# Escaping the EU directive on e-cigarettes

written by Clive Bates | 22 December 2015



I've written and presented many times on the utter mess the EU Tobacco Products Directive (TPD 2014/40/EU) has made of regulating low-risk alternatives to smoking: notably Article 20 that regulates e-cigarettes and Article 17 that bans snus.

EU legislation is especially ill-suited to regulating new disruptive and controversial technologies that regulators don't understand – see my discussion of regulating disruptive technology. Directives are produced by a kind of committee pinball game that reflect prejudices, esoteric beliefs and haggling of people with little knowledge of what they are dealing with and no accountability for the outcome or damage done. But once agreed, they are really hard to reverse or amend, and they are a good reason to do only what is necessary at European level.

Here're the escape routes I can think of.

1. Legal action
2. EU institutions recognise their errors and amend the directive
3. The normal process of updating the directive
4. Brexit – the UK leaving the EU and related reform negotiations
5. UK Parliament defies Brussels

6. Subversion, workarounds and civil disobedience
7. What to do?

# 1. Legal action

On 23rd December 2015, we will have the first sign of whether some or all of Totally Wicked legal action at the Court of Justice of the European Union (CJEU) will be successful. This is the release of the opinion of the Advocate General assigned to the case. Think of this as an expert legal opinion offered to the judges in the case. It is likely to be influential but it is not binding and the judges actually hearing the case can take a different view – and this does happen. The CJEU judgement is about whether the parts of the directive that have been challenged comply with the requirements of the EU treaties and conventions – measures must be proportionate, non-discriminatory, have an adequate legal base and respect the right to property.

I think the key issue in the decision will be the scientific and technical literacy of the Advocate General and the judges: the legal position is intimately connected to the scientific evidence because it is the estimation of risks and benefits that will justify or invalidate the 'proportionality' of measures in Article 20. If the court erroneously concludes the risks are serious, then it will be easier to justify burdensome and/or pointless regulations. On the other hand, if it recognises the great benefits to smokers and accepts the risks to others are minimal, then the regulation will be thrown out as disproportionate and discriminatory.

**Update 23 December 2015**: somewhat predictable. Bad science makes bad law:

> *TPD legal argument rests on science and Advocate General has not grasped the science, e.g. claims gateway effect > https://t.co/wK9HyAAKVJ*
>
> *— Clive Bates (@Clive_Bates) December 23, 2015*

… and the briefest possible critique (more to follow)

> *AG #ecig opinion > https://t.co/s8gDQbwbsZ < catalogue of deceitful propaganda points held together by abuse of the precautionary principle.*
>
> *— Clive Bates (@Clive_Bates) December 23, 2015*

**Future legal action**. There is no appeal route after the CJEU decision. But even if unsuccessful, the Totally Wicked case may not be the end of the matter. New cases can be brought using different legal argumentation or evidence. However, the TW case will establish precedents and case law that will inform future cases. It is also possible that specific national implementations will be challenged – for example, use of mandatory medicines classification.

**Legal action to overturn the snus ban**. Swedish Match should challenge this arbitrary ban in court. It tried this in 2003-4 and the case failed on the back of some absurd reasoning by the court. However, much has changed since then in the understanding of harm reduction and in evidence for and recognition of the public health benefits. The fact that the directive contains a section for 'novel tobacco products' at Article 19 blasts away the court's original reasoning.

**Any promise?** Yes, objectively the cases are very strong. The trouble is that they require the court to act as a non-political arbitrator of the law and to grasp the underlying science of risk and benefits. It is impossible to call the result and it is out of our hands.

## 2. EU institutions recognise their errors and amend the directive

The EU legislative institutions (Commission, Parliament, Council) could admit they've cocked it up completely and rethink – *in what would be an unprecedented act of humility*. It is possible to amend a directive at any time, but the process for doing this is the same as writing the directive in the first place (Ordinary Legislative Procedure), and there is quite a barrier to getting it started. **The Commission** generally has the power to initiate this procedure, but I can't see it doing that and inviting more work for itself and a tacit admission that the current legislation is a failure.

A majority of the **European Parliament** can ask the European Commission to bring forward proposals. If the Commission refuses, it merely has to give an explanation.

**The Council** (acting by a simple majority) may request the Commission to

undertake any studies ministers consider desirable for the attainment of common objectives, and to submit to it any appropriate proposals.

**Any promise?** Frankly, I don't think is a promising route unless there is a real will in the European Parliament. So many of those with their hands dipped in the blood are still at the scene of the crime and I doubt they'd want the scrutiny this would create. The Council power to request studies could be useful if its members were suddenly converted to high-quality policy-making. Studies might include: (1) the impact assessment for the e-cigarette measures that was never done – this would allow that expectation may one day be compared to reality; (2) regular review of real-world experience of costs, benefits and unintended consequences as they emerge; (3) inconsistencies in member state implementation legislation that create barriers to free movement of goods.

