



Joint Action on Tobacco Control (JATC)

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0. Executive summary

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 in 24 EU Member States.

Project activities and outputs were clustered into/assigned to nine work packages (WPs), most of which are being implemented by several project partners (hereafter also referred to as WP members).

An internal evaluation designed as process-outcome evaluation accompanied the implementation of the project. Its aim was to assess the implementation of project activities, the delivery of output and to assess the likeliness of the planned outcomes of the JATC project to be achieved.

To this end, it sought to answer three main evaluation questions:

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

This final evaluation report presents the results of the evaluation. It covers the period from 16.10.2017 to 31.10.2020 (month 1 to month 37 of the project). The following sections summarise the main conclusions and recommendations. Details on the respective data basis and findings are presented in chapter 4.

0.1 Process evaluation

0.1.1 Evaluation question 1: Have the intended outputs of the JATC been delivered? Conclusions

Of the 65 outputs due during the reporting period, around half were delivered on time or with minimal delay. For a project with such a large number of project partners from different countries, who had to cooperate closely not only in the overall project but also within individual WPs, this is a good result.

The factors which according to stakeholders affected the timeliness of output delivery are characteristic for multi-country projects with a higher number of project partners than work packages. In the case of the JATC project, such a structure was necessary because the project's objectives required the active involvement of numerous stakeholders. Therefore, most work

packages involved many project partners as WP members and often several of them worked together on one output.

Such a project structure is very complex because it requires a high degree of coordination and communication not only among different work packages, but also within the individual work packages. Regular, continuous communication at all level is challenging but at the same time plays a central role, for it acts as a kind of bracket that holds project partners and work packages together.

An increase of WP members usually leads to a decrease of formal and informal communication, mostly because of organisational challenges such as, for example, finding a suitable date for meetings. Less communication results in less information exchange which has an impact on both coordination and collaboration and finally influence output delivery.

All this has been mentioned in the surveys but also in informal talks at meetings. It is backed by research, which confirms the importance of both formal and informal communication. Formal communication structures such as, for example, regular coordination meetings are important for the organisation of work, allocation of tasks, and information flows among project partners. Informal communication, on the other hand, is essential for practical cooperation. It creates trust among project staff and makes it possible for people who work on the same output to just call their counterparts in another partner organisation in case of a problem.

0.1.2 Evaluation question 2: How can the quality of project implementation be optimized? Conclusions

Since a large part of the quantitative and qualitative feedback relates to the individual work packages, only few general conclusions can be drawn.

General satisfaction with the project

The average satisfaction with the JATC project was quite high during the whole project duration. Also, external challenges like the "Covid-19 crisis" did not lead to a decrease. Even though these are average values, it is quite remarkable for a project of this size and complexity. For it suggests that for a large part of the project staff their original expectations for the project were at least partially met.

Satisfaction with work packages

The results for the individual work packages were also good but showed greater fluctuations in the course of the project with regard to satisfaction with specific items. Although there were no statistically significant differences among the work packages, the data suggests that the vertical work packages faced greater challenges in terms of WP management and communication among WP members. This might be because these WPs consist of more WP members spread over different countries, which renders communication more difficult. At the same time, communication and information exchange among WP members is of utmost importance because of the mutual dependencies among team members regarding the production of planned outputs.

The importance of communication and collaboration within a WP and among WPs for the respondents can also be seen from the comments in the questionnaires. Interestingly, these comments decreased significantly since the beginning of the pandemic. One possible explanation could be that the lack of direct, personal contacts, which had been criticized at the beginning of the project, had suddenly become "normal".

In terms of content, the comments indicate that some of the central objectives of the JATC project such as the accessibility and exchange of EU-CEG data have not yet been satisfactorily achieved in the eyes of many of the respondents.

0.1.3 Recommendations

The complexity of the JATC project is a major challenge for the coordination, communication, and collaboration within and among work packages.

In principle, there are two ways to address these issues. First, you can reduce the complexity of the project by reducing the number of WP members involved in an output, as well as the dependencies among WPs.

Second, one can establish processes and mechanisms that make it easier to deal with the existing dependencies.

In this regard, regular, continuous **communication** plays a key role, as both coordination and collaboration depend on it.

The following measures could be considered to improve both the communication among WPs as well as the communication within WPs:

At the level of work packages

the creation of structures for a regular exchange of information among WP members,
 e.g. via monthly virtual meetings with a fixed agenda. Specific features of conference software that are as close as possible to a face-to-face meeting should also be used, such as bilateral meetings in a separate "virtual room"

- the setting up of a forum where questions can be posted and answered by WP members
- the creation of structures that allow for a regular exchange of information among WPs that need input from one another for the production of outputs
- the organisation of regular meetings with all WP members to share information about the overall project
- the creation of informal information channels that facilitate contacts among project staff working on the same output. For this purpose, personal meetings work best and in some cases might be feasible: for example, if five people from three project partners are working together on a very demanding output a one-day meeting could be organised. Also, specific software could be used to create a space where staff from different WPs who must work together can meet, chat, etc.

At the level of project coordination

- the continuation of the regular steering group meetings with a fixed agenda
- the creation of a communication channel where project staff can anonymously articulate specific concerns, such as ideas, complaints, etc. If the project is being evaluated, this would be a task of the evaluation
- the facilitation of personal meetings: the size of the project and the number of project
 partners makes a personal meeting of all participants, especially at the level of project
 staff, almost impossible. Nevertheless, every possibility of personal meetings should be
 supported. Studies show that even in times of ZOOM, MS Teams, Skype, etc. once-only
 personal meetings significantly improve collaboration

In addition, the **coordination** within and among work packages could be enhanced by adapting the overall project management (PM) as well as the management of individual work packages more closely to the complex project structures. Amongst others, this could encompass the following:

- an inclusion of sufficient "time buffers" in the work plan for the delivery of outputs that depend on the delivery of one or more other outputs
- the use of a PM software that allows to link overall PM with the management of work packages. This would facilitate a joint monitoring of the work schedule and mutual dependencies among different project activities and outputs

Should the second project phase also be accompanied by an **internal evaluation**, the approach used for output evaluation, too, should be adapted more closely to the complex project

structures. To this end, a stronger focus could be put on the of the individual work packages using methods and instruments tailor-made to the information needs of WP leaders and WP members.

0.2 Outcome evaluation

0.2.1 Evaluation question 3: To what extent have the intended outcomes of the JATC been achieved? Which factors supported/hampered their achievement?

Conclusions

It is still too early to draw final conclusions about outcomes triggered by the JATC project. The following paragraphs thus only provide a snapshot at the end of the project and it can be expected that further changes unfold during the next year.

Implementation of the TPDII

One of the major objectives of the JATC was the support and facilitation of the implementation of the TPDII in the EU Member States. Expected project outcomes therefore include the implementation of specific provisions and regulations across all or the majority of countries. At the end of the JATC project stakeholders already observed of the outcomes envisaged, notably

- the implementation of warning labels and graphic warning labels
- regulations of ingredients and additives
- regulations regarding novel tobacco products and e-cigarettes, since there was not much of a regulatory environment before

It was also noted that the competent authorities have started to change administrative processes and internal regulations necessary for the implementation of the TPDII as well as the related training of staff.

The expert group on tobacco policy provides a good platform for information sharing among EU MS, which has helped to reduce the differences in their approach regarding the implementation of the TPDII.

There are, however, still differences concerning enforcement, inspections and control.

Also, there remain some 'grey areas" with insufficient specifications within the TPDII, notably as regards NTPs, which need to be reassessed.

The campaigns conducted in the EU MS to raise awareness of the dangers of tobacco consumption did not achieve the desired results. This is consistent with the experience of other

public awareness campaigns on harmful behaviour, such as HIV prevention, the dangers of physical inactivity, etc. This could be because they focused on providing information and knowledge, but according to scientific studies, lack of knowledge is not the problem. Today, everyone who smokes knows that smoking is unhealthy and contributes to the development of many diseases.

The EU-CEG

The improvement of the EU-CEG was perceived to be the most important outcome of the JATC. Most stakeholders noticed a significant improvement over the project period, notably regarding user-friendliness. Nevertheless, a lot of improvements as well as harmonized approaches in data handling still need to be addressed in the future.

Some of the stakeholders expect the EU CEG to evolve into a more business intelligence-like system with more advanced dashboards for regulators to analyse data and to determine the quality and consistence of the data in a more effective way.

Analysis of tobacco products and risk assessment

With regard to the analysis of tobacco and risk assessment, project outcomes did not unfold yet. The control of ingredients is still challenging, especially for countries with insufficient laboratory and/or chemical analysis capacity. Overall, there are not enough accredited and independent laboratories and/or expertise to analyse tobacco products, e.g. novel tobacco products and smokeless tobacco. Regarding electronic cigarettes in general, there are not enough validated analytical methods for testing the composition of refill containers.

A further and ongoing challenge is the monitoring and regulation of the ever-evolving tobacco product landscape. This is a continuous task of all competent authorities which could be facilitated by the establishment of a network for information sharing.

Presently, assessment frameworks for the evaluation of various novel tobacco products related to their toxicity, addictiveness and attractiveness, as well as validating methods on measuring nicotine emission in e-cigarettes are in the process of being developed.

However, the approaches towards the toxicological evaluation and the risk assessment of tobacco and related products still need to be harmonized.

Collaboration among MS

As a result of the JATC, cooperation among EU Member States has improved significantly, as has cooperation among EU Member States and the EU.

A stronger involvement of project partners in future project phases might strengthen the cooperation even more.

What is still missing, however, are systems for a permanent exchange of information among EU MS, also at an informal level. The systems that are currently in place, for example, EHHP or RAPEX are not defined by the needs of the end users.

0.2.2 Recommendations

During the focus group participants also gave some recommendations for future tasks of competent authorities as did the respondents to the questionnaire. They are summarised below. For the second phase of the JATC project, it could be considered to develop specific activities/outputs to address some of the issues raised.

Implementation of the TPDII

- The TPD II contains grey areas, which should to be clarified. Especially, but not only, concerning NTPs the TPD II needs to be reassessed and adapted. A broadening of the TPD (e.g. concerning advertising and taxation) should be taken into consideration. The creation of a work group to identify and consequently clarify the grey areas, as well as ambiguous parts of the TPD II, could be taken into consideration.
- Future tasks also include the implementation of plain uniform packaging and the removal of descriptors, further and better regulations of e-liquids and ingredients, more focus on novel tobacco products.
- Regarding public campaigns about smoking, it could be considered to give up the
 assumption that smokers are not aware of the negative consequences of smoking.
 Instead, one could do a meta-analysis of studies/evaluations of other interventions
 against harmful behaviour to find out what makes people stick to a behaviour that they
 already know is harmful and use the findings for the creation of new campaigns.

