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

WP4 – D4.2 Sustainability plan, including scenarios for long-term sustainability

Circulation: Public
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Date: 12 November 2020
Doc. Ref. N°: 4.2

JOINT ACTION ON TOBACCO CONTROL

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

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1. Introduction

The aim of the Joint Action on Tobacco Control (JATC) is to support EU Member States (MS) in the implementation of the Tobacco Product Directive (TPD) and in the collaboration and exchange of best practices, consistently with the objectives of the WHO Framework Convention on Tobacco Control (FCTC).

The JATC vertical Work Packages (WP 5, 6, 7, 8 and 9) have conducted activities related to tobacco product monitoring at an EU-wide level through the facilitation of access and the analysis of data within the EU Common Entry Gate (EU-CEG), the assessment of tobacco and e-cigarette product compliance with the TPD, as well as aspects of laboratory harmonisation, and the evaluation of the role of priority additives in tobacco products.

The objective of the horizontal Work Package 4 Integration into national policies and sustainability is to support MS and international institutions through the development of guidance documents for the continuation and sustainability of the JATC WP activities and results. Specifically, the guidance documents produced aim to promote best practices to be integrated in national and international health research and policy-making, with the final goal of reducing public health risks and mitigating consequences of health threats due to tobacco and nicotine consumption.

This WP 4 Deliverable D4.2 *Sustainability plan, including scenarios for long-term sustainability,* indicates possible and affordable paths - some more general, others more practical - related to the tasks of JATC vertical WPs (particularly EU-CEG, WP 7 and WP 8) and the TPD. The paths are described in each of the guidance documents, to be promoted and possibly implemented at national or at EU level, post-JATC. The sustainability scenario is reported in the documents within the *Sustainability* paragraph, where the possibilities of getting resources to conduct the described activities are suggested.

The documents produced are of different types: how to clean and handle EU-CEG data, guidance protocol for a system of reporting suspected adverse effects (AE) for electronic cigarettes and refill liquids, guidance to the checklist for e-cigarette product compliance to the TPD, laboratory analysis for tobacco and nicotine products, recommendations for treating electronic cigarette and heated tobacco product dependence, mapping actors in the field of electronic cigarettes, legal guidance to improve TPD highlighting some gaps, proposal of a system for economic analysis of tobacco and nicotine products. Some of them are more general, giving orientation and advice on some topics, while others are outlining more specifically a step by step process.

These guidance documents will be disseminated through the JATC website (http://jaotc.eu/) and possibly through other public health institutional websites dedicated to topics related to the prevention of tobacco and nicotine consumption. Internal (within any MS) webinars presenting the guidance documents can be also organized involving stakeholders, researchers and other interested parties.

2. Authors and reviewers

Some of the WP 4 authors were also reviewers of the other guidance documents (see author and reviewers details of each guidance document). Among those who were exclusively reviewers there are also external colleagues (see below the external reviewers section).

1. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC

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ANNEX 1) Guidance document on how to clean and handle EU-CEG data

ANNEX 2) Guidance to reporting system of suspected adverse effects (AE) for electronic cigarettes and refill liquids

ANNEX 3) Guidance to the checklist for e-cig compliance to the TPD

ANNEX 4) Laboratory analysis related to tobacco and nicotine products

ANNEX 5) Guidance to recommendations for treating electronic cigarette and heated tobacco product dependence

ANNEX 6) General guidance on mapping actors in the field of electronic cigarettes

ANNEX 7) The Tobacco Data Lake: An IT system to monitor and perform economic analyses of tobacco and nicotine products

ANNEX 8) Certain legislative aspects of national measures to implement TPD with regards to e-cigarettes and heated tobacco products

9. https://ec.europa.eu/health/euceg/introduction_en

Agreement n°:

761297-JATC-HP-JA-03-2016

Guidance document on how to clean and handle EU-CEG data

JOINT ACTION ON TOBACCO CONTROL

Circulation: Public
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Date: 3d November 2020

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

Contents

What are the benefits of data cleaning?

Knowing how to clean EU-CEG data is advantageous for the following reasons:

1. Improves efficiency when using the dataset.
2. Improves the quality of the data.
3. Supports the regulation process.
4. Prevents 'garbage in garbage out' error.

The steps and techniques for data cleaning will vary according to the files assessed in EU-CEG, and are based on routine processes for data cleaning . Hence as each dataset is unique, it is not possible to incorporate all actions that need to be taken into account when using the EU-CEG dataset. However, this guidance document provides **a starting framework** that can be used for assessing the completeness of the EU-CEG database and aid EU MS regulator interpretation of the data.

The workflow is a flow of steps that aim to develop cleaner data and are in principal the following endless cycle:

1. **Inspection:** Detect unexpected, incorrect, and inconsistent data.
2. **Cleaning:** Fix or remove the anomalies discovered.
3. **Verifying:** After cleaning, the results are inspected to verify correctness.
4. **Reporting:** A report about the changes made and the quality of the currently stored data is recorded.

Step 1: Inspection to find the "messy data"

Start data cleaning by inspecting your data. Look in the first instance for the following:

- Are there rows with empty values? Entire columns with no data? Which data is missing and why?
- How is data distributed? Look for outliers.
- Keep an eye out for impossible values?
- Is your data consistent? Why are the same ingredient names written in UPPER, lower or MiXEd case?

Inspecting the data can be done through many different techniques, including "eyeballing" the dataset, or through analysing and visualising the data. For day to day use by the regulator, Excel is sufficient to perform basic data cleaning for basic regulatory actions. For instance, in Excel, you can use the "make a graph" function to visualise the data in EU-CEG.
Note: The entire EU-CEG dataset may not open in Excel, and you may need to make the file smaller before opening and handling.

Software packages such as SPSS, STATA, R and even Microsoft Excel will help you assess and check the EU-CEG data for "messy data". More complex statistical analysis can also be performed to see the distribution of the data, but these should be performed with the help of a statistician/ data analyst. By statistically analysing and visualising the data using statistical methods such as mean, standard deviation, range, etc., a data analyst can find values that are unexpected and either included by mistake or reflect a new product design approach.

Within this guidance document, we refer to activities that should not need in principal advanced data cleaning experience but are based on logical decision making.

Step 2: Commence data cleaning

Depending on the type of data you're handling within EU-CEG, you'll need different cleaning techniques which are described with actual EU-CEG examples below.

2.1 Missing data

Sometimes you will have rows with missing values. Sometimes, almost entire columns will be empty. Start by identifying all the different ways that missing data may appear in EU-CEG. It may appear as values such as "0" or as a "." Or as an "empty cell". It may also include other string variables such as "Not Applicable", "NA", "NULL". For example, in the TNCO and other emissions file, the variables informing on these emissions are mostly missing values (empty cells) or filled with 0.
Dropping (deleting) missing values is not an ideal approach because when you drop observations, you drop information. The fact that the value was missing may be informative in itself.
Action point: Flag for follow up with the manufacturer or importer.

2.2 Outliers

Outliers are data points which are at an extreme. They usually have very high or very low values:

- A cigarette length of 10mm
- A tobacco weight of 200gr
- A cigarette length of 1mm
- A nicotine vial volume >10ml.
- A nicotine tank>2ml

Outliers usually signify either very interesting reported data or a mistake in the data entry. Both are valuable information as this may indicate a new evolving product design (i.e. a new filter, product, design etc.) or it may be a simple clerical error in data entry in EU-CEG. You should never remove an outlier just because it's a "big number." That big number could be very informative for your regulatory process.

Outliers remain a limitation of the current analysis of the EU-CEG dataset (in particular for refill container volume and nicotine concentration, for which outliers are easy to identify)- a thorough cleaning of the EU-CEG dataset by correcting submissions from the manufacturers would improve the quality of the submitted information.
Outliers are especially important in the assessment of ingredients and additives, as high concentrations may indicate a characterising flavour or a specific product composition.
For example, you may notice some suspicious values that are unlikely to happen, but they may be worth investigating before removing. For instance, an e-cigarette vial volume of 200 - does this mean "2ml", or "20ml" or actually "200ml"? In this case, it may be a non-compliant product, and the manufacturer/importer should be notified. Once they are verified as a mistake, you may remove outliers from the data set. Having outliers will impact your analysis by changing the mean values and distribution of the results (for instance in the Greek EU-CEG data, given the wide range of vial volumes reported and outliers, the SD of vial volumes among all products was 122.65ml! – which was due to one entry of 11450ml. After removal or flagging of the 45 outliers the remaining 16,982 entries were compliant.)

PRT_VOL_E_LIQUID[a]

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	-10,00	1	,0	,0	,0
	,00	2	,0	,0	,0
	,69	7	,0	,0	,0
	,75	10	,0	,0	,1
	,80	3	,0	,0	,1
	,90	44	,2	,2	,3
	1,00	41	,2	,2	,5
	1,10	3	,0	,0	,5
	1,20	24	,1	,1	,7
	1,40	4	,0	,0	,7
	1,50	194	1,0	1,0	1,6
	1,70	10	,0	,0	1,7
	1,85	3	,0	,0	1,7
	1,95	24	,1	,1	1,8
	2,00	302	1,5	1,5	3,3
	3,00	11	,1	,1	3,4
	5,00	8	,0	,0	3,4
	9,75	19	,1	,1	3,5
	10,00	19495	96,0	96,0	99,5
	15,00	1	,0	,0	99,5
	20,00	10	,0	,0	99,6
	30,00	45	,2	,2	99,8
	50,00	29	,1	,1	99,9
	60,00	12	,1	,1	100,0
	210,00	1	,0	,0	100,0
	Total	20303	100,0	100,0	

a. EU_MS = GR

In the circle above, one can identify the outliers in the GR EU-CEG data. For instance, with a simple assessment of data entries, one can see that there is 1 product with a 15ml volume, 10 with a 20ml volume, 45 with a 30ml volume, etc.
Action point: Flag outlier for follow up with the manufacturer or importer.

2.3 Invalid data

Contaminated and invalid data is another red flag. For example, a cigarette with a diameter of 3mm. Another example of invalid data for instance, is noted above where the volume of the e-liquid is noted as "-10".
Action point 1: Flag outlier for follow up with the manufacturer or importer.
Action Point 2: For numerical values, make sure all values have a certain measurement unit (mm or ml, or mg etc.) The length of a cigarette, for example, can be in millimetres and centimetres. So, the task here is to convert the measurement to one single unit.

2.4 Inconsistent data

The best way to identify inconsistent representations of the same variable in your EU-CEG data is to visualise them. Plot bar charts per product category.
For instance, there were substantial differences in the reporting of the type of battery in the Greece EU-CEG data, due primarily to the fact that this was a "text" field with no restrictions. Hence, 375 unique responses were recorded and included both text responses such as "LI-ION," "LION" "LiOn"and numeric responses such as "1400mAh".
Strings are usually the messiest part of data cleaning because they are often human-generated and hence prone to errors. For instance, you can check for **typos** or **inconsistent capitalisation.** This is mostly a concern for categorical features, and you can look at your bar plots to check. This is especially noticed in EU-CEG for instance in the cell "ingredient name", where entries of "Nicotine" and "nicotine" and "NICOTINE" and "nikotin" are different responses but mean the same ingredient. Similarly "PROPYLENE GLYCOL", "Propylene Glycol" "1-2 Propylene Glycol", and "PG" are same responses and should be merged under the same response. For string variables, make sure all values are either in lower or upper case.

Action point: When you identify the differences in the variable, standardise all responses into the same format. After we replace the typos and inconsistent capitalisation, the groups become much cleaner.

2.5 Duplicate data

Duplicates are data points that are repeated in your dataset. This may be specifically of interest when assessing TP-IDs or EC-IDs. Please use the latest data (by date) or the active TP-ID if applicable.
Action point: Find the same records and delete all but the most recent. Follow up with the Manufacturer/Importer to flag those TP-IDs that are not longer on the market as inactive.

Step 3: Repeat

Once cleaned, you repeat steps in the Cycle in Section 1. Repeating the cycle helps identify additional or smaller issues. Through cleaning, you may notice that for instance, after the removal of outliers that the data that additional problems arise. Please perform as many cycles as you deem necessary to perform your regulatory activities. Please remember that the more you clean and look at the EU-CEG data, the more you will see patterns and identify "hot spots" that need regulatory action.

Additional Reading/Sources:

- https://towardsdatascience.com/the-ultimate-guide-to-data-cleaning-3969843991d4
- https://www.keboola.com/blog/the-ultimate-guide-to-data-cleaning
- Issues with data and analyses: Errors, underlying themes, and potential solutions https://doi.org/10.1073/pnas.1708279115
- The treatment of incomplete data: Reporting, analysis, reproducibility, and replicability. https://doi.org/10.1016/j.socscimed.2018.05.037

Agreement n°:

761297-JATC-HP-JA-03-2016

Guidance to reporting system of suspected adverse effects (AE) for electronic cigarettes and refill liquids

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Date: 15 September 2020

JOINT ACTION ON TOBACCO CONTROL

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

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1. Introduction

The objective of WP4 "Integration into national policies and sustainability" is to provide long-term sustainability to deliverables and continue activities post JATC by developing a series of "how-to-guides" addressed to regulators and researchers.
The EU Tobacco Products Directive (TPD) 2014/40/ along with the Commission Implementing Decisions EU 2016/586 (2016)10 "on technical standards for the refill mechanism of electronic cigarettes" and EU 2015/2183 (2015)11 "establishing a common format for the notification of electronic cigarettes and refill containers", has established standards for e-cigarette reporting, product safety and packaging.
Specifically, the provisions of EU TPD Article 20 enumerate product labelling, packaging, composition and technical requirements including, but not limited to, child-resistant packaging features, refill container volume, nicotine content levels, health warning labels, informational leaflets, and technical parameters to reduce the risk of spilling during refill or leaking during use.
The WP7 (Task 4.2) produced the deliverable D7.4 "Report on a proposed system for the reporting of adverse effects (AE) for electronic cigarettes and refill liquids" including a short reporting template for the reporting of adverse effects on human health for electronic cigarettes and refill liquids both by economic operators/manufacturers (Annex 1) and by competent authorities (Annex 2), in line with TPD Art. 20 (9): *"**Member States shall require manufacturers, importers and distributors of electronic cigarettes and refill containers to establish and maintain a system for collecting information about all of the suspected adverse effects on human health of these products.** Should any of these economic operators consider or have reason to believe that electronic cigarettes or refill containers, which are in their possession and are intended to be placed on the market or are placed on the market, are not safe or are not of good quality or are otherwise not in conformity with this Directive, that economic operator shall immediately take the corrective action necessary to bring the product concerned into conformity with this Directive, to withdraw or to recall it, as appropriate. In such cases the economic operator shall also be required to immediately inform the market surveillance authorities of the Member States in which the product is made available or is intended to be made available, giving details, in particular, of the risk to human health and safety and of any corrective action taken, and of the results of such corrective action. Member States may also request additional information from the economic operators, for example, on the safety and quality aspects or any adverse effects of electronic cigarettes or refill containers".*
The present how-to-guide is related to the WP7 deliverable D7.4 and aims at providing the necessary steps and modalities that each MS should follow if involved in the development of a system for the reporting of suspected adverse effects (AE) on human health for electronic cigarettes and refill liquids. All the AE must be reported and notified to National Competent Authorities (NCA).

