

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

WP4 - D4.1

Report on TPD mapping and sustainability activities including in house capacity



Circulation: Public
Authors: MoH CY, HCS
Date: M21
Doc. Ref. N°: D4.1



This activity has received funding from the European Union's Health Program (2014-2020) under grant agreement – 761297.

The content of this publication represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

Table of Contents

1. Background	3
2. Methods	3
2.1 General Needs Assessment Questionnaire	3
2.2 Specific Questionnaire on TPD funding and sustainability activities	4
3.1 Results of the Common Needs Assessment Questionnaire – WP4	5
Overall	5
Q7. Rank of the general barriers in order of importance to be addressed	6
Overall	6
Q8. Policy related barriers with the implementation of the TPD	6
Overall	6
Q9. Potential solutions for the policy-related barriers	7
Q10. The most important policy-related barriers	7
Overall	7
Q14. Organizational barriers with the implementation of the TPD	7
Overall	8
Q15. Potential solutions for the organizational barriers	8
Q16. Rank of the organizational barriers	8
Overall	8
Q17. Proposed training content to facilitate the application of the Tobacco Product Directive	8
Overall	9
Q18. Proposed practical changes or additions to facilitate the application of the Tobacco Product Directive	9
Overall	9
Q19. Resources available to regulators (i.e. labs, experts, websites, etc.)	9
3.2 Results of the Specific Questionnaire on TPD funding and sustainability activities – WP4	10
Q1. TPD articles fees that are collected	10
Q2. Fees applied based on each purpose	10
Q4. When feeds are paid	11
Q5. Product/category type for which fees are applied	11
Q6. Have Courts Affairs locally, _____ the fees	12
Q7. Utility of fees	12
Q8. Department/ministry responsible for these fees and therefore is completing this information	12
Q9. Competence of the bodies representing the industry for policies and legislation	13
Q10. Competence of the bodies representing the industry for policies and legislation and please specify the nature of the bodies	13
Q11. Nature of the bodies responsible for vaping/tobacco policy (e.g. Scientific, Administrative, Regulatory) and overall involvement (e.g. Research, Funding, Expertise, or other)	13
4. Conclusions	14

1. Background

Tobacco is undoubtedly one of the main avoidable causes of death. 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. In line with the above, the general objective of the Joint Action on Tobacco Control is to provide support for the implementation of the TPD throughout the 28 EU MS and facilitate the assurance of its long-term sustainability. In terms of sustainability, tobacco control funding across the EU MS, including submission fees to the EU-CEG of fees for implementation of TPD Art7(13) and TPD Art20(2) plays an important role. According to the TPD, fees can be charged to manufacturers and importers of tobacco and e-cigarette products by the EU MS for a plethora of activities. These activities include the verification of the measurements referred to in paragraph 1 of Article 4, the receiving, storing, handling, analysing and publishing of the information referring to tobacco (Article 5) and e-cigarette (Article 20) products, the peer reviewing of the reports required (Article 6), the assessment about whether a tobacco product has a characterising flavour, whether prohibited additives or flavourings are used and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic or addictive effect or the CMR properties of the tobacco product concerned (Article 7), and finally, the authorization of novel tobacco products (Article 19). This funding can be efficiently used to help the EU MS address their gaps and face the potential barriers when it comes to the TPD implementation.

By taking into account the aforementioned, the purpose of this specific deliverable is to map the capacity building and knowledge needs for the effective and efficient application of the TPD across the 28 EU MS and EEA where applicable, to map tobacco control funding across the EU MS, including submission fees to the EU-CEG or fees for implementation of TPD Art7(13) and TPD Art20(2), and also to identify and map in-house and cross border regulatory, scientific and technical capacity resources available to regulators through surveys to EU MS regulators and competent authorities.

2. Methods

2.1 General Needs Assessment Questionnaire

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. Initially a questionnaire was constructed that addressed:

- General barriers in TPD
- Policy-related barriers in TPD
- EU-CEG system barriers in TPD
- Organizational barriers in TPD
- Suitable training content for the application of the TBD
- Changes to facilitate TPD application
- Information related to TPD fees
- Resources available to regulators

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.

Due to insufficient responses, it was deemed necessary to proceed with the construct of a second questionnaire which will be complementary to the first one. The second questionnaire was constructed on a website and was circulate to EU Member States.

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=5). 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 via emails 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.

