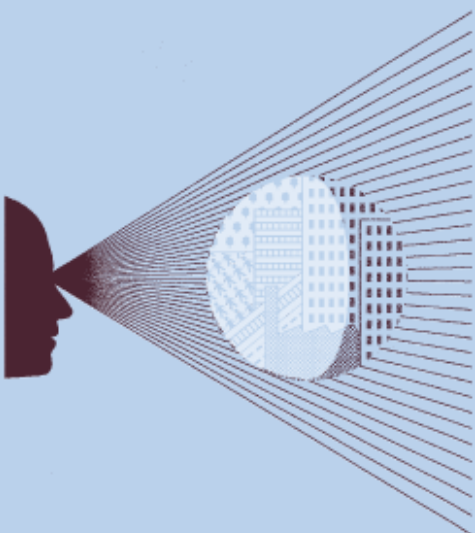


Proposed revisions to the Tobacco Products Directive

**A review of the European Commission's
regulatory impact assessment**

**Prepared for
Japan Tobacco International**

May 28th 2013



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Executive summary

This report, prepared for Japan Tobacco International, reviews the regulatory impact assessment (RIA) undertaken by the European Commission on its proposed revisions to the 2001 Tobacco Products Directive (TPD), issued in December 2012.

In light of the widespread recognition that tobacco products carry risks to health, the tobacco industry is subject to regulation. The 2001 TPD is the main tobacco product regulation at the European level. In line with regulatory best practice, the Commission has undertaken an RIA of the proposed revisions to the TPD.

The purpose of Oxera's review is to assess the RIA from the perspective of best practice in public policy, regulation (including the Commission's own guidelines for RIAs) and economic analysis. The aim is not to question the objectives behind the proposals; indeed, Oxera supports the public health objectives behind tobacco regulation. This report does not assess the merits of current scientific and consumer evidence on tobacco consumption, but it does consider the way in which the RIA refers to existing studies and whether this is in line with regulatory best practice.

Tobacco regulation is a complex field. RIAs are an important tool to evaluate the economic costs and benefits of various policy options. It is commonly accepted that these costs and benefits cannot always be identified with precision. The RIA has used various sources to inform its analysis, including experiences in other countries, bespoke economic research, and some (but not all) of the existing literature. Yet, when reviewed from the perspective of best practice in public policy, regulation and economic analysis, Oxera concludes that the RIA is not sufficiently robust and contains a number of significant shortcomings.

- The internal market is said to be the overall objective of the proposed regulations, but the choice of policies seems to be driven primarily by the public health objectives. Indeed, a number of aspects of the proposed regulations seem to go directly against criteria that are normally considered to be part of a well-functioning internal market (innovation, competition, consumer choice and cross-border trade).
- The baseline scenario is not clearly defined and is not based on (indeed it goes against) available evidence. By assuming that the current trend towards decreasing tobacco consumption will stop, the RIA unduly attributes any further reduction in consumption to the proposed regulations rather than existing regulations or other factors.
- A key public health benefit used in the RIA—2% reduction in tobacco consumption—is assumed rather than derived from analysis. The cost-benefit analysis in the RIA is applied only to the final proposed package of measures, rather than to individual areas separately, and has not been used as a tool to help decide between alternative measures. Distributional impacts and unintended consequences (eg, enhancing illicit trade) of the proposed regulations are not given sufficient weight.
- There is limited reference to evidence or analysis in the RIA to support the proposals on packaging; ingredients and other tobacco products; and track and trace. Labelling regulations may find some support in existing studies, assuming that the Commission's interpretation of this evidence is correct. However, the RIA would still need to consider the costs and benefits of alternative options to the 75% health warning size.

This is not to say that there is no underlying economic case for some of the proposed regulations, or other forms of tobacco regulation. A more robust RIA would benefit regulatory decision-making in this area.

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1 Main findings of Oxera's review

1.1 Overview and scope

This report, prepared for Japan Tobacco International (JTI), reviews the regulatory impact assessment (RIA) undertaken by the European Commission on its proposed revisions to the 2001 Tobacco Products Directive (TPD), issued in December 2012.¹

Oxera is an independent economics consultancy with more than 30 years of experience in the areas of regulation, competition and finance. We have made leading contributions to the development of RIA methodologies in Europe, and have advised the European Commission, national government bodies and private sector clients on RIAs in a variety of industries.²

Existing and proposed new regulation

In light of the widespread recognition that tobacco products carry risks to health, the tobacco industry is subject to regulation at the European, national and international level.

The 2001 TPD is the main tobacco product regulation at the European level.³ It covers areas such as health warnings, a ban on misleading descriptors, ingredients reporting, and maximum tar, nicotine and carbon monoxide yields. EU Member States have their own tobacco regulations. Several of them have gone beyond the minimum requirements of the original TPD.⁴

At the international level, the World Health Organisation (WHO) has a Framework Convention on Tobacco Control (FCTC), which has been supplemented by non-binding guidelines.⁵ A recent development is the adoption on 12 November 2012 of the Protocol to Eliminate Illicit Trade in Tobacco Products, a separate treaty opened for signature in January 2013, which is expected to come into force later in 2013.⁶

The Commission now proposes to revise the TPD. These revisions cover the following broad areas.

- **Labelling:** increasing the size of health warnings on the packaging of factory-manufactured cigarettes (FMCs) and roll-your-own tobacco (RYO) to 75% of the front and the back of the packet, including mandatory enlarged picture warnings.
- **Packaging:** packaging design restrictions for FMCs and RYO.
- **Prohibition, or authorisation, of particular tobacco products:** regulations on ingredients, a ban on menthol cigarettes and other tobacco products with a 'characterising flavour'; a prohibition on the sale of small-diameter or 'slim' cigarettes; and new rules on novel and smokeless tobacco products (STPs).

¹ European Commission (2012), '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 and related products', December; and European Commission (2012), 'Commission staff working document: impact assessment', December. The latter document is hereafter referred to as 'RIA 2012'.

² For an overview of Oxera's credentials in the area of RIAs, see Appendix 1.

³ European Commission (2001), 'Official Journal of the European Commission: Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001'.

⁴ RIA 2012, Annex 3.

⁵ More than 165 countries around the world, including all EU Member States, have signed up to the FCTC.

⁶ WHO Framework Convention on Tobacco Control (FCTC), 'Protocol to Eliminate Illicit Trade in Tobacco Products', available at http://www.who.int/fctc/protocol/illicit_trade/en/, last accessed on March 8th 2012.

- **Traceability and security features:** the introduction of an EU tracking and tracing system at packet level for tobacco products throughout the supply chain (excluding retail).⁷
- **Cross-border distance sales:** a notification obligation on the retailers of tobacco products and the introduction of an age-verification system for Internet sales.

In line with regulatory best practice, the Commission has undertaken an RIA of the proposed revisions to the TPD, which it has published alongside these proposals. As part of the Commission’s process, draft RIAs were reviewed by the Impact Assessment Board. A number of external studies were also commissioned, including economic studies from RAND Europe and Matrix Insight (hereafter referred to as RAND and Matrix).⁸

Scope of Oxera’s review

The purpose of Oxera’s review is to assess the Commission’s RIA from the perspective of best practice in public policy, regulation and economic analysis. One aspect of this is to examine whether the proposed regulations have clearly stated objectives. The aim is not to question the objectives themselves; indeed, Oxera supports the public health objectives behind tobacco regulation.

Oxera has applied an assessment framework that draws on several sources, including the Commission’s own guidelines for RIAs, principles and examples of regulatory best practice developed elsewhere, and sound economic principles of regulation—see Appendix 1.⁹

Other relevant aspects of the review are as follows.

- The review assesses whether the RIA has been carried out on an incremental basis using an appropriate baseline scenario—ie, the scenario that is expected to arise without intervention from the Commission (in economic terms also often referred to as the ‘counterfactual scenario’).¹⁰ The review also assesses whether the Commission has distinguished the impact of the proposed regulations from that of existing regulations.¹¹
- Oxera does not assess or challenge the merits of current scientific and consumer evidence on tobacco consumption and its effects on health, as cited by the Commission in the RIA. However, the review does consider the way in which the RIA refers to existing studies, and whether this is in line with regulatory best practice.

The report is structured as follows:

- overall comments on the Commission’s RIA (sections 1.2 and 1.3);
- review of labelling and packaging proposals (section 1.4);
- review of the proposed regulations covering ingredients, novel tobacco products and STPs (section 1.5);
- review of the proposed regulations in relation to ‘track and trace’ (section 1.6);
- Oxera’s overall conclusions (section 1.7);
- Appendices 1 and 2 provide more detail behind Oxera’s main findings.

⁷ RIA 2012, p. 109.

⁸ RAND Europe (2010), ‘Assessing the impacts of revising the Tobacco Products Directive’, prepared for the European Commission, September. Matrix Insight (2012), ‘Economic analysis of the EU market of tobacco, nicotine and related products’, prepared for the European Commission, May.

⁹ The Commission’s own guidelines and principles include European Commission (2009), ‘Impact Assessment Guidelines’, January; and European Commission (2006), ‘Better regulation—simply explained’.

¹⁰ In this context, incremental means the additional costs, or benefits, judged to arise from the proposed regulations and measures that are over and above those that arise from the existing regulations and measures.

¹¹ The terms ‘baseline’ and ‘counterfactual scenario’ are used interchangeably in this report. The importance of the baseline scenario is underscored in the European Commission’s RIA guidance. European Commission (2009), *op. cit.*, p. 24.

1.2 Overall comments on the RIA: approach, objectives and baseline scenario

1.2.1 The Commission's approach

Tobacco regulation is a complex field. From an economic perspective, there are several challenging and sometimes conflicting considerations when designing policies and regulations—in particular, wider health considerations surrounding tobacco consumption, the behaviour of consumers, the market interaction between suppliers and consumers, and illicit trade.

An RIA is an important policy tool to evaluate and compare the economic costs and benefits of various policy options. It is commonly accepted that these costs and benefits cannot always be identified with precision, especially when policy effects take place in the future. The Commission's RIA has used various sources to inform its analysis, including experiences in other countries with public health measures, bespoke economic research (RAND and Matrix, referred to earlier), and some (but not all) of the existing literature.

1.2.2 The Commission's objectives: internal market or public health?

A well-established principle in relation to RIAs is that it is important to be clear about the objectives of any regulatory intervention.¹²

All Commission IAs must have clear objectives which are directly related to solving the problems which have been identified.

A conceptual problem with the Commission's RIA that arises from the outset is that the objectives of the proposed regulations are unclear. On p. 1, the RIA states:

The overall objective of the revision is to improve the functioning of the internal market.

Public health is then identified as an additional objective, which is:

Taken as a basis for this impact assessment when choosing between different policy options¹³

Having two objectives, and declaring one of them (improving the internal market) as an 'overall objective', creates confusion, which affects the RIA throughout. Most of the analysis in the RIA focuses on public health objectives—this is not surprising, given that tobacco regulation elsewhere is mainly aimed at public health. In contrast, as discussed in various places in this report, in the RIA the internal market objectives appear to be of much less relevance or significance in terms of economic costs and benefits.

Indeed, a number of aspects of the proposed regulations seem to go directly against criteria that are normally considered to be part of a well-functioning internal market. Some of the proposed measures directly seek to restrict innovation, competition, consumer choice and cross-border trade.¹⁴ These measures seem, again, primarily driven by public health considerations (and Oxera therefore does not question them as such). However, this highlights that the Commission's RIA does not meet the basic requirement of being clear about the objectives of the proposed regulation.

1.2.3 The Commission's baseline scenario: clearly defined and evidence-based?

The purpose of setting out the baseline scenario is to show how the tobacco market is likely to develop without the proposed regulations. As such, it is a critical starting point for the RIA

¹² European Commission (2009), op. cit., p. 26.

¹³ RIA 2012, p. 1.

