DG SANCO's Consultation on the possible revision of the Tobacco Products Directive 2001/37/EC (*TPD*)

JTI's Online Response

This document sets out (i) the text of DG SANCO's Public Consultation Document 2010 (in italics in this document) and (ii) JTI's Online Response. JTI's Full Response to the Consultation was filed by email on 16 December 2010.

16 December 2010

JTI is a member of the Japan Tobacco Group of Companies (JT), a leading international tobacco product manufacturer. It markets world-renowned brands such as Winston, Mild Seven and Camel. Other international brands include Benson & Hedges, Silk Cut, Sobranie of London, Glamour and LD. With headquarters in Geneva, Switzerland, and net sales of USD 9.6 billion in the fiscal year ended December 31, 2009, JTI has more than 25,000 employees and operations in 120 countries. For more information, visit www.jti.com.

JTI is a registered interest representative, under number 31290853542-43, within the meaning of EU's European Transparency Initiative.

I. INTRODUCTION

The present Tobacco Products Directive[1] *has the objectives of facilitating the functioning of the internal market in the tobacco products sector while ensuring a high level of protection to public health.*

It mainly covers:

- *the maximum content of tar (10 mg), nicotine (1 mg) and carbon monoxide (10 mg) per cigarette*[2]
- *the health warnings and other labelling requirements*
- *reporting on the tobacco ingredients by the industry to the authorities*
- *ban on misleading texts, names or signs in tobacco packages*
- *ban on oral tobacco.*

The tar, nicotine and carbon monoxide yields per cigarette must be printed on one side of the cigarette packet in the official language or languages of the Member State where the product is placed on the market, so that at least 10 % of the corresponding surface is covered.[3]

All tobacco products should also bear compulsory text warnings on the harmful effects of the consumption of tobacco products on the packages.[4]

Text warnings may be combined with pictures. It is optional for Member States to make picture warnings compulsory in tobacco packages.[5] *Currently, four Member States (Belgium, Romania, The United Kingdom and Latvia) have made picture warnings compulsory. Two Member States plan to do so as of 2011(Spain and France).*

Manufacturers must communicate on a yearly basis to the Member States a list of all tobacco ingredients, together with available toxicological data. The Directive does not foresee any specific assessment of the information provided by manufacturers. The objective is to ensure that consumers have access to data on ingredients.[6]

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1 Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products - Commission statement (OJ L 194, 18.7.2001, p. 26–35).

2 Article 3

3 Article 4

4 Article 5

5 Article 5(3); Commission Decision 2003/641/EC

6 Article 6

Member States may ban the use of ingredients which have the effect of increasing the addictive properties of tobacco products.[7]

Oral tobacco ("snus") is prohibited in the EU, except in Sweden that obtained derogation in its Accession Treaty.[8] *The derogation was granted on condition that Sweden shall take all measures necessary to ensure that oral tobacco is not placed on the market in the Member States for which the Tobacco Products Directive is applicable.*

The Directive includes the so-called "free movement clause". Member States may not ban or restrict the imports on their markets of tobacco products that comply with the Directive.[9]

However, Member States may apply more stringent rules in order to protect public health, insofar as such rules do not prejudice the rules laid down in the Directive.[10]

The Tobacco Products Directive dates from 2001. New international, scientific and market developments require reflecting whether the Directive still fully guarantees an appropriate functioning of the internal market while ensuring a high level of health protection.

This consultation is based on existing knowledge and aims at providing an early opportunity for all stakeholders to input on the possible need to revise the Directive and on the different policy options that such revision might involve.

At the present stage, the Union competence to adopt the different options, their implications on the functioning of the internal market and their proportionality have not yet been fully examined. These issues will be analysed at a later stage when the problems and the policy options are developed further.

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7 Article 13(3)

8 Act of Accession of Austria, Finland and Sweden, Annex XV…

9 Article 13(1)

10 Article 13(2)

II AREAS OF POSSIBLE CHANGE

1. SCOPE OF THE DIRECTIVE

1.1. Problem definition

Since the adoption of the Directive in 2001, the tobacco products market has increasingly diversified.

The Directive does not cover electronic nicotine delivery systems (ENDS), such as electronic cigarettes. Yet they are generally marketed as alternatives to smoking.

Some Member States classify electronic cigarettes that contain nicotine as pharmaceutical products. This means they cannot be put on the market unless they have proven efficacy, safety and quality. However, in many Member States electronic cigarettes (with and without nicotine) are marketed as consumer products with no prior authorisation or safety checks. This results in a legal uncertainty.

In addition, nicotine drinks are in the market in some Member States, and are likely to enter other Member States' markets. There is also an emerging market of nicotine sweets world wide. However, by definition these products are covered by food legislation.[11]

Furthermore, the Directive does not cover cigarette-like products which do not contain tobacco, such as herbal cigarettes, that have similar harmful effects as regular cigarettes.

The legislation of Member States to classify or regulate these products varies. There are no uniform conditions for regulating ENDS and herbal cigarettes. This might imply both a distortion of the internal market and a failure to ensure a high level of health protection in the EU.

1.2. Possible options

Option 1 - No change

Tobacco and nicotine products that are not covered by the Tobacco Products Directive, or other EU legislation (food, pharmaceutical) would remain subject to different legislations in different Member States. The same would be true for products that are smoked, but do not fall under any of the above legislations (such as herbal cigarettes).

Option 2 - Extend of the scope of the Directive

An extension of the scope of the Directive could be envisaged to include novel forms of oral tobacco, herbal cigarettes, and electronic nicotine delivery systems, insofar as they are not already covered by other EU legislation (food, pharmaceutical). Specific safety and quality requirements would be developed for ENDS.

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[11] Regulation 178/2002/EC and The Novel Foods Regulation (258/97)

For cigarette-like products (herbal cigarettes), appropriate indications of contents and health warnings would be required.

New tobacco products would bear harmonised information on harmful substances in the product and health warnings. Member States would require manufacturers and importers to inform competent authorities about all ingredients used in the manufacture of a product.

Novel forms of oral tobacco would be banned similarly to snus.

1.3 Questions

1) Do you agree with the problem definition? If not, please provide explanations.

2) In your view, which option addresses the problem most effectively?

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

JTI'S ONLINE RESPONSE TO SECTION 1: SCOPE OF THE DIRECTIVE

QUESTION 1: Do you agree with the problem definition? If not, please provide explanations.

