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WP6 - D6.1
WP7 - D7.1

**“Needs Assessment
Evaluation from EU MS
regulators”**

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1. Background

Under the European Union (EU) Tobacco Products Directive (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. The submitting information includes, but is not limited to, ingredients, emissions and toxicological data, with the specific parameters defined in the Annexes to Commission Implementing Decision (EU) 2015/2186 for tobacco products and Commission Implementing Decision (EU) 2015/2183 for e-cigarettes and refill containers. Such data is necessary for the EC and MS to carry out their regulatory responsibilities of monitoring the tobacco product landscape in Europe and assessing the attractiveness, addictiveness, toxicity, and health risks associated with the consumption of tobacco products, with the overall objective of ensuring health of the EU population.

The EU Common Entry Gate (EU-CEG) is an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate tobacco and related products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Manufacturers and importers are required to submit through EU-CEG information on any new or modified tobacco product including e-cigarettes and refills before being placed on the market. EU-CEG provides submitters with two different technical options for submitting data: (1) Standalone solution (for companies with a small IT infrastructure) using an XML generator to create the submission and subsequently upload to EU-CEG, or (2) System-to-system solution (for companies with an extensive IT infrastructure or many products), which uses the "e-Delivery network" operated by the EC to allow for information to be securely transferred.

Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent national authority. Furthermore, confidentiality of the data is considered through the option of submitters to indicate the status (confidential/non-confidential) of all submitted data fields, to the extent to which national rules on trade secrets are obliged. However, MS have the authority to determine whether the claims around confidentiality are valid.

This reporting format has substantially enhanced and harmonized the collection of tobacco product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system be evaluated, and potential weaknesses are noted that can be potentially addressed.

With the above in mind the purpose of this current combined deliverable D6.1 and D7.1 of the JATC is to perform an assessment of the current reporting platform and outline the needs, propositions and points raised by EU MS competent authorities (CAs) with regards to tobacco and e-cigarette product reporting in the EU.

2. Methodology

Within the context of the JATC and to avoid unnecessary burden to EU MS regulators it was decided that one common questionnaire should be created that would cover all aspects of the needs assessment across the different WPs of the JATC. This questionnaire was developed by representatives of all WPs in the JATC through the context of an in-person meeting at the Kick-Off of the JATC and multiple teleconferences. The current questionnaire aimed to collect through one common portal feedback from CA on critical issues of the TPD and related to components that the JATC will be addressing or national policy issues which could be addressed within the remit of the Joint Action.

In line with the above one common questionnaire was developed and approved by all members of the participating Common Needs Assessment Working Group. The complete questionnaire is presented

in Annex 1 and included both closed and open-ended questions (Q=133). The questionnaire was comprised of separate domains; each domain is related to a specific area of interest of the Joint Action on Tobacco Control. Domains of this questionnaire included:

- Issues of general TPD issues and the JATC
- Issues of evaluation
- Issues of training and sustainability
- Tobacco and e-cigarette regulatory activities
- Laboratory related questions
- Issues of laboratory measurements
- Questions on retributions - fees to manufacturers and importers
- Questions on priority additives

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

In total, 25 CAs responded to the survey (Within this report, CAs are either the competent authority or the person responsible for EU-CEG data handling), performed during the summer months of 2018, all responses were anonymous, and the results that are reported within this deliverable are aggregated. As data were anonymous, we were unable to assess the geographical distribution of the respondents across the EU MS.

3. Results

3.1 Issues related to TPD implementation and outcomes that the JATC is expected to produce.

To set the stage and to obtain a better understanding of the needs and experiences of CA in EU MS we initially sought to identify areas in which CA have experienced difficulties in the implementation of the TPD in their EU MS (Q2) as seen In Figure 1 below.

