Public consultation on the possible revision of the Tobacco Products Directive 2001/37/EC

Meta Informations

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Questions on the Scope of the Directive

Do you agree with the problem definition? No

If not, please provide explanations
We do not agree with the problem definition for the following reasons: It is incorrect to state that the tobacco products market has increasingly diversified from an ESTA products perspective. With few exceptions, all tobacco products currently on the market, cigarettes, fine-cut, cigars & cigarillo's, pipe tobacco, traditional chewing tobacco, nasal snuff and snus (in one member state), have been on the market from before the 2001 Directive. The fact that individual Member States regulate or classify non-tobacco products under other legislation is understandable as these concern non-tobacco products and should not be included under the Tobacco Products Directive. Only products containing tobacco should be regulated under the Tobacco Products Directive. ENDS and herbal cigarettes are non-tobacco products and should be regulated under regulation more appropriate to their characteristics, being classified as pharmaceuticals, food or another product category for example.

In your view, which option addresses the problem most effectively? No change

Do you recommend any additional option that would effectively address the problem?

Do you have any additional specific comments?
ESTA is of the opinion that all tobacco products should be regulated under the Tobacco Products Directive. This entails that any novel tobacco products that may be marketed in future should fall within the scope of the Directive. That said ESTA wants to point out that a one-size-fits-all approach in the amended Directive is not appropriate. ESTA represents many different "smoking tobacco products", with their individual characteristics, history and use. Pipe tobacco includes for example ingredients that will not be used at all or to the same levels as in other tobacco products. Secondly, a significant number of the ESTA member companies are small and medium sized companies, sometimes family owned, and with a long history. Therefore, the impacts of any new legislation on these companies can be far greater than on large multi-national companies that can to some extent achieve economies of scale. The costs burden will be far greater resulting from the necessary administrative burdens and the need to buy-in the necessary expertise which such companies simply do not have 'in-house'. Finally, some products of ESTA members, for example nasal snuff, are produced regionally, with a regional client base, and represent a very marginal part of total tobacco products consumption. ESTA therefore insists that product differentiation and specificity of ESTA represented products, SME characteristics of several ESTA member companies, and marginal market share of specific ESTA represented products is taken into account when amending the 2001 Directive.

Questions on smokeless tobacco products

Is the problem definition correct? No

If not, please provide your comments and supporting evidence.
The problem definition talks about smokeless tobacco products as a homogenous group and they are not. The products in this category are manufactured differently and used differently by consumers. This is fully recognised in the WHO Tobacco Regulation Report: 'it would be scientifically inappropriate to consider smokeless tobacco a single product for the purpose of estimating risk or setting policies'(www.who.int/tobacco/global_interaction/tobreg/publication/9789241209519.pdf). The broad subdivision of smokeless products can be differentiated into chewing tobacco, nasal snuff and snus. Chewing tobacco and nasal snuff are allowed to be marketed across the EU. Snus is banned in the EU, whilst allowed to be sold in Sweden where it is regulated under food law. The 2008 SCENIHR Opinion on “Health Effects of Smokeless Tobacco Products” clearly assesses the health risks of the different type of smokeless product and where appropriate draws general conclusions for the smokeless category when comparing such products with combustible tobacco products. The problem definition incorrectly selects SCENIHR comments attributable to specific smokeless products and reports them as general finding. ESTA represents manufacturers of nasal snuff products and traditional chewing tobacco that are both legal and covered by the TPD. ESTA would like to correct the problem definition in regard of specific facts relating to the product types manufactured by its members. The problem definition states that all smokeless tobacco products are addictive and can cause cancer. We refer in this case to the section on the use of nasal snuff (pages 92 and 93) of the 2008 SCENIHR Opinion where it is stated that: “In many regions of the world nasal use of snuff is less prevalent than oral use, and fewer studies are available on the association of nasal use of snuff with cancer”. In fact the five studies quoted relate to three studies in India, one in Tunisia, and one South African study dating back to 1955. It is therefore obvious that European nasal snuff use has not been the object of any study on health effects. In fact, one historical study on the Health Effects of Nasal Snuff in the Journal of Laryngology & Otology of September 2003 concludes that there is no evidence of head, neck or other malignancies in relation to the use of (European) Nasal Snuff. In addition to this Study, in the 2004 IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 89 on Smokeless Tobacco, it is stated that: “Studies on the nasal use of snuff did not provide conclusive evidence of a relationship with cancer”. Concluding, the problem definition is poorly constructed and creates confusion by not differentiating between categories of smokeless tobacco products already covered by the current TPD and the one category that is currently banned.

In your view, which option addresses the problem most effectively? Lifting the ban on snus

Do you recommend any additional option that would effectively address the problem?

