EXTERNAL SCIENTIFIC REPORT

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# Impact Assessment of Specific Measures Aimed at Increasing Transparency and Engagement in EFSA Risk Assessment Process[1]

## RAND Europe and VVA Consulting, with ADAS[2]

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## Abstract

The European Food Safety Authority (EFSA) was asked by its Management Board in 2015 to assess the impact of measures to promote trust and confidence in EFSA's risk assessment process under the Transparency and Engagement in Risk Assessment (TERA) project. EFSA commissioned this study in 2015 to develop a methodology that could be applied to the measures identified in the TERA project and conduct a full appraisal on a sub-set of measures. Thirty-five measures were defined and preliminary costs and benefits were identified through desk research and interviews with 41 EFSA staff members. A full impact appraisal was undertaken for nine measures based on an additional 50 interviews with EFSA staff members, Scientific Committee and Panel Members, Member State representatives, industry representatives, non-governmental organisation (NGOs) and consumer group representatives, and academics. Multi-criteria Mapping (MCM) was used to assess seven of the measures. The results show that measures on framing the mandate, consultation on risk assessment methods, consultation on data, publishing meeting minutes, and transparency through the weight of evidence approach were generally assessed optimistically and there was agreement among interviewees on the implementation approach. These measures could be pursued by EFSA. Commenting on opinions could result in increased transparency and use of evidence, but there was no agreement on the implementation approach. EFSA could conduct a feasibility study for this measure. Publishing application information and proactive release of data were supported by most respondent groups but industry stakeholders expected this measure to perform poorly compared with the other measures. Pre-submission engagement with applicants received widely divergent views about implementation and likely impacts. EFSA should investigate this issue through active engagement with industry to determine whether there is sufficient support to warrant the expenditure. Overall, MCM offers an open and transparent way to compare the different conditions and framings that are likely to affect performance of the measures should they be implemented in line with the TERA objectives.



**Key words:** transparency, engagement, risk assessment, multi-criteria mapping

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[2] With support from ADAS, UK.

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## Summary

EFSA has carried out a series of initiatives since 2005 aimed at increasing transparency and engagement with its stakeholders and transforming EFSA into an 'Open Science' organisation. The initiatives were brought together in 2015 under the Transparency and Engagement in Risk Assessment (TERA) project. The present study was undertaken as part of the TERA project.

The main objective of the study was to assess the impact of a set of measures identified by EFSA to promote trust and confidence in EFSA's risk assessment process. The specific objectives as detailed in the Terms of Reference were to develop an impact assessment methodology that could be applied to 35 potential measures that were identified by EFSA and its stakeholders in earlier phases of the TERA project and to conduct a full impact assessment on a sub-set of prioritised measures.

There were two stages to the study: the definition of the measures and the impact appraisal. In the first stage, the study team defined 35 different measures that were pre-selected by EFSA based on desk research and 17 face-to-face (individual/group) and nine telephone interviews with 41 EFSA staff members.

In the second stage, the study team assessed the impacts of the proposed measures. First, the study team conducted a preliminary appraisal for each of the 35 proposed measures for EFSA to use as the basis for a full impact assessment after the conclusion of the present study. Second, the study team undertook a full impact appraisal for a sub-set of nine measures (two of which were combined into one measure). The nine measures were divided into two categories: those that had a high anticipated cost versus those with a medium or low anticipated cost. Two measures were selected for a light touch appraisal: publishing meeting minutes, and transparency through the weight of evidence approach, primarily using a qualitative assessment. Seven measures were selected for an in-depth appraisal using Multicriteria Mapping (MCM): framing the mandate, pre-submission engagement with applicants, consultation on methods, consultation on data, proactive release of data (combining two measures – release of data during and after risk assessment), publishing application information, and commenting on opinions. The full impact assessment was based on 50 additional interviews with EFSA staff members, Scientific Committee and Panel Members, Member State representatives, industry representatives, non-governmental organisation (NGO) and consumer group representatives and academics. MCM is a form of multicriteria analysis that was used to identify quantitative and qualitative impacts of the measures. It is a software-assisted technique used to assess different options, in this case the seven measures that underwent in-depth assessment. The assessment was done through analysing the respective strengths and weaknesses of different options under participant-defined, evaluative criteria. The criteria were pre-defined by the study team; they were transparency, use of evidence and costs.

