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Layman version of the final report
Final dissemination report
Final dissemination report
Interim evaluation report
Final evaluation report
Second half evaluation report
Report on TPD mapping and sustainability activities including in house capacity
Sustainability plan, including scenarios for long-term sustainability
Sustainability plan, including scenarios for long-term sustainability
Report on the principles to distinguish what data is public non confidential
Technical solution for public non confidential data
Proposal of permanent mechanism for sharing of EU-CEG data
Report for M18-34 on the potential improvements/alterations identified
Report for M18-34 on the potential improvements/alterations identified
First report on tobacco product data analysis
Second report on tobacco product analysis
Second report on tobacco product analysis
First report on e-cigarette product data analyses
Report on a proposed system for the reporting of adverse events
Second report on e-cigarette product analyses
Second report on e-cigarette product analyses
Report on the requirements for laboratories
Report on the results of inter-laboratory variability of EU MS emission data
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Project abstract

Smoking and other forms of tobacco consumption are considered the single most important cause of preventable morbidity and premature mortality worldwide. Efforts to reduce the devastation of tobacco-related deaths and illness in the EU consist of the Tobacco Products Directive (TPD), and the WHO Framework Convention on Tobacco Control (FCTC). The TPD lays down rules governing the manufacture, presentation and sale of tobacco and related products. The TPD stipulates that Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities information, via a common entry gate (EU-CEG) – an IT tool designed to ensure uniform application of the reporting and notification obligations, harmonise the submission of data, facilitate comparison and reduce administrative burden.

The general objective of the Joint Action on Tobacco Control will be to provide support for the implementation of the TPD throughout the 28 EU MS through the mining of EU-CEG data, supporting of laboratory collaborations and effort to evaluate priority additives. The specific aims of the project are:

- To ensure appropriate coordination and evaluation
- To support the dissemination of information to the public, regulators and researchers.
- To enhance the ease of access to the data collected through the EU CEG
- To monitor and provide support to the tasks of tobacco and e-cigarette product regulation
- Assist EU MS networking and collaborations between laboratories for tobacco evaluation.
- Support EU MS in the process of monitoring and updating priority additives
- To integrate the JATC results into national policies

With the above in mind, this proposal comes at a perfect timing to aid the regulatory activities that would be needed across the EU MS with regards to the implementation of the TPD across 28 EU MS spanning a population of 508 Million people.
**Work package**

**Work Package 1: Coordination of the action**

Start month: 1  
End month: 36  
Work Package Leader: HCS

**Description of work**

**Objective 1:** To support overall management of the project. (Lead: HCS; Participants: all consortium parties; M1-36)

Task 1.1: Develop and implement a Consortium Agreement. The Consortium agreement will describe the consortium management: a steering Committee, comprised by the representatives of the WP leaders will be created. More general issues will be discussed with all associated partners as part of the consortium assembly. Voting procedures, terms and guidelines will be clearly presented in the Consortium Agreement.

Task 1.2: Monitor and guide the progress of individual WPs. This tasks will monitor the progress of the activities throughout the project and for all parties involved. It will ensure a smooth implementation of the activities outlines in the grant agreement.

Task 1.3: 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.

Task 1.4: Organize, chair and take minutes of meetings of the Steering Committee meetings and Consortium Meetings. The WP1 leader will host a kick-off meeting preferably in Athens (M2, with participants representing all partners) for launching the project, as well as the 2nd and 3rd meeting consortium meetings at an annual basis. The purpose of this meeting will be to share the workplan, brainstorm and ensure common understanding of the approach, methodologies and activities to be performed under the joint action.

**Objective 2:** To coordinate financial management. (Lead: HCS; Participants: all consortium parties; M1-36)

Task 2.1: Communicate rules for financial administration and management, and ensure their implementation by all partners.

Task 2.2: 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 WPO leaders.

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.

**Objective 3:** To support communication activities. (Lead: HCS; Participants: all consortium parties; M1-36)

Task 3.1: Together with the leader of WP2, prepare a structure for external
communication.
Task 3.2: Develop and operate a structure for internal communication, aimed specifically to monitor progress of each WP and to stimulate collaboration between WPs.

