Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP3- D3.1 Evaluation Plan

Circulation: Public
Authors: AGES
Date: 23 April 2018
Doc. Ref. N°: D3.1

This document is part of the project / joint action '761297 / JATC' which has received funding from the European Union's Health Programme (2014-2020)."

Contributing authors (in alphabetical order):

Stefanie Kirchner, BSc, MPH (AGES)

Fiona Pastler (AGES)

Mag. Dr. Iris Schroll (AGES)

Mag. Dr. Friedrich Sövegjarto (AGES)

http://www.jaotc.eu

TABLE OF CONTENT

List of abbreviations and acronyms

AGES	Austrian Agency for Food and Health Safety
LogFrame	Logical Framework for Evaluation
TPDII	Tobacco Products Directive II
WP	Work-package
JATC	Joint Action on Tobacco Control
MS	Member States of the European Union
CEG	Common Entry Gate of the European Union
QQ	Quality Questionnaire
TG	Topic Guide

List of tables

1. Abstract

The `Joint Action on Tobacco Control´ project (hereafter referred to as JATC) is an action funded by the European Union´s Health Programme (2014-2020). It is being implemented by 31 project partners of 28 EU Member States. Both its development as well as its implementation is accompanied by an evaluation concept which is being described in the subsequent chapters.

The main purpose of the evaluation is **to optimize the implementation of the JATC and to ensure that it meets all objectives envisaged.** It has been 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 will a) measure to what extent the project **objectives have been achieved**, b) measure if the **outcomes of the JATC meet the needs of the project´s target group** and c) optimize **the processes** used to ensure that the project activities are implemented as intended[1].

The respective **evaluation plan** specifies the procedures and standards for the implementation, monitoring and evaluation of the project, according to specific **performance & quality indicators**. In terms of methodology the evaluation will apply a mixed-methods design consisting of stakeholders' interviews, focus groups and the collection of feedback on project activities via standardized questionnaires. The recipients of the evaluation results are the project partners of the JATC. Accountability, which highlights cost-effectiveness, would be preliminary relevant for funders and is therefore not focused in this evaluation. This approach is also reflected in the budget for this internal evaluation.

Throughout the project period, but in particular towards the project´s end, the evaluation results will be a useful **guide to make 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 Member States.

2. Project Description

Health Situation in the EU

Smoking and other forms of tobacco consumption are considered the single most important cause of preventable morbidity and premature mortality worldwide, with tobacco being the major single cause for premature deaths in the European Union (EU). The TPDII lays down rules governing the manufacture, presentation and sale of tobacco and related products.

[1] The activities and design of the evaluation, including the objectives and outcomes, are based on the project proposal written by the coordinating team.

One key aspect of the TPDII is the development of an EU common reporting format for submission of data on ingredients contained in tobacco and related products and disclosure of the collected data to the public. Knowledge on tobacco and e-cigarette ingredients, additives and technical design is important to be able to formulate and monitor European tobacco control policies and product evolution.

Project Purpose

The **general objective** of the project is to provide support for the implementation of the TPDII throughout the 28 EU MS.

The **specific objectives** of the project are managed within 9 WPs and formulated as follows.

Objective 1: To ensure appropriate coordination and evaluation.

Objective 2: To support the dissemination of information to the public, regulators and researchers.

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

Objective 4: To monitor and provide support to the tasks of tobacco and e-cigarette product regulation.

Objective 5: Assist EU MS networking and collaboration between laboratories for tobacco evaluation.

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

Objective 7: To integrate the JATC results into national policies and enhance EU networking between MS.

Overall the actions to be performed bring significant added value to the existing public health knowledge as the vast majority, if not almost all of the data submitted, has never been evaluated on a comprehensive scale.

Expected Outcome

The expected outcomes of this project are related to the main target groups and include but are not limited to the following:

- Increased EU MS implementation of the TPDII through the provision of support and technical/scientific capacity to EU regulators.
- Increased EU MS regulator training through the provision of capacity building (toolkits, e-learning).
- Common approach on handling tobacco product evidence based on decisions across EU MS, within the context of their national legislative approach.
- Increased data sharing and collaboration between EU MS on tobacco product regulatory science.
- Responses to questions on `burning topics´ as brought forward by EU MS regulators.

- Increased literacy on tobacco product design, constituents and toxicity by regulators and the public.
- Close monitoring of e-cigarette compliance to the TPDII across the EU MS.
- Increased knowledge of e-cigarette design parameters, ingredients and emissions.
- Enhanced collaboration between EU MS laboratories for tobacco product ingredient and emission measurement.
- Increased scientific scrutiny and decisions on potential priority additives within tobacco products.
- For the general public and researchers, greater access to data on tobacco products and e-cigarettes which would be able to fuel population awareness and enhance research and policy actions. The provision of such public data will be an unprecedented opportunity for tobacco control research.

Resources

The total budget of this JATC is 2.5 Million, for which 80% of European Commission contribution was requested. The criteria of eligibility for this share of contribution are formulated by CHAFEA and were fulfilled for the JATC as outlined in the proposal.

The budget is designed to provide an appropriate level of resources for the successful achievement of its objectives. The major expenditure in the budget is staff cost with 87% of total budget, including salary (83%) and subcontracting (4%).
To reach the expected outcome the distribution of resources was negotiated as follows. 73% of the budget is allocated for the five technical WPs and 27% to four horizontal WPs, including a share of 6% for evaluation activities of WP3.

Activities and Output

The main activities of this project include the development of the functionality of the lately introduced CEG tool. The collection and handling of data on tobacco products and e-cigarettes will be assessed from a legal, regulative and scientific perspective and improved accordingly. It is aimed for the development of a shared perspective of MS on the reported data for the purpose of cooperative data usage. Moreover the independency and an up-to-date approach of activities of MS will be strengthened. A framework for enhanced reporting obligations considering additives will be developed.
The activities are designed taking the national context and history into account while addressing specific technical and legal aspects.

The output of the project includes plans, reports, assessments, compliance checklists, technical solutions, legal consolidations, proposals for future actions and improvements, frameworks and guidelines, leaflets and a website.

Structure

The JATC is organised through four horizontal WPs and five technical core WPs.
The **horizontal WPs** content aims at securing the project's success by **proficient management, organisation and communication.**
WP1: Coordination of the project
WP2: Dissemination of project result
WP3: Evaluation of the project
WP4: Sustainability of project result and integration into national policies

The **technical WPs** content aims at securing the project's success by developing **excellent scientific and technical expertise.**
WP5: EU CEG data extraction and handling
WP6: Tobacco product evaluation
WP7: E-cigarette product evaluation
WP8: Laboratory verification, collaboration and analyses
WP9: Additives subject to enhanced reporting obligations

3. Evaluation Characteristics

The planned evaluation constitutes WP3 of the JATC project and has thus the character of an internal evaluation. It has a participatory approach, and aims at constant interaction between stakeholders and at creating a mutual supportive environment for the benefit of the JATC.

Evaluation Objectives

The evaluation aims at

a) assessing to what extent the project **objectives have been achieved**,
b) assessing if the **outcomes of the JATC meet the needs of the project´s target group**, and
c) optimising the implementation of project activities so as to ensure the production of all outputs envisaged.

Object of the Evaluation

Objects of the evaluation are the JATC project as a whole as well as its work packages.

Type of Evaluation

There are many different ways of classifying evaluations most of which refer to the following features: type of data, methodological approach and evaluation purpose.

- Type of data

One of the most common classifications of evaluation types was developed around 30 years ago by Donabedian (2003) for quality assurance in hospitals. It differentiates between `process quality´, `outcome quality´ and `structural quality´. These dimensions are based on the following data:

- Process data: describe the entire process during the implementation of projects/programs
- Outcome data: data on the impacts on the target group and on the costs of the project/programs
- Structural data: data related to the structural conditions of project implementation, such as location of intervention, qualification of project implementers, target group characteristics, etc.

Since for the planned evaluation all three types of data will be used it will be a combination of structural, process, and outcome evaluation.

- Methodological approach

A second classification refers to the general methodological approach and concerns not only evaluation, but social science in general. It is particularly important in terms of the meaningfulness of the evaluation results and differentiates between:

- Descriptive evaluation: records and documents phenomena without deriving new hypotheses
- Explorative evaluation: aims at the discovery of new phenomena, provides impulses for the development of new hypotheses and theories, results have a preliminary character
- Hypothesis-testing evaluation: aims to test hypotheses and theories, attempts to use the rules of probability theory and closing statistics to distinguish random effects from substantial ones, produces scientifically proven results.

