



Preliminary Assessment Report for Tobacco Products Directive 2014/40/EU and Tobacco Advertising Directive (2003/33/EC)

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SUMMARY

Tobacco consumption is the single largest avoidable health risk, and 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).¹

Despite considerable progress made in recent years, the number of smokers in the EU is still high – 26% of the overall population and 29% of young Europeans aged 15-24 smoke.

The EU is also working with its international partners to reduce global tobacco consumption. EU countries, together with the European Commission, are active partners in the WHO Framework Convention on Tobacco Control (FCTC), a legally binding international treaty that aims to reduce the health and economic impact of tobacco consumption. Conferences of the Parties of the Convention are held every second year where they take decisions, adopt protocols, and issue guidelines.

Taking into account the significant cross border trade of tobacco products and the risk of diverging national legislation, EU-wide rules are necessary for these products. These rules protect consumers across the EU. The Tobacco Products Directive has governed the manufacture, display and sale of tobacco and related products since May 2016.

¹ https://ec.europa.eu/health/tobacco/overview_en

BACKGROUND

ENSP:

ENSP plays a key “watch-dog” role in Europe to prevent the tobacco industry from biasing and slowing down the tobacco control processes nationally and at EU level. The main goal of the organisation is to create a close collaboration within the tobacco control community and a strong and united civil society action against tobacco, providing members with advocacy levers. Similarly, ENSP relies on members’ feedback and input to adjust the activities at EU level.

As national policies and priorities are dynamic, influenced by political constellations, funding opportunities, influence of EU policies and public support for tobacco control, ENSP must regularly and systematically assess both the level and type of support requested from ENSP members across Europe.

The present report outlines the results of the monitoring of TPD and TAD implementation in EU countries as well as an assessment of the level and kind of need expressed in various member countries along with specific topics of future interest.

Tobacco Products Directive 2014/40/EU (TPD):

In April 2014, the European Union (EU) adopted the EU Tobacco Products Directive (2014/40/EU) (TPD), which regulates the manufacture, presentation and sale of tobacco products in the European Union (EU). A spokesperson of the European Parliament described the TPD as “the most lobbied dossier in the history of the EU institutions”. The TPD aims to reduce the different approaches to tobacco regulation in the 28 EU Member States, laying down minimum rules for cigarettes, cigars, pipe tobacco, cigarillos (short and slim cigars), smokeless tobacco (snus), Roll-Your-Own tobacco (RYO), and E-cigarettes. The 2014 TPD repeals and replaces the 2001 TPD (2001/37/EC) and significantly advances public health in Europe, for example it includes