The EU-CEG

In the course of the last three years, the **EU-CEG** portal has greatly improved in terms of accessibility and user-friendliness. However, some features are still missing, for example:

- An additional national data collection system
- Separate areas for public and confidential data
- Functions for the download of public data
- The possibility of extracting information of all the products submitted in a list, where also key data (e.g. amount of nicotine) appears

- The possibility to automatically download pdf files, which were attached to specific ingredients, or to have the name of the pdf document displayed in the bulk download along with the specific entry
- Addition of filter options for all data fields
- Automated notification and data rejection for incorrect data submission
- Submitters should be able to access their own notifications in EU CEG
- Artificial intelligence algorithms to identify non-compliant products and ingredients

Unified guidelines with clear rules for submitters should be established to prevent inconsistent and incorrect submissions.

Discrepancies among MS when it comes to the analysis of EU CEG data allow for further uniformity.

The implementation of a supporting EU CEG data analysis team could be considered. A manual that summarizes the options of the EU-CEG would be helpful as well as a training course.

Analysis of tobacco products and risk assessment

- A harmonized approach of the toxicological evaluation and the **risk assessment**, as well as a common assessment of ingredients and additives should be developed.
- More funding is needed to ensure that every member state has at least one independent laboratory. Networks of scientists and laboratories are crucial for information exchange and need to be maintained even after the project.
- Appropriate measures to facilitate the agreement on uniform test parameters within laboratory tests, analogous to food monitoring, should be considered such as for example the establishment of a respective working group.
- A critical review of literature and studies on NTPs should be conducted. It could be considered to integrate it as an output in the 2nd phase of the JATC.

Collaboration among MS

As the cooperation of EU MS has already improved during the first phase of the JATC project, in the second phase specific outputs could further strengthen it. The currently available systems such as EHHP or RAPEX could be complemented by a platform/forum to share and organize information with moderators of different fields of expertise. Ideally, such a system would also allow an informal exchange of knowledge/information and would be accessible via cell phone.

1. Context and purpose of the project

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 project is to provide support for the implementation of the TPD throughout the 28 EU MS, to improve European public health.

The support should be provided through the mining of EU-CEG data, supporting of laboratory collaborations and effort to evaluate priority additives. The specific aims are the following and should be reached by the efforts within nine work packages with their specific process, output and outcome indicators.

- 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 among laboratories for tobacco evaluation
- Support EU MS in the process of monitoring and updating priority additives
- To integrate the JATC results into national policies

2. Features of the evaluation

2.1. Type of evaluation

The evaluation accompanied the implementation of the JATC project and was conducted by one of the project partners under a separate work package (WP3). It had thus the character of an internal evaluation.

Based on the types of data used the evaluation was a combination of a process, and outcome evaluation. Its main purpose was to support the optimisation of project implementation with a special focus on an improved communication.

2.2. Scope of the evaluation

The evaluation WP ends with the life span of the project and has to deliver its final report until 15.11.2020, one month before the end of the project. Therefore, only activities from **16.10.2017 until 31.10.2020** could be considered. Any actions, evolving issues and emergent outcomes after that date could not be tracked and thus did not feed into the findings of this report.

2.3. Methodology

For data collection and analysis, the evaluation used a mixed-method design drawing on different data sources and types of data, each relating to different indicators.

More specifically, the following methods were used:

Process evaluation:

- a) A target-actual comparison was used to assess the timeliness of output delivery. To this end, the delivery dates of all outputs that constitute milestones or deliverables were tracked via the central project portal and compared to the planned dates of delivery. Seven deliverables were not included in this final evaluation report, since their delivery was only due after the submission of the report. Information on reasons for delays were collected via the QQ on project procedures.
- b) The quality of project implementation was tracked and supported with two standardized questionnaires that were administered during the whole project period. One questionnaire, the QQ on meetings and teleconferences, was only used for internal purposes and served as a tool to support WP leaders. Its findings were communicated to WP leaders, but are not considered in this report. A second QQ on project procedures was distributed three times a year and used to collect the WP members views on and satisfaction with the quality of project implementation.

To complement respective findings, members of the evaluation team participated in 17 steering committee teleconferences and three in-person consortium meetings.

c) Finally, to gain a first overview on outcomes that had already started to unfold during the project period, the evaluation team conducted expert-interviews, focus groups, and disseminated standardized questionnaires to selected experts.

In the course of the project, challenges related to data collection made it necessary to adapt the original plan for data collection and analysis.

2.4. Addressees of the Final evaluation report

This report is the final issue of a set of evaluation documents (D3.1. Evaluation plan, D3.2. Interim evaluation report¹) produced by the **internal evaluation** team.

Its results will be communicated to the EU Commission, the steering group and consortium, as well as the public via the project homepage.

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¹ The deliverables can be downloaded on the Homepage of the JATC (http://jaotc.eu/)

3. Limitations of the evaluation

The evaluation of the JATC project had to face several limitations. They resulted from the timing of the evaluation, constraints in data collection and the measures taken in connection with COVID-19.

In this section, we describe these limitations and their consequences for the evaluation in more detail.

Process evaluation

The evaluation was set up as an "internal evaluation", whereby the evaluation team was one of the project partners and the evaluation was a separate work package (WP3). Evaluation activities were therefore carried out in parallel to project activities implemented by other work packages. Since the evaluation report had to be submitted before the end of the project, it only covers month 1 – month 37 and could not consider seven deliverables that were not due until the end of the project.

Outcome evaluation

The timing of the evaluation also impacted on the assessment of outcomes. Outcome-oriented projects are based on a causal intervention logic, in which activities enable the delivery of outputs, outputs trigger outcomes which finally should lead to impacts. While the implementation of activities and the production of outputs take place during the life-span of the project and thus lie within the control of the project management, the outcomes envisaged need time to unfold and usually only occur after the project ends. Also, their achievement depends to a large extent on external factors. Therefore, a time span of at least several months after the end of the project would have been needed to comprehensively identify project outcomes and to analyse if and how project outputs were taken up and further used by the target group. Since the internal evaluation ends with the project, the outcomes of the JATC project could not really be assessed. Consequently, this evaluation report can only provide a first overview of outcomes that had already started to unfold during project implementation and of indications for further developments.

Constraints in data collection

One of the main tasks of the evaluation was the analysis of the internal project structures and processes with the aim of identifying factors that facilitate or hinder the implementation of project activities. To this end, it is necessary to gather the opinions and experiences of project

staff, which is often done by conducting short, but regular surveys among all persons working on a particular work package. If their composition does not or only slightly change during the project duration, a comparison of the different survey results can be used to gain insights on the development of the work package regarding teamwork, information flows or communication structures. In the case of the JATC project this was only possible to a limited extent. Except for key persons, the people involved in the WPs often changed and it must be assumed that the surveys conducted were at least partially answered by different persons each time. The various survey results for a single work package therefore only provide a limited indication of the development of the work package, but rather represent snapshots of the situation at the time of the survey.

A further task of the evaluation was to monitor the timeliness of the delivery of outputs. This is especially important for large and complex projects, as delays due to the dependencies among outputs can have far-reaching consequences. All deliverables of the JATC project had to be submitted to the project coordinator and be uploaded to the project portal. The evaluation team only had access to the upload date, but no information about the exact date an output was submitted. Therefore, and based on the assumption that the upload of the output would take place at the latest one day after its submission, the upload dates served as delivery dates for the evaluation. However, it cannot be excluded that in some cases much more than one day passed among submission and upload.

Outcome evaluation

One of the biggest challenges in connection with the outcome evaluation was the fact that many potential beneficiaries of the project outcomes, such as EU MS regulators/competent authorities, were themselves actively involved in the JATC project as project partners. Interviewing them about the emerging outcomes is methodologically delicate, as it is then no longer an "internal evaluation" but actually a "self-evaluation". For this reason, the evaluation plan provided for the identification of external interview partners who are 'regularly involved in CEG data handling' or 'regularly involved in collaboration among MS'. However, this proved to be extremely difficult. Eventually, the number of interviews had to be reduced from 14 to 10.

Impacts of the COVID-19 pandemic

For spring/summer 2020 several focus groups with stakeholders were planned to discuss immediate project outcomes as well as the likeliness of longer-term outcomes to occur. But due to the national measures to contain the Covid-19 pandemic and the associated restructuring of processes and workflows within public administrations, many stakeholders could not participate. Only one focus group with five participants took place and a questionnaire was therefore sent out to 66 experts as a substitute, but only 7 people completed it (10,61%).

4. Evaluation results

4.1. Process evaluation

In a project like the JATC, where a large number of project partners are working together for the first time, project and communication structures and modes of collaboration must first be developed. Process evaluation can support this development process by collecting and analysing both objective and subjective process data. Respective results are especially useful for WP leaders and the project coordinator.

The following two sections present the findings and conclusions of the analysis of output delivery (objective process indicator) and the satisfaction of project staff with project implementation (subjective process indicator).

4.1.1. Output delivery

Data basis

For the purpose of the internal evaluation, monitoring data on output delivery was collected and analysed with a view to compare planned and actual delivery. To this end, the output delivery dates indicated in the project work plan were compared with actual delivery dates. For the latter, the **participants' portal** was consulted to verify the date on which documents on deliverables/milestones were up-loaded. This approach was based on the assumption that the up-load of deliverables/milestones would take place within one day after submission. Additional information, notably on reasons for delay and challenges encountered regarding the production of outputs, was collected via the questionnaire on project implementation (QQ project progress), which will be described in section 4.1.2. This topic was also discussed during meetings of the consortium and the steering group attended by a member of the evaluation team and possible reasons for delays were identified.

Findings

The project workplan provided for a total of 72 outputs -38 milestones² and 34 deliverables. This evaluation report covers month 1-37. Within the evaluation period 65 outputs were due - 27 deliverables and 38 milestones. As can be seen from the following table, 14 (21,54%) of these were delivered on time, 15 (23,08%) with a slight delay and 30(46,15%) with a significant delay. 6 outputs were in the final stages at the end of the evaluation period.

² Milestone 12 was withdrawn after the initial project phase

Table 1: Planned delivery dates and upload dates of outputs

Project	Type of output	No. of outputs	Delivered on	Delay < 1	Delay > 1	In finalization ³
period		due according to work plan	time	month	month	
Month 1 - 6	Deliverables	3		2	1	
	Milestones	12	3	5	4	
Month 7 - 12	Deliverables	6		2	4	
	Milestones	8	2	3	3	
Month 13 -	Deliverables	9	2		7	
10	Milestones	6	1	1	4	
Month 19 - 24	Deliverables	4		1	1	2
	Milestones	2		1	1	
Month 25 -	Deliverables	1			1	
30	Milestones	7	1		4	2
Month 31 -	Deliverables	4	2			2
3,	Milestones	3	3			
		65	14	15	30	6

The information obtained during consortium and steering committee meetings as well as comments provided by project staff via questionnaires revealed several underlying reasons for the delays of outputs.

³ As of 03.12.2020 all oft he pending deliverables and milestones, which were due until 31.10.2020, have been delivered.

Related to the complexity of the project structure

- The majority of outputs involved several WP members and thus created mutual dependencies. As a result, a slight delay in the input of one WP member, for example caused by the need for further specification, could trigger a chain reaction and lead to a considerable delay in the final delivery of the output.
- This was reinforced by additional dependencies among outputs, which in some cases caused a sort of "domino effect" of delays in output delivery.

