UK government e-cigarette impact assessment exposes failed and unlawful EU policy

written by Clive Bates | 23 April 2016

New logo for the Department of Health?

The UK Department of Health has published an "Impact Assessment" to accompany its implementation of the Tobacco Products Directive (Tobacco and related product regulations, 2016). As regular readers will know I think Article 20 dealing with e-cigarettes is useless and does little but protect the cigarette trade. I can report that the new Impact Assessment supports that view – so here I provide a short review.

30-second version

- For e-cigarettes, the assessment finds £140m of quantified costs but buries the really big costs without quantifying them. These big costs include the impact of regulation on uptake, switching and relapse to smoking; promoting a black market; and the destruction of small businesses. Many other impacts – e.g. loss of innovation – are merely

ignored.

- That would be bad enough, but the attempt to assign *benefits* to the e-cigarette measures is hilariously thin. These 'benefits' rely on implausible success in addressing *non-problems* – reducing poisoning risks, deterring non-smokers from uptake by warnings, and, amazingly, the crushing power of paperwork bureaucracy to kill off smaller firms as if this is somehow a good thing.
- The failure to identify any material benefits but plenty of plausible costs, including more premature deaths, is an implicit admission of policy failure and vindication of critics.
- Furthermore, it leaves the legality of Article 20 in continued doubt – all this intervention is supposed to be to support free movement of goods in the single market *with a high level of health protection*. Where is the high level of health protection that justifies all this meddling in free trade?

Overall

Basically, an impact assessment is supposed to count up the costs and the benefits of a piece of regulation to check that it isn't, on balance, making the world a worse place. A huge range of assumptions are made and documented, and costs and benefits that are impossible (or inconvenient) to quantify are mentioned to show they weren't overlooked.

Sometimes heroic quantifications are made that really should have been left as unquantified statements. That is the case with this regulation overall. A 1.9% reduction in smoking is assumed and a high value per quitter (£72,000) is estimated. Multiply these together and – boom! – £13 billion is added to the benefit side of the equation. The assumption of reduced quitting comes from the European Commission's own impact assessment (2012 section 5.7 p112), but that in itself was formed purely of assumptions and guesswork.

Here is the money shot from the Impact Assessment page 22:

> *76. Applying the 1.9% reduction expected due to TPD2 gives a decrease of 0.36 percentage points. Applying this to the UK population (16+) gives approximately 200,000 fewer smokers beyond the baseline, spread out across the expected period of impact. On average each additional non-smoker will gain 1.2 life years (discounted) and, valuing each life year gained at £60,000, this*

gives lifetime health benefits of £13 billion.

Against this impressively fabricated benefit, no amount of wasteful, pointless, excessive costs and restrictions can ever be stacked high enough to show the directive to be worthless. That huge but baseless assumption dominates the basic shape of the cost-benefit and sensitivity analysis for the whole assessment. See this extract from the summary table on page 45.

Category	Sub-category	Total cost (millions)
Health gain		**£13,000**
Reduced labelling		**£6.6**
E-cigarettes		**Unquantified**
TOTAL BENEFIT		**£13,000**
Tax loss		**£2,000**
Profit loss	Retail	£78
	Wholesale	£42
	Manufacture	£74
	Total	**£190**
Notifications	Cigarettes/HRT	£0.23
	Cigar/pipe	£1.2
	Priority additives	£8.4
	Herbal	£0.03
	NTPs	£0.034
	Total	**£9.8**
Data storage	Tobacco	£0.64
	E-cigarette	£1.7
	Total	**£2.3**
Labelling	Cigarettes/HRT	£2.6
	"Big 3" Cigars	£0.21
	Other cigar/pipe	£3.6
	Herbal	£0.8
	Total	**£7.2**
Cross-border distance sales	Registration	£0
	Age verification	£0.039
	Total	**£0.039**
Illicit & CBS	Retail profit	£10
	Wholesale profit	£6.1
	Manufacturer profit	£11
	Lost tax	£160
	Total	**£190**
E-cigarette	Advertising	£47
	Sales reporting	£0.93
	Toxicology/emissions	£5.3
	Notification	£2.7
	Familiarisation	£0.17
	Labelling	£52
	Cross-border distance sales	£1.4
	Child/tamper proofing	£9
	Branding	£23
	Total	**£140**
TOTAL COST		**£2,500**

The e-cigarette analysis – the costs and risks

As you can see from the table above, the costs assigned to e-cigarettes regulation amount to £140 million. You can read how these are estimated in para 156 onwards, starting p33. I could probably quibble with every one of these figures, but that's not the most important point. What matters *much more* is the costs that

are not quantified – described as ‘risks’, set out on page 40.

Risks

207. There is a risk that due to the potential price increase and reduction of choice of e-cigarettes, people will choose to switch back to smoking, thus harming their health. This possibility is considered in the sensitivity analysis.

208. There is a risk that a black market will develop with potentially harmful e-cigarette products, due to consumers no longer having the same degree of choice in the legal market.

