From: Joseph Huggard [JH@HuggardConsulting.com]
Sent: 28 June 2013 13:55
To: SCHLYTER Carl
Subject: Tobacco Products Directive Impact Assessment - The Huggard Consulting Group Review
Attachments: Tobacco Products Directive RIA Review May2013.pdf

Dear Mr. Schlyter:

Please find attached a copy of a review of the Impact Assessment (IA) conducted in support of the proposed revision of EU Tobacco Products Directive. We are providing this as it is of direct relevance to the forthcoming discussion and vote in The Committee on the Environment, Public Health and Food Safety (ENVI) on the Commission`s proposal. A hard copy is being sent directly to your office.

Earlier drafts of this IA were found to be inadequate by the Commission's IA oversight body, the Impact Assessment Board (IA Board). In light of these concerns, Philip Morris International commissioned my team to go through the IA in detail and to produce this report which, we hope, illuminates its strengths and weaknesses.

Our report concludes that this particular IA does not meet the Commission's and international standards for such work. The executive summary outlines the central areas of concern, supported by a more detailed examination in the body of the report.

The authors of this report have been actively involved in regulatory impact analysis (RIA) for almost twenty years, dating back to the initial requirement to carry out RIA being incorporated into the 1997 Treaty of Amsterdam. They have worked continuously to promote the provision of a more complete view of the role that RIA plays in informing decision-makers as they seek to address the social and economic goals of citizens and societies.

Should you require any further information on the Huggard Consulting Group's report, how it was constructed or its conclusions, please do not hesitate to contact me directly on +352 305544 or by email at JH@HuggardConsulting.com

Yours sincerely.

Joseph A. Huggard
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Mr. Carl SCHLYTER
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Dear Mr. Schlyter,

Please find enclosed a copy of a review of the Impact As
revision of EU Tobacco Products Directive. We are
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THE HUGGARD CONSULTING GROUP

THE REVISION OF THE EUROPEAN TOBACCO PRODUCTS DIRECTIVE

A REVIEW OF THE ACCOMPANYING IMPACT ASSESSMENT
(COMMISSION STAFF WORKING DOCUMENT)

May 2013

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AUTHORS' NOTE

The authors of this report have been actively involved in regulatory impact analysis (RIA) for almost twenty years, dating back to the initial requirement to carry out RIA being incorporated into the 1997 Treaty of Amsterdam. They have worked continuously to promote the provision of a more complete view of the role that RIA plays in informing decision-makers as they seek to address the social and economic goals of citizens and societies.

The information, conclusions and views presented here reflect the findings of the authors.

The Huggard Consulting Group SARL
www.HuggardConsulting.com
Luxembourg, May 2013

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EXECUTIVE SUMMARY

The European Commission has drawn up a proposal to revise the EU Tobacco Products Directive of 2001. The justification for action ("intervention logic") is set forth as a need to improve the functioning of the EU internal market as well as a need for Union action to reduce smoking prevalence, focusing on the initiation of youth smoking. Thus, the proposed revision of the Directive aims to reduce smoking prevalence, particularly amongst young people, by introducing large pictorial health warnings and placing mandatory restrictions on, amongst other things, packaging and labelling, product forms (ban on slim cigarettes) and additives (ban on characterising flavours, including menthol).

In line with European Commission policy, officials have developed an Impact Assessment (IA) to provide evidence for, and aid, political decision-making. Earlier drafts of this IA were found to be inadequate by the Commission's IA oversight body, the Impact Assessment Board (IA Board). Analysis of the final IA provided with the Commission's proposal shows that most of these inadequacies were not addressed. Combined with other major deficiencies, this gave rise to concerns that the IA is not an appropriate basis for decision-making.

In light of these concerns and given the importance of ensuring that debates about government intervention in this key public health issue are properly informed, Philip Morris International commissioned The Huggard Consulting Group to carry out a top level review of the IA focusing on governance aspects.

This review of the IA concludes that it does not meet the standards of good regulatory practice as set out by the European Commission. The key weaknesses are the following:

- The IA's intervention logic, as highlighted by the IA Board, is weak in not providing adequate evidence of the non-functioning of the internal market or the need for intervention under an internal market rationale.
- The intervention logic related to smoking initiation does not adequately take into account the evidence that social factors are the most important influences on smoking initiation.
- The IA does not acknowledge or adequately take into account the difficulty and uncertainty associated with intervening in a mature issue involving behaviour and lifestyle choices.
- The IA does not provide adequate evidence to support its view that levels of youth smoking are likely to rise across the EU or that long-run decreases are likely to reverse.
- The IA does not advance an adequate and complete analysis of the uncertainties surrounding estimates of costs and benefits.
- The IA fails to present, does not adequately consider or is inconsistent in its approach to alternative policy options.
- The IA does not adequately address the risk of regulatory failure potentially associated with the preferred options.
- The IA inadequately communicates the resultant fundamental uncertainties that all of these weaknesses create for the potential effectiveness of the proposed measures.

These weaknesses have likely resulted because the IA authors, as pointed out in the opinions of the IA Board, did not adequately adhere to the requirements of the European Commission's impact assessment process.

As presented, this IA is insufficient to judge:

- whether action to improve the functioning of the internal market is necessary;
- whether the proposals will deliver improvements in public health and address the complex causes of youth smoking versus focusing on issues that may be peripheral;
- whether the proposed measures will trigger negative unintended consequences, such as commoditisation, down-trading, lower tobacco prices, higher smoking and increased illicit trade.

As a result, this review concludes that the Impact Assessment, developed in support of the proposed revision of Tobacco Products Directive, is an insufficient and inadequate basis for decision-makers to assess the justifications for the proposed regulatory action, its proportionality, or its likely effectiveness.

1. BACKGROUND

1.1. REVISION OF THE TOBACCO PRODUCTS DIRECTIVE

Responding to the European Parliament and Council and recognising scientific, regulatory, and technical changes together with international developments, the European Commission has drawn up a proposal to revise the EU Tobacco Products Directive of 2001[1] (TPD). The declared objective is to improve the functioning of the internal market (Article 114 of the Treaty on the Functioning of the European Union, TFEU) while focusing on reducing smoking prevalence, particularly amongst young people. The Proposal argues that enlarged, pictorial health warnings and mandatory restrictions on, amongst other things, packaging and labelling, product forms (ban on slim cigarettes), and additives (ban on characterising flavours, including menthol) will reduce the "attractiveness" of tobacco products[2] and thus youth smoking initiation and that this needs to be addressed at an EU-level.

Officials have drawn up an Impact Assessment (IA)[3] in support of the proposed revision of the TPD. Good impact assessments follow the European Commission's objective of ensuring that "Commission initiatives and EU legislation are prepared on the basis of transparent, comprehensive, and balanced evidence"[4] and thus help political decision-makers assess alternative policy interventions, including no action by government, explicitly. The Commission's IA Guidelines require that "all policy-decisions should be based on sound analysis supported by the best data available"[5]. Absent this, decision-makers can lack confidence in the credibility and robustness of the assessments and hence of the effectiveness of the proposed measures. (See Annex 1 for a more detailed discussion of governance and impact assessment.)

Earlier drafts of the IA were reviewed on two occasions by the Impact Assessment Board (IA Board), the European Commission's oversight body, working under the authority of the Commission President, with responsibility for assessing the quality of impact assessments. In both cases, the IA Board considered the drafts of the IA to be inadequate on the grounds that they provided insufficient justification for the legislative proposals. The IA Board highlighted significant methodological failings and weaknesses in the rationale for European Union level action[6]. While some of the points made by the IA Board were addressed by discarding certain proposals[7], many of the inadequacies were not. This raises serious concern that the IA developed by officials is flawed and that the proposed legislation risks not delivering the suggested and desired improvements for the internal market or the health of EU citizens.