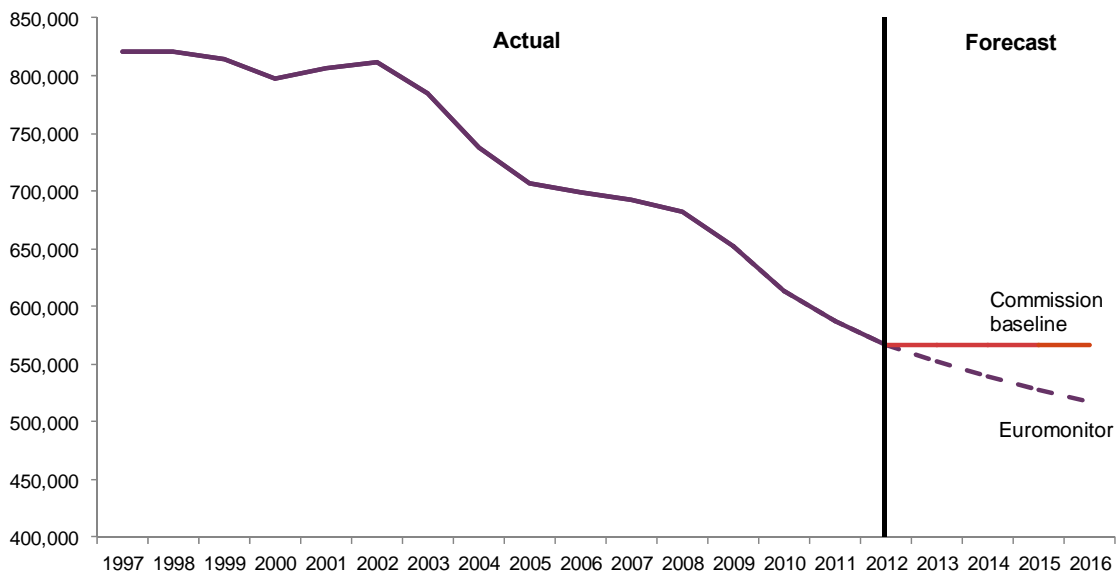
¹⁴ Appendix 1 provides an overview of the criteria used to describe a well-functioning internal market, as inferred from the Commission's other publications.

given that, in line with regulatory best practice, each proposed measure is to be assessed against this baseline scenario in order to determine its incremental costs and benefits.¹⁵

Oxera notes that the Impact Assessment Board commented on the draft RIA recommending that the Commission develop a robust baseline scenario.¹⁶ This would suggest that the baseline scenario was developed in more robust terms only in the subsequent version of the RIA (if, indeed, any further development did take place), rather than forming the starting point for the Commission’s RIA and consideration of policy options.

A significant shortcoming of the Commission’s final baseline, as presented in the final version of the RIA, is that it, in effect, assumes that the regulations currently in place will result in no further reduction in the consumption of tobacco products.¹⁷ As shown in Figure 1.1, there has been a decline in the legal sales (as a proxy for consumption) of FMCs across Europe.¹⁸ The extent to which this is due to existing regulation is not analysed here; the point is that the Commission assumes that, without further intervention, the trend will stop and consumption will remain broadly stable from its current level.

Figure 1.1 Legal sales of factory-manufactured cigarettes in Europe (millions of sticks)



Source: Oxera analysis, based on Euromonitor data and projections, and RIA 2012.

The Commission has presented no evidence to support this assumption of a changing trend. To the contrary, Euromonitor’s projections of sales of FMCs suggest that the recent decrease is likely to continue—see Figure 1.1. In its report for the Commission, RAND equally forecasts a sustained reduction in smoking prevalence.¹⁹ Both Euromonitor and RAND base

¹⁵ According to the Commission’s RIA guidelines: ‘you should list the expected positive and negative impacts of the policy options, including unintended side-effects. This presentation should be made in quantitative terms for all variables for which this is feasible, expressed in deviations from the baseline scenario.’ European Commission (2009), op. cit., p. 48.

¹⁶ RIA 2012, p. 8.

¹⁷ RIA 2012, p. 43.

¹⁸ The Euromonitor data that Oxera has available goes back until 1997, so Figure 1.1 does not show any figures and trends before then. On a separate note, throughout the RIA, the Commission refers to three measures of demand: prevalence, consumption and sales. It is important to be specific about the distinction, although not much hinges on this in Oxera’s review of the RIA. Prevalence is the percentage of the population who consume a particular product. It is likely that consumption and sales are closely related, assuming that most cigarettes sold are subsequently smoked (consumption may differ from legal sales to the extent that there is an illicit market). Trends in consumption (or sales) and smoking prevalence might differ in a scenario where fewer people smoke but where people continue to smoke, each individual smokes more cigarettes. In this report, reference to tobacco sales, consumption and prevalence rates relate to those in the legal market, unless otherwise specified.

¹⁹ RAND Europe (2010), op. cit., p. 88.

the continued decrease on the current market and regulatory situation (ie, not on any revisions to the current regulations or other factors). Indeed, the RAND projections are in its baseline scenario. More detail is provided in section A2.1 of this report.

The implication of the Commission's assumption for the outcome of the RIA is clear: if tobacco consumption continues to decrease over the next few years (as projected by Euromonitor and RAND), in the Commission's RIA that decrease will be fully attributable to the proposed regulations (rather than the existing regulations or other factors) and hence will be, unduly, counted as the consequent benefits of the new proposals.

There is a further, conceptual, shortcoming in the Commission's analysis of the baseline scenario. On p. 43 of the RIA, the Commission states:

Based on this it is assumed that the overall smoking prevalence will remain at the current level if no EU action is taken. The precise prediction of the baseline is, however, of limited relevance for this impact assessment as the impact of all measures is expressed in relative terms, ie, if the consumption/prevalence were to decrease as predicted by Euromonitor, the proposed measures would accelerate the decrease. If, on the other hand, the consumption were to remain stable, it could decrease thanks to the envisaged measures.

This logic is questionable.

- First, it introduces a circularity problem. In essence the Commission is saying here that the baseline scenario does not matter because its proposed measures will in any event reduce the consumption of tobacco products even further than the baseline. However, this defeats the purpose of the RIA, which is precisely to assess whether the proposed measures have their intended effect compared with the baseline, and to assess whether alternative measures could result in an even higher net benefit than the original proposal. Both effects cannot be assumed from the outset.
- Second, contrary to the Commission's statement, the baseline can matter in *absolute* terms (as well as just in relative terms). In theory, if a certain measure achieves a desired fall in consumption compared with a baseline of very high and/or increasing consumption, this could be regarded as more valuable than a fall in consumption with a baseline of already low and/or falling consumption.

In all, the Commission has not established a sound baseline scenario for its RIA, and unduly downplays the importance of the baseline scenario.

1.3 Overall comments on the RIA: methodology, use of assumptions and other technical aspects

1.3.1 Main costs and benefits analysed

The Commission has sought to identify overall costs and benefits assumed to arise from the introduction of its policy proposals. In line with best practice, it has taken into consideration economy-wide effects, as well as the effects on different sectors and stakeholders (to some extent—see below). For example, in relation to costs, the Commission includes the loss of taxation revenue for governments if tobacco consumption declines, while on the benefits side it considers savings in healthcare expenditure and reductions in mortality, or morbidity costs.²⁰

Indeed, the reduction in mortality, or morbidity costs, is by far the most material benefit identified by the Commission, and in this part of the RIA is assumed to arise from an increase in the number of 'healthy life years' from a reduction in tobacco consumption. It is

²⁰ RIA 2012, Annex 5, p. 26.

understood that putting a value on these assumed health benefits is not an exact science, and the Commission has followed a method based on its RIA guidelines.²¹

However, there are a number of shortcomings in the Commission's approach:

- there is a strong reliance on assumptions rather than evidence;
- no RIA is provided for individual policy options, or for variants on the proposed policy options.

Furthermore, there are a number of specific shortcomings in relation to the Commission's treatment of direct costs and of distributional and sector-specific effects. These shortcomings are discussed in turn below.

1.3.2 Reliance on assumptions rather than evidence

It is accepted in regulation that not all costs and benefits can be fully quantified. Sometimes there is no or only limited empirical evidence available to predict the effects of a proposed regulation. In these situations it can be reasonable for regulators to make informed assumptions about the costs and benefits that may arise. However, if they do so, they must make it explicit when and how such assumptions are made.

One crucial assumption in the RIA is that tobacco consumption falls by 2% within five years of the proposed regulation changes.²² This decrease may appear conservative when viewed against the trend and Euromonitor's projections as depicted in Figure 1.1. However, conservative or not, the 2% benefit assumed by the Commission has to be compared with the costs of the proposed regulations in order to assess whether the regulations are proportionate, which is the purpose of the RIA in the first place.

The 2% assumption is a key driver of the Commission's calculations of the benefits of the proposed regulations. However, it is in effect an *assumed* benefit, rather than being based on evidence or on a detailed analysis of the market and demand mechanisms by which the proposed regulations would reduce consumption. This is a significant shortcoming of the RIA.

A closer look at the three main components of this assumed 2% decrease in consumption confirms this (see Figure 14 on p. 115 of the RIA).

- The first component is an assumed decrease in the consumption of FMCs and RYO by 0.2–0.3% attributable to the proposed restrictions on nicotine-containing products (NCPs),²³ STPs and herbal products for smoking.²⁴ In line with good regulatory practice, for NCPs, the Commission acknowledges explicitly that there is a lack of evidence in this area:

It needs also to be stressed that conclusive empirical data is lacking for some of the measures, including NCP (where no electronic cigarettes have been authorised, at this stage, under the medicinal products' legislation).²⁵

²¹ Consistent with its 2009 RIA guidelines, the Commission's approach to valuing health in the RIA is based on findings from surveys and studies of the research project ExternE, establishing a 'typical' range of €50,000 to €100,000 for the value of one life year (VOLY). The Commission explains that the median value of the loss of one year's living is €52,000, irrespective of the age or country of residence of the victim, and has used this figure in its analysis. See RIA 2012, Annex 5, p. 17.

²² RIA 2012, p. 60 and Annex 5.

²³ According to the RIA, p. 15, electronic cigarettes appear to be the most commonly available type of NCP.

²⁴ The Commission assumes that restricting these other products (which are not included in the data in Figure 1.1) will have an indirect impact on the consumption of FMCs and RYO (FMC sales being shown in Figure 1,1): 'it is assumed for the purpose of this impact assessment that the combination of the preferred policy options will lead to a reduction of consumption...beyond the baseline for FMCs and RYO'. RIA 2012, p. 114.

²⁵ RIA 2012, p. 115.

This lack of conclusive evidence because a product is relatively new should not, in itself, prevent a regulator from imposing regulations on the product. However, it is not clear how the Commission has got from this starting position of lack of evidence to the assumption that consumption of FMCs and RYO will fall by 0.2–0.3% because of restrictions on these other products.

- The second component is the assumed 1–1.5% decrease in demand attributable to the proposed regulations on packaging and labelling. The Commission has not quantified this effect through an analysis of its own (eg, an analysis that would show the mechanisms through which the incremental new regulations result in a further fall in demand). Moreover, it has not used primary sources of evidence.

Instead the Commission has relied on secondary evidence from other studies and other jurisdictions (see p. 114 of the RIA). Some of these are not directly comparable as they relate to different public health measures or different regulatory and market contexts. Several of them are in themselves based on assumptions, or on ex ante projections of the assumed impact of a particular tobacco control measure, even when ex post information on the impact of that particular initiative would now be available.²⁶

Furthermore, the Commission does not provide any direct evidence on the assumed impact of packaging design restrictions on the consumption of FMCs and RYO.

- The third component is an assumed 0.5–0.8% decrease in consumption resulting from the regulations targeted at the prohibition of certain ingredients or products, including menthol cigarettes. The Commission gives the impression that there is conclusive evidence to support this assumption where this is not necessarily the case. The Commission assumes that prohibiting certain ingredients may reduce the uptake of other tobacco products, including FMCs:

The US FDA Tobacco Products Scientific Advisory Committee confirmed, on the basis of the extensive review of all available information, that the evidence was sufficient to conclude that it is more likely than not that the availability of menthol FMC increases the likelihood of experimentation and regular smoking beyond the anticipated prevalence if such FMC were not available.²⁷

Again, using the above tentative conclusion as the basis to assume that prohibiting menthol and certain other ingredients will reduce the consumption of regular tobacco products by between 0.5% and 0.8% is not robust.