No. Neither the Consultation nor the RAND Report provides any evidence that electronic nicotine delivery systems, other products that contain nicotine but not tobacco and cigarette-like products which do not contain tobacco require regulation on internal market or public health grounds. Nor have these products been clearly defined. In addition, the Consultation contains no analysis of the EU's competence to extend the scope of the Directive in the manner proposed. The reasons and analysis underlying JTI's position are set out in Sections 8-10 of JTI's Full Response, which will be sent by email to DG SANCO and which forms an integral part of our on-line submission.

QUESTION 2: In your view, which option addresses the problem most effectively?

Option 1 – No change.

QUESTION 3: Do you recommend any additional option that would effectively address the problem?

No.

QUESTION 4: Do you have any additional comments?

In respect of the options presented in the Consultation, as currently drafted, Option 2 would not be an appropriate basis for regulation because it would impose a ban on "new tobacco products" and "novel forms of oral tobacco" (Consultation, p5) without defining what the term means or demonstrating any need for a specific prohibition. A ban would be both arbitrary and disproportionate. Moreover, this option prejudges the outcome of Section 2 of the Consultation ("Smokeless Tobacco Products") and is entirely without scientific foundation. The reasons and analysis underlying JTI's position are set out in Sections 8-10 of JTI's Full Response.

2. SMOKELESS TOBACCO PRODUCTS

2.1. Problem definition

The current regulatory framework bans some smokeless tobacco products ("snus") while others (e.g. chewing tobacco) are freely available in many Member States.

All smokeless tobacco products are addictive and can cause cancer. They also increase the risk of death after a myocardial infarction and may have additional cardiovascular effects as stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of February 2008[12].

For an individual, substitution of smoking by the use of smokeless tobacco products would probably decrease the incidence of some tobacco-related diseases. It has also been proposed that the use of these products could be a way to quit smoking, but at this moment there is not enough scientific evidence available on the efficacy of snus as quitting aid. On the contrary, as all tobacco products, snus causes dependence and according to the evidence from some countries, the use of smokeless tobacco products may lead to subsequent cigarette smoking.

2.2. Possible options

Option 1 - No change

The prohibition on the marketing of tobacco for oral use ("snus") remains unchanged. Other smokeless tobacco products that are perceived as marginal products can continue to be marketed in all Member States.

Option 2 - Lifting the ban on snus

All types of smokeless tobacco products would be freely marketed in the EU, subject to possible requirements for appropriate consumer information such as health warnings.

Option 3 - Ban on all types of smokeless tobacco products

The ban on "snus" would be extended to all types of smokeless tobacco products.

2.3 Questions

1) Is the problem definition correct? If not, please provide your comments and supporting evidence.

2) In your view, which option addresses the problem most effectively?

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

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[12] The SCENIHR Opinion can be found here: http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf

JTI'S ONLINE RESPONSE TO SECTION 2: SMOKELESS TOBACCO PRODUCTS

QUESTION 1: Do you agree with the problem definition? If not, please provide explanations.

No. The distinctions made by the TPD between smokeless products that are banned and those that are permitted are arbitrary and unjustified. The proposals are also inconsistent with research commissioned by DG SANCO.

JTI acknowledges that there is no safe tobacco product, including smokeless tobacco products, and that the use of such products is associated with risks to health. However, the Consultation quotes SCENIHR 2008 selectively on the issue of health risks. As well as finding that, for an individual, substitution of smoking by the use of smokeless tobacco products would probably decrease the incidence of some tobacco-related diseases, SCENIHR also concluded that there was no evidence that the use of smokeless tobacco products was associated with any major health hazard not already associated with cigarette smoking (SCENIHR 2008, p113), and that "in relation to the risks of the … major smoking-related diseases, and with the exception of use in pregnancy, STP [smokeless tobacco products] are clearly less hazardous, and in relation to respiratory and cardiovascular disease substantially less hazardous, than cigarette smoking" (SCENIHR 2008, p114).

Moreover, contrary to the statement that "according to the evidence from some countries, the use of smokeless tobacco products may lead to subsequent cigarette smoking" (Consultation, p5), SCENIHR found no evidence that smokeless tobacco acted as a "gateway" to future smoking. Indeed, referring to research data from northern Sweden, the authors wrote that: "the availability of snus and the way in which it has been used may have been beneficial to public health since the harm to health caused by any use of snus as a gateway into smoking may have been more than outweighed numerically by the numbers quitting smoking for snus… The prevalence of daily smoking in Sweden is currently the lowest in the EU". (SCENIHR 2008, p116). Other scientists have reached similar conclusions. Analysis and full citations of the evidence are set out in Sections 11-13 of JTI's Full Response.

QUESTION 2: In your view, which option addresses the problem most effectively?

Option 2 – Lifting the ban on snus.

QUESTION 3: Do you recommend any additional option that would effectively address the problem?

Yes. JTI believes that adult consumers who choose to use smokeless tobacco products should, once appropriately informed about the health risks, have the opportunity to do so. However, in order to address the concerns that have been expressed concerning the potential appeal of smokeless tobacco products to minors and such products' chemical composition, JTI believes that lifting the ban on smokeless tobacco products should be accompanied by requirements that:

1. All such products carry appropriate warnings and respect other provisions of the TPD concerning labelling, ingredients reporting, etc.

2. All such products meet appropriate quality standards.

3. Such products should not be made available to minors.

Further details and references are set out in Section 12 of JTI's Full Response.

QUESTION 4: Do you have any additional comments?

JTI believes that the ban should be lifted for all smokeless tobacco products, provided that certain requirements are met (see above). This would facilitate the free movement of these goods in the internal market and end the current lack of harmonisation.

It would be important, for legal and business certainty, to ensure that Member States implemented any such revisions to the TPD consistently, so as to allow the free circulation of smokeless tobacco products without additional barriers to trade.