In the light of these public concerns and recognising the importance of ensuring that debates about the intervention of government should be properly informed, Philip Morris International

[1] European Commission "Proposal for a Directive of the European Parliament and the Council on the approximation of the laws, regulations, and administrative provisions of the Member States concerning the manufacture, presentation, and sale of tobacco and related products" COM (2012) 788 Final (TPD Proposal)
[2] Commission press release, IP/12/1391, 19 December 2013
[3] European Commission "Commission Staff Working Document – Impact Assessment accompanying the document Proposal for a Directive of the European Parliament and the Council on the approximation of the laws, regulations, and administrative provisions of the Member States concerning the manufacture, presentation, and sale of tobacco and related products" SWD (2012) 452 Final (Commission IA)
[4] P4, Impact Assessment Guidelines (SEC (2009) 92) European Commission, 15 January 2009 (IA Guidelines)
[5] P6, IA Guidelines
[6] See European Commission Impact Assessment Board "Opinion: DG SANCO – Impact Assessment on a Proposal for a Revision of the Tobacco Products Directive", 21 March 2012 (March IA Board Opinion) and European Commission Impact Assessment Board "Opinion: DG SANCO – Impact Assessment on a Proposal for a Revision of the Tobacco Products Directive", 11 June 2012 (June IA Board Opinion)
[7] P8, Commission IA

has commissioned The Huggard Consulting Group to carry out a top level review of the IA, focusing only on key governance aspects, particularly in relation to the Commission's Impact Assessment Guidelines.

1.2. COVERAGE

This paper assesses the IA developed in support of the proposed revisions of the TPD from a governance perspective. Whilst the impact assessment is an extensive document with many citations and seeks to support numerous proposals, this review limits itself to examining selected key measures and critical flaws in the TPD IA.

In the first part of the review (Section 2), the paper examines the rationale for regulatory action ("intervention logic")[8] set out in the IA. This element of an IA is designed to provide decision-makers with a credible, evidence-based argument, highlighting the problem and its underlying causes, defining future trends (the "baseline"), and justifying the added-value from EU legislation[9,10].

In Section 3 the paper assesses the extent to which the IA examines the possibility of "regulatory failure"[11]. This occurs when legislation fails to achieve its goals, when costs exceed benefits or if significant unintended negative consequences are created, such as new or additional exposure to risk (the "risk-risk paradigm")[12]. A full understanding of these issues is essential if decision-makers are to appreciate the likely impact of the judgements they are being asked to make.

Finally, the paper undertakes an examination of the extent to which the IA respects the integrity of the decision-making process, particularly the use and presentation of evidence (Section 4). It is a clear requirement of the Commission's IA Guidelines that the findings of an assessment must be based on high quality, balanced evidence[13].

2. INTERVENTION LOGIC

2.1. GENERAL

One of the most important principles of good decision-making is that regulatory intervention should be based on a clear, evidence-based understanding of the problem and its causes. This "intervention logic" should also recognise potential trends in the evolution of the problem without further intervention (the "baseline"), as well as assessing evidence of the likely effectiveness of public policy, especially when considering action to manage problems that involve political preferences[14].

[8] The intervention logic is the conceptual link between the problem definition, the proposed actions and the anticipated outcomes. Good intervention logic dictates that without a robust problem definition component, the risk of regulatory failure is significantly increased. The European Court of Auditors defines intervention logic as "the conceptual link between an intervention's inputs and the production of its outputs and, subsequently, its impact in terms of results and outcomes." The European Court of Auditors, Special Report No.3/2010, Impact Assessments in the EU Institutions: Do They Support Decision-Making?

[9] OECD: The OECD Reference Checklist for Regulatory Decision-Making Appendix, Recommendations of the Council on Improving the Quality of Government Regulation – c(95)21/Final

[10] OECD: Regulatory Impact Analysis - Best Practices in OECD Countries (1997)

[11] P26, OECD: Recommendation of the Council on Regulatory Policy and Governance (2012)

[12] See "Risk versus Risk - Trade-offs in Protecting Health and the Environment" edited by Graham J.D. and Weiner J.B. (1995)

[13] P4, IA Guidelines

[14] P13, IA Guidelines

A robust, credible "intervention logic" enhances the capacity of political decision-makers to make informed choices between various policy alternatives (with their potential related impacts). It also provides the basis for proper ex-post evaluation of impacts. It enhances the likelihood that policy actions will target the underlying causes of problems rather than symptoms, thus increasing regulatory effectiveness and building public trust in policy-makers.

2.2. PROPOSED TOBACCO PRODUCTS DIRECTIVE – INTERVENTION LOGIC

The IA advances an "internal market intervention logic" and a "health intervention logic". As explained below, the IA is inadequate to meet the needs of the political decision-makers on both counts.

2.3. INTERNAL MARKET INTERVENTION LOGIC

The IA states that "The overall objective of the revision is to improve the functioning of the internal market"[15]. As highlighted by the IA Board, the IA, however, "does not adequately support internal market based EU legislative action."

Article 26 (2) TFEU states that "[t]he internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties." The internal market thus exists in the interest of economic operators and consumers. The internal market is designed to benefit economic operators by increasing industrial efficiency and providing economies of scale and a competitive environment, conducive to innovation with concomitant benefits to the citizens of the EU. It is also designed to benefit consumers by enhancing consumer choice.

The IA has no clear examination of how the internal market is working under the current Directive – the baseline analysis. The IA Board had pointed this out, highlighting the need "to further demonstrate that the conditions for recourse to Article 114 TFEU are fulfilled" and stating that "the evidence presented, in terms of concrete obstacles for economic operators affecting the functioning of the relevant markets, remains weak"[16]. Without this analysis and associated problem definition, it is not evident which specific impediments to the free movement of goods need to be addressed by EU-level action.

The IA Board, in its two opinions, identified the inadequacies of the draft IA's internal market justification. It asked that the IA "should better take into account that the presented evidence does not suggest any significant negative impacts of the current situation on the functioning of the internal market."[17] It also questioned how measures aimed at removing products or limiting product differentiation would improve the internal market.

The IA lacks a robust evidence-based problem definition which makes it impossible to judge if the assertions of the drafters, e.g., "[h]eterogeneous development in Member States has led to, or is likely to lead to, fragmentation of the internal market"[18] are correct. As a consequence, the reliability of statements such as "[t]he preferred option would ensure a more homogenous development in the EU"[19] also cannot be judged.

[15] P1, TPD Proposal
[16] PP2 & 1, June IA Board Opinion
[17] P2, June IA Board Opinion
[18] P1, Commission IA
[19] P86, Commission IA

Overall, the IA provides no evidence-based discussion on which internal market and related problems are likely to increase or decrease in magnitude or how the internal market would be improved by the proposed measures.

2.4. PUBLIC HEALTH INTERVENTION LOGIC

Focusing on youth smoking, the IA makes the argument that intervention is required because, without action, it is possible that the prevalence of youth smoking will, at worst, increase or, at best, cease its long-run decline. This, the IA attributes to the likely impact of new and existing forms of marketing activity by manufacturers of tobacco products. It is contended that, taken together, new tobacco-based products, characterising flavour additives (such as menthol), physical product characteristics (such as "slim" cigarettes) and branding make tobacco more attractive to young smokers, triggering initial trial and further consumption. It is also argued that some of these factors make quitting more difficult.

As a whole, this package will, the IA argues, tackle youth smoking initiation, reducing overall tobacco consumption and improving public health. Additionally, it is proposed that some existing smokers may be persuaded to quit and tax revenues may be better protected.

A detailed review of the evidence presented by the IA in support of the need to reduce youth smoking, along with an examination of studies not considered in the IA, suggests that the intervention logic related is inadequate to meet the needs of the decision makers. In particular, six areas of weakness have been identified:

- Analysis of Historic and Current Trends in Youth Smoking
- Causes of Youth Smoking
- Expected Future Trends in Youth Smoking ("Baseline")
- Likely Effectiveness of Proposed Measures
- Consideration of Alternative Policy Options
- Absence of Intervention Logic for Certain Proposals

2.4.1. Analysis of Historic and Current Trends in Youth Smoking

If EU intervention is needed to reduce the initiation of youth smoking, then it is essential that political decision-makers are made fully aware, using comprehensive and balanced evidence, of the historic and recent trends in youth smoking in the EU Member States. It needs to be demonstrated to decision-makers that across the EU as a whole, smoking amongst young people is a rising trend or that historic declines are reversing. The IA does not provide clear evidence of this trend, nor does it describe the significant uncertainties surrounding its views about smoking trends.