The planned evaluation will have the character of a descriptive evaluation.

- Evaluation purpose

One of the most important questions in any evaluation is the intended use of its results. In the standard literature, five to six possible purposes are usually distinguished:

- Programming
- Improvement/optimisation (including learning from experience)
- Legitimacy/accountability
- Deepened understanding/knowledge gain
- Strategic purposes
- Improved internal and external communication

The main purposes of the planned evaluation are the optimization of project implementation as well as an improved internal external communication.

Timing of the Evaluation

The evaluation will accompany the implementation of the JATC project.

4. Evaluation Questions

In line with the overall aim of this evaluation, five central **questions** will guide the evaluation of this Joint Action.

1. Have the intended **outputs** of the JATC been delivered? How can they be improved?
2. How can the **quality** of the implementation of the JATC be optimized during the project period?
3. To what extent have the intended **outcomes** of the JATC been achieved? Which factors supported/hampered their achievement?

3.1. To what extent have the **procedures** for reporting, assessing and regulating tobacco ingredients, priority additives and e-cigarettes been improved? How?

3.2. To what extent has the **peer review process** and assessment of comprehensive studies been improved? How?

3.3. To what extent has the work-sharing and **cooperation** between Member States and collaboration with transnational networks been improved with regard to laboratory capacity, verification of submitted data, comparability of submitted data? How?

5. Work Package 3 – Evaluation of the Action

The specific **objectives** of WP3 are

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 the project's quality assurance.
2) to implement the evaluation plan throughout the duration of the project.

The objectives have been formulated to be specific, measurable, acceptable for the target group, realistic and time-bound (SMART), which will be illustrated with the following table. To monitor and evaluate the indicators of evaluation itself is a component of the self-assessment that is important to strengthen objectivity.

Table 1: Indicators of evaluation as component of self-assessment

WP 3 – Evaluation of the Action	
Objectives	**Target Values**
Process and Indicator	---
Create a *Logical Evaluation Framework* consisting of process, output and outcome indicators	1
Finalise instruments for data collection	3
Prepare an evaluation plan	1
Collection and analysis of qualitative and quantitative WP3 evaluation data	3
Write interim evaluation report	1
Develop final evaluation report	1

Output Indicator	---
Logical Evaluation Framework (LogFrame) delivered and approved by WP leaders	1
Instruments delivered	3
Approval for evaluation plan obtained from the steering committee	1
Findings of qualitative and quantitative WP3 evaluation data presented and communicated	3
Interim evaluation report approved by CHAFEA, EC, and steering committee	1
Final evaluation report approved by CHAFEA, EC, and steering committee	1
Outcome Indicator	---
Effective evaluation as identified by the JATC consortium	Results of the *Quality Questionnaire* show a median general satisfaction of at least 7 in the last two questionnaire surveys
Systematic outcome monitoring	All outcomes from WP1-9 are considered in the final evaluation plan at the end of the project

6. Evaluation Team and Stakeholders

The general stakeholder groups for the JATC are defined by WP1 in the proposal. This section highlights the role of stakeholders for internal evaluation activities.

General Stakeholder Group of the JATC

- **EU Regulators and national policymakers, competent authorities from 28 EU MS, 31 partners**

At the beginning of the JATC it is necessary to get an overview of the starting environment which will be assessed against the perceived outcome of the JATC at the end of the project. The 28 EU MS competent authorities are the primary beneficiaries of the outcomes of the JATC and will therefore be focused on for outcome measurement of WP3. They will be represented or nominated by WP leaders.

- **International and national tobacco control stakeholders**, **researchers and general public**

This stakeholder group is indirectly beneficiary of the evaluation results by receiving improved outcomes of the project.

Stakeholders of the Evaluation

The following stakeholders are direct **beneficiaries** of the evaluation results and can expect different types of information, suggestions and recommendations for potential improvements in their work (below marked with **B**).

Some of the stakeholders are also **data suppliers** (below marked with **DS**), which is a common approach if the main purpose of evaluation is to support the developmental process of a project (see section 1. Abstract).

Furthermore they do take an active part in evaluation **activities** (below marked with **A**)

- **JATC Consortium (31 partners)**

DS: Regular participation in the survey on the quality of project processes.

B: Information on the overall project development, explanations for success and potential pitfalls.

- **WP Leaders**

A: Definition of process and output indicators for the objectives of the WPs in the form of deliverables. Review of outcome indicators for the objectives of the WPs. Review of the QQ questions and pilot testing of instruments.

DS: Nomination or representation of interview partners and members of focus groups for outcome measurement.

B: Potential improvements specific to each WP. Feedback on development of specific process, output and outcome indicators of each WP.

- **Coordinator**

A: Definition of expected outcomes of the JATC. Definition of outcome indicators for the specific objectives of the JATC. Review of the instruments for data collection (QQ and TQ). Management of the routine monitoring system as input for the *LogFrame*. Incorporation of evaluation results in adaption of project planning and management.

B: Potential improvements or changes in management and coordination activities to improve the quality of project processes. Suggestions to improve the processes of WPs and outcomes.

- **Steering Committee**

A: Feedback on the evaluation plan. Review of the instruments for data collection. Discussion of evaluation results. Interpretation and definition of propositions.

B: Suggestions for decision making on changes of WP scopes and potential changes in budget distribution.

The most efficient way to use available resources for WP3 is to incorporate the project team in the evaluation activities where appropriate. Nevertheless, specifically in internal evaluations, it is of utmost importance to secure the **independency** and **objectivity** of evaluation activities. Therefore, the persons involved in the JATC from **AGES** are either assigned to the horizontal WP evaluation or to the technical WPs, and the leading function of AGES is limited to WP3. (A list of tasks per person is available in Annex D.)

Moreover, a **subcontractor** specialised in evaluations on international level will address the most sensitive aspects of the evaluation activities and supports the internal evaluation team by offering new perspectives and additional insights. (Subcontractor details are available in Annex E.) The tasks of the subcontractor include the following.

- Review of the evaluation plan and evaluation reports
- Review of the data collection instruments (questionnaires, guidelines for interviews and focus groups).
- Support the qualitative data analysis (interviews and focus groups).

Table 2: Responsibilities of the evaluation team

Individual	Organisation	Role	Responsibilities
Friedrich Sövegjarto	AGES	Supervisor	Advice, primary data collection, reviews
Iris Schroll	AGES	Main Evaluator	Design, methods, instruments, data management, primary and secondary data collection, reports
Stefanie Kirchner	AGES	Evaluator	Methods, instruments, data management, primary and secondary data collection, reports

Juliane Pichler	AGES	Evaluator	Methods, instruments, data management
Fiona Pastler	AGES	Evaluator	Data management, primary data collection, reviews
Birgitta Landfahrer Barbara-Theresa Mayer	AGES	Assistant	Administration, finances, Update *LogFrame*
Tanja Komericki-Strimitzer	AGES	Analyst	Technical support, statistics, qualitative and quantitative data analysis

7. Methodology

7.1. Combination of Methods

Several sources and types of data, each relating to different indicators, are used to evaluate the JATC.

The following table provides an overview on indicators, instruments, quality and types of data used within WP3.

Table 3: Overview on indicators, instruments, quality and type of data

Indicator Type	**Instrument** for Data Collection	**Quality** of Data from Evaluator´s Perspective	**Type** of Data
Process	Participant portal* Additional information will be collected via email correspondence as agreed with the WP leaders	Secondary data	Quantitative

Output	Participant portal* Additional information will be collected via email correspondence as agreed with the WP leaders	Secondary data	Quantitative
Outcome	Qualitative interviews based on topic guide for interviews (TG) Focus groups based on topic guide for focus groups (TG) *Quality Questionnaire* (QQ) on the project progress	Primary data	Qualitative
Quality Assurance	Questionnaire to collect data on the quality of project procedures (QQ)	Primary data	Quantitative and qualitative

*information from the participant portal will be collected by the coordinating team

In social science three major mixed method designs are distinguished that combine qualitative and quantitative data (Kelle 2001). A) The convergent parallel design collects qualitative and quantitative data and examines if the two types of data show similar results. B) The explanatory sequential design starting with quantitative data provides explanations with later generated qualitative findings. C) The explanatory sequential design starting with qualitative data aims at validation and generalizing with quantitative findings.

During the project period all types of data will be collected, monitored and evaluated regularly, in the form of a convergent parallel design.

Where appropriate the qualitative outcome measurement by WP3 will be supplemented with quantitative findings from other WPs to show where different sets of data show similar results.

