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

JTI's Full Response

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, number 31290853542-43, within the meaning of EU's European Transparency Initiative.

EXECUTIVE SUMMARY

A BETTER APPROACH TO TOBACCO REGULATION

Tobacco products carry risks to health. Appropriate and proportionate regulation of the tobacco sector is thus both necessary and right. Among JTI's core beliefs are that:

- Minors should not smoke, and should not be able to obtain tobacco products. It is central to our Code of Conduct, marketing practices, operational policies and the way JTI does business.

- Adult smokers should be appropriately informed about the health risks of smoking before they make the decision to smoke.

For these reasons, JTI supports legislative and regulatory measures on tobacco control which meet the principles of Better Regulation (which are explained more fully below).

The Consultation does not clearly articulate DG SANCO's objectives for reform of the Tobacco Products Directive (***TPD***). However, the apparent key policy rationale for various of DG SANCO's proposals is aligned with JTI's core beliefs, as articulated above. It is therefore in *everyone's* interest that any measures which may ultimately be adopted with the aim of preventing minors from smoking and/or reiterating and emphasising the health risks of smoking, are effective.

DG SANCO's policy and proposals will not, however, be effective if they are not based on, and consistent with, a credible and scientifically rigorous understanding of smoking behaviour. Knowing how and why minors decide to experiment with tobacco products and how they obtain tobacco products are prerequisites for the design of regulatory interventions that will be effective in changing their behaviour. Understanding how adult consumers weigh up the risks and benefits of smoking is critical to designing effective methods to communicate with them about those risks in a way that is likely to cause them to change their behaviour.

Leading experts (notably Professors Steinberg, Dhar and Nowlis) prepared reports for JTI which give their independent opinions on the basis of contemporary scientific thinking, on how the smoking behaviour of adults and minors should best be understood. These experts present DG SANCO with a coherent analysis of smoking behaviour, against which the need for further regulatory interventions can be assessed and their likely success judged. JTI considers that this framework reflects the best contemporary science. It also dictates a new approach to tobacco regulation by DG SANCO.

It flows from these experts' findings that:

- **measures to reduce smoking among minors** will only be effective if they control minors' ability to obtain tobacco products and remove cigarettes from the social networks of teenagers. Access-based solutions take due account of the fact that minors are *naturally* more prone to risk-taking behaviour than adults. As Professor Steinberg explains, decision-making during adolescence is characterised by a heightened emphasis on rewards over risks; a tendency to focus on the immediate, rather than longer term, consequences of a decision; a susceptibility to peer influence; and weak self-regulation. Minors are well aware of the risks of smoking, but may choose to experiment anyway. These factors, together, explain

why a psychological profile characterized by sensation-seeking, peer and family influence (i.e. peers and family members who smoke) and the availability of cigarettes are the main risk factors for smoking.

Accordingly, the provision of further information about the health risks of smoking or measures focussed on packaging are unlikely to be effective; and

- for **measures directed at adult smoking behaviour** to be effective, they would need to target adults' decision-making at the point of consumption, taking due account of the analysis that adults employ when making decisions about risk. They would also need to be more individualised and to be positively framed, in the light of the triggers to smoking behaviour.

  Professors Dhar and Nowlis therefore dismiss the likely effectiveness of interventions that reflect the so-called "traditional model" of consumer decision-making, which is based on the notion that rational consumers will shift their smoking behaviour in accordance with the evaluation of information on the health risks of smoking.

DG SANCO'S ANALYSIS PRODUCES INAPPROPRIATE PROPOSALS

DG SANCO's proposals are based on fundamentally misconceived and outdated notions of smoking behaviours, namely that tobacco packaging and its display are predictors of smoking initiation and that the provision of yet more information about the health risks of smoking will change smoking behaviour. These notions are wrong, and are not supported by the science.

Specifically, even if there is a legal basis for EU action, many of the proposals identified in the Consultation – including plain packaging for tobacco products, hiding tobacco products from view at retail outlets, mandating larger pictorial health warnings and banning all types of smokeless tobacco products – are based on misconceived and out-dated notions of smoking behaviour. They fail to take into account how minors and adult consumers think and act, and would not therefore be effective at changing behaviour if they were introduced.

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

There is simply no reliable evidence to support the key proposals in the Consultation. DG SANCO has the burden to provide clear and reliable evidence to justify the initiatives; 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.

Many of DG SANCO's proposals would involve the unparalleled deprivation of intellectual property rights and brands, which are – as for any producer of consumer products – JTI's most valuable assets. Various proposals unjustifiably infringe fundamental legal rights to property, expression and trade, which JTI considers are critical to protect. Indeed, certain proposals will potentially place the EU and its Member States in breach of their WTO, TRIPS and bilateral investment treaty obligations. **It is wrong for any regulator in a free market economy to go this far, particularly in circumstances where the evidence to support the effectiveness of the proposals is so weak.**

The negative effects of the proposals would be widespread, and show no signs of having been properly considered to date by DG SANCO**.** In particular:

- *Contraband and counterfeit tobacco products would become easier to make, distribute and sell* if proposals such as plain packaging and ingredients bans were introduced. These and other proposals would not stop adults or minors from buying or otherwise obtaining tobacco products: they would simply encourage access from the cheaper, illegal and unregulated market. This undermines the real progress made by OLAF, national enforcement bodies, JTI and other stakeholders to tackle the trade in illicit products and to take action when criminal gangs are caught.

- *The proposals would cause serious and unnecessary damage to competition*. Evidence shows that competition would be reduced and barriers to new market entrants increased by measures such as plain packaging and display bans. They remove the last means by which adult smokers are able to make informed choices about which brand to buy. Consumer choice and product switching will be reduced and confusion created.

- *Proposals would adversely impact Small and Medium sized Enterprises, retailers and tobacco growers.* The negative effects of the proposals in the Consultation will be far wider and deeper than currently envisaged in the RAND Report. For example, there has been no attempt made to date to assess the impact on farmers of Burley and Oriental tobacco if ingredients regulation effectively prohibits the manufacture of classic American blend cigarettes (of which those tobaccos form part).

JTI believes that the proposed approach is so misconceived, the evidence is so weak, and the negative impacts of the proposals so serious, that **DG SANCO must fundamentally reassess its approach and its proposals, and must consider the alternative solutions put forward in JTI's response and summarised below**.

AN OPPORTUNITY FOR BETTER REGULATION

Unfortunately, in addition to the flawed approach to smoking behaviour, the **procedure followed to date by DG SANCO has obvious and serious flaws, and stakeholders have been denied the opportunity to comment on critical issues**. For example:

- the Consultation excluded any analysis of the threshold issues of legal basis, subsidiarity and proportionality;

- neither the Consultation nor the RAND Report has assessed or presented evidence on fundamental EU policies that would be impacted by the Consultation's proposals, including the impact of the proposals on illicit trade, the protection of intellectual property rights, competition and competitiveness, and consumer choice. Whilst many of these were identified early on by RAND Europe as key work streams, there has been no out-put and no evidence, analysis or policy has been provided to stakeholders for comment; and

- DG SANCO has contracted out large areas of work to a body – RAND Europe – whose work is both incomplete and fundamentally flawed. The errors are so

serious that JTI considers that DG SANCO must set the RAND Report aside, and undertake the necessary work itself.

JTI believes that **DG SANCO has no option but to conduct a further consultation**.

This provides an opportunity for DG SANCO, in accordance with Better Regulation principles, to re-consider its traditional approach and to examine the contemporary analysis of smoking behaviour presented by Professors Steinberg, Dhar and Nowlis. Better Regulation requires the completion of the necessary work, to the requisite standard, and having regard to the need for objective, balanced and science-based analysis. In this Full Response, JTI has sought to identify the next steps required by Better Regulation principles.

Accordingly, DG SANCO has the opportunity, if it intends to proceed with a revision of the TPD, to respond through the adoption of rigorous, complete and meaningful processes. Indeed, DG SANCO will need to meticulously follow Better Regulation principles in order to satisfy the Impact Assessment Board.

Less restrictive, more targeted and proportionate solutions

JTI believes that once the "problem" is correctly defined, notably by reference to the contemporary framework of smoking behaviour described above, there is likely to be greater clarity regarding the possible options for regulatory intervention (whether by the EU and/or the Member States).

JTI proposes **less restrictive, more targeted and proportionate ways of achieving shared public policy objectives:**

- criminalisation of, or imposing administrative sanctions for, 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;

- "negative licensing" of retailers, whereby retailers lose the right to sell tobacco products if they are found to have sold products to those under the minimum age on a specified number of occasions and they cannot prove that they took all reasonable precautions and exercised all due diligence to avoid doing so;

- 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);

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

- 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 purchasing by minors.

JTI believes that it has demonstrated, through this response and the presentation of leading experts' independent opinions, its commitment to the development of an appropriate and

proportionate regulatory regime. JTI remains available and willing to participate in the policy and evidence debate that it believes must take place if regulatory goals are to be achieved.

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INTRODUCTION AND SCOPE OF THIS FULL RESPONSE

1. INTRODUCTION

1.1 This Full Response, and the accompanying reports from experts, support JTI's online response to DG SANCO's Consultation on the possible revision of the Tobacco Products Directive (2001/37/EC)(the ***Consultation***). The online submission format limits responses to 4,000 characters per question, and is manifestly an inadequate means of addressing the procedural, policy and evidential issues raised in the Consultation. This Full Response is an integral part of JTI's submission and JTI's online response cannot properly be understood without a full evaluation of this Full Response and the accompanying expert opinions.

1.2 JTI has commissioned a number of leading experts to assist in the review of the problem definitions, assessment of the evidence base, consideration of alternative solutions and to make recommendations. The experts are:

(a) Professor Laurence Steinberg, Distinguished University Professor and Laura H. Carnell Professor of Psychology at Temple University, Philadelphia, United States of America. He is a leading authority on adolescent judgment, decision making and risk taking. His report entitled "*Adolescent Decision Making and the Prevention of Underage Smoking*" (***Professor Steinberg's Report***) is at Annex 1;

(b) Professor Ravi Dhar, George Rogers Clark Professor of Management and Marketing and Director of the Centre for Customer Insights at the Yale School of Management, New Haven, United States of America.

Professor Stephen Nowlis, August A Busch, Jr Distinguished Professor of Marketing in the Olin School of Business at Washington University in St. Louis, United States of America.

Both are award-winning marketing professors at leading universities in the United States, who have published extensively on the subject of consumer behaviour and decision-making. Their report entitled "*Report on Adult Consumer Behaviour and Decision-Making in the Context of Smoking*" (***Professors Dhar and Nowlis's Report***) is at Annex 2;

(c) Professor Daniel Gervais, Professor of Law at Vanderbilt University Law School, United States of America. He is a leading expert on international intellectual property law and author of "*The TRIPS Agreement: Drafting History and Analysis*". His report entitled "*Analysis of the Compatibility of certain Tobacco Product Packaging Rules with the TRIPS Agreement and the Paris Convention*" (***Professor Gervais' Report***) is at Annex 3;

(d) Professor Martin Cave, BP Centennial Professor at the London School of Economics and Political Science, United Kingdom. He is an expert in the design of regulatory policies to achieve economic, and also social, objectives and in the fields of regulatory impact assessments and better regulation. His

report entitled "'*Better Regulation' and certain Tobacco Control Measures*" (***Professor Cave's Report***) is at Annex 4;

(e) Professor Timothy M. Devinney, Professor of Strategy at the University of Technology, Sydney in Australia; Conjoint Professor in the Faculty of Medicine at the University of New South Wales, Australia and a Visiting Professor at the Institute of Management at Humboldt University, Berlin, Germany. He is an expert in consumer survey research, experimental methods and associated statistical analysis. His report entitled "*Analysis of Consumer Research Evidence on the Impact of Plain Packaging for Tobacco Products*" (***Professor Devinney's Report***) is at Annex 5;

(f) Dr Warren J. Keegan, Distinguished Professor of Marketing and International Business at the Lubin School of Business, Pace University, New York, and Visiting Professor at ESSEC, Cergy–Pontoise, France; of Keegan & Company LLC, Rye, New York, United States of America. In particular, he is an expert in consumer survey research and analysis. His report entitled "*Analysis of Consumer Survey Evidence Relevant to DG SANCO's Proposal to Increase the Size of Health Warnings on Tobacco Packaging*" (***Dr Keegan's November 2010 Report***) is at Annex 6;[1] and

(g) Dr Andrew Lilico, Director and Principal of Europe Economics, London, United Kingdom. He is an expert in microeconomic analysis and regulatory impact assessment. His update of his previous reports relevant to the issues in the Consultation,[2] entitled "*Economic Analysis of Restrictions on the Display of Tobacco Products – 2009 Canadian Annual Smoking Data*" (***Dr Lilico's November 2010 Update***) is at Annex 7.

1.3 All of these reports are publicly available at www.jti.com.

This Full Response responds to the Consultation

1.4 The Consultation contains no significant references to policy or evidence. The Consultation makes no reference to the RAND Report.[3] However, the RAND Report

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[1] Dr Keegan has previously prepared four reports which are relevant: (i) *Analysis of Consumer Survey Evidence Relevant to the UK Department of Health's Consultation on the Future of Tobacco Control,* dated 2 September 2008 (***Dr Keegan's September 2008 Report***); (ii) *Analysis of Consumer Survey Evidence Relevant to the UK Department of Health's Consultation on the Future of Tobacco Control – a supplemental report*, dated 18 June 2009 (***Dr Keegan's June 2009 Report***); (iii) *Analysis of Consumer Survey Evidence Relevant to Health Canada's Proposal to Increase the Size of Health Warnings on Tobacco Packaging,* dated 10 March 2010 ***(Dr Keegan's March 2010 Report);*** and (iv) *Analysis of Consumer Survey Evidence Relevant to the Display Ban Requirement in England*, dated 28 April 2010 (***Dr Keegan's April 2010 Report***).

[2] Dr Lilico has previously prepared three reports which are relevant: (i) *Analysis of a Display Ban and/or Plain Packs Requirement in the UK*, dated 2 September 2008 (***Dr Lilico's September 2008 Report***); (ii) a supplemental Report in October 2009 (***Dr Lilico's October 2009 Report***); and (iii) *Economic Analysis of a Display Ban Requirement in England*, dated 28 April 2010 (***Dr Lilico's April 2010 Report***).

[3] This is contrary to the Communication from the Commission, *Towards a reinforced culture of consultation and dialogue – General principles and minimum standards for consultation of*

is stated to be a "*Study to support a DG SANCO Impact Assessment*" (albeit that DG SANCO has added a disclaimer to the RAND Report on its website).[4] The scope and substance of the RAND Report overlap, in part, with the Consultation. An assumption – and no more than an assumption – can be made that DG SANCO intends to rely on the RAND Report in its Impact Assessment (***IA***) process to the extent that the options identified in the Consultation and the RAND Report overlap.[5]

1.5 Accordingly, to that extent, JTI examines and comments on the relevant policy and evidence base in the RAND Report in this Full Response.

1.6 There are numerous policies, proposals and assessments in the RAND Report which find no place in the Consultation. It is presumed that DG SANCO has considered and rejected those proposals. JTI does not agree with these RAND Report proposals, and agrees with their implicit rejection by DG SANCO.

1.7 It follows that this Full Response is <u>not</u> a response to each and every issue raised in the RAND Report, particularly those which have been excluded from the Consultation.

1.8 No meaningful consultation has been held on the RAND Report, which itself suffers from fundamental flaws. DG SANCO invited stakeholders to attend an afternoon meeting on 20 October 2010 to discuss the final RAND Report which had been published approximately three weeks earlier, but prohibited the submission of any written comments on the RAND Report.[6] JTI attended and participated in the meeting, on the express basis that (i) the process could not constitute a "consultation" and (ii) its comments were limited only to the process, and not on the substance of the RAND Report (the substantive debate having been set out in the Consultation).[7] After the stakeholder meeting, DG SANCO both distanced itself from the RAND Report by virtue of the disclaimer, described above, and decided – contrary to its prior stated position – that "*although it is not a written public consultation*", written comments on the RAND Report could be submitted before the end of 2010.[8] Although DG SANCO has allowed a significant period for written comments, it is clear that this process cannot not meet Better Regulation principles for the minimum standards for consultation or constitute a meaningful "consultation":

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interested parties by the Commission COM(2002) 704 final, page 19 ("*consultation documents should include … reference to related documentation (including, where appropriate, Commission supporting documents)*".

4 The disclaimer ("*This document does not represent the point of view of the Commission. The interpretation and opinions contained in it are solely those of the authors.*") was added to the DG SANCO website immediately after a meeting between DG SANCO and stakeholders on 20 October 2010. Available at: http://ec.europa.eu/health/tobacco/key_documents/index_en.htm.

5 JTI sets out in this Full Response why it considers that DG SANCO must not rely on the RAND Report when conducting its IA (see, notably Section 6 below).

6 Email from DG SANCO dated 23 September 2010.

7 See CECCM's letter dated 13 October 2010, and JTI's comments at the 20 October 2010 meeting.

8 DG SANCO letter to CECCM (reference C6/TP/rp(2010)717478), received on 25 October 2010.

(a) DG SANCO has confirmed that the RAND Report is a final document to which no amendments would be made;

(b) The Commission has stated, on its website, that "*[The RAND Report] does not represent the point of view of the Commission*." Accordingly, it is impossible for stakeholders to identify:[9]

(i) "*what issues are being developed*" by DG SANCO;

(ii) "*the context, scope and objectives of consultation*"; or

(iii) the "*specific issues open for discussion or questions*".

DG SANCO has invited written comments on a wide-ranging, 300 page report, from which it has distanced itself on the substance, without any indication as to the purpose or subject-matter of the invitation; and

(c) DG SANCO has, however, attempted to set out issues for consultation – albeit inadequately – in the Consultation. The difference between the processes is marked, and DG SANCO cannot ultimately claim that issues not set out in the Consultation have somehow been subject to separate consultation on account of a mention of them having been made in the RAND Report.

1.9 Accordingly, to the extent that any of the policies, proposals or assessments in the RAND Report (and which are not in the Consultation) is to be given meaningful consideration by DG SANCO as possible revisions to the TPD, JTI requests the opportunity – in accordance with Better Regulation[10] principles – to be consulted on the specific proposals and the evidence.

1.10 Without prejudice to this position, JTI sets out briefly, in Sections 36 - 40 below, its fundamental concerns with a limited number of proposals in the RAND Report which are not adopted in the Consultation, and its agreement with DG SANCO's implicit decision not to proceed with those matters.

Additional matters examined in this Full Response

1.11 Whilst this Full Response essentially corresponds to the structure of the Consultation, JTI considers that it is essential that various additional matters are examined in order to make its response to the Consultation as meaningful and constructive as possible.

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[9] Communication from the Commission, *Towards a reinforced culture of consultation and dialogue – General principles and minimum standards for consultation of interested parties by the Commission* COM(2002) 704 final, pages 17 and 19.

[10] See, most recently, Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, *Smart Regulation in the European Union* COM(2010) 543 final. JTI notes the change of nomenclature from Better Regulation to Smart Regulation. JTI will use the term "Better Regulation" to cover both.

(a) **Manifest incompatibility with Better Regulation principles**: JTI sets out in Section 5 its fundamental concerns regarding the procedures that have been adopted to date, both by RAND Europe and DG SANCO regarding the Consultation, as measured against the EU's general principles of law and Better Regulation principles. In Section 7, JTI also proposes a necessary procedural way forward. JTI believes that DG SANCO will need meticulously to follow the Better Regulation principles if its eventual IA is to meet the requisite standards for a positive opinion from the Impact Assessment Board (***IAB***). A positive opinion is a pre-requisite to the proposal proceeding to the Commission: "*the President has reinforced its* [IAB's] *role further so that in principle, a positive opinion from the IAB is needed before a proposal can be put forward for Commission decision*";[11]

(b) **The illicit trade issue**: JTI sets out a number of critical issues regarding the illicit trade in tobacco products in respect of individual proposals and in Sections 32 – 35 below. The Consultation makes no meaningful reference to illicit trade. The RAND Report has just four paragraphs on illicit trade (and none related to the possible impact of its proposals on illicit trade). This fundamental issue (which RAND Europe had indicated was part of "*other research phases*", but the results of which have never been published)[12] must be addressed by DG SANCO in its IA;

(c) **Critical omissions**: Issues such as consumer choice, competition in the tobacco sector, intellectual property rights (***IPR***), proportionality, subsidiarity and legal basis, to name but a few, have been omitted from the Consultation and the RAND Report. According to the principles of Better Regulation and the Impact Assessment Guidelines (***IAG***), no meaningful IA can be carried out without an examination of these areas. JTI therefore seeks to address these issues in this Full Response and believes that DG SANCO must consult on these issues and the evidence base on which it relies; and

(d) **Primary evidential materials**: The Consultation makes no meaningful reference to any evidence to support any of the proposals. The RAND Report (which its authors admit constitutes no more than a "*rapid review*" of the evidence)[13] also fails to examine vast swathes of relevant primary materials, including those to which it was specifically referred in the Confederation of the European Community Cigarette Manufacturers' (***CECCM***) submission on the Interim RAND Report in January 2010.[14] JTI accordingly considers that DG SANCO must examine the relevant primary materials referred to in this Full Response as part of its IA process.

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[11] *Smart Regulation in the European Union*, page 6, citing *The Working Methods of the Commission 2010-2014* C(2010) 1100.

[12] RAND Report, Appendix C, pages 285, 291, 296 and 301. No results have been made public in the RAND Report or otherwise.

[13] RAND Report, page 7: "…*comprehensive, systematic literature reviews for each body of evidence are not feasible*…", and noting RAND's "*tight time and resource constraints*".

[14] JTI is a member of CECCM. JTI commented on, and supplied primary materials to, the Interim RAND Report through CECCM's submission dated 18 January 2010.

DG SANCO HAS FAILED TO ASSESS ESSENTIAL AND NECESSARY THRESHOLD ISSUES

2. INTRODUCTION

2.1 JTI notes the statement in the Consultation that: "*At the present stage, the Union competence to adopt the different option, their implications on the functioning of the internal market and their proportionality have yet to be examined. These issues will be analysed at a later stage when the problems and the policy options are developed further*".[15] It is also clear that no consideration has been given, to date, to the principle of subsidiarity.

2.2 **These issues are essential and necessary threshold issues which must be addressed before any proposal can proceed**. In JTI's view, these omissions fundamentally undermine the Consultation, and JTI expects proper consideration to be given to these issues, if any proposed revisions to the TPD are taken forward by DG SANCO.

No analysis of legal basis

2.3 The Consultation concerns the possible revision of the TPD which was based on (now) Article 114 of the Treaty for the Functioning of the European Union (***TFEU***). In the absence of any, let alone any sufficient, indication from DG SANCO, JTI assumes that the proposals revising the TPD are intended to be based on Article 114 TFEU.[16] JTI has grave concerns regarding DG SANCO's failure, to date, to identify any legal basis upon which it considers that the EU is competent to legislate for any of the proposals raised in the Consultation, which, in turn, raises serious doubts about DG SANCO's ability to proceed with any such proposals at EU level.

2.4 The EU institutions may only act within the limits of the competences that have been expressly conferred upon them by the Treaties in order to attain any of the

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[15] Consultation, page 3.

[16] Article 114 TFEU provides (in relevant part) that:

"1. *Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.*

2. *Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.*

3. *The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective."*

objectives the Treaties lay down.[17] Each one of the proposed changes to the current regime governing tobacco products laid down by TPD must, therefore, be based on a specifically identified Treaty article.

2.5 A valid legal basis is, consequently, a pre-condition to action by the EU, and is consistently the first issue to be examined by the Court of Justice when it reviews the validity of EU acts. Yet, in the Consultation, it has been entirely left out of account by DG SANCO. This is particularly concerning in the light of the scope and significance of the proposals in the Consultation. The obligation to consult on proposed legal basis is a necessary pre-requisite to the consultation requirement on subsidiarity.[18] The Consultation, to date, has fallen far short of the obligations placed on the Commission under paragraph 14 of the *Interinstitutional agreement on better law-making*, which states that: "*The Commission will provide a clear and comprehensive justification for the legal basis used for each proposal…*".

2.6 This omission from the Consultation could have negative effects on the development of the proposals, the consultation process generally and any final outcome:

(a) there must not only be a chosen legal basis for an EU measure, but one which rests on objective factors amenable to judicial review, including the aim and content of the measure.[19] The choice of legal basis is closely scrutinised both during and after the legislative process;

(b) stakeholders responding to the Consultation are left to assume that the Commission intends to propose a particular legal basis for the proposals, and, in the absence of any clear or comprehensive justifications for choosing that legal basis, to speculate as to how they may best respond to the as yet unidentified issues raised by DG SANCO; and

(c) there is a legislative history[20] and legal precedent[21] of formal objections and challenges being brought to the legal basis, namely Article 114(1) TFEU (formerly Article 95(1) EC), upon which the TPD was made. Yet, many of the

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[17] Article 5(1) and (2) of the Treaty on the European Union (***TEU***). See, as regards the EU institutions themselves, Article 13(2) of the TEU. See also Case C-376/98 *Tobacco Advertising I* [2000] ECR I-08419, paragraph 83.

[18] IAG, paragraph 4.3.

[19] See Case C-211/01 *Commission v Council* [2003] ECR I-8913, at paragraph 38.

[20] See the Opinion of the Committee on Legal Affairs and the Internal Market (for the Committee on the Environment, Public Health and Consumer Policy) on the proposal for the Tobacco Products Directive (recast version) of 16 May 2000 COM (1999) 594, which proposed to reject the Commission proposal (recast version) on the basis that there was no legal basis (it being asserted that "*health policy motives seem to be so dominant a characteristic*"). See also pages 50 and 75 of the Opinion on the Committee on Industry, External Trade, Research and Energy of 24 May 2000, where it stated *inter alia* that as "*the Commission has omitted to specify the Member States and sectors in which, or why, the internal market is not functioning, despite past harmonisation measures, there is obviously no legal basis.*"

[21] Case C-491/01 *BAT* [2002] ECR I-09079; Case C-376/98 *Tobacco Advertising I* [2000] ECR I-08419, paragraph 84.

proposals in the Consultation, even in that brief and unparticularised form, are significantly more extensive than those which led to the TPD. It is, accordingly, reasonable to assume that the legal basis issues raised by the proposals in the Consultation will be far from straightforward.

2.7 DG SANCO's failure to identify a legal basis for proposals in the Consultation presents even more problems. That is because the proposals deal almost exclusively (and the RAND Report entirely) with public health issues. Yet Article 168 TFEU provides only a limited basis for EU action with regard to human health, and specifically excludes any general competence of the EU to adopt tobacco harmonising measures.[22]

2.8 Article 114 TFEU is a "residual" legal basis, that is to say, it should only be employed when no other more specific legal basis is available.[23] It is an internal market facilitator, providing for the adoption of measures for the harmonisation of national provisions which have as their object the establishment and functioning of the internal market. It does not, however, afford the EU a general power to regulate the internal market.[24]

2.9 So long as the internal market objective is achieved, recourse to Article 114 TFEU may be permitted in circumstances where public health is a decisive factor in the choices that the legislator has to make. The competence under Article 114 TFEU must nevertheless be justified by shortcomings in the internal market itself.

2.10 In this regard, JTI notes that Article 114(3) TFEU provides that "*the Commission … will take as a base a high level of protection, **taking account in particular of any new development based on scientific facts***" (emphasis added).

2.11 DG SANCO has not made any attempt to show that any of the proposals would satisfy the conditions which have been consistently laid down by the Court of Justice regarding recourse to Article 114 TFEU.[25] The following conditions are pre-requisites to EU measures being adopted under Article 114 TFEU:

(a) **Member States have taken or are likely to take divergent measures** which may extend to anticipated disparities,[26] as well as those already in existence;[27]

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22 Article 168(5) TFEU provides that:

"*The European Parliament and Council, acting in accordance with the ordinary legislative procedure…may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, **excluding any harmonisation of the laws and regulations of the Member States***." (emphasis added)

23 Case C-533/03 *Commission v Council (VAT)* [2006] ECR I-1025, paragraph 45.

24 Case C-376/98 *Tobacco Advertising I* [2000] ECR I-08419, paragraph 83.

25 Or, more accurately, its predecessor, Articles 95 EC.

26 Case C-491/01 *BAT* [2002] ECR I-09079, paragraph 67.

(b) **The divergent measures must constitute or be likely to constitute an obstacle to trade** and/or distort or be likely to distort competition, thus directly affecting the functioning of the internal market;[28]

(c) **The effect of the obstacle on the internal market must be appreciable**,[29] meaning that the effect cannot be an "*abstract risk*";[30]

(d) **The measure adopted under Article 114 TFEU *"must genuinely have as its object the improvement of the conditions for the establishment and functioning of the internal market*"**,[31] or, put another way, it "*must be intended to improve the conditions*";[32] and

(e) **Harmonisation must be an appropriate response**.[33] The appropriateness of a measure must be assessed[34] notably with regard to the principles of fundamental rights, proportionality, subsidiarity and conferral of powers as provided for in the Treaties.

2.12 When tested against the above conditions, individual measures proposed by DG SANCO fail to meet at least one, if not more, of those necessary conditions, as even the following brief analysis demonstrates. DG SANCO must demonstrate that an appropriate legal basis exists for every proposal it takes forward to the IAB and the Commission.

Have the Member States taken or are they likely to take divergent measures?

2.13 There is no evidence that Member States have taken or are likely to take divergent measures in relation to a number of the proposals in the Consultation. For example:

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27 Case C-380/03 *Tobacco Advertising II* [2006] ECR I-11573, paragraph 51; Case C-210/03 *Swedish Match* [2004] ECR I-11893, paragraph 37; Case C-434/02 *Arnold André* [2004] ECR I-11825.

28 Case C-376/98 *Tobacco Advertising I* [2000] ECR I-08419, paragraph 84.

29 Case C-376/98 *Tobacco Advertising I* [2000] ECR I-08419, paragraph 106; Case C-380/03 *Tobacco Advertising II* [2006] ECR I-11573, paragraph 66, for statements that any distortion of competition must be appreciable.

30 Case C-376/98 *Tobacco Advertising I* [2000] ECR I-08419, paragraph 84.

31 *Ibid.*

32 Case C-380/03 *Tobacco Advertising II* [2006] ECR I-11573, paragraph 80; Case C-491/01 *BAT* [2002] ECR I-09079, paragraph 75.

33 Article 114 TFEU does not afford the Union a general power to regulate the internal market: Case C-376/98 *Tobacco Advertising I* [2002] ECR 1-08419, paragraph 83.

34 Case C-380/03 *Tobacco Advertising II* [2006] ECR I-11573, paragraphs 42-43; Case C-434/02 *Arnold André* [2004] ECR I-11825, paragraph 35; Case C-210/03 *Swedish Match* [2004] ECR I-11893, paragraph 34.

(a) there is no suggestion that any Member State is altering, or may contemplate altering, the consumer information provided in respect of tar, nicotine and carbon monoxide (***TNCO***);[35]

(b) there is no suggestion that any Member State is altering, or may contemplate altering measurement methods. Indeed, DG SANCO itself has expressly acknowledged that "*Member States widely wished to continue using the current ISO smoking regime on an obligatory basis until solid evidence shows that better methods exist to replace them*";[36] and

(c) plain or generic packaging is not currently required, nor is its imposition likely in any Member State.

2.14 Furthermore, certain of the divergences identified in the Consultation, for example concerning the partial use of pictorial health warnings, are expressly permitted and facilitated by the TPD (but give rise to no internal market issues on account of the "internal market" provision of the TPD, namely Article 13).

2.15 Consequently, it appears that DG SANCO is likely to face significant difficulties in establishing that Member States have taken or are likely to take divergent measures in respect of all the proposals in the Consultation.

Do the divergent measures constitute or are they likely to constitute an obstacle to trade, thus directly affecting the functioning of the internal market?

2.16 Here again, the proposals in the Consultation do not satisfy this limb of the Court of Justice's test. For example, some proposals, notably those relating to restrictions or bans of sales from vending machines,[37] concern national "selling arrangements" which are not "obstacles to trade". Consequently, no corrective harmonisation measures are required.

2.17 Other proposals which have been designed to address supposed "obstacles to trade" include the introduction of registration fees and sanctions.[38] However, the proposals in the Consultation, properly analysed and depending on their formulation, may constitute a tax, the harmonisation of which goes beyond the Commission's competence under Article 114 TFEU.

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35 Consultation, Section 3.

36 Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee, *Second Report on the Application of the Tobacco Products Directive* COM(2007) 754 final, page 4, stating that "[*a]ll presently used measurement methods are based on machine testing which is not suitable for assessing human exposure to smoke. One possibility for human exposure assessment would be to use biomarkers, but more research is still needed on this issue.*"

37 Consultation, Section 6. Indeed, Members of the European Parliament, in joint statement with the Chronic Disease Alliance issued on 5 October 2010, included the measure of "*banning cigarette machines*" in a list of actions to be taken "*at national level*" rather than the list of 'EU level recommendations'.

38 Consultation, Section 4.

Is the effect of the obstacle on the internal market appreciable?

2.18 As regards the proposals to extend the scope of the TPD to other products, such as electronic nicotine delivery systems (***ENDS***), herbal cigarettes, and what is termed "novel forms of oral tobacco",[39] DG SANCO would face serious difficulties proving that, even for these niche products with very small market shares, divergences between Member States laws would, nonetheless, constitute appreciable obstacles to trade.

2.19 Similarly, there is no evidence to suggest that differing approaches by Member States (assuming that they exist) as regards the legality of inserts in cigarette packs could have an appreciable effect on the internal market.[40]

Does the harmonising measure genuinely have as its objective the improvement of conditions for the establishment and functioning of the internal market?

2.20 As regards a number of the bans which are proposed, for example, the display ban, the vending machine ban and the ban on Internet and postal sales,[41] DG SANCO's task of demonstrating that such prohibitions would, in fact, be intended to improve the functioning of the internal market is seemingly insurmountable.

Is the harmonising measure appropriate?

2.21 Many of the measures proposed in the Consultation are, even at a first glance, not appropriate to the aim sought to be pursued. For example, certain of the products sought to be brought within the scope of the TPD, such as ENDS,[42] are already regulated in accordance with national Member State laws governing human medicines. A suitable and proportionate response, if required, would be to consider harmonised medicines regulation, rather than introducing unwarranted extensions to the EU regime governing tobacco products.

2.22 Furthermore, various proposals, such as plain packaging, raise serious and significant issues in respect of fundamental rights (for example, to property, to trade, of expression, etc). DG SANCO should not propose any measures that lack legal basis as they are in breach of such fundamental protections.

2.23 In light of the brief examination above, it is clear that the decision to proceed with the Consultation (and the RAND Report) without having established the competence parameters for any proposals was flawed, and has resulted in wasted time and effort by stakeholders in responding to issues that fall outside EU competence. DG SANCO faces significant, and in certain instances insurmountable, challenges in establishing competence for the proposals in the Consultation.

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[39] Consultation, Section 1.

[40] Consultation, Section 3.

[41] Consultation, Section 6.

[42] Consultation, Section 1.

The Consultation contains no proportionality assessment

2.24 Article 1, Protocol 2, Treaty of the European Union (***TEU***) states that the Commission must "*ensure constant respect for the principle… of …proportionality*" and Article 5 of the same Protocol requires that draft legislative acts should be justified with regard to that principle. Article 5 TEU further provides that "*Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties"*. This point is further emphasised in the IAG.[43]

2.25 As well as being enshrined in the Treaty, the principle of proportionality is a general principle of EU law, and is used by the Court of Justice to assess the validity of EU law. The principle comprises three tests. The EU measure:

(a) must be *suitable* for attaining a legitimate aim;

(b) must be *necessary* to achieve that aim, namely it is the least restrictive measure which would achieve that aim and it must not go beyond what is necessary in order to attain it; and

(c) must not have an *excessive* effect on the applicant's interests, i.e. it must not be out of all proportion to the objective being pursued.

2.26 DG SANCO makes no attempt to demonstrate that it has yet satisfied the proportionality requirement or that it has yet addressed any of the issues raised by the IAG in this respect. In particular, it fails to specify clear objectives, by which the proposed options are to be measured.[44]

2.27 The RAND Report similarly lacks proportionality analysis. For instance, the RAND Report recommends the introduction of a ban on vending machines to prevent minors from smoking despite acknowledging that "*given the small proportion of EU consumers who often use these to purchase tobacco products, the quantitative impact would be quite small*"[45] and that "*adolescents are likely to compensate at least partially by using other sources of supply*".[46] The RAND Report also foresees (though does not quantify) substantial costs for tobacco retailers (including sunk costs and foregone profits) incurred as a result of the measure.[47]

2.28 As a consequence of the failure to consider the proportionality of any proposals, the Consultation and the RAND Report, are fundamentally flawed as a basis for any EU action of any nature whatsoever.

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[43] IAG, pages 29-30.

[44] The Consultation on page 3 only sets out very broad objectives of guaranteeing "*an appropriate functioning of the internal market while ensuring a high level of health protection.*"

[45] RAND Report, page 190.

[46] RAND Report, page 225.

[47] RAND Report, page 206 and Table 11.3.6 at page 213.

The Consultation contains no subsidiarity assessment

2.29 Article 1, Protocol 2 TEU provides that the Commission must have "*constant respect*" for the principle of subsidiarity, which is defined by Article 5 TEU as meaning that "*in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level*".

2.30 It is for DG SANCO to demonstrate that it has satisfied the principle of subsidiarity. However, the Consultation makes no mention whatsoever of this principle.[48] This omission is contrary to the recent *Communication from the President, The Working Methods of the Commission 2010-2014* which provides that "*Consultation is also an obligation for every impact assessment: stakeholders should be able to comment on a clear problem definition, **an analysis of subsidiarity**, and a clear description of possible options"*[49] (emphasis added). DG SANCO is proceeding without any input from stakeholders; it must consult on this issue.

2.31 The obligation incumbent on DG SANCO is not an insignificant one. Article 5 of Protocol 2 TEU on the Application of the Principles of Subsidiarity and Proportionality provides that "*Draft legislative acts shall be justified with regard to the principles of subsidiarity and proportionality. Any draft legislative act should contain a detailed statement making it possible to appraise compliance with the principles of subsidiarity and proportionality. This statement should contain some assessment of the proposal's financial impact and, in the case of a directive, of its implications for the rules to be put in place by Member States, including, where necessary, the regional legislation. The reasons for concluding that a Union objective can be better achieved at Union level shall be substantiated by qualitative and, wherever possible, quantitative indicators. Draft legislative acts shall take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens, to be minimised and commensurate with the objectives to be achieved.*"

2.32 Moreover, since the entry into force of the Lisbon Treaty, national parliaments have been given the right to ensure that the Commission and the other institutions respect the principle of subsidiarity.[50] The public health objective of the proposals and their broad scope, including proposals to harmonise matters that appear to raise no, or no significant, internal market issues suggests that the subsidiarity debate is likely to be a lively one. It is all the more remarkable that DG SANCO failed to address this fundamental principle at this stage.

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[48] Similarly, the RAND Report fails to consider whether for each proposed area of change, the actions would be better achieved by action at national, rather than EU level.

[49] Communication from the President, *The Working Methods of the Commission 2010-2014*, Brussels, 10 February 2010, C(2010) 1100, page 12. See also, in the same terms, IAG paragraph 4.3, page 19.

[50] Protocol 2 to the TEU, Articles 7 and 8.

2.33 As a consequence of the complete failure to carry out any subsidiarity analysis, the Consultation (and the RAND Report) are an inadequate basis for any legislative proposals.

Conclusion

2.34 DG SANCO's failure to address these threshold issues of legal basis, proportionality and subsidiarity strips the Consultation of much, if not all, of its purpose. This all the more striking given the extreme nature of some of the proposals being considered. Without DG SANCO having indicated to stakeholders how it considers each of these critical tests have been met, the underlying proposals lack any proper foundation or context. The stakeholders are, consequently, denied any meaningful opportunity to comment and the entire process is fundamentally flawed.

THE CONSULTATION AND THE RAND REPORT ARE FUNDAMENTALLY INCONSISTENT WITH BETTER REGULATION PRINCIPLES

3. INTRODUCTION

3.1 Tobacco products carry risks to health. Appropriate and proportionate regulation of the sector is thus both necessary and right. Minors should not smoke, and should not be able to obtain tobacco products. This is one of our core beliefs. It is central to our Code of Conduct, marketing practices, operational policies and the way JTI does business. Adult smokers should be appropriately informed about the risks of smoking before they make the decision to smoke.

3.2 For these reasons, JTI supports legislative and regulatory measures on tobacco control which meet the principles of Better Regulation.[51] The EU law general principles of good administration and the Better Regulation principles are well developed in the EU and their importance regarding the economic prosperity of the EU is well recognised. For example, the Commission Communication of 8 October 2010 stated that Better Regulation "*is essential if we are to deliver the ambitious objectives for smart, sustainable and inclusive growth set out by the Europe 2020 Strategy*."[52]

3.3 It is against these benchmarks that JTI has considered the Consultation and the RAND Report. Where JTI considers that action contemplated by DG SANCO falls short of these fundamental requirements, JTI has sought to propose effective alternative regulatory solutions that avoid many of the serious unintended consequences of the measures identified. However, JTI will question, and where necessary challenge, regulation that is flawed, unreasonable, disproportionate or without evidential foundation.

3.4 **JTI considers that the Consultation and the RAND Report are fundamentally inconsistent with the principles of Better Regulation**. These principles are identified below. JTI also sets out the steps DG SANCO should take to remedy these issues. JTI considers that any IA produced by DG SANCO will need meticulously to follow the Better Regulation principles if it is to obtain a positive opinion from the IAB, such that the proposal could in principle be put forward for a Commission decision.[53] By way of overview, and in addition to the significant flaws in the Consultation process to address the threshold issues discussed above, Sections 4 - 7:

(a) set out, in broad terms, the general principles of EU law and regulation regarding Better Regulation and good administration, which DG SANCO is obliged to follow;

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[51] Section 3 of Professor Cave's Report outlines the better regulation agenda: in particular it considers the development of different approaches to regulation and the emergence of internationally recognised principles of Better Regulation.

[52] *Smart Regulation in the European Union*, page 2.

[53] *Smart Regulation in the European Union*, page 6.

(b) identify why the RAND Report is flawed and cannot be used as a basis for DG SANCO's IA process, namely:

(i) the RAND Report's analysis is incomplete, in dealing with key issues, evidence and analysis relevant to an IA;

(ii) the RAND Report is so manifestly flawed, both procedurally and substantively, that DG SANCO cannot rely upon its analysis or conclusions in its IA;

(iii) RAND Europe is not properly equipped to carry out this exercise; and

(c) recommend what DG SANCO should do next, namely:

(i) ensure its acts comply with principles of Better Regulation and good administration;

(ii) itself carry out an IA (setting aside the RAND Report), complying with the IAG and other existing guidelines and principles; and

(iii) consult, more broadly, on issues including, *inter alia*, illicit trade, intellectual property, the need for legislative measures, proportionality, subsidiarity and the legal basis for the measures it proposes.

4. GENERAL PRINCIPLES OF BETTER REGULATION AND GOOD ADMINISTRATION

Better Regulation

4.1 The EU has acknowledged that: "*The Better Regulation principles need to be maintained throughout the legislative process. Better Regulation is a joint responsibility of the EU institutions and the Member States – the actors in the legislative process*".[54] The Commission sees Better Regulation as "*one of our core priorities*".[55]

4.2 Key elements of Better Regulation policies are that regulations should be made in accordance with a set of principles, including: necessity; proportionality;

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[54] Available at: http://ec.europa.eu/governance/better_regulation/ii_coord_en.htm#_iia.

[55] *Better Regulation – simply explained*, page 1.

subsidiarity; transparency;[56] accountability; accessibility; and simplicity,[57] making full use of IAs and consultations as tools of good governance.[58] In particular:

(a) any regulation must have a clear legal basis;[59]

(b) the nature and scale of the problem which the regulation seeks to address must be clearly defined;[60]

(c) the objectives of a regulation must be clearly stated and legitimate;[61]

(d) the evidence base must be the best available and reliable; there must be clear evidence to support the proposal;[62]

(e) legislative and other consultative processes should incorporate a regulatory IA in relation to any significant measure.[63] IAs are a "*key tool to ensure that*

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[56] Sufficient transparency of state measures including legislative processes is often a constitutional principle within Member States. In Germany, for example, legislative processes in the parliament have to be open to the general public in order to comply with the constitutional principle of democracy as stipulated in Article 20(1) of the German Constitution, see Article 42(1) of the German Constitution.

[57] Legal rules have to be sufficiently clear and must be understandable by the addressees and for the authorities. This follows from the rule of law, as stipulated, for example, in Article 20(3) of the German Constitution (see German Constitutional Court, decision of 14 February 1978 – 2 BvR 406/77).

[58] SIGMA (Support for Improvement in Governance and Management) is a joint initiative of the EU and the Organisation for Economic Co-operation and Development (***OECD***), principally financed by the EU. Its activities have, to date, focused on assisting central and eastern European countries. See www.sigmaweb.org.

[59] See, for example, Article 13(2) of TEU; and IAG, paragraph 5.2.

[60] See, for example, IAG, section 5.

[61] See, for example, IAG, paragraph 6. According to the German Constitution, a state measure is only proportionate and complies with the rule of law if it serves a legitimate purpose, see Article 20(3) of the German Constitution. In addition, legislative acts must comply with the constitutional principle of specificity as part of the rule of law. The principle of specificity requires that legal rules are drafted as precisely as possible so as to exclude arbitrariness by the authorities. The more intense the impacts of a legal rule, the more precise the legal rule must be (cp. decision of the German Constitutional Court of 22 November 2000 – 1 BvR 2307/94, 1120, 1408, 2460, 2471/95).

[62] For example, the Commission has stated that it seeks to ensure that "*policies are based on the 'best evidence available'*" (*The Collection and Use of Expertise* COM 2002(713), page 4) and the IAG, paragraph 4.1, emphasise the importance of quality evidence: "*Good quality data – facts as well as figures – are an essential part of any IA… Particular attention needs to be paid to quality and credibility of data*". Under German constitutional law, the legislator must try to gain "*sufficiently secure knowledge*" of the circumstances to be regulated and must use all available possibilities to gain such knowledge. The more important the right that will be inhibited by the measure and the more far-reaching the measure, the higher the required level of security regarding the factual basis for the measure (decision of the German Constitutional Court of 27 July 2005 – 1 BvR 668/04). If sufficient knowledge cannot be obtained on a certain matter, the legislator must refrain from regulating. If the evaluation of the legislator later turns out to be wrong, the act becomes illegal and must be corrected.

[63] Available at: http://ec.europa.eu/governance/better_regulation/ii_coord_en.htm#_iia.

Commission initiatives and EU legislation are prepared on the basis of transparent, comprehensive and balanced evidence";[64]

(f) regulators must assess and evaluate existing legislation (including whether it is being effectively enforced) and other options before regulating further;[65] and

(g) regulation must be capable of being complied with and enforced effectively.[66]

4.3 The Commission also emphasised in its recent (October 2010) Communication on *Smart Regulation in the European Union*, the importance of ensuring that there is significant stakeholder input when developing new regulations,[67] as well as the need to "*limit burdens for* [businesses] *to what is strictly necessary, and allow them to work and compete effectively*".[68]

4.4 Applying the principles of Better Regulation to legislative and consultative processes concerning tobacco control in the EU will enable the objectives of the TPD to be met, because they will ensure that the processes are protected from subversion and avoid the adoption of excessive and unnecessary measures.[69] If applied to all

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[64] IAG, page 4.

[65] See, for example, paragraph 16 of the *Interinstitutional agreement on better law-making*. As the Commission has recognised, "*There are alternatives to regulation. Co-regulation (entrusting the achievement of the goals set out in law, for example to the social partners or to non-governmental organisations) and self-regulation (voluntary agreements between private bodies to solve problems by taking commitments between themselves) can be more cost efficient and effective ways to address certain policy objectives than the classic legal tools.*", page 13 of *Better Regulation – simply explained*. See also paragraph 16 of the *Interinstitutional agreement on better law-making* which states that "*The three Institutions recall the Community's obligation to legislate only where it is necessary, in accordance with the Protocol on the application of the principles of subsidiarity and proportionality…*". Page 5 of *Smart Regulation in the European Union* COM(2010) 543 final also states: "*…the Commission intends to: (i) Ensure that all significant proposals for new or revised legislation are in principle based on an evaluation of what is already in place.…*" Under German constitutional law, the principle of proportionality requires the legislator to assess whether there are any measures which are equally suited to reach the policy objective but which, at the same time, infringe the rights of citizens (including companies) to a lesser extent: Article 20(3) of the German Constitution (also see German Constitutional Court, decision of 26 April 1995 – 1 BvL 19/94).

[66] See, for example, paragraph 29 of the *Interinstitutional agreement on better law-making*. On page 4 of the *Smart Regulation in the European Union*, the Commission furthermore states that "*…efforts must continue to reduce administrative burdens where possible. This can best be done as part of a broader approach which takes account of all factors which determine the efficiency and effectiveness of legislation.…"* The objective that a legal obligation must be capable of being complied with can also be based on the principle of proportionality. Under German constitutional law, state measures (like legal acts) are, amongst other things, only proportionate if they are suited to achieve the identified policy objective (see decision of the German Constitutional Court of 10 April 1997 – 2 BvL 45/92).

[67] *Smart Regulation in the European Union*, pages 10 - 11.

[68] *Smart Regulation in the European Union*, pages 10 - 11.

[69] Paragraph 13 of the *Interinstitutional agreement on better law-making* states that: "*In its proposals for directives, the Commission will ensure that a proper balance is struck between general principles and detailed provisions, in a manner that avoids excessive use of Community implementing measures.*"

reform and consultative processes, whatever the context, the transparency, inclusiveness and integrity of those processes as a whole will be improved.

4.5 Adherence to Better Regulation principles benefits the EU legal order because the regulatory framework within which businesses operate is a key determinant of their competitiveness, growth and employment performance. "*A regulatory environment that is well-devised, clear, understandable and as simple as possible is key to protecting citizens' welfare, public health and the environment*".[70] Better Regulation, furthermore, ensures that: "*regulatory structures and processes are relevant and robust, transparent, accountable and forward-looking*";[71] and national economies are improved and their ability to adapt to change enhanced.[72]

General principle of good administration

4.6 In addition to principles of Better Regulation, the EU has long recognised that a principle of good administration should apply to Community bodies dealing with individuals and businesses alike.[73] Article 41 of the Charter of Fundamental Rights of the European Union (the ***Charter***) enshrines good administration as a general principle of law: "*Every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions and bodies of the Union*".[74] The Commission acknowledges that "*The public legitimately expects quality service and an administration that is open, accessible and properly run"*.[75] This obligation includes the need to act in a consistent and proportionate fashion.[76]

4.7 The principle of good administration has been recognised by the Court of Justice and overlaps with Better Regulation principles. The Court has found, for example, the need for a decision-maker to apply due diligence in the decision-making process and adopt its decision on the basis of all information which might have a bearing on the result.[77] In *Oliveira v Commission*, the (then) Court of First Instance found that the Commission was required to re-examine the subject matter of a Decision, to "*take account of all factual and legal information available at the*

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70 *Better Lawmaking 2006* COM(2007) 286 final, page 2.

71 OECD, *Guiding Principles for Regulatory Quality and Performance 2005*, page 1.

72 OECD, *Guiding Principles for Regulatory Quality and Performance 2005*, page 1. See also the Preamble to the APEC-OECD Integrated Checklist on Regulatory Reform.

73 See *inter alia* Court of Justice judgment of 31 March 1992 in Case C-255/90 P *Burban* [1992] ECR I-2253, and (then) Court of First Instance judgments of 18 September 1995 in Case T-167/94 *Nölle* [1995] ECR II-2589, and 9 July 1999 in Case T-231/97 *New Europe Consulting and others* [1999] ECR II-2403.

74 *Explanations Relating to the Charter of Fundamental Rights* 2007/C 303/02, page 28.

75 Available at: http://ec.europa.eu/civil_society/code/quality_en.htm.

76 Available at: http://ec.europa.eu/civil_society/code/general_en.htm. See further Articles 6 and 10 of *The European Code of Administrative Behaviour*. In German law, the duty of the administration to respect the principle of proportionality derives from Article 20(3) of the German Constitution.

77 Case T-73/95 *Estabelecimentos Isidoro M. Oliveira, SA v Commission of the European Communities* [1997] ECR II-384.

time."[78] The obligation on the Commission to carry out a thorough review was stated by the Court to derive "*in particular from the principles of sound administration and equal treatment*".[79] Furthermore, in *Hauptzollamt Muenchen-Mitte v Technische Universitaet Muenchen,* the Court of Justice found that where Community institutions had a power of appraisal in order to be able to fulfil their tasks, respect of the rights guaranteed by the Community legal order in administrative procedures is of even more fundamental importance. In particular, the guarantees include the duty of the competent institution to examine "*…carefully and impartially all the relevant aspects in the individual case…*".[80]

4.8 Good administration also requires the Commission not just to take account of all available information but also to act diligently in the collection of such information. In *Agraz and Others v Commission,*[81] the (then) Court of First Instance suggested that the Commission had committed "*a sufficiently serious breach, within the meaning of the case-law, of the principles of care and of sound administration*" when failing to obtain within a reasonable time-frame, information indispensable to determining the lawfulness of the Commission's actions.[82]

5. THE INTERRELATIONSHIP BETWEEN THE CONSULTATION, THE RAND REPORT AND THE IA IS UNCLEAR AND CONTRARY TO PRINCIPLES OF BETTER REGULATION AND GOOD ADMINISTRATION

5.1 The principles of Better Regulation require Commission processes to be transparent and simple. In particular, it must be clear at the earliest possible stage: what issues are being developed; what mechanisms are being used to consult; who is being consulted and why; and what has influenced decisions in the formulation of policy.[83] Whilst DG SANCO considers that it does "*not see a need for additional consultation on the impact assessment*",[84] it has not provided clarity on any of these points in its Consultation, and there is a lack of transparency as to the on-going IA that is being conducted.

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78 Case T-73/95 [1997] ECR II-384, paragraph 32.

79 *Ibid.* The principle of equal treatment is also a constitutional principle in most Member States. As an example, Article 3(1) of the German Constitution guarantees equal treatment to all citizens, including companies, and has to be respected, *inter alia*, by the legislator and by administrative bodies. The German Constitutional Court derives from the principle of equal treatment a general prohibition on arbitrary use of power; this principle is violated if a proper reason for a certain measure is not given (see decision of 31 May 1988 – 1 BvL 22/85).

80 Case C-269/90 *Hauptzollamt Muenchen-Mitte v Technische Universitaet Muenchen* [1991] ECR I-5469 at paragraphs 13-14. See also Case T-81/95 *Interhotel v Commission* [1997] ECR II-1265, paragraph 63.

81 Case T-285/03 *Agraz and Others v Commission* [2005] ECR II-1063. Not affected by the judgment on appeal in Case C0243/05P *Agraz and Others v Commission* [2006] ECR I-10833.

82 *Agraz and Others v Commission* [2005] ECR II-1063, paragraphs 52 and 54.

83 See *Towards a reinforced culture of consultation and dialogue – General principles and minimum standards for consultation of interested parties by the Commission* COM(2002) 704 final, pages 17 - 18.

84 DG SANCO's letter to CECCM dated 16 November 2010.

The relationship between the three workstreams (Consultation, RAND Report and IA) is unclear

5.2 Paragraph 29 of the *Interinstitutional agreement on better law-making* requires the Commission to combine "*…**in one single evaluation** the impact assessments relating inter alia to social, economic and environmental aspects. The results of the assessments will be made fully and freely available to the European Parliament, the Council and the general public*" (emphasis added). Furthermore, the European Court of Auditors recently stated: "*public scrutiny of legislative proposals is of the utmost importance in relation to the policy objective of better regulation*".[85]

5.3 There is no "*single evaluation*" presented to date and it is not clear from DG SANCO's process: (i) which issues are being examined in the IA and what evidence is relevant to that process; or (ii) how the Consultation and the RAND Report relate to each other.

The purpose of the workstreams is unclear

5.4 The Consultation is a DG SANCO document with a stated aim to provide "*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*".[86] The Consultation does not purport to constitute an IA, or part of an IA itself. It makes no reference to the RAND Report or, indeed, any evidence base of any sort.

5.5 The RAND Report is a report commissioned by DG SANCO, which "*serves as an input to DG SANCO's own impact assessment exercise*",[87] supporting in "*assessing the impacts of revising the Tobacco Products Directive 2001/37/EC*". The RAND Report states that it follows "*the impact assessment guidelines of the European Commission (EC) as far as feasible; **it, however, does not constitute a full impact assessment***" (emphasis added).

5.6 Appendix C[88] to the RAND Report indicates that other "*research phases*" may have been undertaken by DG SANCO or RAND Europe for the purposes of the IA. Critically, these other research phases are stated to have covered "*for example, consumer choice, property rights [and] illicit trade*". No supplemental work-products purporting to constitute those parts have, however, been released, and it is not known whether any such work-product has been delivered to DG SANCO.

5.7 DG SANCO has, furthermore, not clarified what the IA will evaluate as proposals.

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[85] European Court of Auditors, *Impact Assessment in the EU Institutions: Do They Support Decision-Making?* (2010) Special Report No 3, page 24.

[86] Consultation, Introduction.

[87] RAND Report, page xxiii.

[88] See further discussion on this example.

There is a discrepancy in the coverage of the Consultation and the RAND Report

5.8 There are some areas where the Consultation clearly overlaps with the RAND Report, such as in relation to the proposals to introduce pictorial warnings and generic or plain packaging[89] and the proposals to control the supply and access to products by way of age verification, restricting vending machine access and restricting tobacco display and promotion at point of sales.[90] These areas are, on the assumption that the RAND Report is to "support" the issues raised in the Consultation, examined in this Full Response.

5.9 There are, however, a number of key areas where there is a clear discrepancy in the coverage of the RAND Report and the Consultation, raising questions as to the evidential basis for the Consultation and again as to the nature and content of the IA. The discrepancies include the following:

(a) **The Consultation raises options that are not addressed in the RAND Report**. For example, the Consultation proposes developing specific safety and quality requirements for ENDS[91] and raises as an option lifting the ban on smokeless tobacco products, or banning all types of smokeless tobacco products.[92] The RAND Report does not assess such requirements.

None of these options has any identified evidential underpinning. It is impossible for any meaningful consultation to be held on the basis of vague and imprecise statements in the Consultation without any evidential review.

