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ECMA EUROPEAN CIGAR

MANUFACTURERS ASSOCIATION

[deleted as privacy information]
European Commission DG SANCO Unit C6
B-1049 BRUSSELS
Belgium
[deleted as privacy information]

Tilburg, 14 December 2010
Re.: ECMA response to the Public consultation on the possible revision of the Tobacco Products Directive

Dear [deleted as privacy information],

During the stakeholder meeting on the possible revision of the Tobacco Products Directive 2001/37/EC (TPD) on 20 October 2010 you stated that comments on the public consultation document could be submitted via the online consultation form as well as in writing. Via this letter the European Cigar Manufacturers Association (ECMA) would like to inform you about its views on the "areas of possible change" mentioned in the public consultation document that would affect the cigar sector. This implies that we have not answered the questions as regards the areas of possible change that are under "scope of the directive" and under "smokeless tobacco products", as these questions are not relevant for the cigar sector[1]. For each area we will start with a short summary of the options mentioned in the consultation document, followed by an assessment of the consequences for the cigar industry and a conclusion.

3. CONSUMER INFORMATION

According to the consultation document, the current health warning requirements could either remain unchanged or could be improved by making picture warnings mandatory. In the second option, picture warnings would be enlarged, required on both sides of the package and placed towards the top of the pack. Also, information on a telephone service to help quit smoking would be placed on the package, and information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package. Finally it is suggested to introduce plain or generic packaging, which would standardise the appearance of tobacco packaging. Manufacturers would only be

[1] **As these two questions might nevertheless be relevant for individual ECMA member companies, we would like to refer to the possible answers provided by those companies.**

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allowed to print brand and product names, the quantity of the product, health warnings and other mandatory information such as security markings. The package itself would be plain coloured (such as white, grey or plain cardboard). The size and shape of the package could also be regulated.

Mandatory picture warnings

ECMA agrees to the fact that the adult cigar consumer - who is typically an occasional smoker - should be informed about the health risks associated with smoking. However, we are of the opinion that picture warnings are not necessary to achieve that goal. In our opinion, health warning texts such as the ones prescribed by the TPD sufficiently guarantee that the adult cigar smoker is well informed. We are not aware of any scientific data indicating that picture warnings are a more effective means of informing adult cigar smokers than health warning texts. The effect of picture warnings on cigar consumers cannot be predicted by studying the effect on cigarette smokers, as the cigar consumer has a totally different profile (i.e. a male adult of mature age, with mostly an occasional and low consumption). Picture warnings furthermore create disproportionate problems and costs for the cigar industry due to its enormous variety of types, shapes and sizes of packaging as well as the variety of materials used (such as cardboard, tin or wood). Although the total costs accruing to manufacturers of other tobacco products are probably much larger than those accruing to cigar manufacturers, the relative burden of compliance (e.g. costs per revenue) is much higher for cigar manufacturers as cigar manufacturers' brands are typically of much smaller quantities. Costs therefore fall on a much smaller number of units sold.

For all the above reasons, a 'one size fits all' approach to picture warnings for all tobacco products would create disproportionate problems for cigar manufacturers. ECMA believes that the decision whether or not to require picture warnings should remain with the Member States and that the current possibility for Member States, intending to introduce picture warnings, to exclude cigars from the scope of these requirements, should be maintained for the reasons outlined above.

Enlarged warnings on both sides of the package, placed towards the top of the pack

ECMA is of the opinion that there is no evidentiary basis to contend that increasing the current size of health warnings on packs of cigars would further improve the achievement of public health objectives, as there is no credible scientific and empirical research to demonstrate that larger health warnings would 1) produce a degree of awareness of tobacco related health risks amongst cigar smokers that is higher than currently achieved, 2) reduce cigar smoking initiation, 3) increase cigar smoking cessation or 4) reduce consumption rates in continuing cigar smokers. Increasing the size of cigar health warnings would therefore be both unnecessary as well as disproportionate. The further expropriation of the principal display areas of cigar packaging would lead to a series of negative and undesirable consequences, including unjustified limitation on 1) trademarks, goodwill and

brand equity, 2) the ability to communicate with consumers and 3) consumers' rights to product choice, fair competition and product information. Increasing the size of cigar health warnings would furthermore lead to the erosion of the brand equity that has been built up and which is currently attributable to brands and to the serious and unnecessary damage to the legal, fair and competitive market economy in tobacco products. Finally an increase in the health warning size would undermine the ability of members of the legal tobacco industry to brand and distinguish its products from those of its competitors.