Related to communication and collaboration

- Respondents of the surveys also noted an insufficient communication and information exchange among WP members as well as among members of different WPs.
- In this regard, the lack of clarifications on the real possibility to access EU CEG data from countries and the delayed sharing of EU-CEG data was frequently mentioned as a major bottle-neck.

Related to project staff

- Another factor perceived as challenging for output delivery was the turn-over of staff during project implementation.
- Also, in some cases insufficient experiences or qualification of of some project staff was mentioned.

Related to project planning

- Especially in the first half of the project survey respondents noted an insufficient specification of the content of deliverables and milestones in the work plan
- Some of them identified over-ambitious deadlines for deliverables as an important reason for delays.
- In some cases this was aggravated by limited resources, notably insufficient funds to fulfil all necessary tasks.

Related to external/context factors

 From March 2020, the measures implemented due to the Sars-CoV-2 pandemic led to internal organisation changes within most WP members which accounted for additional delays in the delivery of outputs.

Conclusions

Of the 65 outputs due during the reporting period, around half were delivered on time or with minimal delay. For a project with such a large number of project partners from different countries, who had to cooperate closely not only in the overall project but also within individual WPs, this is a good result.

The factors which according to stakeholders impacted on the timeliness of output delivery are characteristic for multi-country projects with a higher number of project partners than work packages⁴. In the case of the JATC project such a structure was necessary because the project's objectives required the active involvement of numerous stakeholders. Therefore, most work packages involved many project partners as WP members and often several of them worked together on one output.

Such a project structure is very complex because it requires a high degree of coordination and communication not only among different work packages, but also within the individual work packages. Regular, continuous communication at all level is challenging but at the same time plays a central role, for it acts as a kind of bracket that holds project partners and work packages together.

The diagram below shows a simplified⁵ system model of how several factors mentioned above inter – relate with each other and with the delivery of an output in which several members of a WP are involved.

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⁴ If the number of project partners equals the number of work packages the complexity of project structures can be reduced by each project partner being responsible for the implementation of a specific work package.

⁵ It is simplified because it does not show all linkages among factors and, more importantly, because it does not take into consideration collaboration with other work packages which creates an additional layer of complexity.

Factors influencing output delivery

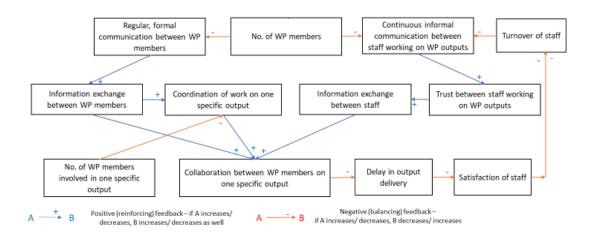


Figure 1: Factors influencing output delivery

As depicted in the diagram, an increase of WP members usually leads to a decrease of formal and informal communication, mostly because of organisational challenges such as for example finding a suitable date for meetings. Less communication results in less information exchange which has an impact on both coordination and collaboration and finally influence output delivery.

All this has been mentioned in the surveys but also in informal talks at meetings. It is backed by research which confirms the importance of both formal and informal communication. Formal communication structures such as, for example, regular coordination meetings are important for the organisation of work, allocation of tasks, and information flows among project partners. Informal communication, on the other hand, is essential for practical cooperation. It creates trust among project staff and makes it possible for people who work on the same output to just call their counterparts in another partner organisation in case of a problem.

4.1.2 Quality of project implementation as perceived by project staff

Data basis

As a complement to the collection of data on output delivery, the evaluation team also collected data on the subjective perception of project implementation by project staff. A special questionnaire (QQ project progress) was used to receive feedback from the people involved in the different WPs about their perception of the quality of important elements of project implementation such as collaboration, information flows, etc.

The survey was created with the online-tool Askallo and was carried out eight times in the course of the project. Each time an e-mail with a link to the online questionnaire was sent to all project staff based on a list received from the project coordinator. Since in this list the people working on the project were only assigned to the partner institutions and not to individual WPs, it was not possible to determine the response rate for each WP.

In total, 1186 questionnaires were sent out during the project, of which 261 were completed and could be analysed for the evaluation.

Table 2: Dates of distribution, number of completed questionnaires and response rate of QQ progress

Time	QQ Distributed	No. of completed questionnaires ⁶	Response rate
April 2018	144	38	26.39%
August 2018	143	36	25.17%
December 2018	144	35	24.31%
April 2019	151	33	21.85%
August 2019	151	31	20.53%
December 2019	151	27	17.88%
April 2020	151	38	25.17%
August 2020	151	23	15.23%
Total	1186	261	22%

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⁶ Recipients of the questionnaire were asked to complete a separate questionnaire for each WP they were involved in. Therefore, the number of respondents might be smaller than the number of completed questionnaires.

Findings

The questionnaire included one general question related to the overall satisfaction of respondents with the progress of the project at the time of the survey. It used a ten-point Likert scale (1= Very dissatisfied,.....10= Very satisfied).

The table below shows the results for each round of the survey:

Table 3: Question: "Please indicate how satisfied you are with the progress of the project at the moment"

Date of survey	Mean value	Standard deviation	No. of respondents (n)
April 2018	6.26	1.82	38
August 2018	6.11	2.28	36
December 2018	7.14	1.71	35
April 2019	6,76	2,1	33
August 2019	6,45	1,98	31
December 2019	6,74	2,14	27
April 2020	6,87	1,99	38
August 2020	6,96	1,9	23

The general satisfaction of respondents with the progress of the project varied among 6.3 and 7.1, which is slightly above average. There is, however, a relatively high standard deviation which indicates a distribution of values among 4.5 and 8.5. Differences among the mean values are not statistically significant.

To receive feedback on each WP the questionnaire included also an item battery. It consisted of six items referring to aspects related to WP management and implementation as well as four items related to communication and teamwork among WP members.

WP management and implementation

- 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

Communication and teamwork

- Cooperation and teamwork among WP members
- Social interaction among WP members
- Allocation of tasks among WP members
- Possibility to exchange information with other WP members

Respondents were asked to indicate their satisfaction with the WPs they were involved in on a five-point Likert scale (1=Very satisfied,...5=Very unsatisfied)

The diagram below provides an overview of the overall satisfaction of respondents with their WP, calculated as mean value across all items.

Overall satisfaction with WP (average score across all items)

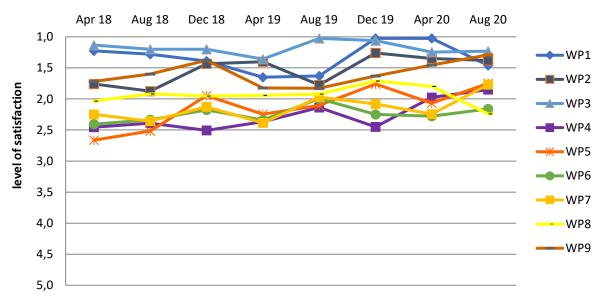


Figure 2: Overall satisfaction with WP (average score across all items)

As can be gathered from the diagram, overall satisfaction was quite high with mean values among 1.0 and 2.5.⁷ A mean value comparison shows no significant differences among the WPs. However, with the exception of WP 4, the overall satisfaction tends to be higher for the horizontal WPs (bluish colours) than for the vertical WPs⁸.

⁷ In this respect it should be taken into account that similar to the question on the general satisfaction with the JATC project here also the answers of respondents are quite diverse.

 $^{^{8}}$ The change in satisfaction over time that can be seen in the diagram should not be interpreted as a

[&]quot;development" of the work packages, as explained in chapter 3.

The satisfaction with individual items was also above average in all WPs with mean values among 1.0 and 2.67. Especially in the vertical WPs, however, there was a tendency for greater dissatisfaction with items related to communication and teamwork among WP members.

In addition, the respondents had the opportunity to explain the reasons for satisfaction or dissatisfaction with their work package in more detail. This opportunity was used quite frequently, whereby the number of comments decreased a little in the course of the project. Throughout the project, there were mainly two topics that were repeatedly addressed: Communication and collaboration, and delays in the implementation of project activities, and the delivery of outputs.

Communication and collaboration

Most of the comments concerned communication and information flow both within a WP and among different WPs. Several respondents stated that they neither had enough information from other WP members nor information about WP progress as a whole. Also, information on milestones and especially task distribution and next steps within the WP were perceived as insufficient. In this context the lack of a personal meeting of all WP members at the beginning of the project was mentioned as a shortcoming of the project. Also, the communication among WPs, collaboration partners and authorities were perceived as insufficient, and caused overlaps in tasks among WPs.

Delays in implementation and output delivery

Delayed outputs were often linked to insufficient task clarification both within and among work packages. Some respondents perceived a deficient compliance of staff of other WP members to fulfil tasks in due time and to make information available to the project teams as well as overall participation and teamwork.

Financial constraints and limited resources were also mentioned as obstacles to project implementations.

Content wise, difficulties to access the EU-CEG data and concerns about the TPD were perceived as major challenges. Amongst others, the ambiguity of the TPD was mentioned several times and doubts about an improved and harmonized implementation of the TPD II were expressed.

Conclusions

Since a large part of the quantitative and qualitative feedback relates to the individual work packages, only few general conclusions can be drawn.

General satisfaction with the project

The average satisfaction with the JATC project was quite high during the whole project duration. Also, external challenges like the "Covid-19 crisis" did not lead to a decrease. Even though these are average values, it is quite remarkable for a project of this size and complexity. For it suggests that for a large part of the project staff their original expectations for the project were at least partially met.

Satisfaction with work packages

The results for the individual work packages were also good but showed greater fluctuations in the course of the project with regard to satisfaction with specific items. Although there were no statistically significant differences among the work packages, the data suggests that the vertical work packages faced greater challenges in terms of WP management and communication among WP members. This might be because these WPs consist of more WP members spread over different countries, which renders communication more difficult. At the same time, communication and information exchange among WP members is of utmost importance because of the mutual dependencies among team members regarding the production of planned outputs.

The importance of communication and collaboration within a WP and among WPs for the respondents can also be seen from the comments in the questionnaires. Interestingly, these comments decreased significantly since the beginning of the pandemic. One possible explanation could be that the lack of direct, personal contacts, which had been criticized at the beginning of the project, had suddenly become "normal".

In terms of content, the comments indicate that some of the central objectives of the JATC project such as the accessibility and exchange of EU-CEG data have not yet been satisfactorily achieved in the eyes of many of the respondents.

4.1.3 Recommendations

The complexity of the JATC project is a major challenge for the coordination, communication, and collaboration within and among work packages.

In principle, there are two ways to address these issues. First, you can reduce the complexity of the project by reducing the number of WP members involved in an output, as well as the dependencies among WPs.

Second, one can establish processes and mechanisms that make it easier to deal with the existing dependencies.

In this regard, regular, continuous **communication** plays a key role, as both coordination and collaboration depend on it.

