European Commission

CALL FOR EVIDENCE FOR AN EVALUATION	
TITLE OF THE EVALUATION	Evaluation of the legislative framework for tobacco control
LEAD DG – RESPONSIBLE UNIT	DG SANTE, B2
INDICATIVE TIMETABLE (PLANNED START DATE AND COMPLETION DATE)	Q1-2022 to Q2-2023
ADDITIONAL INFORMATION	EU Tobacco Control website Evaluation of legislative framework for tobacco control website

This document is for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the document, including its timing, are subject to change.

Political context, purpose and scope of the evaluation

Political context

Today, tobacco consumption is the single largest avoidable health risk, and still the most significant cause of premature death in the EU, responsible for nearly 700 000 deaths every year. Around 50% of smokers die prematurely (on average 14 years earlier than non-smokers). At the same time, tobacco consumption, driven by socio-economic inequalities, among other factors, continues to be the leading cause of preventable cancer, with 27% of all cancers attributed to tobacco use. By eliminating tobacco use, 9 out of every 10 cases of lung cancer could be avoided[1].

This evaluation comes at a time of renewed impetus for tobacco control actions in the EU, brought about by Europe's Beating Cancer Plan. The plan calls for the creation of a 'Tobacco-Free Generation', where less than 5% of the population uses tobacco by 2040, compared to around 25% today.

The legislative framework for tobacco control[2] under evaluation (including the Tobacco Products Directive 2014/40/EU, Tobacco Advertising Directive 2003/33/EC and other related tobacco control policies across the EU) aims to safeguard public health and protect young people from tobacco-related harm. In recent years, tobacco and related products have changed considerably, representing a major challenge. A big variety of emerging products (e.g. heated tobacco products, nicotine-free e-cigarettes and nicotine pouches) has entered the EU market, new virtual environments (including web shops and information society services such as social media) have surfaced and new public health interference strategies of tobacco and related industries have emerged.

Purpose and scope

A rapid rise in emerging products, new technologies and markets under constant development, highlight the need to keep up with these changes and to assess the functioning of the legislation in relation to products' toxicity, addiction and attractiveness, together with appraising how they are being presented and promoted to the public.

Product regulation and regulation of advertising, promotion and sponsorship are two of the key pillars of tobacco control policies, together with other initiatives such as taxation, smoke-free environments and cessation measures. This evaluation will help understand to what extent the legislative framework has functioned in the past, whether it achieved its objectives and how it can support future commitments.

Already in May 2008, the Report on the implementation of the Tobacco Advertising Directive indicated that tobacco promotion had intensified in local merchandising and at points of sale and that the virtual environment was the big challenge. Internet use, the creation of new virtual environments and the use of social media have also expanded since then. More recently, the Report on the application of the Tobacco Products Directive, published in May 2021, suggested that with a more challenging product landscape and evolving use patterns, the scope of the directive may not have managed to keep up with all emerging tobacco and related products, nor provided flexibility to address rapid product developments.

This evaluation will take into consideration the entire time period, from the date of the implementation of both directives until the present. It will encompass all EU Member States and all pertinent implementing/delegated acts. The evaluation will also address both directives in the broader context of other related tobacco control policies implemented at EU and national level, such as sales arrangements and policies implemented in line with specific Articles[3] of the WHO Framework Convention on Tobacco Control. The evaluation will draw on the available information on national legislative instruments on tobacco control, among other sources.

[1] Europe's Beating Cancer Plan

[2] At EU, national and international level, specifically excluding the Tobacco Taxation Directive 2011/64/EU and the Council Recommendation on Smoke-Free Environments 2003/54/EC, which are following separate processes.

[3] Namely: Article 12 (Education, communication, training and public awareness), Article 13 (Tobacco advertising, promotion and sponsorship), Article 14 (Demand reduction measures concerning tobacco dependence), Article 18 (Protection of the environment and the health of persons) and Article 20 (Research, surveillance and exchange of information).

B. Better regulation

Consultation strategy

The consultation for this evaluation will focus on three main activities:

- Call for evidence;
- Public consultation of 12 weeks, in all official EU languages;
- Targeted stakeholder consultations.