Due to the fact that current regulatory requirements in the main cigar markets are for the health warnings to be located on the most visible surfaces parallel to - instead of towards - the top of the pack, the vast majority of the internationally used cigar packs are designed with the health warning area at the bottom part of the most visible surfaces. Requiring the cigar industry to place the warnings towards the top of the pack would result in high redesign costs for the cigar industry.

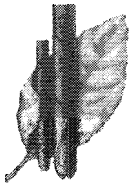
Information on a telephone service to help quit smoking and inserts

ECMA is of the opinion that additional health warning number 10 of annex 1 of the TPD provides sufficient relevant information on cessation and that no changes are needed in this respect. Health warning number 10 appears regularly and enables consumers to be aware of the opportunity to be helped if they wish to quit smoking. Where additional quitting information is required, however, it should be included in the area reserved for the health warnings. Furthermore, ECMA notes that changes to cessation information (e.g. quit line number and website addresses) that are on the pack have significant cost and complexity implications for manufacturers and retailers (recall of "old" product). Member States should therefore carefully evaluate the information they select to avoid frequent changes that can confuse consumers and cause supply chain problems for manufacturers and retailers.

Due to its enormous variety of types, shapes and sizes of packaging and small sales volumes the cigar industry will not be able to add inserts automatically for most of its brands. This implies that for these products compliance could only be achieved by adding the inserts manually by employees.

Plain or generic packaging

ECMA believes that cigar manufacturers have the right to distinguish and differentiate their products from those of competitors. Packaging guarantees origin, quality and investment. Brands and packaging designs are often protected as registered trademarks. Plain packaging would expropriate or fundamentally restrict the essential function of registered trademarks and the right to distinguish products, contrary to national and international law. The development of brand equity and goodwill is fundamental to a market economy, consumer choice, innovation and product development.



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Manufacturers have fundamental rights to communicate with consumers, to the property in their packaging and to conduct their business. Consumers have the right to receive information. Plain packaging breaches these rights. The ability of manufacturers to distinguish their products through packaging provides a key means by which consumers are able to freely exercise their right of product choice. Existing adult cigar consumers use packaging to identify cigar products, easily and without confusion.

Plain packaging is a disproportionate measure, as it would 1) facilitate the trade in counterfeit and contraband tobacco products, 2) result in consumer confusion and 3) negatively impact on the competitive operation of the market for tobacco products. As was already stated before in the context of picture warnings, ECMA believes that the effect of plain packaging on cigar consumers cannot be predicted by studying the effect on cigarette smokers, as the cigar consumer has a totally different profile. Health warnings and plain packaging may have a totally different effect on cigar consumers. For all the above reasons ECMA rejects plain packaging as an option.

ECMA conclusion as regards consumer information
ECMA does not agree to the problem definition as described in the public consultation document. ECMA is of the opinion that option 1 - no change - would be the preferred option for the cigar sector.

However, if changes to the current labelling provisions were nevertheless to be proposed, ECMA recommends an additional option securing that the existing possibilities to apply specific rules to cigars in order to take into account the specificities of the cigar industry, -product and -market are maintained, i.e.:

> The possibility to use irremovable stickers on cigar packs (art. 5.7 TPD);
> The current provision regarding the health warning size on packs with a most visible surface which exceeds 75 cm^2 (art 5.5 TPD);
> A transition period of minimum 2 years after the official publication of the national provisions in order to allow for the necessary changes in the production and for the disposal of stocks (art 14.3 TPD);
> The possibility for Member States, intending to require picture warnings, to exclude cigars from the scope of these requirements.

4 **REPORTING AND REGISTRATION OF INGREDIENTS**

According to the consultation document, the formats and reporting mechanisms f or submitting data on tobacco products ingredients vary between and even within Member States. Therefore, authorities find it difficult to compare and analyse the data. Also, manufacturers and importers may have difficulties to provide requested information using different reporting formats, implying an even heavier burden on smaller manufacturers.

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The suggested solution would be to oblige the industry to use one harmonised reporting format, ideally combined with the electronic submission of data. This could be based on the voluntary reporting format developed by the Commission in May 2007 on how industry could report to Member States. Additionally it is suggested to require a yearly registration fee to be paid to national competent authorities in order to finance their data collection and analysis work on ingredients. Only registered products would be allowed on the market.

