Study supporting the evaluation of the Tobacco control Acquis

Task 2A: Interview Questionnaires

Interviews draft questionnaire: Consumer Association

Perception of the problem and its relevance
Do you believe that new developments in the sector had significant implications for the relevance of the tobacco control legislation in the EU? *There are some new developments, which in our view are very positive. Whereas the questions in the survey were framed in such a way as to imply a risk rather than an opportunity. It's important to recognise that much of the TPD has been effective in promoting its objective: developing the internal market with a high level of protection of human health. Therefore, we think that the tobacco legislation either should stay as it is or it should be improved in the following ways:* - *A recognition that safer nicotine products (SNPs) such as vaping products, HTPs, snus and pouches are all much less risky than smoking and that tobacco control legislation and policy should be proportionate to risk.* - *SNPs replace cigarettes and help people to quit; they provide a public health benefit by displacing smoking with something much less risky. Tobacco control legislation and policy should also reflect opportunity.* - *SNPs function as economic substitutes for cigarettes so we have to be careful with policies that make them more expensive, less easy to access, or less appealing, and less effective as competitors to cigarettes. This would protect the cigarette trade and have the effect of increasing smoking.* - *Focus on unintended consequences: Prohibitive policies focused on reducing vaping among young people can have the effect of increasing smoking among adults and young people, encouraging an illicit market, DIY home mixing, etc.*
Do you believe the provisions of the TPD and TAD are still relevant to tackle today's market reality? *The way we would approach regulation in this field is to draw a distinction between high-risk combustible products and low-risk non-combustible products (vaping, HTPs, smokeless tobacco products and nicotine pouches); combustion is the critical distinction in public health terms. The problem with the TPD and TAD is that they distinguish between tobacco and non-tobacco products rather than combustible and non-combustible. For example, if you ban the advertisement of HTPs, which are direct competitors of cigarettes, you are protecting the incumbent cigarette trade, prolonging smoking, and negatively impacting public health.* *Similarly, the TPD needs to be made more risk proportionate with regards to non-combustible products. The strongest measures need to be reserved for combustible products. In this regard, the final recommendations of the European Parliament's Special Committee on Beating Cancer agreed that risk assessments should always compare non-combustible with combustible products.* *TPD ban on snus is unjustified: Sweden has the lowest rate of smoking and smoking-related disease because of the availability of snus. The ban on snus doesn't promote the internal market with a high level of health protection, it does the opposite. It blocks a product that has been instrumental in driving down smoking rates in Sweden to almost smoke-free status, 17 years ahead of EU targets.*
Which TPD provisions do you believe have lost relevance and pertinence in the EU context? What kind of direct impacts did these provisions have on the tobacco industry? *The ban on snus is ridiculous and political, there is no scientific evidence to support it. In fact, there is a large body of evidence that suggests it should be lifted immediately.* *Some of the provisions of Art. 20 in the TPD which relate to vaping products are counterproductive, such as the 10ml limit on e-liquid container size, which serves no purpose other than to create more plastic waste, more filling activity and encourage workarounds. The 20mg/ml limit on nicotine strengths forces consumers to use larger volumes of liquid using devices that use more energy, which can increase the risk of exposure to potentially harmful compounds. It gives the cigarette product, which delivers a higher amount of nicotine in a faster way, an advantage that is not justified in the market.*

The bans on advertising, promotion and sponsorship of vaping products are counterproductive as they have a lower risk than cigarette products and they are a substitute for and help people quit smoking. These advertisements function as anti-smoking promotion paid for by the private sector. The problem of banning this type of advertising is that it protects the incumbent (the cigarette product), that is the most popular and dangerous. This anti-internal market measure inhibits innovation and the uptake of innovation by EU citizens in favour of the incumbent product (cigarettes).

Effectiveness and efficiency of EU tobacco acquis

Do you believe the current EU tobacco control legislative framework was effective in reducing tobacco consumption? If not, what might be the reasons behind the failure of meeting this public health objective?

The objective should be the development of the internal market with a high level of human health and consumer protection. If the objective is reducing tobacco consumption, it might be able to do it but at a price for public health. If, for example, the TPD reduces the uptake of snus and HTPs it might be efficient in reducing tobacco use but not efficient in protecting health. This is because it doesn't distinguish between high-risk combustible products and low risk non-combustible products. To achieve a high level of health protection you have to make that distinction.

However, we must stress that, despite its flaws, what the EU has done with the TPD is far better than many other jurisdictions, such as the USA or Australia.

Problems that have arisen with tobacco policy in Europe have come when Member States went above and beyond the measures in the TPD and introduced prohibitive policies such as flavour bans and high taxation (e.g., DK, EE, IT, etc.)

Have Member States successfully applied article 18 of the TPD regarding cross border distance sales, particularly to comply with age verification as required by article 16 of the WHO FCTC?

