Making bad law – legal vulnerabilities in the Tobacco Products Directive

written by Clive Bates | 17 September 2013



Are the various proposals for the Tobacco Products Directive now in circulation actually legally robust? It often surprises humble European citizens, but when the EU institutions legislate, on tobacco or anything else, they cannot just do what they think will be popular or what they can get away with. They have to comply with 'laws about laws' set out in the EU treaties. These important constraints on legislative powers are there to protect minority rights and unfashionable causes, and to ensure people or businesses are not harmed by arbitrary, discriminatory, unaccountable or excessive exercise of power. They also carefully balance the responsibilities of the legislatures of the 28 member states and that of the European Union. They are important checks and balances designed into the European treaties and developed by the European Court of Justice. What does all this mean for legislators in the European Parliament and Council?

The two main treaties are:

- Treaty on European Union (TEU)
- Treaty on the Functioning of the European Union (TFEU)

The principles guiding law-making include:

1. Subsidiarity and conferral
2. Proportionality
3. Non-discrimination and equal treatment
4. Appropriate legal base
5. Obligation to consult
6. Precautionary principle

I'm including the 'precautionary principle', even though this is only briefly included in the treaties as an environmental concept. This has been used by the European Commission and some campaigners as a kind of 'override' when there is no evidence to support doing what they want. I'll give a brief explanation of each, and suggest where these six principles raise legal implications.

1. Principles of subsidiarity and conferral

These determine when the EU is has powers to legislate (the formal term is 'competence'). They are also supposed to mean decisions are taken as closely as possible to the citizen – ie only at EU level if necessary. The principle of 'conferral' means the EU may only legislate when it has explicitly been given competence by the member states (ie. it can't just assert competence – in new areas, competence defaults to member states). Subsidiarity means that where competence is shared or unclear the EU should only act if objectives can only be achieved at EU level, or if there are advantages of scale or impact from EU level action. The principles of subsidiarity and conferral are enshrined in Article 5.1-5.3 of TEU and the related Protocol (No 2) on application of the principles of subsidiarity and proportionality.

> *1. The limits of Union competences are governed by the principle of conferral. The use of Union competences is governed by the principles of subsidiarity and proportionality.*
>
> *2. Under the principle of conferral, the Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein. Competences not conferred upon the Union in the Treaties remain with the Member States.*
>
> *3. Under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.*

Implications

Choice of internal market legal base. Application of the subsidiarity/conferral

is why the TPD is cast as an internal market measure – see discussion of legal base below. Article 114 of TFEU on the internal market is a valid legal base, but Article 168 TFEU on public health *explicitly excludes* harmonisation of laws relating to tobacco and alcohol for public health reasons. The primary purpose of the TPD must therefore further the objective of the free movement of goods across borders in the internal market, albeit with a high level of health protection. It should not be using the internal market as a false pretext for public health legislation on tobacco.

Inclusion of advertising and age restrictions etc. Many MEPs instinctively want to add further 'protections' in the TPD or to 'strengthen' it – for example, to regulate advertising or to impose age limits on e-cigarettes. They should not do this as the EU has no competence on age restrictions and only limited competence in advertising (the first tobacco advertising directive 98/43/EC was struck down by the ECJ for overreaching its legal base, and the successor directive 2003/33/EC is restricted to control of cross border advertising). It's not that these are unimportant issues, it is just that they are a matter for the member states – the EU is not the only legislature involved. In fact, adding these protections potentially weakens the directive and also any amendments that include them because they are unlawful. Stronger isn't always better – strategically or tactically. For every MEP who likes the appearance of a stronger directive, there may be another who dislikes the reality of an unlawful measure.

2. Principle of proportionality

The principle of proportionality is laid down in Article 5.4 of the Treaty on European Union.

> *4. Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties. The institutions of the Union shall apply the principle of proportionality as laid down in the Protocol on the application of the principles of subsidiarity and proportionality.*

The criteria for applying it is set out in Article 5 of Protocol (No 2) on the application of the principles of subsidiarity and proportionality annexed to the Treaties.

> *The reasons for concluding that a Union objective can be better achieved at Union level shall be substantiated by qualitative and, wherever possible, quantitative indicators. Draft legislative acts shall take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens, to be minimised and commensurate with the objective to be achieved.*

This means the EU must find the 'lightest touch' approach to achieving its objectives (in this case free movement of goods). The final sentence creates an obligation to seek out the most cost effective. least burdensome way of meeting policy objectives.

