

*Comments of the United States Government  
on the  
European Commission’s Public Consultation Document for  
Stakeholder Consultation Guidelines 2014*

*September 30<sup>th</sup>, 2014*

The United States welcomes the opportunity to provide comments on the European Commission’s Public Consultation Document setting out Draft Stakeholder Consultation Guidelines, published on June 30, 2014 (“Proposed Guidelines”) to support its 2002 *Minimum Standards for Consultation of Interested Parties by the Commission* (“Minimum Standards”). As a major economic and political partner of the European Union (EU), the United States has a substantial interest in EU regulatory activities. As we noted over a decade ago, when the United States contributed comments on the EU’s original *Minimum Standards*, we support the Commission’s objective of improving the quality of its regulations by providing clearer guidance for Commission staff on operational stakeholder consultations, including by ensuring that consultations reach those directly affected by a future regulation. The United States, like the European Union, recognizes the need to consult widely and meaningfully with the public to ensure that its regulations are effective, efficient, and fair. Indeed, consultation practices have been an important feature in U.S.-EU dialogues for over a decade, most recently reflected in a set of “best regulatory practices” set forth by the U.S.-EC High Level Regulatory Cooperation Forum in 2011, including that:

“Regulatory measures should be proposed through an open and transparent process that, to the extent feasible, promotes accountability and participation of citizens and stakeholders, with adequate time, opportunity, and tools (including the Internet) for stakeholder input and public comment at appropriate stages of the policy preparation process in advance of their final adoption.”<sup>1</sup>

Drawing upon these dialogues, U.S. experience domestically, and concerns expressed by U.S. stakeholders, we have set out some general observations and specific suggestions below. The comments are keyed to the main issues addressed in the consultation document—the scope of application of the Guidelines, the objective of consultations, how and when the consultations should occur, who should be consulted, and how stakeholder comments should be considered

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<sup>1</sup> High-level Regulatory Cooperation Forum (HLRCF), United States – European Commission, 2011, *Common Understanding on Regulatory Principles and Best Practices*, Transatlantic Economic Council (TEC), 1-2, available at <http://www.whitehouse.gov/sites/default/files/omb/oir/irc/common-understanding-on-regulatory-principles-and-best-practices.pdf>; HLRCF, United States-European Commission, 2002, *Guidelines on Regulatory Cooperation and Transparency*, available at <http://www.whitehouse.gov/sites/default/files/omb/oir/irc/2002-guidelines-on-reg-coop-and-transparency.pdf>.

and reflected. Where relevant, our comments make reference to concerns identified in the Commission's questionnaire.

In short, these comments identify the following ways in which the guidance might give greater direction.

1. Transparent and universal consultation procedures should be employed in principle for all regulations proposed by the Commission, including "secondary" regulations, to the extent they are of general applicability and prospectively prescribe legally enforceable requirements.<sup>2</sup>
2. The objective of consulting the public should be clarified to explicitly include the goals of testing the factual and analytic bases of and rationale supporting the regulation (as well as the policy choices and conclusions laid out in the proposal), and obtaining additional information and ideas, including from outside of familiar sources and concerning any unintended effects or practical problems the draft regulation may present.
3. The Guidelines should aim to provide for a consistently predictable and transparent approach.
4. To limit the case-by-case approach, the Guidelines should establish a meaningful opportunity for any member of the public to provide comments on the draft text of regulatory proposals and any underlying analysis and factual support (e.g., research and data relied upon in developing the proposal). This opportunity should occur at a stage in the regulatory process that is sufficiently advanced for the public to evaluate precisely the substance of what the Commission is proposing, but not too late for Commission staff to consider those inputs and make changes accordingly. This procedure should be completed before the Commission submits a regulation to the Council and Parliament.
5. The Guidelines could clarify that meetings with targeted stakeholders should be complemented by open internet consultations once the draft text and impact assessments are developed, allowing individuals (EU and non-EU alike) to decide for themselves whether to participate in the consultation at that critical stage when possible regulatory approaches and thoughts have evolved and coalesced into specific regulatory text.
6. More specific guidance should be provided with respect to the consideration of comments and the provision of summary reports and written, reasoned feedback.
7. Internal mechanisms should be established to ensure consistent implementation of the *Minimum Standards*.

The comments are provided with a view to facilitating more extensive and substantive participation by, and feedback to the general public (including individuals, public interest organizations, regulated entities and others); enabling greater flow of information, views and

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<sup>2</sup> For purposes of these comments, we refer to all such measures as regulations.

analysis to the Commission; and promoting important refinements in the quality of the proposed regulations and the accompanying impact assessments.

## ***1. Scope***

The current *Minimum Standards* only apply to a limited portion of the Commission’s regulatory activity—primarily “major legislative initiatives” – leaving the majority of Commission regulatory measures, those setting out detailed implementing and operational features (“secondary” regulations), outside their ambit.

Accordingly, the United States welcomes the related announcement in the REFIT Communication issued on June 18, 2014,<sup>3</sup> that the Commission is considering how to improve public consultations on implementing and delegated acts. Ensuring a robust public consultation process for implementing and delegated acts is critical because it is in the details of implementation that the effectiveness and impact of the regulatory activity will become most evident. Improving transparency in these areas would allow EU regulators to benefit from the insights of outside experts and any market participants – whether in Europe or beyond – that would be required to comply with, or might otherwise be affected by, the proposal. For members of the public, including public interest organizations, the implementation details will be important to ensure consistency with regulatory objectives.

