th ENSP Tobacco Control Conference (Bucharest, March 2019). The corresponding deliverable (D6.1 Report of the WP6 needs assessment evaluation from EU MS regulators) was uploaded to the portal in October 2018.

Objective 2: To assess tobacco product description, tobacco product presentation and sales/market data and investigate into cross EU MS comparability

(Lead ICO, Participants: HCS, BHTC, SIK, ANSES, BfR, CERTH, HTS, HSE, IRFMN, IS, MOHIT, NTAKD, RIVM, NIPH, MS, NLZOH, ICO, CSJA, UK-DOH; Months 6-38)

Task 2.1: To assess tobacco product description data with regards to product submissions, descriptors and product specific data so as to investigate into cross EU MS comparability and map unique and/or emerging product characteristics

In January 2019, the ICO Team organized a meeting with the Spanish national authority in order to assess the EU-CEG data that were still not available to the ICO team for analysis. Due to the technical issues and compatibility problems, ICO Team managed to access the data (for Spain only) in January 2019. After gaining access to the Spanish data, the ICO Team started data exploration procedures reviewing the database structure, completeness and transforming the data into archives that could be further statistically analysed. In February 2019, a member of the ICO team attended the JATC Interim Meeting with the presence of the Subgroup on Ingredients and Composition of tobacco and related products held

in Brussels. In March 2019, the progress of WP6 and a preliminary analysis of the Spanish data on Tobacco products were presented at the ENSP conference in Bucharest.
The following decision points that have been addressed include:
1. WP5, WP6 and WP7 have collaborated in the creation of a Standard Operating Procedure (SOP) for data downloading and analysis, including a data request sheet.

2. WP6 team has commenced the requesting of data following the SOP and is expecting to be able to analyze cross country data as soon as are received.

While the Data Sharing Agreement was being prepared under the WP5 and data from other countries was not yet available, WP6 Team worked on the Data Analyses Plan (Milestone 23). The draft of the Plan was prepared by ICO Team and circulated among the WP6 Partners, after receiving and consolidating the comments from Partners; the document was completed and shared with the Project Consortium.

Task 2.2: To evaluate tobacco product presentation and sales/market data so as to investigate into cross EU MS comparability and map unique and/or emerging product characteristics
While the process of the data sharing was extended, in 2019 ICO Team had access to the Greek dataset in addition to the Spanish one. To advance the progress of the WP6, it was decided together with the Steering Committee to make a first wave of the data analyses for these two countries (corresponding to the D6.2 and MS23). The draft report was circulated among the partners for the discussion and its final version consisted of the following sections: (1) completeness and consistency of all tobacco product data; (2) descriptive analysis for each of the 12 tobacco products; (3) cross-tabulation of the main presentation, description and ingredient variables per year and product; (4) specific TPD queries; (5) overall completeness of the variables in the data files. This report completed the Deliverable 6.2 and was submitted in January 2020.

Objective 3: To monitor tobacco ingredient and additive data in light of supporting actions under TPD
(Lead ICO; Participants: HCS, BHTC, SIK, ANSES, BfR, CERTH, HTS, HSE, IRFMN, IS, MOHIT, NTAKD, RIVM, NIPH, MS, NLZOH, ICO, CSJA, UK-DOH; Months 6-38)
Task 3.1: To perform an assessment of the tobacco ingredients and additives in relation to their function, weight and registration within REACH and CLP classification and evaluate trends and product associations
After the report for Greece and Spain was completed, WP6 Team started to work on country-specific reports as other 10 countries (Belgium, Czechia, Denmark, France, Italy, Lithuania, Latvia, Malta, The Netherlands, and Slovenia) shared their data within JATC. The data for these countries were downloaded by ICO Team in February 2020. Downloaded files contained country-specific data introduced to EU-CEG from June 2016 and October 2019. The COVID pandemic impacted the availability of ICO staff for the project and work on the WP6 was paused for a few months. In May 2020, the ICO Team renewed the work on the final data analyses for these 10 countries and in July 2020 draft reports were sent to the stakeholders in each of the 10 countries. During August-September 2020, ICO Team held communication with those partners who shared their feedback either via email or teleconferences. During September-November 2020, the reports were polished and submitted to the coordinators as the Deliverable 6.3. As suggested by the coordinators, before finalising the D6.3, the country representatives were contacted to consent sharing of the TP-IDs and CAS numbers present in the report as it is a public deliverable. No

objections were received from country stakeholders. The AGES team, as a WP6 partner, worked on the Austrian data and prepared an extensive report for Austria. Given that the Data Sharing agreement was not signed by this country, Austrian report was not incorporated into the public Deliverable 6.3; however it was circulated to the coordinators and other key stakeholders complying with data confidentiality requirements. The final results of the 12 countries analyses were presented by the ICO Team at the JATC Final Conference on December 4th 2020.

Task 3.2: To investigate into the associations between declared tobacco product information (recipe) vs. measured tobacco product information in relation to tobacco product submitter notifications (product modification, new product notification etc.) and in line with TPD Art 5(1) and Task 3.3: In collaboration with WP8, to qualitatively assess the submitted emission data for tobacco products.

As established at the beginning of the project, this task would not be possible to complete within the JATC project as laboratory evaluation of the tobacco products to contrast information introduced in the EU-CEG would finally not be conducted.

Task 3.4: To identify and further evaluate products that have characterising flavours or containing the additives with characteristics described in TPD Art7(6-7)

This task was part of the final report of the WP6 (D6.3) described above in the Task 3.1.

Objective 4: To evaluate the toxicological/addictive data submitted for tobacco products, also including information on priority additives (4.1 lead ICO/4.2 lead RIVM; Participants: All WP partners; Months 6-38) *Task 4.1: Evaluate the toxicological information on additives in line with TPD Art5, p3*

As requested by the Project Coordinators during the April 2019 8th JATC Steering Committee teleconference, WP6 prepared and presented to the Steering Committee a report pre-D6.2 on Novel Tobacco Products based on the data available in the EU-CEG Spanish data set. This report was also circulated to the representatives of the Spanish national authority coordinating EU-CEG in Spain. Working on this report has allowed us to understand, handle and transform the data into readable and analyzable files with statistical software. We have been able to create the scripts to massively work with the files and generate the necessary datasets. The preliminary results indicate that neither priority additives nor toxicological data are properly notified in the database since most of the information must be retrieved from the pdf files. This is an important issue to be addressed by the JATC Steering Committee.

Task 4.2: To obtain the data on priority additives as reported per brand and product type, and to perform a qualitative and quantitative analysis of the types of basic submitted information

Quantitative data on priority additives were analysed within D6.3 and reported for each country separately. The collaboration with RIVM was also developed providing the requested data from the countries that shared data within the JATC project. The Milestone 25 (List of additional additives that could be subject to enhanced reporting obligations) was prepared and completed by RIVM in November 2020.

