Tobacco Products Directive – what next and what can be done?

Dog's breakfast: update on the TPD

As the revised Tobacco Products Directive (TPD) draws closer to implementation by 20 May 2016, many are wondering what can be done about this dire piece of legislation – at least as it applies to 'tobacco harm reduction': e-cigarettes (Article 20), novel tobacco products (Article 19) and snus (Article 17). I have discussed its multiple failings here: What's wrong with the tobacco products directive for vapour products and here's Chris Snowdon's concise briefing for EPICENTER

But what can be done now…? This post is in three parts:

1. Where we are
2. What can be done
3. Options for making progress – a few ideas

1. Where we are

How did we get here?

Defective process. Most of the problems arise from the way this legislation was made – in a closed series of meetings (the 'trilogue' process) between October and December 2013. This meant completely new legislation was created in a secretive process without consultation, without proper impact assessment, no national parliamentary scrutiny, without adequate scientific input and without the normal procedures for making new legislation through the Ordinary Legislative Procedure. The trilogue is not supposed to be a forum for conjuring up legislation out of thin air – but for resolving differences of detail between the Council, Parliament and Commission. The European Ombudsman is finally making inquiries into the transparency of the trilogue process *generally*, but she'd already that ruled my complaint about this abusive legislative corner cutting was inadmissible in 2014. The snus ban is possibly the worst bit of negligent grandstanding legislation ever seen. However, the Directive did become law in May 2014 and has to be transcribed into national law by 20 May 2016.

Now it gets complicated..!

Launching the TPD in May 2016

The directive is fixed. The TPD itself is fixed and became European law on 19 May 2014. This isn't actually a law that is binding on citizens or businesses, but on member states (the 28 governments of EU), which are required to introduce domestic legislation to comply with the directive by 20 May 2016. Member state governments and national parliaments cannot change the directive, they can only deal with any options, flexibilities and ambiguities in the directive or in some cases go further than required. This is what the Department of Health consulted on over the summer. Given there was no consultation on the directive (Article 20) itself, I feel this exercise was a little patronising – but responded all the same with this: Lipstick on a Pig.

Kafkaesque transitional provisions. The directive bites from 20 May 2016. There are transitional provisions at Article 30 which mean e-cigarettes and e-liquids on the market before 20 November 2016 have until 20 May 2017 to comply (see

implementing regs s50.5). However, it isn't quite that simple: the notification regime at Article 20.2 requires detailed notification information to be submitted *6 months in advance* of placing a new product on the market. TPD compliance for e-cigarettes and liquids in the UK means complying with s.36-38 of implementing regulations (product requirements, information requirements, and product presentation requirements respectively) that will come into effect on 20 May 2016 – these are currently in draft form. So this is the situation:

- For products already on the market at 20 May 2016. Manufacturers and importers have to bring the products into TPD compliance by 20 May 2017 and must complete the notification process before 20 November 2016. Note that a product becomes a 'new product' if it has to be changed to make it TPD compliant.
- For products to be placed on the market between 20 May 2016 and 19 November 2016. Manufacturers have to bring the products into TPD compliance by 20 May 2017 and complete the notification process on 20 May 2016. Yes, I did say on 20 May 2016 (see implementing regs s30).
- For products to placed on the market after 20 November 2016. The product must comply with the TPD at launch, and the notification will need to have been done 6 months prior to launch. So a product brought out in December 2016 for Xmas will need notification details entered in June 2016 and be fully TPD compliant at launch.
- By 20 May 2017, everything on the market should be fully TPD-compliant.

Got that..?

Big computer, big headache. Each member state requires notification of new products – but the EU will have a single computer portal to help with notification.

Notification information will be fed into a central European computer system and shared with all member states, starting on 20 May 2016, the day the system goes live. That's the same day everyone wanting to put new products on the market between May 2016 and 19 November 2016 has to load up their notification data and transmit it seamlessly to the member states. Language translation – I'm sure that will just work. Big demand on an hurriedly constructed IT system on day one.

What could possibly go wrong?

Death by paperwork. Negligible effort has been expended to make any of this less bureaucratic – other than the high-risk idea of running it all on one big computer portal. It's almost as if the costs and burdens are seen as a benefit – a bad habit transmitted from regulating tobacco companies, where bureaucrats couldn't care less how expensive and wasteful the regulation is. So some manufacturers will potentially have to notify *thousands* of products, many that are almost entirely the same, into this computer system. See my comments on the notification regime: Death by paperwork: e-cigarette notification regime.

What is all this for and what will be done with it?

