19.2.2013

NOTICE TO MEMBERS

(21/2013)

Subject: Reasoned opinion by the Italian Senate 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)0788 – C7-0420/2012 – 2012/0366(COD))

Under Article 6 of the Protocol (No 2) on the application of the principles of subsidiarity and proportionality, any national parliament may, within eight weeks from the date of transmission of a draft legislative act, send the Presidents of the European Parliament, the Council and the Commission a reasoned opinion stating why it considers that the draft in question does not comply with the principle of subsidiarity.

Under Parliament’s Rules of Procedure the Committee on Legal Affairs is responsible for compliance with the subsidiarity principle.

Please find attached, for information, a reasoned opinion by the Italian Senate on the above-mentioned proposal.
ANNEX

Senate of the Republic

16th term

RESOLUTION OF THE 12TH STANDING COMMITTEE

(Health and hygiene)

(Rapporteurs: Bassoli and D'Ambrosio Lettieri)


Pursuant to Senate Rule 144(1) and (6)

Forwarded to the Presidency on 6 February 2013
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The 12th Standing Committee,


– appreciating that the main aim of the proposal for a directive is the need to update and complement the Tobacco Products Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001, in the light of the latest scientific, international and market developments,

– whereas Italy has always been one of the countries that has paid the most attention to tobacco control and protection of non-smokers, through a composite legislative framework ranging from Law No 584 of 11 November 1975, concerning the prohibition of smoking in certain premises and on public transport, to the recent provisions introduced by Article 7 of Decree-Law No 158 of 13 September 2012, amended by Law No 189 of 8 November 2012, which prohibited the sale of cigarettes to persons under the age of 18, raising the upper age limit of 16 provided for in Article 25 of the Consolidated Law on the protection and assistance of motherhood and childhood, under Royal Decree No 2316 of 24 December 1934,

– whereas, amongst the priorities of its legislative activity, the Health and Hygiene Committee of the Senate has devoted a substantial amount of its time to consideration of a specific bill (Senate Act No 8) laying down provisions for the protection of health and the prevention of harm from the use of tobacco products; whereas this bill, while not having completed the parliamentary process, resulted in a broad convergence between the different political parties regarding the need to deter consumption of tobacco products and thus prevent the damage caused by smoking,

– noting in particular that the key points of the aforementioned legislative initiative are, in addition to the raising of the minimum age for the purchase and consumption of tobacco products from 16 to 18 – which has now entered into force under Article 7 of Decree-Law No 158 of 2012 – as follows: a ban on smoking in schools (Article 5); the establishment of a fund for the prevention and reduction of harm caused by smoking, for the purpose of carrying out information and prevention campaigns (Article 6); the control of the characteristics, quantity and quality of products placed on the market and consumed by the public – since the measurement and verification of the content of tobacco processing by-products, such as tar, nicotine and carbon monoxide, are an absolute prerequisite for the protection of consumer health; and the requirement for manufacturers of tobacco products to state the content of the substances contained in those products in the leaflet inside cigarette packets and packs of other tobacco products (Article 7),

– welcoming the objectives of the proposal for a directive in question, which, by revising Directive 2001/37/EC and with a view to ensuring the highest possible level of health protection, seeks to: update already harmonised areas to overcome the obstacles encountered by Member States in bringing their national legislations into
line with new market, scientific and international developments; adopt product-related measures not yet covered by the Tobacco Products Directive (TPD), insofar as heterogeneous development in the Member States has led to, or is likely to lead to, fragmentation of the internal market; and ensure that provisions of the directive are not circumvented by the placing on the market of products that are not compliant with the TPD,

noting that the Commission has adopted the proposal for a directive on the basis of Article 114 of the Treaty on the Functioning of the European Union (TFEU), with the aim of ensuring the functioning of the internal market while ensuring a high level of health and consumer protection by reducing the propensity to smoke, especially among children and teenagers; in this regard, the Commission expressly refers to the World Health Organisation (WHO) Framework Convention on Tobacco Control as the cornerstone of its legislative action, justifying the introduction of the proposed measures with the guarantee that the international provisions and agreements will be better implemented at EU level,

reiterating that, in this respect, Italy can rightly be considered one of the most 'virtuous' in the European Union, in that, through legislation that is substantially balanced and a system of tobacco product sales that is strictly controlled, on a licensing basis, its public health goals have been achieved in full, whilst at the same time providing substantial tax revenues,

whereas it is hardly necessary to point out that Italy has acted on the provisions of the WHO Convention very promptly, both by introducing the so-called Sirchia Law (Law No 3 of 16 January 2003) and regulating the sale of tobacco smoking products from vending machines and, more recently, by banning the sale of such products to under-eighteens, irrespective of any legislative or regulatory action seeking to harmonise national laws; moreover – an aspect that deserves special attention – Italy has adopted a taxation policy on tobacco products that has had excellent results in terms of discouraging people from smoking; official statistics show that from 2003 to 2012 the number of smokers in Italy fell from 27.6 % to 20.8 % – a major achievement that is not shared by many other EU countries which, despite having rules that are sometimes more stringent, still have higher smoking rates,