2. Scope

The main purpose of the system for the reporting of adverse effects is monitoring the AE for the use of electronic cigarettes and refill liquids in order to possibly improve the safety and protect the health of users by reducing the likelihood of reoccurrence of the AE (at least of those that can be controlled in the short-term). This is to be achieved by the evaluation of the reported AE and the dissemination of information, which could be used to prevent the AE reoccurring or to alleviate the consequences of such AE.
This guide is intended to facilitate the uniform application and implementation of the system for reporting AE related to the electronic cigarette and/or refill liquids (i.e. any untoward medical occurrence, unintended disease or injury, or untoward clinical signs in users) by actions to be put in place. The reporting form set out in this guidance applies to products after their placing on the market. Indeed, problems may only become apparent after wide-spread or long-term use. Moreover, self-made electronic cigarettes and liquids, the availability on the web of a variety of products of uncertain quality, the continuous evolving design and changing technology of the products; strengthen the importance to detect any AE related to this practice and consequently to warn users

about the potential risk of health harm.
This guide applies to or involves:

- Economic operators (manufacturer, distributor, importer);
- National Competent Authorities (NCA);
- Public health institutes/medical institutions (in this case they may manage the surveillance system and then report to NCA)
- Healthcare professionals (e.g. from local health care units, hospitals, anti-poisoning centres, smoking cessation services, etc.);
- Users or nonusers.

Each Member State should bring this AE guidance document to the attention of the relevant Ministry in their Member State who may disseminate it to key stakeholders (e.g. health professionals).

3. Actions

3.1 AE reporting system

The reporting system is based on two forms for AE reporting. The reporting form templates are given in the Appendix of this document, which was presented as Deliverable 7.4 of the JATC project.
The first form (Annex 1. *Short reporting template for the reporting of adverse effects for economic operators*) is for Economic operators (manufacturer, importer, distributor), that receive the form from users and/or health professionals. Then, the economic operators send the notification to the competent authority. In fact, according to Article 20.9 of TPD, manufacturers, importers and distributors must maintain a system for collecting information about all of the AE on human health of these products.
The reporting to the NCA for the economic operators is mandatory.
The second form (Annex 2. *Short reporting template for the reporting of adverse effects for competent authorities*) is for the users and health professionals for **voluntary** reporting of AE.
Users, patients and health professionals send the form directly to the competent authorities. It should be recommended to report the problem also to the manufacturer or distributor shown on the label and to the store where the product was purchased.
To report, it is not necessary to be certain of a cause/effect relationship between the AE and the use of the product(s) in question. Suspicion of an association is sufficient reason to report.
When a manufacturer, healthcare professional, researcher, public health official, or a user, report about AE incidents related to electronic cigarettes and refill liquids, most importantly contributes to the public health safety and protection; The NCA's role is to investigate the AE and take action as required; while the economic operator is responsible for reducing the harm of electronic cigarettes.
It is also essential to prevent consumers from modifying or adding substances (chemicals, compounds, ingredients or combination of ingredients) to other than those intended by the manufacturers and to know how these changes affect the health, frequency, and patterns of consumer use of the products. It is currently is possible to purchase 0% nicotine liquids to which consumers may add nicotine (which is regulated) which therefore enables consumers to have access to large volumes of nicotine containing liquid. Electronic cigarettes can be modified by consumers as parts are widely sold which enables consumers to modify these products. Legislative provisions to restrict these activities would increase safety. Hence, manufacturers should identify methods of changing the manufacturing process or product design features for electronic cigarettes that will reduce or prevent consumers from modifying products.
The AE reporting system furthermore helps to identify the product or other substances (such as a broad range of chemicals, including nicotine, tetrahydrocannabinol (THC) and other cannabinoids, along with other agents (i.e. diluents and other additives, pesticides, opioids, poisons, heavy metals, and toxins) that may be the cause of the AE.

3.2 What to report

Reporting from users, manufacturers, healthcare professionals should concern products that are damaged, defective, contaminated, smell or taste wrong, as well as any unexpected health or safety problems that may have been caused by being exposed to a product.
Types of health or safety problems could include:

- fires or explosions
- burns or other injuries
- accidental or unintended product exposures involving children
- poisonings and other toxicities
- allergic reactions
- any AE following use of or exposure to a product.

3.3 Report by whom and to whom

The economic operator receives the form from users and/or health care professionals and shall notify the relevant NCA about AE incidents for any technical or medical reason. For instance, a manufacturer must put in practice eventual safety corrective actions, as a consequence of the use of flawed or malfunctioning electronic cigarettes and/or altered refill liquid (and/or accessories). Each manufacturer should submit a report to the relevant NCA for recording and evaluation. The NCA after receiving the notification from the economic operator, monitors the investigation of the AE incident carried out by the manufacturer and the related corrective actions, such as removing the product from the market, and to contact the media to notify the public.
The NCA should take any further action that may be necessary to supplement the actions of the manufacturer. Depending on the outcome to the investigation, any information necessary for the prevention of further incidents (or the limitation of their consequences) should be disseminated by the NCA. Where an AE leads to a serious risk and the criteria set out above are met, a notification may need to be sent by the market surveillance authority (voluntarily or imposed by the NCA) through the **Safety Gate rapid alert system** (https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm), to enable the European Commission to alert other Member States. When the notification is verified by the European Commission, it will be disseminated to market surveillance authorities via the Safety Gate as an alert for consideration and action where required.
Where an NCA is not the market surveillance authority, systems should be in place to ensure that the market surveillance authority are notified in such instances (Article 20. 9 of the TPD and market surveillance legislation:
https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:EN:PDF).
Member States should ensure that organisations and individuals involved in purchasing electronic cigarettes and refill liquids are aware that their co-operation is vital in providing the first link in the vigilance chain. In order to enhance the efficiency of the Reporting System, the NCA should encourage the reporting of AE incidents by the users and other professionals involved. Any AE incident report should be available to the other European Competent Authorities and to other National Competent Authorities.
General practitioners/doctors, Healthcare professionals at poison centres, Local healthcare units, Hospitals or Smoking cessation services, Pharmacists, Nurses, Users or their carer compile the form and send it to the NCA (e.g. to the Ministry of Health or Public health institute if in charge of the surveillance system, in this case the institute sends urgent and periodic reports to the NCA).
It is possible also to send the form both to economic operators and the competent authority. In this case indicate if the form was also sent to the manufacturer/distributor of the product (add a short note in the space next to the date, in item 27 of the competent authorities form). This information helps to link the report on the AE incident to the reports filed by other sources.
The AE reporting should be done even if the reporter is not sure the product caused the AE, or does not have all the details. Just fill all the sections that apply to the report.
The users/patients identity and privacy is held in strict confidence by NCA and protected according

to the General Data Protection Regulation (EU) 2016/679 (GDPR). The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.
Reporting can be done:

- by phone to competent authority, toll-free number……..;
- by phone to economic operator ……;
- online through an online reporting portal https://……;
- by downloading, completing and then submitting the form to NCA and/or economic operator by fax……or email…….

The above information should be available (besides the Ministry of Health /Public Health institutes websites) for example also on the packaging of the e-cig products and on the websites selling e-cig products.

3.4 Causality assessment

The association between the use of the electronic cigarette and/or refill liquid and the occurrence of each AE shall be assessed as following:

1) Unknown: the reporter has no information about the cause;

2) Unrelated: when the AE is not a known AE of the product; the AE has no temporal relationship with the use of the product; the AE does not follow a known response pattern to the e-cigarette (if the response pattern is previously known) and is biologically implausible; the discontinuation of e-cigarette use and reintroduction of its use do not impact on the AE; AE involves a body-site or an organ not expected to be affected by the electronic cigarette; the AE can be attributed to another cause (e.g. an underlying or concurrent illness/ clinical condition, an effect of another device, drug, treatment or other risk factors);

3) Unlikely: the relationship with the use of the electronic cigarette and/or refill liquid seems not relevant and/or the AE can be reasonably explained by another cause, but additional information may be obtained.

4) Possible: the relationship with the use of the electronic cigarette and/or refill liquid is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed or no information has been obtained should also be classified as possible.

5) Likely/probable; the relationship with the use of the electronic cigarette seems relevant and/or the event cannot be reasonably explained by another cause, and additional information may be obtained.

6) Certain, the AE is associated with the electronic cigarette and/or refill liquid use when: the AE is a known AE of the product; the AE has a temporal relationship with electronic cigarette use; the AE involves a body-site or organ expected to be affected by the electronic cigarette; the AE follows a known response pattern to the electronic cigarette (if the response pattern is previously known); the discontinuation of electronic cigarettes and reintroduction of its use (or increase of the level of exposure) impacts on the AE; other possible causes (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out; harm to the subject is due to error in use.

3.5 What Information to put in the AE report?

When reporting an AE, include information about:

- The affected person (can be a user but also a nonuser)
- Brand name and manufacturer of the electronic cigarettes and refill liquid
- Where the electronic cigarette was purchased
- Whether the electronic cigarettes was modified in any way or whether there was a device malfunction
- Use of or exposure to tobacco products, medications, supplements, substances of abuse or toxins around the same time. Information on the use of concomitant medical products can frequently provide insight into previously unknown interactions between products, or provide an alternative explanation for the observed AE. Please list product names and therapies or any other medical products (drugs, medical devices, etc.) that the patient was using at the time of the AE. Do not include products used to treat the patient after the event.
- Details about the pattern of product use or exposure before the AE (duration, amount and intensity of product use) as well as the time between the latest use and the AE. This information is particularly useful in the evaluation of a suspected AE. What happened when the electronic cigarette was stopped and then restarted?
- Dosage of nicotine, types of flavourings used or mixed substances.
- Health effects details: specific areas of the body affected, symptom progression, how long symptoms lasted, course of recovery, and any medical testing, care and treatment. In particular, a life-threatening AE should be checked if you suspect that the patient was at substantial risk of dying at the time of the AE or if the use or continued use of the device or other medical product might have resulted in the death of the patient. Disability caused by an AE means a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.
- Underlying health conditions, relevant medical history. Knowledge of other risk factors can help in the evaluation of a reported AE.
- Whether product use continued or not after the AE
- Whether the AE was reported elsewhere, such as to the manufacturer (item 27 of the form, add information in the blank space next to the date)

Relevant medical documents, photos, or other documents that include or supplement this information can also be included or reported, ensuring patient confidentiality as per Helsinki guidelines.

3.6 Reporting timelines

For voluntary reporting, users and health professionals must report to NCA or economic operator or to both as soon as possible. In the case the economic operator gets the notification of AE by the user or health professional, it must report to the NCA as follows:

- for the AE which indicate an imminent risk of death, serious injury, or serious illness and that requires prompt remedial action users: immediately, but not later than 2 calendar days.
- for any other AE: immediately, but not later than 7 calendar days following the date of awareness by the economic operator of the new reportable AE or of new information in relation to an already reported AE.

The NCA in charge of the surveillance system should issue a complete report every six months. The report should include: conclusions relating to safety and quality of electronic cigarette device and liquids, AE on health, eventual risks of self-made device and liquids and eventual warnings about specific brands of electronic cigarettes and liquids. If the health/safety issue is serious, an urgent report should be immediately issued and information disseminated to the public. As above described in paragraph 3.3, i.e. that "any AE incident report should be available to the other European Competent Authorities and to other National Competent Authorities", a network should be established in order to ensure a simultaneous communication and exchange of information among NCAs.

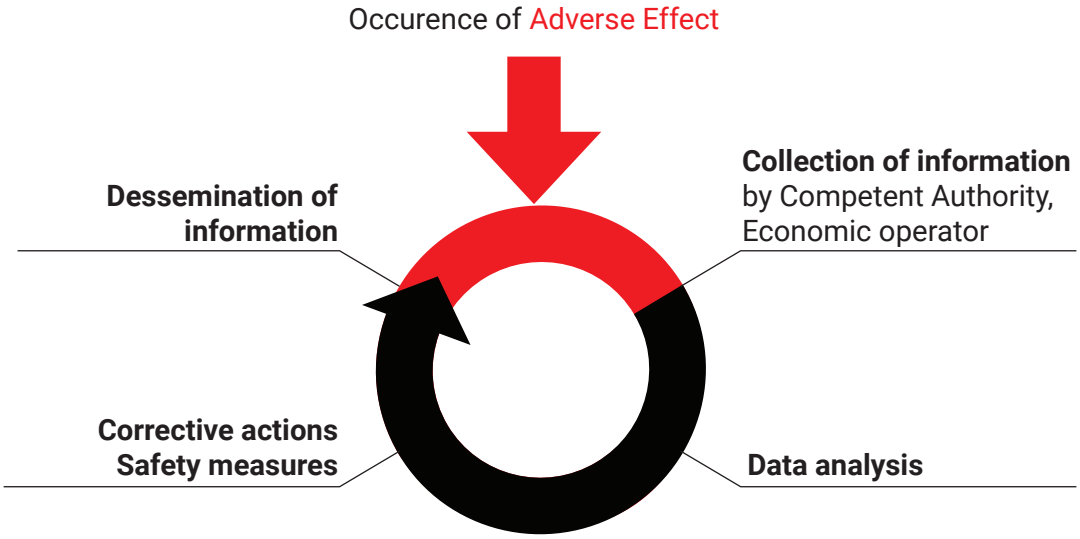
3.7 Data Analysis

Data analysis should be performed with conclusions drawn by someone with appropriate expertise (NCA or Public Health institution).