The following measures could be considered to improve both, the communication among WPs as well as the communication within WPs:

At the level of work packages

- the creation of structures for a regular exchange of information among WP members,
 e.g. via monthly virtual meetings with a fixed agenda. Specific features of conference software that are as close as possible to a face-to-face meeting should also be used, such as bilateral meetings in a separate "virtual room"
- the setting up of a forum where questions can be posted and answered by WP members
- the creation of structures that allow for a regular exchange of information among WPs that need input from one another for the production of outputs
- the organisation of regular meetings with all WP members to share information about the overall project
- the creation of informal information channels that facilitate contacts among project staff working on the same output. For this purpose, personal meetings work best and in some cases might be feasible: for example, if five people from three project partners are working together on a very demanding output a one-day meeting could be organised. Also, specific software could be used to create a space where staff from different WPs who must work together can meet, chat, etc.

At the level of project coordination

- the continuation of the regular steering group meetings with a fixed agenda
- the creation of a communication channel where project staff can anonymously articulate specific concerns, such as ideas, complaints, etc. If the project is being evaluated, this would be a task of the evaluation
- the facilitation of personal meetings: the size of the project and the number of project partners makes a personal meeting of all participants, especially at the level of project staff, almost impossible. Nevertheless, every possibility of personal meetings should be supported. Studies show that even in times of ZOOM, MS Teams, Skype, etc. once-only personal meetings significantly improve collaboration

In addition, the **coordination** within and among work packages could be enhanced by adapting the overall project management (PM) as well as the management of individual work packages more closely to the complex project structures. Amongst others, this could encompass the following:

- an inclusion of sufficient "time buffers" in the work plan for the delivery of outputs that depend on the delivery of one or more other outputs
- the use of a PM software that allows to link overall PM with the management of work packages. This would facilitate a joint monitoring of the work schedule and mutual dependencies among different project activities and outputs

Should the second project phase also be accompanied by an **internal evaluation**, the approach used for output evaluation, too, should be adapted more closely to the complex project structures. To this end, a stronger focus could be put on the of the individual work packages using methods and instruments tailor-made to the information needs of WP leaders and WP members.

4.2. Outcome evaluation

Besides processes, outputs and the quality of project implementation, this evaluation addresses also the outcomes of the JATC. In project logic, the term 'outcomes' refers to the changes triggered by project outputs. Depending on the project duration, outcomes usually start to unfold after the finalization of a project. The internal evaluation, which ends with the JATC, could therefore only attempt to identify indications of emerging changes. To this end, the situation at the beginning of the project was compared to the situation at its end.

4.2.1. The starting environment

Data basis

A comprehensive perspective on the starting environment was gained by conducting ten semi-structured interviews among February and April 2018. Interview partners were EU regulators and EU-CEG experts from five European regions. Topics addressed included the 'implementation of the TPDII', 'the EU-CEG, 'analysis of tobacco products and risk assessment', 'cooperation among member states', and the JATC.

In addition, WP6 and WP7 conducted a 'Common Needs Assessment with the aim to understand the issues, barriers and potential gaps regarding the areas covered by the JATC. It was conducted in the form of a standardized, written survey among 25 competent authorities¹⁰ who participated in the survey during the summer months of 2018¹¹. A detailed description of the methodology and the complete survey results can be found in the report on the survey results.¹²

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⁹ A list of interview partners can be foundAnnex

¹⁰ Within the report, competent authorities refer to either the competent authority or the person responsible for EU-CEG data handling

¹¹ The questionnaire was developed by representatives of all WPs in the JATC during an in-person meeting at the Kick-Off of the JATC and several teleconferences. It has been approved by all members of the participating Common Needs Assessment Working Group.

¹² Needs Assessment Evaluation from EU MS regulators; Deliverable D6.1 and D7.1

4.2.1.1 Baseline Survey – Common Needs Assessment

Below, results of the Common Needs Assessment which are related to project outcomes or expected project outcomes respectively are summarized.

Findings

The following diagram shows the areas in which respondents expected the JATC project to bring about changes i.e. produce outcomes.

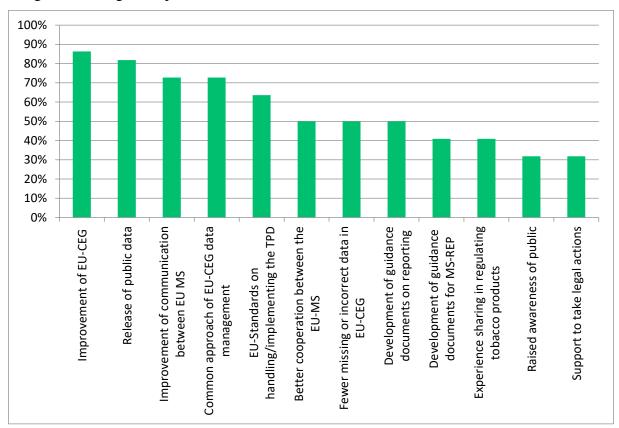


Figure 3: Expected Outcomes of the JATC

From 80 to 90% of the respondents and thus most frequently mentioned were 'Improvement of EU-CEG data handling' and 'Release of public data', followed by 'Common approach in EU-CEG data handling' and 'Iimprovment of communication and information exchange among EU MS' which roughly 70% found important.

Barriers identified by the survey referred mostly to the implementation of the TPD in EU MS and EU-CEG.

Concerning the implementation of the TPD a lack of

- staff with specialized knowledge
- a list of market surveillance authorities
- local laboratories for ingredient analysis
- a central information platform/database
- a database of data on ingredients and emissions of tobacco products

were perceived as the most important.

The marriers related to the utilization of EU-CEG/MS-REP were identified as

- Lack of information on 'what is considered confidential data'
- Incomplete or wrongly completed submissions
- Difficulty to extract and make use of individual data within MS-REP system
- Uncertainty on how to make use of MS-REP data due to lack of statistical processing capacity
- Ability to share EU-CEG data across EU MS

4.2.1.2 Interviews

The following section presents an overview of the perception of stakeholders interviewed.

Findings

Implementation of the TPD

The **TPDII** was completely transposed into national laws, yet the practical implementation of the regulation, including track and trace issues, required a lot of work. The collection of fees is a controversial issue to finance corresponding duties of member states.

Though there was a good legislative framework, new product categories, technical equipment, non-nicotine liquids and characterising flavours required new discussions and specific regulations. Interview partners mentioned the lack of product specific regulations (e.g. notifications of novel products), the agreement on scientific methodologies (e.g. regarding standardisation), and the lack of a uniform approach to implementation (e.g. packaging) as challenging. They also found the communication and coordination among and within member states difficult, which for example caused some confusion about the responsibilities of different stakeholders of the TPDII. Moreover, procedural and practical challenges such as a lack of reporting by companies, the monitoring of cross-border distance sale and fee calculation were identified.

In terms of the level of information of the general public, all interview partners perceived an increase in knowledge about the dangers of tobacco products.

The EU-CEG

Interviewed partners were largely satisfied with the basic purpose and functionality of the **EU-CEG**, but stressed the need to improve public access to information on ingredients of tobacco and non-tobacco products as well as corresponding contact details of companies. It was pointed out that crucial requirements for data management in the EU-CEG reporting tool for MS and manufacturers were not yet fulfilled, such as time efficient data handling and user friendliness, data extraction and analysis performance and automation. Technical improvements concerning the generation of reports, an alert system for notifications, the systematisation and automation of data imports, the submitters access to up to date information and options for file validation are mentioned along with the need for better submitter information to avoid redundant data. The European Commission was expected to provide a harmonised ready to use approach for confidentiality and the disclosure of information.

Analysis of tobacco products and risk assessment

The awareness of available laboratories for tobacco and non-tobacco product **analysis** varied among interview partners. Progress was identified in the development of standards for sampling and testing of tobacco products and partially for e-cigarettes and liquids, yet approaches differed among MS. Analytical skills needed to be developed and independence was an issue in cases where expenditures related to testing were borne by the manufacturers. Building up expertise was mentioned as being a big challenge.

Improvements could have been made with the analysis of characterising flavours, harmful ingredients beyond TNCO, prioritisation of chemical substances for analysis, exposure scenarios in cooperation among MS' laboratories, and fund management by an independent authority. Interview partners also stressed the need for critical reviews of tobacco product studies.

Cooperation among MS

Overall, interview partners perceived the cooperation among MS to function very well, to be very lively and fruitful for national developments. Communication channels mentioned included meetings in Brussels, online discussions, working groups and subgroups. This notwithstanding, some interview partners suggested to establish an additional, regular exchange format for enforcement authorities and a forum to support daily problem solving. In order to strengthen its role in guidance and coordination, it was found that the EC should take more

action with regard to supporting communication, making summaries of specific solutions and disseminating detailed meeting minutes of expert groups.

4.2.2. Situation at the end of the project

Data basis

To obtain a comprehensive overview of the challenges and changes during the project period as well as future tasks one focus group with five participating stakeholders was conducted, complemented by the dispatch of a standardized questionnaire which was answered by eight stakeholders.

The participants were EU Regulators, EU CEG experts, collaboration partners, WP members and leaders, from five European regions.

Both the focus group and the questionnaire addressed the same topics as the expert interviews.

4.2.2.1 Focus Groups and Survey

Findings

Implementation of TPD II

During the period of the Joint Action on Tobacco control, the implementation of the TPD II was the main task, especially in countries that had a delayed transposition.

Since the national legislation with transposed TPD II provisions was published, the economic operators were informed by the competent authorities about the changes in the legislation and were guided how to succeed in meeting the legal requirements connected with a new tobacco traceability system. After the transitional period and after the withdrawal of the non-compliant products the economic operators cope with the legislation. There are some ongoing problems though, especially because of the recent application of the tobacco traceability rules.

Although changes in regulatory provisions did not impact every country significantly, some participants mentioned a high activity level due to measures that needed to be implemented and an increase in regulations of tobacco products, e-cigarettes and especially novel tobacco products.

The transposition of the TPD II into national legislation led to changes in internal regulations and in performing the controls, which required a thorough training of field inspectors. The

increase in administration related to the EU-CEG and the advisory role for the economic sector is seen to be demanding on human resources.

TPD II marked a milestone for **e-cigarettes**, in that it introduced regulations and respective controls of e-cigarettes and e-liquids, especially of toxic and CMR ingredients. The advertisement of electronic cigarettes is now controlled too. However, the specification and definition of the new requirements turned out to be very demanding and time consuming for public administrations. Manufacturers try to avoid regulatory provisions of the TPD II for example with "Do-it-yourself" products¹³.

At the time the TPD II was written there was little information on **novel tobacco products** available (e.g. heated products, herbal products, tobacco product alternatives and nicotine pouches). Therefore, they are not well covered by the TPD II. In fact, new products that cannot be assigned to one of the existing categories emerge constantly. This makes the regulation of these products more and more complex. Many of the members of the focus group and respondents of the survey see novel tobacco products as the challenge of the future and advocate for a common European strategy in this area, including the provision of better information to the general public. This requires an adequate legislative answer to new developments on the market which takes into account a high level of protection for human health. The challenge here is the ability of NTPs and e-cigarettes to create poly-addictions. The addictive element is not necessarily nicotine but can be flavour, smoking sensation or the smoking device itself, just to name a few.

Regarding **tobacco products** the main changes occurred due to the adoption of regulations. These changes include for example pictorials on cigarette packs, the menthol ban and the prohibition of internet sales, which also applies to related products.