Publishing proposed implementing and delegated acts, and soliciting public comment before their further consideration by other institutional bodies, does not necessarily require an extensive “impact assessment,” which often includes the use of outside consultants. Rather, the guidance could direct Commission staff, under normal circumstances to: (1) publish draft texts, along with explanations of the need for a regulation, the rationale for the proposed approach and the data, research and other factual or scientific basis for the proposal (or a summary thereof); and (2) consider and respond to public comments received in a revised draft before submitting a formal proposal to any “comitology” or other political or expert committees for later approval.

Transparent consultation procedures open to any member of the public should be employed in principle, for any delegated and implementing acts that would impose requirements of general applicability and prospective effect, including those that could potentially affect only a particular segment of the general public, or a category or class of similar entities. Rather than resolve the question of whether to consult the public based on a case-by-case determination of a regulation’s “importance” or whether a regulation requires a formal impact assessment, there would be greater consistency and predictability if the Guidelines included a presumption that such a procedure would apply in normal circumstances, with narrow exceptions explicitly laid out.

The current *Minimum Standards* also omit standards development work from their ambit. As part of such work, the Commission sends a mandate to a European Standardization Organization (ESO) after a development and review process with a selected group of stakeholders. The mandate development process is not transparent. Further, the consultation is targeted and, hence,

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<sup>3</sup> *Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook*, COM (2014) 368 final (June 18, 2014), available at [http://ec.europa.eu/smart-regulation/docs/com2014\\_368\\_en.pdf](http://ec.europa.eu/smart-regulation/docs/com2014_368_en.pdf).

does not involve all interested stakeholders. As part of the guidance, it would be useful to specify the steps in this process, including allowing input on the draft mandate from any interested party.

## **2. Purpose, role and effect of consultations**

The broader benefits of transparency in regulatory development have long been championed in the international context, including by the Organisation for Economic Co-operation and Development (OECD), which has noted that,

“Transparency is one of the central pillars of effective regulation, supporting accountability, sustaining confidence in the legal environment, making regulations more secure and accessible, less influenced by special interests, and therefore more open to competition, trade and investment.”<sup>4</sup>

The OECD and World Bank have observed that public consultation can increase the quality of regulatory policies in many ways, including bringing into the discussion the expertise and perspectives of those directly affected by the regulation and by helping regulators balance competing interests and identify and reduce unintended effects and practical problems.<sup>5</sup>

As stated by the Commission over a decade ago when publishing the final *Minimum Standards*:

“[G]ood consultation serves a dual purpose by helping to improve the quality of the policy outcome and at the same time enhancing the involvement of interested parties and the public at large. A further advantage is that transparent and coherent consultation processes run by the Commission not only allow the general public to be more involved, they also give the legislature greater scope for scrutinising the Commission’s activities (e.g. by making available documents summarising the outcome of the consultation process).”<sup>6</sup>

In addition to informing the public, the opportunity to comment can help the policymaker by allowing the public to critique and improve the analytic basis for a proposal, challenging the regulatory agency’s interpretation of data and research, analytical assumptions and methodologies, factual findings, policy judgments, and assessments of the impact of a proposal, and providing supplementary and/or alternative data and research. The public can further help the policymaker by suggesting specific changes to the proposal, as well as offering alternative approaches to addressing the problem. Another function is to obtain input on specific questions and requests for comments from the Commission, concerning particular aspects of the proposal.

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<sup>4</sup> OECD, 2011, *Regulatory Policy and Governance: Supporting Economic Growth and Serving the Public Interest*, 119, available at <http://www.oecd.org/gov/regulatory-policy/regulatorypolicyandgovernancesupportingeconomicgrowthandservingthepublicinterest.htm>.

<sup>5</sup> OECD, 2011, *Policy Framework For Investment User’s Toolkit, Chapter 10 – Public Governance*, 17, available at <http://www.oecd.org/investment/toolkit/policyareas/publicgovernance/41890394.pdf>; World Bank: International Finance Corporation (IFC), 2010, *Better Regulation for Growth: Regulatory Governance in Developing Countries*, 23, available at <http://apps.americanbar.org/intlaw/ilrc/Regulatory%20Governance%20in%20Developing%20Countries.pdf>.

<sup>6</sup> *Towards a Reinforced Culture of Consultation and Dialogue – General Principles and Minimum Standards for Consultation of Interested Parties by the Commission [Minimum Standards]*, 5, COM (2002) 704 final, (Dec. 11 2002), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:en:PDF>.

As envisaged in the *Minimum Standards*, when opportunity to comment is bolstered by accountability mechanisms, including written, reasoned “feedback,” the administrative record can provide scope for subsequent consideration and deeper understanding by other branches of government, as well as the general public.

As outlined further below, consultations should be structured to ensure maximum opportunity to elicit such public input. Accordingly, in many parliamentary systems, as well as in the United States, an opportunity for written comment is typically provided after what is believed to be the best option has been tentatively selected and distilled into proposed regulatory text. The concrete detail of the text enables members of the public to sharpen and focus their views and their selection and use of supporting arguments, studies and data.

Against this backdrop, several statements in the Guidelines seem to communicate mixed messages about the purpose of a public consultation, and even appear to unduly narrow the definition and purpose of consultations to “enhancing the involvement of interested parties” at the expense of the *Minimum Standards*’ other and equally important stated purpose, improving the quality of the policy.

