

ROADMAP

Title of the initiative: **Revision of the Tobacco Products Directive**
Type of initiative (CWP/Catalogue/Comitology): CWP
Lead DG/contact person/details: DG SANCO
Expected date of adoption of the initiative (month/year): 12/2011
Date of modification: 25.3.2010
Version No:

Initial IA screening & planning of further work

A. Context and problem definition

(i) What is the political context of the initiative? (ii) How does this initiative relate to past and possible future initiatives, and to other EU policies?

The Tobacco Products Directive 2001/37/EC has two objectives: (1) facilitating the functioning of internal market in tobacco products sector and (2) ensuring a high level of public health.

There are still differences between the Member States' laws and other provisions on the manufacture, presentation and sale of tobacco products which impede the functioning the internal market.

Smoking continues to be the largest single cause of preventable death and disease in the EU, accounting for 650 000 deaths a year. Smoking remains the main cause of preventable morbidity and premature death in Europe. The smoking prevalence remains still high with an average of around 30 %. It is even more worrying that prevalence of smoking by young people is still significant, and although a slight downward trend in smoking of boys can be seen, there is an upward trend in smoking by girls. Therefore, its reduction of can significantly decrease the burden of diseases and premature deaths and thus increase healthy life years and productivity.

The European Parliament has repeatedly asked the Commission to revise the Tobacco Products Directive since 2007. Also, by the adoption of the REACH Regulation (1907/2006), the Commission declared its commitment to promote work on tobacco ingredients develop it further by the next review of Directive¹.

The European Parliament's Resolution of 2007 on the Green Paper "Towards a Europe free from tobacco smoke: policy options at EU level", asked Member States to reduce smoking young people by 50% by 2025 and that young people's health is a priority. Therefore, all changes that would prevent young people from taking up smoking and which lead them to quit are very important.

The Second Report on the implementation of the Directive of November 2007 (COM (2007) 754 final) showed that the Directive is implemented in Member States, and outlined potential areas for changes. Moreover, since the adoption of the Directive, substantial changes have taken place in the field of tobacco control in the EU and world wide. The need for the revision of the Directive has been highlighted by the European Parliament, Member States and stakeholders.

Related initiatives include the Tobacco Advertising Directive (2003/33/EC) which bans cross-border tobacco advertising and sponsorship. The EU has also – to a certain extent harmonised tobacco excise duties, the most recent legislation dates from 16 February 2010 (Council

¹ See the Commission's statement on tobacco ingredients on the Council website: <http://register.consilium.europa.eu/pdf/en/06/st16/st16908-ad01.en06.pdf> (REACH is item 30, the tobacco declaration starts on p. 16). Together with the other declarations made on the REACH Regulation, it is included in the minutes of the meeting of the Environment Council of 18 December 2006 at which REACH was adopted (reference 16908/06 Add 1)

Directive 2010/12/EU of 16 February 2010 amending Directives 92/79/EEC, 92/80/EEC and 95/59/EC on the structure and rates of excise duty applied on manufactured tobacco and Directive 2008/118/EC. Direct subsidies for tobacco growing are phased out as from 2010.

What are the main problems identified?

- The labelling rules are still different within Member States, in particular with respect to the use of picture warnings (internal market concern)
- Existing reporting system for the tobacco ingredients is complex for industry and makes it difficult for competent authorities to analyse the data in the absence of harmonised formats (internal market concern)
- Member States have introduced different positive and/or negative lists of ingredients (internal market concern)
- Consumers are not sufficiently informed about the harmful effects of tobacco products (internal market and health concerns)
- Information on tar, nicotine and CO on cigarette packages is misleading for consumers (internal market and health concerns)
- Products bought over the Internet often do not bear health warnings in the language of the country of the destination and are available for under-aged (internal market and health concerns)
- Directive does not cover new nicotine and tobacco products: electronic cigarettes, nicotine drinks, tobacco chewing gum and toothpaste that are heavily marketed (internal market and health concerns)

Who is affected?

Member States, citizens, tobacco industry (including distributors) and retailers.

(i) Is EU action justified on grounds of subsidiarity? (ii) Why can the objectives of the proposed action not be achieved sufficiently by Member States (necessity test)? (iii) As a result of this, can objectives be better achieved by action by the Community (test of EU Value Added)?

The EU action is justified in order to ensure free circulation of goods on equal conditions that ensure high level of human health (Article 114 TFEU).

B. Objectives of EU initiative

What are the main policy objectives?

1. Maintain good functioning of the internal market
2. Decrease tobacco related morbidity and mortality

Specific objectives:

1. Harmonise the presentation of warning labels and improve consumer information, especially to vulnerable groups
2. Improve mechanisms for reporting and analysing tobacco products
3. Harmonise the regulation regarding the presence of harmful, addictive and attractive substances in tobacco products
4. Regulate market access to tobacco products

5. Enable speedy adaptation to technical and scientific progress

Do the objectives imply developing EU policy in new areas or in areas of strategic importance?

No

C. Options

(i) What are the policy options? (ii) What legislative or 'soft law' instruments could be considered?
(iii) Would any legislative initiatives go beyond routine up-date of existing legislation?

1. No change

No review to scope and content of the Directive, Member States can act on their own initiative within the terms of the existing legislation. International obligations like the WHO Framework Convention on Tobacco Control would continue to exist.

2. Elements for policy options

The ongoing Impact Assessment will address the impact of each change and the impact of various combinations of changes. Based on the results of the Impact Assessment one or several changes listed below may be introduced. Varying degrees of intervention are set out for each possible change.

