Participation in European agencies: Keeping promises in institutional practice
Pernus, S.

Citation for published version (APA):
Chapter 7: Public Consultations

So far, we have investigated the question of the fulfilment of the promises of participation within the internal structure of the agencies. The aim of the present chapter however, is to depict another form of participation, namely the agencies’ externally oriented consultation regimes. Indeed, public consultations are a topic in their own right, they follow a different logic from the internal participation in the sense that they provide an opportunity for those situated outside the agency structure – either the public in general or interested parties – to be involved in the exercise of the agencies’ rulemaking tasks and to influence the process by means of their input. It is understood that the agencies’ consultation regimes have been put in place in order to accomplish a spectrum of promises, ranging from promoting more informed and better outcomes in respect of agencies’ rulemaking, ensuring inclusiveness of, and responsiveness to the regulated sectors, fostering compliance and implementation, and enhancing the transparency of agencies’ operation, enabling monitoring and building trust in the agencies’ rulemaking. In the sections below, whether the promises of public consultations initiated by the EASA, the EBA, the EFSA and the EMA are accomplished will be analysed in terms of access and the quality of deliberation.

7.1 Public Consultations in European Agencies: A Participatory Regime in Its Own Right

Public consultations, like structures of internal participation, are defined as formalised interactions between the agencies and non-institutional stakeholders, which are intended to fulfil certain promises. Such interactions are shaped by a set of rules and practices determining access to agencies’ rulemaking activities, as well as the overall quality of deliberation. However, in comparison to the agencies’ internal participatory structures, which offer access to organised interests or representatives thereof, public consultations are understood as a relationship between the agencies and a wider audience, comprising both organised and non-organised interests. In this regard, European agencies are expected to be less selective and more “open to whoever wishes to have a say in the matter at issue.”

A number of agencies’ founding regulations envisage public consultations. However, as previously observed by Craig, such agencies’ constituent acts “differ in the extent to which they impose any legal requirements to consult [...]” In fact, the overall context of agencies’ consultations—not only in terms of a general duty to consult, but also in terms of the development of agency practice in this regard—may vary from one case to the next. In general, public consultations are expected to fulfil one or more of the following promises: (i) assist in the improvement of the quality of the agencies’ rulemaking, (ii) enhance both inclusiveness of interested parties or the public at large and the responsiveness of agencies’ outcomes to these constituencies, (iii) promote compliance and implementation, and (iv) advance transparency and enable monitoring.

---

2 See Chapter 2, Section 2.2.
of agencies’ rulemaking activities, and help to build trust in relation to these activities. However, at present there is no common approach to agency consultations that would apply across different cases and guide the achievement of the aims sought through mechanisms of consultation. In particular, there is no policy that would resemble the general principles and minimum standards underpinning the consultation relationship between the European Commission and interested parties. It is true that the Commission approach to consultations has been introduced in a “different reality”, in particular as it applies to policy initiatives that are subject to an extended impact assessment. Nevertheless, it is assumed that in essence, the principles and standards introduced by the Commission could and should equally guide consultations conducted by the agencies with regard to their rulemaking activities if they intend to fulfil one or more of the central promises specified above. In order to ascertain to what extent this is the case, we need to look at the agencies’ consultation regimes. Prior to beginning the analysis of the selected cases however, the European Commission’s approach to consultations should be considered briefly as it will serve as a normative benchmark for the assessment of the agencies’ consultation arrangements.

So far, the 2002 Commission Communication has been the most explicit attempt to define the principles and standards for consultation of interested parties. The general principles of Commission consultations echo those highlighted in the Commission White Paper on European Governance: participation, openness, accountability, effectiveness, and coherence. First, the principle of participation is defined as the Commission’s commitment to an “inclusive approach when developing and implementing EU policies, which means consulting as widely as possible on major policy initiatives.” Additionally, in 2015 the Commission introduced a new Better Regulation Agenda, in which it pledged to consult, for the very first time, as a matter of general policy, on draft delegated and implementing acts with potentially significant impact. This is a major change in the approach to consultations, considering that it broadened “the scope of application of minimum standards” beyond “mayor policy initiatives” and legislative acts. However, such Commission consultations may be omitted in the cases when “extensive consultation has already taken place during the preparation of the act (such as that undertaken

---


6 The scope of application of the Commission’s minimum standards on consultations has since been expanded. See below.


by an EU Agency).”

At this point it is still too early to interpret what qualifies as “extensive consultation” at agency level; however, in its Better Regulation Guidelines, the Commission indicates that such consultation includes consultations on regulatory technical standards carried out by the EBA. Therefore, it is all the more important to inspect access to, and the actual inclusiveness of, agency consultations, in particular those connected to agency rulemaking that eventually leads to the adoption of binding implementing rules (including the EASA opinions addressed to the Commission and the EBA draft technical standards which are submitted to the Commission for adoption). Second, consultations should also be guided by the principles of openness and accountability, which effectively means that “the processes of administration and policy-making must be visible to the outside world if they are to be understood and have credibility.”

Third, to be effective, consultations need to begin as early as possible, and therefore involve interested parties “at the stage where they can still have an impact [...]”. Finally, the Commission needs to ensure that its consultation processes are coherent and include “mechanisms for feedback, evaluation and review.”

Moreover, the Commission Communication also laid down minimum standards for consultations. The actual application of such standards is understood to be pivotal for the fulfilment of the promises of consultation. First of all, the Commission established that consultation processes should have a clear content. This entails that “all communications relating to consultation should be clear and concise, and should include all necessary information for the facilitation of responses.” Second, the Commission needs to commit to ensuring that “all relevant parties are given an opportunity to express their opinions.”

Third, in order to raise awareness the consultation documents need to be available on the internet and announced at a “single access point”. Fourth, there should be adequate time allocated to consultations and the minimum consultation period needs to amount to at least twelve weeks. Finally, there needs to be a proper acknowledgement of the contributions received (e.g. via an individual or a collective response to consultation) - the results of open public consultations must be published on the internet and an adequate feedback, explaining how the results were taken into account in the proposal should be provided.

The Commission approach to public consultations has been recognised as an “important step in fostering consultation within the EU”, and has been subject of inquiry on numerous occasions.

---

15 Ibid.
16 Ibid.
18 Ibid.
19 Ibid, p. 20.
20 Ibid, p. 21; In 2012, the minimum period for the reception of responses was extended from the initial eight weeks to twelve weeks. See, European Commission (2012), p. 8. However, according to the Commission’s better regulation agenda, the planned timelines for consultations on draft delegated and implementing acts will be considerably shorter: “[D]elegated acts will be open to the public at large on the Commission’s website for four weeks [...]. Important implementing acts [...] will also be made public for four weeks [...]. See, European Commission (2015b), p. 5.
in both political science and legal scholarship literature. Nonetheless, the extent to which any general principles and minimum standards of consultation akin to the ones listed above would apply in the case of European agencies, and their relevance for accomplishing the promises of agencies’ consultations, are questions that so far have not been examined. Therefore, when considering the consultation regimes of the four agencies under scrutiny – the EASA, the EBA, the EFSA and the EMA – the Commission principles and standards will be used as a normative yardstick to assess the fulfilment of the promises of agencies’ consultation. The table below provides an overview of the consultation principles and standards and their assumed relevance for either the question of access or the overall quality of deliberation.

| Table 7.1 Overview of the Consultation Principles and Standards and their Relevance |
|---------------------------------|---------------------------------|
| **Access**                      | **Quality of Deliberation**     |
| **General Principles**          |                                 |
| - Participation (ensuring wide participation). | - Coherence (consistency and transparency of consultation processes). |
| - Openness and accountability.  |                                 |
| - Effectiveness.                |                                 |
| **Minimum Standards**           |                                 |
| - Consultation of all relevant parties. | - Clear content of the consultation process. |
|                                 | - Publication.                   |
|                                 | - Time limits for participation. |
|                                 | - Acknowledgement and feedback.  |

As in the previous empirical chapters regarding participation in the internal agency structure, the analysis of agencies’ public consultations will focus on the four sample agencies and will be based on an assessment of the relevant rules and practices, and supported by empirical evidence (both interview data and consultation documentation published on agencies’ websites). First, we will address access to public consultations. In particular, the following questions will be posed: How is access to consultations regulated in each of the cases? What is the nature of agency rulemaking (e.g. drafts of eventually binding implementing rules or regulation by soft law) that interested parties are granted access to? What promises of consultation can be identified? How open are agency consultations? What audience is granted access, and who is the “public”? What are the problematic aspects of access in terms of carrying out the identified promises of consultation?

---


24 See Chapter 2, Sections 2.3.1 and 2.4.
Second, we will inquire into the quality of deliberation in public consultations, characterised by three facets – information, commenting, and recognition (i.e. feedback) – which are believed to both individually and collectively govern the delivery of the promises of consultation. Through these two loci of analysis I will attempt to ascertain to what extent the promises of agencies’ consultations are genuinely fulfilled.

7.2 THE NUTS AND BOLTS OF ACCESS TO PUBLIC CONSULTATIONS

The present section delves into access to agencies’ public consultations. The consultation relationship is defined by rules, laid down either in the agencies’ founding regulations or internal policy documents, which outline the opportunity of interested parties situated outside the agency structure or public at large to access agencies’ rulemaking activities. By fulfilling their duty to consult, the agencies may promote the fulfilment of one or more promises of consultation specified above. Agencies’ consultation arrangements differ in regard to the nature of agencies’ rulemaking tasks that allow access, as well as in terms of the addressees (i.e. the audience) of such consultations. Hence, in order to identify the intended promises of agency consultations, we need to consider these essential features of access. We must also pinpoint possible limitations of access, which might detrimentally affect the fulfilment of the identified promises of consultation.

7.2.1 The Nature of Agencies’ Rulemaking, Consultation Approaches and the Promises of Consultation

All four agencies under scrutiny engage in regulatory activities, which may encompass either drafting of eventually binding implementing rules adopted by the Commission or regulation by soft law. Whereas the magnitude of the quasi-regulatory powers varies between the agencies, it is believed that their rulemaking activities will have “crucial normative authority for the subsequent stages of decision making at the [Commission] level, especially in policy areas characterized by high levels of technical and scientific expertise, uncertainty and complexity of goals.” Thus, in order to fully appreciate agencies’ consultation arrangements, it is beneficial to briefly recall the nature of agencies’ rulemaking activities. At the same time, we will examine the rules guiding the consultation approaches of the four sample agencies and, for each case, identify the intended promises of consultations. On the whole, the importance of consultations on agency rulemaking is set out in the founding regulations of the EBA, the EASA, and the EFSA, whereas the EMA founding regulation does not explicitly foresee the agency’s consultations.