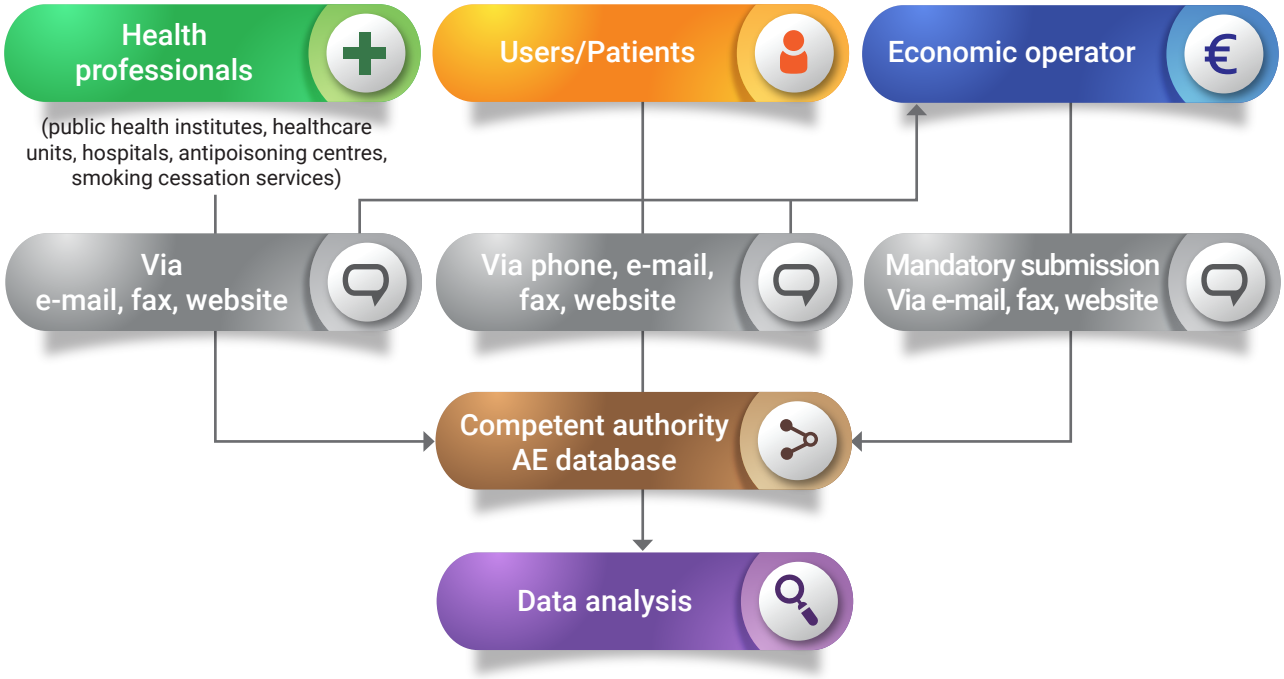
3.8 Use of the reporting data

The data and conclusions derived from the AE reporting form may result in corrective or preventive actions to reduce risk. For example, a manufacturer can change the labelling/instructions for use, the manufacturing processes, the device design; competent authorities may take action to bring products into compliance, withdraw and recall products and use sanctions available to them to protect public health.

3.9 Safety cycle



3.10 Data processing flow



4. Development

The “Reporting system of suspected adverse effects (AE) for e-cigarette and refill liquids” is developed to monitor the adverse effects on health among electronic cigarette users or nonusers. Each MS can adjust it on country-level aspects and to make the information flow process even more convenient. If MS have any suggestions to improve the reporting system, they can report it to the European Commission. Neverthelss it should be considered to establish a system at European level.

5. Sustainability

The national authorities may consider the contribution of a section of the EU-CEG fee or e-cigarette product taxes for the development and implementation of a reporting system on suspected AE for electronic cigarettes and refill liquids. Public reporting burden for this collection of information is estimated to average one hour per response for both voluntary and mandatory report, including completing and reviewing the collection of information. Other time (and costs) are necessary for gathering and maintaining the data received, to analyse them and evaluate the information in order to disseminate information to the public urgently or periodically.
National circumstances and priorities should be taken into account during the development and implementation process.

6. Appendix

Annex 1. Reporting form for Economic operators

Reporting form of suspected adverse effects (AE) for electronic cigarette (e-cig) and refill liquid

Patient individual data

1. Initials or Record number	2. Year of birth	3. Sex ❑ M ❑ F	4. Weight (kg)	5. Height (cm)

6. Ethnicity/race (optional)

7. Pregnancy ❑NO ❑YES, week _____
Breastfeeding ❑NO ❑YES

Description of AE

8. AE start (date) _____
❑ during e-cig use
❑ after e-cig use, specify after how long:
_____

9. Causes of AE
❑ inhalation ❑ e-cig explosion ❑ poisoning from the refill liquid (by ingestion) ❑ skin absorption
❑ more intense use of e-cig, describe _____
Other _____

10. Symptoms

❑ throat irritation	❑ coughing up of blood	❑ headache
❑ sore throat	❑ bleeding form the nose	❑ dizziness
❑ dry mouth	❑ anaphylaxis	❑ vertigo
❑ mouth ulcers	❑ sweating	❑ tremors
❑ dry cough	❑ abdominal pain	❑ restlessness
❑ laryngospasm	❑ high blood pressure	❑ tachycardia
❑ asthma	❑ vomiting	❑ bradycardia
❑ shortness of breath	❑ skin rash	❑ eye irritation
❑ bronchospasm	❑ nausea	❑ nose irritation
❑ chest pain	❑ diarrhoea	❑ burn and scalds

❑ worsening of pre-existing conditions:_____
❑ other_____

11. If use of the e-cig was stopped did the AE stop?
❑ NO ❑ YES

12. Treatment of the AE
❑ NO ❑ YES
Describe_____

13. Seriousness of AE
❑ required a visit to doctor
❑ admitted to hospital
❑ disability
❑ life threatening
❑ death

14. Outcome
❑ discharged after doctor visit
❑ recovered,
how long_____
❑ fatal _____(date)
❑ unknown

15. Comments on causal relationships between e-cig and AE
❑ certain ❑ likely ❑ possibile ❑ unlikely ❑ unrelated ❑ unknown **note**_____

16. Describe any other detail (e.g. duration of the AE, complications/sequelae and any relevant laboratory results)

17. Exclusive use of e-cig ❑ YES ❑ NO **If answered NO specify :**
❑ dual user, how long _____
Duration of smoking before e-cig start _____
If user of other tobacco product, specify_____

18. Use of E-cig containing
❑ nicotine ❑ nicotine+flavours, specify_____
❑ only flavours _____
❑ mixed substances _____

19. Nicotine concentration (mg/ml):
❑ rechargeable e-cig (refillable through the e-liquid bottle)
_____
❑ disposable e-cig _____
❑ disposable cartridge_____

20. Duration of e-cig use
❑ less than 1 month ❑ 2-3 months
❑ 4-6 months ❑ more than 6 months

21. Restart e-cig use after AE
❑ YES ❑ NO
Symptoms returned
❑ YES ❑ NO

22. Is the electronic cigarette used at the time of the symptoms the same as normally used? ❑ YES ❑ NO

Specify the brand _____ **Sales point** ❑ specialized seller ❑ pharmacy ❑ internet ❑ tobacconist ❑ retail seller ❑other
If answered NO it changed: ❑ e-cig ❑ cartridge ❑ refill liquid ❑ self-made e-cig ❑ self-made/mixed liquid **note**_____
Specify the new brand (e-cig and/or liquid) _____ **Sales point if different** _____

23. Medications, NRT and/or other products based on medicinal plants, homeopathic, food supplements etc. used at the time of the appearance of the AE ❑ YES ❑ NO **If YES Specify** _____
Dosage, route of administration and duration of use: _____

24. Current or past relevant medical history (illnesses, allergies, alcohol use, drugs of abuse, etc.)

Manufacturer, importer, distributor

25.

26. date ..... **Send this form to: Competent authority or market surveillance authority**.....

Address ..... **Email**.....**Fax**.....

Annex 2. Reporting form for Competent authorities

Reporting form of suspected adverse effects (AE) for electronic cigarette (e-cig) and refill liquid

Patient individual data

1. Initials or Record number

2. Year of birth

3. Sex ❑ M ❑ F

4. Weight (kg)

5. Height (cm)

6. Ethnicity/race (optional)

7. Pregnancy ❑NO ❑YES, week _____

Breastfeeding ❑NO ❑YES

Description of AE

8. AE start (date) _____

❑ during e-cig use

❑ after e-cig use, specify after how long: _____

9. Causes of AE

❑ inhalation ❑ e-cig explosion ❑ poisoning from the refill liquid (by ingestion) ❑ skin absorption

❑ more intense use of e-cig, describe _____

Other _____

10. Symptoms

❑ throat irritation ❑ coughing up of blood ❑ headache

❑ sore throat ❑ bleeding form the nose ❑ dizziness

❑ dry mouth ❑ anaphylaxis ❑ vertigo

❑ mouth ulcers ❑ sweating ❑ tremors

❑ dry cough ❑ abdominal pain ❑ restlessness

❑ laryngospasm ❑ high blood pressure ❑ tachycardia

❑ asthma ❑ vomiting ❑ bradycardia

❑ shortness of breath ❑ skin rash ❑ eye irritation

❑ bronchospasm ❑ nausea ❑ nose irritation

❑ chest pain ❑ diarrhoea ❑ burn and scalds

❑ worsening of pre-existing conditions: _____

❑ other _____

11. If use of the e-cig was stopped did the AE stop?

❑ NO ❑ YES

12. Treatment of the AE

❑ NO ❑ YES

Describe _____

13. Seriousness of AE

❑ required a visit to doctor

❑ admitted to hospital

❑ disability

❑ life threatening

❑ death

14. Outcome

❑ discharged after doctor visit

❑ recovered,

how long _____

❑ fatal _____(date)

❑ unknown

15. Comments on causal relationships between e-cig and AE

❑ certain ❑ likely ❑ possibile ❑ unlikely ❑ unrelated ❑ unknown **note** _____

16. Describe any other detail (e.g. duration of the AE, complications/sequelae and any relevant laboratory results)

_____

17. Exclusive use of e-cig ❑ YES ❑ NO **If answered NO specify :**

❑ dual user, how long _____

Duration of smoking before e-cig start _____

If user of other tobacco product, specify _____

18. Use of E-cig containing

❑ nicotine ❑ nicotine+flavours, specify _____

❑ only flavours _____

❑ mixed substances _____

19. Nicotine concentration (mg/ml):

❑ rechargeable e-cig (refillable through the e-liquid bottle)

_____

❑ disposable e-cig _____

❑ disposable cartridge _____

20. Duration of e-cig use

❑ less than 1 month ❑ 2-3 months

❑ 4-6 months ❑ more than 6 months

21. Restart e-cig use after AE

❑ YES ❑ NO

Symptoms returned

❑ YES ❑ NO

22. Is the electronic cigarette used at the time of the symptoms the same as normally used? ❑ YES ❑ NO

Specify the brand _____ **Sales point** ❑ specialized seller ❑ pharmacy ❑ internet ❑ tobacconist ❑ retail seller ❑other

If answered NO it changed: ❑ e-cig ❑ cartridge ❑ refill liquid ❑ self-made e-cig ❑ self-made/mixed liquid **note** _____

Specify the new brand (e-cig and/or liquid) _____ **Sales point if different** _____

23. Medications, NRT and/or other products based on medicinal plants, homeopathic, food supplements etc. used at the time of the appearance of the AE ❑ YES ❑ NO **If YES Specify** _____

Dosage, route of administration and duration of use: _____

_____

24. Current or past relevant medical history (illnesses, allergies, alcohol use, drugs of abuse, etc.)

_____

_____

Reporter information

25. Title

❑ general doctor ❑ pharmacist ❑nurse

❑ hospital doctor ❑ consumer or his/her carer

❑ medical specialist ❑other _____

26. Contact details

Name + Surname

Address

Phone Fax

E-mail

27. date……

Send this form to fax……**email**……**address**……

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

Guidance to the checklist for e-cigarette product compliance to the TPD

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Date: 15 September 2020

JATC JOINT ACTION ON TOBACCO CONTROL

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

Table of contents

1. Introduction

The EU Tobacco Products Directive (TPD) 2014/40/ EU9 along with Commission Implementing Decisions EU 2016/586 (2016)10 and EU 2015/2183 (2015)11, has established standards for e-cigarette reporting, product safety and packaging. Specifically, the provisions of EU TPD Article 20 enumerate product labelling, packaging, composition and technical requirements including, but not limited to, child-resistant packaging features, refill container volume, nicotine content levels, health warning labels, informational leaflets, and technical parameters to reduce the risk of spilling during refill or leaking during use.

The comprehensive "Checklist for e-cigarette product compliance to the TPD" was developed by experts from EU Member States (EU MS) and is one of the outcomes of the European Commission working group project JATC – Joint Action on Tobacco Control.

The broader objective of the "Checklist for e-cigarette product compliance to the TPD" is to support, among other measures, the activities of the EU MS in ensuring that electronic cigarettes and refill containers are placed on the market in compliance with the TPD.

The aim of the checklist is to facilitate the assessment of e-cigarette and refill container product compliance with the TPD for economic operators and regulators) under the auspices of TPD Article 20. (1) including, but not limited, to Article 20. (3-4) and implementing act 2016/586.

2. Scope

This guidance document will support economic operators and regulators on the assessment of electronic cigarette and refill container products against legislative requirements. This guidance will also give direction on the correct population of fields in the "Checklist for e-cigarette product compliance to the TPD".

3. Rules

When filling in the "Checklist for e-cigarette product compliance to the TPD" special attention should be paid to the following:

3.1. Information about inspection

- Ensure that all information is accurately recorded.
- Accurately record the date and time of the inspection.
- In the Inspection type cell record the reason for the inspection (e.g. whether it was proactive or reactive control, etc.)
- In the Inspecting Officer/s cell record the full name/s of the inspector(s).
- In the Contact Person cell record the full name/s of the contact person/s present at the inspection.
- In the Position/Title cell record the official position of the Contact Person/s.
- In the Additional Information cell record any other relevant information about the inspection that was not covered in the previous or following points.

3.2. General Information about the economic operator

- Fill in carefully all of the requested information.
- In the Name cell record the full legal registered name of the company.
- In the Address cell record the legal registered address of the company.
- In the Business Type cell record the business type (e.g. manufacturer, importer, distributor, retailer, etc.)
- In the Product Type cell specify the type of product(s) being placed on the market by the economic operator e.g. electronic cigarettes, refill containers etc.