Most of these changes would require changes in the binding legislation, while some changes could be introduced via non-binding instruments, such as Commission or Council Recommendations, practical guidance documents etc. to encourage Member States to introduce their own legal measures to better implement the Directive. Various optional arrangements could also be introduced into the Directive (similar to the optional regime for picture warnings presently).

- (a) Adjusting the scope of the Directive by including tobacco leaf, new and emerging tobacco and nicotine products, and paraphernalia;
- (b) Changes to the labelling requirements :
 - replacing quantitative information on tar, nicotine and carbon monoxide (TNCO) on cigarette packages by the qualitative information on harmful substances and information on cessation services;
 - making pictorial warnings compulsory;
 - introducing enlarged warnings;
 - introducing warnings on both sides of the package;
 - introducing standardised packaging;
- (c) Introducing reporting and registration requirements (including sanctions for industry in case of non-delivery of ingredients data) and accompanying fees;
- (d) Regulating the ingredients of tobacco products:
 - introducing common list of ingredients with tackling toxicity, carcinogenicity, mutagenicity, attractiveness and addictiveness;
 - setting limits for other yields and also for other tobacco products;
 - further decreasing maximum limits for TNCO;
- (e) Revising the sales arrangements for tobacco products:
 - aligning availability of tobacco and nicotine replacement therapies;
 - introducing standard package size;
- (f) Allow for adaptations of technical nature:

- reporting formats;
- amendment of the common list of ingredients;
- requirements for testing and verification laboratories.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Yes:

- the internal market (MARKT, ENTR)
- protection of minors, education and sensitization campaigns (EAC)
- indirect link to smoking in workplaces (EMPL)
- implications to international trade (TRADE).

Explain how the options respect the proportionality principle

Possible areas for changes do not go beyond the stated objectives. The principle of proportionality will be addressed in the Impact Assessment.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the Impact Assessment Guidelines pages 32-37), even if these impacts would materialise only after subsequent Commission initiatives?

Public health impacts

- All the changes are expected to affect positively the health of citizens including life expectancy, mortality and morbidity. Envisaged changes are expected to work towards better cessation information, smoking prevention and less consumption.

Economic impacts

- By reducing the tobacco consumption, an EU initiative is expected to reduce medical and other costs associated with tobacco related diseases (lung cancer, heart disease, stroke, and chronic lower respiratory diseases) and to result in substantial cost savings. However, it cannot be estimated at this point what scale of reduction might result from the envisaged changes. Medical costs include primary care, emergency care, hospital inpatient care (including day cases and cardiac rehabilitation systems), outpatient care, and medications. Non-medical costs include home and family care, productivity costs due to mortality and productivity costs due to morbidity (such as sickness absences). The macroeconomic cost of tobacco-related diseases has been estimated at 2.46 billion euro per year. This consists of over 1.3 billion euro constituting medical expenditure on tobacco-related diseases (including €560 million accounted for by non-smoking staff) and over 1.1 billion euro constituting non-medical costs linked to productivity losses (including €480 million accounted for by non-smoking staff).
- As regards the costs, all options are expected to have an impact on the price of cigarettes as the registration and market control fees will enter as a cost component into the cost calculation of the tobacco industry.
- The amendments will add administrative tasks and costs for the Member States competent authority and business e.g. yearly registration and marketing fees for tobacco brands, additional testing etc.

- Some elements work mostly through less consumption due to better information and more successful quit attempts. These elements options are likely to have less direct economic impact (some even positive impacts) on the tobacco industry.
- The revenue from tobacco sales across the EU in 2007 is estimated at €67,089 million². The number of staff employed in the tobacco industry across the EU-27 in 2004 is estimated at 67,000³.
- As some of the envisaged changes aim at decreasing tobacco consumption, they imply decreasing production and certain job losses for the tobacco industry. However, it has to be borne in mind that e.g. cigarette production is a highly automated and not very labour-intensive production. In addition, there will be new jobs created mainly in R&D and the laboratory and registration system for tobacco products ingredients being set up. Also, an increased demand for cessation services and nicotine replacement therapies is expected and this may create new jobs in the healthcare sector and in the pharmaceutical industry.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No.

Could the options have significant impacts on (i) simplification, (ii) administrative burden or on (iii) relations with third countries?

No.

E. Planning of further impact assessment work

When will the impact assessment work start?

The basic work for the impact assessment started mid-2009. The report will be finalised by April 2010. Thereafter, a public consultation will be made. The Impact Assessment report will be drafted and submitted to the IA board by the end of 2010.

(i) What information and data are already available? (ii) Will this impact assessment build on already existing impact assessment work or evaluations carried out? (iii) What further information needs to be gathered? (iv) How will this be done (e.g. internally or by an external contractor) and by when?
(v) What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Stakeholders have been consulted on the interim report on the impact assessment that outlined a baseline scenario. All comments will be taken into account in the final report.

Which stakeholders & experts have been/will be consulted, how and at what stage?

On the interim report (done in Dec 2009):

- Member States
- tobacco industry associations as well as retail sale associations at EU level
- pharmaceutical industry

² The most recent data on tobacco industry revenues across the EU-27 are available for the year 2006, which were extrapolated to 2007 by Eurostat using short-term indices (source: ESTAT)

³ Source: Eurostat

- public health NGOs

On the draft Impact Assessment (mid-2010):

- general public in addition to the above