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Work Package 8 - Laboratory verification, collaboration and analyses

Deliverable 8.1

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JOINT ACTION ON TOBACCO CONTROL

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1. Background

Laboratory measurements are essential for effective application of various provisions of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 (referred as Tobacco Products Directive, TPD, in following text). In particular, according to article 4, the competent authorities (CA) of all the European Union (EU) Member States (MS) "shall communicate to the European Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, and shall update that list whenever any change is made". The list of approved laboratories, available online at https://ec.europa.eu/health/sites/health/files/tobacco/docs/approved_laboratories_en.pdf, currently includes 18 laboratories from 14 countries (AT, DE, EL, ES, FR, HU, IE, IT, LT, LV, NL, PL, SI, UK). The independent laboratories should verify the tar, nicotine and carbon monoxide (TNCO) emission levels of cigarettes (using ISO standards). The TPD requires that these laboratories are independent. Therefore they "shall not be owned or controlled directly or indirectly by the tobacco industry" and "the verification process should be protected from tobacco industry influence". It is important to note that, according to the TPD, MS CAs may use laboratories located in other EU MS.

TPD article 3 entitled "Maximum emission levels for tar, nicotine, carbon monoxide and other substances" sets the maximum levels for TNCO in cigarettes. EU MS should notify the Commission any maximum emission levels they set for emissions other than TNCO, including flavours, and for emissions from tobacco products other than cigarettes, including electronic cigarettes. However, the TPD does not regulate several aspects of the verification process, e.g., when the tobacco products should be verified, who supplies tobacco samples, when and how to verify emissions other than TNCO from cigarettes, and all emissions from other tobacco products, including electronic cigarettes. Moreover, although the TPD states that "MS may charge manufacturers and importers of tobacco products proportionate fees for the verification" of TNCO emission levels, it is not clear who is going to pay the laboratory analyses and how.

In order to map the current status quo of EU MS laboratories performing analyses on tobacco and e-cigarettes, and therefore to better understand the laboratory capacity and requirements, the availability of specific operating procedures or protocols and, particularly, the independency of laboratories from the tobacco industry, we prepared a structured questionnaire to be filled by various MS CAs.

2. Methodology

A questionnaire (Annex 1) was designed to collect from various MS CAs updated information about their needs and the current state-of-the-art of the verification processes, including laboratory presence, activities, specific norms regulating the verification analyses of various tobacco products and e-cigarettes, with a focus on the independency of the laboratories from the tobacco industry. The specific questions were developed by the team of the JATC WP8 leader (IRFMN), and then revised by representatives of all partners involved in WP8 (HCS, AGES, BfR, CERTH, HTS, NVSPL, RIVM, NLZOH, CSJA).

The questionnaire included 3 sections:

- The first section of the survey (i.e., "laboratory related questions") was composed by two tables, including multiple structured questions. The tables collected information on the laboratories that various EU MS CAs have appointed for analyses on tobacco, electronic cigarette and heated tobacco products. Moreover, CAs were asked to provide details on all the possible analyses requested to the laboratories over the last 4 years, including a question about source of financial support for analysis and sample collection.
- The second section (i.e., "issues of laboratory measurements"), referred to the availability of specific programmes that each CA possibly followed to verify and control tobacco products at a national level.
- The third section (i.e., "questions on retributions–fees to manufacturers and importers"), mainly based on open questions, focused on fees (i.e., retributions), if any, charged to manufacturers and importers of tobacco products under the TPD (2014/40/EU).

Given that, besides WP8, other JATC WPs (i.e., WP3, WP4, WP5, WP6 and WP7) also needed to conduct a survey to enquire CAs their needs on different topics, including in particular the EU-Common Entry Gate (EU-CEG), we decided to integrate our WP8 questionnaire in a unique Common Needs Assessment Survey (i.e., "Joint Action on Tobacco Control – EU MS Regulator Survey"; Annex 2; A2), as a single chapter (A2:Q43-Q58,Q62-Q71).

