



Agreement n°: 101035968 - JA-01-2020 - HP-JA-2020 / HP-JA-2020-2

Work Package 8 - Smoke-free environments (SAFE) and tobacco advertising, promotion, and sponsorship (TAPS) legislation in Europe

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

-

Authors: **Catalan Institute of Oncology (ICO) in collaboration with WP8 partners**

November 2022

Version	Date	Author	Reviewers and date
First draft	21 st October 2022	Catalan Institute of Oncology (ICO) Esteve Fernández Dolors Carnicer-Pont Anna Mar López	NIJZ: Helena Koprivnikar NPHO: Efstathios Papachristou IRFMN: Chiara Stival CIPH: Ivona Keć XQNS: Joseba Zabala 4 th November 2022
Second draft	18 th November 2022	Catalan Institute of Oncology (ICO) Esteve Fernández Dolors Carnicer-Pont Anna Mar López	NIJZ: Helena Koprivnikar NTAKD: Darius Sadaunykas 28 th November 2022



. This activity has received funding from the European Union's Health Program (2014-2020) under grant agreement N°101035968.

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

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

1	Rationale	4
2	Objectives.....	5
3	Activities.....	6
3.1	CONSULTATION TO EXPERTS	6
3.1.1	Methods.....	6
3.1.1.1	Steps of the consultation	6
3.1.1.1.1	Identification and selection of experts:	6
3.1.1.1.2	Designing, programming and testing questionnaire	7
3.1.1.1.3	Inviting experts to participate in the consultation	7
3.1.1.1.4	Survey filling out and data collection.....	8
3.1.1.1.5	Data management and analyses.....	8
3.1.1.1.6	Selection of best practices	9
3.1.1.1.7	Report writing of consultation findings	9
3.1.1.2	Ethical considerations	9
3.1.2	Expected results.....	10
3.1.2.1	Weight of evidence paper on barriers and opportunities for SFE and SHA protection (Deliverable 8.1, due on March 2023, month 18).....	10
3.1.2.2	Web-based repository of best practices (Milestone 8.4, due on March 2023, month 18)	10
3.1.2.3	First proposal of best practices obtained from the data analysis of the consultation to be presented in the Symposium and to be placed in the web-based repository	11
3.2	SYMPOSIUM (Milestone 8.3, due on May 2023, month 20)	12
3.2.1	Methods.....	12
3.2.2	Expected results.....	13
3.2.2.1	First proposal of best practices.....	13
3.2.2.2	Video Summary.....	13
3.2.2.3	Position paper on best practices for SFE and SHA protection (Deliverable 8.2, due on August 2023, month 23)	13
4	Annexes.....	15
4.1	How to evaluate potential best practices.....	15
4.2	Example of content of a best practice document.....	19
4.3	Correlation table: WP8 consultation questions related to WP4 assessment criteria & Irish structure of a best practice.....	21
4.4	Proposed structure for a weight of evidence paper on barriers and opportunities to support expansion of SFE.....	21
4.5	Web based repository of best practices on SFE (example of structure)	22

**Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for
smoke and aerosol-free environments in Europe**

4.6	Proposed structure for a position paper on best practices for the expansion of SFE	26
4.7	Other background information of one country as example (Spain).....	27
5	Glossary of terms	30
6	Abbreviations	30
7	References	31

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

1 Rationale

Introduction

Second-hand smoke (SHS) is the combination of the smoke that comes from burning tobacco products with the smoke that is exhaled by the individual smoking (Öberg et al., 2010).

In 2004, 40% of children, 35% of women and 33% of men were exposed to SHS in indoor settings on a regular basis. That also translated on 1% of worldwide deaths being caused by SHS (Öberg et al., 2011). According to the 2019 Global Burden of Disease Study, SHS was associated with the death of around 1.3 million non-smokers in that year and was a weighting factor for around 37 million DALYs (disability adjusted life years). According to this data, SHS was the 13th leading level 3 risk factor for deaths in 2019 (GBD, 2019).

Impact and health consequences of SHS

Evidence found a link between being exposed to SHS during pregnancy and preterm births (Wagijo MA et al., 2015; Hoyt AT et al. 2018; Ashford KB et al., 2010) as well as with diagnosed asthma during childhood. (Simons et al., 2014). Moreover, SHS exposure during childhood has been associated with more risk of not only asthma but also respiratory infections and other health issues such as neurodevelopmental disorders -Attention Deficit Hyperactivity Disorder -ADHD, Conduct Disorders, Learning disabilities, Cognitive delays (Tandon M. et al., 2014; Wendy M. et al., 2021; Mahabee-Gittens EM, et al. 2021) and a higher risk of infant death syndrome and mortality (Faber et al., 2017).

SHS is an important contributing factor on some cancers, especially lung and breast cancer on people who have never smoked before but have been exposed (Kim et al., 2018; Gram et al., 2022; Huang et al., 2022). It has also been associated with impactful negative effects to the cardiovascular system (Barnoya & Glantz, 2005) and with chronic obstructive pulmonary disease and ischemic heart disease (Carreras et al., 2019). Also, research found that SHS can impact not only physical health but also mental health, as an association was found between SHS and a higher risk of developing mental health issues such as depression and panic attacks (Taha & Goodwin, 2014).

Smoke-Free Environments Policies

In 2003 the WHO Framework Convention on Tobacco Control (WHO FCTC) was adopted to later be enforced in 2005. This international treaty came about to offer a response to the tobacco epidemic, having its focus on protecting population's health (WHO, 2003). Likewise, in 2009 MPOWER measures were introduced (WHO, 2009). These strategies, alongside the evidence on the negative health effects of SHS, have led to the design and implementation of smoke-free environments policies around the world (Carreras et al., 2021; Semple et al., 2022).

According to the 2021 WHO Report on Global Tobacco Pandemic, around 1.8 billion of the world population reside in countries that have smoke-free policies at a comprehensive level (WHO, 2021).

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

Smoke-free legislations have shown to be effective and have a positive impact as people who live in countries that have smoke-free bans are less exposed to SHS, especially if they have comprehensive legislations rather than partial bans (Schiavone et al., 2022). Moreover, smoke-free legislations can not only have a very positive effect on SHS exposure but also change behaviours beyond the ban itself, such as not smoking at home (Mons et al., 2012; Tattan-Birch & Jarvis, 2022) and reduction in smoking prevalence in women (Bird et al., 2020).

Current challenges and limitations

However, it is not only traditional tobacco products and SHS that need to be considered when we talk about smoke-free environments (Gallus & Fernandez, 2022). Second-hand aerosols (SHA) come from the heating of tobacco or liquids in electronic nicotine delivery devices (ENDs). The use of electronic cigarettes or novel tobacco products produces aerosols containing different hazardous substances (Amalia et al., 2021).

Evidence has found that SHA produced by electronic cigarettes contains toxic substances that are harmful (Fernández et al., 2015; Haggart et al., 2021; Amalia et al., 2022). Moreover, the use of electronic cigarettes or heated tobacco products increase levels of harmful substances in the air of enclosed places (Li L et al. 2020; Schober W et al. 2019; Cancelada L et al.2019; WHO study group 2019). However, most of the legislations in European Countries are not comprehensive enough when it comes to electronic cigarettes and other novel tobacco products (Amalia et al., 2022). Therefore, protection against SHA should be taken into account when creating or trying to expand or enforce policies (Haggart et al., 2021).

Another challenge is the lack of a global and common legislation regarding smoke and aerosol free environments (SAFE). The level of protection offered to non-smokers varies depending on the country they live in and this is mainly a consequence of the differences between policies across countries (Schiavone et al., 2022). Additionally, we must take into account there are also differences in the terms of compliance and enforcement of these legislations (Semple et al., 2022).

Another issue is that, even though SHS is decreasing, mainly because of the positive effects of proper legislations, exposure is still significant in some private settings (Fu et al., 2018). Additionally, it is important to highlight the impact of the tobacco industry which makes it actively difficult to continue with the effort to protect people from SHS and tobacco products in general (Wipfli & Samet, 2011).

In the last decades, there have been significant improvements when it comes to protecting the population from SHS, especially thanks to the design and implementation of SAFE legislation. Nonetheless, there is a further need to ensure comprehensive legislation for SAFE and extend it beyond indoor spaces. This takes us to the goals of the present project.

2 Objectives

To assess barriers and opportunities to protect population from exposure to second-hand tobacco smoke and from exposure to aerosols produced by electronic cigarettes, heated tobacco products and other novel tobacco products .

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

To identify best practices to protect the population from exposure to second-hand tobacco smoke and from exposure to aerosols produced by electronic cigarettes, heated tobacco products and other novel tobacco products.