Objective 4: To provide scientific support to individual WPs. (Lead: HCS; Participants: all consortium parties; M1-36).
Task 4.1: Provide timely scientific advice on the plans, progress and outcomes of the each WP.
Task 4.2: Undertake any other action that may benefit the work in WPs, such as organising special workshops on common research interests.

Objective 5: To communicate and report to the EC. (Lead: HCS; Participants: all consortium parties; M1-36)
Task 5.1: Invite representatives of the EC to attend the project meetings and dissemination events.
Task 5.2: Prepare an interim report and one final report to the EC.

Objective 6: To address emerging issues related to the implementation of the TPD for which the JATC could contribute scientifically (Lead: HCS; Participants: all consortium parties; Months 1-36)
Task 6.1: To maintain a connection of experts that can provide feedback on issues that may arise during TPD implementation with regards to tobacco product reporting.

Objective 7: To manage issues of ethics, confidentiality and absence of a conflict of interest (Lead HTS; Participants: all consortium parties; Months: 1-6)
Task 7.1: To manage issues of ethics and to ensure that all participating partners adhere to confidentiality and have an absence of conflict of interest.

Work Package 2: Dissemination
Start month: 1
End month: 36
Work Package Leader: BATUT-IANPH

Description of work
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: IPH, Participants: HCS, MOHCY, SE, LSMU, BATUT, external contractor; M1-36).
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.
Task 1.2: Project website/social media development and maintenance. The website
is conceived as ‘dynamic’ in the sense that continual updates will be made as the project work advances. The project website must include sufficient information for the general public, researchers and regulators to be informed of the impact and progress of the project. Website development will be provided to an external subcontractor. As the website and social media accounts (i.e. twitter) will be the public face of the project the information provided will be in layman format with the ability to identify further detailed material deeper within the website. Within the above, small “snippets” of key information will be used and may be released to the public and stakeholders so as to increase engagement.

Task 1.3: 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 in all research WPs. This will aim to disseminate information for the public, stakeholders and policy makers in all official languages, in a digital format, in order to promote health literacy in this field. The project leaflet will be designed and also printed for use at external dissemination events. Dissemination will take place both through traditional but also social and electronic media so as to ensure a broader outreach and the reaching of appropriate target audiences identified in Section 3 of this proposal. Three newsletters will be released throughout the duration of the project, one in each year so as to maintain interest among the stakeholders.

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: IPH, Participants: all WP partners; M2-36).

Task 2.1: Network development and upkeep. In order to ensure that the project findings reach the relevant end users, it is critical to perform a stakeholder analysis and identify and build partnerships with regulators, professionals and other stakeholders involved in tobacco control, public health policy and practice. This network will be provided with the information produced through the JATC and will be able to maximize its outreach. The members of these target groups have been previously described above. This task will have direct feedback from and will provide 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 (Lead: HCS, Participants: all WP partners; M31-36).

Task 3.1 We will organize the final project conference where the final findings of the project will be presented as will the overview of all related outcomes and reports, so as to facilitate potential sustainability of the JATC. The final project conference will take place in Brussels, with the involvement of all involved parties, tobacco control stakeholders and policymakers. We aim that this conference be followed by 200 participants and will request that this takes place within the European parliament building if feasible. The digital material of the conference will be disseminated to larger audiences through the networks of participating stakeholders and will also include a dissemination report that will
Work Package 3: Evaluation of the action

Start month: 1
End month: 36
Work Package Leader: AGES

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

Task 1.1. To define process, output and outcome indicators. Process, output and outcome indicator are defined in close cooperation with WP leaders and delivered to steering group. The proposal, including the tasks and deliverables of each WP, is used as a starting point for the definition of indicators by evaluators. Written and personal conversation will assist WP leaders to define additional indicators where needed and determine the final version. A Logical Evaluation Framework (LogFrame) is developed, by systematically merging specific objectives of technical and horizontal WPs with activities, process, output and outcome indicators, as well as methods, and delivered to Coordinator (M3). The LogFrame provides an overview and is used throughout the project period.