2.2 Specific Questionnaire on TPD funding and sustainability activities

Within the context of mapping the TPD funding and sustainability activities a dedicated questionnaire was developed by WP4 collaborators and was sent out digitally (OneClick Survey) to be completed by EU-MS. Specifically, the contact points of each country were contacted through the public list https://ec.europa.eu/health/sites/health/files/euceg/docs/contact_point_en.pdf. The questionnaire aimed to collect information regarding tobacco control funding across the EU MS, including submission fees to the EU-CEG or fees for implementation of TPD Art7(13) and TPD Art20(2), and also included questions in order to map in-house and cross border regulatory, scientific and technical capacity resources available to regulators that are needed to ensure the up-take of the outcomes of Joint Action and the mechanisms that will be set-up after the completion of this project. Domains of this questionnaire included:

- Fees collection based on TPD articles
- Nature of fees
- Frequency of fee application
- Purpose of fees
- Consistency of fees
- Usage of fees
- Responsibility of fees collection
- Competence of the bodies representing the industry for policies
- Nature of responsible bodies for tobacco policy and involvement

This questionnaire was sent out digitally (Oneclick Survey) to be completed by the CA, primarily those involved with EU-CEG monitoring and tobacco/e-cigarette product regulation. The responders were presented with different options and were asked to select what applied in their case based each question. If nothing was applicable for that question, they were asked to provide a brief explanation (open-ended answer) for what happens in their country. 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.

3.1 Results of the Common Needs Assessment Questionnaire – WP4

Q5. General barriers with the implementation of the TPD

Response rate: 12 out of 15 countries

The completion of the survey suggested that the lack of staff with specialized knowledge on tobacco, electronic cigarettes and other related products' ingredients and additives as well as the lack of local laboratories for tobacco, electronic cigarette and other related product ingredient analysis were identified as the most common barriers with the implementation of the TPD in the ten out of twelve participating countries (83.33%) that recorded their answers. Only one country reported that the lack of staff with specialized knowledge on tobacco, electronic cigarettes and other related products' ingredients and additives is not a general barrier. The lack of a continually updated list of market surveillance authorities available for electronic was also considered to be a general barrier for 7 out of eleven countries (63.64%), and the remaining percentage gave no response. Another significant finding was that more than half of the countries did not provide a response in terms of whether the lack of a needed central information platform/database containing evidence-based scientific reference data on tobacco, electronic cigarettes and other related products (54.55% among 11 countries) and the lack of needed database on routinely updated data on ingredients and emission of tobacco products (63.64% among 11 countries). This possibly suggests a need for training for the existence and maintenance of electronic record keeping of tobacco products as well as related databases. One country recorded that another barrier was the lack of a common position regarding certain aspects of the TPD, like dimensions of the packaging or the application of article 13, how to evaluate tobacco products with distinctive flavours, how to evaluate the novel tobacco products, how to evaluate the e-liquids, the nicotine basis etc. The results of this item suggest that many countries face similar difficulties in terms of the general barriers with the implementation of the TPD in their country, and also approximately equal needs in terms of training in some aspects of the implementation of the TPD.

Overall

- ✓ To make suggestions to governments for staff increase, and training possibilities for existing staff in terms of specialized knowledge on tobacco, electronic cigarettes and other related products.
- ✓ To make suggestions to local either government or private sector for laboratory expansion and increase of available laboratories for tobacco, electronic cigarette and other related product ingredient analysis.
- ✓ To make suggestions to ministries for creation of list for market surveillance authorities for electronic tobacco products.

Q6. Potential solutions for the general barriers

Response rate: 7 out of 15 countries

The suggested solutions for the general solutions were as follows:

1. improvement of the EU-CEG
2. To create a MS common expert panel for the peer review of the toxicological information on the additive's priority list
3. To count with different verification laboratories to analyze all the category of products
4. As it is a purpose of WP4- Integration into National Policies and Sustainability it is very important to enhance effective and efficient integration into national policies and training
5. education through webinars and guidance
6. Increased knowledge of e-cigarette design parameters, ingredients and emissions
7. Other list on laboratories (not only approved laboratories Art 4[2])
8. Member-states should get consensus agreement on certain grey areas of the TPD implementation.

9. Guidelines for implementation.
10. EU-CEG improvement in order to allow the disclosure of non-confidential information to the public
11. EU-CEG improvement in order to allow the identification of non-compliant products.