209. There is a risk that people may misinterpret the regulation, and think all e-cigarettes are medicines or regulated to the same standards and scrutiny as medicines, giving them false confidence in e-cigarettes.

210. There is a risk that the regulations will create barriers to entry for small and medium enterprises, thus reducing competition in the market.

211. There is a risk that restrictions on what products can be sold may cause businesses to incur significant costs in terms of losing stock and changing manufacturing processes. Decisions are ongoing regarding what restrictions need to be implemented, so this cost could not be monetised at the time of this impact assessment.

Oh dear. People might be harmed by this directive – that’s an unusual thing to confine to the depths of a technical report – it should be the primary concern. And what if the ban on advertising reduces the number switching…? Same worries.

177. There may be potential benefits of increased health and reduced addiction if the restrictions on advertising reduce the number of non-smokers taking up e-cigarette use. There may also be potential negative health implications if the restrictions on advertising reduce the number of consumers switching from tobacco products to e-cigarettes. Survey evidence suggests that the vast majority of e-cigarette users are current or ex-smokers, with use by never smokers negligible. The potential for the restrictions on e-cigarettes to impact on the expected reduction in smoking prevalence, by discouraging smokers from switching to e-cigarettes, is explored in the sensitivity analysis.

Comments on these risks

These are all quite serious things (other than 209) and all tend to reinforce 207. These are what we might call 'unintended consequences', though they are completely foreseeable. But 207 is the clincher and big money is involved in this. Remember, we've already seen U.S. evidence suggesting these harmful unintended consequences are real. We need to make sure we are monitoring it here in Europe.

According to ONS, there are currently 2.2 million people vaping in Britain, 850,000 former smokers using e-cigarettes and 720,000 former-smokers that once used e-cigarettes, but don't use either now. Quite big numbers reached over the 4-5 years over which vaping has risen in Europe.

So let's try an example. Suppose these risks mean we have just 4,000 fewer quits per year as a result of risk mentioned in 207? Then we apply the calculation made on the benefits side: 4,000 x £72,000 = £288 million. Oh dear, that's more than twice the costs of £140 million that have been totalled up for ten years. And what if the effect is much larger than 4,000/year? Or that future innovation blocked by the directive would raise this figure?

My point is that the costs are dominated by small changes in the uptake and quitting impact of e-cigarettes – not by the paperwork burdens they are forcing on manufacturers and other stuff they've actually quantified. No-one is suggesting that the directive will increase the uptake of e-cigarette as alternatives to smoking [not listed as a benefit in 80-83], so this risk is strongly asymmetric towards the side of more death and disease.

Black markets (para 208) have many potential risks, including increasing some of the risks the TPD attempts to micro-manage. These may include risks with liquids composition and quality, the packaging transporting and handling liquids, labelling, as well as harms associated with criminalising a supply chain, related enforcement costs and the impact on legitimate sellers.

Distorting the market by wiping out small firms (210,211). That is not what directives are meant to do – perhaps we could call this a "tobacco industry support cost".

Several costs or detriments are missing:

- the hampering of innovation needed to create better products by pointless technical limitations and higher costs to bring products to market – this will affect switching in future
- the damage that advertising bans do to competitiveness within a market and the effect of reducing the return to innovation
- the off-putting impact of excessive labelling, silly leaflets or warnings that are disproportionate and factually wrong (nicotine, as delivered by e-cigs, is not "highly addictive")
- the degradation of brand value and affinity – brands are an important dimension of attractiveness in consumer markets, and advertising bans inhibit brand development

The e-cigarette analysis – the benefits

Benefits from e-cigarette provisions are set out on page 23:

> *80. There are further expected benefits from the provisions on e-cigarettes. The requirements for childproof containers, along with the restrictions on size and nicotine strength will reduce the risk of poisonings due to consuming e-liquids. This will provide some benefit in the form of fewer accidents and potential deaths.*
>
> *81. The warning labels and restrictions on advertising are expected to reduce the appeal of e-cigarettes to non-smokers. This will help prevent individuals acquiring an addiction to nicotine.*
>
> *82. The requirements for product notifications may also put off producers with lower standards and therefore may improve the general safety standards of the industry. This may mean public bodies have more confidence in promoting e-cigarettes as an alternative to smoking, therefore leading more smokers to switch to e-cigarettes. The notification requirements will also mean consumers can access more information on e-cigarette products.*
>
> *83. These benefits are left unquantified due to the significant difficulties in estimating them and the fact that they do not form part of the costs to business.*

Comments on the benefits

Containers (80) are already mostly child resistant and could easily have been

made mandatory under consumer protection regulation. So the *difference* the TPD makes is negligible. The size and strength limits have no material impact on poisoning risk and even if 100% of poisoning harms were to be eliminated, it would make virtually no difference as these harms barely exist. Much more likely is harm arising from black market trade in super strong nicotine liquids (>99%) or similar, in poor packaging with misleading labelling. These issues are discussed in a 2014 letter from experts to the European Commission, complaining about the anti-scientific basis of the directive.

