EU Directive

# TOBACCO PRODUCTS

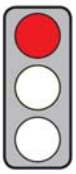
cep**Policy Brief** No. 2013-12 of 25 March 2013

Centrum für Europäische Politik

## KEY ISSUES

**Objective of the Directive:** The Commission would like to combat tobacco consumption, particularly among young people, and at the same time harmonise the rules on tobacco products.

**Affected parties:** All citizens, tobacco companies, advertisers, wholesalers, retailers.



**Pro:** –

**Contra:** (1) The Commission's proposals are paternalistic and excessive. They represent major interference in public and entrepreneurial freedoms.

(2) In particular, a blanket ban on products with "characterising flavour", whilst it may protect young people against substance abuse, also patronises responsible adults.

(3) The appropriate means of protecting young people is national child welfare legislation which works primarily by prohibiting sales.

## CONTENT

### Title

**Proposal COM(2012) 788** of 19 December 2012 for a **Directive** of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the **manufacture, presentation and sale of tobacco** and related **products**

### Brief Summary

- **Context and objectives**
  - About 700,000 people die each year in the EU as a consequence of tobacco consumption. The vast majority of smokers start consumption at a young age.
  - The Commission wants to combat tobacco consumption, particularly among young people (e.g. Recital No. 15), and at the same time harmonise the regulations on tobacco and related products.
- **Scope of application**

  The Directive contains – diverging – regulations particularly on "tobacco products" and "nicotine-containing products" (Art. 2; see cep**Overview**).
  - "Tobacco products" contain tobacco usable for consumption (Art. 2 (34)). The products "primarily targeted" by the Commission (p. 3) are
    - cigarettes (Art. 2 (7)),
    - roll-your-own tobacco (Art. 2 (28)) and
    - "smokeless tobacco products" not involving a combustion process (Art. 2 (29)), e.g. nasal and chewing tobacco.
  - "Nicotine-containing products" contain nicotine for consumption rather than tobacco (see Art. 2 (22), Art. 1 (1) f), e.g. E-cigarettes, which vaporise liquids.
- **Ban on "characterising" and other flavours**
  - **Cigarettes, roll-your-own tobacco and smokeless tobacco products**
    - Products with a "characterising flavour" are banned (Art. 6 (1), 10).
    - Whether a flavour is "characterising" depends on whether the additives give the product "a flavour other than tobacco" (Memo/12/1005, p. 4; Art. 2 (4)), e.g. in the case of menthol cigarettes or liquorice-flavoured nasal and chewing tobacco (Citizen's Summary, p. 3).
    - Whether a flavour can be regarded as "characterising"
      - will first be determined by the Member States who then notify the Commission of this assessment (Art. 6 (1);
      - can also be determined by the Commission itself, such as by setting maximum levels (see Art. 6 (2), (3)).
    - If a flavour is not "characterising", the Member States may only prohibit the use of the additives as long as they are not "essential" for manufacture (Art. 6 (1)).
    - Filters, papers, capsules and adhesives, in particular, are prohibited from containing any aromas (see Art. 6 (5)).
  - **Other tobacco products (apart from cigarettes, roll-your-own tobacco and smokeless tobacco products)**

    The Commission may extend the ban on "characterising" and other flavours to include other tobacco products if, in ten Member States, there is a 10% increase in the sales volume of the respective product group (e.g. cigars) generally, or an increase of 5 percentage points in the prevalence level in the under 25s consumer group (Art. 6 (10), Art. 2 (30)).
- **Ban on other ingredients**
  - **Cigarettes**
    - Maximum yields of tar, nicotine and carbon monoxide are laid down for cigarettes (Art. 3 (1)).
    - The Commission can adapt the maximum yields and measurement methods (Art. 3 (2), Art. 4 (3)).