7.2.Outcome Measurement, Control Groups and Sampling

A standard approach for the assessment of outcomes is the counterfactual design, i.e. the comparison of intervention group and control group, in order to ensure that changes observed can really be attributed to the project/the intervention.

Since the whole possible population of EU MS regulators/competent authorities will possibly be invited to take part in the outcome measurement, no control group can be formed.

Nevertheless, it is appropriate to use a random selection process to identify interview partners with the criteria 'regularly involved in CEG data handling' and 'regularly involved in collaboration between MS'. As Morgan (2014) argues,

> *"this process of randomly drawing from a larger pool comes closer to the experimental procedure of `random assignment´ by removing the researcher from the decision about who will or will not be interviewed. Hence, rather than using random sampling for generalizability, a random selection from a pool of people who all meet your defining criteria eliminates any claim that you made a `biased´ choice about who to include as data sources."* (Morgan 2014:134)

The interview partners are separated by European region (see table 4) and responsibility (regulators and EU-CEG experts). Based on these criteria, an unrestricted randomisation will be performed and a total of 14 persons selected. In case of non-participation another person from the same region and the same profession will be randomly selected.

Table 4: List of European regions and countries (Ständiger Ausschuss für geographische Namen, StAGN, 2018)

European Region	**Country**
Southeast Europe	Bulgaria, Cyprus, Greece
Southern Europe	Italy, Malta, Portugal, Spain
Central Europe	Austria, Croatia, Czech Republic, Germany, Hungary, Poland, Slovakia, Slovenia
Western Europe	Belgium, France, Ireland, Luxembourg, The Netherlands, United Kingdom
Northern Europe	Denmark, Estonia, Finland, Latvia, Lithuania, Sweden

7.3.Benefit by Cooperation Between Work Packages

Monitoring and Evaluation

The monitoring of indicators is preliminary under the responsibility of WP1. Additional monitoring by WP3 is only put into place where new indicators are defined. The following table highlights central aspects of monitoring and evaluation (Salama, 2017).

Table 5: Comparison of monitoring and evaluation

Attribute	Monitoring	Evaluation
Main Focus	Collecting Data on Progress	Assessing Data and Critical Stages of the Process
Sense of Completion	Sense of Progress	Sense of Achievement
Time Focus	Present	Past – Future
Attention	Details	Big Picture
Inspiration	Motivation	Creativity
Periodicity	Continuous	Continuous
Support	Implementation of a Plan	Designing the Next Planning Cycles
Output Processing	Progress Indicators Need to Be Closely Monitored by a Few People	Evaluation Results Need to Be Discussed, Processed and Interpreted by All Stakeholders

Stakeholder Satisfaction and Recommendations for CEG-Data Handling

WP5 collects data on the satisfaction of MS competent authorities with the CEG system and provides recommendations for the improvement of data handling throughout the project period. WP3 conducts interviews on the starting environment (as part of the outcome measurement) and asks competent authorities about the satisfaction within the domain 'The EU-CEG in your country'. The information gathered with the interviews will be communicated to WP5 as input for the development of the CEG Questionnaire.

Outcome Measurement and Dissemination

Cooperation between WP2, WP3 and WP4 is fostered for the design of the data collection instruments, to have most appropriate outcome measurement questions, and for the dissemination of results for stakeholders.

8. Data Collection

8.1.Indicators

Process, output and outcome indicators are defined in close cooperation with WP leaders and delivered to the steering committee. 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.

Monitoring and evaluation will be guided by an M&E matrix. It has the format of a *logical framework*, yet adapted to the needs of the project. It summarizes the main project elements and will be used throughout the project period (see Annex B).

8.2. Instruments

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. This **quantitative secondary data** is evaluated with reference to the *LogFrame* matrix.

Most of the outcome indicators to monitor the overall expected outcome in the areas `enhancement of knowledge and literacy´, `collaboration between member states´ and `accesses to data´ are measured with three new instruments for **qualitative and quantitative primary 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´ is communicated to leader of WP5 as input for the development of EU-CEG questionnaire (see Annex A). The interviews are held with regulators and EU-CEG experts via webconferences at the beginning of the project. Interviewers´ notes and records are collected, analysed and findings interpreted according to the methods proposed in section `data analysis´.

Secondly, a **topic guide for focus groups** is developed to evaluate the outcomes at the end of the project period (see Annex A). Focus groups addressing the aggregated topics from the interviews

are held with representatives of each WP as well as the regulators and EU-CEG experts on general meetings at the end of the project. Where possible, the same interview partners for interviews and focus groups are chosen. Interviewers´ notes and records are collected, analysed and findings interpreted. Where applicable results will be communicated to WP leader 5 with the aim to feed into the initial development and final interpretation of EU-CEG questionnaire findings.

Thirdly, a **quality questionnaire** with the aim to monitor and evaluate the project´s procedures and quality throughout the project period is finalized and delivered to the steering committee (see Annex C). The questionnaire is divided into two parts (`Meetings and Teleconferences´ and `Project Progress´) and includes the domains `organisation of meetings´, `information quality´, and `communication and team work´. The questionnaire will be distributed digitally with an anonymous online survey tool to all participants of the Joint Action on a regular basis.

8.3. Reliability, Validity, and Bias

Reliability and Validity

If new instruments are used for data collection it is of importance that these instruments are established as reliable and valid.

Reliability on the one hand specifies that the collected data is `stable´ over time and across different persons. On the side of respondents this means that the interpretation of the questions does not significantly differ. Therefore, a review of instruments by WP leaders and pilot testing will be made. On the side of the evaluators this means that the interpretation of the findings on the same set of data does not differ significantly between evaluators (inter-tester reliability) or for one evaluator in different situations (intra-tester reliability). Therefore, two evaluators will analyse the same sets of data.

Validity on the other hand expresses that the collected data is the accurate information for the scope of the project. Again, a review of WP leaders will provide input for the appropriateness of asked constructs to the environment and project scope.

Bias in Data Collection

Interviewing participants in situations with two or more persons can provoke a bias due to social desirability. To minimise potential undesirable behaviour of interview partners the instruments and specifically the wording of the questioning will be reviewed by an external evaluator.

9. Data Analysis

Quantitative Data

The findings of the QQ will be analysed with SPSS and displayed with spider diagrams and linear models to visualise the development of the project´s situation over time. This is a common method used in participatory evaluation.

Qualitative Data

For the analysis of empirical data generated with interviews and focus groups, coding in accordance with the methods of Grounded Theory proposed by Strauss and Corbin (1998), an inductive approach to find categories (see also Mayring 2000), is applied:

Open coding: *"The analytical process through which concepts are identified and their properties and dimensions are discovered in data."* (Strauss & Corbin, 1998:101)

Axial coding: *"The process of relating categories to their subcategories, termed `axial´ because coding occurs around the axis of a category, linking categories at the level of properties and dimensions."* (Strauss & Corbin, 1998:123)

Selective coding: *"The process of integrating and refining the theory."* (Strauss & Corbin, 1998: 143) 53/130

The coding process will be supported by the computer program atlas.ti V7. Three main factors supported the decision for computer-aided coding: first, the number of interviews and other qualitative data; second, the amount of codes that evolved after the analysis of the first interviews; third, the possibility for quantitative data analysis. The evolving categories will be used for quantitative data analysis including co-occurrence analysis.

In the coding process the participants are approached as experts of their realities and the interviewer merely as the collector of information. This approach and the research question made it an appropriate choice to conduct the interviews in a narrative fashion. Narrative interviews are an appropriate method to get a better understanding of the meaning of a topic in a specific context and are therefore central in explorative studies.

10. Data Interpretation

As illustrated in section `methodology´ a mixed set of sources and methods is used to generate a comprehensive set of data. Qualitative and quantitative data will be triangulated where possible to strengthen the validity of the interpretation.

Moreover, the interpretation of the findings will be discussed within the steering committee to make most appropriate conclusions. Thereafter, the results will be communicated to JATC participants (see section `communication and reporting plan´) and are open for comments.

11. Timeline of Evaluation Activities

The following table shows a timeline of the main evaluation activities over the project period of three years. The first section illustrates core and general evaluation activities. The second and third sections specify activities for primary data collection on the project´s quality and the expected outcomes. The last section shows central steps to assure that the evaluation of this JATC is interactive, participatory, and becomes a joint learning process.