This analysis of the IA identified key deficiencies in the following areas:

- A long-run analysis of "trends and underlying drivers in smoking prevalence, particularly in young people"[20] and a coherent explanation of the trends, at EU or Member State level, are not included in the IA. Such an analysis is necessary for decision-makers to assess the relevance of the proposed measures and to review their potential effectiveness. Evidence that the prevalence of smoking amongst young people has on average fallen across Member States is not addressed (see Box 1). The IA acknowledges that "[p]eer group

[20] March IA Board Opinion

pressure/behaviour is obviously the most important factor for smoking initiation", however it does not address the fundamental question of what type of legislation is likely to be effective or justified if social factors are the key influences on long-run trends and levels of youth smoking.

- The IA provides inadequate evidence of a sustained increase in youth smoking throughout the EU. It does not, for example, demonstrate that slight increases in the already low levels of youth smoking in some Member States are either likely to persist or occur in other countries as well. Unless there is evidence of EU-wide problems then Community-level regulatory action is difficult to justify and may be more effective at Member State level. This is particularly the case given the weakness of the internal market intervention logic.

- Differences between youth smoking trends in Member States and amongst different demographic groups are not set out in the IA. Neither is there an analysis of what are the actions Member States have taken to influence these trends. Unless these complexities are explained to decision-makers, there is a danger that the justification for EU intervention may be misleading.

BOX 1: Trends in Youth Smoking

The Impact Assessment states that "The Health Behaviour in School-Aged Children (HBSC) study of WHO Europe from 2012 indicates an increase in smoking prevalence in 14 Member States for 15 year old boys and in nine Member States for 15 year old girls."[1] We could not find this statement in the cited report. This statement appears to have been drawn from the drafters' own comparison between the cited HSBC 2012 report and a previous HSBC 2008 report. The interpretation of this data is open to question due to the margin of error in the studies being larger than the difference found in many of these individual countries. In fact, in a comparison of previous reports, the HBSC average for the same metric from the same tables, "15-year olds who smoke at least once a week" shows an overall decrease in prevalence. The tables show a decrease from > 23% in the 2004 report[2], to 19% in the 2008[3] report and 18% in the 2012 report[4].

[1] P14, Commission IA
[2] Currie C, et al., eds. (2004) Young people's health in context. Health Behaviour in School-aged Children (HBSC) study: International report from the 2001/2002 survey. Copenhagen: WHO Regional Office for Europe
[3] Currie C, et al., eds. (2008) Inequalities in young people's health. Health Behaviour in School-aged Children. International report from the 2005/2006 survey. Copenhagen: WHO Regional Office for Europe
[4] Currie C, et al., eds. (2012) Social determinants of health and well-being among young people. Health Behaviour in School-aged Children (HBSC) study: International report from the 2009/2010 survey. Copenhagen: WHO Regional Office for Europe

2.4.2. Causes of Youth Smoking

Central to the intervention logic set out by the IA is that EU-level action is needed to address marketing activity by tobacco manufacturers as the key driver of smoking initiation by young people. Whilst, as noted, the IA acknowledges, that "peer group pressure/behaviour is obviously the most important factor for smoking initiation" the main thrust of the arguments in the IA is that combinations of brand, new product technologies, and product features are those that demand to be addressed[21]. As this is a core assumption, it should be supported by a robust evidential base. Such evidence is not provided, calling the assumption into question.

[21] P11, Commission IA

Extensive evidence suggests that social factors, parental behaviour and peer group pressure are the major drivers of initial smoking activity by young people rather than the attractiveness of tobacco products. While this is briefly acknowledged in the IA, their potential impact on the outcome of any regulatory intervention is not developed to support the evaluation of the options.

BOX 2: Causes of Youth Smoking

Conrad, KM "Why children start smoking cigarettes: predictors of onset"[1], a paper which is cited over 700 times in peer reviewed publications, studied almost 300 measures of predictors of youth smoking behaviour drawn from 27 separate studies. These studies found strong evidence of predictors in a variety of social factors such as peer and school bonding, sibling smoking, and rebelliousness/risk-taking behaviour.

These findings have been repeatedly confirmed since 1992, including by many studies in EU countries (see, e.g., Muttarak 2012[2], Mercken 2011[3], Legleye 2011[4]).

Furthermore, Special Eurobarometer 385[5], an EU-wide survey of 13,159 smokers and ex-smokers, shows that the main reported reasons for initiation are peer influence (79%) and parental smoking (21%).

[1] Conrad et al. (1992) Why children start smoking cigarettes: predictors of onset. Br J Addict 87(12):1711-24
[2] Muttarak et al. (2012) Why do smokers start? European Journal of Cancer Prevention 22(2):181-6
[3] Mercken et al. (2011). No smoke without fire: The impact of future friends on adolescent smoking behaviour. British Journal of Health Psychology 16(1):170-88
[4] Legleye et al. (2011). Widening inequalities in smoking initiation and cessation patterns: A cohort and gender analysis in France. Drug and Alcohol Dependence 117:233–241
[5] Special Eurobarometer 385. Attitudes of Europeans towards tobacco. European Commission 2012

By failing to address, in an adequate manner, the role of social issues, particularly parents and peers, in driving experimentation with tobacco by young people and the uncertainty this creates around the likely effectiveness of proposed measures or the risk of regulatory failure, the IA cannot support informed decision-making. Decision-makers cannot judge the reliability of estimates of the likely effectiveness of legislative action if the proposed interventions do not target primary causes and particularly if the uncertainty this causes is not explicitly addressed.

2.4.3. Expected Future Trends in Youth Smoking ("Baseline")

It is a requirement of the European Commission that all IAs undertaken by officials establish a baseline with a strong factual basis, expressed in quantitative terms[22].

A high quality baseline describes the likely trajectory of the problem, assuming no new regulatory interventions. When dealing with the management of lifestyle risks, such as consumption of tobacco, it clearly should assess the combined impact of long-run behavioural trends and social attitudes, as well as existing and planned regulatory interventions. They provide decision-makers with the context within which the proposed interventions are expected to operate, as well as ensuring that economic impacts are calculated solely on the basis of marginal costs and benefits.

The baseline included in the IA assumes that without further EU-level intervention there will be no additional reduction in levels of smoking, proposing that it is likely that the recent (downward) trends in prevalence would "revert" (*sic*)[23]. It is assumed, in the IA analysis, that any long-term,

[22] P24, IA Guidelines
[23] P43, Commission IA

underlying and progressive reduction in general smoking levels will be offset by increased smoking amongst young people triggered by "innovative" marketing activity of tobacco manufacturers. It is also expected that Member States will not take further actions – an assumption the IA Board criticized. This baseline assumption lacks a robust evidential basis and its overall approach appears flawed.

There are a number of weaknesses in the IA's approach to setting the baseline:

- The IA does not adequately consider evidence suggesting that levels of smoking may fall steadily in the future, without further government action. A study by Rand Europe, as part of the IA process, projects a decline, under the normal conditions of a baseline scenario, of 7-8 percentage points over a period of 17 years[24]. In its economic analysis of the EU tobacco market, Matrix Insight expects the volume of cigarette sales to fall by 7% by 2015[25]. By ignoring this and other similar evidence (see Box 3), the baseline shown in the IA masks the uncertainties inherent in the regulatory proposals, limiting the capability of decision-makers to make informed choices.

- As indicated above, there is strong evidence that social factors are the major reasons why young people begin smoking. The impact of this on the baseline estimate included in the IA is not addressed. A more balanced and comprehensive approach is needed, otherwise there is a risk that decision-makers may be misled as to the strength of the claimed links between marketing activity and levels of youth smoking.