Work Package 7: E-cigarette product evaluation (Months 1-38) (Lead Beneficiary: HCS)

Objective 1: To perform a needs assessment of EU MS regulators with regards to aspects of priority for e-cigarette products within EU-CEG. (Lead: HCS, Participants: BHTC, ANSES, CERTH, BfR, DOHI, HSE, IRFMN, ISS, MOH- IT, HI, NTAKD, RIVM, NOMA, MS, ICO, CSJA, UK DOH,Months 1-6)

Task 1.1: To perform a qualitative needs assessment of EU regulators, so as to flag issues of importance with regards to e-cigarette products

This activity was performed and finalized during RP1, so as to identify potential areas of prioritization that could address the needs of EU MS regulators. Within this process, a questionnaire was sent to all EU MS regulators in which their opinions and experience were requested. This process commenced immediately after the beginning of the JATC, so as to set the base, of the expectations and potential pending issues that EU MS regulators may had. This survey was performed in close collaboration with Task 1.1 of WP6 and led to the submission of deliverable D7.1, in October 2018.

Objective 2: To assess e-cigarette product data as submitted data via the EU-CEG

(Lead HCS, Participants: BfR, DOHI, HSE, IRFMN, HI, ISS, MOH-IT, DGS, ICO, UK DOH, Months 6-38)

Task 2.1: To assess e-cigarette submission description data and technical design data as included within Section 3 and 6 of Annex 1 of the Commission Implementing Decision 2015/2183

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority. This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level. With the above in mind, the purpose of this task was to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

- ✓ The datasets used were those requested via the data request forms (provided in Annex B of JATC D5.3) and were extracted from EU-CEG in October of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.
- ✓ Data were handled according to JATC deliverable 5.3 and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

Objective 3: To monitor reported e-cigarette liquid ingredient and emission data in line with TPD Art20(2) (Lead IRFMN, Participants, HCS, ANSES, BfR, CERTH, HTS, DOHI, ISS, HSE, HI, NTAKD, RIVM, ICO, UK DOH; Months 6-38)

Task 3.1: To perform a statistical analysis of the data provided by EU-CEG on e-liquid ingredients and additives in relation to their function, weight and registration within REACH and CLP classification and evaluate trends and product associations

This task commenced upon receipt of the datasets provided by WP5. Initially a pilot approach was performed using the data from two EU MS, Greece and Spain – due to ease of access to the EU-CEG datasets. The preliminary analyses contained an assessment of the CAS numbers within the refill liquids, and an assessment of the most frequent ingredients in e-liquids as per EU-CEG> The initial assessment was performed and submitted as Deliverable 7.3, in January 2020. Following the initial pilot evaluation a complete assessment of the reported e-cigarette liquids ingredients was performed using the dataset of 13 EU MS. Cross country comparisons were performed and indicated that in principle the refill liquids had a similar qualitative composition within the top 10 most commonly identified substances. Ingredients, mean recipe quantities, concentrations, functions and flavours were presented for each EU MS within the context of a national report. Further assessment between HCS and ANSES led to the identification of almost 1000 unique CAS ingredients noted across the e-liquids in products within EU-CEG. This analysis – with a breakdown of results per EU MS - was presented within the context of Deliverable 7.5.

Task 3.2: To assess the emission data and their equivalent emission protocols as submitted through EU-CEG and to collect and scientifically review emission protocols for e-cigarettes that are under development by different international bodies

The data available in EU-CEG was assessed prior to the sharing of individual EU MS data and the data were noted to be very heterogenous with regards to reporting at a single EU MS level- hence the combined analysis and reporting of emission data and protocols within EU-CEG from a cross EU MS perspective was deemed to be non feasible – especially in the absence of homogenized emission protocols. The initial assessment deemed further evaluation and analysis non beneficial.

Task 3.3: To evaluate issues of product production and safety and flag aspects that may need further evaluation by EU MS regulators

One of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. For each of the produced reports we provided each competent authority with an Annex with a breakdown of the TP-ID of products that were non-compliant to the below parameters.

- Vial volume >10ml
- Vial volume invalid (0ml)
- Vial volume missing
- >2ml - Disposable, containing nicotine
- >2ml - Individual part
- >2ml - Rechargeable device only
- >2ml - Refillable device only
- >2ml - Refillable e-liquid

- invalid (0ml) - Individual part
- Nicotine concentration >20mg/ml
- Nicotine concentration missing
- Reporting no CAS

The complete results of the evaluation of non compliance and flagging of aspects that may need further evaluation by EU MS was submitted to each EU MS as the results were produced throughout Q1 and Q2 of 2020. The final deliverable – D7.5 including the information on all 13 EU MS that were provided with feedback was submitted in December 2020.

Objective 4: To create a checklist to monitor e-cigarette product compliance to the TPD and support EU MS in the development of a system for the collection of information about suspected adverse effects on human health in line with Art20(9). (Lead HCS, Participants: AGES, DOHI, ISS, HSE, , HI, NOMA, ICO, UK DOH, Months 1-24)

Task 4.1: Create a checklist that would aid monitoring of e-cigarette product compliance to the TPD under the auspices of TPD Art20(1) and including but not limited to Art20(3-4) and implementing act 2016/586

(Months 1-18)

Within this Task that was finalized during RP1, WP7 created a clear and comprehensive checklist in the form of an xls file, to facilitate the monitoring of e-cigarette product compliance to the TPD (both for manufacturers and regulators) under the auspices of TPD Art20(1) and including, but not limited, to Art20(3-4) and implementing act 2016/586. This checklist covered relevant EU regulations, also including the REACH and CLP compliance for e-cigarette product compliance. This led to deliverable D7.2, submitted in April 2019. To aid issues of sustainability this deliverable was transformed into a “guidance document” and for dissemination purposes this was transformed also into a manuscript prepared for submission to a peer reviewed journal.

Task 4.2: Support the EU MS in the development of a system for the reporting of information on suspected adverse effects on human health in line with TPD Art.20(9), and it's cross-referencing with national data

(Months 1-24)

The EU Tobacco Products Directive (TPD) 2014/40/ EU9 along with Commission Implementing Decisions EU 2016/586 (2016)10 and EU 2015/2183 (2015)11, has established standards for e-cigarette reporting, product safety and packaging. Specifically, the provisions of EU TPD Article 20 enumerate product labelling, packaging, composition and technical requirements including, but not limited to, child-resistant packaging features, refill container volume, nicotine content levels, health warning labels, informational leaflets, and technical parameters to reduce the risk of spilling during refill or leaking during use. Within RP1, WP7 also commenced the process of developing a sheet for the reporting of information on suspected adverse effects on human health in line with the TPD. This activity was led by ISS, and the preliminary format of this reporting sheet was presented at the Interim Meeting in February 2019. Over the following period this was finalized and prepared as a deliverable (D7.4) provided in November 2009 that included a short reporting template for the reporting of adverse events both by economic operators as also by competent authorities. This deliverable was further transformed into a sustainability “how to guide” and as a manuscript for submission.

Work Package 8: Laboratory verification, collaboration and analyses (Months 1-38) (Lead Beneficiary: IRFMN)

Objective 1: To develop requirements of independent laboratories for ingredient evaluation

(Lead IRFMN, Months 1-24). *Task 1.1: To map the current status quo of laboratories that currently perform analyses for EU MS, so as to evaluate laboratory capacity, requirements, protocols and independence*

During RP1, a questionnaire for Competent Authorities (CA) was designed and integrated (Q_CA1) as one chapter in the JATC Common Needs Assessment Survey, which was conducted in July-August 2018. The WP8 survey was conducted principally with the scope to map the current status quo of laboratories and to identify analytical analyses on tobacco products required by the CAs, with particular attention to their independence from the tobacco or electronic cigarettes industry. Due to a few issues previously reported (See JATC D8.1, Conclusions), the large majority of WP8 questions were answered by only a few respondents. Therefore, a new survey (Q_CA2) was conducted in December-January 2019, based on a simplified questionnaire.