A common compulsory reporting format combined with the electronic submission of data
ECMA supports the principle of the common reporting format for ingredients disclosure as suggested by the DG SANCO "Practical Guide on ingredient reporting" dated 31 May 2007. We also support the principle of a sustainable, robust and secure electronic database system of the type developed by EMTOC, that could be used for collecting and holding ingredient data and potentially other brand specific information, under the condition that 1) consistency is ensured between the "Instructions" and the "Terms of Use" documents with a view to ensure adequate protection for competitively sensitive information and trade secrets, 2) ingredient data integrity for each individual ingredient entry will be fully maintained in the EMTOC ingredients list and 3) any future changes in the XML schemas are communicated immediately to all users and allow sufficient time for implementation.

We consider it to be critical that all EU Member States agree to and adopt a common, harmonised reporting format for ingredient disclosure and accept tobacco product ingredients submission via the latest set of templates in order to move to the EMTOC reporting system. This adoption should be facilitated and/or endorsed by the Commission. We would therefore welcome an initiative from the Commission to make this Practical Guide binding for the EU Member States and to incorporate an electronic reporting system like EMTOC.

Fees and sanctions
ECMA considers the possibility of yearly registration fees paid to national authorities as well as the possibility to apply penalties in case of non-compliance to be a responsibility of the individual Member States. Although not explicitly mentioned in the TPD, Member States currently already have the possibility to apply registration fees and / or penalties.

In this context it is worth mentioning that, according to article 6.1 of the TPD, manufacturers or importers currently have to provide the *available* data on toxicology or addictiveness of ingredients. For the cigar industry the word "available" is of vital importance, as most cigar manufacturers do not have the means to do research on their own and therefore rely on data published in the publicly available scientific literature. If it would be suggested to apply penalties in case of non-compliance with the delivery of toxicological data on tobacco products, such a measure would disproportionally affect the

small to medium sized manufacturers of cigars. The current provision, stipulating that the ingredients list shall be "accompanied by the toxicological data *available* to the manufacturer";, should remain unchanged, as well as the authority of individual Member States to decide whether or not registration fees and/or penalties should be applied.

ECMA conclusion as regards reporting and registration of ingredients
ECMA does not agree to the problem definition, in particular as regards the suggested regulation at the EU level of a yearly registration fee paid to national competent authorities in order to finance their data collection and analysis work on ingredients. However ECMA supports the analysis as regards the format and reporting mechanisms for submitting ingredients data.

ECMA supports option 2, i.e. a situation in which the tobacco industry would be obliged to use one harmonised reporting format, ideally combined with the electronic submission of data. This could be based on the voluntary reporting format developed by the Commission in May 2007 on how industry could report to Member States.

5, REGULATION OF INGREDIENTS

According to the consultation document, the existence of different positive lists in some Member States and negative lists in others lead to the authorisation of different ingredients used in the manufacturing of tobacco products. As a result substances that can be used in one Member State may not be used in another. One of the options proposed is the introduction of basic criteria to be used by the Member States for restricting or prohibiting the use of certain ingredients in the manufacturing of tobacco products. The criteria may be related to toxicity, the attractiveness and the addictiveness of a product when consumed (oral tobacco) or smoked (the combustion/inhalation effect). Another possibility would be the establishment of a common list of tobacco ingredients. The list, either a positive or a negative one, would be based on the toxicity, the attractiveness and the addictiveness of a product when consumed or smoked.

Introducing the basic criteria on the EU level
ECMA believes that any decision to allow or ban the use of a specific ingredient should be based on a full scientific assessment of whether the ingredient increases the inherent risks associated with smoking. ECMA is concerned with the use of the term "attractiveness" in the context of tobacco product ingredients, without defining meaning, scope or context, and rejects the notion of "attractiveness" as a valid public policy objective against which ingredients should be regulated. "Attractiveness" per se fails established criteria for issue definition in terms of it being a regulatory goal or objective: it is lacking in any evidential foundation and is inherently uncertain and arbitrary.

In addition ECMA is not aware of a credible scientific basis upon which it could be considered that some ingredients may be "addiction enhancing".

The final SCENIHR opinion recently issued concludes that:
> No tobacco additives which are addictive by themselves have so far been identified (Opinion 4);
> Current methods are not adequate for a reliable quantification of "attractiveness" in humans (Opinion 9).

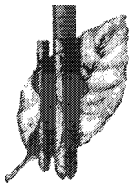
In order to ensure the proper functioning of the market economy, legitimate cigar manufacturers have the right to compete by developing and differentiating their products to facilitate adult consumer choice. In order to avoid the creation of unjustified, unnecessary and disproportionate obstacles to the functioning of the internal market for tobacco products, ECMA appeals to the Commission to discourage the Member States from adopting any national restrictions in this area until the above issues have been satisfactorily addressed at an EU level.