(b) **The RAND Report considers a number of policy options that are not considered in the Consultation**. For example, the RAND Report proposes a ban on tobacco ingredients that are carcinogenic, mutagenic or toxic for reproduction (***CMR***s) or that form CMRs during pyrolysis in order to establish a common list of ingredients. The RAND Report also puts forward further policy options such as to introduce maximum limits for other yields and ingredients.[93] There are numerous examples.[94]

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89 Consultation, Section 6.2 and RAND Report, Chapters 7 and 8.

90 Consultation, Section 1.2 and RAND Report, Chapter 11.

91 Consultation, Section 2.2.

92 Consultation, Options 2 and 3.

93 RAND Report, Chapter 10.

94 For example, the RAND Report includes: (i) a proposal to extend the TPD to include tobacco leaf; (ii) a proposal to introduce an additional measurement method for TNCO and set maximum limits accordingly; (iii) a proposal to introduce maximum limits for others yields and ingredients; (iv) a proposal to continuously decrease the maximum limits for TNCO and other yields and ingredients; (v) a proposal to set up an EC laboratory for the evaluation of tobacco and smoking products; (vi) a proposal to harmonise the legal buying age of 18 in order to avoid sales to minors; (vii) a proposal to introduce minimum or standard package size; (viii) a proposal to introduce market control fees proportionate to the number of outlets the product is sold in; (ix) a proposal to integrate the external health costs of smoking into the calculation of the fees; and (x) a proposal to internalise the external costs of smoking by requiring full liability and payment of the health costs of smoking by the tobacco industry to national health systems.

It is unclear whether DG SANCO has abandoned these possible policy options, or whether they remain within DG SANCO's IA process. Whilst JTI assumes that the RAND Report's proposals have been rejected, DG SANCO must clarify the ambiguities that it has created.

5.10 It is clear, therefore, that DG SANCO must clarify its process and consult again in order to meet Better Regulation principles.

6. THE RAND REPORT IS FUNDAMENTALLY FLAWED: DG SANCO MUST NOT RELY ON IT

6.1 In this Section, JTI sets out the procedural flaws of the RAND Report. In particular, the RAND Report is incomplete (Section A), the analysis is inadequate and insufficient (Section B) and RAND Europe does not have the necessary expertise (Section C). **JTI considers that the RAND Report is so flawed that it cannot meaningfully be used by DG SANCO even to support the development of its own IA. The RAND Report should be set aside by DG SANCO.** DG SANCO should either independently review the evidence or commission further – independent and balanced – expertise on relevant areas, with input from and the involvement of all relevant stakeholders.

A. THE RAND REPORT IS INCOMPLETE

The RAND Report and the Consultation fail to consult on key issues that affect the outcome of the analysis and which are required by the IAG

6.2 Article 2, Protocol 2 TEU states that "*Before proposing legislative acts, the Commission shall consult widely. Such consultations shall, where appropriate, take into account the regional and local dimension of the action envisaged …*" The *White Paper on European Governance* further clarifies that "*the quality of…EU policy depends on ensuring wide participation throughout the policy chain – from conception to implementation*".

6.3 Notably, both RAND Europe and the Consultation fail to consider the factors required by the IAG which are set out below, despite RAND Europe stating in a letter to a cigarette manufacturer on 7 January 2010 that: "*…there are no questions on wider impacts of regulations on, for example, consumer choice, property rights, or illicit tobacco trade. These issues are covered by other research phases and results are combined in the final report RAND Europe will deliver to the European Commission*".[95] No such research phases appear in the final RAND Report. No evidence has been made public for consultation.

6.4 Other important issues, such as the impact of the proposals on (i) the functioning of the internal market, (ii) tobacco growers, (iii) suppliers and service industries, (iv) international trade, and (iv) research and development have all been substantially ignored. A few of the omissions are examined below.

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[95] RAND Report, page 285. See also the remainder of Appendix C for further examples of similar letters.

Illicit trade

6.5 The IAG require that an IA assesses whether any options "*have an effect on security, crime or terrorism*".[96]

6.6 In its response to the Interim RAND Report, CECCM highlighted the failure to take into consideration the phenomenon of the illicit trade in tobacco products.[97] The RAND Report does not address this issue, even though RAND Europe identified it as a research phase. As a result the RAND Report fails to assess the scale and evolution of the illicit trade in tobacco, and the possible unintended consequences of the proposed changes in regulation.

6.7 JTI believes that governments should be encouraged to adopt comprehensive strategies to tackle cigarette smuggling and product counterfeiting, an area of concern which is causing substantial losses to governments and industry stakeholders.[98] Any future IA must properly (a) consider the underlying reasons and triggers for illicit trade in tobacco products (including the impact of current regulation, on illicit trade), (b) evaluate the scale of the problem and (c) assess both the impact that any proposed changes to the TPD's regime would have on illicit trade and the impact that the existence of illicit trade would have on the ability of such changes to achieve their identified policy objectives.

6.8 JTI addresses the issue of illicit trade both in respect of individual proposals and in Sections 32 – 35 below.

Intra-EU trade

6.9 The IAG indicate that a key question when assessing economic impacts in the context of an IA is whether any options have an impact on "*Competitiveness, trade and investment flows*".[99] Furthermore, given that the likely legal basis of any revisions to the TPD is Article 114 TFEU, the issue of intra-EU trade is critical.

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[96] IAG, page 36.

[97] JTI considers that there are three categories of illicit trade products:

- contraband products: genuine products diverted from the legitimate supply chain and sold without domestic duty paid in a country other than their intended market of retail sale;
- counterfeit products: products protected by IPR which are manufactured / faked without authorisation from the rights owners; and
- illicit white cigarettes: brands manufactured legitimately in one market and sold knowingly to traders who transport them to another country where the products are sold illegally without domestic duty paid.

[98] The gravity of the impact of illicit trade is further highlighted in L. Joossens and M. Raw's 2008 research paper cited by the RAND Report at page 75: "*the illicit tobacco trade results in huge losses of revenue of governments, estimated at $US40-50 billion in 2006, and in increased consumption and thus health problems because it makes tobacco available more cheaply.*" Joossens, L. and Raw, M., "Progress in combating cigarette smuggling: controlling the supply chain", *Tobacco Control* (2008) 17:399-404.

[99] IAG, page 33.

6.10 The Consultation states that it is not examining legal basis at this time. In addition, neither the Consultation nor the RAND Report consider the impact that the proposals would have on:

(a) trade between Member States;

(b) the competitive position of tobacco manufacturers and the process of competition in the EU;

(c) consumer choice and competition within the EU; and

(d) intra-EU trade and the global competitive position of EU firms.

Consumer choice

6.11 The IAG indicate that a key question when assessing economic impacts in the context of an IA is whether any options have an impact on "*Consumers and households*", including whether an option has "*an impact on the quality and availability of the goods/services they buy, on consumer choice and confidence"*.[100]

6.12 In the few instances where the RAND Report does discuss potential impact on consumers, it does so cursorily and without adequate analysis. For example, the RAND Report makes sweeping statements concerning the supposed lack of any "*negative social impact*" of the proposed display and vending ban: "*some adult smokers would be affected as they would not be able to access vending machines as a source of tobacco products, but effect would be minimal as they could legally turn to other sources of purchase (e.g. retail shops). No negative social impact foreseen*" and "*Impact* [of display ban] *likely to be strongest on youths although some adult smokers and would-be quitters may also be positively affected. No negative social impact foreseen*".[101] The bases for this analysis are not disclosed.

6.13 It is clear that RAND Europe foresaw the need to carry out a research phase on the issue of consumer choice, but it has failed to include any meaningful analysis in the RAND Report.

IPR

6.14 The IAG indicate that a key question when assessing economic impacts in the context of an IA is whether any options have an impact on "*property rights*".[102]

6.15 As will be examined in more detail in the Section below regarding plain packaging, the existence and enforceability of IPR have been recognised as of paramount importance to the functioning of the internal market and as a necessary incentive for investment in research and development and innovation. The development of brand equity and goodwill is fundamental to market economies,

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[100] IAG, page 34.

[101] RAND Report, Table 11.2.8, page 202.

[102] IAG, page 34.

consumer choice, innovation and product development. Furthermore, JTI has invested very substantially in its IPR, brands and products.

6.16 The Consultation and the RAND Report fail meaningfully to identify or evaluate the impact the proposed changes considered will have on IPR, particularly changes to the labelling requirements (such as plain packaging and larger health warnings). If the RAND Report had properly considered possible effects on IPR, it would also have realised the potential contradictions with current Commission policy, which are discussed further below.

DG SANCO fails to take into account existing legislation

6.17 Better Regulation requires a regulatory environment that is "*clear, understandable and as simple as possible*".[103] DG SANCO, in failing to take into account existing EU legislation, inappropriately layers regulation upon further regulation. By way of example:

(a) when discussing options for packaging and labelling, DG SANCO fails to consider the Directive on Unfair Commercial Practices,[104] which aims to ensure that consumers can make informed and meaningful decisions by preventing misleading or aggressive marketing, and unclear, inaccurate and unsubstantiated claims made by traders in the EU;[105] and

(b) when proposing a cross-border retail sales ban over the Internet, DG SANCO similarly fails to consider the Directive on the Protection of Consumers in respect of Distance Contracts,[106] which focuses on protecting consumers buying goods over the Internet, as well as in other distance selling arrangements.[107]

Failure to take into account relevant evidence and EU policies

6.18 The RAND Report omits relevant materials. Various non-exhaustive examples are identified below; further examples are set out in the Sections on specific proposals. The failure to consider relevant materials – notably those which have been identified to RAND Europe as part of the process or which are held by DG SANCO (which commissioned RAND Europe's work) – undermines the credibility of the RAND Report. Furthermore, the Consultation and the RAND Report contradict other EU and Commission policies.

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[103] *Better Lawmaking 2006*, page 2.

[104] Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market (OJ 2005 L149/22).

[105] Commission Staff Working Document: *Guidance on the Implementation / Application of Directive 2005/29/EC on Unfair Commercial Practices*. Sec (2009) 1666, page 6.

[106] Directive 1997/7/EC of the European Parliament and of the Council of 20 May 1997 on the Protection of Consumers in respect of Distance Contracts (OJ 1997 L144/19).

[107] Directive 1997/7/EC of the European Parliament and of the Council of 20 May 1997 on the Protection of Consumers in respect of Distance Contracts (OJ 1997 L144/19).

No reference to the material submitted pursuant to Article 6 TPD

6.19 Pursuant to Article 6 of the TPD, JTI and other tobacco companies have provided annually to Member States, for subsequent communication to the Commission, a vast volume of information on ingredients used in the manufacture of tobacco products and "*all available toxicological data*" regarding those ingredients.

6.20 The RAND Report makes no reference to any of this material.

6.21 Indeed, the RAND Report suggests that there is insufficient data available to analyse the toxicological properties of ingredients. RAND Europe has therefore ignored the largest and most comprehensive source of relevant material on this topic.

6.22 DG SANCO has all of this information available to it. Accordingly, DG SANCO must examine and evaluate this data as part of any proposals on the regulation of ingredients.

No reference to SCENIHR

6.23 The RAND Report fails to take into account of the Commission's Scientific Committee on Emerging and Newly Identified Health Risks (***SCENIHR***) draft *pre-consultation opinion on Addictiveness and Attractiveness of Tobacco Additives*, published on 6 July 2010 by DG SANCO (the ***pre-consultation opinion***). This pre-dated the September 2010 RAND Report. The final opinion, *Addictiveness and Attractiveness of Tobacco Additives* was adopted on 12 November 2010 (***SCENIHR 2010***). The final opinion does not depart markedly from the pre-consultation opinion in relation to the conclusions discussed below.

6.24 SCENIHR was mandated by DG SANCO to examine a subject that RAND Europe (whose work was commissioned by DG SANCO) was also to evaluate. It is inexplicable that the RAND Report ignores the pre-consultation opinion.

6.25 By way of example, the RAND Report suggests that "*a number of additives and ingredients currently used in tobacco products contribute to increasing both their addictiveness and attractiveness to consumers*".[108] DG SANCO's expert working group, by contrast, reached a radically different opinion: "*In conclusion, apart from the possible action of combustion products of sugars (acetaldehyde and similar compounds that enhance the action of nicotine by inhibition of MAO* [monoamine oxidase]*), there is no evidence as yet that additives enhance the addictiveness of nicotine and therefore tobacco*".[109]

6.26 SCENIHR 2010 also reaches a number of relevant conclusions in relation to the "addictiveness" and "attractiveness" of tobacco ingredients:

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[108] RAND Report, page 179.

[109] SCENIHR 2010, page 84. Materially identical language appeared at page 84 of the pre-consultation opinion.

(a) no tobacco ingredients, which are addictive by themselves, have so far been identified;[110]

(b) it is "*uncertain*" whether technical characteristics of cigarettes, such as ventilation (paper, filter), the density of the tobacco and the geometry of the cigarette "*lead…to a higher risk of addiction*";[111]

(c) many "*extrinsic factors*" influence the "attractiveness" of tobacco products, and not only the ingredients used in the products themselves;[112]

(d) animal models do not currently exist to measure the "attractiveness" of tobacco products, and human testing methods are inadequate in this regard;[113] and

(e) it is "*very difficult to identify the role of individual additives in enhancing attractiveness*" and there is indeed a growing trend in several countries of using "natural" tobacco products marketed as containing no additives.[114]

6.27 These conclusions, as noted, appeared in identical or materially identical form in the pre-consultation opinion which pre-dated the RAND Report and which was available to RAND Europe. Yet they do not appear to have been considered in the RAND Report, and are often contradicted by the RAND Report. This not only indicates that RAND Europe has not considered all relevant material (and a major scientific review by one of the Commission's own expert committees would seem an obvious source of useful information for the authors), but also calls into question RAND Europe's ability to process the material that it has considered – since its own conclusions are so different from those of the Commission's expert working group.

6.28 DG SANCO must now itself, as part of the IA process, review and assess all available evidence on the, as yet unspecified, issues under consideration.

Contradiction with other EU and Commission policies

6.29 The IAG recommend that options should be assessed against criteria of coherence with other overarching EU policy objectives.[115] However, the proposals notably for plain packaging and larger health warnings are at odds with the EU policy on the protection of intellectual property rights. For example, the Directive on the enforcement of IPR[116] states *inter alia* that: "*the protection of intellectual property is*

[110] SCENIHR 2010, page 4. Identical language appeared at page 4 of the pre-consultation opinion.

[111] SCENIHR 2010, page 4. The pre-consultation opinion concluded that "*it does not seem that technical characteristics can enhance the addictive potential of tobacco products*" (page 84).

[112] SCENIHR 2010, page 70. Identical language appeared at page 69 of the pre-consultation opinion.

[113] SCENIHR 2010, page 11. See further paragraph 26.41, below. Identical language appeared at page 10 of the pre-consultation opinion.

[114] SCENIHR 2010, page 11. Identical language appeared at page 10 of the pre-consultation opinion.

[115] IAG, page 29.

[116] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights.

important not only for promoting innovation and creativity, but also for developing employment and improving competitiveness".[117] This directive further recognises the right for an inventor or creator to legitimately profit from his/her creation.[118]

6.30 The RAND Report advances measures, for example plain packaging, that will undermine IPR and brand value.

6.31 Further, the RAND Report provides a number of observations with respect to competition in tobacco manufacturing in the EU and makes certain assumptions regarding tobacco manufacturers' likely behavioural responses to certain proposals in the Consultation. These include statements regarding the relevant geographic market, the characteristics of an oligopolistic market, barriers to entry and the competitive dynamics of the market. For present purposes, JTI notes that those observations and assumptions are not wholly consistent with the Commission's previous analyses in respect of tobacco manufacturing.[119] Nor are they supported by any substantive analysis in the RAND Report itself.

Failure to take into account relevant evidence identified to RAND Europe in January 2010

6.32 Reiterating the CECCM response on 18 January 2010, there are a number of relevant materials which RAND Europe needs to consider for its analysis. The vast majority of these suggestions have been ignored in the RAND Report, even in cases where they resolve apparent issues with lack of data that RAND Europe has experienced, such as in relation to health impacts. Specifically, the RAND Report states that it had not been able to provide substantial quantitative data on the positive health impacts of additional regulation, as, *inter alia*: "*…the evidence of the health impacts of many new measures, such as large pictorial warnings and display bans, has so far relied on data gathered through small experimental set-ups or perception surveys and there is very little evidence available that relates to changes in smoking behaviour in the wider population and overall prevalence rates*".[120] Set out below are examples of a number of omissions, referenced in the CECCM response, including studies that deal particularly with the health impacts of plain packaging and pictorial health warnings specifically:

(a) **Dr Lilico's September 2008 Report and Dr Lilico's October 2009 Report**. Dr Lilico has stated that there is, as yet, no credible statistical evidence that the

[117] Recital 1 of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights. See also, Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee, *Enhancing the enforcement of intellectual property rights in the internal market*, COM(2009) 426 final.

[118] Recital 2 of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights.

[119] See, notably, relevant merger control decisions in the tobacco manufacturing sector: Case No COMP/M.5086 – *BAT / Skandinavisk Tobakskompagni*, 27 June 2008; and Case No COMP/M.4424 – *JT / Gallaher, 21 February 2007*; Case No COMP/M.4581 – *Imperial Tobacco / Altadis*, 18 October 2007.

[120] RAND Report, page 254.

introduction of display bans has been associated with reduced smoking prevalence. In particular, there is no evidence of such an effect in respect of those aged 15-19. Dr Lilico has also concluded that display bans are strongly and materially correlated with increased smoking prevalence amongst 15-19 year olds;

(b) **JTI's submission to Health Canada dated 12 June 2009**. In 2001, the Canadian federal government increased the size of on-pack health warnings from 25% to 50% of the principal display area of the pack and introduced pictorial warnings. In order to evaluate the possible effectiveness of the new warnings, it commissioned a series of annual "Wave" surveys from Environics. These studies started with a baseline survey of the 25% black on white, white on black text-only messages in use until 2000, followed by similar surveys conducted twice yearly from 2001 to 2007, among both adult and youth populations, following the introduction of the 50% pictorial warnings. JTI has reviewed extensively the data from these Wave surveys in order to evaluate the response to larger health warnings in Canada. This analysis has shown that, according to the federal government's own data, the larger pictorial warnings did not enhance awareness of the health risks of smoking or change smoking behaviour;

(c) **the UK Government's Future of Tobacco Control Consultation** (the ***FTC Consultation***).[121] The UK Government concluded that the evidence base for plain packaging was insufficient. It is therefore difficult to explain how RAND Europe can arrive, in the absence of any credible evidence,[122] at such a markedly different position from the UK Government, who have looked at this issue in substantial detail;

(d) **Dr Keegan's September 2008 Report and Dr Keegan's June 2009 Report**. In relation to the effectiveness of consumer surveys, which are used extensively in the RAND Report, Dr Keegan has noted, amongst other things, that "*observing what people do is a better predictor of behaviour than recording how people respond to questions about what they think they will do, or what they think others will do, or what they report they have done*";[123]

(e) **the OECD published in June 2008 a report entitled "*The economic impact of counterfeiting and piracy.*"**[124] Chapter 13 of this report addresses the impact of counterfeiting and piracy on the tobacco sector;

(f) **the World Customs Organisation published in 2008 a report entitled "*Customs and Tobacco Report 2008.*"**[125] This report provides an overview of

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[121] Available at: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_085120.

[122] RAND Europe itself acknowledges that there is no observed data on the impact of plain packaging on consumer behaviour, pages pp 131, 133-134.

[123] Dr Keegan's September 2008 Report, page 9.

[124] Executive summary is available at: http://www.oecd.org/document/4/0,3343,en_2649_34173_40876868_1_1_1_1,00.html.

the results of the efforts of Customs administrations worldwide in counteracting the illicit trade in tobacco products;

(g) **HM Revenue & Customs' (the UK tax authority's)** ***Departmental Autumn Performance Report***, published in 2008, sets out figures relating to the UK taxation regime;[126]

(h) the **World Bank's report "*Understand, and measure and combat tobacco smuggling*"** provides a clear methodology on how to measure and calculate the scale of illicit trade;[127] and

(i) the **International Tax and Investment Center produced in December 2009 a summary report** of the presentations and discussions held at its international conference in Brussels, Belgium, on 4 to 9 November 2009.[128]

6.33 None of these materials have been identified in the RAND Report as having been reviewed or analysed.

6.34 The purpose of the December 2009 – January 2010 process regarding the Interim Report can be questioned if the input from three leading tobacco manufacturers is simply ignored. This further evidences the failure by RAND Europe to consider relevant materials.

The RAND Report proposes measures even where it acknowledges there is no evidential base

6.35 The RAND Report fails to discount options for which it acknowledges no or insufficient evidence is available, with some of the evidence relied upon being "*of very poor quality in terms of comprehensiveness as well as reliability*".[129] Clear evidence is necessary to support regulatory intervention. However, the RAND Report proceeds to draw conclusions and make recommendations, even in circumstances where it is acknowledged that no such evidence exists to justify a proposal. The authors become policy advocates. DG SANCO must itself reach conclusions based upon scientific and reliable evidence; it is clear that the RAND Report cannot be used as a basis for objective and balanced evaluation of evidence.

6.36 For instance the RAND Report recommends:

(a) the extension of the scope of the TPD to include ENDS despite acknowledging that the "*health effects of* [electronic cigarettes and other ENDS] *are*

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[125] Executive summary is available at: http://www.wcoomd.org/files/1.%20Public%20files/PDFandDocuments/Enforcement/TOBACCO%202008%20EN%20web.pdf.

[126] Available at: http://www.hmrc.gov.uk/about/autumn-report-2008.pdf.

[127] Available at: http://www1.worldbank.org/tobacco/pdf/Smuggling.pdf.

[128] The website of the International Tax and Investment Center is available at: http://www.iticnet.org.

[129] RAND Report, page 253.

ambiguous, not well known, and have not been studied in any comprehensive way";[130]

(b) the introduction of information leaflets and inserts despite acknowledging that "*there is little information available on the potential health impacts of inserts with supplementary information*";[131]

(c) the introduction of plain packaging despite acknowledging that "*no observed data currently exist on the impact of plain packaging on consumer behaviour*";[132]

(d) replacing quantitative TNCO labelling with qualitative information on smoke constituents despite acknowledging that the evidence of the "*impact of qualitative versus quantitative information of TNCO yields is scarce*";[133]

(e) the introduction of maximum limits for other yields and ingredients, despite having found "*very limited evidence regarding the health impacts*" of introducing such a measure;[134]

(f) a ban on additives classified as CMRs in order to establish a common list of ingredients despite acknowledging that there is a "*general lack of research and knowledge available regarding the health effects of individual ingredients and additives used in tobacco product*" and that the RAND Report has had to rely on very few qualitative sources only;[135]

(g) a ban on vending machines despite acknowledging the lack of any quantitative estimates of the impact such measure would have on tobacco consumption;[136] and

(h) measures banning promotions and display of tobacco products in retail stores despite acknowledging that most of the evidence available to support these measures relies on self-reported behaviour, rather than observed behaviour, typically including relatively small samples of the population at large and is subject to context-specific conditions.[137]

B. RAND EUROPE'S ANALYSIS IS INADEQUATE AND INSUFFICIENT

6.37 The IAG indicate that: "*good quality data – facts as well as figures – are an essential part of any IA. …Particular attention needs to be paid to quality and*

[130] RAND Report, pages 120-121.

[131] RAND Report, page 135.

[132] RAND Report, page 131.

[133] RAND Report, page 134.

[134] RAND Report, page 177.

[135] RAND Report, page 174.

[136] RAND Report, page 190.

[137] RAND Report, page 194.

credibility of data".[138] There is, furthermore, the need for a "*diversity of viewpoints*", including the consideration of divergent views.[139] There are a number of significant limitations in the approach taken in the RAND Report, which appear contrary to the IAG and are set out below.

Failure to scrutinise evidence relied upon

6.38 The RAND Report fails to scrutinise the research it relies upon. Whilst disappointing, this is unsurprising, given, in particular, RAND Europe's acknowledgment that it has carried out "*rapid*" rather than comprehensive "*systematic evidence reviews*".[140] RAND Europe effectively acknowledges its lack of thoroughness. It is clear that RAND Europe has not sought to verify whether the research is of adequate "quality and credibility". As a result, RAND Europe adopts conclusions based on unsound research.

6.39 By way of example:

(a) the RAND Report relies on a paper published by the Danish Cancer Society (***DCS***) as evidence that certain CMRs increase the inherent toxicity of cigarette smoke.[141] However, the RAND Report does not disclose that this paper is a short English summary, published online, of a report published by Nielsen et al. in 2007, which is available only in Danish. In addition, RAND Europe does not clarify that DCS did not analyse primary data, but conducted a "*literature study on the existing publically available chemical, toxicological, medical science information on the topic*";[142]

(b) the RAND Report places heavy reliance on the 2007 UK Department of Health Impact Assessment on pictorial health warnings. In one instance, in particular, the RAND Report, when attempting to demonstrate the potential decline in tobacco consumption caused by pictorial warnings states that the UK Department of Health's IA "*concluded that the introduction of pictorial warnings on all tobacco packs with rear warning labels taking up at least 40 percent of the back of packs would produce a 0.5 percent reduction in the UK's smoking population*".[143] A review of the source data reveals that these were estimates rather than hard facts;[144]

(c) the RAND Report presents limited evidence in respect of the impact of a plain packaging measure. Of the 14 documents cited in the RAND Report in the section entitled "Plain or Generic Packaging", only three are studies which

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138 IAG, page 18.

139 IAG, pages 9 and 12.

140 RAND Report, page 253.

141 Projekt Børn, Unge & Rygning, *Tilsaetningsstoffer I cigaretter Et litteraturstudie* (2007).

142 Danish Cancer Society, *Tobacco Additives – A study of the available literature*, Summary, Copenhagen, 2008.

143 RAND Report, page 128.

144 *UK Department of Health Impact Assessment*, 2007.

present primary consumer survey research in respect of plain packaging.[145] This ignores the selection of other consumer survey evidence which exists in respect of plain packaging, such as the UK Government's FTC Consultation, which has previously been provided to RAND Europe. The UK Government concluded that the evidence base for plain packaging was insufficient. The RAND Report fails to explain how it can arrive, in the absence of any credible evidence, at such a markedly different position from the UK Government, and other governments,[146] that have looked at this issue in greater detail than RAND Europe appears to have done;[147]

(d) the RAND Report's findings regarding the health impacts of labelling are, to a great extent, a summary of a summary of academic literature produced by Sambrook Research International[148] on behalf of DG SANCO. There is no indication that RAND Europe even looked at, let alone scrutinised, the underlying primary research;[149] and

(e) the only evidence cited in the RAND Report to support the proposition that "*quantitative information on cigarette packs is misleading for consumers because they may think that lower TNCO yields indicated on packs mean that a tobacco product is less risky to their health; some of them may even decide to smoke lower TNCO yields in preference to quitting*"[150] is a paper by the Australian Commonwealth Department of Health and Aged Care.[151] However, this paper was itself a government "*discussion paper… designed to seek community views on new health warnings*",[152] whose authors warned was "*not intended to be a complete review of the literature.*" Indeed, following the consultation exercise to which this paper relates, Australia opted to retain on-pack TNCO labelling, based on the same ISO standards used by the EU today.

Use of pejorative language

6.40 Some of the language used in the RAND Report is, in JTI's view, inappropriate and gives reason to question its objectivity. For example, the continued

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[145] See in the RAND Report references to Germain et al. (2009) and Wakefield et al. (2008).

[146] See also Australian Senate Community Affairs References Committee report "*The tobacco industry and the costs of tobacco related illness,*" (December 1995) which concluded that there was "*not sufficient evidence to recommend that tobacco products be sold in generic packaging*".

[147] RAND Report, pages 131-134.

[148] Sambrook Research International, *A Review of the Science Base to Support the Development of Health Warnings for Tobacco Package*, report prepared for the European Commission, Directorate-General for Health and Consumers, available at http://ec.europa.eu/health/tobacco/docs/warnings_report_en.pdf , 2009.

[149] RAND Report, pages 128 - 129.

[150] RAND Report, page 134.

[151] Commonwealth Department of Health and Aged Care, *Review of Health Warnings on Tobacco Products in Australia – Discussion Paper*, Canberra: Commonwealth Department of Health and Aged Care, 2001.

[152] *Review of Health Warnings on Tobacco Products in Australia – Discussion Paper*, page 2.

reference to "*tobacco epidemic*" is pejorative[153] and suggests that the RAND Report has pre-judged the outcome of its research and the need for further measures on the grounds of public health.

6.41 Furthermore, the RAND Report raises unwarranted and unsubstantiated ethical concerns about the approach taken by tobacco companies when providing information regarding the administrative burdens and compliance costs of the TPD: "*it is likely that the tobacco manufacture and retail industries are motivated to disclose higher than actual cost figures, which would decrease the probability of additional regulation being imposed on them*".[154]

6.42 These unsubstantiated concerns can be contrasted with the over-estimates used by RAND Europe in its calculations of potential changes to prevalence on the basis of its recommendations. The RAND Report notes – at page 283, in Appendix B – that prevalence changes (of -0.5%) have been adopted, although greater than the World Bank suggestions, in order to "*identify maximum impacts. Therefore our estimates should be considered overestimates.*" Nowhere in the body of the RAND Report are these overestimates identified, even where the prevalence effects are used as a basis for the recommendations.

6.43 Indeed, the RAND Report states, in a manner entirely contradictory to the methodological Appendix B, that the report "*… is likely to err on the conservative side with regard to the estimation of the health benefits of tobacco product regulation.*"[155] The RAND Report lacks balance and objectivity.

Lack of weight given to evidence challenging RAND Europe's thesis

6.44 The RAND Report gives little weight to evidence provided by the tobacco industry, on the rare occasions when such evidence is even referred to (see further Section 6.32 above). Furthermore, RAND Europe either ignores or gives insufficient weight to other evidence that does not suit its preferred policy recommendations.

The RAND Report fails to meet its own stated objective of "objectivity" and "balance"[156]

6.45 Evidence from the tobacco industry is only referred to on three occasions in the RAND Report. In each instance, the reliability is questioned on the basis of possible undue influence by the industry over the findings. For example, "*any source*

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[153] The Oxford English Dictionary defines "epidemic", for a disease, as "*normally absent or infrequent in a population but liable to greatly increased frequency and severity*" and "*a temporary but widespread outbreak of a disease*". This term is therefore manifestly unsuitable and inaccurate to describe the use of a legal product and the continually falling prevalence and consumption rates of tobacco use in the EU.

[154] RAND Report, page 26. See also, RAND Report's repetition of these assertions at pages xxii, 246 and 254.

[155] RAND Report, page 254.

[156] RAND Report, pages i, xxiv, 253, 254.

of evidence linked to the tobacco industry should be carefully considered in the light of this industry's long history of trying to influence tobacco control policy".[157]

6.46 The "reliability" of evidence is only examined in the context of tobacco industry evidence – no such scrutiny is undertaken in respect of other evidence (even if, as demonstrated by various attached expert reports, the evidence base is unreliable when examined against international standards).

6.47 The RAND Report fails to acknowledge that many of the other authors cited in the RAND Report are actively trying to influence tobacco control policies, and that many are funded by public health bodies. For example, in advocating the effectiveness of pictorial warnings, the RAND Report relies on a 2009 International Tobacco Control Policy Evaluation Project which concludes that large pictorial warnings results in increased consumer awareness about the health effects of smoking (compared to consumers who only had access to text warnings), and that vivid images are more easily noticed and remembered by consumers.[158] However, the RAND Report fails to mention that this project is primarily funded and conducted by government health departments, government affiliated organisations, and research institutes funded by the government. Moreover, the remaining private organisations involved in the project include advocacy groups such as cancer societies.[159] The RAND Report fails to caution readers against the reliability of conclusions reached by public health researchers and private lobby groups who may desire to advance their own agenda.

Evidence not suiting RAND Europe's preferred policy recommendations

6.48 Elsewhere, the RAND Report ignores data that do not suit its preferred policy recommendations. For example, in relation to the health risks posed by smokeless tobacco products, despite the lack of evidence, the RAND Report purports to rely on SCENIHR's 2008 report (***SCENIHR 2008***)[160] as a basis for emphasising the potential negative health effects of smokeless tobacco products.

6.49 However, in doing so, it ignores a number of key findings in SCENIHR 2008 which are contrary to RAND Europe's propositions. For example, a key finding of SCENIHR 2008, is 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 2008 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,[161] and that, overall (with the exception of use in pregnancy), smokeless tobacco products are "*clearly less hazardous, and in*

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[157] RAND Report, page 132. See also RAND Report, page 195.

[158] RAND Report, page 130.

[159] International Tobacco Control Policy Evaluation Project, *FCTC Article 11 Tobacco Warning Labels – Evidence and Recommendations from the ITC Project* (2009).

[160] DG SANCO, SCENIHR, *Health Effects of Smokeless Tobacco Products*. Adopted 6 February 2008 (not – as it is noted in the RAND Report – 2007), after public consultation.

[161] SCENIHR 2008, page 113.

relation to respiratory and cardiovascular disease substantially less hazardous, than cigarette smoking".[162] SCENIHR 2008 also found no evidence that smokeless tobacco acted as a "gateway" to future smoking.

Survey data is out-of-date

6.50 In many instances, the survey data used by RAND Europe is out-of-date. For example, Figure 3.4 purports to show cigarette consumption in a number of EU Member States between 1970 and 2000.[163] Table 3.4 presents smoking prevalence figures for youth aged 15 years old across a number of EU countries between 1997 and 2005.[164] More recent data is, however, available and could have been factored into both of these sets of graphs. The use of such out-of-date data ignores other data-sets which exist both at EU level and nationally in the EU Member States.[165]

6.51 Even on the data which the authors have included, it is noted that the percentage of daily smokers in the total population is declining. The RAND Report makes no attempt to explain how this general downward trend impacts the need to further regulate the tobacco industry, as demonstrated *inter alia* by Figure 3.1.[166]

C. RAND EUROPE DOES NOT HAVE THE NECESSARY EXPERTISE

6.52 DG SANCO has failed to ensure that RAND Europe has an appropriately qualified team. In particular and as explained further below, RAND Europe's team does not have the required qualifications for key areas of work; and fails to understand the IA process, which is reflected in recent critique from the IAB.

The authors and organisation are not properly qualified to assess the evidence reviewed

6.53 The IAG requirement for high quality and credible data means that there is a need for critical analysis of the evidence by trained individuals who can not only interpret the evidence but also determine whether the methodology employed was adequate. This is supported by the Commission's *Guidelines on the use of expertise*, which state that the Commission must "*always: (i) seek advice of an appropriately* ***high*** *quality*; *(ii) be* ***open*** *in seeking and acting on advice from experts*; *and (iii)*

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[162] SCENIHR 2008, page 114.

[163] RAND Report, page 33.

[164] RAND Report, page 41.

[165] Numerous Member States release sales data for tobacco products. The French Eco-santé databases (available at: www.ecosante.org) list a number of sources of statistical data on tobacco consumption across the Member States, many of which are calculated on the basis of data supplied by tax and revenue authorities or other sources of sales data. Available at: www.ecosante.org/OCDEENG/813010.html.

[166] RAND Report, page 30.

ensure that its methods for collecting and using expert advice are effective and proportionate"[167] (emphasis added).

6.54 RAND Europe cannot provide a "***high*** *quality*" analysis, as its team does not possess the qualifications which are necessary to assess the evidence contained in the RAND Report. By way of example, Chapters 3 (background for tobacco use and its health effects), 6 (baseline scenario), 10 (ingredients) and 12 (comparing the options) all raise highly technical questions which require input from toxicologists, epidemiologists and biomedical scientists. The RAND Europe team has no members with identifiable experience in these areas, and instead has a heavy bias towards the social sciences.[168]

RAND Europe does not understand the purpose of Impact Assessment

6.55 The *Smart Regulation* paper states: "*given that we depend on businesses, in particular small and medium enterprises, to get us back on the path of sustainable growth,* ***we must limit burdens*** *for them to what is strictly necessary, and* ***allow them to work and compete effectively***" (emphasis added).[169] In other words, the IA process seeks to **minimise** the regulatory burden on stakeholders.

6.56 RAND Europe's approach to its task is contrary to these IA principles. RAND Europe proceeded on the basis that increasing cost to the industry, driving up prices for consumers and reducing profitability are legitimate objectives and desirable outcomes, whilst failing to analyse the knock-on effects that such burdens will have.[170]

6.57 DG SANCO cannot safely rely on a report, as an input into an IA, when that report has been prepared on the basis of a philosophy that contradicts the Commission's approach and the IAG.

6.58 Further, it is clear that the RAND Report has had no regard to the potential legal basis of any revisions to the TPD. On the basis that Article 114 TFEU is the likely legal basis, DG SANCO will need to establish the internal market imperative for the revisions; however, the RAND Report proceeds solely on the basis of public health considerations. The EU has no competence to harmonise the laws and regulations of the Member States for public health objectives. Accordingly, the RAND Report approaches the issues it examines from an incorrect perspective, contrary to EU competence.

The IAB has criticised DG SANCO and RAND Europe's past collaboration

6.59 The Commission has recently confirmed that "*…in principle a positive opinion from the IAB is needed before a proposal can be put forward for Commission*

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[167] *Communication from the Commission on the collection and use of expertise by the Commission: principles and guidelines*, COM (2002) 713, page 10.

[168] Available at: http://www.rand.org/about/people/.

[169] *Smart Regulation in the European Union*, page 2 (emphasis added).

[170] RAND Report, page xxix.

decision".[171] It is therefore important that DG SANCO ensures it complies with the IAG and that the external advice it obtains is of a high quality - which it has so far failed to do. The flaws in RAND Europe's current collaboration with DG SANCO, should, however, have been expected, given the IAB's recent criticism of their collaboration on two other reports regarding food labelling and smoke free environments:

(a) *food labelling*: RAND Europe produced reports and survey data,[172] which fed into DG SANCO's IA. The IAB when considering the IA stated that: "*the presentation of the evidence and the analysis that has been carried out for this Impact Assessment should be considerably improved and expanded on a number of points…*".[173] Specifically: problem definitions needed to be clarified; policy options were presented unclearly; the data collected to analyse effect on administrative burdens was not compatible with the requirements of the EU Standard Cost Model; and impacts on small and medium enterprises (***SMEs***), self-packaging (retail) outlets and outlets selling non-prepackaged foods were not analysed properly, both in terms of depth and consistency; and

(b) *smoke free environments*: RAND Europe was asked to again feed into DG SANCO's IA, by considering the health, social and economic impacts of exposure to tobacco smoke in the EU-27 and examining the likely impacts of five alternative policy options.[174] The IAB cited similar failings to the food labelling assessment, stating *inter alia* that: "*the report should* ***present the expected impacts more cautiously****. The report should present the expected impacts with the qualification that* ***these are outcomes of projections made on the basis of very strong assumptions****. It should also clarify that the evidence base for the projected effect of using particular policy instruments is* ***weak*** *(surveys), and that the effects could vary considerably according to the actual content of such policies*" (emphasis added).[175]

6.60 It is noteworthy that some of the authors of the RAND Report were also involved in these earlier workstreams.[176]

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[171] *Smart Regulation in the European Union*, page 6.

[172] *Assessing the impact of revisions to the EU's horizontal food labelling legislation* (2008) and *Technical Report: Assessing the impact of revisions to the EU nutrition labelling legislation* (2008).

[173] *Impact Assessment on a Draft Proposal for a Regulation of the European Parliament and the Council on Nutrition Labelling of Foodstuffs*, SEC(2008) 97, page 2.

[174] Commission Staff Working Document, *Accompanying document to the proposal for a Council Recommendation on smoke-free environments: Impact Assessment*. RAND Europe produced a technical report: *Analysis to support the Impact Assessment of the Commission's smoke-free initiatives*, SEC(2009) 328 final, page 8.

[175] *Impact Assessment on a Proposal for a Council Recommendation on Smoke-free Environments* SEC(2009) 896, page 2.

[176] For example, Jan Tiessen and Lila Rabinovich are listed as authors of both the food labelling technical report and the RAND Report.

6.61 As JTI has demonstrated, the RAND Report suffers from a number of procedural and substantive flaws so far-reaching that DG SANCO cannot safely use it even to support the development of its own IA. JTI next describes the procedural steps that it considers DG SANCO is obliged to take.

7. THE PROCEDURE DG SANCO MUST FOLLOW

7.1 DG SANCO must ensure that it acts in accordance with the principles of Better Regulation and good administration, including establishing a legal basis and adhering to the principles of proportionality, subsidiarity and transparency.[177] DG SANCO will need to receive a positive opinion from the IAB on these issues, as a minimum, for any proposal to proceed to the Commission.

7.2 Specifically, DG SANCO must prepare an IA which "*is rigorous and comprehensive, and is based on accurate, objective and complete information*".[178] Moreover, it must itself be responsible for the preparation of the IA and cannot delegate policy choices to RAND Europe. As section 4.2 of the IAG indicates: "*The lead service always remains responsible for the content and quality of the IA report. When you use external experts for parts of the IA, the terms of reference should make clear that contractors should follow the key analytical steps set out in Part II of these Guidelines. If you use external experts to carry out public consultations, you must ensure that they adhere to the Commission's minimum standards*".

7.3 In addition, paragraph 16 of the *Interinstitutional agreement on better law-making* obliges the Commission to "*…recognise the need to use, in suitable cases or where the Treaty does not specifically require the use of a legal instrument, alternative regulation mechanisms*". The possibility of discontinuing existing EU action must always be considered as a viable option.[179]

7.4 Of particular concern, in the light of the Consultation and the RAND Report is that DG SANCO must "*establish the 'drivers' – or causes – behind the problem (how*

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[177] DG SANCO's obligation to adhere to the principles of proportionality, subsidiarity and transparency will also enable its compliance with existing interinstitutional agreements to improve the quality of law in the EU. For example, *Interinstitutional agreement on better law-making*, paragraph 2 states "*…the three Institutions agree to observe general principles such as democratic legitimacy, subsidiarity and proportionality, and legal certainty. They further agree to promote simplicity, clarity and consistency in the drafting of laws and the utmost transparency of the legislative process*". The latter point echoes the *Interinstitutional Agreement on 22 December 1998 on common guidelines for the quality of drafting of Community legislation* which states in Recital 2, "*according to the case-law of the Court of Justice, the principle of legal certainty, which is part of the Community legal order, requires that Community legislation must be clear and precise and its application foreseeable by individuals. That* ***requirement must be observed all the more strictly in the case of an act liable to have financial consequences and imposing obligations on individuals in order that those concerned may know precisely the extent of the obligations which it imposes on them***" (emphasis added).

[178] *Inter-Institutional Common Approach to Impact Assessment*, paragraph 5.

[179] IAG, page 30.

particular factors lead to the problem). This will help you to tackle causes rather than symptoms".[180]

7.5 Better Regulation principles, and their impact on the future conduct on this process, are also examined in Professor Cave's Report.

DG SANCO must clarify its IA process

7.6 In order to ensure that DG SANCO prepares an IA which complies with Community law, the IAG and Commission guidelines on working with experts, DG SANCO must clarify, specifically:

(a) the issues to be addressed by the IA;

(b) the legal basis for any proposals it is considering;

(c) the evidence considered;

(d) the quality of analysis of the evidence;

(e) the proportionality of the proposals considered; and

(f) whether the proposals comply with the principle of subsidiarity.

DG SANCO must undertake its own analysis

7.7 DG SANCO must itself undertake RAND Europe's analysis of evidence afresh, on account of the failures of the RAND Report. To rely upon the RAND Report in the IA process would render its results unsafe and susceptible, as a minimum, to a negative opinion from the IAB.

DG SANCO must consult

7.8 In light of the failures of the current processes, and in order to comply with Protocol 2 TEU, the Commission must also consult on numerous issues before it completes its IA:

(a) **IAG omissions**: the issues (and associated evidence) that must be examined under the IAG, but which have not to date been presented to the public or examined in the RAND Report, such as:

  (i) illicit trade;

  (ii) competition;

  (iii) IPR;

  (iv) consumer choice and rights;

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[180] IAG, page 22.

(v) cross-border investment flows;

(vi) impact on the investment cycle;

(vii) burdens on SMEs;

(viii) budget and resource impact on the different levels of government;

(ix) innovation and research;

(x) relations between EU and developing countries; and

(xi) media pluralism and freedom of expression.

(b) **matters outside the Consultation**: any proposal it intends to consider that falls outside the existing Consultation, for example issues or proposals identified in the RAND Report but which are not included in the Consultation, must be subject to consultation;

(c) **threshold issues**: the legal basis, subsidiarity and proportionality assessment for each proposal in the IA must be consulted on;

(d) **evidence to support Consultation assertions**: where proposals in the Consultation are not addressed in the RAND Report, no evidence base *at all* has been presented. The evidence base for any such DG SANCO proposal must be examined through consultation; and

(e) **re-do the evidential analysis**: as DG SANCO should set aside the RAND Report and itself re-do the evidential analysis within the IA process, its work and the evidence on which it relies should be subject to examination through consultation.

7.9 JTI fundamentally disagrees with DG SANCO's recent statement that it does "*not see a need for additional consultation on the impact assessment.*"[181] It is clear from the above that additional consultation is necessary if DG SANCO is to comply with Better Regulation principles.

Conclusion

7.10 DG SANCO must comply with the rules of the Treaties and Better Regulation principles when preparing proposals for legislation. It is the Commission's duty to act in this way, a duty which JTI and all other stakeholders and citizens are entitled to insist DG SANCO respects. JTI is committed to engagement with DG SANCO on issues regarding tobacco regulation, on the basis that DG SANCO itself abides by procedural requirements and engages meaningfully with its obligations and the evidence. Failure to do so may invalidate any resulting amendment to the TPD.

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[181] DG SANCO's letter to CECCM dated 16 November 2010.

THE SCOPE OF THE TPD (CONSULTATION SECTION 1)

8. INTRODUCTION

8.1 DG SANCO notes in its problem definition in Section 1 of the Consultation that the TPD does not cover:

(a) ENDS, such as e-cigarettes;

(b) other products that contain nicotine but not tobacco, such as nicotine drinks and nicotine sweets; or

(c) cigarette-like products which do not contain tobacco, such as herbal cigarettes.

8.2 DG SANCO notes that, while falling outside the scope of the TPD, these products (together, ***out-of-scope products***) are regulated inconsistently by the Member States. For example, ENDS are classified by some Member States as pharmaceutical products, requiring pre-marketing authorisation, while others view them as general consumer products, requiring no specific approvals. Nicotine drinks and sweets may be regulated as food products.

8.3 The Consultation proposes two options: no change, or the extension of the scope of the TPD to cover out-of-scope products. As part of this second option, DG SANCO proposes that "*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*", while "*novel forms of oral tobacco would be banned similarly to snus*".[182]

8.4 JTI believes that, at present, the only appropriate option is Option 1: no change. Option 2, as currently drafted, would not be an appropriate basis for regulation because it would impose a ban on "*novel forms of oral tobacco*"[183] without defining what the term means or demonstrating any need for a specific prohibition. The 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. However, DG SANCO's statements concerning "*new tobacco products*" appear uncontroversial, since it is already the case that tobacco products (new or otherwise) are subject to constituents information, health warning and ingredients disclosure requirements. See further paragraphs 10.1-10.8, below.

9. DEVELOPING AN APPROPRIATE REGIME

9.1 JTI believes that all consumer products should be subject to appropriate regulation and that all products containing tobacco, which are marketed in the EU, should be regulated under the TPD. The Commission has stated elsewhere that ENDS

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[182] Consultation, page 5.

[183] *Ibid.*

will be subject to the TPD if they contain tobacco, and that even a marginal amount of tobacco is enough to mean that such products fall within the TPD's scope.[184]

9.2 However, DG SANCO has not adequately demonstrated a need for out-of-scope products – which do not contain tobacco – to be brought within the scope of the TPD or otherwise regulated.

Inadequate evidence that out-of-scope products require regulation

9.3 Neither the Consultation nor the RAND Report provides any evidence that out-of-scope products require regulation on internal market or public health grounds. In particular, the RAND Report is silent on what health risks (if any) out-of-scope products pose, or what actual harm (if any) they cause.

9.4 Indeed, the authors of the RAND Report note that "*the use of products that contain nicotine but not tobacco, such as electronic cigarettes or nicotine drinks, is very low*"[185] and that "*knowledge about these products in terms of their use, manufacturing and composition remains poor*".[186] As regards smoking products which do not contain tobacco, such as herbal cigarettes, the authors write that information is "*underdeveloped*", but that such products have not been of major concern to Member State regulators. They state that "*the overall impression is that they are niche products with fairly stable or even stagnating market shares*".[187]

Inadequate definition of out-of-scope products

9.5 Neither the Consultation nor the RAND Report offers clear definitions of the types of out-of-scope products which DG SANCO contemplates bringing within the scope of the TPD. In particular, no definition is offered for ENDS.

9.6 Providing adequate definitions and defining the revised scope of the TPD will require careful drafting. For example, the inclusion of all "*products which are marketed as alternatives to tobacco products*" (as proposed in the Consultation) would risk catching pharmaceuticals such as nicotine replacement therapy products. Conversely, provisions which state that out-of-scope products should be included within the scope of the TPD "*insofar as they are not already covered by other EU legislation (food, pharmaceutical)*"[188] should be avoided, since:

(a) all consumer products are "*covered by other EU legislation*" (e.g. Directive 2001/95/EC on general product safety); and

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[184] European Commission, *Orientation Note – Electronic Cigarettes and the EC Legislation*, Brussels, 25.05.2008, page 2.

[185] RAND Report, page 116.

[186] RAND Report, page 117.

[187] RAND Report, page 117.

[188] Consultation, page 4.

(b) such language would lead to continued differing interpretations[189] of how these products should be regulated at a Member State level. For example, one Member State might continue to take the view that a particular product should be regulated as a tobacco product, and another that the same product should be treated as a medicinal product.

9.7 Before any new definitions relating to out-of-scope products are formally proposed, JTI and other stakeholders should be given the opportunity to comment on the wording of those definitions.

10. OPTIONS FOR CHANGE

10.1 On the basis of the above, JTI believes that, at present, the only appropriate option is Option 1: no change. To the extent that DG SANCO is concerned as to the safety of out-of-scope products, JTI notes that these products are covered by other EU legislation with public health objectives (food or pharmaceuticals regulation or, at a minimum, Directive 2001/95/EC on general product safety).

10.2 In addition to extending the scope of the TPD to cover out-of-scope products, Option 2 contains statements in respect of "*new tobacco products*" and "*novel forms of oral tobacco*". The purpose of these statements is unclear. It may be that DG SANCO is simply affirming that, if there were no other changes to the TPD beyond those proposed here, new products containing tobacco would continue to be treated as tobacco products, and new oral tobacco products (unless intended to be smoked or chewed) would continue to be prohibited.[190]

10.3 However, if DG SANCO's intention is to attempt to impose separate regulation in respect of "*novel forms of oral tobacco*", in particular, this would be inappropriate for the reasons described below.

10.4 First, any new prohibition on novel forms of oral tobacco would be arbitrary, and would not accurately reflect developments in the science that have occurred since the date that the existing Article 8 prohibition was introduced. Indeed, as described at Section 12 below, JTI strongly believes that the current ban should be lifted for all smokeless tobacco products, provided that suitable controls are put in place.

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[189] RAND Report, pages 118-120.

[190] Article 8 of the TPD currently prohibits the placing on the market of "*tobacco for oral use*" in all of the Member States apart from Sweden, which has a derogation from this prohibition that is guaranteed by its Treaty of Accession. Tobacco for oral use is defined as "*all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets, or in a form resembling a food product*" (Article 2(4) of the TPD). The key practical effect of these provisions is that chewing tobacco may be freely placed on the EU market, whereas the sale of snus and snus-like products, which are not chewed, is prohibited, except in Sweden (which was granted an exemption to the ban when it joined the EU in 1995). Norway, which is a member of the EEA but not the EU, likewise obtained a derogation from the prohibition (Article 1(1) of Decision of the EEA Joint Committee 31 January 2003).

10.5 Second, the question of how, if at all, the TPD should be modified to deal with smokeless tobacco (including oral tobacco) is considered in the context of Section 2 of the Consultation. Seeking to prohibit "*novel forms of oral tobacco*" here therefore prejudges the outcome of the present consultation exercise in that regard. If, in the context of Section 2 of the Consultation, it was ultimately decided that the status quo should be maintained, or that all smokeless tobacco products should be banned, then non-chewing oral tobacco could presumably not lawfully be marketed in the EU (except in Sweden) or in EEA states (except in Norway). If, as JTI believes should be the case, the ban were lifted, then presumably "*novel forms of oral tobacco*" could lawfully be sold throughout the EU, provided that they complied with applicable requirements.

10.6 Third, neither the Consultation nor the RAND Report define what is meant by "*novel forms of oral tobacco*" or provides any evidence as to how these products are or may be used, or what harm they cause or may cause.

10.7 Fourth, it follows that there is no justification for a separate prohibition on "*novel forms of oral tobacco*" on a precautionary basis. In particular, neither DG SANCO nor RAND Europe has identified potentially negative effects flowing from the introduction of such (hypothetical) products and there has been no scientific evaluation of such (hypothetical) products.[191]

10.8 Finally, a prohibition on "*novel forms of oral tobacco*" might also have a negative impact on the future development of potentially reduced exposure and/or risk products. As described at paragraphs 12.6 – 12.12, below, SCENIHR 2008 was a comprehensive review of the health effects of smokeless tobacco products (including Swedish snus). SCENIHR 2008 concluded that such products are "*clearly less hazardous*" than cigarette smoking and that, in any event, there was no evidence that the use of smokeless tobacco products was associated with any major health hazard not already associated with cigarette smoking. It follows that smokeless tobacco products may, in future, offer fruitful avenues for future research and development.

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[191] *Communication from the Commission on the precautionary principle* COM(2000) 1 final, page 13.

SMOKELESS TOBACCO PRODUCTS (CONSULTATION SECTION 2)

11. INTRODUCTION

11.1 DG SANCO states in its problem definition in Section 2 of the Consultation that the current regulatory framework bans some smokeless tobacco products ("snus"), while others (e.g. chewing tobacco) are freely available in many Member States.[192] Besides keeping the status quo, the options proposed by the Consultation for discussion are "*lifting the ban on snus*" (option 2) and introducing a "*ban on all types of smokeless tobacco products*" (option 3).

11.2 JTI accepts elements of DG SANCO's problem definition, namely its description of the distinction drawn by the current EU prohibition on smokeless tobacco products between tobacco for oral use (unless intended to be smoked or chewed) and other smokeless tobacco products. However, JTI considers that DG SANCO:

(a) quotes SCENIHR 2008 selectively in relation to the health risks of smokeless tobacco products (see paragraphs 12.6-12.10, below);

(b) ignores SCENIHR's and other organisations' conclusions on the potential role of smokeless tobacco products in harm reduction (see paragraphs 12.11-12.12, below); and

(c) fundamentally mischaracterises the evidence in relation to such products' potential role as "gateway" products to subsequent cigarette smoking (see paragraph 12.15, below).

11.3 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, 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.

11.4 In JTI's view, the current prohibition on tobacco for oral use should therefore be lifted. The prohibition is arbitrary (being based solely on intended mode of use) and does not accurately reflect developments in the science that have occurred since the date that the prohibition was introduced.

12. LIFTING THE BAN ON TOBACCO FOR ORAL USE

12.1 JTI believes that all smokeless tobacco products that meet appropriate legal and technical requirements should be permitted for sale in the EU. Specifically, JTI supports option 2 ("*lifting the ban on snus*"), provided that:

(a) the ban is lifted for all smokeless tobacco products, and not just tobacco for oral use/snus;

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[192] See further footnote 190 above.

(b) requirements are put in place that any smokeless tobacco product placed on the EU market must:

(i) meet appropriate quality standards, such as those detailed in the European Smokeless Tobacco Council (***ESTOC***) regulatory proposal,[193] in order to address concerns raised by SCENIHR and others about such products' chemical composition;

(ii) respect other provisions of the Directive concerning labelling, ingredients reporting, etc.; and

(c) consistent with other tobacco products, Member States prevent the sale of such products to minors.

Lack of scientific justification for continued ban on tobacco for oral use

12.2 The EU ban on tobacco for oral use was first introduced by Council Directive 92/41/EEC.[194] The purpose of the ban was to harmonise Member States' divergent rules concerning oral moist tobacco products,[195] which the Commission regarded as dangerous,[196] addictive, and as holding "*a particular attraction for young people*".[197] There was also concern that such products might act as a "gateway" to smoking among minors.

12.3 The recitals to Council Directive 92/41/EEC noted that such products were "*particularly attractive to young people*", and that smokeless tobacco products generally were "*a major risk factor as regards cancer*". However, Directive 92/41/EEC permitted chewing tobacco, and other types of smokeless tobacco that did not fall within the definition of "*tobacco for oral use*", to be sold in the EU, provided that they carried the specific warning: "*Causes cancer*".[198]

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[193] Available at: http://www.estoc.org/regulation/estoc-s-way-forward.

[194] Directive 92/41/EC introduced a new Article 8a into the existing Tobacco Labelling Directive (89/622/EEC), which prohibited the placing on the market of tobacco for oral use in substantially the same way as does Article 8 TPD.

[195] Commission, *Proposal for a Council Directive amending Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products* COM(90) 538 final – SYN 314, page 3. The proposal noted that the UK and Ireland had already banned oral moist snuff tobaccos, and that Belgium was planning to do so.

[196] The Commission's findings as to health risks of oral moist tobacco products were based in part on the 1986 U.S. Surgeon General's Report, which suggested that moist snuff tobacco sold in the U.S. contained high levels of nitrosamines, Polonium-210 and other carcinogenic substances. See European Commission, *Proposal for a Council Directive amending Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products* COM(90) 538 final – SYN 314, page 6. However, as noted at paragraph 12.18, below, SCENIHR's 2008 report on smokeless tobacco reported that levels of substances of concern in Swedish snus were significantly lower than in U.S. products.

[197] *Ibid*, pages 6-7.

[198] Article 3 of Directive 92/41/EEC, introducing a new paragraph 2a into Directive 89/622/EEC.