3 Activities

To achieve the objectives, the following activities will be developed:

1. A consultation to experts to identify country-specific best practices to protect the population from SHS and SHA.
2. A symposium to present and enhance discussion on findings obtained from the consultation.

3.1 CONSULTATION TO EXPERTS

This consultation will follow a specific methodology, with the aim to simplify the process as much as possible. Therefore, no more than one round of consultation to experts will be conducted. Quantitative and qualitative information will be collected by means of an electronic form. However, if clarifications are needed, experts will be contacted again individually to retrieve further information.

3.1.1 Methods

3.1.1.1 Steps of the consultation

3.1.1.1.1 Identification and selection of experts:

The leading organization for this task is NIJZ (Slovenia). This task has the goal of creating a contact list of experts in the field of smoke and aerosol-free environments (SAFE) and exposure to second hand smoking (SHS). Particularly, within this activity it is foreseen to identify and select between 3 and 4 national experts per country for 30 European countries. Overall, it is expected that the list will be composed by 90 to 120 experts. To achieve this goal, the following sources will be approached:

1. The JATC2 coordination team's contact list of all authorities working with tobacco regulation (policymakers and regulators, researchers and tobacco inspectors) for 28 European countries, prepared in JATC2.
2. ICO-IDIBELL previous contacts (the UK, Romania, Bulgaria and Poland).
3. Smoke Free Partnership (SFP): <https://www.smokefreepartnership.eu/> .
4. European Network for Smoking and Tobacco Prevention (ENSP): <https://ensp.network/> .
5. JACT2 partners within the list of EU Member States.

An e-mail with a brief explanation on what kind of experts are needed and what would be required and expected from them will be sent out to the above-mentioned sources. The experts will need to be able to identify and describe national best practices to achieve smoke-and aerosol-free environments. Any type of smoke-free environments, including both private and public environments, outdoor and enclosed places, and protection from tobacco smoke from conventional cigarette and tobacco products for smoking as well as on the protection from exposure to aerosols from novel tobacco products like heated tobacco products, e-cigarettes, etc. are included.

The experts may come from the field of smoke-free regulation, research, enforcement or NGO.

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

3.1.1.1.2 Designing, programming and testing questionnaire

The online questionnaire that will be used for the consultation (M8.1.) will be designed using a previously created core questionnaire that was formulated by Work Package 4 (M4.4.), as the main source. The goal of this first questionnaire (M4.4.) was to identify relevant policies and best practices in relation to tobacco endgame strategies, smoke and aerosol free environments, the Tobacco Product Directive (TPD), and the Tobacco Advertising Directive (TAD) in Member States.

The online questionnaire described in this protocol (M8.1) will be elaborated by ICO-IDIBELL and IRFMN and will gather and adapt questions, both on barriers and opportunities as well as on relevant policies and best practices to achieve smoke and aerosol free environments.

Once the questionnaire is drafted, all WP8 partners will be asked to review it and provide feedback. Once an agreement is reached between all parties, the questionnaire will be ready for **programming**, task lead by IRFMN. This process will be conducted using SurveyMonkey to transpass the questions into the desired format: an online questionnaire. This configuration will allow to reach the experts and collect the information needed safely and efficiently.

The questionnaire contains:

1. A consent form.
2. Section 1: to assess barriers and opportunities to the expansion of smoke and aerosol free environments.
3. Section 2: to identify best practices with reference to smoke and aerosol free environments. Each best practice has a specific link.

The features of the questionnaire allow:

- To save the responses and return to the questionnaire.
- To attach documents or links to complement the expert's information.

The questionnaire will be **tested** by some of the organisations within WP8 before the questionnaire is shared with the experts. IRFMN will send the first version of the online questionnaire to CIPH, NTAKD, OKPI, HDIR, XQNS, UIC and Nofumadores.org with some brief instructions regarding how to complete the questionnaire and specially the goals of the testing: assessing the time needed to complete the questionnaire and its feasibility. The organisations involved will have 20 days to test the questionnaire and give feedback.

3.1.1.1.3 Inviting experts to participate in the consultation

An **invitation email explaining** the objectives of the consultation, the instructions to complete the online questionnaire and the **links** to access both section 1 and section 2 of the online questionnaire will be sent to all the **expert key informants** identified by the WP8 coordinators (ICO-IDIBELL). Given that some countries provide more than 3-4 names, experts that appear in the reserve list can be approached if needed to ensure enough participation and information.

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

3.1.1.1.4 Survey filling out and data collection

Each expert key informant will be asked to provide information of up to 4 best practices and there will be specific online links for each best practice.

Since the questionnaire has almost 60 questions and many of them require text development, the process of filling it out may require several days. Therefore, it will be designed in a way that allows the expert to save, stop and retake the questionnaire at the point that it was left.

Data collection will be automatic since the survey is online, operated through SurveyMonkey.

Follow up of data collection will be done on a weekly basis through programming the outputs (IRFMN). Reminders will be sent to experts with uncompleted questionnaires (ICO-IDIBELL) on a regular basis taking into account specific circumstances (for instance, annual leave or availability).

The questionnaire will remain open for up to 12 weeks from its launch.

Protocol of follow-up of experts

- Excel file to monitor the consultation process, which will be shared between ICO-IDIBELL and IRFMN.
- Email invitation to participate in the consultation sent to the experts previously identified.
- Email reminders sent on a regular basis taking into account the experts' specific circumstances and progress.
- Monitoring of responses to retrieve further information if needed .
- Regular communication with experts regarding replies on participation (affirmative or negative) and questions.
- Acknowledgement email when the questionnaire is completed.
- Email invitation to reserve experts if needed.

3.1.1.1.5 Data management and analyses

Step 1: Assessing quality and completeness of data is the first step of data management and will be done regularly as the answers to the questionnaire become available. Particularly we will assess:

- Number of answers received (total and per country; % of non-response).
- Number of Best Practices (BP) received per country.
- Completeness of information: number of questions not responded (overall %; and question-specific details).
- Correctness of links and/or documents provided.

Step 2: Data extraction and description:

Descriptive data of Section 1 of the questionnaire which focuses on **barriers and opportunities** will be compiled by OKPI.

Descriptive data of Section 2 reporting about the **best practices** will be analysed and described using Stata, to create classes or groups of best practices and their main characteristics by selected variables (scope , topic of the practice, target population, level of jurisdiction, etc.) will be done by ICO-IDIBELL.

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

A specific template for a **Summary sheet of each best practice** will be designed to organize the information according to the WP4 criteria alongside the criteria used in a best practice in Ireland. The questions from WP8 consultation will be organised to align with the above mentioned criteria (see Annex 4.1). This will be done by IRFMN and ICO-IDIBELL.

Additional information on best practices may be obtained by web links and PDF documents uploaded while answering the survey. Therefore, **best practices content analysis** will focus on two different but complimentary topics: 1) experts' written comments and 2) documents (PDF or links) provided by the experts. The information from the above mentioned will be summarized in a **narrative report** to allow synthesis and readability of the results. All these results will be discussed with WP8 partners and collaborating WPs.

Step 3: Revision of each best practice Summary sheet and scoring

Summary sheets of each best practice will be reviewed ensuring that: 1) each expert response is extracted by two reviewers, 2) the reviewers will not be from the same country as the expert. In case of doubts, the reviewer will inform the coordinators and another reviewer will be consulted. A **data scoring** form will be prepared to ensure consistency, (See Annex 4.1). Steps 2 and 3 will be done by CIPH and IPHS along with ICO-IDIBELL.

3.1.1.1.6 Selection of best practices

3.1.1.1.6.1 Criteria to choose best practices: (see Annexes 4.1 and 4.2)

The quantitative and qualitative analyses will serve to identify:

- 1) real best practices, (EU definition).
- 2) potential best practices, (EU definition).
- 3) "other" practices that cannot be considered real nor potential best practices because they lack the elements to be assigned to those categories.

WP8 coordinators will **promote an on-line session** with all WP8 partners for all other collaborating WPs to share and discuss the best practices collected and to do a preliminary consensus choice of ten best practices that will be further discussed at a dedicated Symposium (see below).

3.1.1.1.7 Report writing of consultation findings

Preparation of a DOCUMENT and a PRESENTATION for DEBATE at the Symposium within the ECToH Conference

Resulting from the process of selection of best practices, there will be a graded list of best practices from where we will be able to select the ten with highest scoring.

