



Mr. Vytenis Andriukaitis

European Commissioner for Health and Food Safety
Rue de la Loi / Wetstraat 170
B-1049 Bruxelles/Brussel
Belgique/België

Geneva, 22 September, 2015

Dear Commissioner Andriukaitis,

I am writing on behalf of Japan Tobacco International to express our serious concern that the Commission, via DG SANTE, is acting outside its remit in relation to guidance documents prepared under Directive 2014/40/EU on tobacco products (the 'Directive').

The two documents in question, the draft non-binding Guidance¹ Document developed by consultants to the Commission² and a so-called 'Non-Paper' prepared by DG SANTE, relate to the placement of Combined Health Warnings ('CHWs') on tobacco packs.

In these documents, DG SANTE and the external consultants allege that CHWs must be applied only on the flat surface of cigarette packs with bevelled edges and round corners, purportedly (as stated in the 'Non-Paper') because this would enhance the visibility of the CHWs.

Our position is that these two documents are in conflict with the Directive and go beyond the scope of the relevant Implementing Act, as DG SANTE is trying to force a certain interpretation of the Directive despite not having any mandate to do so for the reasons set forth below and, in more detail, in the attached explanatory note.

1. The Directive empowers the Commission to define the technical specifications for the layout, design and shape of the CHWs, taking into account different pack shapes. The Directive therefore does not authorize the Commission to address the placement of CHWs. The placement of CHWs is already defined in the Directive³.
2. In addition, Recital 28 of the Directive and the legislative history⁴ reinforce that the Directive allows for the continued use of bevelled edges and round corners packs.

DG SANTE has informed stakeholders several times that it is not in a position to provide any interpretation of the Directive, since, as they specify at the end of the 'Non-Paper', only the Court of the Justice of the EU (CJEU) can provide a definitive interpretation of the Directive. We have previously expressed our concern with the choice of consultants for the Guidance Document who suffer from an inherent lack of impartiality: Burson-Marsteller has a policy not to

¹ The draft Guidance Document 'Editing of combined health warnings on smoked tobacco packaging' associated with the Directive's secondary legislation (Implementing Act Article 10(4) of the Directive on 'the technical specifications for the layout, design and shape of the combined health warnings, taking into account the different packet shapes').

² A consortium led by Burson-Marsteller and the Smoke Free Partnership, subcontracted to a.o. Butcher & Gundersen, acting under the mandate from the European Commission (DG SANTE).

³ Articles 8(2) and 10(1)e.

⁴ An amendment aiming at prescribing that cigarette packs should only have sharp edges was rejected (Amendment 29 from MEP Handzlik - [http://parltrack.eu.wiki.org/dossier/2012/0366\(COD\)](http://parltrack.eu.wiki.org/dossier/2012/0366(COD))).

work with tobacco companies and the Smoke Free Partnership promotes extreme tobacco control policies, including standardized packaging.

By producing a 'Non-Paper', irrespective of it containing several "disclaimers", DG SANTE has exceeded its remit and is surreptitiously encouraging Member States to adopt an incorrect interpretation of the Directive and play a role reserved to another institution (the CJEU).

[REDACTED]

[REDACTED]

Since we understand the draft non-binding Guidance Document has yet to be finalized we trust that these points will be urgently addressed by the Commission and its contractors and that you will ensure that DG SANTE formally repeals its 'Non-Paper' and informs Member States accordingly.

We would be glad to answer any questions you may have and would appreciate an opportunity to discuss these concerns with you in the very near future.

Yours sincerely,



[REDACTED]

JTI is a leading international tobacco company headquartered in Geneva, Switzerland. Today, our company has over 26,000 employees and operations in 120 countries. In the EU, we employ around 10,000 people in 25 offices, 7 factories and 4 R&D centers across Europe. JTI is registered in the EU Transparency Register under the identification number 71175716023-03.

Explanatory Note

From a content point of view:

- Recital 28 of the Directive and the legislative history⁵ reinforce that the Directive allows for the continued use of bevelled edges and round corners. Applying the CHWs over the bevelled edges or round corners can be done such that the surface area covered is (i) equivalent to that on a pack without such edges or corners (as it is unambiguously clearly stated in said Recital), (ii) fully visible as demanded by article 8(3), and (iii) covering 65% of the external front and back surface as required by article 10(1)c.
- Extending the CHWs into part of the bevelled/rounded edges, will in no way affect the graphical integrity or visibility of the CHW, as the main content of the CHW will remain on the flat front or back surface.
- The Directive requires cigarette packs to be cuboid and Recital 28 explicitly permits bevelled edge and round corner packs thereby classifying them as cuboid. The definition of cuboid is a geometric shape with 6 faces. According to the Directive, the bevelled and rounded edges should therefore not be seen as separate sides, allowing printing on them.
- DG SANTE dismisses the argument that Directive 2001/37/EC permits printing on bevelled/rounded edges. While true that there is no explicit reference to such packs in Directive 2001/37/EC, the printing of Health Warnings (HWs) on the full front and back visible surface has occurred for many years throughout the EU and other countries. Had any authority of any Member State considered such HWs were distorted or were not properly visible, it would likely have been raised. As this did not happen for 13 years, claims that this practice would distort CHWs make no sense.
- The Non-Paper wrongly mentions Canada as an example where CHW printing is prohibited on the bevelled edges. In fact, Canada, a country well-known for its comprehensive tobacco regulation, **requires** printing CHWs on the bevelled/round corner edges. The Canadian regulation stipulates CHWs printing on the full "display area" which explicitly includes the bevelled sides. There is no restriction to only print on the front/back flat surface. In fact, printing on only the flat surface of bevelled packs is prohibited. The Canadian legislator would not require printing which distorts the visibility and legibility of the CHWs.
- DG SANTE makes an irrelevant and misleading reference to "scientific literature and internal industry documents" which allegedly show that bevelled and round corner packs are more "attractive" to consumers. On this it is important to note that the documents mentioned are not relevant in this context. One is an Australian survey and the other is based on industry documents dated many years ago, 1973-2002, (i.e. even before Directive 2001/37/EC). More importantly, since the Directive explicitly permits the packs in question, any discussion on "attractiveness" is moot. The packs are permitted even if the claims about "attractiveness" were to be true (which we strongly oppose).

⁵ See footnote '4'

From a process point of view:

- The Guidance Document and Non-Paper address areas not covered by the Directive. The Directive only authorizes the Commission to address the technical specifications for the layout, design and shape of CHWs, NOT to the placement of CHWs. The consultants and DG SANTE have, therefore, encroached on areas where the Directive is sufficiently clear and gone beyond the secondary legislation, which is not in their remit. In short, the Guidance Document and the Non-Paper patently go against the very provisions of the Directive.
- Article 10(4) of the Directive states that the Implementing Act will take into account the different pack shapes – this has clearly not happened in the Guidance Document.
- By issuing a Non-Paper, DG SANTE is attempting to exert undue influence and ex-post trying to steer Member State interpretation, which is not in its remit.
- DG SANTE is using consultants to go beyond the letter of the Directive and, by giving an ambiguous status to documents, it weakens the text of the Directive which has (allegedly) as its main purposes to enhance the internal market.
- Although the draft non-binding Guidance Document specifies that *"The content of this report represents the views of the B-M SFP [Burson-Marsteller Smoke Free Partnership] consortium and is its sole responsibility; it can in no way be taken to reflect the views of the European Commission [...]"*, its "interpretation" is further endorsed by the Non-Paper.