taking note of the favourable comments made by the 10th Committee on 16 January 2013, accompanied by the following remarks: 'the committee calls on the committee responsible to consider carefully whether the proposal for a directive complies in full with the subsidiarity principle; points out that the measures in the proposal for a directive that provide for a standardisation of tobacco products will have an adverse effect on industrial trademarks and, by making it more difficult to trace a product, are likely to prevent the effective combating of smuggling and counterfeiting',

whereas, in this case, however, there appear to be some well founded critical aspects of the substance of the proposal for a directive which suggest that the principles of subsidiarity and proportionality, as laid down by the Union Treaty and its implementing Protocol, have not been fully complied with,
Expresses, pursuant to Protocol 2 to the Treaty on the Functioning of the European Union (TFEU) 'on the application of the principles of subsidiarity and proportionality', a negative reasoned opinion for non-compliance with the principles of subsidiarity and proportionality, for the following reasons:

(1) There appears to be a problem in assessing the compliance of the proposal for a directive with the subsidiarity principle. This principle applies insofar as the Commission has established Article 114 TFEU on the approximation of the laws of the Member States as the legal basis of the proposal for a directive, in order to ensure the functioning of the internal market on the basis of high levels of health protection (shared competence between the Member States and the European Union).

The proposed directive, however, does not appear to be aiming to harmonise/approximate the laws of the Member States on tobacco products. Article 24 of the proposal, in fact, states, that the Member States are free to adopt different, more stringent national provisions. The proposal for a directive encourages Member States to act independently in different areas such as: measuring emissions other than nicotine, tar and carbon monoxide; further tests to measure ingredients; requirements to prohibit products containing specific additives; the introduction of a licensing system for new products and the introduction of stricter rules on packaging (such as plain packaging). These proposals form the basis for significant differences between Member States and consequent restrictions on the free movement of goods. Therefore, it is unjustified to refer to Article 114 of the TFEU as the legal basis for the proposal;

(2) Some inconsistencies have also been found with regard to the fact that the Member States are given an appropriate level of margin for implementation of the proposal for a directive. The power to adopt delegated acts, conferred on the Commission by Article 22, is likely to be too broad in both its substance – by covering at least 16 areas relating to the production, packaging and sale of tobacco products – and duration, thus strongly delimiting the legislative power of the national parliaments.

Indeed, 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) confers on the Commission the power to adopt delegated acts to adapt the maximum yields laid down in paragraph 1, i.e. the yields of tar, nicotine and carbon monoxide of cigarettes that are placed on the market or manufactured in the Member States; however, these aspects seem precisely to be essential elements of the legislative act, given that they refer to the content of the products that are the subject of the proposed directive.

(3) In particular, the subsidiarity principle would appear to have been infringed in the following areas:

(a) Novel tobacco products: the Commission imposes severe restrictions on the placing on the market of low-risk products and, in so doing, actually discourages investment in
research, innovation and development, since not only does it not provide for the establishment of an ad hoc regulatory framework for novel tobacco products, but, on the contrary, it makes the rules even more discouraging (e.g. prevents consumers from being informed of the lower risk associated with consumption of these products, including through statements backed up by scientific evidence). This is in spite of the fact that Recital 8 of the Tobacco Products Directive currently in force expressed 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'.

With the de facto prohibition of so-called low-risk or novel products, the European Union is preventing Member States from introducing health policies to reduce smoking-related risks;

(b) Commoditisation and prohibition of entire categories of products: the Commission has justified its measures relating to the standardisation of packaging and the ban on selling entire categories of products that are currently legal – such as 'slim' cigarettes, menthol cigarettes and packets of 10 (which, in fact, would also determine the standardisation of the product) – by its desire to reduce the attractiveness of tobacco products and the concern that a certain type of product or package may lead consumers to believe it is less harmful.

The unjustified prohibition of these legal products not only appears to conflict with the first stated purpose of the proposal, namely to promote the internal market, but would also lead to the commoditisation and subsequent erosion of its value, by encouraging (a) consumers to switch to cheaper products; (b) competition to be based on price alone, leading to a reduction in the average price of tobacco products, and (c) a sharp increase in the illegal market (smuggling/counterfeiting), as standard packaging would be easier to replicate. The negative impact of this on legal sales outlets, the tax system and the industry would be substantial. Furthermore, the results achieved by the proposed new directive would run counter to the other key objective of the proposal, namely the protection of public health.

It is worth noting that, historically, the European Union has sought to establish harmonised rules on the labelling of products, while the appearance of a product and its outer packaging have always been regulated at the national parliament level. With this new proposal for a directive, the EU is seeking, for the first time, to take almost total control of the appearance, shape and design of the product and packaging, without there being, inter alia, any valid scientific evidence in support of the effectiveness of these measures in health terms.