Task 1.2: To collect and review laboratory-based protocols for ingredient, contents and emission evaluation within all EU MS authorities (Months 1-20)

In the WP8 questionnaires (Q_CA1 and Q_CA2), specific questions were included referring to the presence of standardized laboratory-based protocols in different EU MS. IRFMN attended the Workshop in Geel on 11-12 October 2018. On that occasion, WP8 started collecting data from GoToLab network members as well as protocols used in different approved laboratories from various EU-MS. In March-April 2019, a questionnaire for laboratories (Q_Lab) was developed and circulated by the end of April to the laboratories identified with Q_CA1 and 2 and through collaboration with GoToLab, to obtain information on the analysis conducted by them, protocols used and ingredients analysed. The questionnaire (Q_CA1 and Q_CA2) has been circulated and comments have been collected (May-June 2019) from WP8 participants and elaborated to be included in D8.1 Supplementation. A questionnaire for laboratories (Q_LAB1), to collect and review protocols for emission evaluation of tobacco products and electronic cigarettes, was prepared and sent to laboratories within EU-MS**.**

Task 1.3: To develop laboratory capacity requirements for ingredient, content and emission evaluation (Months 8-24)

The first internal meeting, attended by all WP8 partners, was organized during RP1 (Milan, 17-18 January 2019). WP8 leaders presented the findings from Q_CA1 and Q_CA2 to WP8 partners, GoToLab and EU representatives and discussed intensively the technical requirements (methods, equipment, standards, etc.) of tobacco products laboratories. They also discussed the main challenges and/or difficulties the laboratories faced. Based on the discussion and that on laboratory independence, a preliminary WP8 recommendations and suggestions document was drafted, which was circulated among the meeting participants to obtain a common agreement. Results from the questionnaire Q_CA1 and Q_CA2, were collected from wp8 partners, discussed, analysed and included in D8.1 Supplementation (July 2019).

Laboratory capacity requirements, discussed during the first internal meeting, have been organized in Questionnaire for Laboratories (Q_LAB1), and results have been collected from 28 response records

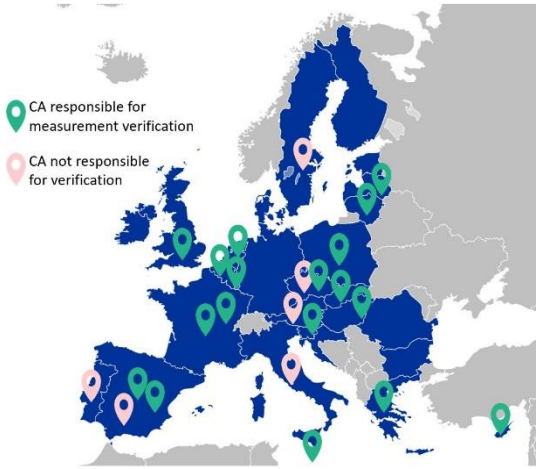
received from 17 different EU countries. Main results showed that TPD approved laboratories are limited, only 14 within EU, and regulators use also non approved laboratories. The number of analysis requested by regulators is extremely limited and is mainly related to conventional cigarettes emissions. In the verification process we observed possible intrusion of the tobacco industry, with samples supply and direct payment to the laboratory for verification analysis. Laboratories consistently recognized a lack of financial support for verification.

Objective 2: To review laboratory analysis activities performed by MS and to assess comparability across laboratories (Lead IRFMN, Months 1-38)

Task 2.1: Review of laboratory activities routinely performed by MS competent authorities, critically evaluating the quality of these activities and the independence of the corresponding laboratories (Months 1-24) Data obtained from the Q_CA2 on the verification analyses requested in 2017-2018 were analyzed during RP1. These analyses were mainly limited to TNCO in conventional cigarettes, only a few on electronic cigarettes, and even less on other products like heated tobacco products, oral tobacco, herbal tobacco, cigars, pipe. Results from (Q_LAB1) were reviewed and D8.2 was prepared in draft (July 2019) and sent to WP8 partners for consultation (Sep 2019). In general laboratories are equipped with standard instrument, few have state-of-the-art instrumentation (like mass spectrometry) and are not able to verify new products, like e-liquids, and new parameters (also regulated like vitamins for example). There is a lack of standardized methods for e-cigarettes and heated tobacco products (HTP). There is uncertainty about CMR compounds emissions (and methods to use for them) for E-cigs and HTP.

Task 2.2: To perform replicate laboratory measurements to compare ingredient data for tobacco products across verified laboratories (Months 25-38)

During the 2nd JATC Interim Meeting (Feb 2020) we presented a proposal to overcome the serious difficulties in obtaining original data from several EU MS. Instead of collecting data from independent laboratories it was decided to start a collaborative program, developing a Standard Operating Procedure, in order to actually collect original analytical data and information about laboratory measurement. As a result, a SOP was developed for measuring analytes in e-liquids. Samples have been sent to 27 EU and TobLabNet laboratories and result were collected and analyzed. EU independent laboratories showed a good instrumental capacity, and only one z-score above 3 (unsatisfactory) and 2 above 2 (questionable), overall. Few laboratories had mass spectrometry analytical capacity. Due to pandemic situation, deliverables, with statistical validations were delayed to December 2020. Results indicated that laboratories are able to work on new methods, to adapt the new SOP, and their analytical quality is excellent. Results have been used for D8.3 and 8.4. Moreover, the JATC SOP for lab analysis served as the base for a new WHO TobLab Net SOP for methods to determine nicotine, glycerol, propylene glycol in e-liquids.



Objective 3: To develop collaborations and communication with other international activities on tobacco laboratory assessment. (Lead CSJA, Months 10-38)

Task 3.1: To develop collaborations and communication with other large international initiatives so as to enhance collaboration on the area of tobacco product emission evaluation (Months 10-38)

In RP1, IRFMN researchers attended the Workshop organized by the Joint Research Centre in Geel (11-12 October 2018), involving the participation of 34 experts of the chemical analysis of tobacco products from 14 EU countries and WHO. This was also the occasion to start developing communication with other large international initiatives, including GoToLab and WHO TobLabNet. In the first WP8 internal meeting, our Consortium started developing collaborations between the WP8 participants and these international networks. From the IRFMN, two separate applications were sent to obtain individual membership of TobLabNet: one representing the Laboratory of Lifestyle Epidemiology, to join TobLabNet as a Research Member; another, representing the Laboratory of Mass Spectrometry, to join TobLabNet as a Testing Member. In Oct 2019 the laboratory became a TobLabNet member, entering the laboratories network.

A network of EU independent laboratories has been created, and enlarged to TobLabNet laboratories and independent Italian University laboratories. The SOP developed in Task 2.2 has been finalized with the EU and WHO TobLabNet laboratories and discussed in the 2nd internal WP8 meeting (Mar 2020). Results were reported in D8.3 (Nov. 2020). It must be stressed that the whole SOP has been developed and validated within the COVID-19 pandemic. All laboratories, even during the lock-down imposed by most of the countries, have been able 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.