Task 1.2. To finalise instruments for WP3 data collection. Most process and output indicators are monitored by the Coordinator and measured through routine monitoring systems implemented in the project, including meeting minutes, reports and assessments. Most of the outcome indicators, to monitor the overall expected outcome in the areas 'enhancement of knowledge and literacy', 'collaboration between member states' and 'access to data', are measured with three new instruments for data collection. Firstly, a topic guide for semi-structured interviews is developed to gain a comprehensive perspective on the starting environment. Content related to 'access to data' are communicated to leader of WP 5 as input for the development of EU-CEG questionnaire. Secondly, a topic guide for focus groups is developed to evaluate the outcomes at the end of the project period. Thirdly, a quality questionnaire, with the aim to monitor and evaluate the projects procedures and quality throughout the project period, is finalised and delivered to steering group. The content of the topic guides and the questionnaire are finalised and delivered to the steering group.

Task 1.3. To prepare and obtain approval of the evaluation plan from the steering committee. Evaluation plan is finalised, including communication and reporting plan, methods, techniques and instruments for data collection. (M4). The evaluation plan, as the guiding document for the whole period of the JATC, includes a stakeholder assessment, the evaluation questions, evaluation design and timeframe, a description of the data collection process, the LogFrame, a communication and reporting plan and a section on the analysis and interpretation of the data.

Objective 2: To implement the evaluation plan throughout the duration of the project (Lead: AGES, Participants: all WP partners; M4-36).

Task 2.1. To implement the evaluation plan. Overview evaluation activities is obtained, tasks/duties of the evaluation are distributed in the evaluation team and
to WP leader for decentralised activities. Specific duties are communicated to other WP leaders and the project team in a general session.

Task 2.2. To collect and analyse qualitative and quantitative WP3 evaluation data. Qualitative primary data is collected for outcome measurement and quality assurance. The quality questionnaire, including the domains ‘information quality’, ‘organisation of meetings’, ‘communication and team work’, is distributed digitally with a survey tool to all participants of the Joint Action on a regular basis. Data is collected with an online tool and analysed with statistical methods. Semi-structured interviews on the starting environment are held with representatives of the each WP via webconferences and on general meetings at the beginning of the project. Interviewer’s notes and records are collected, analysed and findings interpreted.

Focus group Work Package 4: Integration into national policies and sustainability

Start month: 1
End month: 36
Work Package Leader: MoH CY

Description of work

Objective 1: To map the capacity building and knowledge needs for the effective and efficient application of the TPD e across the 28 EU MS and EEA where applicable. (Lead MOH-CY, Participants, all WP partners; Months 1-12, 24-36)

Task 1.1: This objective is to help the EU MS understand their gaps so that these can be identified at the beginning of the project. Its aim is to the capacity building and knowledge needs. The proactive data collection process would collect information outside those already collected in EU-CEG. This task will be performed at the beginning (M1-M12) and the last year of the project (M24-36).

Task 1.2: To map tobacco control funding across the EU MS, including submission fees to the EU-CEG or fees for implementation of TPD Art7(13) and TPD Art20(2) through a survey to EU MS regulators and competent authorities (M1-M9, M24-M30).

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 up-take of the outcomes of the Joint Action and the maintenance of the mechanisms set up as part of the JATC (M1-M9, M24-M30).

The above tasks, 1.1, 1.2, and 1.3 will be performed through a survey that will contain both closed and open ended questions that will allow for a qualitative and quantitative analysis of the data. The content of the survey will be developed through discussions among WP4 members during both phases.

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 HCS; Participants: all WP partners; Months 1-36)

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.

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.

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.

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. They may coincide with the Y2 and Y3 meeting.

Work Package 5: Common Entry Gate (CEG) data extraction and handling
Start month: 1
End month: 36
Work Package Leader: FoHM

Description of work

Objective 1: To identify the variables that should be considered public within the information submitted via the EU common entry gate (EU-CEG) and to facilitate making this information available to the general public (Lead FOHM, Participants: all WP partners; Months 1-36)

Task 1.1: To identify the variables that should be considered 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). (M1-9) [D5.1]

The information classification model will be suggested by information security specialist. The model will use existing models from, a)EU-CEG information classification model, b)EU information classification model and if adoptions to existing models are needed use ISO/IEC 27002:2014 chapter 8.2 as theoretical
background to draft an EU-CEG information classification model that with focus on the aspect confidentiality. In task 1.1 the model will be used to classify data in EU-CEG that is “non-confidential public”. The participants will evaluate the classification model and the instructions to MS on how to apply the model. The classification will be approved by EU-CEG system owner [SANTE] before send out to all MS with data in EU-CEG. The aim is that the classification of “TPD non-confidential public” data by the WP will be accepted by EU-CEG MS as proposed.