However, regarding regulations related to **additives**, some countries are perceived to be lacking behind. Some additives, as for example menthol, which has inhalation facilitating properties, should be banned under the TPD II but due to implementation issues, so far only a few countries have banned it.

It was also mentioned that a lot of awareness raising measures to increase the public knowledge on the risks of tobacco are being implemented, yet with only limited effects. .

¹³ The manufacturer sells the e-cigarettes, the base of the liquid, the flavours and the nicotine separately. Only the nicotine needs to be notified under the TPD II.

The EU-CEG

The EU CEG is seen to be a big success of the JATC. It facilitates exchange among MS by providing codeable information. The EU CEG was established and step by step new features were added. After initial problems, it is perceived to be well developed and extremely useful.

The front office of the EU CEG, where manufacturers submit their products, has not changed in the last years. Changes were made at the back-end which is the member states reporting tool MS-REP. It has evolved from a read-only interface to a more advanced interface with, for example, the possibility to share datasets, thanks to the JATC data sharing agreement. There is also the possibility to get raw .xml product files on a monthly basis since the end of 2018. This is very useful to analyse the composition of products and to put these datasets into databases to make multivariate statistical analyses.

The main problem with the EU CEG system is the huge amount of information, which are difficult to manage. Currently, all registrants upload all kinds of documents, and the evaluation becomes very confusing and time consuming.

Frequent duplication of product submissions still seems to be an issue. As written in the TPD II, the possibility that the manufacturer and the importer will communicate the same product is foreseen. However, if an importer communicates the product, the information will not be transferred to other importers, who are commercial competition (referring to the submission itself on the portal, as well as packaging and leaflet designs). This leads to some products being communicated several times, which generates immense clutter within the database. It also creates difficulties for inspections in the market by brand. Not only are many of the submissions inconsistent, incorrect or duplicated, but manufacturers are frequently correcting notifications after submission.

The EU-CEG was designed to reduce the workload for manufacturers. However, submitters complain about the system not being user friendly. Participants mentioned that submitters request help because they lost .xml files they uploaded or ask for a list of products they uploaded.

It is also important for each individual country to know that EU CEG only works with sufficient bandwidth; a simple "fast" internet connection is not enough. The IT departments of many research institutions overlook this.

Analysis of tobacco products and risk assessment

No big changes in risk assessment were observed. Mostly novel tobacco products are subject of toxicological evaluation and risk assessment. Novel tobacco products do not yet fall under the TPD II. Therefore, manufacturers circumvent various tobacco laws. National laws stipulate an authorisation process for novel tobacco products.

Good examples are the smokeless heated herbal products, herbal cigarette papers, shisha steam stones and gels, vitamin inhalators and nicotine pouches. For some of these products there are no specific rules in the legislation. However, they should be covered because they may be used as a substitution for the smoking of tobacco and may be widely used by young people.

There is lack of accredited laboratories and of knowledge to analyse tobacco products, e.g. novel tobacco products, smokeless tobacco (excluding the emission measurement in cigarettes). Regarding electronic cigarettes, in general, there are not enough validated analytical methods for testing the composition of refill containers. Additionally, inadmissible ingredients are not treated equally among MS.

Collaboration among MS

The JATC is perceived to have strengthened the cooperation and collaboration among MS.

Regular meetings of expert groups were seen to be fruitful regarding information exchange (e.g. issues with the implementation of the TPD II, tobacco product data analysis, testing of tobacco products and e-cigarettes, trends in tobacco use, regulatory impact of fees on the market, testing tobacco products and e-cigarettes and market surveillance practices across the EU).

The use of a common EU MS email is useful for queries that arise, for example, in reference to any breach of a product, which allows to learn the position of each country in a short amount of time. However, email is not the right medium in the long run, because the current system lacks structure. It is very vulnerable, since it depends on the contacts and knowledge of single persons, which can be lost, for example, due to staff fluctuation.

4.2.3. Conclusions

It is still too early to draw final conclusions about outcomes triggered by the JATC project. The following paragraphs thus only provide a snapshot at the end of the project and it can be expected that further changes unfold during the next year.

Implementation of the TPDII

One of the major objectives of the JATC was the support and facilitation of the implementation of the TPDII in the EU Member States. Expected project outcomes therefore include the implementation of specific provisions and regulations across all or the majority of countries. At the end of the JATC project stakeholders already observed of the outcomes envisaged, notably

- the implementation of warning labels and graphic warning labels
- regulations of ingredients and additives
- regulations regarding novel tobacco products and e-cigarettes, since there was not much of a regulatory environment before

It was also noted, that the competent authorities have started to change administrative processes and internal regulations necessary for the implementation of the TPDII as well as the related training of staff.

The expert group on tobacco policy provides a good platform for information sharing among EU MS, which has helped to reduce the differences in their approach regarding the implementation of the TPDII.

There are, however, still differences concerning enforcement, inspections and control.

Also, there remain some 'grey areas" with insufficient specifications within the TPDII, notably as regards NTPs, which need to be reassessed.

The campaigns conducted in the EU MS to raise awareness of the dangers of tobacco consumption did not achieve the desired results. This is consistent with the experience of other public awareness campaigns on harmful behaviour, such as HIV prevention, the dangers of physical inactivity, etc. This could be because they focused on providing information and knowledge, but according to scientific studies, lack of knowledge is not the problem. Today, everyone who smokes knows that smoking is unhealthy and contributes to the development of many diseases.

The EU-CEG

The improvement of the EU-CEG was perceived to be the most important outcome of the JATC. Most stakeholders noticed a significant improvement over the project period, notably regarding user-friendliness. Nevertheless, a lot of improvements as well as harmonized approaches in data handling still need to be addressed in the future.

Some of the stakeholders expect the EU CEG to evolve into a more business intelligence-like system with more advanced dashboards for regulators to analyse data and to determine the quality and consistence of the data in a more effective way.

Analysis of tobacco products and risk assessment

With regard to the analysis of tobacco and risk assessment, project outcomes did not unfold yet. The control of ingredients is still challenging, especially for countries with insufficient laboratory and/or chemical analysis capacity. Overall, there are not enough accredited and independent laboratories and/or expertise to analyse tobacco products, e.g. novel tobacco products and smokeless tobacco. Regarding electronic cigarettes in general, there are not enough validated analytical methods for testing the composition of refill containers.

A further, and ongoing challenge is the monitoring and regulation of the ever-evolving tobacco product landscape. This is a continuous task of all competent authorities, which could be facilitated by the establishment of a network for information sharing.

Presently, assessment frameworks for the evaluation of various novel tobacco products related to their toxicity, addictiveness and attractiveness, as well as validating methods on measuring nicotine emission in e-cigarettes are in the process of being developed.

However, the approaches towards the toxicological evaluation and the risk assessment of tobacco and related products still need to be harmonized.

Collaboration among MS

As a result of the JATC, cooperation among EU Member States has improved significantly, as has cooperation among EU Member States and the EU.

A stronger involvement of project partners in future project phases might strengthen the cooperation even more.

What is still missing, however, are systems for a permanent exchange of information among EU MS, also at an informal level. The systems that are currently in place, for example, EHHP or RAPEX are not defined by the needs of the end users.

4.2.4. Recommendations

During the focus group participants also gave some recommendations for future tasks of competent authorities as did the respondents to the questionnaire. They are summarised below. For the second phase of the JATC project, it could be considered to develop specific activities/outputs to address some of the issues raised.

Implementation of the TPDII

- The **TPD** II contains grey areas, which should to be clarified. Especially, but not only, concerning NTPs the TPD II needs to be reassessed and adapted. A broadening of the TPD (e.g. concerning advertising and taxation) should be taken into consideration. The creation of a work group to identify and consequently clarify the grey areas, as well as ambigious parts of the TPD II, could be taken into consideration.
- Future tasks also include the implementation of plain uniform packaging and the removal of descriptors, further and better regulations of e-liquids and ingredients, more focus on novel tobacco products.
- Regarding public campaigns about smoking, it could be considered to give up the assumption that smokers are not aware of the negative consequences of smoking. Instead, one could do a meta-analysis of studies/evaluations of other interventions against harmful behaviour to find out what makes people stick to a behaviour that they already know is harmful and use the findings for the creation of new campaigns.

The EU-CEG

In the course of the last three years, the **EU-CEG** portal has greatly improved in terms of accessibility and user-friendliness. However, some features are still missing, for example:

- An additional national data collection system
- Separate areas for public and confidential data
- Functions for the download of public data
- The possibility of extracting information of all the products submitted in a list, where also key data (e.g. amount of nicotine) appears
- The possibility to automatically download pdf files, which were attached to specific ingredients, or to have the name of the pdf document displayed in the bulk download along with the specific entry
- Addition of filter options for all data fields
- Automated notification and data rejection for incorrect data submission
- Submitters should be able to access their own notifications in EU CEG
- Artificial intelligence algorithms to identify non-compliant products and ingredients

Unified guidelines with clear rules for submitters should be established to prevent inconsistent and incorrect submissions.

Discrepancies among MS when it comes to the analysis of EU CEG data allow for further uniformity.

The implementation of a supporting EU CEG data analysis team could be considered. A manual that summarizes the options of the EU-CEG would be helpful as well as a training course.

Analysis of tobacco products and risk assessment

- A harmonized approach of the toxicological evaluation and the risk assessment, as well
 as a common assessment of ingredients and additives should be developed.
- More funding is needed to ensure that every member state has at least one independent laboratory. Networks of scientists and laboratories are crucial for information exchange and need to be maintained even after the project.
- Appropriate measures to facilitate the agreement on uniform test parameters within laboratory tests, analogous to food monitoring, should be considered such as for example the establishment of a respective working group.

• A critical review of literature and studies on NTPs should be conducted. It could be considered to integrate it as an output in the 2nd phase of the JATC.

Collaboration among MS

As the cooperation of EU MS has already improved during the first phase of the JATC project, in the second phase specific outputs could further strengthen it. The currently available systems such as EHHP or RAPEX could be complemented by a platform/forum to share and organize information with moderators of different fields of expertise, Ideally, such a system would also allow an informal exchange of knowledge/information and would be accessible via cell phone.¹⁴

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¹⁴ An example would be 'Slack' which can be installed on the PC but also be downloaded as an App to the cell phone. There are, however, many other solutions available.