Table 6: Timeline of evaluation activities

	Evaluation Activities	Y1				Y2				Y3			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Process, Output Evaluation Management	Communication and reporting plan finalised	3											
	Instruments, methods and techniques defined	x											
	Evaluation plan distributed		**5**										
	Instruments for data collection finalised (*LogFrame*, *QQ*, Topic Guides)	x											
	Indicators defined		4										
	Indicators monitored			x	x	x	x	x	x	x	x	x	x
	Indicators evaluated			x	x	x	x	x	x	x	x	x	x
	Evaluation managed, communicated, coordinated and overviewed	x	x	x	x	x	x	x	x	x	x	x	x
	Evaluation results reported						**18**						**36**
Project´s Quality Assurance	*Quality Questionnaire* finalised	3											
	Quality Questionnaire distributed		x	x	x		x	x	x		x	x	
	Qualitative data analysed		x		x		x		x		x		x
	Quantitative data analysed		x	x	x		x	x	x		x	x	x
	Results of *Quality Questionnaire* communicated			x			x					x	

Outcome Measurement	Topic Guides for Interviews and Focus groups finalised	3											
	Interviews (semi-structured) on starting environment held	x	**6**										
	Focus groups on procedure, processes and cooperation improvements held									x	x	**33**	
	Qualitative data analysed	x	x							x	x	x	
Adaption of Evaluation	Results of *Quality Questionnaire* reviewed						x						
	Improvement for project procedures suggested							x					
	Results of indicator evaluation reviewed						x						
	Evaluation plan adapted							x					

Violet: month of milestone

Orange: month of deliverable

12. Communication and Reporting Plan

As stated in the initial section ‘Summary’ the central purpose of this evaluation is to support the developmental process of this project. Continuous communication is crucial to participatory evaluation approaches. Regular communication measures include but are not limited to the following:

- Face to face conversation
- Telephone calls
- Email
- Web conferences
- General meetings
- Topic meetings
- Publications on the website of the JATC
- Surveys
- Interviews and focus groups

The following table illustrates when, to whom and how major results and selected outputs are communicated.

Table 7: Communication and reporting plan

Communication Activities	Format	Delivery Month	Target Group	Method
Communication and Reporting Plan	Table	M3	Coordinator, WP leaders	Email
Instruments incl. *Quality Questionnaire,* Topic guide for semi-structured interviews and focus groups	Document	M3	Coordinator, WP leaders	Email
Process, Output and Outcome Indicators	Table	M4	Coordinator, Steering Committee	Email, Web Conferences
Evaluation Plan incl. *Logical Evaluation Framework*	Document	M5	CHAFEA, Coordinator, Steering Committee	Email, Consortium Meeting
Evaluation Results	Ppt. Presentation	M18/36	Coordinator, WP leaders, Consortium	Email, Consortium Meeting
Results of Quality Questionnaire	Ppt. Presentation, Short Report	M13/14 and M25/26	Coordinator, WP leaders, Consortium	Email, Consortium Meeting, Web Conference
Findings of Interviews and Focus Groups	Document, Ppt. Presentation	M6/33	Coordinator, WP leaders	Email, Web Conferences
Interim Evaluation Report	Document	M18	CHAFEA, Coordinator, Steering Committee	Email, Web Conferences, Consortium Meeting
Final Evaluation Report	Document	M36	CHAFEA, Coordinator, Steering Committee	Email, Web Conferences, Consortium Meeting

13. Limitation of Evaluation and Findings

No focus will be laid on inputs to the JATC (which would be central to prospective evaluations) and no assessment will be made of the (initial) allocation of resources for activities, including cash, supplies, personnel, equipment and training.

Outcome measurement is limited in the sense that it relies on the perceptions of participants of interviews and focus groups. No other primary quantitative data is collected by WP3 to measure the efficacy of the JATC.

Since there will be a high standard of confidentiality, especially with the collected data from survey, there will be limitations in the findings in the sense that critical issues raised may not be fiercely discussed with individual respondents. This includes a low risk of misinterpretation of results, which shall be moderated with a comprehensive review of instruments by several actors before they are used. Moreover, final conclusions will be drawn after discussion in the steering committee; a process is able to highlight potential ambiguities.

14. Ethics and Confidentiality

This evaluation approaches a high standard of **confidentiality**. Where data from individuals is collected, no track of identity will be made. This relates to interviews, focus groups and surveys.

The sampling or data collection methods are free from any bias in terms of race, ethnicity, gender, sexuality, parental status, ages, religion and disability. If related criteria are collected, it will be anonymous and only for the purpose of analysing, categorising and interpreting data.

There can be the need of justifying evaluation findings. In this case either anonymous indirect quotations or direct quotations with consent of respondents may be used as supportive elements.

Records are kept for 5 years after the end of the project.

The evaluation team devotes itself to the following values and **principles**, which are based on the CERN statement of ethics (Hughes & Nieuwenhuis, 2005:73):

- Evaluation as an essential element in the design and planning of any project, programme or innovative process.
- Evaluation that is integral to organisational and programme activities and not `bolted-on´.
- Evaluation that spans the whole lifecycle of a project or programme and which is formative as well as summative.
- Evaluation that is client centred, based on a non-dependency relationship and leading to long term client autonomy and sustainability.
- Evaluation that recognises the diversity of stakeholders and responds to their different needs by offering a wide range of review and evaluation products, tools and processes.
- Evaluation as a skilled intervention and a specialist field of knowledge and practice.
- Evaluation that is ethical, transparent, professional and responsible.
- Evaluation which is informed by a range of different approaches and theoretical perspectives to ensure congruence between the review and evaluation process and the policies, processes and practices being reviewed.

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Annex

A) Topic Guide for Interviews and Focus Groups (draft March 2018)

Declaration of consent for participation in interview

Joint Action on Tobacco Control- WP3 Evaluation of the action

Dear participant,

Thank you for agreeing to be interviewed on the starting environment of the Joint Action on Tobacco Control Project. Please read the following consent form carefully. If you have any questions do not hesitate to ask your interviewer. Before the interview can start both you and your interviewer should sign two copies of the consent form. You will be given one copy; the interviewer will keep the other copy. The interview will take approximately 60 minutes.

With your signature you approve to following:

- The interview will be audio recorded and a transcript (for parts of the interview) will be produced.
- Access to the interview transcript will be limited to the WP3 Evaluation of the action team and researchers who are part of the research process.
- The transcript of the interview will be analysed by Stefanie Kirchner/Fiona Pastler/Iris Schroll.
- Your interview will be anonymised. Any quotations or summary interview content cannot be referred to you in the future.
- Data relevant to the individual and data related to the content will be kept separate in order to remain the confidentiality of the participant.
- The transcript/the recording will be kept five years from the end of the project and will be destroyed afterwards.

Your participation is voluntary and your time and effort cannot be compensated financially. At any time and without giving reasons, you can withdraw from participation or demand that your data be (partly or fully) deleted. You will be given the chance to correct any factual errors in the transcribed parts before publication of the interim evaluation plan.

Any variation of the conditions described above will only occur with your explicit approval.

With your signature you confirm that you have read and understood the text of the declaration of consent and that all of your questions have been answered satisfactorily.

_____ _____

Name of the participant (in block letters) Signature of the participant

_____ _____

Name of the interviewer (in block letters) Signature of the interviewer

Date and place: _____

Date of webconference: _____

Between: _____ and _____

Topic Guide for semi-structured interviews

Introduction

- Introduce yourself
- Thank person for taking time for you today and offering to take part in this interview
- Tell participant what the interview will be about and which topics are covered
- Ask participant if you were allowed to do a tape recording
- Inform participant that notes may be taken during the interview to be able to come back to certain points later
- The participant is free to ask questions at any stage of the interview
- The participant is free to cut out passages of the transcript if he/she requests it
- If the participant wants to withdraw from the study, their data will not be used

Topics/Questions

<u>Implementation of the TPD II</u>

1. Please tell me something about the current situation in your home country regarding the implementation (administrative/operative) of the TPD II.
2. What would you like to change regarding the TPD II on European level?

   Topics for the participant:
   - Responsibilities
   - Current and future process of implementing the TPD II
   - Satisfaction and improvement
   - Challenges
   - Dissemination to public/target group and knowledge
   - Role of the European Commission

The EU-CEG in your country

3. Please tell me something about the current situation concerning the EU-CEG in your home country.

4. What would you like to change regarding the EU-CEG on the European level?

   Topics for the participant:
   - Operation of the system and updates
   - Responsibilities
   - Access to data, data handling and management
   - Additional features/other national data collection systems relating to the EU-CEG
   - Reporting process
   - Satisfaction and improvement
   - Role of the European Commission

Analysis of tobacco products and risk assessment

5. Please tell me something about the tobacco product testing and evaluation in your home country.

6. In your opinion, what would you like to change in the tobacco product testing and evaluation in your home country and on the European level?