- The IA does not explore the effectiveness of existing measures in the baseline, particularly by Member States. Average smoking prevalence in Europe has declined and continues to decline. For example, the IA could have looked at Germany. Smoking prevalence among young people aged 12 to 17 years has dropped to 11.7% in 2011 from 27.5% in 2001. Smoking prevalence among young adults aged 18 to 25 has also declined significantly during the same period, from 44.5% to 36.8%[26]. The IA, whose declared objective is to reduce smoking prevalence, should have looked at how Germany achieved these substantial declines in consumption.

[24] Rand Europe "Assessing the Impacts of Revising the Tobacco Products Directive" 2010, a report for DG SANCO of the European Commission (Rand Europe)
[25] P25, Matrix Insight report: Economic analysis of the EU market of tobacco, nicotine and related products, 2012 (Matrix Insight)
[26] Drug affinity among young in the Federal Republic of Germany, Federal Central Office for Health Education (BZgA), 2011

BOX 3: Baseline

The Impact Assessment does not adequately explore the effectiveness of existing measures in the baseline. Average smoking prevalence in Europe has declined since the 1950's and continues to do so in Europe on average over the past decade, according to trends from Eurobarometer[1], the RAND report[2] and the Matrix Insight[3] report.

Current projections see this trend continuing. The volume of the EU cigarette market has declined by 23.3% from 2000 to 2010 according to Euromonitor which also predicts a continued reduction from 2010 to 2015. Two projections made by the RAND report indicate a continued reduction based on WHO data in youth smoking[4] up until 2027.

The Impact Assessment states that "In the absence of further tobacco control measures at EU level, it is likely that the trend in prevalence would revert (*sic*)" [6]. No data is cited in the IA in support of this statement.

[1] The European Commission's Special Eurobarometers 239, 272c, 332 and 385 show a general decline in smoking prevalence across the EU since 2002
[2] Rand Europe
[3] P32, Matrix Insight
[4] PP88 & 89, Rand Europe
[5] Bogdanovica (2011) "Smoking prevalence in the European Union - a comparison of national and transnational prevalence survey methods and results". Tobacco Control 20(1):e4
[6] P42, Commission IA

A balanced approach to estimating the baseline would recognise the possibility of continued falls in consumption of tobacco and give due consideration to marketing factors not being a significant driver of youth smoking initiation. Within this context, the baseline would recognise the likely limits of so-called marketing innovation by manufacturers to erode underlying shifts in consumption behaviour. Such an estimate would not preclude further government action rather it would help decision-makers to understand the level of uncertainty and hence judge better the likely effectiveness and proportionality of any proposed measures. It would also enhance the credibility of the "intervention logic" amongst all stakeholders, including Member States.

2.4.4. Likely Effectiveness of Proposed Measures

When dealing with long-established risks, particularly those that result from lifestyle choices, the "intervention logic" should pay particular attention to the question of the likelihood that possible public policy actions will be effective. A number of claims are made in the IA about the likely effectiveness of possible measures, particularly in two areas: the role of menthol in triggering smoking activity amongst young people; and, the positive role of enhanced warning labels and attendant reductions in branding in reducing the attractiveness of tobacco products to young smokers.

In both cases, however, the evidence presented appears neither balanced nor complete. The IA does not consider a large number of studies that show no significant link between menthol as a characterising flavour or warning labels and initiation of youth smoking. This limits the capacity of decision-makers to understand fully the uncertainties related to the effectiveness of the proposed tobacco control measures. This general concern was also voiced by the IA Board of the European Commission[27].

[27] June IA Board Opinion Section (B) Overall assessment - "Finally, uncertainties related to the effectiveness of the identified tobacco control measures should be reflected in the conclusions"

BOX 4: Menthol

The evidence base for the proposed ban on menthol cigarettes is far from comprehensive. None of the literature cited in the IA shows that menthol triggers smoking initiation amongst young people in the EU. While it is noted that the market share of menthol has increased in Germany[1] the IA does not mention that in Germany over the same period, youth smoking rates have significantly decreased, possibly reaching an all-time low in 2011[2].

The IA also appears to selectively interpret some of the studies it quotes: Citing SCENIHR (2010)[3], the IA explains that menthol facilitates deeper inhalation as well as smoking uptake among young people. However, the Committee stated that "…there is a lack of evidence regarding the specific impact of menthol on smoking behaviour..." and that "[T]he potential for menthol … to influence smoking initiation and behaviour is discussed in the report but the data are inconclusive".

The IA does not address key peer-reviewed studies on menthol, such as:

- Cubbin et al. examined a sample of over 20,000 individuals from the 2005 US National Health Interview Survey and concluded "The results do not support the hypothesis that menthol smokers initiate earlier, smoke more or have a harder time quitting compared with non-menthol smokers."[4]
- King et al., in Australia, found: "… markedly declining numbers of younger smokers experimenting with and developing settled preferences for menthol brands…"[5]

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[1] P36, Commission IA – "[t]he market share of menthol [cigarettes] has more than doubled in Germany in the past ten years, from 1.3 to 3%"

[2] Drug affinity among young in the Federal Republic of Germany, Federal Central Office for Health Education (BZgA), 2011

[3] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). Addictiveness and Attractiveness of Tobacco Additives. November 2010

[4] Cubbin et al. (2010). The intersection of gender and race/ethnicity in smoking behaviours among menthol and non menthol smokers in the United States. Addiction 105:32 38

[5] King et al. (2012) The Decline of Menthol Cigarette Smoking in Australia, 1980–2008. Nicotine & Tobacco Research 14(10):1213-20

There are further concerns that, in a number of instances, studies and their findings, whilst cited within the IA and used to support its claims, have not been reported fully or have not been interpreted in a sufficiently balanced way.

BOX 5: Packaging and Labelling

Despite the IA citing considerable ex-ante evaluation speculating on the effectiveness of enlarged, graphic health warnings, they do not cite Gospodinov & Irvine 2004[1], a study on the smoking prevalence of over 20,000 individuals in Canada before and after the implementation of regulation requiring a pictorial warning and increasing the warning size. This is similar to the IA's policy Option 1 for packaging and labelling, namely "combined warnings (picture plus text) of 75% displayed on both sides of the packages of tobacco products". This study concludes "that the warnings have not had a discernible impact on smoking prevalence". Furthermore, a recent systematic review which screened over 17,000 references[2] concludes on this topic that "For health warnings on tobacco products and restrictions on tobacco advertising, the lack of robust studies makes firm conclusions difficult." and that "[i]n three studies of young people, health warnings did not appear to change attitudes or smoking behaviour". Despite the range of evidence found by systematic reviews on this subject, the IA appears to have only identified evidence which affirms the policies on more stringent packaging and labelling measures.

[1] Gospodinov & Irvine (2004) Global Health Warnings on Tobacco Packaging: Evidence from the Canadian Experiment. Topics in Economic Analysis & Policy 4(1):1-23
[2] Thomas et al. (2008) Population tobacco control interventions and their effects on social inequalities in smoking: systematic review. Tobacco Control 17:230–237

Finally, as mentioned above, there is inadequate examination of the experience of Member States such as Germany with a view to analysing what measures have been successful and which have not, as a means of a benchmark for the current proposals.

2.4.5. Consideration of Alternative Policy Options

In addressing the development of policy options the European Commission guidelines clearly set out the need to consider options that are realistic. They instruct policy developers to "keep an open mind" and to respect proportionality by defining options that do "not go beyond what is necessary to achieve satisfactorily the objective which has been set"[28]. The guidelines also require officials to "explain clearly the reasons for excluding certain options from further analysis"[29]. A number of the IA's proposed measures, in addition to being hampered by being derived from inadequate problem definition, do not follow the Commission's IA guidelines in relation to policy options.

For example, the IA does not give any consideration to alternative options to a ban on slims cigarettes. In addition to the absence of an intervention logic around this proposal, as highlighted in section 2.4.6, the IA presents no other option for consideration.

