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RESOLUTION OF THE 12th STANDING COMMITTEE

(Hygiene and Health)

(Rapporteurs: BASSOLI and D'AMBROSIO LETTIERI)

approved at the afternoon sitting of 30 January 2013

ON THE

PROPOSAL 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 (COM(2012) 788 final)

under Article 144(1) and (6) of the Rules of Procedure

Communicated to the Office of the Prime Minister on 6 February 2013

TYPOGRAPHICAL SERVICE OF THE SENATE (150)

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The Committee,

Having examined document (COM(2012) 788 final) containing the proposal 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;

Acknowledging that the main objective of the proposal relates to the need to update and supplement Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on tobacco products in the light of subsequent scientific, international and market developments;

Recalling that Italy has always been at the forefront of tobacco control and the protection of non-smokers, by means of a composite legal framework, running from Law No 584 of 11 November 1975 prohibiting smoking in certain establishments and on public transport to the recent provisions introduced by Article 7 of Decree-Law No 158 of 13 September 2012, converted into law and amended by Law No 189 of 8 November 2012. The latter introduced a ban on the sale of cigarettes to those under 18 years of age, by raising the limit of 16 years provided for in Article 25 of the consolidated text on the protection of maternal and child health laid down in Royal Decree No 2316 of 24 December 1934;

Taking into account that, among its legislative priorities, the Hygiene and Health Committee of the Senate of the Republic has given particular attention to the examination of an associated draft law (Senate act No 8) on the protection of health and the prevention of damage arising from the consumption of tobacco products, which, while not having completed the parliamentary procedure, has received broad support from the various political parties in terms of the need to discourage the consumption of tobacco products and thereby prevent the damage caused by smoking;

Emphasising that, in addition to raising the minimum age for buying and consuming tobacco products from 16 to 18 years of age (now implemented by Article 7 of Decree-Law No 158 of 2012), the main points of the above legislative initiative include banning smoking in schools (Article 5), establishing a fund for the prevention and reduction of harm caused by smoking in order to conduct information and prevention campaigns (Article 6), monitoring the characteristics, quantity and quality of products placed on the market and consumed by the public – since measuring and verifying the contents of products derived from processed tobacco, such as tar, nicotine and

carbon monoxide is an absolute prerequisite for protecting consumers' health – and obliging manufacturers of tobacco products to indicate the content of the substances in those products on the leaflet inside cigarette packets and the packaging of other tobacco products (Article 7);

Supporting the objectives of the proposal for a Directive, which, by revising Directive 2001/37/EC and with a view to ensuring the highest level of health protection, seeks to update areas already harmonised in order to overcome the obstacles encountered by Member States in adapting their respective national legislation to the new international, scientific and the market developments, adopting product-related measures not yet covered by the Directive on tobacco products in so far as heterogeneous development in Member States has led to, or is likely to lead to, fragmentation of the internal market, and ensuring that the Directive is not circumvented by the placing on the market of products that do not comply with the Directive on tobacco products;

Noting that the Commission has adopted the proposal on the basis of Article 114 of the Treaty on the Functioning of the European Union (TFEU), with the aim of safeguarding the functioning of the internal market and ensuring a high level of health protection for citizens, by reducing the prevalence of smoking, especially among young people. In that respect, the Commission explicitly refers to the Framework Convention on Tobacco Control of the World Health Organisation (WHO) as the cornerstone of its legislative action and justifies the proposed measures by guaranteeing better implementation of international agreements in Europe;

Reiterating that in this respect Italy can rightly consider itself among the most 'virtuous' of EU countries, since, through largely balanced legislation and a system for the sale of tobacco products that is rigorously controlled on the basis of authorised retailers, it has fully achieved the public health aims, while securing significant tax revenue;

Needless to say, Italy has swiftly implemented the WHO Convention, by means of both the 'Sirchia' Law (Law No 3 of 16 January 2003) and regulations on the sale of smoking products from vending machines. More recently, it has also raised the minimum age for buying tobacco products to 18, irrespective of legislative or regulatory efforts to harmonise national laws. Moreover, significantly, Italy has adopted a tax policy on smoking products that has produced excellent results in terms of discouraging tobacco use. Official statistics indicate that the number of smokers in Italy fell from 27.6 % to 20.8 % between 2003 and 2012. Few EU countries, even those with stricter rules, have been so successful;

Noting the favourable comments expressed by the 10th Committee on 16 January 2013, in particular: 'the relevant Committee is invited to carefully assess whether the proposal for a Directive fully complies with the principle of subsidiarity; it is noted that the measures in the proposal, which provide for standardisation of tobacco products, undermine trade mark law and may impede the effective control of smuggling and counterfeiting by preventing the tracing of products';

Considering that, in the case in question, there seems to be substantiated evidence that the proposal may not fully comply with the principles of subsidiarity and proportionality set out in the EU Treaty and the implementing Protocol.

