

# **Business and Regulatory Impact Assessment Toolkit**

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# Business and Regulatory Impact Assessment Toolkit

For further support or guidance, please contact the New Deal for Business Delivery Unit at [businessregulationengagement@gov.scot](mailto:businessregulationengagement@gov.scot)

## Role of this Guidance Document

This toolkit provides guidance and information on how to complete a Business and Regulatory Impact Assessment (BRIA). It sets out why completing an assessment is an important part of policy development, helpful to both officials and stakeholders.

Officials should use the BRIA template provided to complete their assessment. The guidance provided in this document covers each section of the BRIA template.

Signed BRIAs should be published on gov.scot using APS. Please contact APS when you have a draft version completed to request a quote and initial accessibility compliance check of your draft file. This will allow any issues to be addressed in advance of providing the final version for publication.

## Impact Assessments and policy development

Impact assessments are an integral and necessary part of evidenced-based policy development as well as being a useful tool to inform project plans. They aim to improve and support the Scottish Government decision making processes. They allow officials to collate and set out for stakeholders information which can identify the likely positive and negative impacts of a change in policy or introduction of regulation. Additionally it can set out any mitigating actions that may be taken as a result to address specific issues.

Impact assessments form an important part of the Policy Cycle from developing a rationale for the proposal, through identification of objectives, to options appraisal, monitoring and evaluation. More information is available on the [Green Book UK Government webpage](#).

It can therefore provide the basis of informing the 'best policy option'. Impact assessments provide a structured process for considering implications of proposed policies and actions while there is still an opportunity to shape the proposals and mitigate against any negative impacts.

## Business engagement and the New Deal for Business

Recognising the importance of engaging early with businesses to deliver better policy, the Scottish Government has committed to implementing the [recommendations of the New Deal for Business Group](#). Officials should consider the New Deal for Business and how their approach aligns with the [Business Engagement Principles](#).

More detailed advice and guidance on engagement with business is available in the Business Engagement Handbook. This should be used by officials when engaging with business during policy development, assessment and implementation. The Business and Regulatory Impact Assessment can then be used to help record that engagement and set out the identified impacts on business.

Businesses have a core role in the Scottish economy providing goods, services and employment. They are also an important stakeholder in helping deliver the aims and objectives of the Scottish Government in service of the people of Scotland. It is therefore vital the Scottish Government considers how its policies affect them – neutrally, positively and/or negatively – and takes steps to ensure businesses are engaged in the process of policy development and implementation. Many policy options will affect businesses by design, by encouraging them to do or cease certain things to meet preferred set outcomes. However, whether by design or not, all policy has the potential to place direct costs and burdens on business or indirectly impact their operations.

Understanding the potential impacts allows Ministers to make the better decisions that can achieve the desired outcomes without unnecessarily affecting businesses and the Scottish economy. It also allows Ministers to put in place mitigations to

implement policy proposals in the most effective way possible by minimising any negative impacts, taking into account the needs of business.

When considering Business Engagement, officials should consider 3 core principles:

- SG policy development will be aligned and transparent with early, iterative and meaningful engagement with business community stakeholders.
- All areas of SG will improve communication with the business community
- All areas of SG will develop improved understanding of the impact of policy on the business community

## **Purpose of the Business and Regulatory Impact Assessment process**

BRIAs should be used to help officials assess the costs, benefits and risks of any proposed primary or secondary legislation, voluntary regulation, codes of practice, policy changes or guidance that may have an impact on the public, private or third sector or regulators. A BRIA is one tool that forms part of the policy development cycle, and alongside other impact assessments, engagement and consultation, can help Ministers and officials in considering policy options and making decisions.

Officials should complete a BRIA or identify why one is not needed. This is the case even where the additional burdens are not obvious. In such cases it can either help confirm understanding that the impact is minimal or help address unintended impacts which had not been identified initially. The content of a BRIA should be proportionate to the problem involved and the size of the proposal and should take into account our international legal obligations around regulatory transparency and good regulatory practice. A partial BRIA should be published alongside any public consultation to support gathering feedback from those stakeholders affected by the change.

While the broad impact on business is important, the Scottish Government is also concerned about the impact on particular groups or specific sectors which may be affected differently. BRIA helps officials in assessing the impact of the proposed policies on these groups too.

As well as general costs and impacts, the BRIA helps consider other aspects of policy and regulation that will be important both to businesses and from a wider regulatory perspective, for example potential Internal Market/ EU Alignment or International Trade concerns and the impacts on anybody which is required to enforce any measures.

The BRIA is a helpful tool when engaging with external stakeholders. They can provide an opportunity to explain to stakeholders:

- what the issue is, supported by evidence
- why the government is proposing to intervene;
- what businesses are already doing in this space,
- what other policy activities are in place to address the issue
- which options the government is considering, and which one (if any) is preferred;
- how and, to what extent, new policies may impact on them, on business more widely and on Scotland's competitiveness;
- the estimated costs and benefits of proposed measures.

It is easier for stakeholders such as businesses to engage with policy where there is a clear, appropriately detailed BRIA that allows them to understand the proposals and provide feedback, for example on any costs or unintended consequences that officials may have missed or underestimated.

The BRIA should also support consideration of other implementation aspects of the policy/ regulation, such as Legal Aid impacts and contribution towards Fair Work goals. Of particular importance for regulatory options but relevant for all policy is considering whether the proposals are in line with our international legal obligations and how compliance will be promoted or enforced, if relevant. Achieving the aims/ objectives will be dependent on businesses complying with the policy. Where this includes a regulatory requirement, the BRIA should consider how this will be verified and by who, and what enforcement actions or penalties will be used if needed.

## **Impacts on Small and Mirco Business**

It is vital that officials consider the impact on small businesses<sup>1</sup>, which make up most businesses registered in Scotland. Whilst these businesses form an important part of the economy, they are more likely to have limited available resources, in particular time. This can mean it is harder for them to engage with the Scottish Government, respond to public consultations, understand requirements and comply with Scottish Government's policy and regulations. Any additional costs resulting from implementation of a new policy or regulation may also be harder to absorb for small businesses.

Officials therefore need to make sure this is considered when making decisions about policy and who policy should apply to. Officials should ensure they proactively engage with these businesses to help them mitigate any negative impacts and support them as the policy/regulation is implemented. Impacts may not be straightforward – for example changes to turnover may result in small businesses reaching VAT registration thresholds that have wider impact than the direct costs from Scottish Government policy.

Where the regulatory proposals also affect Small and Micro Business overseas (e.g. those exporting to Scotland), you are obliged (under international trade agreements) to include them in your considerations.

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<sup>1</sup> The generally accepted definition of a small business is under 50 employees, as used by both UK and EU legislation. This can be used as a guide when considering impact, and as the basis for a definition when considering who policy should/ should not apply to

## **When should a BRIA be undertaken?**

The Scottish Government expects the completion of a BRIA as best practice for any policy proposal (this includes new policy, regulations or guidance). The Scottish Government is also required under the UK-EU Trade and Cooperation Agreement (TCA) to conduct an impact assessment for any major regulatory measure. Where a BRIA is not completed, the justification should be shared and agreed with Ministers. BRIAs should be proportionate to the significance of the policy and the magnitude of the expected impact; however without undertaking assessment it will be difficult to understand the significance and size. Even where the impact is not expected to be significant, a clearly drafted and evidenced BRIA can either confirm this, help with engagement with affected stakeholders or help identify unexpected or unintended consequences.

Engaging with businesses and identifying impacts at an early stage of policy development is important in ensuring the outcomes are realistic and as effective and beneficial as possible. This engagement should begin as soon as the underlying issue is first identified. Officials are expected to start development of a BRIA early in the policy development cycle, and as feedback is collected and analysis developed the BRIA can be refined. A Partial BRIA can be published at any point to support engagement with stakeholders, but any formal consultation must be accompanied by a Partial BRIA setting out the Scottish Government's understanding of the issue and potential impacts at that point.

## **Defining a business**

A BRIA requires officials to consider the impact of proposed policies, regulations etc. on businesses. The Business engagement handbook sets out in more detail what is meant by 'business', but broadly it covers 'any organization or enterprising entity engaged in commercial, industrial, or professional activities'. We recommend that officials take as broad an approach as possible to defining 'business'. This will include commercial enterprises, social enterprises, not for profit organisations and third sector/ public organisations undertaking commercial activities in Scotland. This includes businesses abroad importing or investing into Scotland.

## Completing an Impact Assessment

This guidance should be used alongside the [Business and Regulatory Impact Assessment \(BRIA\) template](#) when undertaking the Business and Regulatory Impact Assessment (BRIA). The guidance and template have been developed to help officials undertake the BRIA in the most effective and consistent way. The content, details and size of each BRIA will be dependent on the subject; however, each BRIA must follow the provided template. This ensures consistency across policy areas, as well as helping confirm that each section has been considered.

Portfolio areas are responsible for the content of their own BRIA. The New Deal for Business Delivery Unit owns the BRIA template and can provide advice on completion, but does not currently provide a Quality Assurance service for completed BRIAs - [businessregulationengagement@gov.scot](mailto:businessregulationengagement@gov.scot).