12.4 In 1999, the Commission published its proposal for the TPD.[199] While the recast version of this proposal did not propose repealing the prohibition on tobacco for oral use (or the continuing, arbitrary distinction between chewing and other forms of oral tobacco), it did recommend replacing the existing, specific warning with a warning that: "*Smokeless (or oral, as appropriate) tobacco can damage your health*". This new warning would be required not only for chewing tobaccos, but for other permitted smokeless tobacco products (e.g. nasal snuff), as well as for snus sold in Sweden (which, as noted, had negotiated an exemption from the ban on oral tobacco when it acceded to the EU). The Commission advocated this change because:

> "*scientific opinion no longer supports a strong warning as is currently set out in Directive 92/41/EEC ('Causes Cancer'). It is therefore proposed to replace this warning with a more general one. This will better reflect the established health risks for such product…*".

12.5 In other words, by 1999, the Commission had (in JTI's view, quite correctly) accepted that smokeless tobacco products did not pose the same health risks as had been claimed in the early 1990s, when the original prohibition on their placing on the market was introduced. This was also the view of the European Parliament's Committee on Industry, External Trade, Research and Energy, which, during the European Parliament's consideration of the draft TPD, called for the deletion of its Article 8, on the basis that the Commission had identified an evolution in scientific opinion and that, "*prohibition therefore is not required*".[200]

12.6 The Commission recognised the fact that the science has evolved since the early 1990s, when this prohibition was first introduced, in 2007's second report on the application of the TPD. There, it was noted that: "*In order to obtain a better understanding of the health effects of various smokeless tobacco products and their role in smoking cessation and initiation, DG SANCO requested an opinion from its Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).*"[201] The Commission's mandate to SCENIHR expressly referenced the evolution of the science: "*Given recent developments with regard to the composition of some smokeless tobacco products and the claims that the use of smokeless tobacco could*

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[199] European Commission, *Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (recast version)*, OJ C150E, page 43. 2000/05/30 (Celex no. 599PC0594).

[200] Committee on the Environment, Public Health and Consumer Policy, *Report on the proposal for a European Parliament and of the Council directive on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (recast version)* (1999/0244(COD)) (Rapporteur: Jules Maaten), page 63. The justification offered by the Industry, External Trade, Research and Energy Committee for deleting Article 8 of the draft TPD, set out in its opinion to the Environment, Public Health and Consumer Policy Committee, was as follows: "*In the explanatory memorandum, the Commission states that in respect, however, of health warnings to be indicated on such products and in respect of other smokeless tobacco products (e.g. nasal snuff), scientific opinion no longer supports a strong warning: Prohibition therefore is not required.*" (emphasis as original)

[201] Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee, *Second Report on the Application of the Tobacco Products Directive*, COM(2007) 754 final, page 9.

reduce harm associated with tobacco products, DG SANCO wishes to review the scientific basis for the current regulatory framework".[202] In its second report on the application of the TPD, the Commission agreed to be bound by SCENIHR's findings in this regard: "*The final scientific opinion on the health effects of smokeless tobacco products will form the scientific basis for any future risk management decision of the Commission on this issue*".[203]

12.7 The evolution in the science was in fact recognised by SCENIHR in the 2008 final review that resulted from the Commission's mandate.[204] In the Consultation, DG SANCO correctly describes the conclusions of SCENIHR 2008 as being that "*for an individual, substitution of smoking by the use of smokeless tobacco products would probably decrease the incidence of some tobacco-related diseases*".[205]

12.8 However, on the evidence of the Consultation, it now appears that DG SANCO wishes to depart from its earlier stated intention to use SCENIHR 2008 as the basis for the future regulation of smokeless tobacco products. The material from SCENIHR 2008 that DG SANCO cites in the Consultation is, with the exception noted above, negative and partial.[206] The extracts cited give the impression that SCENIHR 2008 amounts to an indictment of smokeless tobacco products, which is far from the case. For example, the Consultation misquotes the first part of one of SCENIHR 2008's conclusions on cardiovascular diseases[207] – elevating SCENIHR's finding that "*it appears that the use of smokeless tobacco increases the risk of death after myocardial infarction…*" to a statement that smokeless tobacco *does* increase this risk – and omits the remainder of the relevant sentence in SCENIHR 2008 ("... *but that it does not increase the risk of myocardial infarction*"). DG SANCO also ignores SCENIHR's finding that "*if snus use increases the risk of myocardial infarction it does so to a less extent than smoking*",[208] and that, overall, in relation to cardiovascular disease, a "*conservative conclusion*" would be that "*substitution of smoking by snus use would, in due course, reduce the cardiovascular mortality that currently arises from tobacco use by at least 50%.*"[209]

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[202] SCENIHR, *Request for a scientific opinion on Health Effects of Smokeless Tobacco Products.* Available at: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_004.pdf.

[203] Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee, *Second Report on the Application of the Tobacco Products Directive*, COM(2007) 754 final, page 9.

[204] DG SANCO, SCENIHR, *Health Effects of Smokeless Tobacco Products*. Adopted 6 February 2008, after public consultation.

[205] Consultation, page 5.

[206] Aside from the statement above concerning the probable relative risk implications of substitution of smokeless tobacco products for smoking at an individual level, the Consultation reproduces only negative findings from SCENIHR 2008 concerning such products (e.g., "*All smokeless tobacco products are addictive and can cause cancer. They also increase the risk of death after a myocardial infarction and have additional cardiovascular effects as stated in [SCENIHR 2008].*" (Consultation, page 5.)

[207] SCENIHR 2008, page 96.

[208] SCENIHR 2008, page 114.

[209] *Ibid.*

12.9 In fact, contrary to the impression given by the Consultation, SCENIHR 2008 concluded overall 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,[210] and that, overall, "*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*."[211] Similar conclusions were reached in 2007 by the UK Royal College of Physicians[212] and the New Zealand Health Technology Assessment Agency.[213]

12.10 In relation to the likely population-level effects of permitting the free circulation of smokeless tobacco products in the EU, SCENIHR 2008 cited recent cohort studies in northern Sweden, which had suggested 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. Although this undoubtedly reflects the effect of other tobacco control measures, this is not necessarily the sole explanation as Sweden ranks only 6th amongst the EU 25 countries in terms of overall tobacco control policy implementation, behind Iceland, UK, Norway, Ireland and Malta, all of which have higher smoking prevalences than Sweden (TNS Opinion & Social 2006). It is therefore possible that the particularly low smoking prevalence in northern Sweden reflects some of the estimated attributable effect of the availability of STP (Swedish National Board of Health and Welfare 2005)*".[214]

12.11 Data of this sort has led others, including the UK's Royal College of Physicians,[215] ASH UK[216] and the American Association of Public Health Physicians

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[210] SCENIHR 2008, page 113.

[211] SCENIHR 2008, page 114. The RAND Report misrepresents SCENIHR's overall conclusions, focusing exclusively on the health risks posed by smokeless tobacco products (without considering the issue of relative health risks). See RAND Report, page 46.

[212] Royal College of Physicians, *Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians* (2007), London: RCP. Available at: http://www.tobaccoprogram.org/pdf/4fc74817-64c5-4105-951e-38239b09c5db.pdf.

[213] Broadstock, M., *Systematic review of the health effects of modified smokeless tobacco products*, NZHTA Report 2007; 10(1). Available at: http://nzhta.chmeds.ac.nz/publications/smokeless_tobacco.pdf.

[214] SCENIHR 2008, page 116.

[215] Royal College of Physicians, op. cit, page 161.

[216] Under the heading "Harm Reduction", ASH UK's website (accessed 10 November 2010) states that: "*One way of reducing the harm caused by tobacco may be to facilitate the switch from smoked tobacco products to the use of 'clean', non-tobacco, nicotine products.*" ASH UK then cites a number of studies on this issue. Available at: http://www.ash.org.uk/current-policy-issues/harm-reduction-product-regulation/harm-reduction

(***AAPHP***)[217] to conclude that encouraging cigarette smokers to switch to smokeless tobacco products, subject to appropriate controls, could form an important part of reducing the harm associated with smoking. The AAPHP reconfirmed its support for a tobacco harm reduction strategy that includes the use of smokeless tobacco in June 2010, in a recent report which stated that new scientific developments on this issue between 2008 and 2010 – i.e. since the date of SCENIHR's analysis – had "*significantly strengthened*" the case for such a strategy:[218]

> "*In October 2008 the American Association of Public Health Physicians (AAPHP) became the first medical organization in the U.S. to officially endorse tobacco harm reduction as a viable strategy to reduce the death toll related to cigarette smoking. Since the AAPHP endorsement there have been numerous contributions to the scientific literature that add to the scientific foundation for tobacco harm reduction. This report describes these published studies, which include meta-analyses of the risk of cancer and cardiovascular diseases among smokeless tobacco (ST) users and evidence from clinical trials that ST is an effective substitute for cigarettes. It also discusses American studies concerning whether ST use is a gateway to smoking and other topics relevant to tobacco harm reduction. The new research significantly strengthens 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.*"

12.12 Despite this evidence, others have suggested that permitting the sale of smokeless tobacco products might have adverse population-level effects.[219] However, SCENIHR 2008 observed that a recent paper by Gartner et al. had estimated that, even accounting for the possibility of some uptake of smokeless tobacco products by

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[217] In 2008, the AAPHP published a white paper concerning tobacco harm reduction strategies, which concluded: "*For smokers unable or unwilling to quit (that is, they are unable or unwilling to overcome their addiction to nicotine), encouraging them to switch to the lowest risk ST products would be an effective way for them to reduce their risk of tobacco-related illness and death.*" (page 3). Available at: http://www.aaphp.org/special/joelstobac/20081026HarmReductionResolutionAsPassedl.pdf.

[218] Rodu, B. and Nitzkin, J., *Update on the Scientific Status of Tobacco Harm Reduction, 2008-2010*, prepared for the American Association of Public Health Physicians. Available at: http://www.aaphp.org/special/joelstobac/2010/harmredcnupdatejuly2010.html.

[219] A recent, much cited paper by Meija, A.B., Ling, P.M. and Glantz, S.A. (2010) attempted to model the aggregate health impacts of a free market in such products in the US, and concluded that "*even if replacing cigarettes with e-cigarettes or snus significantly reduces the individual user's use of death, a public health strategy based upon promoting such nicotine-administration products may save few if any lives*". However, prominent members of the public health community have criticised this research's flawed methodology. For example, the Chair of the Tobacco Control Task Force of the AAPHP accused the authors of having run "*a number of Monte Carlo assumptions based on a set of totally unrealistic assumptions to reach the conclusion that promoting smokeless tobacco as a safer alternative to cigarettes is unlikely to result in substantial health benefits at a population level*". The correct conclusion, in his view, was that "*The currently available science gives us very good reason to believe on a basis of far more likely than not, that such a harm reduction initiative [permitting the sale of smokeless tobacco products] will achieve the desired public health benefits among smokers.*" (Available at: http://tobaccocontrol.bmj.com/content/19/4/297.abstract/reply#tobaccocontrol_el_3474.).

minors, and in terms of aggregate public health impact, "*the overall effect is therefore likely to be beneficial*".[220] The authors also suggested that concerns about potentially adverse population-level effects could be addressed by other means, citing a study by Levy et al. (2006), which estimated that the impact of introducing a product such as snus to the U.S. market, promoted with a warning stating: "*This product is addictive and may increase your risk of disease. This product is substantially less harmful than cigarettes, but abstaining from tobacco use altogether is the safest course of action*", would be an overall decrease in the prevalence of smoking of between 1.3 and 3.1 percentage points over five years.[221] Other scientists have taken a similar view. For example, Bates, Fagerström et al. (2003) concluded that it was "*unlikely*" that lifting the ban would lead to negative overall population effects, but that if this were the case then "*policy drivers such as taxation and modifications of the product standards could be used to trim demand*".[222]

Addressing concerns that smokeless tobacco products may be used by minors

12.13 As noted at paragraph 12.2 above, a key justification for the original prohibition on tobacco for oral use was that some smokeless tobacco products (particularly snus) were considered to be "*particularly attractive to young people*". Concerns have also been expressed that their use might act as a "gateway" to smoking.

12.14 Concerns of the sort described above do not appear to be justified, based on the extant scientific evidence.

12.15 JTI is aware of no reliable evidence that shows that smokeless tobacco products are "*particularly attractive*" to minors, and SCENIHR concluded that the question of whether such products acted as a gateway to future smoking had not been systematically evaluated.[223] However, SCENIHR also noted that the evidence from northern Sweden (where the ban on tobacco for oral use does not apply) was that "*gateway progression from snus to smoking [had] not been a significant problem in Swedish young people*".[224] This is supported by data from the most recent World Health Organization (***WHO***) Health Behaviour in School-aged Children (***HBSC***) study, as reported in SCENIHR 2010, which show that the weekly smoking prevalence rate among Swedish 15 year-old boys was the lowest for all EU Member States surveyed, while the equivalent rate for Swedish 15 year-old girls was the second lowest in the EU. Both figures were significantly lower than the EU average weekly prevalence rate for 15 year olds.[225] Other scientists have reached similar

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220 SCENIHR 2008, page 117.

221 SCENIHR 2008, page115.

222 Bates, C., Fagerström, K., Jarvis, M.J., Kunze, M., McNeill, A., Ramström, L. "European Union policy on smokeless tobacco: a statement in favour of evidence based regulation for public health". *Tobacco Control* (2003) 12:360-367, page 362.

223 SCENIHR 2008, pages 5, 12, 107-108.

224 SCENIHR 2008, page 116.

225 SCENIHR 2010, Table 5 at page 78. The reported weekly smoking rate among Swedish boys in the 2001-2002 HSBC survey was 11.1 per cent (as compared to an average level of 23.47 per cent

conclusions. Bates, Fagerström et al. (2003) noted that "*the data do not show that initial smokeless tobacco use adds to the propensity to become a smoker*".[226] Foulds et al. (2003) reached similar conclusions on the basis of the Swedish data[227]. Furberg et al. (2005) interpreted the Swedish data as showing that "*snus use was associated with smoking cessation but not initiation*".[228]

12.16 To the extent that such concerns persist, however, JTI's view is that they can be more proportionately addressed by subjecting smokeless tobacco products to e.g. the TPD's requirements on labelling and warnings (see paragraph 12.20 below) and by prohibiting the sale of these products to minors.

Addressing concerns over the chemical composition of smokeless tobacco products

12.17 SCENIHR 2008 stated that smokeless tobacco products contained nicotine, as well as compounds that have been identified as carcinogens, such as certain non-volatile tobacco-specific nitrosamines (***TSNA***, such as NNN and NNK) and *N*-nitroamino acids.[229] The authors stated that some forms of smokeless tobacco product also contained polycyclic aromatic hydrocarbons.[230] The presence of such compounds in oral tobacco also formed part of the Commission's explanation for the original prohibition.[231]

12.18 On this basis, it may be appropriate for DG SANCO, in the context of repealing the current prohibition on the EU sale of tobacco for oral use, to address concerns over the constituents of smokeless tobacco products. A simple way of achieving this would be for any revised version of the TPD to mandate that smokeless tobacco products may only be placed on the EU market if they meet defined standards. JTI supports the standard proposed by ESTOC.[232] It appears that the use

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among the Member States surveyed). The equivalent rate for Swedish girls was 19.0 per cent (as compared to an average level of 24.16 per cent).

226 "*Smokers may move to smokeless tobacco or use smokeless tobacco to quit, where they would otherwise have continued to smoke. Starters on smokeless tobacco may continue as smokeless users but [might] otherwise have started with cigarettes, so that smokeless tobacco is a diversion from smoking. In both the USA and Sweden, most smokeless tobacco use cannot be a gateway to smoking, either because smokeless users never started smoking or because they started smoking first. For the minority who started using smokeless before cigarettes, they may or may not have had their smoking caused by smoking use*". Op. cit. (emphasis as original), page 362.

227 Foulds, J., Ramström, L., Burke, M., & Fagerström, K., "Effect of smokeless tobacco (snus) on smoking and public health in Sweden", *Tobacco Control* (2003) *12*, 349–359.

228 Furberg, H., Bulik, C. M., Lerman, C., Lichtenstein, P., Pedersen, N. L., & Sullivan, P. F. "Is Swedish snus associated with smoking initiation or smoking cessation?", *Tobacco Control* (2005)*14*, 422–424.

229 Pages 24 and 119.

230 *Ibid*.

231 *Proposal for a Council Directive amending Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products* COM(90) 538 final – SYN 314, page 6. See footnote 196, above.

232 Available at: http://www.estoc.org/regulation/estoc-s-way-forward.

by European tobacco manufacturers of standards similar to the ESTOC standard may have contributed to the reductions in levels of certain compounds of concern that were reported by SCENIHR in its 2008 report.[233]

Subjecting all smokeless tobacco products to the requirements of the TPD

12.19 Smokeless tobacco products that are currently permitted to be sold in the EU (e.g. chewing tobacco) must meet warning, ingredients disclosure and other requirements under the TPD. Table 1, below, sets out JTI's understanding of the provisions of the TPD that apply to permitted smokeless tobacco products.

Directive requirement relevant to obligations of tobacco product manufacturers	**Applies to smokeless tobacco products?**
Article 3: Maximum tar, nicotine and CO yields.	No. Cigarettes only.
Articles 4(1)-(2): Measurement methods for tar, nicotine and CO yields.	No. Cigarettes only.
Articles 4(3)-(5): Measurement of other smoke constituents and disclosure to national authorities.	Yes, if Member States so require. The wording refers to "*tobacco products*".
Article 5(1): Labelling of tar, nicotine and CO yields.	No. Cigarettes only.
Articles 5(2)-(3): Rotating health warnings.	No. Does not apply to "*tobacco for oral use and other smokeless tobacco products*".
Article 5(4): Requirement for warning that: "This tobacco product can damage your health and is addictive".	Yes. This is a special warning that applies to "*tobacco products for oral use, where their marketing is permitted under Article 8, and smokeless tobacco products.*"
Article 5(5): Warning size requirements.	Yes. The Article 5(4) warning must cover not less than 30% of the most visible external surface of the packaging (32% where two official languages, 35% where three). There are different size requirements for "*products other than cigarettes*" whose most visible surface area exceeds 75cm^2
Articles 5(6)-(8): Other requirements re warning (font size, method of printing, attribution).	Yes.
Article 5(9): Batch-marking.	Yes.
Article 6: Ingredients disclosure and dissemination.	Yes. Refers to "*manufacturers and importers of tobacco products*".
Article 7: Descriptor ban.	Yes. Refers to "*packaging of tobacco products*".

Table 1: Directive requirements applicable to permitted smokeless tobacco products

12.20 If the ban on other smokeless tobacco products were lifted:

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[233] SCENIHR 2008, page 25, reported that "*[i]n recent years there has been a declining trend in NNN and NNK levels in moist snuff in Europe that the manufacturers attributed to selection of raw materials with low levels of TSNA and inhibition of nitrosation reactions during the processing and storage of products (Osterdahl et al. 2004). The moist snuff produced and purchased in Sweden in this study had an average value of NNN and NNK 0.5 and 0.2 µg/g wet weight (Stepanov et al. 2006). Two brands with similar manufacturing process as the one used in Sweden to reduce harmful nitrosamines, had mean levels of 0.98 and 2.2 µg NNN/g and 0.18 and 0.26 µg NNK/g wet weight, respectively*".

(a) the requirements listed in Table 1 would presumably apply to all smokeless tobacco products. The fact that the packaging of such products would have to carry the special health warning mandated by Article 5(4) of the TPD would address the concerns expressed in the Consultation[234] that "*all smokeless tobacco products are addictive and can cause cancer*"; and

(b) other controls applicable to tobacco products (e.g. the Tobacco Advertising Directive (2003/33/EC)) would also presumably apply to smokeless tobacco.

Member States should not be permitted to impose barriers to the free circulation of smokeless tobacco products

12.21 Permitting smokeless tobacco products to be placed on the EU market, subject to the conditions already described, would serve internal market objectives by creating a free and unhindered market in smokeless tobacco products that met the requirements already described and by ensuring that Sweden was no longer treated differently from other Member States in this regard. The position of Norway[235] would also be regularised.

12.22 In order to meet these internal market objectives, it would be important to ensure that Member States implemented any such revisions to the TPD consistently. This would also create necessary legal and business certainty. JTI believes that Member States should be required to allow the sale of smokeless tobacco products in their markets, provided that they meet appropriate quality standards and comply with the revised TPD, without setting further regulatory obstacles of their own (e.g. pre-authorisation requirements or requirements that products comply with Member State-level positive or negative ingredients lists).

13. RESPONSE TO PROPOSED BAN ON ALL SMOKELESS TOBACCO PRODUCTS

13.1 Option 3 of Section 2 of the Consultation is to ban all smokeless tobacco products (including those which are currently permitted for sale in the EU today, such as chewing tobacco and nasal snuff). JTI strongly opposes such action:

(a) **neither the Consultation nor the RAND Report sets out any evidence whatsoever in support of extending the prohibition in this way**. Nor does either document consider the potential impact of such an extension, e.g. on those adult consumers in some Member States (such as Germany) who prefer chewing tobacco to other tobacco products;

(b) in order for the Commission to justify a decision to extend the current prohibition, based wholly or in part on Article 114 TFEU, DG SANCO would need to demonstrate that this was justified on the basis of new developments based on scientific facts (Article 114(3) TFEU). However, as described above, **the scientific data since 2001 suggests that the correct course would be to lift the current ban, not to extend it**;

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[234] Consultation, page 5.

[235] See footnote 190, above.

(c) any ban on all smokeless tobacco products could not lawfully extend to those EU and EEA members which have derogations from the existing ban on oral tobacco that are guaranteed by Treaty (Sweden) or otherwise (Norway).[236] **Such a ban would thus continue to be inconsistent with internal market rules and the current lack of harmonisation would continue**; and

(d) such a prohibition might also have a negative impact on the future development of potential reduced exposure products (***PREPs***).

[236] See footnote 190, above.

CONSUMER INFORMATION (CONSULTATION SECTION 3)

14. INTRODUCTION

14.1 Section 3 of the Consultation refers to "*Consumer Information*".

14.2 Although there is already a very high level of awareness of the health risks of smoking amongst EU consumers, effective communication is essential in order to ensure that smokers continue to be reminded of those risks. JTI supports the continued provision of information to consumers about the health risks of smoking.

14.3 Regulators have access to a variety of communication vehicles by which this shared goal can be achieved. On-pack health warnings are one such vehicle among many. In markets where warnings are mandatory, such as in the EU, JTI complies with all legal requirements. JTI voluntarily places a health warning on all its cigarette packs and marketing (where permitted) where JTI is not required to do so by law.

14.4 However, effective communication should not rely on on-pack health warnings alone. Regulators should consider a mix of communications vehicles. Recent official research[237] suggests that, where various vehicles are used, television is cited by today's adult consumers and youth as the main source of information on smoking and health.[238] Print media, newspapers and magazines and the Internet[239] are also important sources of information. Public authorities should therefore consider introducing or expanding existing public health information programmes. It seems that DG SANCO itself recognises this. On 7 October 2010, it issued a tender for the organisation of a communication campaign aimed at encouraging smoking cessation targeting, in particular, young adults, an initiative with a budget of €16.8 million.[240]

14.5 JTI is concerned, at the outset, that Section 3 of the Consultation ignores the importance of a varied media mix for effective communication with consumers, and defines the "problem" of consumer communication solely by reference to tobacco product packaging. The problem definition, and hence the possible options are flawed as unduly narrow, contrary to the evidence.

Consumer communication and tobacco product packaging

14.6 Section 3 of the Consultation proceeds on the basis that there are various "problems" related to tobacco packaging. Before addressing each of the specific possible options, it is important to address certain fundamental misconceptions that

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[237] See, notably, Surveys by Environics Research Group Limited, *The Health Effects of Tobacco and Health Warnings on Cigarette Package*, Wave 13, Survey of Adults and Adult Smokers (2008), page 14; *Survey of Youth* (2008), page 14.

[238] Youth also cite schools as a main source of information.

[239] The popularity of the Internet as a source of information amongst youth on the risks associated with smoking has also been identified in surveys. See, notably, Elliott and Shanahan Research for the Australian Department of Health, *Evaluation of the effectiveness of graphic health warnings on tobacco products* (2008), page 174.

[240] Available at: http://ted.europa.eu/udl?uri=TED:NOTICE:292569-2010:TEXT:EN:HTML

underlie DG SANCO's problem definition. DG SANCO's "problems" regarding tobacco packaging are based upon a series of assumptions and assertions that are wrong, and which have the effect of incorrectly defining the debate regarding tobacco packaging.

(a) Packaging is not a predictor of smoking by minors

14.7 The Consultation proceeds on the basis that "*packaging and product features are increasingly used to attract customers, to promote products and brand image*".[241] However, **the notion that tobacco product packaging is a predictor of smoking by minors or initiation is misconceived**. It is notable that the Consultation does not identify packaging as a predictor for the onset of smoking by minors. Any definition of the "problem" of tobacco packaging by reference to smoking by minors or initiation is fundamentally flawed.

14.8 JTI's response in relation to issues of smoking among minors is guided by Professor Steinberg's Report. His report draws on research on adolescent decision-making and risk-taking and on the implications of this research for discouraging and/or preventing underage smoking, and JTI hopes and intends that it is of assistance to the Commission in evaluating the proposals set out in the Consultation.

14.9 Professor Steinberg's expert view is that minors' experimentation with tobacco must be seen in the context of other risk-taking behaviours (e.g. driving while drunk or having unprotected sex).[242] Such risk-taking behaviour is, according to contemporary models, a natural function of adolescent brain development.[243] Minors' decision-making is characterised, in particular, by a heightened sensitivity to rewards, versus risks, and a tendency to focus on the immediate, rather than longer term, consequences of a decision.[244] In terms of smoking initiation, this means that, while research consistently shows that minors are well aware of the health risks of smoking, many will choose to smoke anyway because they choose to focus on the short-term rewards rather than on those longer-term health risks.[245]

14.10 The rewards that are particularly relevant to minors, as far as both smoking and many other risky behaviours are concerned, are stimuli such as social status or peer admiration. This helps explain why, according to the research, the main risk factors for smoking among minors are a psychological profile characterised by sensation-seeking, peer and family influence (i.e. peers and family members who

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[241] Consultation, page 6.

[242] Professor Steinberg's Report, pages 2 and 12.

[243] In particular, according to the "dual systems model", heightened risk-taking in adolescence is a natural byproduct of the asynchronous maturation of brain systems that govern incentive processing (which is responsive to emotion, reward, and novelty) and cognitive control (which is responsive to emotion regulation and planned decision making). The more rapid development of the incentive processing system, as compared to the cognitive control system, helps explain why middle adolescence is a prime time for experimentation with smoking and other risky activities. See Professor Steinberg's Report, pages 2 and 12-14.

[244] Professor Steinberg's Report, pages 2 and 14-17.

[245] Professor Steinberg's Report, page 15.

smoke), and their ability to obtain cigarettes.[246] The latter two risk factors are interlinked because in contrast to adults, who are legally permitted to purchase cigarettes, and whose primary source of cigarettes are retail stores, minors frequently obtain cigarettes through other means: primarily, by "bumming" or buying them from friends, some of whom may be of legal age to purchase cigarettes, or by asking older individuals to purchase them for them (i.e. proxy sales).[247]

14.11 It follows that **continuing efforts to prevent minors from smoking by emphasising the potential harms of smoking to them are unlikely to be effective – minors are already well aware of those risks, but choose to experiment with smoking (and other risky behaviours) anyway**. There are reasons to doubt that "more of the same" will be effective for the proportion of minors who continue to experiment with cigarettes, despite previous regulatory interventions.[248] In Professor Steinberg's opinion, the very notion that minors' knowledge of the risks of smoking has a strong influence on their decision to smoke, which has motivated most efforts to discourage underage smoking, is questionable.[249]

14.12 A key finding of Professor Steinberg's Report is therefore that **policies that limit minors' ability to obtain cigarettes are likely to have a greater impact than those that attempt to diminish minors' interest in smoking**. As he writes: "*A proportion of adolescents in the EU smoke cigarettes, in spite of their knowledge of the health risks of doing so and society's best efforts for the last three decades to deter them from doing so, and it is likely that they will continue to do so for so long as cigarettes are available to them. Stopping them from obtaining cigarettes, and combating peer influence by removing cigarettes from peer networks, is key*".[250]

14.13 On the basis of the above, JTI believes that packaging is not a predictor of smoking by minors and that none of the proposed measures regarding packaging are likely to have an impact on smoking initiation by minors. The proposals have no rational connection with the legitimate public policy goal of tackling smoking by minors. Put another way, the "problem" is incorrectly defined, and the proposals are not appropriate to address the problem.

(b) Packaging is not a determinant feature of adult consumer smoking behaviour and decision-making

14.14 The Consultation appears to proceed on the basis that packaging is a "problem" regarding adult smoking behaviour. However, the premise that packaging plays an important or any role in the determination of adult smoking behaviour and decision making (other than for brand identification, differentiation and choice) is misconceived. The Consultation's premise, that packaging is a "problem" by reference to adult smoking behaviour and decision making, is flawed.

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246 Professor Steinberg's Report, pages 3 and 17-19.

247 Professor Steinberg's Report, pages 3 and 10.

248 Professor Steinberg's Report, page 18.

249 Professor Steinberg's Report pages 3 and 21.

250 Professor Steinberg's Report, page 22

14.15 JTI's response in relation to the issues of smoking among adults is guided by Professors Dhar and Nowlis's Report.

14.16 The proposals on packaging put forward by DG SANCO appear to rely on what Professors Dhar and Nowlis refer to as the "traditional model" of consumer behaviour. As set out in their report, the traditional model of consumer decision-making takes an information processing approach to behavioural change. It works on the premise that in order to change a certain behaviour, it is important and necessary to provide the appropriate information and, if you do so, then this will result in a shift in behaviour in response. In accordance with the traditional model, if consumers do not alter their behaviour, this is evidence that they are somehow not fully informed or have an information deficit. Thus the proposals put forward by DG SANCO (i.e. including introducing larger (pictorial) health warnings and plain packaging) appear to rely on the notion that consumers are not fully aware of the risks of smoking and therefore providing additional information or drawing attention to that or similar type information will result in a change of behaviour.[251]

14.17 However, Professors Dhar and Nowlis's Report sets out that this notion is flawed for the following reasons. Adult consumers in 2010 in developed countries have a very high level of awareness of the serious health risks of smoking and yet they continue to smoke. Awareness regarding the risks of smoking is effectively a constant in adult smokers' decision-making framework. Further, smokers engage in smoking, not due to a lack of awareness, but due to many different factors including: affiliated attachment (characterised by a strong emotional attachment to smoking), habit/addiction, cognitive enhancement (smoking to improve cognitive functioning), craving (smoking in response to urges to smoke often prompted by specific cues), social-environmental goals (characterised by smoking due to social stimuli or contexts that invite smoking), taste and sensory properties (characterised by the desire to smoke to experience the orosensory/gustatory effects of smoking), weight control and the ritual of smoking. The costs of smoking (including the well known health risks) are weighed against these factors or benefits in the decision making process by the individual at that specific time. Different weight will be attributed to the various factors at different times over the course of a smoker's life-time, producing different behavioural outcomes.[252]

14.18 While the proposals put forward by DG SANCO, including larger (pictorial) health warnings and plain packaging, seek to make the information on packs more salient, the framework described by Professors Dhar and Nowlis shows that adult consumers do not make decisions simply based on the information they receive. Consequently, the proposals will not be effective in influencing adult decision making and smoking behaviour.[253]

14.19 Professors Dhar and Nowlis put forward a comprehensive framework for adult smoking consumer behaviour and decision making which considers and takes into

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[251] Professors Dhar and Nowlis's Report, paragraphs 2.4-2-5.

[252] Professors Dhar and Nowlis's Report, paragraphs 3.1-3.3.

[253] Professors Dhar and Nowlis's Report, paragraphs 2.11, 5.20 and section 4.

account the factors and variables which influence adult smoking behaviour and decision making.[254] Current understandings of decision-making involving risks and the weighting of costs and benefits better address smoking, an activity for which many potential costs are cumulative, occur far in the future for most smokers and do not materialise in all instances (whereas most benefits of smoking are immediate and certain). It is now understood, for example, that:

(a) people discount future risks excessively – future consequences are given less weight relative to more immediate consequences;[255]

(b) people are influenced by intertemporal preference reversals where immediate benefits are preferred over more long term benefits;[256] and

(c) people are subject to optimism bias whereby an immediate benefit is acceptable to the consumer on the basis that they will change their behaviour in the future.[257]

14.20 On the basis of these current understandings, Professors Dhar and Nowlis put forward a framework which describes the factors which influence adult smoking consumer behaviour and examines the influence of:

(a) habitual behaviour - the decision to smoke for many regular smokers is habitual or characterised by sequences that repeat at particular times and as a result of certain habitual contextual cues;[258]

(b) consumer goals and motives - most consumers' behaviour is goal directed (with goals being active or inactive at different times depending on competing goals) where positive goals are more effective in changing behaviour than negative goals;[259]

(c) peer influences – despite what most consumers acknowledge, one of the most powerful determinants of how consumers behave is how they think others will behave in a similar situation;[260]

(d) role of consumer mindsets - consumers can look at the same information very differently whether it is imminent or in the more distant future;[261] and

(e) self-control and the resolution of tempting tradeoffs - a major reason why consumers engage in certain pleasurable behaviours even if they consider

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254 Professors Dhar and Nowlis's Report, section 5.

255 Professors Dhar and Nowlis's Report, paragraph 4.15.

256 Professors Dhar and Nowlis's Report, paragraph 4.16.

257 Professors Dhar and Nowlis's Report, paragraph 4.16.

258 Professors Dhar and Nowlis's Report, paragraphs 5.4-5.7.

259 Professors Dhar and Nowlis's Report, paragraphs 5.8-5.10.

260 Professors Dhar and Nowlis's Report, paragraphs 5.11-5.12.

261 Professors Dhar and Nowlis's Report, paragraphs 5.13-5.15.

them to be less desirable, is their difficulty to exercise self-control. The ability to exercise self control varies according to different situations.[262]

14.21 In seeking to change adult consumer smoking behaviour, interventions must take these factors into account. If they are not taken into account, interventions are likely to be less, or not at all, effective.[263]

14.22 On the basis of the above, **JTI believes that packaging - and specifically the provision of information through, for example, larger (pictorial) health warnings on packs or the introduction of plain packaging - is not a determinant factor in adult smoking behaviour or decision making and that none of the proposed measures regarding packaging, which fail to take the above factors into account, will have an impact on adult smoking behaviour**. The Consultation's proposals are not therefore appropriate to address the (correctly identified) problem. Even if it were possible to increase the already very high levels of awareness through larger (pictorial) health warnings and plain packaging, it would not prove effective in producing the desired behavioural outcome of reduced consumption or increased quitting.

(c) The fundamental role of tobacco packaging

14.23 Tobacco is a legal product and effective communication of the health risks of smoking can and should be achieved without having a disproportionate impact on legitimate competition, consumer choice, intellectual property rights and freedom of expression. Packaging is one of the essential components of brand competition: it is the means by which consumers identify, obtain information about and choose tobacco products, easily and without confusion. Distinctive product packaging is the primary tool for developing brand equity, innovation and non-price competition.

14.24 In an economic system in which individuals, rather than governments, make the majority of decisions regarding economic activities and transactions, the ability of manufacturers to distinguish their products through packaging provides a key means by which consumers are able to freely exercise economic rights of purchase.

14.25 The free exercise of economic rights to purchase relies on choice. Smoking is an adult choice and JTI believes in openness and transparency about the products adult smokers choose to purchase. **Packaging is used by adult smokers to identify, obtain information about and choose tobacco products, easily and without confusion**.[264]

14.26 Packaging is fundamental to consumer choice in a competitive market, particularly where other channels of interaction with consumers are restricted.

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[262] Professors Dhar and Nowlis's Report, paragraphs 5.16-5.17.

[263] Professors Dhar and Nowlis's Report, paragraphs 5.18-5.20.

[264] This is further supported by Professors Dhar and Nowlis's Report at paragraph 6.25: "*packaging serves the purpose of aiding consumers in the choice of their favorite brand. For the purchase of cigarettes, which is typically associated with strong brand preference, packaging thus helps regular smokers to identify the brand they typically purchase.*"

Distinctive product packaging is fundamental to facilitate inter- and intra-brand[265] 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. Manufacturers and consumers must be able to identify and distinguish products. This is an essential function of packaging and trade marks. Packaging also:

(a) **facilitates brand navigation** at point of sale: packaging makes a product readily recognisable and allows existing adult smokers to easily find their preferred JTI product;

(b) **reaffirms brand equity and identity**: in many markets, packaging is one of the last remaining, and therefore an essential, means by which JTI identifies and differentiates its products;

(c) **enables consumer choice**: branding, and in turn the packaging that supports that branding, facilitates greater product variety and thereby increases consumer choice;

(d) **supports product innovation**: JTI innovates in packaging design and conveys information to consumers, on the pack, about product changes and improvements;

(e) **maintains quality standards**: packaging serves as a symbol to consumers that JTI stands behind its products. It provides an incentive to manufacturers to preserve the integrity of their products, and so protects consumers;

(f) **inhibits illegal activity**: distinctive packaging complicates the manufacture of counterfeit products and provides an incentive to manufacturers to preserve the integrity of their products; and

(g) **assists intermediate distributors and retailers**: distinctive product packaging facilitates the product supply and stocking processes.

14.27 These principles underlie, notably, the public policy justification for the availability and grant of exclusive intellectual property rights in relation to packaging.

14.28 Tobacco companies need, and have a right, to distinguish and differentiate their products, without confusion, from those of their competitors.[266] In this regard, tobacco packaging performs a fundamental role in respect of existing adult smokers

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[265] Inter-brand is used in this document to refer to navigation and competition between different brands of tobacco product (i.e. Benson & Hedges and Camel) whereas intra-brand refers to navigation and competition between members of the same brand family (i.e. Benson & Hedges Gold or Benson & Hedges Silver).

[266] This right has been expressly recognised by the Court of Justice and the Canadian Supreme Court. In case C-491/01 *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd* [2002] ECR I-11453, the Court of Justice expressly recognised, whilst upholding Article 7 of the TPD: "*the fact remains that a manufacturer of tobacco products may continue…to distinguish its product by using…distinctive signs*."

who have already made the decision to purchase a tobacco product. Evidence demonstrates that the vast majority of consumers have decided to purchase a (specific) tobacco product prior to visiting the retail outlet at which they make that purchase. Moreover, as stated in Professor Steinberg's Report, it is unlikely that impulse purchasing in retail stores plays any role in minors' acquisition of cigarettes.[267] Assertions that packaging incites minors to start smoking, or minors or adults to smoke more, or not to quit, are unsubstantiated.

14.29 Instead, this evidence supports the analysis that packaging plays a fundamental role in brand navigation, brand differentiation and intra-brand competition. Consumers in virtually all Member States can easily identify their preferred product or select an alternative product at the point of sale.

14.30 JTI therefore rejects the premise of the "problem definition" in Section 3 of the Consultation. JTI also rejects assertions in the RAND Report, such as that "*the evidence in the literature reviewed shows that promotions and displays of tobacco products do play a key role in triggering tobacco product purchases by underage consumers in particular – as well as by regular smokers, smokers attempting to cut down or quit altogether, and non-smokers*".[268]

(d) Tobacco packaging is not promotional advertising

14.31 As discussed above, packaging is used by adult smokers to identify, obtain information about and choose tobacco products, easily and without confusion.

14.32 The flawed premise of the "problem definition" is exemplified, in this regard, by the notion that packaging is advertising. JTI rejects the allegation that the cigarette pack itself constitutes a form of promotional advertising and that it should be regulated as if this was the case.

14.33 The current tobacco control regime in the EU separates out its regulation of (a) the advertising and promotion of tobacco products; and (b) the labelling and design of the pack itself. Directive 2003/33/EC is the primary legislative measure relating to the advertising and promotion of tobacco products. By contrast, it is the TPD that regulates pack labelling. The distinction has been affirmed by the Commission in its considerations of commercial communications going back to 1996.[269] Reinforcing this distinction, tobacco product packaging and labelling is not explicitly included within the definitions of tobacco "advertising" in the legislation of any EU Member State.

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[267] Professor Steinberg's Report, pages 4 and 29.

[268] RAND Report, page 192.

[269] In the Commission's Green Paper, *Commercial Communications in the Internal Market*, COM(96) 192 final, page 1, the Commission treated commercial communications as covering "*all forms of advertising, direct marketing, sponsorship, sales promotions and public relations*", but "*Packaging is not included*". The Commission explained that "*(i) packaging and labelling regulations should be kept separate from non-pack commercial communication regulations and (ii) the pack is typically part of the in-house manufacturing process rather than part of that element of the marketing mix which is sub-contracted to a specialist service provider as is the case for the commercial communication activities covered by this Green Paper.*"

14.34 Similarly, the WHO Framework Convention on Tobacco Control (***FCTC***) deals with these issues separately.[270] Article 13 of the FCTC sets out the requirements relating to tobacco advertising, promotion and sponsorship. By contrast, Article 11 of the FCTC sets out its requirements relating to the packaging and labelling of tobacco products. A clear dividing line is therefore drawn between these requirements in the FCTC.[271]

14.35 The Consultation's categorisation of tobacco packaging as advertising has therefore abandoned the position clearly and correctly adopted previously by the EU and Member States that tobacco packaging is not, in itself, advertising. Without any evidential basis or expert analysis, DG SANCO incorrectly asserts that packaging should be treated as advertising.

14.36 Additionally, there are good public policy reasons for treating differently the advertising and promotion of tobacco products and the labelling and design of the pack itself:

(a) expert evidence demonstrates that product packaging is one element of the much broader field of integrated marketing communications (also known as "IMC") and is not "*promotional marketing or advertising*" as generally understood in academic writing or practice;[272] and

(b) tobacco packaging performs a fundamental role in respect of those consumers who have already made the decision to purchase a tobacco product. In essence, distinctive packaging makes a product readily recognisable and allows existing adult smokers to find easily their preferred product.

14.37 JTI accepts that one of the roles of tobacco product packaging is to reaffirm brand equity and identity. Indeed, packaging is generally one of the last remaining, and therefore an essential, means by which JTI's products identify and differentiate themselves from those of other manufacturers. However, JTI does not accept the contention that the cigarette pack itself constitutes a form of promotional advertising and that it should be regulated as if this was the case.

14.38 It would therefore be illegitimate and unjustified to introduce regulation on the basis of an exaggerated definition of "advertising" and the misapplication of evidence unrelated to tobacco packaging itself.

14.39 JTI therefore takes issue with the imprecise and inaccurate mixing in the RAND Report of the display of tobacco products and point of sale advertising. Section 11.2.2 of the RAND Report is entitled "*promotions and displays of tobacco products in retail stores*" and considers arguments and evidence without discernment between these separate issues. Evidence on advertising is inappropriately applied to tobacco packaging and its display.

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[270] Available at: http://www.who.int/tobacco/framework/WHO_FCTC_english.pdf.

[271] JTI notes that the non-binding Guidelines on Articles 11 and 13, issued by the Conference of the Parties, merge these separate provisions, without any evidential basis for doing so.

[272] Dr Keegan's September 2008 Report, page 3.

(e) "Attractiveness" is a flawed public policy objective

14.40 In order for legislative measures on tobacco control to correspond to the principles of Better Regulation, such measures must be (amongst other things) necessary to achieve a legitimate public policy objective. JTI considers that it is neither appropriate nor legitimate to frame a public health policy objective on an amorphous and vague concept such as "attractiveness".[273]

14.41 **"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**.[274] As a result, "attractiveness" *per se* is not, and cannot be, a self-standing objective that can justify tobacco regulation.

14.42 Furthermore, no scientific criteria have been developed to assess, and regulate on that basis, the "attractiveness" of tobacco products.

14.43 JTI therefore rejects "attractiveness" *per se* as a public policy objective, and considers that it adds nothing to the need to identify and assess a relevant underlying policy rationale. "Attractiveness" simply acts as an umbrella term, and DG SANCO must identify, articulate clearly and assess the evidence against the underlying public policy objective(s). JTI acknowledges that, assuming an appropriate legal basis exists in the Treaties, DG SANCO can seek to achieve a high level of protection of public health through specific objectives such as prevention of smoking by minors, combating illicit trade and increasing smoking cessation.

14.44 JTI considers therefore that statements in the Consultation and the RAND Report, such as "*tobacco packaging and product features are increasingly used to attract consumers*"[275] and "*generic or plain packaging has been shown to reduce the attractiveness of cigarette packages…*",[276] are meaningless in terms of regulatory process and Better Regulation principles. DG SANCO must specify clearly and accurately the public policy objective(s) that underlie any concerns, so that the evidence and proposals can be assessed against these objectives and not subjective, amorphous and vague concepts such as "attractiveness".

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[273] The *Shorter Oxford English Dictionary* defines "attractive" as "*having the property or capacity of attracting towards oneself or itself by influencing will and action; having the property of attracting interest, attention, affection, desire, etc.; interesting, pleasing, alluring.*"

[274] The OECD's first principle of good regulation (OECD 1997 Guidelines) concerns issue identification: "*Is the problem correctly identified? The problem to be solved should be precisely stated, giving clear evidence of its nature and magnitude, and explaining why it has arisen*". Further, Professors Dhar and Nowlis state, at paragraph 6.16 of their Report, that "*the regular adult smoker has decided to smoke having balanced numerous factors, including the risks of smoking. It is unlikely that by simply making the package less attractive, if that was the goal, this would overcome or sufficiently affect the weighting of the inputs to change smoking behavior.*"

[275] Consultation, page 6.

[276] RAND Report, page xxiv.

The objective of labelling and packaging regulation concerns behaviour

14.45 The flaws in the Consultation's problem definition are compounded by the absence of clear regulatory objectives. JTI notes that the Consultation makes no attempt to define the objectives of its proposals. In the absence of clear objectives, it is virtually impossible to evaluate "effectiveness" or "proportionality". The RAND Report identifies "*changing their [consumers'] behaviour*" as the most important issue. JTI is concerned, however, that despite "changing behaviour" being the most important issue, the vast majority of evidence referred to by RAND Europe does not assess changes in behaviour by reference to the proposals (and indeed RAND Europe ignores various sources on behaviour, including those that were supplied by CECCM in its response on 18 January 2010 to the Interim Report).

14.46 JTI has sought, in this Full Response, to identify with more precision the public policy objectives that can be distilled from the Consultation and the RAND Report, in order that effectiveness and proportionality can be assessed against the evidence.

Assessing the Consultation's proposed measures

14.47 Against this background it is clear that the proposals in Section 3 of the Consultation are flawed from the outset. DG SANCO should conduct a thorough reappraisal of the implicit, but flawed assertions that underpin its approach to packaging. JTI, nevertheless and in addition to these fundamental concerns, addresses below the proposals regarding:

(a) plain packaging (Section 15, below);

(b) "enlarged" health warnings (Section 16, below);

(c) mandating pictorial health warnings (Section 17, below);

(d) tar, nicotine and carbon monoxide information on packaging (Section 18, below); and

(e) inserts (Section 19, below).

15. PLAIN PACKAGING

Introduction

15.1 JTI is greatly concerned by the proposal in the Consultation to introduce so-called plain packaging for tobacco products (it is also described in the Consultation as "generic packaging"). **JTI wishes to emphasise its categorical opposition to such a measure.** 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 brands, which are – as with any consumer product – JTI's most valuable assets. This would be manifestly disproportionate.

15.2 JTI notes the statement in the RAND Report that "***some*** *governments have been reluctant to consider seriously the introduction of plain packaging*" (emphasis added).[277] In fact, no government in the world has adopted plain packaging legislation. It was considered by the Canadian and Australian governments in the mid-1990s,[278] but rejected by both. Indeed, the Australian Senate Community Affairs References Committee concluded that there was "*not sufficient evidence to recommend that tobacco products be sold in generic packaging*".[279] This view was repeated in 2008 by the UK Department of Health, which – having sought views on plain packaging as a regulatory initiative - has decided not to introduce it as part of current changes to tobacco regulation given that "*the evidence base needs to be developed*".[280] More recently, in March 2010, the Lithuanian Parliament voted against the constitutionality of a plain packaging proposal. Although the Australian government has proposed a policy of introducing plain packaging (June 2010), no legislative steps have yet been taken.

The fundamental role of tobacco packaging

15.3 JTI has set out above the fundamental role of tobacco packaging to explain why it is not, and should not be, a mere vehicle for communicating government-mandated health warnings. There is a heavy burden on governments that seek to displace the constitutional rights, including IPR, of consumers and manufacturers which are designed to protect competition and economic policy.

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[277] RAND Report, page 133.

[278] Expert Panel Report for Health Canada, *National Survey of Teens: Knowledge, Attitudes, Beliefs and Smoking Behaviours, When Packages Can't Speak: Possible impacts of plain and generic packaging of tobacco products* (1995); Health Canada, Ottawa. Report of the Senate Community Affairs References Committee, *The tobacco industry and the costs of tobacco related illness* (December 1995).

[279] Report of the Senate Community Affairs References Committee, *The tobacco industry and the costs of tobacco related illness* (December 1995). Albeit JTI notes that the Australian Preventative Health Taskforce has proposed plain packaging in its Report (*National Preventative Health Strategy - the roadmap for action*) dated 1 September 2009.

[280] In a statement accompanying its review of responses to its *Consultation on the Future of Tobacco Control*, the UK Department of Health stated that: "…*the evidence base needs to be developed. The Government has committed to keep this under review and build on the evidence before taking further action*".

15.4 JT owns a broad range of sophisticated IPR in relation to its tobacco products (including both unregistered and registered national and Community trade marks, design rights,[281] patent rights and other rights). Its portfolio of trade mark rights includes approximately 7,570 applications and registrations in respect of tobacco products sold in the various Member States. In this context, trade marks may take a variety of forms including word marks (such as for characters comprising an unstylised brand name), and non-word marks (such as device or figurative marks, including for logos, designs, stylised characters and combinations of both logos and stylised characters, colour marks (whether alone or claimed as an element of another type of mark), and the shape of goods or their packaging).

15.5 By way of example, the following illustrates the trade mark registrations which relate to Winston Redvolution, a JTI product.

15.6 Extensive efforts are taken to protect such rights by way of a rolling programme of trade mark applications, registrations, oppositions, renewals and enforcement actions. Those enforcement efforts include registered trade mark infringement actions and actions to protect its unregistered proprietary rights (e.g. by way of a passing off claim in the UK or Ireland or a claim under national unfair competition laws) by JTI, in addition to actions taken by regulatory enforcement agencies.

15.7 The existence and enforceability of IPR have been recognised as of paramount importance to the functioning of the internal market and as necessary incentives for investment in R&D and innovation. The development of brand equity and goodwill is fundamental to market economies, consumer choice, innovation and product development. It flows, as economic value, through all levels of the supply chain.

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[281] In relation to JTI's registered Community design rights, Article 19 of the Council Regulation of 12 December 2001 on Community designs (6/2002/EC) provides that a "*registered Community design shall confer on its holder the exclusive right to use it.*"

15.8 In addition to the status attributed to them by Community legislation,[282] the commercial and consumer protection significance of IPR have been consistently reaffirmed by the Commission and the Council. For example:

(a) "*In today's knowledge-based society intellectual property rights (IPR) are **vital business assets, encouraging innovation and creativity** by ensuring a fair return on investment. IPR play an increasingly important role, fostering economic growth by protecting and enabling inventors, designers and artists to benefit from the commercial value of their creations. **This results in an essential cycle of business development, knowledge and further innovation. Moreover, trade marks in particular can have a beneficial effect on consumers, in many cases signifying quality and a reassurance that the products and services they buy are legitimate, safe and reliable***"[283] (emphasis added).

(b) "*Intellectual property rights are a cornerstone of a creative, competitive, wealth-generating, knowledge-based society*".[284]

(c) The Council of the European Union emphasises "*the importance of protecting intellectual property rights, which are fundamental to promoting culture and diversity, and for drawing full benefit from the research, innovation and creative activity of European undertakings, especially small and medium sized enterprises, in order to support growth and jobs in the European Union and make Europe more competitive in the world*".[285]

(d) "*Intellectual Property Rights (IPRs) are a key asset of the EU, ensuring its leading role in the "knowledge economy". The EU can only remain competitive, if it can rely on innovation, creativity, quality, and brand exclusivity*".[286]

15.9 JTI has invested very substantially in its IPR, brands and products, and this is reflected in the strong brand equity of JTI's brands across the Member States. JTI's brands are worth billions of US dollars.

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[282] By way of illustration, see Recitals 3 to 13 of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights. See also paragraphs 15.48 - 15.60 below.

[283] *Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee – Enhancing the enforcement of intellectual property rights in the internal market* COM(2009) 467 final. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0467:FIN:EN:PDF.

[284] *Intellectual Property Rights: Commission comes forward with practical, non-legislative measures to combat counterfeiting and piracy* (09/1313) 14 September 2009. Available at: http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1313&.

[285] Council Resolution of 1 March 2010 on the enforcement of intellectual property rights in the internal market (OJ 2010/C 56/01).

[286] *All you want to know about the Anti-Counterfeiting Trade Agreement (ACTA)*, Brussels, 20 October 2010. Consolidated text of Agreement (October 2010) available at: http://trade.ec.europa.eu/doclib/docs/2010/october/tradoc_146699.pdf.

Inter- and intra-brand competition

15.10 Given that it has both branding and functional roles, the packaging of tobacco products can be understood as having a continuing, independent function in itself, as well as being an integral and inseparable part of what is purchased by adult smokers when they buy a tobacco product. Dr Andrew Lilico explains this further at paragraphs 1.8 and 2.2 to 2.6 of his September 2008 Report.

15.11 The small physical size of tobacco packaging and the manner of point of sale purchase necessitates that a tobacco packet be readily recognisable to trade and consumers not only by its brand name but also by the overall design of the packaging.

15.12 JTI invests and innovates in its packaging design and quality in order to compete with product available to existing adult smokers. JTI and other companies, both within the tobacco sector and also in the context of other Fast Moving Consumer Goods (***FMCG***), use product packaging in a myriad of ways and this scope for creativity motivates efforts to differentiate the product from others. Packaging comes in many different shapes, sizes, colours, designs and materials. One specific, functional example is the way a cigarette pack opens. As well as packs using a flip-top lid, consumers can choose soft packs, 'push and slide' packs and front opening packs (as in a classic cigarette case).

15.13 Consumers are entitled to expect a product to be of a quality consistent with previous experience and to hold the trade mark proprietor liable for failure to perform.[287] In that context, trade marks guarantee the identity of origin of the marked goods or services to the consumer by enabling him, without any possibility of confusion, to distinguish the goods or services from others which have another origin.[288] If packaging is no longer distinctive:

(a) competition is distorted because consumers are less able to identify their choice of product or select alternative products; and

(b) the responsibility of the trade mark proprietor to the consumer is potentially jeopardised as consumers are less likely to be sure of the origin and quality of the goods they buy.

15.14 None of these issues are identified in the RAND Report. Section 8.3.2 considers, in two paragraphs, the "*impact on tobacco market*" of, amongst others, plain packaging. The assessment is taken solely from a two page analyst's report from Morgan Stanley in 2008, and refers to a loss of brand value and commoditisation. There is no thorough consideration of these issues, and no

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[287] Schecter (1927) 40 Harv LR 813.

[288] Professor Gervais' Report, paragraph 44: "*Modern trademark theory has recognized that trademarks protect not only the owners of marks but also consumers, especially by reducing search costs. Trademarks allow consumers to identify lawful products that they wish to purchase. They can normally expect a certain quality that they associate with a given trademark. By making all packages more or less similar, this function, which is tied to the essential function of a trademark to guarantee the origin of products bearing the mark, is impaired.*"

consideration at all of the impact on inter- and intra- brand competition, or on the illicit trade.

DG SANCO has failed to provide any reliable evidence demonstrating that the proposal will achieve legitimate public health objectives

15.15 The burden lies on DG SANCO to justify the introduction of plain packaging. DG SANCO must provide reliable evidence demonstrating clearly that plain packaging will achieve identified policy objectives.

15.16 However, it is unclear on which public policy objectives DG SANCO is proposing to justify the introduction of plain packaging. It is of the utmost importance that DG SANCO should establish the objectives sought by the proposal and provide evidence in support of those objectives. Absent identified objectives, the evidence cannot be properly assessed against the public policy goal.

15.17 Notwithstanding the absence of any clearly stated public policy objectives to justify the introduction of plain packaging in the Consultation (which is contrary to the principles of Better Regulation), JTI notes DG SANCO's overarching objective in introducing further regulation as seeking to impact smoking behaviour. In this regard, JTI considers that DG SANCO – if it can establish a legal basis for its proposal – could seek to change smoking behaviour in terms of:

(a) reducing uptake of smoking by minors; and

(b) increasing cessation both among minors and adults.

The RAND Report's approach to evidence is flawed

15.18 In terms of providing reliable evidence that clearly demonstrates that plain packaging will achieve behavioural objectives, JTI acknowledges that, as no country has introduced plain packaging, no observed evidence will exist relating to changes in smoking behaviour in the wider population and overall prevalence rates.[289] In JTI's view, the principles of Better Regulation require DG SANCO, in these circumstances, to be even more vigilant to ensure that the available data is the "best available" and "reliable" (i.e. of the requisite quality). JTI does not agree that evidence can, properly, be "*extrapolated*" from other measures,[290] and JTI has serious concerns about the reliance by RAND Europe (and potentially DG SANCO) on "*data gathered through small experimental set-ups or perception data*" when the methodologies of those studies are not adequately examined. Whilst the absence of observed data may make it necessary to examine other data types, DG SANCO must not compromise on the quality of that data. Professor Cave states:

> "*What is key, to satisfy better regulation principles, is that the regulator does not compromise as to the quality of the evidence he takes into account. Indeed, the absence of direct evidence as to whether a measure like plain*

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[289] RAND Report, pages 131 and 254

[290] RAND Report, page 254

packaging actually 'works', in my opinion, increases the responsibility on the preparer of the RIA to ensure that the evidence relied upon is objectively reliable and of sufficient quality to justify pursuing the measure. The more draconian or intrusive the measure proposed, the greater the burden on the regulator to ensure this is the case. As a result, in the 'first mover' scenario (and in other situations which I consider below), the regulator should be prepared to commission impartial, credible research to inform the impact assessment if the evidence is not available".[291]

15.19 Two points are relevant here regarding the quality of the evidence relied upon by RAND Europe:

(a) The RAND Report cites only attitudinal consumer research; but it is well established that people are not particularly reliable at self-assessment. Dr Keegan considers that "*recall reliability is an important methodological consideration*" when reviewing the evidence.[292] In his report, he states that "*observing what people do is a better predictor of behavior than recording how people respond to questions about what they think they will do, or what they think others will do, or what they report they have done*" and, moreover, that "*it is well established that consumer recall of past behaviors can be inaccurate, as the time elapsed between the event and the time of reporting can distort respondents' perceptions*".[293] This view was repeated in a report prepared for the UK Department of Health in which the authors examined the literature in respect of plain packaging and concluded that "*there are important gaps in the evidence base*" and that, in particular, there have been "*no ecological studies to examine the real world effects of plain packaging nor have there been any longitudinal studies to assess the cause and effect relationship between packaging and smoking*";[294]

(b) good research will attempt to circumvent the problem of a gap between attitudinal and behavioural data. Professor Devinney speaks to the issue of "*attitude-behaviour gap or the difference between 'stated' intentions and 'revealed' or actual purchases*" in paragraphs 2.4 and 2.5 of his report. In noting that plain packaging does not exist anywhere in the world, Professor Devinney states that in such circumstances "*researchers must be cognizant of the degree to which the experimental task creates an outcome that can be linked specifically to behaviour*".[295] To attempt to reduce the problem of the "*attitude-behaviour gap*" in consumer research, Professor Devinney states that "*good research*" will focus on three factors*:*

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[291] Professor Cave's Report, paragraph 6.6.