The whole survey was an anonymous investigation based on 76 questions, converted in a SurveyMonkey platform. This questionnaire was to be completed by the CA, primarily those involved with EU-CEG monitoring and tobacco/e-cigarette product regulation. 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). As different chapters cover different topics, anonymous participants were allowed to skip those chapters that they regarded as non-relevant to their current activities. Moreover, in each chapter, participants also had the option to answer only questions for which they felt comfortable and competent to respond to, and skip questions that did not concern them. However, all respondents had to read all questions within each chosen chapter before they could finish the survey, so as to ensure that they had the possibility to view and potentially respond to all questions.
A report on all the aggregated data collected through the survey was automatically generated by the SurveyMonkey system. The partial report inherent to each chapter was sent to the corresponding WP leader. In date 17 September 2018, we received the report including aggregate data on the answers to all question from the chapter belonging to WP8 (Annex 3; A3:Q43-Q122).

3. Results

In total, 15 regulators participated in the WP8 questionnaire, although they skipped most of the questions. Therefore, WP8 questions were answered by a mean of 3.9 regulators. For each question, answers ranged between 0 and 7.

3.1. Laboratory related questions.

3.1.1 Laboratory details

Aiming to understand the current use by CAs of independent analytical laboratories in each EU MS to perform analyses on tobacco products and e-cigarettes, we prepared the first section of the survey (i.e., laboratory related questions) to collect: i) details on all the laboratories used to perform analyses on tobacco, e-cigarettes and heated tobacco products (HTP), and ii) for each laboratory, details on the analyses requested by CAs currently or over the last 4 years (2015-2018), including type of analysis, report type, and particularly sampling source and payment channel. The questions on the sampling source served to understand if the current practice permits the analyses of samples provided by the industry; more importantly, the questions on the payment channel served to understand if the current practice allows a direct payment from the tobacco industry to "independent laboratories".
For each laboratory (or analysis) employed by the CA over the last 4 years, participants were asked to answer 8 questions (A2:Q43-Q50). Each participant could provide data up to 6 different laboratories (or analyses) repeating 6 times the same 8 questions. Therefore, the corresponding responses are available in A3:Q43-Q98.
In A2:Q43 (**laboratory details**; responses in A3:Q43,Q52,Q61), we asked the details of various laboratories engaged by the CAs to perform analyses on tobacco and other products. Out of 15 regulators participating in the WP8 chapter, 10 (67%) skipped this question and 5 participants (33%) provided their answers. Respondents provided the details of 6 different laboratories from 4 countries. According to TPD article 4, the EU MS shall select the independent laboratories for the verification of TNCO measurements from a list provided by the European Commission. This list is composed by laboratories approved and monitored by EU MS CAs. Only 2 out of 6 laboratories nominated were included in such list. Not all the respondents provided information on details as the name of contact person and email address of the laboratories.
In A2:Q44 (**type of product the laboratory can analyse**; responses in A3:Q44,Q53) we asked the

participants to list all the products that the corresponding laboratories were capable of analysing. This multiple-choice question was responded by 5 participants, providing a total of 8 analyses that the laboratories could analyse. The most common products that the laboratories could analyse were e-cigarettes (7/8; 88%) and boxed cigarettes (6/8; 75%). A few laboratories were capable of analysing roll your own tobacco (2/8; 25%), cigars and pipe tobacco (1/8; 13%), oral tobacco (1/8; 13%) and herbal products for smoking (3/8; 38%). Regulators reported that none of the laboratories was capable of performing analysis on water pipe tobacco (0/8; 0%) or novel tobacco products (0/8; 0%).