At the start of an impact assessment, it is important to identify:

- the analytical support required and the external stakeholders who may be affected or expected to support or input;
- the problem, its scale and the context in which it arises;
- evidence and nature of the problem; and
- the probability that it will occur and frequency.

BRIA should be approved by relevant Ministers and published on the relevant policy area's section of the Scottish Government website, alongside any other relevant documentation. A BRIA is expected to be considered for all policy and regulation developed unless it is clear there will be no impact on businesses or regulators. If, having appropriately consider the impacts, policy leads do not feel there is a need to carry out and publish a BRIA, they should advise the relevant Minister and seek agreement as part of the Ministerial submissions on the subject. The justification for this should be provided and may be subject to scrutiny from Ministers and the independent Regulatory Review Group.

A Partial BRIA can be completed and published during the policy development process to support engagement and allow feedback on the expected impacts to be gathered. It may contain more options and less detail, setting out officials understanding at that point. A Partial BRIA must be published alongside any public consultation/ significant stakeholder feedback exercise, with a Final BRIA published later based on refinement and further development.

Officials should consider the broad range of stakeholders that may engage with a BRIA such as businesses, their representative organisations and members of the public, both in and outside Scotland. It may be helpful to use existing stakeholder groups or to establish one with external stakeholders to support development of the policy proposals and BRIA, Terms of Reference can be drafted to support any confidentiality requirements. Every effort should be made to ensure the contents of the BRIA are presented in as accessible a format as possible.

The Scottish Government uses APS to publish its Impact Assessments. They may provide some feedback on accessibility of the document, and so should be provided



with the document to be published as promptly as possible. They should not be used as reviewers of the content, which remains an SG responsibility.

Completion of a BRIA may be outsourced. However, officials who own the policy proposals remain responsible ensuring the content meets expectations and is accurate. The final document is an SG publication, and so should be done so by APS.

## **Evidence sources**

Information on the business base in Scotland is available on the business and innovation statistics section of the Scottish Government website in the Businesses in Scotland and the Scottish annual business statistics publications.

Information on the business conditions is available on [the business and innovation statistics section of the Scottish Government website](#) in the Latest Business Insights and Conditions Survey (BICS) survey publications.

A summary of key business resilience metrics from the BICS publication by sector has been compiled by the Office of the Chief Economic Adviser and is available to officials. This was a commitment in the New Deal for Business work to monitor and report business resilience regularly using a consistent set of business resilience metrics that can also be used in Business Regulatory Impact Assessments. These include

- Economic performance overall, and by sector and trend since pandemic.
- How long cash reserves will last, by sector and trend since the pandemic.
- Business risk of insolvency, by sector and trend since the pandemic.
- Business debt repayments as share of turnover, by sector and trend since the pandemic.
- Confidence in meeting current debt obligations, by sector and trend since the pandemic.
- Difficulties recruiting employees, by sector and trend since the pandemic.
- Ability to get the materials, goods or services needed from within the UK/EU, by sector and trend since the pandemic.

A synthesis of the performance of the Scottish economy including a synthesis of latest business conditions is [published monthly on the Scottish Government website](#).

## Available guidance

This guidance is designed to be used alongside the provided BRIA template (as well as accessibility IA guidance?). It covers each section of the template, what is expected to be included as well as guidance on how to complete.

Example BRIAs will be available from the New Deal for Business Delivery Unit at [businessregulationengagement@gov.scot](mailto:businessregulationengagement@gov.scot). The template and structure of the BRIA has been updated, and so older examples may look different. However, it may still be helpful to consider how they undertook the process of completion, and how costs/impacts have been presented.

Guidance on other impact assessments is available to officials on the Scottish Government intranet and from the relevant teams.

Consumer Scotland is responsible for issuing the guidance for the Consumer Duty and further information can be found [on the Consumer Scotland website](#).

In conjunction with this toolkit please refer to the [APS Publishing Compliance Guidance](#) which gives advice on accessibility compliance when preparing your document. In addition to that guidance please also refer to the [Impact Assessment Template Compliance Guidance \(APS Group\)](#) document which highlights some of the key requirements, along with visual examples.

## **BRIA Title**

A standard title format is recommended to promote consistency and make documents easier to find, ensuring that it is clear what is the BRIA covers:

**“Policy/ Regulation Title – [Partial] Business and Regulatory Impact Assessment – Date”**

## **Introduction**

Officials should provide a brief introduction to the BRIA. This can cover the policy area and the evidenced issue under consideration, what actions have already been taken and how officials have approached the completion of the impact assessment. This section should note whether the document is a Partial or Final BRIA (and if Partial, when the final version will be published).

## **Executive Summary**

Provide a short (maximum 2 page) summary of the content of the BRIA, based on the headings set out below and provided in the template. Providing an executive summary is helpful in engaging Ministers and stakeholders, in particular, where the rest of the BRIA contains significant detail.

Most businesses operating or trading in Scotland are classified as small or micro enterprises, and therefore may not have time to review everything published. An effective summary will help them engage with the policy proposals, and thus provide feedback that allows officials to better deliver outcomes.

The content of the Executive Summary should reflect the content of the document. Content will vary depending on whether the document is a full or partial BRIA.

A partial BRIA can set out a summary of the expected outcomes and impacts (positive and negative) that have been identified - this should include the intended outcomes as well as any additional/ unintended costs or benefits for businesses. Any key mitigating actions that are under consideration can also be highlighted. The summary should set out how the Partial BRIA will be further developed to deliver the final version alongside any further published announcements.

The full BRIA should cover all the options that have been assessed but may highlight specific option that are being recommended and taken forwards. It should detail the engagement that has been done across different stakeholder groups, next steps and implementation plans.

## **Issue and why it needs to be addressed**

### **Intended outcomes**

### **Options**

### **Sectors affected**

**Engagement completed, ongoing and planned**

**Anticipated impacts (intended and unintended, positive and negative) and mitigating actions**

**Enforcement/ Compliance**

**Recommendations/ Implementation Plans**

**Evaluation and Monitoring of implementation/ Review of BRIA**

# Section 1: Background, aims and Options

## Background to policy area

Any government action should have a clear rationale, which should be articulated at the earliest possible stage of policy development. Analysis of the rationale (such as market failure or other objectives) should underpin the evidence base for policy development. It also provides a guide to the likely additional costs and benefits that may occur because of any proposed intervention.

Officials should look to set out any relevant background to the current situation in the policy area and the evidence of need for action. It is expected that the BRIA will be published alongside other policy documentation, and officials can look to avoid repetition by linking to relevant information available elsewhere. However, a brief summary should be included within the BRIA to ensure those reading the document have sufficient context.

Relevant background may include where any existing policy frameworks, guidance, regulations or ongoing action relevant to the subject exist, particularly where it also affects businesses. This will include both Scottish Government policy as well as industry owned voluntary action.

The background should make clear why the options under consideration are being proposed – for example to address specific issues or market failures, in response to stakeholder feedback, or to meet other requirements.

## Purpose/ Aim of action and desired effect

Given the reasons for action noted, officials should clearly set out the desired effects and outcomes of the actions. This should include how they will contribute to wider Scottish Government strategic or economic aims and objectives.

Consideration of the rationale for the policy intervention should also be outcome-focused, taking account of the National Performance Framework and the Government's [National Strategy for Economic Transformation](#). Officials should consider the impact of the proposals on the outcome to deliver a shared understanding of how government and business work together on achieving a Wellbeing Economy.

Desired outcomes should be set out with as much specificity as possible to ensure businesses understand the aims, and the benefits and impacts can be measured. Outcomes that are too generic or undefined will make it difficult to assess both the impacts on business and other stakeholders, and how effectively the policy proposal has been once implemented. Officials should consider what the outcomes would be **if no action was taken**. While taking no action may not be a reasonable option (or possible where there are statutory/ international requirements), it will provide a baseline to demonstrate why action is needed.

When considering action, officials should identify both what the ideal outcome would be as well as what a minimum acceptable result would be to address the issue/ concern that prompted the action. In some situations, these may be the same; however, in other cases once the impacts of options are considered, certain outcomes may be judged to have too significant a cost compared to less extensive but still acceptable outcomes.

## Options (considered so far/ still open)

At the preliminary stages of policy development all the options should be identified, together with their potential for achieving the stated objectives. Officials should set out which options have been proposed so far to address the identified issue/ concern and achieve the desired outcomes. All robust and reasonable options under consideration which may be taken forwards should be considered. Options must be assessed against the status quo or 'do minimum' situation. This will help draw out the implications of no or minimal action and act as a baseline against which to assess the other options. If doing nothing is not a valid option (for example there are statutory/ legal requirements to act), this should be clearly set out.

When identifying options, officials should consider different ways to reach the desired outcomes with voluntary action being considered first. The BRIA should set out each option, how it could achieve the desired outcome, and what type of action it is.