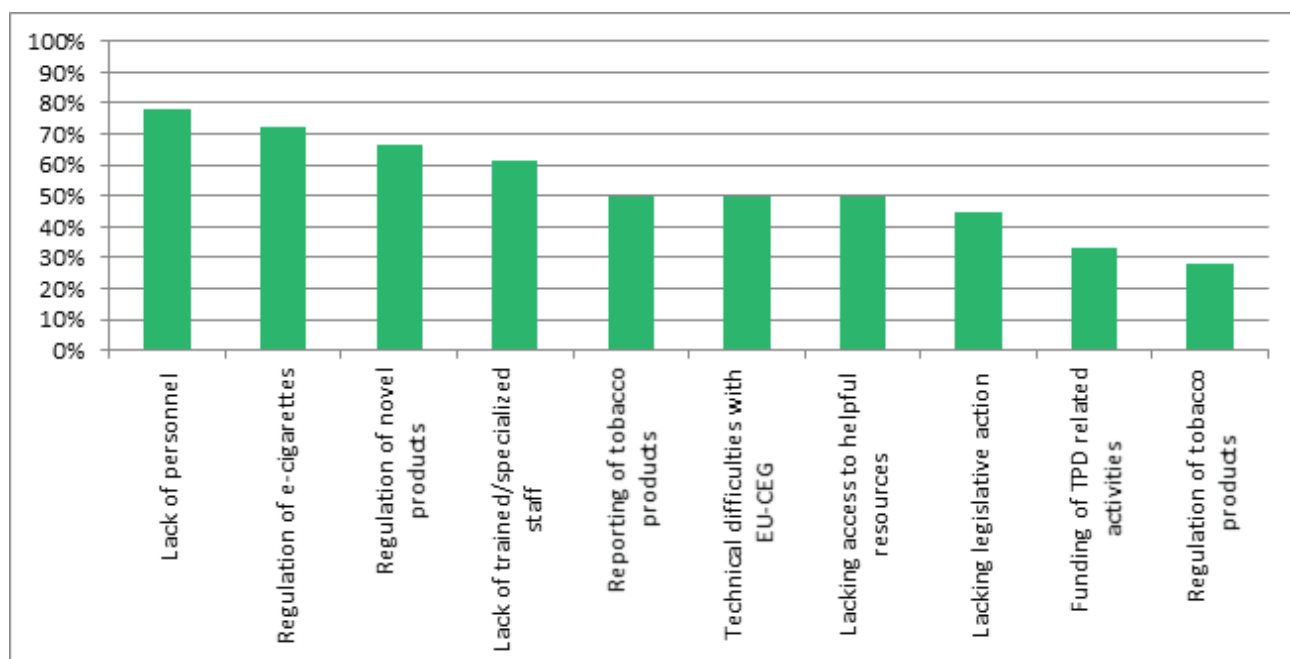


FIGURE 1. AREAS IN WHICH COMPETENT AUTHORITIES HAVE EXPERIENCED DIFFICULTIES IN THE IMPLEMENTATION OF THE TPD

According to Figure 1, a clustering of factors was noted between issues that appear at the national level and issues that are potentially solvable at the EU level. The most pressing area in which CA have experienced difficulties include the lack of personnel to help implement the TPD at a national level (n=15/20 respondents), and the lack of trained or specialized staff (n=12/20) indicating the necessity to support CA training opportunities in the area of tobacco product regulation in areas specific to the TPD while difficulties in legislative implementation were also noted as potential national issues (n=8/20).

On the contrary, the primary issues included the difficulties that CA face in the regulation of e-cigarettes (n=13/20), novel tobacco products (n=12/20), technical issues with the EU-CEG (n=11/20) and issues related to the reporting of tobacco products by the industry (n=11/20). Other areas in which difficulties were faced were reported with lower percentages.

Subsequently, respondents were requested to note in Q3 which primary outcomes they expect as CA from the JATC, to which the most common response was directly related to the use and utility of the EU-CEG.

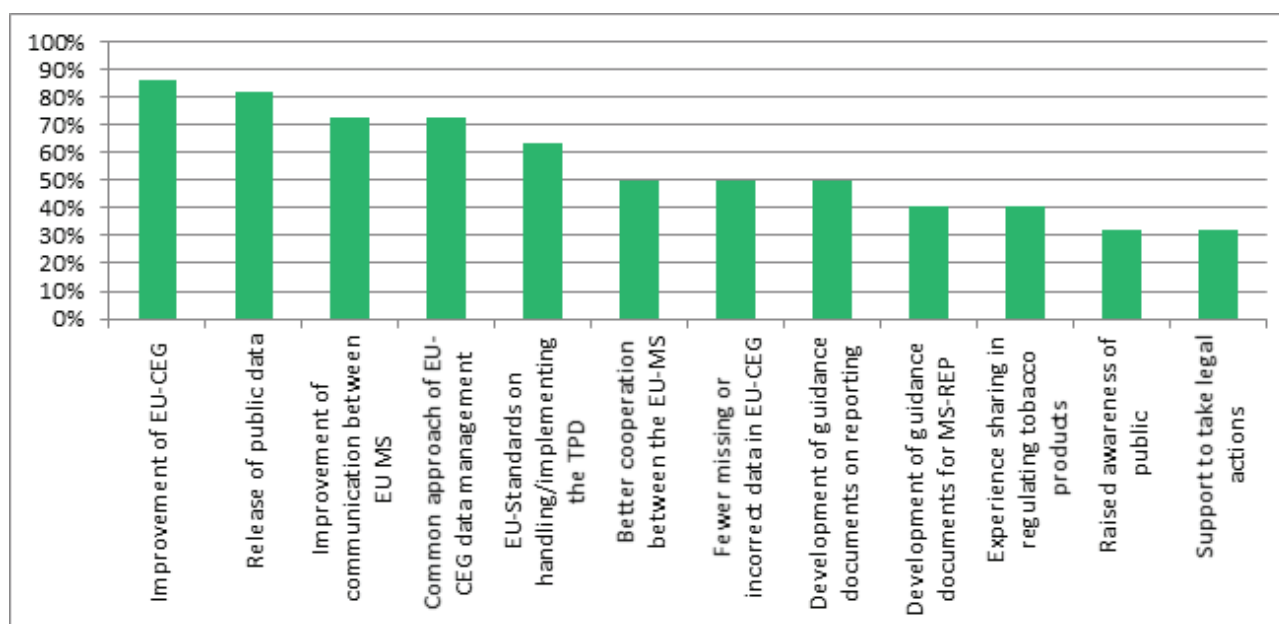


FIGURE 2. PRIMARY OUTCOMES EXPECTED FROM THE JATC BY THE CAS

The response, “improvement of EU-CEG data handling” (n=19/22) was noted the highest followed by “improved release of data to the public” (n=18/22) and a “common approach in EU-CEG data handling” and “improved communication and information exchange between EU MS” was also noted by 16/21 CA, with other responses reported with lower percentages. Notably, the importance of creating guideline documents for EU-CEG and MS-REP, a task of WP4, were reported by 11/22 and 9/22 CA respectively. The results of Q4 (“Which WP topics are the most important for you to be covered by the JATC”), were completely aligned with the above as the majority of respondents noted that issues related to “EU-CEG submissions and data handling” (17/22 CA).