- In the Additional Information cell record any other relevant information about the inspection that was not covered in the previous or following points.

3.3. Product Description

- In this section is assessed the unit packet and outside packaging of the product paying particular attention to the following:
  - the illustrations,
  - texts (e.g. advertising, ingredients, health warning(s)),
  - labelling,
  - size,
  - material,
  - design, etc.
- When opening the package pay attention to:
  - the smell;
  - material;
  - length, size,
  - design, etc.
- Do not forget to point out the non-compliances observed when assessing the unit packet or outside packaging.
- When completing the form, ensure that only one statement is made in each cell.

3.4. Product assessment

- In this section, assess the product against the legal (TPD, CLP, REACH) requirements.
- Ensure all products are notified to the EU-CEG database. Do not forget to check the first submission date.
- Ensure the system for collecting information about adverse effects is provided where relevant.

3.5. Product labelling

This section should be filled in for each product assessed (additional forms will be required)

- In this section pay attention to the following features: consideration needs to be given to the use of the terms unit packet and outside packaging in this section
  - Are health warnings provided on the unit packet and outside packaging? If yes, is the health warning as prescribed in the checklist?
  - If the health warning is provided, check if it is on the two largest surfaces of the unit packet and, if there is additional outer packaging, whether it also includes the health warning.
  - Does the health warning fulfil the requirements set out in the checklist?
  - It is necessary to ensure that the health warning does not hide or interrupt tax stamps, price marks, tracking and tracing marks, or security features on unit packets.
  - When assessing the unit packet and outside packaging, ensure that all necessary information is provided (ingredients, nicotine content and delivery per dose, batch number, recommendation to keep the product out of reach of children).
  - Open the unit packet to check if the information leaflet has been provided. Consideration needs to be given to peel and reveal information leaflets.
  - If the information leaflet is provided, it should be assessed to ensure that all the required information is included.
  - When assessing refillable electronic cigarettes and refill containers, ensure that instructions for refilling including diagrams are provided. Are diagrams easily understood and clear?
  - Ensure that labelling on unit packets and any outside packaging does not include any promotion or indicates that a product is less harmful or has positive properties for health.

Consider Article 20. 4 (b) (ii) in that it includes the electronic cigarette and refill container.
  - Pay attention to the overall image of the labelling. Does it make any reference to food or cosmetic products or to taste or smell?
  - Ensure that the unit packet and any outside packaging does not contain any vouchers or hint to any economic advantages. Consider Article 20. 4 (b) (ii) in that it includes the electronic cigarette and refill container.
  - Ensure that the refill container and electronic cigarette representation is according to the product presentation requirements (TPD Article 13. 1).
  - As labelling should also comply with CLP regulation, make sure that all necessary health warnings are on the labelling (hazard pictograms, signal words, hazard statements, precautionary statements, etc.)
  - Pay attention that name of manufacturer and/or importer and/or supplier must be on the labelling.
  - Touch package to make sure that tactile warning of danger is there.

3.6. Product packaging

- When assessing electronic cigarettes and refill containers, pay attention to:
  - The size of the nicotine containing refill container. The volume must not exceed 10 ml.
  - If there are disposable e-cigarettes or single use cartridges, pay attention to their volume. It should not exceed 2 ml.
  - Ensure that refillable tanks are according to the TPD requirements (especially by volume)
  - Request documentation to determine that refill containers are child- and tamper proof.

3.7. Composition

- Pay attention in the Composition part to:
  - Pay attention to the nicotine content. It should not exceed 20 mg/ml.
  - Look at the list of ingredients. Pay attention if there are any prohibited components on in the list. Look at the documentation. What is the purpose of each ingredient, and what is the purity grade of ingredients?

NB! The notifications in the MSREP will need to be examined to assess the aforementioned section from 17-19 of the checklist. Any questions must be communicated to the manufacturer/importer or whomever has notified the products. Retailers, distributors and some importers may not be able to provide this information.

3.8. Technical requirements for electronic cigarette and refill mechanism

- Examine the technical requirements for electronic cigarettes and refill containers mechanisms and assess the following:
  - What is the refill mechanism for refillable electronic cigarettes and refill containers?
  - Does the refill container have the appropriate nozzle length? Does it emit no more than 20 drops of refill liquid per minute in standard conditions?
  - Has the width of the nozzle or the width of the opening of the tank been indicated in the instructions for use to ensure compatibility?
  - Does the refill container and electronic cigarette operate by means of a docking system? Has the type of docking system which the electronic cigarette and refill container are compatible with been indicated in the instructions for use?

3.9. Material safety data sheet (REACH)

- Pay attention in the Material Data Safety Sheet (REACH) part to:
  - If liquid contains nicotine and classified as hazardous, it should have safety data sheet.
  - Pay attention to the language of the safety datasheet.
  - Does safety datasheet have 16 sections? Do they comply with REACH-regulation?
  - Look the classification (art 2.2 in safety datasheet) on the safety data sheet. Are the same elements as on the labelling?
- In the Comments cells add any additional information that may be relevant and helpful for the assessment of the product.

3.10. Inspection Outcome

- In this section, make the conclusions about the inspection.
- This is the final part of the checklist where the decision about the products compliance with the TPD has to be presented.
- In presenting the final outcome, be as accurate as possible, giving arguments that support the final decision.

4. Development

The proposed comprehensive "Checklist for e-cigarette product compliance to the TPD" is developed to aid in the e-cigarette and refill container product compliance assessment process. Additions can be made at Member State level according to local Legislative requirements. You may add additional points, aspects and information to the checklist to make the compliance assessment process even more convenient. In addition, if you have any suggestions to improve the checklist or this supporting document for filling in the checklist, please give your suggestions to the European Commission.

5. Sustainability

The science of e-cigarettes is still an evolving field including the assessment process of their safety, therefore, minor and comprehensive updates of e-cigarettes and refill containers will affect the assessment of compliance to the TPD due to which it is regularly needed to keep the "Checklist for e-cigarette product compliance to the TPD" up to date in accordance to the latest scientific evidence and legislation.
National circumstances and priorities, as well as national strategies should be taken into account during the assessment of e-cigarettes compliance to the TPD for the most sustainable assessment process.

6. Appendix. Checklist for e-cigarette product compliance to the TPD | Doc. Ref. N°: Deliverable 7.2

Information about inspection	
Date:	
Time:	
Inspection Type:	
Inspecting Officer(s):	
Contact Person:	
Position/Title:	
Additional information:	

General information about company	
Name:	
Registration No:	
Address:	
Contact number, e-mail:	
Business Type:	
Product Type:	
Additional information:	

Product description	
1	
2	
3	
4	
5	

	Product Assessment	Legislative act and Article	Compliance
1	The notification is submitted in electronic form six months before the intended placing on the market	TPD 20.2.	
2	Manufacturers, importers and distributers of electronic cigarettes and refill containers has established and maintain a system for collecting information about all of the suspected adverse effects on human health of these products	TPD 20.9.	
Comment:			

Labelling		Legislative act and Article	Compliance
3	Unit packets of electronic cigarettes and refill containers carrys one of the following health warnings in the official language of the Member State where the substance or mixture is placed on the market:	TPD 20.4.b.iii	
3,1	'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'	TPD 20.4.b.iii	
3,2	'This product contains nicotine which is a highly addictive substance'	TPD 20.4.b.iii	
4	The health warning comply with the requirements:	TPD 20.4.c	
4,1	it appears on the two largest surfaces of the unit packet and any outside packaging	TPD 12.2.a	
4,2	it is printed in black Helvetica bold type on a white background and occupies the greatest possible surface reserved for the health warning	TPD 9.4.a	
4,3	it is placed at the centre of the surface reserved for them	TPD 9.4.b	
4,4	on cuboid packets and any outside packaging it is parallel to the lateral edge of the unit packet or of the outside packaging	TPD 9.4.b	
4,5	it covers 30 % of the surfaces of the unit packet and any outside packaging (Proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with more than two official languages)	TPD 12.2.b	
4,6	the health warnings may be affixed by means of stickers, provided that such stickers are irremovable. The health warnings shall in no way hide or interrupt the tax stamps, price marks, tracking and tracing marks, or security features on unit packets. Health warnings shall be surrounded by a black border of a width of 1 mm inside the surface area that is reserved for these warnings	TPD 8.3, 8.4, 8.6.	
5	Unit packets and any outside packaging of electronic cigarettes and refill containers:	TPD 20.4.b	
5,1	include a list of all ingredients contained in the product	TPD 20.4.b.i	
5,2	a list of all ingredients contained in the product is in descending order of the weight	TPD 20.4.b.i	
5,3	include an indication of the nicotine content of the product and the delivery per dose	TPD 20.4.b.i	
5,4	include the batch number	TPD 20.4.b.i	
5,5	include a recommendation to keep the product out of reach of children	TPD 20.4.b.i	
6	Unit packets of electronic cigarettes and refill containers include a leaflet with information on:	TPD 20.4.a	
6,1	instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers	TPD 20.4.a.i	
6,2	contra-indications	TPD 20.4.a.ii	
6,3	warnings for specific risk groups	TPD 20.4.a.iii	
6,4	possible adverse effects	TPD 20.4.a.iv	

6,5	addictiveness and toxicity	TPD 20.4.a.v	
6,6	contact details of the manufacturer or importer and a legal or natural contact person within the Union	TPD 20.4.a.vi	
7	Refillable electronic cigarettes and refill containers include appropriate instructions for refilling, including diagrams	DECISION 2016/586 2.2.	
8	The labelling of unit packets and any outside packaging and the electronic cigarettes and refill containers itself do not include any element or feature that:	TPD 13.1.	
8,1	promotes a product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions	TPD 13.1.a	
8,2	suggests that a particular product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits	TPD 13.1.b	
8,3	makes any reference to the taste or smell of an electronic cigarette or refill container	TPD 13.1.c	
8,4	resembles a food or a cosmetic product	TPD 13.1.d	
8,5	suggests that a certain product has improved biodegradability or other environmental advantages	TPD 13.1.e	
9	The unit packets and any outside packaging do not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers	TPD 13.2.	
10	The labeling contains information about the nominal quantity of the mixture in the package	CLP 1272/2008 17.1.b	
11	Nicotine-containing liquid is classified in accordance with legislation	CLP 1272/2008 3., 4., 5., 6., 9., 10., 11., 12., 13., 14., 15., Annex I	
12	In accordance with classification nicotine-containing liquid package labeling includes:		
12,1	If the nicotine-containing liquid is placed on the market in refill container, cartridges or tanks without outside packaging refill container, cartridges or tanks labeling includes:		
12.1.1	hazard pictograms	CLP 1272/2008 17.1.d, 19., 31.4.	
12.1.2	signal words	CLP 1272/2008 17.1.e, 20.	
12.1.3	hazard statements	CLP 1272/2008 17.1.f, 21.	
12.1.4	precautionary statements	CLP 1272/2008 17.1.g, 22.	

12.1.5	product identifier	CLP 1272/2008 17.1.c, 18.	
12.1.6	name and contact information of the supplier	CLP 1272/2008 17.1.a	
12,2	If the nicotine-containing liquids refill container, cartridges or tanks is placed on the market with outside packaging		
12.2.1	Refill container, cartridges or tanks labeling includes:		
12.2.1.1	hazard pictograms	CLP 1272/2008 17.1.d, 19., 31.4.	
12.2.1.2	product identifier	CLP 1272/2008 17.1.c, 18.	
12.2.1.3	name and contact information of the supplier	CLP 1272/2008 17.1.a	
12.2.2	Outside packaging labeling includes:		
12.2.2.1	hazard pictograms	CLP 1272/2008 17.1.d, 19., 31.4.	
12.2.2.2	signal words	CLP 1272/2008 17.1.e, 20.	
12.2.2.3	hazard statements	CLP 1272/2008 17.1.f, 21.	
12.2.2.4	precautionary statements	CLP 1272/2008 17.1.g, 22.	
12.1.5	product identifier	CLP 1272/2008 17.1.c, 18.	
12.1.6	name and contact information of the supplier	CLP 1272/2008 17.1.a	
13	Nicotine-containing liquid package (refill container, cartridges, tanks, outisde packaging) need to be fitted with a tactile warning of danger	CLP 1272/2008 Annex II 3.2.	
Comment:			
Packaging		**Legislative act and Article**	**Compliance**
14	Nicotine-containing liquid is only placed on the market in:	TPD 20.3.a	
14,1	dedicated refill containers not exceeding a volume of 10 ml	TPD 20.3.a	

14,2	disposable electronic cigarettes or in single use cartridges and that the cartridges or tanks do not exceed a volume of 2 ml	TPD 20.3.a	
15	Electronic cigarettes and refill containers are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage	TPD 20.3.g CLP 1272/2008 35.2. second part	
Comment:			

Composition		**Legislative act and Article**	**Compliance**
16	The nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml	TPD 20.3.b	
17	The nicotine-containing liquid does not contain:	TPD 20.3.c	
17,1	vitamins or other additives that create the impression that electronic cigarettes and refill containers has a health benefit or presents reduced health risks	TPD 7.6.a	
17,2	caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality	TPD 7.6.b	
17,3	additives having colouring properties for emissions	TPD 7.6.c	
17,4	additives that facilitate inhalation or nicotine uptake	TPD 7.6.d	
17,5	additives that have CMR properties	TPD 7.6.e	
18	Only ingredients of high purity are used in the manufacture of the nicotine-containing liquid. Substances other than the ingredients referred to in point (b) of the second subparagraph of paragraph 2 of this Article are only present in the nicotine-containing liquid in trace levels, if such traces are technically unavoidable during manufacture	TPD 20.3.d	
19	Only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health in heated or unheated form	TPD 20.3.e	
Comment:			

Technical requirements for electronic cigarette and refill mechanism		**Legislative act and Article**	**Compliance**
20	Electronic cigarettes deliver the nicotine doses at consistent levels under normal conditions of use	TPD 20.3.f	
21	Refillable electronic cigarettes and refill containers are only placed on the market if the mechanism by which the electronic cigarettes are refilled meets one of the following conditions:	DECISION 2016/586 2.1	
21,1	it entails the use of a refill container possessing a securely attached nozzle at least 9 mm long, which is narrower than and slots comfortably into the opening of the tank of the electronic cigarette with which it is used and possessing a flow control mechanism that emits no more than 20 drops of refill liquid per minute when placed vertically and subjected to atmospheric pressure alone at 20 °C ± 5 °C; indicate the	DECISION 2016/586 2.1.a, 2.2.	

	width of the nozzle or width of the opening of the tank in the instructions for use in a manner that enables consumers to identify the compatibility of refill containers and electronic cigarettes		
21,2	it operates by means of a docking system which only releases refill liquids into the tank of the electronic cigarette when the electronic cigarette and refill container are connected; in the instructions for use, the types of docking system with which such electronic cigarettes and refill containers are compatible	DECISION 2016/586 2.1.b, 2.2.	
Comment:			
Material safety data sheat (REACH)		**Legislative act and Article**	**Compliance**
22	Safety data sheet is available if nicotine-containing liquid meets the criteria for classification as hazardous in accordance with CLP 1272/2008	REACH 1907/2006 31.1., 31.3.	
23	The safety data sheet is in an official language of the Member State where the substance or mixture is placed on the market	REACH 1907/2006 31.5.	
24	The safety data sheet is compliant with legislative acts	REACH 1907/2006 31.1., 31.6., Annex II	
25	Based on the classification elements appearing on the label are the same that are indicated in article 2.2. of safety data sheat	REACH 1907/2006 Annex II 2.2.	
Comment:			
Inspection Outcome			
Comment:			

Agreement n°:

761297-JATC-HP-JA-03-2016

Guidance for Laboratory analysis of tobacco and related products

Circulation: Public

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Date: 3d December 2020

JATC JOINT ACTION ON TOBACCO CONTROL

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

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1. Introduction

The EU Tobacco Products Directive (TPD) 2014/40/EU sets out measurement methods for emission levels in tobacco products [Article 3, 4] and regulates ingredients [Article 7]. It requires manufacturers and importers to submit a notification to the competent Member State authorities regarding novel tobacco products to be placed on the market, in terms of toxicity, addictiveness and attractiveness, and electronic cigarettes (e-cig), with regard to toxicological data on the product's ingredients, emission levels, nicotine concentration in liquids, doses and uptake under normal conditions.