3.1.2 Analysis details

In A2:Q45-Q50 (responses in A3:Q45-Q50,Q54-Q59) the participants were further asked to provide information on each analysis they, as CAs of their MS, have ordered to laboratories in the last 4 years. In total, 5 participants provided information on 9 analyses (A2:Q46; **type of analysis performed**; responses in A3:Q46,Q55) conducted in 2017 and 2018 (A2:Q45; **year of request**; responses in A3:Q45,Q54), only. Overall, 4 out of 9 analyses (44%) examined TNCO. The type of analysis conducted was specified through an open question in 8 out of 9 responses (88%). Analyses focused on "propylene glycol, glycerol and flavours" (3), "propylene glycol, glycerol and nicotine" (1), "pesticides, heavy metals, preservatives, aroma compounds" (1), "oral tobacco" (1), "amount of nicotine" (1) and "e-cigarette according to national analysing program" (1).
A2:Q47,Q48 (**financial support for the analysis**; responses in A3:Q47,Q48,Q56,Q57) were designed with the aim to understand the flow of payment of each analysis performed by various laboratories, ordered by CAs. We wanted to understand who the entity supporting the analyses was, if the industry (or the distributor) directly paid the fee (invoice) to the laboratory or if the industry paid through a third party (as the CA). Originally, Q47 was intended to understand what the selection criteria for the laboratory were (see Annex 1), and therefore why the corresponding laboratory was chosen. This question was mistakenly replaced in the conversion into the SurveyMonkey version. Therefore, Q47 and Q48 referred to the same repeated question. We received a total of 16 responses from both questions (Table 1). Overall, 13% reported a direct payment from the tobacco industry, and 19% reported an indirect payment.

Who supported financially the analysis and who paid the invoice to the laboratory?	N	%
A) CA -> CA ->Laboratory	1	7%
B) tobacco industry -> tobacco industry -> Laboratory	1	7%
C) tobacco industry -> CA -> Laboratory	3	21%
D) I don't know	0	0%
E) Other -> Other -> Laboratory	9	64%

Table 1: Overall distribution of responses to A2:Q47,Q48.

Those reporting option E (Other -> Other -> Laboratory), specified the flow of the payment of analyses. Specifications included the following:

- "Fees based on sales volume according to Ordinance regarding the determination of a cost-covering annual fee for the monitoring of tobacco products and related products and of cost-covering fees for the authorisation of novel tobacco products…"
- "Laboratory belongs to national government. The lab does not perform analysis for the industry, but only for the control and verification annual plan. So, industry does not pay fee (invoice)"
- "Industry and CA do not pay fee (invoice). Lab does not carry out controls for the industry, just for the annual programme of verification and control testing"
- "There is not any payment from the industry"
- "There is no payment"
- "The Ministry of Health" (2 times)
- "The Regional Administration" (2 times)

The large majority of analyses, therefore, are not paid by the industry.
We also asked the source of the samples used for the analyses (A2:Q49; **supplied samples**; responses in A3:Q49,Q58). Among the 9 responses, 2 (22%) analyses used samples collected at sales points (shops), 1 (11%) from tobacco seizures, 4 (44%) at distributers warehouses, 0 (0%) at producer factories, and 2 (22%) from other sources (Figure 1), including manufacturers.

