Review of the Regulatory Impact Analysis on the Public Health (Standardised Packaging of Tobacco) Bill 2014

A Report for JTI Ireland

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Executive Summary

Government's commitment

The Programme for Government (March 2011) [1] re-affirmed the commitment - as set out in Cabinet procedures since 2006 - that Government Departments and State agencies will be required to carry out Regulatory Impact Analysis (**RIAs**) ***before*** Government decisions are taken. This reflects best practice at EU and OECD level. In the words of the Taoiseach: *good quality regulation is central to economic recovery and job creation*.[2]

Scope of the report

Against this background, this report assesses the RIA carried out by the Department of Health (**the Department**) on the Public Health (Standardised Packaging of Tobacco) Bill 2014 (**the Bill**) and its compliance with the current Cabinet Handbook and Government guidelines on RIAs and the conduct of public consultation on draft legislation and in relation to the Government's policy on the pre-screening of Bills by Oireachtas Committees. The report identifies some serious shortcomings, compliance gaps and areas for improvement.

The RIA is non-compliant and flawed

The RIA was published long after the Government took a decision to legislate and is as a consequence not in compliance with the Cabinet's own procedures. While a RIA was eventually published it was only made available after the Oireachtas Joint Committee on Health and Children (**the Joint Committee**) had issued its report on the General Scheme of the Bill and after the Oireachtas had begun to debate the Bill. The fact that the Minister for Health did not highlight the RIA during these debates illustrates the low importance and significance attached to the RIA.

The evidence provided in this report suggests that only one conclusion is possible: the RIA is fundamentally flawed both in terms as to how it was conducted and in relation to many elements of the substantive evidence used to justify primary legislation as the sole means to achieve the stated policy objectives.

In order to be credible and bearing in mind that the Department will be conducting future RIAs on sensitive subjects such as alcohol and obesity, it behoves the Department to conduct a revised RIA to take account of the identified shortcomings of the current version and in particular to address the reservations expressed by ten Member States on the Bill.

Important findings

Some important findings, as follows, are presented.

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[1] Department of the Taoiseach, *Programme for Government,* March 2011.

[2] Department of the Taoiseach, *Regulating for a Better Future; a Government Policy Statement on Sectoral Economic Regulation*, Foreword by An Taoiseach, July 2013.

1. The rules of the Cabinet Handbook on RIAs and the guidelines set down by the Department of the Taoiseach on the carrying out of a RIA and on public consultations in relation to the RIA were not met and in some cases were totally ignored.
2. The RIA on the Bill was retro-fitted i.e. it was prepared to justify a policy decision previously taken. The Cabinet in approving the preparation of the General Scheme of the Bill did not have the benefit of having to hand balanced evidence to support the Bill's provisions, or indeed evidence to support alternative approaches.
3. The Joint Committee in its consideration of the Bill did not meet the standards set out in the Government's approach to Better Regulation.
4. Again in breach of the RIA guidelines, a RIA was not carried out on the draft Tobacco Products Directive, nor has one been carried out as regards its transposition into Irish legislation.

Stakeholder consultation and engagement not up to standard

The Department did not comply with practically all of the guidelines used by the European Commission in relation to public consultations. For example, public consultations on standardised packaging in other jurisdictions gave respondents some time to make detailed submissions. [3] While some consultations required responses to set questions, not one jurisdiction other than Ireland ruled out of order from the outset a critical review of policy proposals other than those which strictly fitted pre-determined policy on tobacco control. Nor is it clear, insofar as submissions sought to influence policy-makers/legislators, the extent to which these were taken into account in the RIA as part of the iterative process of determining public policy. Not only did the Department and the Joint Committee consultations fail to meet best practice and EU standards but they did not respect prevailing Government guidelines on the correct manner for the conduct of stakeholder consultations. As a consequence both sets of consultations were flawed and as a result the integrity, completeness and robustness of the policy-making process has been jeopardised.

The specific impacts, costs, benefits and burdens of the Bill have not been identified

A further and significant flaw in the RIA is that the unique impacts, costs, benefits and burdens attributable to the Bill were not provided. International evidence about standardised packaging was cited but the impacts, costs and benefits in Ireland using Irish research were not presented; because such data does not exist. In addition, it was a serious mistake that stakeholders were not asked for detailed inputs on these impacts, costs, benefits and burdens. Given that the Bill is a significant piece of legislation, and in compliance with Government guidelines, a detailed Cost Benefit Analysis (**CBA**) on the Bill should have been completed.

Where is the RIA on *Tobacco Free Ireland*?

A RIA was never carried out to identify the impacts, costs and benefits of the policy framework for tobacco control as set out in *Tobacco Free Ireland,* nor did this document consider a range of

[3] There have been concerns expressed by stakeholders, including JTI, regarding impact assessments on similar draft legislation in other jurisdictions, in particular in relation to the consultation process and the substance of the analysis. For example, JTI has commented extensively on the UK plain packaging proposal: http://www.jti.com/how-we-do-business/key-regulatory-submissions/

alternatives to primary legislation. The drawing up of this core reference document did not comply with the key principles of Better Regulation, in particular as regards stakeholder engagement in the policy formulation phase. As a consequence all subsequent actions justified under this policy framework are arguably not based on a wide body of up-to-date and relevant research based on Irish circumstances and conditions. Given the inherent deficiencies and flaws in the findings of *Tobacco Free Ireland*, RIAs conducted in respect of individual Bills that seek to give effect to the policy framework are using a singularly biased basis to justify the use of legislation over other forms of regulation. Furthermore, under the Public Spending Code, a CBA should have been carried out as part of the policy review that resulted in the publication of *Tobacco Free Ireland*.

Options other than standardised packaging legislation should have been considered to attain policy objectives

The European Commission normally presents a long menu of policy options as part of its pre-legislative process and goes into some detail in assessing the impacts of each option. The RIA did not explain why two options only had been assessed and in that regard the Department did not comply with the Cabinet Handbook and Government RIA guidelines. The RIA also fell short by failing to provide a full justification of the respective impacts of these options. These shortcomings are a direct consequence of the Government having taken an earlier decision to legislate; one option only. Contrary to all the rules and international best practice, the RIA was then produced at a much later date to justify such a decision and to create the impression that an options appraisal was conducted.

Key Recommendation – The Oireachtas should consider a revised RIA

Given these major shortcomings, there is a strong argument that the Department of Health should conduct a credible and compliant RIA and that debate by the Oireachtas on the Bill should be suspended until this revised RIA is to hand.

Chapter 1

Introduction

This report assesses the Regulatory Impact Analysis (**RIA**) carried out by the Department of Health (**the Department**) on the Public Health (Standardised Packaging of Tobacco) Bill 2014 (**the Bill**).

Specifically, the report assesses the RIA's compliance with current Cabinet procedures and Government guidelines on RIAs and the conduct of public consultation of draft legislation and in relation to the Government's policy on the pre-screening of Bills by Oireachtas Committees.

The report identifies some serious shortcomings, compliance gaps and areas for improvement having regard to EU and OECD recommendations about best practice in the conduct of RIAs and public consultations on draft legislation.

The report is based on desk top research only.

Chapter 2 sets out the key process features of the RIA and the background to the Bill. The reliance placed on the RIA's evidence as the Bill has progressed through the Oireachtas is also reviewed.

Chapter 3 analyses the RIA in detail to evaluate the extent to which it complies, or fails to comply, with current Cabinet procedures and Government guidelines on RIAs. In particular, the RIA is evaluated to ascertain if it is an adequate basis for informing policy-makers and legislators.

Chapter 4 analyses the extent to which the public consultation exercise which supposedly informed the RIA complies, or fails to comply, with current Cabinet procedures and Government guidelines on RIAs. The key issue is whether the RIA was, in fact, informed by a balanced view of stakeholder feedback.

The impacts, costs and burdens for both the private and public sectors that might arise should the Bill be enacted are addressed in **Chapter 5**.

In compliance with Cabinet procedures and Government guidelines on RIAs and having regard to the emerging findings, **Chapter 6** looks at the options assessed in the RIA.

Compliance with the key principles of Better Regulation, which are proportionality, accountability, consistency, transparency and targeting and clarity of policy objectives, as they relate to the RIA are assessed in **Chapter 7**.

The report's conclusions appear in **Chapter 8**.

The report has not addressed issues such as smoking behaviour, illicit trade, pricing and competition, nor the quality of the evidence that has been used in the RIA.

Chapter 2

Key Features of the Irish RIA and the Background to the Bill

What is a RIA?

A RIA is, according to the Cabinet procedures, *an assessment of the likely effects of a proposed new regulation or regulatory change*. [4] It involves a detailed analysis to ascertain whether or not the proposed new regulation would have the desired impact. It helps to identify the side effects and any hidden costs associated with regulation. Cabinet procedures also state that RIAs should clarify the desired outcomes of the proposed regulatory change. It also provides for consultation with stakeholders **prior to** proposals being submitted to Government to ensure that their views and interests are understood during the regulatory process.

Typically, a RIA would assess and quantify all the direct and indirect impacts of proposed legislation or new policy proposals. In addition, the administrative burdens and compliance costs (on both the public and private sectors) of the preferred options are to be evaluated and quantified. A Cost Benefit Analysis (**CBA**) is required in relation to more complex issues. The RIA should also cover issues, as appropriate, such as environmental and health impacts, distribution effects and the implications for competition and competitiveness.

The current (2009) definition that applies, with subtle differences of emphasis, is that *a RIA is a tool used for the structured exploration of different options to address particular policy issues*. *It is used where one or more of these options is new regulation or a regulatory change and facilitates the active consideration of alternatives to regulation or lighter forms of regulation*.[5]

Requirements about RIAs in Cabinet Handbook

As this report evaluates the extent to which the RIA complies with Cabinet procedures/ Government guidelines, the key section of the Cabinet Handbook (para 3.3) is set out hereunder for ease of reference.