The IA does not present and discuss the policy option of banning candy and fruity flavours while not banning traditional menthol cigarettes. "Traditional use" is defined in the IA as use "for at least 30 years"[30] and the concept is used in a policy option to allow for derogation at Member State level for "traditional use" smokeless tobacco products[31]. Menthol cigarettes, in many Member States, have been used for much longer than 30 years. The IA fails to consider a "traditional use" exception for menthol cigarettes as a less restrictive alternative to a complete ban.

[28] P29, IA Guidelines
[29] P30, IA Guidelines
[30] Glossary of Terms, Commission IA
[31] Glossary of Terms, Commission IA

For increased size of pictorial warnings the preferred option of "75%/75%" is proposed in the IA as there being "**no less stringent measure** [emphasis in original] available to reach the objective of improving the internal market while protecting public health"[32]. The IA explains that this has been suggested after a "thorough analysis of scientific evidence and international experience"[33], which is not presented in the IA. The available work, which was commissioned from Rand[34] in preparation for the IA, concluded that there was "no quantification available" of the difference between 50%, 75% or 100% health warnings. The IA fails to provide an examination of, or reasons for rejecting other options, such as 50% health warnings. This makes the IA inconsistent with the European Commission's IA Guidelines. It also makes it very difficult for political decision-makers to judge the proportionality of this measure.

Overall, the apparent failure to systematically examine the proportionality of a range of policy options does not follow the IA guidelines and thus fails to provide an adequate basis for political decision-makers' assessment of the likely effectiveness of the proposals.

2.4.6. Absence of Intervention Logic for Certain Proposals

Above, questions are raised about the quality and credibility of the intervention logic put forward to support a number of the proposed measures. Alongside these significant deficiencies, there is an absence of formal justification for regulatory action in a number of areas, including restrictions on pack closure mechanisms and size and, of particular significance, a ban on slim cigarettes.

The "intervention logic" justifying the proposed ban on slim cigarettes has not been developed. The proposal to ban them is based on a claim that they constitute a misleading promotional device that undermines warnings about the harmfulness of smoking. Decision-makers are not made aware of this proposal in the "intervention logic" sections of the IA. Rather, this measure first appears within the review of options for packaging and labelling requirements.

Slim cigarettes represented 5.25% of all cigarettes sold legally in the EU in 2011 (30.5 billion cigarettes[35]). In light of the scale of the economic impact of banning this category of products, it would be reasonable to expect that this would be drawn to the attention of decision-makers when setting out the rationale for regulatory action. Slim cigarettes should have been separately identified as a specific problem that required an appropriate policy response. By doing this, the IA would have allowed decision-makers to weigh up the evidence of the problem and arguments for the likely effectiveness of the proposed actions, enabling them to make an informed decision. This cannot be achieved on the basis of the current IA.

In addition, there are serious flaws in the evidence cited in support of the proposed ban. The IA lacks any empirical data and it does not highlight the significant limitations of the studies it quotes or any of the associated uncertainties.

[32] Glossary of Terms, Commission IA
[33] Glossary of Terms, Commission IA
[34] P139, Rand Europe
[35] Source: Philip Morris International

BOX 6: The Option of Banning Slim Cigarettes

No country has banned or otherwise restricted slim cigarettes. Therefore, there is no data that would allow an empirical ex-post analysis of the impact of a ban on slim cigarettes on smoking prevalence.

The IA offers no evidence, either internationally or from the EU, that people take up smoking or fail to quit because they believe that slims are less harmful. The IA fails to present robust data in support of this proposed ban.

Specifically, the IA relies on two surveys of smokers' beliefs about the relative risks of cigarettes[1] and how smokers rank these cigarettes in terms of attractiveness, quality and taste[2]. These studies do not provide any evidence on smokers' actual behaviour nor do they contribute to quantifying the problem. In addition, the IA misrepresents the findings and conclusions of the studies:

- Borland, in Australia, actually found that "Standard stick length/diameter was perceived as the most attractive and highest quality stick." Borland also highlights that "…we cannot make any strong claims about changes to stick characteristics translating into changes in smoking", something the IA fails to acknowledge.
- Mutti acknowledges that "to our knowledge there is no empirical research to indicate whether longer or smaller diameter cigarettes are perceived as less harmful".

[1] Mutti et al. (2011) "Beyond Light and Mild – Cigarette Brand Descriptors and Perceptions of Risk in the International Tobacco Control Four Country Survey". Addiction 106(6):1166-75
[2] Borland et al. (2012) "Effects of stick design features on perceptions of characteristics of cigarettes." Tobacco Control

3. REGULATORY FAILURE

3.1. GENERAL

"Regulatory failure" occurs when legislative or regulatory interventions fail to deliver on goals, when the costs of regulations exceed their benefits, or when regulations trigger significant, negative unintended consequences, such as exposure to additional risks. In developed societies with mature regulatory frameworks, the risk of regulatory failure increases whenever governments seek to expand or deepen the scope of intervention in the behaviour of individuals or businesses[36]. This is particularly the case when governments take action to manage risks that result from lifestyle choices.

Extensive research suggests that, in these circumstances, the scope for additional benefits from regulatory action is limited: the "low hanging fruits" of regulatory benefits from risk management actions have been obtained, leaving predominantly complex problems, often with multiple causes. A further problem is that risk management rule-making is seeking to shift behaviour, something that is, axiomatically, hard to predict. Indeed, actions taken to manage complex risks may trigger other, greater risks or create costs that significantly outweigh benefits[37].

[36] See "Risk versus Risk- Trade-offs in Protecting Health and the Environment" edited by Graham J.D. and Weiner J.B. (1995). The difficulties of regulating risks in mature regulatory contexts, highlighting the potential for costs to exceed benefits when focusing on small, complex problems, is also considered in Morrall J. F. "Saving Lives: A Review of the Record" (AEI-Brookings Joint Center For Regulatory Studies Working Paper 03-6, 2003)
[37] This phenomenon has been highlighted by leading academics, most notably Graham and Weiner, and has been recognised by regulators in many OECD countries. See, for example, US Office of Management and Budget "Updated Principles for Risk Analysis" (2007)

This issue has been recognised by the OECD, and the importance of taking it into account when taking regulatory decisions is highlighted in its guidance on regulatory policy issued in 2012, where it encourages members to "[e]valuate the likely effectiveness of risk strategies against their capacity to … minimise unintended consequences and 'risk-risk' tradeoffs"[38]. The European Commission has also responded, requiring officials to highlight uncertainties and potential for new risks when drawing up impact assessments, as a means of addressing the issue of regulatory failure, acknowledging that "[t]he actions of public authorities can also have results that are not in the best interests of society"[39].

3.2. PROPOSED TOBACCO PRODUCTS DIRECTIVE – ASSESSMENT OF RISK OF REGULATORY FAILURE

Within the IA the risk of regulatory failure is not properly addressed. Instead, the IA emphasises the scale of forecast net benefits and highlights the extent of the evidence used to support the "intervention logic". Neither of these materially assesses the possibility that interventions may fail.

Benefits of intervention will, it is argued, significantly exceed costs. The IA claims that, within five years, the proposed interventions will reduce consumption of tobacco by 2%. Any losses in tax revenues from reduced consumption will, it is also proposed, be more than offset by savings in healthcare costs, higher productivity, and the social gains of increased life expectancy.

A further benefit will occur, it is estimated, because changes in spending patterns from cutting down on consumption of tobacco will generate additional employment, more than balancing any losses because of reduced production of tobacco products. In overall terms, the IA argues that the proposed interventions will deliver significant economic and social benefits to the EU. Any threats or uncertainties related to this forecast outcome are not explored in any detail.

The IA fails to highlight significant uncertainties, ignores the possibility of negative, unintended consequences and does not address major potential threats to the effectiveness of proposed government actions. There are four main areas of concern:

- Benefits of Intervention
- Commoditisation and Risk-Risk
- Illicit Trade
- Costs of Intervention

3.2.1. Benefits of Intervention

There are significant weaknesses in the arguments used by the IA to justify the claimed health benefits of the proposed policy measures.