   Topics for the participant:
   - Laboratories in your country
   - Stake of the tobacco industry in these laboratories
   - Critical review of studies on tobacco products
   - Study findings
   - Role of the European Commission

Cooperation between EU MS

7. Please tell me your view of the cooperation between Member States regarding the topic tobacco.

8. What would you like to change regarding cooperation between Member States on the European level?

   Topics for the participant:
   - Implementation of the TPD II

- EU-CEG
- Tobacco product analysis
- Useful cooperation
- Exchanging experiences
- Role of the European Commission

Joint Action on Tobacco Control

9. Do you know the Joint Action on Tobacco Control?

   Topics for the participant:
   - Important fields/areas
   - Outcome of the JATC
   - Expectations

10. Is there anything important you want to tell us that we have not mentioned?

Declaration of consent for participation in focus groups

Joint Action on Tobacco Control- WP3 Evaluation of the action

Dear participant,

Thank you for agreeing to participate in our focus groups as part of the *WP3- Evaluation of the action of the Joint Action on Tobacco Control Project*. Please read the following consent form carefully. If you have any questions do not hesitate to ask the interviewer. Before the focus group can start both you and the interviewer should sign two copies of the consent form. You will be given one copy; the interviewer will keep the other copy. The focus group will take 60 minutes approximately.

With your signature you approve to following:

- The focus group will be audio and video recorded and a transcript (for parts of the focus group) will be produced.
- Access to the focus group transcript will be limited to the *WP3 Evaluation of the action team* and researchers who are part of the research process.
- The transcript of the focus group will be analysed by Stefanie Kirchner/Fiona Pastler/Iris Schroll.
- The focus group will be anonymised. Any quotations or summary interview content cannot be referred to you in the future.
- Data relevant to the individual and data related to the content will be kept separate in order to remain the confidentiality of the participant.
- The transcript/the recording will be kept five years from the end of the project and afterwards will be destroyed.

Your participation is voluntary and your time and effort cannot be compensated financially. At any time and without giving reasons, you can withdraw from participation or demand that your data be (partly or fully) deleted. You will be given the chance to correct any factual errors in the transcribed parts before publication of the final evaluation plan.

Any variation of the conditions above will only occur with your further explicit approval.
With your signature you confirm that you have read and understood the text of the declaration of consent and that all of your questions have been answered satisfactorily.

_____	_____
Name of the participant (in block letters)	Signature of the participant
_____	_____
Name of the interviewer (in block letters)	Signature of the interviewer

Date and place: _____

Date of focus group: _____

Between: _____ and _____

Topic Guide for focus groups

Introduction

- Introduce yourself
- Thank everybody for participating today and offering to take part in this group
- Tell group participants what the focus group will be about and which topics are covered
- Ask participants if you were allowed to do a video recording
- Inform the group that notes may be taken during the interview to be able to come back to certain points later
- The participants are free to ask questions at any stage of the interview
- The participants are free to cut out passages of the transcript if they request it
- If a participant wants to withdraw from the study, their data will not be used

Topics/Questions

<u>Implementation of the TPD II</u>

1. Referring to the period of the last three years (of the project), what happened on the European level regarding the implementation of the TPD II?
2. What was the reason for the changes you saw?
3. What would you like to see in the future in your country and on the European level?

   Topics for the participants:
   - Changes
   - Current and future process of implementing the TPD II
   - Your own view/opinion
   - Satisfaction and improvement
   - Future tasks/challenges
   - Enhancement of public´s knowledge

The EU-CEG in your country

4. Referring to the period of the last three years (of the project), what happened on the European level concerning the EU-CEG?

5. What was the reason for the changes you saw?

6. Where would you like to see changes in the future regarding the EU-CEG?

   Topics for the participants:

   - Updates of the system
   - Access to data, data sharing, data handling and management
   - Additional features/Other national data collection systems
   - Long term educational intervention
   - Reporting process
   - Improvements
   - Future prospects/challenges/tasks

Analysis of tobacco products and risk assessment

7. Referring to the period of the last three years (of the project), what happened on the European level concerning tobacco product testing and evaluation?

8. What was the reason for the changes you saw?

   Topics for the participants:

   - Availability of Laboratories
   - Tobacco product information
   - E-cigarette product data
   - Long term educational intervention
   - Critical review of studies on tobacco products
   - Divergent study findings
   - Common approach
   - Communication and collaboration
   - Priority additives

Cooperation between EU MS

9. Referring to the period of the last three years (of the project), what happened on European level concerning the cooperation between Member States?

10. What was the reason for the changes you saw?

    Topics for the participants:

    - Implementation of the TPD II
    - EU-CEG
    - Tobacco product analysis
    - Useful cooperations
    - Partnership and information flow
    - Exchanging experiences
    - Future prospects

11. Is there anything important you want to tell us that we have not mentioned?

B) Logical Framework to the Joint Action

WP	Overall Objective	Specific Objective	**Purpose** Outcome Indicator	Target Value	**Results** Output Indicator	Target Value	**Activities** Process and Indicator	Target Value
WP1-Coordination	To ensure appropriate coordination and evaluation	To support overall management of the project.	Effective coordination as identified by the JATC project team through internal evaluation	Interim and final evaluation report show improved results of the Quality Questionnaire (QQ) by at least 5% (ratio across domains) in the last two questionnaire surveys	Consortium agreement signed by all parties.	31	Consortium agreement developed.	1
			Enhanced common understanding and sharing of the workplan within the JATC project team	Results of Quality Questionnaires on the meetings show a median satisfaction of 2 in the category `information quality´ in the last two questionnaire surveys	Project meeting minutes written	3	Project´s meetings held	3
					Steering committee meeting minutes written	3	Steering committee meetings held	3
			Enhanced collaboration between EU MS´ national authorities and EU-CEG experts and third parties or networks	Results of interviews and focus groups show improvement in the category `Cooperation between EU MS´	Established network	3 interactions	Ensure collaboration between individual WPs by linking up with third parties and networks	1
		To coordinate financial management.	Effective financial management as identified by the beneficiaries	Receipt of total grant amount of each beneficiary as defined in the grant agreement until the end of the project and communicated to the WP3 team by the WP1 team	Grant agreement signed by all parties.	31	Grant agreement developed.	1
					First periodical technical and financial report delivered.	1	Interim financial report written	1
					Final report approved by CHAFEA and EC	1	Final report written	1

		To support communication activities.	Enhanced knowledge and literacy of the JATC identified by regulators and competent authorities	Results of interviews and focus groups show improvement in the Joint Action on Tobacco Control across all domains	Set up of structure for external communication (with WP2)	1	Preparation of a structure for external communication (with WP2)	1
			High satisfaction of communication in the JATC communicated by the consortium	Results of Quality Questionnaires on the project progress show a median satisfaction of 2 in the domain `information quality´ and `communication and teamwork´ in the last two questionnaire surveys	Set up of structure for internal communication	1	Preparation of a structure for internal communication	1
		To provide scientific support to individual WPs.	High satisfaction in regards to the workshops communicated by the consortium	Results of Quality Questionnaires on the meetings show a median satisfaction of 2 in the category `information quality´ and a general median satisfaction of 7 in the last two questionnaire surveys	Special workshops on common research interests held	3	Organise special workshops on common research interests	3
		To communicate and report to the EC.	Extensive participation of EC in general meetings of the JATC	Participation of at least 1 member of the EC in 100% of consortium and steering group meetings	Attendance of (a) representative(s) of the EC at consortium and steering committee meetings and the final conference	100% attendance	Invitation of representatives of the EC to project meetings and dissemination events	3
		To address emerging issues related to the implementation of the TPD for which the JATC could contribute scientifically.	Effective issue management as identitied by the consortium	Results of interviews and focus groups show improvement in the Joint Action on Tobacco Control across all domains	feedback activities provided by the network of experts	6	Establish a network of experts providing feedback during the project period	min 6 experts