The impact analysis showed that framing the mandate, consultation on risk assessment methods, consultation on data, publishing meetings minutes, and transparency of the weight of evidence approach were generally assessed optimistically by interviewees and there was agreement among them on the implementation approach. These measures could be pursued by EFSA.

Framing the mandate was the most positively assessed by all six groups of respondents. It would increase transparency and improve use of evidence potentially resulting in a clearer and better-framed mandate. Consultation early in the process would help make the rest of the process more visible to stakeholders. EFSA would need to consider processes of documenting and communicating the outcome of the public consultation and how the Authority considered feedback provided to stakeholders. The use of evidence could also be improved with this measure by helping to identify weaknesses in the risk assessment questions and data sources and/or gaps early in the process. Costs of this measure would mainly fall on EFSA, but would be relatively low if restricted to self-tasking. Benefits are likely to outweigh costs for this measure provided that EFSA ensures a transparent process.

Consultation on risk assessment methods would be effective at improving the use of evidence and ensuring that EFSA draws on the latest and the best expertise available for risk assessment methods.

A discussion on the most appropriate risk assessment methodologies at the beginning of the work of the working group is likely to add scientific value and robustness to the rest of the process. The measure could contribute to increased transparency under the condition that EFSA documents the criteria for experts selected to participate in a targeted consultation, the outcome, and the justification and criteria for accepting comments. This measure would be limited to particular cases and so would not be used frequently and the groups of people who would contribute would be small. Costs for attending expert meetings would most likely be borne by EFSA. Potential cost savings may arise in the long run if the most appropriate methods are used and accepted by stakeholders. The extent to which benefits outweigh costs will depend on EFSA's ability to target the most relevant experts to participate in the consultation. Benefits should outweigh costs if EFSA can ensure that they capture the most relevant expertise and ensure a transparent and well-documented consultation process for non-participants.

Consultation on data would improve EFSA's access to, and use of, evidence by improving and widening the evidence-base used in risk assessments. The measure could help to avoid inconclusive opinions and make opinions more robust. EFSA would need to consider how to implement procedures that would enable trust in the source and quality of the data received and that the data received through the call would be structured in a useful way that would facilitate the risk assessment and not delay it. Transparency would also improve with the measure, at a minimum by disclosing data gaps, regardless of the results of the call. Transparency could be greater if EFSA disclosed the data source and how data were assessed and used. Benefits should outweigh costs if EFSA can have a relatively high degree of trust in the data and use the data efficiently in the risk assessment process, without considerable time spent on data cleaning, checking and transformation. Stakeholders identified potentially high costs for data collection, cleaning, transformation and evaluation in cases where a call was applicable to their own areas of interest/research, or for Member States where they collect data on a relevant issue. Academics, NGOs and consumer groups have relatively fewer resources at their disposal to contribute to a call compared with other groups.

Publishing meeting minutes was relatively uncontroversial, although there are a few considerations for EFSA to make if it chooses to implement the measure. First, Panel Members may feel that they are unable to express their views freely and they may be less willing to express divergent views compared with the current situation. Second, EFSA will need to take any commercially sensitive information discussed into account and ensure that this information is not conveyed through the minutes.

Transparency through the weight of evidence approach could contribute to increased transparency of the entire EFSA risk assessment process from problem formulation to evidence synthesis. This would provide stakeholders with better insight into EFSA's work and an understanding of the quality, reliability and relevance of data and how it was used during the evidence assessment. It could also improve the use of evidence and ensure a consistent approach and harmonisation across EFSA's scientific outputs. There were no major implementation costs or ongoing costs associated with this measure.

Commenting on opinions could result in increased transparency and use of evidence, but there was no agreement on the implementation approach. EFSA could conduct a feasibility study for this measure. Publishing application information and proactive release of data in general risk assessment were supported by most respondent groups but industry stakeholders expected this measure to perform poorly compared with the other measures.