[292] Dr Keegan's September 2008 Report, page 9.

[293] Dr Keegan's September 2008 Report, page 9.

[294] See Moodie, C., Hastings, G., Ford, A., *A Brief Review of Plain Packaging Research for Tobacco Products; Report prepared for the Department of Health* (September 2009), page 19.

[295] Professor Devinney's Report, paragraph 2.4.

(i) **Incentive compatibility** which "*addresses the extent to which the methodology used by the researcher allows (or makes) subjects reveal their true behaviour*";[296]

(ii) **Inference of salience** which "*addresses the degree to which the sheer addition of a factor that would otherwise not be part of the consumer's decision is all of a sudden added into the mix*";[297] and

(iii) **Context** which "*addresses the degree to which individuals are being asked to make it outside the context in which it might normally be made*"[298].

In his review of the publicly available consumer survey studies on plain packaging, Professor Devinney concludes that "*none of the studies examined meet reasonable incentive compatibility requirements*"; the studies "*failed to provide experimental or situational contexts that created a scenario in which the individual would be applying the decision model that they used when making purchasing decisions*" and that, as the studies concentrated entirely on stated preferences and attitudinal measures, "*one cannot assume any predictive accuracy with respect to actual purchasing behaviour*".[299]

15.20 Professor Cave makes two further important points, which JTI endorses, namely that where it is necessary for the regulator to commission research because, for example, the regulator is acting in a "first mover" scenario and/or because the existing evidence base is non-existent or poor:

(a) it would normally be appropriate for the regulator to await that evidence before implementing the measure in respect of which the research is being commissioned;[300] and

(b) it would be consistent with the Better Regulation principle of transparency for the regulator to publish that evidence once it is available, so that it can be reviewed and considered by others.[301]

There is no reliable evidence to support the introduction of plain packaging

15.21 JTI believes that, on the basis of expert analysis of the publicly available consumer survey studies relevant to plain packaging, **there is no reliable evidence to suggest that plain packaging will lead to a change in actual smoking behaviour**, either by way of a reduction in smoking uptake by minors or increased smoking cessation among minors or adults.

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[296] Professor Devinney's Report, paragraph 2.5(a).

[297] Professor Devinney's Report, paragraph 2.5(b).

[298] Professor Devinney's Report, paragraph 2.5(c).

[299] Professor Devinney's Report, paragraph 5.2(c).

[300] Professor Cave's Report, paragraph 8.27.

[301] Professor Cave's Report, paragraph 6.9.

15.22 JTI has commissioned expert analysis by Dr Keegan and Professor Devinney to review the evidence in respect of plain packaging to determine whether it constitutes reliable evidence that such a measure will achieve a goal of changing actual smoking behaviour. The materials reviewed by Dr Keegan and Professor Devinney in reaching their conclusions in their respective reports are not limited to the materials relevant to the Consultation; the conclusions reached by Dr Keegan and Professor Devinney are based on their collective review of all publicly available consumer survey evidence in respect of plain packaging published to date.

15.23 DG SANCO advances no evidence in the Consultation to support the proposal to introduce plain packaging.

15.24 Whilst the RAND Report refers to fourteen documents in the section entitled "*plain or generic packaging*", only three are studies which present primary consumer survey research in respect of plain packaging.[302] Each of the three studies has been subject to expert analysis by Dr Keegan or Professor Devinney. They have found that the studies do not constitute reliable evidence that plain packaging will impact on actual smoking behaviour.[303]

15.25 The key flaws in each study identified in the RAND Report are set out below:

(a) **Wakefield et al. (2008).**[304] This study is put forward by RAND Europe in respect of its assertion that "*plain packs with increasingly few pack design elements are perceived increasingly unfavourably in terms of smokers' appraisals of the packs, the smokers who might smoke such packs. and the inferred experience of smoking a cigarette from these packs*".[305] In his June 2009 Report, Dr Keegan states that this study "*suffers from an inherently flawed design*" and that "*it does not examine the direct impact of plain packaging on actual smoking behaviour, but rather seeks to measure respondents' ratings*". Dr Keegan concludes that "*the weaknesses of the Wakefield et al. study design and the authors' skewed data analysis prevent me from drawing any meaningful conclusions from this research as to whether plain packaging would lead to a reduction in youth smoking uptake or change smoking behaviours more generally*".[306]

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[302] RAND Report, pages 131-134.

[303] This finding is further supported by Professors Dhar and Nowlis who, in assessing some of the evidence from a consumer behaviour perspective note, at paragraph 6.24 of their Report: "*there does not appear to be any reliable research showing that plain packaging would be an effective way to get adult smokers to smoke less or to quit. Further, there is no reason to think that packaging would somehow detract from the impact of a health warning.*"

[304] Wakefield, M., Germain, D., Durkin, S.J., "How does increasingly plainer cigarette packaging influence adult smokers' perceptions about brand image? An experimental study", *Tobacco Control* (2008) Vol. 17, pages 416-421.

[305] RAND Report, page 133.

[306] See Dr Keegan's June 2009 Report, pages 21–24.

(b) **Germain et al. (2009).**[307] This study, which is referred to at page 131 of the RAND Report, was conducted in Victoria, Australia with respondents between the ages of 14 and 17. Having considered the study in his report, Professor Devinney states that "*a major flaw of the study is in its set-up*"[308] and that it "*potentially biased those involved by identifying the purpose of the study as changing policy and the sponsor as the Cancer Council of Victoria*".[309] Professor Devinney concludes that *"the researchers note that the design of their study allows them to determine the value of specific elements of the pack on perceptions; however, what they cannot say is the degree to which such perceptions ultimately lead to specific choices in the context in which realistic purchases are being made and the decision to smoke or not to smoke is being made. … Because the study cannot blind the subject to its intent and because the researchers focus very specifically on the packaging facets alone – e.g., things like font size – they ignore the overall decision model that the consumer would be expected to use when making actual purchases. … This is important if the evidence from the study is to be used to form part of sound policy making decisions. By not accounting for the 'excluded' elements of the decision model, the researcher may significantly overstate the importance of the things that were studied, while significantly understating those facets that were excluded."*[310]

(c) **Hammond and Parkinson (2009).**[311] This study, which is referred to at page 131 of the RAND Report, does not address plain packaging. However, Professor Devinney states that "*it draws a number of unsupported conclusions with respect to plain packaging*".[312] Notwithstanding that this study is not relevant to the plain packaging debate, Professor Devinney states that the experimental design of the study is "*inefficient, not allowing for an appropriate statistical analysis*"[313] and moreover that the study suffers from "*bias*".[314] Professor Devinney has concluded that this study "*provides no valid evidence to support the propositions that the packaging information is "misleading" and "deceptive" and that "these terms are equivalent in the minds of many smokers when used on packaging*"" and that it "*inappropriately extrapolates findings to the plain packaging issue, when these questions were not themselves studied specifically".*[315]

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[307] Germain, D., Wakefield, M., Durkin, S.J., "Adolescents' Perceptions of Cigarette Brand Image: Does Plain Packaging Make a Difference?", *Journal of Adolescent Health* (2009)Vol. 46, No. 4.

[308] Professor Devinney's Report, paragraph 4.33.

[309] Professor Devinney's Report, paragraph 5.5(a).

[310] Professor Devinney's Report, paragraph 4.37.

[311] Hammond, D., Parkinson, C., "The Impact of Cigarette Package Design on Perceptions of Risk", *Journal of Public Health* (2009) Vol. 31, pages 345-353.

[312] Professor Devinney's Report, paragraph 4.16.

[313] Professor Devinney's Report, paragraph 4.19.

[314] Professor Devinney's Report, paragraph 4.20.

[315] Professor Devinney's Report, paragraph 4.22.

15.26 In addition, JTI notes that the RAND Report relies on a report by Sambrook Research International entitled "*A review of the science base to support the development of health warnings for tobacco products*" (the ***Sambrook Report***) to make the assertion that plain packaging may:[316]

(a) "*reduce the attractiveness and identification of the link between tobacco packaging, brands and consumer attractiveness, especially among young people;*

(b) *increase the effect, message recall and credibility of health warnings; and*

(c) *reduce the false beliefs relating to health messages*".

15.27 Beyond JTI's rejection of any of these statements as a legitimate basis on which to introduce a plain packaging measure (which has been discussed in more detail above), of critical importance to note is that the Sambrook Report is itself a secondary source of research, conducting a review of the existing literature rather than presenting original market or consumer survey data.

15.28 There is no indication that RAND Europe reviewed the evidence cited in the Sambrook Report. However, expert analysis of the underlying publicly available consumer survey evidence cited in the Sambrook Report in support of the above proposition in the RAND Report has determined that it is unreliable. The key limitations in respect of the underlying consumer survey research relevant to plain packaging in the Sambrook Report are set out below:

(a) **Goldberg et al. (1995):**[317] This study suffers from key methodological flaws, such as the use of conditioned responses, and the other limitations discussed by Dr Keegan.[318] These flaws are in part recognised by the study itself. The study also makes a number of causal conclusions which, in Dr Keegan's view, are not actually supported by the results of the research conducted.[319]

(b) **Beede and Lawson (1992):**[320] This study suffers from an unreliable data collection method and unsupported conclusions. Dr Keegan notes that the data collection process for this study was methodologically unsound and did not produce supportive quantitative findings.[321] Further, Dr Keegan notes that the authors link brand differentiation (resulting from branded packs) and smoking uptake behaviour despite the fact the study does not support this conclusion.

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316 RAND Report, page 131.

317 Expert Panel, *When Packages Can't Speak: Possible Impacts of Plain and Generic Packaging of Tobacco Products* (1995), prepared at the Request of Health Canada.

318 Dr Keegan's September 2008 Report, pages 19-21.

319 Dr Keegan's September 2008 Report, pages 21-24.

320 Beede, P., Lawson, R., "The Effect of Plain Packages on the Perception of Cigarette Health Warnings", *Public Health* (1992) 106, pages 315-322.

321 Dr Keegan's September 2008 Report, page 14.

(c) **Rootman and Flay (1995):**[322] This study is – in Dr Keegan's view – not reliable science. It is limited to the selective reporting of data and verbatim responses and is written in strong advocacy language.[323]

(d) **Environics Research Group – Youth**[324] **and Adult**[325] **Studies (2008)**: These studies suffer from a number of design flaws, which are outlined by Dr Keegan.[326] As Dr Keegan notes, the studies do not examine the direct impact of plain packaging on smoking uptake or smoking behaviours more generally, but simply gauge respondents' reactions to a novel plain pack and collect non-scientific public opinion data.

15.29 Having taken account of its expert analysis of the evidence relevant to plain packaging in the RAND Report, and the underlying evidence in the Sambrook Report which is in turn relied on in the RAND Report, JTI considers that the rejection by RAND Europe of similar criticisms made by Padilla and Watson (2010) is unfounded.[327]

15.30 Consistent with the expert analysis by Dr Keegan and Professor Devinney, the UK Department of Health acknowledged in its May 2008 consultation document that the research evidence in support of mandating plain packaging is "*speculative*"[328] as it relies on asking people what they might do in a certain situation and assumes that changes in the packaging will lead to changes in behaviour. This view was repeated by the UK Department of Health when it decided not to introduce plain packaging as part of current changes to tobacco regulation given that "*the evidence base needs to be developed*".[329] The body of evidence has also been recognised as being both "*small and necessarily experimental*".[330]

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322 Rootman, I., Flay, B., Phil, D., *A Study on Youth Smoking, Key Figures and Findings*. (1995). A Joint Research Project by: University of Toronto, University of Illinois at Chicago, York University, Ontario Tobacco Research Unit, Addiction Research Foundation.

323 Dr Keegan's September 2008 Report, page 18.

324 Environics Research Group, *Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Youth* (2008). Final report prepared for Health Canada.

325 Environics Research Group, *Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Adult Smokers* (2008). Final report prepared for Health Canada.

326 Dr Keegan's June 2009 Report, pages 18-21.

327 RAND Report, pages 131-132. The fact that the Padilla and Watson report was produced at the request of PMI neither (1) is a reason to reject it *per se* (as to do so would be contrary to Better Regulation principles and the principle of equality) nor (2) undermines the validity of its concerns, so long as conducted to internationally accepted standards of scholarship.

328 UK Department of Health's Consultation on the Future of Tobacco Control, paragraph 3.75.

329 In a statement accompanying its review of responses to its *Consultation on the Future of Tobacco Control*, the UK Department of Health stated that: "*…the evidence base needs to be developed. The Government has committed to keep this under review and build on the evidence before taking further action*".

330 Freeman, B., Chapman, S., Rimmer, M., *The case for the plain packaging of tobacco products*, Becky Freeman, Tobacco Control (Reports on Industry Activity from Outside UCSF (University of California, San Francisco)) Available at: http://repositories.cdlib.org/tc/reports/generic.

15.31 DG SANCO cannot rely on the flawed research in the RAND Report to justify plain packaging, **even** if there is no observed data available.[331]

DG SANCO's other 'reasons' for seeking to mandate plain packaging

15.32 JTI notes the following statements in the Consultation which appear to be additional reasons for seeking to mandate plain packaging:

(a) "*packaging is an advertising tool not covered by the current Directive. Tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image*"*;* [332]

(b) "*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*"*;*[333] and

(c) "*several other elements of the current package design … often distract consumers from the health warnings*".[334]

15.33 In addition, JTI notes that the RAND Report considers the health and social impacts of the introduction of plain packaging, and states that:

(a) "*reduction in smoking prevalence through reduced brand attractiveness is likely, but effect currently not quantifiable on a population level*";[335] and

(b) "*warning labels would be more visible and consumers would benefit from readability of warnings*".[336]

15.34 JTI does not consider that these points are, of themselves, legitimate public policy objectives nor that they justify the adoption of plain packaging.

15.35 First, as set out above, JTI rejects the allegation that the cigarette pack itself, and the use of colours on tobacco product packaging, constitute a form of promotional advertising and that they should be regulated as if this was the case.

15.36 Second, as also explained above in the Introduction to this Section, JTI considers that it is neither appropriate nor legitimate to frame a public health policy objective on an amorphous and vague concept such as "attractiveness".

15.37 Third, JTI wishes to clarify certain misconceptions perpetuated by some commentators regarding colour usage on tobacco packaging, including that colour

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331 In this context, see Professor Cave's Report at paragraphs 6.3-6.6.

332 Consultation, page 5.

333 Consultation, page 5.

334 Consultation, page 7.

335 RAND Report, page 141.

336 RAND Report, page 141.

acts as a misleading indication of the relative health risks of smoking one particular product in comparison with another.

15.38 JTI and other tobacco manufacturers use pack colours to enable consumers to differentiate between different products (e.g. mentholated and non-mentholated cigarettes) and brand styles. There is real complexity and variance in the use of colour by JTI and across the tobacco industry. For example, packaging may feature single or multiple colours, various shades/intensities of colours, colour designs, colour backgrounds, etc. Further, colour usage varies across cigarette brand families, across a portfolio of brands, by different manufacturers and by individual market. This distinctiveness helps both the consumer and the shopkeeper quickly locate the product that the consumer wishes to purchase. Tobacco products are no different to any other branded consumer good in this regard.

15.39 Consumer understanding of, and responses to, colour are subjective. They vary according to factors such as a consumer's cultural background, gender, socio-economic status, age, education and visual ability. Leading studies on consumer understanding of colour confirm that the meaning and effect of colour *per se* defies generalisation.[337] Colours do not have an inherent meaning as to health or risk. The colours used by JTI on product packaging are not intended to, and do not, communicate any message as to the health risks associated with smoking a pack of cigarettes, relative or otherwise. Consumers in fact take smoking-related health messages from a variety of different sources and media, including on-pack health warnings, and are well aware of the health risks of smoking.

15.40 No regulator has found that colour use on tobacco product packaging communicates misleading messages to consumers about the safety or otherwise of the product, despite the existence in many markets worldwide of both general and tobacco-specific regulation prohibiting misleading marketing practices. In two of the cases that have considered this point expressly, the notion that colours were misleading was rejected:

(a) the relevant Dutch authorities rejected the contention that the use of the colour blue in the background of advertising for a tobacco product misleadingly communicated the impression that the product was "clean and healthy";[338] and

(b) in a May 2010 ruling in the course of class action proceedings, a District Court in Israel considered that the use of colours on tobacco packaging was unlikely to deceive consumers. The judge stated that the use of colours on cigarette packaging "*assists consumers to identify and buy the cigarettes that they wish*

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[337] See, for example, Grossman, R. and Wisenblit J., "What we know about consumers' color choices", *Journal of Marketing Practice* (1999) 5(3), pages 78-88.

[338] *D Snel v JT International Company Netherlands BV*, decision of the Dutch Advertising Standards Commission (Second Chamber), Dossier 01.0570, 11 December 2001. A complaint was submitted to the Dutch Advertising Standards Commission in October 2001 which alleged that the use of the colour blue in the background of advertising for MILD SEVEN would misleadingly communicate that the product is "clean and healthy". The Commission rejected the complaint and found that the colour blue could not be assigned the meaning suggested. The use of the colour was not considered to create the impression that the cigarettes were natural or healthy.

to smoke... In this way, that accordingly also assists retailers in selling the cigarettes".[339]

15.41 In light of the above, it would be inappropriate for DG SANCO to introduce legislation prohibiting the use of colour on packs on the assumption that it misleads consumers.

15.42 Even if it were the case that colour usage on one or more tobacco products was "misleading", which JTI does not accept, it would be neither necessary nor appropriate to introduce new measures (such as plain packaging) to prohibit such conduct. Community law is already harmonised in this regard in light of both Article 7 of the TPD and the Unfair Commercial Practices Directive.[340] Article 6(1) of the Unfair Commercial Practices Directive provides that a commercial practice shall be regarded as misleading if it contains false information and is therefore untruthful. It also covers the presentation of a consumer product which deceives or is likely to deceive the average consumer.[341] Horizontal legislation, such as the Unfair Commercial Practices Directive, should be preferred to new and additional vertical legislation. The proposal to introduce plain packaging is therefore unnecessary to address the identified issue.

15.43 JTI notes that the only support offered by DG SANCO for its statement that "*light coloured packages are perceived to deliver lower amounts of tar, have a smoother taste and, in some case[s], to be less risky for the health of consumers*"[342] is a recent Eurobarometer survey.[343] However, DG SANCO significantly misrepresents the findings of Eurobarometer 2010 in this regard. Eurobarometer 2010 did not ask respondents about whether pack colour indicated lower levels of tar or a smoother taste, and so provides no support for DG SANCO's statements in this regard. As far as DG SANCO's suggestion that "*light coloured packages are perceived… in some case[s], to be less risky for the health of consumers*" is concerned, the only evidence provided by Eurobarometer 2010 is that 10 per cent of respondents considered "*the colour of cigarette packs*" to be "*an indication of whether a cigarette brand could be less harmful compared to others*". Respondents were not asked whether "*light coloured packages*" (or indeed darker coloured ones) created that effect, nor were they asked whether they in fact believed that any particular colour or shade of packaging indicated reduced health risks.[344] In any event, the fact that, even by

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339 Class Action File 1560-08 *Zvi Numberg et al. v. Philip Morris Products et al.*, judgment of 16 May 2010 (District Court in Tel Aviv-Jaffa, Farago J).

340 Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market (OJ 2005 L149/22).

341 This is the case even if the information is factually correct.

342 Consultation, page 6.

343 European Commission, Special Eurobarometer 332, *Tobacco*, May 201 (***Eurobarometer 2010***)

344 Simply because a consumer does not rule out the possibility that a particular coloured package may indicate a particular level of safety does not mean that coloured packaging does in fact do so, in view of (for example) the health warnings on the packet and consumers' knowledge of the health risks of smoking. Respondents were not asked appropriate follow-up questions that might have given an indication as to whether they actually believed particular pack colours or shades to have this effect.

asking a highly leading question,[345] those responsible for Eurobarometer 2010 were only able to elicit a positive response on this issue from 10 per cent of respondents hardly suggests that this is a significant problem. It follows that Eurobarometer 2010 does not, in fact, support DG SANCO's statement in the problem definition or justify changes to the TPD in relation to pack colour.

15.44 Lastly, as to the relationship between health warnings and packaging, JTI considers that increasing the prominence or salience of health warnings on pack is not, of itself, a legitimate public policy goal capable of justifying a plain packs measure. Expert analysis by both Dr Keegan and Professor Devinney explains that 'noticing' something – such as health warning on a tobacco product – would not necessarily translate into a change in actual smoking behaviour by consumer survey respondents.[346] Therefore, it is essential for DG SANCO, and the evidence relied upon by the RAND Report in this regard, to demonstrate convincingly that introducing plain packaging would not only enhance the "visibility", "prominence" or "salience" of health warnings; it would result in changes to smoking behaviour (such as reducing smoking uptake by minors).

Plain packaging will impede and restrict lawful activity, whilst facilitating illegal activities

15.45 The potential economic, policy and legal effects of any regulatory proposal should be balanced carefully before action is taken. The RAND Report has failed to do this. As set out below, a range of serious consequences would flow were DG SANCO to take forward plain packaging as a regulatory initiative. Given that its adverse effects are manifest, and in the absence of reliable evidence, plain packaging is flawed and would breach JTI's fundamental rights.

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

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[345] The question asked of respondents (QD15) was "*Do you think that any of the following is an indication of whether a cigarette brand could be less harmful?*" (Eurobarometer 2010, page 125 (not numbered)). The interviewer was then asked to read out, in turn, the following: "*The taste, such as menthol or sweet flavours", "The tar or nicotine levels indicated on cigarette packs", "The colour of cigarette packs", and "Specific terms in the brand's name, such as 'silver', 'blue' or 'natural'"* (*idem*). The initial question clearly predisposes the respondent to consider that, at the very least, the options they are about to hear *may* indicate that a cigarette brand may be less harmful than another (a possibility that may not previously have occurred to him or her). The respondent is also likely to have been conditioned to answer positively, because he or she presumably knew that the survey was being conducted on behalf of the European Commission (although the authors have not disclosed whether respondents were told this or not). The previous Eurobarometer survey (2008) also exhibited serious methodological flaws, as discussed by Dr Keegan's November 2010 Report, paragraphs 263-266.

[346] This is further supported by Professors Dhar and Nowlis who state, at paragraph 6.20 of their Report: "*any alteration…to draw attention to the health warning seems superfluous as the awareness of the health risk is already high for the regular adult smoker*"… "*there is no credible evidence based on our analysis of adult consumer decision making to suggest that current packaging somehow distracts consumers from paying attention to health warning messages.*"

(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.

15.47 Each of these issues is examined below.

Deprivation of property and/or the impairment of fundamental rights

The fundamental right to property

15.48 A plain packaging measure, if it could be adopted at all, would represent an extraordinary attempt by DG SANCO to deprive JTI of its most valuable assets. Deprivation of property is presumed to be disproportionate and hence unlawful unless JTI is compensated at the full value of its property, which is worth billions of US dollars.[347]

15.49 The fundamental right to property is recognised in Article 1 of Protocol 1 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (the ***ECHR***). The ECHR guarantees that every person is "*entitled to the peaceful enjoyment of his possessions*" and that property rights are "*practical and effective*".[348] Article 6(3) TEU states that the rights guaranteed by the ECHR, including the right to property, "*shall constitute general principles of the Union's law*".[349] The right to property is also enshrined in the Charter, which states that "*everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions*".[350] The Charter is now binding and has "*the same legal value as the* [TEU and the TFEU]".[351] In fact, the Court of Justice has found that "*measures*

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[347] See in this regard *Sporrong and Lönnroth v Sweden* (1982) 5 EHRR 35; *R (o.a.o. Nicholds & Ors) v Security Industry Authority* [2006] EWHC 1792 (Admin); *James v UK* (1986) 8 EHRR 123; *Allard v Sweden* (2004) 39 EHRR 14; *Hentrich v France* (1994) 18 EHRR 440; and *Lallement v France*, application no. 46044/99, available in French only.

[348] *Sporrong and Lönnroth v Sweden* (1982) 5 EHRR 35, paragraph 63.

[349] Article 6(3), TEU.

[350] Charter of Fundamental Rights of the European Union, Article 17(1).

[351] Article 6(1),TEU.

which are incompatible with observance of the human rights thus recognised are not acceptable in the Community".[352]

15.50 It is established EU case law that the right to property "*form*[s] *part of the general principles of Community law. However, those principles are not absolute but must be viewed in relation to their social function. Consequently, the exercise of the right to property and the freedom to pursue an economic activity may be restricted, provided that any restrictions in fact correspond to objectives of general interest pursued by the Community and do not constitute in relation to the aim pursued a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed*".[353]

15.51 This protection extends to intellectual property rights,[354] such as JTI's IPR and the goodwill of the business associated with the use of these rights. Effective and adequate protection of such rights is enshrined in both national, Community and international law.[355] In *British American Tobacco (Investments) Ltd*, the Court of Justice recognised tobacco manufacturers' right to property in their trademarks.[356]

15.52 Reflecting this fact, within the EU, trade marks can be protected at the national level (under national laws implementing the Trade Mark Directive[357]) and/or by registration at the Community level (under the provisions of the Community Trade Mark Regulation (the ***CTMR***)).[358] Trade marks registered at the Community level are protected for the whole of the territory of the EU. National registrations provide

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[352] C-112/00 *Schmidberger v Austria* [2003] ECR I-05659, paragraph 73, re-affirming C-260/89 *ERT* [1991] ECR I-2925, paragraph 41; Case C-299/95 *Kremzow* [1997] ECR I-2629, paragraph 14.

[353] Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health and Others* [2005] ECR I 6451, paragraph 126. See also Case C-210/03 *The Queen, on the application of Swedish Match AB, Swedish Match UK Ltd v Secretary of State for Health* [2004] ECR I-11893.

[354] Recital 11 of the Community Trade Mark Regulation provides that trade marks are "*to be regarded as an object of property*" (see further Articles 16 to 24) and Article 17(2) of the Charter specifically states that "*Intellectual property shall be protected*" within the right to property enshrined in Article 17. See further *Anheuser-Busch Inc v. Portugal* (2007) ECHR 40 (ECHR, Grand Chamber) at paragraphs 66 to 72; Case C-479/04 *Laserdisken ApS v. Kulturministeriet* [2006] ECR I-8089 at paragraph 65; Case C-275/06 *Productores de Musica de Espana (Promusicae) v. Telefonica de Espana SAU* (Grand Chamber) [2008] ECR I-271 at paragraph 62; *Smith Kline and French Laboratories Ltd v Netherlands* (1990) 66 DR 70 and *IRC v Muller & Co's Margarine Ltd* [1901] AC 217, 223.

[355] Case C-89/99 *Schieving-Nijstad VOF v. Groeneveld* [2001] ECR I-5851, paragraph 35; Case C-49/02 *Heidelberger Bauchemie GmbH*, [2004] ECR I-6129, paragraphs 19 - 21; and Case C-245/02 *Anheuser-Busch Inc v. Budejovicky Budvar, narodni podnik* [2004] ECR I-10989, paragraphs 42 and 55 - 57.

[356] Case C-491/01 *The Queen and Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd supported by Japan Tobacco Inc. and JT International SA* [2002] ECR I-11453, paragraphs 149-153.

[357] Directive 2008/95/EC of the European Parliament and of the Council of 22 October 2008 to approximate the laws of the Member States relating to trade marks (codified version)(OJ 2008 L299/25).

[358] Council Regulation (EC) 207/2009 of 26 February 2009 on the Community trade mark (codified version)(OJ 2009 L78/1).

protection only for the territory of registration.[359] JTI is the proprietor of both national trade mark registrations and Community trade mark registrations.

15.53 The specific subject matter of a trade mark includes not only the essential function, which is to guarantee the origin of the goods or services concerned,[360] but also associated functions including the function of communicating to consumers the product's quality, integrity and reliability, as well as other characteristics, and the goodwill or investment function.[361] As a proprietor of such trade marks, JTI has a legitimate interest, related to the specific subject matter of the trade mark right, which it is entitled to protect.[362]

15.54 Use by JTI of its trade marks is recognised by Community[363] and international[364] law as being a central and essential element of trade mark ownership.

15.55 Registration of a trade mark confers the exclusive right on the proprietor to prevent third parties not having his consent from doing certain specified acts. In particular it allows the proprietor to prevent acts by a third party that will "*affect or be liable to affect the functions of the trade mark*".[365] The protection conferred by

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[359] The provisions of the Trade Marks Directive mirror those of the CTMR for the purpose of ensuring that the protection conferred by registration is, in substance, the same under both regimes. The rights of the trade mark proprietor are exhaustively defined in the Trade Marks Directive and the CTMR: Articles 5 to 7 of the Trade Marks Directive; and Articles 9, 12 and 13 of the CTMR.

[360] Case C-206/01 *Arsenal Football Club plc v. Reed* [2002] ECR I-10273, paragraphs 48 and 49; Case C-245/02 *Anheuser-Busch Inc v. Budejovicky Budvar, narodni podnik* [2004] ECR I-10989, paragraph 69; and Case C-17/06 *Céline Sarl v. Céline SA* [2007] ECR I-7041, paragraph 16.

[361] Case C-487/07 *L'Oréal SA v. Bellure NV* [2009] ECR I-5185, paragraph 58; Joined Cases 236/08 to C-238/08 *Google France and Google* [2010] ECR I-0000, paragraph 77; Case C-558/08 *Portakabin Ltd v Primakabin BV* [2010] I-0000, paragraph 30. This line of case law reflected some of the Court of Justice's earlier case law in particular: Case C-348/04 *Boehringer Ingelheim KG v. Swingward Ltd* [2007] I-3391, paragraph 43; Case C-427/93, 4-29/93 and C-436/93 *Bristol Myers Squibb v. Paranova* [1996] ECR I-3457, paragraph 76; and Case C-337/95 *Parfums Christian Dior v. Evora* [1997] ECR I-6013, paragraph 45.

[362] Joined Cases C-427/93, C-429/93 and C-436/93 *Bristol Myers Squibb v. Paranova and others* [1996] ECR I-3457, paragraph 75.

[363] Recital (9) of the Trade Marks Directive makes clear that "*in order to reduce the total number of trade marks registered . . . in the Community . . . it is essential to require that registered trade marks must actually be used or, if not used, be subject to revocation*'. Recital (10) of the CTMR states "*There is no justification for protecting Community trade marks or, as against them, any trade mark which has been registered before them, except where the trade marks are actually used*." See Articles 10 to 12 of the Trade Marks Directive and Articles 15, 42(2), 51 and 99(3) of the CTMR under which rights may lapse or become unenforceable.

[364] See, for example, Article 15.3 of the *World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights* (Available at: http://www.wto.org/english/tratop_e/TRIPS_e/TRIPS_e.htm. (***TRIPS***) (which states that "*Members may make registrability depend on use*") and Article 19.1 of TRIPS (relating to whether trade marks may be cancelled for non-use), as described in Professor Gervais' Report, paragraphs 18, 21 and 27. See also paragraphs 23 to 26, 28, 30, 31, 33, 57(a), 59, 66, 67 and 106 of Professor Gervais' Report.

[365] Case C-17/06 *Céline Sarl v. Céline SA* [2007] ECR I-7041, paragraph 16; Case C-487/07 *L'Oréal SA v. Bellure NV* [2009] ECR I-5185, paragraph 58; Joined Cases 236/08 to C-238/08 *Google*

registration of a trade mark is broader for marks which have a particularly distinctive character as a result of the use made of them,[366] and for marks with a '*reputation*'.[367] Registration also confers the legal right to object to the way in which the goods are subsequently presented for sale.[368]

15.56 As noted above, JTI's established property rights are its most valuable assets, reflecting its investment in its brands. JTI's brands are worth billions of US dollars.

15.57 A plain packaging measure would be a complete prohibition on the use of a substantial part of JTI's trade mark portfolio in the Community as soon as it came into effect. Such a measure would involve the suppression of the information, communication, and goodwill functions of the registered trade marks to a degree that undermines the commercial rationale for trade marks as recognised by the Court of Justice, and protected under Community trade mark legislation.[369]

15.58 JTI would be left unable to exploit its IPR commercially, which would render them, for all practical purposes, valueless in the Community. At the very least, mandating plain packaging, would prevent JTI from making the paradigm use of its trade marks, that is to say on the packaging of the product itself, thereby depriving JTI of the benefit and economic value of the specific subject matter of such marks.

France and Google [2010] ECR I-0000. paragraphs 75, 76; and Case C-558/08 *Portakabin Ltd v Primakabin BV* [2010] I-0000, paragraph 26.

366 See Article 5(1)(b) of the Trade Marks Directive; Article 9(1)(b) of the CTMR; and Case C-251/95 *Sabel BV v. Puma AG* [1997] ECR I-6191, paragraph 24.

367 Case C-487/07 *L'Oréal SA v. Bellure NV* [2009] ECR I-5185, paragraphs 34 and 59, where the Court of Justice held, *inter alia*, (1) that the protection conferred by registration of a trade mark is broader under Article 5(1)(a) of the Trade Marks Directive/Article 9(1)(a) of the CTMR than it is under Article 5(1)(b) of the Trade Marks Directive/Article 9(1)(b) of the CTMR (see also Joined Cases C-23/08 to C-238/08 *Google France v Louis Vuitton* [2010] ECR I-0000, paragraph 78); and (2) that the protection conferred by registration of a trade mark is broader under Article 5(2) of the Trade Marks Directive/ Article 9(1)(c) of the CTMR than it is under Article 5(1) of the Trade Marks Directive/Article 9(1)(a) of the CTMR. This principle is also recognised in Article 6*bis* of the Paris Convention for the Protection of Industrial Property of 1883 (Available at: http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html#P19_138) (the ***Paris Convention***) and Articles 16.2 and 16.3 of TRIPS in relation to well-known marks. As paragraph 25 of Professor Gervais' Report notes, "*preventing or substantially restricting the use of a mark may prevent its development and the acquisition of well-known mark (or mark with a reputation) status and, consequently, the broader scope of protection associated with such status.*"

368 See Article 7(2) of the Trade Marks Directive; and Article 13(2) of the CTMR.

369 The enforcement of the rights conferred by the registration of a trade mark cannot continue to operate if the mark loses its commercial raison d'être, which is to create an outlet for the goods that bear the sign of which it is composed as distinct from the goods of other undertakings. See Case C-495/07 *Silberquelle GmbH v. Maselli Strickmode GmbH* [2009] ECR I-137; C-40/01 *Ansul* [2003] ECR I-2438 and Case C-442/07 *Verein Radetzky-Orden* [2008] ECR I-9223. Further, the Court of Justice has recognised the important significance of trade marks both at the point of sale (Case C-361/04 *Claude Ruiz-Picasso v. OHIM* [2006] ECR I-643, paragraphs 39 and 40; and Case C-24/05 *August Storck KG v. OHIM* [2006] ECR I-5677, paragraphs 71 and 72) and post-sale (Case C-361/04 *Claude Ruiz-Picasso v. OHIM* [2006] ECR I-643, paragraph 46; and Case C-245/02 *Anheuser-Busch Inc v. Budějovický Budvar* [2004] ECR I-10989, paragraph 60. See also C-206/01 *Arsenal Football Club* [2002] ECR I-10273).

Forcing brand names to be written in a standard typeface, colour and size is also an intolerable restriction on the normal and fair use of JTI's word trade marks.

15.59 Mandating plain packaging would destroy the substance of the property to such a degree that there would, at least, be a *de facto* deprivation, and – depending on the formulation of the measure – potentially a *de jure* deprivation. This equates to the total extinction of ownership and protection, and goes beyond "*impairing the very substance of the rights guaranteed*".

15.60 A plain packaging requirement would, depending on the formulation of the measure, have at least the following IPR-related impacts:

(a) the protected functions of JTI's registered national and Community trade marks, in particular the communication function and goodwill or investment function, will be suppressed;

(b) to the extent that JTI was prevented from using its trade marks on the packaging of its products, its ability to take action:

  (i) to prevent acts by a third party that affect or are liable to affect the functions of the national or Community trade mark would be impaired;[370]

  (ii) to protect its national and Community trade marks with a reputation would be diminished and ultimately extinguished. That is to say the rights to extended protection for JTI's registered trade marks with a reputation and to oppose further commercialisation of goods would ultimately be lost;[371] and

  (iii) to oppose trade mark applications and apply to invalidate trade mark registrations at either a national or Community level would likewise be affected;[372]

(c) JTI will lose its rights, including in respect of its unregistered trade marks, thereby preventing it from being able to rely on such rights in the context of proceedings either at the national or Community level;[373]

(d) JTI's national and Community trade marks would be liable to be revoked;[374]

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[370] See Article 5 of the Trade Marks Directive; and Article 9 of the CTMR. See further Case C-17/06 *Céline Sarl v. Céline SA* [2007] ECR I-7041; Case C-487/07 *L'Oréal SA v. Bellure NV* [2009] ECR I-5185, paragraph 58; Joined Cases 236/08 to C-238/08 *Google France and Google* [2010] ECR I-0000, paragraphs 75, 76; and Case C-558/08 *Portakabin Ltd v Primakabin BV* [2010] I-0000, paragraph 26.

[371] See Article 5(2) of the Trade Marks Directive and Article 9(1)(c) of the CTMR.

[372] See Article 4 of the Trade Marks Directive and Article 8 of the CTMR.

[373] Whether for infringement/protection of such rights under national law including by means of a claim for unfair competition or in the context of trade mark opposition proceedings as to which see Article 4(4)(c) of the Trade Marks Directive and Article 8(4) and Article 52(1)(c) of the CTMR.

(e) in Member States where Article 3(2)(a) of the Trade Marks Directive has been transposed, JTI's national trade mark registrations would be liable to be declared invalid, and JTI would be unable to register national trade marks relating to tobacco product packaging;[375] and

(f) to the extent that JTI is deprived of its trade mark registrations:

(i) JTI would be deprived of its ability to prevent third parties not having JTI's consent from doing certain specified acts;[376]

(ii) JTI would be deprived of its ability to oppose trade mark applications and apply to invalidate trade mark registrations at either a national or Community level;[377] and

(iii) Community and national regulatory authorities would be deprived of their ability to take action to tackle illicit trade of tobacco products whether by criminal prosecutions for trade mark infringement or under Regulation (EC) No. 1383/2003.[378]

15.61 The destruction of the substance of JTI's IPR would have a direct impact on the value of its assets. According to international standard ISO 10668:2010[379] on brand valuation, the appraisal of a brand's value "*shall include an assessment of the legal protection afforded to the brand, identifying…the legal parameters influencing negatively or positively the value of the brand*". This standard states that those legal parameters include "*distinctiveness…scope of use…extent of use…notoriety/extent to which [the] brand is well-known…[and] ability of the owner to enforce legal rights*". Plain packaging adversely affects each of those parameters, thereby significantly reducing the value of the relevant trade marks.

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374 On the basis of Article 12 of the Trade Marks Directive and Article 51 of the CTMR.

375 Under Article 3(2)(a) of the Trade Marks Directive, "*[a]ny Member State may provide that a trade mark shall not be registered or, if registered, shall be liable to be declared invalid where and to the extent that: (a) the use of that trade mark may be prohibited pursuant to provisions of law other than trade mark law of the Member State concerned or of the Community*". In Member States that have transposed this Article (for example, the United Kingdom), any EU plain packaging measure would therefore entitle the local intellectual property registries to reject applications for, or invalidate registrations of, non-word tobacco trade marks. See also paragraphs 15.67 to 15.68 below, and paragraphs 21, 59 and 68 of Professor Gervais' Report.

376 On the basis of; Articles 5 and 7(2) of the Trade Marks Directive and Articles 9 and 13(2) of the CTMR.

377 On the basis of Article 4 of the Trade Marks Directive and Article 8 of the CTMR.

378 Regulation 1383/2003/EC of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property. Action by the national or Community authorities can only take action where goods suspected of infringing IPR are in the process of being introduced into or exported from the Community customs territory. Where, to a large extent, trade mark protection is not available in relation to tobacco products such authorities will not be in a position to prevent importation of counterfeit tobacco products (i.e. counterfeit tobacco products in the packaging legally used throughout the rest of the world).

379 Available at: www.iso.org.

The EU's and Member State's obligations under international intellectual property laws

15.62 In addition to the points outlined above, the burden would be on the EU and Member States, as World Trade Organization (***WTO***) members, to demonstrate that a plain packaging measure is consistent with their obligations under TRIPS and other international law obligations on intellectual property rights.[380] JTI believes that the adoption of a plain packaging measure would be in violation of these international obligations, and could give rise to disputes under the WTO Dispute Settlement Understanding. JTI's view is based on the opinion of Professor Gervais on the interpretation of TRIPS and the Paris Convention.

15.63 In particular, Article 20 of TRIPS requires that:

> "*The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings.*"

15.64 Plain packaging would be a special requirement encumbering the ability of JTI (and other manufacturers) to distinguish its goods through its trade marks from those of other entities. It would prohibit the use of non-word marks on packaging and would also require JTI to use its word marks "in special form". IP Australia, which administers Australia's patent, designs, trademarks and other IP systems and advises the Australian government on IPR issues, has even gone so far as to opine that "*this Article was drafted with the intention of restricting mechanisms like plain packaging*".[381]

15.65 JTI acknowledges that WTO members may, in certain limited circumstances, take advantage of flexibilities within TRIPS to address public health concerns.[382] Article 8.1 of TRIPS allows for members to "*adopt measures necessary to protect public health*". However, this Article is not an exception, but rather a statement of principle. Furthermore, the final part of this Article stipulates that such measures have to be consistent with the rest of the provisions of TRIPS. There are, therefore, threshold issues as to whether Article 8 can be used at all to override a breach of Article 20.

15.66 JTI believes that the EU would be unable to demonstrate that plain packaging is genuinely "justified" (Article 20) or "necessary" (Article 8) to achieve a legitimate public policy objective. Having regard to, first, the lack of reliable evidence that the

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[380] The EU has the burden of demonstrating that a measure comes within a permitted exception: *United States – Gasoline*, Panel Report, WTO Document WT/DS2/R,20 May 1996, paragraph 6.20.

[381] Parliamentary Secretary briefing B09/4084, 22 September 2009, authored by Ian Goss, IP Australia; document released under Freedom of Information requests (FOI 138 of 1660).

[382] *Thailand – Restrictions on Importation and Internal Taxes on Cigarettes*, Panel Report, DS10/R-375/200, 7 November 1990.

assumed public health objectives would be achieved by plain packaging[383] and, second, to the availability of less trade restrictive alternative measures,[384] JTI considers that plain packaging will breach TRIPS.

15.67 Other relevant international IPR treaty provisions include Article 7 of the Paris Convention and Article 15.4 of TRIPS. Article 7 states that:

> "*The nature of the goods to which a trademark is to be applied shall in no case form an obstacle to the registration of the mark.*"

15.68 Article 15.4 of TRIPS is essentially the same. Plain packaging deprives JTI of the ability to use non-word trade marks for tobacco products. In the context of EU trade mark law,[385] the DG SANCO proposal would restrict trade mark registrations solely by reference to the "*nature of the goods*", and so would also violate these Articles.

15.69 In such circumstances, a plain packaging measure would also be in breach of the requirements of the WTO Agreement on Technical Barriers to Trade.[386] This may have the consequence of an adverse ruling against the EU.

15.70 In addition to Professor Gervais' opinion, the international law concerns regarding plain packaging have been expressly recognised by both governments and expert bodies:

(a) IP Australia has advised[387] the Australian Government that "*plain packaging may not be consistent with Australia's intellectual property treaty obligations*". IP Australia acknowledges that "*requiring plain packaging would be regarded as encumbering* [within Article 20 of TRIPS] *the ability of an entity to distinguish its goods through its trade marks from those of other entities. IP Australia's understanding is that this Article* [20] *was drafted with the intention of restricting mechanisms like plain packaging.*" Further, on

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383 As set out in this Full Response, there is, without doubt, no prevailing scientific consensus (or sufficient evidence) that plain packaging would bring about a material contribution to the EU's public health objectives (see *Brazil-Tyres*, Appellate Body Report, WT/DS332/AB/R, 3 December 2007, paragraph 151).

384 *Thailand-Cigarettes*, at paragraphs 73-74; see also Sections 41 - 44 of this Full Response.

385 See footnote 375 above in relation to Article 3(2)(a) of the Trade Marks Directive.

386 JTI believes that mandatory plain packaging would, accordingly, be contrary to Article 2.2 of the Agreement on Technical Barriers to Trade (***TBT***), Available at: http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm, which provides that: "*Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create*".

387 Parliamentary Secretary briefing B09/4084, 22 September 2009, authored by Ian Goss, IP Australia; document released under Freedom of Information requests.

Article 8(1) of TRIPS, IP Australia notes that "*it seems unlikely that this Article could be used to avoid Article 20*";[388]

(b) the International Trademark Association (***INTA***) has submitted its opinions on plain packaging to various governments since 1994;[389] and

(c) the US Chamber of Commerce wrote to the Australian government to express its position that plain packaging would "*significantly infringe upon global IP and trademark protections*", including inconsistency with TRIPS, the Paris Convention, TBT and the Australia-US Free Trade Agreement.[390]

Treatment of IPR in the RAND Report

15.71 Given the complexities of these issues, and the number of interested parties who have commented on the IPR issues associated with the introduction of plain packaging, it is unacceptable that the RAND Report suggests that IPR concerns are merely issues which have "*been brought to the fore by the tobacco industry*".[391]

15.72 It is clear from the analysis above that the examination of IPR in one paragraph[392] in the RAND Report is wholly insufficient. Indeed, the conclusion that "*various trademark attorneys…have come to the conclusion that plain packaging would not violate the tobacco industry's intellectual property rights*" is unfounded and incorrect. What is more, the RAND Report cites this conclusion based solely upon an article in the Australian newspaper, *The Age*, and a blog entry on www.crikey.com.au. The inappropriateness and inadequacy of RAND Europe's work is palpable.

Freedom of expression

15.73 Freedom of expression, both to impart and receive communication, is commonly recognised as a cornerstone of democratic society.[393] In the EU, this right is protected by the Charter.[394] It is also protected by Article 10 of the ECHR, whose principles are regarded as part of the "*general principles of the Union's law*".[395] This

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388 Supra footnote 381.

389 See notably INTA's letter to the Canadian Standing Committee on Health, 27 April 1994, to the Department of Health and Ageing, Australia, 24 February 2004.

390 Letter from Myron Brilliant, Senior Vice President, Chamber of Commerce of the United State of America, dated 26 February 2010 to the Senate Standing Committee on Community Affairs, Australia.

391 RAND Report, page 133.

392 RAND Report, page 133.

393 See German Constitutional Court, decision of 10 October 1995 (1 BvR 1476, 1980/91).

394 Charter, Article 11.

395 Article 5(3) TEU. As an example for the protection of the freedom of expression in the Member States, Article 5(1) of the German Constitution grants a constitutional right of freedom of expression. The German Constitutional Court declared this right to be "*one of the most fundamental and highest-ranking human rights*" (decision of 14 May 1985 – 1 BvR 233, 341/81).

protection has been interpreted by the Court of Justice, following ECHR jurisprudence,[396] to extend to commercial freedom of expression.[397]

15.74 JTI acknowledges that this freedom is not an absolute right and that the protection of the public health is a valid objective, for the purposes of which restrictions may be necessary in a democratic society.[398] **The burden is on DG SANCO to justify any restriction on "*reasonable grounds*"**.[399] This has been interpreted to mean that "clear" and "cohesive" evidence is required to show that a measure is necessary and proportionate.[400] DG SANCO must demonstrate that: (a) the measure is rationally connected to legitimate public policy objectives; (b) there should be no less restrictive alternative measures that achieve the same ends; and (c) there must be proportionality between the deleterious effect of the measure and its salutary effects. **Plain packaging meets none of these tests**.

Freedom to trade

15.75 The freedom to trade and conduct business are rights protected under Community law. Article 15 of the Charter states "*everyone has the right to engage in work and to pursue a freely chosen or accepted occupation*" and that "*every citizen of the Union has the freedom to seek employment, to work, to exercise the right to establish and to provide services in any Member State*".[401]

15.76 Such freedoms are an essential element of free-market economics that must be exercised under conditions of equality. It includes the freedom to engage in an economic or commercial activity and the freedom to contract.[402]

15.77 It is established EU case law that the freedom to pursue a trade or profession "*form part of the general principles of Community law. However, those principles are not absolute but must be viewed in relation to their social function. Consequently, the exercise of the right to property and the freedom to pursue a trade or profession may be restricted, provided that any restrictions in fact correspond to objectives of*

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396 ECHR cases *Markt Intern v Germany*, judgment of 20 November 1989, Series A, No 165; *VGT Verein gegen Tierfabriken v Switzerland*, judgment of 28 June 2001, 2001-IV.

397 See, for example, Case C-71/02 *Karner v Troostwijk* [2002] ECR I-03025, paragraph 51; Case C-245/01 *RTL Television* [2003] ECR I-0000, paragraph 73. For the Member States, see German Constitutional Court, decision of 8 October 1996 (1 BvR 1183/90).

398 Article 10(2), ECHR; Case C-380/03 *Germany v Parliament and Council* [2006] ECR I-11573, Opinion of AG Leger, paragraph 215.

399 ECHR cases *Markt Intern v Germany*, cited above, paragraphs 25 and 26; *Groppera v Switzerland*, judgment of 28 March 1990, Series A, No 173, paragraph 55.

400 Case C-376/98 *Germany v Parliament and Council* [2000] I-8419, Opinion of AG Fennelly, paragraphs 159 and 161.

401 Charter, Articles 15(1) and (2). Article 15(3) also states, "[n]*ationals of third countries who are authorised to work in the territories of the Member States are entitled to working conditions equivalent to those of citizens of the Union*". See Article 12(1) of the German Constitution; the right of freedom to trade also applies to companies, cp. Article 19(3) of the German Constitution.

402 See for example with regard to German law the decisions of the German Constitutional Court of 11 July 2006 (1 BvL 4/00) and of 1 March 1979 (1 BvR 532, 533/77).

general interest pursued by the European Community and do not constitute in relation to the aim pursued a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed".[403]

15.78 Infringements of this right are contrary to public policy unless there is a legitimate interest meriting protection and the restraint is reasonable and proportionate.[404] In this regard, the burden lies again with DG SANCO as a matter of fundamental rights. As with the freedom of expression, it is clear that any proposal to restrict JTI's freedom to trade must withstand this constitutional scrutiny. Plain packaging fails to do so.

Protections under bilateral investment treaties (BITs)

15.79 The plain packaging proposal also affects the investments made by JTI in the EU which are protected under relevant BITs. JTI has its headquarters in Geneva, Switzerland. The Swiss Confederation has entered into a number of BITs with EU Member States, including Bulgaria, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia and Slovenia.

15.80 Each of the BITs confers substantive protections on investments notably made by investors of one contracting party in the territory of the other. "*Investments*" expressly include, amongst others, intellectual property rights. JTI has invested in each of the relevant Member States of the EU, and is therefore protected by the substantive protections of the BITs. Whilst the precise terms of each BIT differ slightly, JTI essentially benefits from the following key protections, in particular:

(a) "fair and equitable treatment" which requires the relevant Member States to maintain stable and predictable investment environments consistent with reasonable investor expectations; and

(b) the prohibition on direct or indirect expropriation (or any other measures having the same effect) of investments, unless (i) the measures are justified in the public interest on a non-discriminatory basis and (ii) provision is made for effective and adequate compensation.

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[403] Case C-200/06 *Metronome Musik GmbH v Music Point Hokamp GmbH* [1998] ECR I-01953 at paragraph 21.

[404] See Joined Cases C-143/88 and C-92/89 *Zuckerfabrik Süderdithmarschen AG v Hauptzollamt Itzehoe and Zuckerfabrik Soest GmbH v Hauptzollamt Paderborn. Reference for a preliminary ruling: Finanzgericht Hamburt et Finanzgericht Düsseldorf* [1991] ECR I-00415, where the Court of Justice analysed the effect of a special levy on the sugar producers' right to trade. See also Joined Cases C-37/02 and C-38/02 *Di Lenardo Adriano Srl, Dilexport SrL v Ministero del Commercio con l'Estero* [2004] ECR I-6911, where the Court of Justice discussed the restriction of tariff quotas in a Commission regulation on operators' right to trade in the banana industry. See also Joined Cases C-184/02 and C-223/02 *Kingdom of Spain and Republic of Finland v European Parliament and Council of the European Union* [2004] ECR I-7789, where the Court of Justice analysed the regulation of road transport industry's driving restrictions in respect of self-employed drivers' right.

15.81 The BITs contain investor-state dispute resolution provision, which would allow JTI to bring arbitrations directly[405] against the relevant Member State, notably under the auspices of the International Centre for Settlement of Investment Disputes (***ICSID***), to protect the rights conferred on them. Proceeding with a plain packaging measure could therefore expose the relevant Member States to challenge.[406]

15.82 JTI considers that DG SANCO should not propose measures that would, if adopted, place relevant Member States in breach of their BIT obligations. Furthermore, as the relevant Member States are bound to promote investments by Swiss investors and to "*constantly guarantee the observance of the commitments it has entered into*",[407] those Member States should not take steps within the forum of the EU, such as voting for a plain packaging measure, that will breach their BIT commitments. DG SANCO's proposals therefore create significant legal and diplomatic risk exposure for at least 11 Member States under BIT obligations.

Undermining progress being made in tackling the illicit trade in tobacco products

15.83 JTI believes that mandated plain packaging will significantly impede and restrict the lawful activity of manufacturers, while unintentionally facilitating illicit trade.[408] It is not alone in this view.[409] Ultimately, this will jeopardise the objectives of the FCTC regarding elimination of all forms of illicit trade.

15.84 These impacts are made more serious by the tendency of criminal gangs to evolve their activities to take advantage of regulatory developments or to focus on new activities where one form of illicit trade has been made more difficult or less profitable.

15.85 The impact of plain packaging on the illicit trade has been expressly recognised by the Australian Government. IP Australia has stated, "*Requiring plain*

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405 None of the BITs between the Swiss Confederation and the EU Member States requires the prior recourse to national remedies before an investor can commence the dispute resolution procedures.

406 JTI notes that there are precedents for such challenges regarding tobacco control legislation. In March 2010, PMI commenced proceedings against Uruguay before an ICSID arbitral panel regarding Uruguayan legislation imposing health warnings comprising 80% of the front and back panels of cigarette packaging.

407 See, for example, Article 11 of the BIT between the Czech and Slovak Republic and the Swiss Confederation, dated 5 October 1990. Equivalent provisions are included in other BITs between the Swiss Confederation and EU Member States.

408 These issues are examined in more detail in Section 35, below.

409 The UK Government's Response to the FTC Consultation states that most of the respondents opposed to "*plain packaging*" suggested that such a requirement would stimulate counterfeit and illicit trade (available at: http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_091382, page 25).

packaging would make it easier for counterfeit products to be produced and would make it difficult to readily identify those counterfeit products".[410]

15.86 JTI expects plain packaging to have a number of unintended consequences as regards illicit trade. In summary, JTI is extremely concerned that mandating plain packaging will:

(a) facilitate the manufacture of counterfeit products;

(b) remove key cost constraints for counterfeiters, as each pack is essentially the same;

(c) complicate regulator investigations/prosecutions;

(d) result in the continued creation of branded packs by counterfeiters, without JTI being able to enforce its trade marks;

(e) increase the trade in "illicit whites";

(f) crystallize pack design for the benefit of counterfeiters;

(g) frustrate tracking and tracing initiatives;

(h) restrict the ability to identify counterfeit product; and

(i) impair the ability of enforcement authorities, as well as JTI, to take infringement action.

15.87 To the extent that plain packaging facilitates the trade in counterfeit and/or contraband cigarettes, increases demand for contraband and risks undoing much of the progress made in tackling this trade, it will have these additional negative consequences:

(a) undermining the EU and the FCTC's illicit trade objectives;

(b) posing risks to consumers;

(c) worsening social inequalities;

(d) depriving governments of revenue;

(e) causing significant losses to legitimate business; and

(f) profiting serious criminal organisations.

15.88 By way of practical example, criminal gangs have in recent years focussed on the contraband trade in "illicit whites". In essence, 'illicit whites' are brands manufactured legitimately in one market, either taxed for local consumption or

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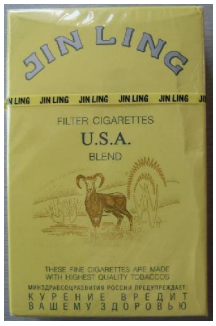
[410] Parliamentary Secretary briefing B09/4084, 22 September 2009, authored by Ian Goss, IP Australia; document released under Freedom of Information requests (FOI 138 of 1660).

untaxed for export, and sold knowingly to traders who transport them to another country where the products are sold illegally without domestic duty paid. Needless to say, this "destination market" will have significantly higher tax rates than the "source market".

15.89 Particular brand identity or notoriety has been gained in recent years by the illicit white brand "Jin Ling", manufactured by Baltic Tobacco Factory in Kaliningrad and other production sites in Moldova and the Ukraine. The factory in Kaliningrad is said to have a production capacity of 24 billion cigarettes a year, which is equivalent to 7% of legal European imports.[411]

15.90 Jin Ling's pack design resembles the iconic brand Camel,[412] launched in 1913 save that it features a goat instead of a camel.



