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European Smoking Tobacco Association

ESTA specific concerns related to RAND Europe Interim report 'Assessing the Impacts of Revising the Tobacco Products Directive' (PM- 3441-EC)

Introduction

The European Smoking Tobacco Association (ESTA) represents the interests of the European manufacturers, distributors and importers of fine-cut (rolling) tobacco, pipe tobacco, chewing tobacco and nasal snuff tobacco. The 49 members of ESTA are mainly small and medium sized companies and include member associations from the European Union and the European Economic Area.

Smoking tobacco comprises approximately 9% of the total market for tobacco products in the EU, around 8% for fine-cut tobacco and less than 1% for pipe tobacco.

Following below are ESTA comments on the interim report by RAND Europe 'Assessing the Impacts of Revising the Tobacco Products Directive' (RAND Europe, PM- 3441-EC, November 2009) prepared for the European Commission Directorate-General for Health and Consumer Protection to provide support in assessing the impacts of revising the Tobacco Products Directive 2001/37/EC (the 'Directive') on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.

ESTA and ESTA members acknowledge the review process of the Directive and current analysis of its impact and effectiveness. ESTA values the call for consultation of all stakeholders, and remains committed in contributing in open, transparent and inclusive regulatory processes.

General comments on the RAND interim report

a) *Purpose, structure and content of the report*

ESTA finds the purpose of the interim report unclear, as it currently does not appear to constitute a baseline scenario or a foundation for an impact assessment. ESTA feels that the report's structure and methodology needs substantive improvement, clarifying information selection and use, and outlining the reasons for considered regulatory changes. In the context of the latter, the Commission should explain the reasons for any possible regulatory intervention, what the precise policy objectives are, and what the concrete policy options are, including an assessment of EU competencies regarding the proposed regulatory measures.

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ESTA thinks that the absence of clarity on policy objectives hinders the substantiveness of our response.

The information used in the interim report is often outdated and of questionable relevance. Much of the data predates relevant EU regulatory processes, rendering it obsolete in assessing the impact of regulation on tobacco prevalence.[1] It would be essential for the report to also establish the impact of the current Directive, which has been implemented in the Member States since 2002. ESTA therefore encourages RAND to seek more up-to-date and reliable data sources.

The interim report does not provide for a comprehensive assessment of the impact of other existing tobacco regulation. ESTA strongly feels that clarification of policy objectives and outline of future policy directions would be helpful to create a more solid framework for the report. Furthermore, the interim report should more closely follow the *Impact Assessment Guidelines*[2], in particular in consideration of subsidiarity and proportionality. In addition, the report should consider specific impacts on small and medium size companies (SMEs) and competition.

Finally, the interim report should refrain from using unbalanced and biased language and terminology such as '*tobacco epidemic*' (pp. 23, 25, 26, 28, 33 and 34). Overtly negative and emotional references give little confidence in the '*objective analysis*' that RAND Europe strives to. In addition, references used throughout the interim report seem to be limited and many sources that do not support the views of DG SANCO have been omitted or not been found.[3]

The detailed comments that follow in the second part of this contribution are not exhaustive but indicative of ESTA's concerns. ESTA would welcome an opportunity to comment on a next version of the report.

b) Implied uniformity of tobacco sector

Throughout the interim report, the term '*tobacco industry*' is widely used. ESTA feels that the way this term is used implies uniformity. It does not reflect realities of the complexities of the tobacco sector. In particular, it does not reflect the market presence of SMEs, especially those involved in non-cigarette tobacco products. The report provides no references to the size of these businesses, but it outlines '*the main players*' (pp. 48-51) noting that '*the global tobacco industry is largely concentrated in the hands of five companies*.' We strongly feel that this, one-size-fits-all approach, ignores the complexities of the tobacco sector in Europe.

ESTA represents products that are often produced by small and medium size companies where administrative cost of compliance to regulation is disproportionally higher than for the big companies. This should be taken into the account when administrative costs and burden are calculated for the review of Directive (p. 62). To

[1] Some of the more recent examples show a different picture of impact of tobacco regulation. In Ireland despite high tobacco tax, the smoking ban and a law against the public display of cigarettes for sale introduced in 2009, the number of smokers has steadily risen since 2002 from 27% to 33% 2009. Department of Health and Children, 'Survey of Lifestyle, Attitudes and Nutrition (SLÁN).'