Laboratory measurements are essential for the effective application of the TPD provisions 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 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".

A preliminary **Competent Authority Survey** performed by the Joint Action on Tobacco Control (JATC) WP8 partners, on all EU MS received 40 response records (including 16 non-informative ones) by 24 respondents from 19 countries.

Main findings revealed that a relatively high proportion of CAs have not ordered any verification analyses during the last 2 years; apart from two CAs with strong verification programmes, most CAs required only a limited number of analyses. The requested analyses are limited to cigarettes and, even less, to electronic cigarettes, while verifications of other products (novel tobacco products, oral tobacco, herbal tobacco, cigars, pipe) are negligible. Finally, a relative high proportion of CAs required verification to non-approved laboratories (also for TNCO).

A **Laboratory Survey** has also been completed within WP8, based on responses from 28 independent laboratories of 17 MS, among laboratories identified by former GoToLab contact lists and/or the EU-Common Entry Gate (EU-CEG) database. The selected laboratories were performing cigarettes, e-cigarettes, herbal and novel tobacco products analyses and verifications.

Results indicated that the laboratories appear to be equipped with standardized instruments, where applicable. Laboratories that perform verification of parameters listed in Art. 3 of the TPD within EU MS, are present in a relatively limited number of countries. Levels of other compounds are analysed also in a very limited number of MS. For cigarettes TNCO and e-cig/HTP nicotine parameters, the used methods follow international standards with accredited and validated laboratory procedures. A lack of standard methods is reported, while ISO works on the development of new methods for new analytes. Methods are required for testing emissions from electronic cigarettes and refill containers, as well as for testing the delivery of nicotine doses from electronic cigarettes, so as to ensure that they are at consistent levels [Article 20. 3. F].

Nicotine, glycerol and propylene glycol concentrations in liquids are the only parameters verified with standard procedures by CA accredited laboratories. The market is under a fast evolution for both devices and components. E-cigarettes and vaping topographies are evolving: several mouth-to-lung vapers evolved in direct-to-lung vaping with different, and unknown, toxicity aspects. Additional products are introduced on the market, while new ingredients like nicotine salts and non-tobacco nicotine, either synthetic or extracted from non-tobacco plants, are newly released on the market. Toxicity knowledge is rapidly evolving, especially for acute exposures, posing new milestones for analytical approaches and verification needs, especially for analytes other than nicotine, including compounds that possess CMR (carcinogenic, mutagenic and toxic for reproduction) properties.

The need for enhanced collaboration between EU MS with regard to emissions and ingredient analysis in various tobacco products and e-cigarette liquids considered in the TPD is also apparent. New products appear on the market and are available to consumers through the internet. New compounds are found in the emissions and new analytical methods appear continuously in the scientific literature. While the final CEN-ISO methods are not available, analyses on new compounds should be performed using validated and agreed analytical methods from international organizations or, if not available, using peer-reviewed independent publications. Methods independent from industry are preferred, when available, and approved independent laboratories need to exchange information.

Supporting collaborations across laboratories, with identification of suggested methodologies and test analyses would be an efficient way to ensure laboratory capacity to verify the submitted data and support the enforcement.

New analyses require that testing laboratories will need more expensive instrumentation. The cost of verification analyses will increase if MS want to have an internal verification program. The costs will be an important consideration for the laboratories. As fee structures differ in MS, consideration should be given to a common approach being applied.

According to the TPD,EU MS may charge manufacturers and importers of tobacco products proportionate fees/retributions for the verification (at least) of TNCO emission levels. CAs provided information on the retribution of verification analyses for different tobacco products and electronic cigarettes. The large majority of analyses conducted in 2017-2018 were not paid by the tobacco industry and all the respondents consistently recognized a lack of financial support for the verification. For this reason, most CAs, from the JATC WP8 survey, believed that the fees for the verification analysis of cigarette tobacco, electronic cigarettes and other tobacco products should be fully or partially covered by manufacturers.

These fees, or proportionate retributions, should support independent laboratories in order to increase the number of verification programs and the number of MS with approved laboratories and to expand collaborations among laboratories. Mostly importantly, it would allow for the development and validation of analytical approaches for new products and emissions of new potential toxic compounds. In order to preserve the laboratory independency from tobacco (and e-cigarette) companies, however, no direct payment (from industry to laboratory) should be admitted.

With the bridging this collaboration gap, the TPD represents a milestone in the control of tobacco ingredients and emissions for public health protection.

2.Definitions

In order to assist EU MS in networking and promote collaborations between laboratories for tobacco evaluation, it is imperative to define guidance for the requirements and financial support of such independent laboratories.

Tobacco products: for the purpose of this Guidance, it refers to the terms in the TPD “roll-your-own tobacco” [Art. 2.3], “tobacco products” [Art. 2.4], “novel tobacco products” [Art. 2.14] including heated tobacco products (HTP), “electronic cigarettes” [Art. 2.16], “refill containers” and “nicotine-containing liquids” (e-liquids] [Art. 2.17]

3. Background

Within JATC WP8, members developed an internal Standard Operating Procedure (SOP) for measuring nicotine, glycerol and propylene glycol in e-liquids.

This method, designed for EU regulation, is based on a collaborative exercise of 31 independent laboratories. Fifteen of them are from the EU former GoToLab network and from MS approved independent laboratories, eleven from WHO TobLabNet and five from Universities. The JATC e-liquid SOP is currently validated following ISO 5725, and is under publication.

4. Scope

The main purpose of the approved independent laboratories is the verification of tobacco products (as from Chapter 2, including make your own (MYO) tobacco, filler tubes, refill containers (e-liquids), flavour capsules, electronic cigarettes, etc.) in order to protect consumers' health and ensure the safety of new devices on the market.

This is achieved by continuous, high-quality, standardized verification programs within EU MS.

This guidance is intended to facilitate such approved independent laboratories in developing all necessary capacities (technologies, knowledge and expertise) to react to new demands from national CA in order to cover verification needs in a homogeneous approach, within MS. The guidance will therefore cover approaches on how to develop a sustainable system to create an effective collaboration network among laboratories.

This guidance involves:

- EU approved laboratories [Article 4(2) of the TPD];
- Tobacco economic operators (manufacturer, distributor, importer);
- National Competent Authorities (NCA);
- TobLabNet members (World Health Organization);
- Universities, Public Health institutes, Medical Institutions that develop analytical approaches for contents and emissions from tobacco products with potential adverse effects.

5. Actions

Tobacco EU Laboratory Netwok

Laboratories should be able to create and maintain a network, this will support the exchange of information regarding new and old methods, analytes and tobacco products on the EU market. It will also contribute effectively to the assessment of the health effects of emissions. The exchange of information regarding new potentially toxic compounds is the starting point for collaborative studies.

Specific activities include, but are not limited, to:

- Literature exchange
- Analytes other than TNCO
- Limitation to ISO methods
- Methods development
- Nicotine emissions
- E-cig emissions other than nicotine
- Methods application
- Interlaboratory exercise
- Interlaboratory collaborations
- Accreditation

Independence among approved laboratories

The laboratory network (also, in case it is an agency of a corresponding CA) should not accept any direct payment from the tobacco (including electronic cigarette and e-liquids) industry. For

verification analyses, the laboratory should always be paid through a third entity (e.g., the CA), which should act as a firewall to ensure that commercial interests are separated from laboratory activities. To prevent any conflict of interest, independency should follow membership criteria of WHO TobLabNet laboratory membership.1

Financial Resources - The Fee for Tobacco Laboratories

With reference to the coverage of costs for Independent laboratory testing tobacco products (including electronic cigarettes and refill containers) we support the recommendations by WHO.1,2

Accordingly, the manufacturer should bear all costs of testing. The development of a fee (contribution to the costs) for laboratory tests (Fee for Tobacco Laboratories; FTL) will be fundamental to support, through high-quality analytical data, the legislation and harmonization process of tobacco products verification at the EU level.

Financial resources to support an FTL should arise from at least one of the following:

- an aliquot or an extension of the contribution to the costs for the EU-CEG system that countries are enforcing for all tobacco products (traditional and novel tobacco products) and electronic cigarettes;
- a dedicated annual fee, specific for different tobacco products, coming from volume sales (import levels) of the product to be tested;
- other strategies recommended by WHO within the "covering costs" sections.[1,2]

6. Development

The proposed "Guidance for Laboratory analysis of tobacco and related products" is developed to assist EU independent laboratories in the creation of a stable collaborative network. The starting point will be the EU participants network that was created during the JATC laboratory exercise for the e-liquid SOP.

With the Tobacco EU Laboratory Network, it will be possible:

- to collect and share information on new potentially toxic emissions, new analytical methods, new devices and new emerging products coming from the global market through Internet marketing distribution channels;
- to validate new methods and instrumental approaches in an EU laboratory harmonized approach for contents and emissions in tobacco products;
- to adapt analytical approaches to new smoking habits (with a special focus on novel tobacco products);
- to increase EU quality of verification data.

7. Sustainability

Regular revisions of the tobacco products taxation policy are needed. Designated tobacco taxes require a proportion of it to be allocated to tobacco control programmes. This should be used to establish a sustainable fees system for tobacco laboratories, a FTL, that will ensure the sustainability of all EU independent laboratories for the development and maintenance of collaboration and communication among them. An extension to other international activities and academic centres is essential to support data quality at the top, for tobacco products, electronic cigarettes emission and contents evaluation.

The opportunity to create a FTL is available now, **using aliquots of the contribution to the costs for EU-CEG,** contribution that most EU MS currently enforce. The FTL is identified according to current and future needs of tobacco regulations. All capabilities and opportunities reinforce national value

and strategic importance of tobacco data. FTL should be managed in a way that will guarantee laboratory independence from tobacco products industry, including cigarettes, electronic cigarettes and novel tobacco products manufacturers, importers and distributor and/or retailers.

8. Note: A Global view from WHO: Art.9 in The WHO Framework Convention on Tobacco Control (WHO FCTC)

As a reminder, financial support from tobacco manufacturers, as a means for financing tobacco product regulations, has been well- discussed and documented by WHO. Article 9 of FCTC ("Regulation of the contents of tobacco products") states:

"The Conference of the Parties, in consultation with competent international bodies, shall propose guidelines for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions. Each Party shall, where approved by competent national authorities, adopt and implement effective legislative, executive and administrative or other measures for such testing and measuring, and for such regulation."

In FCTC/COP4(10)2 Annex, Article 2.3 ("Financing") and Appendix 1 ("Descriptive examples of means of financing tobacco product regulation measures"), taxes, fees and other revenue collection strategies are discussed and proposed as valid alternatives.

These strategies are supported as alternative sources to implement the **Fee for Tobacco Laboratories proposed in this guidance.**

9. References

1. World Health Organization. Tobacco Product Regulation: Building Laboratory Testing Capacity; 2018.
2. FCTC/COP4(10) Partial guidelines for implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (Regulation of the contents of tobacco products and Regulation of tobacco product disclosures). ANNEX. PARTIAL GUIDELINES FOR IMPLEMENTATION OF ARTICLES 9 AND 10 OF THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

Agreement n°:

761297-JATC-HP-JA-03-2016

Guidance to recommendations for treating electronic cigarette and heated tobacco product dependence

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Date: 15 September 2020

JATC JOINT ACTION ON TOBACCO CONTROL

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

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1. Introduction

There is strong evidence that any clear smoking cessation advice from healthcare professionals (e.g., physicians, nurses, dentists) can increase smokers' motivation to quit[1]. Generally, guidelines for treating tobacco smoking dependence and supporting smoking cessation urge all health professionals to provide a minimum of brief smoking cessation advice to all patients including current tobacco consumers and ex-smokers to quit smoking and avoid relapsing, respectively[1,2]. Electronic cigarettes (e-cigarettes) and heated tobacco products (HTPs) are continuing to gain popularity and acceptance by consumers worldwide[3,4]. However, many health professionals are uncertain about the potential benefits or adverse effects of these novel products[5,6]. E-cigarettes, although regulated under the Tobacco Products Directive (TPD), are not classified as tobacco products in European legislation and many e-cigarette users perceive them as an effective smoking cessation aid or less harmful alternative to conventional tobacco products, despite the increasing evidence that e-cigarette vapour is not harmless[7]. Assessment of tobacco smoking dependence in medical practice usually do not consider e-cigarettes or HTPs dependence. The ultimate goal of treating nicotine dependence should be to stop using all tobacco and/or nicotine delivery device use. New generations of HTPs have become popular in the recent years and have different design and technical characteristics than earlier versions[5,8,9]. Several studies have been conducted on HTPs since their emergence, although most of these were not independent from tobacco industry[4,5,8]. Health impacts of HTPs are sparsely explored as these products have not been on the market for long enough[8]. HTPs are widely promoted using messages that explicitly or implicitly claim they are safer and less toxic alternatives to conventional cigarettes[9,10]. Conclusions cannot yet be drawn about their ability to assist with quitting smoking, since HTPs are addictive products and instead of switching completely from tobacco smoking to HTP use, many HTP user are dual/poly-user (use HTPs and conventional cigarettes and/or e-cigarettes concurrently)[10,11]. Moreover, HTPs are increasingly attractive to both smoker and non-smoker young people raising a new threat in the gateway effect and possibly creating a new nicotine addicted population[4-6].