Annex I

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Overall Objective	Specific Objective	Purpose Outcome Indicator	Target Value	Results Output Indicator	Target Value	Deliverable planned	received	Milestone planned	received	Activities Process and Indicator	Target Value	Deliverable planned	received	Milestone received	
			Interim and final evaluation report show		İ	platified	İ	planned				pianneu		platified	Comments
			improved results of the Quality		; 		i !						į	ļ	
		Effective coordination as identified by	Questionnaire (QQ) by at least 5% (ratio												
		the JATC project team through interna		Consortium agreement											
ordination		evaluation	questionnaire surveys	signed by all parties.	31	-	ļ			Consortium agreement developed.	1				
	To support overall management of the				i 			15.02.2018 +					İ	į	
	project.		Results of Quality Questionnaires on the		<u> </u> 		1	15.02.2019 +	02.03.2018 + 03.02.2020	1			İ	İ	
	ļ projecti	_	meetings show a median satisfaction of 2 i		3	3		15.12. 2019	19.03.2019	Project's meetings held	3				The last minutes were moved to
		project team	the category `information quality' in the last two questionnaire surveys	Steering committee meeting minutes written	3		ļ			Steering committee meetings held	3				
					- 		; 								
		Enhanced collaboration between EU	Results of interviews and focus groups							Ensure collaboration between individual					
		MS' national authorities and EU-CEG experts and third parties or networks	show improvement in the category Cooperation between EU MS′	Established network	3 interactions					WPs by linking up with third parties and networks	1				
		l l	Cooperation between EO MS	Grant agreement signed by all	i .	7i 				Hetworks			İ	į	
				parties.	31	 -				Grant agreement developed.	1				
	To coordinate financia		Receipt of total grant amount of each				į								
	management.		beneficiary as defined in the grant agreement until the end of the project and	First periodical technical and	i : 1	i 15.04.2019	02.04.2020			Interim financial report written	1		ļ		
		 Effective financial management as	communicated to the WP3 team by the	Final report approved by	<u> </u>	. 13.04.2013 	1 02.04.2020				*				
		identified by the beneficiaries	WP1 team	CHAFEA and EC	1	15.12.2020				Final report written	1				
		-	ne Results of interviews and focus groups	Set up of structure for	<u> </u> 	 									
WP1		JATC identified by regulators and competent authorities	show improvement in the Joint Action on Tobacco Control across all domains	external communication (with WP2)	1		į			Preparation of a structure for external communication (with WP2)				ļ	
To ensure appropriate	To summent		Results of Quality Questionnaires on the	(With Wi 2)	 	•				communication (with WY 2)	-				
coordination and evaluation	To support communication activitie	S. I	project progress show a median		i 								İ		
			satisfaction of 2 in the domain `information	on											
		High satisfaction of communication in the JATC communicated by the	quality' and `communication and teamwork' in the last two questionnaire	Set up of structure for			į			Preparation of a structure for internal					
	į	consortium	surveys	internal communication	1		į !			communication	1		į		
					! 		;								
			Results of Quality Questionnaires on the meetings show a median satisfaction of 2 i	in	ļ		ļ								
	To provide scientific	 High satisfaction in regards to the	i	i	! 		; 								
	support to individual	workshops communicated by the	general median satisfaction of 7 in the last							Organise special workshops on common					
	WPs.	consortium	two questionnaire surveys	held	3	} 				research interests	3				
				Attendance of (a) representative(s) of the EC at	i I		į						į		
	İ		 Participation of at least 1 member of the E		<u> </u> 					Invitation of representatives of the EC to			İ	İ	
	To communicate and	Extensive participation of EC in general	1	committee meetings and the			į			project meetings and dissemination					
	report to the EC.	meetings of the JATC	meetings	ifinal conference	100% attendance	! 	i i			events	3			İ	
	To address emerging issues related to the						į								
	implementation of the				<u> </u> 		i i				İ			İ	
	TPD for which the JATC	Fff - time in a second	Results of interviews and focus groups	Condition to the Street was the de-	į		İ			E a difference and a formation of the					
	could contribute scientifically.	Effective issue management as identitied by the consortium	show improvement in the Joint Action on	feedback activities provided by the network of experts	1	 				Establish a network of experts providing feedback during the project period	min 6 experts				
	To manage issues of		Tobacco Control across all domains		-										
	ethics, confidentiality ar	d l				<u> </u> 	i i			5 50 5 50 5 6000	į ¦		İ	İ	
	absence of a conflict of interest.			COI forms signed by all partners	31		į			Absence of conflict of interest (COI) and confidentiality forms written	1			15.10.2018 11.09.20	18
	interest.				; 3 <u>1</u>	 	 			confidentiality forms written	<u> </u>			13.10.2010	
							į						ļ		
				Final dissemination report			į			Dissemination plan and stakeholder				ļ	
ssemination	To disconsistate accorde	L.		delivered	1 1000 ::::::::::::::::::::::::::::::::	15.12.2020)			analysis developed	1				
	as possible, the policy	ly Enhanced knowledge and awareness o	on		1000 visits in 6 months from date		į			Project Logo developed (Ms.)			į		
	recommendations of th	ithe JATC and TPD among target	results of interviews and focus groups	i Project website visited	of website launch		j 			Project Logo developed (Ms.) Project's website launched (Dev.)	1	15.02.2018	28.02.2018	15.01.2018 12.12.20	i 17¦
	project to the target	the current IATC proposal by the IATC	show improvement in the Joint Action on		! 										
	audiences identified in	project team regulators and FII-CEG		laymen report available on	100 Davimla a da		į			laymen report prepared and agreed with		45 42 2020			
	section 3 of the curren JATC proposal.	t experts		the website and downloaded Project leaflets handed out to	100 Downloads	 				consortium partners	1	15.12.2020			
	j			stakeholders	50		į			Project's leaflet developed	1	15.01.2018	04.02.2018	ļ	
					1,000 followers on										
	į			Social media account liked	overall social media	1	ļ			Catablish a sasial madia appearance	1		į	İ	
				and followed by other users Project newsletter	appearance	; 				Establish a social media appearance	1 				
				disseminated to public	300 subscribers	į	;			Send out a project newsletter	3				Tipe
					 								ļ	İ	stakeholder's
							į								list was
					İ		ļ						ļ		completed and delivered with a
					! !								 		delay so as to also incorporate
					ļ		į į						į	İ	the participant
				List of tobacco control] 				j !	į !	İ		stakeholders of
To support the dissemination				stakeholders and regulators delivered				15 10 201	00 10 30	2018 Perform a stakeholder analysis	4				both the 3rd IENSP
information to the public,	i	i	i	denvereu	i	·i	i	15.10.201	.0; 09.10.20	.01011 enorm a stakenoluer dildiysis	1	ł	;	¦	Unternational

	regulators and researchers	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 regulators, competent authorities, EU-CEG experts and WP members	Results of interviews and focus groups show improvement in the domain 'Cooperation between EU MS'	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	
			Results of the Quality Questionnaire on	Written documentation on stakeholders engagement collected 20			Presentations for stakeholders at events and conferences held	6	
		Increased awareness for the To organize a final project achievements of the JATC as identified by the participants	meetings show a median satisfaction of 2 in the category `information quality' and `communication and teamwork' after the	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. To implement the evaluation plan throughout the duration of the project. Systematic outcome monitoring	Results of the Quality Questionnaire show a median general satisfaction of at least 7 in the last two questionnaire surveys All outcomes from WP1-9 are considered in the final evaluation plan at the end of the project	Instruments delivered (and interviews held, focus groups held) Approval for evaluation plan obtained from the steering committee Findings of qualitative and quantitative WP3 evaluation data presented and communicated		15.01.2018 16.01 15.01.2018 16.01 15.01.2018 17.01 15.04.2018 16.04	Create a Logical Evaluation Framework consisting of process, output and outcome indicators 1.2018 1.2018 1.2018 1.2019 1	1 15.03.2018 1 15.04.2019 1 15.11.2020	
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.	Ishow improvement in the Joint Action on	Outline on the mapping of activities and capacity from 28 EU MS regulators delivered 1 Questionnaire disseminated to the EU MS 60% response rate Outline on the mapping of the current status quo of TPD implementation 2 Outline on the mapping of the tobacco control funding Report on TPD mapping and sustainability activities including in-house capacities delivered 1 Action Plan for sustainability activities delivered 1 Sustainability plan, including scenarios for long-term sustainability delivered 1	15.04.2019 09.06.2019		Survey of activities and capacity from EU MS mapped Develop a questionnaire for mapping and sustainability Map the current status quo of TPD implementation across the EU MS Map tobacco control funding across the EU MS Map in-house and cross border regulatory, scientific and technical capacity resources Develop an action plan for sustainability activities Sustainability plan detailed	1 1 1 1 1 1 1 15.12.2020	5.01.2018 07.03.2018
		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 of MS E-learning material by EU MS 1 download from regulators downloaded each of 28 MS Update of the status quo of the repository for long term planning given to project team 1 Participation of stakeholders, NGOs, researchers and regulators 70% attendance		15.12.2019 04.02	"How-to" guides developed and uploaded "How to" guide platform created and fully functional Continuous feeding of the platform with reports and dissemination material External joint meetings organised	5 1 3	5.01.2019 5.02.2019 08.02.2019

					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 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.	Established legal basis for regulators	Results of interviews and focus groups show improvement in the domain `The EU CEG in your country' Results of interviews and focus groups	Imodel/framework, with focus Ion identifying public non- confidential data for classifying data in EU-CEG Approval of classification model/framework by EU MS and DG Sante Report on the defined legal aspects of assessing other EU MS data in the JATC project	28	28.09.2020 15.06.202	30.06.2020	Analysis of variables that should be considered public and not confidential in EU-CEG system (performed by Hellenic Cancer Society, HCS) Develop a classification model/framework in collaboration with a legal specialist Organisation of a webconference for EU MS in JATC project to evaluate and receive feedback on the classification model/framework Outline the legal requirements of assessing other EU MS data in the JATC	1
			and EU-CEG experts for publishing and sharing non-confidential data within the JATC project period		Data exchange template for the sharing of data within the JATC project produced and delivered to JATC participants	1 15.07.2018	27.08.2018		project Produce a template for the sharing of data within the JATC project	1
	To enhance the ease of access to the data collected through the EU-CEG	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	Results of interviews and focus groups show improvement in the domain `The EUCEG in your country´	Report on technical solution for securely accessing and processing public nonconfidential data including best practices on making data available to the general public at national level delivered Insights about other EU MS best practices on making data available received EU MS datasets ready and delivered to the relevant	1 15.05.2020	03.12.2020		Develop a technical solution in EU-CEG for the transfer of data for analysis in collaboration with DG Sante Organisation of a webconference about best practices from EU MS on how to make data available to the general public Collect the list of variables that are requested by WP6-9 and send this list to Hellenic Cancer Society (HCS) so they can	1 15.01.2019 19.03.2019
		each EO Wis.	Expansed sharing of data among EU	Decults of interviews and focus groups	vertical WPs Second round of EU MS Idatasets ready and delivered to the relevant vertical WPs	4	15.01.202 15.10.202	19.03.2019 19.03.2019 18.10.2019	create the individual datasets 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.		Results of interviews and focus groups show improvement in the domain `The EU CEG in your country' Results of interviews and focus groups show improvement in the category `The EU	sharing of EU-CEG data Report for M1-18 and M18-34 on the potential improvements and/or alterations of the EU-CEG	i i	7.03.2018 +		Propose a permanent mechanism for the sharing of EU-CEG data based on the findings from legal and IT specialists Perform an active data collection process	1 15.04.2020 29.09.2020 1 15.07.2018 24.09.2018
			the group of EO-CEG experts	CEG in your country	Report to WP1 on the tasks performed under WP5	2 15.10.2020 1	29.09.2020		from EU MS regulators on the EU-CEG Summarize findings and solutions from the whole WP5 project	15.07.2018 24.09.2018
WP6- Tobacco product evaluation		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 EUCEG in your country'	Needs assessment questionnaire returned by EU - MS regulators Report of the WP6 needs assessment evaluation from EU regulators	min 12 1 15.10.2018	26.10.2018		Develop a needs assessment questionnaire for EU MS regulators Analysis of data for WP6 from needs assessment questionnaire	1 15.01.2018 07.03.2018 1
		product information as	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 Initiation of first wave and second wave of product data analyses completed	1 2 15.04.2019	15.10.2018 15.2.2020 31.01.2020	05.11.2018 + 12.05.2020	Data sets from EU MS regulators regarding requirements for EU-CEG collected from WP5 Assess tobacco product description data and tobacco product presentation and sales/market data Perform a statistical analysis of the tobacco ingredients and additives in relation to their function, weight and	3
	To monitor and provide support to the tasks of tobacco and ecigarette product regulation	product ingredient and	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		03.12.2020		registration within REACH and CLP classification Assess the associations between declared tobacco product information (recipe) vs. measured tobacco product information Qualitatively assess the submitted emission data for tobacco products (collaboration with WP8) Identify and further evaluate products that have characterising flavours or containing additives described in TPD Art7(6-7)	1
		data submitted for	Greater awareness on toxicological/additive products by EU	Results of interviews and focus groups show improvement in the category	Evaluation of toxicological information delivered	1		1	Evaluate the toxicological information on additives in line with TPD Art5, p3	1