All relevant input and evidence will be taken into account, including data sources, data about costs and societal impact, as well as data on the potential benefits and detriments of the initiative. The outcome of those consultation activities will complement evidence obtained from other sources, such as a desk review of existing articles in scholarly journals, grey literature, outcomes of relevant EU- and/or Member State-funded projects, non-commercially and/or commercially available databases.

The Commission may use additional *ad hoc* consultation methods such us conferences, workshops and events, as well as Commission expert groups. Responses to the call for evidence and the public consultation will be accepted in any of the 24 official EU languages. A synopsis report covering all formal consultation activities (the call for evidence, the public and targeted consultations, conferences, workshops, etc.) will be published on the 'Have Your Say' web portal. The results of the consultation will be published on the 'Evaluation of legislative framework for tobacco control' webpage, which will also provide information on upcoming consultation activities and events.

Why are we consulting?

The multiple consultation activities aim to ensure that the policy work is carried out in an open and transparent manner, informed by the best available evidence and backed by the comprehensive involvement of stakeholders. The consultation's objectives are:

- to help identify knowledge gaps;
- to identify new sources of evidence and increase the evidence base;
- to collect qualitative and quantitative data to support policy-making (e.g. socio-economic determinants);
- to gather information on implementation challenges, barriers, promotors and facilitators;
- to ascertain evidence-based practices;
- to assess what worked (less) well and to see where there is room for improvement in the future;
- to better understand the different views, problem perceptions and arguments of the various stakeholder groups.

To that end, knowledge and qualitative/quantitative data will be gathered on the implementation of the Tobacco Products Directive, the Tobacco Advertising Directive and other related tobacco control policies implemented across the EU, as well as evidence on regulated products and information about emerging challenges.

Target audience

Contributions from both the general public (e.g. non-experts and experts responding in an individual capacity) and organisations are welcome. Nonetheless, the following tobacco control stakeholders are targeted:

- Representatives of national public authorities, public health and internal market regulators, law enforcement and customs bodies;
- EU decentralised agencies and other bodies;
- International, transnational, national, regional and local municipal structures and other public authorities or organisations active in tobacco control;
- Scientific experts, academic and research institutions and public health communities;
- Standard-setting bodies and organisations, such as the International Organization for Standardization and CEN, the European standards body;
- Non-governmental organisations (NGOs), consumer organisations and civil society;
- Social partners, such as chambers of commerce, employers' organisations, business organisations, trade union organisations and representatives of professions or crafts;
- Tobacco and related products industry, including SMEs, manufacturers, distributors and retailers, as well as upstream suppliers of tobacco and related products industries.

Data collection and methodology

As well as the various consultation activities, an evidence mapping will be produced, identifying the information gaps and knowledge/evidence requirements for the evaluation work. As part of this process, robust evidence, which will embed credibility and transparency into the policy process, is being compiled. This includes:

- Report on the application of the Tobacco Products Directive;
- Support study to the report on the application of the Tobacco Products Directive;
- Study on smoke-free environments and advertising of tobacco and related products;
- Report on the implementation of the EU Tobacco Advertising Directive;
- Study on 'Consumer preference and perception of specific categories of tobacco and related products';
- Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)'s opinion on electronic cigarettes;
- Special Eurobarometer 506 (on attitudes of Europeans towards tobacco and electronic cigarettes);
- Deliverables of the Joint Action on Tobacco Control, which supported the implementation of the Tobacco Products Directive in the EU countries;
- Data and evidence gathered as part of the evaluation and impact assessment on the previous Tobacco Products Directive (2012 proposal on the Revision of the Tobacco Products Directive);
- Monitoring data on sales of tobacco and related products, online sales and promotion, products' consumption, among other data, available through commercial data platforms.

The most complete evidence base possible will be compiled and findings quantified, for example by:

- contracting qualitative and quantitative research and data collection activities/studies;
- contacting stakeholders (e.g. targeted surveys and case studies);
- purchasing databases;
- collecting scientific evidence on health risks and benefits, toxicological outlooks, emerging products characteristics, standards and methods; and
- creating models for cost-benefit analysis, disease burden (including simplification and burden reduction) and health related indicators.