Proactive release of data during general risk assessment received divergent views on its potential contribution to improved transparency and use of evidence among respondent groups. The measure could contribute to improvements in the ability of the public to scrutinise how EFSA reaches its conclusions under the condition that data is made available publicly. Improved transparency would also depend on whether data were accompanied by explanatory notes and background information. This measure is likely to imply moderate costs to EFSA under the condition that the release of data can be implemented in an automated way. The extent to which benefits outweigh costs will depend on how data ownership issues are resolved. Member State representatives identified potential high

indirect economic impacts if national data were misused. Industry identified potential indirect economic impacts associated with this measure due to competition and market distortion concerns.

Publishing application information was also positively assessed by all stakeholder groups with the exception of industry respondents. It would be most effective at improving transparency in EFSA's risk assessment process related to regulated products and thereby establish trust and confidence in the conclusions reached. Performance under this criterion will depend on how commercially sensitive data will be defined and redacted. The measure could also help to contribute to the better use of evidence by allowing for greater data availability, which may spur innovation and scientific progress. This measure is likely to imply higher costs to EFSA than publishing data for general risk assessment due to the need to go through application data to remove only data that should be considered confidential and ensure that no confidential data is accidently released. The extent to which benefits outweigh costs will depend on how EFSA resolves issues related to confidentiality of application data. Benefits should outweigh costs if EFSA can ensure that the applicant's right to confidentiality is balanced with other stakeholder groups' requests for transparency. Industry interviewees identified potentially high costs for themselves and potential indirect economic impacts associated with this measure due to competition and market distortion concerns.

Commenting on opinions could improve transparency generally where EFSA provided an organised response to comments; that is, simply providing an opportunity for comments will be insufficient for improving transparency without engagement from EFSA. The measure could also improve EFSA's use of evidence where commenting identifies gaps, uncertainties and/or errors or inaccuracies in the opinion. The measure could also improve future risk assessments through learning from the comments on previous opinions. The potential costs to EFSA from this measure are high, particularly as the measure is likely to be most supported where EFSA engages with the comments in a structured way. There is a high degree of divergence among respondent groups about the best approach to implementation and, as a result, uncertainty about the degree to which it could improve transparency and use of evidence. As a result, no conclusion can be drawn about the efficiency of the measure.

Pre-submission engagement with applicants received widely divergent views about implementation and likely impacts. This measure could improve transparency for applicants in particular, but would not improve transparency more generally (i.e. for non-applicants). It could also improve EFSA's use of evidence by decreasing uncertainty regarding the evidence applicants need to provide to EFSA in order to meet the requirements, which could improve the quality of application data as well as the risk assessor's understanding of the data and its limitations. However, pre-meetings could introduce bias between EFSA and the applicant that would negatively affect the use of evidence in the assessment. EFSA is also likely eventually to request the information, so it does not necessarily expand available evidence, but rather make it available sooner and thus more efficiently. The costs will be very high to EFSA if the measure involves pre-meetings for every application. If industry paid for part or all of the costs, it could be more feasible. The measure would be efficient for industry because, despite the meeting costs, the opportunity could result in greater efficiency for assessing applications under the assumption that the resulting information about what information EFSA requires to make a decision would lead to fewer stop-the-clock procedures and rejections. Opposition to the measure by non-industry stakeholders and the potential risks to EFSA's reputation by appearing biased towards industry could outweigh any benefits to EFSA through cost effectiveness achieved by reducing the amount of time needed to assess applications. Guidance documents were actively considered to be unhelpful by industry representatives and therefore may be a waste of EFSA resources. EFSA should investigate this issue through active engagement with industry to determine whether there is sufficient support to warrant the expenditure.

MCM allows issues that are important to stakeholders to be raised and robustly assessed and compared with others, which makes it easy to implement across a range of issues. The method is time-consuming, however, and requires appropriate resources. EFSA would need to prioritise those measures that merit a more detailed assessment. Overall, the information and data elicited using MCM provided a rich and highly nuanced picture for EFSA of the different conditions and framings that are likely to affect performance of the measures should they be implemented, and take into account these

views when considering how to implement them in order to become a more transparent and open organisation.