Any Memorandum (for Government)

a) *Seeking approval for legislation involving changes to the regulatory framework including the transposition of EU Directives and Regulations must be accompanied by a Regulatory Impact Analysis.* ***The RIA should be conducted in advance of the Memorandum seeking approval for the General Scheme of a Bill****. The RIA should be summarised as part of the Memorandum and the RIA document should be included as an Appendix to the Memorandum.*

[4] Department of the Taoiseach, *Cabinet Handbook*, December 2006.
[5] Department of the Taoiseach, *Revised RIA Guidelines; How to Conduct a Regulatory Impact Assessment,* June 2009.

b) *Seeking approval for a Government Order involving changes to the regulatory framework must be accompanies by a RIA.*

Where a RIA falls to be considered, the steps of the RIA model as outlined in Appendix III must be followed. The RIA must be summarised in the body of the Memorandum, and ***this summary must address all of the impacts*** *set out in Appendix III. The RIA document must also be included as an Appendix to the Memorandum.*

Tobacco Control Policy Framework

The policy framework for tobacco control under which the Bill was justified - *Tobacco Free Ireland* was published on 3 October 2013; four months after the Government decided to legislate in relation to standardized packaging. [6]

Thus the Government's May 2013 decision to legislate was taken while work on a strategic policy framework for tobacco control had not concluded.

In any event, a RIA should have been carried out as part of this policy review.[7] The absence of such a RIA in breach of Government guidelines allowed the Department to bring forward a series of policy recommendations without adequate reference to the use of alternatives to regulations.

As the regulatory impacts, costs, benefits and administrative burdens of the Government's strategy on tobacco control was never assessed by way of a RIA, the relevant extract from the June 2009 guidelines is set out hereunder to highlight this lacuna.

> *2.18 Regulations are sometimes initiated in response to the recommendations of a particular Policy Review Group. When these Groups have reported, the expectation tends to be that their recommendations will be accepted and this means that subsequent scope for the use of alternatives is limited. Therefore, when any Policy Review Group is formed, the terms of reference must include a requirement to take account of the principles of Better Regulation. [8] In particular, its terms of reference must specify that consideration be given to the potential for the use of alternatives to regulation prior to recommending regulatory solutions. Any reports or reviews produced by the Group should then indicate how it took account of the Better Regulation principles in conducting its work. Where primary legislation or significant regulatory change is being proposed, a RIA should be produced as part of the work of the Review Group. The Group's final report would then include a RIA, if appropriate.*

It is important therefore to emphasise at the outset that not only was the process in carrying out a robust and timely RIA on the Bill in breach of Cabinet rules but the very policy framework underpinning the Government's tobacco control policy is also fundamentally flawed as it was conducted without reference to the principles of Better Regulation, which require *inter alia* that

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[6] Department of Health, *Tobacco Free Ireland*, October 2013.

[7] Para 2.18 of revised RIA guidelines (2009). An example of a RIA carried out by a policy review group is that prepared by the Company Law Review Group as part of their report on the General Scheme of the Companies Consolidation and Reform Bill 2007.

[8] Department of the Taoiseach, Regulating Better, *White Paper setting out the six principles of Better Regulation*, January 2004.

detailed stakeholder consultation should be undertaken to inform a proposed policy and options other than legislation.

Tobacco Free Ireland was published under the *Health Ireland – Framework for Improved Health and Wellbeing*, which was also not the subject of a RIA (or a CBA) despite being a significant policy initiative with resulting implications for Exchequer expenditure.[9]

The Bill's RIA

The RIA on the Bill, which was initiated in September 2013, was published in August 2014; after the Oireachtas (Seanad) had started its debate on the Bill and over a year after the Government had decided to legislate in breach of Cabinet procedures.[10]

In addition to an executive summary, the RIA contains the following chapters.

1. Description of the policy context
2. Policy objectives and evidence
3. Identification and description of options
4. Analysis of costs, benefits and other impacts

The RIA has two appendices covering the key recommendations of the Oireachtas Joint Committee on Health and Children (Appendix A) (**the Joint Committee**) and the outcome of the consultations with relevant stakeholders (Appendix B).

Background to the Bill

On 23 May 2013, the Government gave approval to the Minister for Health to proceed with the development of a General Scheme of a Bill to introduce standardised packaging for tobacco products.

On 19 November 2013, the Government approved the publication of the General Scheme of a new Public Health (Standardised Packaging of Tobacco) Bill and to proceed with the drafting of legislation based on the General Scheme and to submit the General Scheme of the Bill to the Joint Committee.

The General Scheme was subsequently referred to the Joint Committee with a remit to review the General Scheme and to report on its deliberations to the Minister. This pre-legislative scrutiny process was to facilitate consultation with key stakeholders before the Bill was finalised and was to be presented to the Houses of the Oireachtas for consideration as part of the formal legislative process. The Joint Committee sought and received submissions on the General Scheme and held a series of public hearings between 23 January and 13 February 2014.

For some unexplained reason, the Joint Committee conducted its public debates during the same period when stakeholders were required to provide inputs to the Department's RIA.

[9] Department of Health (2013), *Health Ireland – Framework for Improved Health and Wellbeing 2013-2015.*
[10] Department of Health, Public Health (Standardised Packaging of Tobacco) Bill 2014, *Regulatory Impact Analysis Final,* July 2014.

The Joint Committee published its report on 3 April 2014.[11]

Debate on the Bill

On 10 June 2014, the Government approved the publication of the Bill.

The Bill was presented to the Seanad on 11 June 2014 with the Order for Second Stage taken and concluded on 17 June 2014. The Seanad completed the Committee and Report Stages on 25 June 2014.

The Second Stage of the Bill began in Dáil Éireann on 2 July 2014 and the debate continued on 3 July, 1 and 2 October 2014.

While reference was made to 'evidence' supporting the Bill, the Minister for Health did not refer at all to the RIA while speaking on the Bill in the Seanad and in the Dáil.

Nor is the RIA referenced in the Explanatory and Financial Memorandum that was published with the Bill.

None of the eleven senators who spoke on the Bill to date made reference to the RIA and only two of the 22 TDs who spoke in the Dáil referred to the RIA.[12] One TD noted that retailers had called for a RIA (...*they have reasonable concerns about the unintended consequences for their business*) but did not appear to be aware of that a RIA had been published.[13] Another TD said *Deputies do not know what the cost benefit and impacts of the Bill are and this information should be made available to Deputies so they know for what they are voting*. [14] He added *the Minister is inviting the Dáil to vote for a pig in a poke as long as the RIA conducted on this Bill remains unpublished*.

To date, there has been no discussion on the Bill before the Oireachtas on alternative forms of regulation (other than legislation) or on the administrative costs and burdens falling on the retailers and tobacco companies who will have to implement the legislation or on the public sector that is responsible for compliance.

RIA Process Features

On 7 February 2014, the Department invited a limited number of stakeholders to make submissions in a prescribed format on the draft RIA on the Bill in the following terms.

> *In line with the RIA guidelines published by the Department of the Taoiseach, the Department of Health is undertaking a RIA on the proposed legislation. The RIA is to consider the costs, benefits and impacts of the proposals.*

[11] Houses of the Oireachtas, Joint Committee on Health and Children, *Report on hearings in relation to the General Scheme of the Public Health (Standardised Packaging of Tobacco) Bill 2014*, April 2014.
[12] Houses of the Oireachtas, Dáil Debates, 17, 24 June, 2,3 July, and 1, 2 October 2014
[13] Houses of the Oireachtas, Dáil Debates, 3 July 2014, contribution from Deputy Maureen O'Sullivan, page 32.
[14] Houses of the Oireachtas, Dáil Debates, 3 July 2014, contribution from Deputy Finian McGrath, page 34.

In this context, I would like to invite you to submit your organisation's views on the General Scheme of the Public Health (Standardised Packaging of Tobacco) Bill 2013, a copy of which is attached for your convenience.

Please note that your submission shall be deemed eligible for publication and you are asked that your organisation submit one submission only and to restrict your submission to the following areas:

i) Comments which relate directly to the specific provisions contained in the General Scheme only, on a Head by Head basis; and/or
ii) Comments which relate to identified omissions from the General Scheme on a Head by Head basis.

It is important to note that material submitted outside the criteria set out above will not be considered by the Department.

This call for submissions on the RIA was not in conformity with several key principles of Better Regulation, including the following:

1. A wide stakeholder consultation was not undertaken; only a limited number of parties were asked to contribute.
2. Parties were restricted about the scope of their submissions. For example, views that addressed alternatives to legislation and other options were deemed non-compliant.
3. Parties were given just two weeks to respond. No explanation was given for such a short time period.
4. The Department decided before submissions were received that only issues raised which were compatible with *Tobacco Free Ireland* would be considered.

These serious flaws in the RIA process and the consequences for informed evidence-based policy making are addressed in more detail later in the report.

One can but conclude that the conduct of a RIA so late in the decision-making policy cycle was a case of going through the motions; a case of being seen to tick the boxes.

Some 15 submissions - all from businesses or business associations - were made and these have been published on the Department's web site. It appears none of the advocacy groups or public bodies who made submissions to the Joint Committee made submissions on the draft RIA. It can only be concluded therefore that there was limited public consultation on the draft RIA.

The RIA on the Bill was published in August 2014 i.e. after debate on the Bill in the Seanad had begun.[15]

The RIA also references the Protection of Children's Health from Tobacco Smoke Bill 2014, which it is noted was not the subject of a RIA.[16]

[15] Department of Health, Public Health (Standardised Packaging of Tobacco) Bill 2014, *Final Regulatory Impact Analysis*, 2014.
[16] Department of Health, Protection of Children's Health from Tobacco Smoke Bill, 2014.