Age restriction for vaping products is a matter of Member States. For example, Ireland still does not have an age restriction in place. Member states insist on subsidiarity for age controls.

Some Member States have banned online cross border distance sales, but this causes major problems as well as people do not find the product they want and end up relapsing to smoking, given cigarettes are always available everywhere. Vape products are far more diverse and niche products will only be accessible via online sales.

In some ways, people can circumvent provisions on cross border distance sales very easily. People can always access websites from countries outside the EU.

Did article 7 specifically provide interpretation challenges that affected the effectiveness of the article?

A distinction must be more carefully drawn between combustible and non-combustible. The ban on characterising flavours should be only applied to combustible tobacco products. It would be helpful if people could switch from menthol flavoured cigarettes to menthol flavoured non-combustible products like HTP.

In the article, there is a list of prohibited additives, which does not represent a problem. Obviously, additives that have material CMR properties (carcinogenic, mutagenic, reprotoxic) should be banned. The big risk is that Member States are extending the list of additives to ban characterising flavours in e-cigarettes, for example. This would be ineffective and counterproductive.

Was article 7 effective in guaranteeing a high level of human health protection and ensuring the smooth functioning of the internal market?

No, because if that was the objective then you would have to make a distinction between combustible and non-combustible products, while now the distinction is between tobacco and non-tobacco products. The flavour ban should be restricted to combustible products.

Have the TPD provisions on e-cigarettes, contained in article 20, being effective? Please explain why yes or not.

Par. 1 we are happy with parallel medical and consumer routes to market and can see advantages in both, provided no further action is taken to force consumer products through the medical pathway.

Par. 2 we support the notification regime, which works well, but Member States and the European Commission should never turn it into an authorization regime.

Par. 3a the limits on refill containers and tank sizes create more waste and refilling activities, it generates workarounds that can make the products less safe. The limits serve no useful purpose and add risks, they should be removed or set higher.

Par. 3b the nicotine strength cap at 20mg/ml is a barrier to innovation based on a misunderstanding of how consumers subconsciously regulate ('titrate') their nicotine intake, it does not achieve the objective and it does not control the amount of nicotine that users are exposed to. It does, however, encourage larger devices operating at higher energies, use of larger volumes of liquid and leads to higher toxicant exposure.

Par. 3c there is no problem with the current prohibited list of additives, the problem is Member States (or in future the EU) greatly extending the scope to include characterising flavours or a whitelist of ingredients allowed in e-liquids. That would be disproportionate and counterproductive. It would favour the cigarette trade, encourage a black market, DIY home mixing, and increase the risk of people using dangerous products (e.g., essential oils or oil-based flavours). The rest of para 3 is okay.

Par. 4: a leaflet detailing risks, toxicity, etc is not required for tobacco products for smoking, so this is not proportionate or non-discriminatory and works in favour of cigarettes trade. Packaging: the problem of health warnings that only stress risks is that they deter the use of vaping products when they should encourage people to switch to less risky products. So, the health warnings on vaping products don't optimize health protection in the internal market because they create a barrier to switching from high-risk to low-risk products.

Par. 5: this measure effectively extends to the main provisions of the Tobacco Advertising Directive to vaping. However, vaping or e-cigarette advertising basically functions as private sector pro-health anti-smoking advertising, considering the high levels of smoking in the EU. This measure works against pro-health innovation and protects the incumbent cigarette trade. So, this works counter to the objective of high level of health protection in the internal market.

Par. 6 we discussed under the question about Article 18 (cross border internet sales) above.

Par. 7 [disclosure of sales information] and 8 [publication of sales information] are fine.

Par. 9 [adverse effects reporting and response] is fine but must not be overused to make new policy or effectively extend the directive.

Par. 10: only refers to the potential risks, but it should say the potential risks and "considerable opportunities to public health associated with the use of e-cigarettes".

Par. 11: this is or should be an emergency provision and it should not be used more generally. Similar considerations as par. 9

Par. 12: it depends on what the commission does with its delegated authority.

Par. 13: is fine.

The Directive as a whole has been a success for the EU. Although it's not as good as it could be, which we've already discussed, it has been effective in promoting the internal market with a high level of protection for human health, with the exception of the ban on snus.

Do you believe the costs borne by the tobacco industry are proportionate in relation to the social and economic benefits of European citizens? Is there a fair distribution of compliance costs between the main actors?

Compared to other jurisdictions, the compliance costs are relatively modest – but we as consumers have limited insight into any distorting effects. From a consumer perspective the dominant policy cost comes from taxation rather than compliance.