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# 1. Introduction

This contract was awarded by EFSA to: RAND Europe and VVA Consulting.

Contractor: RAND Europe and VVA Consulting, with ADAS, UK.

Contract title: Impact Assessment of Specific Measures Aimed at Increasing Transparency and Engagement in the EFSA Risk Assessment Process

Contract number: RC/EFSA/SCER/ 2015/01 – implementing Framework contract No SANCO/2012/02/011

EFSA has invested in openness and transparency as part of its role to provide risk assessments and communication on the food supply chain. The Authority has carried out a series of initiatives since 2005 aimed at increasing transparency and engagement with its stakeholders. In 2015, all of the initiatives and related activities required to transform EFSA into an 'Open Science'[3] organisation were brought together under the Transparency and Engagement in Risk Assessment (TERA) project. The present study[4] was undertaken as part of the TERA project with the objective of assessing the impact of a set of measures identified by EFSA to promote trust and confidence in EFSA's work among partners and stakeholders through increased transparency and engagement during the risk assessment process. The specific objectives of the study were to develop an impact assessment methodology that could be applied to 35 potential measures that were identified by EFSA and its stakeholders in earlier phases of the TERA project and to conduct a full impact assessment on a sub-set of prioritised measures.

The measures that were assessed in this study relate to different types of EFSA risk assessment activity and occur at different stages in the risk assessment process. Risk assessment involves three main stages: request, assessment and adoption. The first stage is a request for scientific advice or a decision by EFSA to undertake self-tasking. During the second stage, EFSA sets up an expert working group and undertakes the risk assessment. Finally, the assessment is adopted at a Panel meeting, or sent back to the working group for further consideration. The measures assessed in this study were designed to improve transparency and engagement at each stage.

# 2. Data and Methodologies

There were two main stages to the study: the definition of the measures, and the impact appraisal. In the first stage, the study team defined 35 different measures that were pre-selected by EFSA. The measures were defined based on desk research and 17 face-to-face and nine telephone interviews with a total of 41 EFSA staff members.

In the second stage, the study team assessed the impacts of the proposed measures at two different levels. First, the study team conducted a preliminary appraisal for each of the 35 proposed measures for EFSA to use as the basis for a full impact assessment after the conclusion of the present study.

Second, the study team undertook a full impact appraisal for a sub-set of nine prioritised measures. The measures were divided into two categories: those that had a high anticipated cost versus those with a medium or low anticipated cost. Two measures were selected for a light-touch appraisal, primarily using a qualitative assessment: publishing meeting minutes and transparency of the weight of evidence approach. Seven measures were selected for an in-depth appraisal using Multicriteria Mapping (MCM): framing the mandate, pre-submission engagement with applicants, consultation on methods, consultation on data, proactive release of data for general risk assessment (combining two

[3] Open Science represents an evolution in the way research is conducted, with a move towards increased transparency, collaboration, communication and participation. EFSA has developed a plan for the transformation of the Authority into an 'Open EFSA' (EFSA 2014b). The move to increased openness is also in line with European Commission policy on both Open Science (EC 2015a) and open government (EC 2015b)

[4] 'Impact Assessment of specific measures aimed at increasing transparency and engagement in the EFSA Risk Assessment process' (RC/EFSA/SCER/2015/01). The study was commissioned by EFSA and was delivered by RAND Europe and VVA, Consulting with the support of ADAS, UK.

measures – release of data during and after risk assessment), publishing application information, and commenting on opinions. The full impact assessment was based on 50 additional interviews with EFSA staff members, Scientific Committee and Panel Members, Member State representatives, industry representatives, non-governmental organisation (NGO) and consumer group representatives and academics.

MCM is a form of multicriteria analysis that was used to identify quantitative and qualitative impacts across the measures. MCM is a software-assisted technique used to assess different options, in this case seven measures that underwent in-depth assessment. The assessment is done through analysing the respective strengths and weaknesses of different options under participant-defined, evaluative criteria.