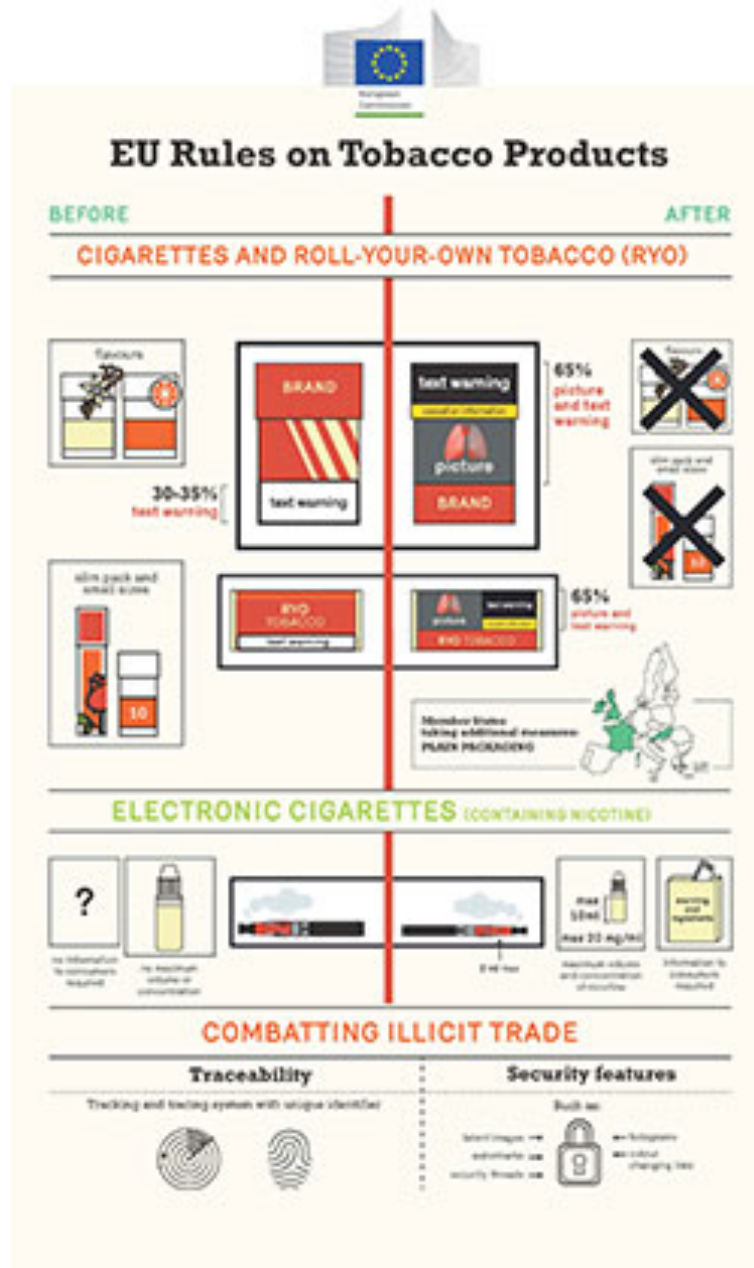
a ban on 'characterising' flavours and an increase of graphic health warnings from 30-40% to 65% on the front and back of the pack. For a detailed overview of the 2014 TPD provisions, see : Tobacco Control Measures. The revised EU Tobacco Products Directive (TPD) entered into force on 19 May 2014. On 20 May 2016 the new rules were transposed into national tobacco control legislation².

In particular, the Directive:

- ✓ Prohibits cigarettes and roll-your-own tobacco with characterising flavours
- ✓ Requires tobacco industry to report to EU countries on the ingredients used in tobacco products
- ✓ Requires health warnings on tobacco and related products: combined health warnings (picture, text and information on how to stop) must cover 65% of the front and back of cigarette and roll-your-own tobacco packages
- ✓ Sets minimum dimensions for warnings and prohibits small packages for certain tobacco products
- ✓ Bans promotional and misleading elements on tobacco products, e-cigarettes and herbal products for smoking
- ✓ Introduces EU-wide tracking and tracing to combat the illicit trade of tobacco products
- ✓ Allows EU countries to prohibit internet sales of tobacco and related products
- ✓ Sets out safety, quality and notification requirements for electronic cigarettes
- ✓ Obliges manufacturers and importers to notify EU countries about novel tobacco products before placing them on the EU market

² The European Parliament and the Council of the European Union,

- ✓ Ban on cross-border tobacco advertising and sponsorship



Tobacco Advertising Directive 2003/33/EC (TAD):

The Tobacco Advertising Directive (2003/33/EC) introduces an EU wide ban on cross-border tobacco advertising and sponsorship in the media other than television. The ban covers print media, radio, internet and sponsorship of events involving several EU countries, such as the Olympic Games and Formula One races. Free distribution of tobacco is banned in such events. The ban covers advertising and sponsorship with the aim of direct or indirect effect of promoting a tobacco product.

On 12 December 2006 the Court of Justice confirmed the validity of the Directive³. The Court held that the conditions warranting the choice of Article 95 of the EC Treaty as the legal basis were met. Notably, the Court held that journalistic freedom of expression, as such, remains unimpaired and the editorial contributions of journalists are therefore not affected⁴.

Tobacco advertising and sponsorship on television is banned by the Television Without Frontiers Directive (89/552/EEC). In the context of the Framework Convention on Tobacco Control (FCTC), the European Community was active in the development of strict international guidelines to protect its population against tobacco advertising from third countries.

The European Commission was a key facilitator in the working group whose task was to develop comprehensive draft guidelines on the implementation of Article 13 of the Convention⁵ and to present recommendations on key elements of a protocol on cross-border advertising, promotion and sponsorship, complementary to these guidelines.