- In section 1.1, the Proposed Guidelines state that consultation “is the process which the Commission collects “opinions and views from citizens and stakeholders....” which “needs to be distinguished from data collection and collection of expertise. The collection of expertise is largely done through expert groups...”<sup>7</sup>
- Similarly, the Guidelines admonish that, “While stakeholder consultation may generate illustrative examples or data, its main objective remains to give stakeholders the possibility to express their views.”<sup>8</sup>
- Section 1.6 suggests that consultations could be differently structured based on “the difference between collecting views or opinions (subjective) and collecting evidence, data or facts (objective).”<sup>9</sup>

Section 1.2 proffers a further reason for consulting: “Consultation of external parties increases the legitimacy and hence the quality and credibility of Commission proposals.”<sup>10</sup> It also notes the key opportunity to collect even contrary external views. It does not explain precisely how. Indeed, by emphasizing the Commission’s goal as “seeking a comprehensive overview of differing interests,”<sup>11</sup> it misses an opportunity to underscore the importance of specific information or questions that may test and improve the Commission’s proposals. While consultations certainly allow the expression of public views and opinions, the public’s opportunity to respond to all aspects of a proposal by noting advantages or flaws in the regulatory authorities’ assumptions, conclusions and tentative approach or presenting new

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<sup>7</sup> *Draft Stakeholder Consultation Guidelines 2014: Public Consultation Document [Proposed Guidelines]*, 4 (emphasis added), available at [http://ec.europa.eu/smart-regulation/impact/docs/scgl\\_pc\\_questionnaire\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/docs/scgl_pc_questionnaire_en.pdf).

<sup>8</sup> *Id.*

<sup>9</sup> *Id.* at 8.

<sup>10</sup> *Id.* at 4.

<sup>11</sup> *Id.*

argument and/or additional evidence is critical. It helps to both (1) ensure that “decisions are based on the best available information” and (2) “increas[e]the . . . credibility” of the proposal by demonstrating the subsequent reasoned consideration of additional information and alternative perspectives in the decision-making process.

The advisability of seeking supplementary expertise, or bringing the consultation documents to the attention of particular audiences (in “expert” groups), does not reduce the importance of structuring consultations to obtain better information and test underlying assumptions and conclusions. This would improve the quality of the policy outcome, separate and apart from allowing “the general public” to be involved.

Accordingly, we suggest that the introductory sections of the Guidelines be clarified to underscore the key role of consultations in testing the substantive aspects of a proposal, (e.g., the effectiveness of the proposal in achieving regulatory objectives) and obtaining new or additional evidence, whether objective or subjective, whatever the source, that could improve the quality of the regulation and supporting analysis. A clarification of these objectives in the initial pages of the Guidelines and elsewhere could help ensure that the consultation is structured to allow the public to receive sufficient and timely information in order to play this key role and provide useful information and views in return.

### ***3. The Value of a Consistently Predictable, Transparent Approach***

While the Proposed Guidelines helpfully provide much greater detail than the *Minimum Standards*, they largely appear to still leave decisions of when, how and whom to consult to the discretion of Commission staff, “on a case-by-case basis in line with [the Commission’s] right of initiative.”<sup>12</sup> Numerous consultation “tools” are listed, but for each regulation, the regulator appears free to determine the nature and scope of the consultations. Beyond the general internet outreach performed for an impact assessment early in the process, there is no operational direction to ensure a minimum guarantee of a meaningful consultation that will reach a maximum number of potentially interested parties with relevant views and information to contribute. The absence of such direction means that there is no predictable process that outside stakeholders can rely on to know precisely how and when they could expect to participate meaningfully in the Commission’s regulatory development process.<sup>13</sup>

The absence of such a “minimum standard” not only potentially impedes fulfillment of the overall objective of improving regulatory quality, but also risks dampening the engagement of interested individuals and entities outside the EU. In effect, it would require any interested entity, for every new proposal, to devote time and resources to engage directly with the

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<sup>12</sup> *Id.* § 1.3, at 5. It is unclear whether the case-by-case approach is retained with the objective of preserving maximal executive discretion, but such discretion is in any event not curtailed by particular modes of consultation; rather stakeholder consultations only help regulatory authorities in the executive branch—together with other executive departments—determine the best regulatory approach when initiating regulations. The Guidelines underscore that “the relevance of [the 10 step process] will vary on a case-by-case basis depending on the consultation’s objectives.” *Id.* § 1.5, at 6.

<sup>13</sup> *Id.* § 1.4, at 5.

responsible office to determine how consultations will be structured and how best to engage in the process.

In Questions 2 and 3, the Proposed Guidelines raise concerns about “disappointingly low” rates of participation, and affirm the Commission’s objective, to “engage or enable more stakeholders to take part,” “reach and engage underrepresented groups of stakeholders” and “identi[fy]... the right target audiences.”<sup>14</sup> Such shortcomings can be overcome, and stakeholders are more likely to participate and meaningfully engage in government-sponsored consultations, if they have access to all the relevant detailed information and analysis on the internet, at a single point in time when the outcome can be influenced, and in a manner in which they can expect that submissions are fully considered.