Q7. Rank of the general barriers in order of importance to be addressed

Response rate: 10 out of 15 countries

7 countries ranked the lack of staff with specialized knowledge on tobacco, electronic cigarettes and other related products' ingredients and 6 countries rated the lack of local laboratories for tobacco, electronic cigarette and other related product ingredient analysis as the first general barrier of importance to be addressed. Third in importance was the lack of a needed central information platform/database containing evidence-based scientific reference data on tobacco, electronic cigarettes and other related products, then the lack of needed database on routinely updated data on ingredients and emission of tobacco products, and finally the lack of a continually updated list of market surveillance authorities available for electronic cigarettes and refill containers.

Overall

- ✓ To make suggestions to governments for staff increase, and training possibilities for existing staff in terms of specialized knowledge on tobacco, electronic cigarettes and other related products.
- ✓ To make suggestions to local either government or private sector for laboratory expansion and increase of available laboratories for tobacco, electronic cigarette and other related product ingredient analysis.
- ✓ To make suggestions to academic institutions and governmental organizations to compose central information platform/database containing evidence-based scientific reference data on tobacco, electronic cigarettes and other related product.

Q8. Policy related barriers with the implementation of the TPD

Response rate: 11 out of 15 countries

Based on the responses the most important policy related barrier with the implementation of the TPD was:

1. the lack of specific guidelines for the unified application of the TPD across member states (e.g., differentiations across national legislations),
2. the lack of TPD-related legislation in my country,
3. lack of intersectional communication in the health system and other related government domains,
4. lack of political support for the application of the TPD,
5. financial limitations in supporting the necessary steps for applying the TPD,
6. lack of specific guidelines for the unified application of the TPD across member states (e.g., differentiations across national legislations) and lack of specific guidelines for the unified application of the TPD across member states (e.g., differentiations across national legislations).

All of the countries recorded lack of specific guidelines for the unified application of the TPD across member states (e.g., differentiations across national legislations) as an identified policy related barrier. Financial limitations in supporting the necessary steps for applying the TPD was identified as a policy related barrier whereas the lack of TPD-related legislation in my country was not identified as a policy related barrier by the majority of the countries (9).

Overall

- ✓ To make suggestions to the Governmental Legal Control Systems (ministries, and law enforcement) for the formation and implementation of a unified legal guideline protocol.

- ✓ To make suggestions to the Governmental Legal Control Systems (ministries, and law enforcement) for the composition of TPD laws among all state members and the agreement to an execution system for these laws (collaboration within ministries and identified agents and plan for law enforcement).
- ✓ To make suggestion to different governmental ministries for the agreement of an intraministrial and extraministrial communication protocol.

Q9. Potential solutions for the policy-related barriers

Response rate: 4 out of 15 countries

Suggested solutions for the above policy barriers were:

1. To recruit more resources in the Unit.
2. To enhance the cooperation of all administrative Departments involved in the implementation.
3. We faced a lack of political support during the implementation process of Directive 2014/40/EU.
4. Better communication between related government bodies. But there is a need for education of all the staff who is involved in TPD activities.
5. EU MS regulator training through the provision of capacity building
6. To increase the resources in the Unit.
7. To enhance the cooperation with all the national administrative Departments involved in the implementation.

Q10. The most important policy-related barriers

Response rate: 10 out of 15 countries

Policy related barriers based on importance:

1. Financial limitations in supporting the necessary steps for applying the TPD & Lack of specific guidelines for the unified application of the TPD across member states (e.g., differentiations across national legislations) [of equal high importance]
2. Lack of political support for the application of the TPD.
3. Lack of intersectional communication in the health system and other related government domains.
4. Lack of enforcement of TPD-related legislation in my country
5. Lack of TPD-related legislation in my country.

Overall

- ✓ To make suggestions to governments for the financial support for TPD application.
- ✓ To make suggestions to the Governmental Legal Control Systems (ministries, and law enforcement) for the formation and implementation of a unified legal guideline protocol.
- ✓ To make suggestions to the Governmental Legal Control Systems (ministries, and law enforcement) for the composition of TPD laws among all state members and the agreement to an execution system for these laws (collaboration within ministries and identified agents and plan for law enforcement).
- ✓ To make suggestion to different governmental ministries for the agreement of an intraministrial and extraministrial communication protocol.