Authors: Oliver Sauer and Sebastian Czuratis | sauer@cep.eu
CEP | Kaiser-Joseph-Strasse 266 | 79098 Freiburg | Germany | Telephone +49 (0)761 38693-105 | www.cep.eu

– **All tobacco products (including cigarettes)**
  - Maximum yields for other emissions are set by the Member States. The Commission can harmonise them if these emissions increase the toxic or addictive effect "in an appreciable manner". (Art. 3 (3))
  - There is a ban on products with additives (Art. 6 (4)), which
    - mask the health hazards of the product (e.g. vitamins),
    - associate them with energy and vitality (e.g. caffeine and taurine) or
    - colour the smoke or steam (e.g. E-cigarettes).
  - There is a ban on additives which increase "in an appreciable manner" the toxic or addictive effect. The examination procedure is the same as that used for "characterising flavours". (Art. 6 (7)–(9))

► **Other bans**
– Slim cigarettes with a diameter of less than 7.5 mm are prohibited (Art. 12 (2)).
– Tobacco for oral use (snus) remains banned with an exemption for Sweden (Art. 15).

► **Warnings**
– **Cigarettes and roll-your-own tobacco**
  - Each package carries (Art. 8 (1), (2), Art. 9)
    - a "general warning" that smoking is deadly,
    - an "information message" about the carcinogenic ingredients and
    - a "combined health warning".
  - Package in that sense are the "unit packet" and the "outside packaging". A "unit packet" is the smallest individual packaging placed on the market, e.g. the cigarette packet (Art. 2 (36)). "Outside packaging" is any other non-transparent packaging in which the products are placed on the market, e.g. carton of cigarettes (Art. 2 (24)).
  - The "combined health warnings" are comprised of a text warning listed in Annex I and a "corresponding" colour photograph specified in the Commission's "picture library" (Art. 9 (1) a, (3) b).
  - The "general warning" and the "information message" together cover 50% of the surface on which they are printed, for cigarette packets the lateral sides (Art. 8 (3)). The combined text-picture warnings cover 75% of the surface on which they are printed, for cigarette packets the front and back (Art. 9 (1) c).

– **Labelling of tobacco for smoking other than cigarettes and roll-your-own tobacco**
  - The Commission may extend the requirements for warnings relating to cigarettes and roll-your-own tobacco to cover other tobacco products for smoking (e.g. cigars). The requirements for this are the same as for "characterising" and other flavours. (Art. 10 (5), Art. 2 (30))
  - Until then, less onerous requirements will apply (Details: Art. 10 (1)–(3)).

– **Smokeless tobacco products**
  Each package carries a text warning of the danger to health and the addictive potential (Art. 11 (1)), covering 30–35 % of the surface on which it is printed (Art. 11 (2)).

– **Nicotine-containing products**
  For products with a nicotine level exceeding the threshold (Art. 18 (1)), each package carries a text warning about the nicotine content and danger to health (Art. 18 (3)), covering 30-35 % of the surface on which it is printed (Art. 18 (4)).

► **Appearance and content**
– **Roll-your-own cigarettes and tobacco**
  - Unit packets of cigarettes have a cuboid shape and contain at least 20 cigarettes (Art. 13 (1)).
  - A unit packet of roll-your-own tobacco must have "the form of a pouch" and contain at least 40 g tobacco (Art. 13 (1)).

– **All tobacco products**
  - It is prohibited to give the package or the product a misleading appearance (Art. 12 (1).
  - This specifically includes misleading colours (Art. 12 (2), e.g. the use of the colours gold and white for allegedly "light" products (SWD(2012) 452, p. 32), not to mention the labels "light","ultra-light" and "mild" themselves (see Recital No. 23).

► **Security features**
– **Roll-your-own cigarettes and tobacco**
  - The unit packets carry a unique identifier allowing for traceability (Art. 14 (1) and an additional security feature (Art. 14 (8)).
  - The data thus recorded – including the "intended market of retail sale" and the identity of all intermediaries (List: Art. 14 (2)) – are electronically processed (Art. 14 (4)) and administered by an independent third party commissioned by the manufacturers and importers (Art. 14 (6)). The competent authorities have access to the data at all times (see Art. 14 (6)).

– **Tobacco products other than cigarettes and roll-your-own tobacco**
  The requirements for cigarettes and roll-your-own tobacco apply but only after a period of five years following the expiry of the transposition date (Art. 14 (10)).

► **Placing the products on the market**
"Placing on the market" means making the products available to consumers in the EU, including by means of distance sale and/or cross-border sales (Art. 2 (25)).
– **All tobacco products**
  Prior to placing the products on the market, manufacturers and importers must notify the competent authorities and publish on the internet (Art. 5 (1), (2), (5)):

- a list of all ingredients, classified according to brand name and type, in descending order of weight, and a separate statement of the reasons for their inclusion;
- the classification under Regulation (EC) No. 1907/2006 on chemicals and Regulation (EC) No. 1272/2008 on substances and mixtures;
- toxicological data on dangers to health and addictive effects.