3.2 Barriers related to the implementation of the TPD in EU MS

Within this domain of questions, CAs were requested to provide feedback on the different barriers related to the implementation of the TPD in their EU MS. Three groups of barriers were assessed, 1) general barriers, 2) policy barriers, 3) organisational barriers. For each of the barrier, groups noted CAs were provided with the opportunity to suggest potential solutions

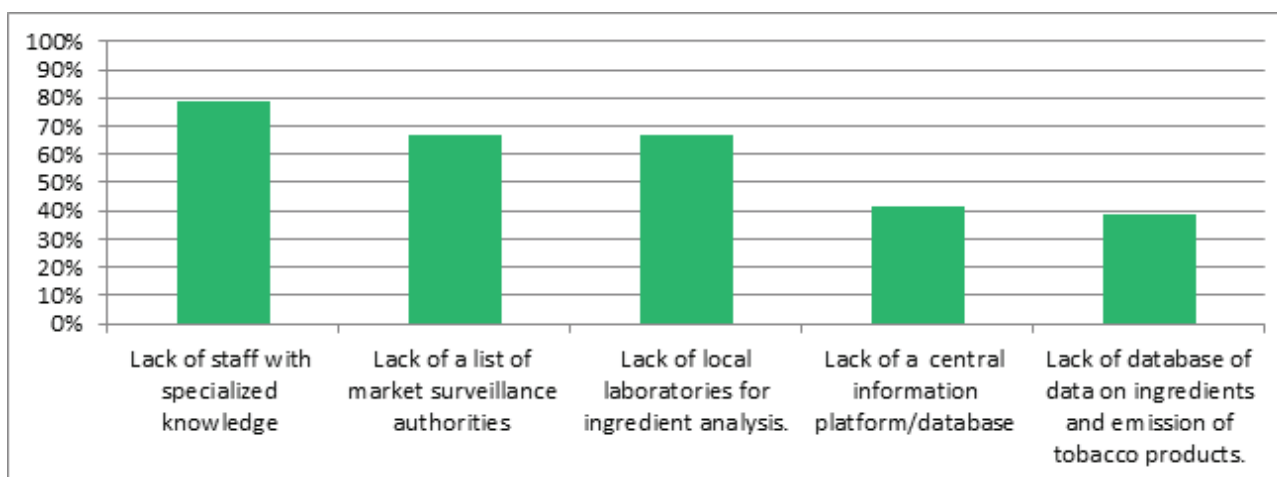


FIGURE 3. GENERAL BARRIERS FACED IN THE IMPLEMENTATION OF THE TPD

The most highly ranked general barrier was the lack of staff with specialised knowledge, followed by the lack of central information available via a platform/database that would provide evidence and information. These two primary barriers can be linked together as a “lack of training/resources” an aspect that will be addressed within the remit of WP4 of the JATC. Respondents provided the following potential solutions to the above general barriers:

- ✓ *EU-CEG improvement to allow the disclosure of non-confidential information to the public*
- ✓ *EU-CEG improvement to allow the identification of non-compliant products.*
- ✓ *Promote exchanges at the European level between the agents responsible for product surveillance.*
- ✓ *Develop an alert system identifying abnormalities for products/ingredients using the EU-CG database. Give access to all MS to produced alerts.*
- ✓ *Training education through webinars and guidance increased knowledge of e-cigarette design parameters, ingredients and emissions.*
- ✓ *Guidelines for TPD implementation.*
- ✓ *To count with different verification laboratories to analyse all the category of products.*
- ✓ *Another list on laboratories (not only approved laboratories Art 4(2))*
- ✓ *To create an MS common expert panel for the peer review of the toxicological information on the priority additives list.*

As noted from the above four primary solutions were proposed which are related to specific WPs of the JATC and these include: a) improvement of EU-CEG (as it can be performed through WP5,6,7), b) increased training and education for regulators (directly related to WP4) and c) laboratory verification (related to WP8) and d) creation of an expert panel for the review of information from the additives priority list (a task directly related to WP9).