Work Package 9: Additives subject to enhanced reporting obligations (Months 1-38) (Lead Beneficiary: RIVM)

Objective 1: To compose an assessment/evaluation framework and guidelines for "good experimental practising" (GEP). (Lead RIVM, Participants, HCS, SIK, ANSES, BfR, ANSES, IRFMN, RIVM, Months 1-8)

Task 1.1: To provide guidelines on how the enhanced reporting documents on priority additives will be judged and an assessment and evaluation framework will be composed

Within RP1, WP9 created and produced both an assessment/evaluation framework and guidelines for «good experimental practising», for the panellists and the industry respectively. This collectively was submitted in RP1 as D9.1. These guidelines continued to be followed during RP2.

Objective 2: To facilitate peer review of the enhanced reporting information submitted by a panel of suitable experts. (Lead RIVM, Participants, HCS, SIK, ANSES, BfR, ISS, RIVM, CSJA, Months 9-30)

This objective is addressed through five specific tasks

i. Task 2.1: To obtain, (translate) and evaluate the type of information on enhanced reporting of priority additives that is submitted (Months 9-18);

ii. Task 2.2: To create, organize and coordinate an appropriate panel of scientists that would comprise the peer review panel outlined in TPD Art 6, p4. Participants: HCS, SIK, BfR, ISS, RIVM (Months 10-20);

iii. Task 2.3: To facilitate the peer review process of the evaluation of the submitted information on priority additives outlined in TPD Art6, p4 and request if necessary supplementary information regarding the additives concerned. Participants: RIVM, HCS, BfR, ISS (Months 12-22);

iv. Task 2.4: To peer review reports of priority additives on toxicity, addictiveness and attractiveness Participants: HCS, ANSES, BfR, NIPH, eventually subcontractors selected from potential international experts, Months 12-24);

v. Task 2.5: To create a final report and provide a summary of the submitted information on priority additives and report this towards the general public (Participants: RIVM, HCS, SIK, BfR, Month 24)

In RP1, WP9 created an independent review panel comprised of experts from different fields, for the assessment of the documents (preparatory for Deliverable 9.3). All experts signed the Conflict of Interest form and acquired access to the enhanced reporting documents on priority additives. During several teleconferences and a physical kick-off meeting (8 February 2018, Brussels) with the independent expert group and supporting group, the working structure and content of the documents were discussed. The independent expert group and group supporting experts worked on a general report focusing on the methodology and reporting of the enhances reporting documents. During the JATC Interim meeting, a presentation was given about the work performed and deliverables completed in WP9. Furthermore, an overview of the issues around the reporting and regulation of priority additives were addressed and discussed with MS. As follow up on this discussion, WP9 attended the expert group meeting (21 March 2019, Brussels) and drafted two letters to support MS in their work:

- A Letter for MS on obtaining information on priority additive diacetyl, sent by EU-MS
- A letter to manufacturers with a request for additional information (according to TPD Art. 6.4), that was sent by EC on behalf of MS and JATC.

With regard to the analysis of products in WP6 (cigarettes) and 7 (e-cigarettes), questions were identified, with information being analysed from EU CEG data on priority additives in tobacco products.

A complete review of the submitted industry documents was performed by the review panel members and partners of WP task 2.4. Outcomes and issues were discussed at the interim meeting in Brussels, February 2020. 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. The outcomes have been presented during the closing meeting on December 4th, 2020.

Objective 3: To evaluate the comprehensiveness of the assessment/evaluation template for the types of studies (Lead NIPH, Participants, RIVM, HCS, ANSES, BfR, CSJA, Months 23-30)

Task 3.1: To perform an evaluation of the comprehensiveness and utility of the provided assessment/evaluation framework for the priority additives through focus group discussions with the panel of experts (Participants: HCS, ANSES, BfR, RIVM, NIPH, CSJA, Month 23) *and Task 3.2: To prepare a report on the utility of the assessment/evaluation framework, including if necessary, suggestions that would enhance its improvement* (Participants: HCS, ANSES, BfR, RIVM, NIPH, CSJA)

After thorough review of the studies provided by the industry (objective 2), the review panel and partners criticized the methodology and comprehensiveness of the delivered data (see D9.3, Chapter 2). Based on the substantial shortcomings of the reports it was concluded that placing the responsibility for assessing priority additives on the tobacco industry is not suitable (see Chapter 2 for more information). In light of this conclusion, and after in-depth discussions among the partners of WP 9 task 3, it was decided that an assessment of the assessment/evaluation framework for the evaluation of industry studies, was no longer applicable.

Objective 4: To provide feedback on additional additives that could be subject to enhanced reporting obligations in collaboration with WP6 and WP7 (Lead BfR, Participants, RIVM, HCS, Months 27-30).

Task 4.1: To provide feedback on additives and in cooperation with WP6 and WP7 prepare a report on additives that could potentially be added to the list of additives subject to enhanced reporting obligations, including its supporting evidence.

Deliverable 9.4 was developed in collaboration with WP 6, and outlines several substances that could be target for further investigation by MS. In brief, the review panel concluded that placing the responsibility for assessing priority additives on the tobacco industry is not suitable. The industry has a clear motivation to keep their products on the market, and also to maintain sales numbers, and therefore cannot be considered an unbiased part. Instead, assessment of additives in tobacco products should be based on independent sources and be performed by independent experts.

Based on these outcomes, it was also concluded that no new priority list according to article 6 of TPD should be established. Therefore, the adjusted aim of task 4 was to provide member states and researchers with a list of selected additives that should be considered for further assessment using independent literature.

2. Project 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 has been 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.
- ✓ **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 quantitive and qualitative perspective. In total over 1,000 unique CAS numbers were identified and a patter 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 and were reviewed by a panel of 10 experts and 8 additional panel members and a complete report/assessment was prepared.
- ✓ **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. Part 4 is an overview of substances which are already prohibited for the use in tobacco products in Germany and Hungary. The compilation should encourage other member states to ban these additives in tobacco products or e-liquids as well.

2.2 Target Groups and Added Value

As it was the case in RP1, during RP2 JATC continued to successfully engage and reached the main target groups as intended, including the following:

- **EU MS Regulators:** They were the primary target group of the JATC, due to their direct relevance with the topics covered by the JATC. They constituted the main beneficiaries from the JATC as the actions and tasks performed addressed aspects of the TPD that had to be addressed by EU regulators within the context of TPD implementation at national level. In order to ensure a wider use of research evidence and its translation into public health policy and subsequent public health gain, EU regulators were engaged in all aspects/phases of the project. It is important to note that

the participating partners in JATC, were by majority either EU MS regulators or relevant competent authorities across EU MS and were actively engaged in the project.

- **Tobacco control stakeholders**: These were the secondary group that benefited from project results through interactions at both the "dissemination" (WP2) and the "networking and sustainability level" (WP4). Tobacco stakeholder group included patient organisations, international institutions (WHO), and national and international bodies. Stakeholder networks with broad outreach across the European region and that have close collaborations with national stakeholders active in tobacco control also contributed to better stakeholder involvement.
- **Researchers**: This group benefitted from the use of knowledge produced as outcomes of the JATC project. Researchers were targeted under WP2 and WP4 so as to enhance their awareness of such data and enhance the usage of the wealth of data collected through the EU-CEG.
- **The general public:** The public benefited indirectly from the implementation of JATC through the support that the JATC provided to EU regulators – in their central role in transposing and implementing the TPD in their respective EU MS.

