

13 September 2012

AmCham EU's response to the European Commission Consultation on Smart Regulation

Collecting evidence and monitoring results

1. Smart regulation requires monitoring results and collecting high quality data over time. This is neither easy nor free of costs:

(i) How can the Commission best organise this process?

Involving stakeholders from a very early stage of the legislative process will invariably improve the quality of the data used within the Impact Assessments.

Having quality data is essential and we believe the private sector can help the Commission in getting access to the best and most up-to-date data there is.

Given the complexity of the EU legislative process it should also be mandatory for the Commission to revise its Impact Assessments in view of the finalised legislation, especially if the original proposal is significantly amended by the legislators. We refer to the examples of the RoHS and WEEE recasts, where the legislators' choice to change both Directives' scope is meant to be justified, not assessed, in post legislative impact assessments.

(ii) Do you have concrete suggestions on how to minimise the resulting administrative burdens?

A significant reduction in administrative burden for the Commission could be achieved by having the two legislators contributing to the process of better regulation. The European Parliament has taken important steps in this direction by setting up its own Impact Assessment Directorate. This aims at doing a fitness check of the Commission's Impact Assessments and at evaluating the impact of significant compromise amendments proposed by MEPs.

The Council should also move in this direction.

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A concrete coordination between the institutions will be required.

Evaluation

2. Stakeholder involvement can benefit the quality and focus of evaluation even before this is actually carried out:

(i) Do you have good practice examples of how stakeholders can contribute to the definition of evaluation priorities?

AmCham EU welcomed the Commission's attempt to improve stakeholder contributions to the ex ante evaluation of priorities through the extension of the Consultation period.

It is extremely important to engage stakeholders from a very early stage of the legislative process to encourage them to join in a reflection on important policy questions and to promote shared analysis and thinking.

AmCham EU, however, hopes that the extension of the consultation period is not going to preclude the Commission from sharing draft Impact Assessments with key stakeholders for a check on facts and methodology.

(ii) Do you find the planning of Commission evaluation accessible and useful?

AmCham EU welcomes the Commission's efforts to publish their multiannual Evaluation programme. Our members, however, believe that more can be achieved in informing stakeholders of the legislative timeline.

(iii) How do you usually become aware of planned EU evaluations?

Unfortunately we are not yet at a stage where we become aware of planned EU evaluations in a structured and predictable way. Most of the time it is through informal means.

3. Do you find particular shortcomings in any of the following areas in the Commission evaluation approach and/or practice:

(i) Planning

Stakeholders should be given more information on the timeline of proposed legislations, in particular with regards to those that fall outside the annual work programme and are not accompanied by roadmaps.

(ii) Extent and timing of stakeholder consultation

The timing of stakeholder consultation, now that it has been extended, seems appropriate. We have however noticed a trend whereby the Commission has been publishing more and more crucial consultations during the holiday period. In order to allow membership led organisations to provide the most

detailed and complete response possible, we would encourage the Commission to publish consultations at times when member companies are able to provide concrete examples to corroborate the responses.

(iii) Scope / comprehensiveness

As the amount of EU legislation increases over the years, AmCham EU has noticed a proportional increase in the number of delegated acts passed by the legislators. Many of the decisions taken via delegated acts have significant impacts. We therefore feel that the scope of consultations should also be extended to some crucial delegated acts which could result in substantial economic, environmental and/or social impact on a specific sector or on major interested parties.

Where EU legislation sets a firm deadline for the preparation of delegated acts (as is often the case in financial services regulation, for example, where the European Supervisory Authorities are tasked to produce secondary legislation) sufficient time should be provided for stakeholder consultations and for the preparation of impact assessments.

AmCham EU also feels that, on top of economic, social and environmental impacts, Consultations should also be launched when there is a significant trade impact.

Where appropriate, for example in the field of financial services where there is an extensive international programme of regulation under the auspices of the G20, these impact assessments should consider the impact of the proposal on global regulatory convergence.

In certain circumstances there may be justifiable reasons for the EU to take an approach that differs from that being proposed by international standard-setters or that being taken by regulators in other parts of the world. But the Impact Assessment process should assess the effects of this so that EU legislators, and stakeholders more broadly, are fully informed.

(iv) Assessment of ex post costs

We find that Impact Assessments tend to omit compliance costs from their analysis. This is especially problematic when issues which may impact these compliance costs are left to be addressed by delegated acts.

This was one of our concerns about the discussions surrounding the implementation of the Fuel Quality Directive's Art 7.a. The administrative burden, and costs of associating different Green house gas emission (GHG) values

to different types of crude oil could be enormous, and were never analysed by the Commission. We welcome the recent decision to run an impact assessment on the implementation of article 7.a, but once again, stakeholders are not involved in these discussions, and do not know if these questions will even be addressed in the upcoming impact assessment.

(v) Assessment of ex post benefits

A systematic post-implementation monitoring and evaluation of new, or amended, legislation should be developed by the Commission in order to establish the actual impact of legislation.

The Commission, Council and European Parliament should commit to discuss these ex post assessments.

We also find that some impact assessment's cost benefit analysis will focus on social, economic or environmental costs, without analysing whether the benefits in one field, may not lead to disproportionate costs in others.

We find this is especially the case for Impact Assessment on EU environmental policy where the environmental benefits exist, but can be difficult to quantify, and the associated economic costs can be enormous but will not be assessed thoroughly.

An example of this is the Water Framework Directive (WFD), which identifies priority hazardous substances for which concentration limits are aimed at the reduction or removal of these substances from surface water. These concentration limits are set out in the Environmental Quality Standards (EQS) Directive. A proposal was made for the inclusion of pharmaceutical substances in the scope, while DG SANCO has only just initiated an investigation into the impact of pharmaceuticals on the environment. The decision to ban chemicals substances for an environmental benefit was taken without regards of the social implications of banning active ingredients in the contraceptive pill.