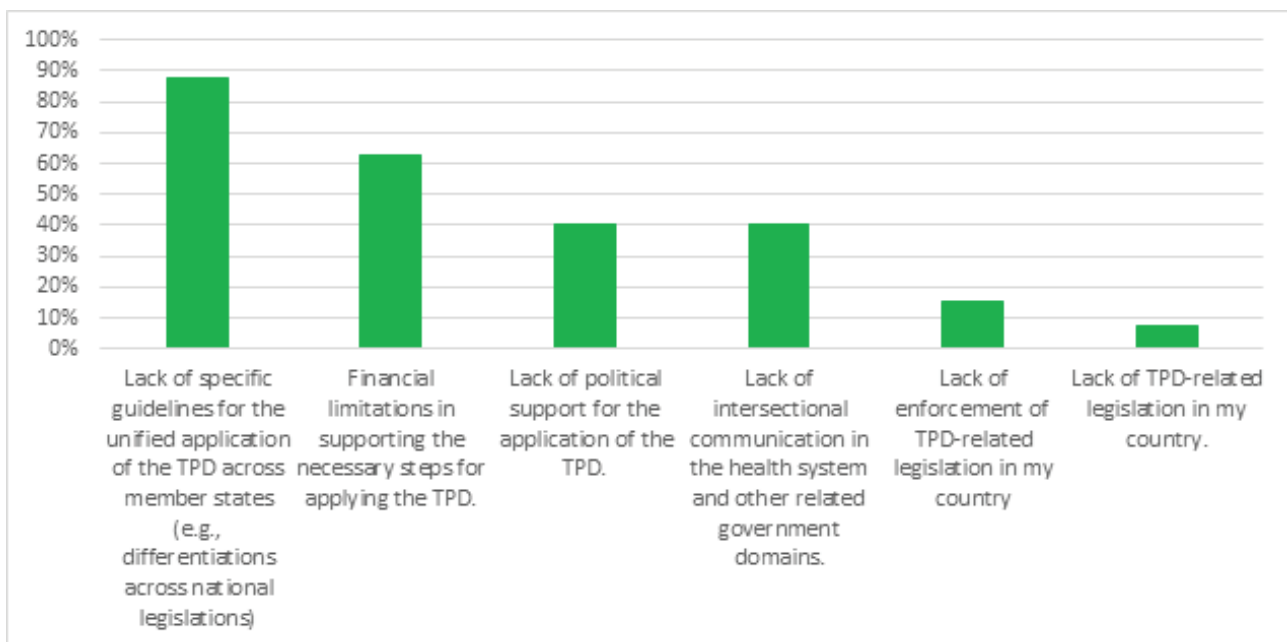


FIGURE 4. POLICY BARRIERS RELATED TO THE IMPLEMENTATION OF THE TPD

As noted in Figure 4 above, the most critical policy-related barrier identified was the lack of specific guidelines for the unified application of the TPD across the EU MS, followed by financial limitations, the lack of political support and the lack of the intersectional communication. With regards to the above policy-related barriers the below potential solutions were brought forward:

- ✓ *To recruit more resources in the Unit.*
- ✓ *To enhance the cooperation of all administrative Departments involved in the implementation.*
- ✓ *Better communication between related government bodies.*
- ✓ *There is a need for education of all the staff who is involved in TPD activities.*
- ✓ *EU MS regulator training through the provision of capacity building*

With regards to the proposed solutions although the JATC cannot impact the communication between related government bodies nor can it increase the funding to recruit more resources it can, however, contribute to EU MS regulator training through the provision of capacity building in WP4. In contrary to the general and policy-related barriers the organisational barriers related to the implementation of the TPD were very specific and can be summarized within three bullet points

- ✓ *Lack of sufficient staff involved in the implementation of the TPD.*
- ✓ *Enforcement of TPD is a too multi-disciplinary, cross-departmental process and this is problematic regarding co-ordination of tasks.*
- ✓ *Enforcement of TPD is too centralised in my EU MS missing out on information and expertise from other regional/local relevant agencies.*

3.3. Proposed capacity building content and practical changes

In light of the responses brought forward with regards to the organisational, general and policy-related barriers to the implementation of the TPD across EU MS it was noted that primarily capacity building activities and improvements of EU-CEG were noted as the most important aspects to be tackled.

Hence, CAs were subsequently requested to provide their perspective, on what training content may facilitate the application of the TPD in their EU MS. Responses were predefined, and each respondent could select multiple training topics, for which the responses were as follows:

- ✓ *70% of CAs reported the need for specific training on performing more technical work and statistical analysis of the data within MS-REP*
- ✓ *70% - Training on the enforcement and interpretation of TPD articles that are specifically related to novel tobacco products and electronic cigarettes*

- ✓ 60% - General training on interpreting the significance of submitted EU-CEG data.
- ✓ 50%- Training in the application of market surveillance legislation such as RAPEX (Rapid Exchange of Information System) and the ICSMS systems (The internet-supported information and communication system for the pan-European market surveillance).
- ✓ 50% - Training in the assessment of websites that sell tobacco, tobacco-related products and electronic cigarettes for compliance with TPD.
- ✓ 45% - Cross-discipline training on applying the TPD through different regional/local agencies and control bodies (e.g., customs, the ministry of health, the ministry of commerce, the ministry of finance, other related authorities)
- ✓ 40% - Training on best practices for raising awareness of tobacco, electronic cigarettes and other related products
- ✓ 40% - Training on ingredient recording tools used by the industry
- ✓ 35% - Training on the best practice methodology for enforcing the TPD across member states
- ✓ 35% - Training in ISO standards referenced in TPD and any other standards that may be of relevance to support the enforcement of the TPD.

As noted above the primary area in which the CAs noted that initial training and capacity building should be focused on within the context of the JATC cover aspects related to the technical handling of data in EU-CEG the topic on which we will focus on within the context of this current report. In addition to the above, the CAs were requested also to suggest types of practical changes that may facilitate the TPD in their EU MS. As seen in Figure 5 below, practical changes that were noted included the “establishment of a communication network”, “increased availability of laboratory testing facilities”, “creation of a central knowledge database” and “creation of a common guidance manual for the application of the TPD.”