Actions may include:

- Scottish Government guidance/ policy statement
- voluntary/ self-regulation by businesses
- Co-developed codes of practice
- SG influence via other routes (provision of grants, new requirements on existing grants/ procurement)
- new Regulations via primary/ secondary legislation

Officials are recommended to consider at the start alternative approaches such as codes of practice or voluntary regulation whenever a legislative approach is under consideration. This will ensure that impacts on businesses are appropriate to the outcome required, but also that Scotland aligns with relevant international obligations (see further sections below). Officials should also consider how options fit with the Scottish Government's 'Better Regulation' approach which states that all regulation should be:

- Transparent – with clearly understood reasoning and scope
- Accountable – with clarity on who is responsible for the regulation
- Proportionate – with only enough requirements to meet the desired outcome
- Consistent – applied fairly to different businesses/ stakeholders<sup>2</sup>
- targeted where appropriate – only applying to those that need to meet the requirements to meet the desired outcome

Voluntary regulation is a mechanism that can be used within a regulatory framework as an alternative to statutory regulation, to achieve a particular outcome through a change in behaviour. It typically involves industry and/or professionals developing voluntary agreements or standards, pledges, codes of practice, certification and accreditation schemes, to regulate behaviour or standards to achieve a particular outcome. The Scottish Government's involvement may vary from no involvement to

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<sup>2</sup> Fair application does not mean all businesses must necessarily be subject to the same requirements. For example, it may be appropriate to exempt smaller businesses from some requirements where the burden of meeting them was greater than the benefits/ contribution to the desired outcomes



the measure being government-sponsored. It can be a more agile form of regulation in that it can be put in place faster, can be more flexible and adaptable to introduce and update, and requires a commitment from those involved. It does not preclude later introduction of statutory regulation, for example where it is determined the voluntary regulation has been ineffective in meeting desired outcomes.

For regulations that affect business, it is vital to also consider alternative approaches, flexibilities or exemptions for regulating small and micro-firms. In considering whether alternative approaches may be appropriate, ensure early and appropriate discussion with relevant businesses, consistent with the New Deal for Business and Business Engagement Principles. The Engagement section contains more information on consulting businesses and the types of issues to explore in assessing whether alternative approaches may be appropriate.

## Sectors/ Groups affected

Officials should look to identify which business sectors/ groups will be affected by or are in scope of the different options set out above, so that the impact of each option can be better evaluated. Options may have beneficial impacts on some groups and negative impacts on others. It is important to be as specific as possible and to work with stakeholders to validate assumptions. All significant groups affected by the options should be considered, particularly businesses, and informal consultation can be used at an early stage to help identify groups.

Relevant groups may include:

- **Businesses** – A core focus of the BRIA. The Scottish Government is committed to ensuring appropriate understanding of the impact of policy (both intended and unintended consequences) to make decisions that meet objectives without unduly impacting the economy.
- **Organisations in the third sector** – policy proposals may also affect voluntary and charitable sectors, either through their role in delivery or by affecting these groups in a similar way to businesses. It is important that these are duly considered. Colleagues elsewhere in the Scottish Government may already have links with these organisations. Alternatively, officials can contact organisations directly, and the Scottish Council for Voluntary Organisations may be a useful starting point.
- **Local Authorities** – the roles and responsibilities of local authorities are many and diverse and include a range of regulatory roles. Early and ongoing engagement with COSLA and a range of local authorities is likely to be an essential element of developing options and assessing their relative impact. Local Authority regulators can also be engaged via the Society of Chief Officers of Trading Standards in Scotland and the Society of Chief Officers of Environmental Health in Scotland
- **Regulators** – including consideration of the impact on existing activities and performance, and the resource and skills implications of the assorted options. Local Authorities deliver a considerable proportion of regulatory activity in Scotland, but other regulators may be relevant.
- **Consumers / Competition Assessment** - The impact on consumers should be noted, for example when their access to goods or services is restricted or

is likely to become more expensive. When considering the impact of policies, the effect on the ability of businesses to compete in the market and what effect this might have on consumers should be considered. Introducing competition in the delivery of policy may add value.

When considering affected groups, officials should ensure that they include both those directly affected and those who may be subject to indirect impacts. Impacts on groups/ sectors will not necessarily be negative, - when assessing impacts, officials are expected to consider benefits as well as costs. Identifying who these will apply to is important in considering options.

Directly affected sectors will be easier to identify – for example, any businesses subject to the requirements/ guidance that is proposed. However, officials should consider how broadly these are applied. Where regulations are to be drafted, these will need to clearly define who is/ is not subject to the requirements in a way that meets the Better Regulation principle of targeted regulation. This means avoiding application to business/ sectors where it would not contribute to the desired outcomes/ objectives of the policy/ regulation.

Indirectly affected groups may be harder to identify. Key groups to consider are:

- Consumers affected by the changes
- Businesses which provide goods/ services to those directly affected
- Businesses which rely on goods/ services from those directly affected
- Business operating in related/ parallel activities not directly subject to the requirements

While indirect impacts may be harder to identify and detail, they should not be ignored. They will be important in considering the overall impact to businesses and the economy that result from different options.

## **Section 2: Engagement and information gathering**

### **Engagement Approach**

The overarching approach to engagement should be detailed by officials, covering the full length of the planned policy/ regulation development. Where possible timelines for different key planned actions should be set out.

The groups that have been engaged with should be set out in the relevant sections below. Each individual comment does not need to be set out in the BRIA; however, a summary of views is helpful. The content of feedback should be used when considering the options under consideration and the potential costs/ impacts/ benefits in the relevant sections later in the BRIA. More detailed reporting of feedback may be provided as an annex/ alongside policy documentation.

Officials should consider the different groups (in and outside Scotland) that it will be important to engage with and recognise that each group may require different approaches to engage effectively. Key stakeholder groups will include a combination of other Scottish Government officials, the independent Regulatory Review Group, public sector bodies, business stakeholders (including both business organisations and individual businesses as relevant), and consumers. Other stakeholders may be relevant for specific policies or regulations, for example the third sector, academic experts, or other representative groups.

Officials should consider the most appropriate mechanism for engaging each stakeholder – for example, small businesses may have limited resources and time and be unable to respond to detailed public consultation. This includes considering how engagement is done in a way that maximises the opportunity for relevant stakeholders to participate, including harder to reach groups. Engagement should also be done in a way that is inclusive, with any communications done in a way that is accessible and that allows stakeholders to understand what is being asked of them.

The New Deal for Business Group recommendations and Business Engagement Principles recommends that business stakeholders should be engaged as early as possible to ensure that the broadest range of feedback and options are considered. Similarly, the Verity House agreement should be considered when approaching public sector agreement and specifically around possible enforcement/ compliance options to be delivered by Local Authorities.

Officials should consider which businesses/ sectors they are engaging with and any existing guidance covering such engagement. For example, the Scottish Government is a party to the World Health Organisation's Framework Convention on Tobacco Control, specifically Article 5.3. This means that we take our obligation to protect the development of public health policy and tobacco control generally from the vested interests of the tobacco industry seriously. When considering policy in

these areas, stakeholders being engaged should be asked to declare any direct or indirect links to, or funding received from, the tobacco industry.

While every effort should be made to avoid face to face meetings with the tobacco industry, on rare occasions a meeting may need to be held. An example may be a meeting to enable effective regulation of the tobacco industry and tobacco products. When deciding whether to meet with the tobacco industry, officials should consider a range of questions including, but not limited to, the following.

- What is the role of the tobacco industry or representative in the meeting?
- What is the government's role at the meeting?
- Who is involved in organising the meeting?
- Who is providing funding for the meeting?
- Who is attending the meeting?
- Where is the meeting being held?
- What is the scope for informal, unstructured engagement with the tobacco industry, and how can this be avoided?
- How could the interaction be perceived by other external stakeholders?
- How can transparency be maintained throughout the meeting?

Before such a meeting, a clear agenda should be set, and no other items of business should be discussed other than those agreed in the agenda. When opening the meeting, the chair should remind attendees of the government's article 5.3 obligations and should stop the meeting if these obligations are breached. Minutes should be recorded and published online.

# **Internal SG Engagement/ Engagement with wider Public Sector**

## **Internal SG engagement**

In developing policy, officials should look to engage as early as possible with colleagues in other areas of SG that may have an interest in the affected sectors or be impacted by the policy proposals. They should seek to understand what other policy development is ongoing that may interact with the options being considered. Working together on policy development allows officials to deliver more effectively and efficiently, and can present a single aligned approach to businesses. It avoids contradictory policy decisions that work against each other, reduces the likelihood of insufficient resources being available to deliver (both internally and within stakeholders), and reduces the risk of resistance among stakeholders caused by overload.

This cumulative impact of policy is important to consider in line with the New Deal for Business approach. The impacts of single policies on business can be significant without considering the total impact of multiple new requirements and the timing of implementation of various changes.

SG officials in relevant areas will be able to provide advice on specific sections of the BRIA, for example the Internal Market, International Trade and EU alignment sections. In particular officials should ensure that they have engaged with DITI on investment. The Investment Strategy and Delivery Unit should be engaged to consider the impacts on private capital investment attraction into Scotland, and the Inward Investment Policy Unit should be engaged to consider the impacts on foreign direct investment and inward investment into Scotland.