Implications

Medicines regulation for e-cigarettes. The safest form of recreational nicotine will be treated as though it is the most dangerous. Unless forced into the definition of a medicine, which it clearly is not, then it will be forced of the market. Other forms of regulation, built on consumer protection law and standard setting have not been adequately considered, but would be far less burdensome than medicines regulation.

The ban on snus. It is clearly a disproportionate measure to a ban on a product which has a *net beneficial effect* on health where it is not banned. Even if it did not substitute for cigarettes (which is where the net benefit comes from) and it was merely 95-99% less damaging than cigarettes, it would a health risk that is not out of the ordinary in absolute terms.

The measures taken to regulate the least risky products are the most extreme.

3. Principle of non-discrimination

The principle of equal treatment or non-discrimination is recognised as a general principle of EU law. This is not encoded explicitly in the treaties but has emerged through case law, for example, see: Case 304/01 Sept 2004 *Spain v European Commission* para 31

> *... the principle of equal treatment or non-discrimination requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is*

objectively justified.

And the idea is put clearly in 1991 by the Advocate General Tesauro in his widely cited opinion on case C-63/89 .

> *It should be pointed out that the principle of equal treatment is fundamental not only because it is a cornerstone of contemporary legal systems but also for a more specific reason: Community legislation chiefly concerns economic situations and activities. If, in this field, different rules are laid down for similar situations, the result is not merely inequality before the law, but also, and inevitably, distortions of competition which are absolutely irreconcilable with the fundamental philosophy of the Common Market.*

Implications

The discrimination in the Tobacco Products Directives is quite extraordinary.

- Cigarettes can be placed on the market, but much safer snus is banned (Article 15).
- Novel tobacco products can be placed on the market through a notification procedure (Article 17), but e-cigarette vendors must face the multiple burdens of securing a medicines license (Article 18). It is therefore much easier to place a low-risk nicotine product on the market if it contains tobacco than if it doesn't.
- Smokeless tobacco products that are placed in the mouth and sucked are banned, but those placed in the mouth and chewed are allowed (definitions in Article 2)

None of the discrimination above can be justified on health grounds. In fact there is a compelling case to remove the discrimination in each case for health reasons. It is, in other words, doubly wrong: violating an important EU principle and harming health too.

4. Legal base – internal market & free movement of goods

Like all EU legislation, the TPD has to have a 'legal base' (a justification for legislation under the treaties). In this case, the directive is justified as an internal market measure. Article 26 TFEU defines the an internal market of movement of

goods, services and capital. Para 2 states

> *2. The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties.*

Article 114 TFEU creates the legislative powers to develop the internal market in paragraph 1, and defines important objectives – including for health – for the internal market in (the badly worded) para 3.

> *3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.*

Note that the EU Treaties do refer to public health measures (see Article 168 of the TFEU), but this is primarily and deliberately defined as promoting co-operation. It does create a legal base for public health measures, but with the intention of preventing cross border problems. It also *explicitly rules out harmonisation of national laws for tobacco policy*. Article 168(5) states that the EU institutions…

> *…may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States. [emphasis added]*

More broadly the concept of a 'legal base' (or *vires* to use the legal terminology), means that there must be some grounding in law for actions taken by an authority, such as a medicines regulator or government. A medicines regulator is given powers to regulate medicines, not abattoirs, beer or nuclear power stations. The powers granted to an authority can only be applied to those activities set out in a definition used in the legislation. Article 1.2 of the medicines directive

2001/83/EC gives these definitions of a medicine:

> *2. Medicinal product:*
> *(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or*
> *(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.*

If those definitions do not apply, then the directive does not apply and regulators have no powers. On the other hand, if those definitions do apply, then the products must be classed as medicines and regulated under the directive.

Implications

Snus ban does not aid free movement. It is pretty obvious that a ban on placing the product on the market does not facilitate free movement of goods. The case must therefore rest on achieving a high level of health protection. But there is now only evidence that suggest snus is highly net beneficial. When last tested in court c-210/03 Swedish Match vs UK Secretary of State for Health the ECJ upheld the ban, but by arguing that too little was known of the health risks, and that the product was 'novel'. Much more is known now, the protective 'exit' gateway effect is recognised, and if it is 'novel' it could be authorised as a novel product under Article 17 of the directive.