Added value: The work of JATC during RP2 continued to be focused on addressing the issue of tobacco product monitoring at an EU wide level –an activity that would be impossible to be done by one, or a few, EU MS by themselves. Overall the actions performed in RP2 were working towards bringing significant added value to the existing public health knowledge on tobacco control as the vast majority, if not almost all of the data submitted via EU-CEG, has never been evaluated on a comprehensive scale.

2.3 Further usage of the project's results

Further use of the project's results transpires beyond initial intended outcomes. Bi- and multilateral communication and cooperation structures evolved due to the interaction space the project provided and laid the fruitful ground for an exchange on specific TPD related implementation approaches. Key future use of the results of the project will be the implementation of tobacco product data analyses across EU MS, the harmonisation of laboratory procedures, the development of compliance checklists for e-cigarettes in the EU and the evidence brought forward on priority additives that can fuel legislative actions.

2.4 Major problems and lessons learned

The most challenging aspect of the JATC was also one of the projects strengths – the number and diversity of its partners. The JATC included national and regional regulators, non governmental organisations, research institutes, universities and both tobacco specific and non tobacco specific entities. This broad spectrum allowed for a multidisciplinary approach combining both regulators with researchers which increased the complexity in communication but allowed for an augmented output.

2.5 Dissemination activities during and after the project

Dissemination activities during the project: The dissemination actions performed during the joint action on tobacco control are described in detail within Deliverable D2.1. Within the 36 months of project implementation, numerous activities have been implemented to disseminate information and project's results to the public, regulators and researchers. Within the JATC a dissemination plan for the

development and reporting of dissemination activities was prepared. This dissemination plan included detailed information of whom should be contacted and had all the methods needed to perform the dissemination activities of the JATC. The main dissemination channels and methods included:

- ✓ Creation of a visual identity
- ✓ Preparation of leaflet
- ✓ Website of the project
- ✓ Exchange of project related information with JATC partners
- ✓ Placement of JATC information at external websites and meetings
- ✓ Preparation of newsletters with the main achievements of the project
- ✓ Participation at relevant conferences, including but not limited to:
    - JATC Kick off Public event, 2017
    - 14th TID Annual Conference in Izmir October, 2018
    - 3rd ENSP-CNPT SRP International Conference on Tobacco Control, Madrid, 2018
    - 1st Interim Meeting of the Joint Action on Tobacco Control (JATC), 2019
    - 4th ENSP International Conference on Tobacco Control, 2019
    - Participation at the EU Health Program High Level Conference in Brussels, 2019
    - Participation in JRC meetings in Geel, Belgium, 2019
    - Participation of WP8 in the WHO Expert Meeting, 2019
    - 2nd Interim meeting in Brussels, 2020
    - JATC participation at the 8th European Conference on Tobacco or Health, 2020
    - The final conference, 2020

Dissemination activities after the project: Following the end of the JATC the project will continue its dissemination activities through promoting its deliverables to the target groups, as also through communicating the scientific results of the JATC to peer reviewed journals. At the time of writing WP4, WP7, WP8 and WP9 have already outlined potential manuscripts for submission to the ENSP scientific journal, *Tobacco Prevention and Cessation*.

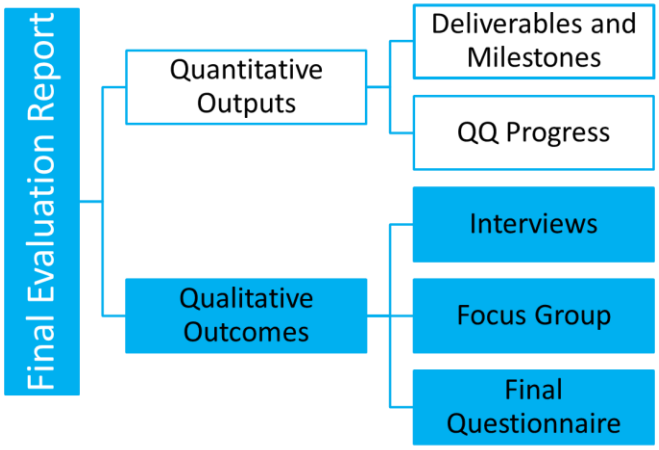
2.6 Project website

- ✓ As the website is the public face of the project, the information provided is in layman format with the ability to identify further detailed material deeper within the website. Within the above, small "snippets" of key information were used and released to the public and stakeholders to increase engagement.
- ✓ In total, there were >50,000 page views and 13,500 unique users on the www.jaotc.org website. Complete information on the website is available in D2.1- Final Dissemination Report.
- ✓ During the lifespan of the project, data were collected from the partners to update the information on participants' page of the JATC website. This was necessary due to changes in the JATC partners' teams.
- ✓ WP2 regularly communicated with JATC partners to identify potential information to be uploaded at the News page of the website and to inform them about JATC outcomes uploaded on the JATC website.
- ✓ All approved outcomes of the JATC are uploaded onto the JATC website -which will remain operational at least 2 years after the end of the project.

3. Overview of the evaluation activities and results

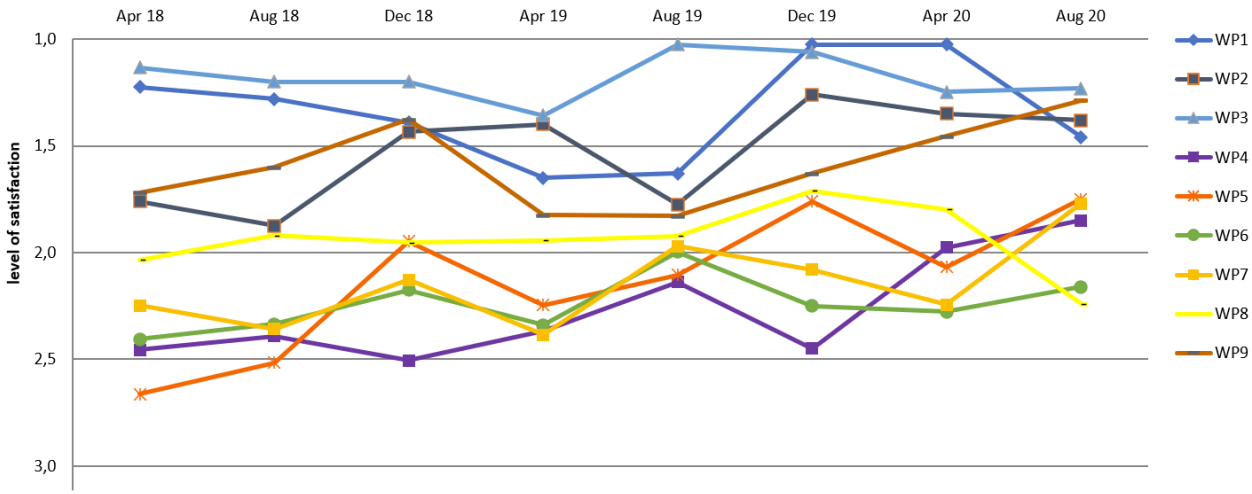
3.1 Participant or partner feedback

The main purpose of the evaluation of the JATC was to optimize the implementation of the JATC and to ensure that it meets all objectives envisaged. It was designed in a way that ensures a joined learning process for all stakeholders involved by generating useful information and knowledge to improve the project and the outcomes and outputs. To this end it a) measured to what extent the project objectives have been achieved, b) measured if the outcomes of the JATC met the needs of the project´s target groups and c) optimized the processes used to ensure that the project activities were implemented as intended. As outline below, an integral part of the evaluation plan was partner feedback.



