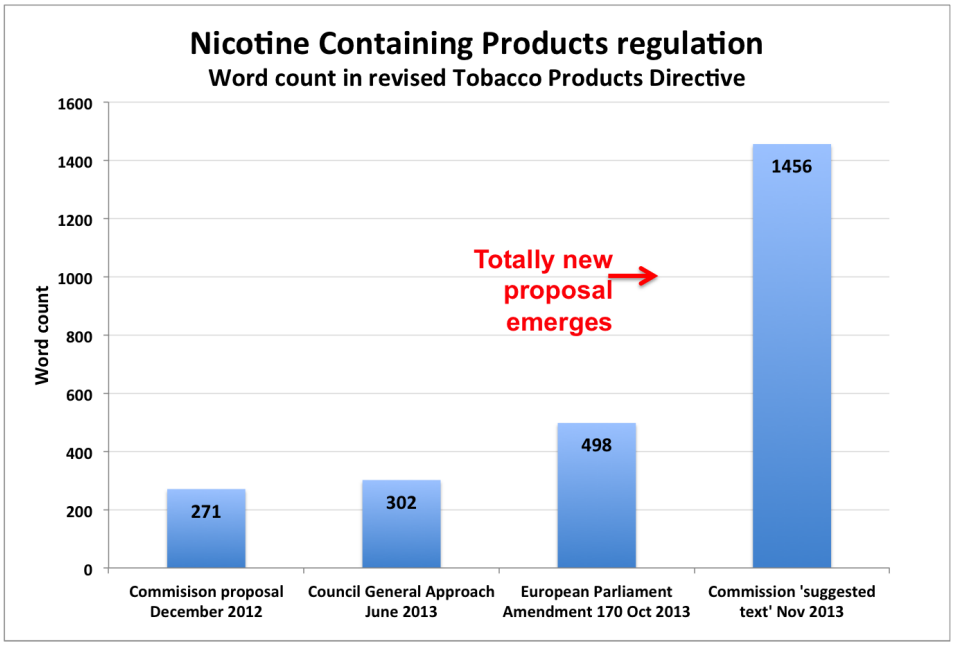
Embarrassingly poor EU policy-making – follow the rules and do a proper job on e-cigarettes

written by Clive Bates | 2 December 2013



A new proposal? For e-cigs the proposal is now five times the size and completely different to the original (word counts don't include recitals)

From behind closed doors in Brussels, an utter mess is emerging from the EU on regulation of nicotine containing products such as e-cigarettes. Officials who seem to know very little about these products and appear to care even less about the users and the potential, are in a frantic huddle making up new legislation as they go along. The chart above shows how the text is ballooning with new ideas for rules, restrictions and burdens (see the evolving texts here), most of which will cause more harm. The idea of further 'strengthening' e-cigarette regulation would have the twin counterproductive effects of:

(i) in many different ways, weakening the appeal of e-cigarettes relative to cigarettes, therefore reducing switching and causing more harm to health, and;

(ii) by raising significant barriers to entry, wiping out many legitimate e-cigarette small businesses and aiding tobacco and pharmaceutical companies in dominating

the e-cigarette market (see investment analyst views).

Much of what is proposed is unjustified, violating principles of proportionality, non-discrimination and the requirement for a proper legal base – in this case, for development of the internal market. It seems many of those involved in Council discussions have forgotten or never realised that these products are *beneficial for health* and represent a huge opportunity to displace smoking with something 99% less dangerous.

There are two ways to address this woeful state of affairs:

(1) Policy. Continue to point out that nearly all the proposed measures are ill-informed, ill-judged and likely to defend the entrenched cigarette oligopoly, creating the one unintended consequence no-one involved wants. This would be easier if the meetings were not behind closed doors, the papers confidential and anyone with knowledge as consumer, business or public health expert excluded. The policy critique is summarised here.

(2) Process. Address the profound weaknesses in the policy-making process that is leading to (1) above. In my view, this is the better course, providing a structural solution rather than addressing the random consequences of poor policy making done on a piecemeal basis. In fact, if the EU just followed its own rules (see full discussion below) we would have a much better policy making process *and much better policy as a result*. The EU requires four main initiatives to inform its policy making process – and these are consistent with other work on good policy-making:

1. Evidence based justification – the measures must make sense, have the desired effect, comply with EU rules and principle etc
2. Impact assessment – costs, benefits, risks and unintended consequences should be assessed for a range of alternatives – including do nothing
3. Consultation to take the views of those affected and experts – this is not a nice-to-have but a right for those affected by government action to put their views across
4. Scrutiny – by national parliaments and though the EU legislative procedure. National parliaments remain at the heart of democracy in Europe (see Prime Minister Cameron's Europe speech Fourth Principle)

Er… no, none of this is being done for the new proposals for regulating e-cigs.

Good policy-making explained…

I'd like to go into more detail about these process issues – and what should be done.