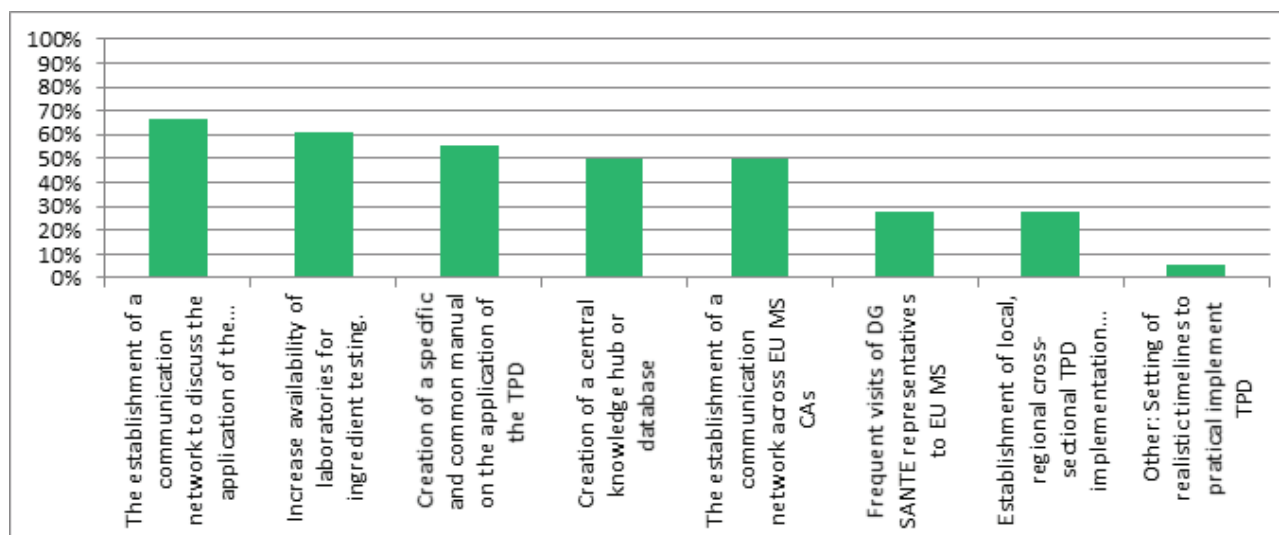


FIGURE 5. PRACTICAL ASPECTS WHICH MIGHT FACILITATE THE APPLICATION OF THE TPD IN YOUR COUNTRY

3.4 Barriers related to the utilisation of EU-CEG/MS-REP

As previously noted in Figure 2 earlier, one of the primary outcomes that is expected from the JATC is the improvement in the utility of the EU-CEG/MS-REP system and hence the CAs were asked to report on barriers which impact the utilisation of the system. Both predefined and open-ended answers were allowed for which the respondents provided their feedback as seen below in Figure 6 and the open box comments noted below.

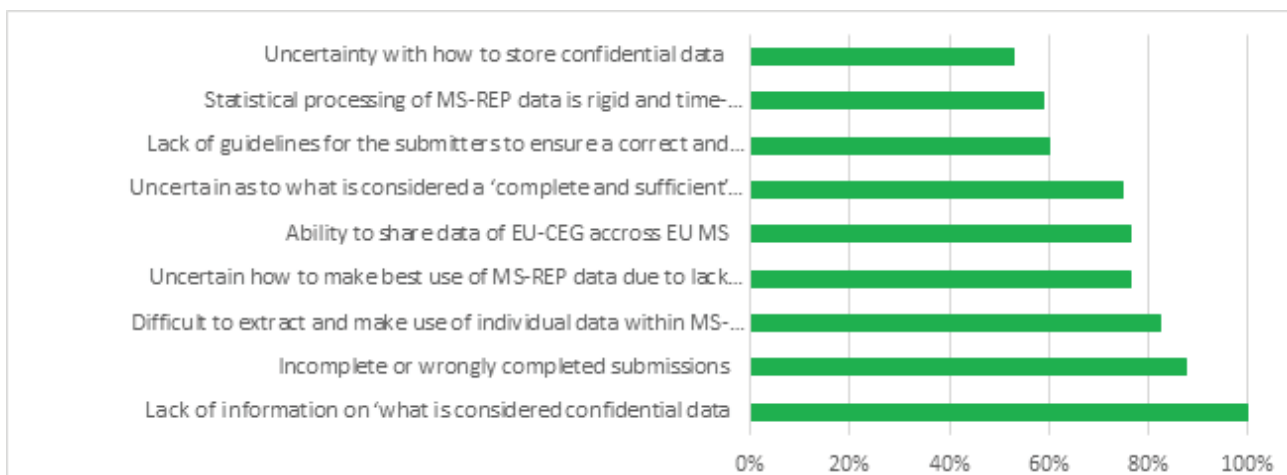


FIGURE 6. BARRIERS RELATED TO THE UTILISATION OF EU-CEG/MS-REP

As seen above the primary barrier, reported by all of the respondents (17/17 CAs), was the “lack of information on what is considered confidential data”, followed by “difficulty to extract and make use of individual data” (14/17) and “incomplete/wrong submissions” (14/17), “lack of statistical processing capacity in the system”, the “ability to share data investigated through EU-CEG”. Open ended responses from EU MS CA also brought forward additional barriers to be addressed within the EU-CEG/MS-REP system including:

- ✓ Bulk download of data should be made available to the member states.
- ✓ Global overview of submitted ingredients across manufacturers and products.
- ✓ There is a high number of duplicate submissions.
- ✓ Lack for duplicity of registers on EU-CEG.
- ✓ Assessment of secrecy/confidentiality is difficult.
- ✓ Lack of guidelines for the national authorities that use the EU-CEG.
- ✓ As a person responsible for the EU-CEG submissions I am not able to access the reporting tool for submitters. I would like to have the opportunity to access the reporting tool.
- ✓ The guidance for reporting of the data would be very useful.