First, as discussed above, the possibility that the causes of initiation of youth smoking are primarily social, hence limiting the possible effectiveness of the proposed measures, is not adequately addressed. If actions do not target underlying causes, this creates considerable additional uncertainty as to the scale of the health benefits that may arise. Because of the structural failings of the intervention logic, the measures may risk not producing any social gains for citizens.

[38] P16, OECD: Recommendation of the Council on Regulatory Policy and Governance (2012)
[39] P21, Part III: Annexes to IA Guidelines

Second, the estimates of the IA are fundamentally different from those drawn up by Rand Europe[40], who carried out the detailed analysis in support of the IA. Rand estimated that, over a seventeen-year finite horizon, a more restrictive set of measures than those assessed in the current IA will deliver only a 0.5% reduction in smoking prevalence[41]. The IA does not provide the necessary detailed rationale explaining why the new proposal would be four times[42] more effective than the estimates of the Rand experts.

Finally, some of the specific claims made in the IA, assessing the discrete benefits of individual measures, are based on selective interpretation of studies and on studies that do not meet well-established standards of evidence. It is not appropriate, for instance, to make claims about the likely effectiveness of proposed measures on the basis of ex-ante projections of the potential impact of similar measures in other jurisdictions.

BOX 7: Lack of Supporting Evidence for Benefits

Many of the studies used as supporting evidence in the IA are ex-ante, that is, speculation on the impact of its proposed measures on prevalence. This is the case even when ex-post studies exist which have shown lack of measurable effectiveness of these same measures (see Box 5).

The IA concludes that "Pictorial warnings appear to be more effective than texts among persons with lower levels of literacy and particularly in young people", citing a letter to the Editor that does not even examine pictorial warnings but assesses the readability of US text warnings on alcohol, cigarette, and smokeless tobacco containers[1].

The IA also states "[i]n a number of countries, sweet and tasteful tobacco products are the most preferred tobacco products among children and adolescents as well as experimenting smokers" [2], citing a web based survey of an ex-ante evaluation measuring "positive/negative expectancies" and "intention to try". The study does not include any information on what brands were actually used by the smokers among the respondents nor any evidence that the brand attributes measured were causally related to smoking initiation. This cannot be considered adequate evidence on which to base the IA's statement[3]. Market-based data is necessary to sustain this type of statement.

[1] Malouff et al. (1992) "Readability of health warnings on alcohol and tobacco products". American Joumal of Public Health 82(3):464
[2] P101, Footnote 368, Commission IA
[3] Ashare et al. (2007) "Smoking expectancies for flavoured and non-flavoured cigarettes among college students". Addictive Behaviors 32:1252–1261

3.2.2. Commoditisation and Risk-Risk

Tobacco control measures seek to shift the behaviour of potential or existing smokers: governments are attempting to shape lifestyle choices. If they are to be successful, regulatory interventions need to take into account the complex reasons why people begin to smoke or choose one type of product or brand.

Due to the maturity of regulation in this area, one of the most important challenges facing new or strengthened tobacco control measures is to ensure that they avoid creating incentives that may trigger increases in smoking prevalence. Good impact assessments demonstrate that the potential

[40] Rand Europe
[41] Rand Europe
[42] P114, Commission IA

for the proposed action to create new risks has been considered fully, taking into account all relevant evidence and highlighting related uncertainties to decision-makers.

Many of the measures examined in the IA seek explicitly to limit branding and product differentiation. This approach will likely make it much more difficult for tobacco manufacturers to sustain premium pricing strategies. In turn, this "commoditisation" can lead to down-trading, as consumers seek lower prices as a determinant of product value. Lower average prices may tend, depending on precise price elasticity relationships, to encourage more smoking and act to increase youth initiation.

The potential consequences of this are serious and yet they are not explored in the IA. To address this adequately, the IA should have contained scenarios exploring the possible impacts on smoking levels of down-trading by customers in response to loss of brand value and less product differentiation. Instead, the IA simply affirms that manufacturers will not be confronted with commoditisation[43].

This is one of the critical uncertainties surrounding the overall proposal and should have been fully explored in the analysis with the risks being drawn to the attention of policy-makers.

BOX 8: Commoditisation

A variety of research has uncovered a strong link between price and smoking behaviour which is broadly accepted and used[1].

Rand state in their report that further labelling measures including large pictorial warnings could lead to a loss in the contribution of brand to the value placed by consumers on premium products, resulting in commoditisation and a drop in prices[2]. An analysis of the price elasticity of the demand for tobacco products in eleven European countries[3] estimated short-run price elasticities of −0.3 to −0.4 and long-run price elasticities ranging from −0.2 to −1.5, with the typical value close to −1.0. A meta-analysis of price elasticity in tobacco[4] found an average price elasticity of –0.48. This means that if the price were to drop by 10% then tobacco consumption would be expected to rise by 4.8%. If Rand is correct in expecting a commoditisation effect then tobacco consumption will be expected to increase. The Impact Assessment claims that no such commoditisation will occur with even larger pictorial warnings[5] and does not explore the risk and uncertainty related to this contention.

[1] See for example Chaloupka & Warner (2000) "The Economics of Smoking". Handbook of Health Economics, in: A. J. Culyer & J. P. Newhouse (ed.), Handbook of Health Economics, edition 1, volume 1, chapter 29, pages 1539-1627 Elsevier.
[2] Rand Europe states that "Two interrelated effects could be expected, a loss in brand value and a commoditization"
[3] Nguyen et al. (2012) Demand for Tobacco in Europe. An Econometric Analysis of 11 Countries for the PPACTE Project. Juvenes Print, Tampere, Finland 2012
[4] Gallet and List. (2003) Cigarette demand: a meta-analysis of elasticities. Health Economics 12(10):821–35
[5] P87, Commission IA, "Under the provisions considered under option 1, manufacturers would be confronted neither with commoditisation of the market nor with a prohibition of the use of trademarks on the package"

3.2.3. Illicit Trade

Consumption of counterfeit and contraband cigarettes by EU consumers erodes tax revenues, defeats tobacco control measures, stimulates criminality and potentially creates additional health risks. In 2010, illicit trade in cigarettes accounted for 8.25% of total trade in the EU and it was

[43] P88, Commission IA

forecast to increase by 1% per year in the next five years[44,45]. In the IA, the risk that the proposed measures may create incentives for its continuing growth is discounted[46]. The IA incorporates measures to further strengthen traceability and security of legal products, arguing that these will contribute to limiting overall illicit trade.

The IA does not consider the evidence available in the published literature[47] and submitted in the consultation process that illicit trade increases youth smoking. Illicit trade makes tobacco far more accessible to underage smokers. Suppliers of illicit products, unlike the legitimate retailer, are not subject to any legal constraints and offer lower cost cigarettes to the most price sensitive group. Thus, illicit trade has the potential to directly affect the IA's central objective, namely reducing youth smoking.

The risk of regulatory failure from possible increases in illicit trade as a consequence of other proposed measures should have been explored explicitly in the IA.

3.2.4. Costs of Intervention

An important argument made within the IA is that there are unlikely to be any major economic costs, if the proposed measures are introduced. Instead, the IA suggests that the economy will be strengthened through net job creation. Such an analysis risks increasing the attractiveness of the proposal to decision-makers, limiting their concerns about the need to consider potential policy trade-offs. It is, however, an incomplete and insufficiently balanced narrative.

First, as discussed above, the IA fails to assess the potential cost linked with commoditisation and illicit trade. Second, looking in detail at the estimates of economic impact, the IA fails to highlight a number of important uncertainties and risks. In the first place, the estimate of job creation nets off two distinct phases of economic activity: an initial reduction in employment as consumer spending on tobacco falls, then an increase in employment as spending shifts. The IA does not highlight the risks surrounding these estimates: they are two distinct processes, taking place at different times and subject to two different sets of assumptions. Recognising this challenge, the IA Guidelines require short and long-term impacts, for instance, to be disclosed separately. A further problem is that the economic model used to calculate impacts appears to give insufficient weight to potential initial job losses in the retail sector, as a result of lower spending on tobacco. If, as estimated within the IA, over 600,000 jobs in retail outlets depend on tobacco sales, then a 2% reduction in turnover places at least 12,000 jobs at risk. This risk was not highlighted in the IA.