Good policy making – what the experts say

There is a huge amount written about good policy making in many countries and languages. For just one very good example, see the Institute for Government Better Policy Making theme. Its excellent report, *Making Policy Better* should be required reading in Brussels. It lists the following characteristics of good policy-making:

- Clarity on goals
- Open and evidence-based idea generation
- Rigorous policy design
- Responsive external engagement
- Thorough appraisal
- Clarity on the role of central government and accountabilities
- Establishment of effective mechanisms for feedback and evaluation

Er… none of this applies to the way the new legislation for e-cigarettes is being created.

UK Government approach to better policy making

This isn't just clever think tanks – the UK civil service has a lot of similar stuff – for example this document 'Does your policy pass the five tests' appears on its Better policy making web page. The five tests are:

> PURPOSE – Are you absolutely clear what the Government wants to achieve?
> ROLE – Are you absolutely clear what the Government's role is? Is there definitely a problem here that can only be fixed through some form of Government intervention?
> EVIDENCE – Are you confident that you are providing world-leading policy advice based on the very latest thinking?

CREATIVITY – Are you confident that you have explored the most radical and creative ideas available in this policy space…including doing nothing?
DELIVERY – Are you confident that your preferred approach can be delivered?

No, none of these tests are passed.

Or take the recent UK government enthusiasm for 'open policy making' – see for example What is Open Policy-making? and Who is the Open Policy Maker? … *No, nothing 'open policy' about this process*.

European Union approach to good policy making

Actually the EU takes a more formal legally based approach to the disciplines of policy-making. It is coded into the European Union treaties and designed to keep EU legislation aligned with the agreed purpose of the EU. I have already discussed some of this in *Making bad law: legal vulnerabilities in the tobacco products directive* – and I think much of what is proposed is vulnerable to legal challenge. But a key text to understand is the snappy-sounding Protocol on the Application of the Principles of Subsidiarity and Proportionality (as usual, a title to secure the maximum citizen engagement! I'll refer to it the 'protocol' from now on…) This protocol is how the EU is supposed to implement Article 5 of the Treaty on European Union, governing some fundamental principles. The Protocol starts with a noble aspiration:

> *WISHING to ensure that decisions are taken as closely as possible to the citizens of the Union*

Ah yes, the citizens.. they are entirely excluded. Now on to the substance. Elements of good policy making in the EU include:

1. Evidence-based justification and requirement to give reasons

> *Protocol Article 5. Draft legislative acts shall be justified with regard to the principles of subsidiarity and proportionality. Any draft legislative act should contain a detailed statement making it possible to appraise compliance with the principles of subsidiarity and proportionality.*

> *Treaty on Functioning of the European Union Article 296: Legal acts shall state the reasons on which they are based and shall refer to any proposals,*

initiatives, recommendations, requests or opinions required by the Treaties.

Situation. There is no justification for most of the measures proposed in public health terms and in EU terms they are disproportionate, proposed without justification for departing from the principle of free movement of goods on health grounds. No written evidence-based case has been made to justify them. The draft recitals contain evidence-free misunderstanding or misinformation about e-cigarettes that cannot for the basis for the policy and would not stand up in court. *No, there has been no evidence-based justification for the raft of policies in the new text*.

2. Impact assessment

> *Protocol Article 5 (continued). This statement should contain some assessment of the proposal's financial impact and, in the case of a directive, of its implications for the rules to be put in place by Member States, including, where necessary, the regional legislation. 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.*

Situation. No attempt has been made to assess the impacts and unintended of the various policy ideas included in the European Parliament's text or the Commission's attempt to turn this into a compromise proposal with the Council. The impact assessment that was issued with the Commission proposal covers entirely different measures, and not in adequate depth. Many of the measures – banning most flavours, setting arbitrary nicotine density thresholds, banning advertising, requiring dose delivery standards, demanding excessive warnings, banning refillable units, requiring child-proofing, raising costs through bureaucratic demands and pointless tests… etc. All of these have significant potential unintended consequences leading to greater harms. *No, there has not been any attempt to assess the impact of these measures*.

3. Consultation

> *Protocol Article 2. Before proposing legislative acts, the Commission shall consult widely. Such consultations shall, where appropriate, take into account the regional and local dimension of the action envisaged.*
>
> *Treaty on the European Union Article 11.3. 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.*

Situation: there as been no consultation on the approach to regulating nicotine containing products, whether to regulate them as medicines (the original position of the Commission.Council) or through regulation directly specified in in the directive (the new approach). In the Commission's 2010 consultation, the only consultation question related to whether NCPs should be included in a TPD revision (see consultation document 1.2) not on how they would be regulated. *No, the process isn't even conducted in public let alone allowing for views of consumers, businesses and experts.*

4. Scrutiny by national parliaments

> *Protocol Article 4. The Commission shall forward its draft legislative acts and its amended drafts to national Parliaments at the same time as to the Union legislator. The European Parliament shall forward its draft legislative acts and its amended drafts to national Parliaments. (underline added)*

Situation: the proposal for Article 18 sent to national parliaments in december 2012 is now dead and has been replaced by something completely different and five times the length. Either the amended proposal from the European Parliament (amendment 170) or the new proposal coming from the Commission should be formalised as a new legislative proposal and sent to national parliaments for scrutiny. They have the right to comment and to send reasoned opinions. *National parliaments have been sidelined – so far.*

A number of national parliaments have submitted reasoned opinions at the beginning of the year. The scrutiny status of each national parliament is listed here along with reasoned opinions and contact information. If you are concerned with the policy-making process in Europe PLEASE look at this.