Within the meaning of Protocol 2 to the TFEU on the application of the principles of subsidiarity and proportionality, the proposal conflicts with the principles of subsidiarity and proportionality, for the following reasons:

1) Firstly, there is a problem in terms of the proposal's compliance with the principle of subsidiarity. The principle applies since the Commission has proposed as the legal basis of the proposal Article 114 TFEU on the approximation of the laws of the Member States, in order to ensure the functioning of the internal market on the basis of high standards of health protection (shared competence between the Member States and the European Union).

However, the proposal does not seem intended to harmonise/approximate the laws of the Member States on tobacco products. Article 24 of the proposal actually stipulates that Member States are free to adopt different, and more stringent, rules in the area. The proposal encourages Member States to act autonomously in various areas, such as: measuring emissions other than tar, nicotine and carbon monoxide; further tests for measuring ingredients; requirements for prohibiting products containing specific additives; introducing an authorisation system for new products; introducing stricter packaging rules (e.g. generic packets). These proposals may lead to significant differences between Member States and consequently restrict the free movement of goods. Therefore, it does not appear justified to refer to Article 114 TFEU as the legal basis of the proposal.

2) There are some inconsistencies with regard to granting Member States sufficient discretion concerning the scope of the proposal. The power to adopt delegated acts, conferred on the Commission by Article 22, may be excessively broad, both in terms of content – covering at least 16 areas relating to the production, packaging and sale of tobacco products – and duration, thereby severely restricting national parliaments' legislative power.

Article 290 TFEU allows the legislator to 'delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act.'

For example, Article 3(2) empowers the Commission to adopt delegated acts in order to adapt the maximum levels laid down in Article 3(1), i.e. the tar, nicotine and carbon monoxide yields of cigarettes marketed or manufactured in the Member States. However, such aspects appear to constitute essential elements of the legislative act, since they indicate the content of the products covered by the proposal.

3) In particular, the principle of subsidiarity is infringed in the following areas:

a) Novel tobacco products: the Commission will impose severe restrictions on the placing on the market of low-risk products and de facto discourage investment in research, innovation and development, since not only does it fail to set out an ad hoc regulatory framework for novel tobacco products, it makes the regulatory parameters even more dissuasive (e.g. it prevents consumers from being informed about the low risks associated with such products, including through claims based on scientific evidence). This is despite the fact that recital 8 of the current Directive on tobacco products refers to the need for such regulation: 'A revision of the regulatory framework needs to evaluate evidence-based claims for tobacco products designed and/or marketed to "reduce risk", or for which harm reduction is claimed by the manufacturers.'

Through the de facto ban on low-risk or novel products, the EU will prevent Member States from implementing a health policy that reduces the risks associated with tobacco smoke.

Commoditisation and the ban on entire categories of products: the measures on standardised packaging and the ban on sales of entire categories of currently legal products, such as slim and menthol cigarettes and packets of 10 cigarettes – which would de facto also lead to the standardisation of products – are justified by the Commission by the desire to make tobacco products less attractive and the concern that a certain type of packet or product could lead consumers to believe the product is less harmful.

The unjustified ban on such legal products, in addition to being in conflict with the first stated aim of the proposal – to promote the internal market – would lead to commoditisation and the associated erosion of value. This would encourage (a) consumers to switch to cheaper products, (b) rivals to focus only on price, thus lowering the average price of tobacco products, and (c) the rapid spread of the black market (smuggling/counterfeiting), since standard packaging would be easier to copy.

The above would lead to serious adverse consequences for legal resales, the tax authorities and the industry. In addition, the effect of the proposal would undermine its other fundamental objective, i.e. safeguarding public health.

It is worth noting that historically the European Union has tried to establish harmonised rules for labelling products, while the appearance of a product and the external packaging has always been regulated by national parliaments. Under the new proposal, the EU is seeking for the first time to take virtually exclusive control over the appearance, shape and design of the product and packaging, without any scientific or other evidence to substantiate the effectiveness of such measures from the point of view of health.

Lastly, greater attention should be paid to the widely advertised marketing of electronic cigarettes. As shown by a recent opinion of the Higher Institute of Health, they raise public health concerns, as they may encourage people to start smoking conventional tobacco-based cigarettes and create nicotine dependence. The risk is significant, in particular for young people, considering how easy it is for them to find such products on the internet.