E-cigarette licensing as medicines does not aid free movement. The medicines directive means that products are banned until authorised as medicines. The licensing process creates a significant barriers to entry and will drive out all but the largest firms from the market. It will also make it too costly and burdensome to licence most of the thousands of products and variations on the market, so there will be a *de facto* ban on many products. No health rationale exists for inhibiting these products from free movement within the EU, and on the contrary a strong *health* rationale exists to allow them on the basis that they increase the overall appeal of e-cigarettes to users.

Misclassification of e-cigarettes creates poor law. Regulators are having to accept that e-cigarettes are not medicines unless the vendor makes a therapeutic

claim. For example, the UK regulator the MHRA says in its Q&A:

> *25. Why is the MHRA leaving unlicensed medicines on the market if there are no guarantees on safety, quality and efficacy?*
>
> *Existing electronic cigarettes on the market, and other NCPs that make no medicinal claim, will not require a medicine licence until the European Commission's revised Tobacco Products Directive is transposed into UK law*

This reveals a subtlety worth understanding. Despite what we often say, the proposal in TPD does not classify e-cigarettes as medicines. It simply bans any e-cigarette that doesn't have a medicines marketing authorisation. But what happens if the e-cigarette falls outside either definition of medicine? *The directive is, in fact, a ban on the free movement of goods that are not medicines*. This peculiar formulation has been examined in detail by the Sir Francis Jacobs QC, a former Advocate General of European Court of Justice, in an opinion for ECITA. After examining this issue and other aspects of the directive, he concludes:

> *In our view this is an unreasonable measure, which is liable to be annulled as being contrary to the principle of proportionality and/or the principle of non-discrimination.*

This view was also picked up by the Legal Affairs (JURI) Committee of the European Parliament, in its formal Opinion on the directive proposal, arguing that it is disproportionate and lacking a legal base.:

> *Article 18 of the proposal prohibits nicotine-containing products (NCP) such as e-cigarettes containing a certain nicotine level if they are not authorised pursuant to Directive 2001/83/EC (the Medicinal Products Directive). It is, however, quite unclear if these products (which are much less harmful than tobacco products) even fall under the scope of the Medicinal Products Directive. For products which do not fall under the Directive, this would effectively constitute a ban. Banning products which are less harmful than tobacco products and which can be a means of smoking cessation is certainly not in line with the public health aims of the proposal.*

So the specialist committee with a legal focus believes that the legality is weak… and it follows up with a comment about the validity of its legal base in a footnote:

> *Article 18 also lacks a valid legal base as it is in no way aimed at improving the conditions for the establishment and functioning of the internal market. Pursuant to the Commission, the provision will allow NCP to move freely across borders as they would benefit from the mutual recognition procedure under the Medicinal Products Directive (Impact Assessment, page 8). However, this is already the case without Article 18, as any NCP which qualifies as a medicinal product is already now subject to the Medicinal Products Directive. The only effect Article 18 has is that it prohibits the placing on the market of NCP that are not authorised pursuant to the Medicinal Products Directive.*

Regrettably, the views of the JURI committee did not prevail in the voting in the lead committee (ENVI – Environment, Public Health and Food Safety), leading to its report. But that is a reason all MEPs should be concerned – it is likely that ENVI has proposed an unlawful measure, and not without warning from an expert committee. The better proposal would be amendment 65 suggested by JURI – or some variation on it. This should form the basis of a new amendment voted on by the whole plenary of the Parliament on October 8th.

Verdict – these measures do not promote free movement of goods, in fact they severely constrain it. At there same time there is no compensating argument that such restrictions support a high level of health protection – in fact they will damage health.

5. Obligation to consult

The obligation to consult interested parties emanates from Article 11.1-11.3 of the Treaty on European Union (TEU) which states:

> *1. The institutions shall, by appropriate means, give citizens and representative associations the opportunity to make known and publicly exchange their views in all areas of Union action. 2. The institutions shall maintain an open, transparent and regular dialogue with representative associations and civil society. 3. The European Commission shall carry out broad consultations with parties concerned in order to ensure that the Union's actions are coherent and transparent.*

Implications

Consultation on e-cigarettes / NCPs. The Commission did hold a consultation in 2010 on the directive. However, for 'nicotine containing products' it only consulted on whether these should be included in the revision of the tobacco products directive and if so, that they said that 'specific safety and quality standards would be developed…'. Option 1 was no change (ie continue with national legislation).