Chapter 3

Compliance with Cabinet Procedures and Government Guidelines on RIAs

Introduction

The RIA system in Ireland was introduced following the publication of the OECD's peer report *Regulatory Reform in Ireland*. [17] The report found that, while the Strategic Management Initiative was fostering a new regulatory culture, slow reform of Ireland's regulatory governance could be a bottleneck to sustained growth. Following an assessment of a pilot project, [18] a revised model was introduced across all Departments and Offices and suitable guidelines were published.[19]

An independent review of the operation of RIAs was completed in 2008, which indicated that, overall, good progress had been made. [20] However, it gave rise to a range of recommendations in relation to how the RIA model could be amended and improved. Subsequently, the Government issued revised RIA guidelines, which expanded the scope of RIAs to cover the work of policy review groups and removed the distinction between a Screening and a Full RIA. In addition, it was determined that the level of analysis should be proportionate to the significance of the proposal in question. Importantly, RIAs should be conducted at an early stage and before a decision to regulate has been taken. Ideally, a RIA should also be used as the basis for consultation.

The current version of Cabinet procedures contains detailed guidelines as regards the carrying out of RIAs.[21] These formal procedures do not reflect the changes introduced in the revised RIA guidelines published by the Department of the Taoiseach in 2009, for example as regards the requirement that a full CBA is required in cases where significant impacts will result; RIAs are required within four weeks of EU proposals being published; and RIAs should be pro-actively disseminated to key stakeholders. [22]

In summary, the main current requirements are as follows.

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[17] OECD, *Better Regulation in Ireland*, 2010.
[18] Department of the Taoiseach, *Report on the Introduction of Regulatory Impact Analysis*, 2005.
[19] Department of the Taoiseach, *RIA Guidelines: How to Conduct a Regulatory Impact Analysis,* 2005. These guidelines were informed *inter alia* by an assessment made by the Institute of Public Administration in 2005 which reviewed critically the pilot testing of the application of RIA in five Government Departments and Offices.
[20] Department of the Taoiseach, *Regulatory Impact Analysis: An Operational Review*, 2008.
[21] Department of the Taoiseach, *Cabinet Handbook*, December 2006.
[22] Department of the Taoiseach, *Revised RIA Guidelines: How to Conduct a Regulatory Impact Analysis*, June 2009. There is no single generic model of RIA used internationally. These guidelines were tailored to the Irish context.

RIAs – Current Requirements

1. **An RIA must be carried out before a Memorandum goes to Government seeking permission to regulate i.e. as early as possible in the regulatory development process.**
2. **The level of detail depends on the significance of the proposal; the more significant the impacts are likely to be, the deeper the analysis should be.**
3. **All RIAs are to include an analysis of options, including a 'no policy change' option as a benchmark for comparison purposes. Alternative forms of regulation such as voluntary Codes of Practice are to be considered.**
4. **Once the text of a Bill has been agreed by Government, the RIA must then be published on the Department's web site along with a link to the published Bill.**
5. **RIAs should be actively disseminated to key stakeholders.**
6. **Where revised changes to a Bill are submitted an up-dated RIA is required.**
7. **RIAs must be conducted on all proposals for EU Directives and on 'significant' EU Regulations before they are agreed and no later than four weeks after the publication of the proposal in order to inform Ireland's negotiating position.**
8. **Once EU laws are adopted, a separate RIA should be prepared on the available transposition options.**
9. **All significant Statutory Instruments are to be subjected to a RIA and the RIAs should be published and actively distributed to stakeholders.**
10. **A formal cost benefit analysis is required in the case of the most significant proposals; the costs, benefits and impacts of all options should be monetised or quantified.**

Source: Revised RIA Guidelines, Department of the Taoiseach (2009)

In other words, all Government policy must be justified on the basis of robust and credible evidence and all stakeholders should be engaged early on in the process and throughout the policy formulation process in a transparent manner.

While the conduct of RIAs applies to Departments and Offices, Government guidelines clearly state that other public bodies (including local authorities, the Health Service Executive (**HSE**) etc.) as a matter of best practice should use RIAs as a regulatory tool to assist in the identification of the costs, benefits and impacts of their regulations since these can have significant impacts on business competitiveness.

It has also been clarified in the revised guidelines that RIAs must be completed in all situations where proposals for significant legislation are envisaged i.e. those which involve a change to the

regulatory environment. The level of detail should be commensurate to the significance of the proposal. This proportionality rule applies not only to the analysis of costs, benefits and impacts but to the entire RIA process, including the number of options considered, the nature of the consultation process and the treatment of enforcement, compliance and review.

Main Benefits of a RIA

These are as follows.

Main Benefits of a RIA

1. **RIAs can contribute to economic efficiency by highlighting aspects of regulation which limit consumer choice and the level of competition in the economy. RIAs help to identify potential burdens on business and ensure that they are kept to a minimum.**
2. **Because the RIA process includes consultation with a wide range of stakeholders, it also provides an opportunity for those potentially affected by regulations to highlight any unforeseen consequences that may not previously have been considered.**
3. **RIA is also a means of improving the quality of governance by increasing the transparency and legitimacy of the regulatory process.**
4. **RIA is designed to increase the efficiency and effectiveness of the public sector by the provision of quality advice given to Ministers.**
5. **RIA also contributes to achieving value for money and efficiency by generating more detailed information in relation to cost and allowing more extensive analysis of alternative options for achieving policy objectives.**
6. **RIAs also contribute to achieving the six principles of Better Regulation (necessity, proportionality, consistency, effectiveness, transparency and accountability).**

Source: Revised RIA Guidelines, Department of the Taoiseach (2009)

The rules on RIAs do not apply to the Finance Bill, emergency, security and some criminal legislation.

Does the RIA Comply with Cabinet Procedures and Government Guidelines?

In this section, the main Cabinet procedures and Government guidelines are set out and the extent to which the RIA on the Bill complies with all the requirements is assessed.

Table 1 The RIA's Compliance with Cabinet Procedures and Government Guidelines

Cabinet Guidelines	Compliance Assessment
An RIA must be carried out before a Memorandum goes to Government seeking permission to regulate i.e. as early as possible in the regulatory development process.	On 23 May 2013, the Government approved the General Scheme of the Bill. The preparation of the RIA began in September 2013 i.e. several months after the Cabinet considered the Minister for Health's proposals, and was published in August 2014. This guideline was not met.
The level of detail depends on the significance of the proposal; the more significant the impacts are likely to be, the deeper the analysis should be.	In introducing the Bill, the Minister for Health made it clear that this legislation was indeed very significant: *we are walking through a public health epidemic and its time we woke up*.[23] Given the importance attached to the Bill does the RIA go into the required level of detail? In an Irish context the RIA is relatively detailed. The quality of the analysis is a separate issue of course.
All RIAs are to include an analysis of options, including a 'no policy change' option as a benchmark for comparison purposes. Alternative forms of regulation such as voluntary Codes of Practice are to be considered.	The RIA listed two options only: no policy change and the introduction of legislation. Other options were not presented or referenced. This guideline was not met. An assessment of the options that should have been evaluated is set out in Chapter 6.
Once the text of a Bill has been agreed by Government, the RIA must then be published on the Department's web site along with a link to the published Bill.	The RIA is on the Department's web site but was not published when the Bill itself was published. This guideline was not met.
RIAs should be actively disseminated to key stakeholders.	It is understood that the Department sent the RIA to key stakeholders.
Where revised changes to a Bill are submitted an up-dated RIA is required.	The Minister made no reference to the RIA in his speeches in the Dáil and Seanad and there is therefore no evidence that a revised RIA will be prepared to take account of substantial

[23] Houses of the Oireachtas, Dáil Debates, 2 July 2014, page 52.

	amendments to the Bill that have already been introduced and the reservations of ten Member States on the Bill. This guideline has not been met.
RIAs must be conducted on all proposals for EU Directives and on 'significant' EU Regulations before they are agreed and no later than four weeks after the publication of the proposal in order to inform Ireland's negotiating position.	An Irish RIA was not prepared on the draft EU Tobacco Products Directive (**TPD**), or if it was it was never published or shared with stakeholders. The Bill seeks to implement part of the TPD but the RIA does not assess the impacts of these provisions. This guideline was not met.
Once EU laws are adopted, a separate RIA should be prepared on the available transposition options.	The Minister for Health, nor the Department, has signaled that a RIA on the available transposition options under the TPD will be prepared. This guideline was not met.
A formal cost benefit analysis is required in the case of the most significant proposals; the costs, benefits and impacts of all options should be monetised or quantified.	A CBA has not been prepared on the Bill, nor on *Tobacco Free Ireland*, the policy programme underpinning the Bill. Such a CBA would seek to identify and quantify the costs and benefits deriving from the Bill alone. The RIA does not attempt in any detail to assess the unique impacts, costs and benefits of the Bill but addresses the much wider issue of tobacco control. This guideline was not met.

Source: EPS Consulting

Irish Government Economic and Evaluation Service (IGEES)

In launching the Government's policy statement on economic regulation, the Taoiseach said *good quality regulation is central to economic recovery and job creation*.[24] Encouragingly, the statement also said that the Central Expenditure Evaluation Unit of the Department of Public Expenditure and Reform (**D/PER**) now has responsibility for developing central capacity, providing training, support and monitoring compliance in the area of RIAs. However, the scope of the policy statement is limited to sectoral regulators only and does not apply to RIAs on Bills not involving regulators.

Furthermore the focus (and resources) appears to have shifted from the carrying out of RIAs to the conduct of economic evaluation studies as they relate to public expenditure (capital and current).

In 2012, and as part of this reform agenda, the Government decided to set up the IGEES within D/PER to enhance the evaluative and economic capacity of the civil service. [25]

[24] Department of the Taoiseach, *Regulating for a Better Future; a Government Policy Statement on Sectoral Economic Regulation*, July 2013. The policy statement does not apply to financial regulation.
[25] http://igees.gov.ie/

To date, the IGEES has not evaluated health policies but has focused its efforts on the Comprehensive Review of Expenditure.[26] This is perhaps understandable as the Department of Health is but one of only two Departments that are not (as yet) members of the IGEES Management Board. This also suggests that the Department of Health is not benefitting from the evidence-based policy analytical skills and best practice techniques promoted by the IGEES.

[26] Government of Ireland, *Comprehensive Expenditure Report 2015-2017*, Stationery Office, October 2014.