[2] European Commission, *Impact Assessment Guidelines*, 2009, SEC(2009) 92, p.6.

[3] Examples include: J Hansen et al., 'When the death makes you smoke: A terror management perspective on the effectiveness of cigarette on-pack warnings,' *Journal of Experimental Social Psychology* 46 (2010) 226–228; G Hastings and L MacFadyen, 'The limitations of fear messages,' *Tobacco Control*, 11 (2002) 73-75; W. G. Manning, 'The Taxes of Sin: Do Smokers and Drinkers Pay Their Way?,' *The Journal of the American Medical Association*, Vol. 261 (1989), No. 11; Environics Research Group Limited (for Health Canada), *The Health Effects of Tobacco and Health Warning Messages on Cigarette Packages*, 2001-2007; M J Stewart, 'The effect of advertising bans on tobacco consumption in OECD countries,' *International Journal of Advertising*, 12 (1993) 155-180.

ensure the highest level of accuracy, ESTA urges RAND Europe that any information collected on the cost to business, intended for this interim report and impact assessment process, must be objective to the individual product categories as well as to the size of business. Only this approach will guarantee a balance and proportionality of the future regulation avoiding the prejudices of one-size-fits-all policy.

In relation to indirect jobs connected to the tobacco sector, page 43 references and includes a quote from the World Bank Economics of Tobacco Toolkit. ESTA supports calls for clarity on indirect jobs, but feels that this quote and subsequent references are imprecise and anecdotal, obscuring the realities of the job markets relating to the growing, processing, manufacturing, storage and sales of tobacco products.

Section 4.1.4., Manufacturing sector (pp. 46-48), outlines manufacturing of tobacco products only at the top national level. This approach disregards the fact that manufacturing of non-cigarette tobacco products is, in many cases, conducted by SMEs and that their manufacturing processes are often more labour intensive with lower output per employee. Therefore, ESTA urges objectivity to other tobacco products to ensure proportionality.

On pages 19 to 22, the interim report reviews 'evidence of effectiveness', on the effectiveness of regulations in the different areas of sales arrangements in reducing use of tobacco products. ESTA feels that as the current approach considers alignment of measures on all tobacco products, and because there are significant differences (as outlined throughout these comments), the interim report should consider to establish a separate 'evidence of effectiveness' analysis for each tobacco product considered for inclusion within the scope. This will ensure proportionality and efficiency of the future regulation.

c) Lack of distinction between tobacco products

The current interim report provides no clear distinction between, or even lists tobacco products that are considered for inclusion in the scope of the Directive. This remains the case in all sections of the report, from health impacts to cost of tobacco regulation. ESTA strongly feels that this adverse bundling together of all tobacco products will only lead to inaccuracies and prejudices in the assessment and analyses of current and future regulations. The interim report should attempt to better delineate between different tobacco products considered for inclusion and conduct multifaceted analyses that will ensure accurate and relevant results. We would recommend that RAND study general reference texts, for example Ernst Voges (Ed.), *Tobacco Encyclopedia*[4], to improve its understanding of the different products and their distinct manufacturing processes.

ESTA represents two types of smoking tobacco products, fine-cut tobacco and pipe tobacco, as well as some smokeless tobacco products such as nasal snuff and chewing tobacco. In reality these are all very different products with regard to manufacturing, retail and consumer use.

Smoking tobacco is defined[5] as tobacco which has been cut or otherwise split, twisted or pressed into blocks and is capable of being smoked without further industrial processing or tobacco refuse put up for retail sale which does not fall under Articles 3 (cigars and cigarillos) and 4 (cigarettes) and which can be smoked.

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[4] Ernst Voges (Ed.), *Tobacco Encyclopedia*, 1984, Mainzer Verlagsanstalt und Druckerei Will und Rothe GmbH & Co KG, Mainz.

[5] EU Directive 95/59/EC, OJ L 291, 6 December 1995, page 40.