Overall, the Commission's quantitative assessment on the impact of its proposed measures on the consumption of FMCs and RYO is not well evidenced. Furthermore, the mechanisms by which the assumed reduction is expected to arise are also not clearly set out.

Section A2.2 of this report analyses the impact of those assumptions on the overall cost–benefit analysis (CBA). From this analysis it is clear that the overall net benefit assumed by

²⁶ For example, the Commission refers to a UK government study mentioning a 0.5% reduction in consumption due to pictorial health warnings, but this figure itself 'was based on the assumption that warnings would have a fifth of the impact of the tobacco advertising ban'. Department of Health (2007), 'The introduction of picture warnings on tobacco packs: final regulatory impact assessment', August, p.10. The Australian study referred to by the Commission was undertaken by Applied Economics based on projected prevalence rates in 2011. Applied Economics (2003), 'Cost–benefit analysis of proposed new health warnings on tobacco products', report prepared for Commonwealth Department of Health and Ageing, December. Of the Canadian evidence presented on p. 114 of the RIA, the Commission says that 'it should be emphasized that at the time of the Canadian assessment picture-based warnings were already in use which could limit the additional impact to be expected.' As noted earlier, that same logic applies to the Commission's own RIA—the Commission needs to be explicit about the *incremental* effect of the proposed new regulation over and above the effects of the existing regulation.

²⁷ RIA 2012, p. 102.

the Commission is sensitive to the assumption of a 2% reduction in the consumption of FMCs and RYO.²⁸

1.3.3 No RIA of individual policy options

The Commission's RIA guidelines recommend that the costs and benefits of the policy options are considered alongside each other, relative to the baseline.

For all of the options you analyse (including the 'no EU action' option), you need to consider all the relevant positive and negative impacts alongside each other...thinking in terms of costs and benefits of the various options provides a powerful framework for the analysis.²⁹

An RIA is intended to inform the choice between policy options, not just as a mechanism to test the selected policy option. Yet the Commission has undertaken an overall CBA for the latter purpose only. It has not assessed all viable options in each policy area. For example, in relation to health warnings on the packaging of FMCs and RYO, the Commission has not identified or discussed any options other than to have written and pictorial health warnings that are 75% of the packaging of tobacco products—compared with the current standard of 30–40%. It has not explored whether its objectives could be met with health warnings that cover, say, 50% or 60% of the size of the packet.³⁰

In addition, the Commission has not undertaken a full CBA for each policy option, or group of options that are similar in nature. Instead it has decided on its preferred options in each area, grouped these options together, and then provided an overall CBA for those options. In following such an approach, the RIA is inconsistent with the Commission's own guidelines:

You should also avoid 'bundling' individual elements/sub-options of different options into a 'preferred' option after the analysis, as this makes it difficult to assess the impact of the preferred option as a whole against the baseline.³¹

It follows that, in line with its guidelines, the Commission should undertake a CBA for each of the areas of the proposals separately. It has not done this.

1.3.4 Treatment of direct costs

In the summary of costs and benefits from a society and governmental perspective presented in Table 3.14 of the RIA, the Commission, for reasons that are unclear, does not include the various direct costs (one-off and ongoing) to the tobacco manufacturing industry. Earlier in the RIA (pp. 122–123) the Commission does consider these additional costs (and cost savings), and they should have been included in the summary of costs and benefits of the proposals.

Oxera notes that inclusion of these costs would not change the overall picture emerging from Table 3.14, as the Commission's assumed benefits are an order of magnitude higher than the costs. It is nonetheless conceptually incorrect to exclude them, especially given the doubts about the assumptions regarding the benefits, as noted above.

1.3.5 Distributional and sector-specific effects

In the Commission's RIA the cost increases to the tobacco industry are downplayed because 'in any event additional costs are likely to be passed on to consumers taking into account the

²⁸ The Commission's RIA provides a sensitivity analysis of the 2% assumption in order to show the impact of reductions of 1%, 3%, 4% and 5% in the consumption of FMCs on the net benefit presented in its overall CBA. See RIA 2012, Annex 5, p. 31.

²⁹ European Commission (2009), op. cit., p. 45.

³⁰ Indeed, RAND's report for the Commission (referred to above) shows that the incremental benefits related to health warnings that are 50% of the packaging (p. 221) are exactly the same as health warnings that are 75% of the packaging (p. 229). Furthermore, the 75% option may have an additional cost related to the 'impact on brand equity for branded producers (p. 229)'. It is not clear why the Commission appears not to have considered this part of the RAND report in the RIA (to the extent that it is not mentioned therein). The Commission considers the option of plain packaging, and rejects it.

³¹ European Commission (2009), op. cit. January, p. 31.

significant market power of the tobacco manufacturers'.³² Likewise, revenue losses to the tobacco industry are downplayed because 'money not spent on tobacco is expected to be spent on other sectors which would then benefit'.³³

In a similar vein, in relation to government taxation revenues, the Commission states that:

Disregarding VAT appears justified as money not spent on tobacco products is expected to be spent on other goods and/or services, which in turn generate VAT. From this perspective, a reduction in tobacco consumption should be 'VAT neutral'.³⁴

From a policy perspective, however, the Commission's general approach to assume away distributional impacts is not consistent with best practice in developing RIAs. In general, while it is an important objective of an RIA to consider the overall net costs and benefits to the economy, it is also relevant to consider how different economic stakeholders may be affected in different ways. Distributional and sector-specific effects do matter in this regard. They need to be made explicit in any overall summary of the costs and benefits of a proposed regulation. It also needs to be made explicit whether the costs and benefits to any particular sector are given the same weight as, or less or more weight than, the costs and benefits to other sectors.

Using the same logic as above, in respect of the impact of the proposals on employment in different sectors, the RIA states that:

In terms of employment it is estimated that jobs lost in tobacco will be off-set by jobs gained in other sectors, as money not spent on tobacco is spent on other goods/services.³⁵

The Commission's assumption about the impact on employment is based on an input-output analysis, which in turn is based on analysis originally undertaken in the Matrix report.³⁶ Input-output analysis is a tool that is commonly used in RIAs. The main observations from a methodological review of the Matrix analysis are provided in Appendix 2 of this report.

In the extreme, the Commission's approach to downplay distributional and sector-specific effects would mean that any policies aimed at promoting (rather than curtailing) a specific sector would be less likely to meet the RIA test. That is to say, any RIA of a policy to promote, say, broadband uptake or a particular agricultural region, would not count the revenue or employment benefits to that activity as a RIA benefit because it means less money spent and workers employed elsewhere. From a pure net economic welfare perspective there may be a case for this, but it is not how sector policies and regulations are generally evaluated.

Moreover, the fact that costs and benefits are passed up or down the vertical supply chain does not mean that they are irrelevant. For the purpose of a RIA, a direct cost caused by a new regulation is always a net cost to the economy, regardless of where it originates in the chain.³⁷

³² RIA 2012, p. 122.

³³ RIA 2012, p. 123.

³⁴ RIA 2012, Annex 5, p. 26. Oxera notes that the premise that the reduction in tobacco consumption is tax-neutral is questionable; this is because tobacco products tend to generate proportionately higher tax than most other products. Oxera has not analysed this effect further.

³⁵ RIA 2012, p. 124.

³⁶ Matrix Insight (2012), op. cit.

³⁷ Oxera also notes that the Commission's economic logic on pass-on (cited above) is not in line with economic theory. Full-cost pass-on normally occurs in perfectly competitive markets. In markets where firms have market power, pass-on is not full. (It is also noted that the Commission does not substantiate the comment that tobacco manufacturers have significant market power.) See Oxera and a multi-jurisdictional team of lawyers led by Dr Assimakis Komninos (2009), 'Quantifying antitrust damages:

1.3.6 Unintended consequences: are these taken into account?

Unintended consequences often arise whenever new regulations are introduced. In any RIA, it is good practice to identify such unintended consequences so that they can be minimised (if they are negative unintended consequences). Indeed, the Commission's RIA guidelines explain that:

In your analysis of impacts, you should address the likely economic, social and environmental impacts—both intended and unintended—for each option, as well as potential trade-offs and synergies.³⁸

One unintended consequence that may arise from the Commission's proposals—particularly the proposed ban on certain products (eg, menthol cigarettes)—is a possible increase in illicit trade. This is a common economic phenomenon: prohibiting the supply of a product for which there is demand tends to drive up its price, and hence attracts illicit supplies.

There are three main types of illicit tobacco product:³⁹

- **contraband**: which the Commission defines as products that have been diverted into illicit trade, not respecting the legal requirements in the jurisdiction of destination;
- **counterfeit**: which the Commission defines as brand-protected products that have been falsified without the brand owner's consent;
- **cheap or illicit whites**: which the Commission defines as cigarettes produced (often legitimately) in their country of origin at very low cost, destined to be sold illegally in other jurisdictions and not respecting the legal requirements in the jurisdiction of destination.

Oxera has no particular expertise in analysing the workings and drivers of illicit trade. However, there appears to be no obvious basis for the Commission's statement that:

It is important to underline that the preferred policy options do not—in the assessment of the Commission—lead to increased illicit trade.⁴⁰

Indeed, this statement also appears inconsistent with a statement made elsewhere in the RIA in the context of menthol cigarettes:

Sales lost from menthol cigarettes would therefore be partially off-set by sales of other FMC or by efforts to acquire the products outside the EU or illicitly.⁴¹

Illicit trade is further discussed in section 1.6. Some of the proposals put forward by the Commission do seek to tackle aspects of the illicit market for FMCs and RYO (in particular the proposals on the 'track and trace' system—see section 1.6 below). However, this is separate from the RIA's omission to consider possible unintended consequences of prohibiting products.

1.3.7 The main policy areas compared

The Commission's proposals cover the following broad areas: labelling; packaging; the prohibition, or authorisation, of particular tobacco products; and traceability and security

towards non-binding guidance for courts', study prepared for the European Commission Directorate General for Competition, December.

³⁸ European Commission (2009), op. cit., p. 31.

³⁹ RIA 2012, 'Glossary of terms' provides all definitions.

⁴⁰ RIA 2012, p. 6.

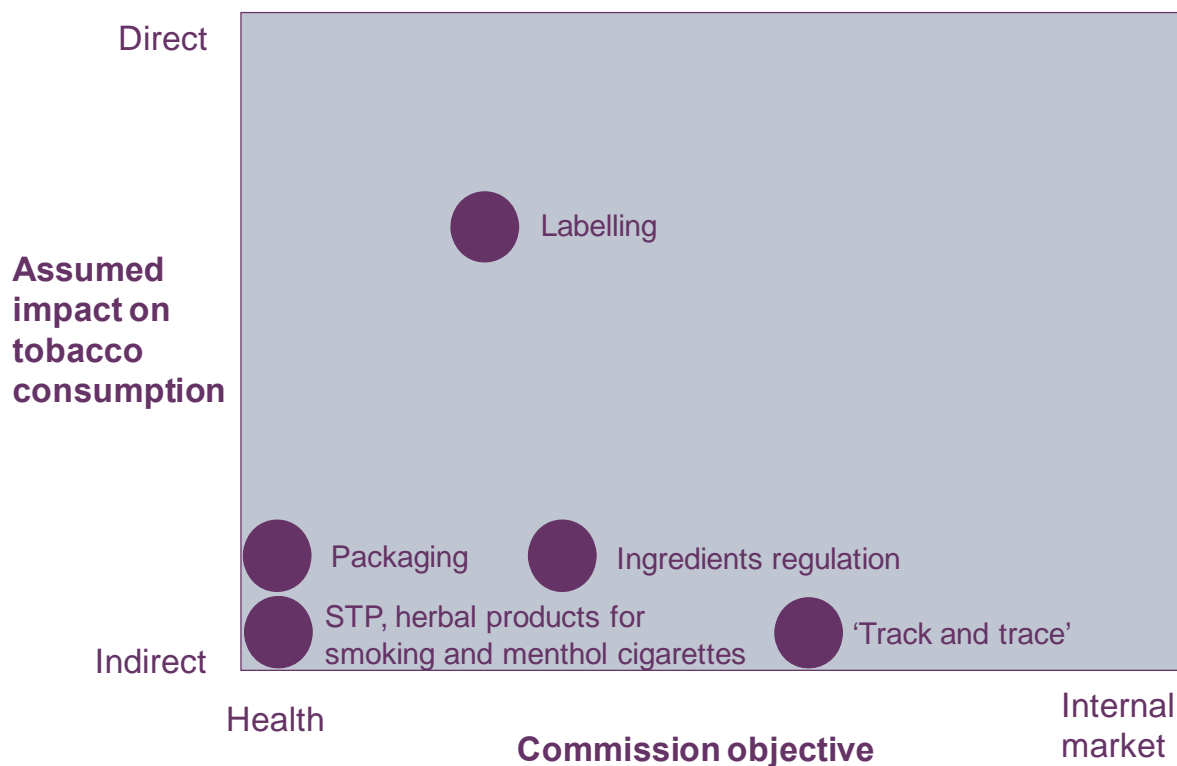
⁴¹ RIA 2012, p. 101.

features.⁴² In the following sub-sections (1.4 to 1.6) Oxera assesses these areas separately, given the differences between them with respect to:

- the objectives of each proposal (internal market or public health); and
- how each proposal is assumed to affect (directly or indirectly) the consumption of regular tobacco products, which the Commission defines as FMCs or RYO.