JTI believes that the ban should be lifted now because the science in relation to smokeless tobacco products has evolved significantly since the early 1990s, when the ban was first introduced. SCENIHR noted that research suggested that, in terms of aggregate health impact, the overall effect of permitting the sale of smokeless tobacco products was likely to be "beneficial" (SCENIHR 2008, p117). Other public health bodies such as the UK's Royal College of Physicians and the American Association of Public Health Physicians (AAPHP) have likewise concluded that encouraging cigarette smokers to switch to appropriately regulated smokeless tobacco products could form an important part of reducing the harm associated with smoking. In a recent report (Rodu, B. and Nitzkin, J. (2010)), AAPHP noted that scientific developments between 2008 and 2010 had "significantly strengthen[ed] AAPHP's position on harm reduction, which encourages inveterate smokers – who are unable or unwilling to abstain from all nicotine and tobacco – to switch to lower risk smokeless tobacco products." Analysis and full citations of the evidence are set out in Section 12 of JTI's Full Response.

JTI strongly opposes Option 3. Such a step would run counter to recent scientific developments. Neither the Consultation nor the RAND Report sets out any scientific evidence whatsoever in support of extending the prohibition in this way. Nor does either document consider the potential impact of such an extension, eg on the significant numbers of adult consumers in some Member States (such as Germany) who prefer chewing tobacco to other tobacco products. Moreover, any ban on all smokeless tobacco products could not lawfully extend to those EU/EEA members which have derogations from the existing ban on oral tobacco that are guaranteed by Treaty (Sweden) or otherwise (Norway), and would thus promote a continued lack of harmonisation. It might also have a negative impact on the future development of potentially reduced exposure products. See further Section 13 of JTI's Full Response.

3. CONSUMER INFORMATION

3.1 Problem definition

Currently the use of pictorial warnings by Member States is limited. It does not cover all tobacco products and their visibility is limited. Currently, combined warnings shall cover not less than 40 % of the back side of the package[13]*. Evidence shows that pictorial warnings if properly sized and well placed are an efficient measure to inform the public about the dangers of smoking, and they are particularly effective among vulnerable groups. The bigger the size of the picture warning, the more effective it is.*

The current situation, whereby some Member States have made such warnings compulsory and others not, has lead to a disparity in labelling throughout the EU and has an impact on the functioning of the internal market as well as in consumers' awareness and consequently, the impact in their smoking behaviour.

Packaging as an advertising tool is not covered by the current Directive. Tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image.

According to a recent Eurobarometer, published in May 2010[14]*, light coloured packages are perceived to deliver lower amounts of tar, have a smoother taste and, in some cases, to be less risky for the health of consumers.*

Several other elements of the current package design e.g. graphic illustrations generating evocative images such as luxury, freedom and glamour, often distract consumers from the health warnings.

The current requirement of putting on the cigarette packages the measured levels on tar, nicotine and carbon monoxide yields has shown to be misleading for consumers because they might think that lower levels indicate that a product is less risky to their health. Some consumers might even decide to smoke or increase their consumption of cigarettes with lower levels of tar, nicotine and carbon monoxide in preference to quitting.

The Directive does not explicitly regulate labelling of water pipes. There is a widespread belief among consumers that use of water pipe is a relatively safe practice but recent studies have shown that it is not a safe alternative to cigarette smoking.

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[13] 2003/641/EC: Commission Decision of 5 September 2003 on the use of colour photographs or other illustrations as health warnings on tobacco packages http://eurlex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32003D0641&model=guichett

[14] Results of the survey can be found here: http://ec.europa.eu/health/tobacco/docs/ebs332_en.pdf

3.2. Possible options

Option 1 - No change

Pictorial warnings remain optional in the Member States. Different labelling patterns in the Member States will continue to exist. Water pipes remain without health warnings.

Option 2 - Improve consumer information

> ***Option 2 a - Picture warnings*** *would become mandatory in all Member States. They would be enlarged; required on both sides of the package and placed towards the top of the pack.*
>
> ***Option 2b - Information on the levels of tar, nicotine and carbon monoxide (TNCO)*** *measured by machine in cigarette yields, would be replaced with general information on harmful substances in tobacco products and in particular in their burnt forms. Also, information on a telephone service to help quit smoking would be placed on the package.*
>
> ***Option 2c - Information on harmful substances in tobacco products*** *that cannot be placed on the package would be placed inside the package. These inserts would also include more detailed information on health effects of tobacco consumption and provide information on how to quit smoking.*

Option 2d - Health warnings would be placed on water pipes.

Option 3 - Introduce generic or plain packaging

Plain or generic packaging would standardise the appearance of tobacco packaging. Manufacturers would only be 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.

3.3 Questions

1) Do you agree with the problem definition? If not, please provide explanations

2) In your view, which option addresses the problem most effectively?

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

JTI'S ONLINE RESPONSE TO SECTION 3: CONSUMER INFORMATION

QUESTION 1: Do you agree with the problem definition? If not, please provide explanations.

No. Fundamental misconceptions underlie DG SANCO's problem definition.

1. It is not the case that EU consumers (whether adults or minors) are uninformed about the health risks of smoking. Their level of awareness is very high. While JTI supports the continued provision of information to consumers about the health risks of smoking, in order to ensure that they continue to be reminded of those risks, introducing new measures – such as enlarging health warnings or mandating pictorial warnings – in an attempt to "inform the public about the dangers of smoking", and thereby change their smoking behaviour, is misconceived.

2. Packaging is not a risk factor for minors' smoking. In the opinion of Professor Steinberg, a leading authority on adolescent judgment, decision making and risk taking whose report is appended to JTI's Full Response, none of the proposed measures regarding packaging is likely to have an impact on smoking initiation by minors.

3. Nor is packaging a determinant feature of adult consumer smoking behaviour and decision-making.

4. DG SANCO defines the "problem" of consumer communication solely by reference to tobacco product packaging, which ignores the fact that effective communication should not rely on on-pack warnings alone. Regulators should consider a mix of communications vehicles, including television, print media, newspapers and magazines and the Internet.

5. Distinctive product packaging is fundamental to facilitate inter- and intra-brand navigation and competition, and is the primary tool for developing brand equity, innovation and non-price competition. It is not, and should not be, a mere vehicle for communicating government-mandated health warnings.

6. The cigarette pack itself does not constitute a form of promotional advertising and should not be regulated as if it were.

7. "Attractiveness" *per se* is not, and cannot be, a self-standing basis that can justify tobacco regulation: it is lacking in any evidential foundation and is inherently uncertain and arbitrary. As a result, "attractiveness" *per se* is not, and cannot be, a self-standing objective that can justify tobacco regulation. Furthermore, no scientific criteria have been developed to assess, and regulate on that basis, the "attractiveness" of tobacco products.