The full information of all practices will be available in a full report. Furthermore, this report will have a **list of links that will be classified by type of best practice, area and beneficiaries where this applies.**

3.1.1.2 Ethical considerations

Participation in the experts' consultation and symposium described in this protocol will be completely **voluntary**. Experts will have the right to withdraw at any point of the consultation.

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

Experts' will be **informed about the objectives** of JATC2 and WP8, specifically those regarding the experts' consultation, to ensure they make an informed decision in regards to participation. Moreover, the possibility to consult with WP8 leaders (ICO-IDIBELL) on a one-to-one basis will be offered to correctly solve potential doubts or concerns and to manage expectations.

An informed consent will be obtained by **ticking affirmatively** the two final questions of the first page of the online questionnaire. If these two fields are not completed, the investigators will have to remind the expert to tick them. Otherwise, that particular questionnaire will not be usable.

WP8 coordinators will ask the experts permission to include their names in the reports derived from the consultation.

Conflict of interest. All the experts will be asked about potential conflict of interests with the consultation aim. No experts with links with the tobacco and/or electronic cigarette industry will be included in the experts' panel.

3.1.2 Expected results

3.1.2.1 Weight of evidence paper on barriers and opportunities for SAFE and SHA protection (Deliverable 8.1, due on March 2023, month 18)

A **weight of evidence** paper that assembles evidence supporting the expansion of SAFE on indoor and outdoor spaces will be written by ICO-IDIBELL and IRFMN in collaboration with NPHO, IPHS, NIJZ, XQNS based on the literature review done by NPHO and the intermediate report from the data analysis done by OKPI. This evidence will come from the assessment on barriers and opportunities of Member States in regard to implementing interventions that aim to enforce and expand SAFE in a national and transnational framework. The sources for this evidence will be the experts completing the online questionnaire as well as other existing evidence supporting the expansion on SAFE. This weight of evidence paper will be the **Deliverable 8.1. of WP8 of JATC2**.

Proposed structure of weight of evidence paper (see Annex 4.4)

3.1.2.2 Web-based repository of best practices (Milestone 8.4, due on March 2023, month 18)

A **web-based repository** will be created in order to make available the results of the experts' consultation. It will be designed by CNPT and ICO-IDIBELL with the collaboration of all the partners involved in WP8. This will be the **Milestone 8.4 of JATC2_WP8**. The information shown will be the details of all best practices to protect the EU population from SHS/SHA exposure collected during the experts' consultation.

Proposed structure of web based repository with one example of Best Practice (see Annex 4.5)

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

3.1.2.3 First proposal of best practices obtained from the data analysis of the consultation to be presented in the Symposium and to be placed in the web-based repository

After the selection of best practices by consensus (on-line session), ICO-IDIBELL will liaise via regular online meetings with NPHO, leader of JATC2_WP2 (dissemination), DSTA, leader of JATC2_WP6 (enforcement on tobacco regulation), and with CIPH, IRFMN and IPHS to deliver a first draft with a selection of ten to fifteen best practices on SAFE.

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

3.2 SYMPOSIUM (Milestone 8.3, due on May 2023, month 20)

Within the activities of the Association of European Cancer Leagues (ECToH) Congress that is expected to be held on April 2023 in Madrid (<https://www.ectoh.org/>), a pre-Conference session will be organized to share findings of the consultation with diverse tobacco control experts and stakeholders to present, discuss and enrich the findings of the consultation. The organisation of this symposium is the **Milestone 8.3 of the WP8** and is due on month 20 of the project (May 2023).

A symposium is generally defined as a meeting organised so that experts in a given field can meet, present research, and discuss issues and trends or make recommendations for a certain course of action. In the scope of the WP8, the symposium will be organised after the experts' consultation is done and preliminary selection of best practices, to discuss them and to **consolidate the selection of 10 best practices** on smoke and aerosol-free environments in Europe.

3.2.1 Methods

Preparation

As described above, prior to the symposium, the expert consultation will be conducted, and ten best practices will be identified by the WP8 Partners and other collaborating WPs. Additionally, another 5 best practices will be also selected as back up practices in case there are discrepancies when debating the first ten proposed best practices at the symposium. The results of this consultation will be the main "product" to be presented and discussed to the panel during the symposium.

Panel selection: 5-7 panellists from different European countries will be invited in advance (in January 2023) to be part of the symposium panel. The pre-selected list will be decided by the WP8 Partners within one of the WP monthly meetings and they will be further invited to join the symposium by the ICO-IDIBELL Team. The preliminary list of the selection criteria of the panellists are: 2-4 researchers, 2-3 policymakers, 2-3 activists in tobacco control from different European countries with extensive experience (15+ years) in the field of tobacco control. Once the pre-selected experts are invited and confirm their participation, the final list of the experts will be confirmed.

The panellists will be approached and invited to the Symposium at least 2 months before the Symposium by the WP8 Team, with a brief description of the main aim and panelists' expected contributions. At least 3 weeks before the symposium, WP8 team will share with the panellists: 1) brief summary of the symposium, its objectives, format and agenda; 2) a summary of the consultation methodology and the main results; 3) the discussion points of the symposium so that the panellists can prepare in advance; 4) conditions of the participation (voluntarily, coverage of travel expenses, mentioning of the panel contribution in dissemination activities, etc.); 5) contact details.

Proposed format

The following roles of the participants of the symposium could be foreseen: chairperson, discussion moderator, expert panel, secretary (taking notes and preparing minutes), project partners and audience.

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

Proposed agenda for the symposium:

- Welcome (chairperson welcomes the participants, explains the objectives of the symposium and announces the agenda)
- Brief introduction of the methodology of the consultation and 10 best practices
- Round of individual feedbacks of the experts according to the questions shared in advance (10 min per expert), preliminary proposed questions:
 - General feedback on the materials received.
 - Does the selection of 10 best practices (and 5 back up BPs) seem to be appropriate?
 - Is there any other BP known to the expert that deserves a place among the 10 best practices? Why?
 - Which BPs have promising results but lack a proper evaluation?
 - Are there any recommendations for other consultations conducted in the future?
- Moderated discussion based on the individual feedback and consensus
- Questions from the audience and answers
- Closure

Synthesis

Based on the discussion debate, minutes of the meeting will be prepared, summarising main points discussed and the consensus reached on 10 best practices. This will be further translated into the main results: final list of ten best practices; video summary; position paper.

3.2.2 Expected results

3.2.2.1 First proposal of best practices

The **preliminary list of 10 best practices (and 5 back up best practices)** will be prepared after the consultation by ICO-IDIBELL. This list might change after the symposium. If any modifications need to be done, the final list of 10 best practices will be prepared and shared with stakeholders.

3.2.2.2 Video Summary

A short video (60-90 seconds) will be prepared **to summarise the main findings of the Symposium and to highlight 10 best practices** on smoke and aerosol-free environments in Europe. This video will be prepared in collaboration with NPHO (WP2-dissemination) and project coordinators. It will be used for dissemination and communication activities.

3.2.2.3 Position paper on best practices for SAFE (Deliverable 8.2, due on August 2023, month 23)

A position paper on best practices for SAFE and evidence supporting the expansion of smoke and aerosol-free environments will be prepared after the symposium by ICO-IDIBELL with IRFMN in

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

collaboration with NPHO, CIPH, NIJZ and OKPI. Reviewed by all WP8 partners. This position paper stands for the **Deliverable 8.2** and should be prepared by month 23 of the project (August 2023).

Proposed structure of position paper (see Annex 4.6)

The purpose of a position paper is to generate support on an issue: in this instance, smoke and aerosol-free environments in Europe. It will describe the position of WP8 partners on what are 10 best practices on smoke and aerosol-free environments in Europe, what areas are not covered by existing best practices and recommendations (general and country-specific ones) for next steps in ameliorating the smoke and aerosol-free environment landscape in Europe. This position paper will incorporate supportive evidence derived from the experts' consultation and weaknesses of the authors' opinion.

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

4 Annexes

4.1 How to evaluate potential best practices

The criteria herein described are proposed for the interested researchers and experts who might consider to evaluate a potential best practice [16, 17].

Only proposals complying with the compulsory criteria ('relevance', 'effectiveness' and 'participation') will be evaluated.

"Good", "best" or even "promising" practice are all synonymous terms and indicate a public health measure that produces desirable outcomes in improving health in real-life settings and which can be adopted elsewhere [1,18].

Nonetheless, following the European assessment criteria, a best practice should show evidence of effectiveness and efficiency, possible replicability in another setting, sustainability, ethical soundness, relevance, and community and stakeholder participation [1, 16-18].

The assessment of a potential best practice should include Exclusion, Core and Qualifier criteria and their own sub-criteria, hereinafter described.