As part of this engagement, officials are encouraged to discuss the proposed options with the [Regulatory Review Group](#). This is an independent group put in place to provide advice to officials and Ministers on regulatory options and associated implementation. They can advise on workable solutions to the agreed issue – for example whether voluntary regulation would be a reasonable approach to the problem, and the implications of each from an implementation and impact perspective. The RRG is supported by Scottish Government officials through a secretariat function and is not a replacement for external discussion. Early engagement with the RRG to screen the proposal is recommended and Ministers may ask to formally refer the policy proposal to them as part of the evidence gathering and decision-making process.

## **UK/ Devolved Administrations**

Beyond SG, it is important to consider UK Government and other devolved administrations.

Officials should set out how they have engaged with those administrations to understand where there are parallel or contradictory policy measures taking place. When considering options, it will be important to consider what level of alignment is

best for the policy outcomes. Differences from other parts of the UK may be appropriate on policy grounds, where different outcomes are being targeted. However, it should be recognised that it will be more difficult for businesses that operate across the UK where they are subject to different requirements across administrations.

Aligning policy proposals may provide benefits in strengthening the messaging and effectiveness of policy interventions. It can also make it easier to implement and for businesses to comply. This can help more effectively meet the desired outcomes while reducing the costs/ impacts on business.

Engaging with other administrations can help officials understand the impacts of policy, where work has already been undertaken (noting the application to Scotland may differ) as well as considering international approaches. Lessons learned from development/ implementation should be considered where these may benefit the approaches being taken by SG.

Officials are expected to consider and set out possible Internal Market implications in the relevant section of the BRIA below.

## **Wider Public Sector**

Engagement with other parts of the public sector is also key to ensure the impact of a policy/ regulation is as effective as possible. In Scotland, Local Authorities (and COSLA as their representative) will be key stakeholders, but other public bodies may also have interest. Local Authority regulators can also be engaged through the Society of Chief Officers of Trading Standards in Scotland and the Society of Chief Officers of Environmental Health in Scotland.

Where there will be compliance/ enforcement responsibilities, officials should identify as early as viable options for where these could sit. This may be an existing regulatory body (for example Local Authority Environmental Health/ Trading Standards, Police Scotland etc.). Officials should be cognisant of the existing requirements on regulators when adding further requirements and ensure these bodies have been engaged to understand the practical options and implications. These can be set out in the relevant section below.

Other public bodies will be able to provide feedback on aspects of the costs, investment outcomes and wider impacts/ benefits for business. The enterprise agencies (Scottish Enterprise/Scottish Development International, Highlands and Islands Enterprise and South of Scotland Enterprise) will be important, but other organisations such as the Scottish National Investment Bank and Scottish Futures Trust may be able to provide feedback on policy.

## **International**

Engagement with government organisations in other countries can be important if trade of specific countries with Scotland may be affected by the policy proposals.

Policy makers in foreign governments who are planning or may have implemented similar regulations can be a good source of advice and good practice and international regulatory cooperation should be considered as a useful tool in policy development.

## Business Engagement

In December 2021, the Scottish Government published a [Business Principles Agreement](#) establishing an overarching framework for working constructively with business. The Agreement, based on trust and mutual respect, sets out a shared commitment to co-development, collaborative delivery and collective assessment of all policy impacting on business.

As part of the Impact Assessment, officials should set out how they are engaging with businesses, their representative organisations and the third sector to gather feedback and help identify the impacts from the options under consideration. Officials should also set out what future engagement is planned.

Businesses must be engaged as early as possible in a meaningful way. Understanding and setting out the impact cannot effectively be done without engaging with business. Where international trade is likely to be affected by any proposed regulations, SG is obliged under international agreements to include affected businesses abroad in this engagement.

Officials should detail what business engagement has been undertaken and what is planned, setting out who has been involved and any key feedback that has been provided. When describing the engagement with business, it should be clear what information and which options have been presented to them.

The Scottish Government agreed Business Engagement Principles with business to guide engagement. We are also committed to the New Deal for Business Group's recommendations on improving how it engages with businesses. Key considerations will be:

- Engage with a broad base of businesses – A **minimum expectation** is that officials should engage with 6 – 12 businesses, as well as any engagement with business organisations. Engaging with more businesses will provide more feedback, helping improve the policy development further, and this minimum will not be enough in many cases to gather sufficient information. Officials should consider what engagement will be necessary to get adequate feedback. In particular officials should ensure they engage with sufficient businesses representing different economy sectors (including a sufficient number of small businesses) to get appropriate feedback and ensure sufficient understanding of the impacts.
- Engage as early as possible – Engaging with business and their representative organisations as early as possible ensures that there is sufficient time for policy to be developed based on feedback. It also avoids negative impacts and reputational damage when businesses learn about policy via other routes.
- Engage flexibly across channels – In person meetings provide valuable feedback and help positively display engagement. However, it may be challenging for some businesses to engage in these meetings, and so officials should look for other ways to gather feedback.

When engaging with businesses, officials should ensure they engage across all relevant sectors that may be impacted by the policy/ regulations. They must also



ensure they have adequately consulted to understand the impact on **small businesses**. Given the limited resources available to some of these organisations, it will be important to make engagement as easy and worthwhile as possible for them.

When planning engagement, officials should ensure they consider

- **business capacity to engage** – individual businesses will engage with the Scottish Government in addition to “the day job” and being considerate and respectful of their time is crucial. This applies to many of the business representative organisations who are small businesses.
- **respect business stakeholder time** – think about the best time to engage once you have a basic idea of a policy initiative to set out early thinking and seek ideas on impact. Keep engagement meetings short and focused and allow plenty of notice for early engagement. Consider what other policies are being developed at a similar time that could be linked to your policy.
- **commercial sensitivity** – some subject matters may mean some businesses will consider the feedback or experience they offer to be commercially sensitive. In these circumstances smaller groups or one to one engagement may be preferable.
- **stakeholder comfort** – small business owners who are not used to participating in roundtables with large groups may feel uncomfortable and unable to get their points across in such settings

Where individual businesses have been engaged with directly, it is helpful to set out numbers, names where appropriate, size, sector, and locations along with what form the engagement took.

Annexes can be used to share more detailed feedback/ results of engagement.

## **Public Consultation**

Public consultation can provide a valuable source of feedback on policy, particularly for significant policy proposals/ planned regulations. Under the UK-EU TCA the Scottish Government also has obligations in regards carrying out public consultations. It is not a specific part of the BRIA process, but where it is being or has been undertaken the details can be set out here. This should include a summary of what options were presented as part of the consultation. Partial BRIAs should be provided alongside consultations to demonstrate current Scottish Government understanding of potential impacts.

Where public consultation has provided feedback on the consequences for businesses, this should be factored into the costs/ benefits set out below. Wider comments not relevant to this assessment do not need to be included (but may be relevant for the wider set of Impact Assessments).

While consultations are useful, it is still expected officials undertake direct engagement with business or their representative organisations as set out above. Due to competing resource demands, small businesses or individuals may struggle to engage with written consultation. To help with this, consultations should be clear, jargon-free and focussed.

## **Other Stakeholders**

Officials will likely engage with groups not covered by the sections above. This may include (but not limited to) Trade Unions, other third sector organisations, academics or representative bodies who have views on policies or regulation. Details of those who have been engaged and that have provided feedback relevant for the BRIA should be set out here.

## Section 3: Costs, impacts and benefits

Officials should identify where different options impact on different groups and consider whether the options change the distribution of costs, impacts and benefits within and between groups. This will provide evidence to:

- compare the relative costs and benefits of policy options aimed at addressing the problem;
- support final policy recommendation and help determine whether the benefits from the policy options justify the costs;
- demonstrate the options than legislation i.e. voluntary regulation;
- show why has each option been accepted or rejected.

Impacts on businesses can be set out in both a quantitative and qualitative way. Officials should consider what they are asking business/ the public to do directly, and how this may change behaviour.

It is often difficult to predict accurately the exact costs and benefits so where necessary officials should use estimates and/or ranges. This should state whether these estimates/ranges represent extreme values or the most likely range of outcomes. Where there is uncertainty, this should be clear and set out any assumptions used to arrive at estimates/ranges and any plans to further address this.

Officials should show costs and benefits as monetary values where this is possible. This will allow easier comparison between the costs and the benefits of each option. The direct costs – i.e. costs directly attributable to the policy or intervention of each option should be expressed as monetary values.

Where prices for goods and services are involved, finding monetary values is usually straightforward. In the absence of prices, officials can, in consultation with economists, consider if monetary quantification using economic valuation techniques is possible. Analytical colleagues can also provide advice and guidance on other forms of quantification which could be used where appropriate. For example, number of lives saved, increased manpower requirements, changes in emission levels or new equipment needed. Such measures should allow options to be compared but may not allow the relative costs and benefits to be weighed up.