To address the above barriers, potential solutions were requested from the CA respondents, the following which is brought forward:

- ✓ Additional features to the EU-CEG/MS-REP system.
- ✓ More tailor-made options for filtering data.
- ✓ The ability to perform bulk downloading for member states directly extracted from MS-REP.
- ✓ Provide a monthly ready-to-publish dataset with a commonly agreed format among all EU MS. Should no agreement occur, provide the largest dataset so that each MS can select the records and fields for publication.
 - Provide a business intelligence interface to query and export data and PDF files directly from MS-REP.
 - Make it possible for MS-REP users to “flag” some records to prevent wrong submissions to remain within the database and to manage withdrawals.
 - Stronger validation rules within EU-CEG XML CREATOR and GATEWAY to prevent wrong data. For example, alert for a very low or very high numeric value or a value not consistent with another one. Limit free text as much as possible: ingredients should be selected from a reference table curated by MS-REP users.
- ✓ To complete the guidelines to facilitate the filling of information, as well as, to clarify the most controversial issues.
- ✓ To make obligatory the filling in EU-CEG of some fields which are optional now.
- ✓ Education for the staff involved in the TPD activities in my country by the EU experts.
- ✓ To publish the guidance for submitters.
- ✓ To establish which data are considered confidential.

- ✓ Enhance common approach on handling tobacco product evidence-based decisions across EU MS, within the context of their national legislative approach through webinars and guidance.
- ✓ To write and complete guidelines to make clear the most controversial issues.
- ✓ To make obligatory the filling in of certain fields in the EU-CEG, which are optional at this moment. (repetition?)
- ✓ Confidential-field should be completed with an open text field to provide reasons for confidentiality.

3.5 Issues related to the submission of data through EU-CEG

3.5.1 Types of issues in data submission as noted by CAs

As the entry gate for all data submitted to EU MS CAs, the EU-CEG plays an important role in assuring the quality and utility of the data available to EU MS regulators. It is important then for us to assess the factors that may influence this process. Indeed, in response to our question “have you noted issues related to the submission of data through EU-CEG”, 13/14 CAs responded positively. For which the following main issues were identified:

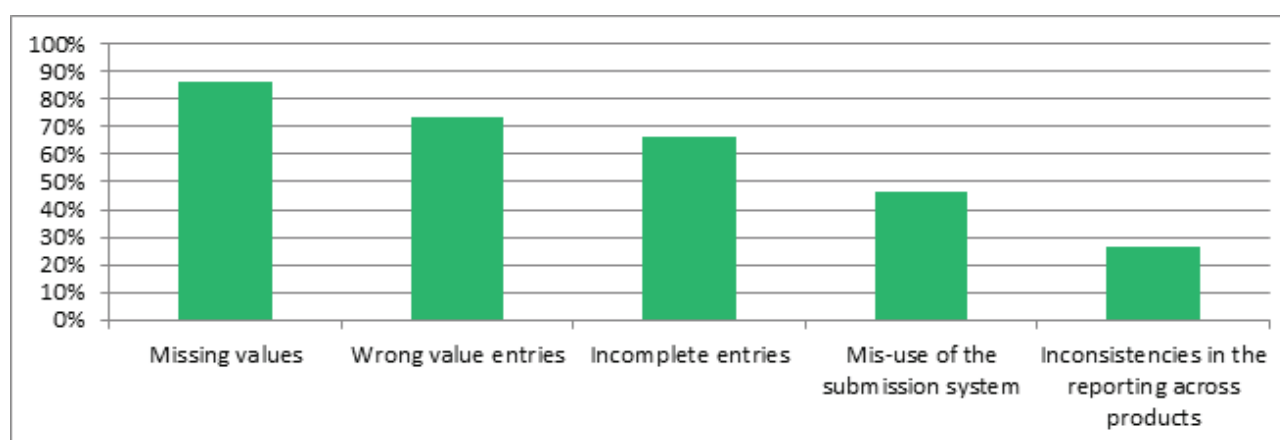


FIGURE 7. ISSUES RELATED TO THE SUBMISSION OF DATA IN EU-CEG

For the above key issues, examples were requested from the CA, to which the responses were as follows:

- ✓ Completely missing or irrelevant toxicological data about submitted products, Incomplete product disclosure
- ✓ missing values
- ✓ wrong value entries: the confusion of unit (packages, kg, pieces)
- ✓ wrong dates or wrong units for dimensions, weights, quantities or volumes
- ✓ misuses: use a unique TP-ID as a proxy to report all 2015 sales volumes for many products; use different TP-ID to report different production batches of the same standard recipe
- ✓ inconsistencies: the sum of recipe quantities is different from the product weight; the six compliance declarations (production conformity, high purity, consistent dosing, child tamper proof, quality safety, non-risk) are not uniformly “true”.
- ✓ Missing value: of the volume of the product
- ✓ In the ingredient entry, there are several fields without filling in.
- ✓ Missing information on tobacco product ingredients
- ✓ Missing/wrong brand type, subtype names, missing ingredients and emissions
- ✓ Product brand, subtype names are missing, or wrong, unit of measure is misunderstood (or wrongly notified), ingredients are missing, emissions are missing
- ✓ Certain additives do not have quantities
- ✓ The CMR toxicity never exists or is not available
- ✓ Certain additives are reported twice with different values.
- ✓ Certain ingredients are reported, but with no quantity or with zero milligrams.