Q14. Organizational barriers with the implementation of the TPD

Response rate: 12 out of 15 countries

The majority of the countries responded the lack of sufficient staff involved in the implementation of the TPD as an organizational barrier with the implementation of the TPD in my EU MS (16.67% reported the opposite). Enforcement of TPD is a too multi-discipline, cross- departmental process and this is problematic in terms of co-ordination of tasks and Enforcement of TPD is too centralized, missing out on information and expertise from other regional/local relevant agencies was not identified as

an organizational barrier with the implementation of the TPD in my EU MS by the majority of the countries but a smaller percentage reported the opposite opinion (30% and 18.18% respectively). Only one country did not respond if enforcement of TPD is a too multi-discipline, cross- departmental process .

Overall

- ✓ To make suggestions to governments for staff increase, and training possibilities for existing staff in terms of specialized knowledge on tobacco, electronic cigarettes and other related products.

Q15. Potential solutions for the organizational barriers

Response rate: 1 out of 15 countries

“Education for the staff involved in the TPD activities in my country by the EU experts” was the only feedback in regards potential solution for organizational barriers.

Q16. Rank of the organizational barriers

Response rate: 10 out of 15 countries

Organizational related barriers based on importance:

1. Lack of sufficient staff involved in the implementation of the TPD.
2. Enforcement of TPD is too centralized in my country missing out on information and expertise from other regional/local relevant agencies.
3. Enforcement of TPD is a too multi-discipline, cross- departmental process and this is problematic in terms of co-ordination of tasks.

Overall

- ✓ To make suggestions to governments for staff increase, and training possibilities for existing staff in terms of specialized knowledge on tobacco, electronic cigarettes and other related products.
- ✓ To make suggestions to agents for intragoverental communication for frequent meetings and symposia.
- ✓ To make suggestion to different governmental ministries for the agreement of an intraministrial and extraministrial communication protocol.

Q17. Proposed training content to facilitate the application of the Tobacco Product Directive

Response rate: 12 out of 15 countries

Feedback supported that specific training on performing more technical work and statistical analysis of the data within MS-REP, general training on interpreting the significance of submitted EU-CEG data, training on the enforcement and interpretation of TPD articles that are specifically related to novel tobacco products and electronic cigarettes, cross-discipline training on applying the TPD through different regional/local agencies and control bodies (e.g., customs, ministry of health, ministry of commerce, ministry of finance, other related authorities), and Training in the assessment of websites that sell tobacco, tobacco- related products and electronic cigarettes for compliance with TPD, training in the application of market surveillance legislation such as RAPEX and the ICSMS systems, and training on ingredient recording tools used by the industry as training contents might facilitate the application of the TPD. Little responses indicated training on best practices for raising awareness of tobacco, electronic cigarettes and other related products, training on the best practice methodology for enforcing the TPD across member states, and training in ISO standards referenced in TPD and any other standards that may be of relevance to support the enforcement of the TPD as training content that might facilitate the application of the TPD.

Overall

- ✓ To make suggestions to governments, ministries and academic institutions for their collaboration for training possibilities for specialized knowledge on performing more technical work and statistical analysis of the data within MS-REP, on interpreting the significance of submitted EU-CEG data.
- ✓ To form a unified council from EU in regards the legal aspect of TPD; law enforcement, specific guidelines, and interpretation of TPD articles that are specifically related to novel tobacco products and electronic cigarettes.
- ✓ To make suggestions to government and ministries of how to enforce and interpret TPD articles that are specifically related to novel tobacco products and electronic cigarettes
- ✓ To make suggestions for the composition of a team (to cross-discipline training) with clear indication of each party's responsibilities (or ministry's) so that a step-by-step procedure of applying of the TPD is formed. To form a communication protocol between involved parties (or ministries) when it comes applying the TPD through different regional/local agencies and control bodies.
- ✓ In addition, to suggestion #4, to all the involved parties to attend appropriate training facilitated by the government or academic institutions or laboratories or experts to acclimate them with assessment of websites that sell tobacco, tobacco-related products and electronic cigarettes for compliance with TPD, and for the application of market surveillance legislation such as RAPEX and the ICSMS systems, and on ingredient recording tools used by the industry as training contents might facilitate the application of the TPD.

Q18. Proposed practical changes or additions to facilitate the application of the Tobacco Product Directive

Response rate: 11 out of 15 countries

The majority of the countries identified the following practical changes to aid the facilitation of TPD in their countries: Increase availability of local or easily accessible laboratories for ingredient testing (81.82%), the establishment of a communication network across EU member state competent authorities to discuss the application of the legislation (72.73%), the establishment of a communication network across EU member state competent authorities, market surveillance authorities and networks set up through the Joint Action for Tobacco Control (63.64%).