³ Case C-380/03 Germany v. European Parliament and the Council, judgment of 12 December 2006.

⁴ Paragraph 156 of the judgment

⁵ Article 13 of the Convention lays down the obligations of the Parties to ban or restrict tobacco advertising, promotion and sponsorship.

SURVEY METHOD

Method

Implementation of the TPD and TAD in EU countries was researched through an online questionnaire and via directly email. The questionnaire consisted of 12 questions on the national implementation of the provisions in the TPD and the TAD and the involvement and support of ENSP in these areas. The questionnaire was circulated to all ENSP members.

ENSP members within EU countries were chosen as a reliable source of information on both TPD and TAD implementation and stakeholder involvement, based on their activities history and the level of their involvement and knowledge about national tobacco control legislation and advocacy activities.

The survey resulted in full answers (answers to all relevant questions) from 24 members from 17 European Union countries. Among the respondents, five countries did not meet the Tobacco Products Directive (TPD) transposition deadline that was May 20, 2016.

Topics to be Covered

To analyze the level and type of support requested by ENSP members, the present report focuses on the 12 questions from the survey:

- The impact of package design;
- Novel tobacco products,
- Ingredient information,
- E-cigarettes and waterpipe tobacco.
- Tobacco Advertisement.
- Illicit Tobacco Trade

Limitations

The survey is made on the basis of the areas of need reported by the responding ENSP members and other tobacco control stakeholders in the European Union countries, and may thus be subject to biases such as personal interpretation of the organisation's need, time available for filling in the questionnaire and perception of country needs by the respondents.

Additionally, in most cases only one national stakeholder responded to the survey. However almost all of the countries analysed have more than one stakeholder active in tobacco control.

It is assessed that these potential sources of deviation do not impede on the validity of the report, but require that results be considered in the light of the potential limitations and specific insights shared by stakeholders.

RESULTS

In total, 24 participants took place in the survey from 17 European Union countries. These were Austria, Belgium, Bulgaria, Cyprus, Denmark, France, Hungary, Ireland, Italy, Lithuania, Luxemburg, Poland, Romania, Slovenia, Spain, Sweden and The Netherlands.

Tobacco Products Directive (TPD) transposition deadline

Among respondents, five countries (Cyprus, Luxemburg, Slovenia, Poland and Romania) did not meet the Tobacco Products Directive (TPD) transposition deadline that was May 20, 2016.

Packaging and Labeling

Among respondents, only five countries reported to have implemented plain packaging (Belgium, France, Ireland, Slovenia and the Netherlands), while two others (Cyprus and Luxemburg) have implemented Pictorial and text warning above (> 65% of the front and back of

packages) according to TPD requirements. The remaining reported to have implemented Pictorial and text warning according with TPD minimum requirements (65% of the front and back of packages).

Ireland reported that the prevalence of smoking had dropped from 23% in 2015 to 17% in 2019, which means there are now an estimated 165,000 fewer smokers than there were five years ago as an impact of the implementation of the packaging and labeling.

EU Common Entry Gate (EU-CEG) system

All countries reported that the EU Common Entry Gate (EU-CEG) system was operational at national level. However, only in 12 countries it was reported that EU-CEG system is used to collect information on other products such as novel tobacco products, herbal smoking products and nicotine-free e-cigarettes. Austria, Bulgaria, Denmark, France and Ireland reported that did not use the EU-CEG system for information on other products.

Determination of Characterizing Flavours on Tobacco Products

According the participants responses, only two countries (Spain and Sweden) do not prohibit the placing on the market of cigarettes and roll-your-own tobacco with a characterizing flavour.

E-Cigarettes

Article 20 of the TPD focuses on electronic cigarettes. This article enforces implementation of many rules such as maximum nicotine concentration and volume for cartridges, tanks and nicotine liquid containers etc. Two countries, which are Austria and Spain, have not yet enforced these rules.

Art 15 and 16 Fighting Illicit Tobacco Trade

Articles 15 and 16 of the TPD provide for EU-wide systems of traceability and security features for tobacco products to address the issue of illicit trade. Luxemburg reported that this system was not operational in the country.