If the Guidelines could provide for at least one clear procedure of this nature that will be consistently employed, with enough early notice to the public of this opportunity to engage meaningfully, it would not only allow all interested stakeholders, regardless of domicile, to contribute, but also reduce costs associated with participating in regulatory development – an aspect that is particularly significant for individuals, small- and medium-sized enterprises and new entrants. When such a “safety net” consultation approach is consistently made available to the public, the public at large can share some responsibility to more closely follow those issues of interest and contribute information in a timely manner. As noted in a variety of international contexts, “[W]ithout some kind of standardization and consistency, it is very difficult for stakeholders to understand when and how to participate in the system. This is particularly true for outsiders such as potential investors and foreign trading partners.”<sup>15</sup>

#### ***4. Content and timing of a consultation document***

**Clear consultation tool.** The objective laid out in Minimum Standard A (reprinted on page 6 of the Proposed Guidelines) is: “Consultation documents are clear, concise and include all necessary information.”<sup>16</sup> The Guidelines also state that “Consultation . . . can take various forms and can be implemented through different consultation methods (open, public, targeted etc.) and tools (documents, questionnaires, surveys, hearings, etc.), the most important of which are covered by these Guidelines.”<sup>17</sup> The Guidelines also recommend that in preparing consultation webpages, “Information to facilitate and encourage stakeholder input should be included,”<sup>18</sup> but leaves up for further interpretation what information should be shared with the public. Similarly, the “Overview of consultation tools” in Annex 1 references “consultation questionnaires” and “consultation documents,” as does the description of the internet procedure to reach the general public, but there is no explicit direction in the Guidelines on their minimum content. Further direction would seem advisable; in 2012, the Commission’s staff paper detailing the review of

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<sup>14</sup> *Id.* at 2.

<sup>15</sup> APEC, 2011, *Good Regulatory Practices in APEC Member Economies – Baseline Study*, 30, available at [http://publications.apec.org/publication-detail.php?pub\\_id=1323](http://publications.apec.org/publication-detail.php?pub_id=1323); see World Bank 2010, *supra* at 10-11.

<sup>16</sup> *Proposed Guidelines, supra* at 6; *Minimum Standards, supra* at 19.

<sup>17</sup> *Proposed Guidelines, supra* § 1.1, at 4.

<sup>18</sup> *Id.* § 1.7.1, at 14.

the Commission's Consultation Policy also noted concerns that, under current practice, consultation documents "were not always comprehensive or sufficiently clear."<sup>19</sup>

The Proposed Guidelines include a general policy recommendation to provide "sufficient information and ideas on which the Commission services want to consult in order to facilitate meaningful stakeholder input,"<sup>20</sup> but do not elaborate on the kinds of information that would facilitate such input, or suggest a template for different stages or contexts. The Guidelines recognize that "[i]n some cases, multiple consultations at different stages of the decision process can be envisaged,"<sup>21</sup> and footnote 21 further explains that this could entail, "[a]llowing, e.g., for an early first consultation on the problem definition, subsidiarity analysis and policy options, and a later second one on estimated impacts of policy options and/or on policy recommendations."<sup>22</sup> Recognizing the different needs of the early, "stage 1," consultation (refining the problem, exploring options) from those of the later, "stage 2," consultation is perhaps key to identifying the appropriate consultation tool.

**Documents appropriate for different stages.** Consistent with such a "two-stage" approach, further guidance on the appropriate consultation documents at each specific stage should be provided, as the content of the consultation document needed "to facilitate meaningful stakeholder input" is very much linked to the stage at which it is disseminated. Guidance for the second consultation on estimated impacts of policy options and/or policy recommendations would be particularly useful, given that the current Commission practice appears largely to consult the broader public only in the first stage of problem definition and overview of available options. Consistent with footnote 21 of the Proposed Guidelines, the OECD has observed, "in designing regulation governments need to be aware of the incidence of regulatory costs on businesses and citizens and of disproportionate impacts on small to medium-sized enterprises and micro businesses."<sup>23</sup>

The Guidelines do not proffer any particular way for informing such awareness; the estimated impacts of policy options or recommendations are rarely published for review and comment by the public in order to be considered in developing the final Commission proposal to the Council and Parliament.<sup>24</sup> Given that the Proposed Guidelines recognize that meetings with groups (whether through expert groups or broader conference formats) are subject to "selection biases," risk perceptions of "privileged access," are "insufficient from a more general consultation perspective" and "should only be used to complement a wider consultation process,"<sup>25</sup>

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<sup>19</sup> *Review of the Commission Consultation Policy: Accompanying the Document [2012 Consultation Policy]*, 13, SWD (2012) 422 final, (Dec. 12, 2012), available at [http://ec.europa.eu/smart-regulation/better\\_regulation/documents/document\\_travail\\_service\\_part1\\_en.pdf](http://ec.europa.eu/smart-regulation/better_regulation/documents/document_travail_service_part1_en.pdf).

<sup>20</sup> *Proposed Guidelines, supra* § 1.6.3, at 13.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.* Footnote 21.

<sup>23</sup> OECD, 2012, *Recommendation of the Council on Regulatory Policy and Governance*, 24, available at <http://www.oecd.org/governance/regulatory-policy/49990817.pdf>.

<sup>24</sup> This lack of clarity in consultation documents can be problematic because, the less specificity that is provided during the public consultation, the more iterative and time consuming the process becomes for stakeholders because of need to engage DGs for additional information. This can lead to a feeling of "over-consultation."

<sup>25</sup> "Disadvantages" cited on pages 26-29.

operational elements of this wider transparent open consultation process should be set out explicitly for accomplishing the objectives of this key “second stage” of regulatory development.