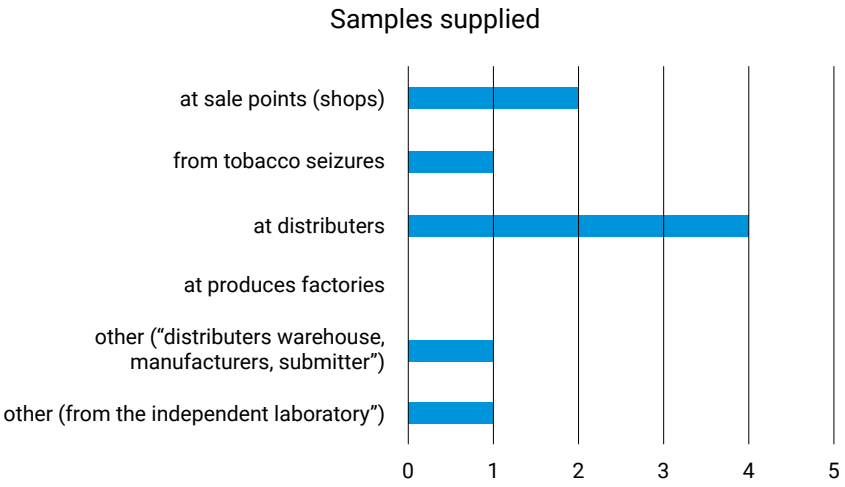

Figure 1: Distribution of sources of analysed samples

We also asked in what form the CA received results of the verification analyses from various laboratories (A2:Q50; **reports or data obtained from laboratories**; responses in A3:Q50,Q59). Overall, 5 participants provided 9 responses, including 7 (78%) in the form of report (7; 78%), and 2 (22%) in the form of both data and report.

3.2 Issues of laboratory measurements

This section enquired participants to provide information on the availability of specific programmes that each CA possibly followed to verify tobacco products in each EU MS.
A single-choice question (A2:Q52; **frequency of analysis of each tobacco product/brand**; response in A3:Q99) required the CA to indicate the preferred timing or frequency of analysis for various products analyzed by independent laboratories. Out of 15 regulators, 4 (27%) provided a response and 11 (73%) skipped the present question. Of 4 respondents, 2 (50%) answered at launch of the product, 1 (25%) when it is modified and 1 (25%) every two years; none (0%) answered annually. This question was erroneously re-formulated (A2:Q56; response in A3:Q103) with a slightly different wording, providing likely coherent answers. Respondents also provided a suggestion in both questions to either define a written protocol and to add a random verification from time-to-time.
Another question (A2:Q53; **availability of regular verification programme**; response in A3:Q100) asked about the possible availability of a programme for the verification of tobacco products. Out of 7 respondents, 3 (43%) reported to have a verification programme and 4 (57%) reported they did not have one. Also this question was erroneously re-formulated (A2:Q57; response in A3:Q104), with the same wording, providing similar answers. Those with a verification programme available were asked where they plan to obtain the samples for verification and control of tobacco products (A2:Q54; planned sample source for analyses; response in A3:Q101). Respondents reported either from inspectors for Official Control or different product-specific plans (i.e., from distributers/ warehouses for cigarettes; at sale points and from inspectors for Official Control for other products, including cigars, e-liquids and herbal products). This question was also erroneously re-formulated (A2:Q58; response A3:Q105), with the same wording. In this case, it was given the possibility to provide multiple choices. Out of 3 respondents, 3 (100%) reported "at sales point", 3 (100%) reported "at distributors (warehouse)" and 1 (33%) reported at producer factories.

An open question required the CAs to add any comments or needs they could have on the issue of TPD approved laboratories (A2:Q62; **comments or needs**; response in A3:Q102). Overall, 3 regulators answered. All of them have recognized a lack of financial support to achieve the capabilities to meet testing requirements (in one case, such laboratory was not available).

3.3 Questions of retributions – fees to manufacturers and importers

The TPD (2014/40/EU) clearly states that EU MS may charge manufacturers and importers of tobacco products proportionate fees for the verification of the measurements of TNCO. In the third section of our questionnaire, we were interested in understanding the current state-of-the art of such fees (i.e., retributions), if any, charged to manufacturers and importers of tobacco products.
A specific question (A2:Q63; **retributions for analysis**; responses in A3:Q110) required the CAs to indicate if there were retributions for analyses and other control tasks on tobacco products in their country. Overall, 7 participants responded: 2 (29%) participants reported that there were no retributions while 5 (71%) reported that retributions were charged for the analyses. Three of the latter participants provided related documents or law text describing the composition of the retribution, as follows:

