Regulatory Policy Committee	**Opinion**	
Impact Assessment (IA)	Alignment of various EU directives with the New Legislative Framework	
Lead Department/Agency	Department for Business, Innovation and Skills	
Stage	Consultation	
IA Number	Not provided	
Origin	European	
Expected date of implementation (and SNR number)	6 April 2016 (SNR11)	
Date submitted to RPC	2 April 2015	
RPC opinion date and reference	30 April 2015	RPC15-BIS-2355
Overall assessment	**AMBER**	

RPC comments

The IA is fit for purpose provided the Department addresses the points set out in this opinion. The IA identifies and describes the impacts of the proposals and includes some illustrative estimates of costs. The Department intends to gather evidence through consultation to enable robust estimates of costs and benefits to be made and to test supporting assumptions.

The IA should clarify how notified bodies' costs will be met. If recovered from companies, this would be a direct cost to business and should be included in the calculation of the equivalent annual net cost to business.

The IA also needs to provide details of gold plating, including any through exercising derogations to retain existing harmonised UK standards that are higher than the EU minimum. The IA will need to explain, at the final stage, whether or not the impact of this places the proposals in scope of One-in, Two-out and reflect the impacts in the equivalent annual net cost to business (EANCB) figure.

Background (extracted from IA)

What is the problem under consideration? Why is government intervention necessary?

The New Legislative Framework (NLF) is a framework of common general principles and rules that aims to make legislation on the Single Market for Goods clearer, more consistent and understandable, and more effective. EU Decision 765/2008 lays down provisions that are intended to be incorporated into future EU product harmonisation legislation and existing product legislation when it is revised or re-cast. Subsequently, in order to bring existing product harmonisation legislation into line with the Decision, an "alignment package" was introduced to align nine existing EU directives to the NLF and would apply to subsequent directives.

What are the policy objectives and the intended effects?

To meet the UK's legal obligation to implement the directives, and to harmonise the provisions of the directives so that their text is consistent for the sectors affected. The aim is to protect consumers better from non-compliant products, make product safety legislation easier to understand and use, and to make it easier to make, distribute and sell products in the EU.

1 Victoria Street, London SW1H 0ET +44 (0)20 7215 1460
regulatoryenquiries@rpc.gsi.gov.uk www.gov.uk/rpc

Proposal

To implement the directives by revoking and replacing the existing legislation. This will allow the UK to meet its legal obligation to implement the amended directives.

Identification of costs and benefits, and the impacts on business, civil society organisations, the public sector and individuals, and reflection of these in the choice of options

The IA explains that existing legislation is complex and inconsistent, with products often being regulated by several legal instruments with different objectives. They, therefore, often use different terminology. The proposals are to implement nine revised EU directives to bring existing product legislation into line with the New Legislative Framework (NLF). The IA explains that legislation is the only realistic option as failure to transpose the new directives would risk infraction.

The IA explains that the proposal is to implement the provisions of the directives through common definitions and responsibilities for manufacturers, importers and distributors of products. The IA identifies and describes the impacts of the proposals and includes some illustrative estimates of costs. The Department intends to gather evidence through consultation to test its estimates and supporting assumptions.

The proposal will have an impact on manufacturers (e.g. product labelling – ensuring they all bear conformity markings), importers (e.g. an increased role in ensuring that only safe products are placed on the market), distributors and consumers as well as notified bodies that assess conformity of products. Notified bodies must inform notifying authorities about negative conformity assessment results.

Many of the changes associated with the proposals will present both costs and benefits. For example, new traceability and labelling requirements and the need to retain documents for 10 years will lead to increased costs for manufacturers and others in the supply chain. The Department anticipates that the overall costs and benefits will be modest given that the proposal is mainly to align existing legislation rather than introduce many new requirements. The additional data collection and storage costs are expected to be marginal given that many firms already keep some records, many of them stored electronically.

The IA explains that the proposals will result in notified bodies incurring costs in seeking accreditation. These costs are expected to be passed on to manufacturers. The IA should clarify how these costs, along with any increase in ongoing costs (e.g. as a result of reinforcement of notification requirements), will be met. If the costs are recovered from companies, this would be a direct cost to business and should be included in the calculation of the EANCB figure.

The introduction of a set of common requirements will make it easier for businesses to understand their obligations as these will not vary between directives. Harmonisation will facilitate movement of goods in the internal market and level the playing field between manufacturers. This might have positive implications for competition. The IA should consider whether the proposal to retain existing higher UK standards undermines this objective.

As presented, the RPC is not able to reconcile the illustrative estimates in the IA's evidence base with the net present value and EANCB figures recorded on the first page of the IA. This should be made clear and the final stage IA should explain the basis of the calculation of these figures in a One-in, Two-out section.

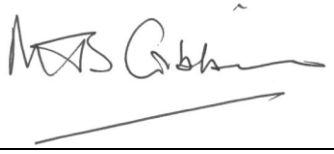
Comments on the robustness of the small & micro-business assessment (SaMBA)

The proposals are European in origin. A SaMBA is therefore not required. However, as the proposal appears to include elements of gold plating, the Department should consider including in the IA, analysis of the impacts of these elements on small and micro-businesses.

Comments on the robustness of the One-in, Two-out (OITO) assessment

The IA indicates that the Department considers the proposals to be out of scope of OITO but doesn't explain why. If this is because the proposals are of European origin, this would appear to be reasonable and consistent with paragraph 1.9.9 ii of the Better Regulation Framework Manual (March 2015). However, this should be made clear in the IA.

The Department acknowledges a degree of gold plating in transposing the directives but does not provide details. Such proposals could be in scope of OITO as per paragraph 1.9.9 ii of the Better Regulation Framework Manual. The Department proposes to exercise derogations available in the directives to retain higher UK standards than the EU minimum. These could be out of scope of OITO in line with past interpretations of paragraph 1.9.9.ii of the Better Regulation Framework Manual and page 7 of OITO FAQs. The final stage IA will need to provide details to enable the RPC to determine whether or not the proposals are in scope of OITO and to be able to validate an EANCB figure.

Signed  **Michael Gibbons,** Chairman