Quantification of benefits is important but often challenging. Monetary quantification of benefits can use economic valuation techniques and economists can advise on this. Analytical colleagues can also provide advice and guidance on other forms of quantification which could be used where appropriate. For example, number of lives saved, increased staff requirements, changes in emission levels or new equipment needed. Such measures should enable options to be compared but may not always allow the relative costs and benefits to be weighed up.

Cost considerations should not be limited to only those that can be enumerated. Identifying the order of magnitude of costs that cannot be specifically identified will be helpful. Setting out the qualitative description of what is expected will also be

important in providing a complete description of the impact and allowing businesses to understand what is expected of them.

Qualitative description of the impacts should also be used to support quantitative analysis and where quantitative impacts are not available or applicable. For example, officials may be able to identify changes in behaviour that may affect how businesses operate but cannot initially put a cost on it. Engaging with businesses using this approach can also help to better understand the direct costs and monetary value of the impacts.

While officials are expected to identify and set out costs, benefits and impacts, it is important to note that these should be balanced with the overall aims/ objectives of the policy. The existence of costs should not prevent policy decisions from being taken, but they should be used to determine the best course of action overall.

## **Quantified Costs to Businesses**

Direct costs are likely to be things businesses will need to pay for to meet the specific aims of the policy/ regulation – licenses/ registration, conformity assessment, changes to premises. It should also cover direct identifiable impacts to business incomes/ outgoings - for examples if prohibiting/ limiting the sale of a specific type of good, setting out the current market figures.

Officials should set out how these costs impact across different businesses/ sectors. Side by side comparison the direct costs to businesses from each proposed option will help evaluate their overall impact.

Indirect costs will be those which are not a core part of the stated policy/ regulation but will result from its implementation within businesses or through the supply chain. For example, businesses may need to increase staff levels or provide additional training to staff to ensure they comply with the policy/ regulation. Similarly, where a business is not directly covered by the policy but relies on goods/ services from a sector that is, they may be impacted by higher costs or more difficulty accessing the goods/ services.

## **Other impacts**

Officials should set out the additional impacts that have been identified, but where a cost/ economic impact has not (or cannot) been quantified. This may include changes in behaviour, such as business changing focus/ sector that may result from the policy. Some of the impacts in this section may be quantified via engagement with businesses.

## **Scottish Firms International Competitiveness**

Officials are expected to consider both competition impacts from the consumers' perspective and international obligations in the relevant sections below. However, when considering the costs/ impacts on businesses they should set out how it may

affect the competitiveness of Scottish firms internationally from the perspective of those firms.

Impacts will be relevant where Scottish firms operate internationally and are in competition with businesses not subject to the policy (i.e. those that do not operate in Scotland). Policy proposals that add costs or restrictions to Scottish firms that do not apply to international competitors may affect their ability to compete, by increasing costs or limiting the goods or services they are able to offer internationally. Note that under World Trade Organisation (WTO) law, regulations should not be applied to imported or domestic products in a manner which would provide protection for Scottish business.

Scotland's ability to compete internationally to attract global capital investment should also be considered. Investors have a choice where they invest and there will be global competition for capital investment.

## **Benefits to business**

In addition to the negative impacts of additional costs, officials should set out how businesses may benefit from the policy/ regulation options being considered. Some benefits will be easier to estimate than others. Consulting economists for advice as early as possible can help put a monetary value on the benefits. Examples may be reduced costs for business, improved access to goods/ services, or more streamlined processes saving staff time.

## **Small business impacts**

Small businesses make up most businesses in Scotland, and at the same time have fewer resources available to respond to new policy/ regulations.

Officials should consider specifically how the policy proposals will affect small businesses. Key issues for this group will be any requirements on businesses that are likely to be resource intensive (taking up staff time or additional costs and changes to operations) given they are more likely to have limited capacity to absorb.

The assessment should set out whether costs scale with the size of affected business, or whether there is a fixed minimum cost for all businesses. It should also note how the distribution of benefits of the proposal could be spread between a self-employed, micro, small, medium business.

In addition to costs, officials should consider how the regulatory burden varies between businesses of varied sizes. Significant reporting/ compliance requirements will be harder for small businesses to meet. Similarly, the relative impact on a self-employed, micro, small, or medium business of penalties for non-compliance can be detailed, for example by expressing costs as a percentage of turnover.

Appropriate engagement with small businesses will be vital in understanding the impacts on them, including indirect and secondary effects. For example, changes in turnover (which may not affect net overall profits) may affect businesses standing

with regards to VAT registration. This can result in additional costs and burdens on small businesses not directly associated with the policy.

Officials should consider whether flexibility options/ exemptions could assist a micro, small, medium business to meet the requirements of the proposal in a way that still ensures the overall aim of the policy/ regulation is being met. More information on how such exemptions have been considered should be set out in the Enforcement and Compliance section of the BRIA

## **Investment**

Large scale private capital investment is needed to enable Scotland's just transition to net zero. The First Minister's Investor Panel provided proposals to help to make Scotland a globally competitive investment destination. This includes ensuring the implications for investors and investor sentiment are taken into consideration when policy is formulated or legislation developed across all of Scottish Government. This also needs to apply to how policy is delivered

At a national level, Scotland is seeking to achieve an economic and investment landscape which has a competitive advantage in attracting private capital investment into key strategic sectors. Consideration should be given to the investor friendly landscape Scotland is trying to create, and give every effort to creating and promoting this competitive advantage.

At a sectoral level, such as renewable energy and the hydrogen economy, Scotland is working to create and support sectors which have the potential to become world leading industries, where our competitive advantage would see us operating as a leading exporter. Officials should consider how this policy would impact the competitiveness of Scotland's leading sectors.

Officials should set out how the proposed policy aligns with the recommendations of the First Minister's Investor Panel to make Scotland a globally competitive investment destination. They should consider whether the proposed policy or regulation has the potential to make Scotland a more, or less, attractive place for global investment. Where there is an impact on investors and investment sentiment, officials should identify whether there is scope for mitigation and how this has been considered

## **Workforce and Fair Work**

The Scottish Government is committed to the principles of Fair Work. Officials should consider any identifiable impacts the policy options may have on the workforce, for example supporting inclusive recruitment or improving job satisfaction.

When considering the impact on businesses from new policy/ regulations, officials should consider how these align with Fair Work First principles and how implementing them may affect businesses ability to act in accordance.

For example, officials may want to consider whether increased costs will reduce the ability/ likelihood of paying workers the Real Living Wage.

Officials should also consider how the different policy options may promote the Fair Work First principles by making it easier for businesses or otherwise encouraging them to take positive steps towards embedding them.

Further information on the seven Fair Work First principles is available on [the Scottish Government website](#).

## **Climate Change and the Circular Economy**

The Scottish Government is committed to reaching Net Zero by 2045, and promoting a Circular Economy in Scotland

Officials should consider whether any of the proposed policy options are likely to impact on businesses ability to contribute to deliver a Circular Economy in Scotland.

For example, officials may wish to consider for each option

- Does it align with the aims of the Circular Economy & Waste Route Map?
- Will the policy contribute to responsible production and responsible consumption?
- Will the policy drive sustainable reduction, reuse or recycling of resources?
- Will it increase or decrease goods or services consumed in Scotland?
- How can the policy options under consideration be used to promote Circular Economy aims to achieve maximum positive impact for communities and businesses in Scotland?

Officials should also note that businesses may have their own plans for moving towards net zero, and their own circular economy plans. Any potential impacts that may prevent businesses meeting these aims should be set out.

## Competition Assessment

In addition to looking at the impact on individual firms, it is important to consider the impact that a regulation or policy might have on competition between firms. Where regulations restrict competition – for example by making it harder for new firms to enter a market – this can increase costs for consumers or other businesses in the supply chain for these markets.

Policy proposals can also have the outcome (by design or not) to increase competition within the market. A competitive market is one where businesses, large and small, can compete to deliver services and products to consumers. Competitive markets drive innovation, productivity, sustainable economic growth and provide consumers with a choice of goods and services. These costs and opportunities need to be factored into the BRIA.

The overall aim of the competition assessment is to find a policy approach which encourages competition within the market, subject to achieving the wider policy objectives. The main elements of the competition assessment are:

- identifying the relevant markets, products or services which might be affected by a policy
- identifying possible restrictions on competition in these markets resulting from the policy proposals, by answering the following questions:
  - Will the measure directly or indirectly limit the number or range of suppliers?
  - Will the measure limit the ability of suppliers to compete?
  - Will the measure limit suppliers' incentives to compete?
  - Will the measure affect consumers' ability to engage with the market and make choices that align with their preferences?
  - Will the measure affect suppliers' ability and/or incentive to introduce new technologies, products or business models?

A competition concern may be identified if at least one of the above conditions is met. Officials should set out how the policy/ regulation answers each of the considerations above and provide evidence about the nature of potential competition impacts.

If any of these options increase competition, or help create a more level playing field for sectors, then this should be detailed also.

The Competitions and Market Authority (CMA) provides guidance on carrying out competition assessments and can provide informal advice in particularly complex cases. [Guidance is available at on the gov.uk website](#). Economist colleagues can also help in answering whether the proposals are likely to prevent, restrict or distort competition in any of the affected markets.