---

25 See Chapter 2, Sections 2.3.2 and 2.4.
26 See also, E. Chiti (2013), pp. 96-98 and 100-103.
with interested parties. As will be shown below, this is due to the fact that the EMA founding regulation does not expressly entrust the agency with (quasi-)rulemaking powers. Nevertheless, the EMA responsibility to consult with interested parties is laid down in the agency’s guidelines concerning the procedure for the adoption of soft law measures.\textsuperscript{28} For the sake of clarity, I will consider each of the cases (i.e. agencies) individually.

\textit{A) European Banking Authority (EBA)}

By virtue of its rulemaking powers, the EBA is among the most powerful quasi-regulatory European agencies. In particular, the EBA is empowered to develop draft regulatory technical standards in financial services which are submitted to the Commission for endorsement by means of delegated acts pursuant to Article 290 TFEU in order to give them binding legal effect.\textsuperscript{29} Also, the agency is entrusted with developing draft implementing technical standards that are submitted to the Commission for adoption by means of implementing acts in accordance with Article 291 TFEU.\textsuperscript{30} Such draft standards are of a purely technical nature and “shall not imply strategic decisions or policy choices.”\textsuperscript{31} Once the EBA submits draft regulatory or implementing technical standards to the Commission, the latter decides whether to reject or endorse them (fully, in part or with amendments); however, given the relevant technical expertise of the agency, the Commission should not depart from the content of the draft technical standards without prior coordination with the EBA.\textsuperscript{32} Furthermore, in areas not covered by regulatory or implementing technical standards, the EBA has the power to issue guidelines and recommendations, in order to pursue the establishment of “consistent, efficient and effective supervisory practices.”\textsuperscript{33} Such soft rules are addressed to competent national authorities or financial institutions,\textsuperscript{34} which need to “make any effort to comply with them.”\textsuperscript{35}

The EBA founding regulation mandates the agency to conduct “open public consultations” with regard to draft regulatory\textsuperscript{36} and implementing\textsuperscript{37} technical standards (i.e. drafts of eventually binding rules), as well as guidelines and recommendations (i.e. soft law measures),\textsuperscript{38} and provide “interested parties” with a “reasonable opportunity to comment on proposed measures.”\textsuperscript{39} In the case of technical standards, consultations are to be conducted before the drafts are submitted to the Commission for endorsement.\textsuperscript{40} This definition of public consultations on draft technical

\begin{footnotesize}
\begin{enumerate}
\item Art. 10(1) of Regulation (EU) No 1093/2010, as subsequently amended.
\item Ibid. Art. 15(1).
\item Ibid. Art. 10(1) and 15(1).
\item Ibid.
\item Ibid. Art. 16(1).
\item Ibid.
\item Ibid. Art. 16(3).
\item Ibid. Art. 10(1).
\item Ibid. Art. 15(1).
\item Ibid. Art. 16(2).
\item Ibid. Para. 48 of the Preamble.
\item Ibid. Art. 10(1) and 15(1).
\end{enumerate}
\end{footnotesize}
standards at the agency level is important, as there are no consultations envisaged at the subsequent Commission level of rulemaking.\textsuperscript{41} Indeed, in its Better Regulation Guidelines, the Commission specifies that in instances where draft technical standards prepared by the EBA “have been subject to full public consultation before being submitted to the Commission and for which the Commission does not have the intention to significantly modify them”, there will be no consultation at the Commission level.\textsuperscript{42}

Whereas the EBA founding regulation does not explicitly refer to the promises of the agency’s consultations, the EBA Public Statement on Consultation Practices\textsuperscript{43} is more telling in this respect. In particular, this EBA policy states that the aim of consultations is “to build consensus where possible between all interested and affected parties on what legislative or regulatory approach or supervisory practice is appropriate and to improve the decision making process of the EBA.”\textsuperscript{44} By consulting, the agency will (a) benefit “from the expertise of market participants, consumers and end users, notably by identifying and analysing regulatory or supervisory issues and possible solutions”, (b) give the participants an opportunity to assist the EBA “in the determination of whether a problem exists which requires a regulatory or a supervisory action, and the form of appropriate action”, (c) provide “opportunities for alternative approaches to a given issue to be considered”, (d) obtain “information and views on the potential impact of proposals, in particular responses [that] may provide critical data for the development of an Impact Assessment”, (e) obtain “feedback on the EBA’s work”, and (f) promote “understanding of the work of the EBA and its role.”\textsuperscript{45} Accordingly, it can be claimed that the EBA consultations are intended to carry out the whole spectrum of the central promises as outlined.\textsuperscript{46} First, considering points (a), (d) and (e) above, the EBA consultations may be assumed to contribute to better and more informed agency’s rulemaking. Second, consultations might be oriented towards ensuring inclusiveness (i.e. balancing of different interests), as well as responsiveness of agency outcomes (see points (b), (c), (d) and (e)). Third, consultation of interested parties prior to the adoption of a draft technical standard or a soft law measure may be identified as enhancing the probability of adherence and fostering implementation (points (b), (c) and (f)). Finally, the EBA consultations may be understood as means of enhancing transparency and enabling monitoring of agency rulemaking activities (points (e) and (f)).

\textsuperscript{41} See also, European Commission (2015b), p. 5.
\textsuperscript{44} Ibid, p. 1.
\textsuperscript{45} Ibid.
\textsuperscript{46} See Chapter 2, Section 2.1.
B) European Aviation Safety Agency (EASA)

The EASA is another European agency with far-reaching rulemaking powers. The EASA, on the one hand, issues opinions (i.e. draft rules) addressed to the Commission. In this way the agency assists the Commission in the drafting of European aviation safety rules. Where the EASA opinions consist of technical rules, the Commission must coordinate with the agency prior to making any changes to their content. On the other hand, by means of publishing certification specifications, including airworthiness codes and acceptable means of compliance, as well as guidance material for the application and implementation of the founding regulation, the EASA engages in regulation by soft law. Such agency rules need to “reflect the state of the art and the best practices” in the fields of civil aviation and “be updated taking into account worldwide aircraft experience in service, and scientific and technical progress.”

The EASA founding regulation provides that the agency needs to establish “transparent procedures” for the issuing of both draft rules addressed to the Commission and soft law measures. Such procedures need to ensure that the EASA “publishes documents and consults widely with interested parties, according to a timetable and a procedure which includes an obligation on the [agency] to make a written response to the consultation process.” Accordingly, the EASA management board adopted a decision determining the agency’s rulemaking procedure, which includes consultations as a normal step in the development of a rule.

Similarly as in the case of the EBA, once the drafting of a technical rule in the field of civil aviation enters the Commission stage of rulemaking, it is understood that there will be no further opportunity for interested parties’ input in the form of public consultations. Thus, one can argue that the EASA consultations carry a significant weight. Whereas neither the EASA founding regulation nor the agency specifies any concrete promises of such public consultations, it appears from the provisions in place that the EASA consultations are intended to fulfil an array of promises pertaining to the effectiveness of the agency’s rulemaking. First, the input of participants may increase the range of information and relevant knowledge that will be available to the agency in the rulemaking process. Second, the notion of wide consultations with interested parties and the obligation of the EASA to provide feedback suggests, on the one hand, the promotion of inclusiveness, and on the other hand, a certain degree of responsiveness in the agency’s rulemaking. Third, given that the addressees of such consultations will eventually have to implement and comply with the outcome of the agency’s rulemaking, it can be suggested

---

47 Arts. 18(a) and 19(1) of Regulation (EC) No 216/2008, as subsequently amended.
48 Ibid. Art. 17(2)(b).
49 Ibid. Art. 18(c).
50 Ibid. Art. 19(2).
51 Ibid. Art. 52(1).
52 Ibid. Art. 52(1)(c).
that the EASA consultations are capable of promoting interested parties’ adherence. Finally, the
obligation of the agency to publish (consultation) documents can be understood as a means of
enhancing transparency and enabling monitoring over agencies’ rulemaking activities.

C) European Food Safety Authority (EFSA)

The EFSA is a further example of an agency with quasi-regulatory powers. Most notably, the
agency assesses risks associated with the food chain and thus provides scientific advice and
support for European legislation and policies in all fields that have a direct or indirect impact
on food and feed safety.\[55\] Within this remit, the EFSA rulemaking activities primarily include
preparation of scientific opinions that serve as the scientific basis for the drafting and subsequent
adoption of European measures (i.e. rulemaking to the extent that final measures will be acts of
general scope).\[56\] The EFSA may issue such scientific opinions at the request of the Commission,
the European Parliament or a Member State, as well as on its own initiative.\[57\] In practice, the
EFSA scientific opinions may take a variety of forms, ranging from opinions (for example risk
assessment), statements (less detailed scientific documents) or guidance (explaining the principles
behind the EFSA’s procedures and approaches to scientific risk assessments to assessors, risk
managers, and applicants for authorisation), issued either by the EFSA Scientific Committee or
the Scientific Panel (both in charge of providing scientific advice to European decision-makers).\[58\]
The agency is also entitled to provide scientific and technical assistance to the Commission, which
may include support in regard to the establishment or evaluation of technical criteria, as well as in
the development of technical guidelines.\[59\] Such assistance however, “does not require scientific
evaluation by the Scientific Committee or a Scientific Panel,”\[60\] and is generally denominated
by the agency as “other scientific output.”\[61\] In particular, such scientific outputs may include
statements, guidance, or scientific reports of the agency, which are prepared by an EFSA working
group or by the EFSA scientific staff.\[62\] According to the EFSA founding regulation, in order take
informed risk management decisions (i.e. decisions made to address potential threats in the food
chain as identified in risk assessment), the EU institutions and the Member States need to take
into account the results of risk assessment, in particular the agency’s scientific opinions.\[63\] This,
as remarked by Chalmers, “bestows indirect legal effects upon the [EFSA’s] opinions” and thus
gives the agency a “considerable normative authority.”\[64\]

55 Art. 22(2) of Regulation (EC) No 178/2002, as subsequently amended.
56 Ibid. Art. 22(6).
57 Ibid. Art. 29(1).
59 Art. 31(1) of Regulation (EC) No 178/2002, as subsequently amended.
60 Ibid.
62 Ibid.
63 Art. 6(3) of Regulation (EC) No 178/2002, as subsequently amended.
532-562, p. 540.
The case of the EFSA is another example where the relevance of consultations is stressed in the agency’s founding regulation. In particular, the EFSA regulation determines that “there should be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it.” Moreover, the regulation explicitly provides that the EFSA needs to develop “effective contacts with consumer representatives, producer representatives, processors and any other interested parties.” Open and transparent development of food law is understood to be “necessary to ensure [...] consumer confidence and the confidence of trading partners.” We have seen before that one manifestation of involving interested parties in the work of the EFSA was the establishment of the Stakeholder Consultative Platform (a form of internal participation), which advises the agency on general matters concerning interested parties. Moreover, in order to foster interactions with interested parties regarding its rulemaking activities, the agency adopted an internal policy on public consultations, namely the EFSA’s Approach on Public Consultations on Scientific Outputs. This policy defines public consultations as “the creation of an effective exchange on a draft scientific output [a generic term for both scientific opinions and other scientific output] based on a decision of [the EFSA] to seek comments from the public, namely non-institutional stakeholder, which include academics, NGOs, industry and all other potentially interested and affected parties.”

