

The Official Controls (Miscellaneous Amendments) Regulations 2024

Lead department	Department for Environment, Food and Rural Affairs
Summary of proposal	The proposal is to enable the implementation of the Border Target Operating Model (BTOM), a global risk-based model for sanitary and phytosanitary (SPS) border controls for Great Britain.
Submission type	Impact assessment (IA) – 19 th April 2024
Legislation type	Secondary legislation
Implementation date	30 April 2024
Policy stage	Final
RPC reference	RPC-DEFRA-5337(1)
Opinion type	Formal
Date of issue	15 May 2024

RPC opinion

Rating¹	RPC opinion
Fit for purpose	As originally submitted, the IA was not fit for purpose. The RPC had concerns over the use of the appropriate counterfactual in relation to the calculation of the EANDCB, missing familiarisation costs and the SaMBA. The Department has addressed these concerns, and the RPC now finds the IA to be fit for purpose, however, there are significant areas for improvement. Generally, the IA would benefit from improvements to the presentation of impacts, for example, clearly stating which impacts fall on which groups.

Business impact target assessment

	Department assessment	RPC validated
Classification	Qualifying regulatory provision (OUT)	Qualifying regulatory provision (OUT)
Equivalent annual net direct cost to business (EANDCB)	-£124.2 million (initial IA estimate) -£689.8 million (final IA estimate)	-£689.8 million (2019 prices, 2020 pv) against the Official Controls Regulations

¹ The RPC opinion rating is based only on the robustness of the EANDCB and quality of the SaMBA, as set out in the [Better Regulation Framework](#). RPC ratings are fit for purpose or not fit for purpose.

*counterfactual (see
EANDCB section below)*

Business impact target (BIT) score	-£3,449.1 million	-£3,449.1 million
Business net present value	£5,937.7 million	
Overall net present value	£8,279.8 million	

RPC summary

Category	Quality ²	RPC comments
EANDCB	Green	As originally submitted, the RPC had concerns with the counterfactual position used when calculating the EANDCB. The Department has since adjusted their counterfactual by using the Official Controls Regulation (OCR) position. The IA notes that this represents a scenario with no further legislation, and, on this basis, it appears to be in line with a traditional 'do nothing' counterfactual. The RPC considers this to be acceptable as the primary counterfactual in the IA. However, the IA would benefit from providing further explanation. The IA appears to correctly identify direct and indirect costs to business but would benefit from providing further justification for this. The IA appropriately includes estimates of the cost to business against the 'as is' counterfactual. This shows a net increase in cost and will more closely reflect business experience. The IA should present this assessment more transparently.
Small and micro business assessment (SaMBA)	Green	The Department argues against exemption for small or micro businesses as this would not meet the policy objectives. As originally submitted, the RPC also found the SaMBA to be not fit for purpose as it did not consider mitigations for small and micro businesses who the IA explains are likely to face disproportionate costs. The SaMBA now includes mitigations the Department has put in place to reduce the burden on small and micro businesses. The IA should expand its assessment to include a specific section on the impact upon medium-sized businesses.
Rationale and options	Weak	The IA briefly outlines the rationale for intervention. Whilst the IA helpfully explains the policy context, the rationale is generally lacking in evidence. The IA needs to provide supporting evidence from evaluating the arrangements in place pre-EU Exit to strengthen the justification for moving to a new regime, as well as comparing the UK's border control model to that of other countries. The IA outlines the options considered and helpfully explains why alternatives to the preferred option have been discounted. The IA would benefit from explaining how the short-list of options was arrived at and why alternatives were discounted.

² The RPC quality ratings are used to indicate the quality and robustness of the evidence used to support different analytical areas. The definitions of the RPC quality ratings can be accessed [here](#).

Cost-benefit analysis	Weak	<p>The IA provides a reasonable level of monetisation of the costs and benefits to business of the proposal and provides a qualitative assessment of the social benefits. The Department provides upper and lower bounds for the estimated impacts throughout the IA to demonstrate uncertainty. It is not always clear what assumptions and evidence underpin these estimates. The approach to calculating the NPSV and how this differs from the business NPV should be made clearer. The IA needs to clearly state which impacts fall on which group.</p>
Wider impacts	Weak	<p>The IA briefly considers trade implications of the proposal. Given the proposal directly impacts trade, this section is underdeveloped, and the IA needs a more proportionate assessment on this impact. The IA should also provide further consideration of the risk to biosecurity and public health in the UK.</p>
Monitoring and evaluation plan	Weak	<p>The IA states the SI does not include a statutory commitment to a post-implementation review (PIR) as the Department intends to evaluate the BTOM as a whole. This approach appears reasonable however, the IA should provide a high-level timeline for when monitoring and evaluation is planned to take place. In doing so, the IA should provide further detail at this stage, for example, outlining key research questions they intend to address as part of the evaluation and link these back to the policy objectives.</p>