## Consumer Duty

As of April 2024, the consumer assessment section of the BRIA has been replaced by the Consumer Duty. This is a statutory duty introduced by the [Consumer Scotland Act 2020](#) which came into force on 1 April 2024. It places a duty on relevant public authorities in Scotland, including the Scottish Government, to improve the extent to which consumers are considered in strategic decision-making. A key principle of the Duty will be to ensure all public bodies are working towards improving outcomes for consumers as part of their strategic decision making process.

The [Consumer Scotland Act 2020](#) defines a consumer as an individual or small business who buys, uses or receives goods or services in Scotland, or could potentially do so, supplied by a public authority or other public body. This definition should be applied when applying the Duty.

It is recommended that officials familiarise themselves with the Consumer Duty guidance prior to completing this section. Consumer Scotland has responsibility for issuing the guidance. The [guidance](#) sets out how to complete an assessment of the Duty. The Consumer Policy team within the Scottish Government has responsibility for answering all other consumer-related queries.

If officials are not required to carry out a BRIA, they should still complete a Consumer Duty template, which can be found on the Consumer Scotland [website](#).

When developing your policy, officials must consider:

- The impact of decisions made on consumers in Scotland.
- The desirability of reducing harm to consumers in Scotland.

Although the Duty applies to all consumers, policy officials are encouraged to consider the impact of strategic decisions on consumers living within vulnerable circumstances, with the intention of avoiding harm being brought to them where appropriate. As set out in the Act, policy officials should:

- Publish information around the steps taken to meet the Duty (i.e. publishing the BRIA or, where a BRIA is not required, publishing the Consumer Duty assessment).
- Have regard to the [guidance](#) produced by Consumer Scotland.

### Meaning of Consumer as per the Consumer Scotland Act 2020

- (1) In this Act, “consumer” means —
- (a) an individual —
    - (i) who purchases, uses or receives, in Scotland, goods or services which are supplied in the course of a business carried on by the person supplying them, and
    - (ii) who is not purchasing, using or receiving the goods or services wholly or mainly in the course of a business carried on by the individual, or

- (b) a business (including a business carried on by an individual) —
  - (i) which is no larger than a small business, and
  - (iii) which purchases, uses or receives, in Scotland, goods or services which are supplied in the course of a business carried on by the person supplying them.

(2) For the purposes of subsection (1) —

- (a) a consumer includes both an existing consumer and a potential consumer,
- (b) a person who uses services includes, in relation to postal services, an addressee.

## **Ministerial Sign-Off**

As part of the Duty, policy officials now require their relevant Cabinet Secretary or Minister to confirm that they are content that officials have considered the impact on consumers as required by the [Consumer Scotland Act 2020](#) in completion of the Consumer Duty section of this BRIA.

# **Section 4: Implementation considerations**

## **Enforcement/ Compliance**

When considering compliance, you should assess what activity has been undertaken to identify the levels that are needed as a minimum, would be viewed as a reasonable accepted outcome, and would be desired as the best outcome. Given these and available resources, officials should identify what level of compliance/ enforcement activity can be expected

In order for policy proposals to be effectively implemented, there will be a requirement for business and stakeholders to comply with the expectations. Officials should consider how this will be encouraged/ enforced and monitored for each option and set this out in the impact assessment. Compliance and enforcement will vary by policy proposal and approach – for example, regulation is likely to have a higher compliance expectation and include enforcement powers.

## **Promoting Compliance**

Officials should detail how the Scottish Government and its partners will promote compliance with the new policy. This should include plans to share information, set expectations among the public and businesses, and encourage those affected to take any necessary action.

## **Monitoring Compliance**

Key considerations for monitoring compliance/ implementation that should be covered include:

- Responsibility – There must be clarity on who is responsible for monitoring compliance with each option. This should consider the cost and resource implications for those expected to carry out monitoring work, and how it aligns or conflicts with existing workload;
- Existing vs new monitoring mechanisms – Existing monitoring mechanisms may be usable where applicable to reduce implementation requirements, though they may need to be adapted. If new monitoring mechanisms are proposed, officials should consider the burden on those who are subject to multiple monitoring activities;
- Compliance against the overall policy objective and delivery success measures – Officials should be clear about what the levels of compliance are needed as a minimum, what would be viewed as a reasonable accepted outcome, and what would be desired as the best outcome. These should be measured against the overall policy objectives;
- Process – How will compliance be monitored, the frequency of monitoring and how it will be reported?;
- Impact on business – What level of resource/ cost will be required by businesses/ stakeholders to demonstrate their compliance? Officials should consider how this applies across sectors/ groups/ types of business and

whether some groups (such as small businesses) may be disproportionately impacted by some approaches.

Officials should consider how monitoring and reporting can be aligned with existing mechanisms and activity. This may help reduce the burdens on businesses and regulators, and make it easier for businesses to comply with the requirements.

## **Enforcement and Sanctions**

In some cases where legislation has put in place requirements, it will be appropriate to put in place enforcement mechanisms beyond monitoring of compliance. These should set out the responsibilities, powers, and process for those who are expected to take enforcement action.

When considering enforcement options, officials must engage fully with local authorities and COSLA, relevant existing regulators (and their sponsor teams) and the Public Service Reform Directorate as relevant.

Regulators in Scotland are supported by the Strategic Regulators Code of Practice and expected to act in line with the '4 Es approach' – they should engage, explain, encourage, and enforce only when necessary.

In all cases, officials must engage with those who may carry enforcement responsibilities/ act as regulators as early as possible to allow the plans and expectations to be clearly agreed. Key considerations will be the same as monitoring compliance, with some additional requirements:

- Responsibility – who will have specific responsibility for taking enforcement actions/ pursuing them as necessary?
- Powers – what powers will the regulator have to support its enforcement work. Officials should consider what powers are necessary to deliver the desired outcome while also considering the rights of business/ individuals who are subject to those powers?
- Resources – what resources are required to deliver enforcement responsibilities? Where regulators have other activities and work, officials should agree (with relevant SG colleagues as required) the relevant priorities for regulators and what levels of enforcement activity can be reasonably expected.
- Sanctions/ penalties – what will the sanctions/ penalties be on those who are determined to be non-compliant with the requirements? These may range as appropriate for the legislation. They may include facing improvement instructions, directions to close or Fixed Penalty Notices. Officials must make sure that all penalties are proportionate and in line with wider expectations. Legal colleagues should be consulted on these options as part of developing legislation, and officials should consider what other stakeholders need to be involved to implement (for example the Scottish Courts and Tribunal Service)

## **Exemptions**

Officials should consider whether there is scope for exemptions to requirements and enforcement actions for certain groups where there is an undue impact, and it does

not conflict with the overall policy objective. In particular, this may be relevant for small and micro businesses. Possible exemptions and implementation considerations that may be considered for such businesses include:

- Full exemptions – certain defined businesses not subject to requirements
- Partial exemptions – certain defined businesses not subject to some of the requirements or subject to different warnings/ sanctions
- Opt-in/ voluntary compliance – certain business allowed to opt in to regulatory regimes rather than automatically expected to comply
- Extended transition periods – certain defined businesses allowed a longer period before compliance is required
- Temporary exemptions - Exempt defined businesses for a period of time where immediate compliance would harm their business (e.g. where a product needs to be redesigned)
- Different requirements by size – less onerous requirements, less frequent inspections, registration rather than licensing
- Financial Aid – Support for small businesses to meet compliance costs

# UK, EU, and International Regulatory Alignment and Obligations

The Scottish economy is interconnected with the rest of the UK, Europe, and the world. Scottish Government officials must therefore consider impacts beyond domestic business implications.

The context within which Scottish Government policy is developed changed on 31 December 2020 when the UK left the EU single market. This section of the BRIA requires policy makers to consider the impact of the proposals on, and within this changed context. It specifically requires consideration of three distinct, but related regulatory factors related to leaving the EU: intra-UK trade, international trade, and the Scottish Government's EU alignment policy. Relevant policy teams lead on these specific subjects and will be able to provide further advice.

Leaving the EU means that regulatory features that were relevant when part of the EU single market fell away upon exit, and the UK now has a new regulatory landscape. In addition, the Scottish Government has a commitment to maintain alignment with the European Union where this is possible and within Scotland's interest. This requires policy makers to understand and engage with this new context and its potentially complex interactions with devolved policy and devolved policy impacts.

## Internal Market/ Intra-UK Trade

The UK's exit from the EU single market on 31 December 2020, created a new regulatory landscape within which devolved policy operates. For internal ('intra') UK trade, two significant regulatory features were introduced:

- the United Kingdom Internal Market Act 2020; and
- Common Frameworks

## The United Kingdom Internal Market Act 2020

[The United Kingdom Internal Market Act 2020](#) came into force when the UK left the EU single market on 31 December 2020.