Chapter 4

Compliance with Guidelines on Stakeholder Consultation

Introduction

Consultation is a key element of a RIA. As well as contributing to the framing of regulation, effective consultation promotes a greater understanding of proposals and consequently better compliance with Irish legislation. In addition, it guards against the possibility of involving only those who are most vocal or best resourced to express views on particular policies or regulations.

The Cabinet Handbook (step 4) states that a formal consultation process should be held within reasonable timeframe for responses. Views expressed during this process are to be summarised and addressed in the RIA.

The Department of the Taoiseach's RIA guidelines (Section 5, paras 4.60 to 4.62) are more explicit and recommend the following.

1. *Consultation with key stakeholders should take place as early as possible in the RIA process so that it can feed into the analysis of the costs, benefits and impacts.*
2. *Where possible, a draft RIA should be used as the basis for consultation.*
3. *Formal consultation should be carried out in respect of more significant regulatory proposals and, at a minimum, informal consultation (i.e. not necessarily publically advertised or all-inclusive) should always be undertaken.*
4. *All affected parties should be consulted (in addition to all Departments and Offices), including the social partners and relevant interest groups.*
5. *A summary of views conveyed through the consultation process should be set out as part of the RIA.*
6. *The RIA should contain a brief response to key issues raised.*
7. *Where the final regulatory proposals do not take on board points and issues raised during the consultation process, this should be explained where possible.*
8. *RIAs should be published online on Departmental web sites and as early as possible.*

The key point is that ***the RIA should be conducted at an early stage and before a decision to regulate has been taken. Ideally, RIA should be used as a basis for consultation.***

Detailed (and separate but complementary) guidelines about public consultations are in force.[27]

[27] Department of the Taoiseach, *Reaching Out: Guidelines on Consultation for Public Sector Bodies*, 2005.

Main Benefits of Consultation

1. **It assists the decision-making process by ensuring that interested parties can express their views on a policy.**
2. **It helps to gather useful information to inform the evidence base for making regulations, including the identification of (non-regulatory) alternatives.**
3. **It supports the rationale for a regulatory intervention or shows that the perceived need for that intervention is not confirmed by the facts.**
4. **It helps to inform decisions on strategic planning or investment.**
5. **It strengthens the focus of public bodies on the needs of the public.**
6. **It brings Government closer to the citizen (and facilitates greater transparency).**
7. **It empowers individuals and communities to strengthen their role in society.**
8. **It contributes to a shared understanding of issues and work towards agreed solutions.**
9. **It can identify the likely pitfalls or possible unintended consequences of a proposal.**

Source: Guidelines on consultation for public sector bodies (2005)

Thus not only should RIAs be informed by stakeholder inputs they should be seen to be done as an effective verification mechanism to ensure all relevant issues are comprehensively addressed. Above all else a balanced view reflecting public feedback should inform policy-making.

The fostering of dialogue is about the engagement of policy-makers with all stakeholders in sectors affected by regulation and the conduct of such dialogue in a fully inclusive and transparent manner. Notwithstanding considerable development and formalisation of consultation procedures, the evidence from Ireland suggests that such processes are frequently not very open, and linked to this, the requirement to consider alternatives to traditional regulation is frequently not given full or equal consideration.[28]

Consultation on the Draft Irish RIA

On 7 February 2014, several months after the Government had decided to legislate, the Department wrote to a limited number of 'relevant' stakeholders, including the tobacco industry and retail organisations, seeking views on the General Scheme of the Bill.

The Minister for Health told the Dáil the previous July that in line with the RIA guidelines published by the Department of the Taoiseach, *my Department will conduct a RIA on the proposed legislation*

[28] Brown, C. and Scott, S. Regulation, Public Law and Better Regulation, *European Public Law* 17, No 3 (2011): 467-484..

and that consultation with all relevant stakeholders is an integral part of the RIA process, which will also consider the costs, benefits and impacts of the proposal.[29]

Respondents were given two weeks within which to respond. Best practice at EU level is that a 12 week consultation period should have been used.

In addition, respondents were told to restrict their comments to the General Scheme and identified omissions: otherwise the Department would not consider the material.

Furthermore the Department's RIA (page 31) made clear that only submissions that were compatible with overall tobacco control policy as set out in *Tobacco Free Ireland* were considered. Refusing to assess submissions that challenged core policy objectives is not the basis for conducting an objective stakeholder consultation which seeks to get informed opinion. Not allowing stakeholders comment on the projected impacts, costs and benefits of the Bill is another serious omission, which (again) undermines the credibility of the RIA.

All the 15 submissions received were published on the Department's web site.

The RIA listed the main concerns made under each Head but did not provide a point-by-point response to the reservations that were expressed. The RIA made clear that drafting changes only were considered where these were compatible with overall tobacco control policy as set out in *Tobacco Free Ireland*.

The responses received in Ireland fell well short of the level of interest in similar draft legislation in other jurisdictions. The question could well be asked as to why a country of a comparable size such as New Zealand engaged with nearly 300 stakeholders whereas the Department of Health was satisfied to get the views of just 15 stakeholders.

Oireachtas Pre-legislative Scrutiny

The Joint Committee was briefed on the Bill's General Scheme by the Minister for Health and Children and the Chief Medical Officer on 5th December 2013.

The purpose of the pre-legislative scrutiny was to facilitate consultation with key stakeholders before the Bill was finalised and presented to the House for consideration as part of the formal legislative process.

This pre-legislative scrutiny is quite separate from the conduct of a RIA and the seeking of views on its findings and recommendations.

The General Scheme has no legal effect and is subject to the legal advice of the Office of the Attorney General. Typically, once the Heads of a Bill are approved by Government the legislation is drafted by the Office of Parliamentary Counsel and published as a Bill. Thus the Joint Committee recognised that the General Scheme was at a preliminary stage of the legislative process and that the Bill, once published, can potentially vary from the provisions outlined in the General Scheme.

[29] Houses of the Oireachtas, Dáil Debates, 16 July 2013, page 127.

The Joint Committee invited written submissions from interested groups and individuals and held a series of meetings between 23 January and 13 February 2014 with 43 key stakeholders and experts, including representatives from the tobacco industry. Many committee members had misgivings about direct engagement with the tobacco industry.[30]

The Joint Committee report, in addition to setting out 26 recommendations that dealt with several tobacco-related measures other than those addressed in the Bill, set out key facts and figures about smoking; general points about the General Scheme of the Bill; current law and policy; intellectual property rights; and key provisions and stakeholder comment.

The RIA acknowledges that *many contributors spoke more generally on the area of tobacco control and on aspects of the area not related to standardised packaging*. As a result only 13 of the 26 recommendations addressed specific points related to the General Scheme; these are listed in Appendix 1 of the RIA. According to the RIA, these 13 recommendations were taken into account by the Department in the drafting of the Bill but it is not stated how this was done or what provisions were adapted to reflect the views of the Joint Committee. It was clear, however, that the only issues entertained were those considered to be compatible with overall tobacco control policy as set out in *Tobacco Free Ireland*.

The Joint Committee did not consider the Department's draft RIA or if it did it is not mentioned in their report.

Several stakeholders (for example Retail Ireland and South Dublin Chamber) argued that there was no credible evidence that standardised packaging as a policy proposal would lead to a reduction in youth smoking or prevent youth initiation.[31] Ibec also pointed out that the proposals being considered by the Joint Committee, in accordance with Cabinet guidelines, should be the subject of a RIA. [32]

A failure of the process is that the RIA did not take into account or refer to the contrary views of a number of key stakeholders, including expert evidence presented for and behalf of tobacco manufacturers.

The Joint Committee decided not to wait until evidenced-based research - a critical element of a RIA - was available.[33]

Australia's Public Consultation[34]

In April 2011, the Australian Government began a 60-day public consultation period to allow the Australian and international community to comment on the proposed Tobacco Plain Packaging Bill

[30] Houses of the Oireachtas, Dáil Debates, 3 July 2014, page 37.
[31] op cit. Houses of the Oireachtas report, Volume 2, Appendix 1.
[32] IBEC, presentation to the Oireachtas Joint Committee on Health and Children, 6 February 2014.
[33] op cit. Houses of the Oireachtas report, page 43.
[34] The following sections demonstrate how public consultations were carried out in some countries about plain packaging. The report does not pass judgment on the substance of the matters or as to the adequacy of the process which was followed during these consultations.

2011. [35] The Department of Health and Aging's consultation paper outlined the Government's approach to implementing plain packaging, its response to the design testing and targeted consultations and provided an explanation of the key provisions of the Bill, which was released at the same time. Limited scientific evidence to justify the Bill was provided. Some 265 submissions were received; some 99 supported the Bill with 158 opposed. Some 44 submissions were received from overseas respondents. Effort was made to present the comments of the submissions clearly and accurately.[36]

New Zealand's Public Consultation

On 23 July 2012, the New Zealand Ministry of Health issued a consultation document on the proposal to introduce plain packaging of tobacco that set out the Government's proposal and a separate Regulatory Impact Statement which informed the Government's decision in principle to proceed with plain packaging. The paper included twenty key questions to guide respondents' feedback. [37] Some 292 submissions were received, with 48 from overseas respondents. All submissions were reviewed and responses were provided to all the key issues that were identified.[38]

UK's Public Consultation

On 16 April 2012, The UK's Secretary of State for Health published a consultation paper on standardised packaging of tobacco products. The paper indicated that a report of the evidence on plain packaging had been reviewed in accordance with the Department of Health's Research Governance Framework. [39] Respondents were given some 12 weeks to indicate their views to 15 consultation questions; this period was extended by a month in order to allow more people to respond. A consultation-stage RIA was published alongside the consultation paper. More than 668,000 responses were received.

The following table compares the consultations undertaken on the RIA and by the Joint Committee against the European Commission's (2013) *Code of Good Practice for Consultation of Stakeholders*.