Overall

- ✓ To make suggestions for increase of available Laboratories
- ✓ To make suggestions for governments for the composition of a committee or council with facilitators from different ministries for the application of the legislation on a European level.
- ✓ To make suggestions for governments for the composition of a committee or council with facilitators from different ministries and the formation of a communication protocol for the EU members
- ✓ To make suggestions for governments to appoint facilitators from different ministries who will undergo training for market surveillance.

Q19. Resources available to regulators (i.e. labs, experts, websites, etc.)

Response rate: 6 out of 15 countries

Available resources to regulators in member states:

1. Labs, experts, websites
2. Experts

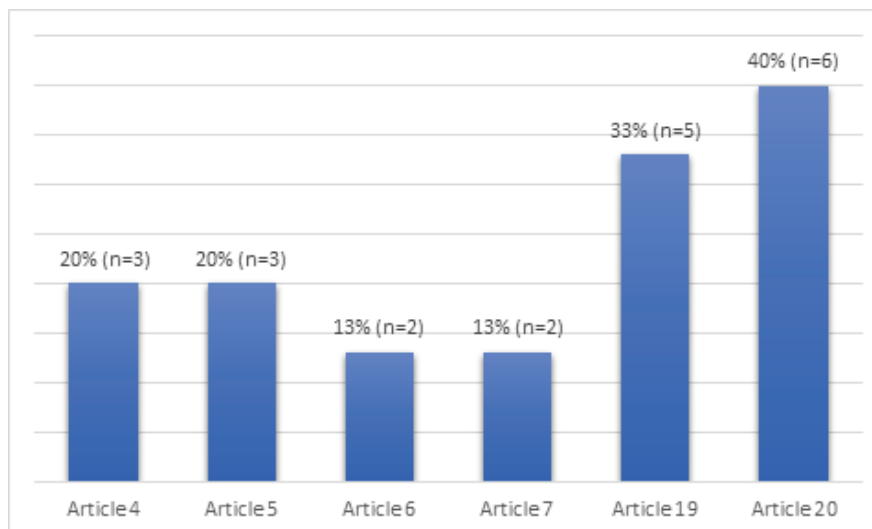
3.2 Results of the Specific Questionnaire on TPD funding and sustainability activities – WP4

Q1. TPD articles fees that are collected

Response rate: 15 Contact Points responded to this question.

It is of great importance to be mentioned that 53% (n=8) of the participants mentioned that no fees are applied for any of the Articles included in the answers. Regarding the countries which apply fees, the majority of them collects fees for Article 20 (40%) and Article 19 (33%) as shown in Figure 1.

Figure 1. Percentage of EU MS which apply fees for the following Articles.

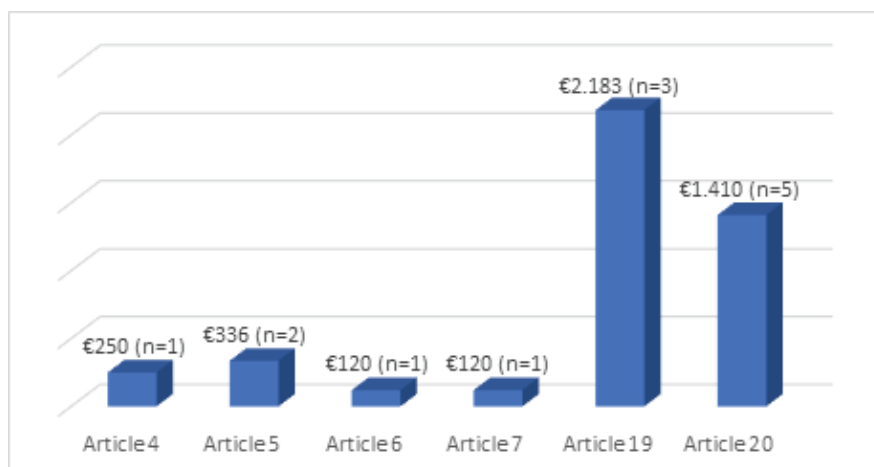


Q2. Fees applied based on each purpose

Response rate: 13 Contact Points responded to this question.

The second question of the survey referred to the approximate amount of fees that each EU MS collect for the Articles presented in Figure 2. The highest average amount of money required from the EU MS seems to be linked with the Article 19 and it is 2.183 euro (max: 5000 euro/min: 550 euro), while Article 20 follows with 1410 euro (max: 5000 euro/min: 50 euro). The fees for all the other Articles are lower, ranging from 120 euro for Article 6 and 7 to 336 euro for Article 5.