Overall the QQ progress questionnaires were sent out 8 times throughout the duration of the project, with an average opening rate of 22% - a percentage that is acceptable when one takes into account that the entire emailing list of JATC members included also auxiliary staff, financial staff, grant management staff, PLSIGN, LEARs etc. Overall ratings of WPs ranged from 6.3 to 7.1 on a 0-10 scale with regards to the general satisfaction of the project – with significant differences between WPs.

Using a 1-5 scale, with 1 very satisfied the scores per WP across time are depicted as follows



- Overall partner feedback noted general satisfaction with the project, with satisfaction consistently high which was remarkable for the size and complexity of the project. However, the expectations of members was partially met for some aspects with fluctuation regarding satisfaction with specific items. Moreover, it was noted that vertical WPs faced greater challenges however cooperation among EU MS has increased. Overall partners noted that a system for permanent exchange of information among EU MS (including informal communication) is needed to enhance bilateral communication.

3.2 Process evaluation

Below we present, in tabular format the process indicators of the specific objectives of the project.

Specific Objective 1: Effective Coordination of the project

Process Indicator(s)	Target	Reached
Consortium agreement developed	1	1
Conflict of Interest (COI) and confidentiality forms are written	1	1
Project's meetings	3	3
Steering Committee meetings	3	18
Evaluation group questionnaires and meetings	1 (3)	1 (2)

Specific Objective 2: To support the dissemination of information to the regulators and general public

Process Indicator(s)	Target	Reached
Project's website launched	1	1
Project's conference	1	1
Project's leaflet developed	1	1
Dissemination plan developed	1	1
Presentations and stakeholder interactions at events and conferences	6	11

Specific Objective 3: To enhance the ease of access to the data collected through the EU-CEG

Process Indicator(s)	Target	Reached
Difference between EU-CEG "public non confidential" data, "non-public non confidential" data and "confidential" data	1	1
Technical/legal framework for the sharing of data reported data in EU-CEG	1	1
Proposal of mechanisms for sharing EU-CEG data between EU-CEG MS and the JATC-project	1	1
Proposal of mechanism for sharing EU-CEG data between EU-CEG MS permanently	1	1

Specific Objective 4: Monitor and provide support to the tasks of tobacco and e-cigarette product regulation

Process Indicator(s)	Target	Status
Data from EU MS regulators regarding requirements for EU-CEG	28	19
Analysis plans for tobacco and e-cigarette products	2	2
Checklist for e-cigarette product compliance created	1	1
The proposed system for adverse event reporting outlined	1	1

Specific Objective 5: Assist EU MS networking and collaborations between laboratories for tobacco evaluation

Process Indicator(s)	Target	Reached
Collection of information from EU MS on tobacco laboratories. Within WP8, we will collect information about EU tobacco laboratories and their activities.	20 EU MS	28 Laboratories from 17 countries
Collection of data from EU MS laboratories. Within WP8, for each EU laboratory, we will request to obtain analytical data for predefined products, which will be critically evaluated and re-analysed at a European scale.	5 labs	17 labs
Networking meeting with EU and international laboratories. Task 3.1 of WP8 has been specifically designed to develop collaborations and communication with large international initiatives, including GoToLab and TobLabNet, to further improve networking between labs.	1	3

Specific Objective 6: Support EU MS in the process of monitoring and updating priority additives

Process Indicator(s)	Target	Status
Identification of good experimental practising guidelines	1	1
Obtainment of priority additive data and supporting information	1	1
Recruitment of peer reviewers, experts in the field	10	18
Peer review process commenced	1	1

Specific Objective 7: To integrate the JATC results into national policies

Process Indicator(s)	Target	Status
Mapping survey of activities and capacity from EU MS	1	1
Creation of “how to” guides	3	8
Creation of “how to” guide platform/site	1	1
Sustainability plan detailed	1	1

3.3 Output Evaluation

Specific Objective 1: Effective Coordination of the project

Output Indicator(s)	Target	Status
Signed consortium agreement by all parties	1	1
COI forms signed by all partners	34	34
Project meeting minutes	3	3
Periodically cost statement and activity reporting	2	2
Interim and final reporting	2	2
Evaluation feedback response	75%	Approx. 30%

Specific Objective2: To support the dissemination of information to the regulators and general public

Output Indicator(s)	Target	Status
Visits to the project website	1000	50,000
Participation in the JATC final conference	100	120
Project leaflets handed out	500	1000
Project result reports disseminated	3	3
International and National Tobacco control stakeholders engaged	20	>250

Specific Objective 3: To enhance the ease of access to the data collected through the EU-CEG

Output Indicator(s)	Target	Status
Requirement specification on technical and administrative security measures to protect EU-CEG-data depending on the level of need for protection from WP5 and EU MS classification of EU-CEG data.	1	1
Information sharing agreement template for sharing data within the JATC-project produced and implemented.	1	1
Information sharing agreement template for sharing data permanently between EU MS in place.	1	1
The technical solution for making EU-CEG MS publish public non-confidential data	1	1
The technical solution for sharing EU-CEG data with WP6-9	1	1
The technical solution for the permanent sharing of EU-CEG data between EU MS.	1	1
The proportion of EU MS that provide public data	28 (100%)	n/a
The proportion of EU MS that provide some form of confidential data	20 (70%)	19
The proportion of EU MS that upload public data	28 (100%)	n/a
Greater sharing of data by EU MS to other EU MS	14	15

Specific Objective 4: Monitor and provide support to the tasks of tobacco and e-cigarette product regulation

Output Indicator(s)	Target	Status
The first wave of product analyses for domains in EU-CEG	4/5 domains	4/5
The second wave of product analyses for domains in EU-CEG	5/5 domains	4/5

Specific Objective 5: Assist EU MS networking and collaborations between laboratories for tobacco evaluation

Output Indicator(s)	Target	Status
Networking meeting minutes, including minutes from the two internal meetings of WP8	1	1
Capacity for EU MS laboratories identified, within WP8, laboratory capacity requirements will be provided in D8.2	1	1
Report on emission protocols concluded laboratory capacity requirements would be provided in D8.3	1	0
Networking with other laboratories in the EU and internationally	10	28

Specific Objective 6: Support EU MS in the process of monitoring and updating priority additives

Output Indicator(s)	Target	Status
Inventory on reports on priority additives obtained and categorised	15	15
Peer review meeting minutes	2	2
Assessment/Evaluation Framework	1	1
Good experimental practice guidelines	1	1
Trained experts in document review	12	18
Report with reviewers' judgement on each priority additive	15	15

Specific Objective 7: To integrate the JATC results into national policies

Output Indicator(s)	Target	Status
Mapping activities and capacity from EU MS regulators	28/28	25+
Downloads/sharing of material by EU MS regulators	28/28	n/a
Uptake of e-learning material by EU MS regulators	20 (70%)	n/a

3.4 Outcome Evaluation

Specific Objective 1: Effective Coordination of the project

Outcome Indicator(s)	Target	Status
Effective coordination as identified through internal evaluation	n/a	Completed

Specific Objective2: To support the dissemination of information to the regulators and general public