[35] Department of Health and Aging (Australia), *Consultation Paper, Tobacco Plain Packaging Bill 2011*, Exposure Draft, 7 April 2011.
[36] *Public consultation on the exposure draft of the Tobacco Plain Packaging Bill 2011: summary of submissions,* report prepared by Biotext Pty Ltd., Canberra, September 2011.
[37] Ministry of Health (New Zealand), *Proposal to Introduce Plain Packaging of Tobacco Products in New Zealand, Consultation Document,* July 2012.
[38] *Submissions' Analysis on the Proposal to Introduce Plain Packaging of Tobacco Products in New Zealand*, Allen + Clarke, 21 November 2012, Wellington, New Zealand.
[39] Department of Health, Social Services and Public Safety (UK), *Consultation on Standardised Packaging of Tobacco Products*, April 2012.

Table 2 Comparison of Irish Consultations Against EU Best Practice

EU Standard	D/Health Consultation	Oireachtas Consultation	Additional Comment
Plan **consultations early in the policy-development process.**	Consultation on the RIA started after Government policy had been determined.	Consultation on the Bill started after General Scheme had been approved.	Consultations on the RIA and the Bill should have started before Government policy was determined.
Explain **why the consultation is taking place and that stakeholders' views will be taken into account**	Respondents were told to submit views in compliance with a prescribed format.	Stakeholders were given an opportunity to contribute to the drafting of the Bill.	There is no evidence that the views expressed were fully taken into account.
Involve **the widest spectrum of stakeholders**	Only a limited number of stakeholders asked for comments; 15 submissions received.	Interested stakeholders asked to submit views on the General Scheme: 28 presentations were made	Compared to public consultations undertaken in other jurisdictions the level of response was quite low.
Organise **consultations in ways which are convenient and accessible; 12 weeks should be allowed**	Respondents were given two weeks to respond.	Respondents were given two weeks to respond.	Compared to public consultations undertaken in other jurisdictions Irish authorities required responses within a very short time frame and well outside what is considered to be best practice.
Analyse **the input and data received and distinguish between evidence and opinion**	This type of analysis was not completed.	This type of analysis was not completed.	
Give feedback **to stakeholders in a way that clarifies how the decisional outcome was reached**	No evidence was provided as regards the extent to which any submissions were taken into account. It was clarified however, that only inputs that were compatible with overall	13 recommendations based on submissions received were taken into account on the basis that that were compatible with	By setting restrictions on what merited consideration e.g. proposals other than those which were fully aligned with Government policy, respondents clearly could not influence

	tobacco control policy would be considered.	overall tobacco control policy.	policy outcomes or the choice of alternatives to primary legislation.
Report **back on the next steps in the policy-making process and their timeline**	Stakeholders (at least those from industry) have not been communicated with since their submissions were made in February 2014.	Stakeholders (at least those from industry) have not been communicated with since their submissions were made in February 2014.	There is no on-going dialogue with all interested stakeholders.
Communicate **the consultations and their results clearly and directly**	Submissions are accessible on the D/Health web site as is the text of the final RIA.	Submissions appear on Oireachtas web site as does the final report.	This conforms with best practice guidelines.
Act **on the findings to improve policy**	RIAs on other tobacco control measures have been promised.		
Evaluate **consultations and review the process to inform future consultations**	No evidence in the public domain about lessons learned and how these will influence future consultations on the Department's RIAs.	No evidence in the public domain about lessons learned and how these will influence future consultations on Health Bills.	

Source: European Commission Code of Best Practice on Stakeholder Consultation and EPS Consulting

Chapter 5

Impacts, Costs, Benefits and Burdens

Introduction

The Cabinet Handbook (step 3) requires that RIAs involve a detailed and rigorous analysis of costs and benefits and their distribution under the following headings:

- National competitiveness, including employment;
- The socially excluded or vulnerable groups;
- The environment;
- Whether the proposal involves a significant policy change, including impacts on competition and consumers;
- North-South, East-West relations;
- The rights of citizens and human rights; and
- Compliance burden on third parties e.g. citizens and business.

The Department of the Taoiseach RIA guidelines (para 4.38) clarifies that this list is indicative and if other impacts arise they must be included in the RIA. The guidelines make it clear that the level of analysis should be proportionate to the significance of the proposal and that the consultations on the proposal should assist policy-makers determine if the proposal is, in fact, significant.

In addition, the guidelines set out (Appendix D) how the required multi-criteria analysis should be conducted. Decision rules for a CBA are also supplied (Appendix D, page 67 et seq) as are instructions as to how to measure the administrative burdens on business (Appendix E). Finally, the guidelines set out (Appendix F) how public service implementation costs are to be calculated.

There is a lack of robust evidence to support some of the important assumptions at the core of the Bill's rationale and in other cases statistics used to justify this particular piece of legislation cannot, in fact, be attributed to the impact of the Bill exclusively.

This Chapter assesses whether and to what extent the RIA complies with the Cabinet Handbook and the Government's guidelines and with the more recent Public Spending Code. [40]

[40] Department of Public Expenditure and Reform, Circular 13/13, 2 September 2013. A cost benefit analysis is required for all programmes with current expenditure over €20m with an annual spend of at least €5m. The general principle of cost benefit analysis is to assess whether or not the social and economic benefits associated with a project are greater than its social and economic costs.

Impact Assessment

The Department clarified in writing to stakeholders (in February 2014) that the RIA would consider the costs, benefits and impacts of the proposals.

To assist the Department in this task the Government RIA guidelines (paras 4.39 to 4.59) provides detailed guidance about the six minimum issues that require to be evaluated and how costs, benefits and impacts are to be shown in the RIA (page 16); none of these six issues were addressed in any level of detail.

The Department looked at two options only.

In presenting the case for the status quo (no change) the Department stated by not legislating this would not involve any direct financial costs to the State but that such an approach ***may*** lead to substantial (but unquantified) indirect health costs. The primary benefit for not legislating was that the State would avoid litigation. No other possible benefits were cited or identified. All the impacts listed were negative: failure to legislate would reflect badly on the State's commitment to protecting health to the fullest possible extent.

The same comment applies to the Department's attempt to set out the costs, benefits and impacts of the proposed legislation. For example, while reference is made to a reduction in Exchequer receipts no attempt was made to produce a precise figure or even an approximation of this loss. Reference is made to savings due to reduced deaths and illness but again there is no quantification of these savings even in ballpark figures. The costs (not quantified) associated with possible legal challenges are mentioned in a general way. The costs to manufacturers in relation to altering packaging are mentioned but not quantified.

In the section on impacts, the RIA notes that the measure represents the latest strand in the comprehensive range of tobacco control legislation. This is not an 'impact' but an expression of the significance of the Bill in the overall policy framework. The next part of the impact section notes that evidence suggests that standardised packaging can reduce the appeal of tobacco products.

It is very clear that the Department has either fundamentally misunderstood the requirements of the RIA guidelines as regards the level of detail and analysis needed to support an impact assessment, or it has chosen to ignore the guidelines.

Public Spending Code

In assessing the Exchequer funds spent on tobacco-related illnesses and in identifying the savings across the healthcare sector resulting from a range of tobacco control measures proposed and in place, the Department and the HSE are required to adhere to the Public Spending Code. This Code is designed to ensure that the State gets the best possible value for the resources at its disposal. A key principle is consultation with and participation by stakeholders.

The HSE's Service Plan for 2013 [41] identifies its priorities, within *the Health and Wellbeing Framework* (which has an overall budget of €594m), as including the implementation of the

[41] HSE, National Service Plan 2013.

recommendations of the *HSE Tobacco Control Framework* and the Government's strategy *Towards a Tobacco Free Society: Report of the Tobacco Free Policy Review Group* and enforcement of the *Public Health (Tobacco) Acts* and tobacco control legislation. [42] Thus arguably a full CBA should be undertaken under the Code about the value for money of the tobacco control programme. Such a CBA would test the veracity or otherwise of data used to support the Bill and indeed other related actions and measures. In addition, the CBA should assess and quantify the costs of alternatives to regulation such as investment in educational and awareness raising campaigns.

Providing the data to support a CBA should not be an issue as the HSE's Health Intelligence Ireland unit has published guidance about the carrying out of evidence-based healthcare policy analysis; a practice that is defined as the *conscientious, explicit and judicious use of current best practice in making decisions*.[43]

Key Statistics

A review of the key statistics quoted to justify the Bill demonstrates that they are all out of date; do not reflect current trends; are somewhat contradictory; and quite a few are inaccurate. Therefore one might question the robustness of the base data that was used to justify the proposal in the first instance. Certainly, the data suggests that policy alternatives to legislation are far more impactful and in the absence of any comparative analysis it was an error to opt for legislation only.

The confusion about statistics and costs prompted one TD (Deputy Finian McGrath) to remark: *Deputies do not know the cost benefit and impacts of the Bill. This information should be made available to Deputies so they know what they are voting (for).*[44]

Commission's Impact Assessment

The Commission's Impact Assessment (**IA**) on the draft TPD set out in considerable detail the economic impacts of the three primary policy options in the field of packaging and labelling. These included one-off costs for manufacturers noting the economies of scale that would result if an EU-wide requirement was adopted. The IA also examined social and health impacts and the administrative burden on businesses. The difficulty which retailers would face was set out. In relation to the option of legislating for standardised packaging, the IA analysed the new market dynamics that might result, including the low entry barrier for non-branded products. The IA concluded *that the precise economic effects of standardised packaging are difficult to quantify at present due to lack of empirical data and experience with standardised packaging in Member States and other countries*.[45]

[42] HSE, *Tobacco Control Framework*, February 2010.
[43] Health Intelligence Ireland.
[44] Oireachtas, Dáil Debates, 3 July 2014, page 34.
[45] European Commission, *Impact Assessment accompanying the proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products*, SWD (2012) 452 final, 19 December 2012.

The Administrative Burden

Appendix E of the Department of the Taoiseach RIA guidelines spells out in considerable detail how Departments should measure the administrative burdens arising from proposed legislation.

The administrative burden of regulation on business refers to the time and cost of the administration associated with compliance, such as preparing reports and making returns to Government departments, agencies and regulators where such record keeping and reporting would not otherwise be undertaken by business.