MCM is distinct from other decision analysis techniques of this type in that its aim is not to identify a best decision, but instead to identify the different underlying reasons, or criteria, that influence people's perceptions of the relative performance of different options (Stirling 1997, 1998; Stirling and Mayer 2001). The result of an MCM assessment is qualitative and quantitative information that illustrates the conditionalities and framings associated with each perspective on the measures. This information takes the form of 'sensitivity maps', which are presented as performance ranking charts that are evaluated by the analyst to identify key features of the perceived performance of different measures under different conditions and by different groups.

An MCM exercise typically has five stages:

**Stage 1 – choosing options:** The agreed list of seven measures to evaluate was established. Each of the measures was expanded and clarified by the study team. These seven measures formed the 'core' options presented to every interviewee.

**Stage 2 – developing criteria:** Criteria are the principles by which the measures were judged. Due to the complex nature of the exercise, the large number of interviewees across the European Union, and the relatively large number of measures to be evaluated, the study team pre-defined three evaluative criteria that interviewees were given the option to use, re-interpret or set aside. The three criteria were: transparency, use of evidence and costs. Interviewees were free to define their own criteria and/or add to the definition of the study team's suggested criteria.

**Stage 3 – scoring the measures:** During this stage, each measure was evaluated by the interviewee according to how well it was deemed to perform under each criterion defined in the previous stage. The performance assessments reflect the extent to which each measure would allow an individual criterion to be fulfilled under optimal (optimistic) and non-optimal (pessimistic) assumptions and conditions and interviewees were asked to give maximum and minimum scores, respectively (usually on a scale of 1 to 10).

**Stage 4 – weighting the criteria:** In the weighting stage, the interviewee assessed the relative importance of each criterion against the others. These weightings, together with the scores, determined the final performance rankings of each of the measures evaluated.

**Stage 5 – reflecting on outcome:** The final 'map' of performance rankings drew together technical judgements of option performance, uncertainties and priorities concerning the relative importance of each criterion and was discussed with each interviewee to confirm that it represented their views on the measures.

## 3. Assessment and Results

Empirical analysis of respondent perspectives by the study team was informed both by the performance rankings and underlying framings as expressed by interviewees in detailed assessments of the measures. The performance rankings of each measure are presented first, followed by qualitative analysis. Figure 1 provides a mock version of the MCM performance ranking chart that is provided for the measures in the analysis. The figure shows the performance of a hypothetical measure across the different respondent groups. The respondent groups are presented along the y-axis, and the x-axis provides a relative scale of performance from low to high (or minimum to

maximum). The bars represent the aggregated range of option performance as expressed during the interview, where the further the ranking range extends to the right, the better an option's performance was deemed to be by interviewees. The extreme lower and upper ends of the ranking ranges for each measure are represented as the means respectively of the pessimistic (minimum) and optimistic (maximum) rankings obtained in each case.[5]

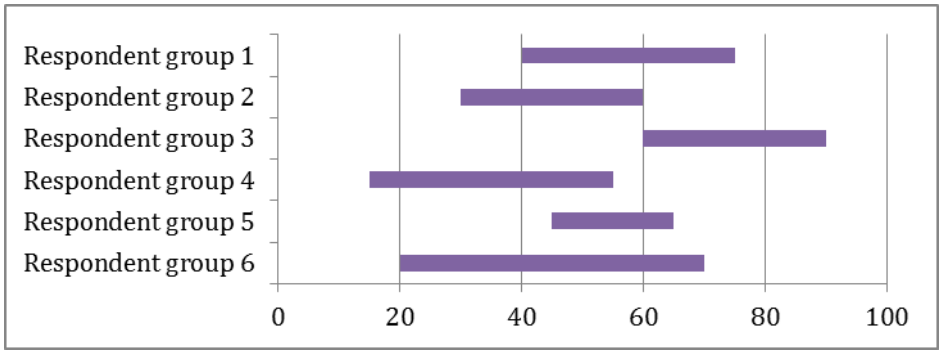


**Figure 1: Example of a performance ranking chart**

The horizontal scale is normalised in all of the performance ranking charts for each measure such that the maximum value on the x-axis indicates an option that scored consistently highest in every interview under all possible criteria, while a value of zero indicates that an option scored consistently lowest in every interview under all possible criteria.