The Exclusion criteria will assess adequacy and completeness of the information provided, and specifically the following aspects (sub-criteria):

- **Relevance:** The description of the practice should include information whether it is a priority public health area, a strategy or a response to an identified problem at Local/Regional level, National level or European level, and/or put in place to support the implementation of legislation.

- **Intervention characteristics:** The choice of the target population is clearly described (scope, inclusion and exclusion group, underlying risk factors, etc. A detailed description of the methodology used is provided. SMART (Specific, Measurable, Assignable, Realistic, Time-related) objectives are defined and actions to take to reach them are clearly specified and easily measurable. The indicators to measure the planned objectives are clearly described (process, output and outcome/impact indicators). The contribution of the target population, carers, health professionals and/or other stakeholders as applicable was appropriately planned, supported and resourced. The practice includes an adequate estimation of the human resources, material and budget requirements in clear relation with committed tasks. Information on the optimization of resources for achieving the objectives. An evaluation process was designed and developed including elements of effectiveness and/or efficiency and/or equity including information affecting the different stakeholders involved. The documentation (guidelines, protocols, etc.) supporting the practice is presented properly, referenced throughout the text and easily available for relevant stakeholders (e.g. health professionals) and the target population.

- **Evidence and theory based:** Scientific excellence or other evidence (e.g. grey literature) was used and analysed in a conscious, explicit and thoughtful manner. The intervention is built on well-founded theory/principles and is evidence based. The relevant concepts are stated and explained.

- **Ethical aspects:** The practice guarantees ethical values. The practice must be respectful of the basic bioethical principles of Autonomy, Non-maleficence, Beneficence and Justice. The practice includes measures aimed at protecting the rights of individuals, according to national and European legislation. Conflicts of interest (including potential ones) are clearly stated, including measures taken. Relevant information is adequately presented to patients/persons, ensuring conscious and informed decision making.

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

The Core criteria will assess the effectiveness and efficiency of the practice as well as the equity (sub-criteria) as follows:

- **Effectiveness and Efficiency of the intervention:** The practice must work and achieve results that are measurable. The practice has been evaluated from an economic point of view. The practice includes an adequate estimation of the human resources, material and budget requirements in clear relation with committed tasks.
- **Equity:** As the reduction of inequities is a major issue in Europe, a practice that includes elements that promote equity, should be ranked higher (for example, if considering a gender perspective).

The Qualifier criteria will assess transferability of the practice to other settings/contexts, its sustainability, ability to foster collaboration among different sectors and the inclusion of stakeholders (sub-criteria), as follows:

- **Transferability:** This criterion refers to the practice capacity to being transferred to other settings or scaled up to a broader target population/geographic context. The practice uses instruments that allow for replication (e.g. a manual with a detailed activity description). The description of the practice includes all organizational elements, identifies the limits and the necessary actions that were taken to overcome legal, managerial, financial or skill-related barriers. A communication strategy and a plan to disseminate the results has been developed and implemented. The practice has already been successfully transferred. The practice shows adaptability to difficulties encountered during its implementation.
- **Sustainability:** The practice can be implemented over a long period of time with no (or minor) additional resources, adapting to social, economic and environmental context. The practice has institutional/financial support, an organizational and technological structure and stable human resources. The practice presents a financial report. The practice provides training of staff in terms of knowledge, techniques and approaches in order to sustain it. A sustainability strategy has been developed taking into account a range of contextual factors (e.g. health and social policies, innovation, cultural trends and general economy, epidemiological trends). A contingency plan has been drawn up.
- **Participation:** The structure, organization and content (also evaluation outcomes and monitoring) of the practice was defined and established together with one or more of the following: the target population and families or caregivers and more relevant stakeholders and civil society; Mechanisms facilitating participation of several agents involved in different stages of the intervention as well as their specific role, have been established and well described; Elements are included to promote empowerment of the target population (e.g. strengthen their health literacy, ensuring the right skills, knowledge and behaviour).
- **Intersectoral collaboration:** Ability of the practice to foster collaboration among the different sectors involved. The practice has been jointly implemented by several sectors. A multidisciplinary approach is supported by the agents involved. A continuum-of-care approach is encouraged through collaboration between social, health and/or other services. The practice sets up coordination arrangements involving all different stakeholders (e.g. professional associations, public institutions, educational establishment, employers).

To assess a potential best practice, the evaluation is sequential, starting with the Exclusion Criteria. The threshold score for each exclusion aspect/item/sub-criterion, is n. 3 “Good. The proposal addresses the criterion well, but a number of shortcomings are present”; being the grouping score

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

[threshold for these criteria, equivalent to 13 out 20 points \(68%\)](#). If these Exclusion Criteria are passed, then you can proceed with the Core criteria and the Qualifier criteria assessment.

In the final rating, only practices summing up 34 to 50 points (i.e. 68%) as a minimum total score are labelled as "best".

[For the details on the scoring, see next chapter "Scoring for each item and final assessment"](#).

Assessment criteria: scoring for sub-criteria and final assessment

This scoring has already been previously proposed in the assessment guidelines of the iPAAC joint action [17].

Each sub-criterion will be assessed on a scale from 0 to 5.

Justification on the score awarded may be described briefly in the corresponding section.

[Proposals achieving an overall score of 34 out 50 points \(68%\) or more will be considered "best practice"](#).

Please complete the following **summary evaluation chart**:

Criteria	Score	
1-Relevance	<input type="text"/>	} Exclusion criteria (13 out 20 points)
2-Intervention characteristics	<input type="text"/>	
3-Evidenceand/or theory based	<input type="text"/>	
4- Ethical aspects	<input type="text"/>	
5-Effectiveness, efficiency	<input type="text"/>	} Core criteria (max 10 points)
6- Equity	<input type="text"/>	
7- Transferability	<input type="text"/>	} Qualifier criteria (max 20 points)
8- Sustainability	<input type="text"/>	
9-Participation	<input type="text"/>	
10-Intersectoral collaboration	<input type="text"/>	} 34 out 50 (68%) = Best Practice
	<input type="text"/>	

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

The points, rating and the description of the scoring for each sub-criterion

0 – Proposal fails to address the criterion or cannot be assessed due to missing or incomplete information.	<input type="radio"/>
1 – Poor. The criterion is inadequately addressed or there are serious inherent weaknesses.	<input type="radio"/>
2 – Fair. The proposal broadly addresses the criterion, but there are significant weaknesses.	<input type="radio"/>
3 – Good. The proposal addresses the criterion well, but a number of shortcomings are present.	<input type="radio"/>
4 – Very good. The proposal addresses the criterion very well, but a small number of shortcomings are present.	<input type="radio"/>
5 – Excellent. The proposal successfully addresses all relevant aspects of the criterion. Any shortcomings are minor.	<input type="radio"/>

Justification/argument (max 750 characters)

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

4.2 Example of content of a best practice document

This content description is taken from a best practice implemented in Ireland (*Tobacco Free Ireland - Ireland's tobacco control policy and programme operating under the Healthy Ireland Framework for Health and Wellbeing 2013-2025, year 2017*), and fulfilling the assessment criteria above reported. In general, important items to be present in a best practice document should be:

1-Description of the practice

1.1- Was the design of the intervention appropriate and built upon relevant data, theory, context, evidence, previous practices (including pilot studies)?

2.1- Did the design thoroughly describe the practice in terms of purpose, SMART objectives, methods (i.e. recruitment, location of intervention, concrete activities, and timeframe (sequence, frequency, and duration))?

2-Target population

2.1- Was the target population/s defined on the basis of needs assessment including strengths and other characteristics?

2.2- Was the engagement of intermediaries/multipliers used to promote the meaningful participation of the target population?

3- Equity

3.1- In design, were relevant dimensions of equity adequately taken into consideration and targeted (i.e. gender, socioeconomic status, ethnicity, rural-urban area, vulnerable groups)?

3.2- During implementation, were specific actions taken to address the equity dimensions?

4- Empowerment and participation

4.1- Was the intervention designed and implemented in consultation with the target population?

4.2- Did the intervention achieve meaningful participation among the intended target population?

4.3- Did the intervention develop strengths, resources and autonomy in the target population? (i.e. assets-based, salutogenic approach)

5- Comprehensiveness of the intervention

5.1- Did the intervention have a comprehensive approach to health promotion addressing all relevant determinants, (i.e. including social determinants) and using different strategies (i.e. setting approach)?

5.2- Was an effective partnership in place during the implementation of the practice (i.e. multidisciplinary, intersector, multi-sector, and alliances with main stakeholders)?

5.3- Was the intervention aligned with a policy plan at the local, national, institutional or at international level?