Smoking tobacco which has more than 25% by weight of the tobacco particles with a cut width of less than 1 mm shall be deemed to be fine-cut tobacco for the rolling of cigarettes. This can be adjusted in national legislation according to the intended use. Other smoking tobacco, i.e. that with a cut width of 1 mm and more, is pipe tobacco.

The present report uses the term '*roll-your-own cigarettes*' implying that this represents a tobacco product. This is a misrepresentation as there is no such product on the EU market. Fine-cut tobacco, regulated by the current Directive, is a semi-finished product, used by an end user to assemble a fine-cut smoking article.

Pipe-tobacco is a traditional tobacco product whose use in Europe predates all other forms of tobacco use. It is defined by its wider cut width than fine-cut tobacco, and comes in a variety of forms from loose tobacco to compressed blocks. Pipe tobacco by itself cannot be smoked. The consumer must combine it with one of a wide variety of pipes available. The amounts of tobacco used vary for each consumer and the combination of pipe and tobacco is far from standard. Pipe tobacco smoking involves great variability in the way in which pipe tobacco is prepared and smoked by the consumer. In addition, although ESTA does not represent the pipe making sector and in consideration to the interim report calling for the inclusion of pipes (p. 8), we would advise RAND to approach pipe manufacturers for the provision of information that will ensure accuracy of analysis.

For smokeless tobacco, the interim report should recognise that there is broad variation of products. These should be listed and analysed separately. The following graph is reproduced from a recent article on smokeless tobacco.[6] It represents smokeless tobacco products consumed in Europe and the USA and gives a comprehensive overview of the variations and differences between these products.

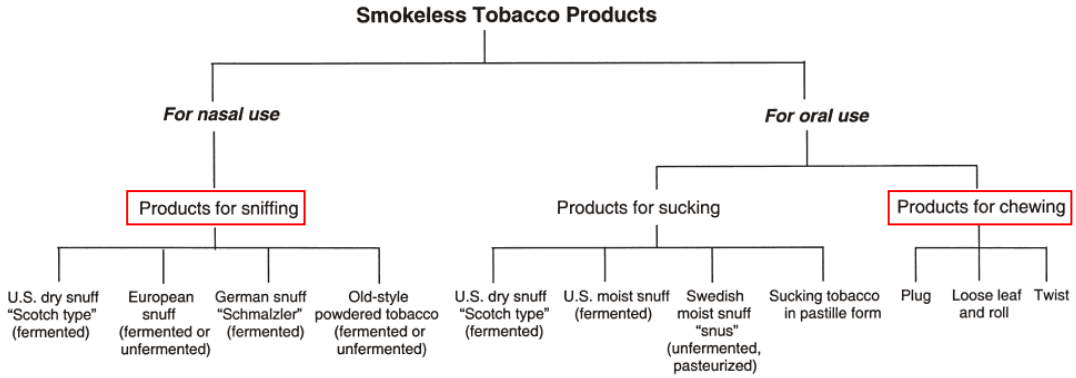

Figure 1. Smokeless tobacco products consumed in Europe and the USA. In Europe including Great Britain, "snuff" is used to denote sniffing tobacco while in the USA this word is the term for oral tobacco; U.S. dry snuff may be consumed by sniffing or sucking.

ESTA represents manufacturers of products for sniffing and products for chewing as presented above (framed in red). ESTA would like to point out that nasal snuff and chewing tobacco products are not banned in the EU, in contrast to the marketing of moist snuff and snus which is only allowed in Sweden. The statement on page 2 of the report where it is stated that '[…] *the Directive [2001/37/EC]* […] *banned the marketing of oral tobacco in the EU.*' is therefore incorrect. Furthermore, the ban on marketing of moist snuff was already in place in the 1992 Directive (92/41/EEC).

[6] Hubert Klus et al 'Smokeless Tobacco – An Overview', September 2009, *Beiträge zur Tabakforschung International/Contributions to Tobacco Research*, Volume 23, No. 5., p.250.

d) New versus traditional products

The interim report introduces and uses throughout the document the term '*emerging products*' (see 3.1.7) for non-cigarette tobacco products. ESTA feels that this is inaccurate and misleading. By use of this term it could be implied that all tobacco products other than cigarettes are new and on the increase. This is largely incorrect as many of the mentioned products (pipe tobacco, snuff, chewing tobacco) have long history of use in Europe. Furthermore, the market shares of most of these products are in decline (e.g. use of pipe tobacco has more than halved in the last thirteen years, from 6,987 tones in 1995 to 2,635 tones in 2008).