As explained more fully in JTI's Full Response, DG SANCO's proposals are based on fundamentally misconceived and outdated notions of smoking behaviours. JTI, and leading experts, present a coherent analysis of smoking behaviour which reflects best contemporary science. It dictates a new approach to tobacco regulation. Against this

background, it is unsurprising that the proposals in the Consultation are inappropriate and ineffective.

In any event, DG SANCO has the burden to provide clear and reliable evidence to justify each and every proposal; it is unable to do so. Indeed, leading experts have looked carefully at the evidence advanced in support of DG SANCO's proposals, notably by RAND Europe, and they agree that there is no reliable evidence that those proposals would actually work. The evidence is assessed in detail in Sections 15-19 of JTI's Full Response and experts' reports.

Nor has there been any meaningful attempt to address the proportionality and impact of each proposal, notably regarding intellectual property rights, consumer choice, competition, illicit trade, legal basis and subsidiarity. These issues are examined in Sections 2 and 6 of JTI's Full Response.

The Consultation also contains no analysis of the EU's competence to adopt the different options, the implications of those options for the functioning of the internal market or their proportionality. It is contrary to Better Regulation principles to proceed with measures for which no legal basis for EU action exists and which may be both wholly inappropriate for the internal market and disproportionate.

QUESTION 2: In your view, which option addresses the problem most effectively?

Option 1 – No change.

QUESTION 3: Do you recommend any additional option that would effectively address the problem?

Yes. The Consultation contains no analysis of the EU's competence to adopt the different options, the implications of those options for the functioning of the internal market or their proportionality. It is contrary to Better Regulation principles to proceed with measures for which no legal basis for EU action exists and which may be both wholly inappropriate for the internal market and disproportionate.

DG SANCO must seek to achieve its public policy objectives through less restrictive means. DG SANCO must assess and evaluate existing legislation (including whether it is being effectively enforced) and other options before enacting new measures.

DG SANCO must reassess its understanding of adult and youth smoking behaviour. Leading experts opine that tobacco packaging and its display is not a predictor of smoking initiation and that the provision of yet more information about the health risks of smoking will not change smoking behaviour. In the opinion of Professor Steinberg, policies that limit adolescents' ability to obtain cigarettes are likely to have a greater impact than those that attempt to diminish adolescents' interest in smoking. Above all, he believes, removing cigarettes from the social networks of teenagers is crucial.

Less restrictive, more targeted and proportionate solutions exist to ensure that consumers continue to be reminded of the risks of smoking and that minors do not

smoke and are not able to obtain tobacco products. JTI sets out its proposals in detail in Sections 41-43 of its Full Response.

QUESTION 4: Do you have any additional comments?

The problem has been wrongly defined and the proposals are not appropriate to achieve the stated public policy objectives.

In any event, for the reasons set out in detail in JTI's Full Response and the accompanying expert reports, each of the proposals in Options 2 and 3 are flawed. Two of the options are examined below, and the remainder in the Full Response.

Option 3 – JTI is categorically opposed to plain packaging. It would unjustifiably infringe fundamental legal rights to property, expression and trade, which JTI considers are critical to protect. It would also involve unparalleled deprivation of trademarks and brands, which are – as with any consumer product – JTI's most valuable assets. It would be manifestly disproportionate. No government in the world has adopted plain packaging legislation.

The burden lies on DG SANCO to justify the introduction of plain packaging. There is no reliable evidence to support the introduction of plain packaging. Expert analysis by Dr Keegan and Professor Devinney, whose reports are appended to JTI's Full Response, has found that there is no reliable evidence to suggest that plain packaging will lead to a change in smoking behaviour. In the expert opinion of Professor Steinberg, neither this nor other packaging-based measures proposed by DG SANCO are likely to have any meaningful impact on those groups of minors who continue to experiment with smoking.

Mandatory plain packaging for tobacco products would also lead to a series of negative and undesirable consequences, including:

(a) the deprivation and/or impairment of JTI's fundamental rights including the right to property, freedom of expression and freedom to trade;

(b) the erosion of the brand equity that has been built up and which is currently attributable to JTI's brands, and a disproportionate impact on JTI as a premium brand owner;

(c) undermining the progress being made in tackling the illicit trade in tobacco products;

(d) the serious and unnecessary damage to the legitimate economic interests of tobacco manufacturers, their connected industries and competition across the Member States; and

(e) a diminished contribution to the economy of each individual Member State.

Option 2(a) – JTI rejects the proposal to increase the size of on-pack health warnings. The Consultation does not indicate the possible size of the "enlarged" warnings.

Enlarging health warnings is in breach of the principles of Better Regulation and is disproportionate, unwarranted and unnecessary:

(a) DG SANCO has cited no reliable evidence which demonstrates that increasing the size of the health warnings will achieve its objectives of enhancing awareness of the health risks of smoking or changing smoking behaviour.

(b) Larger health warnings interfere disproportionately with JTI's commercial rights, in particular its trademarks, goodwill and the value of its brands. They also interfere with the freedom to communicate with existing adult smokers (and consumers' rights to product choice, fair competition and product information).

(c) Larger health warnings engage legal rights that are protected by: the Treaties, international trade treaties, intellectual property laws and bilateral investment treaties.

The evidence, arguments and solutions on the options set out in the Consultation are examined fully in JTI's Full Response and accompanying expert reports.

4. REPORTING AND REGISTRATION OF INGREDIENTS

4.1. Problem definition

The formats and reporting mechanisms for 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.

Manufacturers have concerns about their trade secrets. The level of industry compliance with the data reporting requirements varies.

Collection and analysis on the reported data on ingredients requires substantial resources for national competent authorities. It has proven difficult to get financing for the development, validation and carrying out of the appropriate toxicological and addictiveness tests.

4.2. Possible options

Option 1 - No change

Information on ingredients will be submitted by tobacco industry using different formats in different Member States.

Option 2 - Establish a common compulsory reporting format

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.[15]

Option 3 - Introduce fees and sanctions

There would be a yearly registration fee 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.

Effective, proportionate and dissuasive penalties applicable in case of non-compliance with the delivery of data on tobacco products ingredients would be required.

4.3 Questions

1) Do you agree with the problem definition? If not, please provide explanations

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[15] Practical guide can be found here: http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/practical_guidance_en.pdf

2) In your view, which option addresses the problem while supporting the objectives of the directive most effectively?