Lastly, it should be pointed out that more attention should be paid to the marketing of the widely publicised electronic cigarettes. According to a recent opinion of the Istituto Superiore di Sanità (Institute of Health), electronic cigarettes are a source of concern for public health, as they could be a risk factor in the initiation of tobacco-based cigarette smoking, potentially resulting in nicotine dependence. This risk is especially great for young people, considering how easy it is for young customers to find these products on the internet.
16 January 2013

The Committee,

– having considered the act COM (2012) 788 final, with regard to the sections falling within its competence, welcomes this act, but wishes to make the following remarks:

– Calls on the committee responsible to consider carefully whether the proposal for a directive complies in full with the subsidiarity principle;

– Points out that the measures in the proposal for a directive that provide for a standardisation of tobacco products will have an adverse effect on industrial trademarks and, by making it more difficult to trace a product, are likely to prevent the effective combating of smuggling and counterfeiting.
The Committee,

– having considered the act COM (2012) 788 final,

– whereas the aim of that proposal is 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 and that such a review, in addition to being provided for by the directive itself (Article 11), had also been called for by the Council (Recommendation of 30 November 2009) and the European Parliament (Resolutions of 15 September 2011 and 24 October 2007),

– whereas its aim is also to adapt the directive to market developments (following the emergence of products such as electronic cigarettes), international developments (pursuant to the adoption, in May 2003, of the World Health Organisation's Framework Convention on Tobacco Control, to which both the EU and all Member States are parties) and scientific developments,

– having regard to:

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

the adoption, in May 2003, of the World Health Organisation Framework Convention on Tobacco Control,

the outcome of the public consultation launched by the Commission between 24 September and 17 December 2010, in addition to that of the Eurobarometer survey of May 2012,

– Approves in full the aims of:

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

- Agrees 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);

- Expresses, in relation to the matters falling within its competence and with specific reference to the power to adopt delegated acts conferred on the Commission (Article 22), a negative reasoned opinion pursuant to Protocol No 2 to the TFEU on the application of the principles of subsidiarity and proportionality;

Article 22 of the proposed directive, in fact, contains delegations of powers relating to essential elements of the act, thus running counter to the express provisions of Article 290 TFEU. This is the case for the powers delegated in Article 3, paragraphs 2 and 3, Article 6, paragraphs 3 and 9 and Article 18, paragraphs 2 and 5. In the first two cases, the power to adopt delegated acts can prevent certain products from being marketed within the European Union, while in the third it can alter the description of such products for the purposes of the legislation applicable for their placing on the market. In all cases the very scope of the directive and the products that are subject to it would ultimately be changed.

The committee would point out that Article 114 of the TFEU has been correctly entered as the legal basis of the act in question. It is solely and exclusively within the competence of the Union that the European legislator can delegate to the Commission the adoption of non-legislative acts of general application, in the cases and in the manner laid down in Article 290 of the TFEU (which expressly provides 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 delegation of powers in relation to the essential elements listed above constitutes, within the competence of the Union under Article 114, an excessive and unjustified transfer of power to the Commission, which could:

- represent excessive federal disproportionality in relation to the regulatory autonomy of the Member States and could adversely affect their competence pursuant to Article 5(3) of the Treaty on European Union;

- undermine the prerogatives of the national parliaments, depriving them indefinitely of the opportunity to express their views on compliance with the principles of subsidiarity and proportionality in all the acts adopted in the exercise of the delegation.

In other words, while the Union's competence to legislate on tobacco and
related products has been ascertained, independent action by the Commission that does not fulfil the criteria of necessity and added value is unjustified and adversely affects the competences of the Member States. Further legislative action in the fields referred to in Article 3, paragraphs 2 and 3, Article 6, paragraphs 3 and 9 and Article 18, paragraphs 2 and 5, can easily be taken by the co-legislators.

Again with reference to the system of delegation of powers, the committee has strong reservations about the indefinite duration of those powers and the opportunity for the Commission to independently withdraw some exemptions in undefined, general circumstances (‘if there is a substantial change of circumstances as established in a Commission report’). This is the case in Article 6(10), Article 10(5) and Article 13(4).

Finally, with reference to the substance of the act, the committee calls for a careful assessment as to the feasibility of potentially:

- using so-called low-risk or novel products (Articles 17-19);
- keeping on the market packets containing fewer or slimmer cigarettes.

These products can be instrumental in implementing a policy to progressively discourage people from smoking, or getting them to give up their smoking habits. In other words, restricting or standardising the supply to the public of tobacco products does not, per se, reduce the propensity to smoke. It could, however, lead to increased smuggling while creating difficulties for smokers who have made every attempt to wean themselves off tobacco products.