The policy-making process for new nicotine containing products (e-cigarettes)

Why it is so unsatisfactory. The European Parliament rightly rejected an ill-considered proposal to regulate e-cigarettes as medicines. This was burdensome, restrictive, costly and unlawful – and you can read the case for and against in this line by line critique. As the Parliament rightly asserted, it makes no sense to make it harder to put e-cigarettes on the market than cigarettes of novel tobacco products. The trouble is that is exactly what the medicines proposal did and the new proposals under discussion would do. The process is now conducted behind closed through 'trilogue' meetings – the next being 3rd December 2013, 11th December and 16th December, with a view to securing agreement before Xmas. The negotiators are apparently worried that a Greek presidency that starts in 2014 will be pro-tobacco and will not draw the directive to a conclusion at all. If the Council agrees a proposal there will be great pressure on the European Parliament to accepts or risk losing the whole directive. So the whole thing is really a 'bounce' into supporting ridiculous proposals.

You can take action…

I have already discussed the importance of talking to elected representatives (MEPs and MPs) about how bad the policy is becoming, and I urge you to keep up that effort – you will find many are responsive and open-minded and as concerned as you that we do not kill off one of the most promising health innovations of the Century with the dumbest EU regulation in history. If you want to take action on process too, here are two suggested ideas.

1. Press for more national parliament scrutiny in every member state. The proposal for regulating e-cigarettes has now changed so much that national parliaments should now scrutinise the proposals again (see the national parliament positions here for positions taken, progress of scrutiny and and relevant contact information). The working 'suggested text' has now reached five times its original length and has been amended to be unrecognisable from the original Commission proposal – adopting a completely different and non-medical approach. Please see my letter to the UK House of Commons European Scrutiny Committee on this. This UK committee has also expressed its concern about law-making in secret in its 28 November report on reforming the European scrutiny

system: see especially the section on Limité (restricted circulation) documents and the conclusion, which states:

> *...we recommend that if there are substantive changes during trilogue negotiations the Government should provide Supplementary Explanatory Memoranda on documents which have cleared scrutiny (or deposit the new version of the document, with a new Explanatory Memorandum) automatically, rather than on request (thereby re-imposing the scrutiny reserve).*

2. Press for a new legislative proposal. The Parliament, Council and Commission should now accept that this policy is important enough to get right, and that they need to give it significant attention. The Commission should now develop a new legislative proposal to introduce in the next session after the May 2014 election – that would allow for justification, impact assessment, consultation and scrutiny – and the quality of legislation would be vastly improved for it. The development of a legislative proposal through *ad hoc* 'non-papers' circulated at closed Council Health Working Group meetings is completely unsatisfactory. The trilogue negotiating process is not designed to bring about a fundamental change of approach – that should be a cause for a new legislative proposal with all the disciplines that go with it. So my suggested strategy is the following:

(1) Bring the tobacco parts of the TPD to a rapid and satisfactory agreement – there should be no problem with this.

(2) On an interim basis, regulate e-cigarettes by more forceful application and enforcement of the substantial body of safety and consumer protection legislation that already exists and press the e-cigarette industry to set and reach higher standards.

(3) Take the European Parliament's proposed amendment as starting point and recognition that the products are not medicines in law or reality, and develop a new legislative proposal, with evidence-based justification, impact assessment and consultation to develop a workable and proportionate regulatory framework that is compatible with the internal market legal base.

No emergency – do a proper job. It is important to recognise that there is no health or safety problem that justifies hasty and confused 'emergency' regulation. The e-cig market is growing at the expense of cigarettes, users seem content or

excited, there are not great safety concerns, the products are far less dangerous than smoking and marketed to adults, there is no public spending, there are no signs of bad gateway effects or anything much going wrong – and plenty going well. This isn't an argument for having no regulation – far from it – it is a argument that the job should be done properly. If it is done properly, then it could probably be done quickly with a shorter lead in – meaning the regulation could be in place almost as soon as envisaged by the Council.

The alternative: is that the Council / Commission put forward proposal that are too restrictive, amounting to a *de facto* ban, and the Parliament, under pre-election pressure from thousands of vapers rejects the whole directive. Or MEPs give in and face the consequences from voters.