**“Consultation stage” publication of the text and impact assessment.** The need for further involving stakeholders “before the decision of the Commission” and providing them with more advanced consultation documents was also highlighted in the “Common Position Paper of the five European independent advisory boards for cutting red tape and better regulation” submitted on September 21, 2012 during the Commission’s review of the operation of its consultation practices (“Common Position Paper”). The paper suggested involving stakeholders “when the working level preparation of the draft legislative proposal and of the impact assessments has been finalized,” and included the following recommendation:

“The Commission should produce ‘consultation stage’ impact assessments, i.e. draft impact assessments with a preliminary assessment of the expected costs, which should be published ...along with the legislative proposals in the consultation process. This would systematically allow consultees to comment on the evidence base, serious alternative options and assumed costs and benefits and to allow the final impact assessment to be robust.”<sup>26</sup>

The recommendation to publish working level-approved text and impact assessment is consistent with U.S. experience and observation: a commitment to broad-based consultation not only requires timely solicitation of input, but is critically dependent on the extent and quality of information submitted for public scrutiny. In order to obtain valuable reactions and key information from the public, a consultation document must be both sufficiently detailed and advanced to enable members of the public to ground their comments on specific solutions (rather than on broad policy options).

**Similar models.** Within the EU, the Technical Regulation Information System (TRIS), appears to provide a similar approach, in which Member State ministries seeking to prepare or amend a technical regulation must post a draft text on the internet, allowing the Commission, other Member States and any stakeholders to review it--at a stage when substantive amendments can still be made--to ensure the measure would not impede the free flow of goods within the EU Single Market. The ministries of many OECD members with parliamentary systems, including EU Member States, also regularly distribute a draft text of proposed legislation, increasingly on the internet, for stakeholder review and comment before they submit final, potentially revised, proposed legislation to their respective legislatures.

In the context of Federal rulemaking in the United States, pursuant to the Administrative Procedure Act (1946), agencies usually request public comment on the text of a proposed rule and any underlying analysis before they proceed to final decisions. In addition, an assessment of the regulatory impacts of the proposed rule, as applicable, are made available for public comment. The materials for public comment are available on the internet. This public comment

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<sup>26</sup> Adviescollege toetsing regeldruk (ACTAL, the Netherlands); Nationaler Normenkontrollrat (NKR, Germany); Regelradet (Sweden); Regulatory Impact Assessment Board (RIAB, Czech Republic) and Regulatory Policy Committee (RPC, United Kingdom), 2012, *Common Position Paper of the Five European Independent Advisory Boards for Cutting Red Tape and Better Regulation*, 4, available at [http://ec.europa.eu/smart-regulation/consultation\\_2012/docs/public\\_authority/common\\_position\\_paper\\_en.pdf](http://ec.europa.eu/smart-regulation/consultation_2012/docs/public_authority/common_position_paper_en.pdf).

process not only enables agency regulations and underlying assumptions to be tested through public scrutiny, but also ensures equitable treatment of all potentially affected parties by allowing anyone to provide evidence in the administrative “public record” to support their views or objections to the rule.<sup>27</sup> This opportunity effectively levels the playing field for those who operate far from the nation’s capital, particularly ordinary citizens, small- and medium-sized enterprises (SMEs) and foreign companies. Absent such procedures, such actors would be unlikely to obtain information about pending regulations, unless they could afford to hire consultants to do so. Moreover, in a final rule, the agency explains how the substantive information presented in comments was taken into account. The administrative record—which is publically available and including the text of the final regulation, supporting analyses, public comments and agency responses to public comments—is used by the U.S. judicial branch in the event there is a legal challenge to a final rule brought by a member of the public.

**A “first stage” consultation does not compensate for the absence of a later opportunity.** At present, to the extent the *Minimum Standards* apply to Commission-developed regulations, the information published or made available by the particular authorities at the time of the request is during the “first stage” of problem definition. This information does not tend to be sufficiently detailed to elicit specific public comments that would help authorities fully appreciate the eventual regulation’s potential implications. The Commission’s current practice of publishing “Green Papers” and other descriptive communications has been informative and can elicit general reactions in this “first stage” of problem definition and “subsidiarity analysis;” an opportunity for written comment would be most advantageously timed, however, if it were provided after what is believed to be the best option has been tentatively selected.

If only one opportunity to comment is provided during policy development, and if it comes before the narrowing down of options actively considered to a single best option (which would include tentative judgments about the coverage and level of stringency of the option), commenters would face a difficult choice about the most effective strategy in preparing their comments. For instance, they may decide to guess which option might ultimately be selected in the future and guess what supporting data, analyses, and policy arguments they might give for favoring that option. They could then focus their available resources on analyzing and commenting in detail on that one option, but in doing so they would risk having focused on the wrong option. Alternatively, they may decide to spread their resources out over multiple possible options and provide general comments on each.

If the Commission were to provide an opportunity to comment at the stage of decision-making when it has made tentative decisions, it would enable interested parties and the public at large to focus their comments to the best effect. The need for detailed information at this stage is especially important for those that do not have the resources to follow-up directly with institutions in Brussels for more information or clarity.

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<sup>27</sup> The public comment process is further enhanced by providing the public with the name and contact information of an individual official who can address questions.