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

6- Ethical considerations

6.1- Was the intervention implemented equitably (proportional to needs)?

6.2- Were potential burdens (including harm) of the intervention addressed (for the target population)?

7- Evaluation

7.1- Did the evaluation results achieve the stated goals and objectives?

7.2- Did the intervention use a defined and appropriate evaluation framework for assessing structure, processes and outcomes? (i.e. validated tools, evidences of the results of the evaluation linked to actions to reshape the implementation accordingly, efficiency assessment of the intervention (after implementation)(e.g. cost versus outcome)

7.3- Did the intervention have any information/monitoring system in place to regularly deliver data aligned with evaluation and reporting needs?

7.4-Specifically, what has been measured? Process (respondents, method, and participants' satisfaction); effects (impact/outcomes); others.

8- Sustainability

8.1- Is the continuation of the intervention ensured through institutional ownership that guarantees funding and human resources, and/or mainstreamed?

8.2- Is there a broad support for the intervention amongst those who implement it?

8.3- Is there a broad support for the intervention amongst the intended target population?

9- Governance and project management

9.1- Did the intervention include an adequate estimation of the human resources, material and budget requirements in clear relation with committed tasks?

9.2- Were sources of funding specified in regards to stability and commitment?

9.3- Were organisational structures clearly defined and described (i.e. responsibility assignments, flows of communication and work and accountabilities)?

10- Potential of scalability and transferability

10.1- Is the potential impact on the population targeted assessed (if the intervention is scaled up)?

10.2- Are there specific knowledge transfer strategies in place (evidence to practice)?

10.3- Is there an analysis of requirements for eventual scaling up such as foreseen barriers and facilitators, available? (i.e. resources, organisational commitment, ...)

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

4.3 **Correlation table:** WP8 consultation questions related to WP4 assessment criteria & Irish structure of a best practice (CHRODIS)

Structure of a best practice (e.g.Ireland)	WP4 Assessment criteria	WP8 Consultation questions
1- Description of the practice	Intervention characteristics	<i>B1,B2,B3, C1, C2, D1, J1, K1</i>
2- Target population	Evidence and/or theory based	<i>G2</i>
3- Equity	Equity	<i>Q1</i>
4- Ethical considerations	Ethical aspects	
5- Empowerment and participation	Participation	<i>H1</i>
6- Comprehensiveness of the intervention	Relevance	<i>B4,B5, B6, E1, F1, F2, F3, F4, G1</i>
7- Evaluation	Effectiveness, efficiency	<i>L1, M1, N1</i>
8- Sustainability	Sustainability	<i>P1</i>
9- Governance and project management	Intersectoral collaboration	<i>E2</i>
10- Potential of scalability and transferability	Transferability	<i>O1, O2</i>

4.4 Proposed structure for a **weight of evidence paper on barriers and opportunities to support expansion of SAFE**

- 1- Definition of weight of evidence
- 2- Assembling the evidence into lines of evidence of similar type
- 3- Weighing the evidence
- 4- Integrating the evidence
- 5- References from literature review

Reliability, relevance and consistency are three basic considerations for weighing evidence.

Tips for writing a Weight of Evidence

- A proper weight of evidence approach includes, as a minimum, two separate study records for the property - also when using textbook values. One single value from a secondary data source is not sufficient as a weight of evidence.
- Choose an expert who has expertise in the relevant properties and study methods. This expert will need to assess the reliability, relevance, adequacy of the available data and judge whether the combined evidence is enough to draw a conclusion about the property or effect of the substance.
- Make this expert judgement transparent and understandable by documenting all information used, all steps carried out in the evaluation process and all conclusions drawn.
- Provide a scientific justification and documentation of the underlying evidence.
- Provide all information that is relevant in your dossier. ECHA or the other authorities do not have the same detailed knowledge about your substance as you.

**Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for
smoke and aerosol-free environments in Europe**

4.5 Web based repository of best practices on SAFE (example of structure)

Title: Smoke Free Homes. eg.
B1. Title/Name of the practice. Please indicate the title/name of the practice (in original language and English translation, if the original language is not English). Please do not use acronyms.
1- Description of the practice = Intervention characteristics
<i>Questions of WP8 questionnaire: B2,B3, C1,C2, D1, J1, K1 enforcement</i>
1.1- Was the design of the intervention appropriate and built upon relevant data, theory, context, evidence, previous practices (including pilot studies)?
C1. Please summarize this best practice. Please briefly describe the best practice and its main characteristics. For example, was it an intervention on general population or a specific population group? Or was it a policy or about a novel change on organisational/managerial models?
C2. Possible source of information where the practice is described: Please provide more information on the practice such as link to a website, link to any available documents (reports, articles).
1.2- Did the design thoroughly describe the practice in terms of purpose, SMART objectives, methods (i.e. recruitment, location of intervention, concrete activities, and timeframe (sequence, frequency, and duration))?
B2. Type of practice. Please select all that apply for this practice
B3. Which is the current phase of the best practice?
D1. Duration of the practice
D1 bis. Please provide start date. If you don't know the exact date please refer to the closest month and year and choose 15 as day.
J1. What methods are/were used in the practice? Methods should be explicitly linked to the objectives. They should describe how the (specific) objectives were reached, what were the essential tasks performed, e.g. intervention protocol, survey methods, panel of experts, training development, etc. Please provide sources of information (online references)
J1 bis. If relevant, please upload possible documentation.
K1. Enforcement of the practice. Please describe if the practice has been enforced. Please provide information on how the enforcement was set and who/which entity was in charge of the supervision and controlling of its compliance.
2- Evidence and/or theory based = Target population
<i>Question: G2</i>
2.1- Was the target population/s defined on the basis of needs assessment including strengths and other characteristics?
G2. If any, which is the specific target population? The target population are persons or entities who are expected to be/were positively affected by the action. Please mark all that apply. If there is no specific target population, tick "general population".
2.2- Was the engagement of intermediaries/multipliers used to promote the meaningful participation of the target population?

3- Equity = Equity

Questions: Q1

3.1- In design, were relevant dimensions of equity adequately taken into consideration and targeted (i.e. gender, socioeconomic status, ethnicity, rural-urban area, vulnerable groups)?

Q1. What are the equity and ethical principles underpinning the practice? Please provide information about e.g. ethical review and oversight, ethical training for staff and stakeholders and of the strategy for managing adverse events. When individual data is collected, please also indicate if individual's rights have been protected (according to national and European legislation). Please describe how absence of conflicts of interest is taken into account regarding the activities.

3.2- During implementation, were specific actions taken to address the equity dimensions?

4- Ethical aspects = Ethical considerations

Question Q1

4.1- Was the intervention implemented equitably (proportional to needs)?

Q1. What are the equity and ethical principles underpinning the practice? Please provide information about e.g. ethical review and oversight, ethical training for staff and stakeholders and of the strategy for managing adverse events. When individual data is collected, please also indicate if individual's rights have been protected (according to national and European legislation). Please describe how absence of conflicts of interest is taken into account regarding the activities

4.2- Were potential burdens (including harm) of the intervention addressed (for the target population)?

5- Participation = Empowerment and participation

Questions: H1

5.1- Was the intervention designed and implemented in consultation with the target population?

H1. Have the target population and other stakeholders been involved in the adoption/development, implementation or evaluation of the practice? Please, specify in which phase (development, implementation or evaluation) they have been involved in.

5.2- Did the intervention achieve meaningful participation among the intended target population?

5.3- Did the intervention develop strengths, resources and autonomy in the target population? (i.e. assets-based, salutogenic approach)

6- Relevance = Comprehensiveness of the intervention

Questions B4, B5, B6, E1, F1, F2, F3, F4, G1, K1

6.1- Did the intervention have a comprehensive approach to health promotion addressing all relevant determinants, (i.e. including social determinants) and using different strategies (i.e. setting approach)?

B4. Who has the responsibility of the practice? Please indicate which is/are the entity responsible/promoter entity(ies) of this initiative. Please select all that apply.

6.2- Was an effective partnership in place during the implementation of the practice (i.e. multidisciplinary, intersector, multi-sector, and alliances with main stakeholders)?

F3. Does the best practice focus on public or private settings?

**Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for
smoke and aerosol-free environments in Europe**

F4. What are the objectives of the practice? Please select all that apply.
6.3- Was the intervention aligned with a policy plan at the local, national, institutional or at international level?
B5. Name of the entity(ies) in national language and English and acronym. Please describe/name the responsible/ promoters of this best practice.
B6. Please specify also the responsibility of the entity(ies):
E1. What is the geographical scope of the practice?
F1. What is the justification (need or problem) and context (existing evidence and theory) for developing this practice?
F2. What is the overall goal of the practice? The overall goal is the general indication of the practice's contribution to society in terms of its longer-term benefits.
G1. Target settings. Please select all that apply.
7- Effectiveness, efficiency = Evaluation
<i>Questions: L1, M1, N1</i>
7.1- Did the evaluation results achieve the stated goals and objectives?
L1. What are the main outcomes of the practice? Please describe the most important quantitative and/or qualitative obtained results and main lessons learned. Please clearly and precisely summarize the main outcomes regarding achieved improvements, impact and/or eventual negative effects, and whether or not the desired outputs and outcomes of the practice changed during the implementation of the practice. The outcomes are the changes that have occurred because of the practice i.e. when the specific objectives/overall goal are reached.
M1. What indicators are used in the monitoring of the process and outcome of the practice? Indicators are variables measuring the performance of an action and the level to which the set objectives are reached. Process, output and outcome/impact should be reported.
N1. Has the practice been formally evaluated?
N1 bis. If you answered "Yes" or "Not yet": Please specify the organizations that conducted the evaluation. Please explain how the evaluation was carried out (both process and outcome). Please also describe the planned evaluation methods if the evaluation is agreed and foreseen. Please also describe if any economic evaluation took/will take place.
7.2- Did the intervention use a defined and appropriate evaluation framework for assessing structure, processes and outcomes? (i.e. validated tools, evidences of the results of the evaluation linked to actions to reshape the implementation accordingly, efficiency assessment of the intervention (after implementation)(e.g. cost versus outcome)
7.3- Did the intervention have any information/monitoring system in place to regularly deliver data aligned with evaluation and reporting needs?
7.4- Specifically, what has been measured? Process (respondents, method, and participants' satisfaction); effects (impact/outcomes); others.

8- Sustainability

Questions: P1

8.1- Is the continuation of the intervention ensured through institutional ownership that guarantees funding and human resources, and/or mainstreamed?

P1. Sustainability. Please select all that apply.

8.2- Is there a broad support for the intervention amongst those who implement it?

8.3- Is there a broad support for the intervention amongst the intended target population?

9- Intersectoral collaboration = Governance and project management

Questions: E2

9.1- Did the intervention include an adequate estimation of the human resources, material and budget requirements in clear relation with committed tasks?

E2. How was the practice funded?

9.2- Were sources of funding specified in regards to stability and commitment?

9.3- Were organisational structures clearly defined and described (i.e. responsibility assignments, flows of communication and work and accountabilities)?

10- Transferability = Potential of scalability and transferability

Questions: O1, O2

10.1- Is the potential impact on the population targeted assessed (if the intervention is scaled up)?

O1. Level of transferability and/or scalability. Please select the most suitable option from the following.

10.2- Are there specific knowledge transfer strategies in place (evidence to practice)?

10.3- Is there an analysis of requirements for eventual scaling up such as foreseen barriers and facilitators, available? (i.e. resources, organisational commitment, ...)

O2. Have any barriers or challenges been identified in the transfer or scaling up?

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

4.6 Proposed structure for a position paper on best practices for the expansion of SAFE

- 1- Summary
- 2- Endorsements
- 3- Background
- 4- Objectives of the paper
- 5- Relevance and current status
- 6- Position proposal (e.g: The EU and MS should **enforce expansion of SFE in all outdoor terraces of bars and restaurants**)
 - a. Arguments in favour based on facts, data and evidence with links
 - b. Counter-arguments to be considered and reasons why the arguments are still valid
- 7- Conclusions
- 8- References from literature review

Ten Tips for Writing a Strong Position Paper

- Select a timely, relevant topic with two clear opposing sides.
- Conduct thorough preliminary research, collecting evidence supporting arguments for and against your position.
- Identify your intended audience. You should tailor your tone depending on who the paper is written for (the public, other scientists, policymakers, etc.).
- Clearly state your position on the topic.
- List and refute the counter-arguments to your position.
- Include supporting data and evidence to back up your argument.
- Properly attribute your sources using correct citation.
- Keep it simple! Position papers don't need to go into excessive detail. Present your points clearly and briefly.
- Each paragraph in the paper should discuss a single idea.
- Have someone proofread your paper to ensure it reads well and looks professional.

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

4.7 Other background information of one country as example (Spain)

Country specific findings from the survey done by DG Santé exploring legislation for traditional tobacco, e-cig and heated tobacco products (HTP) should also be cross checked with the information provided by experts and key informants of the consultation. See below Tables of findings for Spain:

		Compliance level						
Smoke-free environments		"Traditional" tobacco products for smoking	E-cigarettes	Heated tobacco products	Is there a plan to extend the ban(s) in the future or introduce additional ones?	"Traditional" tobacco products for smoking	E-cigarettes	Heated tobacco products
General workplaces	Indoor workplaces	Full ban	Partial ban	Full ban	Yes - There is a plan to extend the cover of the related products (ecigs and herbal products) to the tobacco products	High	High	High
	Outdoor workplaces	Partial ban	Partial ban	Partial ban	No	High	High	High
Enclosed public spaces (e.g. town hall,		Full ban	Full ban	Full ban	No	High	High	High
Health care facilities	Health care facilities, <u>indoors</u>	Full ban	Full ban	Full ban	No	High	High	High
	Health care facilities, <u>outdoors</u> (e.g. outside, but on facilities' grounds)	Full ban	Full ban	Full ban	No	Moderate	Moderate	Moderate
Residential care facilities		Partial ban	Partial ban	Partial ban	No	High	High	High
Educational facilities	Schools (e.g. primary and secondary), <u>indoors</u>	Full ban	Full ban	Full ban	No	High	High	High
	Adult learning premises (e.g. universities and vocational learning centres), <u>indoors</u>	Full ban	Full ban	Full ban	No	High	High	High
	Schools (e.g. primary and secondary), <u>outdoors</u> (e.g. terraces, garden seating)	Full ban	Full ban	Full ban	No	High	High	High
	Adult learning premises (e.g. universities and vocational learning centres), <u>outdoors</u> (e.g. outside but on facilities' grounds)	Partial ban	Partial ban	Partial ban	No	High	High	High
Public transports		Partial ban	Partial ban	Partial ban	Yes - We will ban the use of all this products even outdoors	High	High	High
Prisons		Partial ban	Partial ban	Partial ban	No	High	High	High
Hotels and accommodation	Hotels	Partial ban	No ban	Partial ban	No	High	High	High
	Private home stays	Partial ban	No ban	Partial ban	No	High	High	High
Restaurants and bars	Restaurants and eating establishments, <u>indoors</u>	Full ban	No ban	Full ban	Yes - We plan ban ecigs and herbal products	High	N/A	High
	Bars and drinking establishments, <u>indoors</u>	Full ban	No ban	Full ban	Yes - We plan ban ecigs and herbal products	High	N/A	High
	Restaurants and eating establishments, <u>outdoors</u> (e.g. terraces, garden seating)	Partial ban	No ban	Partial ban	Yes - We plan ban all tobacco and related products	Moderate	N/A	High
	Bars and drinking establishments, <u>outdoors</u> (e.g. terraces, garden seating)	Partial ban	No ban	Partial ban	Yes - We plan ban all tobacco and related products	Moderate	N/A	High
Outdoor public spaces	Playgrounds or other spaces frequented by children and young	Full ban	Full ban	Full ban	No	High	High	High
	Public parks	No ban	No ban	Full ban	No	N/A	N/A	N/A
	Public beaches	No ban	No ban	No ban	Yes - We will explore a legal ban in order to go further of this initiative	N/A	N/A	N/A
Private areas	Cars	No ban	No ban	No ban	Yes - We plan the ban of tobacco products when there is minors and pregnant	N/A	N/A	N/A
	Homes	No ban	No ban	No ban	No	N/A	N/A	N/A

**Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for
smoke and aerosol-free environments in Europe**

Gaps in the national legislation (Spain)	
Is there a plan in your country to include other environments (not covered in Section 3.3) in smoke-free environment legislation?	<i>No, our plans to extend the smoke free environments are already included at Section 3.3</i>
Is there a plan in your country to include other products in smoke-free environment legislation?	<i>0 - Our plan is establishing the same requirements to other related products as ecigs and herbal products.</i>