## 3. The normal process of updating the directive

The TPD has built into it 'a report', which is described at Article 28, and this is part of the process of updating the directive to take account of new developments. It requires the Commission to provide an assessment of how well the directive is contributing to the smooth running of the single market and to point out where it might require amendment in the light of scientific and technical developments. Point g. of the terms of reference deal specifically with e-cigarettes:

> *… the Commission shall pay special attention to:*
>
> *(g) market developments concerning electronic cigarettes and refill containers considering, amongst others, information collected in accordance with Article 20, including on the initiation of consumption such products by young people and non-smokers and the impact of such products on cessation efforts as well as measures taken by Member States regarding flavours;*

I guess you can see from this that the legislators were working on the basis that it's all threat and no opportunity. The most important catch is that this report must be done ***no later than 20 May 2021***. Then the process of drawing up a new directive *might* begin. The last update was to the 2001 Tobacco Products Directive, which was updated by the 2014 TPD – 13 years in the making.

**Any promise?** This is the most ponderous route to reform and by then so much

damage is likely to have been done it would be irreversible. There may be some points of pressure: pushing for that report to be done in installments, with the e-cigarette assessment being done in 2018. There is a trade-off between how quickly this report can be done and how much experience there would be available to review. This call would become more persuasive if there was widespread evidence of unintended consequences, subversion, civil disobedience and non-compliance.

## 4. Brexit – the UK leaving the EU and related reform negotiations

The UK Conservative government elected on 7 May 2015 has committed to holding a referendum on exit from the EU no later than 2017 – this 'British exit' is sometimes known as *Brexit*. In doing this, the Prime Minister is hoping to negotiate for "*a new settlement for the United Kingdom in a reformed European Union*" in return for our continuing membership. Does this have any potential for reform at all?

**Does leaving the EU help?** No. I think UK leaving the EU will not fix this problem at all. If there is a *Brexit*, UK is likely to have to comply with this directive anyway [I think the Norway model would apply – but that's a longer discussion] and we would lose one of the more progressive voices from the process of reforming it.

**Is the politics of Brexit relevant?** Yes. There are now about 3 million vapers in the UK, and many will find this directive to be the crystallisation of all they despise about the European Union – petty, meddling, arrogant, aloof, indifferent, incompetent, anti-scientific, bureaucratic, and wholly unaccountable for the consequences. Given the polls in the UK are now very close and moving towards 'out' and given the main 'out groups' (Leave.EU and Vote Leave) are well endowed and ramping up their campaigns, we can expect this dire piece of legislation to become more politically charged as the campaign evolves.

**Can something be done in the renegotiation?** First question: is there a will to act? Unlikely that there is *yet*, but… there is probably a political will not to have thousands of disgruntled vapers voting for an exit. And the Prime Minister has just shown he understands the value of e-cigarettes. In answer to a parliamentary question on 17 December:

*Q7.[902729]*

***Mark Pawsey (Rugby) (Con):*** *By the time the House next meets for questions, many people will have started their new year's resolutions. For many, one resolution will be to give up smoking. Given that Public Health England recently stated that e-cigarettes are 95% safer than tobacco and half the population is unaware of that fact, will the Prime Minister join me in highlighting the role that e-cigarettes can play in helping people give up tobacco for good?*

***The Prime Minister:*** *Certainly, speaking as someone who has been through this battle a number of times, eventually relatively successfully, lots of people find different ways of doing it, and clearly for some people e-cigarettes are successful. We need to be guided by the experts, and we should look at the report from Public Health England, but it is promising that over 1 million people are estimated to have used e-cigarettes to help them quit or have replaced smoking with e-cigarettes completely. We should be making it clear that this a very legitimate path for many people to improve their health and therefore the health of the nation*

**What could happen?** I doubt that there would be a direct deal related to this particular directive on the table – it isn't anywhere big enough at the level these negotiations are working at.  But you never know, and that should not stop anyone writing to the Prime Minister, MPs, MEPs and demanding that something is done to sort out this mess. How the politicians then do something is another matter.  But that doesn't mean it could not be tackled indirectly… Mr Cameron has set out his negotiating agenda in a letter to Donald Tusk, President of the European Council. There are two relevant strands in Mr Cameron's letter. Firstly under 'competitiveness':

*In particular, for all we have achieved in stemming the flow of new regulations, the* ***burden from existing regulation*** *is still too high. So the United Kingdom would like to see a target to cut the total burden on business. (emphasis added)*

Secondly under 'sovereignty':

*I want to see the EU' s commitments to subsidiarity fully implemented, with clear proposals to achieve that. As the Dutch have said, the ambition should be "Europe where necessary, national where possible".*

The UK focus on the burden from existing regulation is a valuable 'hook' – something in the official negotiation that is relevant for this cause. The focus on sovereignty suggests that what might replace EU regulation is national regulation until such time as the EU can produce decent regulation, and show that it is necessary to have EU level regulation at all – and it has failed on both counts so far.