**Clarifications regarding “subjective” information.** We would also recommend that the Guidelines provide more precise guidance on the potential value of both “collecting views or opinions (subjective) and collecting evidence, data, or facts (objective).”<sup>28</sup> A public consultation will often supply regulatory authorities with both objective and subjective (anecdotal) data, with the goal of providing the regulatory authority with the best information available. We agree that actual evidence or data submitted by commenters is extremely valuable in further deliberations on the ultimate policy outcome. But the value of the information presented by the comment should not be solely determined by whether the information is characterized as subjective or objective. For example, information obtained from a facility regarding that facility’s operation or experience could be considered “subjective,” but it remains extremely valuable, as that entity may be the only reliable source of such information. It may be more useful for the Guidelines to distinguish between those comments that raise substantive issues or concerns, and those that merely express a policy preference, without supporting information.

**Broad-based consultations do not preclude supplementary means of consulting.** A robust public consultation process during the later stage, involving publication of the tentative regulation and draft impact assessment, for example, does not preclude other forms of stakeholder outreach, such as early outreach before the content of a measure is fully defined or the full consideration of alternatives has begun. Nor would it preclude different types of outreach like public meetings or web-based consultations, or even targeted outreach to specific stakeholders that may be reached more directly through such mechanisms. Instead, notification of proposed measures with an opportunity to comment at a point when such comments may still be taken into account ensures that stakeholders inside and outside the EU whose interests are unknown to regulators can learn of forthcoming regulations and provide their input. It would also address at least one of the concerns reflected in the current Consultation Document, that “consultations do not always ask the right questions at the right time and sometimes fail to reach those directly affected.”<sup>29</sup> Moreover, the “disadvantage” cited in the Guidelines, that open consultations are “resource intensive” and “time intensive” does not correspond to U.S. experience. As recently observed in the context of the Asia Pacific Economic Cooperation forum, internet-based consultation is catching on precisely because it is an efficient methodology for obtaining public input.

**Questionnaires inadvisable.** Similarly, the Proposed Guidelines cite favorably the practice of employing questionnaires during internet consultations, but more specific guidance concerning the use of questionnaires as a means of eliciting public comment would seem to merit consideration. Page 23 sets out an extensive set of circumstances in which questionnaires might be used, and the many “disadvantages” of such an approach, but additional caution should be signaled. In and of themselves, as a consultation tool, questionnaires are unlikely to generate information that is useful or relevant in a rulemaking. For questionnaire responses to have utility and be relevant to a regulation, they would need to describe the population affected by the regulation. However, to produce such generalizable information, the regulatory authority would need a representative sample—not an open-ended solicitation for public comments—of the relevant population in order to accurately describe it and generalize the questionnaire results to

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<sup>28</sup> *Proposed Guidelines, supra* §1.6, at 8.

<sup>29</sup> *Id.* at 1.

all of the entities that would be affected by the regulation. Moreover, as noted on page 24, and as heard from stakeholders during the 2012 Review of the Commission Consultation Policy, questionnaires are of limited value in eliciting responses and can even skew results; respondents complained of “insufficient predefined character spaces for answers, the use of leading questions and simple yes/no alternatives which do not allow stakeholders to express their views.”<sup>30</sup> On the basis of such observations, it would make sense for the Guidelines to make clear that questionnaires are not in and of themselves an appropriate means of consulting, and that specific questions included with the consultation document should be framed as optional, not restricting the scope of public inputs. Guidance could require that the consultation document provide ways to submit comments and views on all aspects of the document.

**The opportunity to comment should be unfettered.** In the same spirit of encouraging public engagement and with the objective of “opening up the policy-making process to get more people and organizations involved in shaping and delivering EU policy,”<sup>31</sup> it is unclear why the Guidelines condition submission of public comments on registration in the Transparency Register. This condition appears to unduly conflate the goal of transparency concerning government officials’ meetings with special interests (lobbying), with the objective of allowing non-government officials to contribute openly to a public consultation along with all other stakeholders. Requirements that appear onerous can in themselves be a disincentive to participate in a public engagement process, leading to a low response rate. In the United States, lobbying registration is not required to submit written or oral views to the Executive Branch; rather, any oral or written opinions submitted during a rulemaking become part of a public record, and any final rule must stem from that record.<sup>32</sup> In order to submit public comments on regulations.gov, the U.S. central website for Federal agencies, only an internet connection is required; other information is optional.

## 5. *Who is consulted and how*

The United States generally shares the objective of the Commission’s “basic rule,” to “consult broadly and transparently among stakeholders who might be concerned by the initiative, seeking the whole spectrum of views in order to avoid capture by specific constituencies.”<sup>33</sup> However, consultation steps 2 and 3, setting out extensive methodologies for “stakeholder mapping” and selecting consultation methods for “relevant” stakeholders based on pre-established criteria, appear<sup>34</sup> to rely too heavily on individual Commission staff to identify the relevant target groups and avoid excluding those potentially affected.<sup>35</sup> To address that concern, we suggest that the

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<sup>30</sup> *2012 Consultation Policy, supra* at 13.

<sup>31</sup> *Commission White Paper on European Governance*, 2, COM (2001) 482 final, (July 25, 2001), available at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52001DC0428&from=EN> .

<sup>32</sup> U.S. executive branch employees are also subject to strict prohibitions against accepting a meal or any other unsolicited gift with a market value of more than \$20 per occasion and \$50 aggregate in a calendar year from a single source. 5 C.F.R. 2635.204.

<sup>33</sup> *Proposed Guidelines, supra* at 9.

<sup>34</sup> *Id.* §§ 1.6.2-1.6.3, at 11.