Consent was sought from the devolved legislatures to the legislation and no devolved legislature gave consent. The Scottish Parliament and the Senedd Cymru voted to withhold consent. The Scottish Government lodged a legislative consent memorandum ([available on the National Records website](#)) advising against giving consent, in which it stated that the Act, *"...undermines both the devolution settlement and agreed processes that are already established to agree common frameworks and ways of working across the UK following EU exit."*

The United Kingdom Internal Market Act 2020 contains provisions as follows:

- Part 1 introduces new market access principles of mutual recognition and non-discrimination for goods;

- Part 2 provides for market access for services (mutual recognition of authorisation requirements and non-discrimination of service providers);
- Part 3 introduces a new system for the mutual recognition of professional qualifications;
- Part 4 provides for the creation of a new reporting, advising and monitoring function for the Competition and Markets Authority (CMA) by creating the Office for the Internal Market (OIM) within the body;
- Part 5 contains provisions relating to the Northern Ireland Protocol;
- Part 6 gives UK Ministers powers to spend directly in devolved policy areas;
- Part 7 reserves subsidy control; and
- Part 8 adds the Act to the list of protected enactments in Schedule 4 of the Scotland Act 1998.

Parts 1-2 of the Act should be considered in particular when developing policy that has potential market impact.

## **Part 1: Goods**

The mutual recognition principle means that goods which have been produced, or imported into one part of the UK and which meet regulatory requirements in that part of the UK, may be sold in any other part of the UK, free from any relevant requirements that would otherwise apply to their sale in that other part.

The non-discrimination principle prohibits direct or indirect discrimination based on treating local and incoming goods differently.

These rules are subject to certain exclusions set out in the Act.

Where proposals introduce or change legislation that relates to the sale of goods, you should take appropriate advice and consider:

- whether the proposals will result in policy divergence between UK nations, and the nature and potential impacts of divergence;
- whether the market access principles of the Act are relevant and in what way they interact with the proposals, particularly in terms of policy effect, including whether there is an exclusion for the policy area within the Act; and
- whether there is a relevant Common Framework.

## **Part 2: Services**

Service providers who are authorised to perform a service in one part of the UK may not need a separate authorisation to perform that service in another part. The non-discrimination provisions of this Part prevent direct and indirect discrimination against service providers located in another part of the UK.

These rules are subject to a number of exclusions set out in the Act.

Where the proposals relate to the provision of services, for example, an authorisation requirement for the provision of services, you should consider:

- whether the proposals will result in regulatory divergence between UK nations, and the nature and impacts of any divergence; and
- whether the mutual recognition and non-discrimination principles are relevant and in what way they interact with the proposals, particularly in terms of policy effect, including whether there is an exclusion for the policy area within the Act.

## Part 3: Professional Qualifications

Part 3 provides for a system for the mutual recognition of certain professional qualifications that are regulated in law across the UK. It introduces an “automatic recognition” principle for a professional qualified in one part of the UK to be treated automatically as qualified in respect of that profession in another part of the UK, as well as setting out the situations where the automatic recognition principle does not apply.

Where proposals relate to regulation of professional qualifications you should consider:

- whether the proposals will result in regulatory divergence between UK nations, and the nature and impacts of any divergence; and
- whether the provisions of the Act are relevant and in what way they interact with the proposals, particularly in terms of policy effect, including whether there is an exclusion for the professional qualifications within the Act.

## Common Frameworks

When considering intra-UK impacts and proposals, you should also establish whether the policy area is covered by one or more Common Framework(s). The Common Frameworks programme was agreed by the four governments of the UK in 2017 to establish common approaches in some areas that were governed by EU law, and that are within areas of devolved competence. More information relating to the basis on which the programme was established and the principles underpinning Frameworks can be found in [the Joint Ministerial Committee \(EU Negotiations\) Communiqué of October 2017](#). Common Frameworks are the Scottish Government’s preferred means of managing post EU policy divergence across the UK, on the basis of progress by agreement and respect for devolution. In 2021, a process was developed by the governments of the UK to consider exclusions to the UK Internal Market Act (2020) for agreements reached in Common Framework areas. [The process is available on the gov.uk website](#).

Where policy areas are covered by an existing Common Framework you should consider:

- as above for intra-UK trade impacts; and
- relevant impacts of agreements reached within Common Frameworks relating to managing policy divergence and any exclusions required to be agreed within a Common Framework, as per the agreed process linked to above.

## Contact

For further guidance on Common Frameworks, contact the team in the Constitution and Cabinet Directorate ([IMAFrameworksTeam@gov.scot](mailto:IMAFrameworksTeam@gov.scot)).

## Assessment

In all cases you should record and evidence the intra-UK regulatory impacts and interactions.



## International Trade Implications

The Scotland Act and Scottish Ministerial Code convey an overarching duty on Scottish Ministers to comply with international law and treaty obligations. Following departure from the EU, the UK is responsible in its own right for remaining compliant with international obligations, including with respect to the World Trade Organization (WTO), and Free Trade Agreements. This obligation extends to devolved matters, meaning that new policy and regulations introduced by Scottish Ministers are potentially subject to legal challenge if they do not comply.

The purpose of these questions is to ensure that:

- policy makers are giving due consideration to the impacts that regulatory policy could have on international trade into, and out of, Scotland, and
- policy teams have factored the potential notification responsibilities that may arise from this into their timelines for policy development and legislation

Policy teams are responsible for ensuring their policy complies with WTO law and other international obligations, such as those within free trade agreements. Officials should seek SGLD advice where necessary. In some cases there will be a requirement to notify WTO members ahead of any regulatory changes.

## International Obligations

The WTO is the international body which establishes and manages the rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and freely as possible. This is achieved through its overarching principles of non-discrimination between member states and transparency.

In order that the international trading environment remains stable and predictable, members are required to notify measures relevant to particular WTO Agreements. These include, but are not limited to, the following:

- **The Technical Barriers to Trade (TBT) Agreement** requires WTO members to notify in advance changes to technical regulations, standards and procedures for assessing standards conformity.
- **The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)** concerns the application of food safety and animal and plant health regulations. It requires members to notify measures taken to ensure food is safe for consumers, and to prevent the spread of pests or diseases among animals and plants.
- **Agreement on Subsidies and Countervailing Measures (SCM)** addresses the use of subsidies by governments that may have an impact on trade.
- **The Government Procurement Agreement (GPA)** sets out the framework for government procurement of goods and services between WTO members, ensuring that suppliers of goods and services from other member states are treated no less favourably in securing government procurement than domestic suppliers.

There are other WTO Agreements which could have implications for Scotland's policy making, for example in agriculture, fisheries and services trade.

Each agreement contains specific requirements for notifying other WTO members of policy and regulatory changes, and criteria for determining whether a measure is notifiable. The reference or otherwise to international standards is a material factor. The requirement to notify can have a significant impact on legislative timetabling.

As the UK's independent trade policy evolves international obligations may change over time. Compliance with WTO obligations can also help to meet similar obligations under Good Regulatory Practice and Regulatory Cooperation (GRPRC), Technical Barriers to Trade (TBT) and Sanitary and PhytoSanitary (SPS) Chapters of Free Trade Agreements, such as the UK-EU Trade and Cooperation Agreement (TCA).

## **Impact on International Trade**

Relevant changes to regulation that could affect trade and investment include:

- the ability of Scottish businesses to trade or provide services overseas, or
- the ability of overseas businesses to export to the Scotland or provide services to Scotland
- foreign investors/companies operating in Scotland being impacted differently from UK-owned companies/investors
- the assets of foreign investors/companies being removed from them or substantially taken out of their control.

The ability of businesses to trade within Scotland should be captured within the impact assessment. However, the ability of overseas businesses to export to Scotland is also an aspect that policy makers will need to consider.

When answering this question, policy makers should consider the following considerations for assessing impacts on international trade:

- Does this measure have the potential to affect imports or exports of a specific good or service, or groups of goods or services?
- Does this measure have the potential to affect trade flows with one or more countries?
- Does it place particular technical requirements upon (imported) goods?
- Does this measure include different requirements for domestic and foreign businesses?
  - i.e. are imported and locally produced goods/services treated differently and not on a level playing field?
  - i.e. are any particular countries disadvantaged compared to others?

Where you answer yes to any of the above questions, please provide a description and assessment of the rationale, and contact WTO Compliance Enquiries ([wto@gov.scot](mailto:wto@gov.scot)) and SGLD to discuss potential notification responsibilities.

## **International Standards**

Some WTO Agreements and FTAs encourage members to 'base' regulatory measures on relevant international standards, where they exist.

If a relevant international standard (or parts thereof) would support compliance with a measure that achieves a legitimate policy objective, policy makers are encouraged to consider using relevant international standards as a basis for the measure.

Please contact WTO Compliance Enquiries ([wto@gov.scot](mailto:wto@gov.scot)) within the Directorate for International Trade and Investment (DITI) for further advice to complete the assessment, for advice on potential notification responsibilities under WTO agreements and for further guidance on identifying international standards.

## EU Alignment consideration

In this section you should consider if the measure is likely to impact on the Scottish Government's policy to maintain alignment with the EU.