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

JTI'S ONLINE RESPONSE TO SECTION 4: REPORTING AND REGISTRATION OF INGREDIENTS

QUESTION 1: Do you agree with the problem definition? If not, please provide explanations.

No. Although differences remain between the reporting mechanisms for submitting data on tobacco product ingredients in the Member States, the "problem" that DG SANCO identifies is the failure by the EU or Member States to conduct the necessary scientific research.

The EU Practical Guide on Reporting on tobacco product ingredients has increased the degree of harmonisation. JTI reports information on ingredients to most Member States on the basis of the Practical Guide. Various issues, such as the cut-off levels for non-tobacco materials for the purposes of public disclosure, clarification regarding ingredient quality changes and alternative material reporting, have been resolved in discussions with the competent national authorities. Any revision to the TPD or the Practical Guide must take account of the solutions agreed with Member States.

DG SANCO notes correctly that manufacturers have concerns about their trade secrets. The identity of ingredients and their combinations are highly valuable and legally protected trade secrets that deserve proper protection. Any EU reporting regime that ignores the legal protection given to such information – whether regarding the steps necessary to protect trade secret information held by the Commission or the Member States, or the prohibition on disclosing trade secrets to third parties – would be unlawful.

The current lack of a harmonised reporting system is not the reason why "authorities find it difficult to analyse and compare the data". The suggestion is that the data could be analysed and compared as soon as the remaining differences in the reporting system have been removed. That is clearly not the case. As DG SANCO acknowledges, there are currently no common, validated methodologies for the analysis of ingredients data. Indeed, the Conference of the Parties to the FCTC decided methodologies for testing and measuring contents and emissions of tobacco products must be developed and validated before ingredients can be regulated on that basis (FCTC/COP1(15)). Information on ingredients has been submitted to the authorities since 2002, and further data will be submitted by manufacturers and importers of tobacco ingredients under REACH from 1 December 2010. Authorities should use this information to develop and validate methodologies for the testing and measuring of ingredients, including the information made available under REACH.

Further, we do not believe that Member States find it "difficult to get financing" for the development, validation and carrying out of the appropriate tests. Member States can introduce proportionate registration fees. Belgium has already done so and Austria, Germany and the Netherlands charge a fee for using the Electronic Model Tobacco Control (EMTOC) system. There is no need for registration fees to be included in the TPD.

These issues are examined more fully in JTI's Full Response.

QUESTION 2: In your view, which option addresses the problem most effectively?

Option 2 – Establish a common compulsory reporting format.

QUESTION 3: Do you recommend any additional option that would effectively address the problem?

JTI rejects Option 3. JTI does not believe that it is either appropriate or necessary for the TPD to deal with registration fees or sanctions for non-compliance. As stated above, Member States can already impose registration fees on manufacturers and importers of tobacco products.

Similarly, the EU legal order requires Member States to adopt all the measures necessary to ensure that a directive is fully effective, in accordance with the objective which it pursues. Sanctions must in any event be effective, proportionate and dissuasive. The option set out in the Consultation is therefore unnecessary.

The proposal also does not contain an analysis of EU competence to introduce registration fees or sanctions. This proposal is radically different in nature and effect from the existing TPD. It may amount to a taxation measure, for which there is no competence in the Treaties.

Moreover, there is no evidence of any divergent national measures in this regard that would, or would be likely to, constitute an obstacle to trade, thus directly affecting the functioning of the internal market. Further, JTI does not see how the imposition of either registration fees or sanctions would improve the functioning of the internal market. Introducing harmonised registration fees and sanctions would not be aimed at facilitating the free movement of tobacco products, but rather at financing data collection and analysis of tobacco product ingredients. Imposing fees and sanctions would not improve the conditions for the functioning of the internal market.

Furthermore, a public authority can only charge fees when it is providing a service and when the fees are based on the costs of providing that service (see e.g. Joined Cases C-392/04 and C-422/04). Compulsory payments to government that are not based on the costs of providing a specific service are a tax, for which the EU has no competence. As a result, any registration fees for the analysis of ingredients data must be strictly based on the costs of conducting such an analysis. However, no cost assessment has been presented. Indeed, RAND Europe concedes that "the costs for such work are, however, unclear and the analysis of ingredients has not yet started on the European level. It is therefore not possible to assess the overall costs".

Finally, the Consultation makes no mention of the Commission's previous desire to summarise and take into account the information made available under REACH in relation to tobacco ingredients, in order properly to exploit synergies between the REACH and the TPD regimes. Consideration of the format and extent of ingredients data submitted under REACH may be instructive in evaluating the proposal to specify ingredients data reporting formats under the TPD.

See further Sections 20-22 of JTI's Full Response.

QUESTION 4: Do you have any additional comments?

JTI's endorsement of a common compulsory reporting format is subject to that solution being EMTOC (see http://www.rivm.nl./tabakinfo/emtoc/).

JTI supports DG SANCO's proposal to establish a common compulsory reporting format. JTI shares common goals with regulators regarding ingredient reporting: regulatory authorities should have information about tobacco products in order to make informed decisions based on sound science. Similarly, consumers should also have meaningful, non-proprietary, information about the tobacco products they consume. At the same time, this reporting system must be consistent with fundamental protection of trade secrets relating to the identity of the ingredients and their combinations as well as the manufacturing process.

JTI has been working with regulators to achieve progress in setting up the EMTOC system and finding solutions to the issues raised by ingredients reporting. EMTOC provides an efficient, electronic system for the submission of information on tobacco product ingredients based on the Practical Guide with appropriate legal and practical protections. However, there remain unresolved questions, e.g. regarding the ownership and financing of the system. JTI is prepared to contribute to financing the EMTOC system, provided that any fees are strictly based on the costs of running the EMTOC system. The funds must be used in a targeted, cost-effective and transparent way. However, no breakdown of future costs for the maintenance of EMTOC has been provided so far.

Further, adopting EMTOC requires significant preparation. This involves more than installing a piece of software (e.g. several trial runs had to be conducted in Austria before the system went live). It should be recognised that adopting EMTOC in several Member States simultaneously – or let alone on an EU-wide basis – would present a considerable technical and logistical challenge. We strongly recommend building upon the Austrian experience to minimize the risk of severe problems in the implementation of EMTOC on a wider basis.

More information is provided in JTI's Full Response.