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. (M6-30) [D5.2]

A report to clarify the legal situation between EU-regulation, MS national legislation and existing contracts between owner and MS as information owners regarding EU-CEG will be produced by external legal specialist. The legal report will focus on the aspects of MS publishing public non-confidential and share non-confidential and confidential data and how to deal with classification of data by manufacturer and importers when this is not in line with TPD. The results from the report will additionally be the basis of legal requirements for publishing and to share non-confidential public data. To identify technical requirements on security measures for publishing data from EU-CEG to general public existing security requirements for EU-CEG will be used as basis. Additional technical and administrative requirements will be drawn from ISO/IEC 27002 chapter 9 (Access Control), chapter 10 (Cryptography), chapter 12 (Operation Security), chapter 13 (Communication Security) and chapter 14 (System Acquisition, development and maintenance). The requirements will be documented by information security specialist in a format agreed on with system owner [SANTE]. Quality check of the requirements, both legal and technical will be done by all WP5 partners.

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 FOHM, Participants: HCS, BHTC, NCPA, SIK, TA, ANSES, MOHIT, NTAKD, NOMA, MS, NLZOH, CSJA, FOHM, UK-DOH, 1-36 Months)

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 FOHM, Months 1-36) [D.5.3; D5.4]

A report on the legal situation of accessing/transfer information up to the level of business confidential regulated in EU-regulation, MS national legislation and existing contracts between EU-CEG system owner and MS in the role of information owners will be produced by external legal specialist. The classification model in task 1.1 will be extended to classify also confidential data and most likely also non

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**Work Package 6: Tobacco product evaluation**

Start month: 1
End month: 36
Work Package Leader: ICO
Description of work

Objective 1: To perform a needs assessment evaluation of EU regulators with regards to aspects of priority within EU-CEG (Lead ICO; Participants: HCS, BHTC, SIK, ANSES, BfR, CERTH, HTS, HSE, IRFMN, IS, MOHIT, NTAKD, RIVM, NIPH, MS, NLZOH, ICO, CSJA, FOHM).

Task 1.1: To perform a qualitative needs assessment of EU regulators so as to flag issues of importance to EU MS. (M6) Within this process a questionnaire will be sent to all EU MS regulators in which their opinions and experience will be requested with regards to their potential areas of priority that they wish to handle first. This process will commence immediately with the start of their JATC so as to set the base, expectations and issues that EU MS regulators may have. It is likely that this survey will be performed in close collaboration with Task 1.1 of WP7 (handling e-cigarettes).

Objective 2: To assess tobacco product information as submitted data via the EU-CEG (Lead ICO, Participants: HCS, BHTC, SIK, ANSES, BfR, CERTH, HTS, HSE, IRFMN, IS, MOHIT, NTAKD, RIVM, NIPH, MS, NLZOH, ICO, CSJA, FOHM).

At the start of Objective 2 we will create an analysis plan. A list of priority analyses/investigations will be formulated so that when the data for WP7 becomes available that analyses can be quickly performed.

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.

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.

Both the above tasks can commence at a theoretical level from M6, however the actual data analysis needs the existence of original data from WP5. In light of the above, a list of priority analyses/investigations will be created so that when the data becomes available that analyses can be quickly performed. These priority analyses will be also based on the information collected through the survey in Task 1.1 of W6.

Objective 3: To monitor tobacco product ingredient and additive data (Lead ICO; Participants: HCS, BHTC, SIK, ANSES, BfR, CERTH, HTS, HSE, IRFMN, IS, MOHIT, NTAKD, RIVM, NIPH, MS, NLZOH, ICO, CSJA, FOHM, UK-DOH; Months 6-36) [D6.2 and D6.3]

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. This statistical and qualitative analysis can take place only after the provision of the original data in WP5.