ESTA specific comments

a) ESTA represented products in the EU markets

ESTA would like to point out that some of the literature reviewed is outdated (for example, pp. 23-32) and that it almost solely focuses on the use of cigarettes, whereas this is referenced to 'tobacco' in general. ESTA feels that this is confusing and misleading. As one of the elements of this interim report is the scope of tobacco regulation, ESTA would advise further focus on securing the best available and most up-to-date data for the different product categories. A generic and indifferent approach prejudices revision of the scope of the current impact assessment. ESTA collects estimates of total sales data for the products we represent and could provide input or guidance on request.

Market movements are also misrepresented: on page 7 it is noted that '*the use of some of these tobacco products is increasing in some European countries. This is for example the case for 'roll-your-own' (RYO) cigarettes, which are becoming more popular across Europe*.' This is somewhat misleading by its reference to 'some countries' only. Data available to ESTA shows a relative overall stability in the EU consumption of fine-cut tobacco. Although there are noticed increases in some markets, most of these are from a very low base. On the other side, there are major declines in other fine-cut markets (e.g. a traditionally large volume market such as the Netherlands) which account for a large share of total EU fine-cut market.

There are some major inaccuracies about prevalences: on page 32 it is stated that '*an ITC survey of the UK*, […] *found that roll-your own (RYO) cigarettes are used by* […] *28.4 percent of the UK population* […] *in 2001*.' This reference is misquoted. According to the quoted study[7], 28.4% is the percentage of UK smokers, not of the UK population as stated in the interim report, who at one time tried a RYO smoking article. According to the same survey, those who combine cigarettes and RYO occasionally represent 11.6% of the smokers and in 2001, the actual RYO smokers represented 16.8% of UK smokers. Furthermore, ESTA would suggest that 2001 data might only be relevant when used in comparison with 2009 data.

With regard to prevalence of smokeless tobacco products, on page 33 it is noted that '*an estimated one in ten EU citizens have tried non-combustible forms of tobacco once or more, and 2 percent use non-combustible forms of tobacco daily or occasionally (Eurobarometer 2009).*' This is inaccurate and methodology is

[7] D Young et al, 'Prevalence and attributes of roll-your-own smokers in the International Tobacco Control (ITC) Four Country Survey', *Tobacco Control*, 2006 June; Vol. 15, Supplement 3, pp. iii76–iii82

questionable. The figures reported for smokeless (non-combustible) tobacco show a high level of data inaccuracies in Eurobarometer Survey on Tobacco 2009. For example, in Romania 6% regular or occasional non-combustible tobacco use is reported amongst the respondents. ESTA, representing the smokeless tobacco categories noted (NB snus is banned in Romania), has enquired with its member in Romania who reported that there is, to their knowledge, no national production of smokeless tobacco products and that there is only a single importer into Romania. This importer has imported in the first 11 months of 2009, a total of 60kg of smokeless tobacco products. This represents a negligible part of the Romanian tobacco market, strongly questioning the 6% prevalence as noted in the Eurobarometer Survey.

As for the methodology, it is noted that '*one in ten EU citizens who have tried smokeless tobacco*'; this according to the Eurobarometer survey[8] is based on those who '*have at least once in their life tried non-combustible tobacco products.*' (p. 9) ESTA feels that this timescale, 'at least once in their life' is of questionable relevance for inclusion in the section on prevalence of tobacco products.

The reality is that fine-cut tobacco has a market share of around 9% of the total market for tobacco products in the EU, pipe tobacco just under 1%, and smokeless tobacco under 0.05%.

b) Regulation of ESTA represented products

The Directive recognised the distinction between the specific tobacco products. These specificities were notably recognised in relation to information on maximum TNCO yield information (Article 3) and application of health warnings (Article 5). In 2005 and in 2007 the Commission published reports on the application of the Tobacco Products Directive.