The need to reduce the administrative burden on business is a priority at EU level. Specific targets have been set by the European Council and by a number of Member States. There is obviously a strong rationale for such moves given the fact that regulation imposes a significant cost on business.

In March 2008, the Irish Government decided on a 25% target for administrative burden reduction, to be achieved by 2012. This followed a report from the Business Regulation Forum in April 2007 which recommended that a burden reduction programme should be introduced and that a reduction of 25% in administrative costs could save Irish business in the order of €500 million annually. [46] It is also in line with the European Commission's own target to reduce the administrative burden of EU regulation by 25% by 2012.

The (then) Tánaiste and Minister for Enterprise, Trade and Employment was given responsibility for co-ordinating the cross-Government effort to measure and reduce administrative burdens on business, deriving from domestic regulation, but it was (and is) the responsibility of each Government Department to carry out measurement and simplification with a view to reaching the Government target. The Department of Jobs, Enterprise and Innovation (**D/JEI**) is now leading this process by quantifying the current burden of regulation under its remit. The approach adopted involved reviewing all the legislation under the responsibility of the Department and the identification of a prioritised list of Information Obligations (**IOs**) identified for measurement in the fields of company, employment and health and safety legislation.

In July 2011, the Government agreed a project, led by the D/JEI Business Regulation Unit, to measure the administrative burden on business arising from regulation under the responsibility of seven Departments (Communications, Energy and Natural Resources, Social Protection, Agriculture, Food and the Marine, Environment, Community and Local Government, Public Expenditure and Reform, Health and Transport, Tourism and Sport) and Revenue. This initiative was informed by international experience that 90% of administrative burden comes from fewer than 5% of the administrative requirements in regulation. The Irish approach to conducting a base-line measurement has therefore been to identify that 5% before measuring, thus making the project much more efficient.

The measurement project found an overall administrative burden on business of over €1.55 billion per year. This quantum, however, does not include significant Departments such as Health, nor does it capture the IOs imposed by many State bodies and organisations such as the HSE.

[46] Department of Enterprise, Trade and Innovation, S*econd Report of the High Level Group on Better Regulation,* 2009.

The High Level Group on Business Regulation is active, broadly representative and is seeking to persuade Government to take the Better Regulation agenda far more seriously than is currently the case. The Group acknowledges that administrative burdens act as a drag on economic growth and divert economic resources away from productive activity. Reducing these burdens increases competitiveness and supports job growth. [47] There is no evidence that this message is being taken seriously by the Irish Government. For example, the Group's recent (2012) recommendations about RIAs and business impacts have not been implemented.

The RIA did not quantify the administrative burden on retailers, the tobacco and business. While the RIA mentioned these burdens and their associated costs, no attempt was made - as is required under the RIA guidelines - to quantify these amounts.

[47] Department of Jobs, Enterprise and Innovation, the High Level Group on Business Regulation, 2012 Report, page 9.

Chapter 6

Options Appraisal

Introduction

The Cabinet Handbook (step 2) states that a RIA should include a 'no action' option where relevant and at least one approach which is either an alternative to regulation or an alternative form of regulation to the traditional approach. In addition, the RIA should contain a summary of the performance of each option and an identification of a preferred option where appropriate (step 7).

Citing international best practice, the Department of the Taoiseach RIA guidelines state that a 'no policy change'/'do nothing' option should be included as this would serve as a useful benchmark against which other option**s** (plural) can be compared. It also clarifies (para 4.12) that all RIAs must include an analysis of options even where Government has committed to regulate.

Drawing on OECD best practice, the guidelines state (Appendix J) *that efficient and effective policy is only possible if all available instruments are considered*.

According to the (2009) RIA guidelines alternative forms of regulation include the following.

Type	**Example**
'Command and Control' – regulations which prescribe/proscribe certain actions	Most regulations
Self-regulation – control of activities by the private parties concerned without the direct involvement of public authorities	Advertising Standards Authority
Co-regulation – control of activities by a combination of action from private parties and public authorities	Law Society
Performance-based regulation – where the regulator sets standards and leaves it to the regulated entity to determine how best to meet these standards	Regulations which set emissions standards for vehicle manufacturers

Source: Revised RIA Guidelines, Department of the Taoiseach (2009)

The literature cites the deployment of a wide range of alternatives to classical rule-based models of regulation.[48]

This Chapter assesses the extent to which the Department's RIA and the Joint Committee's report considered options other than legislation and the conclusions that were drawn.

Options Listed in the RIA

The RIA listed just two options: no policy change and the introduction of legislation.

This is because prior to the conduct of the RIA the Government had opted for one course of action: primary legislation. The Government took this decision in breach of the Cabinet Handbook.

The RIA did not reference the options identified by the Joint Committee; see below.

Contrary to the Cabinet Handbook and Government RIA guidelines other options were not assessed nor did the Department explain why other options were not evaluated.

Many of the submissions made on the draft RIA had expressly asked that options other than legislation be considered.

These included the following:

1. Administrative sanctions for the purchase or attempted purchase, and the consumption, of tobacco by minors;
2. Reinforcing retail access prevention measures, such as the 'Show Me ID – Be Age OK' programme;
3. Greater resources and manpower for effective, targeted enforcement strategies; and
4. Strengthening targeted public information campaigns to quickly and effectively raise awareness of negative licensing schemes and the criminalisation of proxy purchasing by adults for minors.

Also contrary to the Cabinet Handbook and Government RIA guidelines (and in contrast to other Irish RIAs)[49] the respective costs and burdens of these two options and the impacts were not quantified in detail.

Options Identified by the Joint Committee

Several alternatives to standardised packaging in achieving the aim of a reduction in smoking prevalence were identified in the Joint Committee's report, which recommended that the Minister consider some of these proposals.[50]

Options included a ban on proxy purchasing (i.e. the purchasing by adults of cigarette products for those under 18 years of age); higher taxation; more investment in public education programmes; the

[48] op cit. Brown and Scott.
[49] For example, the RIA carried out on the Legal Services Regulation Bill 2011.
[50] op cit, Houses of the Oireachtas report, page 70 et seq.

need for more investment in cessation and quit programmes; regulating the sale of e-cigarettes; and prohibiting the sale of cigarettes in licensed premises.

Options Identified in New Zealand

The New Zealand RIA on their proposed standardized packaging legislation listed the following options:[51]

1. Status quo;
2. Increased and refreshed health warnings;
3. Regulatory change to require plain packaging of tobacco products;
4. Increased public education;
5. Voluntary agreements with industry or self-regulation; and
6. Supply control measures.

Under scenarios 1 to 3, the RIA assessed the impacts for Government, for the tobacco industry and printing and design companies, and for smokers and society.

The RIA was concluded after a three month consultation period.

Options Identified by the European Commission

Detailed guidance is provided by the European Commission for its officials as regards the assessment of policy options as part of an overall IA. [52] The Department's RIA options appraisal falls short on nearly every count when compared to what is considered to be best practice.

EU Guidelines on Policy Options Appraisal

1. **Considering a wide range of 'realistic' policy options will force you to think 'out of the box' and will also provide greater transparency.**
2. **Policy options must be closely linked both to the causes of the problem and to meet the desired policy objectives.**
3. **The set of options should include:**
   - **A 'no policy change' baseline scenario;**
   - **Self- and co-regulation;**
   - **International standards where these exist; and**
   - **Where legislation already exists, improved implementation and enforcement.**
4. **Narrow down the options by screening them for technical and other constraints, and by assessing them against the criteria of effectiveness, efficiency and coherence with other policy objectives.**
5. **Explain clearly the reasons for excluding certain options from further analysis.**
6. **Avoid presenting only the status quo option, the 'extreme' option and the preferred option.**

[51] *Regulatory Impact Statement: Plain Packaging of Tobacco Products*, Ministry of Health (New Zealand), November 2012. See also footnote 34.
[52] European Commission, *Impact Assessment Guidelines*, SEC (2009) 92, 15 January 2009 (pages 29-31).

Chapter 7

Compliance with the Principles of Better Regulation

Introduction

In Ireland the key principles of Better Regulation have been identified as follows.

Ireland's Better Regulation Principles

Clarity of Policy Objective: ***the nature and the scale of the problem which the regulation seeks to address must be clearly defined and the objectives of the regulation must be clearly stated and legitimate.***

Targeting and Proportionality**:** ***regulation should be focused on the particular problem identified and be no more intrusive than is required and proportionate to the goal*.**

Evidence-based Assessment: ***the evidence base for the policy must be both the best available and reliable; there must be evidence to support the proposal over alternative options; and impact assessments must be conducted and must be as accurate and complete as is reasonably practicable.***

Incremental value**:** ***regulators should review and evaluate existing legislation and other options before regulating further.***

Enforceability: **regulation should be capable of being complied with and enforced effectively.**

Source: Regulating Better: Government White Paper (2004)

This Chapter assesses the extent to which the RIA reflects these key principles.

Clarity of Policy Objective

The key issue is: ***the nature and the scale of the problem which the regulation seeks to address must be clearly defined and the objectives of the regulation must be clearly stated and legitimate.***

The Cabinet Handbook rules (step 1) states that all RIAs describe the background to the issue and the identification of policy problems to be addressed and the objective(s) behind the proposal.

The RIA sets out three primary policy objectives as follows.

1. To decrease the appeal of tobacco products.
2. To increase the effectiveness of health warnings on tobacco packaging.
3. To reduce the ability of packaging of tobacco products to mislead consumers about the harmful effects of smoking.

In respect of each policy objective the RIA cites key reviews which were used to form the evidence base for the policy objectives as set out. The use of this evidence is considered below in more detail.

The RIA (page 52) notes that the majority of stakeholders objected to the introduction of standardised packaging.

The following concerns were set out in the RIA:

- Restrictions on the use of trademarks;
- Consumer/customer/retail staff confusion;
- Effects on retailers' businesses;
- Increases in illicit trade;
- Erosion of brand equity;
- Damage to competitive market economy;
- Damage to intellectual property rights;
- Breaches to international treaties and constitutional rights; and
- Cost.