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). Within this process we will statistically evaluate the differences and assess if these variables are appropriately used (or misused) by the manufacturers or importers.

Task 3.3: In collaboration with WP8, to qualitatively assess the submitted emission data for tobacco products. The common reporting format collects information on emissions of tobacco products and within this Task collaborations between WP6 and WP8 will be facilitated so as to combine the data analysis of WP6 with the
laboratory verification processes of WP8.

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 may also support activities outlined in Commission Implementing Decision (EU) 2016/786 of 18 May 2016 laying down the procedure for the establishment and operation of an independent advisory panel assisting Member States and the Commission in determi

Work Package 7: E-cigarette product evaluation

Start month: 1
End month: 36
Work Package Leader: HCS

Description of work

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, UKDOH, 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 would aid the identification of potential areas of prioritisation and that could address the needs of EU MS regulators. Within this process a questionnaire will be sent to all EU MS regulators in which their opinions and experience will be requested. This process will commence immediately with the start of their JATC so as to set the base, expectations and issues that EU MS regulators may have. It is likely that this survey will be performed in close collaboration with Task 1.1 of WP6 (handling tobacco products). [D7.1]

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, FOHM, UKDOH, Months 6-36) [D7.3 and D7.5]

At the start of Objective 2 we will create an analysis plan. A list of priority analyses/investigations will be formulated so that when the data for WP7 becomes available that analyses can be quickly performed. This data comes from EU-CEG and as available through the mechanisms outlined in Art20(7) of the TPD. These priority analyses will be also based on the information collected through the survey in Task 1.1 of W7.

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. Within this task the relevant data as provided by WP5 will be analysed with statistical software at a quantitative level so as to investigate into cross EU MS comparability and map unique and/or emerging product characteristics. This process will be repeated for each time original data is provided by WP5.

Task 2.2: To monitor product presentation (as included within Section 3 of Annex 1 of the Commission Implementing Decision 2015/2183) and sales/market data (as specified in TPD Article 20(7) as collected by the competent authorities so as to investigate into cross EU MS comparability and map unique and/or emerging
product characteristics.
Task 2.3: Evaluate the toxicological information on ingredients as submitted through EU-CEG and in line with TPD Art20(2) and Sections 3,4 and 6 of Annex 1 of the Commission Implementing Decision 2015/2183 with regards to the product's ingredients and emissions, including when heated, and referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect.
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, FOHM, UK-DOH; Months 6-36) [D7.3 and D7.5]
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. Task 3.2: To assess the emission data and their equivalent emission protocols as submitted through EU-CEG (according to Section 3 of Annex 1 of the Commission Implementing Decision 2015/2183) and to collect and scientifically review emission protocols for e-cigarettes that are under development by different international bodies. This will be performed in cooperation with WP8. The methodologies of these emission protocols will be compared and a report will be prepared comparing all e-cigarette emissions from EU-CEG and international protocols. A snow ball analysis technique will be used to identify the relevant international; protocol

Work Package 8: Laboratory verification, collaboration and analyses
Start month: 1
End month: 36
Work Package Leader: IRFMN

Description of work
Objective 1: To develop requirements of independent laboratories for ingredient evaluation (Lead IRFMN, Months 1-24) [D8.1 and D8.2]
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 independency. Within this task, various MS competent authorities will be enquired, through specific surveys, to collect updated information about the laboratory presence, activities, and distribution across various countries. (M 1-12) IRFMN will prepare a draft of the specific survey form, necessary to map EU laboratories and their activities, which will be submitted to all MS CAs. Each WP8 partner will review the draft. By consensus, a final form will be prepared. IRFMN will submit to all MS CAs the final version of the questionnaire. WP8 partners will assure, also through direct contact, that the forms are filled by various CAs within the scheduled timetable for all the 28 MS. A report will be prepared by IRFMN in collaboration with all WP8 partners.
Task 1.2: To collect and review laboratory based protocols for ingredient, contents and emission evaluation within all EU MS authorities (M1-20). Through the
collaboration with MS competent authorities, we will collect protocols for emission evaluation of both tobacco products and electronic cigarettes. The available protocols will be critically reviewed by WP partners in WP8 (Tobacco) and WP7 (e-cigarettes) respectively.