Finally, the latest research into the most appropriate way to assess the impacts of regulatory proposals suggests that estimates of economic cost should recognise "adjustment costs". These are the lags and delays in shifting economic activity, one of the consequences of regulatory-induced behavioural change, between markets, geography, and workers with different skill levels.

[44] P39, Commission IA
[45] Latest estimates confirm that illicit trade is increasing. The Project Star study conducted annually by KPMG shows that the illegal trade of cigarettes in the EU has been increasing over the last six years. In 2012 the levels rose to 11.1%, compared to 10.4% in 2011 (Project Star 2012 Results, KPMG, 16 April 2013)
[46] "It is important to underline that the preferred policy options do not – in the assessment of the Commission – lead to increased illicit trade." (Commission IA, Footnote 31).
[47] North of England Illicit Tobacco Study 2011

It is now recognised that these lags could be significant particularly when economies have spare capacity, challenging the value of using traditional equilibrium and other models[48].

A more appropriate way of informing policy-makers of the possible indirect economic costs would have been to highlight quantitatively likely job losses (after recognising adjustment costs and impacts on the retail sector), with a qualitative commentary describing the possibility that new jobs may be created elsewhere, depending upon shifts in consumer spending. In this manner, the IA could avoid the misleading perception that the proposed measures are "cost-free".

4. USE AND PRESENTATION OF EVIDENCE

4.1. GENERAL

Since its introduction in 2002, the European Commission has built one of the most respected impact assessment systems in the world[49]. The Commission's approach provides officials with a comprehensive framework for drawing up and assessing legislative and regulatory proposals.

Within the IA standards are clear requirements for the use of evidence. Impact assessments should, the IA guidelines state, be based on balanced evidence, good quality data, and robust analysis. Moreover, these requirements are endorsed by the European Commission's Communication on the collection and use of evidence. This requires policy choices to be based and up-dated on the basis of the best available evidence[50].

If this is not universally achieved then the integrity of the decision-making process risks being undermined, eroding the European Union's reputation. Poor quality IAs risk creating precedents, triggering further reductions in analytical standards and lower quality policy proposals.

Whilst the IA is detailed and provides a narrative covering all relevant decision-making stages, it does not comply satisfactorily with the standards set out in the Commission's Impact Assessment Guidelines. In addition to problems identified in earlier sections of this report, the Use and Presentation of Evidence is a cause for concern.

The approach taken in the IA incorporates the use of evidence, of different types, to support judgements, arguments, and proposals. Whilst this suggests the developers of the IA recognised the focus of the European Commission on evidence-based decision-making, a number of significant problems are apparent:

- **Lack of explicit evidential standards** – the IA fails to include a comprehensive statement setting out the approach taken to the collection and use of evidence.

  In this environment, most evidence from natural sciences is of only limited relevance: the harmfulness of tobacco products is well appreciated. Instead, policy-makers must rely upon evidence from social sciences and from the private sector, including market research organisations. It is well recognised that ideology or economics may play a part in distorting the quality and reliability of studies. Evidence of this type is complex,

[48] See, for example, Davis and von Wachter "Recession and the Costs of Job Loss" (Brookings Papers on Economic Activity, 2011), Masur and Posner "Regulation, Unemployment, and Cost-Benefit Analysis" (University of Chicago Law School Working Paper, 2011)
[49] Communication from The Commission to The European Parliament, The Council, The European Economic and Social Committee and The Committee of the Regions – EU Regulatory Fitness
[50] European Commission "Communication from the Commission on the Collection and Use of Expertise by the Commission: Principles and Guidelines" (2002)

difficult to interpret and often contradictory or of poor quality. Its interpretation is fraught with uncertainties.

Therefore, so as to ensure that the strengths and weaknesses of such evidence are properly understood by decision-makers, it would be expected that the IA explicitly states the approach taken. For instance, assessments of the effectiveness of measures should be based on properly conducted ex-post studies; usage data should come from professional market research, as should data on purchasing behaviour; studies describing actual usage should be given priority over those measuring perceptions or intentions to buy. There is no discussion of such requirements being established to inform the collection and use of the evidence cited in the IA. Ideally, the IA should have considered explicitly the appropriate methodologies for assessing findings based on the "weight-of-evidence" approach. On many occasions in the IA, the findings of poor quality studies appear to be treated equally with those from more robust work. Before examining the weight of ideas, all studies should have been assessed on the basis of quality, reliability, and relevance, using transparent standards.

Such standards are necessary to increase the quality of decision-making. Their absence makes it very difficult for political decision-makers to make informed decisions about the robustness of the "intervention logic" or the likely effectiveness of the proposed measures.

- **Lack of balanced disclosure** – a feature of much of the evidence cited in the IA is the limited recognition of other studies that set out conflicting or contradictory findings. Important examples include the failure to adequately take account of the social causes of youth smoking or its decline in some EU countries; the lack of recognition of evidence that larger pictorial health warnings may not reduce smoking rates; the failure to highlight evidence that there may be no link between menthol cigarettes and youth smoking initiation; and excluding evidence of the possible negative impact of the proposed measures on illicit trade, down-trading, and increased consumption.

BOX 9: Selective Disclosure

Examples of selective disclosure include the absence of literature which calls into question the effectiveness of packaging interventions. For example a systematic review[1] which examined actual changes in prevalence as a result of packaging or a study[2] which found no discernible effect of such interventions. The IA does however cite many papers and surveys which discuss attractiveness of packaging without quantifying this in real term effects.

The IA cites a variety of sources of varying quality and relevance, including, for example a campaign document when considering the options around packaging which "encourage or facilitate initiation by young people"[3]. This factsheet does not mention ingredients or packaging. It only states that the path to smoking addiction starts at a very young age.

[1] Thomas et al. (2008) Population tobacco control interventions and their effects on social inequalities in smoking: systematic review. Tobacco Control 17:230–237
[2] Gospodinov & Irvine. (2004) Global Health Warnings on Tobacco Packaging: Evidence from the Canadian Experiment. Topics in Economic Analysis & Policy 4(1):1-23
[3] P48 and Footnote 216, Riordan, The path to smoking addiction starts at very young ages. Washington, DC: Campaign for Tobacco-Free Kids; 2009. http://www.tobaccofreekids.org/research/factsheets/pdf/0127.pdf (accessed 28 Nov 2012); Commission IA

- **Selective interpretation of evidence** – in order to ensure that decision-makers are properly informed about the robustness of the case for change, it is essential that the limitations of specific studies are recognised and highlighted and that their findings are fully reported. Selective interpretation and reporting must be avoided, as should the use of evidence for purposes for which it is not appropriate. In a number of instances, it appears that these standards have not been met fully. Examples include a failure to draw the attention of decision-makers to the weaknesses of studies which rely on the self-reporting of behaviours or perception and the incomplete reporting of the findings from assessments by scientific committees or from social surveys.

BOX 10: Selective Interpretation of Evidence

The IA, in its Baseline Scenario, sets out to describe "how the tobacco market is expected to evolve in the coming years if no changes are made to the TPD" [1]. In this section it states: "Also the new marketing strategies for tobacco for smoking are expected to continue. This applies in particular to innovative and appealing **tobacco packaging** (*emphasis in original*)…. The development is even expected to aggravate under the baseline scenario, especially following stricter advertising regimes in Member States and taking into consideration that packaging constitutes an important factor in choosing a FMC brand (23%),"[2] citing Eurobarometer 2012 (Eurobarometer 385). This statement takes data related to factors determining existing smokers' choice of brand and appears to apply it to the development of the market overall, thus conflating two entirely different concepts, creating the impression that packaging is a major influence in how the market will develop. Additionally, it does not fully report the data related to the "23%" number, failing to explain that packaging is the least important factor for existing smokers in choosing a brand, with 76% of the smokers surveyed saying it was "not important"[3].