Most overtly stupid provision? It's a crowded field but for sheer 3D silliness, this award must go to the false, misleading and perverse requirement to label e-cigarettes with the following warning – 37(4)

> *Each unit packet and any container pack of the electronic cigarette or refill container must carry a health warning consisting of the text: "This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers"*

- *False* – this has to go on products that are sold without nicotine, like most refillable devices, tanks or mods.
- *Misleading* – nicotine isn't highly addictive or even addictive *per se*, it depends on how rapidly it is absorbed (its pharmacokinetics) – we know this from NRT studies.
- *Perverse* – ideally e-cigarette users will become non-smokers. This message is imploring dual use or continued smoking.

Of course this is a ridiculous message, but it still has to be splashed over 30% of the packaging in bold black and white, adding to the perception that these products are harmful rather than vastly safer than cigarettes.

What else is to come?

The directive includes so-called 'implementing acts'. These are details that the legislature leaves to the Commission to sort out – implementing detail rather than the big picture bureaucratic harassment that MEPs and Council ministers like to involve themselves in. The Commission lists these: Implementing the Tobacco

Products Directive. For e-cigarettes, there are two implementing acts and one report in preparation – here is the status at 20 Sept 2015.

11.	Article 20(10)	Report	Potential health risks to public health from refillable electronic cigarettes	Q2 2016	• External contract : **→started 01/2015. Contract: PRECISE[c] →Stakeholder involvement started 05/2015** • Member States/Expert Group consultations • Adoption by the Commission
12.	Article 20(13)	Implementing act	Technical standards for the refill mechanism for electronic cigarettes	Q2 2016	• External contract : **→started 01/2015. Contract: PRECISE[d]** **→Stakeholder involvement started 05/2015** • Member States/Expert Group consultations • Adoption by the Commission
13.	Article 20(13)	Implementing act	Reporting format for electronic cigarettes	Q4 2015	• External contract : **→started 05/2014. Contract: EUREST** **→Stakeholder input started 08/2014[e]** • Member States/Expert Group consultations • Adoption by the Commission

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I have seen nothing of the report on 'potential health risks to public health from refillable electronic cigarettes' or 'technical standards for the refill mechanism' – and have commented on the reporting format here.

Note that the EUREST consortium includes an anti-smoking activist group with no relevant experience, ENSP, that has been hostile to e-cigarettes and harm reduction and advocates member states going beyond requirements the directive. The PRECISE consortium is more opaque.

Gold plating. In the UK the Department of Health and devolved administrations will also have to finish regulations and add any gold-plating they want to include (for example, the Scots plan to ban all e-cigarette advertising even though this isn't required by the directive).

2. What can be done?

How can the TPD be changed?

Not easily. There are three ways:

1. By legal action that challenges the directive by showing that it violates European Union treaties or conventions – like a constitutional challenge. This is live right now, through the case brought by Totally Wicked – explained here Totally Wicked Challenge to Tobacco Products Directive and on the Totally Wicked dedicated Article20LegalChallenge website, where you can show your support for the case. The case will be heard on 1st October 2015 at the Court of Justice of the EU.

> Support this case!! Please show your support before 29 September – we need to communicate the broad base of support for the case and the deep concern about this useless legislation. On 29th September, Totally Wicked will be handing in the petition at Parliament – see New Nicotine Alliance call to arms. We don't know when the court will actually issue a decision – hopefully before May 2016 – they are clearly trying to expedite it and will be hearing three TPD related cases in the same 2-day session. I think the TW case is very strong, but I also think the court acts politically, and may reflect individual preferences of the justices hearing the case. If the case is successful it will be important to have a clear view of what should take its place and press the authorities to take that approach and not some random knee-jerk reaction.
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> Other cases? Note there may be other e-cigarette cases in future – especially if member states go beyond the directive or implement it improperly. However, they would need to work with whatever precedents were set in the Totally Wicked case.
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> Snus ban? I think Swedish Match should man up and bring a case to against the snus ban… a subject I will return to. And yes, I realise it is unusual for public health advocates to call on tobacco companies to take legal action, but it follows logically from everything I have written on this site about snus – eg. this letter.

2. By the amendment of the directive. This would require a new directive to amend or withdraw parts of the TPD. The European Commission has the '*power of legislative initiative*' in the EU. This means new directives and amendments can only be done with a new Commission proposal and then by going through the same 'ordinary legislative procedure' that was used to agree the TPD in 2013. The Commission is unlikely to want to do this, to put it mildly – though if the legal action is successful, or partly successful it may have no choice but to open it up –

depending on what the court finds.

Can the Commission be *required* to make a new proposal? No. But there is a concept known as the "*power of political initiative*". There are three relevant ways a political initiative can be made in this case:

> *Parliament (by a majority of its component Members) may ask the Commission to submit a proposal in cases where Parliament thinks EU legislation is needed to help implement the Treaties. If the Commission refuses to submit a proposal, it 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.*
>
> *A Commission proposal may also follow a European Citizens' Initiative. [a petition of at least one million signatures with a minimum number from at least seven member states collected in one year]*

These are not especially promising routes.