15.91 Jin Ling has been called "*the first international illicit brand*"[413] which was "*made to be smuggled*".[414] According to reports by investigative journalists, Jin Ling is manufactured to order. Smugglers can buy Jin Ling from the factory at a price per box of 20 U.S. cents or €0.16. A container of ten million cigarettes costs US$ 102,500. The return on such a shipment for the smugglers is said to be tenfold, i.e., over US$ 1 million per container.[415]

15.92 While Jin Ling has been seized in many European countries, it has been particularly successful in Germany where it has been alleged to have become a Top Ten brand by volume.

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411 Euromonitor, *Illicit Trade in Tobacco Products – A World View*, July 2010, Slide 50 ("*Case Study: Jin Ling – The First International Illicit Brand*").

412 An old Camel pack is used for comparison purposes.

413 *Ibid.*

414 Shleyov, R. , Candea, S., Campbell, D., Lavrov, V., "Made To Be Smuggled. Russian Contraband Cigarettes 'Flooding' EU", *International Consortium of Investigative Journalists (ICIJ)*, October 19, 2008. The ICIJ is a project of the Center of Public Integrity in Washington, D.C.

415 See also: Bräuninger, M. and Stiller, S., *Ökonomische Konsequenzen des Konsums von nicht in Deutschland versteuerten Zigaretten. Hamburgisches WeltWirtschaftsInstitut*, 2010. The study investigates the situation in Germany. The authors calculate a profit of 900% on Jin Ling for the smugglers with a 5% risk of being apprehended.

Measures taken by JTI to address illicit trade in the EU

15.93 The introduction of plain packaging would also undermine JTI's considerable efforts in combating the illicit trade in tobacco.

15.94 JTI has made reducing illicit trade in tobacco products a key business priority. In addition to working with national authorities in numerous markets, often through Memoranda of Understanding, JTI has entered into an historic agreement with the Commission and all 27 Member States of the EU to combat the illegal trade in cigarettes in the European territory. JTI continues to offer solutions to illicit trade issues.

Erosion of brand equity and a disproportionate impact on premium brand owners

15.95 JTI is a premium brand owner and central to its EU product portfolio are its premium cigarette brands, including Winston, Camel, Benson & Hedges, Silk Cut, Sobranie of London and LD. JTI has invested very substantially in its brands, as reflected by the brand awareness and strong positive associations that the brands have engendered amongst adult smokers.

15.96 Plain packaging eradicates branding and will erode brand equity most notably in leading, premium brands. Premium brand owners, such as JTI, will therefore be disproportionately affected as they have most to lose. The RAND Report correctly notes that "*those with a larger portfolio of high-margin brands are likely to incur higher costs by implementing the suggested measures*".[416]

15.97 The discriminatory effect of plain packaging for JTI (and other premium brand owners) would be exacerbated if plain packaging was to lead to 'downtrading' in consumer purchasing and the eventual commoditisation of tobacco products. Again, this would impact JTI to a greater extent than other tobacco manufacturers in various different Member States which are more reliant on non-premium value brands.

Serious and unnecessary damage to legitimate economic interests and competition

15.98 Dr Lilico's expert consideration of plain packaging as a potential regulatory measure in the UK identifies that it would be likely to have significant repercussions on the operation of the market in tobacco products. JTI considers that it is highly likely that, were DG SANCO to mandate plain packaging, it will result in:

(a) a significant reduction in the typical 'brand switching' activity that JTI would normally expect to see carried out by existing adult smokers across the Member States, as consumers' navigation between brands is frustrated;

(b) a corresponding increase in brand consolidation as consumers are left to request and purchase those brands of tobacco products familiar to them;

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[416] RAND Report, page 152.

(c) a significant reduction in consumer choice in legitimate tobacco products as JTI and other manufacturers who comply with legislative requirements are hampered in their ability to successfully launch new brands into the market; and

(d) a barrier to new entrants as entities seeking to enter the tobacco market will be unable to compete effectively with existing market participants on any basis other than price. As identified in respect of the UK in Dr Lilico's September 2008 Report, at paragraphs 5.22 to 5.23, the erosion of the competition position that brands afford would very probably result in an increased focus upon price as one of the most important remaining dimensions of competition.[417]

15.99 As identified by Dr Lilico at Sections 4 and 5 of his September 2008 Report, the operation of competitive markets provides stimulus for innovation and the provision of products with distinct characteristics, a wider choice and greater efficiency. In the absence of the ability to distinguish products by virtue of packaging, manufacturers may be reluctant to invest in R&D and new products and/or would be forced to rely on product pricing as the primary basis for competing and distinguishing its brands from those of its competitors. Dr Lilico states, at point 8 of the Summary of the September 2008 Report's Findings, that "*a plain packs requirement* [in the UK] *would probably all-but end product innovation*" and that the negative competition effects would be noticeable and material.

15.100 Plain packaging could also lead, for practical purposes, to the crystallisation of market shares such that the competitive process is undermined and market shares become (more or less) fixed.

15.101 Various effects may flow:

(a) **market dynamics will be impaired**: as Dr Lilico finds in his analysis in respect of the UK, the dynamics of concentration are likely to be very noticeably impaired, with materially greater market power of well-established brands and loss of competitive position for firms that depend upon innovation or brand proliferation.

(b) **price effects/potential commoditisation**: an anticipated market reaction to plain packaging would be rapid falls in the prices of premium product, and then price stabilisation later as ongoing competitive pressures are reduced. Manufacturers could increasingly be forced to compete on the basis of price.

As Dr Lilico notes at paragraph 5.24 of his September 2008 Report, the risk of counterfeit and contraband increasing might well limit the scope for tax rises to offset these price falls.

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[417] This issue is also addressed at paragraphs 8.18-8.21 of Professor Cave's Report, where it is noted, amongst other things that mandated plain packaging may lead to "*a greater focus on price competition*".

(c) **lowering of quality standards**: a downward shift in product prices could lead to a reduction in the quality of tobacco products as margins are impacted. Further, where price becomes increasingly significant as the key product differentiator, there is an increased opportunity for others to enter the market with poor quality products through brands with no lasting presence, meaning those market entrants can effectively avoid responsibility for substandard products.

(d) **a reduction in consumer choice and a barrier to new entrants** (other than those reliant on lower prices as a differentiator), as discussed above.

15.102 Plain packaging would, in JTI's view, also be likely to impact on the operation of a fair and competitive market in tobacco products as it would generate genuine confusion amongst existing smokers who, at the point of sale, would be unable to recognise their preferred brand of JTI product.

15.103 Consumers, having made a decision to purchase a tobacco product and on entering a shop, would be faced with a gantry of identical looking packaging.

15.104 Instead of being able to easily recognise their preferred brand, it is likely that material delay and inconvenience would be incurred in determining which of the various packets is the desired product. If consumers ultimately discern that their preferred brand is unavailable, they will then be unable to navigate easily and freely between the alternative products on sale. The inability of consumers to recognise their preferred product is likely to result in consumer dissatisfaction. This may result in unintended loss of customers for JTI and could potentially lead to the loss of franchise to another brand on a temporary or permanent basis.

15.105 Consumers proactively seek information about the products that they wish to purchase. Restricting the ability of consumers to make informed purchasing decisions would also be contrary to the free flow of information which underpins a successful market economy.

15.106 Plain packaging would similarly cause significant confusion and disruption for participants in the product supply chain. For retailers and wholesalers, tasks which would have relied upon visual pack recognition, such as re-stocking, shelving and pack selection at a customer's request, will be made more difficult if that point of reference is removed. This may lead to an increase in the administrative burden for retailers due to the added time required to stock gantries in an appropriate manner and/or locate products in response to consumer requests.

Diminished contribution to the economy

15.107 Any change to the packaging of JTI's products that is required as a result of plain packaging is likely to lead to significant job losses and reductions in income and economic activity in the EU on the basis of:

(a) a shift from the legitimate to the illicit trade; and

(b) 'downtrading' from premium to cheaper legal tobacco products.

15.108 Such a change will also represent a significant transition cost for JTI.

15.109 Plain packaging will undermine any future investment and innovation by the tobacco sector in packaging which will have severely detrimental economic impacts on numerous service industries, including pack designers, pack manufacturers and printing and ink suppliers.

Alternative solutions

15.110 JTI considers that there are less restrictive, more targeted and proportionate alternative solutions that would avoid the unnecessary, unjustified and disproportionate effects of plain packaging. These are set out in Sections 41 - 43, below.

16. PROPOSAL TO 'ENLARGE' HEALTH WARNINGS

Introduction

16.1 JTI rejects DG SANCO's proposal to increase the size of on-pack health warnings on the principal display area of the pack. The Consultation suggests that health warnings be "enlarged" without any reference to the possible size of the enlarged warnings. The RAND Report, in turn, considered measures to "*enlarge warnings to 50% of both sides of the pack and place them at the top of the pack*", "*increase the size of warnings to 75% of both sides of the pack*" and "*increase the size of the warnings on the back of the pack to 100%*".

16.2 JTI considers that the proposal to enlarge 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 assumed objective of changing smoking behaviour.

Instead, DG SANCO has sought to rely on methodologically flawed studies, while failing to take into account evidence which suggests that such warnings will not be effective. In particular, cross-sectional wave survey evidence was collected in Canada before and after health warnings increased in size from 25% to 50% (with pictures).[418]

The evidence demonstrates that the larger pictorial warnings do not change smoking behaviour;

(b) The proposal would have **serious negative and undesirable consequences** on the legal, fair and competitive market economy in tobacco products, including undermining the ability of the legal tobacco industry to brand and distinguish its products;

(c) The proposal would engage various **legal rights**, that are protected by: the Treaties (e.g. freedom of expression and the right to property), international trade treaties (e.g. the WTO and TBT), intellectual property laws (e.g. the Paris Convention, TRIPS and EU/national laws) and BITs;

(d) The proposed larger health warnings **interfere disproportionately with JTI's commercial rights**, in particular its trade marks, goodwill and the value of its brands. It also interferes with the freedom to communicate with existing adult smokers (and consumers' rights to product choice, fair competition and product information); and

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[418] Surveys by Environics Research Group Limited, *The Health Effects of Tobacco Health warnings on Cigarette Packages*, Wave 1 to Wave 13 Surveys of Adults and Adult Smokers and Surveys of Youth, 2001-2007. Canada was the first country in the world to introduce pictorial health warnings covering 50% of the principal display surfaces of the pack.

(e) It is **disproportionate and contrary to Better Regulation principles** for regulators to rely excessively on on-pack health warnings, whilst under utilising and failing adequately to consider other communication vehicles.

16.3 In addition, DG SANCO also states, in Option 2(b), that "*information on a telephone service to help quit smoking would be placed on the package*". It is unclear whether this proposal seeks to change the use of the existing areas of the package that are mandated by the TPD for health warnings, i.e. to change the content of the warnings to include a quit-line, or to require an additional mandated mention on tobacco packaging. It seems likely that providing both information on smoke constituents and quit-line details would require a significantly larger amount of space on the pack than is currently mandated for TNCO yield data, particularly in Member States where multiple language versions would be required.[419] Furthermore, as the TPD already mandates that each tobacco packet carries a rotating additional warning, one of which provides "*Get help to stop smoking: (telephone/postal address/internet address/consult your doctor/pharmacist)*" (i.e. a quit-line),[420] JTI presumes that the proposal seeks to mandate a further health warning message to the package regarding quit-lines, of unspecified size, in addition to the existing mandated space. The quit-line proposal is simply a further attempt to enlarge health warnings.

16.4 Updating health warnings can be done without further restricting the tobacco industry's trade marks and eroding the brand value and good-will associated with its premium brands. JTI considers that to press ahead with larger health messages, in the absence of any reliable evidence and in the face of legal and commercial risks, is disproportionate, unwarranted and unnecessary.

16.5 If the health warnings under contemplation by DG SANCO amount, in effect, to plain packaging, JTI reiterates its categorical opposition to plain packaging for the reasons set out in Section 15 above.

The objectives behind DG SANCO's proposal

16.6 DG SANCO does not identify the public policy objectives underlying its proposal to increase the size of health warnings. JTI notes the vague nature of the proposal and that the Consultation merely states that, in respect of health warnings, "*the bigger the size, the more effective it is*".[421] This is not efficient or fair public policy, nor does it accord with Better Regulation principles.

16.7 JTI submits that it is of the utmost importance that DG SANCO (i) identifies the technical specifications in respect of increasing the size of the health warning and; (ii) should establish the objective sought by the proposal and provide evidence in

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[419] Indeed, the RAND Report states (page 148): "*Crucial aspects of such measures are the length of the text, its style, its placement, its content and the frequency of change of wording.*"

[420] TPD, Article 5(2)(b), Annex 1, additional health warning no. 10. JTI notes that the RAND Report makes no mention of the existence of this warning in its consideration of "quit-lines", referring solely to Australian data (RAND Report, page 135).

[421] Consultation, page 6.

support. JTI assumes that the objective behind the proposal is to change smoking behaviour. Introducing larger health warnings will not achieve this objective.

DG SANCO and the RAND Report have failed to provide any reliable evidence demonstrating that the proposal will achieve legitimate public health objectives

16.8 DG SANCO cites no evidence in the Consultation in support of the proposal to increase the size of health warnings. According to the principles of Better Regulation and the general principles of the right to property, freedom of expression and proportionality, the burden lies on DG SANCO to justify increasing the size of the warnings. DG SANCO must provide reliable evidence demonstrating clearly that increasing the size of health warnings will achieve its (currently inarticulated) policy objectives.

16.9 The RAND Report nevertheless undertakes a review of selected literature in respect of health warnings. Whilst asserting that the evidence suggests that "*increasing the size of warnings to 75% of both sides of the pack*" will lead to a reduction in smoking prevalence, the RAND Report also acknowledges that "*there is little evidence of observed change as a result of labels on tobacco products*".[422]

16.10 From the outset, JTI notes that the RAND Report cites a variety of studies that collect and/or evaluate original consumer survey research, rather than presenting its own original survey research. The RAND Report is a secondary source on the topic of larger health warnings, but undertook no critical analysis of the evidence that it was summarising. Additionally, the RAND Report repeatedly cites the Sambrook Report regarding its findings on larger health warnings. The RAND Report cites the Sambrook Report in respect of a number of statements including, but not limited to, the following:

(a) "*Warnings combining text and pictures are shown to be more effective than text alone and bigger sized labels are more effective than smaller ones*";[423] and

(b) "*In addition, there is wide-ranging evidence that different consumer groups (i.e. young, female, older consumers etc) react to different messages and pictures*".[424]

16.11 As discussed above in paragraphs 15.27 - 15.28, of critical importance to note is that the Sambrook Report is also a secondary source of research, conducting a review of the existing literature rather than presenting original market or consumer survey data. The RAND Report is therefore a tertiary source of evidence in this regard. RAND Europe has acknowledged that it has not conducted a "*comprehensive, systematic literature review*" as it was operating under "*tight time and resource constraints*".[425] RAND Europe has not itself reviewed the available primary evidence

[422] RAND Report, page 135.

[423] RAND Report, page 130.

[424] RAND Report, page 130.

[425] RAND Report, page 7.

on the potential impacts of increasing the size of health warnings on cigarette packs, such as the studies referred to in the Sambrook Report.

16.12 Should DG SANCO rely on the RAND Report in its IA, it would be proceeding four steps removed from the primary data. JTI would expect DG SANCO to undertake its own analysis of evidence.

16.13 In contrast to the approach adopted in the RAND Report, Dr Keegan has undertaken an in-depth comprehensive analysis of the studies put forward in the RAND Report and the Sambrook Report in respect of larger health warnings to determine whether DG SANCO's proposal to "*enlarge*" health warnings is based on reliable evidence.

16.14 In Dr Keegan's November 2010 Report, he states that "*DG SANCO cites no evidence to support the Proposal* [to increase the size of health warnings on cigarette packs]. *Therefore, in undertaking this task, I have examined each study on the topic of increasing the size of health warnings cited in the RAND Report. I have done so to determine the extent to which these studies provide reliable evidence in support of the proposition that increasing the size of cigarette pack health warnings, as proposed in Option 2(a) of Section 3, would impact smoking behaviour among consumers*".[426]

16.15 Having reviewed the evidence cited in the RAND Report (including analysis of the evidence relied on in the Sambrook Report in respect of the size of the health warning), Dr Keegan has concluded that "*I have found that no study provides reliable evidence as to the potential behavioural impact of increasing the size of the health warning labels on cigarettes*".[427]

16.16 Dr Keegan notes that the RAND Report and the Sambrook Report cite a variety of different types of studies on the topic of increasing the size of health warnings. He states that "*some of* [these] *studies have the <u>potential</u> to inform the debate regarding possible behavioural impacts of increasing the size of the health warnings on cigarette packs. Such studies include those that collect or examine primary data and have a behavioural element – i.e. attempt to measure potential way(s) in which an increase in the size of health warnings could impact consumers' smoking behaviours*".[428]

16.17 In setting out his approach in evaluating such studies, Dr Keegan found it necessary to "*conduct a full analysis of each study's design, execution, results, and conclusions*". Further, and in contrast to the approach adopted by RAND Europe, Dr Keegan states that "*one must assess to what extent each study measures the variables it sets out to measure, whether data collection is undertaken objectively, whether the results are presented and interpreted objectively, the degree to which the study is*

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[426] Dr Keegan's November 2010 Report, paragraph 4.

[427] Dr Keegan's November 2010 Report, paragraph 11.

[428] Dr Keegan's November 2010 Report, paragraph 8.

statistically rigorous, and whether the authors' conclusions are supported by the data".[429] The key limitations in respect of these studies are set out below:

(a) **The ITC Project/ITC Summary Document (2009).**[430] The ITC Project is cited in support of the statement that "*labels that are larger and contain more 'vivid' warnings are more likely to have a lasting impact on consumers than less prominent, text-only warnings*".[431] Dr Keegan states that his ability to assess the ITC Project and all studies that are based on ITC data is "*significantly impeded by the ITC's policy of selective disclosure of its survey data*", and therefore "*all studies based on ITC data should be considered with caution*". In addition, Dr Keegan notes that there are additional methodological limitations in respect of the ITC Project including "*inappropriate use of the cohort study design, an inconsistent questionnaire across study waves, country comparisons which do not adequately account for inherent differences between compared populations, leading questions, and potentially biased data collection procedures*".[432]

(b) **Hammond et al. (2006)**.[433] This study is put forward in the RAND Report to support the statement that "*there is evidence in the literature that the size of the warnings impacts on the consumers' awareness and behaviour, with larger warnings being more effective*".[434] In fact, Dr Keegan finds that this study "*fails to account for cultural differences that may exist between its samples, and does not directly test for any specific impact of an increase in the size of health warnings on consumer smoking behaviour*".[435]

(c) **Hammond et al. (2007)**.[436] This study is cited in the Sambrook Report to corroborate the statement that "*large, prominent warnings are significantly more effective than more obscure warnings*".[437] Once again, this study relies on the use of ITC data. Dr Keegan considers that this study makes "*inappropriate use of the cohort design and makes uncontrolled country comparisons*". Further, the only relevant behavioural question in this study

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[429] Dr Keegan's November 2010 Report, paragraph 9.

[430] *International Tobacco Control Policy Evaluation Project*, launched in 2002, ongoing, and International Tobacco Control, "*FCTC Article 11 – Tobacco Warning Labels: Evidence and Recommendations from the ITC Project*" (2009).

[431] RAND Report, page 129.

[432] Dr Keegan's November 2010 Report, paragraphs 10 and 77–115.

[433] Hammond, D., Fong, G.T., McNeill, A., Borland, R., Cummings, K.M, "Effectiveness of Cigarette Warning Labels in Informing Smokers about the Risks of Smoking: Findings from the International Tobacco Control (ITC) Four Country Survey", *Tobacco Control* (2006) Vol.15, pages 19-25.

[434] RAND Report, page 130.

[435] Dr Keegan's November 2010 Report, paragraphs 10 and 116-131.

[436] Hammond, D., Fong, G.T., McNeill, A., Borland, R., Cummings, K.M, "Text and graphic warnings on cigarette packages: Findings from the International Tobacco Control Four Country Study" *American Journal of Preventative Medicine* (2007) Vol. 32, No.3, pages 210-217.

[437] Sambrook Report, page 118.

"*shows no link between behavioural change and warning label changes, and therefore does not provide insight as to the impact of larger health warning labels on consumer behaviour*".[438]

(d) **Elliott and Shanahan (2008)**.[439] This study is put forward in the RAND Report to support the statement that "*there is evidence in the literature that the size of the warnings impacts on the consumers' awareness and behaviour, with larger warnings being more effective*".[440] By contrast, Dr Keegan considers that "*this study suffers from a number of limitations, including excessive passage of time between data collection waves, significant question design issues, and subjective, potentially misleading presentation of the study results*".[441]

(e) **Environics (2008)**.[442] This study, which is comprised of a youth survey and separate adult survey, is referenced at pages 43 and 118 of the Sambrook Report in respect of the size of the health warning. Dr Keegan considers that the study "*suffers from significant limitations*"; it largely reports on attitudinal data "*which has no bearing on potential behavioural outcomes of an increase in health warning label size*" and that "*the only behavioural question presented to respondents is without context and, therefore, wholly uninformative*".[443]

(f) **Joossens (2004)**.[444] This study is cited in the Sambrook Report to corroborate the statement that "*large, prominent warnings are significantly more effective than more obscure warning*".[445] In his review of this study, Dr Keegan considers that "*a significant limitation of this study is that the questionnaire is not provided; it is therefore unknown what was asked of respondents*" and that the study "*also suffers from an inappropriate study design and leading questions*".[446]

16.18 Dr Keegan notes that the RAND Report and the Sambrook Report cite additional documents which do not have the potential to inform regarding the potential behavioural impacts of increasing the size of the health warning. These

[438] Dr Keegan's November 2010 Report, paragraphs 10 and 132-144.

[439] Shanahan, P, Elliott, D., "*Evaluation of the Effectiveness of Graphic Health Warnings on Tobacco Product Packaging*", *For the Australian Government, Department of Health and Ageing* . (2008), pages 1-230.

[440] RAND Report, page 130.

[441] Dr Keegan's November 2010 Report, paragraphs 10 and 145-177.

[442] Environics Research Group, *Consumer Research on the Size of Health Warning Messages – Quantitive Study of Canadian Adult Smokers* (2008) and *Consumer Research on the Size of Health Warning Messages – Quantitive Study of Canadian Youth* . (2008), prepared for Health Canada.

[443] Dr Keegan's November 2010 Report, paragraphs 10 and 178-198.

[444] Joossens, L., *Investigation into the effects of health warnings on cigarette packets in Belgium* (2004), Belgian Minister of Public Health and Social Affairs, pages 1-18.

[445] Sambrook Report, page 118.

[446] Dr Keegan's November 2010 Report, paragraphs 10 and 199-207.

documents include two studies which are "*focus group studies, which [are] exploratory in nature, carr[y] no statistical weight and the results of which cannot be generalized to broader populations outside of the study sample*"[447] and two studies which only present attitudinal/opinion data ("*attitudinal data is not a reliable indicator of potential behavioural change associated with a policy shift*").[448] Further, two additional documents are cited which do not present or analyse any original data[449] and, contrary to Better Regulation, an additional document is put forward in the Sambrook Report which does not appear to be publicly available.[450]

16.19 JTI believes that the comprehensive and systematic analysis of the primary material cited in the RAND Report, and in the Sambrook Report, conducted by Dr Keegan fundamentally undermines the RAND Report's conclusion, on a "*rapid review*" of the evidence, that "*the larger the warnings, the more effective they tend to be*".[451] Dr Keegan's conclusion is that there is no reliable evidence on which to reach this conclusion.

16.20 This view is further supported by Professors Dhar and Nowlis who reviewed various studies relied on in the RAND Report from a consumer behaviour perspective. They conclude, at paragraph 6.12 of their Report:

> "*much of the existing consumer research on the effect of health warning messages,… which we have reviewed uses an improper methodology in the ways we have described above. The work is flawed because of demand artifacts, which result in responses that are likely not what the consumer*

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[447] See: (i) O'Hegerty, M. et al., "Young Adults' Perceptions of Cigarette Warning Labels in the United States and Canada", *Preventing Chronic Disease – Public Health Research Practice, and Policy* (2007), Centre for Disease Control and Prevention, Atlanta, Vo. 4, No. 2, pages 1-9, which is cited at page 118 of the Sambrook Report and discussed by Dr Keegan at paragraphs 267-271 of his November 2010 Report and; (ii) BRC Marketing and Social Research, *Smoking Health Warnings Study – Optimising Smoking Health Warnings Stage 2 – Text, Graphics, Size and Colour Testing* (2004), prepared for the New Zealand Ministry of Health, which is cited at page 131 of the RAND Report and page 118 of the Sambrook Report, and is discussed in Dr Keegan's November 2010 Report, paragraphs 274-278 .

[448] See (i) Createc Report prepared for Health Canada, *Effects of Modified Packaging Through Increasing the Size of Warnings on Cigarette Packs: Quantitative Study of Canadian Adult Smokers* (2008) and *Effects of Modified Packaging Through Increasing the Size of Warnings on Cigarette Packs: Quantitative Study of Canadian Youth Smokers and Vulnerable Non-Smokers* (2008) which are cited at pages 43 and 118 of the Sambrook Report and discussed at paragraphs 250-262 of Dr Keegan's November 2010 Report; and (ii) Flash Eurobarometer 253, European Commission, *Survey on Tobacco – Analytical Report* (2008) which is cited at page 118 of the Sambrook Report and discussed at paragraphs 263-266 of Dr Keegan's November 2010 Report.

[449] See (i) UK Department of Health, *The Introduction of Picture Warnings on Tobacco Packs – Final Regulatory Impact Assessment* (2007), which is cited at page 130 of the RAND Report and discussed at paragraphs 272-273 of Dr Keegan's November 2010 Report and; (ii) Zatonski, W., "Democracy and Health: Tobacco Control in Poland", in *Tobacco Control Policy: Strategies, Successes and Setbacks: Six Country Case Studies* (2003), which is cited at page 118 of the Sambrook Report and discussed at paragraphs 279-280 of Dr Keegan's November 2010 Report.

[450] See Ministry of Health Romania, *Evaluation of the impact of diverse tobacco control measures* (2008) which is cited at page 118 of the Sambrook Report.

[451] RAND Report, page xxiv.

actually believes but are instead what the consumer thinks is the appropriate answer. This work is also flawed because it assumes that consumers are able to predict what will influence their, or others' behavior, when in fact much research shows that consumers are not able to accurately do this. Finally, this work is flawed because it does not account for the fact that survey questions are often asked when consumers are not in the same mindset as they are when they are craving a cigarette or are currently smoking. As a result, it is impossible to form any valid conclusions based on this research."

Evidence that the proposed larger warnings will fail to achieve public policy objectives

16.21 The RAND Report refers to (unreliable) evidence in Australia and New Zealand, and fails to consider sufficiently evidence from Canada which suggests that the proposed larger health warnings will fail to achieve the assumed objectives. **Cross-sectional wave survey evidence from Canada, the first country in the world to introduce pictorial health warnings covering 50% of the principal display surfaces of the pack, demonstrates that larger pictorial warnings there did not enhance awareness of the health risks of smoking or change smoking behaviour**.[452] This conclusion was reached in Dr Keegan's March 2010 Report and in Professors Dhar and Nowlis's Report. JTI believes that DG SANCO should take this evidence, which is examined in more detail below, into account when evaluating its proposal.

16.22 When the Canadian government increased the size of their health warnings from 25% to 50% of the principal display area of the pack and introduced pictorial health warnings, it commissioned a series of Wave Surveys from Environics both immediately before and in the years after their introduction (the ***Canadian Wave Surveys***).

16.23 The Canadian Wave Surveys started with a baseline study of the 25% black on white, white on black text-only messages in use until 2000, followed by similar surveys conducted twice yearly from 2001 to 2007, among both adult and youth populations, following the introduction of the 50% pictorial health warnings.[453]

16.24 The Canadian Wave Surveys indicate that the smokers questioned believed the larger pictorial warnings to be marginally more effective than their predecessors at reminding them of the health effects of smoking, as well as getting them to smoke less in the presence of others, increasing their desire to quit or getting them to smoke less. However, it is well established that people are not particularly reliable at self-assessment. Indeed, Dr Keegan states in his report that "*observing what people do is a better predictor of behavior than recording how people respond to questions about what they think they will do, or what they think others will do, or what they report*

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[452] See footnote 418, Baseline Survey and subsequent Wave 1 to Wave 13 Surveys of Adults and Adult Smokers and Surveys of Youth, 2001-2007.

[453] See footnote 418, Baseline Survey and subsequent Wave 1 to Wave 13 Surveys of Adults and Adult Smokers and Surveys of Youth, 2001-2007.

they have done"[454] and, moreover, that "*it is well established that consumer recall of past behaviors can be inaccurate, as the time elapsed between the event and the time of reporting can distort respondents' perceptions*".[455]

16.25 The problems with recall reliability are born out in responses to questions in the Canadian Wave Surveys, which illustrate the gap between attitudes or self-assessment and actual behaviour:

(a) Daily consumption among continuing regular smokers, both adult and youth, showed no decline between 2000 and 2002. Notwithstanding what the subjects of the surveys said about the would-be effectiveness of larger graphic health warnings at encouraging them to smoke less, this does not translate into actual reported behaviour.[456]

Professors Dhar and Nowlis state, with regard to Wave 5: "*This survey shows that cigarette consumption, for either those who smoke every day or those who smoke on occasion, was not affected by the new health warnings, at least as of July 2002. This survey also shows that neither quit attempts, number of times tried to quit, nor potential quitters were influenced by these new health warnings. This is a very important finding, because it provides useful evidence, using a more appropriate methodology, that the proposed changes to the health warning messages are not likely to be effective. This finding was confirmed by another study (Gospodinov and Irvine 2004), which found that the Canadian warnings had no effect on smoking prevalence, nor a statistically significant effect on the amount smoked at a high confidence level.*"[457]

(b) Likewise, the larger graphic warnings were not successful at getting more smokers actually to attempt to quit. Environics concluded, in 2007, that "*there have been no significant changes since the November-December 2000 baseline survey in the proportion that stopped smoking for at least 24 hours at least once in the past year*".[458]

16.26 There has, of course, been a decline in overall prevalence of smoking in Canada since the beginning of the decade, as indicated by the Canadian Wave Surveys as well as other on-going Health Canada surveys. Indeed, prevalence data in Canada over the past decade shows a clear downward trend. It is, however, not altogether surprising that smoking should continue a sustained and steady downward trend that began four decades ago.

16.27 Given the above data from the Canadian Wave Surveys, it is impossible to attribute any identifiable portion of the decline to the larger size of the warnings.

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[454] Dr Keegan's November 2010 Report, paragraph 56.

[455] Dr Keegan's November 2010 Report, paragraph 237.

[456] Wave 13, Survey of Adults and Adult Smokers, pages 5-6; Survey of Youth, page 6.

[457] Professors Dhar and Nowlis's Report, paragraph 6.15.

[458] Wave 13, Survey of Adults and Adult Smokers, page 7; Survey of Youth, page 7.

Moreover, a further Canadian study[459] undertook an econometric analysis comparing tobacco consumption in Canada over the last six months of 2000 and the first half of 2001. The authors were of the view that such a measure as health warnings introduced on January 1, 2001, would have an effect, if any, in the very near term. The study showed that none of the decline observed in the first half of 2001 could be attributed to the new warnings.

16.28 The finding in this study that the introduction of the larger pictorial warnings did not lead to a reduction in prevalence of smoking appears to be consistent not only with the Health Canada prevalence data illustrated above, but also with the fact that, throughout the period from their introduction in 2001 to the Wave 13 Survey in 2007, the same warnings did not lead smokers to maintain any substantive increase in their past year quit attempts.

16.29 The Canadian Wave Surveys thus provide data showing that, in Canada, extending mandated warnings from 25% to 50% of the cigarette packages and introducing pictures did not enhance awareness of the health risks of smoking or change smoking behaviour. If anything, the new style of warning was less conducive to frequent reading by smokers than the smaller black and white messages that preceded them.[460]

The disproportionate and adverse consequences of the proposal

16.30 Not only have DG SANCO and the RAND Report failed to provide any reliable evidence demonstrating that its proposal to introduce larger health warnings would achieve public health objectives, the Consultation proposal would also lead to a series of negative and undesirable consequences, including:

(a) the **unjustified limitation on the use of JTI's trade marks**, thereby impairing the substance of those rights and the associated goodwill and value of its brands;

(b) the **unjustified limitation on JTI's ability to communicate with its consumers**, and on consumers' rights to product choice, fair competition and product information;

(c) 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; and

(d) the **serious and unnecessary damage to the legal, fair and competitive market** economy in tobacco products.

16.31 Furthermore, the proposal would contravene various legal rights, which are recognised in constitutional provisions protecting fundamental rights and freedoms,

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[459] Gospodinov, N. and Irvine, I.J., "Global Health Warnings on Tobacco Packaging: Evidence from the Canadian Experiment", *Topics in Economic Analysis & Policy* (2004) Volume 4, Issue 1.

[460] Wave 13, Survey of Adults and Adult Smokers, pages 5-6; Survey of Youth, page 6.

international treaties, intellectual property laws, BITs and competition and economic policy.

The proposal will have severe effects on JTI's trade marks and packaging

16.32 DG SANCO's proposal to 'enlarge' health warnings may, depending on any particular proposal taken forward, limit the space left for manufacturers' trade marks and branding to such a critical extent as to potentially undermine the legal, fair and competitive market economy in tobacco products. Indeed, enlarged health warnings could effectively amount to plain packaging, in which case JTI reiterates its categorical opposition to plain packaging for the reasons set out in Section 15 above.

16.33 In any event, the proposal may create brand selection confusion among consumers, denies them the right to choose and not to be misled into buying an unwanted product, as well as undermining their right to brand preference information. It will seriously curtail not only the manufacturers' right to communicate with their consumers and use their trade marks, but also consumers' rights to product choice and information.

16.34 As already observed at paragraph 15.4 above, JT owns a broad range of sophisticated intellectual property rights in relation to its products which are protected by national, EU and international law. The proposal to restrict, without compensation, JTI in the use of its trade marks amounts to an unjustified and disproportionate interference with JTI's property rights. JTI's trade marks are worth billions of US dollars.

The proposal will have a disproportionate impact on JTI as a premium brand owner

16.35 Increasing the size of health warnings will only serve to further restrict legal products' packaging and impair the value of their trade marks. Most consumers are ready to pay a premium to purchase goods bearing a trade mark that they associate with a guarantee of quality. In the present situation, those consumers are asked to pay a premium to stay with their favourite legal brands. JTI's established property rights are its most valuable assets, reflecting its investment in its brands. The proposed measures will only serve to reduce the premium value of JTI's and the legal tobacco industry's trade marks. Indeed, the RAND Report itself acknowledges that large health warnings or plain packaging could "*have impacts on the functioning of the tobacco market and its key players. Two interrelated effects could be expected, a loss in brand value and a commoditisation*".[461]

The proposal will have serious costs impacts

16.36 The short term financial impact to JTI of the proposal is significant. The costs include design costs, unsold inventory and technical printing costs and other costs involved in the transition from one set of warnings to another. Such costs should be considered as both high and unnecessary, given DG SANCO's failure to provide any

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[461] RAND Report, page 152.

reliable evidence that such warnings will be more effective at achieving its public health objectives.

Legal issues created by the proposal

16.37 The proposal by DG SANCO to "enlarge" health warnings engages numerous legal rights. When the proposal is considered as a whole, it is clear that numerous legal rights are unjustifiably impacted.

16.38 The importance of trade marks and other IPR is such that owners' rights are protected by the Charter and the ECHR (e.g. freedom of expression and the right to property), general principles of EU law and national trade mark laws and international commitments to which the EU adheres as signatory.

16.39 The Court of Justice has considered the issue of the size of health warnings in Case C-491/01, *British American Tobacco (Investments) Ltd*. In terms of the decision in that case, the proposal may not leave manufacturers "*sufficient space*" to affix their trademarks, such that "*normal usage is no longer possible*" and the very substance of the trademark rights are impaired.[462] In this regard, Advocate General Geelhoed noted as part of the justification for the existing TPD's health warnings of 30% and 40% of the front and back of the pack that this "*amounts to even less than 50%.*" Various of the Consultation proposals significantly exceed this threshold.

16.40 Relevant international commitments of the EU include TRIPS and the TBT. The proposal also affects the investments made by JTI in the EU which are protected under BITs. To increase the size of health warnings on tobacco packaging, without any reliable evidence to demonstrate that it will achieve any legitimate public health objectives, may – depending on the terms of the proposal adopted - put the proposal in conflict with these legal rights.

Alternative solutions

16.41 The RAND Report fails to examine any form of consumer communication other than packaging to address the assumed public policy objectives, and so DG SANCO must itself review the alternatives and the evidence base for each of those alternatives. JTI considers that there are less restrictive, more targeted and proportionate alternative solutions that would avoid the unnecessary, unjustified and disproportionate introduction of larger health warnings. These are set out in Sections41 - 43, below.

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[462] See Case C-491/01, *British American Tobacco (Investments) Ltd* [2002] ECR I-11453, paragraph 132, and Opinion of AG Geelhoed, paragraph 266.

17. PROPOSAL TO MANDATE PICTORIAL HEALTH WARNINGS (*PHWS*)

17.1 Option 2(a) under Section 3 of the Consultation proposes that pictorial warnings become mandatory in all Member States.

17.2 JTI believes that DG SANCO has, to date, put forward no adequate evidential basis for the introduction of mandatory pictorial health warnings and, in any event, JTI is concerned by the apparent absence of proportionality and subsidiarity in the proposed approach.

The evidence on PHWs from Canada undermines the proposal

17.3 Behavioural evidence suggests that the proposed larger pictorial health warnings will fail to achieve the assumed objectives. As discussed in more detail above, cross-sectional wave survey evidence from Canada, the first country in the world to require the introduction of pictorial health warnings covering 50% of the principal display surfaces of the pack, demonstrates that larger pictorial warnings there did not enhance awareness of the health risks of smoking or change smoking behaviour. This behavioural evidence is entirely absent from the RAND Report.

Mandating PHWs would be disproportionate and inconsistent with the principle of subsidiarity

17.4 JTI believes that it would be disproportionate and contrary to the principle of subsidiarity for the EU to mandate PHWs throughout the EU.

17.5 The burden is on the Community institutions, and in this case, DG SANCO, to demonstrate that mandating PHWs is appropriate and necessary to the attainment of the EU's internal market/public health objectives, and that action cannot be sufficiently achieved by Member States.

17.6 During the legislative process that led to the enactment of the TPD, the EU evaluated textual health warnings and PHWs, and adopted textual health warnings. Member States were given the option to adopt PHWs in line with common rules to be established by the Commission (which have indeed since been adopted).

17.7 In adopting the TPD, the Commission and the legislators balanced the respective roles between Member States and the EU. It concluded at that time that the EU's objectives could be achieved by affording Member States discretion regarding PHWs. There is no explanation as to why the EU's objectives now require the EU to mandate PHWs (and so remove the options available to the Member States). Similarly, the fact that the TPD afforded Member States discretion and enabled a difference in health warning regulation between Member States cannot be used to justify mandating PHWs on the basis of the very difference created by the TPD.

17.8 Further, the scientific evidence published since 2001 offers no unequivocal reason to depart from the evaluation made at that time.

17.9 Accordingly, as there has been no significant change in the scientific evidence on the efficacy of PHWs since 2001, mandating PHWs cannot be either appropriate or

necessary for the pursuit of the EU's internal market, nor can it be in accordance with the principle of subsidiarity.

18. INFORMATION ON THE YIELDS OF TAR, NICOTINE AND CARBON MONOXIDE (*TNCO*)

Introduction

18.1 DG SANCO states in its problem definition in Section 3 of the Consultation that: "*The current requirement of putting on the cigarette packages the measured levels on tar, nicotine and carbon monoxide yields has been shown to be misleading for consumers because they might think that lower levels indicate that a product is less risky to their health*."

18.2 Option 1 proposed by DG SANCO is for no change. Under Option 2b, DG SANCO suggests that on-pack indications of machine measured TNCO yields should be removed, and replaced with "*general information on harmful substances in tobacco products and in particular in their burnt forms*."

18.3 In JTI's view, Option 1 (no change) is at present the only possible outcome, since JTI fundamentally disagrees with DG SANCO's problem definition. DG SANCO has not made the case for:

(a) removing on-pack information concerning TNCO yields; or

(b) providing information concerning "*harmful substances in tobacco products*" (in place of TNCO yield numbers).

18.4 To justify changes to the current regime, DG SANCO would need to have advanced reliable scientific evidence to support each of the proposals above and to have assessed the proportionality and regulatory impact of each. Distinct evidence and analysis would need to be provided to support each distinct proposal.[463] However, neither the Consultation nor the RAND Report provide such evidence in support of any of these proposals, and there has been little (if any) attempt to address their proportionality and impact.

Inadequate evidence that on-pack TNCO labelling is misleading and that it causes actual consumer detriment

18.5 Neither the Consultation nor the RAND Report discloses adequate evidence to support a change to the status quo as regards on-pack TNCO yield labelling.

18.6 First, while DG SANCO asserts that consumers find on-pack TNCO labelling misleading, on the basis that they "*think that lower [TNCO] levels indicate that a product is less risky to their health*", neither the Consultation nor the RAND Report contain any evidence whatsoever to support this claim. The only external[464] reference given by RAND Europe to support this proposition is a 2001 consultation paper,

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[463] For example, even if DG SANCO were able to demonstrate that the removal of TNCO yield labelling was justified (which it has not done), a separate assessment of the evidence base, proportionality, impact etc. would be required to support any additional changes to product packaging.

[464] I.e., other than papers generated by DG SANCO itself.

issued by the Australian federal government, which asked for stakeholders' views in relation to possible changes to health warnings on tobacco products in Australia. This paper does not support the statements made by RAND Europe in relation to the supposedly misleading effects of TNCO information.[465] JTI also notes that, following the Australian consultation exercise to which this paper relates, Australia opted to retain on-pack TNCO labelling, based on the same ISO standards used by the EU today.[466]

18.7 Second, neither the Consultation nor the RAND Report establishes that products with lower levels of machine-measured TNCO are not, in fact, less risky to smokers' health on a population basis.

18.8 Third, all tobacco products sold in the EU (other than tobacco products for oral use and smokeless tobacco products) are required to carry rotating health warnings, as mandated by Article 5 of the TPD. These warnings do not differentiate between products with higher or lower machine measured TNCO yields; the message is simply: "*smokers die younger*", "*smoking clogs the arteries and causes heart attacks and strokes*", "*smoking causes fatal lung cancer*", etc. The same warnings appear on tobacco products, irrespective of yield. If, as DG SANCO presumably

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[465] RAND Report, page 134. RAND Europe cites a paper by the Commonwealth Department of Health and Aged Care (2001) to support the proposition that: "*There is evidence that quantitative information on cigarette packs is misleading for consumers because they may think that lower TNCO yields indicated on packs mean that a tobacco product is less risky to their health; some of them may even decide to smoke lower TNCO yields in preference to quitting*" (page 134). Later, the same paper is cited to support the statement that: "*most sources we have identified in this area conclude that quantitative information on TNCO yields is misleading for consumers and that new ways of informing them more effectively should be found*".

The paper cited (Commonwealth Department of Health and Aged Care, *Review of Health Warnings on Tobacco Products in Australia – Discussion Paper*, Canberra: Commonwealth Department of Health and Aged Care, 2001; Available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/4FA9E17EB0A1FB6ECA25776900054914/$File/warndis.pdf) was a "*discussion paper… designed to seek community views on new health warnings*" (page 2 of that paper). The authors warned that the paper "is not intended to be a complete review of the literature" (*ibid*). Specifically, readers were told that: "*Your thoughts on health warnings to counter consumer perception around tar yield and descriptors on packages are also invited*" (page 17). This paper does not itself constitute sound scientific evidence – rather, it is a consultation document that is, by its authors' admission, based on an incomplete review of the data.

Moreover, in relation to the supposedly misleading effects of TNCO yield notation, the authors state only that: "*There is a risk that many smokers are reassured by the tar readings on cigarettes and it is believed that many smokers have changed to low-tar brands in preference to quitting.*" (page 17, emphasis added). It is misleading for RAND Europe to "upgrade" these more qualified statements to assert that TNCO yield information "is" misleading to consumers (RAND Report, page 134).

The RAND Report also cites another paper (page 135) – namely, O'Connor et al. 2006. However, the primary conclusion of that study, as described by RAND, appears to be that many consumers do not pay much attention to on-pack TNCO labelling (which is hardly evidence of a pressing need to alter the TPD in this regard).

[466] See sub-regulation 19(8) and regulation 20 of the Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations 2004. Available at: http://www.smoke-free.ca/warnings/laws/australia.pdf.

believes, these warnings are meaningful and operative in terms of consumer behaviour, then their effect would be to "correct" any belief that one product might be safer than another. It is improbable, and has not been argued or evidenced by DG SANCO or RAND Europe, that smokers of products with lower machine measured TNCO levels do not know that those products pose hazards for health, or that this knowledge is somehow overcome by any health messages they are alleged to take from on-pack TNCO labelling.

18.9 Fourth, even if a significant proportion of EU consumers did take erroneous health messages from on-pack TNCO labelling, there would be no justification for changing the *status quo* in the absence of evidence that this had an impact on actual consumer behaviour (i.e., that the presence of on-pack TNCO labelling was causing EU consumers to begin smoking, when they would not otherwise have done so; to smoke more cigarettes per day than they would otherwise have done; or not to quit, where they would otherwise have done so).

18.10 Needless to say, neither the Consultation nor the RAND Report provide any evidence of consumer detriment in this regard. Professor Steinberg's Report is clear that the main risk factors for smoking among minors are a psychological profile characterised by sensation-seeking, peer and family influence (i.e. peers and family members who smoke), and the availability of cigarettes[467] - factors which do not include on-pack TNCO labelling. Other research suggests that the quit rates among smokers of products with lower machine-measured TNCO yields are substantially the same as those among smokers of products with higher yields.[468]

18.11 Taste is an important reason why smokers choose any cigarette. The machine-measured tar and nicotine yields of a given brand style are a key, but not the only,[469] determinant of a brand style's taste and of other sensory characteristics. Each consumer has his or her own preferences as to what he or she likes to smoke. For present purposes, it should be noted that some consumers prefer the milder taste of cigarettes with lower yields of tar and nicotine, while others prefer "full flavour" cigarettes. To the extent that EU consumers do use TNCO yield information to distinguish between brand styles, JTI believes that they do so on the basis of taste.

Alternative solutions

18.12 Even were it the case that some EU consumers are misled by on-pack TNCO yield information, and that this has a measurable adverse effect on smoking behaviour – and, as noted, neither the Consultation nor the RAND Report demonstrates either of these things, there are likely to be less restrictive, more targeted and proportionate

[467] Professor Steinberg's Report, pages 3 and 17-19

[468] Evans, N and Joossens, L., *Consumers and the Changing Cigarette*, Health Education Authority, London (1999). Haddock, C.K., Talcott, G.W., Klesges, R.C. et al., "An examination of cigarette brands switching to reduce health risks", *An. Beha. Med.* (1999) 21, pages 129-134. Hyland, A., Hughes, J.R., Farrelly, M. and Cummings, K.M., "Switching to low tar cigarettes does not increase or decrease the likelihood of future quit attempts or cessation", *Nicotine & Tobacco Research* (2003) 5(5), pages 665- 672.

[469] For example, the flavourings and casings used in a particular brand style may also play an important role.

solutions available than removing TNCO labelling from packs. Possible alternatives might include providing more information to consumers to the effect that products with lower machine measured TNCO levels are not necessarily safer than any other product, and that there is no such thing as a safe cigarette. Such information could be provided (if the need to do so was established) by inserting a new rotating warning into Annex I to the Directive. This option has not been investigated by RAND Europe and does not appear to have been considered by DG SANCO.

Inadequate evidence to support the provision of "qualitative constituent information" in place of on-pack TNCO labelling

18.13 Option 2b proposes not only the removal on on-pack machine measured TNCO yields, but also their replacement with "*information on harmful substances in tobacco products and in particular in their burnt forms*".

18.14 JTI's response to this proposal is necessarily provisional, because DG SANCO has not disclosed what "*information on harmful substances*" it is considering mandating. Before any revised TPD is proposed JTI and other stakeholders must have the opportunity to review the relevant wording.

18.15 The evidence provided by DG SANCO to support this measure is wholly lacking. While the RAND Report states that "*it… appears that replacing such [TNCO quantitative] information with qualitative information could contribute to informing consumers better about the health risks of smoking and that it might encourage some to quit smoking altogether*", its authors provide no evidence whatsoever to support these assertions.[470] Indeed, they concede that "*evidence of the impact of qualitative versus quantitative information of TNCO yields is scarce*". The Consultation is silent on the issue.

18.16 JTI also notes that the goal of "*informing consumers better about the health risks of smoking*"[471] presupposes that EU consumers are in fact unaware of the health risks of smoking, or that they would change their smoking behaviour (i.e. not start smoking, smoke fewer cigarettes, or quit) if they had greater information available to them. Neither the Consultation nor the RAND Report provides any evidence to support these propositions. In fact, in Professor Steinberg's opinion, minors are well aware of the health risks of smoking, but choose to smoke anyway, and efforts to prevent minors from smoking by emphasising the potential health risks of smoking alone to them are unlikely to be effective.[472] As for adult consumers, it is clear that

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[470] Of the two references stated at page 134 of the RAND Report, one is to the Australian consultation paper already discussed (which is not a primary scientific source), and the other is to a study by O'Connor and others (2006) which, on RAND Europe's analysis, at best supports the proposition that "*there is an urgent need to develop more effective ways to communicate the toxic ingredients of cigarette smoke to smokers in a way that is more meaningful than the current FTC/ISO yields*" (RAND Report, page 135) – which is by no means the same as demonstrating that the provision of "*general information on harmful substances in tobacco products and in particular in their burnt forms*" (Consultation, page 7) would be "*more effective*" or "*more meaningful*", whatever those metrics may mean.

[471] RAND Report, page 134

[472] Professor Steinberg's Report, pages 19-22.

adults are very well aware of the serious and life threatening risks of smoking. Adults make decisions relating to their smoking behaviour based on such awareness and in full knowledge of such risks. Such risk awareness is effectively a constant factor in the decision-making processes involved in smoking behaviour.

18.17 Even if DG SANCO had demonstrated that providing information about smoke constituents to consumers would "better inform" consumers about the health risks of smoking and/or encourage them not to begin smoking or to quit, a more proportionate means of providing this information would likely be to modify the content of the existing rotating health warnings mandated by Article 5 of the TPD. This issue is being investigated by DG SANCO and so negates the proposal in the Consultation.

19. INSERTS

19.1 The Consultation proposes (Option 2(c)) that information that cannot be placed on the pack would be placed inside the pack. The Consultation describes "inserts" as "*including more information on health effects of tobacco consumption and provide information on how to quit smoking*".

19.2 The RAND Report acknowledges that "*the evidence base to support the introduction of inserts is much less developed than the evidence supporting the introduction of larger health warnings and plain packaging*".[473] Given the severe limitations with the evidence base for the latter two proposals, it is clear that there is no adequate evidence base on which to proceed with the proposal. The reference, in the RAND Report, to requirements in Canada ignores the fact that the majority of packs in Canada are "slide and shell" and not "flip top box" configurations, as predominantly used in the EU.

19.3 Moreover, as explained above, the goal of "*informing consumers better about the health risks of smoking*"[474] presupposes that EU consumers are in fact unaware of the health risks of smoking, or that they would change their smoking behaviour (i.e. not start smoking, smoke fewer cigarettes, or quit) if they had greater information available to them. Neither the Consultation nor the RAND Report provides any evidence to support these propositions. In fact, as stated at paragraph 18.16, both adults and minors are well aware of the health risks of smoking.

19.4 Further, from a manufacturing perspective, the compulsory application of inserts poses significant technical difficulties. Inserts are not technically possible for soft packs and various other tobacco products packaging.

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[473] RAND Report, page 140.

[474] RAND Report, page 134.

REPORTING AND REGISTRATION OF INGREDIENTS (CONSULTATION SECTION 4)

20. INTRODUCTION

20.1 DG SANCO states in its problem definition in Section 4 of the Consultation that "*the formats and reporting mechanisms for submitting data on tobacco products ingredients vary between and even within Member States*" and that, therefore, "*authorities find it difficult to compare and analyse the data*". It further notes that it has "*proven difficult to get financing for the development, validation and carrying out of the appropriate toxicological and addictiveness tests*." In relation to the first point, DG SANCO suggests establishing a "common compulsory format" (Option 2); in relation to the second, it suggests introducing "fees and sanctions" (Option 3).

20.2 JTI considers that these options do not address the identified underlying issue, namely the need for DG SANCO and/or the Member States to undertake the necessary scientific analysis. Amending the TPD, as proposed, will not address this issue at all.

20.3 **JTI shares common goals with DG SANCO regarding ingredient reporting: regulatory authorities in the Member States 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.

20.4 As set out more fully below, the identity of ingredients and their combinations are highly valuable trade secrets which deserve proper protection. JTI considers that any EU reporting regime that ignores intellectual property law protections – 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 – will be flawed and unlawful.

21. INGREDIENTS AND TOXICOLOGICAL DATA REPORTING

Article 6 of the TPD and its operation

21.1 Pursuant to Article 6 of the TPD, Member States "*shall require manufacturers and importers of tobacco products to submit to them a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type.*" The reported information must be accompanied by "*toxicological data available to the manufacturer or importer.*"

21.2 Ingredients information has been submitted to Member States since 2002. JTI provides information on ingredients (including toxicological data regarding those ingredients) annually to authorities in all Member States. Further data will be submitted by manufacturers and importers of tobacco ingredients under REACH[475]

[475] Regulation of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (***REACH***) (1907/2006/EC) (OJ L 396, pages 1–849).

from 1 December 2010. Authorities should use this information to develop and validate methodologies for the testing and measuring of ingredients, including in the light of the information made available under REACH.

21.3 *The Practical Guide on 'Reporting on tobacco product ingredients*' published in May 2007[476] (the ***Practical Guide***) has brought a fair degree of harmonisation in relation to the reporting format under the TPD. However, as RAND Europe acknowledges, a number of Member States require manufacturers to use a different format. For example, Cyprus, the Czech Republic, Estonia, Hungary and Slovenia either require or have requested manufacturers to use the Three List Model.[477] Further, differences remain as to whether information is to be provided in paper or electronic form.

Establishment of a standardised reporting system

21.4 JTI supports the development of an EU standardised reporting system that provides proper trade secret protection and operates in accordance with Better Regulation principles, notably international regulatory efficiency. However, the establishment of an EU standardised reporting database system raises issues of principle and of practice. Central issues include the management and ownership of data and the databases, protecting confidentiality and trade secrets and technical security.

Protecting JTI's competitive position

21.5 JTI's brands are its most valuable assets which are worth billions of US dollars. In order to protect its investments and innovation, JTI closely guards as trade secrets the identity of ingredients and their combinations, as integral to its unique products and brands. Their protection from disclosure lies at the heart of the competitive process and is valuable intellectual property. This is consistent with the approach in other industries (e.g. the protection of the Coca-Cola® recipe as a trade secret).

21.6 Article 6(2) of the TPD states that "*due account shall … be taken of protection of any information on specific product formulae which constitutes a trade secret.*"

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[476] *The Practical Guide on Reporting on tobacco product ingredients of 31 May 2007* (SANCO) C6 TPE/ub D(2007) 360206).

[477] The Three List Model comprises the following information on tobacco product ingredients, and has been adopted – in regulation or practice – by numerous countries:

(a) a composite list (in alphabetical order) of all ingredients added to tobacco in the manufacture of tobacco products;

(b) a composite list (in descending weight order) of all ingredients of non-tobacco components used in the manufacture of tobacco products; and

(c) a generic by-brand list (in descending weight order) of ingredients used in the manufacture of each of the tobacco products.

The EC Treaty also provides trade secret protection.[478] Trade secrets, including information on the identity of ingredients and their combinations, are also protected by the ECHR,[479] international law (especially by TRIPS;[480] national Constitutions and legislation such as in the U.S.,[481] Canada,[482] Malaysia and Singapore.[483] In essence, information constitutes a trade secret if:[484]

(a) reasonable measures have been taken to keep that information secret;

(b) the information has economic value; and

(c) that value derives from the fact that it is neither generally known nor readily ascertainable by the public or by competitors through legitimate and proper means.

21.7 Tobacco ingredients and their combinations clearly meet these criteria. For example, flavour formulations are known to a very limited number of people within JTI and are subject to strict confidentiality arrangements. By keeping this information secret and closely guarding it, JTI protects the identity of its brands.

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[478] See, for example, 78/253/EEC Commission Decision of 23 December 1977 relating to the proceedings under article 85 of the EEC Treaty (Campari): the European Commission held that the makers of Campari were entitled to withhold information on the herbal blend and the use of certain colourings, given that this was a product, the composition of which, being the "*particular characteristic of Bitter Campari*" formed a trade secret.

[479] Trade secrets are a property right whose protection is enshrined in Article 1 of the First Protocol to the ECHR. In this regard, the Court of Justice has also on several occasions expressly recognised that the right to property is guaranteed in the Community legal order "*in accordance with the ideas common to the constitutions of the Member States, which are also reflected in the Additional Protocol to the European Convention for the Protection of Human Rights and Fundamental Freedoms*" (see, *inter alia*, Case 44/79 *Hauer* [1979] ECR 3727, paragraph 17. See also Article 17 of the Charter).

[480] Trade secrets are part of the intellectual property rights covered by TRIPS. They are dealt with in section 7, entitled "Protection of Undisclosed Information", Article 39(2).

[481] Trade secrets are property rights protected by the Takings Clause of the Fifth Amendment – see *Ruckelshaus v Monsanto Co.*, 467 U.S. 986 at 1003-04; and *Philip Morris, Inc v Reilly* [2002] USCA1 329; see also the Uniform Trade Secrets Act; and the common law codified in Chapter 4 of the Restatement (Third) of Unfair Competition, subsections 39-45.

[482] Protection is given to trade secrets as "commercial confidences" (see *Saltman Eng'g Co., Ltd v Campbell Eng'g Co. Ltd*, (1948), (1963), 3 All ER 413, at 414 (C.A.), *R.L. Crain Ltd v Ashton Press Manufacturing Co. Ltd.*, [1949], 2 D.L.R. 481 (Ont. H.C.). Canada has sought to harmonise with the U.S. and courts now follow standard US and NAFTA definitions of trade secrets.