Monitoring and enforcement	
Does national legislation on smoke-free environments or other measures provide for a mechanism and/or infrastructure to ensure monitoring/enforcement?	<i>Yes, monitoring and enforcement is done by the autonomous regions in coordination with the Spanish Health Ministry</i>
Details on the bod(ies) responsible for monitoring/enforcement	<i>Name: Multiple names Level of operation (national, regional, local): All levels Description of responsibilities: Redacting acts of infractions and other administrative tasks. Additional information:</i>
How compliance is monitored with the existing legislation on smoke-free environments	<i>Monitoring and enforcement is done by different civil servants with different responsibilities, from visits to place done by inspectors and police forces and giving course to the administrative process done at the health services of the Central and regional governments.</i>
How potential breaches are investigated	<i>Data about opened administrative process are compiled by the Spanish Health Ministry with the collaboration of the autonomous regions.</i>
Whether there is a complaint system	<i>No, but they can use the general police telephone number.</i>
Whether the complaint system includes an obligation to investigate upon receipt of a complaint	<i>0</i>

**Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for
smoke and aerosol-free environments in Europe**

<i>Whether national law enables any interested person or non-governmental organisation to initiate legal action against illegal smoking in smoke-free environments</i>	Yes
<i>Whether there are sufficient financial resources available for enforcement</i>	Yes
<i>Whether there are sufficient human resources available for enforcement</i>	Yes
<i>How engaged civil society organisations have been in supporting the monitoring and effective enforcement of the smoke-free bans</i>	Very engaged
<i>Civil society organisations' role/actions</i>	We collaborate with different stakeholders as Non smokers rights associations and consumer organisations. They are not part of official controls but they it collaboration is included in our list of partners of enforcement available at this site and helping citizens to defend its rights: https://www.mscbs.gob.es/ciudadanos/proteccionSalud/tabaco/Como_Denunciar.htm
<i>Protecting children and adolescents</i>	
<i>Whether there are strategies and/or other measures to reduce exposure to second-hand smoke of children and adolescents</i>	Yes
<i>Details on the content of these strategies/measures</i>	Measures to reduce exposure to are done mostly by autonomous regions, the Ministry aired a mass media campaign aimed at youth last 2007, available at this site: https://www.mscbs.gob.es/ciudadanos/proteccionSalud/tabaco/Campana2017/campana2017_Dejar_de_fumar.htm
<i>Whether youth / child exposure to second-hand smoke is monitored</i>	Yes
<i>Details on how youth / child exposure to second-hand smoke is monitored</i>	Survey specifically aimed at children. ESTUDES survey: https://pnsd.sanidad.gob.es/profesionales/sistemasInformacion/sistemaInformacion/pdf/ESTUDES_2018-19_Informe.pdf

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

5 Glossary of terms

- Expert/Key informant: a person with special knowledge, skill or training in a field, which makes them an expert source from which to obtain information.
- Best practice: is a relevant policy or intervention implemented in a real life setting and which has been favourable assessed in terms of adequacy (ethics and evidence) and equity as well as effectiveness and efficiency related to process and outcomes.
- Potential Best practice: an intervention, policy, practice or initiative in Tobacco control implemented at national, regional or local level and not recognized as best practice by an official European body, but which would be susceptible to being if it fulfilled the criteria of a European Best Practice.

6 Abbreviations

BPs	Best practices
CIPH	Croatian Institute of Public Health
CNPT	Comité Nacional de Prevención del Tabaquismo
DSTA	Danish Safety Technology Authority
ECHA	European Chemical Agency
ECToH	European Cancer and Tobacco or Health
ENSP	European Network for Smoking Prevention
ENDs	electronic nicotine delivery devices
EU	European Union
FCTC	Framework Convention on Tobacco Control
HDIR	Helsedirektoratet
ICO	Institut Català d'Oncologia
IDIBELL	Fundacio Institut D'investigacio Biomedica De Bellvitge
IRFMN	Istituto Di Ricerche Farmacologiche Mario Negri
JATC	Joint Action on Tobacco Control
MS	Member States
NIJZ	Nacionalni inštitut za javno zdravje
NPHO	National Public Health Organization
NTAKD	Narkotiku Tabako Ir Alkoholio Kontroles Departamentas
OKPI	Országos Korányi Pulmonológiai Intézet (National Korányi Pulmonology Institute)
SAFE	Smoke and Aerosol Free Environments
SHA	Second hand aerosol
SHS	Second hand smoke
SMART	Specific, Measureable, Achievable, Realistic and Timely
TAD	Tobacco advertising directive
TPD	Tobacco product directive
UIC	Universitat internacional de Catalunya
WHO	World Health Organization

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

WP Work package
XQNS Sociedad Vasco Navarra De Prevencion Del Tabaquismo (Porque nosotros sí)

7 References

- Amalia, B., Fu, M., Feliu, A., Tigova, O., Fayokun, R., Mauer-Stender, K., & Fernández, E. (2022). Regulation of Electronic Cigarette Use in Public and Private Areas in 48 Countries Within the WHO European Region: A Survey to In-country Informants. *Journal of Epidemiology*, *32*(3), 131–138. <https://doi.org/10.2188/jea.JE20200332>.
- Amalia, B., Liu, X., Lugo, A., Fu, M., Odone, A., Van Den Brandt, P. A., Semple, S., Clancy, L., Soriano, J. B., Fernández, E., & Gallus, S. (2021). Exposure to secondhand aerosol of electronic cigarettes in indoor settings in 12 European countries: data from the TackSHS survey. *Tobacco Control*, *30*(1), 49–56. <https://doi.org/10.1136/tobaccocontrol-2019-055376>.
- Ashford, K.B., Hahn, E., Hall, L., Rayens, M.K., Noland, M., & Ferguson, J.E. (2010). The effects of prenatal secondhand smoke exposure on preterm birth and neonatal outcomes. *J Obstet Gynecol Neonatal Nurs*. Sep-Oct;39(5):525-35. doi: 10.1111/j.1552-6909.2010.01169.x.
- Barnoya, J., & Glantz, S. A. (2005). Cardiovascular effects of secondhand smoke: nearly as large as smoking. *Circulation*, *111*(20), 2684-2698.
- Bird Y, Kashaniamin L, Nwankwo C, Moraros J. Impact and Effectiveness of Legislative Smoking Bans and Anti-Tobacco Media Campaigns in Reducing Smoking among Women in the US: A Systematic Review and Meta-Analysis. *Healthcare (Basel)*. 2020 Jan 16;8(1):20. doi: 10.3390/healthcare8010020. PMID: 31963154;PMCID: PMC7151169.
- Cancelada L, Sleiman M, Tang X, Russell ML, Montesinos VN, Litter MI, Gundel LA, Destailats H. Heated Tobacco Products: Volatile Emissions and Their Predicted Impact on Indoor Air Quality. *Environ Sci Technol*. 2019 Jul 2;53(13):7866-7876. doi: 10.1021/acs.est.9b02544. Epub 2019 Jun 17. PMID: 31150216.
- Carreras, G., Lachi, A., Cortini, B., Gallus, S., López, M. J., López-Nicolás, Á., Soriano, J. B., Fernandez, E., Tigova, O., Gorini, G., Castellano, Y., Fu, M., Ballbè, M., Amalia, B., López, M. J., Continente, X., Arechavala, T., Henderson, E., Lugo, A., ... Castillo, E. G. (2021). Burden of disease from second-hand tobacco smoke exposure at home among adults from European Union countries in 2017: an analysis using a review of recent meta-analyses. *Preventive Medicine*, *145*, 106412. <https://doi.org/10.1016/J.YPMED.2020.106412>.
- Carreras, G., Lugo, A., Gallus, S., Cortini, B., Fernández, E., López, M. J., Soriano, J. B., López-Nicolás, A., Semple, S., Gorini, G., Castellano, Y., Fu, M., Ballbè, M., Amalia, B., Tigova, O., Continente, X., Arechavala, T., Henderson, E., Liu, X., ... Pérez, P. (2019). Burden of disease attributable to second-hand smoke exposure: A systematic review. *Preventive Medicine*, *129*, 105833. <https://doi.org/10.1016/J.YPMED.2019.105833>.
- Faber, T., Kumar, A., Mackenbach, J. P., Millett, C., Basu, S., Sheikh, A., & Been, J. V. (2017). Effect of tobacco control policies on perinatal and child health: a systematic review and meta-analysis. *The Lancet Public Health*, *2*(9), e420–e437. [https://doi.org/10.1016/S2468-2667\(17\)30144-5](https://doi.org/10.1016/S2468-2667(17)30144-5).
- Fernández, E., Ballbè, M., Sureda, X., Fu, M., Saltó, E., & Martínez-Sánchez, J. M. (2015). Particulate

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

Matter from Electronic Cigarettes and Conventional Cigarettes: a Systematic Review and Observational Study. *Current Environmental Health Reports*, 2(4), 423–429. <https://doi.org/10.1007/s40572-015-0072-x>.