Revision of the TPD 2014/40/EU

Few participants recommended that *in the coming revision of the TPD the Commission reinforce Article 24 (2) that allows member states to go beyond the directive in order to protect public*

health while others mentioned the need for a revised TPD to include a definition for novel tobacco products as well as their regulation with a similar treatment of all tobacco products.

Advertisement and Sponsorship

Some participants reported that was of paramount significance the total ban of Internet sale of tobacco products. Other participants highlighted the need for banning production and sale of slim cigarettes. Despite the fact that tobacco advertising and sponsorship is restricted in the EU with a wide ban on cross-border tobacco advertising and sponsorship in the media and a ban on print media, radio, internet and sponsorship of events involving several EU countries, such as the Olympic Games, four countries reported that these rules were not implemented. The countries that responded negatively were Austria, Italy, Poland and Sweden.

Ban on cross border tobacco advertisement

The ban on cross border tobacco advertisement was a critical concern for participants. Key recommendations for this issue were:

1. To decrease the number of packages that someone can bring from another country,
2. To restrict promotion of menthol cigarettes produced in non-EU countries,
3. To limit promotion on Internet and social media.

CONCLUSIONS

The survey results highlighted specific areas of priority and support to be provided to members and EU countries, tailored to national circumstances and status of implementation of the TPD and TAD provisions.

- ☒ In Spain and Sweden - Prohibit the placing on the market of cigarettes and roll-your-own tobacco with a characterizing flavour.
- ☒ Austria, Belgium and Spain - Enforce the rules in Art 20 of the TPD.
- ☒ Belgium and Luxemburg - Enforce the Art. 15 and Art. 16 with regards to traceability, as well as to control bringing tobacco products individually from other countries.
- ☒ For all 17 countries – Regulate e-cigarettes the same as all other tobacco products.

- ☐ Reviews and appropriate amendments to TPD should be undertaken frequently as new societal, technical and scientific developments occur especially with current rapid development of novel tobacco product and e-devices.
- ☐ Austria, Italy, Poland, Romania and Sweden - Implement the ban of the sponsorship of events.
- ☐ The majority of countries - Limit cross border advertisement in particular the Internet advertisement and the promotion in the neighboring non-EU countries.

ACKNOWLEDGEMENTS

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Country	Name and / or institution / organisation
Austria	Manfred Neuberger, Professor emeritus at Medical University of Vienna
Belgium	Observatoire de la santé du Hainaut, Province de Hainaut
Bulgaria	Smoke-Free Life Coalition
Cyprus	University of Cyprus
Cyprus	Nektarios Vrachimis - Cyprus' National Addictions Authority
Denmark	Danish Cancer Organisation
Espanya	Dolors Carcier Pont - CATALAN INSTITUTE OF ONCOLOGY
France	Prof. B. Dautzenberg - Paris sans tabac and ACT
Hungary	Tibor DEMJÉN - Ministry of Human Capacity, Focal point for tobacco control
Ireland	Patrick Doorley - Chair of the ASH council of The Irish Heart Foundation
Ireland	Prof. Luke Clancy TobaccoFree Research Institute - and Dr. Maurice Mulcahy – HSE Ireland
Italy	Dr. Marco Castrechini, M.D. - "Sapienza" University of Rome, Public Health Researcher
Italy	Maria Sofia Cattaruzza - Italian Society of Tabacology (SITAB) / Sapienza University of Rome
Italy	Silvano Gallus - Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Milan, Italy
Lithuania	Lithuanian Tobacco and Alcohol Control Coalition
Luxembourg	Lucienne Thommes, Fondation Cancer Luxembourg
Poland	Krzysztof Przewozniak - President, Foundation "Smart Health - Health in 3D"

Romania	Prof. Florin Mihaltan - Romanian Society of Pneumology
Romania	Healthy Romania Generation 2035 Association
Slovenia	Slovenian Coalition for Public Health, Environment and Tobacco Control
Spain	Raquel Fernández Megina - Nofumadores.org
Sweden	ThinkTank Tobaksfakta
The Netherlands	Youth Smoking Prevention Society
The Netherlands	Health Funds for a Smokefree Netherlands (Gezondheidsfondsen voor Rookvrij), formerly the Dutch Smokefree Alliance (Alliantie Nederland Rookvrij).