Do you have any additional specific comments?
ESTA does not believe that banning one product or another should be based on an arbitrary decision and can only have merit if a full scientific assessment, based on scientific evidence with clear and internationally recognized criteria has been undertaken. ESTA rejects option three and would favour allowing all smokeless tobacco products to be marketed in the EU.

Questions on the consumer information

Do you agree with the problem definition? No

If not, please provide explanations
Concerning Pictorial Warnings, ESTA notes that the background document does not clearly indicate that the provision is optional. It also does not remind that the reason for making this optional was to enable Member States to determine what's best for them taking into account e.g. their national circumstances and specificities, the consumer profiles and the volume of the different tobacco products and whether all or only some categories should be covered. As a consequence, there are indeed different national rules, however, ESTA does not understand why this is now qualified as a distortion of the internal market. Indeed, Member States can require pictorial warnings on some or all products categories. ESTA does not agree with the statement that "tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image". ESTA rejects the notion of "attractiveness" as a valid regulatory goal or objective as it fails established criteria. The packaging of tobacco products do not lead to smoking initiation and smoking increase. Any packaging, whether it is of food stuffs, tobacco or any other good, needs to communicate to its consumers what product it contains, who produced it and the key features of the product. It also needs to distinguish in the course of trade. It is clear that (package) branding enables a consumer to easily identify (and re-identify when re-purchasing) the product and the producer (trust) allowing the consumer to make an informed purchase decision in terms of quality and sensory expectation. ESTA notes that on the 30th November 2009 the Council invited the Commission to "analyse the legal issues and the evidence base for the impact of plain packaging, including on the functioning of the internal market". ESTA is not aware that such an analysis has been done or that any results have been made available. Therefore the legality, effectiveness and proportionality of such a measure should be carefully explored before such a measure is considered further.

In your view, which option addresses the problem most effectively? (more than one option can be chosen unless you choose "No change") No change

Do you recommend any additional option that would effectively address the problem?

Do you have any additional specific comments?
Concerning Health Warnings, ESTA acknowledges the international public health

concerns associated with smoking of tobacco products and supports sensible regulation of tobacco products based on sound science and respecting the different characteristics of the various tobacco products. ESTA therefore supports informing consumers via clear and easily understandable health warnings which are based on sound science and are proportionate. ESTA believes that the current size and message of the textual health warnings adequately serve this purpose. Thus ESTA is opposed to any further increase of the area currently reserved for health warnings and questions the scientific and empirical evidence to justify such a measure. In addition, ESTA also opposes mandatory pictorial warnings at EU level, again questioning the scientific and empirical evidence to justify such a measure. Indeed it can be questioned whether the mandatory printing of pictorial warnings on e.g. pipe tobacco packages would have the intended effects pursued by the Commission, taking into account, the profile of pipe smokers and the long term declining market for this product (which nowadays represents only approx. 0,5% of the total EU market for tobacco products). It has to be noted that no impact assessment was carried out on the effectiveness of the pictorial warnings before the 2003 Commission Decision was adopted. Research since shows an attitudinal change, but not a behavioural change, while no significant reduction in consumption has been reported. However, such research is based on cigarette smokers not on consumers of ESTA represented products. The technical difficulties of placing inserts in tobacco packages should be recognized by the Commission as it would prove impossible to place inserts in nasal snuff or chewing tobacco packages. With regard to pipe and fine-cut tobacco the impact of such an insert on the tobacco itself (as physical contact may occur) need to be scientifically assessed. But more importantly it is unclear to ESTA what the motives and policy objectives are for placing inserts inside the tobacco packaging. ESTA believes that introducing plain packaging is an unreasonable and unjustified measure. Plain packaging would breach the legal and treaty obligations relating to intellectual property rights, international trade, the EU acquis and Member State laws/national constitutions. In addition –in line with the principle of proper functioning of the internal market- companies have the right to differentiate their products to facilitate the choice of their adult consumers. There is no evidence to suggest that plain packaging would curtail the uptake of smoking by young people or improve the awareness of risk associated with smoking: the objectives pursued by the legislator. Therefore, apart from demonisation of tobacco products, the expected health benefits from such measure are unclear and at this stage purely speculative. ESTA also urges the Commission to assess the impact that plain packaging will have on illicit trade as legal tobacco packages will be more difficult to distinguish from illicitly traded products in the supply chain. ESTA would like to highlight that further demands for reserved space on packaging would impinge on the intellectual property rights and trademarks of the companies. ESTA is of the opinion that the legislator should define the relevance of providing additional information to consumers. Understanding complex or scientific data requires a scientific background and might be confusing for most consumers whilst at the same time overly simplistic information risks misinforming the consumer.