5. REGULATION OF INGREDIENTS

5.1. Problem definition

Attractive substances are added into tobacco products such as liquorice to increase the smoothness of the smoke and menthol to enable deeper inhalation. During the process of burning majority of additives form substances that are carcinogenic, mutagenic and/or toxic for reproduction.

There are no common conditions for the internal market ensuring a uniform high level of health protection. Some Member States allow a number of listed ingredients (so-called positive list) while some others have banned certain ingredients (so-called negative list). Some other Member States have both negative and positive lists. 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.

5.2. Possible options

Option 1 - No Change

Member States continue to be free in regulating tobacco products ingredients.[16] *Industry has to comply with different national regulations on positive and/or negative lists of ingredients for the manufacturing of tobacco products.*

Option 2 - Introducing the basic criteria on the EU level without a common list

The Directive would lay down the 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).

Member States would retain the right to have national bans according to national circumstances in so far as this would be deemed necessary and proportionate to protect public health.

Option 3 - Establish a common list of tobacco ingredients

The list would be based on the toxicity, the attractiveness and the addictiveness of a product when consumed (oral tobacco) or smoked (the combustion/inhalation effect).

Option 3a – Establish a positive common list of tobacco products ingredients

Only those ingredients that are on the list can be used for the manufacturing of tobacco products.

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[16] Article 13(3) of the Tobacco Products Directive (2001/37/EC).

Option 3b - Establish a negative common list of tobacco ingredients

Listed ingredients cannot be used in the manufacturing of tobacco products (except subject to restrictions and conditions laid down).

5.3 Questions

1) Do you agree with the problem definition? If not, please provide explanations

2) In your view, which option addresses the problem most effectively?

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

JTI'S ONLINE RESPONSE TO SECTION 5: REGULATION OF INGREDIENTS

QUESTION 1: Do you agree with the problem definition? If not, please provide explanations.

No. The regulation of tobacco product ingredients is not currently harmonised. JTI considers that ingredients regulation presents an opportunity for coherent, scientifically sound and targeted regulation that meets principles of Better Regulation. JTI has proposed in March 2010 to DG SANCO a framework for developing the regime to regulate tobacco product ingredients. The framework should be workable in practice, proportionate and based on sound science and clear risk assessment principles.

Many substances, when burned, can form compounds that are carcinogenic, mutagenic and/or toxic. JTI believes that there exists sufficient practice and experience on which to build international methodologies for the measurement and assessment of ingredients on the basis of toxicity. JTI employs a well-established toxicological assessment and testing programme, which can provide a platform for discussion and progress at EU level. Through these tests, JTI ensures that the ingredients which it uses in its products do not increase the inherent toxicity of tobacco products.

JTI fundamentally disagrees with the statement that "attractive substances are added into tobacco products such as liquorice to increase the smoothness of the smoke and menthol to enable deeper inhalation". For example, the Commission's own expert working group on the "attractiveness and addictiveness of tobacco ingredients" acknowledged that "current data are inconclusive" as to whether menthol could enable deeper inhalation (SCENIHR 2010, p55). The inclusion of menthol has no effect on smoking prevalence, smoking behaviour or on quit rates.

JTI does not accept that ingredients should be regulated on the basis of "attractiveness". "Attractiveness" fails established criteria for issue definition and no scientific criteria have been developed to assess the "attractiveness" of tobacco products, let alone to regulate on that basis. In its recent opinion, SCENIHR described attractiveness by reference to a bewildering range of criteria, including "extrinsic factors" such as price, packaging etc. (SCENIHR 2010, p70), – which underlines the subjective, uncertain and arbitrary nature of the concept. SCENIHR also noted that "given the subtle interactions between different factors… identifying and measuring the influence of individual additives on attractiveness of products is difficult" (SCENIHR 2010, p70).

JTI does not accept the suggestion that a policy objective of ingredient regulation should be to make smoking less pleasurable. Smoking is an adult choice. Ingredients facilitate choice as they play a significant role in the development of unique cigarette brands to meet consumer preferences, particularly regarding taste and aroma. Investment in brands and brand styles drives consumer product choice, competition and innovation. Ingredients also play a critical role in the development of new tobacco products and potentially reduced exposure products.

The issue underpinning the suggested notion of "attractiveness" as a criterion for ingredients regulation is the need to prevent minors from taking up smoking. The Commission stated in its First Report that a rationale of ingredients regulation may be to "ban those that are that only used to attract children." JTI does not use flavours or any other ingredients for this purpose. Minors should not smoke and should not be able to obtain tobacco products. But banning ingredients is not the solution to this issue. The considerable body of evidence and research which exists on the predictors for smoking initiation does not suggest that ingredients play any meaningful role in this regard.

See further Sections 25-26 of JTI's Full Response.

QUESTION 2: In your view, which option addresses the problem most effectively?

Option 1 – No change.

QUESTION 3: Do you recommend any additional option that would effectively address the problem?

DG SANCO suggests as Option 3 that a common list of ingredients could be established. Clearly, a common list cannot be established before methodologies for testing and measuring of ingredients have been developed and validated and common criteria for the assessment and approval have been established.

Once adequate methodologies and criteria have been established, a recognised scientific body should be entrusted with testing and assessing the toxicity of tobacco product ingredients under intended conditions of use. The body should be sufficiently experienced and adequately funded, and the experts should represent a range of relevant scientific disciplines. Its procedures should be transparent, provide for stakeholder participation and be subject to proper oversight and scrutiny.

The choice of the type of ingredients list, in which regulatory decisions are captured, should provide adequate transitional provisions and take adequate account of legitimate expectations created by existing regulation. The list must be amendable, so that ingredients regulation does not stifle the development of new technology products.

However, JTI rejects any ban of ingredients in the absence of clear and convincing scientific evidence that this would reduce the inherent risks of smoking. Further, ingredients bans like the Canadian Bill C-32 are no model for Europe. Consumers in Canada prefer Virginia-style cigarettes which contain no, or hardly any, flavour additives. Most consumers in the EU, however, prefer classic American blend cigarettes; they could no longer buy their preferred product. Issues would arise under international trade law (e.g. WTO). Consumers would be deprived of legitimate choices between existing conventional tobacco products. Competition in the tobacco market would be distorted, and incentives to innovate would be damaged. Tobacco manufacturers' ability to introduce new technology products would be compromised.