<sup>35</sup> The Guidelines define “relevant parties” as those “affected by the policy, those who will be involved in the implementation of the policy, those that have a stated interest in the policy, and those that have knowledge and expertise about the issue as well as those that support or can block solutions related to the issue. *Id.* §1.6.2(3), at 9.

Commission simply let interested parties identify themselves, instead of the Commission selecting the “relevant” parties or “target groups” to consult.

As set out above, giving public access to detailed information, such as draft proposals and supporting analytical documentation during the “second stage” of regulatory development, would allow for a party’s informed determination of whether or not to engage. An open, public comment procedure consistently applied during this more advanced stage of regulatory development would significantly mitigate the risk of missing “relevant parties” because it provides for a minimum level of engagement that is equally applicable to all. Providing an open consultation process during this period also allows participants to submit more candid views, without fear of not being selected to participate in groups or meetings that may be assembled in the future. In the U.S. view, a meaningful consultation process requires full transparency and openness to the participation of all interested stakeholders, EU and non-EU alike.

Given the breadth of these potentially interested parties in many cases, it would appear to be quite challenging for a single Directorate-General to be confident that it has identified all “relevant parties” in the European Union, not to mention “stakeholders and citizens outside the European institutions and bodies.”<sup>36</sup> In fact, it is unlikely that internal analysis could identify or reach all new entrants or foreign actors. The risk of excluding “relevant parties” is much higher where the consultation process is based on an internal analysis of which stakeholders should be consulted.

There need not be a choice “between open public or targeted consultations,”<sup>37</sup> if targeted consultations are not treated as a substitute for a meaningful, broad-based consultation process in the later, more advanced stage of regulatory development, when a text of the proposal could be made available for public review. These tools can complement each other. Indeed, in the U.S. experience, agencies tend to use formal advisory groups and less formal means to reach out to stakeholders at the problem definition and scoping stages of regulatory development, while ensuring, through “notice and comment” on the regulatory text later on, that critical evaluation and key technical information are obtained from a much broader universe of the public at large. Contrary to the suggestion that targeted consultations alone produce useful information, U.S. experience is that, given an opportunity to comment on technical files and detailed proposals, stakeholders provide very helpful technical submissions from the public at large. Indeed, it is common practice in U.S. proposals that requests for views, technical or otherwise, on specific aspects of a proposed regulation are specifically sought from commenters.

Over-reliance on meetings with invited stakeholders during the stage at which specific provisions of a future regulation are in play, as largely envisaged on page 22, risks not only excluding those who may be able to identify unintended effects or raise practical problems and concerns, but as noted by the Proposed Guideline “fiches”, there are inherent risks associated with targeted consultations. As noted on pages 27-33 of the Guidelines, limiting consultations to expert groups and similar entities runs the risk of privileged access and complaints from those not involved, as well as concerns about non-representative input. As a substantive matter, reliance

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<sup>36</sup> *Id.* § 1.1, at 4.

<sup>37</sup> *Id.* § 1.6.2, at 12.

on a group of experts or targeted respondents can produce an “echo chamber” effect, in which only the views that a regulator expects to hear are heard, as well as a risk of the “selection bias” also mentioned in the Guidelines.

Opening up the consultation processes is also consistent with international expert opinion over the last decade. In 2009 the OECD noted, “Consultation will be less effective if confined to a selected group.”<sup>38</sup> Additionally, the *2005 APEC-OECD Integrated Checklist* elaborated:

“Public consultation should not be limited to insiders, such as already established businesses, but should be open to all interested parties. Good practice in this area may be encouraged by clear guidance to regulators on how consultations are to be conducted. Wide discretion on who is to be consulted and how on given regulatory proposals may dilute the intended benefits of broad based consultation. In particular, new entrants, SMEs or foreign stakeholders may be at a disadvantage in informal consultations.”<sup>39</sup>

## **6. Consideration of public comments**

While the draft reinforces the *Minimum Standards*’ requirement that Commission staff acknowledge and provide “adequate feedback” in response to public comments, the *Proposed Guidelines* could be fleshed out to include operational elements to ensure that “feedback” properly reflects a considered decision-making process. In other parliamentary systems, as well as in the United States, posting all public comments (subject to protection of confidential information) promptly, considering and providing a written discussion in response to each substantive issue raised in comments (including changes made as a result of comments with which authorities agreed) are key to demonstrating to members of the public that their opportunity to comment is truly meaningful. Regulatory authorities demonstrating their willingness to listen, grapple with the issues raised by the comments, provide written, reasoned responses and make changes in their proposals tend to assure commenters that they are being heard, and that making the effort to participate in the regulatory system is productive and worthwhile; this in turn encourages participation. The Guidelines could help serve these broader objectives and provide greater transparency with some further practical changes in this regard.

**Publication of public comments.** Rather than wait until two weeks after the consultation is closed,<sup>40</sup> Commission staff should be encouraged to publish public comments as they are received. Some commenters may wish to promote a discussion of particular issues, and publishing their comments earlier will allow others to respond.

**Summary report of public comments.** With respect to the consultations envisaged for “first stage” problem definition (of the kind currently undertaken under the Impact Assessment Guidelines), it is unclear why the Commission’s summaries of these comments, which are expected to “accompany the new initiative through Inter-Service Consultations to adoption,”<sup>41</sup>

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<sup>38</sup> OECD, 2009, *Indicators of Regulatory Management Systems*, 42, available at <http://www.oecd.org/gov/regulatory-policy/44294427.pdf>.