Coherence and complementarity of the legislative framework, and further scope for EU Action

Are all the definitions contained in the TPD and TAD coherent among them? How so? *The problem is the broad use of 'tobacco products', which now contains within it products that have vastly different risk profiles i.e. combustible and non-combustible. So, definitions should distinguish between combustible products and non-combustible products. Also, there is a distinction for smokeless tobacco products but there is not a distinction made for HTPs which are very low risk. There is no basis for differentiating between 'traditional' smokeless products (virtually no regulation) and oral tobacco (a ban) depending on whether is sucked or chewed once placed in the mouth. That is obviously absurd.*
Overall, are the provisions of the TPD and TAD coherent and complementary with the obligations of the EU and Member States towards the WHO FCTC? *Broadly speaking yes, because the EU had a significant role in negotiating the FCTC, making sure that the text was consistent with its directives. The FCTC does not really require Member States to do very much in any particular time, and there are caveats for Member States to implement it under their constitutional framework. For the most part the TPD and TAD are consistent with the FCTC. This does not mean that the FCTC is perfect, far from it. The EU should seek to improve the FCTC by making a clear distinction between combustible and non-combustible products. The EU should use its considerable negotiating power at COP10 to further the goal of risk-proportionate regulation, awareness of trade-offs and unintended consequences.*
Specifically, have Member States adequately applied WHO FCTC Article 13, banning all forms of tobacco advertising, promotion, and sponsorship? Has there been sufficient action from the EU in this area? *Here, the issue is whether FCTC Art. 13 is fit for purpose: it does not distinguish between combustible and non-combustible products. The EU TAD bans cross border advertising. EU originally wanted to ban all advertising but that was found to be unconstitutional by the European Court of Justice. The EU "constitution", meaning the TEU and TFEU, limits the role of EU in implementing Art 13. But the EU does do everything that it can do under FCTC Art.13.*
Are EU Member States taking effective measures to promote cessation of tobacco use and prevention of tobacco dependence as required by Article 14 of the WHO FCTC? Is there a need of further action from the EU on this area? *The simplest way to get people to stop smoking is to decouple smoking cessation and nicotine cessation. The demand for nicotine is much more robust and inelastic than any particular way of taking it, such as smoking. By switching to another nicotine product which does not involve combustion, users achieve nearly all the benefits of abstinence but are also more likely to succeed and more people are likely to try. If the aim is to reduce health burdens by reducing smoking, people should be encouraged to switch to a product with nicotine but without combustion. Hostility to tobacco harm reduction is hostility to the best way of getting people to quit smoking with the least possible effort and the greatest chance of success.*
Coordination and EU Added Value
Do you believe the TPD and TAD missed out on possible added benefits from not including policies in areas that are currently out of scope? *There would be benefits from having a sound regulatory regime for nicotine pouches, setting manufacturing standards, regulating the amount of nicotine, packaging, and labelling guidelines etc. Same as there is for e-cigarettes, creating a lightly regulated market focused on consumer protection. Banning these products, banning flavours, or imposing even lower limits on nicotine would make them ineffective alternatives to cigarettes and protect the incumbent cigarette trade. So, it would be good to include nicotine pouches in the scope of TPD or TAD, but with risk-proportionate consumer protection provisions, mindful of unintended consequences.* *On snus, the ban should be lifted and there should be a standards-based approach, such as the GothiaTek standard (though less exacting), which could also regulate all the South Asian smokeless products currently on the market. This would provide a model for what the EU should be doing to facilitate the internal market with a high level of health protection for citizens, replacing an unjustifiable ban with pro-health consumer protection regulation.*

We are very concerned about indications that bans on flavour may be under consideration (as they have been in some member states). On flavours: 3 different ways to look at them:

(i) as a chemical recipe (i.e., a mix of chemical ingredients),

(ii) as a sensory characterization (e.g., apple flavour) and

(iii) as a flavour descriptor (i.e., the language used to describe it in terms of marketing).

Risk proportionate regulation of harmful ingredients (i) is justified, it's already in the directive. There should not be any restriction in terms of sensory characterisation (ii), as it would be counterproductive because it prevents people to quit cigarette smoking .There could be some guidance on limiting flavour descriptors (iii), it would be reasonable for the EU or member states to have a say in terms of, for example, descriptors or labelling that appeals to children (cartoons etc), infringement of copyright or trademarks, etc. but definitely not to ban broad categories of flavours, or particular flavour ingredients, unless they are toxic at the levels in use in vaping products.

Acceptability of the legislative framework

Do you believe the EU tobacco control legal framework is acceptable, given the inherent and insoluble conflict between the public health interests and the tobacco industry's activities?

It is acceptable but not optimal, it could be improved, but it is likely that if modified it would become worse rather than better. We don't accept the premise that the objective to achieve a high level of public health is not compatible with the activities of the tobacco industry. The tobacco industry wants to modernise itself and the market; consumers, public health, and the industry would benefit from a regulatory framework that encouraged a market-wide move to non-combustible products. The EU can make risk-proportionate regulations that allow and encourage consumers to switch to non-combustible products. This is the big strategic decision for the European institutions to make as they consider further developments in tobacco and nicotine regulation.