There are numerous reasons for e-cigarette use, most commonly, smoking cessation and a hypothetical harm reduction mainly among adults, while curiosity, variety of flavors and appealing appearance of e-cigarette devices drive young people to experiment and use these products[12]. Currently, the evidence is inadequate to recommend e-cigarettes for smoking cessation[12]. However, there is some evidence that frequent use of e-cigarettes and the use of nicotine containing e-cigarettes may be associated with increased smoking cessation compared to less frequent use of e-cigarette and the use of e-liquids not containing nicotine[12]. Some smoking cessation guidelines recommend – with low certainty – the short-term, exclusive use of nicotine containing e-cigarettes for smokers who failed to quit with approved cessation therapies, but are still motivated to quit smoking[13]. Complete switching from conventional cigarettes to e-cigarettes should be a transitional period as the ultimate goal should be to quit e-cigarette use completely[12,13]. However, more recent e-cigarette devices can deliver nicotine in a similar way to conventional cigarettes, resulting similar or even greater nicotine dependence than for conventional cigarette smoking, making it difficult to quit successfully[12]. Moreover, e-cigarettes may also maintain psychological and sensory dependence[14].

To date, guidelines for treating tobacco dependence ignore to consider treating e-cigarette and HTP dependence, leaving alone physically and/or psychologically addicted e-cigarette and HTP users who may be or may be not motivated to quit e-cigarette or HTP use in any age group.

2. Scope

To provide a recommendation and guidance for incorporating the treatment of e-cigarette and HTP dependence in guidelines for treating tobacco dependence and supporting smoking cessation.

3. Actions

In order to explore different aspects of current national e-cigarette-related and HTP-related situations, several studies should be conducted by national public health authorities and/or universities with tobacco expert research teams and/or national focal points for tobacco control, such as the followings:

- Epidemiologic analyses on the prevalence and characteristics of e-cigarette and HTP use among both adults and adolescents;
- Surveys on e-cigarette-related and HTP-related knowledge, attitudes and clinical practice (monitoring of e-cigarette and/or HTP use and routine advice to consumers to quit e-cigarette and/or HTP use) of healthcare professionals (especially practicing physicians) should also be assessed to plan and outline future developments of e-cigarette and HTP-related health issues in graduate and postgraduate trainings for healthcare professionals;
- Studies on e-cigarette and HTP users' intention to quit, their interest in different cessation services (e.g., individual or group cessation counseling for smoking and vaping cessation at local healthcare units and hospitals, mobile apps for cessation, online self-help cessation services, and online cessation counseling), and the effectiveness of different cessation services should be conducted by using different study designs of observational studies and clinical trials. If possible, criteria similar to the assessment of tobacco abstinence should be applied for the assessment of abstinence from e-cigarette use;
- Based on future scientific evidences and best practices, comprehensive guidelines for treating tobacco dependence integrated with e-cigarette and HTP use dependence treatment interventions should be developed;
- Contributors of situation analyses and professional recommendation development should be public health professionals, experts in tobacco science in collaboration with health professional organizations, healthcare workers and key stakeholders with relevant expertise in the fields of tobacco and e-cigarette sciences and in smoking cessation;
- All research and guidelines must be protected from any conflict of interest;
- Target population of updated guidelines:
  - all healthcare professionals, including physicians, dentists, pharmacists, nurses and other healthcare workers who should apply brief smoking cessation advice including also e-cigarette or HTP use cessation;
  - healthcare professionals who manage and provide smoking cessation support.
- Guidelines and their updates should be freely provided to healthcare professionals (for instance, by publication on specific healthcare websites, e.g., Ministry of Health, National Public Health Institution, National Medical Chamber, National Focal Point for Tobacco Control) in order to acquire the necessary skills to improve their cessation supporting strategies.

4. Development

The following aspects should be considered during the development of recommendations for treating e-cigarette and HTP dependence, in parallel to the treating tobacco dependence guidelines:

- Minimal intervention or brief advice for cessation and the **5As** strategy should also be tailored for e-cigarette users[1,15,16] :
  - ***Ask*** and document all tobacco use, including novel nicotine delivery products, that is, e-cigarette and HTP current/former/never use. Furthermore, exclusive e-cigarette/HTP or dual use (combustible tobacco product and e-cigarette and/or HTP use concomitantly), frequency of use and nicotine concentration of the e-liquid would also be valuable to record.

Assessing nicotine/cigarette dependence is routinely used in the clinical diagnosis of tobacco dependence. Several aspects of dependence overlap between nicotine containing e-cigarette and tobacco product use, however, beyond the presence of nicotine in the e-liquid, unique features of e-cigarette use such as the flavourings and the device appeal may also contribute to dependence, including the behavioral aspect. Therefore, development of short and psychometrically appropriate e-cigarette dependece measures for routine clinical assessment is needed.

- ***Advise*** e-cigarette and/or HTP users to quit in a clear and personalized manner. Emphasize that e-cigarette and/or HTP use carries risk, its long-term health effects are unknown, e-cigarette and/or HTP use is addictive, dual use should be avoided, and advice to quit completely e-cigarette and all tobacco use.
- ***Assess*** readiness to quit e-cigarette and/or HTP use. For e-cigarette users and/or HTP users who are not motivated to quit, adaptation of brief motivational interviewing by using the **5Rs** strategy in smoking cessation counseling practice may also enhance motivation to quit vaping and/or HTP use. For e-cigarette users and/or HTP users who are motivated to quit e-cigarettes, health professionals should provide assistance in cessation. Studies on the effectiveness of motivational techniques enhancing e-cigarette users' and/or HTP users' motivation to quit are needed.
- ***Assist*** in cessation. For e-cigarette users and/or HTP users who are ready to quit, health professionals should provide behavioral counseling and first-line cessation medication. Studies are needed to assess the effectiveness of behavioral counseling and first-line smoking cessation medications in vaping cessation. If a health professional is not a trained cessation counselor, the patient who is willing to quit e-cigarettesand/or HTP use should be referred to a smoking cessation service or quit-line. Novel cessation techniques like online cessation services and smartphone applications may also support e-cigarette and/or HTP use cessation, but these also should be rigorously studied[17].
- ***Arrange*** follow-up supports. Monitoring the cessation process, adherence to behavioral and/or pharmacotherapy, and recording e-cigarette/tobacco use status at each follow-up would be also useful in vaping and/or HTP use cessation. In-person, by phone and/or using novel techniques (online support, mobile apps) for follow-ups could be appropriate although these should be tested.

- Consider supporting vaping and/or HTP use cessation in high risk populations, e.g., adolescents, pregnant women, and patients with chronic diseases.
- Recommendations for treating e-cigarette and HTP use dependence should be included in graduate and postgraduate training program on tobacco cessation for health professionals.

5. Sustainability

The science of smoking cessation is an evolving field, therefore, minor and comprehensive updates of cessation guidelines are needed and regularly based on the latest scientific evidences and best practices. National circumstances and priorities should be taken into account during the updates of national smoking and nicotine cessation strategies.

6. References

1. European Network for Smoking and Tobacco Prevention (ENSP): Guidelines for treating tobacco dependence, 2018. Brussels: European Network for Smoking and Tobacco Prevention; 2018.
2. Fiore M.C., Jaen C.R., Baker T.B., et al. Treating tobacco use and dependence: 2008 update. Rockville MD: USDHHS, U.S. Public Health Service; 2008.
3. Kapan A, Stefanac S, Sandner I, Haider S, Grabovac I, Dorner TE. Use of electronic cigarettes in European populations: A narrative review. Int J Environ Res Public Health. 2020;17(6):1971.

4. Ratajczak A, Jankowski P, Strus P, Feleszko W. Heat Not Burn Tobacco Product - A New Global Trend: Impact of Heat-Not-Burn Tobacco Products on Public Health, a Systematic Review. Int J Environ Res Public Health. 2020; 17:409. doi: 10.3390/ijerph17020409.
5. Simonavicius E, McNeill A, Shahab L, Brose LS. Heat-not-burn tobacco products: a systematic literature review. Tob Control, 2019; 28:582-594. doi: 10.1136/tobaccocontrol-2018-054419.
6. Erku DA, Gartner CE, Morphett K, Steadman KJ. Beliefs and Self-reported Practices of Health Care Professionals Regarding Electronic Nicotine Delivery Systems: A Mixed-Methods Systematic Review and Synthesis. Nicotine Tob Res. 2020; 22:619-629. doi: 10.1093/ntr/ntz046.
7. National Academies of Sciences, Engineering, and Medicine. 2018. Public health consequences of e-cigarettes. Washington, DC: The National Academies Press. doi: 10.17226/24952
8. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization; 2019.
9. World Health Organization, Tobacco Free Initiative: Heated Tobacco Products (HTPs) Market Monitoring Information Sheet, 2018.
10. Glantz SA. Heated tobacco products: the example of IQOS. Tob Control. 2018; 27:s1–s6.
11. Queloz S, Etter JF. An online survey of users of tobacco vaporizers, reasons and modes of utilization, perceived advantages and perceived risks. BMC Public Health. 2019; 19:642. doi: 10.1186/s12889-019-6957-0.
12. U.S. Department of Health and Human Services. Smoking Cessation. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.
13. The Royal Australian College of General Practitioners. Supporting smoking cessation: A guide for health professionals. 2nd edn. East Melbourne, Vic: RACGP; 2019.
14. Bold, K.W., Sussman, S., O'Malley, S.S., et al. Measuring e-cigarette dependence: Initial guidance. Addict Behav. 2018; 79:213–218. doi: 10.1016/j.addbeh.2017.11.015
15. Prochnow, J.A. E-cigarettes: A Practical, Evidenced-based Guide for Advanced Practice Nurses. The Journal for Nurse Practitioners, 2017; 13:449-455. doi: 10.1016/j.nurpra.2017.03.015
16. Mendelsohn, C.P. Electronic cigarettes in physician practice. Internal Medicine Journal, 2018; 48:391–396. doi: 10.1111/imj.13761.
17. Etter, J.F. Are long-term vapers interested in vaping cessation support? Addiction, 2019; 114:1473–1477. doi:10.1111/add.14595

Agreement n°:

761297-JATC-HP-JA-03-2016

General guidance on mapping actors in the field of electronic cigarettes

Circulation: Public

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Date: 3d December 2020

JATC JOINT ACTION ON TOBACCO CONTROL

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

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1. Introduction

Electronic cigarettes (e-cigarettes) are devices designed to simulate smoking act (such as by means of vaping) and using liquids with or without nicotine and flavorings. E-cigarettes are defined by TPD as products that can be used for consumption of nicotine-containing vapour via a mouthpiece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges[1].

Available scientific knowledge about the safety of these relatively new devices is inconclusive yet, particularly because of the continuous changing and evolving design of the devices/liquids including self-made ones. Long-term health consequences of e-cigarette use on morbidity and mortality are currently unknown. Smokers who completely switch from combustible cigarettes to appropriately regulated and original e-cigarettes use may reduce their health risk, although e-cigarettes are not harmless. In contrast, e-cigarettes are not safe for youth, pregnant women, and non-smoker adults[2].

From a public health perspective, e-cigarettes might pose both threats and benefits. Therefore, it is key to develop and implement policies to minimize adverse consequences of e-cigarette use that may exacerbate the tobacco epidemic, while maximizing the potential benefits of its use to public health. EU Member States have adopted legislative actions to regulate e-cigarettes, which are in line with the policy objectives of the WHO FCTC. Nevertheless, competent authorities and other organizations responsible for implementing e-cigarette-related legislative measures may not conduct harmonized and transparent work, faced with difficulties regarding e.g. the implementation of some measures or boundaries of competences. Therefore, it would be necessary to extensively identify national authorities, stakeholders, and other organizations responsible for developing, implementing, and monitoring policy and health-related measures of tobacco and nicotine products including e-cigarettes. In many countries, public and private organizations, and nongovernmental organizations (NGOs) are either thought to be unrelated or sometimes not identified with a role in e-cigarette-related tasks. These organizations could be e.g., ministries of health, finance, agriculture or economy/innovation/technology, national public health institutes, national institutes of pharmacy, national focal points for tobacco control, addiction centers, national tax and/or customs administrations, police force, national laboratories, as well as academic institutes and NGOs in the field of tobacco control. These organizations may have different roles in the field of tobacco and nicotine products, including e-cigarettes, but they need to be connected to each other in order to collaborate and effectively implement relevant policies. Accurate mapping of authorities, stakeholders and other organizations with legislative and scientific competences in the field of e-cigarette could clarify the role and tasks of each member leading to more effective and collaborative practical implementation of e-cigarette-related policy interventions.