These numbers should be thought of as a guide for minimum and maximum assessments, rather than as strict numerical values. MCM is firstly a qualitative interview method, which makes use of a structured quantitative assessment process. Despite the presentation and reference to the performance charts throughout the analysis, it is the qualitative interpretation of the charts as provided in the supporting text that is most important. In the discussion, the charts illustrate for the reader whether respondents provided assessments that were relatively high or relatively low. This relative assessment of 'high' or 'low' is not based on numerical values *per se* but on visual patterns and the analyst's understanding of the qualitative assessments provided by interviewees.

Within the MCM analysis package it is also possible to explore different features of the scoring, such as the relative use of uncertainty and ambiguity between individual respondents. Analysis of uncertainty provides insight into how individuals within a respondent group made use of a large or small range for their scores. Ambiguity illustrates how individuals within a respondent group differed in their scoring. Uncertainty and ambiguity results are highlighted where relevant to provide additional context.

## 3.1. Measure 1: Framing the mandate

The first measure assessed by the study team involved consultation and engagement with stakeholders on framing the mandate on issues of high public interest. EFSA receives requests for scientific advice from the Commission, Parliament and Member States and undertakes scientific work on its own initiative (self-tasking). The first stage in the risk assessment process on receipt of a request or upon self-tasking is to frame the mandate. EFSA does not engage in dialogue with stakeholders during the framing of any mandates. EFSA is considering whether to engage with stakeholders on framing the mandate for specific requests and some self-tasking where there is likely to be high public interest. Stakeholder engagement could take the form of a public consultation, meetings with interested stakeholders, or other methods. The stakeholder engagement could be open to any interested parties. EFSA could provide details about the consultation on its website.

[5] It is possible to view the extrema for each bar, in addition to the ranked means. Due to limitations of the software package, however, this cannot be displayed by measure.

Overall, this measure was one of the most positively assessed by all six respondent groups in that when compared across all the measures, this measure was more consistently thought to have the potential to perform well. The normalised optimistic scores across all the aggregate assessments were over 70 base points, a feature that no other measure shared (Figure 2). This indicates that overall there was agreement across all stakeholder groups that this measure had strong potential to perform well under optimistic conditions. The measure was most positively viewed by Member State representatives, NGO and consumer group representatives, and academic representatives, as these groups offered the highest optimistic scores and associated conditions for successful implementation of the option that satisfied all the associated qualitative criteria.

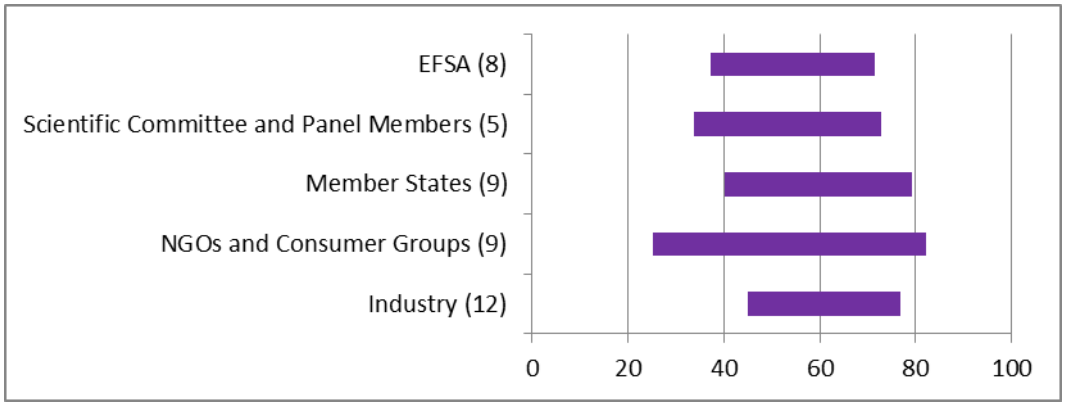


**Figure 2: Measure 1 (M1) overall assessment under all evaluative criteria**

The assessment of the measure is also notable for the convergence of views under the assessment as evidenced by the overlap and similar pattern of scoring across all perspectives. Overall, respondents agreed with the basic premise of the measure's expected outcome, which is that consultation on the framing of the mandate may lead to better formulated risk assessment questions and increase transparency of the process.

