Regulatory Policy Committee	**OPINION**	
Impact Assessment (IA)	Health Protection (Ships and Aircraft) Regulations	
Lead Department/Agency	Department for Health	
Stage	Consultation	
Origin	International	
IA Number	3019	
Date submitted to RPC	05/04/2013	
RPC Opinion date and reference	02/05/2013	RPC13-DH-1701(2)
Overall Assessment	**AMBER**	

The IA is fit for purpose. The consultation should be used to test the assessment that there will be no net costs to business, in particular that the 'IN' relating to the element that goes beyond international requirements will have a zero net cost.

Identification of costs and benefits, and the impacts on small firms, public and third sector organisations, individuals and community groups and reflection of these in the choice of options

The IA has addressed the issues raised in our previous Opinion (28/02/2013), discussing how the proposals governing impacts upon business, specifically relating to familiarisation costs and whether there are costs to compliant businesses. It also now identifies a measure that goes beyond the requirements of the International Health Regulations (IHR), affecting the One-in, Two-Out assessment (see below). The assumptions should now be tested through the consultation. Further details of what should be tested are stated below.

Costs to business. The IA assesses the net costs to business from the proposals to be zero. This is on the basis that any costs would be minimal and that there might be some small gains from the additional clarification in the proposed regulations and the replacement of specific duties by more general requirements. This should be tested during consultation. More specifically, the following should be tested :

- that the introduction of sanctions for non-compliance will not lead to additional costs to businesses in demonstrating compliance;
- the lack of any significant familiarisation and training costs to businesses;
- that the preferred option " imposes fewer requirements on industry" (paragraph 19). Further explanation should be provided to support the assumption;
- that none of the monetised costs also involve a net cost to business, e.g. the cost to individuals from additional quarantine;

Costs to local authorities (paragraph 50) of training their employees on the new regulations are now included in the overall estimates. The robustness of these should also be tested during consultation.

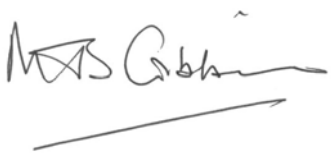
Compliance with International Health Regulations (IHR). The IA says that one of the policy objectives is "to ensure that the UK is compliant with the World Health Organisation's IHR 'all hazards' approach" (paragraph 13). To assist in the

consultation, the IA should, discuss how the proposal meets IHR compliance without going beyond its requirements (except in relation to sanctions for non-compliance).

Additional information. The previous version of the IA included a section 'Information Gathering' (pages 5-6) which showed how pre-consultation was used to inform these initial estimates. This was helpful and it is recommended that it is re-inserted into the IA.

Have the necessary burden reductions required by One-in, Two-out been identified and are they robust?

The IA says the regulations go beyond IHR requirements only by the imposition of sanctions for non-compliance. The IA states: "*On this basis, we consider these regulations to fall within the scope of OITO methodology*…*we consider option 2 to be an IN*" (paragraph 63) but "*since compliance with the regulations is done at zero cost, we consider the net cost to business under option 2 is zero*" (paragraph 64). On the basis of the evidence provided, this appears to be a reasonable assessment and consistent with the Better Regulation Framework Manual (paragraph 2.9.12). However, the consultation will have to be used to strengthen the evidence supporting this assessment (as indicated in the comments above) so that it can be validated at final stage.

Signed  **Michael Gibbons,** Chairman