The importance of mapping of actors for better tobacco control policy is supported by several WHO and EU documents[3,4,5,6] including the following:

- The WHO FCTC that asserts the importance of strategies to reduce both demand and supply, and provides a framework for tobacco control measures to be implemented at the national,

1. DIRECTIVE 2014/40/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (Tobacco Products Directive) - Article2 Paragraph 16
2. WHO EN&NNDS 2020
3. WHO FCTC: https://www.who.int/fctc/implementation/cooperation/who-fctc-5-2-a-stakeholder-arguments-tobacco-control.pdf?ua=1
4. EU Commission consultation strategy: https://ec.europa.eu/health/sites/health/files/tobacco/docs/2016_consultation_strategy_en.pdf
5. WHO EURO Report on tobacco trends: https://www.euro.who.int/__data/assets/pdf_file/0009/402777/Tobacco-Trends-Report-ENG-WEB.pdf?ua=1 (About stakeholder involvement on pages 15-16: Exploring other innovative forms of monitoring population tobacco-related behaviours and practice)
6. EU CHRODIS Joint Action document on stakeholder mapping: http://www.chrodis.eu/wp-content/uploads/2015/04/D01-02.1-Stakeholder-mapping.pdf

regional and international levels;

- Stakeholder analyses to identify key actors and assess their knowledge, interests, positions, alliances, and importance related to the policy. These allow policymakers and managers to interact more effectively with key stakeholders and to increase support for a given policy/ program. When these analyses are conducted before the implementation of a policy/ program, policymakers and managers can detect and take action in order to prevent potential misunderstandings or oppositions in relation to the policy/ program. When a stakeholder analysis and other key tools are used to guide the implementation, the policy/program is more likely to succeed[7]. Interference from the tobacco industry and lack of coordination between sectors and relevant stakeholders still remain main barriers to tobacco control.
- Contribution from NGOs and other members of the civil society not affiliated with the tobacco industry, including health professional bodies, women's/youth/environmental/consumer groups, academic and health care institutions to tobacco control efforts at national and international level[8].
- Recommendations for Member States:
  - o Invest in communication, education and training measures, giving priority to evidence-based mass media quit-smoking and social marketing campaigns that warn of the dangers of tobacco and the risks to children from exposure to second-hand smoke, and support the introduction and enforcement of regulations, including, but not limited to, those targeted at social groups with special needs;
  - o Promote an active and multidisciplinary tobacco and ENDS research programme to address gaps in knowledge; inform policy and invest in translating research into practice;
  - o Engage with tobacco control advocates, academics and the civil society in co-designing, monitoring and evaluating tobacco control interventions support efforts through appropriate training, capacity-building and appropriate information;
  - o Facilitate the participation of all relevant sectors, particularly health, finance, economy, education, environment and trade; develop and sustain partnerships with broader stakeholders, such as the civil society and researchers, in order to achieve the objectives of the WHO FCTC.

2. Scope

This document aims to provide a guide on how to identify national authorities and other organizations as well as stakeholders with e-cigarette-related legislative and scientific competences. This guide also seeks to provide core recommended measures in order to explore current tasks of identified authorities and other organizations, as well as stakeholders, and to examine their difficulties in the implementation of e-cigarette-related policies, mainly attributed to collaborative shortcomings or boundaries of competences.

By successfully conducting the mapping process, national authorities with e-cigarette-related tasks could:

- have an overview of other authorities/organizations working on e-cigarette-related topics;
- be able to collaborate with other authorities/organizations, in case tasks on e-cigarette-related border areas arise;
- identify e-cigarette-related legislative gaps;
- determine to what extent the EU Common Entry Gate (EU-CEG) is used by relevant authorities/ organizations.

7. https://www.who.int/workforcealliance/knowledge/toolkit/33.pdf
8. WHO Framework Convention on Tobacco Control

3. Actions

3.1. Review and identification

Identifying authorities, organizations, NGOs, academic institutes, and other members/actors who have a role in e-cigarette-related market surveillance, control, and public health programs would be essential to successfully implement tobacco and nicotine product control policies.

3.1.1. National authorities/organizations

The first step of the mapping process – identification of national competent authorities/organizations – includes the review of existing e-cigarette-related information on:

- EU and national legislation;
- National relevant data of the EU-CEG[9] system;
- WHO documents;
- Protocols of the national ministry of health for controlling tobacco and e-cigarette use.

During the review process, it is recommended to consider the following aspects:

- the identification of the competent national authorities and their tasks
- the harmonization of national legislation with the relevant EU legislation
- The allocation of e-cigarette-related legislative tasks to national authorities

Based on data and information obtained, it would be necessary to highlight:

- liabilities accomplished;
- liabilities not accomplished;
- liabilities without clear assignment of a competent authority/organization.

3.1.2. Stakeholders and academic centers

The regulation of several questions related to the TPD lies within the jurisdiction of Member states, allowing thus for different interpretations among countries.
The mapping of stakeholders and academic centers or research groups involved in the e-cigarette field would boost collaborative work and would foster TPD implementation and e-cigarette-related interventions. The identification process of e-cigarette-related stakeholders and academic centers could potentially include:

- national cessation centers;
- health professional societies, such as public health/respiratory societies ;
- societies on tobacco addiction and research;
- workshops or research groups in higher education;
- scientific research groups;
- national addiction centers.

3.2. Assessing the tasks of identified authorities/organizations

Identified authorities/organizations will be assessed in terms of their role and responsibilities regarding e-cigarettes. Their tasks/functions will be explored with regard to their strengths and limitations, while each authority/organization will be evaluated on the basis of knowledge of their e-cigarette-related responsibilities.

Methods of assessment include:

- Online questionnaires: Questionnaires provide a comprehensive and efficient way of retrieving large amounts of information from a broad sample of people or institutes, given that data can be collected promptly. Questionnaires constitute an effective means of measuring behaviors, attitudes, preferences, and opinions.

9. https://ec.europa.eu/health/euceg/introduction_en

- In-depth interviews. The use of in-depth interviews allows for the collection of high-quality detailed information, the discovery of subjective experiences that could turn into valuable insights and the application of additional or follow-up questions, where applicable.

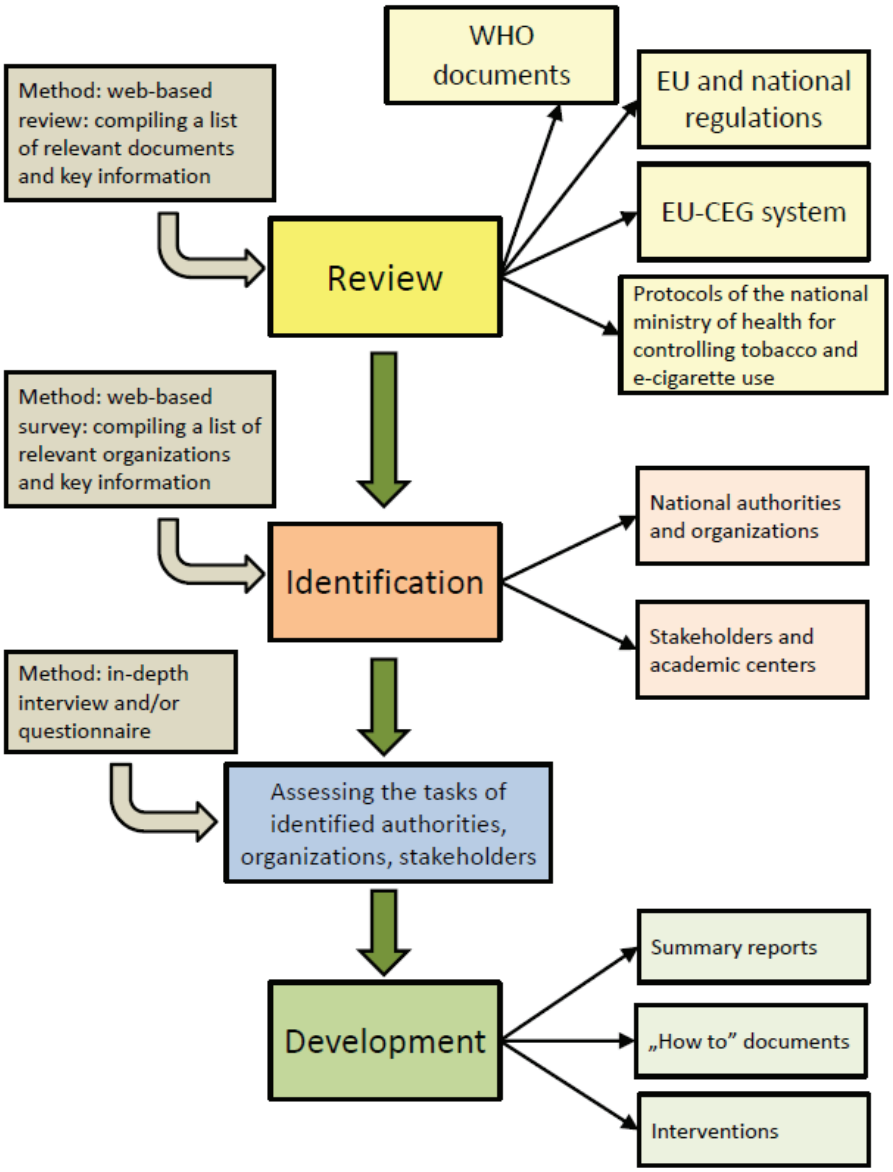
During the first contact with the identified authorities/organizations, it would be worth using an online questionnaire to assess their tasks, strengths and limitations. In case an authority/organization declares significant limitations or difficulties in its e-cigarette-related tasks, an in-depth interview might be necessary to extensively explore the issue.

Recommended core questions for national authorities/organizations could focus on:
- the e-cigarette-related tasks of the authority/organization;
- the type of data the authority/organization stores and handles;
- the type of information the authority/organization shares on its website;
- the experience the authority/organization has with tobacco/e-cigarette companies
- the experiences the authority/organization has with regard to the use of the EU-CEG system;
- the checklist for e-cigarette product compliance with the TPD the authority/organization could potentially use, as recommended by the EU, as well as the relevant experience, if applicable;
- the boundaries of e-cigarette-related tasks the authority/organization might be faced with;

Any collaboration the authority/organization might have with other authorities/organizations in dealing with boundaries of e-cigarette-related tasks. If the authority/organization declares such a collaboration, this will have to be assessed for operating in accordance with the established procedures; on the opposite side, the authority/organization should report on its intentions to develop such a collaboration.

Recommended core questions for organizations/research groups could focus on:
- the e-cigarette-related tasks of the organization/research group;
- the engagement the organization/research group might have in e-cigarette-related policy planning and/or implementation;
- the ability of the organization/research group to find sufficient information on the relevant authorities' websites;
- the composition of each organization/research group, in terms of persons dedicated to and with expertise in e-cigarette-related topics;
- the acquaintance of the organization/research group with e-cigarette-related national legislation and the TPD.

3.3 Flowchart



4. Development

The mapping process and identification of e-cigarette-related competences of authorities/ organizations/stakeholders could provide an impetus for more effective collaborative decision-making and the development of relevant national guidelines. Collaborative frameworks could include either online discussions, further training or in-person meetings.

Member States may conduct several studies at the national level, including:

- Summary reports on the assessment of harm perception, attitudes, the use of e-cigarettes and new tobacco products in the general adult population;
- Specific "how-to" documents, e.g. where to find relevant information, how to use the EU-CEG system and what is the experience using it, how to respond to gaps explored by the survey;
- Interventions such as mass media communication campaigns, infographics, integration in gradual medical education, to inform the general public and broaden the knowledge of future health professionals vis-à-vis the health risks of e-cigarettes and new tobacco products;
- Proposals for revision of the TPD to include nicotine delivery products.

5. Sustainability

The cooperation of identified relevant authorities/organizations/stakeholders should be effective and sustainable. Several activities could support sustainability:

- Regular revisions of e-cigarette-related national and EU legislation;
- Contact (at least on an annual basis) with identified relevant authorities/organizations/stakeholders involved in the e-cigarette field;
- Regular monitoring of the roles, activities and needs of the identified relevant authorities/organizations/stakeholders;
- Regular monitoring of the progress of collaborative work;
- Monitoring the appropriate use of the EU-CEG and its optimizations;.
- Evaluation of mass media and/or targeted intervention campaigns to increase public awareness on e-cigarette-related hazards;
- As a result of the mapping process, creation of a platform of collaboration for stakeholders including governmental, non-governmental, and academic organizations, in order to collaborate in the prevention and control of e-cigarette use.

The introduction of an EU-CEG maintenance fee falls under the competence of each Member State; the collection of the fee could partly cover the costs of the above-mentioned activities.

Agreement n°:

761297-JATC-HP-JA-03-2016

The Tobacco Data Lake: An IT system to monitor and perform economic analyses of tobacco and nicotine products

Circulation: Public

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Date: 22nd October 2020

JOINT ACTION ON TOBACCO CONTROL

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

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1. Introduction

Smoking causes substantial social, health and economic damage worldwide. Since 1990, we have lost more than 27 million people in the EU due to this harmful addiction.[1] The negative impact of smoking on health has been widely documented since 1950s, and several studies have focused on quantifying the smoking-related economic burden to countries worldwide. It is essential to highlight that most of these studies have just focused on traditional tobacco products. However, the increasing consumption of electronic cigarettes and novel tobacco products (e.g., heated tobacco) makes it necessary to widen the scope of such analyses.

Economic analyses related to all types of tobacco products are essential in the development process of potential targeted measures in order to create an effective tobacco control policy and protect the population from the harmful effects of nicotine addiction. Towards this direction, advanced information technology (IT) systems could help us collect, store and analyse large amounts of data to help us monitor consumption trends and market developments.

2. Scope

The scope of this guidance is to highlight the concept of a novel complex tobacco IT system, a Tobacco Data Lake, and its potential in developing and performing economic analysis on all products under the Tobacco Products Directive (TPD), including novel tobacco products.

3. Justification of Actions

Besides the significant health and social burdens, smoking also causes serious economic damages. Its costs are multiple times higher than tax revenues gained from tobacco products on a global level. The WHO estimates that globally smoking costs trillion dollars annually due to extra healthcare costs and missed work, while tax revenues earned from tobacco products only comprised 269 billion dollars in 2013–2014.[2]

The tax policy is the most effective tool in the fight against smoking. Still, there are huge differences between the tax legislation of the EU countries, especially when it comes to new technologies. E-cigarettes are currently not subject to a harmonised tax under the Directive 2011/64/EU, as the growing popularity and increasing consumption started after the adoption of the Directive. Between 2013 and 2017, the number of e-cigarette users in the EU has doubled (from 6 to 12 million).[3]

Heated Tobacco Products (HTP) appeared on the market after the Directive 2011/64/EU entered into force, so they are also not explicitly mentioned in it. The market share of these products is continuously growing, HTP have been introduced in at least 17 EU MS, and the number of users has quadrupled between 2017-2018.[4] Electronic cigarettes and novel tobacco products such as HTP are not explicitly covered by that Directive, but this does not mean that they should not be included in economic analyses.

Data is a key player not only at the national but also at the EU level. The **development of a complex tobacco IT system (Tobacco Data Lake)** could support the legislation and harmonisation process of novel tobacco products on EU level and could contribute to the more effective fight against smoking.