<sup>39</sup> APEC-OECD, 2005, *Integrated Checklist on Regulatory Reform*, 29, available at <http://www.oecd.org/regreform/34989455.pdf>.

<sup>40</sup> *Proposed Guidelines*, *supra* § 1.7.3, at 16.

<sup>41</sup> *Id.* § 1.8.2(1), at 20.

are required to “not exceed 10 pages.”<sup>42</sup> As drafted, the Proposed Guidelines only require a summary report at the “adoption of a proposal or initiative by the Commission. Limiting such a report to ten pages would in some cases appear to put form over substance. The focus of the final summary report should be on the content and the need to communicate results effectively to others, not on its length. Specific direction could perhaps be usefully added to the Guidelines to require the summary report to reflect all significant issues or concerns presented in submissions to the Commission on a proposal or issue. The Guidelines helpfully specify that the summary should include all inputs received: not just those submitted through the web-based open consultation but also through other consultation activities.<sup>43</sup> To be useful, this could easily require that the regulatory authority prepare summaries that are longer than 10 pages in length.

**Consideration of public comments.** The Guidelines explicitly recognize that “generally responses to consultations are not statistically representative of the target population.”<sup>44</sup> They might be further clarified, however, to avoid the potential for Commission’s staff to characterize some submissions as more “representative”<sup>45</sup> than others when “feeding the results into policy preparation.” In analyzing the comments, Commission staff could be directed more explicitly to focus on the merits of the substance of the public submissions and not the source, number, or groupings of stakeholders. The Guidelines relay a mixed message in placing at a premium inputs provided by larger groups, companies, or associations because they appear to recommend categorizing submissions by stakeholder category.<sup>46</sup> The information and concerns submitted by individuals, small- and medium-sized enterprises, new market entrants, and companies or other interests that are not directly members of EU associations may get lost in this process. Greater emphasis on substance of the submissions does not minimize the utility of being aware of the stakeholder groups and their views, but rulemaking should not be considered akin to a referendum.

**Feedback on how contributions were considered.** The United States welcomes the Guidelines’ specific recommendations on how to publish reactions (“feedback”) to commenters on whether-- and if so how-- comments were taken into account and why options were chosen. As foreseen in the *Minimum Standards*, providing stakeholders with the regulator’s written, reasoned view on the merits of the substantive issues raised in their comments, and an explanation for significant revisions from the previously published text, is key to securing public confidence in stakeholder consultations. This also functions as an accountability mechanism that demonstrates the value of participation and improves the quality of the regulatory outcome.

Given that one of the stated objectives of feedback is to “make explicit the link between respondents’/participants’ input, impact assessment or any other factor that justifies the options the Commission proposes,”<sup>47</sup> the circulation of examples or a template for how best to provide such feedback can be useful. The Commission has acknowledged concerns about insufficient feedback and follow-up of input, recognizing that “[p]roviding timely and better quality

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<sup>42</sup> *Id.* §1.8.2(2), at 20.

<sup>43</sup> *Id.* § 1.8.2(1), at 20.

<sup>44</sup> *Id.* §1.8.1, at 17.

<sup>45</sup> *Id.* at 18-19.

<sup>46</sup> *Id.* §1.8.1(1), at 17.

<sup>47</sup> *Id.* §1.8.2(2), at 20.

feedback, clearly showing how and to what extent the input to the consultation influences policy shaping, would improve the transparency of the policy-development process and solicit better responses to consultations.”<sup>48</sup> Rather than direct the Commission to provide “general feedback” on “major clusters,”<sup>49</sup> the Guidelines could specify that feedback be focused and specific on particular issues that were raised. Failure to provide meaningful feedback would not only be contrary to the objectives of the *Minimum Standards*, but could lessen participation in future consultations because stakeholders will not be able to understand whether or how their contributions were dealt with, and why Commission staff agreed or disagreed with those contributions.

### **7. Consistent implementation by Commission staff**

One issue not addressed in the Proposed Guidelines is how the Commission will ensure that Directorates-General follow the *Minimum Standards*. This weakness was identified in the staff report for the Review of the Commission Consultation Policy (“existing Commission minimum standards in this area should be better respected.”)<sup>50</sup> The report also stated that the Commission has had an uneven record of publishing individual contributions and summary reports.<sup>51</sup> To address these shortcomings, the Commission should set out procedures for ensuring that regulatory authorities follow the *Minimum Standards*, including considering and responding to public input, and identify the judicial or administrative procedures available to hold an office accountable for its failure to do so.

Effective accountability mechanisms would provide Commission staff with an incentive to demonstrate that they have adhered to those standards. If procedures do not currently exist, some form of recourse could be explicitly established for stakeholders who believe their right to be consulted has not been upheld. For example, if a party considers that a particular office has not offered the opportunity to comment on a regulation or provided “reasoned feedback” on relevant issues raised in public comments, they could be provided the opportunity to lodge a complaint with a central authority of some kind and seek redress. Internal procedures should also ensure that no regulatory proposal goes forward without an adequate explanatory memorandum.

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<sup>48</sup> 2012 Consultation Policy, *supra* at 16.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> The staff report found that in 2010, the Commission conducted a total of 97 consultations but did not publish individual contributions in 36 of those consultations or summary reports in 47 of the consultations. In 2011, the Commission administered 130 consultations, yet failed to publish individual contributions in 46 instances and summary reports in 53 of the consultations. *Id.* at Figure 6.