**Any promise?** Yes, maybe. Can this directive and its approach to citizens be made the exemplar of how bad the European Union legislative process is? Undoubtedly: it is a poster child for all that is wrong with EU law-making. Then the question is what will be agreed to meet the UK's demands about the burden of existing regulation? Some new mechanism? A challenge process initiated by the member states? A review of impact assessments, legality and scientific advice? Perhaps a critical mass of national parliaments will be able to 'call in' bad regulation and review it? Who knows… but whatever is done to meet that requirement will be the most promising way to address this directive through the *Brexit* negotiations and EU reform. All of this would be a major struggle with only a limited chance of success – and, given the progress of negotiations, may already be too late.

## 5. UK parliament defies Brussels

I've included this because I've heard it mentioned a few times. It is not possible to do this lawfully – directives are binding in UK law and the democratic assent for them is provided by the European Parliament and European Council, rather than Westminster. The Commission would bring legal action against UK government in what is known as 'infraction' proceedings. It might be possible for parliament to limit the penalties and enforcement spending – and/or require civil servants to demonstrate value for the public money spent on this – though value-for-money tends to go out of the window when the government decides it is going to waste money on compliance with bad legislation. Almost all spending on 'the war on drugs' is in that category.

**Any promise?** There's very little prospect of a Westminster showdown with directly Brussels in my view – it just doesn't work that way. But UK parliamentarians can be very influential in pressing the government to sort out the mess by more legally workable means. I think vapers should strongly and consistently press politicians in capitals and in Brussels to sort out this mess and

explain what it means for them – let them work out how.  The most useful thing UK parliament could do right now is to hold a select committee inquiry into the policy and science behind this directive and the (truly terrible) process by which it was made.

## 6. Subversion, workarounds and civil disobedience

One mistake legislators often make is to assume that everyone will comply with their laws and act in the way they expect. This is unlikely, and I expect to see the considerable ingenuity applied to subverting this directive and showing how worthless it is. I am not saying this is good, just that it is inevitable when regulation this poor is introduced.  Some possible failures:

- A trend to cottage industries making low-cost e-liquids from concentrated nicotine liquid and flavours and selling locally and informal markets in whatever containers they want
- Hoarding and freezing of liquids
- A trade in illicit high concentration nicotine solutions to support cottage industries and DIY
- A trend to buying devices and liquids outside the EU over the internet, in person or by courier for personal use. Expect duty-free shops on the periphery of the EU to load up with gear and liquids and expect the Chinese internet sales to rocket (see these for example on Alibaba)
- Isle of man will become the UK vapers' paradise and the destination for UK vape-fests – matching its success in online gambling and plans to be a Bitcoin centre [update: some doubts expressed about whether IoM can do this – I will investigate]
- Trade in 'spare parts' for existing units bought overseas and non-compliant plug-and-play upgrades to devices
- A trend to 'binary' products where the active ingredients are sold separately and mixed by the user – with flavors sold for food purposes
- Space fillers installed in tank systems to allow larger tanks when removed
- Mislabelling stronger liquids
- A meltdown in the registration / notification system which will fail and leave the competent authorities and Commission at fault
- Advertising by word of mouth, social media and on the internet on servers

outside Europe
- Non-commercial UK-based portals to non-EU suppliers
- Trading Standards Officers unable to cope and giving low priority to harmful regulation

Please help me develop this list… I would be grateful for advice from others more expert than me on what sort of workarounds we are likely to see…

**Any promise?** Yes. I don't think politicians and regulators will see this is as a desirable state of affairs compared to a market that has reasonable pro-consumer regulation and quality control – and they would be right, it isn't. The question is whether they will detect these developments and act to reverse them decisively enough to stop these activities becoming entrenched while legitimate businesses fail or struggle to comply.  This needs to be linked with the way governments monitor the impacts of the directive and used as a basis for early revision of its most egregious failings.

## What to do?

It's basic politics – in the run up to 20 May 2016, politicians who represent vapers and vapour businesses in their constituencies – MPs, MEPs, ministers – needs to know how poor this legislation is and why that matters for health, wellbeing, and welfare. Specific asks might include:

- A proper monitoring regime to capture damage to health and small business, and other unintended consequences… (and benefits, if any).
- An early review and report on Article 20 in the light of changing scientific knowledge and experience
- A 'red tape' challenge to this especially poor piece of burdensome regulation under the Prime Minister's plans for more competition
- An inquiry by the Health Select Committee, European Scrutiny Committee or Lords Science and Technology Committee, Lords EU Committee into the policy and policy-making process that led to this directive
- Suggestions welcome…