- MEPs are still defending the useless legislation that they produced in 2013, with little sign of remorse or contrition.
- Member states are busy on the detailed implementation of the bad legislation they jointly produced. They would not want the bother of redoing it and undoing all their careful preparation. In fact, many are hard at work making it worse than it needs to be – so there is not much sign of good will at present. Update: if you want to grasp the hostility of the Commission and member states – look at the minutes of their May meeting (h/t Dodderer).
- A European Citizens Initiative, the European Free Vaping Initiative was tried in 2013/14 and gathered 181,000 signatures. Maybe a 2016/17 initiative would have more impact once the mess was more obvious? Alternatively, like many petitions, it could create the *appearance* of action, achieve nothing and deflect from more useful political activity.

3. By expediting the next update of the directive. This is really a variation on 2. above, as it still needs a Commission proposal and new legislative process. The

key to this is Article 28 of the TPD, "report". This has to be done '*no later than five years from 20 May 2016*' – so it could be done in say 2018, rather than wait for 2021, though the Commission absolutely will not do this without a lot of pressure or obvious failures of the directive. It is the trigger for updating the directive in the ordinary course of events.

> *In the report, the Commission shall indicate, in particular, the elements of the Directive which should be reviewed or adapted in the light of scientific and technical developments, including the development of internationally agreed rules and standards on tobacco and related products*

This process could be the focus of efforts to bring problems with the directive to the fore. One way of doing this will be the annual reporting under Article 20.7 of the TPD – the first of which is due in May 2018 to refer to the calendar year 2017, and the duty of the Secretary of State to monitor market developments.

> *Member States shall monitor the market developments concerning electronic cigarettes and refill containers…*

It would be good if industry associations could fund a 'State of Vaping' annual report with a 2015 baseline. Consumers could also work out a way to characterise the damage (or benefits) that the directive is causing.

Can other things be changed?

Anywhere a member state has gone beyond the minimum requirements of Article 20 or is otherwise 'gold-plating' then there is a case to resist through national parliaments and any 'better regulation' machinery there is in country. Although most of the details are settled in the TPD, I believe it is always worth responding to consultations on implementing detail – not least to put views on the record should there be future legal actions or other scrutiny of the actions of officials and ministers.

3. Options for making progress – a few

ideas…

1. Litigation. Sign up to support the Totally Wicked legal case before 29 September 2015 – do it here. Join the TW petition handover at parliament on 29th
2. Accountability. Build the simple proposition that the TPD Article 20 is the worst European regulation ever made, the inclusion of e-cigarettes in the TPD was a mistake, that Article 20 of the directive will cause harm without doing anything good (see here), that it was made in an opaque and unlawful process (see here) and everyone involved should [be ashamed][apologise][resign] *delete as appropriate*. This is about holding health ministries, politicians and regulators to account for the utter mess they have made – and getting them to play a more positive role (see here). That is the starting point for change and should be a period of intense activity from 1 Oct to 20 May 2016.
3. Gold plating. Fight every excessive measure or wasteful gold plating that goes beyond the minimal interpretation of what the TPD requires.
4. Scrutiny. Encourage retrospective parliamentary scrutiny of the TPD – both the measures (useless and damaging) and the process (outrageously opaque). For England, I would like to see the Health Select Committee, Public Administration and Constitutional Affairs Committee and/or European Scrutiny Committee examine Article 20 and how it was made.
5. Reaction to litigation. Press health officials / ministers to adopt a coherent alternative approach should Totally Wicked be partly or wholly successful, not another knee jerk reaction – this could be a focus in the period between the court hearings and decision
6. A better alternative. Work on having defining a consensus alternative regulatory regime. Persuasion to change regulation will be more convincing if there is a well-designed alternative – possibly using the emerging BSI or CEN standards. Press to bring forward the report under Article 28.
7. Government monitoring. Press member states to be clear how they will "*monitor market developments*" and to capture baselines data – this needs to be set up properly with public visibility of the monitoring
8. Business and consumer monitoring. Document TPD impacts from both personal consumer or business perspective – consumers could keep a kind

of diary or dedicate a forum to these impacts, businesses should carefully record impacts of the directive. An annual State of Vaping review.

9. Challenge. Keep up the efforts to correct misleading reporting and commentary in the media and do not allow false information or assertions about the TPD to go unchallenged.
10. Capacity. Widen and deepen advocacy networks – encourage circulation of information and analysis, and calls for action.

Please let me have your suggestions in the comments and we can debate, refine and prioritise this list.

I'm afraid the problem with EU directives is that they are very hard to undo – that is why they should be used sparingly, made with due regard for the EU treaties, and designed with great care and transparency – i.e. not in the shoddy way the TPD Article 20 was made.

Is this the worst EU law ever made?