Such a formulation leaves the EFSA with a certain margin when deciding when to consult. According to the EFSA policy on consultations, the agency will consider the need to conduct public consultations in the following circumstances: (i) whenever there is a new type of question in areas where the agency “has not issued opinions previously and where public consultations would ensure that the knowledge on different types of approach and information is available for risk assessment or developing risk assessment methodologies”, (ii) in the context of complex or emerging scientific issues, especially if the agency “is dealing with particular issues where science has progressed substantially in the past or which [include] novel technologies where information and approaches in risk assessment are still to be developed”, and (iii) in regard to documents of horizontal nature or risk assessment approaches (e.g. risk assessment methodologies, principles or processes), “where a broad range of comments sought will support the clarity and effective respect of the scientific output.” All in all, the EFSA’s approach suggests that the promises of consultations are threefold. First of all, consultations on the agency’s draft scientific outputs seem important for “gathering views, data sources and comments that should in turn ensure

---

66 Ibid. Art. 42.
67 Ibid. Para. 22 of the Preamble.
69 Ibid, p. 3.
70 The EFSA’s Approach on Public Consultations moreover states that the agency may organise public consultations on scientific opinions, statements and guidance documents of the Scientific Committee or Panels, statements, guidance documents and scientific or technical reports of the EFSA, and the agency’s “self-task outputs”. However, the EASA considers that it is not in the position to organise public consultations on scientific opinions of the Scientific Committee or Panels on the so-called regulated substance, where the legal framework limits the agency’s ability to consult with the public (e.g. opinions on applications), statements of the Scientific Committee or Panels adopted in urgent or emergency situations, and on the conclusions from the Pesticides Peer Review Process and Reasoned opinion on maximum residue levels, where only institutional consultations are foreseen. Ibid, pp. 5-6.
71 Ibid, p. 4.
72 Ibid.
73 Ibid, p. 5.
the completeness, the clarity and the effective respect of [such] outputs." Second, the EFSA consultations appear to be relatively open to a variety of interested parties, which suggests that inclusiveness (i.e. balancing of different views) is another intended promise of consultation. Third, it is assumed that consultations also ensure that the EFSA "is seen, and perceived, as a glasshouse" and thus promote transparency of the agency’s rulemaking. In relation to the former, and as is evident from the EFSA founding regulation, such consultations can be understood as a means of building trust and gaining public confidence in the EU food safety system.

**D) European Medicines Agency (EMA)**

The case of the quasi-regulatory engagement of the EMA differs from others in one crucial aspect: the EMA founding regulation does not explicitly entrust the agency with rulemaking powers. However, the EMA intensively publishes scientific guidelines, i.e. soft law measures, which are adopted by the agency’s scientific committees – the Committee for Medicinal Products for Human Use, the Committee for Medicinal Products for Veterinary Use, and the Committee for Herbal Medicinal Products. In fact, the EMA scientific guidelines are referred to in the annexes to Directives 2001/82/EC (on European code relating to veterinary medicinal products) and 2001/83/EC (on European code relating to medicinal products for human use). These Directives are also explicit with regard to the normative quality of such agency soft law measures, stating that in assembling a dossier for application for marketing authorisation, applicants need to take into account the EMA scientific guidelines. Moreover, according to the EMA internal policy on rulemaking, namely the Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework (henceforth, the EMA Rulemaking Procedure), "scientific guidelines aim to provide a basis for practical harmonisation of the manner in which the Member States and the [agency] interpret and apply the detailed requirements for the demonstration of quality, safety and efficacy." The agency thus strongly encourages applicants and marketing authorisation holders to follow these guidelines, whereas “alternative approaches may be taken, provided that these are appropriately justified.”

The case of the EMA differs from those above for another reason: the duty of public consultations emanates from the EMA Rulemaking Procedure, and not from the agency’s founding regulation. This policy was put in place to describe and define the agency’s soft law measures and to provide a “harmonised procedure” for their development. As stated in the EMA Rulemaking Procedure,
the agency may conduct public consultations at two different stages of drafting a guideline. First, consultations with “relevant interested parties” are envisaged with regard to a “concept paper,” which is a “public document […] primarily intended to convey the need for discussing specific issues, innovations or controversial key-points at any stage of the development of medicinal products with a view to laying down the foundation for future guidelines. A concept paper should point out the issues to be covered in the guideline, but should not elaborate already on the solutions.”84 As part of the overall response to such consultations, interested parties are invited to provide “possible solutions for developing a guideline.”85 The comments received in the course of consultations on a concept paper will be considered by the EMA in the drafting of the future guideline.86 Second, the EMA also conducts consultations with “interested parties” at the further stage of rulemaking, namely once the guidelines are drafted.87 In the course of such consultations, the “interested parties are encouraged to highlight inconsistencies of the proposed draft guidelines with related guidelines in other regions.”88

As for the promises, it appears from the agency policy that the EMA consultations are primarily aimed at exploring and weighing possible solutions for developing a guideline and gaining information on the factual situation of the proposed draft guidelines. Given that the agency intends to consult relevant interested parties, this also suggests a certain degree of inclusiveness and responsiveness of agency rulemaking. However, in contrast to the consultation arrangements of the EBA, the EASA and the EFSA, there is, essentially, no indication that the promises of the EMA consultations are primarily intended to go beyond the purely instrumental rationale. In particular, considering the EMA rules on consultation, there is no explicit notion of the promise of transparency or any explicit aspiration to build trust in the agency’s rulemaking activities. However, it is believed that both transparency and trust could emerge as a “side effect” or a “spill-over” effect of other, intended promises of consultation, such as inclusiveness and the need for more informed EMA regulatory outcomes. But this is certainly not the main promise of participation in the EMA rulemaking.

7.2.2 Definition of “Public” in European Agencies’ Consultations

Given that the agencies’ founding regulations provide little practical insight as to who exactly the addressees of public consultations are – they refer to either the public at large or interested parties – elucidation of the matter demands pressing beyond these provisions. In order to define the “audience” of agency consultations (i.e. determine who can formally access agency rulemaking via consultations) and to establish whether everyone who matters for the carrying out of the particular promises of consultation identified in each of the cases is provided with an opportunity to be involved, we need to consider the agencies’ rules, as well as their practices, as revealed by the empirical evidence.

---

84 Ibid, pp. 10-11.
85 Ibid, p. 11.
86 Ibid.
87 Ibid, p. 12.
88 Ibid.
As seen above, the EBA consultations are guided by the agency’s founding regulation, as well as the EBA policy on consultation practices, adopted by the main decision-making body of the agency, i.e. the Board of Supervisors. The EBA founding regulation interchangeably refers to “open public consultations” and consultations with “interested parties”, and beyond this, provides no definition of the potential audience. The EBA Public Statement on Consultation Practices is, however, more explicit in this regard. In particular, this policy reveals that the agency intends to “target the full range of interested parties, including market participants (e.g. credit institutions, investment firms, etc.), consumers and other end-users, as well as their representative associations.” Considering that the EBA does not intend to limit its consultations to a particular group of interested parties, one may argue that the agency generally aims for an inclusive approach. This means that, as a rule, everyone who is of significance for the fulfilment of the previously identified promises of the EBA consultations (i.e. more informed regulatory outcomes, inclusiveness and responsiveness, fostering implementation and compliance, and enhancing transparency and monitoring of the EBA rulemaking) is to be included. The empirical evidence, however, confirms that due to the technical nature of the EBA consultation documents there are de facto limitations of the audience. In the words of an EBA official,

As such, most of the inputs [...] come from the parties who have a direct interest in a certain topic. If you look at the list of interested parties who submit their responses to consultations, of course, most of them come from the banking industry and market participants because they are the main users [of financial services] and also most affected by our documents. We are open to all views, but again, you would generally not see a normal citizen submitting comments, because our [consultation documents] are rather technical. Therefore, [one that would want to participate in the EBA consultations] needs to have necessary background knowledge. (Respondent #10)

This practical limitation is potentially capable of undermining the effective fulfilment of the identified promises of the EBA consultations, in particular that of inclusiveness (balancing of different interests, for example the interests of the banking industry and those of consumers or the users of banking services) and the responsiveness of the agency’s regulatory outcomes, as well as reducing the diversity of information that is available to the EBA in the course of rulemaking. In other words, it is believed that consultations are in fact limited to a restricted group of interests. Such limitations can be understood to be inherent to consultations on documents of a highly technical nature and thus cannot be ameliorated through law; however such limitations could potentially be reduced by a change of practice. For example, the EBA could publish more general, non-technical versions of such consultation documents and thus reach out to a wider audience. Moreover, one may argue, formally at least, that the involvement of a wide variety of interested parties (including consumers and end users) in the internal EBA Banking Stakeholder Group, which was established to help facilitate consultations with stakeholders in regard to the agency’s rulemaking activities, could neutralise this deficiency of access to a certain degree. As pointed out in the previous chapter, the Banking Stakeholder Group and interested parties situated

89 Articles 10(1), 15(1) and 16(2) of Regulation (EU) No 1093/2010, as subsequently amended, establish the EBA duty to conduct “open public consultations”, whereas Paragraph 48 of the Preamble specifically refers to consultations with “interested parties”.

90 European Banking Authority (2012b), p. 2.
outside the agency structure (i.e. via public consultations) are consulted at the same time about the same documents. Given its inclusive membership, it is assumed that the EBA consultative Group could, in theory, compensate for the said limitations of access to the agency’s public consultations and ensure that different interests are indeed represented and heard.