IRFMN will prepare a draft of the survey form on the protocols used for ingredient, contents and emission evaluation which will be submitted to various European laboratories, both identified in Task 1.1 and proposed by international experts (Task 3.1). Each WP8 partner will review the draft. By consensus, a final questionnaire will be prepared. IRFMN will submit to all European laboratories the final version of the form possibly supported by a cover letter from each corresponding CA. In case of non-response of European laboratories, we propose to notify it to the corresponding national CA, in order to jointly decide how to improve response rate. IRFMN, CERTH, CSJA and RIVM, with the contribution of all WP8 partners, will conduct the review of the laboratory based protocols. The review will form the base of the discussion on laboratory capacity requirements at the internal Meeting 1 (Task 1.3).

Task 1.3: To develop laboratory capacity requirements for ingredient, content and emission evaluation. (M 8-24) The criteria used for approval and the methods of monitoring applied will be defined by consensus during a dedicated meeting (WP8 internal Meeting 1, M14) among WP8 participants and will include but are not limited to ISO fulfilments, instrumental capacity, lab independency.

The WP8 internal Meeting 1 will be organized in Milan by IRFMN. During the meeting, after having defined the internal rules to reach consensus agreement, WP8 partners will define a list of chemicals categories, instruments and methods to be considered for the laboratory capacity requirement documents, also taking into account the review developed in Task 1.2. For each chemicals category considered, WP8 partners will provide during the meeting a proposal on the capacity requirements for independent laboratories. IRFMN, CERTH and CSJA will then prepare a draft of the requirements, to be revised by all other WP8 partners. WP8 partners will then identify possible lacks of internationally agreed approaches on laboratory testing for tobacco products and electronic cigarette data. The proposed laboratory testing approaches and requirements will be described in the report [D8.2].

Objective 2: To review laboratory analysis activities performed by MS and to assess comparability across laboratories. (Lead IRFMN, Months 1-36) [D8.3 and D8.4]

Task 2.1: We will review laboratory activities routinely performed by MS competent authorities, critically evaluating the quality of these activities a
Task 1.1: Compose of an assessment/evaluation framework and guidelines for ‘good experimental practising’. To provide guidelines on how the enhanced reporting documents on priority additives will be judged an assessment and evaluation framework will be composed. This framework will be of importance for both the JA consortium, the panel of peer reviewers, and the tobacco industry. Aspects that will be included in this framework are the parameters and boundaries defining which information is regarded as good/sufficient, and in which situation more information is needed. Information of the recently published SCHEER opinion II on Additives used in Tobacco Products will be used as a basis for this framework. To anticipate on the study design and parameters used for enhanced reporting by industry themselves, we will prepare a ‘good experimental practicing’ (GEP) guideline. In this guideline experimental study characteristics will be described and recommended which will also be used to judge the studies on priority additives by the peer reviewers in the assessment and evaluation framework. For the different type of studies these guidelines will elaborate for example on the preferred study design, experimental exposure (and control) conditions, exposure duration and intensity, sample size etc. Scientific information and best practices in experimental designs in each field of research (toxicity, addictiveness and characterising flavours), will be used as basis for the composition of the GEP guidelines. RIVM and BfR will be concerned with the writing of these documents, partners in this task will add and review in the process both by regular teleconference calls and by electronic document editing.

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, FOHM. Months 12-36).

Task 2.1: To obtain, (translate) and evaluate the type of information on enhanced reporting of priority additives that is submitted. (Months 12-36). CSJA will evaluate the submitted documents describing experimental results per priority additive, by examining duplicates between products, manufacturers and countries. An inventory of the available documents on each priority additive will be reported on by CSJA in collaboration with RIVM. Any lack of reports on specific topics will be recorded and consequences and actions will be discussed. In addition, results of the analysis on basic information on these priority additives will be obtained by RIVM from WP6 and incorporated in the evaluation. In the case of an excessive amount of enhanced reporting documents submitted, a selection of the most relevant documents will be made for each priority additive by CSJA and RIVM. If (selected) reports are only available in the local language, these must be translated into English.