Response to initial review

As originally submitted, the IA was not fit for purpose for the following reasons:

1. Issues with the EANDCB:
 - a. *Counterfactual/baseline*: The Department originally used the import control regime which was previously proposed for July 2022 as the main counterfactual to measure the impact of the proposal against. Since the UK Government decided in April 2022 to not introduce these SPS controls, as they were still considered to be overburdensome, the use of this position as a counterfactual appeared incorrect to the RPC and therefore did not appear to be a suitable counterfactual.
 - b. *Scope of impacts*: The IA stated that importers will already be facing costs associated with certification and documentary checks, which were introduced from 31st January 2024. The Department argued that these costs are out of scope of the IA, however, appeared to have not been accounted for within a previous IA. The RPC expects to see justification for this.
 - c. *Missing impacts*: The Department did not include familiarisation costs in the initial IA as traders are expected to already be familiar with the new requirements. The RPC did not find this justification to be sufficient. The Department needed to either include familiarisation costs or provide sufficient justification for it not being proportionate or appropriate.
2. The RPC also found the SaMBA to be not fit for purpose as it did not consider mitigations for small and micro businesses who the IA explains are likely to face disproportionate costs.

The Department has now:

1. Made the following changes to the EANDCB:
 - a. *Counterfactual/baseline*: The Department has revised its central estimate to use the Official Controls Regulations (OCR) scenario (see below) as the main counterfactual to estimate the impacts of the proposal against. The Department argues this best represents a scenario in which no further legislation is implemented.
 - b. *Scope of impacts*: The Department has provided justification for why certification and documentary checks, which were introduced from 31st January 2024, are out of scope of this IA.
 - c. *Missing impacts*: The Department has estimated familiarisation costs and has assumed these to be the same under all options.
2. Provided a more detailed SaMBA, including mitigations the Department has put in place to reduce the burden on small and micro businesses.

Summary of proposal

The Border Target Operating Model (BTOM) was published in August 2023 and sets out a new global model that will be introduced in stages. The model relates to import controls on sanitary and phytosanitary (SPS) goods, applying to imports such as live animals, germinal products, animal products, plants and plant products and high-risk food and feed of non-animal origin from the EU into Great Britain.

This proposal forms part of a series of SIs that will be laid to implement the BTOM. This IA refers to the changes proposed to be implemented under The Official Controls (Extension of Transitional Period) (Miscellaneous Amendments) (No 2) Regulations 2024, which will come into force on 30 April 2024.

The IA considers the following options:

- **Option 0: 'As is'** – The current import control regime. This option represents the Transnational Staging Period (TPS), which the UK has operated since EU Exit. This is the transitional period between SPS regimes where controls are applied to non-EU imports and very limited controls are applied to EU imports.
- **Option 1: Official Controls Regulations (OCR) (Counterfactual)** – This option represents the scenario if no further legislation were introduced. In this case the transitional legislation (option 0) would expire and SPS controls would revert to the OCR. These controls would mirror the current non-EU regime.
- **Option 2: July 2022 (Previous policy option)** – This option represents the import control regime, which was previously proposed for July 2022, but the Government decided not to introduce in April 2022. This approach imposes higher burdens on business, including providing export health certificates and documentary checks regardless of the risk category of goods.
- **Option 3: BTOM (Preferred option)** – A global risk-based SPS import control regime as published in the BTOM. This option includes the following measures:
 - Re-categorisation of certain regulated plants and plant products according to risk.
 - Introduction of the new risk categorisation model for animals and animal products from the EU and RoW and risk based SPS controls on consignments from the EU transiting the landbridge of GB for animals and animal products.
 - Documentary checks to take place remotely in advance of the goods' arrival.
 - Prohibitions and restrictions on meat preparations to be managed by market access and health certification from 30 April 2024.

The Department assesses the impact of the preferred option against the counterfactual i.e. the OCR. The preferred option is therefore estimated to present a savings to business as the new border model is less burdensome than the controls under the OCR.

The Department estimates the EANDCB of the preferred option as -£690 million; the total benefit to business over the ten-year appraisal period is estimated to be £5,940 million and the overall net present social value is estimated to be £8,280 million.

EANDCB

Data and evidence

The IA mostly draws on data from HMRC as well as drawing on sector intelligence, for example the UK Office for Biodiversity and the Food Standards Agency, to estimate the cost to business of the proposal.

The IA uses HMRC customs declarations data to estimate the volume of SPS goods imported from the EU that are subject to controls under each policy option. The IA notes these estimates are based on data from 2021/22 and do not take into account future changes to trade flows (paragraph 36). Annex 1 explains this is the latest data available, however, IA would benefit from further justification as to why 2021/22 is a suitable year to base volume estimates, for example, considering whether the data is affected by the global pandemic and drawing on trends from previous years.