Questions on reporting and registration of ingredients

Do you agree with the problem definition? No

If not, please provide explanations
Concerning the Problem Definition, it is a matter of fact that reporting mechanisms

differ per Member State. It is unclear how any one member state may have difficulty analysing data as a result of its own unique reporting format. Besides this, the 2001 Tobacco Products Directive did not foresee specific assessment of the information provided by manufacturers (Introduction of the Public Consultation Document, page 2, 5th paragraph). However, ESTA wants to emphasise the underlying issue of lack of regulatory guidance provided after the adoption which left member states and ESTA members in the dark on how to report ingredients data. ESTA also wants to point out that small and medium sized companies in ESTA membership have not only a substantial burden resulting from the reporting requirements themselves, but that it is compounded when either no guidance is provided or when different reporting formats have to be used across the EU. The complexity of reporting formats, coupled with a lack of clear definitions, indeed impacts on how companies can respond. Although manufacturers have concerns about their trade secrets, these same manufacturers have made proposals to allow for full reporting and indeed do so in individual member states. The concern should therefore not be a “problem” as the existing legislative framework already allows for the development of a clear and robust reporting format. However, one mandatory reporting format does not exist. Finally, and as with all legislation, compliance costs often occur for business and/or consumers as well as for authorities. The fact that significant costs are involved for national competent authorities results from the objective to have reporting done in the first place. It is up to national competent authorities to have suitable mechanisms in place and many have done so which of course led to significant costs for manufacturers. ESTA can again not understand how a difficulty resulting from agreed legislation has developed into a problem that needs more legislation. ESTA and the smoking tobacco manufacturers have not only highlighted possible issues prior to the adoption of the 2001 Directive, ESTA also has been proposing and supporting the development of a suitable reporting method which takes into account differences per product category.

In your view, which option addresses the problem most effectively? (more than one option can be chosen unless you choose "No change") Establish a common compulsory reporting format

Do you recommend any additional option that would effectively address the problem?

Do you have any additional specific comments?
Option 3 cannot be supported by ESTA and it needs to be noted that this is not a ‘stand-alone’ option as it can only be introduced if a common compulsory reporting format is introduced. Fees and sanctions should remain a competence of Member States, not of the EU, as it will significantly increase costs for business without clear benefits or proportionality. Finally, penalties are a Member State prerogative, and ESTA believes that its members should be treated as any other business. Option 2 is supported by ESTA. We support the principle of the common reporting format for ingredients reporting and the principle of a sustainable, robust and secure electronic database system of the type under development by EMTOC that could be used for collecting and holding ingredients data. ESTA would welcome any initiative from the Commission to make the “Practical Guide” binding in all EU Member States and to incorporate into the Practical Guide the

EMTOC system and proposed solutions to the outstanding issues. ESTA therefore proposes a maximum harmonisation approach. ESTA is of the opinion that the EMTOC system should be further developed, with involvement from tobacco manufacturers and importers, with an agreed set of documents like Instructions, Terms of Use and adequate protection for competitively sensitive and trade secret information.

Questions on the regulation of ingredients

Do you agree with the problem definition? No

If not, please provide explanations
ESTA does not agree with the problem definition as it is overestimating in terms of harmfulness the contribution of ingredients at the levels particular in use to the tobacco smoke. The Problem Definition states that attractive substances are added to tobacco products. ESTA rejects the notion of "attractiveness" as "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. Ingredients are used to develop a differentiated, segmented product portfolio that meets consumer expectations. There is no evidence to support the assertion that the majority of additives form substances that increase the carcinogenicity, mutagenicity and/or reproductive toxicity of the product. Individual ingredient pyrolysis is not a sufficient or necessarily a relevant basis to assess ingredients. There is no internationally agreed basis for the assessment of ingredients, however, the available toxicological data and the available epidemiological data for products with and without ingredients (USA vs Canada) show no difference in disease incidence, prevalence, initiation or quit rates. However, it is correct to state that those Member States that have ingredient regulation in place authorise ingredients on different bases. The question however is, whether this is the main problem that needs resolving first or whether prior to any consideration to the manner in which ingredients are to be authorised the method and criteria for assessment should be developed and agreed.

In your view, which option addresses the problem most effectively? No Change

Do you recommend any additional option that would effectively address the problem?
Unfortunately, none of the options is suitable to address the first and foremost problem of the lack of a single international recognised scientific method of assessment as well as the lack of internationally agreed common criteria for such assessment. Only when these are developed the question arises whether a common, negative or positive list of ingredients is the most suitable. In addition any method should incorporate testing the effects ingredients have on one and another when being burnt. Finally, toxicity is a major consideration, but must be placed in the context of the levels detected, as well as that it needs to be assessed in the context whether these increase the inherent risks associated with smoking. ESTA offers the following points which could assist in developing a sound policy on ingredients. On an ingredients definition, ESTA supports the current definition of ingredients in Article 2(5) of the Directive 2001/37/EC covering 'any substance or any constituent except for tobacco leaf and other natural or unprocessed