Figure 1.2 gives an overview of Oxera’s assessment in this area based on the RIA and the Commission’s interpretation of the evidence presented. The reasoning behind this assessment is set out in the next sub-sections.

Figure 1.2 Overview of the Commission’s proposals



Source: Oxera analysis based on the RIA and the Commission’s interpretation of the evidence.

⁴² The Commission’s regulations on cross-border distance selling are not considered in this report.

1.4 Proposed measures on labelling and packaging

1.4.1 Labelling restrictions

Objectives

The Commission explains that its proposals in this area relate to both the internal market and public health objectives.⁴³

Proposal

The proposal involves increasing the size of health warnings on the labels of FMCs and RYO tobacco packets from a minimum of 30% to 75%⁴⁴ on the front and back of the cigarette packet, and mandating pictorial health warnings.⁴⁵

Baseline scenario

Regulations on labelling are already in place. Article 5 of the 2001 TPD provides for mandatory text warnings covering no less than 30–40% of the packet, with an option for Member States to introduce stricter rules and pictorial warnings.

All Member States are currently compliant with the TPD, as set out in Annex 3 of the RIA. For its baseline scenario, the Commission assumes that disparities in the size and form of health warnings are likely to increase, and that this is to the detriment of the internal market.⁴⁶

Assessment against the internal market objective

The Commission considers that allowing each country to decide on the size (30–40% compared with 75%) and form (written versus pictorial) of health warnings will lead to growing disparities in tobacco regulations across the EU Member States. It sees this as an obstacle to the free movement of goods across Member States and to additional compliance costs for the industry.⁴⁷

From an economic perspective, the significance of these effects is questionable, especially when compared with the intended public health effects. In theory, uniform product labelling requirements can save supply costs and enhance cross-border trade in that product.⁴⁸ However, enhancing cross-border trade in tobacco products does not seem to be a prime objective here, and the potential for cost savings seems limited. (Oxera has not sought to quantify these cost savings; neither has the Commission).⁴⁹ The idea that there can be substantial benefits to the internal market from standard labels, in terms of reduced production or compliance costs, appears to have limited support. The labelling regulations seem to be more related to public health objectives.

⁴³ RIA 2012, pp. 31 and 33.

⁴⁴ The Commission explains that 'the exact size of the warning (75%) has been suggested after thorough analysis of scientific evidence and international experience (Canada, Australia, New Zealand, Uruguay, Mauritius and Mexico) and developments as well as the impact on economic stakeholders', RIA 2012, p. 97. The extent to which the labelling regulations in these countries represent best practice is unclear from the RIA.

⁴⁵ RIA 2012, p. 97.

⁴⁶ RIA 2012, pp. 34 and 40.

⁴⁷ RIA 2012, pp. 34 and 40.

⁴⁸ In this regard one may ask whether labelling can ever be uniform across EU Member States, given that manufacturers have to display health warnings in the main languages spoken in the country of sale (only pictorial warnings can be uniform). The RIA (p. 106) states that 'the protection against illicit supply and protection of young people would be improved and more consumers would obtain products complying with the TPD, including with warnings in their own language.' In addition, the new proposals do not necessarily lead to a fully uniform labelling size, as Member States are able to go beyond the new requirements in the TPD.

⁴⁹ The RIA gives some estimates for the cost increases to the industry of changing the labelling requirements and introducing pictorial warnings, but not on the cost decreases from economies of scale. RIA, pp. 87–88. It is not clear where the evidence refers to the effect of pictures, or the effect of pictures and health warnings, so the link to the effect of the policy proposals cannot be made directly.

Evidence base

The Commission notes that its proposals are also expected to have an indirect impact on stakeholders and national governments:

As explained the various policy options are expected to impact the economic stakeholders and Governments not only in a direct manner (e.g. costs/benefits associated with the implementation of the measure), but also in an indirect manner. Over time the proposed measures are expected to impact on peoples' awareness on the risks associated with tobacco products, which in turn will lead to a change in behaviour.⁵⁰

Indeed, the stated purpose of health warnings on cigarette packaging is to remind smokers of the health risks of smoking. The warnings are intended to affect an individual's decision about whether to consume FMCs and RYO. As such, one would expect the RIA to contain evidence on the impact of the proposals on the behaviour of consumers of FMCs and RYO. The Commission refers to several studies and explains that:

scientific evidence also suggests that bigger pictorial warnings on both sides are more effective than text-only warnings on a range of outcomes, including being a deterrent for new smokers.⁵¹

Oxera has not sought to review or verify the findings in these studies, but notes the following.

- It is important to demonstrate that: i) there is an 'information gap' among consumers about the health risks of smoking; ii) providing information, in the form of larger, or pictorial, health warnings, will reduce this gap; and iii) reducing this gap changes consumer behaviour.
- Similarly, it is important to ascertain whether mandating larger health warnings on cigarette packets, or other such measures aimed at changing behaviour, has a value that is incremental to existing measures—eg, targeted advertising or education campaigns, and health warnings in places where people smoke.

It is also not clear that the Commission has identified whether an 'information gap' currently exists among consumers about the health risks of smoking. Assuming that such an information gap does exist and that the Commission's proposals will change consumer behaviour, it is appropriate to consider what change in behaviour might arise.⁵²

In this regard, the Commission refers to secondary evidence from the UK, USA, Canada and Australia. As discussed in section 1.3, most of the assumptions used by the Commission are based on ex ante projections of the impact of particular tobacco control measures from other RIAs, rather than ex post evidence of the actual impact of such tobacco control measures.

As also noted in section 1.3, there is a question about whether health warnings that are 75% of the packaging of FMCs and RYO will deliver additional benefits over and above health warnings of other sizes, including the existing 30–40% requirement. In its analysis for the Commission, RAND projected no additional benefits in moving from health warnings that are 50% of the packaging to 75%. Indeed, RAND predicted an additional cost related to a loss in branding for the 75% option as compared with smaller warnings.⁵³

A further point on the incremental benefits of the proposed regulations is the finding in the studies quoted by the Commission that the impact of health warnings tends to diminish over

⁵⁰ RIA 2012, p. 113.

⁵¹ RIA 2012, p. 31.

⁵² For the present purposes, Oxera assumes that the body of evidence cited by the Commission sufficiently supports the above two points.

⁵³ RAND Europe (2010), op. cit., pp. 221 and 229.

time (the ‘wear-out effect’).⁵⁴ The Commission notes that regular rotations and updates of the health warnings and messages tend to increase effectiveness. These measures are already prescribed in the current TPD, so the new proposals do not add any incremental benefits in this regard.

Overall assessment

- There seem to be a number of factors that could in principle favour labelling regulations, assuming that the Commission’s interpretation of the underlying evidence is correct—namely, that the size and form (written versus pictures) of health warnings on cigarette packets can affect consumer behaviour and tobacco consumption.

However, the current RIA is not sufficiently robust, in that:

- the internal market costs and benefits (as distinct from the public health costs and benefits) considered by the Commission do not seem to be significant;
- the Commission has not compared options for health warnings of different sizes and how these relate to the evidence cited. It proposes the 75% option, but not, for example, the 50% option (even though RAND finds that the 75% option produces no additional benefit, but does have additional costs). The Commission does consider the option of plain packaging, and rejects it.⁵⁵

1.4.2 Packet design restrictions

Objectives

The proposal for packet design restrictions appears to be aimed at complementing the Commission’s labelling proposals. This is because the Commission’s rationale is that the size and shape of the packaging of FMCs and RYO can detract from the effectiveness of health warnings.

Some of the current packet shapes make it difficult to effectively display health warnings affecting negatively the visibility and legibility of the warning.⁵⁶

As such, the objectives for packaging design restrictions are the same as those for labelling. However, given that the proposal is related to ensuring that the content of the warning is visible, and has limited internal market benefit, the proposal is even more likely to be related to the Commission’s health objective. The Commission also discusses tobacco packaging in respect of the ‘appealing’ nature of particular packaging (new ‘lip stick packets’), which may influence the consumers of such tobacco products—again, this relates to the public health objective.⁵⁷

Proposal

The Commission proposes to mandate that the packets of FMCs must be cuboid in shape and hold a minimum number of cigarettes per packet. Furthermore, it proposes to introduce standards for the materials used and the style of the opening of FMCs—ie, a ‘flip-lid’ opening.⁵⁸

Baseline scenario

Given the flexibility currently available to manufacturers of FMCs, the Commission is concerned about the trend towards innovative packet shapes that may detract from health warnings on FMCs or could encourage people to start smoking. In the baseline scenario,

⁵⁴ RIA 2012, p. 90.

⁵⁵ RIA 2012, p. 55 and pp. 93–96.

⁵⁶ RIA 2012, p. 31.

⁵⁷ RIA 2012, p. 41.

⁵⁸ RIA 2012, p. 91.

therefore, the Commission expects the trend towards innovative packaging to continue, which it considers may have health implications.

Assessment against the internal market objective

From an economic perspective, in a well-functioning market it would be for suppliers, driven by buyer demand and cost considerations, to decide on the appropriate size and shape of the product packaging. Introducing new and innovative packaging is also normally seen as a pro-competitive tool in well-functioning markets.⁵⁹

While the Commission considers that the manufacturers of FMCs could benefit from economies of scale if there are packaging design restrictions on FMCs, it has not explored whether in this case manufacturers are currently really hindered from obtaining such economies of scale. As such, the internal market costs and benefits are likely to be small.

As a separate point, it seems that the Commission has not considered the impact of its proposed packet design restrictions on the ease of replication of the packets, and hence on illicit trade (a possible unintended consequence of prescribing more homogeneous packaging).

Evidence base

The evidence presented by the Commission does not directly test its packet design proposals, given that the evidence cited in the RIA essentially appears to focus on the marketing properties of the packaging of FMCs in the context of plain packaging.⁶⁰ Furthermore, the Commission provides no evidence on the percentage reduction in the consumption in FMCs and RYO that may arise from packaging design restrictions.

Overall assessment

No direct evidence is provided on the impact of packet size and shape on the consumption of FMCs, and the Commission has not undertaken a CBA in this area. From an economic perspective, imposing packaging design restrictions goes against the principles of well-functioning markets. The possible effect on facilitating illicit trade has also not been considered fully in the RIA.

1.5 Prohibition, or requirement for authorisation, of tobacco products and ingredients

Proposal

The Commission proposes to subject a number of products or product types to an outright ban, or otherwise to require authorisation before they are made available in the tobacco market in the EU—see Box 1.1.

Box 1.1 Proposed prohibition, or requirement for authorisation, of tobacco products and ingredients

- Prohibit tobacco products with characterising flavours (eg, menthol), or products with increased toxicity or addictiveness.
- Maintain ban on oral tobacco.
- Subject NCPs above a certain threshold to medicinal products legislation (authorisation).
- Subject all novel tobacco products to a notification (or authorisation) obligation and all STPs to stricter labelling and ingredients regulations and an authorisation regime.
- Ban on slim FMCs.⁶¹

⁵⁹ In this market, the Commission seems concerned that innovation can be aimed at 'misleading' consumers. RIA 2012, p. 91.