The EASA founding regulation is similarly vague in its explanation of the audience towards which the agency’s consultations are directed. Apart from stating that the agency needs to “consult widely with interested parties,” it provides no further definition of the possible addressees of the consultations. We have seen that the EASA rulemaking procedure is implemented by means of an agency decision, adopted by the agency’s management board. According to this internal policy, the EASA consultations are intended to include “any person or organisation with an interest in the rule under development [...] without discrimination on the basis of nationality.” This suggests a relative openness of the EASA consultations to everyone that matters for the fulfilment of the promises of consultations identified above (i.e. the whole spectrum of the central promises of participation). The empirical evidence confirms this assumption. As explained by an EASA official,

Consultations on EASA documents are open to everybody. It does not matter if this is a manufacturer or an individual outside the sector [of civil aviation], everyone is invited to comment and send us their views. (Respondent #2)

The EASA, however, does not keep any concrete statistics as to who exactly participates in practice. In this regard another EASA official remarked,

So far we have not prepared any statistics to see if one group of interests [is more active than the other]. But what we can see, and should of course be happy about, is that the consultation process is widely made use of. The number of comments that we receive certainly confirms that. We receive comments from manufacturers, maintenance organisations, airlines, operators, and general aviation; all different types of interests. [...] We however do expect from certain organisations to react, because it is their very role to look after the interests of certain persons or sectors, so we would be surprised if they would not react. (Respondent #7)

All in all, this confirms that the EASA consultations are open to participants, not only as a matter of law, but also in practice. On the basis of this observation, it can be argued that the rules and practices concerning access support the fulfilment of the previously identified spectrum of the promises of the EASA consultations. However, one can assume that the considerations outlined above in relation to access to the EBA consultations are also valid to a certain degree in this case: the nature of the EASA consultation documents is extremely technical, which, as such, may prevent access of less knowledgeable and experienced individuals. Thus in practice, this may

91 See Chapter 6, Section 6.1.1.
92 See Chapter 6, Sections 6.1.2 and 6.2.2 for practical insights (in particular the possible challenges and deficiencies) on this form of interested parties’ participation.
93 Art. 52(1)(c) of Regulation (EC) No 216/2008, as subsequently amended.
94 European Aviation Safety Agency (2012a), Art. 6(1).
possibly impinge upon the delivery of the promise of inclusiveness. Nevertheless, given that the remit of the EASA rulemaking is highly scientific, it may also be assumed that this promise of inclusiveness was never intended to go beyond the more “relevant” interests (i.e. those interests that will have to work with such rules once they are adopted).

In the case of the EFSA, the founding regulation provides that the agency should establish “effective contacts with consumer representatives, producer representatives, processors and any other interested parties.”95 However, this determination does not refer explicitly to public consultations but to any form of agency interaction with interested parties. Hence, with a view to defining the audience of the EFSA consultations, it is necessary to turn to the agency’s Approach on Public Consultations on Scientific Guidelines. This EFSA policy shows that with regard to consultations, the agency aims for an inclusive approach. As seen above, the EFSA intends to consult the public, which includes academics, NGOs, industry and any other potentially interested or affected party.96 In particular, such “non-institutional stakeholders” may consist of: (i) those parties who have knowledge or scientific expertise to contribute to a scientific output, (ii) those genuinely impacted by an output (e.g. producers or users), as well as (iii) those parties with a general interest.97 This was confirmed by an EFSA official, who stated that the agency regularly receives comments from “industry, academia, scientists and civil society” (Respondent #20). Moreover, the empirical evidence does not hint at any practical problems of inclusiveness. Accordingly, it can be argued, formally at least, that the openness of the EFSA’s consultations to a wide range of participants, including general and affected interests, as well as experts, supports the fulfilment of the identified promises of the EFSA consultations (i.e. gathering information from different sources, enhancing transparency and gaining public confidence). In practice however, it is assumed that the EFSA consultations could be subjected to the same limitations as in the cases of the EBA and the EASA, given the technical nature of the EFSA’s scientific opinions.

The EMA Rulemaking Procedure does not explicitly define the addressees of consultations. Nevertheless, this agency policy states that depending on the subject of consultations, the EMA “expects” comments from the Member States, European industry associations, scientific and academic societies, patients, consumers and healthcare professionals, and other interested parties.98 Individuals, however, “are encouraged to comment via the relevant associations, societies or groups.”99 One may assume that this is relevant for two reasons. On the one hand, such organisations may support individuals in the sense that they have better resources and are more experienced in the formulation of comments, which in turn, may produce more pertinent results of consultations. After all, the EMA consultations are primarily aimed at highlighting possible inconsistencies of the proposed draft guidelines (i.e. investigating and balancing of different solutions and gaining information). On the other hand, this could be more suitable in terms of managing the comments received. Nonetheless, nothing in the written provisions suggests the

---

96 See European Food Safety Authority (2009), p. 3.
agency’s preference towards consulting one group of participants (individuals or organisations) over the other or that access to consultations is controlled in any way (i.e. that the EMA would purposively limit the opportunity of access to a particular group of interests). This agency stance was confirmed by an EMA official in the following terms:

I would not say that we concentrate only on organised interests, as the consultation process is open to everybody. We publish our consultation documents on the website and anybody who wants to comment has the opportunity to do so. So in no way do we control it. We really take the comments as they come. (Respondent #5)

The EMA’s approach to consultations demonstrates a general openness. In particular, it appears that the EMA has an interest in consulting a relatively inclusive variety of interested parties who may potentially secure relevant factual information (i.e. information that otherwise might not be available to the EMA) that would feed into the agency’s rulemaking process.

7.2.3 De Facto Limitations of Access

Having examined the agencies’ consultation arrangements, established the promises and defined the “audience”, it is now time to examine possible limitations of access to public consultations. This consideration is important, as any deficits in terms of access may have negative consequences for the accomplishment of the primary promises of consultation.

The most prominent instance of limitation of access to agencies’ consultation processes takes the form of the language the consultation documents are provided in. When looking at the agencies’ websites, where consultation documents are published, one immediately notices that all consultations are produced only in English. Whereas such consultation practices are compatible with both agencies’ founding regulations and Regulation 1/58 determining the languages to be used by the European Economic Community, they may nevertheless have negative consequences for access to public consultations, and consequently on the delivery of the promises of consultation, in particular inclusiveness, transparency and the range of information gathered. This is due to the fact that, in order to understand and to comment on a consultation document, an individual would need to have a good comprehension of the English language. As most of the agencies’ consultations are conducted on highly specific technical and scientific issues, the language barrier may prove additionally cumbersome.

100 Whereas Article 4 of Regulation 1/58 states that regulations and other documents of general application need to be drafted in the official languages of the Union, this provision only applies to final acts and not to consultation documents. See, Art. 4 of Regulation 1/58, as subsequently amended.

101 It should be noted, however, that, generally, European agencies accept comments on consultation documents in all European languages.
The case of the European Ombudsman inquiry into the EASA consultation practice provides a telling example in this regard and will be presented in detail below. Before delving into the details of this case, it is beneficial to briefly recall the EASA consultation regime. As seen above, the EASA provides expert advice (in the form of opinions) to the Commission on drafting new technical rules in the field of civil aviation. Upon the completion of the drafting of the proposed rule, and before its release to the Commission for endorsement, the agency launches public consultations. According to the EASA internal policy on rulemaking, consultations are intended to target interested parties without discrimination on the basis of nationality. Therefore, to be inclusive in practice, consultations would need to be accessible to a broad range of audiences. However, access to the EASA consultations is rather limited in practice precisely because of the language barriers.

This issue in the above-noted complaint to the European Ombudsman involving the EASA (3419/2008/(AF)(BEH)KM) dealt with an alleged instance of maladministration due to the fact that an EASA consultation document was not translated and published in all official languages of the EU. The background of the complaint was as follows. In 2008, the EASA published a consultation document concerning draft implementing rules for pilot licensing. Later that year a complainant, who was a German amateur pilot, asked the agency to publish a German translation of the consultation document, which was provided in the English language only. The complainant argued that such translation would allow a greater number of German amateur pilots, who had valuable experience but did not possess necessary language skills to deal with this very detailed technical document containing legal terminology, to participate in the public consultation. While the EASA acknowledged the importance of the linguistic diversity and its obligation under the regulation to send its opinions (i.e. draft rules) to the Commission in all official languages of the EU, it however did not consider that this obligation extended to consultation documents. Consequently, the complainant referred the case to the European Ombudsman, stating that thus the EASA unduly restricted the right of interested individuals to comment in the course of public consultations, and maintaining that all agency consultation documents should be equally available in languages other than English. While the Ombudsman concluded that neither Article 32(1) of the EASA founding regulation, nor Regulation 1/58 oblige the agency to translate consultation documents into all official languages of the EU, he nevertheless pointed out that the “principle of good administration” requires administrators to do more than merely adhere to the relevant legal obligations. The Ombudsman also considered it obvious that the right to make comments can only be usefully exercised if interested parties are able to understand the EASA proposals, and that in a democratic society, citizens must be able to participate both effectively and equally. Ideally, this would mean that all agency consultation documents should be made available in all official languages of the EU. Considering limited resources of the EU (for translation of documents into all official languages), the Ombudsman held that a balance has to be struck between the need to enable interested parties to understand and comment on consultation documents, and


103 Art. 32(1) of Regulation (EC) No 216/2008, as subsequently amended.

104 The EASA, however, mentioned in its response to the European Ombudsman inquiry into the complaint, that it had received over 10,000 comments on this particular consultation document, some of which were not drafted in English.
the need for an economic use of public funds. As translating all agency consultation documents into all official languages might entail a disproportionate effort, the Ombudsman suggested that, as an alternative, the EASA could provide a translation of summaries of the main points of its proposals (e.g. translation of explanatory memorandums to the EASA proposals). As part of a friendly solution, the agency offered to translate the titles of its consultation documents, and to provide translation of summaries on request. Whereas the Ombudsman held that such proposal is clearly useful and should be put into practice as it would enable more people to participate in the EASA consultations, he however considered that there still remains a risk that interested individuals might not always realise that a consultation document concerns them, given that the only information available in their language would be the title of the document. This, the Ombudsman held, would prevent interested individuals from availing of the opportunity to make a meaningful contribution to, and effectively participating in the overall consultation process. In conclusion, the Ombudsman determined that the EASA kept refusing to translate its consultation documents or summaries thereof into all official languages of the EU, and established that this constituted an instance of maladministration. Moreover, the EASA website reveals that, to this day, the agency continues to publish its consultation documents in the English language only.105