		lincluding also information JATC project team on priority additives.	assessment'	List of additional additives that could be subject to				 - -	Perform a qualitative and quantitative		
				enhanced reporting obligations delivered	1			15.10.2020	analysis of the data on priority additive 03.12.2020 as reported per brand and product type	!	
		To perform a needs			1			13.10.2020	OS.12.2020 as reported per brand and product typ		
VP7- E-cigarette product		assessment of EU MS	Results of interviews and focus groups	Needs assessment questionnaire returned by EU					Develop a needs assessment		
valuation		regulators with regards to Greater awareness of EU-CEG aspects of priority for e-licapabilities by EU MS regulators	show improvement in the domain `The EU		min 12				questionnaire for EU MS regulators	1	15.01.2018 06.06.2018
		cigarette products within	CEG in your country'	Report of the WP7 needs assessment evaluation from					Analysis of data for WP7 from needs		
		the EU-CEG.		EU regulators	1	15.04.2018	26.10.2018		assessment questionnaire	1	
									Data sets from EU MS regulators		
		To assess e-cigarette Greater awareness on ingredient	Results of interviews and focus groups	Analysis plans for e-cigarette					regarding requirements for EU-CEG		
		product data as function, role and toxicity by EU N		products finalised	1				collected	min 10	
		submitted data via the EU regulators, EU-CEG experts and the							Quantitatively analyse e-cigarette submission description data and		
		CEG. JATC project team	lassessment´	Initiation of first wave and					technical design, product presentation	i i	
				second wave of product data languages completed	2	 		15.10.2018 15.02.2020	and toxicological information on 05.02.2019+ 12.05.2020 ingredients	3	
	To monitor and provide support										
	to the tasks of tobacco and e- cigarette product regulation	To monitor reported e-	. Results of interviews and focus groups	Report on e-cigarette product		15.4.2019 +			To perform a statistical analysis of the		
		'cigarette liquid ingredient'	show improvement in the category	analyses written		15.11.2020	03.12.2020		data provided by EU-CEG	1	
		and emission data in line with TPD Art20(2).	team Analysis of tobacco products and risk	Internal report on the e- icigarette emissions and					i To assess the emission data and their		
				international protocols					equivalent emission protocols as		
				completed	1			15.04.2020	27.11.2020 submitted through EU-CEG	1	
		To create a checklist to monitor e-cigarette				j 		 			
		product compliance to	Doculto of intonvious and forms								
		the TPD and support EU	Results of interviews and focus groups show improvement in the category					 - 			
		a system for the	oliance `Analysis of tobacco products and risk	Checklist for e-cigarettes is	-			 	Checklist for e-cigarette product		15.04.2040
		collection of information monitoring by EU MS regulators	assessment' Results of interviews and focus groups	provided to EU MS	10				compliance to the TPD created		15.04.2019
		about suspected adverse effects on human health	show improvement in the category	Report on a proposed system				 - 			
		in line with Art20(9). Better reporting for adverse even EU MS regulators	ts by Analysis of tobacco products and risk assessment	for the reporting of adverse events written	1	15.10.2019		01.11.2019	Proposed system for adverse event reporting developed	1	
			-							-	
P8- Laboratory		Improvement of TPD approved la	Decrees of independency for all TPD					 			
erification, collaboration nd analyses		independency from the tobacco/	·	Data collection surveys filled out by CAs	min 20				Develop a data collection survey	1	15.02.2018 14.02.2018
,		cigarette industry as identified by	the team and communicated to the WP3 team	1	0					_	
		EU MS´ regulators To develop requirements	within the JATC project period	Report on the status quo of laboratories in use by the EU				 - 	Map the current status quo of		
		of independent		MS' competent authorities	1	15.12.2018	21.11.2018		laboratories	min 17	15.07.2018 24.07.2018
		laboratories for ingredient evaluation.	Written recognition of adoption of the					 		min 10 (i.e., TNCO for	
			proposed capacity requirements for			i i		 		emission, N	
		Adoption of the proposed capacit	i -							for content for	
		requirements for ingredient, containing and emission evaluation at the er	· · · · · · · · · · · · · · · · · · ·	Report on capacity					Develop laboratory capacity	tobacco + N for content /	
		the JATC project by the EU MS'	communicated to the WP3 team within the			 		 	requirements for ingredient, content a		
	Assist EU MS networking and	regulators	JATC project period	laboratories written	1	15.08.2019	16.06.2020		emission evaluation	cigs)	
	collaborations between							 	Develop a data collection form to obtain	I I	
	laboratories for tobacco			Data collection forms filled lout by CAs	min 10				either aggregate or disaggregate result	i i	
	evaluation	analysis activities '	ntory Written recognition of complete						Datasets obtained from EU MS	Ī	
		performed by MS and to CFG as identified by the WPS teal	e EU- compliance of results by the WP8 team and communicated to the WP3 team within the						laboratories on analytical data for predefined products, which will be		
		assess comparability across laboratories.	JATC project period	laboratory variability of EU		i i			critically evaluated and re-analysed at a		
				MS emission data	1	15.09.2019	03.12.2020		European scale	min 5	
				Report on the replication of							
				laboratory measurements	1	15.10.2020	18.12.2020		laboratory measurements	min 1	15.10.2019 02.03.2020
								 	Networking meeting with EU and		
		To develop collaborations Enhanced communication and and communication with	Results of interviews and focus groups	Report on emission protocols concluded	1				international laboratories (incl. GoToLa and TobLabNet) held	min 1 meeting	
		other international States' laboratories as identified	mber show improvement in the category by the \frac{1}{Analysis of tobacco products and risk		T				and roblabively neid	I meeting	
		activities on tobacco FU Member States' regulators	assessment'	Networking meeting minutes, lincluding minutes from the				 	 		
		laboratory assessment.		two internal meetings of		 		15.01.2019	collaboration with already existent		
				WP8, written	2	İ			05.02.2019 + 01.04.2020 international activities)	2	
						i 					
DO Additives subject		To compose an Enhanced sharing of reporting	Dissemination to min 10 people from the								
9- Additives subject enhanced reporting		assessment/evaluation		e Assessment/Evaluation							
igations		for 'good experimental industry	JATC project period	framework finalised	1	15.06.2018	26.10.2018	 	framework	1	
		practising' (GEP). Established guidance for the tobal industry on the kind and design of									
		studies to be performed and asse	ssed practice guidelines from the JATC website					 - 	Good experimental practice guidelines		
		on	within the JATC project period	guideline written Reports on 15 priority	1				identified	1	
				ladditives obtained and				 - -			
		To facilitate recovery:	Results of interviews and focus groups	categorised and inventory	-	45.40.005	27.00.00:-		Priority additive data and supporting		45.0000
		To facilitate peer review of the enhanced	show satisfaction concerning the peer	developed and delivered Experts in document review	1	15.10.2018	27.06.2019		information obtained Peer reviewers, experts in the field	1	15.10.2018 12.11.2018
	Support EU MS in the process of	reporting information	reviewing process in the category `Analysis of tobacco products and risk assessment'	trained	12				recruited	12	
	monitoring and updating priority additives	submitted by a panel of suitable experts. Enhanced information on specific	as communicated by the participants at the	Peer review meeting minutes written	1			 	Peer review process commenced and facilitated	1	
	priority duditives	priority additive(s) for EU MS´	end of the project		_				Write a final report on the peer review	1	
		regulators, EU-CEG experts and the projection of	·	Report on peer review		15 10 2010	02 42 2020	 - 	the enhanced reporting information or		
		, JATE consortium within the proje	u i	outcomes delivered	1	15.10.2019	03.12.2020	! :	priority additives	į 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 priority additive delivered Collaborative meeting	1	To provide feedback on additives and prepare a report 1
	minutes written	1	To organise a collaborative meeting 1
comprehensiveness of the Secure comprehensive assessment/evaluation template for the types of	evaluation report as communicated to the	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 // the LogFrame was updated in jan 2019 referring to the participant portal and it's content

^{**)} 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

ith February 2020

Annex II

QUALITY QUESTIONNAIRE

Dear participant,

The WP3- Evaluation of the action creates and implements 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. 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 answers will be treated confidentially and anonymously. Your participation is voluntary.

Thank you for your cooperation!

