



Joint Action on Tobacco Control (JATC)
Agreement n°: 761297— JATC — HP-JA-03-2016

**WP5 - D5.6 Report for M1-18 on the potential
improvements/alterations identified through
Task 3.1**

Circulation: Public
Authors: SIK, UK-DOH
Date: 13 March 2019
Doc. Ref. N°: D5.6



This activity is part of the project Joint Action 761297/JATC, which has received funding from the European Union's Health Program (2014-2020)

Table of Content

Background	3
Analysis of survey results	3
1. Greater capacity for processing data	4
2. Clearer segregation of confidential and public data	4
3. An increase in accuracy, validity and completeness of data	4
4. An example in practice	5
Conclusions	6

Background

A central objective of WP 5 is to present feedback from EU Member States regulators, focusing on improving the utility of the EU Common Entry Gate (EU CEG). This report supplements the “*Needs Assessment Evaluation from EU MS regulators*” Report of WP 6 & 7 and focusses specifically on how the EU CEG and Member States Reporting Tool (MS Rep) may be further developed to improve the efficient use of accurate, clear and useful data.

The Expert Working Group held on 4 December 2018 highlighted the many enhancements to EU CEG and MS Rep and thanked the SANTE IT team for listening and moving forward to address many of the concerns raised by Member States. Discussions covered many of the topic areas identified here, with the tour de table reiterating the importance of increasing the accuracy, clarity and utility of the data.

Analysis of survey results

Analysis of the survey results was made through categorisation, with each statement being assessed for its relevance to increasing accuracy, clarity and utility of the data. Statements that fell outside these categories were not included in the analysis, nor were statements that covered topics already addressed by the SANTE IT team. Once assessed the relevant statements were sorted into 3 main topic areas, Inputs, Outputs and Support, with both Inputs and Outputs further divided into issues of Clarity or Accuracy. Statements that covered the same topics were amalgamated to form one statement that covered that topic and Support topics were assimilated into the respective Input or Output topic areas. Responses that fell into the Support category were only included where their solutions could be found in improvements to the EU CEG.

Following this process, the majority of statements fell into the Output Utility grouping and addressed the lack of data processing within the EU CEG. Member States almost uniformly believed that the functions of the EU CEG could be improved by the opportunity to segment confidential from public data and the ability to publish public data, “at the push of a button”. In addition to this Member States raised concerns about the ability of the EU CEG to deal with duplicate, inaccurate or false records.

In the topic area of Output Accuracy, the main concern raised was around a better expression of confidentiality within the system. Member States felt that the identification of confidential data was not clear within the current system. This has led to a lack of confidence in publishing and sharing data, reducing the likelihood of Member States performing the related functions of the TPD.

Suggestions within the Input topic areas were similarly focused, revealing only two main concerns. Requests to do with Input Clarity centered on provision of guidance for submitters and those of Input Accuracy addressed the benefits of increased validation rules.

1. Greater capacity for processing data

A greater capacity for centralised data processing through the MS Rep, including a report generator, will require an increasing burden in hardware, software, development time and support. In addition to the above central data processing system and to augment more higher level statistical analyses, it may be necessary to decentralise the processing of data, similar to those implemented with the collection of data. This would allow Member States an increased ability to analyse data, including the ability to exclude duplicate, inaccurate or false records. Furthermore, the Commission may also want to consider implementing a report generator in MS Rep in order to further increase the processing of data by Member States.

2. Clearer segregation of confidential and public data

WP5 also covers the sharing of data between Member States and this includes discussion of how to categorise confidential and public data. A task of WP5 is to identify which variables should be considered public and not confidential, an activity which is planned in 2019. It is clear from Member States' feedback that they would benefit from increased support in identifying data that is public and can be published, and data that is and can be considered confidential which should not be published.

The MS Rep may benefit from an option that would enable Member States to extract records that only report on public data. These records should be presented in a form that can be easily published and could e.g. highlight where data has been provided that has been marked confidential by the industry.

3. An increase in accuracy, validity and completeness of data

Member States uniformly reported a dissatisfaction with the accuracy, validity and completeness of data. The suggestion that this could be addressed was tabled at the Expert Working Group on 4 December 2018. The IT SANTE team explained that the EU CEG was designed with validations, however these caused a large number of submissions to be rejected. They also explained why the introduction of validation rules at this stage would cause substantial data errors within the existing dataset.

This issue is not easily solved, as any decentralisation of this function may result in inputs that are valid in one Member State being invalid in another, leaving manufacturers receiving conflicting and irreconcilable requests to modify their data.

Member States expressed a dissatisfaction that they could not themselves go through the process of making a notification and so often did not understand the difficulties faced by those attempting to make notifications. It was also suggested that allowing access to the notification tool would enable them to better support

notifiers with increasing the accuracy, validity and completeness of data. The ability to analyse data at the Member States' national representative level could be an additional potential solution to this issue, however, in such a case “how to guides” would need to be provided to Member States with limited statistical analysis capacity.

The Commission could further consider the inclusion of a test environment where Member States can learn how to create notifications. This will increase Member States' confidence in providing support to notifiers and provide a missing connection between the input and output functions of the EU CEG.

4. An example in practice

In practical terms this would require the Commission to provide Member States with an application to be loaded onto their own server that would enable them to process the data using an off the shelf data visualisation tool. One advantage of using such a tool would be that the Commission would not be responsible for supporting the method of data processing, allowing them to focus on delivery of an efficient data mapping and presentation function. As an example, if the Commission were to provide the architecture required to set up a SQL server and include a range of views of the data, each Member State would be able to create their own SQL server environment. Once created, with common and custom views, Member States could then easily manipulate the data using an off the shelf data visualisation tool. If Member States were to use the same visualisation tools this would provide the additional benefits of allowing Member States to share views, report schemata and visualisations across a range of products. Moving in this way towards a standardisation of data reporting and presentation would also address directly the core function of the TPD in harmonising the market for tobacco throughout the EU.

Conclusions

The report presents an opportunity for Member States to comment on how they see the EU CEG developing as a framework for the efficient use of data. Recent updates to the EU CEG and MS Rep have been welcomed and are very useful.

Feedback from Member States is clear in the requirements for;

1. Greater capacity for processing data
2. Clearer segregation of confidential and public data, an issue which will be addressed in WP5 of the JATC
3. An increase in the accuracy, validity and completeness of data

The Commission has been clear and proactive in its support for Member States and IT SANTE have made improvements to the EU CEG, including bulk data download and custom report requests. Further developments could enhance the system's utility and final impact on tobacco and e-cigarette regulation in the EU.