Assumptions

Annexes 1 and 2 helpfully set out the assumptions used when estimating the cost to business associated with controls for products of animal origin (POAO) and plant and plant products (P&PP). The IA helpfully states where assumptions have been tested with stakeholders in the absence of data.

Direct/indirect

Whilst the IA appears to correctly identify direct and indirect costs to business (see Section 5), the IA would benefit from providing justification for this, drawing on RPC guidance³.

Counterfactual/baseline

As originally submitted the IA used a counterfactual of the July 2022 proposals being implemented. However, this was not what would happen under a 'do nothing' scenario, nor apparently in accordance with circumstances where different counterfactuals have occasionally been used under the better regulation framework (see RPC case history guidance on counterfactuals⁴). The RPC therefore did not consider that the Department had sufficiently justified its use as the primary counterfactual in the IA. In response, the revised IA uses a new counterfactual of the time-limited transitional legislation expiring and reversion to the Official Controls Regulations (OCR). Whilst the IA indicates that this is not an acceptable policy option, it appears to be a legally viable one. The IA notes that it represents a scenario with no further legislation, and, on this basis, it appears to be in line with a traditional 'do nothing' counterfactual. Whilst there is no framework guidance indicating the use of an alternative counterfactual for these types of measures, the RPC considers this to be acceptable as the primary counterfactual in the IA.

The proposal confers large net benefits against this counterfactual. However, as the IA indicates, this is not a comparison against what businesses are currently experiencing. The latter is represented by the 'as-is' scenario. This scenario appears to involve intervention to extend transitional arrangements and is not regarded as a viable long-term option, in part because it could impact on the UK's international obligations to the World Trade Organisation. The RPC therefore accepts that this is

³ See RPC case histories – direct and indirect impacts, March 2019 ([here](#))

⁴ See RPC case histories – counterfactuals, September 2020 ([here](#))

an assessment of the baseline option rather than the primary counterfactual in the IA. However, the IA appropriately additionally includes estimates of impact against this baseline. This shows a net increase in cost and will more closely reflect business experience, and the change in business burden over the current parliament. The IA should present this assessment against the baseline more prominently.

Presentation of impacts

Whilst option 1 is treated as the counterfactual for the best estimate of the EANDCB, the Department helpfully presents the impact of the preferred BTOM against all other options. This shows that whilst the preferred option represents a saving to business compared to the more burdensome OCR regime, it still imposes additional costs to business compared to the temporary arrangements under the 'as is' scenario (see Paragraph 54). The IA should convert these estimates against the 'as is' counterfactual into EANDCB figures to be more transparent regarding the direct costs businesses will experience.

Missing impacts

As originally submitted, the Department did not include familiarisation costs in the EANDCB. Following RPC scrutiny, the Department has now estimated a one-off familiarisation cost of £2.1 million and assumes this to be the same for all potential control regimes (i.e. options 1, 2 and 3). The IA could benefit from providing justification as to why familiarisation costs are assumed to be the same under all options.

SaMBA

Scope

The IA notes it is not possible to easily distinguish the size of businesses which will be impacted by the proposal due to data limitations (paragraph 74). Instead, the Department uses data on the types of industries most reliant on SPS goods and the size of businesses within these sectors to determine the likely size of businesses which will be impacted by controls on SPS imports. From this, the IA identifies that the majority of SPS goods are used in the manufacturing of food products, where 8 per cent of the import value is accounted for by small or micro businesses. The second sector that relies most heavily on SPS imports is food and beverage services, of which 25 per cent are small or micro businesses (paragraph 75-76).

Exemption

The Department argues against exemption for small or micro businesses as this would not meet the policy objectives of protecting biosecurity. The Department also notes such exemption could be considered a breach of international obligations, namely the World Trade Organisation's most-favoured-nation (WTO MFN) rules. The IA could be improved by further explaining how exemption is not possible.

Impacts

The Department considers the impact of the preferred BTOM model on smaller businesses and concludes they are likely to face disproportionate costs as inspection costs are based on consignments as opposed to the volume of goods. This view is supported by stakeholder feedback.

Mitigation

In order to mitigate against potential disproportionate costs, the Department has undertaken engagement activities with businesses to ensure they are prepared for the new regulation and have the opportunity to feedback concerns. Specifically, the Department has issued guidance on how businesses can reduce the burden of SPS import requirements by using groupage models to reduce transport costs. The IA notes this would be particularly beneficial to small and micro businesses (paragraph 82).

Medium-sized business considerations

The IA should provide an assessment of whether there are likely to be any disproportionate impacts on medium-sized businesses, usually identified as businesses with 50-499 employees, which may justify the consideration of measures to mitigate the burdens on these businesses.