- ✓ *Certain ingredients are reported twice.*
- ✓ *The ranking quantity order is not respected.*
- ✓ *Lots of corrections. At the end is not easy to understand the final valid information.*
- ✓ *All data including the notification “considered confidential”.*
- ✓ *Manufacturers/Importers should receive final validation and acceptance for their product submissions from the member state.*
- ✓ *Direct submission from EU-CEG XML CREATOR (with integrated manual and step-by-step guide) after data consistency check and feedback within the same interface. A feature to replicate easily the same change among several XML product files.*
- ✓ *A more detailed step-by-step guide.*
- ✓ *Clarifications that the herbal products submission is within the tobacco product and specify which fields of the submission are not related to herbal products.*
- ✓ *Translation to other languages than English.*
- ✓ *As it stands now, the database does not allow to identify non-compliant products. If some information is wrongly reported the system should not accept the information. The data should not be accepted without previous validation by the system.*

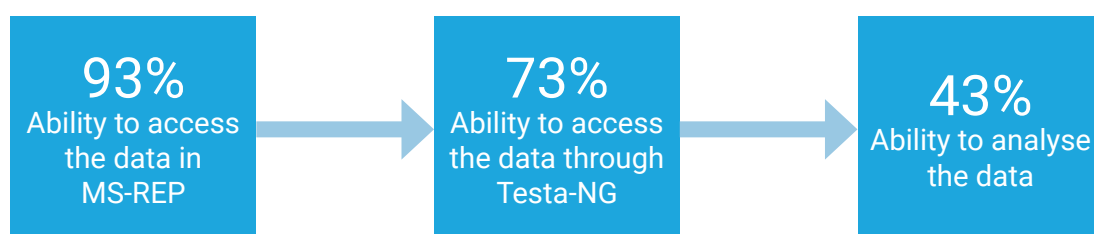
3.5.2 Submitter – CA interactions over EU-CEG data submissions

All the CA have been contacted by the industry with questions on how to submit data through EU-CEG (16/16 CAs) of which 84% reported that the manufacturers/importers of data have identified issues with the EU-CEG system and communicated them to the relative CA. Such issues that were reported include:

- *A manufacturer is unable to delete a submission that has been made by error.*
- *Lack of practicability, not easy to handle.*
- *Manufacturers have problems when registering herbal products as they are “hidden” inside tobacco products.*
- *Problems with the language barrier - MS Reporting tool and all information are provided in English.*
- *The company reported the product using XML creator; the problem was that the products were still not on the list of approved products.*
- *Problems with the XML –files.*
- *Some manufacturers reported difficulties on registration in EU-CEG, and how to submit the data.*
- *We received many requests from submitters regarding the submission process.*
- *Small to Medium Enterprises (SME) note the fact that they have to hire IT experts to submit.*

3.6 Issues related to handling data in MS-REP

There are two sides of the data system the EU-CEG, which is the system seen by the manufacturer/importer when submitting the data and the MS-REP system which is the reporting system as seen by the EU MS regulator. In this section, we refer to the MS-REP as seen by the EU MS regulator. As a base, it is important to note the following statistics with regards to MS-REP.



It is interesting to note that although almost all of the CA that responded to this question can access the data, only 43% of them have been able to perform any type of analysis with the data indicating a missed opportunity in tobacco product regulation. Subsequently, the CAs were requested to note why the analyses were not possible and to suggest potential solutions.

Why analyses were not possible

- The performance was/is not readable. The needed data selection criteria are not available now.
- In EU-CEG there is currently no tool for statistical evaluation of the data, there is only the possibility to search for a certain product or products of a certain company or to select products, e.g. by product type or ingredient with form filters.
- There is furthermore no possibility to download data for the possibility to analyse the data outside the EU-CEG system. Due to a lack of performance already the available search and filter function is not usable for the routine work.
- I would need to be able to download the data in excel format to be able to analyse them as well as to publish them on the website.
- Not easy to access information, too much time-consuming. For example, a manufacturer asked to confirm the selling data that was provided into the system, and it was almost impossible to find. EC was not able to help.

3.6.1 Potential IT or technical functionality that CAs would like to see in MS-REP

- ✓ Search options:
 - o We need a “global overview feature” of submitted ingredients (by type and by ingredient). A click in one ingredient would show which brand and manufacturer uses it. This would help us to quickly identify problems with ingredients.
 - o The EU-CEG must allow to search across certain variables to get an overview of the information registered.
 - o An ability to search if the same product has been submitted in other countries.
 - o A feature to create, edit and update (with a community of MS-REP curators) useful additional reference tables (e.g. ingredients).
 - o The possibility to “flag” and comment records within MS-REP to manage submission withdrawals and recovery of the fees and a proper way to discriminate a product withdrawal from a submission withdrawal.
- ✓ Setting limits:
 - o The system should also allow to set concentration limits for ingredients and show brands that are out of the range limit.
 - o The system should validate the information. Incorrect data should not be accepted by the system.
 - o The ingredients must be recorded with the measurement units pre-defined (The data dictionary is not enough).
 - o The system must allow identifying the products with certain additives or TNCO limits not allowed by the TPD.
 - o It would be nice to implement a kind of tool that detects duplicate records and notifies or deletes them.
- ✓ Bulk download of data:
 - o The download in a single Excel file would be the best option for us, to analyse data.
 - o Export of preselected data (e.g. special substance) for further evaluation.
 - o Extraction in Excel format is essential.
- ✓ Selecting downloaded data:
 - o The given possibility to download specific fields of the submission.
 - o More options for filtering data.
 - o A report generator should be embedded in the system.
 - o Possibility for MS to customise data analysis (selection criteria) and export.
 - o A business objects interface to freely query and export data and PDF.
 - o It should be additionally possible to extract sales volume per sales year.
 - o Certain submissions have to be made on a yearly basis. A list of products for which the yearly submissions are missing or delayed should be easy to extract.
 - o New public front end with a specific view to the date (view to data has to be defined by MS).