Scotland's commitment to remain close to the EU means Scotland will continue to align with the EU where appropriate, and in a manner that contributes towards protecting and advancing standards across a range of policy areas.

### Assessment

Your considerations should include:

- the Scottish Government's commitment to maintain and advance the high standards that Scotland shares with the EU;
- access to EU markets for people, goods, and services; and
- any potential implications for EU alignment associated with the United Kingdom Internal Market Act 2020 or Common Framework agreements.

### Implementation

You will also wish to consider how the policy in question will be implemented. The assumption is that a decision to align will be given effect via existing powers or primary legislation, however there may be times where such methods will not allow the Scottish Government to align or may not be the most effective or efficient method of doing so. Business and Regulatory Impact Assessment: Toolkit 17 of 33

In such cases, section 1(1) of the UK Withdrawal from the European Union (Continuity) (Scotland) Act 2021 provides a regulation making power to maintain Scottish Ministers' ability to keep devolved Scots law aligned with EU law as it develops and where that is in Scotland's best interest.

The Continuity Act policy statement approved by Parliament on 8 June 2022, sets out the factors that Ministers must consider in making decisions in relation to EU alignment.

### Contact

For further advice on alignment please contact the Directorate for External Affairs ([EUAlignmentmailbox@gov.scot](mailto:EUAlignmentmailbox@gov.scot)).

More information on assimilated law is available on the gov.scot website - [Assimilated law \(Retained EU law\) - Europe - gov.scot \(www.gov.scot\)](https://www.gov.scot/resources/consultation-papers/collections/documents/Assimilated-law-Retained-EU-law-Europe-gov.scot)

## Legal Aid

When drafting this section of the BRIA you should consider whether your proposed policy could give rise to increased use of legal processes or create new rights or responsibilities, what implications it may have on fulfilling individuals' right to access to justice through availability of legal aid and any possible expenditure from the legal aid fund.

If your policy will create a new procedure or right of appeal to a court or tribunal, any change in such a procedure or right of appeal, or any change of policy or practice which may lead people to consult a solicitor then it is likely that it will have an impact on the legal aid fund.

You should also consider whether the policy will result in additional people seeking legal assistance or being taken through the courts.

If you identify an impact or are unsure whether your proposed policy will impact the legal aid fund, please contact the Access to Justice team through the BRIA inbox: [legalaidthrawl@gov.scot](mailto:legalaidthrawl@gov.scot), attaching a copy of your draft BRIA.

You should allow ten working days for an initial response, and you should note that your information may be shared with the Scottish Legal Aid Board (SLAB). If your policy is sensitive and cannot be shared with SLAB or can only be shared in part you should state this clearly in your email.

## Digital Impact

Officials should address key challenges around thinking and gathering evidence about the impact of technology on specific industries, firm types, and businesses of varied sizes.

Digital technologies are a central part of everyday life now. Consumers and customers expect easy, digital services. The explosion of smartphone use, online services, and transactions both private (like banking) or public (like road tax) and innovative new markets and platforms like Uber and Amazon have changed the way in which people live, work, and operate. If the Scottish Government does not consider digital / technological advances and their effect on or fit with policies and regulations, then there is a risk of changes being made which quickly become unfit for purpose, and which may require revisiting and amending later and at cost.

Changes to policy, regulation or legislation can often have unintended consequences, should government fail to consider advances in technology and the impact this may have on future delivery. Digital Impacts may include:

- The proposed change is to be delivered in an 'analogue' way, for example it may be a check that requires physical forms filled in by hand and posted. Services and interactions are increasingly moving online. The impact of the change could mean that it would need to be revisited, at cost, at a later stage when services move online.

- The proposed change is to be delivered in an only digital way i.e. via a website – an online transaction – this would have an impact on those without access or capability to get online and may have a cost for both Government and the business or individual to support them to a stage where they can get online.
- Where a change only applies in Scotland or according to Scots law, the assessment must consider online transactions that may originate from outside of Scotland – how would the change be enforced?
- Where a change includes age restrictions – consideration would need to be considered around enforcement, roles, and responsibilities in an online transaction process. This list is not exhaustive however it gives an understanding of digital issues to consider

The digital impact test requires officials to consider whether the changes being made can still be applied effectively should business/government processes changes – such as services moving online.

Officials should set out the consideration given to ensuring that proposals are consistent with the increasing shift of economic, social, and governmental interactions online. For example:

- Does the measure take account of changing digital technologies and markets?
- Will the measure be applicable in a digital/online context?
- Is there a possibility the measures could be circumvented by digital / online transactions?
- Alternatively, will the measure only be applicable in a digital context and therefore may have an adverse impact on traditional or offline businesses?
- If the measure can be applied in an offline and online environment will this have any adverse impact on incumbent operators?

## **Business Forms**

All new forms introduced because of Scottish Government legislation must also be test run as early as possible with appropriate businesses, business organisations and stakeholders to ensure they are clear, simple, and easy to complete. It can be useful to get business/business organisations to help in the development process; however, there is a firm commitment to consult an appropriate sample of 6-12 business likely to be affected by any proposal and they should be engaged on any new forms.

In completing this section of the impact assessment template, officials must provide details of any new forms being introduced and explain how they were developed, what input stakeholders had in their development and the results of the test run.

## **Section 5: Next Steps and Implementations**

### **Recommendations/ preferred options**

Depending on the stage of policy development, officials may be in the position to make recommendations or identify one or more option to be taken forwards. Officials should set out any recommendations with reference to the impact assessment results. Where Ministerial decisions have been made, these should be set out alongside appropriate rationale for transparency. This should note the impacts identified for that option and justify why they are deemed tolerable.

Where options are being taken forwards, any identified mitigating actions to address impacts/ concerns should also be noted

### **Implementation considerations/ plan**

Officials should outline implementation and delivery plans covering the key issues for each option being taken forwards. These are likely to refer to earlier sections and might include:

- ownership – who is responsible for implementation and who will make decisions?
- the aims of implementation – identifying the policy objective and outcomes considered necessary, including success criteria;
- timetable for implementation – key decision points and milestones, specifying where flexibility may or may not exist;
- identification of stakeholders – who will be involved in implementation and who may be more widely affected?
- communication strategy – how officials will share updates, expectations and requirements allowing for early warning to those who will be affected, especially small businesses and other organisations;
- risk management – how this will be done for the delivery and implementation of each option.
- existing initiatives – how the policy/ regulation will align with other ongoing work, including those by other government departments and inspection agencies, and aggregated burdens

Implementation plans can set out further steps that will be taken to gather more details on impacts and consider mitigations. This may include discussing plans with the [Regulatory Review Group](#) to gather feedback.

### **Post Implementation Review**

As part of finalising monitoring arrangements officials must also recognise the need for a formal post-implementation review. This should be within 10 years of regulations/ policy coming into force, and earlier where appropriate for example where coincides with a pre-programmed review.

This review should establish whether implemented policy/ regulations are having the intended effect and whether they are implementing policy objectives efficiently. The implementation review is not intended to review the effects of the policy itself or to determine whether the intended policy is still desirable; However, such a review is recommended and may be carried out in parallel.

Officials should use the final BRIA as the starting point for this work, given that it should establish a baseline and include the success criteria against which the effectiveness of the policy in delivering the objective will be assessed. Key issues for planning this review should include:

- whether the policy objective has been met;
- whether impacts have been as expected, including the costs and benefits;
- views of stakeholders regarding implementation of the policy and whether there have been any unforeseen unintended consequences;
- compliance levels, whether they indicate that the enforcement regime is effective and whether it could be adjusted to be lighter touch/ risk based or needs to be stronger;
- the basis of the review – whether it is statutory (forming part of the legislation) or non-statutory commitment to review;
- criteria for modifying or replacing the policy if it does not achieve its objectives or is viewed as no longer necessary (for example if the issue is no longer relevant);
- confirming that the five principles of better regulation are evident in delivery and outcomes.



# Declaration

The Cabinet Secretary or Minister responsible for the policy (or the Chief Executive of non-departmental public bodies and other agencies if appropriate) is required to sign off all BRIAs prior to publication where they are in support of legislation.

Officials should confirm whether they are completing a partial or final BRIA.

The Consumer Duty also requires that the Cabinet Secretary or Minister responsible for the policy (or the Chief Executive of non-departmental public bodies and other agencies if appropriate) to confirm that they are content that officials have considered the impact on consumers as required by the Consumer Scotland Act 2020 in completion of the Consumer Duty section of this BRIA.

Partial and Final BRIAs should be shared with the Directorate for Business and Better Regulation - [businessregulationengagement@gov.scot](mailto:businessregulationengagement@gov.scot)

Signed BRIAs should be published on gov.scot using APS

Five hard copies of any published BRIA should be sent to the Scottish Parliament Information Centre (SPiCe) and an electronic copy sent to their collections team.

An electronic copy of any published BRIA should be sent for the attention of the Regulatory Review Group.

Where appropriate, one copy each should be sent to the following:

- the lead committee;
- Delegated Powers and Law Reform Committee;
- Parliament Legal Advisors.



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