Figure 2. Average amount of fees that are being collected from the EU MS per Article.



Q3. Frequency of fees paid

Response rate: 15 Contact Points responded to this question.

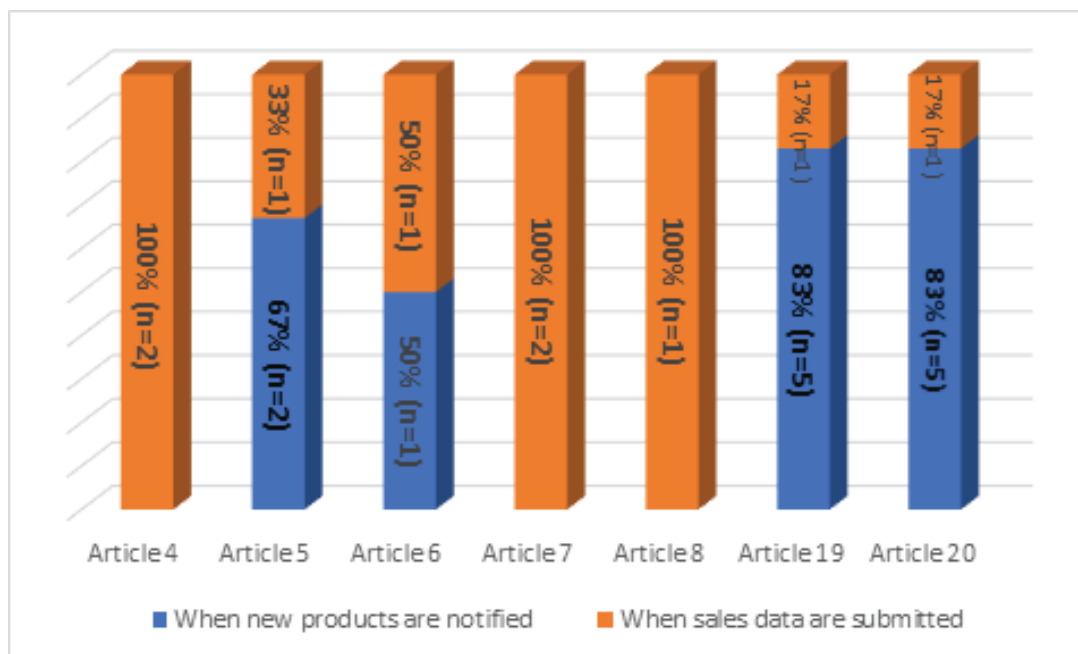
In the third question, participants were requested to answer about the frequency of fee collection. For Article 4 and 7, 2 EU MS representatives stated that the fee is paid annually, while 1 country stated "other". Regarding Article 5, both annually and one-time payment were mentioned by one respondent each, while 1 country stated "other" for both of them. Fees for Article 6 seem to be collected once from 1 EU MS, while the same frequency of payment was referred from 3 EU MS for Article 19. For Article 19, also, there were 2 representatives who stated "other". Finally, with regards to Article 20, 1 EU MS collects fees annually, 3 EU MS once and 2 stated "other". Out of the countries that selected the "other" option, one defines that there is an all-inclusive fee for all articles.

Q4. When feeds are paid

Response rate: 14 Contact Points responded to this question.

Figure 3 presents the data which reflect a timeline of when fees are collected from the EU MS regarding the specific Articles. As seen below, for Articles 4, 7 and 8 all fees are collected with the sales data submission. On the contrary, for Articles 5, 19 and 20 the majority of participants reported that fees are collected when a new product is notified. Finally, for Article 6 the answers were split, showing that half of the countries collect fees when sales data are submitted, while the other half when new products are notified.

Figure 3. Number of EU MS which collect fees either when new products are notified or when sales are submitted per Article.