In the section 3.1.7., 'Emerging products' (pp. 32-34), outline of these products is patchy and inconsistent. It includes detailed references to the products that are seldom used in the EU (*kretek, bidis, chutta*) and these are intertwined with traditional EU tobacco products (e.g. pipe tobacco). The inclusion of global tobacco products without any EU market relevance within the scope of this Directive should be reconsidered. Furthermore, the interim report should only use studies that refer to the relevant products. This lack of distinction is also apparent on pages 34 to 39. ESTA feels that this section should attempt a more systematic assessment of different tobacco products. As mentioned before, in the text, the terms 'tobacco' and 'cigarettes' are used interchangeably compromising analysis of the scope of the Directive. Other tobacco products are again reviewed inconsistently and with irrelevant data. For example: the J.A. Critchley study[9] of health impact of *gutkha* and *toombak* is of limited value as these products are hardly used in the EU.

On page 7 it is stated that '*some tobacco products included in the current Directive are less regulated than manufactured cigarettes*'. ESTA feels that many of these products are not 'less regulated' but that the current regulation is proportional and corresponds to the individual products' characteristics.

[8] Eurobarometer, *Survey on Tobacco: Analytical report*, March 2009, Flash EB Series #253, The Gallup Organisation.

[9] J.A. Critchley, 'Health effects associated with smokeless tobacco: a systematic review,' 2003, *Thorax*, Volume 58, pp. 435-443.

c) Ingredients reporting

Since the publication by the European Commission of common reporting formats, ESTA member companies have, to the extent possible[10], used these formats for the reporting of tobacco ingredients. In addition ESTA member companies are supportive of and collaborate on the development of the EMTOC system to ensure that EMTOC can serve as a workable, secure and solid system for the future reporting of tobacco ingredients in all Member States. ESTA member companies are fully prepared to report their ingredients information using the EMTOC system, provided that their trade secrets are adequately protected.

Amongst other, on the submission of available toxicological data, the interim report states (p. 16) that this '*has not been successfully implemented.*' ESTA points out that the submission of 'available toxicological data' has been done according to the capacities of each manufacturer. Smaller companies often lack appropriate resources to provide comprehensive toxicological data on ingredients. The smoking tobacco industry has been working on the development of an industry database of toxicological data relevant to smoking tobacco products. Such database was especially developed to meet the demand of the SMEs.

Notwithstanding that its members have submitted available toxicological data to the Member States, ESTA is of the opinion that the legislator should define the relevance of providing toxicological data to consumers. In ESTA's view, understanding these data requires a scientific background and might be confusing for most consumers. We therefore urge RAND to assess the potential benefits in providing the consumers with such scientific information.

In its consideration of inclusion of tobacco leaves, the interim report should note that the Directive excludes tobacco leaves, as these do not fall under the scope of the definition of tobacco ingredients. Tobacco leaves are agricultural products and the substances they naturally contain are not added by the manufacturers of tobacco products. RAND should therefore provide for a thorough evaluation of the impact that a change of the 'ingredients' definition will imply as this will have an effect on the entire scope of the Directive.

d) Labelling of ESTA represented products

The interim report should consider that graphic health warnings were not part of the original Commission proposal[11] that resulted in the adoption Directive 2001/37/EC. Therefore, no economic impact assessment has been carried out on the use of graphic health warnings on tobacco packages. Contrary to the apparently more homogenous type of packaging for cigarettes, the packaging of smoking tobacco products is very diverse. The large number of smoking tobacco brands are sold in a wide range of different shapes (round, oval, square, rectangular) and sizes / weights (such as 25-, 40-, 50- and 200 grams) and are manufactured from different materials such as laminated plastics, metals, synthetics and cartons. Taking into account the disproportionate cost burden to both tobacco and printer SMEs to print graphic health warnings, ESTA recommends that the impact of the current labelling requirements are fully assessed by RAND before any changes are considered.

Chapter 5 (Cost and administrative burden of tobacco regulation) includes an overview of the cost of labelling tobacco products (pp. 59-60). ESTA represented products are often produced in small runs and with much longer shelf life than factory made cigarettes. Also, they are in many cases produced by small and medium

[10] In some Member States a different format is required by national legislation.