Task 2.2: To create, organise 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 (Month 21-25).

The first step taken by RIVM (in consultation with consortium partners in this task) is to identify the specific field of expertise that is needed and present in the consortium to perform the peer review on priority additives with regard to toxicity, addictiveness and characterising flavours. Also, an inventory will be made of MS obliged to perform the review of enhanced reporting on priority additives.
themselves. A second step discussed with consortium all partners involved in this task, is to define a method of the peer review procedure, e.g. how to divide the topics (on additive or field of expertise, how many peer reviewers per topic etc.). An
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Layman version of the final report
BATUT-IANPH
Joint Action on Tobacco Control (JATC)
Expected on: 16/10/2020
This is a short (e.g. 10 pages) version of the final report, written for the interested public as a target group.

Final dissemination report
BATUT-IANPH
Joint Action on Tobacco Control (JATC)
Expected on: 16/10/2020
At the end of the project a dissemination report that will indicate the extent of dissemination activities will be developed. The dissemination report will include all public results with qualitative and quantitative indicators and ensuring the visibility of EU co-financing.

Interim evaluation report
AGES
Joint Action on Tobacco Control (JATC)
Expected on: 16/04/2019
The evaluation report of M1-18 activities.

Final evaluation report
AGES
Joint Action on Tobacco Control (JATC)
Expected on: 16/09/2020
The evaluation report of activities from M18-35
Second half evaluation report
AGES
Joint Action on Tobacco Control (JATC)
The evaluation report of activities from M18-36

Report on TPD mapping and sustainability activities including in house capacity
MoH CY
Joint Action on Tobacco Control (JATC)
Expected on: 16/04/2019
An outline of the capacity and sustainability possibilities across EU MS, half way through the project.

Sustainability plan, including scenarios for long-term sustainability
SU (SE)
Joint Action on Tobacco Control (JATC)
Expected on: 16/10/2020
The overall WP4 sustainability plan for the continuation of activities post the JATC.

Report on the principles to distinguish what data is public non confidential
HCS
Joint Action on Tobacco Control (JATC)
Expected on: 16/04/2019
A report that would outline the parameters which could be used to define the confidentiality of submitted data through EU-CEG.
Technical solution for public non confidential data
FoHM
Joint Action on Tobacco Control (JATC)
Expected on: 16/04/2019
This report will provide the technical solution for securely accessing and processing public non confidential data including best practices on making data available to the general public at national level.

Proposal of permanent mechanism for sharing of EU-CEG data
FoHM
Joint Action on Tobacco Control (JATC)
Expected on: 16/04/2020
As data sharing should continue after the end of the JATC, this report would include the proposal of how this activity can be sustained.

Report for M18-34 on the potential improvements/alterations identified
HCS
Joint Action on Tobacco Control (JATC)
Expected on: 16/08/2020
Report for M18-36 on the potential improvements/alterations identified

Report for M18-34 on the potential improvements/alterations identified
HCS
Joint Action on Tobacco Control (JATC)
Report for M18-36 on the potential improvements/alterations identified

First report on tobacco product data analysis
ICO
Joint Action on Tobacco Control (JATC)
Expected on: 16/04/2019
The results of the first data analysis.
Second report on tobacco product analysis
ICO
Joint Action on Tobacco Control (JATC)
Expected on: 16/08/2020
The results of the second data analysis.

First report on e-cigarette product data analyses
HCS
Joint Action on Tobacco Control (JATC)
Expected on: 16/04/2019
First report on e-cigarette product data analyses

Report on a proposed system for the reporting of adverse events
HCS
Joint Action on Tobacco Control (JATC)
Expected on: 16/10/2019
A reporting system for adverse events must be developed as noted in the TPD, this report would outline the requirements for such a system.

Second report on e-cigarette product analyses
HCS
Joint Action on Tobacco Control (JATC)
Expected on: 16/09/2020
The results of the second data analysis. Including information on the e-cigarette emissions and international protocols.
HCS
Joint Action on Tobacco Control (JATC)
The results of the second data analysis. Including information on the e-cigarette emissions and international protocols

Report on the requirements for laboratories
IRFMN
Joint Action on Tobacco Control (JATC)
Expected on: 16/08/2019
A report on the technical requirements and standards that TPD accredited laboratories should use.