– **Novel tobacco products**
Manufacturers and importers must notify the Commission of "novel tobacco products" (Art. 2 (23)), not customarily on the market, six months prior to placing the products on the market (Art. 17 (1)).

– **Nicotine-containing products**
Products with a nicotine level exceeding the threshold (Art. 18 (1)) require authorisation under Directive 2001/83/EG, known as the medicinal products code. The rest do not require authorisation.

- **Distance sales, particularly on-line sales**
All retail outlets engaged in cross-border distance sales must register in advance (Art. 16 (1), (2)) and provide a suitable age-verification system (Art. 16 (4)).
- **Legislative powers of the Commission** (see cep**Policy Brief**)
The Regulation contains 24 powers to issue delegated acts (Art. 290 TFEU; see cep**Analysis**) and four powers to issue executive acts (Art. 291 TFEU; see cep**Policy Brief**).

## Statement on Subsidiarity by the Commission

Since the regulations on tobacco products are already harmonised, it is "very difficult" for Member States to improve consumer protection, especially with regard to on-line sales. In addition, the regulations for individual products e.g. nicotine-containing products, which have not yet been harmonised, undermine the proper functioning of the internal market. (p. 11)

## Policy Context

The applicable Directive 2001/37/EC is repealed (Art. 27(1)). At the same time, the Commission is aiming to comply with the requirements of the WHO Framework Convention on Tobacco Control (FCTC) (inter alia p. 3).

## Legislative Procedure

| | |
|---|---|
| 19 December 2012 | Adoption by the Commission |
| 9 September 2013 | 1st reading in the European Parliament (EP) |
| Open | Adoption by the EP and the Council, publication in the Official Journal of the European Union, entry into force |

## Options for Influencing the Political Process

| | |
|---|---|
| Leading Directorate General: | DG Health and Consumers |
| Committees of the European Parliament: | Environment (leading), rapporteur Linda McAvan (S&D Group, UK); Internal Market; Legal Affairs; Industry |
| Federal ministries: | Consumer Protection (leading) |
| Committees of the German Bundestag: | Consumer Protection (leading) |
| Decision mode in the Council: | Qualified majority (acceptance by majority of Member States and with 255 of 345 votes; Germany: 29 votes) |

## Formalities

| | |
|---|---|
| Legal competence: | Art. 114 TFEU (internal market) |
| Form of legislative competence: | Shared competence (Art. 4 (2) TFEU) |
| Legislative procedure: | Art. 294 TFEU (ordinary legislative procedure) |

# ASSESSMENT

## Economic Impact Assessment

**The proposals of the Commission underline its paternalistic approach** in matters of consumer protection **and are** completely **disproportionate in their scale and content. They represent major interference with public and entrepreneurial freedoms.**

**To be precise,** although **the ban on products with** "**characterising flavour**" **or other additives,** such as vitamins, caffeine and taurine, **and on slim cigarettes** might improve health protection by making smoking unattractive, it also **patronises responsible adults**. The basis of self-determined action on the part of the consumer is information. Photographs of physical damage ("shock pictures"), however, principally serve to scare people off rather than to inform them. The health dangers of tobacco consumption as such are generally known in all the Member States.

## Legal Assessment

### Legislative Competency

As regards the areas which have not yet been harmonised (e.g. nicotine-containing products), the Directive can be based on the competency to approximate laws in the internal market (Art. 114 (1) TFEU). For those areas which have already been harmonised (e.g. warnings), it is immeasurably more difficult. Although the European

Court of Justice (ECJ) recognises that areas which are already harmonised, can be "re-harmonised" (ECJ, Case C-58/08, Vodafone and others, par. 34), it also recognises that consumer protection may be the "decisive" aim of harmonization (ECJ, Case C-58/08, Vodafone and others, par. 36; see Art. 114 (3) TFEU).

#### Subsidiarity

Unproblematic provided harmonization takes place.

#### Proportionality

Compared with the Regulation, the Directive is a milder instrument and suitable for the aim of harmonization.