The RIA addressed the arguments made by stakeholders as regards to illicit trade, impact on retailers, intellectual property, costs and the Bill's relationship with the TPD. Other substantive points made, such as deficiencies in the research used to justify the draft legislation were dismissed or not dealt with.

The Bill's policy objectives were informed by the findings of the report *Tobacco Free Ireland*, which in turn was considered within the new health and wellbeing framework Healthy Ireland – *A Framework for Improved Health and Wellbeing 2013-2025*. An evidenced-based outcomes framework will be developed to assist the delivery of the actions and measures identified and the achievement of targets (for example a reduction of one per cent per annum in smoking initiation rates). In addition to the introduction of primary legislation, the framework sets out other forms of regulation that will be used through all phases of implementation. [53] The Tobacco Policy Review Group that prepared *Tobacco Free Ireland* comprised departmental and HSE officials only. The document was prepared without extensive stakeholder consultation.

[53] Department of Health, *Healthy Ireland*, 2013. The document sets out a vision that will improve the health and wellbeing of all of the population over the next 12 years by way of a 'whole of society' approach to healthcare.

The level of policy ambition is that Ireland will be tobacco free by 2025 and to this end the report lists 60 recommendations and actions that need to be implemented, of which legislating for the introduction of standardised packaging for tobacco products is but one.

In the context of the three specific policy objectives to be achieved by the Bill, the Department identified six *important, effective and evidenced based tobacco control policies* as follows.[54]

1. Monitoring of tobacco use and prevention policies.
2. Protecting people from second-hand smoke.
3. Offering help to people who want to quit.
4. Warning of the dangers of tobacco.
5. Enforcing bans on advertising, promotion and sponsorship.
6. Raising taxes on tobacco.

Thus the Bill is part of a suite of measures designed to tackle tobacco consumption.

The RIA did not seek to 'ring-fence' the unique impacts, costs and benefits arising from the enactment of the Bill and in that regard did not draw a close enough link between the achievement of the Bill's policy objectives and the precise contribution which the Bill would make to those objectives.

Targeting and Proportionality

The key issue is: ***regulation should be focused on the particular problem identified and be no more intrusive than is required and proportionate to the goal***.

Proportionality means striking a balance between the advantages a regulation provides and the constraints that it imposes. The first consideration is the fundamental question: is Government action required in the first place and, if so, should that action be regulatory? [55]

This principle was further clarified by the Department of the Taoiseach RIA guidelines (para 3.2) as follows:

> *Proportionality applies not only to the analysis of costs, benefits and impacts but also to the entire RIA process, including the number of options considered, the nature of the consultation process and the treatment of enforcement, compliance and review.*

Another aspect of proportionality is ensuring that, when framing regulations, the burdens imposed and the penalties for non-compliance are proportionate to the risks.

The Better Regulation principles in noting that *we will regulate as lightly as possible* expressly recommend that Departments promote different ways of regulating and alternatives to traditional regulation as ways of more effectively achieving policy goals (Action 5.2.1).

[54] This framework has been informed by the WTO MPOWER model which was developed to enable countries to implement the Framework Convention on Tobacco Control measures.
[55] op cit. *Principles of Better Regulation*, page 20.

On the other hand, where significant impacts are deemed likely, the deeper the analysis should be. It is a requirement of the Department of the Taoiseach's guidelines (para 3.3) that a formal CBA is required in the case of the most significant proposals. It is clear from the language used in the RIA that the Bill does in fact represent a *significant proposal*. However, a CBA was never carried out.

Nor did the Department, again contrary to Government guidelines, attempt to assess in detail the administrative burden on business arising from the enactment of the Bill.

Nowhere in the RIA does the Department make the argument that the provisions in the Bill are proportionate. It is assumed *fait accompli* that they are; this is not an acceptable level of analysis. Furthermore, no evidence was produced to justify the policy objective in the Bill's Explanatory Memorandum that the *legislation is intended to remove one of the last remaining frontiers for tobacco advertising*. [56]

The Better Regulation principles also commit Government to target new regulations more effectively (page 16).

Because the Bill is but one of 60 proposed measures as part of a much wider tobacco control programme the RIA did not attempt (as it should have) to isolate in sufficient detail the unique problems the legislation sought to address and the counterpart policy objectives that would be met. There ought to have been a rigorous analysis of the nexus between the specific provisions proposed and the stated policy objectives.

Furthermore, the RIA did not mention or consider less intrusive (but arguably more effective) methods such as taxation or spending more on education to secure the stated policy objectives.

A further lapse is that - again contrary to Government guidelines - the Bill does not contain a section requiring a review of the legislation. The Department of the Taoiseach's RIA guidelines (Section 7, para 4.67) expressly states that a RIA should identify mechanisms (such as compliance targets) for periodically reviewing the regulations to evaluate the extent to which they are achieving the objectives and intended benefits.

It might be reasonable to conclude that the Minister for Health wished to introduce legislation regardless of the views of stakeholders. Issues such as the proportional nature of the Bill were it appears cast aside in the rush to have the legislation submitted to Government.

Evidenced-based Assessment

The key issue is: ***the evidence base for the policy must be both the best available and reliable; there must be evidence to support the proposal over alternative options; and impact assessments must be conducted and must be as accurate and complete as is reasonably practicable***.

The Cabinet Handbook rules (Step 2) requires a RIA to include no action where relevant and at least one approach which is either an alternative to regulation (for example, taxation, information

[56] Houses of the Oireachtas, Public Health (Standardised Packaging of Tobacco) Bill 2014, Explanatory and Financial Memorandum, para 3.

campaign etc.) or an alternative form of regulation to the traditional approach (for example, self-regulation, co-regulation etc.).

The Department of the Taoiseach's RIA guidelines (page 11) elaborates a bit further and states ....*we will require higher standards of evidence before regulating*.

Evidence-based policy is public policy informed by rigorously established objective evidence and doing so in a credible manner. It necessitates that the evidence base for the policy must be both the best available and reliable (in the sense that it is *inter alia* impartial, credible and up-to-date) and that there must be clear evidence to support any given proposal over alternative options. Therefore the option of not regulating (the 'do nothing' option) or introducing non-legislative measures should be assessed with equal vigour as the option of introducing legislation.

Evidence-based policy-making is especially important where legislation is being considered for the first time.

Credible evidence and analysis can play a useful, even decisive, role in informing policy-makers' judgments. Using credible evidence can also condition the political environment in which those judgments need to be made. Without evidence, policy-makers fall back on intuition, personal bias, ideology, or conventional wisdom. But the resulting policies can and do go seriously astray (with major adverse cost consequences and unintended negative impacts) given the complexities and interdependencies in society.[57]

The advocates of evidence-based policy rightly urge the incorporation of rigorous research evidence into public policy debates and internal public sector processes for policy evaluation. The primary goal is to improve the reliability of advice concerning the efficiency and effectiveness of policy settings and possible alternatives. Competing sets of evidence and testimony inform and influence policy.

The key enabling factors are:

- High quality information bases;
- Cohorts of professionals with skills in data analysis and policy evaluation; and
- Political incentives for using evidenced-base analysis and advices in governmental decision-making processes.[58]

The evidence set out in the RIA to justify the introduction of the proposed measures by way of primary legislation relied on the following four reports:

1. Evidence Review, Standardised Packaging of Tobacco Products;[59]
2. Plain Tobacco Packaging: A Systematic Review;[60]

[57] Banks, G., *Evidence-based Policy-making, What is it? How do we get it*, Australian Government Productivity Commission, February 2009.
[58] Head, B. (2009) *Evidence-based policy: principles and requirements*, University of Queensland.
[59] Hammond, D., *Evidence Review: Standardised Packaging of Tobacco Products,* a report prepared for the Department of Health*,* University of Waterloo, March 2014.
[60] Moodie, C., et al, (2012) *Plain Tobacco Packaging: A Systematic Review*, Centre for Tobacco Control, University of Sterling, a report prepared for the (UK) Department of Health.

3. Plain Tobacco Packaging Research: An Update;[61] and
4. Standardised Packaging of Tobacco.[62]

These reports are supposed to present the scientific evidence and potential impacts only; they do not look at other arguments such as the proportionate nature of the measures proposed in any level of detail.

Not all the reports come to the same conclusion; Chantler for instance concluded: *there are limitations to the evidence currently available as to the likely effect of standardised packaging on tobacco consumption*.

Nor do the reports consider scenarios other than achieving tobacco control policy objectives by means other than primary legislation.

Importantly, practically all of the research cited was not conducted in Ireland but relates to the situation in other jurisdictions. For example, the Hammond Report for Ireland's Department of Health assessed 75 sources in ten countries but no recent primary research about the potential impact on people's health of plain packaging as it might apply in Ireland was referenced. While the up-date report from the University of Sterling cited 17 new studies none addressed the situation in Ireland.

The evidence submitted by or on behalf of tobacco companies is dismissed as lacking credibility or reliability. For instance, the report of Roland Berger - that was ignored - contains evidence that should have merited closer scrutiny not least because the findings about the loss of jobs and Exchequer revenue. [63] On the other hand, the reports upon which the Department of Health has based the RIA and the policy proposals as reflected in the Bill have been accepted without independent scrutiny.

The RIA does not address some key fundamental issues as follows:

- The impacts that the Bill's provisions on their own will have in meeting the policy objectives that the Bill seeks to address;
- Changes in price elasticity's in the Irish market, willingness to pay and cigarette demand across different price segments due to standardised packaging;
- Effect of standardised packaging on sales and therefore on Exchequer yield from tobacco taxes;
- Changes in market competition and companies' pricing strategies due to the introduction of plain packaging;
- Potential increases in legal and illegal cross-border sales; and
- Market entry of new legal, low priced brands.