DG SANCO should not propose measures that create incentives for illicit trade and undermine the anti-illicit trade measures of the EU, Member States, the FCTC and tobacco manufacturers. Ingredient bans which prohibit the manufacture of products that consumers currently prefer will create a situation in which consumers will buy cigarettes illegally and incentivise counterfeiters to manufacture "authentic" products, and those involved in the illicit trade to import contraband. The illicit trade is unlikely to make any effort to comply with applicable regulation for tobacco products concerning notably ingredients usage, reporting requirements and permitted yield maxima.

See further Section 27 of JTI's Full Response.

QUESTION 4: Do you have any additional comments?

While common conditions for measuring, assessing and approving tobacco product ingredients could be developed, more work needs to be undertaken before such criteria can be laid down in the TPD. The Commission stated in its Second Report that "development in this area depends on the progress of work outlined under Article 6". However, as discussed in the response to the reporting and registration of ingredients Section, further progress needs to be made in relation to establishing a common reporting format. Furthermore, methodologies for testing and measuring of ingredients need to be developed and validated before common criteria for the assessment and approval can be laid down.

Option 2 suggests that the criteria may be related to "toxicity, the attractiveness and the addictiveness of a product." JTI believes that sufficient practice and expertise exists on which to build methodologies and practices for the measurement and assessment of ingredients on the basis of toxicity. JTI employs well-established toxicological testing methodologies and programmes which can provide a platform for discussion. JTI supports the use of clear assessment principles, e.g. ingredients should not increase the inherent toxicity of tobacco products under intended conditions of use.

By contrast, scientists have yet to agree which tests (if any) could be employed to measure the "addictiveness" of tobacco product ingredients under intended conditions of use. JTI considers that the concept of "attractiveness" lacks a credible scientific foundation and that whichever definition of "addictiveness" is used does not affect the fact that people can stop smoking if they are determined to do so. Based upon the available scientific evidence, JTI considers that tobacco products with added ingredients are no more difficult to quit than those that do not contain added ingredients.

If the public policy objective underlying these proposals is, in fact, to address initiation, consumption, prevalence and quitting (rather than "attractiveness"), there is no evidence to support ingredient regulation on this basis:

First, tobacco products with added ingredients are no more widely consumed than those that do not contain added ingredients:

- research shows no significant differences in smoking prevalence, consumption and quitting between classic American blend and Virginia style markets (Lee 2009);

- ecological studies have repeatedly suggested that the inclusion of menthol has no effect on smoking prevalence, smoking behaviour or on quit rates (Muscat et al 2002; Werley MS et al 2007; Hyland A et al 2002); and

- cigarettes that do not contain flavour additives (such as Camel Natural Flavor) are the preferred choice of many consumers worldwide.

Second, the considerable body of evidence and research which exists on the predictors for smoking initiation does not suggest that ingredients play any meaningful role in this regard. The work of societal influences as the primary explanations for smoking uptake by young people is widely acknowledged. Factors that make smoking uptake more likely include peer pressure, parental or family influence, and the desire to appear "cool", independent and more "adult".

"Attractiveness" cannot be used as a shortcut to ingredients regulation or as a substitute for a science-based approach.

See further Sections 23-27 of JTI's Full Response.

6. ACCESS TO TOBACCO PRODUCTS

6.1. Problem definition

*The cross-border sale of tobacco products (via the **Internet**) potentially undermines national tobacco control efforts, in particular the enforcement of the minimum purchasing age as well as the collection of tax revenues. Products sold on the Internet do not always bear health warnings or text warnings are not in the official language(s) of the Member State of the citizen ordering via the Internet. In order to address this compliance issue with legal conditions (e.g. purchasing age, labelling, tax collection), some Member States have either banned or restricted distance sale of tobacco products.*

***Vending machines** are banned in a large number of Member States.*

*The UK has announced that it will prohibit the **display** of tobacco products in large shops from October 2011 and from all other places from October 2013 in England, Wales and Northern Ireland. In Finland it will be prohibited to display tobacco in points of sale as from the beginning of 2012. A similar ban has been announced by Ireland.*

6.2. Possible changes

Option 1 - No change

Member States remain competent to have national measures on limiting the access to tobacco products.

Option 2 – Controlled supply and access

***Option 2a** - Age verification of buyers and other legal conditions (registration, licensing etc.) would be set for cross-border retail sales of tobacco products.*

***Option 2b** - Access to vending machines would be restricted to adults.*

***Option 2c** - Tobacco display and promotion at points of sales would be restricted (e.g. allowing visibility for one package per brand).*

Option 3 – Ban

> ***Option 3a** - Cross-border retail sales of tobacco products would be banned over the Internet. This might also include ban for postal delivery of tobacco to consumers.*
>
> ***Option 3b** - Vending machines would be banned in all Member States.*
>
> ***Option 3c** - Promotions and displays in retail stores would be banned in all Member States.*

6.3 Questions

1. ***Do you agree with the problem definition? If not, please provide explanations***

2. ***In your view, which option addresses the problem most effectively?***

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

JTI'S ONLINE RESPONSE TO SECTION 6: ACCESS TO TOBACCO PRODUCTS

QUESTION 1: Do you agree with the problem definition? If not, please provide explanations.

No. JTI believes that minors should not smoke, and should not be able to obtain tobacco products. Professor Steinberg stresses the importance of policies that limit minors' ability to obtain cigarettes, and believes that these are likely to have a greater impact than those that attempt to diminish minors' interest in smoking.

However, the proposals are not an appropriate means of preventing minors' ability to obtain tobacco products.

First, the Consultation is silent on the rationale for a display ban/restrictions on display and the public health outcomes (if any) they might achieve. Display at the point of sale is fundamental to the operation of a market economy in legal tobacco products, consumer choice, innovation, product information and brand equity. The display of tobacco products enables existing adult smokers to identify, obtain information about and choose tobacco products, easily and without confusion.

The evidence demonstrates that the vast majority of consumers have decided to purchase a (specific) tobacco product prior to visiting the retail outlet. The evidence undermines assertions that packaging at point of sale encourages consumption or stimulates "impulse" purchases. It also confirms that switching by even a marginal number of consumers is important to commercial success.

Professor Steinberg does not believe that impulse purchasing in retail stores plays any role in minors' acquisition of cigarettes (minors who purchase cigarettes in retail stores need to decide in advance where they will do their shopping, so that they can select a vendor who will sell to underage individuals, arm themselves with a fake ID, or prepare a response to a sales person who asks for proof of age).