⁶⁰ RIA 2012, p.11 refers to The Centre for Tobacco Control Research (2012), 'The Packaging of Tobacco Products', March.

⁶¹ The preferred option in the RIA proposes that: 'the tobacco labelling and packaging and the tobacco product itself shall not include any promotional and misleading elements (e.g. misleading colours, symbols, slim FMC)', RIA 2012, p. 91. Furthermore,

Objectives

The Commission's rationale for regulations on STPs, NCPs and novel tobacco products appears to be more to do with health objectives than internal market objectives.⁶² For example, in the case of STPs, the Commission emphasises that:

the question is whether these products can act as entry gates into tobacco consumption.⁶³

The Commission is less clear-cut on its proposals for ingredient regulations. It emphasises the health concerns:

Additives that facilitate deeper inhalation (e.g. menthol) or inhibit the metabolism of nicotine may enhance the addictiveness of nicotine indirectly⁶⁴

but also notes the internal market objectives:

Economic stakeholders are/would be faced with unnecessary compliance costs in terms of country specific familiarisation, reformulations of tobacco products and different production lines for different member states.⁶⁵

Baseline scenario

The Commission expects the market for STPs, NCPs and novel tobacco products to grow in the future.

The rapid development of the traditional STP (oral, chewing and nasal) market is likely to continue under the baseline scenario (new brands, new flavours, new attractive packaging)...In addition, the development of tobacco-free products such as NCP (notably electronic cigarettes)...is expected to continue and even intensify.⁶⁶

In relation to the development of ingredients in cigarettes, the RIA notes that:

Further market development as regards ingredients for combusted tobacco is expected to continue in coming years, in particular in light of the recent development of distinctive flavoured tobacco products.⁶⁷

It is worth noting that the Commission does not develop the baseline in the RIA for the above areas beyond the qualitative assessment set out above—ie, it does not attempt to quantify the pace of growth in these markets.

Evidence base

In relation to qualitative evidence, STPs, NCPs and menthol ingredients are assumed to have an indirect impact on the consumption of regular tobacco products:

It is assumed for the purpose of this impact assessment that the combination of the preferred policy options will lead to a reduction of consumption...beyond the baseline for FMCs and RYO.⁶⁸

However, the mechanism by which the Commission assumes that the regulation of such products will affect the consumption of regular tobacco products is unclear from the RIA.⁶⁹

in relation to the proposed regulations, the Commission states that: 'most FMC currently on the market comply with a standard format, but products with a misleading size ("slim") would be affected', RIA 2012, p. 92.

⁶² RIA 2012, pp. 23–29.

⁶³ RIA 2012, p. 26.

⁶⁴ RIA 2012, p. 37.

⁶⁵ RIA 2012, p. 37.

⁶⁶ RIA 2012, p. 40.

⁶⁷ RIA 2012, p. 41.

⁶⁸ RIA 2012, p. 114.

In relation to the quantitative evidence on the impact of STPs, the RIA notes the following:

There is not conclusive evidence as regards the substitution between STP (including novel non-combusted tobacco products) and smoking products and it is therefore not possible to draw any firm conclusion whether the expected increase in STP use will have an impact on the smoking prevalence.⁷⁰

Furthermore, in respect of the impact of NCPs, including electronic cigarettes, on the consumption of FMCs and RYO, the RIA notes:

It needs also to be stressed that conclusive empirical data is lacking for some of the measures, including NCP (nicotine containing products).⁷¹

The evidence that NCP regulation will reduce the consumption of regular tobacco products is therefore unclear. In relation to the prohibition of particular tobacco ingredients and cigarettes, the RIA states that:

The US FDA Tobacco Products Scientific Advisory Committee confirmed, on the basis of the extensive review of all available information, that the evidence was sufficient to conclude that it is more likely than not that the availability of menthol FMC (factory manufactured cigarette) increases the likelihood of experimentation and regular smoking beyond the anticipated prevalence if such FMC were not available.⁷²

Overall, from the review of the Commission's RIA, it would seem that the assumption that the prohibition, or authorisation, of these products or ingredients will affect the consumption of regular tobacco products is not based on strong evidence. The Commission's assumption that the proposals will reduce the consumption of regular tobacco products, including FMCs and RYO, is therefore uncertain.

As regards other aspects of the CBA, while prohibiting menthol cigarettes and introducing ingredient regulations may reduce costs for the manufacturers of tobacco products, the revenue side of the equation is not considered in the RIA. A ban on menthol cigarettes, for example, may reduce costs from a compliance viewpoint, but it implies a lost revenue stream to manufacturers. The categories of costs and benefits must be made explicit in the RIA (as also noted in section 1.3).

Finally, an outright ban on menthol cigarettes and other products may have the unintended consequence of stimulating illicit trade in such products, as set out in section 1.2. The Commission dismisses such an outcome, but its reason for doing so is not developed.

Overall assessment

As discussed above, the CBA in the RIA is undertaken for the overall package of proposed regulations put forward by the Commission, rather than for separate policy options. The prohibition, or requirement for authorisation, of tobacco products and ingredients is a distinct policy measure that would merit its own RIA. Such an RIA ought to be more explicit about the assumed link between the consumption of STPs, NCPs and menthol ingredients and the consumption of regular tobacco products. It would also need to address more specifically the impact on the current menthol cigarette market, on costs and lost revenues from these measures, and on any potential (unintended) effect on illicit trade.

⁶⁹ For example, it is not clear whether the Commission assumes that regulating such products will reduce the consumption of FMCs given that STPs, NCPs and menthol ingredients may act as 'entry' gates to the consumption of FMCs. See RIA 2012, p. 26. Indeed, this actually contradicts reasoning elsewhere in the RIA in relation to STPs, where the Commission appears to assume that such products will act as a cessation aid for consumers of FMCs: 'the contribution to the reduced smoking prevalence from policy area "STP and extension of the product scope" is primarily expected to result from the possibility that e-cigarettes can develop a potential as a smoking cessation aid under the preferred option', RIA 2012, p.115.

⁷⁰ RIA 2012, p. 44.

⁷¹ RIA 2012, p. 115.

⁷² RIA 2012, p. 115.

1.6 Tracking and security features

Objectives

The Commission's objective in this area relates to reducing the size of the illicit market in tobacco products. The Commission considers that there is also an indirect impact on health, in that:

It strengthens the legal supply chain and ensures that consumers benefit from the safeguards of the TPD.⁷³

Proposal

The Commission's proposal aims to reduce the number of authentic products that reach the illicit market—ie, contraband products. Part of the proposal is to introduce a new 'track and trace' system to enable FMCs and RYO to be tracked throughout the supply chain (excluding retail).⁷⁴

Baseline scenario

The Commission has not provided a baseline scenario for its track and trace policy proposals. It is not clear whether the baseline is:

- a continuation of the current agreements between the Commission, the EU Member States and each of the four largest tobacco manufacturers; or⁷⁵
- different Member States implementing their own track and trace systems—ie, as may happen once the Protocol to Eliminate Illicit Trade is in force.

As such, given that there is no baseline, it is not possible to compare the incremental costs and benefits of the Commission's policy proposals in this area.

Evidence base

The Commission proposes to introduce a new data system so that tobacco products (at the packet level) can be tracked as they progress through the supply chain.⁷⁶ It explains that:

Due to the existing agreements between the four largest tobacco manufacturers and the EU and participating member states...the largest tobacco manufacturers are already implementing some of the requirements foreseen under option 1 and additional costs (eg, associated with the outsourcing of the data storage are considered proportionate when compared with the existing contractual obligations (tracking and tracing at packet level).⁷⁷

The RIA gives the impression that the current system would require only minor adaptation to enable cigarettes to be tracked at the packet⁷⁸ level and that the system is fit for purpose. However, Oxera understands that the existing system under the above-mentioned agreements is very different from that proposed by the Commission—eg, it would apply

⁷³ RIA 2012, p. 110.

⁷⁴ RIA 2012, p. 109.

⁷⁵ A summary of the agreements is provided on the Commission's website, which explains that: 'To address the problem of contraband and counterfeit cigarettes, the anti-fraud office of the European Commission (referred to as OLAF) has signed legally binding and enforceable agreements with the world's 4 largest tobacco manufacturers, in which they agree...to prevent their products from falling into the hands of criminals by supplying only those quantities required by the legitimate market, taking care that they sell to legitimate clients only and implementing a tracking system to help law enforcement authorities if cigarettes are traded illegally', OLAF (2013), available at http://ec.europa.eu/anti_fraud/investigations/eu-revenue/cigarette_smuggling_en.htm, accessed March 19th 2013.

⁷⁶ RIA 2012, pp. 109–113.

⁷⁷ RIA 2012, p. 109.

⁷⁸ The Philip Morris International (PMI) agreement includes a definition for a cigarette 'pack', which is 'a small package containing approximately 20 cigarettes'. PMI (2004), 'Anti-contraband and anti-counterfeit agreement and general release', July, p. 8.

across the wholesale supply chain rather than just the first level of wholesaling after manufacturing.

The Commission has not considered the costs and benefits of the current system, and the incremental benefits and costs that may arise from its proposals. As such, it is not clear that the incremental benefits—in terms of a further reduction in the trade in illicit FMCs—will be material. This is partly because track and trace addresses intra-EU contraband, which is only one of three types of illicit trade—as noted in section 1.2.⁷⁹

Furthermore, it is not clear that the Commission has considered all the options available, including a continuation of the current agreements. From an economic perspective, industry-wide international standardisation of systems such as track and trace can in principle be efficient. However, a government authority unilaterally selecting and imposing one standard often does not lead to the optimal outcome.

Overall assessment

The Commission has not developed a baseline scenario and has therefore not considered the incremental costs and benefits of introducing a new track and trace system—ie, over and above the current track and trace system. The incremental costs may well be high (given the nature of the proposed system), while the benefits may be limited since the proposed system deals only with the intra-EU contraband part of the illicit trade problem, and not with counterfeits and illicit whites. Indeed, there is no analysis to identify the scale of the problem to be addressed by the Commission’s track and trace proposals.

1.7 Oxera’s overall conclusions

In sum, Oxera concludes that, when reviewed from the perspective of best practice in public policy, regulation and economic analysis, the Commission’s RIA is not sufficiently robust and contains a number of significant shortcomings.

- The internal market is stated as the overall objective of the proposed regulations, but the effects are primarily related to public health objectives.
- The baseline scenario is not clearly defined and is not based on (and indeed goes against) available empirical evidence. By assuming that the recent trend towards decreasing tobacco consumption will stop, the RIA may unduly attribute any further reduction in consumption to the proposed regulations rather than existing regulations or other factors.
- There are a number of shortcomings in the Commission’s method and use of assumptions. A key public health benefit used in the RIA—the 2% reduction in tobacco consumption—is assumed rather than derived from analysis. The cost–benefit analysis in the RIA is applied only to the Commission’s final proposed package of measures, rather than as a tool to help decide between alternative measures.
- There is limited reference to evidence or analysis in the RIA to support the proposals on packaging; ingredients and other tobacco products; and track and trace. Labelling regulations may find some support in existing studies, assuming that the Commission’s interpretation of this evidence is correct. However, the RIA would still need to consider the costs and benefits of alternative options to the 75% health warning size—eg, whether its objectives could be met with health warnings that cover, say, 50% or 60% of the size of the packet.

⁷⁹ The Commission’s proposals would only deal with contraband that originated from within the EU—ie, intra-EU contraband, not that which originated from outside the EU.

This is not to say that there is no economic case for some of the proposed regulations, or other forms of regulation; nor does Oxera question the public health objectives behind tobacco regulation. A more robust RIA would benefit regulatory decision-making in this area.