[483] In Malaysia and Singapore, trade secrets are dealt with under the law of confidence (see for Malaysia: *Electro Cad Australia Pty Ltd & 20rs v Mejati RCS Sdn Bhd & 30rs* [1998] 3 AMR 2555; *Coco v Clark* [1969] RPC 41; for Singapore: *X Pte. Ltd. & Anor v CDE* [1992] 2 SLR 996).

[484] See also IPR Helpdesk funded by the CIP Programme and the European Commission. Available at:

http://www.ipr-helpdesk.org/documents/ES_tradesecret_UJ_en_final_0000006449_00.xml.html

The Practical Guide

21.8 The Practical Guide suggested two sets of formats for ingredient reporting: one with the full ingredient information to national regulators and one with fewer requirements for the information to the public.[485] It further "*invites Member States to apply their appropriate rules when dealing with [trade secret] information.*"[486]

21.9 JTI reports information on ingredients to most Member States on the basis of the Practical Guide. However, as stated above, a number of Member States require, or have requested, that tobacco manufacturers use different reporting formats. Various issues have already been resolved in discussions with the competent national authorities in relation to the Practical Guide, such as the cut-off levels for non-tobacco materials for the purposes of public disclosure, clarification regarding ingredient quantity changes, and alternative material reporting. Any revision to the TPD or a revision of the Practical Guide must take account of the solutions agreed with Member States.

EMTOC

21.10 DG SANCO suggests in its Consultation that a common reporting format could be "*based on the voluntary reporting format developed by the Commission in May 2007 on how industry could report to Member States.*"

21.11 Significant progress has been made over the last two years by the Electronic Model Tobacco Control (***EMTOC***) in finding solutions to the issues raised by ingredients reporting. However, there remain unresolved questions regarding, notably, the ownership and financing of the system. JTI is prepared to contribute to financing the EMTOC system, provided the funds are 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.

21.12 EMTOC provides an electronic system for the submission of information on tobacco product ingredients based on the Practical Guide.[487] Four Member States are currently participating in EMTOC,[488] although further Member States as well as other countries have expressed their interest. However, at present, only Austria requires manufacturers and importers to use the EMTOC system for ingredients reporting.

21.13 EMTOC provides an efficient way for tobacco manufacturers to report information on tobacco product ingredients with appropriate legal and practical protections. The relevant national authorities can review and assess the submitted data on a country-by-country basis and publish non-confidential public data on their

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485 *The Practical Guide on Reporting on tobacco product ingredients of 31 May 2007* (SANCO C6 TPE/ub D(2007) 360206).

486 The Practical Guide, paragraph 2.1.

487 The Practical Guide is currently being revised. EMTOC takes account of the revised guidelines as described in the Austrian Ingredient Reporting Ordinance of January 2010.

488 Austria, Belgium, Germany and the Netherlands.

websites. In addition, DG SANCO has access to the data from Member States, which enables it to carry out a cross-country analysis.

21.14 A list of ingredients has been drawn up to serve as a reference for EMTOC. This list can be updated and amended as more information becomes available. Finally, EMTOC enables regulators to make non-proprietary information readily available to the public.

21.15 However, adopting EMTOC requires significant amount of preparation. It involves much more than uploading a piece of software. Several trial runs had to be conducted in Austria before the system went live. DG SANCO and the other Member States should recognise that adopting EMTOC in several Member States simultaneously – or even on an EU-wide basis – would present a considerable technical and logistical challenge. JTI strongly recommends building upon the Austrian experience to minimise the risk of severe problems in the implementation of EMTOC on a wider basis.

Solutions regarding reporting

21.16 JTI strongly supports the continuing development and adoption of a standardised and harmonised ingredients reporting process. The process must be consistent with fundamental trade secret intellectual property right protection and the manufacturing process. EMTOC provides an opportunity to implement a standardised and harmonised electronic reporting system.

22. REGISTRATION FEES AND PENALTIES

22.1 DG SANCO suggests under Option 3 of the Consultation (which is suggested in addition, rather than as an alternative, to Option 2) that:

> "*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.*"

22.2 RAND Europe suggests "*introducing fees for the scientific analysis of tobacco ingredients*".[489] There is no clear recommendation from RAND Europe to introduce sanctions for non-compliance.

22.3 JTI considers that there are serious legal basis obstacles for DG SANCO to overcome in order to demonstrate that the EU has competence to introduce registration fees or sanctions. Neither DG SANCO nor RAND Europe suggests that fees or sanctions would be introduced as a harmonising measure with the objective of improving the conditions for the functioning of the internal market. Neither suggests that differences between national approaches in this regard exist, or are likely to arise,

[489] RAND Report, page 160.

which constitute an obstacle to trade that affects the functioning of the internal market. The proposals also raise significant subsidiarity issues. Further, neither DG SANCO nor RAND Europe provides evidence that the introduction of fees or sanctions is appropriate and necessary.

22.4 DG SANCO claims in its problem definition that "*it has proven difficult to get financing*" for the development, validation and carrying out of the relevant tests.[490] Fees would thus be introduced, according to Option 3, "*in order to finance their data collection and analysis work on ingredients*". There is no suggestion that the TPD would be revised so as to harmonise legislation on registration fees and that this is necessary to remove any obstacles to the functioning of the internal market.

Any fees must be related to the costs of providing a service

22.5 Further, any registration fees would have to be related to, and based on, the costs of providing the service.

22.6 Compulsory payments to regulatory authorities that are not linked to – and based on – the costs of providing a service to the payer of the fees are to be classified as taxes or other "fiscal provisions". The Court of Justice held in joined Cases C-71/91 and C-178/91 *Ponente Carni SpA* and *Cispadana Costruzioni SpA v Amministrazione delle Finanze dello Stato* in relation to the charges for services rendered in the public interest:

> "*A payment the amount of which had no link with the cost of the particular service or was calculated not on the basis of the cost of the transaction for which it is a consideration but on the basis of all the running and capital costs of the department responsible for that transaction would have to be regarded as a tax*".[491]

22.7 This is consistent with the OECD classification of financial levies, according to which "*a fee or charge is levied in connection with a specific service or activity*" whereas taxes are "*compulsory, unrequited payments to general government*".[492] The OECD also requires that fees and charges be "*clearly related to the cost of providing the service*".[493]

22.8 It is important to note in this context that Article 114(2) TFEU excludes taxes and other "fiscal provisions" from the scope of harmonisation measures capable of

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[490] Consultation, page 8.

[491] Cases C-71/91 and C-178/91 *Ponente Carni SpA* and *Cispadana Costruzioni SpA v Amministrazione delle Finanze dello Stato* [1993] ECR I-1915, paragraph 51.

[492] OECD, *Classification of Taxes and Interpretative Guide*. Available at: http://www.oecdwash.org/PUBS/ELECTRONIC/SAMPLES/revenue_methodology2004.pdf.

[493] *Ibid*. The OECD considers that the following would be considered as "unrequited payments" to which tax rules apply: (a) where the charge greatly exceeds the cost of providing the service; (b) where the payer of the levy is not the receiver of the benefit; (c) where government is not providing a specific service in return for the levy which it receives even though a licence may be issued to the payer; and (d) where benefits are received only by those paying the levy but the benefits received by each individual are not necessarily in proportion to his payments.

adoption under Article 114(1) TFEU. The notion of "*fiscal provisions*" has been given a broad interpretation by the Court of Justice. In *Commission v Council (VAT)* the Court of Justice held that:

> *"…by reason of their general character, those words [fiscal provisions] cover not only all areas of taxation, without drawing any distinction between the types of duties or taxes concerned, but also all aspects of taxation, whether material rules or procedural rules*".[494]

22.9 EU legislation in general seeks to meet the conditions for imposing registration fees. For example, REACH states that fees for the registration of chemicals "*should be fixed at such a level as to ensure that the revenue derived from them when combined with other sources of the [European Chemicals] Agency's revenue … is sufficient to cover the cost of the services delivered*".[495]

22.10 Similarly, Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules states that control fees shall "*not be higher than the costs borne by the responsible competent authorities*".[496]

22.11 RAND Europe's proposals in relation to registration fees are simply inept. It suggests that registration fees be introduced to ensure that "*the necessary analysis can be performed in the future*". The RAND Report does not say when and by whom such an analysis should be performed and what such an analysis would entail (what should be tested and measured and what are the criteria?). No cost assessment has been presented. 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".*[497]

22.12 However, Member States cannot collect registration fees before it has been established which specific services they are going to provide, and what the costs will be for providing such services. Equally, the EU itself could only impose common registration fees on tobacco manufacturers if there was an EU agency to conduct the relevant testing and measurement procedures. However, no such agency exits.

22.13 Furthermore, the other measures proposed by RAND Europe – market control fees based on the number of outlets the product is sold in (measure 4) or transferring the direct and indirect costs of smoking to tobacco manufacturers (measure 5) – are clearly unrelated to the costs of any service. Such measures would not only be disproportionate to any objectives pursued under Article 114 TFEU, but would also constitute tobacco taxes, for which the EU has limited and separate competence. A more detailed analysis of these proposals is set out at Section 38 below.

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[494] Case C-533/03 *Commission v Council (VAT)* [2006] ECR I-1025, paragraph 47. See also Case C-338/01 *Commission v Council* [2004] ECR I-4829, paragraph 61.

[495] Second recital to Regulation 1907/2006/EC.

[496] Article 27(4)(a).

[497] RAND Report, page 165.

22.14 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.

Penalties for non-compliance

22.15 As noted at paragraphs 22.3 – 22.4 above, DG SANCO's proposal in relation to penalties for non-compliance fails to address the issue of competence. Moreover, the proposal is unclear (in that it is not clear what type of "penalty" provision is envisaged: general, specific, civil or criminal?) – and unnecessary.

22.16 The EU legal order requires that Member States adopt in their national legal systems all the measures necessary to ensure that a directive is fully effective, in accordance with the objective which it pursues. There is now a general requirement that sanctions must be effective, proportionate and dissuasive.

22.17 Accordingly, even though the TPD does not specifically provide any penalty for an infringement, Article 4(3) TEU requires the Member States to take all measures necessary to guarantee the application and effectiveness of Community law. This has been long established in the case law of the Court of Justice.[498]

22.18 The TPD has therefore been made subject to sanctions in national legal systems, in accordance with the discretion afforded to Member States on the implementation of directives. DG SANCO has not raised any issue of inadequacy in the implementation of sanctions under the TPD, neither in the First and Second reports on the implementation of the TPD nor by way of infringement proceedings against Member States under, now, Article 258 TFEU.

22.19 In the vast majority of Member States, sanctions already exist for non-compliance with ingredients reporting requirements, either under the national tobacco products legislation or as a matter of general criminal or administrative law. In fact, JTI is not aware of any Member State in which a failure to comply with reporting requirements could not lead to some form of penalty or sanction. However, neither the Consultation nor the RAND Report provides any analysis of the situation in the Member States in relation to penalties or sanctions.

22.20 The option set out in the Consultation is therefore without any foundation, as there is no indication that the Member States would breach their legal obligations of implementation in respect of a revised TPD.

22.21 RAND Report concludes, however, that the introduction of penalties might be ineffective and problematic.[499] First, it is noted that the reasons for non-compliance by some companies are not well understood. If this is primarily an issue of capacity

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[498] See, in particular, Case 68/88 *Commission* v *Greece* [1989] ECR 2965, paragraph 23.

[499] RAND Report, pages 160-161.

and expertise in small businesses, then introducing fines and registration requirements may not lead to improvements in compliance.

22.22 Second, the RAND Report states that "*the scientific analysis of ingredients does not depend on having the most comprehensive data set in terms of covering all businesses*".[500] JTI agrees that a scientific analysis of ingredients can be undertaken without having a complete data set for all products on the market. As explained below at paragraphs 26.10-26.18, JTI conducts an analysis of ingredients it adds to tobacco products, to ensure that added ingredients do not increase the inherent toxicity of tobacco products.

[500] RAND Report, page 161.

REGULATION OF INGREDIENTS (CONSULTATION SECTION 5)

23. INTRODUCTION

23.1 In its problem definition to Section 5 of the Consultation, DG SANCO raises the issue that, during the process of burning, a number of ingredients form substances that are CMRs. It notes in this context that there are no common conditions for the internal market in relation to the regulation of tobacco product ingredients. DG SANCO further mentions issues raised by flavour ingredients.

23.2 **JTI proposes below a framework for developing the regime to regulate tobacco product ingredients**. As the Commission stated in its Second Report, "*development in this area depends on the progress of work outlined under Article 6*".[501] The framework proposed by JTI would ensure that, sequentially, reporting requirements, testing and eventual assessment and approval of ingredients can effectively achieve legitimate public policy objectives, whilst recognising the competitive, innovative and manufacturing roles of ingredients.

23.3 An appropriate regime for the regulation of ingredients must fit consistently with other aspects of tobacco product regulation, such as yield testing and product labelling, and must be internally coherent. The fact that the thinking on the regulation of ingredients is currently in a state of flux poses particular challenges from a Better Regulation perspective.

23.4 In the following two Sections, JTI considers the rationale for using ingredients, before JTI develops principles for the assessment and approval of ingredients and responds to DG SANCO's problem definition and the proposals it makes in this regard.

24. RATIONALE FOR USING INGREDIENTS

Consumer Preference, Unique brands and Ingredients

24.1 Smoking is an adult choice and JTI believes in openness and transparency about the products adult smokers choose to purchase. The ability of manufacturers to distinguish their products from competitors provides the primary means by which consumers are able to freely exercise economic rights of purchase.

24.2 Taste is an important reason why smokers choose any cigarette. In order to compete for market share, JTI distinguishes between different brands and brand styles on the basis of a range of factors including in particular their differing taste and other sensory characteristics. Those differences between products are key factors for consumers in developing a preference for and choosing to smoke a certain brand and brand style.

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[501] Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee, *Second Report on the Application of the Tobacco Products Directive*, COM(2007) 754 final, page 10.

24.3 Ingredients play a significant role in the development of unique cigarette brands to meet consumer preferences: e.g. flavour ingredients – even used in minute quantities – may determine, to a significant extent, the aroma and taste of each individual brand. Examples of flavour ingredients used by JTI include chamomile, Valerian root extract and menthol. Indeed, ingredients are essential when particular types of tobacco leaf, such as Burley, are used in cigarettes.

24.4 The ingredients and combination of flavour ingredients used in each brand style is the result of years of investment by JTI. JTI has refined the combinations of flavour ingredients to produce the resulting unique brand, ensuring that each brand style has its own taste and aroma. This significant investment, which is protected by IPR, has resulted in consumers choosing to purchase JTI's brands rather than those of its competitors, and has contributed to the substantial equity of JTI's brands.

24.5 In addition to creating the unique taste and aroma of tobacco products, ingredients help maintain an overall product consistency and quality over time, which is also of vital importance to a successful brand. If the taste of a particular brand style changes over time, consumers may reject a product as they expect a particular aroma and taste to accompany their chosen cigarette brand.

24.6 Ingredients also play a critical role in product innovation, such as in the development of new technology products (***NTP***) such as low ignition propensity products (***LIP***) or PREPs. In this context, ingredients help ensure that the products are able to meet relevant public policy goals in a manner that retains consumer acceptability.

Producing competitively superior products

24.7 Building successful brands and the ability to produce competitively superior products are the basis for JTI's commercial success. For this reason, JTI seeks to have key competitive metrics at the manufacturing stage of tobacco products:

(a) to source and use the right quality tobacco leaf;

(b) to create product specifications, including tobacco blends and ingredients, that consistently meet consumer preferences and expectations for particular brands and JTI products;

(c) to manufacture products that are in excellent physical condition on use; and

(d) to source non-tobacco materials (***NTMs***), such as cigarette paper and filters, that are functional, efficient and acceptable to consumers.

24.8 These metrics have allowed JTI to be successful in meeting consumer preferences, and so gaining market share, in the highly competitive cigarette market:

(a) JTI manufactures and markets internationally recognised brands across the globe, including three of the world's five leading cigarette brands. Each brand has its own distinctive taste and other sensory characteristics: Camel – the

originator of American Blend, Winston – the fastest growing brand worldwide, and Mild Seven – the charcoal filter cigarette;

(b) launched in 1956, Salem was the first filter-tipped menthol cigarette, and remains one of the world's best selling menthol cigarette brands; and

(c) where consumer preference has developed for Virginia-blend products, JTI has been able to meet that preference for premium quality tobacco and blends without, or with very few, flavouring ingredients.

24.9 As ingredients have various functions, competition exists between manufacturers and between suppliers in respect of NTMs, such as cigarette paper and filters, which also contain ingredients. Manufacturers of these NTMs compete to supply tobacco manufacturers, and consider their ingredient formulations as valuable trade secrets.

25. JTI REJECTS INGREDIENT BANS

25.1 JTI rejects any ban of ingredients in the absence of clear and valid scientific criteria and in the absence of evidence that this would reduce the inherent health risks of smoking.

25.2 RAND Europe seems to suggest in the RAND Report that flavour ingredients are not necessary in the manufacture of cigarettes and that "*some types/brands of cigarettes currently claim to be additive free and cigarettes sold in Canada contain only a sparing amount of additives*".[502]

Canada is not an appropriate model for EU legislation on tobacco product ingredients

25.3 DG SANCO should be aware that, on 8 October 2009, Canada enacted Bill C-32 which prohibits the use of many flavours and ingredients in cigarettes and little cigars. However, the Canadian legislation is not an appropriate international model for the regulation of ingredients.

25.4 Bill C-32 is not based upon any meaningful scientific assessment or evaluation of ingredients. Under the professed objective of "*protecting youth from tobacco marketing*", Bill C-32 simply bans the majority of flavour ingredients used in the manufacture of tobacco products, as well as many other ingredients. It therefore effectively bans the manufacture and sale of most current American blend cigarettes in Canada.

25.5 The non-binding partial Guidelines on Articles 9 and 10 FCTC contain a similar proposal to "*prohibit or restrict*" the use of certain ingredients, which in effect – even though couched in different language – largely follows the Canadian model.

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[502] RAND Report, page 175.

25.6 The Canadian legislation has been heavily and widely criticised. At a WTO meeting in Geneva in November 2009, delegations from the United States, the EU, Argentina, Mexico and Switzerland argued that the Canadian legislation restricts trade in legal tobacco products and disadvantages foreign producers.

25.7 Genuine legal concerns exist in relation to the Canadian legislation, even though the majority of consumers in Canada prefer flue-cured tobacco products (so-called Virginia-style cigarettes) which typically contain no, or hardly any, flavour ingredients. In other words, the Canadian legislation will have relatively limited impact in the Canadian marketplace.

25.8 If adopted in the EU, by contrast, this approach would have more dramatic consequences than in Canada:

(a) in most EU markets (with the exception of the UK), the majority of consumers prefer classic American blend cigarettes, which have traditionally contained higher levels of flavour ingredients than those in Virginia-style products. Consumers in the EU could therefore no longer buy their preferred product if the Canadian model were to be adopted;

(b) there would be a marked and immediate effect on tobacco farmers in the EU and worldwide: there is insufficient production of Virginia tobacco leaf worldwide to replace the demand for classic American blend cigarettes, and farmers of Burley and Oriental tobacco, in particular, would be irreparably harmed;

(c) issues would arise under international trade law; JTI shares the concerns that the Canadian legislation could violate international trade laws such as the WTO agreements;

(d) consumers would be deprived of legitimate choices between existing conventional tobacco products, which may create incentives for illicit trade – whether counterfeit or contraband;

(e) competition in the tobacco market would be distorted, and incentives to innovate would be damaged; and

(f) tobacco manufacturers' ability to introduce new technology products, including low ignition propensity and potentially reduced exposure and/or risk products, would be compromised.

Minors should not smoke

25.9 JTI sees itself as being able to play a role in contributing to effective means of preventing minors from obtaining tobacco products. JTI works with regulators and retailers on preventing minors from obtaining tobacco products, and associated measures.

25.10 Public health associations have claimed in the past that cigarette manufacturers use ingredients to make tobacco products more appealing to minors.

Let us be clear: JTI does not use flavours or any other ingredients for this purpose. Furthermore, as explained more fully below at paragraph 26.48, there is no reliable evidence to suggest that the use of flavours causes minors to begin smoking.

Ingredient bans will incentivise illicit trade

25.11 JTI believes that contraband and related counterfeit trade is an issue that needs to be addressed through constructive partnership with governments and public authorities. JTI considers that no regulatory action should be taken which is at odds with the objectives of the EU (and the FCTC) in the context of illicit trade.

25.12 Ingredient bans which prohibit the manufacture of products that consumers currently prefer will create a situation in which consumers will buy cigarettes illegally. It will incentivise counterfeiters to manufacture "authentic" products, and those involved in the illicit trade to import contraband.

25.13 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.

26. ASSESSMENT AND APPROVAL OF INGREDIENTS USED IN TOBACCO PRODUCTS

26.1 The development of an appropriate and harmonised international framework on the regulation of ingredients should be workable in practice, proportionate and based on sound science and clear risk assessment principles.

26.2 The Consultation identifies that there are currently no common conditions for the internal market in relation to the regulation of tobacco product ingredients. It proposes three Options in this regard. Option 1 would mean "*No Change*", i.e. tobacco manufacturers must continue to comply with the different national regulations. Option 2 would mean "*introducing the basic criteria on the EU level without a common list.*" Finally, Option 3 would mean establishing "*a common list of ingredients*" for the EU.

26.3 JTI believes that common conditions for assessing and approving tobacco product ingredients could be developed. However, more work needs to be undertaken in this regard before such criteria can be laid down in the TPD. The Commission stated in its Second Report that:

> "*Given the still limited progress on Article 6 the Commission was not in a position to develop a proposal for a common list of ingredients. Any meaningful work on specific ingredients requires human and financial resources that are currently not yet available*".[503]

26.4 Although some progress has been made since the publication of the Second Report in relation to establishing a harmonised reporting system, it is clear that the

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[503] Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee, *Second Report on the Application of the Tobacco Products Directive* COM(2007) 754 final, page 10.

data gathered so far has not been used to develop harmonised criteria for the assessment and approval (or restrictions) of tobacco product ingredients. There is no evidence that any Member State or the Commission has even attempted to assess the vast amounts of data submitted annually to them.

26.5 Nevertheless, DG SANCO suggests in relation to Options 2 and 3 set out in the Consultation that such criteria "*may be related to toxicity, the attractiveness and the addictiveness of a product when consumed (oral tobacco) or smoked (the combustion/inhalation effect)*".[504]

26.6 RAND Europe promises in the RAND Report that "*the measures it proposes are aimed at **reducing the harm** related to the consumption of a specific tobacco product – in other words to make tobacco use less harmful, **even when prevalence rates remain stable***" [505] (emphasis added).

26.7 As set out in more detail below, **JTI believes that sufficient practice and expertise exists on which to build international methodologies and practices 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 an international level. JTI supports the use of clear assessment principles, for example:

(a) ingredients should not increase the inherent toxicity of tobacco products (the so-called "no change" approach); and

(b) assessment under the intended conditions of use.

26.8 This science-based approach should be contrasted with the position regarding the policy objectives of "addictiveness" and "attractiveness".

Toxicity

26.9 The Consultation argues that "*during the process of burning [, the] majority of additives form substances that are carcinogenic, mutagenic and/or toxic for reproduction*".[506] This sweeping statement has no sufficient scientific basis and does not adequately present the issues raised in this regard. In the following paragraphs, JTI presents its methodology to ensure that added ingredients do not increase the inherent toxicity of tobacco products. JTI will then demonstrate the flaws in the analysis by RAND Europe regarding the presence of CMRs in tobacco products or smoke.

Measuring the toxicity of tobacco products

26.10 There is currently a lack of standardised testing for ingredients added to tobacco in the manufacture of tobacco products. The FCTC Working Group stated in

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[504] Consultation, page 9.

[505] RAND Report, page 173.

[506] Consultation, page 9.

its 2007 Progress Report that "*the testing and measuring of the toxicity of cigarette contents and emissions is an emerging field*".[507] JTI supports efforts to develop standardised testing methods to measure the toxicity of tobacco products.

26.11 JTI believes that sufficient practice and expertise exists on which to build international methodologies and practices for the measurement and assessment of ingredients on the basis of toxicity. In the absence of a regulatory framework regarding the assessment of tobacco ingredients, JTI has a **Product Stewardship Programme** in place to conduct a battery of well-recognised chemical and toxicological tests:

(a) first, a general assessment is conducted for all ingredients considered for use by JTI based on a review of the publicly available information including physicochemical properties, regulatory status in food and other consumer products and scientific literature; and

(b) second, based and depending on the results of the first assessment, chemical and toxicological testing will be selected to examine if the toxicological properties of emissions from tobacco products with and without ingredients are equivalent.

26.12 Through this assessment, JTI's Product Stewardship Programme ensures that ingredients do not increase the inherent toxicity of tobacco products. This "no change approach" seeks to identify the toxicological properties of a tobacco product containing a certain ingredient compared to a control product (without this ingredient) based on an analysis of smoke emissions. An ingredient may be added to a tobacco product if it does not increase the toxicological properties compared to a tobacco product without this ingredient.

26.13 JTI believes that its Product Stewardship Programme is consistent with the Commission's approach stated in its First Report that "*a rationale behind an authorised list of ingredients is – inter alia – to be able to regulate additives that are known not to increase the toxicity…*" of tobacco products.[508]

26.14 Moreover, in its Second Report, the Commission recognised that issues relating to ingredients under the TPD are closely linked to developments under REACH, which, according to the Commission, "*covers the chemical ingredients of tobacco products just like any other chemical substance*".[509] The Commission went on to note that: "*it will be necessary to summarise and to take into account the information on tobacco ingredients made available under REACH in order to avoid*

[507] Conference of the Parties to the WHO Framework Convention on Tobacco Control, 26 April 2007, *Elaboration of guidelines for implementation of the Convention*, Article 9: Product regulation, paragraph 46.

[508] Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee, *First Report on the application of the tobacco Products Directive* COM(2005) 339 final, pages 7-8.

[509] Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee, *Second Report on the Application of the Tobacco Products Directive* COM(2007) 754 final, page 8.

overlaps with the on-going work in the context of the Directive".[510] The Commission gave similar assurances in the context of the REACH legislative process, informing the Council that:

> "*The REACH Regulation covers chemical ingredients to tobacco products like any other chemical substance. As such, they will need to be registered and be subject to evaluation, restriction or authorisation under the REACH system. Some of their effects in burnt form should be covered by any required chemical safety assessments.*
>
> *Once the REACH system is in operation, it will be necessary to summarise and to take into account the information made available under REACH on tobacco ingredients in order to better benefit from the synergies with the ongoing work in the context of Directive 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.*"[511]

26.15 The REACH system is not yet "*in operation*" in this regard, in that the first deadline for the submission of registration data has only just passed. Indeed, the recent, 1 December 2010 deadline applies only to the highest tonnage phase-in substances and those that have been classified as presenting the most significant hazards. It would therefore be entirely inconsistent with the Commission's earlier statements for DG SANCO to propose significant changes to the reporting of toxicology data under TPD until the results of REACH reporting are known and have been given due consideration. More generally, JTI believes that DG SANCO must lead a process, both within the Commission and with external stakeholders, to ensure consistency of approach between any revisions to the TPD and REACH. This dialogue could form part of the discussions that are already underway between the Commission and JTI and other tobacco product manufacturers (via the Tobacco Industry Platform), in relation to the treatment of tobacco products, including ingredients, under the REACH regime.

26.16 JTI also notes that RAND Europe has failed to take any account of REACH, let alone provide an analysis of how the experience and data gathered under REACH could be used in relation to the testing, measuring and assessment of ingredients under the TPD. In fact, the RAND Report does not even mention the REACH regulation once.

26.17 Further, in the absence of a regulatory framework regarding the measurement and assessment of the toxicity of ingredients used in the manufacture of tobacco products, various points are relevant:

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[510] *Ibid.*

[511] Council of the European Union, Addendum to Draft Minutes, 2773rd meeting of the Council of the European Union (ENVIRONMENT) held in Brussels on 18 December 2006, Brussels, 26 January 2007 (02.02), page 16 (Commission statement concerning tobacco additives in the context of the negotiations on REACH and concerning the European Parliament's amendments on tobacco additives).

(a) the majority of tobacco ingredients used by JTI are authorised food additives or are generally recognised as safe (***GRAS***) for use in food products;

(b) the additives used by US cigarette manufacturers have been assessed by prominent toxicologists. In 1994, six US tobacco manufacturers retained a group of prominent toxicologists from independent universities and medical schools to "peer review" their scientific data on all the additives they used. The panel's conclusion, which was made public, was that the ingredients used were "*not hazardous under conditions of use*".[512] Four years later, in 1998, the same group of toxicologists were asked to carry out an essentially identical review on the ingredients being used at that time; they reached the same conclusion as before;[513] and

(c) there is a significant body of independent and peer-reviewed published literature regarding the toxicological assessment of substances used as ingredients. JTI has provided lists of this literature to Member States on an annual basis as part of its submissions under Article 6 of the TPD.

26.18 JTI is committed to conducting a toxicological assessment of the ingredients used in the manufacture of its tobacco products, applying the best available testing methods. Through these tests, JTI ensures that ingredients do not increase the inherent toxicity of tobacco products. This could be used to build international methodologies and practices for the measurement and assessment of ingredients on the basis of toxicity.

RAND Report provides no basis for a ban of specific ingredients

26.19 The RAND Report suggests that banning "*additives that are CMRs or that form CMRs during pyrolysis*" would be "*likely to engender some positive impact albeit currently unquantifiable, on the health both of smokers and passive smokers*".[514] However, it provides no evidence to support a ban of certain ingredients.

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[512] The report concluded as follows: "*The authors of this report, whose qualifications are summarized in the appendix, each independently reviewed the scientific data on ingredients added to cigarette tobacco by six major United States manufacturers. This report represents their consensus on the safety of the ingredients. The material examined was extensive, and included the confidential list of the ingredients added to tobacco in the manufacture of cigarettes. The authors were also provided with summary data of all relevant published and unpublished toxicity tests and reports, as well as the original publications of data when requested. Pyrolysis and transfer rate data, maximum use levels, and annual poundage data for the ingredients were also evaluated. Each scientist independently visited the individual tobacco companies to examine the testing and research programs used for the ingredients. Reports and raw data from the studies were made available and were examined as necessary and each scientist formed an independent opinion regarding the adequacy of the testing and the safety of each ingredient… The panel's conclusion was that the additives and ingredients are 'not hazardous under conditions of use.'*", Doull J., Frawley J.P., George W., Loomis T., Squire R.A., Taylor S.L., *A Safety Assessment of Ingredients Added to Tobacco in the Manufacture of Cigarettes* (March 1994), pages 3 and 8.

[513] Doull J., Frawley J.P., George W., Loomis T., Squire R.A., Taylor S.L., *A Safety Assessment of Ingredients Added to Tobacco in the Manufacture of Cigarettes* (March 1994).

[514] RAND Report, page 181.

26.20 In fact, RAND Europe admits that "*throughout our review of the evidence we have been unable to find any evidence that some countries have successfully banned such ingredients or that these ingredients have been clearly identified*".[515] Indeed, RAND Europe goes on to say that:

> "*We have not been able to find any sources of evidence that point to quantifiable estimates of the impact of individual tobacco ingredients on the health of consumers, and there is only a limited number of sources that have been able to estimate qualitatively the potential impacts of different tobacco ingredients and flavourings on smokers' health*".[516]

26.21 RAND Europe therefore adopts an entirely speculative approach when it concludes: "*Nevertheless, it is still possible to envisage that banning ingredients that have been classified as CMRs would have a positive impact, albeit currently unquantifiable, on the health of smokers and passive smokers alike, given that the nature of these ingredients itself is harmful to health*".[517] The complete lack of evidence for this approach is apparent from RAND Europe's own acceptance that "*more research in this area is needed not only to identify potential CMR ingredients but also to evaluate their likely impact on consumers' health*".[518] Indeed, RAND Europe goes further, concluding that:

> "*carrying out this research is a required step if the ingredients and additives that are most damaging to consumers' health are to be identified and removed from tobacco products*".[519]

26.22 As RAND Europe is forced to concede, the WHO Study Group on Tobacco Products Regulation (***TobReg***) found in its second report that:

> "*Science has not established that reduction of any individual toxicant in machine-measured cigarette smoke, including those proposed in this report, will reduce actual human exposure or disease risk*".[520]

26.23 Further, RAND Europe's categorical rejection of a number of scientific papers demonstrates that their analysis is neither balanced nor objective, as it claims. Rejecting scientifically peer-reviewed articles addressing the evaluation of the potential toxicological effects of ingredients added to cigarettes on the basis that "*some of the authors of journal articles on the subject of tobacco ingredients have direct links with the tobacco industry*",[521] rather than analysing the substance of the evidence, is unbalanced and lacks rigour and objectivity. Many of the scientific

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[515] RAND Report, page 174.

[516] RAND Report, page 176.

[517] RAND Report, page 176.

[518] RAND Report, page 176.

[519] RAND Report, page 176.

[520] TobReg, *The Scientific Basis of Tobacco Product Regulation*, Second Report by a WHO Study Group, WHO Technical Report Series No. 951, page 48.

[521] RAND Report, page 173.

papers dismissed by RAND Europe were peer reviewed, disclosed any conflict of interest, and met the standard for publication in prestigious scientific journals.

Danish Cancer Study and subsequent report by the Danish Ministry of Health

26.24 JTI has set out in paragraph 6.39, above, its concerns regarding the RAND Report's reliance on a paper published by DCS in 2008 as evidence for its contention that certain CMRs increase the inherent toxicity of cigarette smoke.[522] DG SANCO cannot base its policies on a report (the RAND Report) that relies on another report (DCS) that reviews scientific literature, of which only a fraction has looked at primary data. DG SANCO and the Member States should make use of the ingredients data that are reported under Article 6 of the TPD. Why else is the industry reporting these data?

26.25 Further, DCS concluded that "*there is a lack of knowledge on the exact effects of the additives*" and that it called for further research.[523] RAND Europe also fails to report that the Danish Ministry of Health and Prevention subsequently asked DHI, an international consulting and research organisation, to categorise and assess the substances identified by DCS as requiring further investigation. In this report, DHI concluded that:

> "*The overall impression is that the danger to health posed by tobacco products which are already highly toxic is unlikely to be significantly affected by the use of these additives*".[524]

26.26 DHI reviewed the data considered by DCS, including data on 214 of the 249 additives reported by House of Prince, a Danish cigarette company,[525] to the Danish National Board of Health for use in tobacco products, as well as data from an updated literature study. DHI found that no data exist for the majority of the identified substances when consumed after combustion. Further, it found that there are around 75 substances for which there are data and which have very low toxicity. Finally, DHI found that while there were around 83 substances that may have harmful effects on cells or organs in the body, none of these substances are considered capable of causing effects on human health when ingested at the doses used in tobacco. It concluded in its report:

> "*The calculations for these substances generally show that the concentration in the tobacco has to be around 20,000 times higher than is used for a health effect to be manifested as a consequence of smoking*".[526]

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[522] Danish Cancer Society, *Tobacco Additives – A study of the available literature*, Summary, Copenhagen, 2008.

[523] *Ibid.*, at page 9.

[524] DHI, *Tobacco Additives – A study of the available literature*, Summary, Copenhagen, 2008.

[525] House of Prince A/S is now acting under the name British American Tobacco Denmark A/S.

[526] DHI report, at page 5.

26.27 The way in which RAND Europe uses and presents the DCS study — and fails to mention the subsequent analysis by DHI — not only reveals a lack of scientific rigour, but also suggests either extraordinary ineptitude or, at worst, methodological dishonesty and bias. The fact that RAND Europe claims to have been "*limited by both time and resources*"[527] (and so its reviews were "rapid") cannot excuse such scientific failings and renders the RAND Report an unreliable basis for DG SANCO's IA.

RAND Europe's reliance on the ASPECT report

26.28 In discussing a potential ban on certain ingredients, RAND Europe also relies on a report published in 2004 by the ASPECT Consortium.[528] This is yet another example where RAND Europe simply relies on the analysis of another institution, rather than considering primary data.

26.29 The RAND Report relies on ASPECT to conclude that "*it is not the toxicity of the ingredients per se that is most detrimental to health but rather the way in which the ingredients act together during pyrolysis*".[529] As set out at paragraphs 26.11-26.13 above, JTI agrees that consideration should be given in any programme for review of cigarette ingredients to assessment under the intended conditions of use. That is what JTI's Product Stewardship Programme does. This programme ensures that ingredients do not increase the inherent toxicity of tobacco products under intended conditions of use.

26.30 Further, RAND Europe relies on ASPECT to claim that "*many of the ingredients and additives used in tobacco products are not essential to their manufacture and storage and that 'few ingredients were used in cigarettes before 1970'*".[530] JTI disagrees. Camel – the originator of American Blend – was introduced in 1913. As set out at paragraph 24.5 above, ingredients help maintain an overall product consistency and quality over time, and in addition, create the unique taste and aroma of tobacco products. Ingredients also play a critical role in product innovation.

Measurement and assessment of "addictiveness" of ingredients

26.31 DG SANCO suggests that another criterion for the assessment and eventual approval of ingredients may be "addictiveness".

26.32 As the term "addiction" is commonly used today, cigarette smoking is "addictive". Many smokers who say they want to stop smoking report difficulty quitting. Nevertheless, people can stop smoking if they are determined to do so. There is nothing inherent in smoking or in cigarettes that affects the ability of a smoker to decide to quit and to go through with that decision.

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527 RAND Report, page 253.

528 ASPECT, *Tobacco or Health in the European Union – Past, Present and Future*, 2004.

529 RAND Report, page 175.

530 *Ibid.*

26.33 SCENIHR 2010 confirms that "*there is no widely agreed universal standard*" for human studies that can be employed to measure the "addictiveness" of specific tobacco product ingredients or combinations of the same under intended conditions of use.[531] Indeed, its authors concluded that "*no method currently used to define* [the] *addictive potency of a compound can…be considered as adequate.*"[532] JTI considers that, in this context, the concept of "addictiveness" lacks clarity.[533]

26.34 This is true not least because there is no scientific consensus as to what "addiction" means in this context – identifying and justifying such definitions in this regard are necessary prerequisites to formulating tests.

26.35 In any event, based upon the available scientific evidence, JTI's view is that tobacco products with added ingredients are no more difficult to quit than those that do not contain added ingredients.

26.36 Given the absence of scientific methodologies for testing and assessing the "addictiveness" of tobacco products, it may be that the most effective approach for regulators is to proceed with what is practicably feasible and, for the time being, focus the efforts on toxicity testing.

"Attractiveness"

26.37 JTI fundamentally disagrees with the statement in DG SANCO's problem definition in Section 5 of the Consultation that *"attractive substances are added into tobacco products such as liquorice to increase the smoothness of the smoke and menthol to enable deeper inhalation"*. 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 enables deeper inhalation.[534] As noted below, the inclusion of menthol has no effect on smoking prevalence, smoking behaviour or on quit rates.

"*Attractiveness*" *is subjective and arbitrary*

26.38 The notion of "attractiveness" is clearly suggested as a criterion for the regulation of ingredients for want of scientific evidence to support regulatory

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[531] SCENIHR 2010, page 8.

[532] SCENIHR 2010, page 8.

[533] Indeed, the 2007 Report of the Working Group also stated that "*the concept of testing and measuring the … dependence-producing properties of various tobacco products is fairly new and its application to tobacco product monitoring in particular has yet to be defined.*" (Conference of the Parties to the WHO Framework Convention on Tobacco Control, 26 April 2007, *Elaboration of guidelines for implementation of the Convention*, Article 9: Product regulation, paragraph 52). Similarly, the European Commission stated in its *First Report on the application of the Tobacco Products Directive* that "*methodologies for assessing addictiveness are not well developed and not applicable to routine, large-scale monitoring, the development will take several years*." COM(2005) 339 final, page 8; it has subsequently requested a scientific opinion on "*Addictiveness and Attractiveness of Tobacco Additives*" from SCENIHR, which published its final opinion on 12 November 2010 (see paragraph 6.23 above).

[534] SCENIHR 2010, page 54.

measures in relation to toxicity and "addictiveness". However, JTI fundamentally rejects the notion of "attractiveness" as a valid public policy objective against which ingredients should be regulated.

26.39 "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.

26.40 No scientific criteria have been developed to assess, and regulate on that basis, the "attractiveness" of tobacco products. Indeed, SCENIHR 2010 concluded that "*given the subtle interactions between different factors… identifying and measuring the influence of individual additives on attractiveness of products is difficult*".[535] The RAND Report made no reference to SCENIHR's pre-consultation draft, even though it was available before the RAND Report was published.

26.41 JTI agrees with SCENIHR 2010 that "*animal models do not currently exist for the assessment of attractiveness*"[536] and that, as regards studies in human subjects "*the methods used are…not adequate*" for a reliable quantification of "attractiveness" in humans.[537] The inadequacy of current methods for assessing "attractiveness" stems both from the fact that panel studies, surveys and the other experimental measures currently available are inherently subjective and from the fact that "attractiveness" as a metric lacks clarity. This is particularly so, in circumstances where the definition of "attractiveness" used is so wide as to include "*extrinsic factors*" such as price, packaging etc.[538]

26.42 Further, 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. As explained at paragraphs 24.2 – 24.3 above, 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.

JTI rejects RAND Europe's attempt to mix "attractiveness" and "addictiveness"

26.43 The RAND Report states that "*it is clear that ingredients contribute to making tobacco products more palatable to consumers and therefore may increase the addictiveness of these products*".[539] This is an inappropriate attempt to mix the concept of "addictiveness" with that of "attractiveness". Dependence has previously been described by the WHO in pharmacological terms.[540] How, then, would RAND

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535 SCENIHR 2010, page 69.

536 SCENIHR 2010, page 11.

537 *Ibid*.

538 SCENIHR 2010, page 70 ("*the factors influencing attractiveness can be broadly divided into: extrinsic factors (e.g. marketing, packaging, pricing); and intrinsic factors (e.g. taste, smell, sensory attributes and pharmacological factors).*")

539 RAND Report, page 174.

540 *Expert Committee on drug dependence*, Thirty-third report, WHO Technical Report Series, No. 915. Geneva, World Health Organization, 2003.

Europe consider that "addictiveness" and "attractiveness" are to be scientifically related, if addictiveness is a pharmacological measure and attractiveness is a measure of smokers' subjective response to a product, its ingredients and even its packaging? It is important to ensure that these terms are used properly, or at least that the interrelationship between them is clarified.

No evidence to support regulation on the basis of initiation, consumption, prevalence or quitting

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

26.45 Tobacco products with added ingredients are no more widely consumed than those that do not contain added ingredients:

(a) research shows no significant differences in smoking prevalence, consumption and quitting between American blend and Virginia style markets;[541,542]

(b) ecological studies have repeatedly suggested that the inclusion of menthol has no effect on smoking prevalence, smoking behaviour or on quit rates;[543] and

(c) cigarettes that do not contain flavour ingredient (such as Camel Natural Flavour) are the preferred choice of many consumers worldwide.

26.46 In summary, "attractiveness" cannot be used as a shortcut to ingredients regulation or as a substitute for a science-based approach.

Minors should not smoke

26.47 The issue underpinning the Commission's consideration of "attractiveness" as a criterion for ingredients regulation appears to be smoking initiation by minors. 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*".[544] The RAND Report states that "*the use of ingredients for aromatic purposes also raises the issue that they may*

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[541] The tobacco markets in Canada and the UK are predominantly flue-cured, and so products in those markets contain no or very few ingredients. Other markets are predominantly American blend, with more ingredients included.

[542] Lee at al, "Does use of flue-cured rather than blended cigarettes affect international variation in mortality from lung cancer and COPD?", *Inhalation Toxicology* (2009) 21, pages 404-430.

[543] See Muscat et al., "Mentholated cigarettes and smoking habits in whites and blacks", *Tobacco Control* (2002) 11:368-371; Werley M.S. et al., "Possible effects on smokers of cigarette mentholation: A review of the evidence relating to key research questions", *Regulatory Toxicology and Pharmacology* (2007) 47, pages 189-203; Hyland A. et al., "Mentholated cigarettes and smoking cessation", *Tobacco Control* (2002)11, pages 135-139.

[544] Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee, *Second Report on the Application of the Tobacco Products Directive*, COM(2007) 754 final, page 8.

make tobacco products more attractive to young people and children in particular".[545]

26.48 JTI does not use flavours or any other ingredients for this purpose. Furthermore, 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 minors is widely acknowledged.[546] Factors that make smoking uptake more likely include peer pressure, parental or family influence, and the desire to appear "cool", independent and more "adult".[547]

Specific ingredients mentioned in the Consultation

Menthol

26.49 DG SANCO states that menthol is added to cigarettes to "*enable deeper inhalation*".[548] RAND Europe further contends that menthol is added to cigarettes "*to ease the uptake of cigarette smoke and this particular ingredient may act as a local anaesthetic when its concentration is high, as well as giving the smoker a refreshing feeling while the smoke is inhaled*".[549] Again, RAND Europe relies exclusively on the DCS study or, more specifically, the short English summary of it published in 2008.

26.50 However, the available scientific data does not support the contention that menthol facilitates deeper inhalation. For example, as noted, SCENIHR 2010 reported that "*current data are inconclusive*" in this regard.[550] Further, as stated at paragraph 26.45 above, epidemiological data does not suggest that mentholated cigarettes are any harder to quit than unmentholated products, and this in turn suggests that menthol neither causes nor facilitates dependence.

26.51 Furthermore, relying exclusively on the DCS summary paper, RAND Europe fails to report (again) that the Danish Ministry of Health and Prevention asked DHI to review the scientific evidence on menthol and other ingredients. In a report published in September 2009, DHI found that "*no difference in inhalation tidal ratio was found*

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[545] RAND Report, page 175.

[546] E.g. Department of Health, *Consultation on the future of tobacco control* (2008); Department of Health, *Smoking Kills - A White Paper on Tobacco* (1998); Scottish Schools Adolescent Lifestyle and Substance Use Survey (SALSUS) National Report, *Smoking, drinking and drug use among 13 and 15 year olds in Scotland in 2006*.

[547] An Expert Panel Report for Health Canada found that "*practically one hundred percent said the reason they might start smoking or would smoke is to be cool or fit in*", *When Packages Can't Speak: Possible Impacts of Plain and Generic Packaging of Tobacco Products*, prepared at the Request of Health Canada (1995).

[548] Consultation, page 9.

[549] RAND Report, page 175.

[550] SCENIHR (2010) page 92.

between smokers of mentholated and unmentholated products" in a study carrying out post-puff respiration measures.[551] DHI also found that:

> "*In a clinical trial of smoking cessation, where 5887 smokers were included, no difference in success of quitting smoking between smokers of plain versus menthol cigarettes was found as well as no difference in values of carbon monoxide and cotinine.*"[552]

26.52 DHI further stated that while "*data indicate that black Americans are more addicted to nicotine*" this "*cannot be related to smoking mentholated cigarettes*".[553]

Liquorice and other substances

26.53 DG SANCO states that "*attractive*" substances such as liquorice are added to tobacco products "*to increase the smoothness of the smoke*". The RAND Report states that liquorice and other substances, such as fruit extracts or sweeteners, are used to "*reduce the harshness of tobacco smoke*", "*ease the uptake*" and "*make tobacco products more attractive to young people and children*".[554]

26.54 The issue underpinning this debate is smoking initiation by minors. Banning ingredients is not the solution to this issue.

26.55 JTI does not use ingredients to "*mask the harshness of tobacco smoke*", in order to "*ease the uptake*" and "*make tobacco products more attractive to young people and children.*" JTI uses ingredients to facilitate choice for adult smokers – to develop unique brands that meet the preferences of adult consumers regarding taste and aroma. JTI does not accept the suggestion that a policy objective of ingredients regulation should be to make smoking less pleasurable for adult consumers.

26.56 Furthermore, neither DG SANCO nor the RAND Report provides evidence suggesting a link between ingredients and the promotion of tobacco use (i.e. evidence that people become smokers, or are deterred from quitting, as a result of the use of ingredients). In fact, as explained above, based upon the available scientific evidence, there is no evidence to support ingredient regulation on this basis.

Assessment and approval principles and process

26.57 The TPD invites the Commission "*to submit, on the basis of the information provided under Article 6, a proposal providing for a common list of ingredients authorised for tobacco products*".[555]

26.58 JTI supports regulatory action to develop an appropriate and harmonised regulatory framework for ingredient regulation that is workable in practice,

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551 DHI, *Sundhedsmaessig vurdering af 5 tilsaetningsstoffer til tobak*, September 2009, E-4.

552 *Ibid.*, E-5.

553 *Ibid.*, E-6.

554 RAND Report, page 175.

555 Article 12 of the TPD.

proportionate and consistent with other aspects of tobacco regulation. JTI has various proposals as to the principles, processes and procedures that should be applied in accordance with Better Regulation principles.

26.59 JTI's proposals are consistent with the principles, processes and procedures that form the basis of analogous regulatory regimes, such as applicable to chemicals, agrochemicals, environmental regulation, food additives and pharmaceuticals.

Principles of assessment

26.60 **Any assessment and approval process for tobacco product ingredients needs to be based on sound science and clear principles**. JTI considers that there are at least two core principles that should be applied to any assessment of ingredients.

26.61 First, safety assessment principles are reflected, for example, in the Voluntary Agreement on the Approval and Use of New Additives in Tobacco Products in the UK, which specifies that submissions to support the use of new additives "*shall provide sufficient information to demonstrate to the Department's satisfaction that the additive would not increase the hazard of the product*".[556] This reflects the approach taken by JTI, namely that, through the tests conducted as part of its Product Stewardship Testing Programmes, ingredients do not increase the inherent toxicity of tobacco products ("**no change approach**").

26.62 Second, consistent with the safety assessment standard for food additives, GRAS substances and other sectors, and the criteria for approval of cigarette additives in the UK, consideration should be given, in any programme for review of cigarette ingredients, to **assessment under the intended conditions of use**. There may be a number of considerations that are relevant to the assessment of a particular ingredient, depending upon its use in the tobacco product. Relevant considerations include:

(a) the identity of ingredients, the maximum levels of use and the conditions of use;

(b) the physical and chemical properties and natural occurrence in tobacco;

(c) the expected exposure, i.e. the transfer rate to smoke and the likelihood of pyrolysis; and

(d) the toxicological properties, including metabolic and pharmacokinetic characteristics and knowledge on structure/activity relationships.

26.63 To facilitate the evaluation of ingredients used in smaller quantities, an approach involving the concept of "**threshold of toxicological concern**" (***TTC***) is used as a complementary aid to the assessment procedure. The concept of TTC is commonly applied to oral exposure assessments by authoritative bodies, such as

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[556] The Voluntary Agreement also provides that the evaluation of the safety of a new ingredient shall include examination of the structure of the substance, levels of use, transfer rate to smoke and appropriate biological studies, including 90 day pyrolysis inhalation studies.

JECFA and the FDA (U.S. Food and Drug Administration), and has recently been considered for inhalation exposure assessments by industry/regulatory bodies.

Expert review body

26.64 JTI considers that 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.

26.65 The body's work should be based upon carefully developed and explicitly stated safety criteria and risk assessment principles. Its procedures should be based upon Better Regulation principles, and should provide for stakeholder participation, including as to the potential economic impact of its decision. The decisions of such a body (or, if its role is of making recommendations to a political body, the decisions of that latter body) ought to be subject to proper oversight and scrutiny.

Type of List

26.66 DG SANCO states that some Member States allow a number of listed ingredients ("positive list") while others have banned certain ingredients ("negative list"). Some other Member States use a combination of positive and negative lists.[557] It may be added that in some cases, the use of ingredients is permitted as long as it does not exceed a certain maximum limit.

26.67 The choice of the type of list is itself of significance. First, where a Member State already has a list, serious consideration must be given to the legitimate expectations and commercial decisions taken on the basis of this list before any amendment is made. Second, any common list of ingredients would have to provide for sufficient transitional arrangements in order to enable tobacco manufacturers to move to a new regime that could potentially involve the restriction or prohibition of ingredients they have been using for many years, and which contribute to their commercial success.

26.68 Any decision to permit, prohibit or restrict the use of a specific ingredient must be based on a full and appropriate scientific assessment against the identified criteria. Furthermore, the development of any authorised or common list of ingredients also needs to provide a process for adding new ingredients. This is especially important in the context of products which "*may have the potential to reduce harm*"[558] or where product changes are required by future regulation.

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[557] Consultation, page 9.

[558] TPD, Article 11.

27. SOLUTIONS FOR THE REGULATION OF INGREDIENTS

27.1 JTI supports proposals for appropriate regulation of tobacco product ingredients.

27.2 JTI believes that sufficient practice and expertise exists on which to build international methodologies and practices 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 an international level.

27.3 This science-based approach should be contrasted with seeking to regulate on the basis of "addictiveness" and "attractiveness". JTI would propose that the development of methodologies and practices for the measurement and assessment of ingredients on the basis of toxicity is taken forward separately from the consideration of "addictiveness" and "attractiveness".

27.4 JTI considers that a recognised scientific body should be entrusted with testing and assessing the toxicity of tobacco product ingredients under intended conditions of use.

27.5 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.

27.6 Ingredients regulation poses significant challenges. However, more work needs to be undertaken in this regard before criteria for prohibiting, restricting or approving ingredients can be laid down in the TPD. Otherwise the EU risks the imposition of unnecessary, inappropriate and potentially arbitrary restrictions on the ability to innovate and manufacture a wide range of competitive products that meet consumer preferences. JTI considers that its proposals in this document provide a coherent, scientifically sound framework for developing a harmonised regime to regulate ingredients.

ACCESS TO TOBACCO PRODUCTS (CONSULTATION SECTION 6)

28. INTRODUCTION

28.1 Section 6 of the Consultation deals with three issues relating to "*access to tobacco products*":

(a) the potential prohibition on the display of tobacco products in retail outlets;

(b) sales of tobacco products over the Internet; and

(c) sales of tobacco products via vending machines.

28.2 As described below, it appears that DG SANCO views these issues primarily in relation to the issue of smoking by minors, and the need to combat initiation. As stated at the very beginning of this document, JTI believes that minors should not smoke, and should not be able to obtain tobacco products.

28.3 A key finding of Professor Steinberg's Report is that policies that limit minors' ability to obtain cigarettes are likely to have a greater impact than those that attempt to diminish their interest in smoking.[559] In his view:

> "*A proportion of adolescents in the EU smoke cigarettes, in spite of their knowledge of the health risks of doing so and society's best efforts for the last three decades to deter them from doing so, and it is likely that they will continue to do so for so long as cigarettes are available to them. Stopping them from obtaining cigarettes, and combating peer influence by removing cigarettes from peer networks, is key.*"[560]

28.4 As regards adults, it appears on the basis of the RAND Report that DG SANCO considers the proposals as a means to facilitate quitting. Part of the rationale for the proposals seems to be based on concerns about impulse purchasing. However, as set out in Professors Dhar and Nowlis's Report:

(a) regular adult smokers have generally reached a level of consumption that remains stable until they decide to cut down and quit and implement that decision;[561]

(b) the types of cues that induce a desire to smoke occur mostly at home, at work, in the context of socialising and rarely or never at point of purchase. Cues that induce a desire to smoke are generally internally driven as a result of various factors including: motive, habit, to enhance positive emotion or cope with negative emotion, to alleviate boredom. Again, such cues and triggers are likely to occur at point of consumption;[562]

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[559] Professor Steinberg's Report, pages 4 and 22-24.

[560] Professor Steinberg's Report, page 22.

[561] Professors Dhar and Nowlis's Report, paragraph 6.36.

[562] Professors Dhar and Nowlis's Report, paragraph 6.32.

(c) adult smokers tend to buy cigarettes as a regular act and as a habitual response;[563] and

(d) the decision to quit smoking comes as a result of a value system choice and an evaluation of costs and benefits in the context of the individual's specific goals and motivations at that given time. A decision to quit smoking which is properly implemented in such a way is unlikely to be displaced simply by seeing a pack in-store. A smoker who has decided to quit smoking may be subject to urges and cravings to smoke but these are as a result of point of consumption cues (as described in (b) as opposed to point of sale cues, i.e. in-store displays).[564]

28.5 The approach and problem definition regarding access to tobacco products, whether for adults or minors, is flawed, and fails to take account of the framework for decision making. As such, the proposals regarding access are not appropriate to the public policy objectives that can be identified from the Consultation and the RAND Report.

29. PROHIBITION OR RESTRICTIONS ON THE DISPLAY OF TOBACCO PRODUCTS

29.1 Section 6.1 of the Consultation notes that parts of the UK, Finland and Ireland have either introduced, or plan to introduce, bans on the display of tobacco products. The Consultation is silent on the rationale for such measures or the public health outcomes (if any) that they might achieve. The options presented for consultation are:

(a) no change (Option 1);

(b) the introduction of unspecified restrictions on tobacco display and promotion at point of sale (the sole example given being to permit only one package per brand to be visible) (Option 2c); or

(c) ban on all in-store promotion and display (Option 3c).

29.2 JTI fundamentally disagrees with a proposal to introduce a display ban or restrictions on display. In addition to issues of legal basis and subsidiarity, JTI believes:

(a) DG SANCO has not properly identified the policy objectives of such measures;

(b) there is no reliable evidential basis to support restrictions or a ban on the display of tobacco products;

(c) such measures would impede and restrict lawful activity whilst facilitating illegal activities; and

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[563] Professors Dhar and Nowlis's Report, paragraph 6.33.

[564] Professors Dhar and Nowlis's Report, paragraph 6.35.

(d) such measures would have wide-ranging negative effects on competition and the supply chain, notably on retailers.

29.3 As regards the proposal for restrictions on display (Option 2c), 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.

29.4 In light of the above, as well as the fundamental constitutional and property rights that would be engaged by a ban, both the restriction and prohibition of in-store displays are manifestly disproportionate.

Failure to identify policy objectives

29.5 The burden lies on DG SANCO to justify the introduction of display restrictions or a ban. DG SANCO must provide reliable evidence demonstrating clearly that display restrictions or a ban will achieve any identified policy objectives.

29.6 However, it is not evident on which public policy objectives DG SANCO is proposing to justify the introduction of measures in relation to in-store display. The Consultation is silent in this regard.