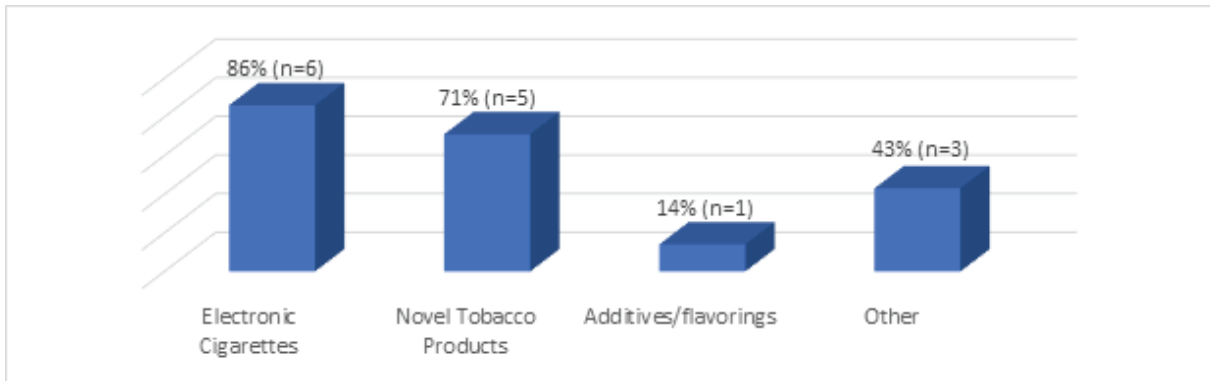


Q5. Product/category type for which fees are applied

Response rate: 7 Contact Points responded to this question.

Regarding the product or category type for which the participating EU MS request fees, electronic cigarettes hold the first place (86%). Also, 71% of the respondents mentioned that fees are applied for novel tobacco products as well, while the percentage for additives and flavorings was much lower (14%). Finally, almost half (43%) of the respondents stated "other" and some of them further clarified with responses like tobacco products, no fees, all-inclusive annual fee for all products; additional fee for notification of novel products only.

Figure 4. Product/category type for which EU MS collect fees.



Q6. Have Courts Affairs locally, _____ the fees

Response rate: 6 Contact Points responded to this question.

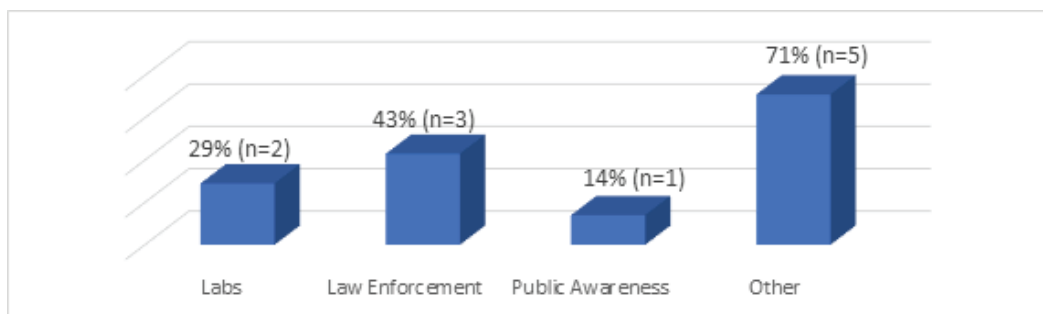
In this question participants were asked to answer whether local Courts Affairs have intervened regarding the abovementioned fees and there were 6 responses in total. According to them, 33% (n=2) of the representatives reported that the local Courts Affairs have challenged the fees regarding the abovementioned articles, 17% (n=1) that the local Courts Affairs have cancelled the fees, while half of them (50%, n=3) stated “other”.

Q7. Utility of fees

Response rate: 11 Contact Points responded to this question.

In an effort to define the utility of the collected fees, a respective question was included in the survey. Based on the data shown in Figure 5, the majority of the respondents stated “other” by which they mean that a) law does not provide specific provision of the fees, b) fees are used for set up and assessment of notifications/oversight activity, c) fees are used for market surveillance measures. Additionally, 43% reported using the fees in order to enforce the implementation of tobacco control policies, 29% claimed providing the fees to laboratories which work on tobacco products, and finally, 14% seem to use them so as to enhance public awareness regarding the negative effects of smoking.

Figure 5. Provision of fees collected from EU MS.