Warning labels (81) have a negative effect on the appeal of the product to the target consumer (smokers) by making the packs look ugly. Even *without* the warning labels, somehow the use by non-smokers is tiny (0.2% of non-smokers say they vape, 2.5% of vapers say they never smoked – ONS). Even if you could eliminate all of this using a warning you would hardly be making any positive impact on health because the risks to users are so low. Even then, you would still have to reckon with the *benefit* that the user is getting from it – i.e. the consumer surplus. Sorry Public Health, I know you don't really understand enjoyment, but it is just possible that non-smokers might enjoy vaping as long as they don't feel in mortal danger. So frightening them off with a disproportionate warning might also be a cost, not a benefit.

Moving on to the real business of government: killing off small firms with bureaucracy (82). This is counted as a benefit? If governments want to have higher standards, then *have higher standards.* Don't just apply crushing burdens that only medium sized companies can cope with, with the assumption that bigger is better – imagine applying that philosophy to food or craft beer?

In summary, these benefits are easy to estimate actually (83). Words like "negligible", "nugatory", "trivial" spring to mind and probably "non-existent" or "negative in reality".

The sensitivity analysis

At several places in the assessment, the Department reassures us it has accounted for all these worrying risks in the sensitivity analysis. That is just smoke and mirrors, frankly.

> *301. Other considerations such as the impact of changes in the illicit market*

> *and the market for e-cigarettes may also impact upon prevalence. It is estimated that over 1 million people are using e-cigarettes, having completely stopped smoking. The regulations on e-cigarettes included in TPD2 may reduce their attractiveness to smokers and could therefore have a negative impact on smoking prevalence. This would detract from the overall reduction in prevalence expected as a result of TPD2. Whilst we do not expect this to happen, the sensitivity analysis considers the impact of TPD2 if the reduction was less due to this or other uncertainties.*

All they did was to show that the assumed negative impact on smoking prevalence of battering the e-cigarette market is smaller than the assumed positive impact on the rest of the directive. Done! What they didn't do was look at the e-cigarette policy costs and benefits in isolation and see how big the unintended consequences would need to be to overwhelm the barely existent benefits. If they had, they would conclude the e-cigarette policy within the directive was strongly net negative and extremely risky – tiny losses in quitting smoking would rapidly overwhelm any benefits.

Summary

- The quantified burdens (£140m) are significant and unnecessary – especially to pile on to an emerging disruptive industry.
- The unquantified costs and harms – from fewer people quitting, more relapsing, and longer dual use – would completely dominate the cost side of the e-cigarette analysis even if faintly realistic assumptions were made.
- It is highly unusual to have a directive with an assessment that identifies extra premature deaths of British citizens as a likely risk – and for this not to feature as a primary concern in both the impact assessment and in the policy-making.
- The claimed benefits are negligible and are, in fact, more likely to be costs. The assessment is at its most unconvincing in trying to claim e-cigarette benefits from TPD.
- The assessment highlights the likely damage to small businesses that are currently viable – mainly through bureaucratic burdens.
- The sensitivity analysis fudges this by looking at the directive as a whole – rather than the e-cigarette costs and benefits in a separate sub-analysis. These e-cigarette policy effects are swamped in the hugely generous

> assumption that smoking prevalence will fall because of the other provisions of the directive. If a cost-benefit analysis was undertaken only of the provisions related to e-cigarettes (Article 20), then this would be strongly negative and consideration of the unquantified risks would scream "don't do this".

I don't want to be unduly critical of the officials that pulled this together. The TPD was not negotiated by them, and it is mandatory and has to be implemented in the UK – the mistakes were made in late 2013 and we are stuck with them. Further, they have actually sign-posted an awareness of these potential costs and limited benefits – something I doubt we will see much of in the rest of the European Union or their equivalents in the United States.

Before anyone makes the point, the UK leaving the EU would not undo this sorry state of affairs. Under any plausible 'Brexit' scenario, we would still be required to comply with the directive, but our influence in changing it would vanish and the situation would be worse than it is now. See Brexit: utopia, dystopia or PONCE? for that argument.

Legal implications

The Department of Health has buried this negative assessment of the cost-benefit balance of Article 20 in the overall TPD cost-benefit analysis. Why does this matter…?

Recall that this directive is justified under the legal base that is designed to promote free movement of goods in the internal market by harmonising regulation. However, all the Article 20 harmonising restrictions and bureaucracy that impede the free movement of goods must be justified with regard to developing the internal market *with a high level of health protection*. (Article 114 of the TFEU)

This Impact Assessment shows that this legal base doesn't hold water because the measures don't really create any benefits, but lots of costs and restrictions on free trade, and clear danger of harm to health, rather than a high level of health protection It would mean Article 20 is unlawful. The sooner it is withdrawn and completely recast, the better.

[Note to officials. A loss of tax is not a *cost*, it is a change in *transfers* within the

economy – the money stays with consumers who gain from it. A different tax base may need to be tapped to raise revenue, creating different transfers].