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**From:** SANCO D4 SOHO and TOBACCO CONTROL  
**Sent:** 06 December 2013 15:56  
**To:** 'antonella.pederiva@ceccm.eu'; [REDACTED]  
**Cc:** SCHNICHELS Dominik (SANCO)  
**Subject:** Minutes meeting of 27 November 2013  
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**Recipient**

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'antonella.pederiva@ceccm.eu'

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SCHNICHELS Dominik (SANCO)

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MAUNU Antti (SANCO)

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[REDACTED]

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Dear Ms Pederiva and Mr [REDACTED]

Please find enclosed the minutes of the meeting in subject, which we intend to publish, unless you have comments by Friday 13 December 2013 cob at the latest.

Kind regards,

**Unit D4 - Substances of human origin and Tobacco control**  
Health and Consumers DG (SANCO) - European Commission

☎ +32 2 29 56790

☎ +32 2 29 59580

✉ [sanco-D4-soho-and-tobacco@ec.europa.eu](mailto:sanco-D4-soho-and-tobacco@ec.europa.eu)

F101 08/70, B-1049 BRUSSELS



**EUROPEAN COMMISSION**  
**HEALTH AND CONSUMERS DIRECTORATE-GENERAL**

Health systems and products  
**Substances of human origin and Tobacco control**

Brussels, 27 November 2013

**MINUTES OF THE MEETING**

**Participants**

**Ronan Barry (BAT), Ben Townsend (JTI), Alessandro Tschirkov (ITG), Antonella Pederiva (CECCM), Kristof Doms (PMI), Thilo Paschke (JTI), [REDACTED] (JTI)**

**SANCO: Dominik Schnichels, Sigrid Wimmer, Antti Maunu, Ingrida Pucinskaite-Kubik, Patricia Murray**

**Date: 27 November 2013**

The main objective of the meeting was for the industry representatives to present their views on **Articles 6** (ingredients), **14** (illicit trade), **25 and 26** (transposition and grace period) of the Tobacco Products Directive under revision. SANCO also asked for comments on **Article 18** (nicotine containing products).

The SANCO representatives underlined that they would be in listening mode, given the current phase of the legislative process (trilogue negotiations ongoing).

**Article 6 – Ingredients**

The industry representatives requested to focus here on the 'positive list' of ingredients proposed by the European Parliament (EP) as well as the EP's Article 6.1(d).

According to the representatives, the concept of a positive list is problematic as no clear set of criteria has been proposed to decide which ingredients qualify (or otherwise). It is also unclear who would take final decisions relating to this. They suggested that a better approach would be to first establish guidelines on procedure whilst engaging transparently with the industry and taking into account previously established list systems, such as EFSA's list for food flavourings and ingredients. Industry representatives also remarked that they did not feel the information they have provided under the current legal framework had been made use of.

The representatives then described how the EP's Article 6.1(d) [proposing to disallow additives that meet the criteria for classification under Regulation 1272/2008, or that result in such substances upon combustion] is of even greater concern to them, as they believe its adoption would mean a de facto ban on all ingredients in tobacco products. They said that

Regulation 1272/2008 is not intended to ban ingredients but to guarantee their safe use and added that ingredients themselves do not increase the toxicity of the products. It is rather the combustion process that does this, as all ingredients become toxic under combustion.

Their preferred approach would be a toxicological assessment of ingredients, excluding CMRs, and comparison of results with and without the additive(s) being tested. They confirmed that industry has the facilities for such tests.

Asked whether the Council's general approach would be preferable, the representatives said that it is a more feasible option (as it includes a report on a possible future list) though they have concerns regarding certain criteria included in the text, for example, 'addictiveness' or 'attractiveness'. Toxicity alone would be a preferable criterion for the representatives – although they reiterated that, once burned, there is no increase stemming from additives in the toxicity of tobacco.

The representatives indicated that they understand the need for action, in particular on characterising flavours, and are also not opposed to the concept of a list in general, as long as criteria are clear.

#### **Article 14 – Track and Trace**

The industry representatives said that they are in favour of tracking and tracing measures but are concerned that the timelines proposed are unrealistic, in particular in view of how far along the supply chain Article 14 requires tracking and tracing to be extended. They claimed that approximately 5000 to 6000 companies would be covered by the measure.

They said Article 14 would mean significant adaptations (e.g. development of technology, involvement of many economic operators etc.) and as the content of the Implementing Acts is not yet known, an implementation would not be possible within the allotted time.

They added that if the EP amendment on technology having no legal or commercial link to the tobacco industry was adopted, the proposal as a whole could not be implemented.

Asked about *Codentify* system used by the industry, the representatives explained that the standards are now developed by Digital Coding and Tracking Association (DCTA) to which all large manufacturers are member. Membership of DCTA would be open to all tobacco manufacturers and it may be willing to share use of *Codentify* with governments/Commission. Asked to what extent *Codentify* complies with Article 14, the representatives said that it is capable of complying fully, but will need extra time. They indicated 4 years from the Implementing Acts could be reasonable, but then decided to reflect on this and send a response in writing [\*in a position paper subsequently received, a minimum of 6 years from the Implementing Acts was mentioned].

The industry representatives indicated it would be useful to split the timeframe, covering initially until the 1<sup>st</sup> customer and then the rest of the supply chain. SANCO pointed out, however, that industry has already committed to covering pack level and 1<sup>st</sup> customer and rolling out beyond this should be the only question discussed here. The representatives agreed

that contractual commitments are in place, but some contracts were entered into only recently (2010). They also indicated that they are still working towards covering to the 1<sup>st</sup> customer.

SANCO said that it will carry out a study how best to implement the tracking and tracing system and invited the industry to cooperate with that project. SANCO also pointed out that the fact that Codentify is a tobacco industry-run body created uneasiness. The representatives said that DCTA is a standard-setting body and does not run the tracking and tracing system. They agreed to send more information in written format.

### **Article 18 – Nicotine containing products**

The industry outlined that it sees the need for product standards, but believes applying pharma legislation goes too far. The EP route is a better approach, but there are gaps in terms of quality assurance. Points remaining to be addressed include child safety, liquid content and labelling. The representatives argued advertising plays an important role and if too restrictive, diminishes the harm reduction potential of these products.

### **Articles 25 – Transposition and 26 – Transitional provision**

The industry representatives said the timeframes being proposed here are unrealistic and fail to take into account time needed to adapt production lines and shelf life of products. They have major concerns in particular regarding timeframes in Article 26. They would like to see 24 months granted for transposition in Article 25 and an additional 24 months to the COM text (total of 48) for the transitional provisions of Article 26. Concerns were expressed about the Council's Article 26.1(a), which the representatives said creates a timeframe anomaly when viewed alongside the Council's Article 26.1 and needs to be addressed. The representatives said that time for machine conversions/ordering of new machines must be allowed (e.g. to adapt to requirements of Articles 13, 8.3, tax stamp requirements etc.) and as an example pointed to the major changes needed to adapt the slim packets. SANCO, however, pointed out that these occupy only 6% of the market. The representatives agreed, but said that the time between ordering and receiving a new machine can be up to 22 months. They said that in Directive 2001/37/EC, 1 year transitional period was granted for cigarette packs and 2 years for other products. Questioned by SANCO regarding average shelf life of a pack they said that this depends on brand and product and indicated it is seldom greater than 12 months. SANCO suggested such a time would likely be for more niche products than cigarettes and pointed out that the industry is not obliged to await transposition by Member States before implementing changes. The representatives disagreed saying that certain provisions are open to interpretation by individual governments.