[11] COM (1999) 594 final, OJ C150E, 30 May 2000, p. 43.

size companies where the costs of packaging and labelling are significantly higher in proportion to the other parts of the manufacturing process. This varies substantially between product categories and ESTA would advise that separate data should be gathered for each product category as well as from large and small manufacturers. This will enable a more accurate analysis.

Considering current regulation on labelling of smokeless tobacco products, the interim report (p. 7) states that '[…] *oral tobacco (where their marketing is permitted) and other smokeless tobacco products are required to carry less substantive health warnings; these are the same for all packs- "This tobacco product can damage your health and is addictive*". This is incomplete and potentially misleading. This reference ignores what the recitals of Directive 92/41/EEC state, i.e. '*Whereas in relation to their effects on health and for the purposes of their labelling, a distinction needs to be made between smoking tobacco products and smokeless tobacco products*.' This Directive was one of three Directives 'recast' into the current Tobacco Products Directive.

The following section (p. 9) includes considerations on labelling of smokeless tobacco products. Apart from moist snus in Sweden, smokeless tobacco products (e.g. nasal snuff, chewing tobacco) represent a negligible share of the EU tobacco market (under 0.05%). These are specific traditional products that have very limited appeal to and are not generally consumed by first-time tobacco users. There is no data on the effectiveness of the proposed measures on smokeless tobacco and this very small industry would be disproportionately castigated. These products are made in very small runs and anything else but maintaining the current single health warning would have a severe impact on manufacturing.

Making a more general comment on an increase of the size of health warnings, it is stated (p. 12) that '*the first of the key factors of health warnings is that the increased size 'enables warnings to compete with other pack elements*.' It is unclear to ESTA what the motives and policy objectives are for what is clearly packaging encroachment and commercial, not health, labelling issue. ESTA understands that the role of health warnings is to provide information on health risks associated with the product rather than to influence the manufacturer's packaging elements or enable generic and indistinctive packaging of tobacco products. ESTA would appreciate that future policy options are clearly delineated, defined and analysed separately.

Reflecting on the concept of plain packaging, the report (p. 12) states that '*some studies have shown that the use of plain packaging for tobacco products could further increase the effectiveness of such warning labels*'. ESTA strongly feels that this is a disproportionate measure as any potential impacts, apart from castigation of tobacco products, of plain packaging are unclear. In a lack of clear definition of what plain tobacco product package constitutes, studies used were inconsistent and difficult to compare.[12]

e) Measuring yields of smoking tobacco products

Generally, consumer making habits for fine-cut tobacco vary considerably both between individual consumers within a country and also between different countries and have a much greater effect on tar and nicotine yields than the choice of tobacco. Fine-cut tobacco has the character of semi-finished product. ISO 15592-3, the only internationally agreed measurement method in this respect, takes this into account by specifying two weights and two different paper variants and is suitable to inform the consumer about the effect of their choice of wrapper and about their method of making the smoking article. Consequently, laboratory results using ISO 15592-3 show a higher measurement variability compared to those obtained from factory-made cigarettes.

[12] Noted in B Freeman et al, 'The case for the plain packaging of tobacco products,' 2008, *Addictio*n, 103, pp. 580–590.

Since its publication in 2003, ESTA has continuingly undertaken technical work in order to identify parameters and procedures within ISO 15592 that contribute to this variability and to explore best possible ways to potentially lower it.

The outcome of this work is of major relevance for defining appropriate tolerance levels for fine-cut tobacco, likewise recognised and established in EU regulations for yields of factory-made cigarettes since many years[13].

The high measurement variability caused by the nature of fine-cut tobacco has not been considered in the interim report and require thorough evaluation to avoid misinterpretation of results and dispute on the accuracy of any information provided on tar and nicotine yields.

On page 7 it is stated that '*hand-rolling tobacco is sold without maximum TNCO yield information on the packs*'. There is a measuring method for the determination of tar and nicotine yields from fine-cut tobacco, ISO Standard 15592-3. The development of this International Standard has been supported by ESTA and its members, and reflects the various consumer habits and choices in regard of wrappers or the amount of tobacco used. The results of tar and nicotine measurements can be expressed as a 'matrix' of four tar and four nicotine yields (i.e. stating the tar and nicotine yields for two tobacco weights in combination with the two different types of wrapper). Following the adoption of the ISO Standard, some ESTA member companies, after consultation with national regulators, have voluntarily introduced yield declarations in the form of the yields matrix on their packaging in many EU Member States. Currently there is no standardized measuring method for determining CO contents in fine-cut tobacco.