- In principle, a data lake is a system or repository of data stored in its natural/raw format. The Tobacco Data Lake is a system or repository of a large amount of structured and unstructured data stored mainly in their raw format, capable of collecting, storing and analysing all types of data related to tobacco products (economic and consumption data). This would help the preparation of economic analyses and the adequate regulatory preparation of novel tobacco products (e.g. harmonising tax policy) by ensuring a constant flow of up-to-date data. With this informatics platform as a foundation, a variety of tools can be used to visualise and analyse data.
- The Tobacco Data Lake system may open the door to new opportunities of data utilisation in many fields of the EU Member States' tobacco control policies. Data Lake's principal capabilities are to be identified according to the needs of tobacco regulations. All of these capabilities and

opportunities reinforce the national value and strategic importance of collecting, storing and mining tobacco data.

- A Tobacco Data Lake could include economic and consumption data of tobacco products (traditional and novel products too): e.g. excise tax rates, production data, revenue data, distribution data, consumption data.

4. Development

The lack of data on novel products at the EU level is a potential issue. Up-to-date information about the consumption habits and trends are necessary for economic analyses as well. Because of these reasons, constant monitoring of the tobacco product market should be established. The development of a complex tobacco IT system (Tobacco Data Lake) would also serve as a prototype for domestic and regional tobacco systems. This IT system would help the development of European actions/ comparative analysis and the preparation of the novel tobacco products' legislation as well.

The proposed Tobacco Data Lake does not contradict the utility of the European Union Common Entry Gate (EU-CEG), as it would have a broader scope. EU-CEG is currently designed to reduce the administrative burden for companies and regulators and make it easier to compare data. It includes information on ingredients, emissions, toxicological data.[5] The Tobacco Data Lake would include data on consumption trends, market development, as well as health impacts. The Data Lake would operate with both structured and unstructured data from various data sources, including information, e.g. from national and EU authorities, market surveillance, national healthcare systems, health insurance organisations.

With the Tobacco Data Lake it would be possible:

- to collect and present evidence on the impact of increasing excise tax on tobacco on generating revenue for state budgets;
- to analyse the change of consumption of tobacco product as a consequence of increased excise tax;
- to monitor the marketing and sales activities of tobacco products;
- to analyse smoking habits (particular focus on novel tobacco products).

5. A model in practice

The Hungarian model is a good pilot for the member states and the EU as a national tobacco IT system is already in place. From 2013 a new tobacco retail system was introduced (tobacco products may only be sold in National Tobacco Shops) and the turnover of these shops is closely monitored. Thanks to the newly developed national IT and data transfer system, commercial data of unprecedented depth and accuracy are available on a national level, making it easier to analyse the size of the tobacco market, as well as to provide more accurate estimates regarding the smoking habits of the population. It is also possible to learn important trends and even to forecast potential health burden.

In Hungary, the data could come from the National Tax and Customs Administration and the National Tobacco Trade Company. The following data is available in Hungary, so all of these can be "uploaded" to the data lake:

- tobacco products prices: retail prices by product type, brand name and unit from 2017.
- amount of tax receipts for cigarette, cigar/cigarillos and other product type
- retail sales data by product type from 2014 as from 01.07.2013 tobacco products can be sold only in National Tobacco Shops.

6. Sustainability

The creation and implementation of a Tobacco Data Lake could help to keep up with the industry and to be able to monitor constantly all segments of the tobacco market, including information on

product taxation.
Tobacco taxes are generally well accepted by the public and raise government revenues. Allocating tax revenues for tobacco control, laboratory network development and other important health and social programmes further increase their popularity. Increasing tobacco taxes also helps expand a country's tax base, increasing tax revenue to fund priority investments and programs, including the expansion of universal health coverage, education for all, and other activities to help countries achieve the Sustainable Development Goals (SDGs).
National authorities should assess the development and implementation of a tobacco IT system, within which national circumstances and priorities should be taken into account during the development and implementation process.

7. References

1. Global Burden of Disease Study 2017. Global Burden of Disease Study 2017 (GBD 2017) Results. Seattle, United States: Institute for Health Metrics and Evaluation (IHME), 2018.
Available from http://vizhub.healthdata.org/gbd-compare/
2. For terms and conditions of use, please visit http://www.healthdata.org/about/terms-and-conditions
3. Tobacco control can save billions of dollars and millions of lives. Geneva, World Health Organization, 2017. http://www.who.int/news-room/detail/10-01-2017-tobacco-control-can-save-billions-of-dollars-and-millions-of-lives
3. COMMISSION STAFF WORKING DOCUMENT EVALUATION of the Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco https://ec.europa.eu/taxation_customs/sites/taxation/files/10-02-2020-tobacco-taxation-report.pdf
4. COMMISSION STAFF WORKING DOCUMENT EVALUATION of the Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco https://ec.europa.eu/taxation_customs/sites/taxation/files/10-02-2020-tobacco-taxation-report.pdf
5. https://ec.europa.eu/health/euceg/introduction_ga

Agreement n°:

761297-JATC-HP-JA-03-2016

Certain legislative aspects of national measures to implement TPD with regards to e-cigarettes and heated tobacco products

JOINT ACTION ON TOBACCO CONTROL

Circulation: Public

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Date: 22nd October 2020

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

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1. Introduction

Directive 2014/40/EU, the Tobacco Products Directive (TPD), lays down rules on the manufacture, presentation and sale of cigarettes, roll-your-own tobacco, pipe tobacco, cigars, cigarillos, smokeless tobacco, electronic cigarettes and herbal products for smoking, as well as novel tobacco products. According to Article 1, TPD aims to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, and to meet the obligations of the Union under the WHO Framework Convention for Tobacco Control (FCTC). Recital 8 also states that health protection should be given high importance, in particular, to reduce smoking prevalence among young people.

2. Scope

The scope of this guidance document is to help national legislators and authorities to implement provisions of the TPD, with particular regard to the specificities of e-cigarettes and novel tobacco products. The guidance focuses on relevant legislative provisions,

- tasks of competent national authorities
- potential gaps in the legislation
- specific open issues under the TPD which remain to be clarified

3. Actions

Relevant legal provisions

The key aspects of TPD are product regulation including but not limited to ingredients and emissions, labelling and packaging, cross-border distance sales, as well as individual product categories such as electronic cigarettes, waterpipe tobacco, herbal products for smoking and novel tobacco products.

An important part of product regulation is the reporting and notification of products on the EU market. Reporting refers to ingredients and emissions of products on the market. At the same time, the notification is related to new products placed on the market by manufacturers or importers and new measures taken by Member States. Reporting obligations include amongst others:

- ingredients and emission of tobacco products (Art. 5) including certain additives (Art. 6)
- ingredients of herbal products for smoking (Art. 22)

The aim of harmonised reporting format and mandatory reporting introduced by TPD is to create a level playing field and facilitate collection, analysis and monitoring of data, to reduce the administrative burden, and to provide a more robust system to handle sensitive data. The reporting system focuses on products particularly attractive to young people. It addresses market developments, including new technologies, and allows for further guidance and developments through delegated acts. The reporting obligations are consistent with the obligation placed on the EU to ensure a high level of protection for human health. The Directive introduced a common mandatory format to fulfil reporting obligations by manufacturers and importers which allows the Member States and the Commission to compare, analyse and draw conclusions from the information received.

Specific documents of interest to regulators may include:

Implementing legal acts on the specific rules of reporting format:

- Tobacco products: Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products
- Electronic cigarettes: Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers

Implementing legal act related to e-cigarettes:

- Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes

EU judicial practice, relevant cases of the European Court of Justice (ECJ):

- C-358/14 Poland vs Parliament and Council
- C-477/14 Pillbox (UK) Limited
- C-547/14 Philip Morris Brands SARL, Philip Morris Limited, British American Tobacco UK Limited vs Secretary of State for Health

3a. Actions for e-cigarettes

Beside traditional tobacco products, the scope of TPD covers new technologies such as electronic cigarettes, herbal products, and novel products. Some of the most important special rules applicable to e-cigarettes under Art. 20 of the TPD are the following:

- safety and quality, ban on certain additives
- packaging and labelling, health warnings
- prior notification (6-months), market surveillance & reporting obligations
- advertising restrictions
- content thresholds for refill container, nicotine concentration, cartridge or tank size
- rules for refillables
- EU MS have the option to take certain further measures like banning flavours or other additives.

Despite the relatively comprehensive text of the TPD, potential gaps in the legislation include:

- notification and reporting for certain devices or their parts, e.g. liquids
- nicotine-free refill liquids are not regulated by TPD
- certain definitions like cartridge, tank, rechargeable, single-use cartridge are missing from TPD
- certain definitions in the EU-CEG are unclear or not specific enough
- regulation of kit-packs
- the delimitation between e-cigarettes and certain other types of products like herbal products or medical devices
- manufacturers, importers and distributors are required to establish and maintain a system for collecting information about all of the suspected adverse effects on human health of e-cigarettes but the details of such a system are not defined
- electronic cigarettes can be modified by consumers as parts are widely sold, enabling consumers to modify these products, which may have health implications.

Main line of legislative actions regarding e-cigarettes:

Member States should ensure that national legislation under the TPD adequately protects citizens and especially young people from the potential harms of e-cigarettes. Information on e-cigarettes and their health effects is crucial hence Member States should ensure that notification procedures and the information system of adverse effects are in place. Legislative provisions to restrict modifying the composition of e-cigarette liquids by consumers may increase safety. However, there are regulatory challenges, especially that e-cigarette market would have to shift towards closed system products like e-cigarette rechargeable with single-use cartridges.

3b. Actions for Novel tobacco products:

Novel tobacco products are defined by Art. 2 para (14) of the TPD. According to Recitals (34), (35) and Art. 19 the manufacture, distribution and consumption need to be regulated. Member States are required by the provisions of the TPD to monitor the development of such products and make

sure that novel tobacco products comply with requirements of the TPD. There is a prior notification obligation with a possibility to introduce authorisation. No further specific rules are provided for, once a product is available on the market, but Member States have the power to ban novel tobacco products.

Potential gaps in the legislation are:

- classification of certain products is unclear
- certain devices or their parts may not fall under the scope of TPD.

Main line of actions to be taken regarding novel products:

In order to comply with the objectives and spirit of TPD, Member States are obliged to control tobacco and related products, including novel products. This obligation includes that national legislators and competent authorities take the necessary measures to ensure that the notification requirements are fulfilled for all novel tobacco products.

3c. Actions for Emerging products:

Authorities have to deal not only with traditional tobacco products but also emerging products, involving health risks, e.g. associated with the use of nicotine. An example is nicotine pouches containing nicotine but does not contain tobacco which may not fall under the definition of tobacco for oral use.

Potential legislative issues are:

- products containing nicotine but no tobacco, do not fall under the definition of tobacco products and in this way, the relevant articles of TPD may potentially not be applicable.
- nicotine-free and imitation products are not defined by the TPD.

The Commission and the Member States have an obligation under TPD to monitor market developments. Such products should be taken into account within a future review of the EU legislation. Also, Member States may consider introducing further measures under Article 24 of TPD.

Legal basis and procedures for notifying further requirements or measures

Member States have the opportunity to introduce certain further requirements or measures in the national legislation, including product regulation or ban on the marketing of certain products. Such measures have to be notified to the Commission.

Specific articles of TPD on notification:

- maximum emission levels from cigarettes set by the Member States (Art. 3)
- measurement methods used by the Member States (Art. 4)
- prohibition of products with characterising flavours, and certain harmful additives by Member States (Art. 7)
- intention of manufacturers and importers to place novel products on the market (Art. 19)
- intention of manufacturers and importers to place electronic cigarettes and refill containers on the market (Art. 20)

For the notification of further requirements or measures to be introduced by the Member States, there are two different legal bases, with some differences in the notification procedures:

- TPD Art. 24 para. 2: the right of Member States to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is justified on grounds of public health – notification

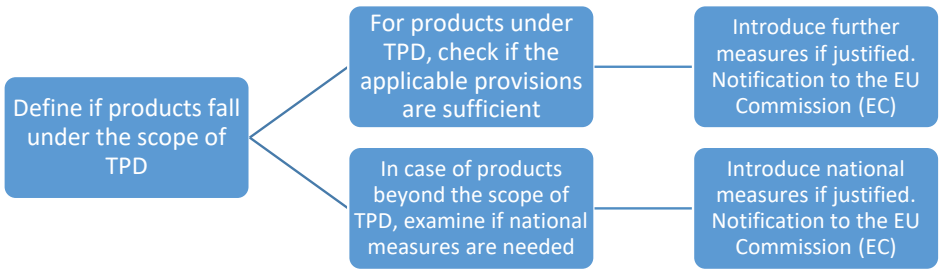
is based on Art. 114 of the Treaty on the Functioning of the EU (TFEU).

- TPD Art. 24 para. 3 and Recital (47): Member States may prohibit certain categories of tobacco or related products, on grounds relating to a specific situations justified to protect public health – notification is based on Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards. National provisions have to be notified by the Member State to the Commission together with the grounds for introducing them. The Commission will approve or reject the national provisions within six months, or in the absence of a decision by the Commission the national provisions are deemed to be approved.

4. Development of Sustainability

Key actions to be taken by the Member States are the following:

- Clearly define products falling under the scope of the legislation, with special attention to new types of products and devices as noted in the flowchart below.
- Within the national scope of the legislation, clarify the responsibilities of manufacturers, importers, and distributors.
- Set up reporting and notification systems and procedures where it is applicable at the national level.
- Nominate competent authorities and clarify competencies including marketing authorisation, notification, registration, control measures, laboratory checks, market surveillance, imposing sanctions.
- Member States can make use of Article 24 of the TPD to adopt further measures, e.g. related to the above mentioned nicotine-free refill liquids or nicotine-free and imitation products.
- It is essential to pay special attention to new technologies with regards to their reporting and notification.



Measures to be taken to further enhance the implementation of the TPD and towards a future review of the legislation at the national and EU level include:

- Implement notification and reporting obligations and take measures to analyse the data and information received.
- Identify legislative gaps and implementation issues.
- Follow market developments, consumption trends and new knowledge on health impacts, e.g. HTPs, products containing nicotine but no tobacco, nicotine-free refill liquids, nicotine-free and imitation products.
- Collect and communicate the above information to national governments and the EU Commission, exchange information with the other Member States.

JOINT ACTION ON TOBACCO CONTROL

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