A1 Background and framework for Oxera's review of the RIA

A1.1 Oxera's credentials and experience

Oxera is an independent economics consultancy based in Oxford, London and Brussels with more than 30 years of experience in the areas of regulation, competition and finance. During this period, Oxera has built a track record and reputation in analysing public policy, price controls, developing regulatory frameworks in a number of sectors such as energy, water, transport, communications, financial services and health. Oxera has also carried out a number of influential policy, regulation and competition studies for the European Commission, including studies on guidance to courts on quantifying antitrust damages and on methods for developing counterfactual scenarios in restructuring state aid cases.⁸⁰

We have made leading contributions to the development of RIA methodologies in Europe, and have advised the European Commission, national government bodies and private sector clients on RIAs in a variety of industries.

Our work on RIAs covers three broad areas:

- developing RIA methodologies for government bodies and regulators;
- reviewing RIAs completed by the European Commission on behalf of other parties.
- developing RIAs on behalf of public authorities and private sector clients.

Examples of our RIA experience that are in the public domain include the following.

- A methodology developed for the UK Financial Services Authority (FSA) on the framework for assessing the benefits of financial regulation.⁸¹
- A conceptual framework developed the Dutch Ministry of Economic Affairs on the costs and benefits of market regulators.⁸²
- A fundamental review of the generic drugs market for the UK Department of Health.⁸³
- A review of the European Commission's economic impact assessment for the introduction of a financial transaction tax.⁸⁴
- A study on the impact of the introduction of secondary trading at community airports, prepared for the European Commission in association with Mott MacDonald.⁸⁵
- An economic review of ownership rules of audit firms and the consequences for audit market concentration, prepared for the Directorate General for Internal Market and Services.⁸⁶
- Economic study on interoperability, service diversity and business models in digital broadcasting markets, prepared for the European Commission.⁸⁷

⁸⁰ Oxera (2009), 'Quantifying antitrust damages, towards non-binding guidance for courts', study prepared for the European Commission, December; and Oxera (2009), 'Should aid be granted to firms in difficulty? A study on counterfactual scenario to restructuring state aid', prepared for the European Commission, December.

⁸¹ Oxera (2006), 'A framework for assessing the benefits of financial regulation', report prepared for the Financial Services Authority, September.

⁸² Oxera (2004), 'Costs and benefits of market regulators, part 1: conceptual framework', report prepared for the Ministry of Economic Affairs, October.

⁸³ Oxera (2001), 'Fundamental review of the generic drugs market', report prepared for the Department of Health, July.

⁸⁴ Oxera (2011), 'What would be the economic impact of the proposed financial transaction tax on the EU? Review of the European Commission's economic impact assessment', report prepared for the association for financial markets in Europe; Assosim (Italian Association of Financial Intermediaries); Nordic Securities Association (NSA), December.

⁸⁵ Mott MacDonald, in association with Oxera (2006), 'Study on the impact of the introduction of secondary trading at community airports', prepared for the European Commission, November.

⁸⁶ Oxera (2007), 'Ownership rules of audit firms and their consequences for audit market concentration', report prepared for the Directorate General (DG) Internal Market and Services, October.

- Assessing the impact on market structure and competition of the proposals that emerged from the retail distribution review, on behalf of the FSA.⁸⁸
- CBA of introducing competition into the Brazilian capital markets, prepared for the Securities and Exchange Commission of Brazil.⁸⁹
- Assessing the impact of mortgage lending reforms, prepared for the FSA.⁹⁰

A1.2 Oxera's assessment framework

In order to assess the Commission's RIA, an assessment framework has been developed, taking into account a number of aspects:

- the European Commission's own guidelines on RIAs;⁹¹
- the recommendations of the Impact Assessment Board;⁹²
- consistency with economic principles, as identified from Oxera's own experience in developing RIAs, academic textbooks⁹³ and other publications on RIAs;⁹⁴
- European Commission documents on the internal market.⁹⁵

A1.2.1 The European Commission's own guidelines on RIAs

As a starting point, the Commission has set out the criteria for assessing policy options, including effectiveness, efficiency and coherence:⁹⁶

- **Effectiveness**—the extent to which the options achieve the objectives of the proposal.
- **Efficiency**—the extent to which objectives can be achieved for a given level of resources/at least cost (cost-effectiveness).
- **Coherence**—the extent to which options are coherent with the overarching objectives of EU policy, and the extent to which they are likely to limit trade-offs across the economic, social and environmental domain.

Other criteria implicit in the Commission's guidelines include the following.

- **The evidence base**—the baseline scenario and the impact of the policy options need to be well evidenced. The impact of recent or expected future developments is to be included in the baseline—eg, the impact of existing or new regulations.⁹⁷
- **Quantification of the baseline and individual options**—the guidelines explain that the baseline and the impact of individual policy options should, as far as possible, be quantified and/or expressed in monetary terms.⁹⁸

⁸⁷ Oxera (2003), 'Study on interoperability, service diversity and business models in digital broadcasting markets', report prepared for the European Commission, February.

⁸⁸ Oxera (2010), 'Retail distribution review proposals: impact on market structure and competition', March.

⁸⁹ Oxera (2012), 'What would be the costs and benefits of changing the competitive structure of the market for trading and post-trading services in Brazil?', report prepared for Comissão de Valores Mobiliários, June.

⁹⁰ Oxera (2010), 'Assessment of compliance costs and indirect costs as a result of the MMR lending reforms', report prepared for the FSA, July.

⁹¹ European Commission (2009), 'Impact assessment guidelines', January.

⁹² European Commission Impact Assessment Board (2012), 'DGSANCO – Impact Assessment on a Proposal for a Revision of the Tobacco Product Directive', July.

⁹³ For example, Layard, R. and Glaister, S. (1994), *Cost-benefit analysis*, Cambridge; and Boardman, A., Greenberg, D., Vining, A. and Weimer, D. (2006), *Cost-benefit analysis: concepts and practice*, Pearson Prentice Hall.

⁹⁴ The OECD gives an overview of economic best practice in relation to RIAs based on methodologies from a range of countries, and a review of the academic literature on regulatory impacts assessments (RIAs). See OECD (1997), 'Regulatory Impact Analysis: best practice in OECD countries'.

⁹⁵ See the references in Box A1.1 below.

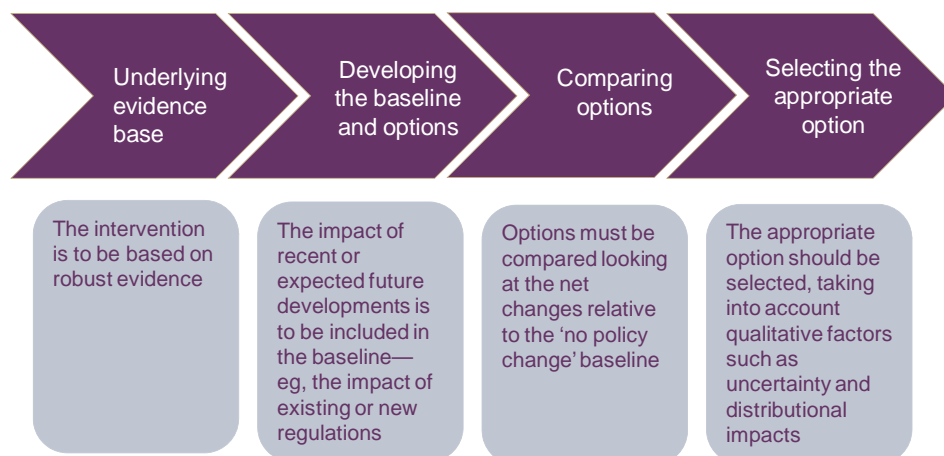
⁹⁶ As reported by the Commission in the RIA 2012, p. 59.

⁹⁷ European Commission (2009), op. cit., p. 24 explains that the Commission's baseline needs to have a strong factual basis and to consider a wide range of factors other than EU intervention.

- **The basis for comparing options**—individual options must be examined based on the net changes compared with the ‘no policy change’ baseline.⁹⁹
- **Selecting the appropriate option**—the guidance explains that the RIA ought to recognise uncertainty in the underlying estimates—eg, using a sensitivity analysis.¹⁰⁰
- **Distributional impacts should be identified**—ie, to reflect that, while options could be beneficial for society as a whole, they may have positive or negative impacts that are spread unevenly across society.¹⁰¹

An overview is provided in Figure A1.1.

Figure A1.1 Overview of the requirements of the Commission’s guidelines



Source: Oxera analysis based on an interpretation of the Commission’s RIA guidelines.

A1.2.2 Criteria from the recommendations of the Impact Assessment Board

The recommendations arising from the IAB review also cover the above areas. This is not surprising given that it is likely that the IAB would have reviewed the impact assessment against the RIA guidelines. The IAB provided recommendations covering the following areas.

- **Better present the problems:** ‘the evidence presented, in terms of concrete obstacles for economic operators affecting the functioning of the relevant markets, remains weak.’¹⁰²
- **Develop a robust baseline scenario:** ‘the report indicates that the tobacco market is likely to grow, despite the foreseeable actions at national level. It should further explain why not all Member States are expected to take further actions.’¹⁰³
- **Better demonstrate the proportionality of policy options:** ‘the report should better justify the legal feasibility and proportionality of prohibiting STP altogether, as well as the proportionality of subjecting e-cigarettes to the medicinal regulatory framework and introducing a notification procedure for Internet sales.’¹⁰⁴

⁹⁸ European Commission (2009), op. cit., p. 24 in relation to the baseline and p.39 in relation to the options.

⁹⁹ European Commission (2009), op. cit. p.31 explains that the RIA should avoid ‘bundling’ sub-options into a ‘preferred’ option after the analysis, as this makes it difficult to assess the impact of the preferred option as a whole against the baseline.

¹⁰⁰ European Commission (2009), op. cit., p. 25.

¹⁰¹ European Commission (2009), op. cit., p. 33.

¹⁰² European Commission Impact Assessment Board (2012), op. cit., p. 1.

¹⁰³ European Commission Impact Assessment Board (2012), op. cit., p. 2.

¹⁰⁴ European Commission Impact Assessment Board (2012), op. cit., p. 2.

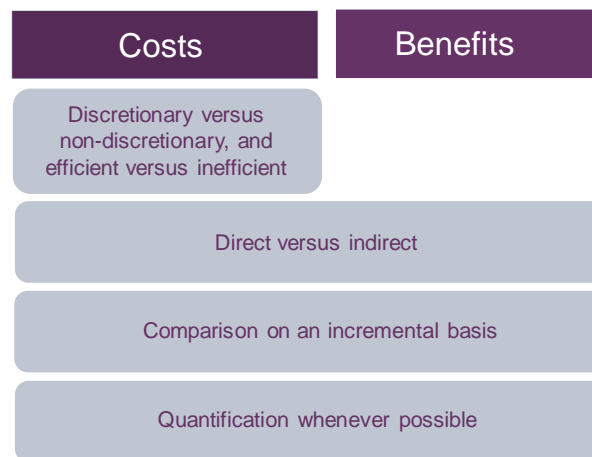
- **Improve the assessments of impacts:** ‘while being more transparent on the overall costs and benefits for economic actors and consumers, the report should better explain how the divergences that are likely to persist at national level (such as those related to the regulation of ingredients) were taken into account...It should also assess in greater detail the administrative costs for national authorities.’¹⁰⁵

The RIA includes a table showing how the Commission considers it has covered the IAB’s recommendations.¹⁰⁶

A1.2.3 Consistency with economic principles

Oxera has considered other criteria from its own experience of assessing RIAs from an economic perspective, from academic textbooks¹⁰⁷ and from other relevant publications. From this review, criteria that relate to the assessment of costs and benefits have been developed, as set out in Figure A1.2.

Figure A1.2 Issues related to the costs and benefits



Source: Oxera.

- **Non-discretionary versus discretionary and efficient versus inefficient costs**—it is important to recognise only the non-discretionary, efficient level of costs that would be incurred as a result of implementing a given policy.
- **Direct versus indirect costs and benefits**—it is important to include direct costs (including compliance costs) and benefits and indirect costs (eg, reduction in innovation, long-term investment, etc) and benefits.
- **Incremental costs and benefits**—it is critical to determine how much additional cost is incurred, or how much additional benefit might be achieved, from the policy intervention—ie, understanding the costs and benefits over and above those in the baseline scenario.
- **Quantification**—it is important to assess the incremental improvements in the market functioning and outcomes that are likely to arise from the new regulations and, where possible, elicit the monetary value of the policy-related net benefits.