tobacco plant parts used in the manufacture or preparation of a tobacco product and still present in the finished product, even if in altered form, including paper, filter, inks and adhesives'. A common list could be supported but such is premature as the pre-conditions of assessment method and criteria should be fulfilled before. Concerning ingredients assessment, ESTA is of the opinion that any decision allowing or banning the use of a specific ingredient has to be based on a full scientific assessment of whether the ingredient increases the inherent risks associated with smoking. In order to consider and implement a ban on any ingredient, there must be a requirement for the Commission to develop a clear definition and scientific basis for such action followed by comprehensive scientific assessment. In this context, the Commission should at least consider the scientific principles developed jointly by the WHO/ FAO Codex Alimentarius Commission (CAC). ESTA supports the application of the scientific principle of "inhalation threshold of toxicological concern" to perform the assessment of ingredients of tobacco products. The principle of threshold of toxicological concern has been successfully applied internationally to the safety evaluation of many chemical substances and food additives. On ingredients and health risks, it is ESTA's view, based on the currently available information and available scientific evidence, that the ingredients used, at the levels used, do not add to the inherent potential harm of tobacco consumption, and neither induce people to start smoking nor affect people's ability to quit. There is no scientific evidence that smoking tobacco products with or without added ingredients pose different levels of health risks. Ingredients are not added to increase the amount of nicotine in tobacco smoke, or to increase the amount or speed of nicotine absorbed into the smoker's body. Finally, there is no credible scientific basis upon which it can be considered that some ingredients may be addiction enhancing. ESTA insists that new rules should only apply to products marketed in EU but not to those manufactured in the EU for export. Tobacco products manufactured inside the Union are also widely exported. That includes export to markets where consumer preferences and legislation differs substantially from ours. To maintain this export and the employment it creates it is therefore imperative that new EU legislation on additives only applies to products marketed inside the Union and not to tobacco products manufactured in the Union for export purposes. Finally, ESTA would like to insist that the EU draws upon the expertise of the tobacco industry when developing the above mentioned policies into measures.

Do you have any additional specific comments?

Questions on access to tobacco products

Do you agree with the problem definition? No

If not, please provide explanations
With regard to the cross border sale of tobacco products via the internet, ESTA considers that this issue is adequately addressed in the Directive 2008/118/EC concerning the general arrangements for excise duty (see section 3 of the Directive on distance selling). Concerning the possible prohibition of the display of tobacco products at points of sale, ESTA does not believe that this falls within the competence of the EU. A thorough legal assessment should therefore take place

prior to considering any initiatives in this regard.

In your view, which option addresses the problem most effectively? (more than one option can be chosen unless you choose "No change") No change

Do you recommend any additional option that would effectively address the problem?

Do you have any additional specific comments?
ESTA believes that smoking is an informed adult choice and supports regulation banning the sale of tobacco products to under-age minors at national level. The compliance with and enforcement of this provision must be done in accordance with national laws. Although ESTA agrees that access to vending machines should be strictly controlled to prevent sales to under-age minors, such regulation is already currently dealt with at national level. However, ESTA does not support the prohibition of vending machines as such, as this would prevent the legitimate access by adult smokers. Moreover, ESTA invites the European Commission to analyse whether any such measure would be within its legal competence. The proposal to ban the display of tobacco products is based on weak evidence, and we strongly believe that such a measure would have adverse unintended consequences. Our major concern is that if the consumer is prevented from seeing the tobacco products a retailer is offering for sale, this will hinder free trade and will distort the competition between different manufacturers. The display of products at the point of sale is a vital part of the purchasing process of those consumers who are seeking to buy a tobacco product - especially when using a particular retail outlet for the first time. Display also 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. Furthermore, suppliers of niche brands are often quite reliant on small shops and these shops are more likely to become vulnerable in the event of a ban. ESTA considers that a display ban of tobacco products will restrict the right of adult tobacco consumers to choose their legal tobacco products from a wide range of brands, prices and new products and will disadvantage small and medium sized enterprises as outlets could stop storing slower selling products. Small retailers in particular rely on display to communicate when they have less mainstream products and brands in stock. A display ban is likely to put pressure on the range of brands stocked by many retailers and the less mainstream products supplied by our member companies are likely to be negatively affected. ESTA is also concerned that the freedom of competition between manufacturers and between retailers would be altered by such a ban which would impact our smaller member companies to a greater extent. Finally ESTA is concerned that a display ban could exacerbate the illicit trade of tobacco products by annihilating the ability for consumers to distinguish between legal and illegal products.ESTA invites the Commission to consider an alternative, more competitively neutral and evidence based strategy to achieve their policy objectives.