		To manage issues of ethics, confidentiality and absence of a conflict of interest.			COI forms signed by all partners	31	Absence of conflict of interest (COI) and confidentiality forms written	1
WP2-Dissemination	To support the dissemination of information to the public, regulators and researchers	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.	Enhanced knowledge and awareness on the JATC and TPD among target audiences as identified in section 3 of the current JATC proposal by the JATC project team, regulators, and EU-CEG experts	Results of interviews and focus groups show improvement in the Joint Action on Tobacco Control and the domain `Implementation of the TPD II´	Final dissemination report delivered	1	Dissemination plan and stakeholder analysis developed	1
					Project website visited	1000 visits in 6 months from date of website launch	Project´s website launched	1
					laymen report available on the website and downloaded	100 Downloads	laymen report prepared and agreed with consortium partners	1
					Project leaflets handed out to stakeholders	50	Project´s leaflet developed	1
					Social media account liked and followed by other users	1,000 followers on overall social media appearance	Establish a social media appearance	1
					Project newsletter disseminated to public	300 subscribers	Send out a project newsletter	3

		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.	Established partnership and information flow between regulators, professionals and other stakeholders involved in tobacco control, public health policy and practice within the JATC project as identified by the regulators, competent authorities, EU-CEG experts and WP members	Results of interviews and focus groups show improvement in the domain `Cooperation between EU MS´	List of tobacco control stakeholders and regulators delivered	1	Perform a stakeholder analysis	1
					Results and relevant information communicated between regulators, professionals and other stakeholders involved in tobacco control, public health policy and practice including all WPs	1	List of regulators, professionals and other stakeholders involved in tobacco control, public health policy and practice prepared and communicated with all WPs	1
					Written documentation on stakeholders engagement collected	20	Presentations for stakeholders at events and conferences held	6
		To organize a final project conference.	Increased awareness for the achievements of the JATC as identified by the participants	Results of the Quality Questionnaire on meetings show a median satisfaction of 2 in the category `information quality´ and `communication and teamwork´ after the final conference at the end of the project period	MS participated in the JATC final conference	80% of invitees	Project´s conference organised	1

WP3- Evaluation of the action	To ensure appropriate coordination and evaluation	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.	Effective evaluation as identified by the JATC consortium	Results of the Quality Questionnaire show a median general satisfaction of at least 7 in the last two questionnaire surveys	Logical Evaluation Framework (LogFrame) delivered and approved by WP leaders	1	Create a Logical Evaluation Framework consisting of process, output and outcome indicators	1
					Instruments delivered	3	Finalise instruments for data collection	3
					Approval for evaluation plan obtained from the steering committee	1	Prepare an evaluation plan	1
		To implement the evaluation plan throughout the duration of the project.	Systematic outcome monitoring	All outcomes from WP1-9 are considered in the final evaluation plan at the end of the project	Findings of qualitative and quantitative WP3 evaluation data presented and communicated	3	Collection and analysis of qualitative and quantitative WP3 evaluation data	3
					Interim evaluation report approved by CHAFEA, EC, and steering committee	1	Write interim evaluation report	1
					Final evaluation report approved by CHAFEA, EC, and steering committee	1	Develop final evaluation report	1

WP4- Integration into national policies and sustainability	To integrate the JATC results into national policies	To map and monitor the current status quo of TPD implementation and create a reporting mechanism to annually monitor the progress and ressources available across the 28 EU MS and EEA where applicable.	Enhancement of TPD II implementation in the EU MS within the project period as identified by the regulators, EU-CEG experts, WP members, and collaborating partners	Results of interviews and focus groups show improvement in the Joint Action on Tobacco Control in the domain 'Implementation of the TPD II´	Outline on the mapping of activities and capacity from 28 EU MS regulators delivered	1	Survey of activities and capacity from EU MS mapped	1
					Questionnaire disseminated to the EU MS	60% respons e rate	Develop a questionnaire for mapping and sustainability	1
					Outline on the mapping of the current status quo of TPD implementation	2	Map the current status quo of TPD implementation across the EU MS	2
					Outline on the mapping of the tobacco control funding	1	Map tobacco control funding across the EU MS	1
					Report on TPD mapping and sustainability activities including in-house capacities delivered	1	Map in-house and cross border regulatory, scientific and technical capacity resources	1
					Action Plan for sustainability activities delivered	1	Develop an action plan for sustainability activities	1
					Sustainability plan, including scenarios for long-term sustainability delivered	1	Sustainability plan detailed	1

		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.	Raised awareness of EU MS regulators on domains covered in the "how to" guides	Results of interviews and focus groups show improvement in the domain `Implementation of the TPD II´ and `The EU-CEG in your country´	E-learning material by EU MS regulators updated	1 update from 70% of MS	"How-to" guides developed and uploaded	5
					E-learning material by EU MS regulators downloaded	1 download from each of 28 MS	"How to" guide platform created and fully functional	1
					Update of the status quo of the repository for long term planning given to project team	1	Continuous feeding of the platform with reports and dissemination material	3
					Participation of stakeholders, NGOs, researchers and regulators	70% attendance	External joint meetings organised	3
					Participation of regulators in the meetings	70% attendance	Internal joint action training seminars for regulators organised	3
WP5- Common Entry Gate (CEG) data extraction and handling	To enhance the ease of access to the data collected through the EU-CEG	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.	Easier identification of public non-confidential data in EU- CEG for EU MS´ CEG experts	Results of interviews and focus groups show improvement in the domain `The EU-CEG in your country´	Report on the principles to distinguish what data is public non-confidential delivered	1	Analysis of variables that should be considered public and not confidential in EU-CEG system (performed by Hellenic Cancer Society, HCS)	1

					Identification of a model/framework, with focus on identifying public non-confidential data for classifying data in EU-CEG	1	Develop a classification model/framework in collaboration with a legal specialist	1
					Approval of classification model/framework by EU MS and DG Sante	28	Organisation of a webconference for EU MS in JATC project to evaluate and receive feedback on the classification model/framework	1
			Established legal basis for regulators and EU-CEG experts for publishing and sharing non-confidential data within the JATC project period	Results of interviews and focus groups show improvement in the domain `The EU-CEG in your country´	Report on the defined legal aspects of assessing other EU MS data in the JATC project delivered	1	Outline the legal requirements of assessing other EU MS data in the JATC project	1
					Data exchange template for the sharing of data within the JATC project produced and delivered to JATC participants	1	Produce a template for the sharing of data within the JATC project	1

		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.	Enhanced access and processing of public non-confidential data as identified by the EU MS´ CEG experts within the JATC project period	Results of interviews and focus groups show improvement in the domain `The EU-CEG in your country´	Report on 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 delivered	1	Develop a technical solution in EU-CEG for the transfer of data for analysis in collaboration with DG Sante	1
					Insights about other EU MS best practices on making data available received	5	Organisation of a webconference about best practices from EU MS on how to make data available to the general public	1
					EU MS datasets ready and delivered to the relevant vertical WPs	4	Collect the list of variables that are requested by WP6-9 and send this list to Hellenic Cancer Society (HCS) so they can create the individual datasets	4
					Second round of EU MS datasets ready and delivered to the relevant vertical WPs	4	Preparation of a second round of EU MS datasets	4

		To enhance utility and propose improvements to the EU-CEG, including on the basis of feedback from EU MS regulators.	Enhanced sharing of data among EU MS´ CEG experts within the JATC project	Results of interviews and focus groups show improvement in the domain `The EU-CEG in your country´	Report on the proposal of permanent mechanism for sharing of EU-CEG data	1	Propose a permanent mechanism for the sharing of EU-CEG data based on the findings from legal and IT specialists	1
			Enhanced utility of the EU-CEG within the group of EU-CEG experts	Results of interviews and focus groups show improvement in the category `The EU-CEG in your country´	Report for M1-18 and M18-34 on the potential improvements and/or alterations of the EU-CEG system	2	Perform an active data collection process from EU MS regulators on the EU-CEG	1
					Report to WP1 on the tasks performed under WP5	1	Summarize findings and solutions from the whole WP5 project	1
WP6- Tobacco product evaluation	To monitor and provide support to the tasks of tobacco and e-cigarette product regulation	To perform a needs assessment evaluation of EU regulators with regards to aspects of priority within EU-CEG.	Greater awareness of EU-CEG capabilities by EU MS regulators	Results of interviews and focus groups show improvement in the domain `The EU-CEG in your country´	Needs assessment questionnaire returned by EU MS regulators	min 12	Develop a needs assessment questionnaire for EU MS regulators	1
					Report of the WP6 needs assessment evaluation from EU regulators	1	Analysis of data for WP6 from needs assessment questionnaire	1
		To assess tobacco product information as submitted data via the EU-CEG.	Greater awareness on ingredient function, role and toxicity by EU MS regulators, EU-CEG experts and the JATC project team	Results of interviews and focus groups show improvement in the category `Analysis of tobacco products and risk assessment´	Analysis plans for tobacco products finalised	1	Data sets from EU MS regulators regarding requirements for EU-CEG collected from WP5	28