Other relevant technical points include the following.

¹⁰⁵ European Commission Impact Assessment Board (2012), op. cit., pp. 2 and 3.

¹⁰⁶ RIA 2012, pp. 8 and 9.

¹⁰⁷ For example, Layard, R. and Glaister, S. (1994), *Cost-benefit analysis*, Cambridge; and Boardman, A., Greenberg, D., Vining, A. and Weimer, D. (2006), *Cost-benefit analysis: concepts and practice*, Pearson Prentice Hall.

- **Time dimension**—it is important to consider the timing of costs and benefits; for example, when costs and benefits are likely to materialise.¹⁰⁸ This is important as, in general, a benefit today is more valuable than that same benefit in a year's time.¹⁰⁹ Therefore, costs and benefits that may arise over a period of time from a particular policy option are expressed as a present value. Furthermore, this means that different policy options can be compared on an equal footing, given that some options may have costs and benefits occurring at an earlier, or later, point in time.
- **Distributional and sector-specific effects**—while policy interventions may result in an overall net benefit, different economic stakeholders may be affected in different ways by that intervention—ie, distributional impacts. It is generally best practice to consider how different economic stakeholders may be affected and to weigh up the impacts before deciding whether to proceed with a policy. As such, the economic concepts of efficiency and equity become relevant.
 - **Efficiency:** the size of the improvement in market outcomes.
 - **Equity:** how the improvement in market outcomes affects different economic stakeholders.

Considering equity therefore captures outcomes that are not necessarily detrimental or beneficial from an efficiency point of view, but may be judged detrimental or beneficial from a distributional standpoint.¹¹⁰

It is therefore important to take into account distributional and sector-specific effects, given that the intervention may not affect all groups in the same way and that differences may even arise within broadly similar groups. This is a significant consideration, which is a requirement set out in many RIA guidelines, including in the OECD's guidelines.¹¹¹

Indeed, the Commission's guidelines note how the RIA must take into consideration distributional impacts that may arise from a policy intervention:

You should always identify who is affected by the impacts and when. Options that would be beneficial for society as a whole may have positive and negative impacts that are spread unevenly across society and over time. You should consider two distinct types of distributional impacts:

- Impacts on different social and economic groups.
- Impacts on existing inequalities.¹¹²

These aspects relating to consistency with sound economic principles are generally covered in the guidance for RIAs, including, for example, the framework for assessing the benefits of financial regulation for the UK FSA,¹¹³ the UK government's impact assessment guidance,¹¹⁴ and the OECD RIA documents.¹¹⁵

¹⁰⁸ See, for example, Department for Transport (2006), 'Cost benefit analysis', February.

¹⁰⁹ This is a well-accepted economic principle. See, for example, OECD (1997), *op. cit.*, p.195, which explains that 'since some benefits that occur in the future have lower present value than those that occur today, one must discount these impacts to reflect this difference.'

¹¹⁰ Oxera (2006), 'A framework for assessing the benefits of financial regulation', September, p. 9.

¹¹¹ OECD (2008), 'Building an Institutional Framework for Regulatory Impact Analysis (RIA)', p.13 explains that 'Regulators should carry out, early in the regulatory process, an informed comparisons on a variety of regulatory and non-regulatory policy instruments, considering relevant issues such as costs, benefits, **distributional effects** and administrative requirements.' [emphasis added]

¹¹² European Commission (2009), *op. cit.*, p. 33.

¹¹³ Oxera (2006), *op. cit.*

¹¹⁴ HM Government (2011), 'Impact Assessment Guidance: when to do an Impact Assessment', August.

¹¹⁵ OECD (2008), *op. cit.*

A1.2.4 European Commission documents on the internal market

Given the internal market objective, the Commission's previous publications on the internal market have been reviewed to establish what the Commission usually means when it refers to a well-functioning internal market. It is important to understand this in order to evaluate the effectiveness of the Commission's proposals—ie, the extent to which the options achieve the objectives of the proposal. In the context of the TPD, this means how well the proposals will achieve the Commission's internal market objective, which the Commission defines as its overall objective:

The overall objective of the revision is to improve the functioning of the internal market.¹¹⁶

The criteria are summarised in Box A1.1.

Box A1.1 Criteria of a well-functioning internal market

Innovation: innovation leads to new products, better quality and products that address the needs of consumers in a better way. Innovation is also necessary to keep ahead of, or keep up with, other (global) competitors.¹¹⁷

(Enhanced) competition: an advantage of a well-functioning internal market is enhanced competition. This leads to improved choice for consumers, lower prices and better quality.¹¹⁸

Growth in GDP and cross-border trade within a well-functioning market, EU GDP can increase more than it does in a fragmented market. Figures diverge from 0.18% to more than 1.8% annually. This growth is also likely to be more sustainable.¹¹⁹

Employment growth: owing to GDP growth, innovation and free movement of personnel, the internal market provides for a growing figure of employment in the EU. For example, between 1992 and 2002, about 2.5 million jobs were created, as a result of the opening-up of frontiers.¹²⁰

Source: Oxera based on EU publications, including RIAs.

The effectiveness of the Commission's objectives is discussed in section 1.2.2.

A1.3 Identifying the assessment criteria

A number of themes emerge from the Commission's RIA guidelines, broad economic principles and other relevant documents. A set of assessment criteria can be distilled from these emerging themes and used, in addition to the Commission's own criteria of effectiveness, efficiency and coherence, for the purpose of reviewing the Commission's RIA. The assessment criteria used by Oxera cover the following areas:

¹¹⁶ RIA 2012. p. 1.

¹¹⁷ European Commission (2010), 'Towards a Single Market Act' COM(2010) 608 Final, October, pp. 4, 5 and 7; European Commission (2004), 'Extended impact assessment of proposal for a directive on services in the internal market', January, pp. 34, 36 and 37; and European Commission (2007), 'Laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another member state and repealing decision: impact assessment', pp. 10, 36, and 37.

¹¹⁸ European Commission (2010), 'Towards a Single Market Act' COM(2010) 608 Final, October, pp. 5, 6, 7–12; European Commission (2004), 'Extended impact assessment of proposal for a directive on services in the internal market', January, pp. 33 and 35; and European Commission (2007), 'Laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another member state and repealing decision: impact assessment', pp. 9, 36, 37, 43 and 44.

¹¹⁹ European Commission (2010), 'Towards a Single Market Act' COM(2010) 608 Final, October, pp. 3, 4, 6, 9; European Commission (2004), 'Extended impact assessment of proposal for a directive on services in the internal market', January, pp. 23, 29, 36 and 37; and European Commission (2007), 'Laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another member state and repealing decision: impact assessment', pp. 42 and 43.

¹²⁰ European Commission (2010), 'Towards a Single Market Act' COM(2010) 608 Final, October, pp. 5 and 7; and European Commission (2004), 'Extended impact assessment of proposal for a directive on services in the internal market', January, pp. 23, 29, 32 and 37.

- the completeness of the costs considered—this focuses on the extent to which all relevant cost implications of a policy are being considered. These may comprise for example, direct/indirect costs, and discretionary/non-discretionary costs;
- assessment of the benefits—this entails considering the direct and indirect benefits, and the extent to which the benefits of the policy options are supported by the evidence base;
- quantification of the impacts—the extent to which the relevant costs and benefits are quantified in monetary terms;
- the basis for comparing options—the extent to which costs and benefits considered are incremental to the costs and benefits that are assumed to arise in the baseline;
- further technical points about analysis in the RIA—this considers specific aspects about the estimation of economic impacts (eg, tax implications, and input/outputs);
- the extent to which distributional and sector-specific impacts are considered in the analysis.

The above criteria have been used as a framework for appraising the RIA, and the outcome of this review is reflected in the main issues discussed in section 1 of this report. The criteria are also used in the context of the Commission’s CBA in section A2.2 below.

A2 Further technical analysis of the RIA

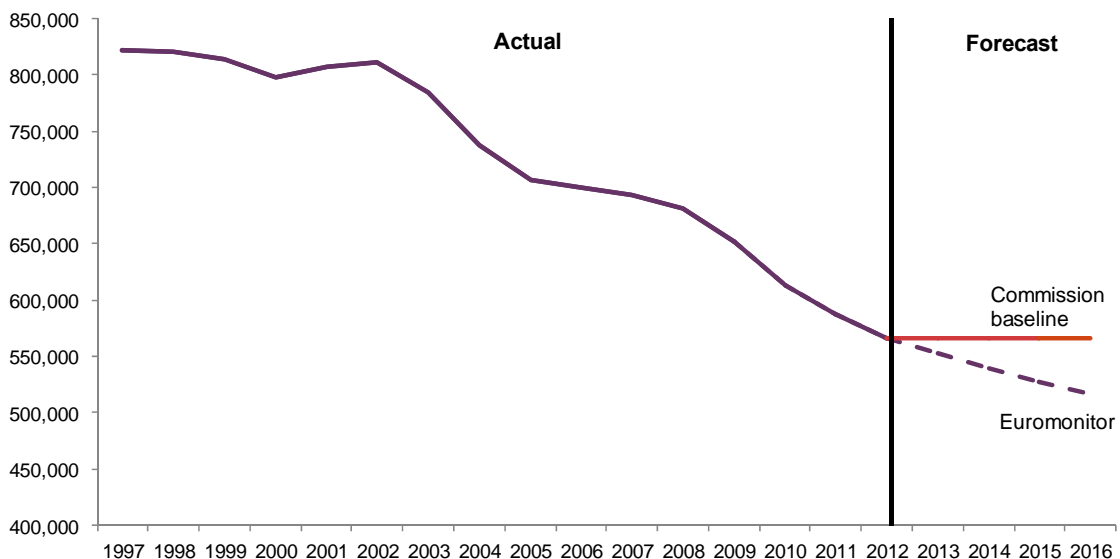
This appendix provides further details of Oxera's technical analysis of the Commission's RIA, including:

- a review of the Euromonitor data on tobacco sales in the context of the Commission's baseline scenario;
- a review of the Commission's CBA;
- a review of the Commission's input–output analysis.

A2.1 Review of tobacco sales

The analysis in this section builds on the analysis set out in section 1.2.3. In particular, it looks further at the reduction in the legal sales of FMCs. Figure A2.1 shows the legal sales of FMCs based on the information available from Euromonitor, as set out in section 1 of this report.

Figure A2.1 Legal sales of factory-manufactured cigarettes in Europe (million sticks)



Source: Oxera analysis, based on Euromonitor projections and RIA 2012.

As shown in Figure A2.1, legal sales of FMCs have been declining since 1997, which is the first year for which Euromonitor data is available. Between 1997 and 2011, the legal sales of FMCs declined by 28%, or 2.4% per year on average. Furthermore, Euromonitor predicts that the sales of FMCs will reduce by a further 12%, or 2.5% per year on average, between 2011 and 2016 (see Table A2.1 below).

Table A2.1 Analysis of the Euromonitor projections

	Legal sales of FMCs	Calculation
1997 (actual)	821,229	Reported
2011 (actual)	587,776	Reported
2016 (forecast)	517,058	Reported
% change, 1997 to 2011	-28.4%	587,776 divided by 821,229 minus 1
% change, 1997 to 2011 (annualised)	-2.4%	(587,776 divided by 821,229) to the power of (1/14) minus 1
% change, 2011 to 2016 (forecast)	-12%	517,058 divided by 587,776 minus 1
% change, 2011 to 2016 (forecast)	-2.5%	(517,058 divided by 587,776) to the power of (1/5) minus 1

Note: Legal sales of FMCs are in millions of sticks.
Source: Oxera analysis, based on Euromonitor data.

However, as discussed in section 1.2.3, the Commission considers that the various regulations currently in place will result in no further reduction in the consumption of tobacco products.