A common list of tobacco ingredients
ECMA supports the generation of a common list of authorised ingredients. Such a list should reflect the scientific principles developed jointly by the WHO / FAO Codex Alimentarius Commission (CAC). We support the principle that new ingredients should be allowed.

ECMA conclusion as regards regulation of ingredients
ECMA does not agree to the problem definition as described in the public consultation document. The focus in the regulation of ingredients should be on whether the ingredients result in increased toxicity of tobacco smoke, and not on arbitrary criteria like "attractiveness" or "addictiveness". It is also for this reason that ECMA rejects options 2 and 3, although it supports the establishment of a positive common list of tobacco ingredients, under the condition that it reflects the scientific principles developed jointly by the WHO / FAO Codex Alimentarius Commission (CAC). For the reasons set out above, ECMA supports option 1, no change.

6, ACCESS TO TOBACCO PRODUCTS

According to the consultation document, the cross-border sale of tobacco products (via the internet) potentially undermines national tobacco control efforts. Vending machines are banned in a large number of Member States, and some Member States have announced that they intend to prohibit the display of tobacco products in points of sale. One of the options proposed is the controlled supply and access via age verification and restriction of tobacco display at points of sale. Another alternative would be to ban internet sales, vending machines and promotions and displays in retail stores.



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Display of tobacco products

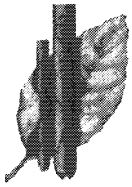
Currently sales arrangements are dealt with in the context of the Council Recommendation of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control. In its report on the implementation of this Council Recommendation (document SEC(2009) 1621 final dated 23 November 2009) the European Commission concluded: "Overall, the implementation of the Recommendation is satisfactory. This concerns in particular the requirement to verify the minimum age for the purchase of tobacco products, the introduction of measures to restrict the use of vending machines by under age persons and the protection from environmental smoke in educational establishments, health care facilities and public transport". In addition to the fact that these measures seem to work satisfactorily, ECMA questions whether there is an appropriate legal basis to incorporate rules on sales arrangements into the TPD, as these measures do not deal with tobacco control in the context of the completion and consolidation of the internal market and the abolition of obstacles to its smooth operation.

We are concerned that as any regulation of tobacco displays at the point of sale would prevent smokers from seeing the full range of tobacco products available to them, this would have a number of adverse consequences, including 1) undermining consumer choice, 2) hindering free trade by making market access far more difficult for potential new market entrants and 3) distorting competition between different manufacturers and importers.

In our view there is no empirical or otherwise robust evidence showing that the display of tobacco products encourages youth smoking initiation, stimulates impulse purchases or inhibits abstention and quitting. There is no conclusive evidence that a display ban would decrease the general smoking incidence.

Due to its small sales volumes, the cigar sector will be disproportionately disadvantaged by any restrictions on the display of tobacco products at point of sale. Smaller and/or newer manufacturers will struggle to compete in an environment where the consumer is unable to see the product choice available. Restrictions will make it very difficult for a company to enter a market through the launch of brands which have not already been well established there. As such any restrictions will create a disproportionate barrier to trade by curtailing the ability of new entrants and brands to access markets; thus, disadvantaging them by comparison to their already present competitors.

Finally it is worth noting that the display of products at the point of sale facilitates choice for those adults who wish to consume tobacco products and are legally entitled to do so. If display is removed this will undermine choice for those consumers and new, smaller or 'niche' brands will be highly disadvantaged, and outlets may well decide not to even stock these brands.



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ECMA conclusion as regards access to tobacco products
ECMA does not agree to the problem definition as described in the public consultation document, as there is no evidence provided as to why bans would improve the functioning of the internal market or advance any public health objectives. As the cigar sector would be disproportionately disadvantaged by any restrictions on the display of tobacco products at point of sale, we support option 1 - no change.

Overall **conclusion**
As we have stated several times before, a "one size fits all approach" for all tobacco products would not work, as it would create a disproportionate burden for the cigar industry. Due to its enormous variety of models, sizes, and brands, its small scale production processes and its many small to medium sized businesses, of which a big part is still family owned, most ECMA member companies simply do not have the resources and know-how to comply with the same rules as big multinational companies with much smaller assortments and higher sales volumes. Therefore we urge DG SANCO to take into account the specificities of the various tobacco products before presenting any proposals to amend the tobacco product directive.

With best regards,

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