The measure would increase transparency and improve use of evidence, potentially resulting in a clearer and better-framed mandate. Consultation early in the process would help make the rest of the process more visible to stakeholders. EFSA would need to consider processes of documenting and communicating the outcome of the public consultation and how the Authority considered feedback provided to stakeholders. The use of evidence could also be improved with this measure by helping to identify weaknesses in the risk assessment questions and data sources and/or gaps early in the process.

There are different ways that the measure could be implemented. Interviewees thought EFSA could consider public online consultations and/or physical meetings with stakeholders. Open consultation would be the most transparent and cost-effective implementation option, both for EFSA and stakeholders. Issues that are highly technical and complex may benefit from face-to-face discussions rather than commenting and in these instances EFSA could consider organising a physical meeting. This measure would be most feasible in terms of self-tasking. Costs of this measure would mainly fall on EFSA, but would be relatively low if restricted to self-tasking. Benefits are likely to outweigh costs for this measure providing that EFSA ensures a transparent process.

## 3.2. Measure 2: Pre-submission engagement

The second measure considered during the MCM analysis involved pre-submission engagement with industry for market authorisation requests through either applicant pre-meetings or publication of pre-submission guidance. EFSA receives requests for market authorisations from industry. Prior to receipt of the application dossier, EFSA does not offer pre-submission meetings with applicants. EFSA is considering whether to offer pre-submission support to applicants by conducting pre-meetings with

applicants and/or developing more detailed guidance documents on the preparation and presentation of applications. EFSA would make guidance documents available to the public.

Overall, pre-submission engagement received divergent assessments among the six groups of respondents (Figure 3).

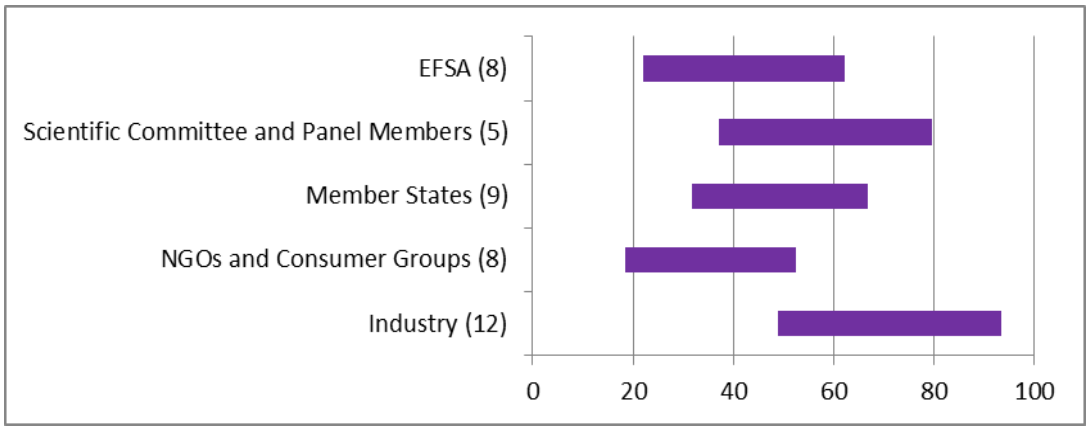


**Figure 3: Measure 2 (M2) overall assessment under all evaluative criteria**

Compared with the other respondent groups, the measure received the highest overall assessment from industry of 94 base points and the highest pessimistic assessment of 49 base points. Scientific Committee and Panel Members optimistically assessed the measure at 80 base points and pessimistically at 37 base points. Conversely, the measure was least favoured by academics, NGO and consumer group representatives and EFSA representatives, receiving the lowest pessimistic assessment of 15 base points, 18 base points and 22 base points respectively, and the lowest optimistic assessment of 56 base points, 52 base points and 62 base points, respectively. The pattern of the rankings shows that there was disagreement on the potential for this measure to perform well and relatively limited overlap within the assessments, and hence limited opportunities for synergies between different implementation conditions across respondent perspectives.