PROJECT PROGRESS

Personal details							
1. What is your ro	le in the JAT	TC project?	•				
☐ WP leader	I	□ WP me	ember	[Stakeholder		Collaboration partner
☐ EU Commissio	n l	☐ CHAFE	A	[☐ Other, please s	pecify	
2. In which WP are	e you involv	ed/do you	participate?				
□ WP 1	□ WP 2	[□ WP 3	[□ WP 4	□ WP 5	□ WP 6
□ WP 7	□ WP8	[□ WP 9	[☐ I am not involve	ed in any of t	ne WPs
☐ Other, please	specify			_			
Information qualit	<u>:Y</u>						
Please specify:							
□ WP 1	□ WP 2	[□ WP 3	[□ WP 4	□ WP5	□ WP 6
□ WP 7	□ WP8	[□ WP 9				

3. Please indicat	e how satisfied	l you are with					
		Very satisfied	Satisfied	Neutral	Unsatisfied	Very unsatisfied	Not applicable
Management o	of the WP						
Implementatio planned activit							
Outputs produ	ced						
Relevance of the documents dis within the WP	patched						
Information ex about tasks con competence ar	ncerning my						
Regular update progress of the	e on						
Comment:							
Communication Please specify: WP 1 WP 7	and teamwork WP 2 WP 8	⊆ wi		□ WP 4	□ WP5	□ WP 6	
4. Please indicat	e how satisfied			Newbook	Uncertified.	Vannatified	Not and Carlo
4. Please indicat	e how satisfied	Very	Satisfied	Neutral	Unsatisfied	Very unsatisfied	Not applicable
4. Please indicat Cooperation as teamwork between teamwo	nd			Neutral	Unsatisfied	Very unsatisfied	Not applicable
Cooperation ar	nd ween WP	Very satisfied	Satisfied			Very unsatisfied	
Cooperation at teamwork between WP m Allocation of to between WP m	nd ween WP on nembers asks nembers	Very satisfied	Satisfied				
Cooperation at teamwork between WP m	nd ween WP on nembers asks nembers xchange	Very satisfied	Satisfied				
Cooperation are teamwork between WP metween	nd ween WP on nembers asks nembers xchange ith other	Very satisfied	Satisfied				
Cooperation at teamwork between WP members Allocation of tabetween WP members WP members	nd ween WP on nembers asks nembers xchange ith other	Very satisfied	Satisfied				
Cooperation at teamwork between WP members Allocation of tabetween WP members WP members	nd ween WP on nembers asks nembers xchange ith other	Very satisfied	Satisfied				
Cooperation at teamwork between WP members Allocation of tabetween WP members WP members	nd ween WP on nembers asks nembers xchange ith other	Very satisfied	Satisfied				
Cooperation as teamwork betweensen WP members Allocation of tabetween WP members Comment: General	nd ween WP on nembers asks nembers xchange ith other	Very satisfied	Satisfied				
Cooperation as teamwork betweensen WP members Allocation of tabetween WP members Comment: General	nd ween WP on nembers asks nembers xchange ith other	Very satisfied	Satisfied				
Cooperation as teamwork between were social interaction of the between WP metween WP metween WP metween were information with WP members. Comment: General 5. Please indicate	nd ween WP fon nembers asks nembers xchange ith other	Very satisfied	Satisfied Grant G	of the project a	t the moment (1		

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!

Annex III

QUALITY QUESTIONNAIRE

Dear participant,

The WP3- Evaluation of the action creates and implements 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. Throughout the project, we will collect data to monitor and evaluate the project procedures and assure quality.

Please take yourself approximately 5 minutes to reflect on each question addressed and try to be as sincere as possible. Your answers will be treated confidentially and anonymously. Your participation is voluntary.

Thank you for your cooperation!

☐ Consortium meeting

MEETINGS AND TELECONFERENCES

Personal details						
1. What is your rol	e in the JATC pro	ject?				
☐ WP leader	□ w	P member	☐ Stakeholder		Collaboration partne	er
☐ EU Commission	n□ CHAFEA		other, please specify			
2. In which WP are	you involved/do	you participate?				
□ WP 1 7	□ WP 2	□ WP 3	□ WP 4	□ WP 5	□ WP 6	□ WP
□ WP 8	□ WP9	☐ I am not in	volved in any of the W	Ps		
☐ Other, please s	pecify		_			
Organisation of me	<u>eetings</u>					
3. Which meeting/	conference did y	ou attend?				
☐ Meeting			☐ Teleconference	e		
☐ Steering Comm	nittee meeting		☐ Steering Com	nittee teleconfe	rence	

☐ Consortium teleconference

☐ Meeting on WP			☐ Teleconfer	ence for WP	_	
☐ Meeting on WP			Teleconfer	ence for WP	_	
☐ Meeting on WP			☐ Teleconfer	ence for WP	_	
☐ Meeting on WP		С	☐ Teleconfer	ence for WP	_	
☐ other meeting, please spec	cify:					
Title: Title: Title: 4. Organisation of meetings h			_	Date (dd/mi	m/yy):/	
	Very satisfied	Satisfied	Neutral	Unsatisfied	Very unsatisfied	Not applicable
Timeliness of notification						
Location of the venue						
Accessibility by plane,		П	П	П	П	
train, etc. Availability of accommodation						
Compilation of the agenda						
Length/Duration of the meetings						
Comment: 5. The meetings' venues: Plea		w satisfied you Satisfied	were with Neutral	Unsatisfied	Very unsatisfied	Not applicable
Premises						
Technical equipment of auditorium						
Acoustics in the meeting room						
Ventilation and air- condition						
Catering	П	П	П	П	П	П
						

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						
7. Have your expectations regar Yes No If not, please specify why or wh			/teleconferen	ce been met?		
8. Please indicate how satisfied 1 2 3 (=worst)	_	n the meeting/t	releconferenc	e in general (1= w	orst; 10= best):	

Thank you for participating!

Annex IV

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 60 minutes approximately.

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 anonymized. 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 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 satisfactorily answered.

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

- o Introduce yourself
- o Thank person for taking time for you today and offering to take part in this interview
- o Tell participant what the interview will be about and which topics are covered
- Tell participant that the questions asked are completely neutral. No judgment, just a portrayal of the current situation.
- 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
- o The participant is free to cut out passages of the transcript if he/she requests it
- o If the participant wants to withdraw from the study, their data will not be used

Topics/Questions

Implementation of the TPD II

- 1. Please tell me something about the current situation in your home country regarding the implementation of the TPD II (administrative and operative).
- 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?

Annex V

Declaration of consent for participation in focus groups

Joint Action on Tobacco Control (JATC – 761297) - 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 Joint Action on Tobacco Control. Please read the following consent form carefully. If you have any questions do not hesitate to ask the interviewer. Before beginning of the focus group, 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 to 90 minutes approximately.

With your signature you agree to the following:

- The focus group will be audio 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 team and researchers who are part of the research process.
- The transcript of the focus group will be analyzed by Irina Gebetsberger-Hartleitner.
- The findings of the focus group will be anonymized. Any quotations or summaries of 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 and the recording will be kept for 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 to 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 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 satisfactorily answered.

Name of the participant (in block letters)	Signature of the participant		
IRINA GEBETSBERGER-HARTLEITNER Name of the interviewer (in block letters)	Signature of the interviewer		

Date of the web-conference: 01.07.2020

Topic Guide for focus groups

Joint Action on Tobacco Control (JATC – 761297) - WP3 Evaluation of the action

- 1. Referring to the period of the last three years (of the project), what happened on the European level concerning the following topics?
- 2. What was the reason for the changes you saw?
- 3. Where would you like to see changes in the future regarding the following topics?

Implementation of the TPD II

- 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

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

Analysis of tobacco products and risk assessment

- Availability of laboratories
- Critical review of studies on tobacco products
- Divergent study findings
- Common approach

Cooperation between EU MS

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

Annex VI

Introduction

Dear participant,

In the beginning of the JATC, WP3 conducted several interviews to assess the status quo and the desired status concerning Tobacco Control. Now, after almost three years of the Joint Action on Tobacco Control we want to assess whether or not there has been an improvement on certain topics, what the challenges were and still are, as well as what kind of changes you want to see in the future.

Following, you find an open questionnaire. Please feel free to write whatever comes to your mind regarding the following topics. With each question, there are some examples of what your answers can include, but these are just suggestions. Your answer can be as short or as long as you see fit. Please reflect back on the past three years of the JATC. What were the issues in the beginning, what did you wish for the future, etc. and what has changed over the course of the project? Are some issues still the same? Where can you see improvement? Did something turn out not the way you anticipated in the beginning? What kind of changes do you want to see in the future? Etc.

Attached is also a declaration of consent. Please return the signed declaration alongside with the questionnaire.

You can answer directly in the word-version of this questionnaire. Each question has a text box for your answer. If you prefer to send me an extra document or provide the answers directly in an email, please make sure that you mark your answers according to the topics:

- 1. Personal Data
- 2. Implementation of the TPD II
- 3. EU-CEG in your country
- 4. Analysis of tobacco products and risk assessment
- 5. Cooperation between EU MS
- 6. Other

Questionnaire

1. Personal Data

W	nat is your role in the JATC project?
	WP leader/member, which WP:
	EU-CEG Expert
	Stakeholder
	Collaboration partner
	EU Commission
	CHAFEA
	Regulator
	Other, please specify
<u>In</u>	which European region are you located?
	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)

2. Implementation of the TPD II

- 2.1 Referring to the period of the last three years (of the project), what happened on the European/National level concerning the Implementation of the TPD II
- 2.2 What was the reason for the changes you saw?
- 2.3 Where would you like to see changes in the future regarding the Implementation of the TPD II?

Topics may include

- Changes
- Current and future process of implementing the TPD II
- Your own view/opinion
- Satisfaction and improvement

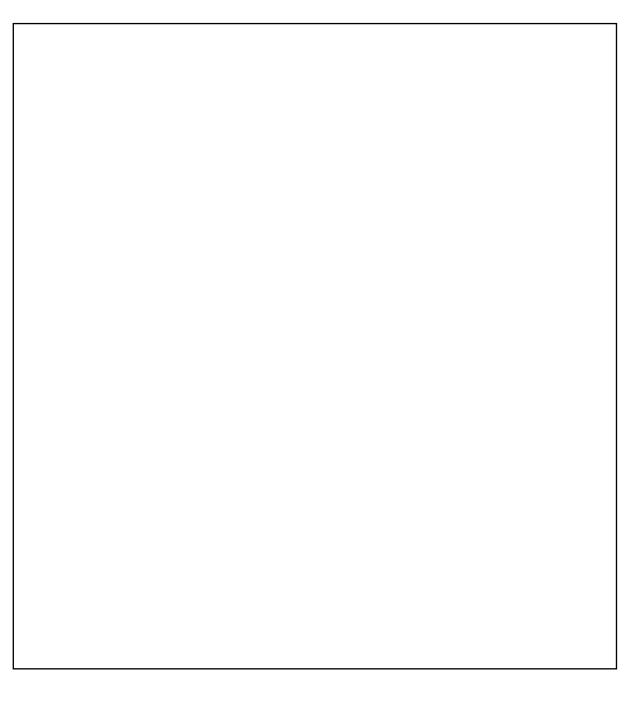
•	Future tasks/challenges Enhancement of public's knowledge				

3. The EU-CEG in your country

- 3.1 Referring to the period of the last three years (of the project), what happened concerning the EU-CEG in your country or on the European level?
- 3.2 What was the reason for the changes you saw?
- 3.3 Where would you like to see changes in the future regarding the EU-CEG?

Topics may include:

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



4. Analysis of tobacco products and risk assessment

- 4.1 Referring to the period of the last three years (of the project), what happened on the European/National level concerning the analysis of tobacco products and risk assessment?
- 4.2 What was the reason for the changes you saw?
- 4.3 Where would you like to see changes in the future regarding the analysis of tobacco products and risk assessment?

Topics may include

Availability of laboratories

Common approach			
5. Cooperation between EU MS			
5.1 Referring to the period of the last three years (of the project), what happened on the			
European level concerning Cooperation between EU Member States?			

5.3 Where would you like to see changes in the future regarding the Cooperation between

Critical review of studies on tobacco products

Divergent study findings

5.2 What was the reason for the changes you saw?

Implementation of the TPD II

EU Member States?

Topics may include

•	Future prospects

EU-CEG

6. Other

Is there anything else you want to add?

Tobacco product analysis Useful cooperations Exchanging experiences

Fe	eel free to comment a	nything that seems	s relevant to you.	

Thank you for taking your time and filling out this questionnaire!

If you have any questions please do not hesitate to ask.