Whilst Euromonitor predicts also some moderate decline in consumption (decrease in volume sales) in the years to come it cannot be assumed that this predicted decrease will in reality continue in the absence of new adjusted tobacco control measures.¹²¹

The Commission has not set out the evidence to support its rationale in this area. Furthermore, its assumption that the predicted decrease will not continue is inconsistent with the projections for tobacco prevalence as set out in the RAND report. The RAND projections are based on a model 'that takes into account previous prevalence to understand current prevalence'.¹²²

Oxera has not had access to the underlying data, or the RAND model, and has therefore been unable to reproduce the analysis. However, as shown in Figures 6.1 and 6.2 of the RAND report, RAND predicts a sustained reduction in smoking prevalence up to 2027.¹²³

Furthermore, RAND uses WHO and OECD data on smoking prevalence as a cross-check on its projections and finds that its forecast average closely follows the 'true' average, based on the WHO and OECD data.¹²⁴

As such, the Commission's assumption—that the reduction in tobacco consumption is likely to stop without further EU intervention—does not appear to be supported by the available evidence.

A2.2 Review of the cost–benefit analysis

Background

The purpose of this section is to replicate the Commission's CBA, as set out in annex 5 of the RIA, taking as given the Commission's main assumptions and figures (apart from the 2% reduction in tobacco consumption) that underpin its CBA. The current section provides some

¹²¹ RIA 2012, p. 43.

¹²² RAND (2010), op. cit., p. 87.

¹²³ RAND (2010), op. cit., p. 88 and p. 89.

¹²⁴ RAND (2010), op. cit., p. 88 and p. 89.

more detail on how Oxera has reviewed the Commission's overall CBA against the assessment criteria from section A1.4.

A2.2.1 Costs considered in the RIA

Direct costs

The CBA does not appear to include direct costs related to the preferred package of policy proposals, as discussed in section 1.3.4 above.¹²⁵ These costs include, for example, the one-off and ongoing costs identified by the Commission that relate to its proposals for packaging and labelling, ingredients regulations and 'track and trace'.¹²⁶

Indirect costs

The Commission's RIA refers to indirect costs, including the reduction in taxation revenues and healthcare expenditure assumed to arise from a reduction in the sales of regular tobacco products, such as FMCs and RYO—as set out in section 1.3.1. However, it appears that the Commission has omitted the indirect costs related to a reduction in profits, which are expected to arise from a reduction in the sales of regular tobacco products.¹²⁷

A2.2.2 Benefits assumed in the RIA

The benefits assumed by the Commission were discussed in section 1.3.2 of this report.¹²⁸

A2.2.3 Technical approach used

This section replicates the Commission's analysis and shows that its assumption about the percentage reduction in the consumption of FMCs and RYO that may arise from its proposals could have a material impact on its technical analysis. The analysis presented in this section is based on that presented in annex 5 of the RIA.

Sensitivity analysis

Table A2.3 presents the net benefit assumed by the Commission from a 2% reduction in the consumption of FMCs and RYO, and the net benefit assumed from a lower percentage reduction—in this example, 0.5%.¹²⁹

¹²⁵ RIA 2012, Annex 5, p. 29.

¹²⁶ RIA 2012, pp.122 and 123 summarises the Commission's assessment of costs in the RIA.

¹²⁷ RIA 2012, Annex 5, p. 29.

¹²⁸ The Commission appears to have misinterpreted the reduction assumed to arise from the new health warnings as set out in the Applied Economics study from Australia. Applied Economics (2003), 'Cost-benefit analysis of proposed new health warnings on tobacco products', report prepared for Commonwealth Department of Health and Ageing, December. The Commission suggests that, in Australia, new health warnings led to a 12.3% decline in smoking prevalence and a 26.3% decline in tobacco consumption per capita from 2001 to 2011, based on the Commission's interpretation of evidence from Australia, which was prepared in 2003 (RIA 2012, p. 114). The estimates of tobacco consumption and smoking prevalence used by the Commission are based only on the reduction assumed to occur in the counterfactual with no new measures in place. If it were to use the evidence from Australia, it would have to calculate the difference between the reduction in prevalence assumed to occur anyway (the 12.3% used by the Commission) and the reduction in prevalence assumed to arise from introducing new warnings.

¹²⁹ The Commission's RIA provides a sensitivity analysis to show the impact of reductions of 1%, 2%, 3%, 4% and 5% in the consumption of FMCs on the net benefit presented in its overall CBA.

Table A2.3 Impact on governments and society, undiscounted (€m)

Reduction in tobacco consumption	2%	0.5%
Decrease in excise tax revenues	-1,587	-397
Decrease in healthcare expenditure	506	127
Decrease in productivity loss due to	165	41
early retirement/deaths	122	30
absenteeism	43	11
Decrease in premature mortality costs	10,334	2,584
Overall net benefit	9,418	2,354

Note: There are insignificant discrepancies between Oxera's and the Commission's calculations due to rounding. Source: Oxera analysis based on RIA 2012, Annex 5.

As shown in Table A2.3, the net benefit is highly sensitive to the percentage reduction in tobacco consumption that is assumed to arise from the Commission's measures. The Commission estimates the present value of the overall net benefit; in doing so, it has considered both the discount rate and the time horizon.

Using the assumptions for the Commission's 'most likely' scenario, the present value of this net benefit for a 2% reduction and a 0.5% reduction is set out in Table A2.4.¹³⁰

Table A2.4 Net benefit, discounted at a 3% discount rate (€m)

	2% reduction	0.5% reduction
Decrease in excise tax revenues	-1,369	-342
Decrease in healthcare expenditures	436	109
Decrease in productivity loss	142	36
Decrease in premature mortality costs	4,936	1,234
Overall net benefit, discounted	4,145	1,036

Note: The present value of the overall net benefit arising from a 2% reduction in tobacco consumption may differ from the numbers presented in the Commission's RIA. This is because it was not possible to replicate directly the Commission's analysis. Source: Oxera calculations.

Again, this confirms that the Commission's analysis is highly sensitive to the assumption on the percentage reduction in the consumption of FMCs and RYO that the Commission assumes will arise from its measures. An overall net benefit still arises, based on the Commission's analysis; given that the benefits that it assumes are an order of magnitude higher than the assumed costs, as discussed in section 1.3.4.

A2.3 Distributional and sector-specific effects

The Commission's RIA covers the expected impact of its policies on employment in different industries, or sectors, using an input–output model. This section builds on the discussion about distributional and sector-specific effects set out in section 1.3.5 above.

A2.3.1 Input–output analysis

The Commission uses an input–output model to estimate the effect of a reduction in the sales of tobacco products on employment in Member States and concludes that a reduction

¹³⁰ The most likely scenario assumes that the reductions in tax revenues, healthcare expenditure and savings in productivity costs occur in five years' time, the reduction in mortality and morbidity costs occurs in 25 years' time. It also uses a 3% discount rate to approximate 'social time preference', based on the long-term government bond yields for Germany, UK and France. RIA 2012, Annex 5, pp. 29–31.

in tobacco sales has no effect on employment (no net loss). This is primarily because it finds that the loss of jobs in the tobacco industry will be compensated by an increase in jobs elsewhere in the economy.

Input–output analysis is a methodology used to measure the impact of changes in demand of a specific industry on the entire economy. An input–output analysis of a reduction in tobacco consumption captures two types of impact:

- the direct impact through the reduction of tobacco production and thereby the reduction in the output of industries that directly supply inputs to the tobacco industry;
- the indirect impact through further rounds of reduction of outputs throughout the supply chain (ie, the reduction in outputs of suppliers to the input industries and their suppliers, and so on).

Together, these two impacts yield the total reduction in the output of the economy due to the reduction in tobacco consumption—technically, the total effect is captured in the input–output multiplier for specific industries. The effect on outputs in each industry can be converted to the impact on employment using the employment–output ratios of the industry in question. The employment–output ratio is calculated for each industry taking the market value for each industry and dividing by the total number of employees in that industry.¹³¹

The Commission’s analysis based on Matrix

The Commission’s analysis primarily relies on the input–output analysis conducted by Matrix.¹³² As such, this section focuses on the analysis in the Matrix report, unless otherwise specified. The Matrix report captures the total impact of a reduction in tobacco consumption through an input–output model available from Eurostat; this model also provides the input–output multipliers for specific industries, based on the employment–output ratios, including the tobacco industry. The analysis proceeds as set out in Box A2.1.

Box A2.1 Input–output analysis by Matrix

- First, the reduction in the consumption of tobacco is assumed to lead to a reduction in tobacco production and sales.
- Second, the fall in outputs of various industries due to the reduction in tobacco production is computed using the input–output multipliers for the tobacco industry. The consequent reduction in employment in these industries is estimated using the employment–output ratios (‘gross effects’).
- The analysis also assumes that the amount that a consumer does not spend on tobacco will be spent on a range of other industries, such as food products, clothing, housing and entertainment. The pattern of spending across different industries is informed by a 1995 study by York University based on a 1990 household survey in the UK which identified people in the household who had recently given up smoking.
- The impact of the increase in expenditure on other industries on economy-wide output and employment is estimated through the corresponding input–output multipliers and employment–output ratios. The gross effect is then adjusted for this increase to estimate the ‘net effect’ of reduction in smoking on the economy-wide output and employment.

The analysis concludes that a reduction in tobacco consumption of 0.5–2% will lead to a net increase in employment in the economy. This is because, while the output and employment in tobacco industry and its supply chain reduce, this is more than compensated by the increase in employment through an increase in expenditure on goods and services in other industries. This is driven by the assumption that, overall, consumers switch their spending to

¹³¹ RIA 2012, Annex 5, p. 35.

¹³² Matrix Insight (2012), op. cit.

more labour-intensive industries with a higher average employment–output ratio relative to the tobacco industry.

Review of the input–output analysis

Oxera’s review highlights some methodological issues with the input–output analysis conducted by Matrix, and how the Commission has used it.

- **The assumption on the amount of freed expenditure spent on other products is questionable.** As noted above, the input–output model assumes that when a smoker stops smoking, the entire sum that was spent on tobacco is now spent on other products. This assumption is crucial for the finding that there will be no impact on employment because, in essence, it assumes neutrality of the CBA (‘CBA neutrality’).

However, this assumption is questionable. While some part of this money may indeed be spent on something else, not all of it necessarily will—the household might save some part of the freed expenditure. Indeed, this has been highlighted as a realistic possibility by previous studies, including the University of York study on which the Matrix data is based.¹³³ As the study notes, in such a case, the net employment effect may be negative in the short term, depending on the amount saved by the ex-smoker. It also shows that if the smoker saves 10% of the freed expenditure, 17% fewer jobs would be created; a savings rate of 25% would imply that 44% fewer jobs are created.

Although these savings may be spent on other products in the long term, and there may be an increase in employment in the future, such future benefits need to be separated out from current benefits, and their values should be discounted using an appropriate discount rate. As such, the timing of when money is spent on other goods can have an impact on the jobs created in other sectors.

- **The analysis assumes that the reduction in consumption will not lead to an increase in consumption in the illicit market.** The Matrix report assumes that the reduction in tobacco sales means that people are quitting, and not buying from the illicit market instead.¹³⁴ If, on the other hand, consumption in the illicit market increases, this would limit the fall in production of tobacco in the input–output analysis, and thereby the negative impact on employment. This also implies that the positive impact on health and productivity is overestimated.¹³⁵

To support this assumption, the analysis cites evidence from a 2010 report that found that, between 2009 and 2010, while the legal market for cigarettes decreased by 39m, the illegal market increased by only 3m.¹³⁶ It is important to verify the reliability of this data and thereby the assumption. In any case, no sensitivity analysis has been conducted by Matrix, or the Commission, to test the impact of changing this assumption.

¹³³ For example, the study highlights that the survey data does suggest that non-smoking households tend to save a higher proportion of their income than households with smokers. Buck, D., Raw, M., Godfrey, C., Sutton, M. (1995), ‘Tobacco and Jobs, The impact of reducing consumption on employment in the UK’. University of York, Centre for Health Economics, p. 11.

¹³⁴ Matrix Insight (2012), op. cit, p. 140 explains that the ‘analysis summarised above assumes that all the reduction in the consumption of cigarettes is the result of quitting, rather than a substitution of illegally purchased cigarettes for legally purchased cigarettes.’

¹³⁵ Ibid., p. 141.

¹³⁶ KPMG (2010), ‘Project Star 2010 results’, August, available at

http://www.pmi.com/eng/tobacco_regulation/illicit_trade/documents/Project_Star_2010_Results.pdf, accessed March 19th 2013.

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