> *Option 2 – Extend of the scope of the Directive An extension of the scope of the Directive could be envisaged to include novel forms of oral tobacco, herbal cigarettes, and electronic nicotine delivery systems, insofar as they are not already covered by other EU legislation (food, pharmaceutical). Specific safety and quality requirements would be developed for ENDS.*

Oh dear… not only did they not consult on the eventual proposal to classify most e-cigarettes as medicines, they actually consulted on doing something else rather different (and more sensible) – setting standards (*specific safety and quality requirements*). That is done through standard-setting legislation, not medicines regulation. In fact the consultation report shows idea to have medicines regulation was advanced by respondents to the consultation (mainly health NGOs) : *it wasn't the subject of the consultation itself*. Note. the consultation closed in December 2010, but the directive proposal wasn't published until 19 December 2012, so the opportunity of the intervening two years to consult on the actual proposal to regulate e-cigs as medicines was lost. I think they just thought they'd landed on an easy risk-averse regulatory 'black box' to deal with these products.

Verdict… completely inadequate consultation.

6. Precautionary principle

This doesn't appear in the treaties as a general principle. There is a reference to environmental risks. It finds its force in the EU from a Commission Decision from 2000 (COM(2000) 1). I tend to see this idea as useful only for certain types of risks – ie. those where the implications are huge for example 'geo-engineering' or where something irreversible and bad might happen – for example release of alien predators to deal with an ecological imbalance. For most risks, there is a

risk or cost associated with both acting and not acting. It certainly doesn't allow for a crude ban on things just because it might theoretically be harmful. You have to look at all the evidence in all its forms, apply some judgement and common sense, and only then decide whether inaction or action is the better course. The Commission guidance certainly does allow for bans or excessive action on the basis of ignorance. The following principles are proposed:

> *Where action is deemed necessary, measures based on the precautionary principle should be, inter alia:*
>
> - *proportional to the chosen level of protection,*
> - *non-discriminatory in their application,*
> - *consistent with similar measures already taken,*
> - *based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),*
> - *subject to review, in the light of new scientific data, and*
> - *capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment*

Implications

The ban on snus is justified in part by reference to the precautionary principle in the Commission's Impact Assessment see for example, page 66.

> *In any event it justifies the application of the precautionary principle, i.e. it justifies not allowing market entry of products, which are addictive and harmful.*

This utterly shallow reasoning, along with the rest of the embarrassingly feeble case to ban snus, is subject to detailed critique in a joint report, by Lars Ramström and me: *A critique of the scientific reasoning supporting the proposed measures relating to oral tobacco*. But in a nutshell, the precautionary principle should not be a source of arbitrary or disproportionate measures to be achieved on the basis of a theoretical risk – it must involve narrowing down as much uncertainty as possible, not simply ignoring the science that confounds the desired prohibitionist policy. But most importantly, those wielding the

precautionary principle have to account for harms that might arise if they stopped something – like the risk of harms arising from removing a much safer product market from the market, especially when there is a mountain of evidence suggesting that the effects in Sweden and Norway have been highly positive. In fact, the really troubling uncertainty in snus policy is how many lives are lost because citizens outside Sweden have been denied access to alternative to smoking.

If the precautionary principle is to invoked, it can only be done in support of lifting the ban on snus.

Further reading

I recommend:

The TVECA legally orientated position paper on e-cigarettes: *E-cigarettes in the Draft Revised Tobacco Product Directive Avoiding a ban on a less harmful alternative*

The opinion of Sir Francis Jacob QC for ECITA: *Opinion – in the matter of the revised tobacco products directive*

Legal Affairs committee (JURI) of the European Parliament. *Opinion on the proposed revision to the Tobacco Products Directive*.

Other measures

In this directive I am personally primarily concerned with the harm reduction agenda and the very poor design of the legislation as it affect that agenda. I think this is by far the most important subject the directive touches on, but it gets it almost all wrong in a way that will cause more harm not less. From this perspective, I have described it as '*a gargantuan dog's breakfast*' and written in despair to politicians. I haven't considered in this briefing whether the legal principles discussed above support other measures in the proposed directive: bans on menthol and other flavours, limits of pack size to ten, ban on slim cigarettes, limits on pack design and, finally, large warnings or, potentially, standardised packaging. That is for others to debate.