(vi) Focus on concrete impacts/achievement of objectives

The actual outcome of simplification measures must be evaluated by the Commission and evaluation results should be made public.

(vii) Assessment of stakeholder and/or Member State specific impacts

The best way to assess the impact a new legislations could have on stakeholders is by allowing them to provide the Commission with facts about their industry. It is crucial that

the Commission analyses such facts on the basis of their quality rather than their provenance as we often notice that certain sensitive industries are marginalised from the debate without rationale.

As for assessing Member States specific impacts, it is important that the Commission encourages Member States to carry out systematic impact assessments of new legislations as currently only a quarter of them conduct them. It is also important that Member States should adopt a uniform methodology to assess the impact of new legislations, in order to enable cross-country comparisons.

(viii) Final quality of the evaluation

An interesting example of the evaluation of adopted legislation is what is currently happening with the REACH review. The review has not been published yet, but AmCham EU members have participated in a number of the studies commissioned to assess the implementation of REACH over the past five years.

Whereas we welcome the Commission's initiative to assess the implementation of this important legislation, **we worry that decisions to legislate may be taken hastily on the basis of input collected before market realities could be clearly assessed and understood at company level.**

REACH is a complex regulation which sets up procedures, some of which are only now starting to take effect. Many of the questions asked in these studies, such as on the cost of complying with REACH, or whether the regulation has had an impact on business operations (ex: phasing out or substitution of substances, relocating operations...) could only be answered by companies on an anecdotal, project by project, basis. It is still too early to see companywide trends and draw conclusions. Using this early input as a justification for legislation could have a negative impact on the REACH regime.

(ix) Extent and transparency of follow up

In order to make the system as transparent as possible, all consultation responses should be made public and the Commission should provide feedback to stakeholders.

For any area of concern, please provide concrete examples as well as practical suggestions on how the Commission could address the underlying issues.

Impact Assessment

- 4. The Commission impact assessment system aims to support well informed policymaking by providing an integrated, transparent**

and accountable analysis of all the significant economic, social and environmental costs and benefits of possible new initiatives. In your view:

(i) Are these the right aims?

AmCham EU has always been very supportive of the Impact Assessment Guidelines and feels that the Commission and its staff should always do their best to follow them. Please refer to answers 3 (iv and v) for more on striking the right balance between economic, social and environmental costs, and making sure that benefits in one field are proportionate to costs in others.

(ii) What can be done to better achieve these aims?

In order to make the process more open and **transparent** the Commission should publish its schedule for conducting impact assessments well in advance providing a detailed calendar of its proceedings. This will allow stakeholders to know when and what kind of information will be required by the Commission.

The Commission should provide feedback on submissions by stakeholders and organise formal as well as informal opportunities to meet with Stakeholders.

The Commission should share draft impact assessments with stakeholders to validate the soundness of the methodological approach and provide facts, analysis and findings

To make the analysis more **integrated** the impact assessment process should be managed by a dedicated project manager who should be able to provide stakeholders with information on the process and be able to serve as interlocutor between stakeholders and the impact assessment team.

The quality and credibility of impact assessments increases if they are substantiated by a sound methodological approach and are science based. For the analysis to be **accountable** it needs to be based on strong factual basis. Impact Assessments should also be conducted without any preconceptions about the resulting legislation. The process should be neutral and should not overlap with political decision-making. To ensure this, stakeholders should be consulted on methodology and facts, not the political desirability of any proposal.

When hiring external consultants to run Impact Assessments, the Commission should encourage the impartiality of these experts. Their assessment should go beyond what Commission objectives may be for an upcoming proposal (see answer 3 (iv and v) on balancing economic, social and environmental costs and benefits). We worry that some experts may target their

analysis to avoid disagreeing with their client. We would welcome guarantees that this is not the case.

Also, given the fact that every impact assessment process may face timing, planning and research difficulties, the Commission should build flexibility into the process to allow changes to the initial planning calendar and to consult stakeholders in this process. The overall quality of the process is paramount. Inconclusive evidence for assessing certain impacts should not lead to inconclusive impact assessment reports but should be a reason to continue research and fact-finding, otherwise the impact assessment cannot properly serve the political decision-making process. The lack of information should not be a reason to leave questions unanswered; there must be a sound basis for legislation.

Impact Assessments on substantive amendments by the European Parliament and Council to Commission proposals should be carried out. Significant improvements have been made in this field by the establishment of the Impact Assessment Unit in the European Parliament and AmCham EU hopes that the Council will also set up its own unit.

- (iii) What use do you make of Commission impact assessment reports?

Impact assessments are extremely important in ensuring evidenced based legislation. This, however, only holds if they use correct data. It is for this reason that our member companies, on receiving the Commission's impact assessment reports, will immediately do a facts check with their own data. As mentioned above, they are often frustrated when there is a mistake with the facts as, given that draft impact assessments are not released, they are unable to do anything about this.

Strategy

5. Do you have other recommendations how the Commission's overall approach to enhancing the quality of EU legislation could be further improved?

AmCham EU believes that all players at the EU level should continue to use the smart regulation principles as guiding lines in their work. The EU institutions should also be key in promoting smart regulation initiatives within all the EU 27 Member States.

An important factor to bear in mind is that part of the administrative burden that businesses face derives from inconsistent national implementation of the requirements of new legislation. The Commission should therefore increase its efforts ensuring its Directives are properly transposed in national legislations without any Gold

Plating which hinders the Single Market and that its Regulations are implemented to their full extent.

CONSULTATION RESPONSE

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate U.S. investment in Europe totaled \$2.2 trillion in 2010 and directly supports more than 4.2 million jobs in Europe.