This case provides an illustration of how language barriers – not only in regard to the EASA, but also to any other agency - might have significant repercussions on the possibility of interested parties accessing agencies’ public consultations and on their ability to provide comments, which may impinge on the fulfilment of any of the central promises of consultation. Arguably, the matter is less problematic in relation to the access of (umbrella) interest organisations to public consultations. It is assumed that such organisations would normally possess the necessary resources to deal with the consultation documents and to comment thereon. Language barriers, however, may have adverse practical effects on the opportunity of “weaker groups” to participate (e.g. individuals, local interest organisations, consumers, end users, etc.), and can lead to substantial inequalities in terms of access, and subsequently to a failure to fulfil the promises of consultation, especially those of an instrumental character (i.e. more informed regulatory outcomes, inclusiveness and responsiveness, and compliance and implementation). Whereas there are practical limits regarding the extent to which this deficiency may be rectified through law, in particular due to the limited EU resources, it would be beneficial if the agencies could, to the extent possible, adapt their consultation practices and thus ensure that the promises of consultation live up to their full potential. For example, one solution might be, as suggested by the European Ombudsman, that the agencies would translate the summaries of their consultation documents, on request at least. Another solution may be that proposed by the Research Network on EU Administrative Law (ReNEUAL). According to the ReNEUAL Model Rules on EU Administrative Procedure (Book II on Administrative Rulemaking), the draft acts and the explanatory memorandum should be published for consultations “in at least those languages which the EU authority [e.g. an agency] in charge of drafting the act has identified as its working languages.”106 In particular, this would


ensure a balance between “the necessity of information being accessible to all Union citizens”
and the “practical requirements of administrative work, which forbid the continuous translation
of so many documents in all official languages.” Arguably, in the case of European agencies
the first solution would be more suitable, given that English is the main working language of the
majority of the sample agencies. In other words, applying the ReNEUAL solution to European
agencies would not at all improve the existing deficits regarding access to consultations.

7.2.4 Conclusion: Access to Agencies’ Consultations and
Fulfilment of Promises

Generally speaking, the analysis conducted above shows that, depending on the nature of a
particular agency’s rulemaking, consultations with interested parties are intended to fulfil different
promises. According to the primary sources, consultations in all agencies are oriented towards
gaining relevant factual information which might contribute to better and more informed, and
thus possibly more effective rulemaking (i.e. drafting of potentially binding implementing rules
adopted by the Commission or regulation by soft law), and ensuring a certain level of inclusiveness
(i.e. balancing of different views) and responsiveness (which arguably allows the drafted rules to
be aligned to a greater extent with the needs of the regulated sector). Moreover, prima facie, it can
be suggested that in the cases where agencies engage in the drafting of eventually binding rules
(in particular regarding the EBA and the EASA), consultation with interested parties, who will
need to work with such rules once they are adopted, promotes implementation and furthers the
likelihood of spontaneous compliance. This form of participation may also enhance transparency
and the monitoring of agencies’ rulemaking and help build confidence. While it was revealed
that in the case of the EFSA consultations the latter constitute the core promises, it was also
demonstrated that transparency, monitoring and trust might not always be the intended purpose
of consultations (i.e. in the case of the EMA), but rather a “side-effect” of other promises of
participation, for example inclusiveness. An overview of the consultation arrangements for each
of the sample agencies, including the primary promises of consultation, is provided below.

107 Ibid, p. 60.
108 According to the EBA, the EASA and the EMA websites English is the main working language. In the case of the EFSA, the
working languages for the dissemination of information of “significant public interest” are English, French, German and Italian.
### Table 7.2 Overview of the Consultation Arrangements in the Sample Agencies

<table>
<thead>
<tr>
<th>Nature of Rulemaking</th>
<th>EBA</th>
<th>EASA</th>
<th>EFSA</th>
<th>EMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft regulatory and implementing technical standards (i.e. drafts of eventually binding rules adopted by the Commission). - Guidelines and recommendations (soft law measures).</td>
<td>Opinions (i.e. drafts of eventually binding rules adopted by the Commission). - Certification specifications, airworthiness codes, acceptable means of compliance and guidance material (soft law measures).</td>
<td>Scientific opinions, which serve as the scientific basis for the drafting of eventually binding European measures. - Statements, guidance, scientific reports (soft law measures).</td>
<td>- Scientific guidelines (soft law measures).</td>
<td></td>
</tr>
<tr>
<td><strong>Audience of Consultations</strong></td>
<td>Full range of interested parties, including market participants (e.g. credit institutions, investment firms, etc.), consumers and other end users, as well as their representative associations.</td>
<td>Any person or organisation with an interest in the rule under development without discrimination on the basis of nationality.</td>
<td>Public, which includes academics, NGOs, industry and any other potentially interested or affected party. Such “non-institutional stakeholders” comprise those who have knowledge and expertise, those genuinely impacted and those with a general interest.</td>
<td>Comments are “expected” from European industry associations, scientific and academic societies, patients, consumers, healthcare professionals and other interested parties. Individuals are encouraged to comment via relevant associations, societies or groups.</td>
</tr>
</tbody>
</table>

Overall, in terms of access, the formal consultation arrangements of the four agencies under scrutiny seem thorough and compatible with the Commission’s approach to consultations. Considering the rules in place, it can be argued that all sample agencies intend to consult a broad variety of interested parties which is in line with the Commission’s general principle of “participation” (i.e. ensuring an inclusive approach when developing and implementing EU policies). Moreover, given that such possibilities for the involvement of interested parties formally exist and are applied, it is understood that consultations make agencies’ rulemaking processes more visible to the outside world. In particular, this corresponds with the Commission’s
general principle of “openness and accountability”. Further, in all four cases interested parties are consulted at the stage where they can still have an impact on the formulation of a rule, which means that the agencies’ consultations formally correlate with the Commission’s general principle of “effectiveness”. What is more, in all four cases, the agencies’ formal arrangements foresee that “relevant parties” have an opportunity to access consultations and express their views, which coincides with the Commission’s minimum standard regarding the definition of target groups in a consultation process. All these findings are important as they confirm that agencies’ consultations in regard to drafts of eventually binding implementing rules and soft law measures are, de facto, subject to similar principles and standards as Commission consultations. Nevertheless, the agencies’ consultation arrangements display a set of deficiencies in practice.

First of all, when defining the “audience” of public consultations in the sample agencies we saw that because of the complexity of the consultation documents, access is rather restricted in practice. Namely, in order to be able to comment, interested parties would need to possess a certain level of knowledge, experience and even expertise on a given topic. Therefore, it is assumed that agencies’ consultations are de facto considerably less accessible to a “normal citizen” or to the public at large, even where the formal rules suggest otherwise (e.g. in the case of the EASA and the EFSA). Accordingly, it can be argued that the promises of consultations are limited to more “relevant” interests, namely to those who will have to apply agency rules (whatever their form) once they are adopted (e.g. interested parties from the regulated sectors). However, to make agency rulemaking more transparent and accessible to the wider public, agencies could publish more general, technically less demanding versions of consultation documents. This would potentially ensure a broader range of information, promote inclusiveness and responsiveness beyond the relevant interests and increase transparency and help build confidence in the agencies’ rulemaking. On the whole, this would additionally promote the credibility of the agencies’ operation and possibly also their effectiveness, which are, as defended in Chapter 1, the core rationales for agencies’ creation.

Moreover, the analysis above pinpointed another critical deficiency in terms of access - the language in which consultation documents are provided. In fact, it was observed that all four agencies under scrutiny publish their consultation documents in English only. This means that access to public consultations is de facto restricted to those interested parties who have a reasonably good understanding of the English language and/or have the necessary resources to deal with such documents. Given that in all cases, the consultation documents are rather complex and technical, it can be assumed that language barriers additionally aggravate access to “public” consultations. All this implies that, in practice, access to consultation is much more limited than we are lead to believe on the basis of the formal provisions. As shown above, due to the fact that the EASA did not translate its consultation documents into all official languages of the EU, the European Ombudsman held that this constituted an instance of maladministration. In terms of the Commission’s general principles and minimum standards, it can be argued that agencies’ consultations are de facto considerably less inclusive (i.e. commenting is restricted to those interests with more resources), open (i.e. not all interested parties will comprehend the agencies’

---

110 See Chapter 1, Section 1.1.2.
111 See for example, P. Craig (2012), pp. 169-170 and 302-303.
rulemaking, which also means that agency rulemaking is less visible to the outside world) and effective (i.e. certain interests will not have the possibility to be involved in the development of a rule and possibly influence its formulation). Therefore, on the basis of this practical limitation of access, it may be assumed that the carrying out of the promises of consultation, especially the possibility of attaining better and more informed regulatory outcomes, inclusiveness and responsiveness, might be considerably hampered. Translating summaries of the consultation documents into languages other than English may improve the consultation practices, at least to the extent that their (financial and other) resources would permit this.

7.3 Quality of Deliberation: Verifying the Influence of Public Consultations

The second part of the inquiry into the agencies’ consultation arrangements concerns the question of the quality of deliberation. The quality of deliberation is one of the defining components of participation: in this case it enables us to determine the actual influence or the difference that participation in consultations makes in the end regarding the primary promises. Three interrelated and mutually reinforcing facets of consultation, namely (i) information, (ii) commenting, and (iii) recognition (i.e. feedback), feed into the quality of deliberation and may thus individually and collectively govern the fulfilment of the promises of consultation.112

According to the Commission approach, for consultations to succeed (i.e. to actually fulfil one or more promises of participation), certain minimum standards need to be applied. The agency “compliance” with the minimum standards through different facets of consultation will allow us to ascertain the overall quality of deliberation and the subsequent accomplishment of the previously identified promises of consultation. When considering the quality of deliberation of the consultation arrangements under scrutiny, the following standards become relevant. First, in terms of information, it is necessary to determine whether the agencies’ consultations have a clear content. In particular, it is important to ascertain whether the consultation documents comprise all essential information, such as particular issues open for discussion and the underlying objective of consultation. Moreover, it is important to verify the addressees’ ability to acquire such information in a concise way at a “single access point”. Second, with regard to commenting, it is relevant to ascertain whether the agencies allow sufficient time for the submission of written responses to consultation documents. At this point, the organisational aspects of consultations from both the agencies’ (e.g. the commenting tools and the form of comments) and the participants’ (e.g. drafting of comments and resources) perspective will be addressed. Finally, concerning the outcomes (i.e. recognition), it is necessary to establish whether and how the agencies acknowledge the participants’ contributions and provide feedback. To assess the overall quality of deliberation and ascertain the actual fulfilment of the primary promises of agency consultations, in following analysis I will rely on the agencies’ rules, as well as the available empirical evidence (i.e. interview data and the information on consultations published on the agencies’ websites).