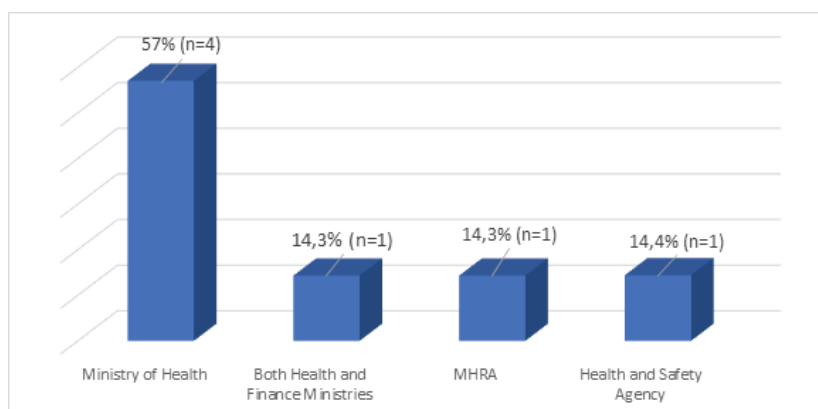


Q8. Department/ministry responsible for these fees and therefore is completing this information

Response rate: 7 Contact Points responded to this question.

With regards to the Departments or Ministries which are responsible for the request and collection of all fees mentioned above, the results are presented in Figure 6. In more detail, the majority of the EU MS, which participated in this survey, reported their Ministry of Health as being responsible for the fees linked to Articles 4,5,6,7,19,20.

Figure 6. Department/ministry responsible for fees application.



Q9. Competence of the bodies representing the industry for policies and legislation

Response Rate: 9 Contact Points responded to this question.

Feedback support that the majority (78%, n=7) of the countries report competence of the bodies representing the industry in terms of policy and legislation on tobacco and vaping products. Additionally, almost half of them (44%, n=4) answered positively regarding the competence of these bodies on reporting and controlling, while a lower percentage (33%, n=3) finds the bodies competent for the enforcement of TPD.

Q10. Competence of the bodies representing the industry for policies and legislation and please specify the nature of the bodies

Response rate: 9 Contact Points responded to this question.

Regarding the bodies that represent tobacco industry in policies and legislation on issues related to tobacco and vaping products, 67% (n=6) of the participants reported that they are governmental, while the remaining 33% (n=3) that they belong to the private sector.

Response rate: 7 Contact Points responded to this question.

For the TPD enforcement, 86% (n=6) of the EU MS stated that the bodies representing tobacco industry are governmental, while 14% (n=1) chose both Governmental and Private Sector.

Response rate: 8 Contact Points responded to this question.

In terms of reporting and control, 75% (n=6) of the EU MS stated that the bodies representing tobacco industry are governmental, while 25% (n=2) chose both Governmental and Private Sector.

Q11. Nature of the bodies responsible for vaping/tobacco policy (e.g. Scientific, Administrative, Regulatory) and overall involvement (e.g. Research, Funding, Expertise, or other)

In this question, participants were asked to specify the overall involvement of the bodies which are responsible for vaping and tobacco policy in terms of research, funding and expertise.

Response rate: 9 Contact Points responded to this question.

Regarding research, all countries reported that Scientific Bodies are involved, 66% (n=6) also mentioned the Regulatory Bodies and 33% (n=3) also the Administrative Bodies.

Response rate: 9 Contact Points responded to this question.

As for the funding, 56% (n=5) of the participants declared the involvement of Administrative Bodies, 44% answered positively about Regulatory Bodies and 22% (n=2) about Scientific Bodies.

Response rate: 8 Contact Points responded to this question.

In terms of expertise, all of the participating countries referred the involvement of Scientific Bodies, 63% (n=5) of them the involvement of Administrative Bodies, and finally 38% (n=3) of them answered positively about Regulatory Bodies as well.

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, the main barriers to the implementation of the TPD that are reported by CAs, focus on the lack of staff with specialized knowledge on tobacco, electronic cigarettes and other related products' ingredients and additives, as well as the lack of local laboratories for tobacco, electronic cigarette and other related product ingredient analysis. Additionally, the lack of specific guidelines for the unified application of the TPD across member states and financial limitations in supporting the necessary steps for applying the TPD also burden the effective TPD implementation. Furthermore, in line with the above an effort was made in order to map the tobacco control funding across the EU MS, including submission fees to the EU-CEG or fees for implementation of TPD and also to identify and map in-house and cross border regulatory, scientific and technical capacity resources available to regulators. In brief, almost half of the countries do not collect fees defined by the Articles 4,5,6,7,19 and 20 and the majority those who do apply fees, mainly focus on Article 19 and 20 for e-cigarettes and novel tobacco products. In terms of utility, most of the EU MS reported that the law does not provide any specific provision of the fees. 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 enhance training and capacity building and facilitate a greater exchange of information and expertise across EU MS with the purpose to aid tobacco product regulation/actions.