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

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

Date: 27 November 2013

The cigarette industry representatives stated that they have concerns on several provisions covered by the General Approach and the EP amendments to the proposal.

The main objective of the meeting was for the industry representatives to present their views on **Articles 6** (ingredients), **14** (tracking and tracing), **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 assessment and approval 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, similar to the process that has been applied for establishing list systems within other sectors, 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 could lead to a de facto ban on all ingredients in tobacco products. They emphasised that the purpose of Regulation 1272/2008 is not to ban substances but to guarantee the safe handling and transport of substances. . They also explained that the industry has the means to test under condition of use that additives do not increase the toxicity of the products. The representatives made the point that, as is the case for all other organic substances, combustion of ingredients results in the generation of toxic substances (as does the combustion of tobacco).

Their preferred approach would be a toxicological risk assessment of ingredients, excluding additives classified as CMRs in unburned form, and comparison of data from the cigarettes with and without the additive(s) being tested under conditions of use (combustion). They confirmed that CECCM member companies and PMI have the facilities for such tests and that they already employ this approach to the risk assessment of ingredients in tobacco products.

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 –and they reiterated that, based on the findings of their testing, there is no increase stemming from additives in the toxicity of tobacco smoke.

The representatives indicated that they understand the need for regulating ingredients, , and are also not opposed to the concept of a list in general, as long as criteria for inclusion and exclusion are clear and based on sound science. The industry restated its objection to a ban of menthol products on this basis.

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 a high number of supply chain operators (including e.g. approx. 5000 to 6000 wholesalers) 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. SANCO confirmed that Article 14 provides the framework for an EU track and trace system. The representatives pointed out that timely Implementing legislation will be crucial in order for the system to be set up.

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. One company indicated 4 years from the Implementing Acts for track and trace to pack level to the 1st customer could be reasonable, but then the industry representatives 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 as needed for all economic operators in the supply chain to be compliant with their respective obligations].

The industry representatives indicated it is necessary to split the timeframe, covering initially the track and trace system until the 1st customer and then the rest of the supply chain. SANCO pointed out, however, that industry has already committed to covering pack level and 1st 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) and the provision to implement track and trace at pack level is subject to technological development without set deadlines. They also indicated that they are still testing technology for covering to the pack level to the 1st 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 would not necessarily address this. 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 that 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 particularly 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 stressed that the time between ordering and receiving a new machine can be up to 22 months and therefore more time was needed. 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.