Second, neither the Consultation nor the RAND Report contains any evidence to suggest that minors obtain tobacco products from the Internet. DG SANCO appears concerned that minors may obtain tobacco products online to evade minimum purchase age and/or age verification requirements. In fact, Professor Steinberg does not believe that Internet purchases by minors represent a significant problem in the EU, which is not surprising as most Internet transactions require credit/debit cards.

A further concern expressed by DG SANCO is that products sold on the Internet do not always bear health warnings in the official language(s) of the Member State of the citizen ordering via the Internet. No evidence is provided in the Consultation to suggest that this is a genuine problem.

JTI does not support the unregulated sale of cigarettes via the Internet. However, JTI is not opposed to the sale of legitimate tobacco products via the Internet provided that they are appropriately regulated so proper tax payments are ensured and access by minors is denied. JTI strongly supports the targeted use of enforcement action against illegitimate Internet sites (including those knowingly selling products to minors).

Third, vending machines for tobacco products are given a cursory mention in the Consultation; it merely asserts that: "*Vending machines are banned in a large number of Member States*". This is not a definition of a "problem".

Overall, JTI's Full Response and the accompanying expert reports demonstrate that DG SANCO (and the RAND Report) have not presented any reliable evidence that the Consultation's proposals would prevent minors from obtaining tobacco products.

The Consultation contains no analysis of EU competence to adopt the different options, the implications of those options for the functioning of the internal market or their proportionality. It is contrary to Better Regulation principles to consult on measures for which no legal basis for EU action exists and which may be both wholly inappropriate for the internal market and disproportionate.

QUESTION 2: In your view, which option addresses the problem most effectively?

Option 1 – No change.

QUESTION 3: Do you recommend any additional option that would effectively address the problem?

Yes. JTI believes that there are better ways of reducing the number of minors who start smoking than a ban (as set out in Option 3) or restrictions on the display of tobacco products (as outlined in Option 2c). Minors should not smoke, and should not be able to obtain tobacco products.

Option 2a proposes that "age verification of buyers and other legal conditions (registration, licensing etc) would be set for cross-border retail sales of tobacco products". JTI is supportive of the introduction of negative licensing. Retailers who knowingly sell tobacco products to minors should lose the right to sell those products. This would be a proportionate method of achieving the legitimate objective of reducing the ability of minors to obtain tobacco products. Negative licensing has the potential to limit minors' ability to obtain tobacco as it may provide a clear deterrent to retailers considering selling to minors.

However, JTI is unable to support a registration system because:

- there is no evidence to suggest that it would have any positive impact on the objective of reducing smoking by minors;

- it would be disproportionate, imposing costs that outweigh any expected benefits; and

- it would be contrary to Better Regulation principles in the absence of an evidential basis which justifies proceeding with such a measure.

In addition to negative licensing, JTI supports the following less restrictive, more targeted and proportionate solutions to address the specific concern of sales to minors:

- criminalisation of "proxy" purchasing by adults; and the criminalisation of, or imposing administrative sanctions for, the purchase or attempted purchase of tobacco products by minors and the consumption of tobacco products by minors;

- reinforcing retail access prevention measures, such as the "No ID No Sale" programme;

- the use of adult identification functions for vending machines (or where vending machines are not equipped with adult identification functions, JTI believes that they should be located solely in areas where only adults are permitted);

- appropriately regulated Internet sales;

- greater resources and manpower for effective, targeted enforcement strategies; and

- targeted public information campaigns to quickly and effectively raise awareness of the negative licensing scheme and the criminalisation of proxy and youth purchasing.

QUESTION 4: Do you have any additional comments?

JTI fundamentally disagrees with the proposal to introduce a display ban (Option 3c) or restrictions on display as: (i) DG SANCO has not properly identified the policy objectives of a ban; (ii) there is no reliable evidential basis to support a ban on the display of tobacco products; (iii) a ban would impede and restrict lawful activity whilst facilitating illegal activities; and (iv) a ban would have wide-ranging negative effects on competition and the supply chain, notably on retailers. JTI also considers that the lack of clarity as to what restrictions are in fact being proposed renders the consultation exercise meaningless in this regard.

The burden lies on DG SANCO to justify the introduction of display restrictions or a ban. The legitimate public policy objectives on which DG SANCO is proposing to justify the introduction of measures in relation to display are unclear. The Consultation is silent in this regard. The RAND Report discloses two apparent objectives regarding display: preventing initiation by minors and to facilitate quitting by adult consumers.

There is no reliable evidence on which DG SANCO could justify a ban on tobacco product display on these, or alternative, public policy objectives. Expert evidence from Dr Lilico and Dr Keegan, whose reports are appended to JTI's Full Response, confirms this view: (a) expert review of available and relevant consumer survey studies on the likely impact of a display ban concludes that there "is no reliable evidence to suggest that a ban on retail display will lead to a reduction in youth smoking uptake or an improved environment for those trying to quit smoking"; and; (b) expert analysis of smoking data for young people in Iceland, Thailand and various Canadian provinces (where such bans have been in place for some time) indicates that they have no discernible impact in accelerating the already existing decline in smoking.

By contrast, evidence clearly shows that a display ban freezes and damages competition: innovation is materially impaired and barriers to new market entrants are

increased. Customer choice and brand switching are reduced and confusion created. Small business retailers will face loss of business (through diversion to larger retailers), and increased operational costs. A display ban would also have serious and widespread negative impacts on the illicit trade in tobacco products – as contraband and counterfeit tobacco products will become easier to distribute and sell. A display ban significantly and unnecessarily impairs JTI's fundamental rights as a commercial entity and is wholly disproportionate to the public policy goals it seeks to address.

Regarding vending machines, JTI believes that access to tobacco vending machines should be strictly controlled to prevent sales to minors. JTI advocates restrictions that are effective in preventing access to tobacco products by minors. We do not, however, support the prohibition of vending machines, which would prevent legitimate access by adult smokers. No provision in the FCTC requires the prohibition of the sale of tobacco products to adults via vending machines. A general prohibition on the use of vending machines is too broad and is unnecessary and – as such – is inconsistent with the Better Regulation principles.

A general prohibition on vending machines would, in particular, be inconsistent with the requirement that regulation must have a clear legal basis and the principles of proportionality and subsidiarity.