29.7 In the absence of any such clarity in the Consultation, the RAND Report discloses two apparent objectives of restricting or prohibiting in-store display: preventing initiation by minors and to facilitate quitting by adult consumers. The RAND Report states: "*it follows that the rationale for restricting or banning promotions and displays in retail stores is primarily twofold: to prevent the uptake of smoking in youths in particular and to remove cues that could trigger the desire to smoke in consumers trying to quit, stay quit* [sic] *or cut down on their tobacco consumption*".[565] For the purposes of the discussion that follows, JTI has assumed that these twin objectives are those which DG SANCO would itself pursue in this regard.

General defects in the evidence base

29.8 The burden lies on DG SANCO to provide clear evidence that restricting or prohibiting in-store displays is likely to result in changes in behaviour which, in turn, are likely to benefit public health (specifically: to reduce smoking initiation by minors and to increase quitting by adult consumers). Before considering the available evidence in relation to display and smoking initiation by minors (paragraphs 29.12 – 29.28) and adult smoking behaviour (paragraphs 29.29 – 29.35), one point of general application must be made.

29.9 JTI is aware of various studies that have been cited in support of a display ban. Putting to one side the actual reliability of such evidence (which is discussed below), much of the research relied upon relates to 'advertising' (or off-pack 'promotional activities') and **not** to 'display' of tobacco products. 'Advertising' research findings are irrelevant. As well as explaining why such studies are not relevant, in his September 2008 Report, Dr Keegan explains:

[565] RAND Report, page 192.

"*Many studies test the effects of retail display in conjunction with the effects of in-store advertising and/or use the terms interchangeably, or use inconclusive results regarding the effect of retail display on smoking behaviours in conjunction with positive in-store marketing results to advocate for increased restrictions on both. In studies where authors group retail display with in-store marketing, it is often impossible to determine any particular effect that is associated with the retail display alone.*"[566]

29.10 Further, the RAND Report does not itself claim that the evidence is clear or compelling. Indeed, in assessing the evidential basis in respect of a display ban, the RAND Report states that "*it is clear that the results of such studies should be carefully considered along with the limitations associated with their methodology. Most of these rely on self-reported rather than observed behaviour, typically include relatively small samples of the population at large and are also subject to context-specific conditions*".[567] Moreover, the RAND Report states that "*no good estimates of prevalence changes on a population level could be obtained from the literature, despite evidence for the positive effects of display and advertisement restrictions on purchasing decisions*".

29.11 JTI considers that, in fact, **there is no reliable evidence on which to justify a ban or further restrictions on tobacco product display**. It is inappropriate and contrary to Better Regulation principles to base policy initiatives on manifestly flawed evidence.

The restriction or prohibition of display will not achieve the objective of reducing smoking initiation by minors

29.12 The RAND Report appears to give the protection of minors from the promotion of tobacco as a key rationale in controlling the display of tobacco products. However:

(a) **DG SANCO and the RAND Report have failed to consider the relative impact of predictors of minors smoking**, such as family and social influences. Many minors do not obtain cigarettes from stores themselves and the risk factors for smoking initiation by minors are various but do not include packaging or the display of tobacco products. A display ban is therefore not an appropriate measure by which to achieve the identified policy objectives.

(b) **JTI is aware of no reliable consumer survey evidence** demonstrating that a display ban or further restrictions will reduce smoking uptake in minors. Rather, proponents of a display ban have tended to rely upon: (i) irrelevant evidence which relates to advertising; or (ii) methodologically flawed studies which do not support a display ban; and

(c) **JTI is aware of no statistical evidence** that a display ban would, in fact, affect rates of consumption or prevalence of smoking amongst minors by

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[566] Dr Keegan's September 2008 Report, page 27.

[567] RAND Report, page 194.

reference to the experience in jurisdictions that have introduced a display ban. In fact, expert analysis indicates that there is no discernable impact in reducing the already existing decline in smoking in those jurisdictions.

The role of retail display of tobacco products in smoking by minors

29.13 JTI's response in relation to issues of smoking among minors is guided by Professor Steinberg's Report. The RAND Report states at page xxv that "*banning the display of tobacco products at the point of sale has been shown to remove smoking cues and reduce triggers for unplanned tobacco purchases in stores. This effect is thought to be particularly strong among adolescents and young people, who are thought to be more susceptible to such promotions*". However, Professor Steinberg's view is that the impact of changes in cigarette packaging or in the display of cigarette packages on smoking by minors is likely to be very small at best.[568] Moreover, in his view, "*there is no evidence to support the proposition that changes in cigarette packaging affect adolescents' experimentation with or use of cigarettes. This is true both with respect to the addition of pictorial warnings and with respect to the substitution of plain or generic packaging*".[569] He also concludes that banning in-store displays of tobacco products on the basis that this will discourage impulse-purchasing by minors is unlikely to be effective, because it is unlikely that impulse purchasing in retail stores plays any role in minors' acquisition of cigarettes. Rather, 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 salesclerk who asks for proof of age.[570]

No reliable consumer survey evidence

29.14 The RAND Report asserts that "*the evidence on promotion and displays of tobacco products in retail stores has shown that they influence purchasing decisions and may have an impact on smoking uptake by youths*".[571]

29.15 JTI disagrees. There is no reliable consumer survey evidence to demonstrate that a display ban will serve to reduce smoking uptake among minors. Dr Keegan has undertaken a detailed and thorough analysis of consumer survey studies on the likely impact of a ban on the display of tobacco products in terms of minors, including those studies cited in the RAND Report. Dr Keegan has prepared the following reports in which he analyses publicly available consumer survey studies in respect of a display ban:

(a) In his September 2008 Report, Dr Keegan reviewed the evidence in the context of the UK Department of Health FTC Consultation. This review covered a wide range of available studies, whether cited in the FTC

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[568] Professor Steinberg's Report, pages 4 and 29.

[569] Professor Steinberg's Report, pages 4 and 28.

[570] Professor Steinberg's Report, pages 4 and 28.

[571] RAND Report, page 200.

Consultation or identified elsewhere, relating to display at point of sale. Dr Keegan's findings are set out at pages 27 to 43 of his September 2008 Report. He concludes that there "*is no reliable evidence to suggest that a ban on retail display of cigarettes will lead to a reduction in youth smoking uptake*".[572]

(b) In his June 2009 Report, Dr Keegan analyses additional studies which have been published or otherwise made available since September 2008 using the same criteria as employed in his original report. In this report, Dr Keegan remains of the view that there is "*no reliable evidence to suggest a display ban will lead to a reduction in youth smoking uptake*".[573]

(c) In his April 2010 Report, Dr Keegan confirms that his view remains the same and concludes that: "*I have seen nothing in the consumer surveys that demonstrates that [a ban] will serve to protect children and young people. Studies that attempt to make this connection ultimately fail to support the position when carefully evaluated*".[574]

29.16 In his review of the consumer survey evidence relevant to a display ban, Dr Keegan has found that the studies are "*unreliable*" in that they "*suffer such serious methodological limitations as not to be meaningful consumer survey research*". This is for a variety or combination of the following reasons:

(a) **biased and/or flawed survey question design**: the use of leading, confusing, unbalanced or misguided questions;

(b) **invalidation by age or environment**: beliefs and behaviours measured in a previous or markedly different regulatory environment, in particular where extensive tobacco advertising was permitted, "*have limited relevance to today's reality and cannot be viewed as predictive*".[575] There is no basis for drawing parallels between the regulatory environments of the locations studied with the environment currently existing across the various Member States;

(c) **measurement of impressions or perceptions of the respondent, or even their perceptions of others', and not actual behaviour**: "*observing what people do is a better predictor of behaviour than recording how people respond to questions about what they think they will do, or what they think others will do, or what they report they have done*";[576]

(d) **lack of statistical significance of findings due to the small sample sizes and the informal nature of focus study groups**: for example, relying on data

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[572] Dr Keegan's September 2008 Report, page 27.

[573] Dr Keegan's June 2009 Report, page 27.

[574] Dr Keegan's April 2010 Report, paragraph 2.8.

[575] Dr Keegan's September 2008 Report, page 5.

[576] Dr Keegan's September 2008 Report, page 10.

collected from just 20 former and current smokers in New Zealand regarding the effects of retail display of cigarettes on smoking behaviours;[577]

(e) **insufficient account of the reliability issues of data collection from minors, in some cases as young as 11**: for example, asking a question for which the respondent child has no factual basis on which to formulate an informed response: "*Do you think other kids your age will try smoking if they see cigarette displays in convenience stores, variety stores or corner stores?*"[578]

(f) **interviewing smokers and ex-smokers in an after-the-fact interview** and asking them to think about prior shopping experiences over the course of their lives, rather than interviewing respondents as they left the retail environment: none of the studies reviewed by Dr Keegan adopted the latter methodology; and

(g) conclusions that are not supported by the research and/or relying on results that are not statistically significant to bolster the study results.

29.17 JTI sets out in more detail below the key limitations identified by Dr Keegan in respect of each individual study cited by RAND Europe as supporting the assertion that "*the evidence is particularly strong with respect to young people who are thought to be more susceptible to such promotions and displays as well as not 'fully capable of understanding the risks of smoking*":

(a) **Henriksen et al. (2004):**[579] Having reviewed the study, Dr Keegan concludes that "*the study does not directly measure the effect, if any, of tobacco marketing on smoking behaviour, but uses the frequency of store visitation as proxy. It is not possible to draw any meaningful conclusion about the possible effect of restricting retail display on teen smoking behaviour based on* [this study] *because the relationship simply has not been tested*".[580]

(b) **Paynter and Edwards (2009):**[581] This study consists of a literature review of existing studies relevant to the topic of tobacco display, but does not present any original consumer survey research. On reviewing the study, Dr Keegan has concluded that "*because this study simply reviews and comments on the results of existing research, I consider it a secondary resource*".[582]

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[577] See Hoek J., Gifford H., & Edwards, R. *Effects of tobacco retail displays on ex-smokers and lapsed quitters*, New Zealand: Massey University, New Zealand: University of Otago (undated).

[578] J. Gottheil Marketing Communications, *The Influence of Tobacco Powerwall Advertising on Children* (March 2005).

[579] Henriksen, L., Feighery, E.C., Wang, Y., Fortmannm S.P., *Association of Retail Tobacco Marketing with Adolescent Smoking.* American Journal of Public Health (2004) 94, pages 2081-2083.

[580] Dr Keegan's April 2010 Report, paragraph 4.24.

[581] Paynter, J. Edwards, R., "The impact of tobacco promotion at point of sale: A systematic review", *Nicotine and Tobacco Research* (2009) 11.1, pages 25-35.

[582] Dr Keegan's April 2010 Report, paragraph 5.65.

(c) **Cancer Research UK Report (2008):**[583] Dr Keegan has found that this study "*suffers from a number of limitations, most notably its willingness to draw conclusions that stray from and are unsupported by the data*"[584] and concludes that the study "*does not provide reliable, objective evidence establishing a relationship between tobacco marketing and brand awareness and smoking uptake*".[585]

29.18 For the reasons described above, the consumer survey studies expressly relied upon in the RAND Report which relate to 'advertising' and **not** display of tobacco products, and those which are not original primary consumer survey research, are irrelevant. Evidence regarding "advertising" cannot be reliably transposed to display. Thus, six studies[586] referred to in the RAND Report should be excluded from the consideration of the display ban assessment.

Statistical evidence of the effect of a display ban

29.19 There is no reliable evidence that the tobacco display bans enforced in Iceland and in Canada have had an impact on smoking initiation by minors (the percentage who have tried smoking) or prevalence (the percentage of daily or current smokers). Indeed, if one looks at smoking behaviour among 15-19 years old between the year of the introduction of a tobacco display ban and 2010, it becomes obvious that this policy has not reduced smoking initiation by minors.

29.20 JTI commissioned an expert economist, Dr Lilico, to conduct an economic analysis of the impacts of plain packaging and point of sale display restrictions in the UK. He produced three reports, the September 2008 Report, the October 2009 Report, a "*supplemental report*" , which evaluates additional data that had become available since his September 2008 report and his April 2010 Report, an additional report as part of JTI's display ban proceedings in England.

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583 Hastings, G., MacKintosh, A.M, Holme, I., Davies, K, Angus, K., Moodie, C., *Point of Sale Display of Tobacco Products* (2008), The Centre for Tobacco Control Research funded by Cancer Research UK.

584 Dr Keegan's April 2010 Report, paragraph 4.141.

585 Dr Keegan's April 2010 Report, paragraph 4.155.

586 Those studies which relate to advertising and display of tobacco products are: (i) Loomis, C., Farrelly, J., Mann, H., "Point of Purchase Cigarette Promotions before and after the Master Settlement Agreement Exploring Retail Scanner Data", *Tobacco Control* (2006) Vol. 15, No.2, pages 140-142; (ii) Slater, S., Chaloupka, F., Wakefield, M., Johnston, L, and O'Malley, P., "The Impact of Retail Cigarette Marketing Practices on Youth Smoking Uptake", *Archives of Paediatrics & Adolescent Medicine* (2007) 161, pages 440-445 and (iii) Di Franza, J., Wellman, R., Sargent, J., Weitzman, M,. Hipple, B., Winckoff, J., "Tobacco Promotion and the Initiation of Tobacco Use: Assessing the Evidence for Causality", *Paediatrics* (2006) 117, 6, pages 1237-1238. These three studies are discussed in more detail in Dr Keegan's September 2008 and June 2009 Reports. Those studies which are not original primary research and are therefore irrelevant are: (i) the UK Department of Health's *Consultation on the Future of Tobacco Control*, May 2008; (ii) Liljenwall, R., "The Power of Point of Purchase Advertising: Marketing at Retail", *Point of Purchase Advertising Intl* (2004); and (iii) *WHO Report on the Global Tobacco Epidemic* (2008), Copenhagen, World Health Organisation, Regional Office for Europe.

29.21 Dr Lilico set out in his September 2008 Report the percentage of people in various age ranges in Iceland, Thailand, Manitoba and Saskatchewan that are daily smokers, for the periods for which data was available at the time.[587] Those jurisdictions have had no display of tobacco product for a period that allows the same evaluation of data and trends before and after the removal of tobacco products from display. Where possible, Dr Lilico ran established statistical tests to assess whether there was statistical impact on prevalence trends. Dr Lilico concluded that "*smoking prevalence is statistically unaffected so far*" by display bans in Manitoba and Saskatchewan[588] and that display bans "*have not yet had any impact*" upon established trends in prevalence and consumption.[589]

29.22 In October 2009, having considered additional data recently made available in Canada and Iceland, Dr Lilico confirmed his view that there is, as yet, no credible statistical evidence that the introduction of display bans has been associated with reduced smoking prevalence.[590] In particular, there is no evidence of such an effect in respect of those aged 15-19.

29.23 Furthermore, having considered the new Canadian data using more detailed and powerful statistical tests than were possible given the information that existed previously, Dr Lilico also concluded that display bans are **strongly and materially correlated** with increased prevalence amongst 15-19 year olds. (Please note that Dr Lilico's work investigates statistical correlation rather than causality. Therefore, it does not seek to establish that the ban is the cause of this prevalence change.) In his April 2010 Report, Dr Lilico remained of the view that "*there is, as yet, no credible statistical evidence from other jurisdictions that the introduction of display bans have been associated with reduced smoking prevalence, and in particular, no evidence of such an effect in respect of those aged 15-19*". Data from various Canadian provinces "*suggest that there is, as yet, no such credible statistical evidence*" while data from Iceland and Thailand "*suggest that, at least so far, display bans have had no measurable impact upon prevalence of smoking, either among the young or among the population as a whole*".[591]

29.24 Following the publication of the most recent Canadian data on how many people smoke cigarettes and how many cigarettes are smoked per day in Canadian provinces, Dr Lilico considered whether the additional data changed the conclusions he previously reached in his April 2010 and October 2009 reports. In his November 2010 Update, Dr Lilico has confirmed that "*the conclusions I reached in the 2009 Report, which are repeated in the* [April] *2010 Report, concerning the impact of the display ban in Canada on smoking prevalence and average number of cigarettes smoked have not changed in light of the data now available*".[592]

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[587] Dr Lilico's April 2010 Report, section 6.

[588] Dr Lilico's April 2010 Report, paragraph 6.14.

[589] Dr Lilico's April 2010 Report, paragraph 6.20.

[590] See Dr Lilico's October 2009 Report.

[591] Dr Lilico's April 2010 Report, paragraph 1.19.

[592] Dr Lilico's November 2010 Update, page 3.

29.25 The conclusion reached in the RAND Report that a display ban would have a potential benefit in reducing prevalence amongst minors is clearly based on an incomplete and selective analysis and/or is arrived at without appropriate reference to the experience of other countries, and is flawed. There is, in fact, no evidence, on the basis of international examples and on the data available, that a display ban would accelerate the already existing decline in smoking by minors across the various Member States.

29.26 JTI therefore believes that a ban on the display of tobacco products will have no discernible impact in reducing the numbers of minors who start smoking. There is insufficient evidence on which DG SANCO can proceed with a display ban on this basis.

29.27 JTI notes that the RAND Report acknowledges a report by Dr Jorge Padilla (and commissioned by PMI) entitled "*The Effectiveness of Display Bans: The Case for Iceland*" in its discussion of the statistical evidence of the impact of a display ban on smoking prevalence.[593] JTI is unaware as to whether this report has been formally reviewed by a statistician on behalf of RAND Europe, however notes that some of the statements made as to the purported limitations of Dr Padilla's report appear to go against what is considered to be good science.

29.28 JTI is therefore concerned that the RAND Report's treatment of Dr Padilla's report does not appear to be a serious or thorough econometrical critique of his work. In addition, JTI is disappointed by the assertion by RAND Europe that "*any evidence funded by the tobacco industry should be carefully considered given the industry's history of interfering with tobacco control policy and of funding research to counter independent research on the health impacts of tobacco*". The fact that Dr Padilla's report was produced at the request of PMI neither (1) is a reason to reject it *per se* (as to do so would be contrary to Better Regulation principles and the principle of equality) nor (2) undermines the validity of its concerns, so long as conducted to internationally accepted standards of scholarship.

The restriction or prohibition of display will not achieve the objective of facilitating quitting by adult consumers

29.29 JTI notes that, in addition to stating that a display ban is "*likely to have a positive impact on adolescent smoking*", the RAND Report also argues that it will also have "*to a lesser extent an impact on adult smokers – in particular those attempting to quit – as all cues would be removed from stores*".[594]

29.30 Neither the Consultation nor the RAND Report contains any analysis at all of the way in which future controls on the display of tobacco products will assist existing adult smokers who are trying to quit. Instead, in the absence of any evidence, the

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[593] RAND Report, page 194.

[594] RAND Report, page xxxi.

RAND Report takes a leap of faith and asserts that "*some adults and would-be quitters may also be positively affected*" following the introduction of a display ban.[595]

29.31 Moreover, neither the Consultation nor the RAND Report present any reliable evidence to suggest that a ban on retail display will lead to an improved environment for those trying to quit smoking. Whilst the RAND Report does not clearly set out or distinguish the evidence base in respect of any proposed public policy objectives, JTI notes that the following publicly available consumer survey studies cited by RAND Europe appear to have relevance to an objective of facilitating quitting by adult smokers:

(a) **Wakefield et al. (2008):**[596] This study is cited in the RAND Report in support of the statement that "*a study…found that 25.2 percent of smokers impulse purchase cigarettes as a result of seeing cigarette displays in retail shops while 38 percent of smokers who had tried to quit in the past 12 months and 33.9 percent of recent quitters experienced an urge to buy cigarettes as a result of seeing the retail cigarette display*".[597] However, this study is fundamentally flawed, as shown by Dr Keegan's review. First, the study is purely attitudinal, asking people to self report on behaviour including their potential reaction to point of sale display. Self report data is of limited reliability. Second, Dr Keegan uses this study as an example of biased survey questions. Dr Keegan concludes that the "*questioning used in this study is leading, suggestive and conditions the respondents to provide answers that support the conclusions the authors wish to reach*".[598]

(b) In respect of the four studies cited in support of the assertion in the RAND Report that "*the results of these studies still indicate that displays and promotions may influence smoking behaviour and increase the likelihood of tobacco product purchases at retail stores*",[599] the limitations of two have been discussed above at paragraph 29.17 (see Henriksen et al. (2004) and Paynter and Edwards (2009)), and the remaining two studies relate to advertising and not display of tobacco products.

29.32 Therefore, these studies do not constitute sufficient evidence of the likely effect of a ban on the display of tobacco products on the purchasing behaviours of existing adult smokers who wish to quit. Moreover, JTI is not aware of the existence of any other evidence that would support a display ban on that account.

29.33 Indeed, Professor Dhar and Professor Nowlis have opined that the suggestion that displays somehow impact on adult consumers' purchasing behaviour and adult impulse purchasing is flawed when considering the framework for consumer

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595 RAND Report, page 202.

596 Wakefield, M., Germain, D., Henriksen, L., "The effect of retail cigarette pack displays on impulse purchase", *Addiction* (2008) 103, pages 322-328.

597 RAND Report, page 193.

598 Dr Keegan's September 2008 Report, page 37.

599 RAND Report, page 194.

behaviour. Smoking is a habit and adult smokers will have various established routines around their smoking behaviour including with regard to their purchasing behaviour. They state: "*if smokers habitually buy cigarettes, and this is a regular act, which they do in a repetitive fashion without prolonged deliberation, then banning cigarette displays is also very unlikely to cause a reduction in smoking. Instead, these smokers are likely to simply stop in a particular store and automatically buy their regular brand, regardless of any displays, and not on impulse, but as a habitual response*".[600]

29.34 Further, they conclude, there is no credible evidence provided to show that displays encourage smokers to buy cigarettes when they would not otherwise have done so. While smokers may make unplanned purchases (i.e. buying a pack earlier than they otherwise would have or in a different store to where they intended to buy), this is not the same as choosing to purchase a product when such a choice would not have been made at all (i.e. even in the future) but for the display. It is clear that, contrary to the RAND Report's assertions, key triggers to smoking occur at the point of consumption and not at point of sale.[601]

29.35 Professors Dhar and Nowlis further consider that "*the suggestion that a ban on displays would assist those smokers wishing to quit is flawed on the basis that it does not take into account the way in which adult smokers decide to quit smoking and implement that decision. Implementing the decision to quit smoking comes as a result of a value system choice and an evaluation of costs and benefits in the context of the individual's specific goals and motivations at that given time. A decision to quit smoking which is properly implemented in such a way is unlikely to be displaced simply by seeing a pack in-store*".[602] Consistent with the framework set out in their report, Professors Dhar and Nowlis state that difficulties in implementing a decision to quit, or prompts to have a cigarette, would tend to come about as a result of point of consumption cues as opposed to point of purchase cues. In light of the above, Professors Dhar and Nowlis conclude that display bans are unlikely to have any effect on adults' smoking behaviour.[603]

Other 'goals' set out in the RAND Report regarding a tobacco display ban

29.36 JTI notes the statement at page 193 of the RAND Report that "*promotions and point of sale displays may also have an impact on regular smokers and the general public at large by reinforcing the acceptability and normalcy of the purchase*". JTI is concerned that the RAND Report appears to be suggesting that the introduction of further controls on the display of tobacco products would help "*denormalise tobacco use*".

29.37 JTI does not accept that "denormalisation" is a legitimate public policy objective that can justify tobacco regulation. "Denormalisation" is not, and cannot be,

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[600] Professors Dhar and Nowlis's Report, paragraph 6.33.

[601] Professors Dhar and Nowlis's Report, paragraph 6.36.

[602] Professors Dhar and Nowlis's Report, paragraph 6.35.

[603] Professors Dhar and Nowlis's Report, paragraph 6.35.

a self standing objective. It is not legitimate to seek to discriminate against, stigmatise or ostracise existing adult smokers, or to treat the purchase or use of tobacco, as "abnormal", "unacceptable" or "tainted". As a policy objective, it runs counter to the hallmarks of a democratic society (notably pluralism, tolerance and broadmindedness), lacks any evidential foundation and is arbitrary. JTI considers that "denormalisation" adds nothing to underlying public health rationale.

29.38 Moreover, in his April 2010 Report, Dr Keegan notes that there is no evidence in respect of "denormalising" tobacco products, and that "*denormalisation is, in my opinion, difficult to define and address in consumer survey research, and none of the studies I have considered for the purposes of preparing this report have addressed empirically this topic*".[604]

A display ban will impede and restrict lawful activity, and facilitate illegal activity

29.39 Any proposed further restrictions on tobacco display would, in all likelihood, lead to a series of negative and undesirable consequences, including:

(a) serious and unnecessary damage to the legitimate economic interests of JTI, its connected industries and the market dynamic of the tobacco sector;

(b) the promotion of counterfeit and contraband tobacco products;

(c) significant and unnecessary impairment of JTI's fundamental rights as a commercial entity; and

(d) the effect on small business retailers.

The importance of display at the point of sale

29.40 The ability of JTI to display its products in retail outlets is one of the last remaining, and therefore critical, means by which JTI maintains connection with existing adult smokers. In summary, the display of products allows JTI to communicate with existing adult smokers so that they can easily, quickly and effectively identify the existence and availability of tobacco products, obtain information about the particular characteristics of those products, and distinguish between, and choose, those products.

29.41 A display ban would deny existing adult smokers their right to be aware of, and to have the information required to make informed choices between, the wide range of tobacco products available in each individual Member State and across the EU.

Opportunity to capture market share

29.42 JTI considers that a display ban would have a profound negative effect on the competitiveness of the EU tobacco market and on consumer information.

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[604] Dr Keegan's April 2010 Report, paragraph 2.3.

29.43 First, both the Consultation and the RAND Report fail to examine how consumers could become aware of new products – particularly new brands – in a display ban environment and taking into account existing communication restrictions, which in many Member States are extensive. JTI believes that a display ban would make new market entry extremely difficult, if not almost impossible.

29.44 Second, the ability of a manufacturer to capture even 0.1% of its competitors' market is critical, making 'brand switching', where an existing adult smoker changes his or her tobacco product of choice, either temporarily or permanently, fundamental to commercial success. Competition in many markets depends on switching by a marginal number of consumers, and the result of switching by only a minority benefits **all** consumers. Dr Lilico demonstrates this at paragraphs 3.7 to 3.15 of his September 2008 report. Point of sale display is therefore critical in facilitating 'brand switching' amongst existing adult smokers.

29.45 Third, it is incorrect to assume that smokers invariably have only one particular brand of cigarette which they always smoke.[605] Many smokers have a favourite second (or even third) brand, which they may smoke occasionally or buy when their preferred brand is unavailable. This is a phenomenon that occurs particularly when retailers are out of stock. Even when smokers display strong loyalty regarding their preferred primary brand, they may be significantly less loyal to their second brand. Point of sale display is therefore a useful tool by which companies can encourage that second brand preference.

29.46 It is therefore clear that point of sale displays are a platform for genuine competition between tobacco companies. It is entirely understandable and entirely legitimate that JTI should wish to facilitate consumers' navigation between different products so that they can easily select an alternative product at point of sale, when they are ready to "brand switch".

Market impacts

29.47 A display ban can be expected to distort competition and impede operation of the free market in a number of important ways, as summarised briefly below.

29.48 First, denying existing adult smokers access to important visual information at the point of sale, including reminders as to brand, price, availability and product characteristics, will result in a reduction of "brand switching" activities. Reduction in awareness of certain brands as a result of a display ban is likely to lead to brand consolidation and tends towards crystallisation of the market, translating into stronger brand loyalty for already successful and established brands. Consumers are unlikely to switch brands where they do not know what alternatives are available or the attributes of such alternatives.

29.49 Second, the inability of consumers to access visual information at point of sale will stifle product and packaging innovation. The evidence demonstrates that the

[605] For example, an OmniTel/H.R. Bruskin study released on 27 March 1984 found that 90% of smokers use only one brand. This leaves the significant figure of 10% of smokers who use more than one brand.

tobacco sector is innovative. Without product display, innovative manufacturers will be denied any opportunity to communicate improvements or changes to existing brands, the existence of new products and to use their product innovations to compete for market share. This will further crystallise the market, prevent new companies and new brands entering the market and reduce consumer choice. One important effect of a display ban would be to prevent manufacturers from conveying information about the availability and attributes of products with features likely to be of interest to existing adult smokers including, for example, products using fair-trade or organic tobacco, as they are developed.

29.50 Expert analysis of the evidence on innovation from other markets in which display bans have been introduced confirms this assessment. Dr Lilico concludes that display bans materially impair new innovation.[606] Further, the negative competition effects arise more quickly than theory would predict, and are much more marked, creating something akin to effective crystallisation for practical purposes.

29.51 Third, the evidence demonstrates that competition will be reduced, between companies and between brands, in a post display ban environment. Dr Lilico carried out a series of empirical investigations to assess the possible impact of display bans in various markets, including Iceland and Thailand. Using sophisticated statistical analyses, Dr Lilico concludes that the introduction of display restrictions marked a break in the competitive process and that the effect of regulation has been that of "freezing" significantly the competitive forces in the market.[607]

29.52 Dr Lilico explains that, while the impact of display bans on Iceland and Thailand in innovation is not yet clear from the data, the negative effects on competition have arisen more immediately than Dr Lilico anticipated and have been much more marked. In Thailand, "*visual inspection suggests that market concentration for cigarette brands remains relatively stable after the Guidelines*" while in Iceland Dr Lilico finds that "*the cost of regulation, in competition terms, has been 46 additional years of limited market competition*". In this report, Dr Lilico considers that the nature of competition in the UK market is such that the situation is "*vulnerable, in competition terms, to the effects of a display ban*".[608]

29.53 Fourthly, it is expected that a display ban, precluding any opportunity for manufacturers to communicate the properties of their brands to consumers, would leave manufacturers to compete primarily on the basis of price. By forcing tobacco manufacturers to compete solely on the basis of product price, the result is a downward pressure on product prices and towards an eventual commoditisation of tobacco products. This would run counter to the policy objective of reducing initiation by minors and consumption – lower prices meaning increased availability and access for minors to tobacco products.

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606 See, for example, point 8 of the Summary of the Report's Findings to Dr Lilico's September 2008 Report, page 40 of Dr Lilico's October 2009 Report and section 7 of Dr Lilico's April 2010 Report.

607 Dr Lilico's September 2008 Report, paragraph 5.35.

608 Dr Lilico's April 2010 Report, section 8.

29.54 Lastly, as Dr Lilico notes in his September 2008 Report, considering the display ban proposed by the UK Department of Health, such a prohibition would have indirect negative effects on employment and tax revenues, on account of the increased opportunities for criminals involved in contraband/counterfeit activities.[609]

The impact of a display ban on illicit trade

29.55 As explained above, the fight against the illicit trade in tobacco products is a critical business priority for JTI. Accordingly, JTI is extremely concerned that a display ban may serve to encourage the trade in illicit cigarettes and thereby, perversely, frustrate the pursuit of DG SANCO's objective of reducing smoking prevalence in minors.

29.56 A display ban will impact on illicit trade in three specific ways:

(a) it may **blur the public's perception of the difference between legal and illicit tobacco products** given the existing trend for illicit products to be sold 'under the counter' by certain retailers. Consumers' resistance to purchasing illegal tobacco products is likely to be diminished;

(b) illicit tobacco products are not only sold by street vendors and at markets but are also sold by a small minority of **unscrupulous retailers, who could more easily blend illicit tobacco products into the supply chain**. This is not the case, currently, where products are displayed in a gantry and consumers will likely find suspicious a retailer who ignores the products on the gantry and instead reaches under the counter to sell illicit products; and

(c) storage of tobacco products "under the counter" is also likely to pose **further challenges to the enforcement activities** undertaken against such traders. For example, where products are to be stored out of sight, it will not always be evident to officers conducting their enforcement activities – or indeed JTI's own sales force representatives – whether certain retailers are using two "under the counter" compartments (one of legal products and a hidden, second one containing illicit products) and therefore it will be more difficult to determine whether illicit products are being supplied to adult smokers. Further, an inspector will not be able to scan visually a gantry on entry into a retail outlet, in order to identify any illicit product.

Impairment of fundamental rights

29.57 The proposal to prohibit the display of tobacco products engages a number of JTI's fundamental rights, which are protected under various legal instruments, including the freedom of expression (to impart and receive information) and the right to trade:

(a) prohibiting display at the point of sale denies JTI its right to trade and to communicate with existing adult smokers about the attributes of its products,

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[609] Dr Lilico's September 2008 Report, section 7.

including its trademarks, and, as a corollary, denies those individuals of their right to receive information; and

(b) prohibiting commercial expression at point of sale impairs the very essence of commercial free speech and JTI's rights to engage in commerce.

29.58 JTI recognises that these freedoms are not absolute rights and that their restriction can, in certain circumstances, be justified. However, the burden lies with DG SANCO to demonstrate that restrictions are necessary and proportionate to achieve, in the least restrictive manner, the identified legitimate public policy goals. For the reasons given above, JTI does not consider that this burden has been met, and infringements of these fundamental rights are not justified.

Effect on small business retailers

29.59 Sales of tobacco products are an important revenue stream for a large number of retailers across a range of different retail businesses. JTI supports fully, and urges DG SANCO to give careful consideration to, the concerns raised to date by retailers – many of whom are SMEs - where similar display restrictions have been proposed, for example in the United Kingdom. In this regard, JTI is aware of the submission made by the UK's Association of Convenience Stores to DG SANCO outlining its concerns in respect of the introduction of the regulatory measures proposed in the Consultation, including the proposed introduction of a display ban. These concerns include:

(a) loss of business through diversion to larger retailers, including loss of secondary and "footfall" purchases, which would disproportionately affect small retailers, with the potential for a significant number of them to go out of business;

(b) an increase in the sale of counterfeit tobacco products, including an increase in counterfeit products entering legitimate trade;

(c) an increase in transaction times;

(d) security implications, such as:

  (i) the loss of the role of gantries in keeping products secure; and

  (ii) the increased likelihood of theft if it takes longer to retrieve a tobacco product or to retrieve it from a location which does not allow the retailer to monitor customer activity; and

(e) the cost of implementation, including shop refits and ongoing costs such as staff training and the need for additional staff to allow for more frequent refills and to monitor customer activity.

30. INTERNET SALES

30.1 Section 6.1 of the Consultation raises, in the context of the question of access to tobacco products, the issue of cross-border sale of tobacco products to consumers via the Internet.[610] It identifies the following concerns in this regard:

(a) 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*"; and

(b) "*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*".

30.2 The RAND Report, in particular, is inconsistent as to the scale of Internet sales of tobacco products to consumers in the EU. The RAND Report states that "*little is known about the total extent of cross-border (internet) sales of tobacco products*"[611] and that "*from the available data we cannot infer what the share of cross-border purchases is*".[612]

30.3 On the other hand, the RAND Report suggests that: "*Overall, internet purchases of tobacco products constitute only a very small proportion of tobacco purchases; therefore we do not expect* [a ban on cross-border Internet sales] *to have a measurable health effect*".[613] This final conclusion is itself at odds with the view expressed elsewhere in the RAND Report that "*…banning cross-border internet sales is likely to have indirect health and social impacts*".[614]

Do minors obtain tobacco products over the Internet?

30.4 A key issue of concern to DG SANCO, in respect of Internet sales of tobacco products, appears to be the possibility that minors may obtain tobacco products online in a way that allows them to evade minimum purchase age and/or age verification requirements.

30.5 Neither the Consultation nor the RAND Report contains any evidence to suggest that minors do obtain tobacco products in this way. In fact, minors primarily obtain cigarettes by "bumming" or buying them from friends, some of whom may be of legal age to purchase cigarettes, or by asking older individuals to purchase them for them (i.e. proxy sales).[615] In Professor Steinberg's view, it does not appear that the

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[610] Consistent with section 6.1 of the Consultation, JTI's comments below address the question of Internet sales as they relate only to consumers.

[611] RAND Report, page xxvi.

[612] RAND Report, page 197.

[613] RAND Report, page xxx.

[614] RAND Report, page 198.

[615] Professor Steinberg's Report, pages 3 and 10.

purchase of cigarettes by minors over the Internet is, as yet, a significant problem in the EU.[616]

Concerns over language of health warnings

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

30.7 In any event, the fact that the language of packaging purchased in one Member State may be different from the native language of the purchaser is true of cross-border purchases of a variety of products. In the context of tobacco products, the same issue arises in respect of (for example) the UK consumer who purchases a carton of cigarettes during a visit to France, or the German tourist who buys a packet of cigarettes from a tobacconist in Poland. It would be illogical to support a prohibition of Internet sales on this basis, given the far more significant volume of non-Internet, cross-border sales that raise the same issue.

Internet sales of illicit trade product

30.8 JTI does not support the unregulated sale of cigarettes via the Internet. JTI recognises that there are Internet sites that are not legitimate and, in some instances, the tobacco products they offer may have been diverted from their intended markets or be counterfeit. Further, it has come to JTI's attention that some Internet sites offering tobacco products for sale actually use JTI's brand names in their address. Such sites and the use of our brand names are not authorised by JTI and have no connection to JTI's companies or any of our other commercial entities.

30.9 The solution to the problem of illicit sites selling tobacco products without proper payment of taxes, and to minors, is to permit legitimate companies to continue to sell through this medium, based on appropriate regulations to target tax evasion and access by minors.

30.10 In addition, JTI strongly supports the targeted use of enforcement action by competent authorities against illegitimate Internet sites (including those knowingly selling products to minors).

Internet sales of legal tobacco products

30.11 JTI recognizes the significant growth of the Internet as a medium for the sale of goods to consumers.[617] JTI is not opposed to the sale of legitimate tobacco

[616] Professor Steinberg's Report, page 10. Further, JTI notes that the ability of minors to purchase tobacco, and other age restricted, products over the Internet is also restricted by the fact that access to a credit/debit card is required.

[617] According to the OECD, 35% of adults in OECD countries purchased goods and services on the Internet in 2008, compared with 26.9% in 2004. See Background Report, *OECD Conference on Empowering E-consumers, Strengthening Consumer Protection in the Internet Economy*, December 2009.

products via the Internet provided that they are appropriately regulated so proper tax payments are ensured and access by minors is denied.

30.12 JTI believes that appropriately regulated Internet sales support its initiatives to combat illicit trade and to help prevent access to tobacco products by minors.

30.13 Controls of this type would supplement existing requirements applicable as a matter of EU law to Internet sales. In view of these existing requirements, tobacco-specific measures beyond those described at paragraph 43.24 as regards age verification and ensuring proper tax payments, would be duplicative and unnecessary. As DG SANCO will be aware, there are a number of directives to protect consumers and also to address concerns (such as data protection) already relevant to the sale of tobacco and other consumer products on the Internet. For example:

(a) Directive 95/46/EC on the protection for individuals with regard to the processing of personal data and on the free movement of such data (known as the Data Protection Directive);

(b) Directive 97/7/EC on the protection of consumers in respect of distance contracts (known as the Distance Selling Directive);

(c) Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal market (known as the E-Commerce Directive);

(d) Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector (known as the Privacy and Electronic Communications Directive); and

(e) Directive 2005/29/EC concerning unfair business to consumer commercial practices in the internal market (known as the Unfair Commercial Practices Directive).

31. VENDING MACHINES

31.1 The issue of vending machines for tobacco products is given only cursory mention in the Consultation. Having asserted that: "*Vending machines are banned in a large number of Member States*",[618] the options presented to stakeholders are:

(a) no change (Option 1);

(b) "*access to vending machines would be restricted to adults*" (Option 2b); or

(c) "*vending machines would be banned in all Member States*" (Option 2c).

31.2 The RAND Report's consideration of vending machines is also brief. In this context, it asserts that:

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[618] Consultation, page 10.

(a) "*a complete ban on vending machines for adolescents … would solve the enforcement problems related to age restrictions on vending machines and could lead to small reductions in youth smoking*";[619]

(b) "*while purchasing cigarettes from vending machines is by no means the only or primary way in which young people access tobacco products in the UK, it is nonetheless a non-negligible source*";[620] and

(c) "*it appears that merely restricting youth access to vending machines is not sufficient to limit the access of young people to tobacco products*".[621]

31.3 The RAND report concludes that: "*…although banning vending machines may have some impacts on youth tobacco purchasing, it would not prevent them from accessing tobacco products altogether*".[622]

Do minors obtain tobacco products from vending machines?

31.4 As noted, minors primarily obtain cigarettes by "bumming" or buying them from friends, some of whom may be of legal age to purchase cigarettes, or by asking older individuals to purchase them for them (i.e. proxy sales). In Professor Steinberg's view, vending machines account for only a very small proportion of the cigarettes smoked by minors and prohibiting them is therefore unlikely to have any significant effect on underage smoking in the EU.[623]

Tobacco vending machines should be strictly controlled

31.5 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 by minors. JTI does not, however, support the prohibition of vending machines, which would prevent legitimate access by adult smokers.[624]

31.6 The sale of tobacco products via vending machines to adult consumers is legitimate. No provision in the FCTC requires the prohibition of the sale of tobacco products to adults via vending machines.[625] A general prohibition on the use of

[619] RAND Report, page xxx.

[620] RAND Report, page 189. In the recent judgment in the English High Court in *Sinclair Collis Limited* v *The Secretary of State for Health* [2010] EWHC 3112 (Admin), 1 December 2010 (the ***Sinclair Collis judgment***), Sir Anthony May stated: "*Although different sources may have varying percentages for those 11–15 year olds* [in the UK] *for whom vending machines are a usual source of cigarettes, the evidence is that some 11–15 year olds do obtain cigarettes from vending machines, and the estimate of 4.5% used in the calculations – admittedly an estimate – is not open to criticism*" (paragraph 58).

[621] RAND Report, page 191.

[622] RAND Report, page xxv.

[623] Professor Steinberg's Report, pages 22-23.

[624] As acknowledged by Sir Anthony May in paragraph 92 of the Sinclair Collis judgment.

[625] Article 16 of the FCTC addresses vending machines and is entitled "*Sales to and by minors*". It does not require the prohibition of vending machines: Article 16(1)(d) provides that Parties "*may*" take measures "*ensuring that tobacco vending machines under its jurisdiction are not accessible to*

vending machines is too broad and is unnecessary and – as such – is inconsistent with the principles of Better Regulation.

Further regulation should only be considered at a Member State level

31.7 The extent to which cigarette vending machines exist and are used varies across markets and is different in different Member States. Therefore, it is more appropriate for legislative controls on vending machines to be taken at Member State rather than at a Community level. Each Member State is in the best position to assess the most appropriate form of controls to prevent access by minors to vending machine within that State (although, as noted, banning vending machines is in any event unlikely to have any significant effect on underage smoking).

31.8 The RAND Report recognises that vending machine control is something that could be addressed at Member State level:

> "*…some impacts could be achieved by Member States implementing stricter measures on their own, as is already the case for … bans on vending machines*".[626]

31.9 Consistent with this analysis, the Members of the European Parliament, in joint statement with the Chronic Disease Alliance issued on 5 October 2010, included the measure of "*banning cigarette machines*" in a list of actions to be taken "*at national level*" rather than the list of "EU level recommendations". This recommendation reflects the absence of a clear basis in law or the Treaty for an EU ban on vending machines.

31.10 Further, the Commission's 23 November 2009, *Report on the implementation of the Council Recommendation of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control*, found that implementation of the Recommendation in the Member States, including the "*introduction of measures to restrict the use of vending machines by under age persons*", was "*satisfactory*".[627]

31.11 For the reasons set out above, a general prohibition on vending machines at a Community level would, in particular, be inconsistent with the principles that the regulation must have a clear legal basis and that other, less restrictive, options should be first considered.[628]

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minors and do not promote the sale of tobacco products to minors." In the light of these provisions, the non-binding Guidelines on the interpretation of Article 13 of the FCTC, which recommend that vending machines should be prohibited, are illogical and inconsistent. The assertion that vending machines constitute a means of advertising is without evidence or credible reasoning, and renders unnecessary and meaningless the text of the FCTC. The Guidelines therefore provide no meaningful aid to interpreting and implementing the FCTC's provisions on vending machines.

626 RAND Report, page xxvii.

627 Brussels, 25 November 2009, 1666/09, SAN 340, page 8.

628 In the context of the Sinclair Collis judgment, Sir Antony May considered the question of the alternatives available to a regulator other than imposing a ban on vending machines, stating that a

Alternative Solutions

31.12 JTI sets out in Sections 41-43 its less restrictive, more targeted and proportionate alternative solutions to address the issue of minors seeking to obtain tobacco products from vending machines.

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relevant question was "*whether the health measure is appropriate, and whether any other less intrustive measure is available which would provide equally good public health protection*" (paragraph 70). However, in the context of this judgment, Sir Anthony concluded that the UK Parliament should be afforded a broad discretion as to whether the measure chosen was best able to achieve the stated aims (paragraph 94 to 96).

ILLICIT TRADE

32. INTRODUCTION

32.1 DG SANCO and RAND Europe both fail to give proper regard to the serious concern that the regulatory measures they are considering (and, in DG SANCO's case, consulting upon) not only fail to achieve their assumed objectives, but also risk exacerbating the illicit trade in tobacco products within the EU. This represents a double failure: first, to consider the impacts that proposed measures might have on the illicit trade in tobacco products; and second, to consider the implications of the illicit trade in tobacco products on the measures under consideration.

32.2 The failure to identify and assess this risk[629] is remarkable given that RAND Europe has previously committed to address this very issue. In the introduction to its 7 January 2010 questionnaire, RAND Europe stated that:

> "*To fill this specific evidence gap, RAND Europe developed this questionnaire focusing on the analysis of costs, in particular the administrative burden and compliance costs that can be associated with the current and any potential future legislation. Thus there are no questions on wider impacts of regulations on,* ***for example,*** *consumer choice, property rights, or* ***illicit tobacco trade. These issues are covered by other research phases and results are combined in the final report RAND Europe will deliver to the European Commission***."[630]

32.3 The absence of this analysis is made more concerning by the scale and impact of illicit trade in the Community. While a precise figure identifying the extent of the trade in illicit tobacco products is difficult to determine, its seriousness has been recognised by a variety of stakeholders:

(a) for **JTI**, the fight against cigarette smuggling and counterfeiting is an important business priority. The same is true of other manufacturers of tobacco products, who, like JTI (see below) have entered into agreements with the Commission to address this issue;

(b) for **the EU**, which has reported that**:** "*it is estimated that around 10 billion euro are lost to the national and EU budgets each year due to the smuggling of both genuine and counterfeit cigarettes. On a single 40 foot container of smuggled cigarettes (10 million cigarettes) the average loss of customs duty,*

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[629] The RAND Report makes only cursory reference to the issue (see, for example, page 28: "*One particular weakness of consumption data is that they exclude illicitly traded tobacco*"). In total, the RAND Report contains just four paragraphs on the illicit trade (and none related to the possible impact of its proposals on illicit trade).

[630] RAND Report, Appendix C, pages 285-301.

excise duty and VAT is €1.5 million. In the UK the loss would be about three times as big because of the UK's higher taxes";[631]

(c) for **Member State competent authorities:** see, for example, comments made by the UK Department of Health in the FTC Consultation: "*…the UK market is still characterised by high levels of illicit tobacco use. The Government's latest estimate is that the illicit share of the tobacco market in the UK is between 8 and 18%. That means that today, of all cigarettes smoked in the UK, one in six is either counterfeit or smuggled. Over half of all hand-rolled tobacco (HRT) is smuggled*";[632] and

(d) for **tobacco control advocates:** "[The] *data highlight the enormous scale of the global illicit cigarette trade, the huge sums of money that governments are losing because of it, and the significant number of lives that could be saved in the future if the illicit trade were eliminated*".[633]

32.4 Increasing concerns have also been raised about the links between the illicit trade in tobacco products and terrorism and organised crime. In Ireland, two high profile cases have recently received significant media exposure, clearly highlighting the level of involvement of organised crime gangs in the illicit trade in cigarettes.[634] A 2008 Congressional study prepared by the U.S. House Committee on Homeland Security concluded that the illicit trade in tobacco products was "*more than just a matter of hundreds of millions of dollars in lost tax revenue – it is a matter of national security*", and that several recently closed cases had highlighted "*the dangerous links between cigarette smugglers and international terrorist groups*".[635] In September 2010, EU Commissioner Šemeta opened a high level conference on EU-US cooperation to tackle cigarette smuggling, noting that: "*There is no doubt that serious organised crime groups are involved in tobacco smuggling. By buying cheap cigarettes, you are threatening your society by encouraging criminality*".[636]

32.5 Given the importance of this issue, both generally and to the matters considered in the Consultation, JTI sets out below:

(a) examples of the measures it has taken to address illicit trade;

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631 Contraband and counterfeit cigarettes: frequently asked questions; MEMO/10/448, Brussels, 27 September 2010. Available at: http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/10/448&type=HTML.

632 FTC Consultation, paragraph 2.29.

633 Joossens, L.; Merriman, D.; Ross, H.; Raw, M., *How eliminating the global illicit cigarette trade would increase tax revenue and save lives* (2008), Paris, International Union Against Tuberculosis and Lung Disease, , page 17.

634 JTI, *The Illicit Tobacco Trade in Ireland Annual Review 2009*, 23.

635 *Tobacco and Terror: How Cigarette Smuggling is Funding our Enemies Abroad*, prepared by the Republican Staff of the U.S. House Committee on Homeland Security, April 2008, pages 6 and 14). Available at: http://chs-republicans.house.gov/list/press/homeland_rep/morenews/cigarettesmuggling.pdf.

636 Press release, Reference: IP/10/1143, Date: 20/09/2010. Available at: http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/1143&type=HTML

(b) its position on illicit trade; and

(c) the likely impact of DG SANCO's Consultation proposals on illicit trade, by reference to the example of plain packaging.

33. MEASURES TAKEN BY JTI TO ADDRESS ILLICIT TRADE

33.1 JTI has been working on a technical level and an executive level with the World Customs Organization (***WCO***), the EU, individual Member States, and several anti-counterfeit associations around the world. JTI is disappointed that the RAND Report fails to acknowledge the measures that it and other industry members have taken to address illicit trade issues. Therefore, JTI summarises these measures below and offer recommendations for future action by DG SANCO in this regard.

Agreement with the European Commission and the EU Member States

33.2 The signing of a 15-year agreement with the European Commission (the ***EU Agreement***), defining JTI's cooperation to combat the illegal trade of cigarettes in the European territory, was announced on 14 December 2007.[637] This historic step received widespread support.[638] All 27 EU Member States are now signatories to the EU Agreement. It includes a series of contributions by JTI, totalling US$400 million over 15 years, which are aimed at helping Member States fight the illicit trade in tobacco.

33.3 The EU Agreement built upon and confirmed a number of initiatives that have been implemented by JTI over the years. It provides for clear processes around seizures and close cooperation with the European Commission, OLAF[639] and the law enforcement authorities of Member States. It also includes a guarantee to make payments in the event of future seizures in the EU of genuine JTI products above defined quantities.

33.4 Other tobacco product manufacturers have entered into similar agreements with the EU.

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[637] See further http://ec.europa.eu/anti_fraud/budget/cig_smug/2007_en.html. The Agreement is available at: http://ec.europa.eu/anti_fraud/budget/cig_smug/cooperation_agreement.pdf and http://www.jti.com/file.axd?pointerid=33745171048747bb92318379cc43e01e&fea4700464604fc8b88976adc1271f86.

[638] From the Commission President, José Manuel Barroso and the European Vice-President for Administrative Affairs, Audit and Anti-Fraud, Siim Kallas, available at: http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/1927&format=HTML&aged=0&language=EN&guiLanguage=en; and the President and CEO of JTI, Pierre de Labouchère, available at: http://www.jti.com/press_home/press_releases/fab8c47e00ac4e19a24a184f9e17eb28/EC-PR_English.pdf.

[639] *Office Européen de Lutte Anti-Fraude*, the European Union Anti-Fraud Office.

Sales integrity programmes[640]

33.5 JTI has developed state-of-the-art sales integrity programmes to ensure the ongoing integrity of JTI tobacco sales.

Know Your Customer

33.6 JTI believes that many of the problems associated with economic sanctions, export controls, illicit trade and money laundering can be addressed through 'know your customer' programmes. To this end, JTI has formally enhanced these programmes, and continues to implement them across our operations. Such programmes ensure that product is only sold to customers who have integrity and can substantially demonstrate their commitment and ability to fully comply with all local laws, as well as to stringent internal standards.[641]

Due diligence and monitoring

33.7 On an ongoing basis, JTI conducts due diligence and monitoring procedures to understand its customers and their business. Proactive monitoring of sales orders placed by customers can ensure that any unusual purchase patterns or quantities are identified, properly investigated and resolved at an early stage.

Track and Trace

33.8 Another cornerstone of the EU Agreement and JTI's position on the FCTC protocol on illicit trade (the ***FCTC Protocol***)[642] is the use of effective tracking and tracing regimes. JTI believes that measures to track and trace the sale of cigarettes, if clearly defined and evaluated, could represent a new tool in the fight against contraband trade and, together with other efforts, will allow JTI and the relevant authorities to tackle illicit trade at its sources of origin. However, it is important that international standards are developed to ensure a uniform approach is adopted. This requires criteria on:

(a) commercially feasible marking and scanning technologies;

(b) database format and content requirements; and

(c) regulations on reciprocal sharing of, and access to, data.

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640 See further JTI's "Sales Integrity Programs" (April 2008). Available at: http://www.jti.com/file.axd?pointerid=bc7c7f1c814644318b4d95c80e431b92&227f2757b26648e08367c968aa457da7.

641 JTI will only supply tobacco products in quantities that are commensurate with legitimate consumption in the intended market of retail sale and refuses to supply tobacco products that exceed such consumption.

642 See: http://www.who.int/fctc/inb/en/. FCTC Article 15(2)(b) considers a practical track and trace regime that would further secure the tobacco supply chain and assist industry and law enforcement agencies in the investigation and prevention of illicit trade, notably by identifying the point of diversion into illegal channels.

33.9 JTI is committed to identifying and implementing viable technologies, including tracking and tracing, which are cost-effective and proven to significantly enhance its existing efforts to stop product diversion and prevent the trade of contraband product.

JTI's Code of Conduct

33.10 The position under the EU Agreement is reflected in JTI's Code of Conduct, which applies to the entire company, including its subsidiaries and affiliates. It also applies to all company employees worldwide, as well as to all company agents and representatives. The Code of Conduct states in unequivocal terms that: "*We cooperate fully with governments and regulatory authorities to help prevent and eradicate illegal trade in our products*".[643]

Memoranda of Understanding

33.11 Among the necessary steps taken by JTI in assisting governments in the fight against the illicit trade in the EU, of particular significance have been various memoranda of understanding with Member State authorities, local tax and customs agencies, including in Germany, the UK and Ireland.[644]

34. JTI'S POSITION ON ILLICIT TRADE ISSUES

34.1 JTI's position on the illicit trade in tobacco products in the EU is, therefore, clear and unequivocal. JTI believes that:

(a) **combining the resources and coordinating the efforts of Community bodies, such as OLAF, Member States and business** is the only solution to this illicit trade. JTI cooperates fully with government authorities, regulators and law enforcement authorities in the fight against illicit trade and consults with them on effective ways to prevent or eliminate tobacco smuggling and counterfeiting in their jurisdictions;

(b) the **FCTC Protocol**[645] **is a positive measure to raise awareness of this growing phenomenon** and provide guidance to member countries on proven policies and approaches to fight against illicit trade;

(c) **no regulatory action should be taken by DG SANCO which is at odds with the objectives of Community law** in the context of the enforcement of intellectual property rights and illicit trade (namely that effective means of

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643 Available at: http://www.jti.com/documents/corp_reponsibility/Code_of_Conduct_english_2008.pdf, page 16.

644 For example, in November 2009, JTI Ireland signed a MoU with Ireland's Revenue Commissioners, consolidating the well-established and ongoing relationship and exchange of information between Revenue and JTI. A week after its signing, the MoU was put in to practice when JTI personnel were asked to assist Revenue with the inspection of tobacco leaf seized at Dublin port.

645 The latest version of the protocol was published by the WHO FCTC on 21 March 2010. See: http://www.who.int/fctc/inb/en/.

enforcing such rights is of paramount importance for the success of the internal market and as infringements of intellectual property rights are increasingly linked to organised crime);[646]

(d) tackling illicit trade is critical to **reducing smoking amongst minors**, as smoking by minors may be encouraged by any regulatory measures that have the unintended consequences of increasing the availability of lower priced, illicit tobacco products;

(e) contraband damages JTI's business and undermines its brands and **JTI is not, and will not be, involved in the illegal sale of its products**. It is committed to fighting the illicit tobacco trade and to preventing its products from ending up on the illegal market; and

(f) **high rates of tobacco taxation increase the incentives for those involved in the illicit trade** of tobacco products and make Member States with the most expensive tobacco prices in the EU targets for criminals selling cheaper cigarettes.[647] Illicit trade continues to be encouraged by: (i) high retail prices driven by high rates of taxation on tobacco products, which are some of the highest rates in the world; and (ii) the potential profits these policy decisions provide for those involved in the contraband trade.

34.2 JTI has highlighted throughout this Full Submission the negative unintended consequences that measures currently being consulted upon by DG SANCO might have in relation to the illicit trade in tobacco products. To highlight the seriousness of its concerns in this regard, JTI summarises below the potential benefits to those involved in the illicit trade of an EU plain packaging measure.

35. PLAIN PACKAGING FACILITATES THE MANUFACTURE OF COUNTERFEIT PRODUCTS

35.1 As introduced in Section 15, above, plain packaging would facilitate the manufacture of counterfeit packaging. The use of colour and 'stylized elements' is one of the factors that make the production of counterfeit product packaging more difficult. It increases the complexity entailed in producing counterfeit goods, based upon techniques that can be implemented effectively by legitimate manufacturers on an industrial scale. However, such techniques are far less economic and more complex to implement on a smaller scale (for example, in a clandestine environment rather than a legitimate factory set-up).

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[646] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004, recitals 3 and 9.

[647] For example, in Ireland and the UK, high tobacco taxation rates and/or tax rates largely in excess of those practised in neighbouring countries has resulted in consumers increasingly purchasing lower priced tobacco products rather than premium brands. This inevitably encourages contraband inflows as smuggling is driven by consumer demand for a cheaper, or banned, product. Ireland currently has the highest tobacco prices in the EU. A pack of 20 cigarettes is €1.46 more expensive than the next highest cigarette prices in an EU member state (the UK). Compared to the Slovak Republic for example, a pack of 20 cigarettes in Ireland is €6.30 more expensive: JTI Tobacco Taxation. Research and Analysis. January 2010.