					Initiation of first wave and second wave of product data analyses completed	2	Assess tobacco product description data and tobacco product presentation and sales/market data	3
		To monitor tobacco product ingredient and additive data.	Greater awareness on product design and evolution by EU MS regulators, EU-CEG experts, and the JATC project team	Results of interviews and focus groups show improvement in the category `Analysis of tobacco products and risk assessment´	Reports on tobacco product data analysis delivered	2	Perform a statistical analysis of the tobacco ingredients and additives in relation to their function, weight and registration within REACH and CLP classification	1
							Assess the associations between declared tobacco product information (recipe) vs. measured tobacco product information	1
							Qualitatively assess the submitted emission data for tobacco products (collaboration with WP8)	1

							Identify and further evaluate products that have characterising flavours or containing additives described in TPD Art7(6-7)	1
		To evaluate the toxicological/addictive data submitted for tobacco products, including also information on priority additives.	Greater awareness on toxicological/additive products by EU MS regulators, EU-CEG experts and the JATC project team	Results of interviews and focus groups show improvement in the category `Analysis of tobacco products and risk assessment´	Evaluation of toxicological information delivered	1	Evaluate the toxicological information on additives in line with TPD Art5, p3	1
					List of additional additives that could be subject to enhanced reporting obligations delivered	1	Perform a qualitative and quantitative analysis of the data on priority additives as reported per brand and product type	1
WP7- E-cigarette product evaluation	To monitor and provide support to the tasks of tobacco and e-cigarette product regulation	To perform a needs assessment of EU MS regulators with regards to aspects of priority for e-cigarette products within the EU-CEG.	Greater awareness of EU-CEG capabilities by EU MS regulators	Results of interviews and focus groups show improvement in the domain `The EU-CEG in your country´	Needs assessment questionnaire returned by EU MS regulators	min 12	Develop a needs assessment questionnaire for EU MS regulators	1
					Report of the WP7 needs assessment evaluation from EU regulators	1	Analysis of data for WP7 from needs assessment questionnaire	1

		To assess e-cigarette product data as submitted data via the EU-CEG.	Greater awareness on ingredient function, role and toxicity by EU MS regulators, EU-CEG experts and the JATC project team	Results of interviews and focus groups show improvement in the category `Analysis of tobacco products and risk assessment´	Analysis plans for e-cigarette products finalised	1	Data sets from EU MS regulators regarding requirements for EU-CEG collected	min 10
					Initiation of first wave and second wave of product data analyses completed	2	Quantitatively analyse e-cigarette submission description data and technical design, product presentation and toxicological information on ingredients	3
		To monitor reported e-cigarette liquid ingredient and emission data in line with TPD Art20(2).	Greater awareness on product design and evolution by EU MS regulators, EU-CEG experts and the JATC project team	Results of interviews and focus groups show improvement in the category `Analysis of tobacco products and risk assessment´	Report on e-cigarette product analyses written	2	To perform a statistical analysis of the data provided by EU-CEG	1
					Internal report on the e-cigarette emissions and international protocols completed	1	To assess the emission data and their equivalent emission protocols as submitted through EU-CEG	1

		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).	Easier long term e-cigarette compliance monitoring by EU MS´ regulators	Results of interviews and focus groups show improvement in the category `Analysis of tobacco products and risk assessment´	Checklist for e-cigarettes is provided to EU MS	10	Checklist for e-cigarette product compliance to the TPD created	1
			Better reporting for adverse events by EU MS regulators	Results of interviews and focus groups show improvement in the category `Analysis of tobacco products and risk assessment´	Report on a proposed system for the reporting of adverse events written	1	Proposed system for adverse event reporting developed	1
WP8- Laboratory verification, collaboration and analyses	Assist EU MS networking and collaborations between laboratories for tobacco evaluation	To develop requirements of independent laboratories for ingredient evaluation.	Improvement of TPD approved lab independency from the tobacco/e-cigarette industry as identified by the EU MS´ regulators	Decrees of independency for all TPD approved laboratories collected by the WP8 team and communicated to the WP3 team within the JATC project period	Data collection surveys filled out by CAs	min 20	Develop a data collection survey	1
					Report on the status quo of laboratories in use by the EU MS´ competent authorities	1	Map the current status quo of laboratories	min 17
			Adoption of the proposed capacity requirements for ingredient, content and emission evaluation at the end of the JATC project by the EU MS´ regulators	Written recognition of adoption of the proposed capacity requirements for ingredient, content and emission evaluation by min 5 EU MS´ regulators collected by the WP8 team and communicated to the WP3 team within the JATC project period	Report on capacity requirements for EU MS laboratories written	1	Develop laboratory capacity requirements for ingredient, content and emission evaluation	min 10 (i.e., TNCO for content/emission for tobacco + NCO for content / emission of e-cigs)

		To review laboratory analysis activities performed by MS and to assess comparability across laboratories.	Compliance of results from laboratory analyses with data reported in the EU-CEG as identified by the WP8 team within the JATC project period	Written recognition of complete compliance of results by the WP8 team and communicated to the WP3 team within the JATC project period	Data collection forms filled out by CAs	min 10	Develop a data collection form to obtain either aggregate or disaggregate results from previously conducted analyses	1
					Report on the results of inter-laboratory variability of EU MS emission data	1	Datasets obtained from EU MS laboratories on analytical data for predefined products, which will be critically evaluated and re-analysed at a European scale	min 5
					Report on the replication of laboratory measurements	1	Commencement of the replicate laboratory measurements	min 1
		To develop collaborations and communication with other international activities on tobacco laboratory assessment.	Enhanced communication and collaboration between the EU Member States´ laboratories as identified by the EU Member States´ regulators	Results of interviews and focus groups show improvement in the category `Analysis of tobacco products and risk assessment´	Report on emission protocols concluded	1	Networking meeting with EU and international laboratories (incl. GoToLab and TobLabNet) held	1
					Networking meeting minutes, including minutes from the two internal meetings of WP8, written	2	WP8 internal meetings 1 and 2 held	2

WP9- Additives subject to enhanced reporting obligations	Support EU MS in the process of monitoring and updating priority additives	To compose an assessment/evaluation framework and guidelines for `good experimental practising´ (GEP).	Enhanced sharing of reporting documents with the JATC consortium, the peer reviewers, and the tobacco industry	Dissemination to min 10 people from the target group by the WP9 team and communicated to the WP3 team within the JATC project period	Assessment/Evaluation framework finalised	1	Compose an assessment/evaluation framework	1
			Established guidance for the tobacco industry on the kind and design of studies to be performed and assessed on	Min 10 downloads of good experimental practice guidelines from the JATC website within the JATC project period	Good experimental practice guideline written	1	Good experimental practice guidelines identified	1
		To facilitate peer review of the <u>enhanced reporting</u> information submitted by a panel of suitable experts.	Enhanced information on specific priority additive(s) for EU MS´ regulators, EU-CEG experts and the JATC consortium within the project period	Results of interviews and focus groups show satisfaction concerning the peer reviewing process in the category `Analysis of tobacco products and risk assessment´ as communicated by the participants at the end of the project	Reports on 15 priority additives obtained and categorised and inventory developed and delivered	1	Priority additive data and supporting information obtained	1
					Experts in document review trained	12	Peer reviewers, experts in the field recruited	12
					Peer review meeting minutes written	1	Peer review process commenced and facilitated	1
					Report on peer review outcomes delivered	1	Write a final report on the peer review of the enhanced reporting information on priority additives	1

		To provide feedback on additional additives that could be subject to enhanced reporting obligations in collaboration with WP6 and WP7.		Results of interviews and focus groups show satisfaction concerning feedback on additional additives in the category `Analysis of tobacco products and risk assessment´ as communicated by the participants at the end of the project	Report with reviewers judgement on other possible priority additive delivered	1	To provide feedback on additives and prepare a report	1
					Collaborative meeting minutes written	1	To organise a collaborative meeting	1
		To evaluate the comprehensiveness of the assessment/evaluation template for the types of studies.	Secure comprehensiveness of the assessment/evaluation template	Positive evaluation outcome in the evaluation report as communicated to the WP3 team by the WP9 team	Evaluation report delivered	1	Evaluation of the comprehensiveness and utility of the provided assessment/evaluation framework for the priority additives performed	1

Note:

*) basis for the development of the LogFrame is the JATC Proposal 07-2017; LogFrame needs to be agreed upon by WP leaders

**) means of verification: process and output indicators are monitored mainly as deliverables in the routine monitoring system by the coordinator outcome indicators are monitored by WP3 with three new instruments

C) Questionnaire for Quality Assurance

QUALITY QUESTIONNAIRE

Dear participant,

The *WP3- Evaluation of the action* creates and implements an evaluation plan to optimise the implementation of the JATC and to ensure that it meets all objectives envisaged. The evaluation has been 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.