OPINION OF THE 10th STANDING COMMITTEE

(INDUSTRY, TRADE, TOURISM)

(Rapporteur: CURSI*)*

16 January 2013

The Committee,

Having examined the parts of document COM(2012) 788 final within its remit, comments favourably on the proposal, with the following remarks:

The relevant Committee is invited to carefully assess whether the proposal for a Directive full complies with the principle of subsidiarity;

The measures in the proposal for a Directive, which provide for standardisation of tobacco products, undermine trade mark law and may impede the effective control of smuggling and counterfeiting by preventing the tracing of products;

OPINION OF THE 14th STANDING COMMITTEE

(EUROPEAN UNION POLICIES)

(Rapporteur: BOLDI*)*

30 January 2013

The Committee,

Having examined document COM(2012) 788 final, considering it is intended to:

Revise Directive 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products. The revision, in addition to being provided for by the Directive itself (Article 11), was advocated by the Council (recommendation of 30 November 2009) and the European Parliament (resolutions of 15 September 2011 and 24 October 2007);

Aadapt the Directive to market developments (with the emergence of products such as electronic cigarettes), international developments (in view of the adoption in May 2003 of the WHO Framework Convention on Tobacco Control, to which the European Union and all Member States are party) and scientific developments;

Having regard to:

the judgment of the Court of Justice of 10 December 2002 in Case C-491/01, which confirmed the validity of Directive 2001/37/EC in terms of its legal basis and compliance with the principles of subsidiarity and proportionality;

the adoption in May 2003 of the WHO Framework Convention on tobacco control;

Having regard also to the results of the public consultation held by the Commission between 24 September and 17 December 2010, as well as the Eurobarometer survey of May 2012;

fully supports the aims of:

- discouraging young people from taking up smoking;
- ensuring that any consumption is based on properly informed decisions;

agrees, in conclusion, with the premise that ‘Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco, health protection should be given high importance, in particular to reduce smoking prevalence among young people’ (recital 8);

within its remit, and with specific reference to the powers delegated to the Commission (Article 22), hereby considers that Protocol No 2 to the TFEU on the application of the principles of subsidiarity and proportionality is not complied with.

Article 22 of the proposal for a Directive refers to delegation of powers relating to essential parts of the act that falls outside the delegation of powers provided for in Article 290. This applies to the delegations in Articles 3(2) and (3), 6(3) and (9), and 18(2) and (5). In the first two cases, the delegation concerns the power to decide that certain products may not be marketed within the EU. In the third case, it concerns the power to change the product description in view of the relevant legislation on placing on the market. In all cases, the scope of the Directive would be changed, as would the products covered by it.

It is recalled that Article 114 TFEU was correctly indicated as the legal basis of the act in question. It is only and exclusively in matters within Union competence that the European legislator may delegate to the Commission the adoption of a number of non-legislative acts of general application in the cases and according to the procedures set out in Article 290 TFEU (which provides expressly that ‘the essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power’).

The above provision on the delegation of power concerning essential elements, within EU competence under Article 114, represents an excessive and unjustified conferral of power on the Commission, which:

- constitutes disproportionate federal encroachment on the legislative autonomy of the Member States and undermines their powers under Article 5(3) of the Treaty on European Union;
- undermines the prerogatives of national parliaments by preventing them indefinitely from commenting on compliance with the principles of subsidiarity and proportionality in all acts adopted by delegation.

In other words, having established the Union’s competence to legislate on tobacco and related products, it seems unjustified and harmful to the powers of the Member States for the Commission to act autonomously without fulfilling the criteria of necessity and added value. Further legislation in the areas referred to in Articles 3(2) and (3), 6(3) and (9), and 18(2) and (5) may well be introduced by the colegislators.

There are also strong reservations with regard to the indefinite duration of the delegation of powers and the Commission's right to unilaterally remove certain exemptions in undefined and generic circumstances ('if there is a substantial change of circumstances as established in a Commission report'). This applies to Articles 6(10), 10(5) and 13(4).

Finally, with reference to the content of the act, a careful assessment should be made of the potential for:

- 'low-risk' or 'novel' products (Articles 17-19);
- continued marketing of smaller packets or thinner cigarettes.

Such products could be a key part of a policy that gradually discourages smoking or leads people to give up altogether. In other words, restricting public sales of tobacco products or basing such sales on undefined, standardised rules will not in themselves decrease the prevalence of smoking. In fact, they could increase smuggling and thereby create difficulties for smokers who have taken steps to give up the habit.