- "For tobacco products in Executive Order under the law, implementing TPD and in Executive Order from our tax authority. For e-cigarettes in Executive Order under the law, implementing TPD."
- "Law Text: 9 (9) Tobacco and Non-Smoker Protection Act (TNRSG), Federal Law Gazette No. 431/1995, in the current Version: "The Federal Minister for Health shall, by regulation and in agreement with the Federal Minister for Finances, determine an appropriate cost-covering annual fee in line with the market, based on the sales figures of related products and tobacco products of the previous financial year under consideration of the actual financial expenditure for control activities from the previous year and the expected financial expenditure for control activities. Before adopting a regulation, the Austrian Economic Chamber is given the opportunity to make a statement. This fee covers the duties to be fulfilled according to this federal law and the regulations adopted based on this federal law, in particular regarding notification activities, control activities, data analysis and evaluation, laboratory inspections, risk evaluation and evaluation of studies. The annual fee does not cover the costs for the authorisation according to § 10a."
- "No fees, but the expenses of analyzing or evaluating the products, if imposed by the regulator, must be supported by the tobacco industry."

We asked regulators from which parties among manufacturers, importers, point of sales, and others they request retributions (A2:Q64; **retribution parties**; responses in A3:Q111), and for what types of tobacco products (A2:Q65; **retribution products**; responses in A3:Q112). Overall, 5 regulators answered the question: all (5, 100%) indicated that the fees are charged to both manufacturers and importers; 2 of them reported that they requested retributions for all tobacco related products and 1 reported cigarettes, while another regulator reported that no retributions had been charged in real life.
An open question required to the regulators to define what the definition of one unit was for the retribution of each type of products (A2:Q66; **retribution unit**; response in A3:Q113). Only 1 regulator answered this question, reporting "cigarettes: per commenced 20 Units RYO: per commenced 40g cigars: per unit cigarillos: per commenced 20 Units liquids: per commenced 10 ml waterpipe tobacco: per commenced 40g tobacco free fillings for waterpipes: per commenced 40g pipe tobacco: per commenced 40g".
Regarding the type of activities in which retribution was request (A2:Q67; **type of activities to be charged**; response in A3:Q114), 2 regulators provided their answers indicating that they requested retributions for "Reporting, testing, sampling, inspections, evaluations, data Analysis and risk Evaluation" or "Examination of prohibited additives EUR 300/examined additive Verification of emission measurements EUR 1,500/product Notifications submitted by virtue of the Tobacco Act EUR 150/notification".

Moreover, we asked the amount of retributions requested by CAs (A2:Q68; **Amount of retributions**; A3:Q114). Only 1 regulator answered this question, reporting that "the fees are based on the sales volume of the previous year".
An open question required the CAs to indicate which institutes were performing the work that was covered by the retributions (A2:Q69; **performing institute**; response in A3:Q116). Overall, only 2 regulators provided their answers, one reporting "the competent authority for market surveillance of TPD and by the tax authority" and one by the TPD approved laboratory.
To better understand the flow of the retributions charged for various analyses, we also asked the regulators where they collected them, directly from the tobacco industry or by a third party, or a mixture of both (A2:Q70; **retribution source**; response in A3:Q117). Among the 3 responses, 2 (66.67%) indicated a full coverage of retribution by tobacco industry and 1 (33.33%) indicated a partial coverage.
In the last question of our questionnaire, we further asked about the frequency of collection of retributions (A2:Q71; **retribution frequency**, response in A3:Q118). Three participants responded as follows: 1) before the analysis; 2) once a year; 3) for notifications twice a year but other retributions are collected after the work is performed".