112 See Chapter 2, Sections 2.3.2 and 2.4.
7.3.1 Information: Does it Pass Muster?

As stated in the Commission approach to public consultations, to ensure effective consultations and facilitate responses, clear content must underpin the consultation process. In particular, consultation documents need to include “a summary of the context, scope and objectives of consultation, including a description of the specific issues open for discussion or questions with particular importance,” as well as contact details and deadlines. It is thus perceived that, in order to guarantee that the intended promises of consultation are carried forward, agency consultation documents would need to meet this minimum standard not only *de jure* but also *de facto*.

The question of the content and the form of consultation documents can be resolved without difficulty through an overview of the relevant provisions contained in the agencies’ policies on public consultations and checked against the agencies’ websites where the consultation documents are published. For example, the EBA Public Statement on Consultation Practices provides that the agency needs to commit to producing “reasoned consultation papers containing proposals, reflecting all relevant aspects of the issues at stake, based on thorough analysis of the issues and objectives of the proposal and, where possible, on quantitative information, expressed in concise and clear language, including preliminary information on their impact, including on cost-benefit analysis, unless this is disproportionate or inappropriate.” In the case of the EASA, the consultation documents, published on the agency’s website would, *inter alia*, need to include the following information: (i) an “explanatory note” describing the development process and the next steps, including the time limits of consultation and date for the publication of the response document, a summary of the proposed changes and full details of significant, contentious or interface issues identified in the course of drafting, (ii) the proposed rule, and if applicable (iii) a regulatory impact assessment. Furthermore, the EFSA’s Approach on Public Consultations on Scientific Outputs provides that “in order to have a successful and meaningful public consultation and to keep the consultation an iterative process, clear information must be provided and the right target groups must be informed in a timely manner.” In particular, the EFSA consultation policy stresses that it is important that the explanatory texts attached to the consultation document “clarify the essential background information regarding the consultation.” This may include relevant deadlines and a foreseen timetable and process for further developments. Finally, in the case of the EMA, the agency’s Rulemaking Procedure provides that draft guidelines, which are subject to consultation, need to contain in addition to its “scientific and technical content”, a cover page, a table of contents, an executive summary, an introduction explaining the background of the proposal, the scope of application (e.g. a selected area of medicinal product development), the legal basis, the proposed timetable, necessary definitions and scientific and legal references to other available information.

114 European Banking Authority (2012b), p. 3.
115 European Aviation Safety Agency (2012a), Art. 5(3).
117 Ibid.
118 Ibid.
119 European Medicines Agency (2009), pp. 11-12.
To ascertain whether such agencies’ rules on the content of the consultation documents are in fact respected, I inspected several consultation documents120 published on the agencies’ websites.121 According to the information available, the content of actual consultation documents is consistent with the provisions indicated above, as well as with the Commission standards. It was also evident from this review that the agencies’ consultation documents are published at “a single access point”, namely the agencies’ websites,122 which de facto corresponds to the Commission’s minimum standards.123 This is considered important to ensure adequate awareness of the public consultations and to allow the public to find information and relevant documentation.124 As there is nothing in the empirical evidence that would suggest the agencies’ departure from the Commission’s minimum standards regarding the content of consultation documents, it can be concluded that in terms of access to information, the quality of deliberation is not affected by faulty practices and that the agencies under scrutiny are promoting the fulfilment of the intended promises of consultation (i.e. as established above).

7.3.2 Commenting: Restricted to Experienced Participants

There are two aspects of the process of commenting that need to be considered in order to establish the overall quality of deliberation and the subsequent fulfilment of the promises of consultation identified in each of the cases under scrutiny. First, in order to carry forward the promises of consultation, the agencies need to provide sufficient time for the preparation and presentation of responses to public consultations. In other words, the opportunity of participants to actually comment on a consultation document, and their capability to effectively contribute to the fulfilment of the promises of consultation, is believed to depend greatly on the time they can de facto dedicate to formulating their views. Second, it is necessary to inquire into the participants’ approach to commenting. This means that in the cases where the comments are submitted by interested parties’ organisations, it is essential to look into how they deal with commenting internally, in order to present different interests, provide comprehensive comments and thus contribute to achieving the aims sought through consultations.

120 At least 20 per agency.
122 Ibid.
124 Ibid.
A) Time Limits for Commenting

As provided for in their internal consultation policies, the EBA allows a three-month consultation period,\textsuperscript{125} the EASA consultation period may vary from a minimum of one month to a maximum of three months,\textsuperscript{126} while the EMA concept papers and draft guidelines need to be released for consultation for a period of, respectively, two to three months and three to six months.\textsuperscript{127} In contrast, the EFSA’s Approach on Public Consultations does not expressly establish any time limits for consultations on the agency’s scientific output. However this internal agency policy states that in order to ensure effectiveness, consultations will be based on “clear timelines.”\textsuperscript{128} The reason for this lack of specificity on explicit deadlines for consultations relates to the fact that whenever the EFSA receives a request for a scientific output (e.g. a request from the Commission to prepare a scientific opinion) these requests will also specify time limits for their delivery.\textsuperscript{129} As further elaborated by an EFSA official,

The deadlines for consultations need to be considered within an overall plan for the delivery of a scientific opinion. For each scientific output we receive a deadline, so we try to plan the consultations in time to get the comments, analyse them and then go back to the [Scientific] Panel to finalise our opinions and publish them. But usually documents are up for consultations for a period of six weeks. (Respondent #20)

In all cases except the EFSA, which as observed above is a specific case, the prescribed deadlines for consultations are generally in line with the Commission minimum standard of allowing at least 12 weeks for the reception of responses to written public consultations. In fact, the agencies’ time-lines for consultations are longer than time-lines for consultations on draft delegated and implementing acts (i.e. four weeks) envisaged by the Commission in its Better Regulation Agenda.\textsuperscript{130} Thus, as a matter of design, one could argue that the agencies’ approaches to public consultations allow sufficient time to formulate comments. Nevertheless, to determine whether such agency deadlines are \textit{de facto} capable of fostering the fulfilment of the promises of consultation, we also need to consider the available empirical evidence and show how this issue is perceived from the perspective of the respondents (i.e. the “audience” of consultations). A note on the empirical evidence is pertinent at this point. Given that the EMA and the EFSA consultations have lower participation rates and a more dispersed “audience” (depending on the particular issue at stake), the author could not collect representative empirical data that would allow the identification of conclusive results. Thus, the majority of the empirical data provided below stems from the EBA and the EASA, where the audience of consultations is more coherent and was easier to identify and approach.

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{125} European Banking Authority (2012b), p. 3.
\item \textsuperscript{126} European Aviation Safety Agency (2012a), Art. 6(4).
\item \textsuperscript{127} European Medicines Agency (2009), pp. 11-12.
\item \textsuperscript{128} See, European Food Safety Authority (2009), p. 6.
\item \textsuperscript{129} See for example, Art. 29(4) of Regulation (EC) No 178/2002, as subsequently amended.
\item \textsuperscript{130} See, European Commission (2015b), p. 5.
\end{enumerate}
\end{footnotesize}
In the case of the EBA, the respondents felt that the agency respects the formal time limits for consultations. Nonetheless, in some cases the point was made that occasionally struggles arise with the formal deadlines. For example, a respondent from a national consumer organisation felt that because of the strict deadlines “the commenting is not always easy. If I wanted to engage in every consultation that is relevant for me, I would not have time to do the [other work within the consumer organisation] that I am here for” (Respondent #31). Therefore, they considered it beneficial to align with an umbrella consumer organisation. In this regard, they considered that “it is easier to comment within the time limits if you work with colleagues. This also ensures that if sometimes I cannot comment in time, a German colleague or whoever else will jump in for me and help me formulate the comments.” Similarly, a respondent from the banking industry explained,

Every time [that we comment] is a fight. That is why it is important that at least we have three months to consolidate the views with the members [of our organisation]. It is difficult, but until now we have always managed to submit comments in time. (Respondent #32)

This is another example of the potential limitations of the EBA consultations, which may affect the fulfilment of the promise of inclusiveness and the range of information that will be available to the agency as a result of consultation (i.e. more informed regulatory outcomes). On the basis of the empirical evidence presented above, and as already observed with respect to access to the EBA consultations, one may assume that, compared to individuals, (umbrella) organisations will be in a better position to provide (timely) comments and to effectively engage in the consultation process. While such deficiencies (inequalities) can be considered inherent to the highly technical work of the agency, it might be suggested that consultation periods should correlate with the complexity of issues at stake. In other words, it would seem that in order to ensure that the intended promises of the EBA consultations are in fact accomplished longer consultation periods are necessary for more complicated matters. In practice, however, this would be possible only to the extent that the strict time limits for the drafting of technical standards (which would eventually become binding rules adopted by the Commission) prescribed in the agency’s founding regulation would allow this.131

Similarly, the respondents from the EASA generally claimed that the agency respects the formal deadlines; however, they also felt challenged by the time limits for consultations. As observed by one respondent from the aviation training industry, “the standard period of three months is, depending on the issue that is at stake, more than enough time or it is a challenge” (Respondent #33). A respondent from the aviation manufacturing industry additionally explained:

Sometimes we still feel very time-pressed. There are sometimes very short actions to be taken and then we have to organise the comments within a couple of weeks. So that is very challenging. Because simply put [our organisation] is very big. First you have to find someone [from the organisation] who is knowledgeable about the topic and see if they are ready to provide some comments. They need time to read the [consultation document].

131 See, Arts. 10 and 15 of Regulation (EU) No 1093/2010, as subsequently amended.
But having people within [the organisation] that understand the importance of rulemaking helps us to deal with the commenting. At the end of the day, [the agency’s rulemaking] could affect our design, it could affect our production and we have to be able to comment. (Respondent #34)

This shows that in the case of the EASA, the participants’ ability to comment within the prescribed time limits will depend significantly on the complexity of an issue open to public consultations, as well as the “in-house” expertise and experience within an interested parties’ organisation that wishes to participate. This also ties in with the earlier observation regarding access to the EASA consultations, where we noted that an individual’s opportunity to comment could be de facto limited due to the highly technical nature of the consultation documents. In terms of the identified promises of the EASA consultations, one could thus argue that in practice, there are limits to inclusiveness, and consequently also to the range of information and relevant knowledge available to the agency in the course of rulemaking. However, it would be far-fetched to regard this matter as a deficiency of design. Furthermore, given that the EASA respects the self-imposed consultation deadlines, and moreover needs to work within a fast-paced rulemaking environment, it is doubtful that this issue could be resolved through a change in practice.