Outcome Indicator(s)	Target	Status
Increased visibility and awareness among EU MS policymakers	28 (100%)	28 (100%)

Specific Objective 3: To enhance the ease of access to the data collected through the EU-CEG

Outcome Indicator(s)	Target	Status
Greater sharing of data by EU MS to other EU MS	14	15

Specific Objective 4: Monitor and provide support to the tasks of tobacco and e-cigarette product regulation

Outcome Indicator(s)	Target	Status
Awareness of EU-CEG capabilities by EU MS regulators	20/28	28
Awareness on ingredient function, role and toxicity	20/28	28
Awareness of product design and evolution	20/28	28
Checklist for e-cigarettes applied in EU MS	3	3 (in the process)

Specific Objective 5: Assist EU MS networking and collaborations between laboratories for tobacco evaluation

Outcome Indicator(s)	Target	Status

Enhanced collaboration between EU MS with regards to emissions and ingredient analysis. Once WP8 objectives are accomplished, laboratory methods will be harmonized throughout the EU MS, improving collaborations among independent laboratories.	n/a	Achieved with the SOP for laboratory analyses

Specific Objective 6: Support EU MS in the process of monitoring and updating priority additives

Outcome Indicator(s)	Target	Status
Update on the number of additives subject to enhanced reporting requirements	n/a	Achieved with D9.4

Specific Objective 7: To integrate the JATC results into national policies

Outcome Indicator(s)	Target	Status
Awareness of EU MS regulators on domains covered in the "how to" guides.	n/a	8 guides created

4. Overview of the dissemination activities

The plan for exploitation and dissemination of the JATC Project results followed the details set out in Section 2.2 of the Description of Action (DoA). The relevant Work Package (WP2) was led by BATUT and supported by the HCS, as well as an external subcontractor. 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 RP2 of the project. A complete and detailed description of all dissemination actions and products is presented within the context of D2.1 – Final dissemination report.

4.1 Strengths and weaknesses of the dissemination activities

The aim of the dissemination plan was to maximize the JATC impact 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. Its 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.

Another weakness was the limited number of manuscripts published within the timeframe of the three years of the JATC, however these will be produced after the end of the JATC. This is commonly noted across EU funded H2020 projects, where most publications are practically written after the end of the study period.

5. Reasons for deviations from Annex 1

5.1 Task and time deviations

During RP2, there were a few deviations to the timeline of delivery of milestones and deliverables, that were primarily taken in order to increase the scientific output of the project. In RP1, an amendment to the delivery dates-timeline for deliverables and milestones was submitted by the JATC Consortium, within the context of the withdrawal of FOHM as a partner. The scientific justification for these changes was submitted with the amendment text. In RP2 (May 2020) a second amendment followed due to the withdrawal of MOH-CY as a partner. Within this amendment, updated timeframes to deliverables were provided so as to maximise scientific content and regulatory pertinence. The impact of COVID-19 lead to an increased duration of the projects by 2 months – and hence JATC became a 38 month project – as approved by Amendment n.3 (September 2020). Below is a description of the implementation deviations, categories as either partner deviations, time deviations and content deviations, presented per WP. For each deviation we present the consequences and the corrective actions taken.

WP1

Time deviations: Effectively none – all deliverables were submitted within ±15 days of the deadline.
Content Deviation: None

WP2

Time deviations: Effectively none – all deliverables were submitted within ±15 days of the deadline.
Content Deviation: The final conference was unable to be planned as a physical meeting due to the COVID-19 pandemic and hence it took the form of a virtual meeting.

WP3

Time deviations: D3.3 was submitted with a slight delay. Extra time was needed to gather more information and to comprehensively analyse the data. The delay is insignificant since the report was due at the end of the project and its findings give suggestions for further actions.
Content Deviations: With regard to WP3**,** for spring/summer 2020 several focus groups with stakeholders were planned to discuss immediate project outcomes, as well as the likeliness of longer-term outcomes to occur. Due to the national measures to contain the COVID-19 pandemic and the associated restructuring of processes and workflows within public administrations, many stakeholders could not participate. Only one focus group with five participants took place and a questionnaire was therefore sent out to 66 experts as a substitute.

WP4

Partner deviations: The Ministry of Health of the Republic of Cyprus (MoH CY) terminated its participation as leader of WP4. The change in WP4 leader from MOH-CY to ISS took place in February 2020. Following this change, ISS became responsible for D4.2 for the remaining months until the end of JATC.
Time deviations: D4.1 was delayed by a few months due to internal administrative reasons within MoH-CY (Report on TPD mapping and sustainability activities including in house capacity). Deliverable 4.2 was delivered by ISS slightly ahead of time.

Content deviations: Within Tasks 2.3 and Task 2.4 the trainings which were planned to be separate trainings of regulators on issues regarding the JATC were not performed as separate dedicated webinars/seminars but within the context of presenting JATC results to the expert subgroups on tobacco policy. This synergy allowed for greater integration of JATC activities with EU MS representatives.

WP5

Partner deviations: In November 2018, the termination of FOHM as a beneficiary was requested due to internal changes within their organisation that took place between the time point that the proposal was submitted and the time point the proposal currently is at. This led to the replacement of WP5 lead by SIK.
Time deviations: Deliverable 5.1 (Report on the principles to distinguish what data is public non confidential) was delayed by 17 months so as to ensure that the agreed definitions would be acceptable to all partners involved. This led to the topic being discussed extensively and commented on by many partner as and competent authorities. The delay however ensured a more cohesive response by EU MS. Deliverables 5.2 and 5.3 were submitted with a 1 month delay, expectable due to the change in WP5 leadership during the initial drafting stages of the work, while D5.4, D5.5 and D5.6 were delayed by approximately 6 months, again due to additional effort needed to conclude these deliverables.

WP6

Time deviations: With regard to WP6, main deviations were related to the extended process of data sharing agreement signature and corresponding significant delay in data release to the WP6 Leaders.
The D6.1 was submitted almost on time (11 days delay). Regarding the Milestones, MS22 and MS23 have been submitted with a few days delay. The Deliverable 6.2 was submitted with the delay due to significant delay in access to the country specific data (delay in data sharing agreement signature and data release). The Deliverable 6.3 was also delayed slightly, mainly due to unavailability of the ICO staff to work on data analysis during the COVID pandemic in 2020. The needs assessment questionnaire (MS22) was presented to the Members of the Expert Subgroup on Ingredients, as they are a specific target group for this questionnaire. This led to a delay in presentation. While the MS24 (Second wave of data analysis) and MS25 (List of additional additives that could be subject to enhanced reporting obligations) were a few months delay mainly due to the COVID-19 pandemic. Some of the WP6 tasks were affected and delayed due to the COVID-19 pandemic, given that ICO staff was involved as epidemiologists in the response to the pandemic, both in the hospital itself and with community public health services.
Content deviations: Overall, WP6 completed the foreseen objectives and tasks. Though, there are a few issues that could not be completed within the project: (1) Analysis of EU-CEG data was envisaged to be done by multiple partners, however due to the security and technical difficulties of sharing entire EU-CEG datasets with multiple recipients, analyses were performed centrally, not peripherally across partners. (2) to contrast the reported data to original analyses as a part of the project as it was early at a project start declined due to logistic and financial burden of such tasks; (3) analysis of tobacco product presentation and sales data due to either lack of such data or large and complex dataset design; (4) to monitor the changes over time due to delay in data sharing process.