- o A permanent deep-link to access directly any version of XML or PDF file from the front page.
- ✓ Data for the public:
 - o Useful “one button” extraction of data which are to be made available for the public.
 - o The EU-CEG must allow the exportation of non-confidential information to disclosure to the public.
 - o Export of the non-confidential data for the publication. It should be made transparent, how many ingredients were reported, but not listed due to the claim of confidentiality to prevent misleading information to the consumer.
 - o Online entry gate/Webpage for consumers (ingredients).
- ✓ Product overviews
 - o Each product should be seen on a full window with several pages if needed, without the need to open several windows. This solution will allow a global understanding of the product, more quick and easy way to see if the notification is OK.
- ✓ Automated reports
 - o A possibility to create XML, XLS, PDF files for all products at once and according to selection criteria and ingredients.
 - o Some new reported/updated products grouped by company and product type.
 - o After collecting a set of XML files from MS-REP (only on submitter XML files and last version available of XML product files) the ability to perform data consistency checks, simple descriptive statistics (unidimensional, bidimensional).
 - o The frequency of use as well as min/mean/max values of the relative amount (w/w) of each ingredient about the tobacco and product weight for all products or separated by the company and/or product type.
 - o Ready-to-publish dataset (monthly).
 - o Sales data per Product ID and year (upon request).
 - o Some products per Product Type and Active/Inactive List (upon request).
 - o The ability to create excels sheets of data with information for all or part of the products.
 - o The extraction of data for the publication on the competent authority’s website.
 - o A list for regulators with products with certain additives or ingredients above certain quantities or products with TNCO above the TPD limits.

3.7 Issues of handling data from a USB disk

Data according to the current status quo can either be accessed via the MS-REP tool or via a USB that is obtained centrally. While the USB does provide data that is bulk downloaded it reflects only a specific “moment in time” and is not updated. Regardless of this drawback, it has the potential to facilitate analyses and product regulation if used efficiently. The figure to the right provides a background for the current status quo of data analysis using EU-CEG submitted information.



It is interesting to note that only one in three CA have obtained the data in USB format with slightly more than one in four able to extract the data. (Into Excel format, XML format, Microsoft Access using Import XML feature, XSL transformation to map records with Product ID and a VBA macro to automate the process.). It was also noted by one CA that there is also a third way to download the information which is “through an automated system to download the XML which then can be added to our own database which has some more features than MS-REP”. [Editorial Note: As the responses were anonymous we were not able to obtain additional information with regards to this automated data harvesting solution.]

3.8 Issues of data analysis within the JATC

With regards to data analysis only 18% of CAs (however this percentage increased to 40% of those who had been able to obtain the USB stick) were able to perform analyses of some sort. However these were restricted to general data overviews, data consistency checks and simple descriptive statistics.

Within the context of the JATC through WP6 and WP7 there is the ability to perform data analyses checks, for which the CA brought forward the following suggested analyses:

- ✓ *specific toxicological questions concerning ingredients, plausibility cross checks for submitters and sales volume with other data sources*
- ✓ *A standard descriptive report for any given dataset: distribution of any variable, statistics per Product Type/ Submitter/Category or Ingredient Function, changes over time.*
- ✓ *A statistical study of priority additives in tobacco products.*
- ✓ *A statistical analysis of ingredients in liquids (for example the most frequent ingredients ...)*
- ✓ *A static analysis of emissions in e-cigs."*

4. Conclusions

The current needs assessment provides a baseline understanding of the issues, barriers and potential gaps identified by a substantial number of CA across EU MS with regards to areas that are under the scope of the activities of the JATC.

In short, both national and international barriers to the implementation of the TPD are reported by CAs, with a specific emphasis on the difficulties faced to regulate and monitor products via the EU-CEG, with more difficulty faced for handling e-cigarettes. With regards to the primary expected outcome of the JATC, CA reported that the improvement of EU-CEG data handling, improved release of data to the public and improved communication and information exchange across EU MS were the areas of primary interest, followed by capacity building activities. These actions were also noted as the primary general barriers to the implementation of the TPD across the EU.

The majority of respondents noted that training and capacity building is essential across EU MS CAs, with specific reference to training on technical issues related to EU-CEG data and training on the enforcement and interpretation of TPD articles that are specifically related to novel tobacco products and electronic cigarettes.

Indeed, the above is corroborated by the fact that although almost all of the CA that responded that they can access the data in MS-REP, less than half of them have been able to perform any type of analysis with the data indicating a missed opportunity in tobacco product regulation. The main reason behind this missed opportunity we attribute to the potential IT architectural limitations of MS-REP and the quality of submitted data. With regards to gaps and solutions, some examples were brought forward by CA and should be taken into account within the development of further JATC deliverables for WP5, WP6 and WP7 and in further EU-CEG refinement.

Overall the gaps identified, and needs to be brought forward indicate the potential next steps that should be taken within the context of the JATC so as to a) suggest improvements to the EU-CEG and MS-REP system, b) enhance training and capacity building, c) allow for a greater exchange of information and expertise across EU MS so as to aid tobacco product regulation – actions which should be addressed within the context of the JATC.