Therefore, throughout the project, we will collect data to monitor and evaluate the project procedures and assure quality. Every 4 months we will send out a quality questionnaire about your subjective perception of the project´s progress. Please take yourself approximately 5 minutes to reflect on each question addressed and try to be as sincere as possible. Your feedback will be treated confidentially and anonymously. Your participation is voluntary.

Thank you for your cooperation!

MEETINGS AND TELECONFERENCES

Personal details

1. What is your role in the JATC project?

☐ WP leader ☐ WP member ☐ Stakeholder ☐ Collaboration partner

☐ EU Commission ☐ CHAFEA ☐ Other, please specify _____

2. In which WP are you involved/do you participate?

☐ WP 1 ☐ WP 2 ☐ WP 3 ☐ WP 4 ☐ WP 5 ☐ WP 6 ☐ WP 7

☐ WP 8 ☐ WP 9 ☐ I am not involved in any of the WPs

☐ Other, please specify _____

Organisation of meetings

3. Which meeting/conference did you attend?

☐ Meeting ☐ Teleconference

(select only one option)

☐ Steering Committee meeting ☐ Steering Committee teleconference

☐ Consortium meeting ☐ Consortium teleconference

☐ Meeting on WP _____ ☐ Teleconference for WP ____

☐ Meeting on WP _____ ☐ Teleconference for WP ____

☐ Meeting on WP _____ ☐ Teleconference for WP ____

☐ Meeting on WP _____ ☐ Teleconference for WP ____

☐ other meeting, please specify:

Title: _____ Date (dd/mm/yy): ____/_____/_____
Title: _____ Date (dd/mm/yy): ____/_____/_____
Title: _____ Date (dd/mm/yy): ____/_____/_____

4. Organisation of meetings held: Please indicate how satisfied you were with…

	Very satisfied	Satisfied	Neutral	Unsatisfied	Very unsatisfied	Not applicable
Timeliness of notification	☐	☐	☐	☐	☐	☐
Location of the venue	☐	☐	☐	☐	☐	☐
Accessibility by plane, train, etc.	☐	☐	☐	☐	☐	☐
Availability of accommodation	☐	☐	☐	☐	☐	☐
Compilation of the agenda	☐	☐	☐	☐	☐	☐
Length/Duration of the meetings	☐	☐	☐	☐	☐	☐

Comment: _____

5. The meetings´ venues: Please indicate how satisfied you were with…

	Very satisfied	Satisfied	Neutral	Unsatisfied	Very unsatisfied	Not applicable
Premises	☐	☐	☐	☐	☐	☐
Technical equipment of auditorium	☐	☐	☐	☐	☐	☐
Acoustics in the meeting room	☐	☐	☐	☐	☐	☐
Ventilation and air-condition	☐	☐	☐	☐	☐	☐
Catering	☐	☐	☐	☐	☐	☐

Comment: _____

Information quality

6. Information quality: Please indicate how satisfied you were with…

	Very satisfied	Satisfied	Neutral	Unsatisfied	Very unsatisfied	Not applicable
Preparation of the speaker	☐	☐	☐	☐	☐	☐
Information delivered	☐	☐	☐	☐	☐	☐
Format of presentation	☐	☐	☐	☐	☐	☐
Comprehensibility of the presentations	☐	☐	☐	☐	☐	☐
Practicability of presented content	☐	☐	☐	☐	☐	☐
Relevance of the documents dispatched within the WP	☐	☐	☐	☐	☐	☐
Information exchange about tasks concerning my competence area	☐	☐	☐	☐	☐	☐
Outcome of the meeting/teleconference	☐	☐	☐	☐	☐	☐

Comment: _____

General

7. Have your expectations regarding the aim of this meeting/teleconference been met?

☐ Yes ☐ No

If not, please specify why or what you have missed:

_____

_____

_____

8. Please indicate how satisfied you were with the meeting/teleconference in general (1= worst; 10= best):

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9	10

(=worst) (=best)

PROJECT PROGRESS

Personal details

1. What is your role in the JATC project?

☐ WP leader ☐ WP member ☐ Stakeholder ☐ Collaboration partner

☐ EU Commission ☐ CHAFEA ☐ Other, please specify _____

2. In which WP are you involved/do you participate?

☐ WP 1 ☐ WP 2 ☐ WP 3 ☐ WP 4 ☐ WP 5 ☐ WP 6 ☐ WP 7

☐ WP 8 ☐ WP 9 ☐ I am not involved in any of the WPs

☐ Other, please specify _____

Information quality

3. In regards to WP ___ please indicate how satisfied you are with…

	Very satisfied	Satisfied	Neutral	Unsatisfied	Very unsatisfied	Not applicable
Management of the WP	☐	☐	☐	☐	☐	☐
Implementation of planned activities	☐	☐	☐	☐	☐	☐
Outputs produced	☐	☐	☐	☐	☐	☐
Relevance of the documents dispatched within the WP	☐	☐	☐	☐	☐	☐
Information exchange about tasks concerning my competence area	☐	☐	☐	☐	☐	☐
Regular update on progress of the WP	☐	☐	☐	☐	☐	☐

Comment: _____

Communication and teamwork

4. In regards to WP ___ please indicate how satisfied you are with…

	Very satisfied	Satisfied	Neutral	Unsatisfied	Very unsatisfied	Not applicable
Cooperation and teamwork between WP members	☐	☐	☐	☐	☐	☐
Social interaction between WP members	☐	☐	☐	☐	☐	☐
Allocation of tasks between WP members	☐	☐	☐	☐	☐	☐
Possibility to exchange information with other WP members	☐	☐	☐	☐	☐	☐

Comment: _____

General

5. Please indicate how satisfied you are with the progress of the project at the moment (1= worst; 10= best):

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9	10

(=worst) (=best)

6. Have your expectations been met so far?

☐ Yes ☐ No

If not, please specify why or what you have missed:

_____

_____

_____

7. Is there something else you want to add?

_____

_____

_____

Thank you for participating!

D) AGES participants in the JATC

Individual, last name	Individual, first name	Contact Details	Department	WP	WP Scope	WP Tasks
Sövegjarto	Friedrich	friedrich.soevegjarto@ages.at	Area for food safety	3	Evaluation	All
Schroll	Iris	iris.schroll@ages.at	Area for food safety	3	Evaluation	All
Kirchner	Stefanie	stefanie.kirchner@ages.at	Area for food safety	3	Evaluation	All
Pichler	Juliane	juliane.pichler@ages.at	Data, Statistics and Risk assessment	3	Evaluation	All
Pastler	Fiona	fiona.pastler@ages.at	Area for food safety	3	Evaluation	All
Schagerl	Monika	monika.schagerl@ages.at	Data, Statistics and Risk assessment	5	CEG data extraction	3.1., 1.1.
Binder	Harald	harald.binder@ages.at	IT Services, Facility Management and Organisation	5	CEG data extraction	3.1., 1.1.
Vejdovszky	Katharina	katharina.vejdovszky@ages.at	Data, Statistics and Risk assessment	6	Evaluation Tobacco Product Reporting	4.1., 4.2.
				7	Evaluation Tobacco Product Reporting	4.1
Kuhn	Thomas	thomas.kuhn@ages.at	Area for food safety	8	Tobacco Laboratory Verification Collaboration	2.1.
Gutternigg	Martin	martin.gutternigg@ages.at	Area for food safety	8	Tobacco Laboratory Verification Collaboration	2.1.

E) Subcontractor Details

Name: Katharina Demel

Expertise:

Evaluation expert for various EU projects and programs. Evaluation expert for DG Research (6th Framework programme), DG JLS (disciplines (I), (II), (III) and (VII) in the fields of asylum, immigration and integration

Focal areas:

- Process evaluations and impact assessments, especially in the fields of migration/integration, (further) education and health
- Evaluation and optimisation of general services
- Counselling on project design and evaluation

Contact details: CORE Consultancy Research Evaluation
Neubaugasse 56/ Top 9
A–1070 VIENNA
AUSTRIA
mail: evaluation@evaluation.co.at
hp: http://www.evaluation.co.at