Report on the results of inter-laboratory variability of EU MS emission data
IRFMN
Joint Action on Tobacco Control (JATC)
Expected on: 16/09/2019
Evaluation of the comparison between European laboratories.

Report on the replication of laboratory measurements
IRFMN
Joint Action on Tobacco Control (JATC)
Expected on: 16/08/2020
Report on the results of the replication tasks.

Report on the replication of laboratory measurements
IRFMN
Joint Action on Tobacco Control (JATC)
Report on the results of the replication tasks.

An assessment/evaluation framework and guidelines for ‘good experimental practicing’
RIVM
Guidelines on how the enhanced reporting documents on priority additives will be judged and evaluation framework will be composed

To report on type of information from the EU-CEG system on enhanced reporting of priority additives
RIVM
Joint Action on Tobacco Control (JATC)
Expected on: 16/10/2018
Report of the information available on priority additives as submitted to EU MS

Report on the peer review of the enhanced reporting information on priority additives
RIVM
Joint Action on Tobacco Control (JATC)
Expected on: 16/10/2019
Report on the peer review outcomes

Evaluation reports and toxicological data on additives which may be subject to enhanced reporting
RIVM
Joint Action on Tobacco Control (JATC)
Expected on: 16/04/2020
Final WP9 report

First periodical technical and financial report
HCS
Joint Action on Tobacco Control (JATC)
Expected on: 16/04/2019
This report describes the activities carried out, milestones and results achieved in the first half of the project. Deliverables can be attached as annexes.
Evaluation reports and toxicological data on additives which may be subject to enhanced reporting
RIVM
Joint Action on Tobacco Control (JATC)
Final WP9 report

Final report
HCS
Joint Action on Tobacco Control (JATC)
Expected on: 16/10/2020
This report describes the project implementation and the results achieved. The deliverables are annexed.

Final report
HCS
Joint Action on Tobacco Control (JATC)
This report describes the project implementation and the results achieved. The deliverables are annexed.

Web-site
BATUT-IANPH
Joint Action on Tobacco Control (JATC)
A website that explains in detail the layman aspects of the project and can be a vehicle for further dissemination.

Report of the WP6 needs assessment evaluation from EU MS regulators
ICO
Joint Action on Tobacco Control (JATC)
Published on: 31/07/2019
This report will outline the results of task 1.1 where EU MS regulators would provide feedback of what they need/expect from the tobacco product data handling in EU/CEG.
Technical solution for securely accessing and processing public non confidential data
FoHM
Joint Action on Tobacco Control (JATC)
Published on: 29/07/2019
As the EU-CEG data are stored centrally and contain also potentially confidential data, this report will indicate the IT solutions for the transfer of data for analyses.

Report for M1-18 on the potential improvements/alterations identified through Task 3.1
FoHM
Joint Action on Tobacco Control (JATC)
Published on: 29/07/2019
This report would propose alterations/improvements to the EU-CEG reporting format and submission process.

Report of the WP7 needs assessment evaluation from EU MS regulators
HCS
Joint Action on Tobacco Control (JATC)
Published on: 29/07/2019
This report will outline the results of task 1.1 where EU MS regulators would provide feedback of what they need/expect from the e-cigarette product data handling in EU/CEG.

Checklist for e-cigarette product compliance to the TPD
HCS
Joint Action on Tobacco Control (JATC)
Published on: 29/07/2019
This checklist would be developed to help regulators monitor in the long term e-cigarette compliance easier.

Report on the status quo of laboratories that
An overview of the status quo of tobacco product laboratories in Europe.

Evaluation plan is finalised, including communication and reporting plan, methods, techniques and instruments for data collection, and delivered to Coordinator and CHAFEA.

As the EU-CEG data belongs to each respective EU MS, specific legal requirements should be met to allow for sharing of data. If needed a template for data exchange agreement will be provided.

A leaflet to promote the project will be produced in the beginning. The leaflet will include information about the project, its objectives and expected outcomes, the partnership etc. and it will be used in all partners’ contacts with stakeholders.

A website that explains in detail the layman aspects of the project and can be a vehicle for further dissemination.