If taking into consideration the inclusion of tar and nicotine information on the packaging of fine-cut tobacco, the current report should consider referencing to ISO Standard 15592-3 as the only available internationally agreed standard for the measurement of tar and nicotine values.

The Netherlands is the only EU Member State that has introduced legislation requiring the printing of tar and nicotine yields on the packaging of fine-cut tobacco. Contrary to the ISO Standard, the Dutch legislation requires the declaration of yields via a single figure each for tar and nicotine and measured with a different type of wrapper than prescribed by the ISO Standard. This method reflects only the Dutch market situation and it is therefore not internationally applicable.

Tar and nicotine ceilings for fine-cut tobacco are meaningless as this is a semi-finished product. Whilst indications can be given on yields by using certain standard definitions (as in ISO 15592) a ceiling does not make sense as the consumer will ultimately shape the product to his own choice through the paper chosen, amount of tobacco, tightness of rolling, adding a filter, etc.

In relation to the cost of complying with the tar and nicotine maximum yields, on page 61 it is noted that '*the evidence regarding the UK (Department of Health, 2002) suggests that the costs of complying with the tar and nicotine maximum yields regulation are minimal as the majority of the tobacco producers produced low yield cigarettes already before the Directive was introduced. Although some minor one-off costs result in the form of testing consumer reactions to the changes*.' Regardless of whether this is a valid point, this clearly relates only to cigarettes and it should be referenced as such. In addition to comments on page 7 of the interim report above, ESTA would call for caution in the introduction tar and nicotine maximum yields of smoking tobacco products.

[13] See Directive 89/622/EEC.

For products where no agreed standard methods for testing of tar and nicotine yields exist, the interim report should recognize that potential costs will be substantive and spread over relatively long period of time, as they should include not only the introduction of measurement requirements, but also development of measuring methods where these are not presently available.

As for the other smoking tobacco category, the determination of yields from a pipe filled with pipe tobacco is technically very complex. Apart from the obvious difficulties in deciding on a standard size, shape and material of construction of the pipe, the method of filling must be investigated and standardised since the method of packing will affect density and therefore yields. In addition there are many different forms of pipe tobacco and variety in preparation of pipe and packing which affects the airflow through the tobacco. Even if the technical issues could be resolved, it is not known whether the ranking of yields obtained using one pipe style, shape and size would be maintained by changing to another. Finally, in the absence of any standard method it is not possible for manufacturers of pipe tobacco to measure tar and nicotine yields.

Levels in smoke for substances commonly called 'Hoffmann analytes' are generally very low (µg or ng) and low levels always lead to high variability in laboratory measurements. Due to the nature of fine-cut tobacco, it is a fair and robust conclusion that any such method would inherit even higher variability than observed for tar and nicotine and could therefore not form a scientifically sound basis to compare individual products.

Only for one substance a measurement method[14] has undergone a full validation process under the strict auspices of ISO. The scope of this ISO Standard is limited to factory-made cigarettes and communicating results for any other tobacco product category is scientifically questionable and misleading.

f) Sales arrangements

On page 16, the report states that no '*research could be identified examining the display of tobacco products in retail outlets*.' ESTA would like to stress that the display of tobacco in the retail environment does not constitute a marketing strategy, but that it enables consumers to easily identify whether or not their preferred brands are in stock. If this possibility is removed, many smaller or 'niche' brands will not survive on the market as many outlets will be forced to delist them, therefore distorting the competition between different manufacturers.

An additional undesired side effect of removing the display of tobacco products at the point of sale is the impact on illicit trade. It needs to be assessed to what extent the lack of visibility of genuine product will make it even easier for illegal counterfeiters, who manufacture and market tobacco products outside of any regulation, to sell their product to the consumer.

[14] ISO 22634 Cigarettes - Determination of benzo(a)pyrene in cigarette mainstream smoke.