Rationale and options

Rationale

The IA briefly outlines the rationale for intervention, stating the need to have official controls in place for SPS goods to ensure food safety whilst facilitating trade. Whilst the IA helpfully explains the policy context, the rationale is generally lacking in evidence. The rationale needs to be strengthened by drawing on relevant data and evidence which demonstrates the importance of border controls for SPS goods, for example, the socioeconomic impacts of biosecurity outbreaks as evidenced in Figure 1. The IA should also refer more explicitly to the strategy paper for the overall BTOM approach which utilises stakeholder feedback. The IA would benefit from evaluating the arrangements in place pre-EU Exit to strengthen the justification for moving to a new regime, as well as comparing the UK's border control model to that of other countries.

Options

The IA outlines the four options considered (see above) and explains why options other than the preferred are not viable (see pages 7-8). For example, the OCR would require significant investment in infrastructure and would not benefit biosecurity. The IA would benefit from explaining how the short-list of options was arrived at, or reference to where this might be found, and why alternatives were discounted. For simplification to the reader the IA would benefit from removing the use of the option covering a proposed July 2022 position on which the Government decided not to progress in April 2022. The inclusion of this within the IA appears to overcomplicate the discussions on a counterfactual position when comparing viable options.

Cost-benefit analysis

The IA provides a reasonable level of monetisation of the costs and benefit to business of the proposal and provides a qualitative assessment of the social benefits, namely maintaining UK biosecurity. This assessment helpfully draws on relevant evidence showing the socioeconomic impacts of biosecurity outbreaks (see Figure 1).

The Department provides upper and lower bounds for their estimated impacts throughout the IA to demonstrate uncertainty. It is not always clear what assumptions underpin these estimates. The IA should present a summary table of key assumptions used, the upper and lower bounds, and the evidence underpinning these. This would allow the reader to clearly see what assumptions have been tested.

The IA includes the changes in the fees to traders associated with physical and identity checks at ports in the NPSV. As stated in the Better Regulation Framework,⁵ fees and charges are exempt from the BIT and therefore are not included in the EANDCB. However, the IA could be clearer in stating that, compared to the counterfactual, the overall cost savings on business is higher than that represented by the EANDCB when the changes in fees are also considered. The IA would also benefit from more clearly presenting the costs/benefits included in the NPSV and business NPV.

Wider impacts

The IA briefly considers trade implications of the proposal. Given the proposal directly impacts trade, the 'potential trade implications' section (paragraphs 71-73) within the IA is underdeveloped. The IA needs to include a proportionate assessment on the impact on trade, referring to the Better Regulation Framework for guidance⁶. The IA should also consider the potential long-term impact on the UK's trading relationships and the impact this has on the biosecurity landscape. The IA would also benefit from considering the impact on future trade deals as this will potentially involve the removal of some checks through mutual recognition.

The IA should provide further consideration of the risk to biosecurity and public health. The IA argues that both the July 2022 and BTOM options reduce the risks to biosecurity compared to the 'as is' (paragraph 69), however, the IA does not sufficiently compare the increased risk of the BTOM compared to the July 2022 approach or the OCR position. Since the BTOM is a risk-based approach to border controls, the IA should discuss these potential risks further. Similarly, the IA should also provide further explanation on public health risks, beyond the brief description in Figure 1, given reducing these is an objective of the proposal. The IA would benefit

⁵ See page 27 of the Interim Better Regulation Framework ([here](#)).

⁶ Guidance on International Trade and Investment can be found in Annex 3 of the Interim Better Regulation Framework ([here](#)).

from an assessment of the risk to human safety and animal and plant health under the current arrangements i.e. with limited controls on EU exports.

Monitoring and evaluation plan

The IA states the SI does not include a statutory commitment to a post-implementation review (PIR) as the Department intends to evaluate the BTOM as a whole once additional measures are implemented later this year. This approach appears reasonable, however, the IA should provide a high-level timeline for when monitoring and evaluation of the BTOM is planned to take place. Whilst it is appropriate to evaluate the BTOM as a whole, the Department should consider attempting to isolate the impact of the separate measures in order to help make an informed decision in relation to future amendments.

The IA briefly outlines initial steps taken to monitor the BTOM including stakeholder engagement, workshops and initial analysis of available data. The IA also explains that the Department will use a combination of trade datasets and external spatially explicit surveillance data to monitor the impact of the BTOM on biosecurity.

Although the monitoring and evaluation plan is dependent on the other measures introduced as part of the BTOM, the IA would significantly benefit from further detail at this stage. For example, outlining key research questions they intend to address as part of the evaluation and link these back to the policy objectives. The Department also recognises the importance of a Theory of Change model, which the IA would benefit from including.

Regulatory Policy Committee

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