35.2 As the use of sophisticated and complex pack design assists in the prevention of counterfeiting (including because it makes counterfeits easier to identify),[648] mandating plain packaging would remove significant barriers to, and actually promote the manufacture and distribution of, counterfeit packaging. The EU Agreement reflects this, in that it states that the determination of whether cigarettes are counterfeit involves consideration of "*the **look**, shape, **colour**, and size of the packaging*" and "*the size, font, **colour**, language and content of the text appearing on the packaging*" (emphasis added).

Removal of key cost constraints for counterfeiters as each pack in the EU becomes essentially the same

35.3 Counterfeit trade would not only be assisted significantly by the fact that a pack of, for example, Benson & Hedges, in plain packaging is easier to replicate than the existing sophisticated and complex pack design. Just as important is the fact that, once a counterfeiter has mastered the plain packaging design for Benson & Hedges, very few design alterations are needed to this master design to produce counterfeit plain packaging versions of each and every other pack sold in the same Member State and therefore across the EU. In effect, **plain packaging proposals risk creating a harmonised internal market for counterfeit tobacco products in the EU**.

35.4 Plain packaging would mean that some of the key cost factors that are currently barriers to the illicit trade market for many putative counterfeiters would be removed in the EU. Packaging uses complex colour pack design and these designs are extremely diverse between the different brand types. These place a significant cost burden on counterfeiters. The designs would disappear if plain packaging were to be introduced.

35.5 Removing this cost of entry, and opening the market to criminals for whom it is not currently economic to manufacture sophisticated counterfeit packs, risks undoing much of the progress made in tackling illicit trade as it is expected to increase:

(a) the number of counterfeiters able to sell "fake" product for the market;

(b) the number of counterfeit products on the market; and

(c) the profit being made by counterfeiters from this illicit trade and, consequently, the sums available for them to invest in further contraband/counterfeit activities and/or other criminal activities.

Plain packaging complicates regulatory investigations/prosecutions

35.6 Enforcement agencies rely on their ability to carry out forensic analysis of counterfeit tobacco packaging to determine its source. Currently, the colour design of such packaging can be analysed in a way that allows Member State enforcement

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[648] In this regard, IP Australia has stated that "*Requiring plain packaging would make it easier for counterfeit products to be produced and would make it difficult to readily identify these counterfeit goods.*"(FOI 138 of 1660; Briefing by IP Australia to Parliamentary Secretary ref B09/4084).

agencies to identify whether one counterfeiter is responsible for the production of a number of fake products seized and that several products were produced on the same machine. Often this provides evidence, which is critical in criminal prosecutions, that links one criminal gang to a large number of fake products seized.[649] Simplifying the pack design, and thereby increasing the number of counterfeit organisations, would inevitably make it harder to link counterfeit packaging to individual counterfeiters.

Continued creation of branded packs by counterfeiters

35.7 JTI is concerned that, if plain packaging is mandated, some counterfeiters will continue to produce cigarettes that are packaged in packs made according to current pack designs. In this way, they will 'adopt' the brand imagery that genuine manufacturers would no longer be allowed to use. This will be assisted by the fact that:

(a) consumers can be expected to assume that branded counterfeit packs made available are not 'fake', but have been produced in jurisdictions outside the EU where plain packaging had not been introduced; and

(b) certain consumers are likely to want to continue to use existing branded packs.

35.8 In this way, the imposition of plain packaging would create an opportunity for the counterfeit industry to:

(a) expropriate manufacturers' branding;

(b) perversely, charge a premium for this fake product; and

(c) shift sales volumes away from legitimate manufacturers.[650]

Plain packaging will result in the increased trade in "illicit whites"

35.9 The evolution of the illegitimate trade in tobacco products is powerfully demonstrated by the increased trade in "illicit whites", commented upon recently by the Commission in the following terms: "*genuine production, and subsequent illegal import, of new cheap brands in countries outside the EU is also a growing problem*".[651]

35.10 The phenomenon of "illicit whites" stems not only from the success of the Know Your Customer programmes implemented in the EU by the major tobacco manufacturers and new supply chain control legislation in certain Member States, which has resulted in a drop in the contraband trade in JTI products by criminal

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649 It has also played an important role in prosecuting criminal gangs for the criminal offence of conspiracy, see - for example - section 1(1) of the UK Criminal Law Act 1977.

650 As a result, both counterfeiters and contraband operators would assume, correctly, that plain packaging would result in a significant increase in demand for illicit products.

651 Contraband and counterfeit cigarettes: frequently asked questions; MEMO/10/448, Brussels, 27 September 2010. Available at: http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/10/448&type=HTML.

gangs. It also reflects the fact that "illicit whites" are not always placed under the same scrutiny as counterfeit products, where the legitimate manufacturer plays a key role in identifying the existence of illicit products and in the enforcement process. JTI is concerned that plain packaging would facilitate this trade in "illicit whites". In JTI's view, it is inevitable that such products would continue to use branded packaging, even in the face of a plain packs restriction, given that certain European consumers are likely to want to continue to obtain existing branded packs.

Plain packaging crystallises pack design

35.11 Mandating plain packaging would also crystallise pack design. Legitimate manufacturers would be denied the opportunity to innovate and compete through packaging in the EU, something that is standard industry practice for all manufacturers of FMCG, including JTI. As a result, counterfeiters would only need to meet a static government-mandated design, rather than having to keep up with manufacturers' evolving packaging innovations and developments. This is another way in which plain packaging would effectively reduce the burden on counterfeiters and open the internal market to new counterfeiters.

Plain packaging frustrates tracking and tracing initiatives

35.12 As noted above, JTI is committed to identifying and implementing viable technologies, including tracking and tracing, which are cost-effective and proven to significantly enhance its existing efforts to stop product diversion and prevent the trade of contraband product. JTI is concerned that the use of plain packaging designs will both (a) undermine such technologies given the use currently made of coloured pack design to determine origin/supply chain history; and (b) necessitate changes to the way in which tracking and tracing is conducted. This is an additional regulatory burden placed on legitimate manufacturers which is not faced by those involved in the illicit trade of products.[652]

Ability to identify counterfeit product

35.13 Consumers' ability to identify counterfeit product would be undermined by plain packaging as pack design is one of the means by which consumers can assess whether they purchased a genuine or counterfeit product. This undermines one of the essential functions of a trade mark, which – as explained above – is to guarantee the identity of origin of the goods so that the consumer can, without possibility of confusion, distinguish the goods from others. Reducing the ability to carry out this visual authentication is likely to:

(a) undermine consumers' ability to identify counterfeit product;

(b) reduce the likelihood that suspicious product would be rejected by them; and

(c) result in less counterfeits being identified and fewer complaints about fake products to manufacturers and Member State enforcement authorities.

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[652] Neither counterfeiters nor manufacturers of 'illicit whites' use tracking and tracing technologies.

35.14 Consumers' perception of product quality is likely to be influenced where – because they are unable to identify a product is counterfeit from its packaging – they believe they are smoking a genuine product.[653] Additionally, the European counterfeit trade will be facilitated where regulation makes it harder for both competent Member State regulators and the industry to identify and detect counterfeit product.

Plain packaging reduces the ability to take enforcement/infringement action

35.15 As explained above, JTI has serious concerns that plain packaging will reduce the ability of enforcement authorities, and JTI, to take action against third parties trading in illicit tobacco products which use JTI's trade marks without consent.

Further unintended consequences relevant to illicit trade

35.16 To the extent that plain packaging facilitates the trade in counterfeit and/or contraband cigarettes and risks undoing much of the progress made in tackling this trade, it will have the following additional negative consequences in the EU.

Further risks posed to consumers

35.17 Reinforcing JTI's concerns, the UK Department of Health has previously noted that the illicit trade in tobacco:

(a) "*…ultimately presents a significant threat to public health in many countries, including the UK*";[654] and

(b) "*…harms health in our communities by creating a cheap and unregulated source of tobacco, undermining the Government's targets for reducing smoking prevalence, especially among young people and those in routine and manual groups*".[655]

35.18 Due to an absence of product-related information being provided to them (see further below), Member State regulators are left unable to determine certain issues of product safety for illicitly traded products and consumers cannot rely on the existence of regulatory oversight that occurs for legitimate products as a result of Community law. This is particularly the case where counterfeiters make no effort to comply with applicable regulation/industry best practice for tobacco products concerning:

(a) **ingredients usage** requirements;

(b) **mandatory ingredients reporting** requirements, such as the requirement to report annually to the Member States a list of the ingredients used in the manufacture of each product and the reasons for the ingredients' use;[656]

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653 After unknowingly smoking a counterfeit product, a consumer might lay fault at the door of the legitimate brand owner, if the cigarette is of lower than expected quality.

654 FTC Document, paragraph 2.25.

655 FTC Document, paragraph 2.26.

656 TPD, Article 6.

(c) **toxicological analysis**, such as that necessary to provide to the Member States all available toxicological data concerning the ingredients used in the manufacture of each product;

(d) **new brand approval**, such as the requirement to notify certain competent authorities at a Member State level (for example, in the UK) of the tar, nicotine and carbon monoxide yields shown on product packaging at the time of launch; and

(e) the testing and verification of **maximum permitted yields of tar, nicotine or carbon monoxide** for tobacco products.

35.19 Those manufacturing counterfeit product may fail to conduct the necessary scientific assessment of their product, product ingredients, smoke constituent yields and manufacturing processes. This results in a lack of transparency to consumers about the product and removes from Member State regulators the ability to determine issues of product safety and from consumers the ability to rely on the existence of regulatory oversight. It also puts the legitimate manufacturer at a clear competitive disadvantage in terms of the regulatory compliance and product stewardship costs associated with meeting all applicable regulation/industry best practice.

35.20 Criminals involved in the illicit trade (including the sale of "illicit whites") will sell to anybody, including minors.

Illicit trade and distribution

35.21 "Illicit whites" and counterfeit tobacco products are generally distributed through unregulated criminal networks that are more accessible to minors than regulated channels, which further undermines public health objectives.

Depriving governments of further revenue

35.22 The Commission has recently estimated that: "*annual losses of revenue in the European Union can be estimated, on the basis of seizures of cigarettes notified by the Member States, at about €10 billion, of which about 10% would be revenue for the European Union budget*".[657]

35.23 Any increase in counterfeit and/or contraband tobacco products would further erode legitimate Member State revenue from tobacco taxes.

Cost to legitimate business

35.24 The Commission recognises that: "*the illegal trade in tobacco harms the interests of legitimate businesses throughout the supply chain, particularly tobacco*

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[657] Contraband and counterfeit cigarettes: frequently asked questions; MEMO/10/448, Brussels, 27 September 2010. Available at: http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/10/448&type=HTML.

manufacturers and retailers".[658] Regulatory measures which have the unintended consequences of increasing the availability of lower priced, illicit tobacco products in the EU will also shift employment opportunities away from the legitimate industry's skilled workforce, including, for example, those within JTI's factories in Member States including Germany, Austria, the UK and Poland to those working for the criminal organisations responsible for illicit trade.

Profits serious criminal organisations

35.25 As noted above, it has long been recognised that the illicit trade in tobacco products profits serious criminal organisations.

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[658] Contraband and counterfeit cigarettes: frequently asked questions; MEMO/10/448, Brussels, 27 September 2010. Available at: http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/10/448&type=HTML.

JTI AGREES WITH THE IMPLICIT REJECTION OF PROPOSALS IN THE RAND REPORT THAT ARE NOT IN THE CONSULTATION

36. INTRODUCTION

36.1 As identified in the Introduction to this Full Response, there are numerous policies, proposals and assessments in the RAND Report that find no place in the Consultation. JTI agrees with the rejection by DG SANCO of those proposals, as reflected in their absence from the Consultation. Indeed, the RAND Report itself rejects or casts serious doubt on many of the proposals.

36.2 No meaningful consultation has been held on the RAND Report; the only public consultation has been through the Consultation. To the extent that any of the policies, proposals or assessments in the RAND Report (which are not in the Consultation) are to be given meaningful consideration by DG SANCO in its IA, JTI considers that DG SANCO must:

(a) ensure that any such proposals comply with EU principles, including, for example proportionality and subsidiarity, as well as setting out a satisfactory legal and evidential basis for any further proposals; and

(b) consult on the specific proposals and the evidence.

36.3 Without prejudice to this position, JTI sets out briefly below its fundamental concerns with a limited number of the proposals in the RAND Report which are not adopted in the Consultation. By considering a sample of the RAND Report's treatment of the proposals that have found no place in the Consultation, it is clear that they suffer from the same procedural and substantive flaws as the remainder of the RAND Report (as assessed above).

37. RAND REPORT'S PROPOSAL TO INCLUDE TOBACCO LEAF IN THE DEFINITION OF INGREDIENTS

37.1 The RAND Report states that it has found no evidence that any country has included tobacco leaf in the definition on "ingredients".[659] Nevertheless, it claims that *"a more comprehensive definition of ingredients that includes the tobacco leaf would be beneficial to consumers by enabling tighter regulation of these ingredients and contributing to informing them better about the tobacco products they are using"*.[660] JTI agrees with DG SANCO's implicit rejection of this recommendation, as the ingredients regime established under the TPD is unsuitable for the regulation of tobacco leaf.

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[659] RAND Report, page 178.

[660] *Ibid.*

The EU definition of ingredients is a workable and effective model

37.2 JTI rejects RAND Europe's proposal. It supports the definition of "ingredients" as included in Article 2(5) of the TPD. This definition reflects the critical distinction between:

(a) ingredients, which are substances used in the manufacture or preparation of a tobacco product and still present in the finished product; and

(b) tobacco leaf and other natural or unprocessed tobacco plant parts.

37.3 The definition in Article 2(5) is workable. It reflects the manufacturing process, in that it is based on the identification of those substances that are *added* to the product for a specific purpose by the manufacturer. This definition of ingredients therefore mirrors the product specifications according to which tobacco companies manufacture their products. As such, it reflects the role of each manufacturer in the design and manufacture of the product. Accordingly, it is these product specifications that form the basis of ingredients reporting and, ultimately, the development of the ingredients regime.

37.4 Furthermore, the existing definition is compatible with the potential regulation of ingredients pursuant to Article 12 of the TPD.

37.5 JTI notes that the partial FCTC Guidelines on Articles 9 and 10 also do not include tobacco leaf in the definition of ingredients.[661] The partial FCTC Guidelines include "*substances that occur naturally in tobacco*" in the definition of "constituents". As mentioned above, the partial FCTC Guidelines indicate that guidance will be proposed at a later stage in relation to disclosure and regulation of constituents.

Tobacco leaf may be regulated – but outside the ingredients regime

37.6 JTI does not object to the regulation of tobacco leaf. However, tobacco leaf should not fall within the definition of "ingredients" and should not be regulated as such.

37.7 First, in contrast to ingredients used in the manufacture of tobacco products, tobacco leaf itself is an agricultural product. As with all agricultural products, the physical and chemical properties of tobacco leaf are subject to natural variations, depending notably on its origin, the climate, soil type and nutrients in which it grows, agricultural practices relating to harvesting, curing and storage and seasonal differences. Accordingly, it would be extremely difficult, if not impossible, for tobacco manufacturers accurately to report levels of substances naturally occurring in tobacco leaf.

37.8 Second, the inclusion of tobacco leaf within the definition of "ingredients" would create insurmountable difficulties at the eventual assessment and approval

[661] Partial guidelines for the implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control, (Draft) FCTC/COP/4/28.

stage of ingredients regulation: it is not practicable or coherent for one set of principles, processes and procedures to be applied to two fundamentally different sets of substances. For example, if the eventual regulation of ingredients prohibits (for a proportionate and justifiable reason) a particular substance, manufacturers would need to adapt their manufacturing processes to ensure that no such substance is added to the product (i.e. the current definition of "ingredients"). However, if that substance is an integral part of natural tobacco leaf, manufacturers would be unable to remove that substance (other than potentially removing the tobacco leaf). The current ingredients regime is therefore unsuitable for the regulation of tobacco leaf as an "ingredient".

37.9 Third, the exclusion of tobacco leaf from the "ingredients" regime is consistent with chemical registration legislation, such as REACH, that does not identify agricultural products as substances which require registration.

37.10 RAND Europe completely ignores the approach taken under the REACH regime, even though the Commission's Second Report suggested that it will be necessary to summarise and to take into account the information on tobacco ingredients made available under REACH in order to avoid overlaps with the on-going work in the context of the TPD.[662]

37.11 JTI agrees with this analysis in the Commission's Second Report. It considers that no new definition of ingredients should be adopted within the EU which is inconsistent with the requirements of other related regulation with which JTI is required to comply, including REACH. An approach which is consistent with existing regulatory measures would meet accepted principles of Better Regulation, and benefit from additional regulatory advantages: it would ensure consistency in the type of information provided by tobacco manufacturers and received by competent regulatory authorities.

37.12 In conclusion, JTI considers that it is more coherent for tobacco leaf to be subject to a separate regulatory regime from the outset. In particular:

(a) to the extent that any unintended presence of individual substances in tobacco leaf may be of concern and may potentially be remedied, this should be directly addressed by regulating tobacco leaf at its source, that is to regulate tobacco farming. Treating tobacco leaf and ingredients in the same way would complicate – and potentially undermine – the establishment of international standards for reporting, testing, assessing and approving of ingredients; and

(b) to the extent that a purported problem exists regarding the transparency of tobacco products, JTI does not object to the sharing of information on our products, such as the type of leaf used, subject to trade secret protection and Better Regulation principles being adhered to. However, there is no coherence in organising this sharing of information on tobacco leaf under the framework of the "ingredients" regime.

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[662] Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee, *Second Report on the Application of the Tobacco Products Directive*,COM(2007) 754 final page 8.

38. RAND REPORT'S PROPOSAL TO TRANSFER DIRECT AND INDIRECT COSTS OF SMOKING TO TOBACCO MANUFACTURERS

38.1 As Measures 5 and 6 in Chapter 9 of its Report,[663] RAND Europe proposes measures to "*internalise the external costs of tobacco use*":

(a) Measure 5 proposes the integration of the costs that Member State healthcare systems are stated to incur as a result of smoking into "*a fee paid by tobacco manufacturers and importers.*"

(b) Under Measure 6, "*tobacco manufacturers would be made liable for health problems deemed to be associated with tobacco use, which would ultimately result in some kind of compensation payment by tobacco manufactures [sic] to health systems at a similar level.*"

38.2 JTI questions why RAND Europe was asked to consider these issues, given that as recently as 2008 the Regulatory Committee established under Article 10 of the TPD stated that: "*This area needs long term work and therefore is not likely to be a part of the Directive*".[664] However, JTI supports DG SANCO's decision not to carry forward these proposals into the Consultation for the reasons set out below.

38.3 First, JTI does not believe that there is a legal basis for introducing either fees to cover the alleged external costs of tobacco use or a civil liability regime of the sort apparently proposed by RAND Europe. First of all, neither would constitute a harmonising measure that is necessary to improve the functioning of the internal market. Further:

(a) a "*fee paid by tobacco manufacturers and importers*" in respect of alleged national healthcare costs is no more than a tax. The EU has no competence in relation to taxes or similar fiscal provisions or in relation to the financing of national healthcare systems;[665] and

(b) a civil liability scheme whose result is predetermined ("*… which would ultimately result in some kind of compensation payment … to health systems at a similar level*") is likewise a tax or a similar type of fiscal provision. Even if the outcome of litigation under such a scheme were not predetermined, it is difficult to see on what basis a tobacco-specific civil liability scheme could be

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663 RAND Report, page 161.

664 Summary Record of the 8th Meeting of the Regulatory Committee established under Article 10 of the Tobacco Products Directive 2001/37/EC, Brussels, 16 April 2006, SANCO C6/TPE/D(2008)/, page 3. Responding to issues of producer liability raised in the second report on the implementation of the Directive, the Regulatory Committee decided that: "*The Commission intends to have a study on liability. This area needs long term work and therefore is not likely to be a part of the revision of the Directive.*"

665 In response to a Parliamentary Question from Jim Higgins MEP (E-8357/10EN) regarding whether a proposal to tax the profits of all tobacco companies operating in the EU could be allowed under the public health derogations in the Treaties, the Commission confirmed (on 25 November 2010) that "*the taxation of companies, including the profits of tobacco companies, is therefore a matter for individual Member States.*"

introduced under Article 81 TFEU or any other basis, particularly in circumstances where RAND Europe has not identified any current, or potential future, divergence between Member States on this issue.

38.4 Second, such measures would be disproportionate, discriminatory and in violation of due process and (in the case of the civil liability scheme) companies' defence rights.[666] They would therefore breach both EU law and, in all likelihood, Member State constitutional and fundamental rights law.

38.5 Third, the civil liability regime apparently proposed by RAND Europe would violate established EU and Member State legal principles concerning the liability of alleged tortfeasors to third party payors. The RAND Report omits to mention that lawsuits for the reimbursement of state health care costs allegedly caused by smoking have already been brought in France and Spain – and have failed. These cases have failed because the liability theories advanced by state plaintiffs are incompatible with Member State law.[667] The RAND Report also omits to mention the failure of product claims brought against manufacturers of tobacco products and other products with known risks, under the EU Product Liability Directive (***PLD***) and other laws.[668] The

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[666] A civil liability scheme of the sort apparently proposed would need, in effect, to constitute a self-contained tobacco liability and claims procedural code, in order to overcome the substantial differences in Member States' general procedural and substantive rules in matters of civil liability. As well as raising profound questions of EU competence (see above), a rewriting of national laws to create a litigation process that would "*ultimately result in some kind of compensation payment*" by the tobacco industry to governments would offend basic constitutional principles in many Member States.

[667] Courts have frequently rejected these cases, both in the EU and in the US, on the basis that healthcare costs payors (such as governments) do not have a direct right of action against an alleged tortfeasor. Rather, courts have found that such claims are subrogatory or derivative in nature, and that the payor can have no better rights against the relevant defendant(s) than did the individual patients to whom it paid healthcare costs. Courts held that the adjudication of such claims therefore required an individual-level consideration of patients' smoking histories, medical files, knowledge of the health risks of smoking, etc. For example, in December 2006, the Court of Appeal of Rennes dismissed an appeal by the *Caisse Primaire D'Assurance Maladie* (CPAM) of Saint-Nazaire (a local health authority in France) against the earlier decision of a first instance court to reject the CPAM's claim against tobacco manufacturers for the reimbursement of the past and future "*costs of treating tobacco-related illnesses*". The CPAM's claim was supported by the *Caisse Nationale d'Assurance Maladie des Travailleurs Salariés* (CNAMTS), which is responsible for managing the French health care system. The Court of Appeal affirmed the first instance court's decision that neither French law nor statute conferred the right on a healthcare costs payor or insurer to bring a direct action against an alleged tortfeasor, and that the CPAM's only right of action was subrogatory in nature. The CPAM's direct action for the reimbursement of benefits paid to its insureds was therefore inadmissible. Although the claimant originally filed an appeal to the French Supreme Court, it discontinued that appeal before its case was heard.

[668] See e.g. the German tobacco cases. In OLG Frankfurt, NJW – RR February 2001, 1471 1, the Frankfurt Court of Appeal dismissed a claim brought under the PLD and national negligence law on the basis that "*It is widely known that smoking can cause severe, even fatal damage to human health and that it is addictive ... and in accordance with the case law on the manufacturer's duty to warn consumers of product risks, no specific warning need be given of such well-known dangers*". The District Court of Bielefeld dismissed a similar claim in 2000 on the basis that: "*The use of legally permitted substances can neither be regarded as the breach of a protective law nor as an illegal or immoral action…The fact that smoking is addictive has been well known for a long time. There is no need to warn about generally well known side effects...*" (LG Bielefeld, 25 January 2000). Various Member States' courts have similarly rejected PLD claims brought against

authors therefore ignore a body of case law which holds that tobacco product manufacturers should not be held liable for the well-known health risks posed by their products.[669]

38.6 Fourth, the RAND Report lacks clarity about what is, in fact, being proposed. In particular, the authors disclose no details of the means by which it is envisaged that tobacco manufacturers would be "*made liable for health problems deemed to be associated by tobacco use*". Instead, they refer those interested in reading a "*detailed discussion of liability*" to a non-peer reviewed study that is not publicly available.[670]

38.7 Fifthly, the RAND Report does not consider the potential effect that the financial impact of its proposals might ultimately have on illicit trade.

38.8 Finally, the RAND Report's attempts to calculate the alleged "*external costs of tobacco use*" exhibit severe methodological limitations. Indeed, the authors acknowledge that "*there are several limitations to our estimates*",[671] including the assumption that estimates of mortality from smoking caused by diseases other than lung cancer may be derived from lung cancer statistics, and that costs estimates for the whole of the EU can properly be "*derived from a single German study*".[672] It is also far from clear whether the authors have properly offset costs that would have been

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manufacturers of (among other things) chocolate, alcohol, liquorice candies and hot coffee, on the basis that the risks that these products might cause harm are well known. Non-PLD cases brought against tobacco manufacturers have been dismissed on the same grounds (see, in particular, the 2004 decision in the case of *Consorts Gourlain -c- SA SEITA*, JCP 2004.II.10004, where the French Supreme Court held that the claimant could not have been unaware of the risks of smoking when he began to smoke in 1976, since by that time health warnings appeared on packaging and information on the health risks of smoking was universally available, as a result of media, press and radio and television reports).

669 Indeed, as noted in a leading UK case (*A and others v National Blood Authority and another* [2001] 3 All ER 289), risks posed by products that were known and obvious were never intended to give rise to liability under the PLD: "*The existence of such products was recognised in an exchange of question and answer by Mrs Flesch MEP to the European Commission, answered by Viscount Davignon on behalf of the Commission in June 1980. The question read in material part as follows: 'This provision ought apparently to be interpreted in the sense that nobody can legitimately expect from a product which by its very nature carries a risk and which has been presented as such (instructions for use, labelling, publicity, etc.) a degree of safety which this product does not and cannot possess, with the result that this product would not therefore be defective within the meaning of the future directive.' The answer was: 'The Commission agreed with the Honourable Member that nobody can expect from a product a degree of safety from risks which are, because of its particular nature, inherent in that product and generally known, e.g., the risk of damage to health caused by alcoholic beverages. Such a product is not defective within the meaning of the Directive.*"

670 Footnote 60 at page 161 of the RAND Report states: "For a detailed discussion of liability, see GHK, *A Study on Liability and the Health Costs of Smoking. Final Report. Study Commissioned by Dg Sanco*, London: GHK, 2010". As at 3 December 2010, this study had not yet been published in any peer-reviewed journal and was not available via searches on either the GHK or Commission websites.

671 RAND Report, page 20.

672 *Ibid*.

incurred by healthcare systems irrespective of smoking,[673] whether they have properly allotted costs between state and private providers in Member States with mixed healthcare provision, and so on. More generally, there is substantial debate within the academic and public health community as to the types of costs that should be included in any calculation of this sort. In particular, in calculations that involve indirect as well as direct costs, it may well be appropriate for revenues derived from tobacco taxation – which the RAND Report forecasts as being significant[674] – to be offset against alleged "*external costs*".

39. RAND REPORT'S PROPOSAL TO INTRODUCE MAXIMUM LIMITS FOR NON-TNCO CONSTITUENTS AND CONTINUOUSLY DECREASE TNCO AND OTHER YIELD MAXIMA

39.1 The RAND Report considered whether "*maximum limits for TNCO and other yields and ingredients*" should be decreased.[675] The authors state that "*the evidence for this measure has been presented in Sections 10.2.2 and 10.2.3 above*", but the analysis of the issue throughout the RAND Report is partial at best. For example, nowhere does the RAND Report explain the background to the introduction of TNCO ceilings provided for by Article 3(1) of the TPD – namely that, for many years, the consensus in the public health community was that lower tar and nicotine cigarettes were likely to be less hazardous than cigarettes with higher machine-measured levels of tar and nicotine for those who do not quit smoking,[676] and that, as a public health measure, it therefore made sense to limit machine-measured TNCO yields.

39.2 JTI does not dispute RAND Europe's conclusion that there is at present "*no strong evidence to recommend decreasing the TNCO in tobacco products*".[677] JTI does not believe that the international consensus is established that further reductions in TNCO yields as machine measured are appropriate to achieve the identified objective. However:

(a) JTI does not accept that there is "*a strong evidence base showing that the current measurement methods for TNCO yields are misleading consumers*".[678]. In any event, it is unclear what relevance the issue of consumer

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673 E.g. fixed costs for hospital buildings or medical and diagnostic devices (such as an MRI scanner) that a hospital would have built and or acquired even had no one smoked. The recoverability (or otherwise) of fixed costs has been an issue in e.g. the U.S. health care costs reimbursement litigation.

674 RAND Report, page 114.

675 RAND Report, page 178.

676 Royal College of Physicians, *Smoking and Health Now*, London, Pitman Medical and Scientific Publishing Co. Ltd., 138 (1971).

677 RAND Report, page 178. JTI notes that the reference to "*TNCO in tobacco products*" is itself indicative of the authors' lack of understanding of tobacco products and/or their carelessness in drafting their report. There is no tar "in" a tobacco product: "tar" is generated only on combustion, and is usually defined as the particulate matter collected on a filter pad in a laboratory, after water and nicotine have been extracted.

678 RAND Report, page 178. See further paragraphs 18.5-18.11 above.

interpretations of on-pack TNCO labelling has to a determination of whether TNCO ceilings under the TPD should be reduced;

(b) nor does JTI accept that TNCO measurement methods are inaccurate, "*given that tobacco manufacturers make use of cigarette design techniques to obtain lower TNCO readings for their products*".[679] ISO and other machine testing methodologies have **never** been intended to replicate actual smoking behaviour or to predict the levels of tar, nicotine and other smoke constituents that any individual smoker will actually inhale.[680] The FCTC's Working Group has recognised this to be the case, stating that "*data on cigarette emissions from machine-generated smoke are not intended to be, nor are they, valid measures of human exposure*".[681] Rather, the purpose of standardised yield numbers generated through machine testing is to deliver consistent results and to permit a system of comparison between products.[682] The ISO methods mandated under the TPD are widely accepted around the world and are "*inaccurate*" only if one wrongly assumes (as the RAND Report appear to do) that their results are intended to be predictive of actual TNCO deliveries.

39.3 The RAND Report goes on to state that "*regarding other yields and ingredients, there is some evidence that decreasing their amounts in tobacco products could be beneficial but there is at present no evidence that such a measure would produce less harmful tobacco products*".[683] While JTI accepts the conclusion that the regulation and continuous reduction of non-TNCO yields and ingredients is not justified by the present state of the science, it notes that:

(a) RAND Europe's conflation of "other yields" (i.e. levels of other smoke constituents measured according to machine testing methodologies) and "ingredients" (i.e. substances added to tobacco in its unburnt form, which may or may not transfer into smoke) once again betrays their ignorance of the subject matter;

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679 *Ibid.*

680 See Federal Trade Commission, *Rescission of FTC Guidance Concerning the Cambridge Filter Method*, Federal Register / Vol. 73, No. 236 / Monday, December 8, 2008 / Notices, p. 74500: "*From the outset, cigarette testing under the Cambridge Filter Method was intended to produce uniform, standardized data about the tar and nicotine yields of mainstream cigarette smoke, **not** to replicate actual human smoking.*" (*Idem. page* 74501, emphasis in original).

681 Elaboration of guidelines for the implementation of Articles 9 and 10 of the Framework Convention on Tobacco Control, Progress Report of the Working Group, FCTC/COP/3/6, 21 August 2008, paragraph 16.

682 The ISCSH (1988) made the following comments about the machine method for measuring tar and nicotine yields: "*Critics of the machine-smoking procedures have frequently failed to understand that values presented in tables published by the DHSS have never been intended to be actual yields obtained by any one smoker. Rather, they enable brands to be ranked. This allows inter-brand comparison under a standard test procedure, presenting the smoker with information to enable him to choose, if he so wishes, a lower yielding brand.*"

683 RAND Report, page 178.

(b) further, RAND Europe's repeated reference to SACTob is also peculiar given that the relevant group is now called the WHO Study Group on Tobacco Product Regulation; and

(c) there is no credible evidence that reducing levels of ingredients used in EU tobacco products would be "*beneficial*" (presumably from a health perspective), and the RAND Report does not trouble itself to cite any such evidence in Sections 10.2.2 and 10.2.3 of the RAND Report, which purportedly provide the data in support of this proposition. RAND Europe states at the beginning of Chapter 10 on Ingredients that: "*The health impacts of the measures subsumed in this area of change are aimed at reducing the harm related to the consumption of a specific tobacco product – in other words to make tobacco use less harmful, even when prevalence rates remain stable*".[684] However, RAND Europe does not consistently evaluate its proposed measures on that basis. In relation to SCENIHR's recent and wide-ranging consideration of the alleged harmfulness, addictiveness and attractiveness of tobacco additives, see paragraphs 6.23 – 6.26 above.

39.4 JTI believes that, to the extent that a problem can be identified, less restrictive, more targeted and proportionate solutions are available (see paragraph 43.30 below).

40. RAND REPORT'S PROPOSAL TO MANDATE A MINIMUM PACK SIZE

40.1 Although not an option being considered in the Consultation, the RAND Report implies, at page 195, that DG SANCO has previously considered or should consider: "*the introduction of a minimum package size and the introduction of a standard package size*". JTI does not currently sell cigarettes in packs of less than ten cigarettes.

40.2 Notwithstanding the fact that – in JTI's view, rightly – the introduction of these measures is not currently being consulted upon, this statement raises two important points:

(a) JTI strongly believes that minors should not be purchasing tobacco products at all, irrespective of the size of the pack of cigarettes; and

(b) JTI's categorical opposition to plain packaging as a regulatory initiative applies to the extent that it would result in "*the introduction of a standard package size*".[685] Plain packaging is examined in detail in Section 15 above.

No evidence to justify regulatory change

40.3 There is a notable absence of evidential support for mandating the size of tobacco products packaging. There is no clear beneficial impact in terms of reducing smoking uptake by minors or cigarette consumption generally. This is reinforced by:

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[684] RAND Report, page 173.

[685] "*Towards a Future Without Tobacco: The Report of the Smoking Prevention Working Group*" , Scottish Executive, Edinburgh, paragraphs 3.18 – 3.21. Available at: http://www.scotland.gov.uk/Resource/Doc/155323/0041722.pdf

(a) comments made in the RAND Report: "*…we envisage that the social impacts of enforcing minimum package size and standard package size will also be mixed. For example, if the smaller package size was banned, some would argue that this would have a positive impact on youths while other would argue that it could contribute to adult smokers increasing the consumption of tobacco*";[686]

(b) the 2006 report of the Scottish Smoking Prevention Working Group, not cited in the RAND Report, which states: "*…there* ***is apparently no objective evidence to demonstrate the effectiveness of banning packets of ten*** *(also known as 'kiddie' packs) as a means of reducing young people's access to cigarettes.* ***In the absence of good evidence for its effectiveness****, we consider that banning the sale of packs of ten in Scotland is unlikely to make a useful contribution to preventing smoking by young people at this stage*" (emphasis added);[687] and

(c) the UK Department of Health's 2008 FTC Consultation, which acknowledged that "*there is less evidence to demonstrate the effectiveness of banning packs of 10 than there is for other proposals within this part of the consultation*". (In JTI's view, this was an indictment of this Member State competent authority's own justification for increasing the minimum size of cigarette packs when the lack of credible evidence for other regulatory initiatives discussed in the FTC Document is considered.)

40.4 Indeed, RAND Europe's proposal to mandate the size of tobacco products packaging runs counter to EU's current approach on regulation of foodstuffs and other types of packaged products.[688] Specifically, regulation of pack sizes "*dates from the 70s, when rules on quantities in which products could be sold were thought to protect consumers…However, since then, the legal framework for consumer protection has significantly developed*".[689] Therefore, RAND Europe's approach is contrary to the current regulatory scheme which focuses on the product itself rather than the pack size of the product.

Negative consequences for existing adult smokers/those seeking to reduce product consumption

40.5 Mandating a minimum package size for cigarettes also, unjustifiably, removes an important element of adult consumer choice. This has been acknowledged previously by Member State authorities which have consulted on similar proposals.[690]

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686 RAND Report, page 176.

687 *Towards a Future Without Tobacco: The Report of the Smoking Prevention Working Group*, page 34.

688 Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for pre-packed products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EC.

689 European Commission Enterprise and Industry, *Legal metrolopy and pre-packaging* (available at: http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/documents/pack-sizes/index_en.htm)

690 See UK FTC Consultation, paragraph 3.87.

It would remove this choice from a large number of existing adult smokers. By way of example, within the UK, 19.2% of the cigarette market comprises 10-pack sales.

40.6 Smaller packs of cigarettes are purchased by many adult smokers in some Member States on a regular basis who may want to manage their day-to-day spending or moderate their consumption. This is reflected in:

(a) the RAND Report itself, which states: "*it is difficult to estimate the likely impacts of the introduction of a standard package size*" and "*some research conducted for the most part in the USA, Canada and Australia has shown that there is a strong association between pack sizes and daily cigarette intake, with higher numbers of cigarettes per pack linked to higher consumption*".[691]

(b) the Scottish Smoking Prevention Working Group 2006 report referred to above, which stated that prohibiting the sale of packs of 10 cigarettes: "*could discourage smokers who are trying to "cut down to quit" by requiring them to buy larger packs*".[692]

40.7 Existing adult smokers who occasionally buy smaller packs instead of their usual larger pack of cigarettes, may do so for a variety of reasons. For example:

(a) when they do not have enough cash to buy a larger pack;

(b) their usual brand of the larger pack is not available at the retail outlet;

(c) to top up their supply of cigarettes; or

(d) to try a different brand where one has been launched on the market; or

(e) to try to limit their consumption.

Disproportionate impact on certain stakeholders

40.8 JTI is also concerned that, as an owner and manufacturer of premium brand 10-packs in certain Member States (such as the UK and Italy), it will be disproportionately affected by increasing the minimum size of cigarette packs. Banning such packs will impact JTI to a greater extent than tobacco manufacturers whose market share consists largely of sub-premium and/or value brands, or even own-label brands. Existing adult smokers of premium brand 10-packs may be unable to afford to purchase larger quantities of the same product, leaving them with no choice but to 'downtrade' to either a brand for which a pack of 20 cigarettes is cheaper than their preferred brand or to an illicit product.

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691 RAND Report, page 196.

692 *Towards a Future Without Tobacco: The Report of the Smoking Prevention Working Group*, paragraph 3.20, page 34. Available at: http://www.healthscotland.com/uploads/documents/3204-BDP3906_(SPWG_report_final).pdf.

A pack size ban facilitates illicit trade

40.9 JTI is concerned that mandating a minimum pack size could drive more smokers to purchase illicitly traded tobacco products, because they could no longer afford to purchase larger quantities of the legitimate product. This is a risk acknowledged previously by the UK Department of Health when it stated that the potential illicit trade impact of banning 10-packs will be likely to have "*the greatest effect on young people and people with less disposable income*".[693] It would be perverse if a regulatory measure imposed by DG SANCO were to increase the exposure of minors and what the FTC Consultation has described as "*deprived communities*" to illicit trade products.

[693] FTC Consultation, paragraph 3.86.

ALTERNATIVE REGULATORY SOLUTIONS

41. INTRODUCTION

41.1 Tobacco products carry risks to health. As appropriate and proportionate regulation of the tobacco sector is thus both necessary and right, JTI approaches tobacco regulation on the basis of rigorous and scientifically-sound analysis of the arguments and the evidence. In accordance with Better Regulation principles, JTI contributes significantly and constructively to the debate and proposes, where appropriate, less restrictive, more targeted and proportionate alternative solutions.

41.2 JTI believes that it has demonstrated, through this response and the presentation of leading experts' independent opinions, its commitment to the development of an appropriate and proportionate EU regulatory regime.

41.3 The apparent key policy rationale for various of DG SANCO's proposals is aligned with with JTI's core beliefs. Whilst JTI's submissions are hindered by both DG SANCO and RAND Europe's clear failure to identify legitimate public policy objectives for the possible revisions to the TPD, reducing minors' uptake of smoking and eliminating minors' ability to obtain tobacco products can be identified as primary objectives of the Consultation. JTI agrees with this priority: "*…between 80 and 90 percent of smokers begin smoking before the age of 18, with the modal age of initiation around 15 years*".[694] Furthermore, the Consultation seeks to ensure that adult smokers are informed about the health risks of smoking before they make the decision to smoke. JTI supports DG SANCO in seeking to achieve these goals through appropriate and proportionate regulatory interventions.

41.4 It is therefore in everyone's interest that any measures which may ultimately be adopted with the aim of preventing minors from smoking and/or reiterating and emphasising the health risks of smoking, are effective. JTI differs however in its identification and assessment of solutions. For the reasons set out above, JTI believes that the proposals in the Consultation are misconceived, and that the evidence does not demonstrate that they would be effective. They would give rise to serious negative consequences.

41.5 JTI considers that DG SANCO must[695] take into account and assess a series of less restrictive, more targeted and proportionate alternative solutions, that are likely to be effective when evaluated against Better Regulation principles and the contemporary framework for smoking behaviour. Accordingly, in these Sections, JTI addresses:

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694 Professor Steinberg's Report, page 2.

695 DG SANCO is required by the Treaty's principle of proportionality, the general EU law principles of good administration, Better Regulation principles, the IAG and the case law of the Court of Justice to identify the *least restrictive* measure to achieve the aim. Once the least restrictive measure is identified, a separate question arises as to whether it is appropriate, in accordance with the principle of subsidiarity, for the EU or the Member States are adopt the measure.

(a) the problem definition, and sets out - on the basis of the opinions of leading experts in the fields of adult and youth behaviour – a coherent and credible behavioural framework within which to assess regulatory initiatives; and

(b) less restrictive, more targeted and proportionate alternative solutions, that have been ignored by both DG SANCO and RAND Europe. In particular, this Section suggests alternative solutions concerning consumer information and access to tobacco product (Sections 3 and 6 of the Consultation); JTI's extensive suggestions regarding ingredients reporting and regulation are set out in Sections 20 – 27 above.

42. EXPERT VIEWS ON PROBLEM DEFINITION AND APPROPRIATE SOLUTIONS

42.1 Before addressing JTI's proposed less restrictive, more targeted and proportionate solutions, it is necessary to recall that JTI does not agree with the approach to adult and minors' smoking behaviour as set out in the Consultation (albeit implicitly) and the RAND Report.

42.2 DG SANCO has proceeded on the basis of outdated and incomplete models of behaviour, in respect of both adults and minors. The proposals in the Consultation are therefore based upon a flawed definition of the "problem". It is unsurprising that, as identified by leading experts, the evidence does not demonstrate that the proposals will achieve their objectives.

42.3 JTI believes that the reports of Professor Steinberg and Professors Dhar and Nowlis are very significant contributions in this regard. These leading experts provide DG SANCO with a stronger and more coherent analysis on which to base its problem definition. Having clarified the real underlying issues, the work of the experts offers DG SANCO a solid foundation on which to identify potential solutions.

43. MEASURES TO ADDRESS SMOKING BY MINORS

43.1 JTI sets out below the alternative regulatory solutions that are less restrictive, more targeted and proportionate as means of addressing smoking initiation by minors and their ability to obtain tobacco products:

(a) criminalisation of, or administrative sanctions for "proxy" purchasing by adults;

(b) criminalisation of, or administrative sanctions for:

  (i) the purchase or attempted purchase of tobacco products by minors;

  (ii) the consumption of tobacco products by minors;

(c) "negative licensing" of retailers, whereby retailers lose the right to sell tobacco products if they are found to have sold products to those under the minimum age on a specified number of occasions and they cannot prove that they took all reasonable precautions and exercised all due diligence to avoid doing so;

(d) reinforcing retail access prevention measures, such as the 'No ID No Sale' programme;

(e) 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);

(f) greater resources and manpower for effective, targeted enforcement strategies; and

(g) targeted public information campaigns to quickly and effectively raise awareness of the negative licensing scheme and the criminalisation of proxy and purchasing by minors.

43.2 JTI has consistently advocated, and actively supported the implementation of, such solutions in various countries, both within the EU and elsewhere. For example, JTI's response to the UK FTC Consultation in September 2008 sets out these solutions. Whilst JTI advocates these solutions, it remains to be established in the EU context whether, having regard to legal basis and subsidiarity, these solutions should be adopted by the EU or by the Member States.

43.3 JTI notes that, in their reports, Professors Cave,[696] Steinberg,[697] Dhar and Nowlis[698] suggest various solutions in addition to some or all of those identified above. JTI does not address certain of these solutions in more detail below:

(a) Professor Steinberg suggests raising the minimum legal purchase age. JTI notes that this ought to be taken into consideration by DG SANCO, but it is clear that the EU would not have competence to adopt such a measure;

(b) Professors Steinberg and Cave suggest increasing the price of tobacco products. Not only does such a measure fall outside the remit of DG SANCO, but the experts have expressly excluded any discussion of the potential for such a measure to increase illicit trade, a factor which is addressed above in Section 32; and

(c) Professors Dhar and Nowlis suggest strategies regarding the content of health warnings. JTI believes that it is the role of the relevant authorities to determine the content of mandated health warnings and other labelling requirements. Further, DG SANCO has an on-going and separate work programme regarding the potential revision of the content of health warnings. JTI recommends Professors Dhar and Nowlis' Report to DG SANCO in this regard.

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[696] Professor Cave's Report, section 9.

[697] Professor Steinberg's Report, pages 22-30.

[698] Professors Dhar and Nowlis's Report, section 7.

Criminalising or imposing administrative sanctions for the proxy purchase of tobacco

43.4 Professor Steinberg identifies that minors "*frequently obtain cigarettes through other means: primarily, by "bumming" or buying them from friends, some of whom may be of legal age to purchase cigarettes, or by asking older individuals to purchase them for them (i.e., proxy sales)*".[699]

43.5 Statistical evidence as to the extent of proxy purchasing of cigarettes is not extensive. However, in the UK context, an NHS survey conducted in 2006 found that 63% of 11 to 15 year old "*pupils who smoked*" had been given cigarettes.[700] Of these, 57% were given them by friends, 12% by siblings and 7% by their parents. Breaking down the figures to those minors classified as regular smokers, 40% regularly bought cigarettes from older people. This suggests strongly that proxy purchasing is an issue that needs to be tackled. In addition, another survey found that only 4.7% of 12 to 17 year olds who had smoked at least one cigarette but less than 100 purchase cigarettes from shops, with the majority obtaining them from friends or family.[701] The UK example is supported by data from other jurisdictions.[702]

43.6 When the UK consulted on criminalising proxy purchasing, the proposal enjoyed retailer support.[703] Moreover, a large majority of the British public also backed the criminalisation of proxy purchasing, with polls demonstrating that 87% to 92% of people surveyed supported such a measure.[704]

43.7 JTI notes in this regard that some Member States have already criminalised the proxy purchase of alcohol.[705] JTI believes that it would be sensible for a similar approach to be taken for tobacco and that such parity of approach is likely to improve the enforcement of each prohibition.

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699 Professor Steinberg's Report, pages 3 and 10.

700 *Fuller E. (2007). "Smoking, Drinking and Drug Use Among Young People in England 2006."* NHS Information Centre, Leeds: http://www.ic.nhs.uk/webfiles/publications/smokedrinkdrug06/Smoking%20Drinking%20and%20Drug%20Use%20among%20Young%20People%20in%20England%20in%202006%20%20full%20report.pdf.

701 Emery S. et al. 1999. "*How adolescents get their cigarettes: implications for policies on access and price*", J. Nat. Cancer Inst. 91(2), 184-186.

702 Professor Steinberg's Report, page 10. See also "*Illegal Tobacco Sales – Report by the Commission of Inquiry on tobacco sales to young people*" SOU 2009:23, page 78.

703 As reflected by the ACS in its 18 August 2008 response to the FTC Document.

704 Populus, Tobacco Alliance Results Summary, May 2008 (http://www.populus.co.uk/tobacco-alliance-smoking-survey-180508.html). The UK Government did not ultimately introduce such a measure.

705 Licensing (Young Persons) Act 2000 - http://www.legislation.gov.uk/ukpga/2000/30/introduction.

Criminalising or imposing administrative sanctions for the under-age purchase of tobacco

43.8 JTI believes that it is an appropriate and necessary counterpart to the criminalisation of proxy purchasing and "negative licensing" (see below) to make it an offence for minors to purchase tobacco.[706]

43.9 The burden of preventing minors from obtaining tobacco products should not rest on retailers alone. A proxy purchase offence would help deliver the message that the responsibility for tackling smoking by minors also lies with those adults who buy tobacco for minors. At the same time, criminalising the under-age purchase of tobacco would encourage minors to take responsibility for their own actions.

43.10 Some might seek to counter such a proposal by raising concerns about criminalising minors. While recognising the legitimacy of such concerns and acknowledging that the age of criminal responsibility is different between Member States, JTI considers that such concerns should be weighed carefully against the important contribution such a measure could make in tackling smoking by minors. Moreover, such concerns can be assuaged if the offence, or administrative sanction, were punishable (as would surely be the case) by non-custodial measures.

43.11 As with the criminalisation of proxy purchasing of tobacco, criminalising the purchase of tobacco products by minors would bring the law on tobacco purchase into line with the law on alcohol in a number of jurisdictions.[707]

Criminalising or imposing administrative sanctions for the consumption of tobacco products by minors

43.12 JTI considers that the final element of the criminalisation strategy is to criminalise the consumption of tobacco products by minors.[708] Such a measure, which is also a mirror of measures that have been adopted in some Member States with respect to alcohol, means that the illogicality of criminalising purchase and sale but not criminalising consumption.

Negative Licensing

43.13 JTI is a strong and consistent supporter of negative licensing whereby retailers face orders prohibiting the sale of tobacco if they persistently sell tobacco products to minors.

43.14 Such schemes have the potential to limit minors' ability to obtain tobacco as they may provide a clearer deterrent to retailers considering selling to those who are under-age than a mere threat of a fine.[709]

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[706] Professor Cave's Report, pages 42-43.

[707] Section 149 of the Licensing Act 2003; Licensing (Scotland) Act 1976, s.68.; Licensing (Northern Ireland) Order 1996.

[708] See Professor Cave's Report, page 43.

[709] Professor Cave's Report, pages 43-44 .

43.15 In jurisdictions which have already introduced such schemes, JTI communicates with retailers about the negative licensing scheme so as to reinforce their important role in terms of preventing the ability of minors to obtain tobacco products, and from a retailer compliance perspective. JTI's communications strategy uses a number of routes that have been previously employed with other changes to legislation, such as the minimum age for sale of tobacco products and changes as a result of the introduction of pictorial health warnings on tobacco products in the UK. The strategy focuses on key trade magazines that are circulated to tobacco buyers on a regular basis. JTI advises retailers of timetables for change, the detail of the new system and retailers' responsibilities. In addition to this, JTI briefs its sales teams, who inform the trade during their sales visits, and our Customer Care Line, who operate our dedicated trade support line. Such measures should ensure that retailers receive relevant information about such schemes and improve their efficacy.

Reinforce retail access prevention

43.16 Retail access prevention programmes have proven to be an effective way of limiting minors' ability to obtain cigarettes. For example, in the UK, 90% of retailers surveyed after the introduction of CitizenCard, the government-approved proof-of-age scheme, believed there to have been a reduction in under-age sales, and 95% were more confident in asking for ID as a result of the campaign.[710] JTI contributes financially to this programme and over 2 million CitizenCards have now been issued.

43.17 CitizenCard also operate the "No ID No Sale" campaign which was launched in January 2004 to promote and publicise all government-approved proof-of-age schemes. More than 225,000 "No ID No Sale" information packs, which include age display posters and guidance on how to respond when faced with customers who are unable to provide proof of age, have been distributed to retailers. Minors can expect to be asked to prove their age, and retailers should accept only the correct ID.

43.18 JTI strongly believes that DG SANCO should encourage Member Sates that do not have such schemes to introduce them and to disseminate "*most effective practice*" among Member States to ensure that such measures are effectively enforced.

Adult identification functions for vending machines

43.19 The RAND Report acknowledges that "*restrictions on vending machines in order to make them less accessible to youths could take many forms such as electronic age verification, ID coin mechanism and remote control*".[711]

43.20 Relevant requirements in place in Member States demonstrate the way in which Governments have endorsed the implementation of three specific models of age verification:

(a) **Electronic age verification**

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[710] Gallaher Group plc, Corporate Responsibility Review 2004, page 23.

[711] RAND Report, page 190.

In Germany, adult identification functions have been in place since 2006, operating predominantly on the basis of electronic chips bearing information on card holder's date of birth, which are common in German credit or debit cards. A reading device in the machine verifies eligibility of the purchaser and enables to proceed with purchase. Many vending machines can also read dates of birth contained in the EU identity cards and driver's licenses, allowing for purchase by eligible tourists who do not hold German bank cards.

Although the RAND Report notes that a study undertaken by Schneider et al. in 2009 concluded that electronic locking devices on German vending machines were not an effective means of limiting minors' ability to obtain tobacco products, the reliability of these conclusions is limited by the fact that studies on which they are based involved very limited sample sizes: in one case 70 - and another 71 - "*smoking pupils under the age of 16*". In any event, as noted above, the Commission has reported that Member States' implementation of Recommendations to restrict minors' access to vending machines has been satisfactory.

Similarly, in Italy, it has been mandatory since November 2009 for all vending machines to be fitted with a magnetic strip or electronic chip reader to verify the age of the customer through a scan of an identify card (as health insurance card, driver's licence or taxpayer's code).

(b) **ID coins**

A mandatory token system has also been in place in Ireland since July 2009. Vending machines in Ireland are allowed in registered clubs and licensed premises with tokens only available from, for example, the bar staff, which may only be provided to adult customers.

A similar token system is used in the Czech Republic, where a remote control system is also permitted as an alternative.

(c) **Remote control**

The control of vending machines by remote control has been mandatory in Spain since 1 January 2006. Since that date, all vending machines have been required to be manufactured or retrofitted with a mechanism which only allows cigarettes to be dispensed following activation - through a cable or radio-operated device – by an authorised person who has first confirmed the customer's age. Machines are required to bear illuminated warnings advising customers that the machine is remote controlled, and all retrofitted devices are required to be certificated and registered before use.

Similar arrangements were introduced by Decree in Portugal in 2007.

43.21 The RAND Report indicates that vending machine use is currently particularly prevalent in Spain, Italy, Austria and Portugal.[712] In each of these Member States

[712] RAND Report, page 190.

vending machine access control regimes are in place. When viewed in this context, it is apparent that a ban on vending machines would impose an unduly onerous and unnecessary requirement on markets where national governments have - rightly in JTI's view – adopted means to restrict vending machine access to adult smokers.

43.22 To the extent that national governments consider it appropriate to seek to prevent minors from accessing cigarettes from vending machines, JTI advocates the use by vending machine operators of adult identification functions in their machines as a proportionate way of achieving this. Such measures would achieve the identified objective, without unnecessarily compromising adult smokers' ability to purchase cigarettes from vending machines if they decide to do so. JTI has experience of introducing such systems in other countries around the world and JTI would be willing to share further information on the costs, timings and technicalities of the different types of adult identification functions available. 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.

43.23 These solutions, and other measures to prevent the sale of tobacco products to minors such as the criminalisation of proxy purchases of tobacco and 'negative licensing', have the potential to be effective means of addressing the specific concern of sales to minors, and less restrictive than prohibiting the use of vending machines.

Internet sales

43.24 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. Appropriately regulated legitimate Internet sales support JTI's initiatives to combat illicit trade and to help prevent access to tobacco products by minors. JTI strongly supports the targeted use of enforcement action by competent authorities at a Member State level against illegitimate Internet sites (including those knowingly selling products to minors).

Greater resources and manpower for effective, targeted enforcement strategies

43.25 The success of the measures discussed above relies heavily upon enforcement authorities to identify incidences of underage sales/purchase and to take action where non-compliance occurs. Effective enforcement is particularly important in the context of the negative licensing scheme. Its provisions operate on a 'three strikes and out' approach. If a retailer is convicted of selling tobacco to minors three times within two years he may be issued with an order prohibiting him from selling tobacco products either personally or on his premises. Proper systems should be in place to enforce these provisions and minimum age laws in general.

43.26 JTI believes that Member States should provide adequate funding to ensure that enforcement authorities are properly able to identify and target individuals who are flouting the law.

Renewed public information campaign

43.27 Although there is already a very high level of awareness of the health risks of smoking amongst EU consumers, effective communication is essential in order to ensure that smokers continue to be reminded of those risks. JTI supports the continued provision of information to consumers about the health risks of smoking.

43.28 Since adult consumers are already very well aware of the health risks associated with smoking, Professors Dhar and Nowlis have set out various parameters and recommendations regarding the formulation of communications.[713]

43.29 In addition, JTI believes that the goal of protecting minors from smoking should be supported by renewed government led public information campaigns, explaining the changes that are being made to tobacco control laws and the effect of such measures. If JTI's proposed solutions identified above as regards the negative licensing scheme and proxy/under-age purchase and consumption are adopted, the impact of such measures would also need to be communicated in this way.

43.30 Moreover, in the specific context of DG SANCO's proposals with regard to TNCO levels, JTI considers that possible alternatives (whose costs and effectiveness would need to be assessed) might include providing more information to consumers to the effect that products with lower machine measured TNCO levels are not necessarily safer than any other product, and that there is no such thing as a safe cigarette. Such information could be provided (if the need to do so was established) by inserting a new rotating warning into Annex I to the TPD.

44. CONCLUSION

44.1 As this Full Response demonstrates, JTI considers the Consultation seriously deficient in a number of respects, including its identification and articulation of the issues and in the collation and evaluation of the evidence. JTI also call on DG SANCO to improve the processes and procedures, in order to adhere to Better Regulation principles.

44.2 JTI considers that this Full Response, and the expert materials annexed hereto, contributes significantly and constructively to the debate concerning how, if at all, the current proposals in the Consultation, or alternative measures, should be addressed. JTI urges DG SANCO to consider this Full Response carefully.

44.3 JTI considers that it has already played and can continue to play a useful role in the development of an appropriate and proportionate regulatory regime for tobacco products, and remains available and willing to participate in the policy and evidence debate.

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[713] Professors Dhar and Nowlis's Report, paragraphs 7.2-7.10.

ANNEX 1: PROFESSOR STEINBERG'S REPORT

ANNEX 2: PROFESSORS DHAR AND NOWLIS'S REPORT

ANNEX 3: PROFESSOR GERVAIS' REPORT

ANNEX 4: PROFESSOR CAVE'S REPORT

ANNEX 5: PROFESSOR DEVINNEY'S REPORT

ANNEX 6: DR KEEGAN'S NOVEMBER 2010 REPORT

ANNEX 7: DR LILICO'S NOVEMBER 2010 UPDATE