On the whole, this reveals that in the case of the EBA and the EASA consultations the level of participants’ engagement could potentially be inadequate due to a combination of strict deadlines and the complexity of documents open to consultation. In practice this can lead to situations where certain interests (in particular individual interests) could be under-represented in the consultation procedures. In other words, this could mean that the benefits of being provided with an opportunity to participate in agency consultations could be severely hampered, if not completely restricted for certain issues. Furthermore, it can be assumed that these findings are not specific to the EBA and the EASA, but could be equally valid in the cases of the EFSA and the EMA. The assumptions are based on the following reasons. First, the content of the EFSA and the EMA consultations is, similarly as with regard to the other two agencies, highly technical and complex. Second, in the case of the EFSA, the consultation period (6 weeks) is considerably shorter than the one of the EBA or the EASA (which generally follow the Commission’s minimum standard of 12 weeks). Third and finally, as seen in terms of access to consultations, the EMA Rulemaking Procedure (which regulates the agency’s consultations) a priori encourages individuals to comment via the relevant associations, which may be interpreted as an actual limitation of inclusiveness.

B) Formulation of Comments: Knowledge and Resources

In terms of commenting, particularly regarding the formulation of responses, certain respondents referred to the importance of possessing knowledge and expertise, as well as necessary resources, in order to be able to effectively contribute to the consultation process. On the one hand, this issue correlates with the participants’ ability to formulate and provide their comments within the prescribed consultation deadlines. On the other hand, one may consider this issue a de facto

---

limitation of the opportunity of commenting, which could impinge on the fulfilment of the promises of consultation. The views expressed below were provided by respondents from interest organisations. However, following the argument *a maiore ad minus*, one may argue that the issues referred to could have an even greater impact on the individuals’ possibility to comment.

For example, in the case of the EBA consultations, one respondent from an umbrella credit and investment institution described the situation as follows:

> When preparing our comments we are working with experts. That means that our organisation is structured around several layers of committees and when it comes to consultations we use the technical level of expertise that we have. Then we launch a call for member input [i.e. the organisations that belong to the umbrella association] on the basis of information that we have gathered, together with the attached public consultation document. We give an internal deadline and gather the feedback to our [response proposal] to see if they can agree. And once again and once again until we can all agree on something and then we release a position. And we never deviate for the view of our member organisations. They can also comment individually, but that will be more difficult. (Respondent #32)

Similarly, one respondent from a national consumer organisation explained,

> Quite often there is a capacity problem for consumer associations to comment on very complicated, very technical consultations. This is one of the reasons why we need to be part of centralised organisations with their seat in Brussels. They support us in the consultation process and gather our views. There are not a lot of resources for that in the consumer movement. That is why I always comment within the European umbrella consumer organisation. So whenever there is an EBA consultation, we would try to find a common ground and present our views together. Then the umbrella organisation finalises the comments and sends them to the EBA. (Respondent #31)

Two general considerations can be drawn on the basis of these statements. First, they show the significance of possessing the relevant resources in order to comment on the EBA consultation documents. One may argue that for an individual (or a smaller organisation) the consultation process may prove to be too cumbersome to participate effectively. Second, and related to the first observation, they demonstrate the benefits of commenting via an umbrella organisation. In particular, it is understood that due to internal expertise and resources, such organisations will be capable of supporting individual interests and will be in a better position to formulate comments. Without such a concerted approach to commenting, the benefits of having an opportunity to participate in the EBA consultations might be severely diminished, if not lost completely.

The issue of resources and expertise also arose in the case of the EASA consultations. In the words of one respondent from the aviation training industry,

> Whenever there is a [consultation document], we first try to identify if there is anything contentious. Then we send the documents to other experts who are part of our organisation
who know the subject in detail and we ask them for their comments. They may comment or not. Then we consolidate everything and make sure that there is a common position of the association on it, and we submit our comments to the agency. (Respondent #33)

Another respondent from an air sports organisation participating in the EASA consultations also referred to the issue of resources. In relation to this matter, they also referred to the previously noted problem of the language of consultation documents. We have observed before that the publication of documents in English only may present a de facto limitation of access to the EASA consultations and may thus affect the fulfilment of the identified promises of consultation. These two issues were described as following:

Within [the organisation] we always comment as a board. We comment on those [consultation documents] that are important for us. We always ask all our members to comment. Some do and some do not. The problem is sometimes with the language. We have told the EASA many times that within our organisation [the knowledge of] English is good, but all those individuals may not be able to read [the consultation documents]. So when there is a document of two hundred pages and we ask our members to comment, they say “it is in English, forget it. We cannot do that.” [...] And it has to be said that even within [our organisation] there are only one or two representatives delivering their comments on the dot. Because [our members] are volunteers. And first of all, they want to fly and reading complicated documents – for that they simply do not have the knowledge or time. (Respondent #35)

This confirms that there might indeed be practical limitations of the EASA consultations, and consequently deficits in carrying out the identified promises. These issues are particularly pertinent for the fulfilment of the promises of inclusiveness and the quality and the range of information available to the EASA in the rulemaking process. In addition, one may argue that concerns relating to the language in which the consultation documents are published may also affect the achievement of enhanced transparency, and could potentially be problematic in relation to compliance and implementation, as some interested parties (in particular individuals) might not fully appreciate the relevance of the envisaged rules.

Similar observations regarding the question of knowledge and resources were also made in the cases of the EMA and the EFSA consultations. In the words of an EFSA respondent from a dieticians’ organisation, “one needs to be an expert [in order to comment], or at least have a certain background. The [EFSA consultation documents] are very technical; the EFSA is a scientific body” (Respondent #36). And again, one EMA respondent from a patients’ organisation recalled,

It is difficult to comment, because these are big documents. Some are really technical and some are complicated. [...] So as a patients’ representative you need to have knowledge, you need to have the negotiation skills, you have to be aware of the overall framework and then maybe you can find the way to make an impact somewhere, for a small part [of a consultation document]. Maybe not the rest, but we can comment here. So you have to know enough to find where you can make an impact. (Respondent #37)
In conclusion, the strict deadlines for consultations, the required knowledge, expertise and resources, as well as the provision of consultation documents in the English language only, may all present problems affecting the overall quality of deliberation and as a consequence, for the achievement of the previously identified promises of consultation.

7.3.3 Recognition: Exhaustive Feedback

The question is then: what happens with the comments received, and what is their impact? According to the Commission approach to consultations, the minimum standard is that the receipt of contributions needs to be acknowledged and that the results of open consultations need to be displayed online, linked to the “single access point”. In particular, depending on the number of comments received and the resources available, acknowledgement can be provided in the form of an individual or a collective response. In order to ascertain that the aims of consultation are achieved, agencies need to ensure that the comments are carefully analysed and provide proper feedback to the responding parties.

The agencies’ commitment to provide feedback is outlined to varying degrees in their internal policies on public consultations. According to the EBA Public Statement on Consultation Practices, the agency needs to give “due consideration to the responses received,” publish all responses (unless the respondent requests otherwise), and prepare a “reasoned explanation addressing all major points raised, as feedback to the consultation process.” Moreover, if the first round of consultation “reveals significant problems, or where the revised proposals are “radically different from the original proposals on which the consultation was based,” the EBA may decide to consult for a second time.

In practice, the EBA feedback on public consultations is incorporated into the final draft of technical standards, guidelines or recommendations. According to such documents, published on the EBA website, the agency provides a summary of all comments received and prepares a general response to public consultations. As further explained by one EBA official,

All the views expressed in the public consultations are carefully analysed and we prepare a general written feedback attached to the final draft standard or a guideline. There is a section in the finalised documents which is called a feedback statement of a consultation and that reflects the comments received. [...] Sometimes the comments are pretty much along similar lines, something that is common to more parties, so this is also summed up in

134 Ibid.
135 European Banking Authority (2012b), pp. 3-4.
136 Ibid, p. 4.
the feedback statement that we publish. Usually, the feedback statement does not go into each single case, each single comment, but provides a general review of the comments received and of the issues raised by different stakeholders or interested parties. And then the final document [i.e. draft technical standard, guideline or recommendation] of course takes the comments into account to the extent possible to improve the quality of rulemaking. (Respondent #9)

The EBA commitment to providing general responses to its public consultations can be perceived as enhancing the quality of deliberation and supporting the fulfilment of the identified promises of the EBA consultations (i.e. more informed outcomes, responsiveness, compliance and implementation, transparency and monitoring). In particular, it can be argued that in terms of feedback, the EBA consultation approach corresponds with the Commission’s minimum standards. Considering that proper feedback is indeed provided (as the consultation responses published on the EBA website attest), and moreover is available at the agency’s website at a “single access point” where everyone can access it, it can be argued that the EBA consultation approach corresponds with the Commission’s minimum standards. All in all, this promotes the promises of enhanced responsiveness and transparency in the EBA rulemaking.

In the case of the EASA public consultations, the EASA Rulemaking Procedure, adopted by means of a management board decision, specifically states the agency’s duty to ensure that the comments are reviewed “with the objective of improving the quality of the [agency’s] measures and ensuring fair and appropriate treatment of all comments received.” Moreover, the agency needs to review the comments received from the respondents and publish the outcome on the agency’s website. The so called “comment response document” needs to include a list of all parties that commented on a rule in question, as well as a summary of the comments received and the EASA’s responses.

The comment response documents published at a “single access point” on the EASA website reveal that the agency is in fact committed to providing thorough feedback. In fact, not only does the agency provide a general response to consultations, most of the time it also responds to every single comment received. This commitment was further elucidated by an EASA official:

I have to say that all comments received are looked really seriously at. We are spending hours and hours on these comments and you have to know that we receive up to 30 or 40 thousand comments on a certain rulemaking. And we have this whole machinery set up to look at the comments manually and discuss them and weight them objectively, because we need to balance different approaches. (Respondent #7)

Moreover, as observed by another EASA official,

138 European Aviation Safety Agency (2012a), Art. 7(1).
139 Ibid, Art. 7(3).
In principle, we look at all the comments and we never make a distinction between individuals or big companies as long as they give a valuable comment. But if for example, we have diverging views of the commentators, where one individual wants to go a certain way, but the majority of companies says “that is not good for competition reasons”, we go with the majority, because then the element of level playing field comes into focus. But in the domain of aviation safety we never make any differences between the comments received. (Respondent #2)

In addition to preparing a detailed response to public consultations, the EASA may also decide to organise a second round of consultations. According to the EASA Rulemaking Procedure, “if the comments received during the public consultation period indicate major disagreements with the proposed rule, or if the result of the review of the comments is that the revised text differs significantly from that circulated at the beginning of the consultation process, [the EASA] may consider further consultation with the stakeholders.” On the whole, it can be argued that in terms of acknowledgement and feedback, the EASA is committed to promoting the previously identified promises of consultation (i.e. more informed regulatory outcomes, inclusiveness and responsiveness, implementation and compliance, transparency and monitoring). The agency’s observance of self-imposed rules on public consultations, as well as consideration of all the comments received, may be interpreted as a practical manifestation of the promises of transparency, responsiveness of the EASA rulemaking, as well as, to a certain extent, inclusiveness (particularly in the sense of balancing different views).