#### Compatibility with EU Law

**The Commission's power to define the "characterising flavour" of tobacco products amounts to a decree from the taste-police.** This is particularly problematic because the legal term "characterising flavour" is, on the one hand, highly unspecific, but on the other hand, is intended to result in product bans. **It is also unacceptable that the Commission is supposed to be able to extend the scope of the Directive. Both aspects are questionable from the point of view of EU law**: decisions which are essential to an area of law should be left up to the European legislature itself (see Art. 290 (1) TFEU).
Under the EU Charter of Fundamental Rights (CFR) the duty to maintain a high level of protection for health and consumers (Art. 35, 38 CFR) is set against the fundamental economic rights of the company affected (Art. 16, 17 CFR). The ECJ allows the legislature a broad scope for discretion when it comes to balancing the opposing positions and has thus already declared the full prohibition of one tobacco product (snus) to be lawful (see ECJ, Case C-434/02, Arnold André, par. 44 et seq.). The ECJ is therefore unlikely to see any breach of fundamental rights in the less extensive restrictions contained in this Directive.

#### Compatibility with German Law

According to the German Federal Constitutional Court (BVerfG) the legislature can also prohibit smoking in public places without exception (BVerfG, 1 BvR 3262/07 i. a. par. 121 et seq.). Even on this point there exists a not insubstantial level of disquiet (accurate dissenting opinion Masing, BVerfG, 1 BvR 3262/07 i. a., par. 184 et seq.) and such **concerns about compatibility with the basic law apply** to an even greater extent **in respect of actual product bans that deny members of the public the opportunity to consume the product of their choice, even in full privacy and without any detriment to third parties** – as in the case of smokeless tobacco products. Thus the ban on products with "characterising flavour", in particular, whilst possibly protecting young people from addictive behaviour, certainly also protects responsible adults from themselves.
E-cigarettes and accompanying liquids do not yet fall under the *Arzneimittelgesetz* (Pharmaceuticals Act – AMG) or the *Medizinproduktegesetz* (Medicinal Products Act – MPG) and therefore currently still do not require authorisation (Administrative Appeal Court Nordrhein-Westfalen, 13 B 127/12, head note 3; see also ECJ Case C-219/11, Brain Products, par. 13, 23 et seq.). The provisions must be adapted accordingly for products above the threshold.

## Alternative Approach

The health dangers of consuming tobacco should – and can – be tackled by the Member States: **the traditional means of protecting young people is national youth protection legislation that works by way of sales restrictions** (see e.g. Sections 9, 10 *Jugendschutzgesetz* (Youth Protection Act – JuSchG))**, and recently also by way of extra taxes** (see Section 1 (1) *Alkopopsteuergesetz* (Alcopops Tax Act)); the EU only has a supplementary competency when it comes to the prevention of addiction (Art. 168 (5), Art. 6 (1) a TFEU). In addition, the need for protection does not continue until the age of 25 (see Art. 2 (30)), but at most up to the age of consent (see e.g. Sections 1, 9, 10 JuSchG). Innocent bystanders are protected by way of targeted bans on smoking in public areas, e.g. the work place. As a rule, in a free society, responsible adults should not be protected from their own addictive behaviour at all.

## Possible future follow-up measures by the EU

The Commission has expressly distanced itself from an EU-wide introduction of plain packaging along the lines of Australia (SWD(2012) 453, p. 96 et seq.). It does seem to be keeping this option open for the future however since it refers to the fact that there is almost no experience with this type of packaging yet (see SWD(2012) 453, p. 97). And the evaluation report, to be submitted no later than five years after the Directive comes into force, will also be devoted to the "package surfaces not [yet] governed by this Directive" (Art. 23 (2) a). The ECJ emphasises in this regard that the "substance" of the trademark rights cannot be touched (see ECJ, Case C-491/01, British American Tobacco and others, par. 150, 132).

## Conclusion

The Commission's proposals are paternalistic and excessive. They represent major interference in public and entrepreneurial freedoms. Specifically, a blanket ban on products with "characterising flavour", whilst protecting young people against substance abuse, also patronises responsible adults. The appropriate means of protecting young people is national child welfare legislation which works primarily by way of sales restrictions and extra taxes.