4. Conclusions

In total, only 15 CAs have participated to the WP8 chapter of the common JATC-EU MS Regulator Survey. Moreover, all the WP8 questions have been skipped by the majority of those 15 participants. Thus, none of the WP8 questions were answered by more than 7 respondents, and WP8 questions received a mean of 3.9 answers. The low response rate notwithstanding, this survey allows us to observe some interesting findings.
First of all, we find that the use of approved independent laboratories is still limited. Actually, according to the TPD, CAs of each EU MS shall communicate to the European Commission a list of approved laboratories, whose independency from the tobacco industry should be substantiated. These qualified laboratories should verify at least TNCO emission levels for cigarettes. Only 18 laboratories from 14 EU MS are currently available in EU. However, we found that among the 6 laboratories engaged by 4 regulators who participated to our survey, only 2 laboratories were TPD approved laboratories.
Only a few regulators reported that laboratories are capable of analyzing products other than cigarettes and e-cigarettes. This suggests that there is a need to identify within EU qualified laboratories, capable of performing analyses on cigar, pipe, water pipe and oral tobacco, and particularly on novel tobacco products (i.e., heated tobacco products).
More importantly, the number of analyses described by regulators was extremely limited. Every regulator had the possibility to describe up to 6 analyses required to various laboratories over the last 4 years. However, only 5 regulators provided information on just a few analyses (in average: 2.2), conducted in 2017-2018. Although an under-reporting of analyses is possible, this finding suggests that the analyses required by regulators remain few nevertheless. This is likely due to the lack of a regular verification programme, reported by the majority of respondents. Accordingly, the need to define a written protocol to verify each tobacco product/brand at least at launch and on a regular basis (plus a random verification from time to time) was suggested by several respondents.
Some of our findings warn against a possible intrusion of the tobacco companies in the verification process. In fact, at least one analysis was financially supported by the tobacco industry, with a direct payment from the tobacco company to the laboratory performing the analysis. This is unlikely acceptable, since with a direct payment - from the industry to the laboratory -, the independence as well as the analysis results may be seriously compromised.
At least one respondent listed manufacturers among the sources of samples used for verification of tobacco products or e-cigarettes. This reflects an additional important issue regarding laboratory dependency. In our opinion, in fact, samples should be collected randomly at sales points, from where the consumers buy tobacco products.
The TPD states that EU MS may charge manufacturers and importers of tobacco products proportionate retributions at least for the verification of TNCO emission levels. The majority of

respondents (although not all) reported that a national legislation regulates such retributions, not only for cigarettes but also for other tobacco products or for e-cigarettes. However, the large majority of analyses conducted in 2017-2018 were not paid by the tobacco industry. Given that all the respondents consistently recognized a lack of financial support for the verification analyses of independent laboratories, retributions from the tobacco (and e-cigarette) industry should be further required. To preserve the laboratory independency from tobacco (and e-cigarette) companies, however, no direct payment (from industry to laboratory) should be admitted.
The present survey on WP8 has several limitations, which jeopardize the integrity of our conclusions. The main limitation is due to the small response rate. The large majority of WP8 questions were in fact answered by 4-5 respondents from 4 countries, only. This sample is far from being representative of the EU MS regulators. The reasons for the low response rate include:

1) The difficulties in comprehension of the WP8 questions, which may have discouraged participants to fill the questionnaire. This was partially due to the complexity of our questions (in particular of the two tables considered in the first section) and also to the conversion of the questionnaire from the Microsoft Word file version to the SurveyMonkey version used for the online fieldwork;
2) The anonymity of the survey. Although it is important to keep the questionnaire anonymous, this did not allow us to send reminders specifically to non responders and, more importantly, to understand if the same regulator has filled the chapter once or more times.
3) The possibility to skip entire chapters (or all the questions within a chapter). This was particularly unfortunate for WP8, whose questions were formulated after those from other chapters (including a total of more than 40 questions). It would have been very helpful if at least the most important questions for each chapter had been considered as mandatory for all the participants.
4) The conduction of the fieldwork in summer time, when many regulators may have started their vacations.

Given the limitations of the present survey, we decided to conduct a new survey, already converted in SurveyMonkey (available online at: https://www.surveymonkey.com/r/JATC_WP8), based on just a few questions, that will allow us to confirm the interesting findings we observed in the present survey.