The commitment to provide feedback on the outcome of public consultations is also evident with regard to the EFSA. The EFSA’s Approach on Public Consultations on Scientific Outputs states the following:

“In line with the principles of openness and transparency [the agency] recognises the importance of providing feedback on the outcome of consultation. The feedback should be provided during and at the end of the consultation process. Having collected comments submitted during a consultation, [the EFSA] commits to preparing a written report on the comments received addressing how these have been addressed by [the agency]. The report lists the number of comments received, summarises the main areas/themes of concern, specifies how these comments were considered by [the EFSA] and highlights if possible how the comments have been dealt with.”

The information available on the EFSA website indicates that the agency indeed publishes reports on the outcome of its consultation processes. Such responses include a full list of the comments received in the course of consultation, and for each and every comment, the agency’s reply to it. Moreover, the agency sorts the comments and responses into different sections (i.e. general and matter specific comments), which makes the response document understandable and easy to

141 European Aviation Safety Agency (2012a), Art. 7(5).
142 This corresponds with Craig’s (positive) view on the EASA consultations. See, P. Craig (2012), pp. 169-170.
143 See, European Food Safety Authority (2009), p. 7.
follow. The EFSA’s approach to the review of the comments and the formulation of feedback was also reflected upon by an EFSA official:

All comments submitted to [the agency] are carefully assessed by a specific unit within the Scientific Panel and [regarding their relevance] some are taken on board and some are not. When preparing a report [on the outcome of a public consultation] we go through all the comments and we see which are relevant. Then we provide a general report where we group all the comments and respond to them. (Respondent #20)

Considering that the EFSA de facto provides clear and detailed responses to its consultations and publishes them at a “single access point”, as envisaged in the Commission’s approach, one may argue that the agency maintains the quality of deliberation and is committed to supporting the fulfilment of the intended promises consultation. In particular, it appears that this agency approach is capable of promoting the promise of transparency, building trust and confidence in the EFSA (quasi-regulatory) operation, and ensuring that the EFSA scientific outputs are clear and effective, all of which were identified as the primary promises of the EFSA consultations.

Last, we should address the EMA approach to dealing with the comments received in public consultations. As provided for in the EMA Rulemaking Procedure, all comments received need to be carefully considered and discussed within the agency (e.g. by a rapporteur or a drafting group responsible for the development of a guideline) and systematically published on the agency website. Moreover, “if considered appropriate and in response to specific justified concerns or divergent views or upon request from interested parties, [the EMA] may convene a meeting with relevant interested parties to discuss aspects of a draft guideline.” Following the examination of the comments, the agency needs to prepare an overview of the main comments that explains the rationale behind their acceptance or non-acceptance and make it publicly available.

The response documents, published on the EMA website, reveal that the agency indeed provides detailed accounts of the comments received and explains how a particular comment was taken into account (e.g. acknowledged, accepted, partially accepted, not accepted). What is also clear is that whenever a comment is accepted, partially accepted or not accepted, the EMA provides concrete reasons why this is the case. Pertaining to this matter, an EMA official provided a more comprehensive account of how the agency deals with the comments received. In their own words:

Usually we issue a report identifying which comments we have received, we group them, and then present the outcomes: this comment was taken on board because it was considered relevant, this comment was not taken on board for these reasons, for instance because we have a legal obligation to behave in a certain way and so we cannot depart from legislation, or for reasons of irrelevance or whatever other reason we may identify.

146 Ibid.
147 Ibid.
In assessing the comments [...] we have to balance the interests of the commentators with the interest of the agency, with the feasibility of the solution, and with the proportionality of the exercise. So there are a lot of elements that are taken into consideration. But in the end we present the outcome of our public consultation. Usually, we also have an info day in the very first weeks after launching a public consultation and then another one at the end of the consultation procedure, additionally clarifying why some comments were taken on board, why we did not consider other comments and how we relied in the input received during the consultation. (Respondent #1)

Generally speaking, the evidence provided above exemplifies the EMA dedication to providing an exhaustive response to the comments received in the process of public consultations. As there is nothing in the empirical evidence that would suggest the agency’s departure from the self-imposed rules on public consultations, one may perceive that the EMA’s approach regarding the provision of feedback corresponds with the above-mentioned Commission minimum standards. Thus it can be argued with a considerable level of certainty that the EMA is committed to ensuring the overall quality of deliberation and the subsequent accomplishment of the identified promises of consultation: exploring and weighing possible solutions for developing a guideline and advancing the range of information relating to the factual situation of the proposed soft law measures.

7.3.4 Conclusion: Quality of Deliberation and the Promises of Consultation

The preceding sections shed light on the quality of deliberation with regard to public consultations of the four agencies under scrutiny. In particular, we explored three interrelated and mutually enforcing facets of consultation, namely access to information, commenting and recognition. Based on the examination of the established rules and the empirical evidence, we could observe the manner and the extent to which the promises of consultation are de facto fulfilled.

In general, the consultation arrangements envisaged in the EBA, the EASA, the EFSA and the EMA de facto resemble the Commission’s approach to consultations. First, it can be argued that the agencies’ rules and practices are compatible with the Commission’s general principle of coherence. We could observe that there is a considerable degree of consistency and transparency in the way the agencies conduct their consultations, and that they have included mechanisms for review of the comments and feedback in their consultation processes. Second, as evidenced by the rules and practices in place, the agencies’ consultations also coincide with the Commission’s minimum standards. Specifically, considering that all consultation documents need to follow a prescribed structure (e.g. a summary of the context, the objective of consultations and the issues open for commenting), it can be claimed that the agencies’ consultations correspond with the Commission’s standard of “clear content of the consultation process”. Furthermore, we could observe that all four agencies publish their consultation documents at the “single access point”, namely their websites, and thus ensure adequate awareness-rising publicity, which
means that their consultation arrangements are consistent with the Commission’s minimum standard of “publication”. Moreover, in most cases, the agencies allow as much or more time for public consultations as envisaged in the Commission’s minimum standard on “time limits for participation” (12 weeks). The only exception is the EFSA, where consultation periods are not formally prescribed. However, in this case the agency is bound to work within the deadlines specified in the request (e.g. by the Commission) to prepare a scientific opinion. It is assumed that this is in line with the Commission’s general principle of effectiveness, which stipulates that a principle of proportionality should be respected. This means that consultations need to be balanced against the agencies’ obligations to European institutions. Finally, the agencies’ consultation arrangements also correspond with the Commission’s minimum standard of “acknowledgement and feedback”. We have seen that all four agencies examined provide detailed responses (individual or collective) to consultations, which are subsequently published at the “single access point” on the agencies’ websites. Therefore, assessed against the Commission’s approach to consultations with interested parties, it can be argued that the agencies’ consultation mechanisms regarding the overall quality of deliberation do not depart significantly from the Commission’s commitments. Nevertheless, the empirical evidence revealed deficiencies of the quality of deliberation, most notably with regard to commenting, which may have negative consequences on the effective fulfilment of the promises of consultation.

On a critical note, the empirical data has shown that that whereas the agencies respect the prescribed timelines for consultations, the interested parties nevertheless struggle to formulate their comments in time. In particular, it is assumed that umbrella organisations, which have more resources and experience, will be in a better position and will be more effective than individuals who wish to comment on a consultation document. Furthermore, when strict deadlines are paired with the complexity of agencies’ consultation documents (which is usually the case) the whole situation may prove too demanding for an individual to engage in commenting. We could also see that respondents from interest organisations referred to the significance of possessing relevant resources, language skills, experience and in-house expertise in order to participate in agencies’ consultations. It can be inferred that, compared to interested organisations, an individual would be in a less advantageous position to effectively participate.\textsuperscript{149} All this points at shortcomings with regard to accomplishing the promises of consultation, especially inclusiveness, the range of relevant information received and transparency of agencies’ rulemaking, as the degree of the interested parties’ involvement could be considerably impaired and the views submitted on consultation documents might not be sufficiently representative. This indicates a recurring pattern of deficiencies in the fulfilment of the promises of consultation, which was already observed with respect to access. In this connection, it can be argued that the inherent shortcomings of access become even more apparent. While such pervasive “deficits” of inclusiveness and representativeness can be attributed to the nature of agencies’ rulemaking, and are therefore likely unavoidable, it would be beneficial if the agencies could provide a remedy. For example, as already suggested in terms of access, agencies could publish less technically demanding

consultation documents (e.g. summaries or simpler texts), which would attract a wider spectrum of commentators. It is believed that this would improve not only the promise of inclusiveness and the range of information available to the agencies, but would also increase agencies’ responsiveness to interested parties and enhance the transparency of their rulemaking towards “weaker” interests. Another solution would be to prolong the consultation deadlines, to the extent possible, so that individuals would have sufficient time to connect with the umbrella organisations which could help them increase their chance of effectively providing comments.

In conclusion, the result is that the “public” consultations of the EBA, the EASA, the EFSA and the EBA exhibit generic shortcomings in the sense that they promote participation of those interested parties who have more resources, more knowledge and more experience of commenting. While it may be argued that the agencies’ consultation arrangements were never meant to go beyond the more “relevant” interests, this is still an interesting insight into interested parties’ participation. In particular, scholars often argue in favour of broader access to participation, more spaces for public deliberation and further regulation (proceduralization) of public consultations, but take the quality of deliberation (i.e. the actual influence that participation can make in the end) out of the equation.150 The above makes clear that even where adequate formal mechanisms for public consultations are in place (e.g. relatively open and unrestricted consultations, adequate deadlines and information, provision of feedback, etc.), the overall quality of deliberation may be insufficient in practice (in relation to what is formally envisaged) and the fulfilment of the primary promises of consultation may be hindered.

150 See Chapter 1, Sections 1.2 and 1.3.