[1] P 40, Commission IA
[2] P 41, Commission IA
[3] Eurobarometer 385

The overall effect of these deficiencies is to mask from decision-makers the uncertainties and risks surrounding the justification for government action, the risks of regulatory failure, and the potential effectiveness of the proposed measures.

5. CONCLUSIONS

The stated objectives of the revision of the Tobacco Products Directive are to improve the functioning of the internal market while reducing further smoking amongst young people and hastening cessation by all smokers. An impact assessment has been produced to support political decision-makers in their analysis of the proposals in the TPD.

This review of the IA concludes that it does not meet the standards set out by the European Commission. The key weaknesses are the following:

- The IA's intervention logic, as highlighted by the IA Board, is weak in not providing adequate evidence of risk of the non-functioning of the internal market under current legislation or the need for intervention under an internal market rationale.
- The intervention logic related to smoking initiation does not adequately take into account the evidence that social factors are the most important influences on smoking initiation.

- The IA does not acknowledge or adequately take into account the difficulty and uncertainty associated with intervening in a mature issue involving behaviour and lifestyle choices.
- The IA does not provide adequate evidence to support its view that levels of youth smoking are likely to rise across the EU or that long-run decreases are likely to reverse.
- The IA does not advance an adequate and complete analysis of the uncertainties surrounding estimates of costs and benefits.
- The IA fails to present, does not adequately consider or is inconsistent in the manner in which it establishes potential alternative policy options.
- The IA does not adequately address the risk of regulatory failure potentially associated with the preferred options.
- The IA inadequately communicates the resultant fundamental uncertainties that all of these weaknesses create for the potential effectiveness of the proposed measures.

These weaknesses have likely resulted because the IA authors, as pointed out in the opinions of the European Commission IAB, did not adequately adhere to the requirements of the European Commission's Impact Assessment process.

As presented, this Impact Assessment is insufficient to judge:

- If action to improve the functioning of the internal market is necessary.
- If the proposals will deliver improvements in public health and address the complex causes of youth smoking versus focusing on issues that may be peripheral.
- If the proposed measures will trigger negative unintended consequences, such as commoditisation, down-trading, lower tobacco prices, higher smoking and increased illicit trade.

As a result, this review concludes that this Impact Assessment, developed in support of the proposed revision of Tobacco Products Directive, is an insufficient and inadequate basis for decision-makers to assess the justifications for the proposed regulatory action, its proportionality, or its likely effectiveness.

The Huggard Consulting Group
May 2013

Annex 1: GOVERNANCE AND IMPACT ASSESSMENT

At the heart of the EU Commission's approach to good governance lies a series of regulatory management processes. These include collection and use of evidence, access to documents, consultation and an impact assessment (IA).

Throughout the OECD area, impact assessments are one of the most widely-used processes for improving the quality of legislative and regulatory decisions. In a wide range of different legal and regulatory settings, it helps regulators improve the effectiveness of regulatory outcomes, whilst, at the same time, reducing the costs of regulatory decisions. IA reduces the risk of regulatory failure.

Good impact assessments are also recognised as an important tool by the WTO TBT Committee in the implementation of the TBT Agreement. The WTO, as part of its principles of Good Regulatory Practice for the effective and "efficient implementation of the agreement", cites the need for mechanisms "for assessing policy options, including the need to regulate …. through an evidence-based process including the use of regulatory impact assessment (RIA) tools."[51]

IA is used to support decisions made by regulators and politicians: it is not a substitute for political action. Nor is it a mechanistic process, basing decisions on simplistic comparisons of quantified costs and benefits. Instead, it encompasses a wide range of qualitative and quantitative methods aimed at systematically and openly assessing the negative and positive impacts of proposed and existing regulation.

IA forms an essential part of a modern, transparent, accountable, and empirically-based regulatory system.

Regulators employ IA tools and processes because, if designed well and implemented effectively, they deliver a wide range of benefits for decision-makers, citizens, and businesses. They enhance the rigour, transparency, and accountability of regulatory decision-making processes, including strengthening consultation. They provide a formal mechanism for better structuring of the decision-making process, helping to ensure that the "need" for government action is justified and based on a credible understanding of cause and effect. They help decision-makers assess alternative policy interventions, including no action by government, explicitly. They highlight the "true" impacts of regulatory decisions, including qualitative benefits, complex costs, and unintended consequences. And, finally, they promote regulatory strategies that maximise net benefits of government action.

The EU's institutions have taken a series of steps to improve the quality of regulatory decision-making over the last 20 years. These have included greater use of outcomes-based laws (the so-called "New Approach" in directives related to product standards); Treaty Protocols on the principles of subsidiarity and proportionality; new methods for consultation; partial impact assessment tools (such as the Business Impact Assessment); and Presidential guidelines for the preparation of legislative proposals by the European Commission[52].

[51] World Trade Organization Committee on Technical Barriers to Trade: Sixth triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade under Article 15.4 http://www.jisc.go.jp/cooperation/pdf/g_tbt_32.pdf

[52] The evolution of the use of benefit-cost analyses and decision-making standards by the European Commission is described in The European Policy Centre "Regulatory Impact Analysis: Improving the Quality of EU Regulatory Activity" (Occasional Paper, 2001)

However, the most important changes have been introduced by the European Commission, the EU institution responsible for initiating new secondary rules and for implementing existing laws, in the period since 2002. In that year, the Commission introduced an integrated impact assessment system, covering economic, social, and environmental factors, and supported by detailed technical guidelines[53]. These changes form part of wider series of initiatives designed to both improve governance and instil a "new regulatory culture" at EU-level[54].

IA requirements and processes were revised and improved further in 2005, 2006, and 2009, reflecting lessons learned from the operation of the new system. The revised requirements for the Commission set out the following approach:

- IA is embedded within a formal six-step framework for policy-making (problem identification; definition of objectives; development of options; analysis of impacts of options; comparison of options; and ideas for monitoring and evaluation);
- IAs are mandatory for all new proposals for secondary legislation and for some other major policy initiatives, and they are based on the principles of "proportionate analysis";
- Mandatory procedural rules for the policy-making process are established, including cross-sectoral consultation within the Commission and final publication of the IAs;
- Extensive policy guidelines support the process and structure procedural requirements. These encourage officials to understand and identify indirect impacts of proposed rules; to make use of outside expertise; to consult with external stakeholders and to review alternatives rigorously. A small number of key technical assumptions are also included in the guidelines, along with ideas about possible quantification techniques for costs and benefits, including on administrative burden;
- The quality of IAs produced by officials is overseen by an IA Board in combination with other internal scrutiny mechanisms. Set up in 2006, this small group of senior Commission personnel examines draft assessments and issues opinions. It reports to the President of the Commission and works through informal, collegial processes rather than using formal powers, such as letters of return as used by the Office of Information and Regulatory Affairs in the United States.

Since 2002, the European Commission has made substantial progress in establishing one of the largest and most comprehensive IA programmes in the world. By the end of 2012, for instance, it had carried out over 500 assessments. Moreover, many of its initiatives have been highly innovative, notably the establishment of a central oversight body (IA Board)[55].

The Commission has demonstrated its ability to implement these requirements as evidenced by, for example, The European Court of Auditors conclusion that "[i]mpact assessment has become an integral element of the Commission's policy development and has been used by the Commission to design its initiatives better"[56]. It has worked to position itself as a global leader in the field of regulatory impact assessments. Continuing this commitment is particularly important when examining controversial proposals such as the TPD, as the EU seeks to defend its reputation for good decision-making.

[53] European Commission "Communication from the Commission on Impact Assessment" COM (2002) 276 final
[54] Most notably, European Commission "White Paper on European Governance" COM (2001) 428 final
[55] See European Risk Forum "Regulatory Impact Analysis" (Policy Brief 01, 2007)
[56] Section IV, Special Report No.3/2010, Impact Assessments in the EU Institutions: Do They Support Decision-Making?