Fu, M., Castellano, Y., Tigova, O., Kyriakos, C. N., Fong, G. T., Mons, U., Zatoński, W. A., Agar, T. K., Quah, A. C. K., Trofor, A. C., Demjén, T., Przewoźniak, K., Tountas, Y., Vardavas, C. I., & Fernández, E. (2018). Prevalence and correlates of different smoking bans in homes and cars among smokers in six countries of the EUREST-PLUS ITC Europe Surveys. *Tobacco Induced Diseases*, 16, 1–13. <https://doi.org/10.18332/tid/94827>.

Gram, I. T., Wiik, A. B., Lund, E., Licaj, I., & Braaten, T. (2021). Never-smokers and the fraction of breast cancer attributable to second-hand smoke from parents during childhood: The Norwegian Women and Cancer Study 1991-2018. *International Journal of Epidemiology*, 50(6), 1927–1935. <https://doi.org/10.1093/ije/dyab153>.

Gallus, S., & Fernandez, E. (2022). Reaping what you sow: England's drastic reduction in childhood secondhand smoke exposure in two decades. *The Lancet Regional Health - Europe*, 15, 100334. <https://doi.org/10.1016/j.lanepe.2022.100334>.

Global Burden of Disease. GBD 2019. <https://www.healthdata.org/gbd/2019>.

Haggart, K., Robertson, L., Blank, M. L., Popova, L., & Hoek, J. (2021). It's Just Steam: A qualitative analysis of New Zealand ENDS users' perceptions of secondhand aerosol. *Tobacco Control*, 30(1), 30–35. <https://doi.org/10.1136/tobaccocontrol-2019-055368>.

Hoyt, A.T., Mark A Canfield, M.A., Romitti, P.A., Botto, L.D., Anderka, M.T., Krikov, S.V., & Feldkamp, M.L. (2018). Does Maternal Exposure to Secondhand Tobacco Smoke During Pregnancy Increase the Risk for Preterm or Small-for-Gestational Age Birth? *Matern Child Health J*. Oct;22(10):1418-1429. doi: 10.1007/s10995-018-2522-1.

Huang, J., Deng, Y., Tin, M. S., Lok, V., Ngai, C. H., Zhang, L., Lucero-Prisno, D. E., Xu, W., Zheng, Z. J., Elcarte, E., Withers, M., & Wong, M. C. S. (2022). Distribution, Risk Factors, and Temporal Trends for Lung Cancer Incidence and Mortality: A Global Analysis. *Chest*, 161(4), 1101–1111. <https://doi.org/10.1016/j.chest.2021.12.655>.

Kim, A. S., Ko, H. J., Kwon, J. H., & Lee, J. M. (2018). Exposure to secondhand smoke and risk of cancer in never smokers: A meta-analysis of epidemiologic studies. *International Journal of Environmental Research and Public Health*, 15(9). <https://doi.org/10.3390/ijerph15091981>

Li L, Lin Y, Xia T, Zhu Y. Effects of Electronic Cigarettes on Indoor Air Quality and Health. *Annu Rev Public Health*. 2020 Apr 2;41:363-380. doi: 10.1146/annurev-publhealth-040119-094043. Epub 2020 Jan 7. PMID: 31910714; PMCID: PMC7346849.

Mahabee-Gittens, E.M., Yolton, K., & Merianos, A.L. (2021). Prevalence of Mental Health and Neurodevelopmental Conditions in U.S. Children with Tobacco Smoke Exposure *J Pediatr Health Care*. Jan-Feb;35(1):32-41. doi: 10.1016/j.pedhc.2020.07.006. Epub 2020 Aug 26.

Mons, U., Nagelhout, G. E., Allwright, S., Guignard, R., Van Den Putte, B., Willemsen, M. C., Fong, G. T., Brenner, H., Pötschke-Langer, M., & Breitling, L. P. (n.d.). *Impact of national smoke-free legislation on home smoking bans: findings from the International Tobacco Control Policy Evaluation Project Europe Surveys*. <https://doi.org/10.1136/tobaccocontrol-2011-050131>.

Öberg, M., Jaakkola, M. S., Woodward, A., Peruga, A., & Prüss-Ustün, A. (2011). Worldwide burden of

Protocol for the JATC-2 WP8 consultation on barriers and opportunities, and Best Practices, for smoke and aerosol-free environments in Europe

- disease from exposure to second-hand smoke: A retrospective analysis of data from 192 countries. *The Lancet*, 377(9760), 139–146. [https://doi.org/10.1016/S0140-6736\(10\)61388-8](https://doi.org/10.1016/S0140-6736(10)61388-8).
- Öberg, M., Woodward, A., Jaakkola, M. S., Peruga, A., & Prüss-Ustün, A. (2010). Global estimate of the burden of disease from second-hand smoke. *World Health Organization*, 81.
- Schiavone, S., Anderson, C., Mons, U., & Winkler, V. (2022). Prevalence of second-hand tobacco smoke in relation to smoke-free legislation in the European Union. *Preventive Medicine*, 154, 106868. <https://doi.org/10.1016/J.YPMED.2021.106868>
- Schober W, Fembacher L, Frenzen A, Fromme H. Passive exposure to pollutants from conventional cigarettes and new electronic smoking devices (IQOS, e-cigarette) in passenger cars. *Int J Hyg Environ Health*. 2019 Apr;222(3):486-493. doi: 10.1016/j.ijheh.2019.01.003. Epub 2019 Jan 23. PMID: 30685192.
- Semple, S., Dobson, R., O'Donnell, R., Zainal Abidin, E., Tigova, O., Okello, G., & Fernández, E. (2022). Smoke-free spaces: a decade of progress, a need for more? *Tobacco Control*, 31(2), 250–256. <https://doi.org/10.1136/tobaccocontrol-2021-056556>.
- Simons, E., To, T., Moineddin, R., Stieb, D., & Dell, S. D. (2014). Maternal Second-Hand Smoke Exposure in Pregnancy Is Associated With Childhood Asthma Development. *The Journal of Allergy and Clinical Immunology: In Practice*, 2(2), 201-207.e3. <https://doi.org/10.1016/J.JAIP.2013.11.014>.
- Taha, F., & Goodwin, R. D. (2014). Secondhand smoke exposure across the life course and the risk of adult-onset depression and anxiety disorder. *Journal of Affective Disorders*, 168, 367–372. <https://doi.org/10.1016/j.jad.2014.07.014>
- Tandon, M., Lessov-Schlaggar, C.N., Rebecca Tillman, R., Hovell, M.F., & Luby J. (2014). Secondhand Smoke Exposure and Severity of Attention-Deficit/Hyperactivity Disorder in Preschoolers: A Pilot Investigation. *Scand J Child Adolesc Psychiatr Psychol*. 2(1):37-40. doi: 10.21307/sjcapp-2014-006.
- Tattan-Birch, H., & Jarvis, M. J. (2022). Children's exposure to second-hand smoke 10 years on from smoke-free legislation in England: Cotinine data from the Health Survey for England 1998-2018. *The Lancet Regional Health - Europe*, 15, 100315. <https://doi.org/10.1016/j.lanep.2022.100315>.
- Tobacco Free Ireland - Ireland's tobacco control policy and programme operating under the Healthy Ireland Framework for Health and Wellbeing 2013-2025. CHRODIS-JA.Addressing chronic diseases and healthy ageing accross the life cycle. www.chrodis.eu, platform.chrodis.eu.
- Wagijo, M.A., Aziz Sheikh, A., Liesbeth Duijts, L., & Been, J.V. (2017). Reducing tobacco smoking and smoke exposure to prevent preterm birth and its complications. *Paediatr Respir Rev*. Mar;22:3-10. doi: 10.1016/j.prrv.2015.09.002. Epub 2015 Sep 21.
- Wendy, M., Sung, H.M., Yanling Shi, Y. (2013) Attention deficit hyperactivity disorder among children exposed to secondhand smoke: a logistic regression analysis of secondary data. *Int J Nurs Stud*. Jun;50(6):797-806. doi: 10.1016/j.ijnurstu.2012.10.002. Epub 2012 Oct 26.
- Wipfli, H. L., & Samet, J. M. (2011). Second-hand smoke's worldwide disease toll. *The Lancet*, 377(9760), 101–102. [https://doi.org/10.1016/S0140-6736\(10\)61922-8](https://doi.org/10.1016/S0140-6736(10)61922-8).
- WHO 2021 WHO study group on tobacco product regulation / Report on the scientific basis of tobacco product regulation: eighth report of a WHO study group.