WP7

Time deviations: No significant deviations in the delivery of WP7 deliverables was noted, with all deliverables uploaded to ECAS either ontime or with a delay <1 month.

Content deviations: (1) Analysis of EU-CEG data was envisaged to be done by multiple partners, however due to the security and technical difficulties of sharing entire EU-CEG datasets with multiple recipients, analyses were performed centrally, not peripherally across partners. (2) The data on emissions of e-cigarettes available in EU-CEG was assessed prior to the sharing of individual EU MS data and the data were noted to be very heterogenous with regards to reporting at a single EU MS level- hence the combined analysis and reporting of emission data and protocols within EU-CEG from a cross EU MS perspective was deemed to be non feasible – especially in the absence of homogenized emission protocols. The initial assessment deemed further evaluation and analysis non beneficial. The time and effort that was planned for this task of WP7 was shifter towards creating reports for EU MS that would help regulators understand the EU-CEG data, its strengths and its weaknesses – through the creation of EU MS reports.

WP8

Time deviations: A number of deviations in the timeframe of submitting deliverables was noted for WP8 – predominantly due to the complexity of developing a network that would facilitate the exchange of information across EU labs. Once this network was established the deliverables processed swiftly. Overall D8.1 was submitted ontime, D8.2 (Report on Lab requirements) -was delayed by 10 months as this was the time needed to obtain the necessary synergy between the multiple EU labs - finally this delay led in a substantially increased scientific and synergistic output as 28 labs finally collaborated – a much higher result than the planned 10 labs outlined in the GA. D8.3 and D8.4 were delayed by 3 and 2 months respectively so as to enhance the delivered output from the 28 participating laboratories and hence this delay was acceptable to the coordination team.

Content deviations: There main deviation was related to the planned EU laboratories data analysis. Data from laboratories database were not available from most of the countries and in the last four years the number of analysis performed in EU MS was extremely limited both in total number and in number of laboratories. This led to a deviation that was needed that leaded to an improved scientific output. WP8 did not used data from laboratories database but developed an internal operating procedure for e-liquids analysis and laboratories participated and supplied original data, to be evaluated. This led to a homogenous process across the European labs and the development of a chemical analysis SOP that was also adopted by WHO TobLabNet.

WP9

Time deviations: D9.2 was due in Month 12; however, it was not submitted until M20 because of the difficulties faced in accessing the EU-CEG data and obtaining legal clearance on what data can be included in this Public Deliverable. If this deliverable were to be confidential, then this time issue would not have arisen, however in the essence of transparency, we have all deliverables open to be public. Regarding the Milestones, only MS35 had a slight delay. After the Covid-19 outbreak in early 2020, several collaborating partners and review panel members were required to prioritize work related to this topic. As a

consequence, they have been less available to do work for WP 9 over the year 2020. This has slowed down the progress and has caused a delay for the deliverable D9.3 and D9.4.

Content deviations: After thorough review of the studies provided by the industry (objective 2), the review panel and partners criticized the methodology and comprehensiveness of the delivered data (see D9.3, Chapter 2). Based on the substantial shortcomings of the reports it was concluded that placing the responsibility for assessing priority additives on the tobacco industry is not suitable (see Chapter 2 for more information). This conclusion impacted the trajectory of objective 9.3 and 9.4. As industry assessment of priority additives is not supported by the review panel and partners, it was decided there would be no merit in evaluating/improving the framework for evaluating industry studies. Based on these outcomes, it was also concluded that no new priority list for enhanced reporting obligations should be established. Therefore, the adjusted aim of objective 4 was to provide member states and researchers with a list of selected additives that should be considered for further assessment using independent literature.

5.2 person-months deviations

Partners with a differentiated effort – Please note that the PMs between partners are non comparable, as each partner has a different monthly rate within staff members.

Partner acknonym	*Deviation in PMs*	*Rationale for deviation*
HCS	*+44*	• *Higher coordination effort needed than envisaged for WP1 (Coordination). Initially 48PM were envisaged for WP1, however 86PM were needed to successfully coordinate the project (+38PM) – approximately an additional +1PM/month for the 38 month duration of the project.* • *The project was extended by +2 Months (15Oct – 15Dec), hence additional effort was needed across WPs, inlight of the challenges induced by COVID-19, on deliverable, report and project closure.*
BHTC	*-2.1*	• *The partner decided for a more observatory role in the project.*
NCPHA	*-3.6*	• *Less effort was needed to perform the planned activities.*
SIK	*-4.6*	• *Less effort was needed to perform the planned activities.*
TA	*-1.4*	• *Use of personnel with a higher PM rate but same scientific output.*
BfR	*-2.4*	• *Use of personnel with a higher PM rate, but enhanced scientific output.*
DOHI	*-0.7*	• *Less effort was needed than planned for the follow up of JATC activities for this Non-EU MS partner*
MOH-IT	*-2.3*	• *Use of personnel with a higher PM rate and less effort performed for WP6/WP7 where additional analyses were planned but not performed on e-cigarette emissions (Section 5.1 – WP6 and WP7 deviations)*
HI	*-3.6*	• *Less effort was performed for WP7, as analyses were performed centrally, not at the EU MS level. (Section 5.1 –WP7 deviations)*
NTAKD	*-1*	• *Less effort was performed for WP6 7, as analyses were performed centrally, not at the EU MS level. (Section 5.1 –WP7 deviations)*
NVSPL	*-1.9*	• *Attributed to the WP8 deviation (Section 5.1 -WP8 deviation)*
RIVM	*-2.1*	• *Less effort was performed for WP6 and WP7, as analyses were performed centrally, not at the EU MS level. (Section 5.1 –WP6 and WP7 deviations)*

NIPH	*+2*	• *Additional effort needed in WP9 activities related to the peer review of priority additive documents.*
NOMA	*-0.5*	• *Less effort was needed than planned for the follow up of JATC activities for this Non-EU MS partner*
MS	*-3.8*	• *Limited activities in RP1 (<0.5PM in RP1) as data sharing and commenting for WP5, WP6, WP7 picked up speed in RP2.* • *Less effort was performed for WP6 and WP7, as analyses were performed centrally, not at the EU MS level. (Section 5.1 –WP6 and WP7 deviations)*
BATUT	*-6.9*	• *Less effort for dissemination actions were needed as the dissemination subcontractor was very effective* • *Lack of an inperson final event at the European Parliament due to COVID-19, hence less effort needed to prepare, perform and report on the final event (Section 5.1 – WP2 deviations)*
NLZOH	*-4*	• *Less effort was performed for WP6, as analyses were performed centrally, not at the EU MS level. (Section 5.1 –WP6 deviations)*
ICO	*+3.3*	• *As WP6 leader more effort was performed as analyses were performed centrally, not at the EU MS level. (Section 5.1 –WP6 deviations)*
CFSJA AGAPA FPS	*0*	• *Changes at the partner level but balanced effort and budget between these third parties*
UK-DOH	*-3.6*	• *No activities performed in RP2*
HTS	*-6*	• *Use of personnel with a higher PM rate* • *Reduction in PM in WP8 attributed to the WP8 deviation (Section 5.1 - WP8 deviation)*

5.3 Unforseen subcontracting

Not applicable in the JATC