[61] Moodie, C., Angus, K., Stead, M., and Bauld, L., *Plain Tobacco Packaging Research: An Update*, The Centre for Tobacco Control Research, University of Sterling, September 2013.
[62] Report of the independent review undertaken by Sir Cyril Chantler, April 2014.
[63] Roland Berger, *The Potential Economic Impact of Plain Packaging for Cigarettes and Fine-Cut Tobacco in Ireland*, 2013. This report was prepared for Philip Morris International Management S.A.

Neither does the RIA assess the cumulative impacts to date of the myriad of tobacco measures introduced since 2001 with a view to isolating the incremental impacts, costs and benefits and burdens of the Bill.

In this context, it would have been helpful to bring about a better balance to the debate on the Bill if the report presenting the results of the *SimSmoke* tobacco control simulation model as applied to Ireland had been included in the RIA as the findings seek to identify the relative contribution of numerous policies to reducing the tobacco health burden.[64] In summary, this report argues that increases in taxation will have the largest impact by far. The report does not provide any evidence about standardised packaging presumably because in 2011 - when the research was carried out - it was not an issue.

The RIA is relying exclusively on data and assumptions that have not been verified in Irish circumstances by Irish consumers. The Hammond report concluded that *it is reasonable to generalise the research findings on packaging from other Western countries in Ireland as the consistency of findings across different countries supports this hypothesis*. That is a value judgment which has not been independently validated and tested by someone who works for neither a tobacco control body nor the tobacco industry.

The RIA quotes selectively Irish respondents in a Eurobarometer survey to justify support for the Bill. A closer reading of the survey suggests that there are many more factors at play when it comes to personal choices about smoking and indeed quitting smoking.[65] If the Department had studied these survey findings in more detail they might have been convinced to attach a much higher priority to other tobacco control measures.

Incremental Value

The key issue is: ***regulators should review and evaluate existing legislation and other options before regulating further***.

The RIA states that a Government decision was made on 28 May 2013 to legislate to introduce standardised packaging for tobacco i.e. before work on the RIA was undertaken. The inevitable conclusion is that the RIA was retro-fitted to justify a policy decision taken without any reference to the available evidence nor to the impacts, costs and burdens of the measure.

The RIA listed 14 tobacco control initiatives that have been implemented since 2001. However, the RIA did not evaluate the impacts to date of these individual actions, or indeed the cumulative impacts of these initiatives.

Nor did the RIA attempt to assess the incremental impact, if any, of the Bill.

Tobacco Free Ireland falls short in the sense that none of the costs and burdens of the 60 proposed actions have been quantified nor have the cumulative impacts of all the actions been identified.

[64] Levy, D., Blackman, K., Currie, L., and Clancy, L., *The Ireland SimSmoke: the effects of tobacco control policies on smoking prevalence and tobacco attributable deaths in Ireland*, April 2011.
[65] European Commission, Special Eurobarometer 385, *Attitudes of Europeans Towards Tobacco*, May 2012.

Ireland is at the forefront in terms of introducing legislation without assessing in detail the impacts, costs and burdens of proposed measures. Not one piece of Irish legislation in the area of tobacco control has complied in full with EU best practice on the conduct of RIAs, nor with Cabinet RIA guidelines.

On the other hand, the RIA acknowledges that no one tobacco control measure in isolation can be effective in reducing tobacco consumption. The RIA points out that a suite of measures is required, including education, taxation and regulation. However, the RIA fails to address never mind assess the impacts and the relative impacts, costs and burdens of all approaches to tobacco control regulation.

Instead the Bill is seen as the primary vehicle to stop people smoking or taking up smoking; despite the fact there is no robust evidence to support this assumption.

What the RIA should have done was to quantify the benefits flowing from the implementation of other tobacco control measures and then assess the net additional benefit that would be derived on the enactment of the Bill. For example, the RIA should have quantified the extent and valuation of the health benefits, if any, of the Bill as a standalone measure.

The RIA also states that one measure (in relation to tobacco control) cannot be viewed as being more effective than another.

This begs the question as to whether other measures could have a higher impact and if this is the case why have these measures not been progressed as a priority.

Enforceability

The key issue is: ***regulation should be capable of being complied with and enforced effectively.***

The Cabinet Handbook (step 5) states that *every RIA should include a detailed description of how enforcement is going to be achieved under each option being considered and an outline of any particular compliance issues and how these are going to be addressed*.

The Department of the Taoiseach RIA guidelines are more explicit about the importance of compliance and enforcement (Section 6, para 4.63) stating that consideration should be given to the costs of public service implementation. A key question that must be addressed is whether the regulations are enforceable within budgetary constraints.

The RIA is silent about public sector compliance costs.

The RIA guidelines (para 4.66) also require that thought must be given as to what levels of compliance are necessary for the regulations to achieve their objectives and importantly that the (compliance) burden placed on State resources, businesses and on other stakeholders is at all times proportionate to the risks associated with the behaviour being regulated.

As the RIA does not set out a risk register it is impossible to determine whether the compliance burden is proportionate or otherwise.

In summary, other than mentioning the enforcement provisions, and clarifying the powers of HSE authorised officers, the practicalities and compliance costs and burdens associated with the legislation were not considered in detail nor was there any attempt to quantify the public sector compliance cost burden.

OECD Best Practice

The extent to which the RIA reflects the OECD's fundamental principles of Better Regulation is set out in **Annex 1**.[66]

[66] OECD, *Recommendations of the Council on Regulatory Policy and Governance*, March 2012.

Chapter 8

Conclusions

The Economic and Social Research Institute (**ESRI**) is of the view that, whatever the policy domain, decision-makers are inclined to make better decisions when they have the relevant factual information, understand the main underlying processes involved, and possess reliable estimates of the likely outcomes associated with the options under consideration. The ESRI believes that Ireland has some distance to go in relation to the more systematic use of evidence in policy-making. [67]

There is now increasing emphasis on credible research evidence; the context is one where greater transparency and accountability are called for.

Within a modern society, it is difficult to argue that the process of policy-making, together with political and public debate that surrounds it, is not enhanced by the timely availability of relevant, peer reviewed, high quality and objective evidence.

Policy-making requires much more research evidence and should take into account values, contexts, implementation challenges, risks and uncertainty.

This idealised picture is at odds with reality and the RIA under review in this report is a clear case to point.

This report demonstrates that only one conclusion is possible: the RIA is fundamentally flawed both in terms of how it was conducted and in relation to many elements of the substantive evidence used to justify standardising packaging as the sole means to achieve the stated policy objectives.

To regain credibility and bearing in mind that the Department will be conducting future RIAs on sensitive subjects such as alcohol and obesity, it behoves the Department to conduct a revised RIA to take account of the apparent shortcomings of the current version and, in particular to address the reservations expressed by ten Member States on the Bill.

Consideration of the Bill within the Oireachtas should therefore be suspended until this revised RIA is to hand.

[67] ESRI (2013) Lunn, P., and Ruane, F., *Using Evidence to Inform Policy*, Gill and Macmillan, Dublin

Annex 1

OECD Best Practice

The Fundamental Principles of Smart Regulation

The principles set out hereunder - agreed by the OECD's Council in March 2012 - were developed by the OECD's Regulatory Policy Committee through a thorough process of public and committee engagement. Thus they are the cutting edge of best practice.

OECD Recommendations

> Commit at the highest political level to an explicit whole-of-government approach for regulatory quality.

Policy must have clear objectives and frameworks for implementation to ensure that, if regulation is used, the economic, social and environmental benefits justify the costs, distributional effects are considered and the net benefits maximised. To achieve these results, a CBA should have been a core element of the RIA. Ideally, *Tobacco Free Ireland* should have been the subject of a similarly rigorous evaluation.

> Adhere to principles of open government to ensure that regulation serves the public interest and is informed by the legitimate needs of those interested in and affected by regulation.

This includes providing meaningful opportunities (including online access) for the public to contribute to the process of preparing draft regulatory proposals and to the quality of the supporting analysis. To ensure that regulations are comprehensive and clear a new RIA should be based on:

- An open and balanced public consultation giving stakeholders 12 week to submit responses.
- Active engagement with all relevant stakeholders.
- The evidence derived from a detailed impact assessment.
- Providing all relevant materials, including supporting analysis, to stakeholders.

Establish mechanisms and institutions to actively provide oversight of regulatory policy, procedures and goals.

The OECD supports the proposition that a body charged with regulatory oversight should be established in all member countries to ensure that regulation serves whole-of-government policy and that its mandate should be to promote high-quality evidence-based decision-making. The HSE is responsible for enforcement of the tobacco control measures but does not engage on a systematic basis with the tobacco industry as part of its regulatory function.

Integrate RIAs into the early stages of the policy process for the formulation of new regulatory proposals.

The OECD recommended to Ireland to introduce several practical suggestions, including the following.

- Consider means other than regulation and a mix of instruments as appropriate.
- Adopt *ex ante* impact assessment practices that are proportionate to the significance of the regulation and identify who is likely to benefit and who is likely to bear the costs.
- The justification of proposed regulation should be expressly identified.
- Costs, benefits and risks should be quantified in cases where significant impacts are identified.
- RIAs should evaluate the impacts on SMEs and demonstrate how administrative and compliance costs are minimised.

The current RIA fell short on all these proposals. A new RIA might take these recommendations on board.

Current regulations should be systematically reviewed to ensure they remain up-to-date, cost-justified, cost-effective and consistent.

This means that RIA should be integrated into programmes for the review and revision of existing regulations with the explicit aim to lessen regulatory costs for businesses as part of a policy to promote economic efficiency. In addition, unintended consequences of regulation should be identified. The RIA and the Bill failed to address the issue of review and this is a significant failing when benchmarked against international best practice.

Apply risk assessment, risk management and risk communication strategies to the design and implementation of regulations to ensure that regulation is targeted and effective.

The OECD told the Government they should consider the use of risk-based approaches in the design and enforcement of regulatory compliance strategies to increase the likelihood of achieving compliance goals and to minimise the imposition of costs on businesses through compliance and enforcement procedures. The RIA and the evidence supporting its conclusions were not based on a detailed risk-based approach specific to Irish circumstances and conditions. The starting point for a new and revised RIA should be such an assessment.