Optimistic and pessimistic assessments generally reflected whether the respondents preferred implementation of the measure to involve case-by-case meetings with individual applicants or guidance documents (and in some cases, a high-level meeting with multiple industry representatives from the same sector). Industry and Scientific Committee and Panel Member respondents mostly preferred individual meetings and so their optimistic assessments were focused on this option, whereas other groups mostly preferred guidance documents (or sector-based meetings). Thus, interpretation of the assessments by the study team for this measure considered that optimistic assessments from non-industry respondents were predominantly based on an assumption that this would involve guidance documents, not meetings. As a result, the differences between optimistic and pessimistic assessments might even be greater than the overall results suggest. The more detailed analysis of ambiguity confirms this hypothesis, as it showed that ambiguity was greatest for industry respondents for this measure, indicating there was a greater proportion of different scores given for this measure within the respondent group than for other measures. Scientific Committee and Panel Members also expressed a high level of ambiguity for this measure, as well as a higher average degree of uncertainty expressed across the group.

This measure could improve transparency for applicants in particular, but would not improve transparency more generally (i.e. for non-applicants). Applicants would benefit from greater transparency about the application and risk assessment process and associated evidence requirements. EFSA, however, could be negatively impacted by appearing biased or too close to industry. Industry representatives generally opposed any publication of information regarding the meetings, including basic information about the meeting having taken place, which limits the options available to EFSA to correct against this potential negative impact. Guidance documents and/or sector-based meetings could be more transparent than individual meetings with applicants.

This measure could improve EFSA's use of evidence by decreasing uncertainty regarding the evidence applicants need to provide to EFSA in order to meet the requirements, which could improve application data quality as well as the risk assessor's understanding of the data and its limitations. However, pre-meetings could introduce bias between EFSA and the applicant, which would negatively affect the use of evidence in the assessment. EFSA is also likely eventually to request the information, so it does not necessarily expand available evidence, but rather makes it available sooner and thus more efficiently.

The costs will be very high to EFSA if the measure involves pre-meetings for every application. Given the large number of applications, the costs could be untenable if borne by EFSA alone, but if industry paid for part or all of the costs, it could be more feasible. The measure would be efficient for industry because despite the meeting costs, the opportunity could result in greater efficiency for assessing applications under the assumption that the resulting information about what information EFSA requires to make a decision would lead to fewer stop-the-clock procedures and rejections. It would also potentially save costs for industry by avoiding unnecessary experiments.

Opposition to the measure by non-industry stakeholders and the potential risks to EFSA's reputation by appearing biased towards industry could outweigh any benefits to EFSA through cost effectiveness achieved by reducing the amount of time needed to assess applications. Guidance documents were considered to be unhelpful by industry representatives and therefore may be a waste of EFSA resources. EFSA should consult with industry before pursuing this approach to determine whether there is sufficient support to warrant the expenditure.

## 3.3. Measure 3: Consultation on risk assessment methods

The third measure assessed by the study team involves consultation on risk assessment methodologies. During the evidence assessment by the EFSA working groups, EFSA does not hold open or targeted consultations on the risk assessment methodologies to be used in individual risk assessments. EFSA is considering whether to conduct consultations with stakeholders on risk assessment methodologies for issues of high public interest. EFSA could undertake different strategies to engage with stakeholders on determining appropriate ways to conduct the risk assessment. For example, EFSA could launch an open or a targeted consultation. The consultation and its outcome could be published on EFSA's website.

Overall, consultation on risk assessment methodologies was assessed positively by all six groups of respondents. The measure was assessed most favourably among academia (90 base points, not shown) and second highest overall among EFSA representatives (85 base points) (Figure 4). Industry, Member State and NGO and consumer group representatives also assessed the measure relatively favourably (close to 80 base points). The measure was scored the lowest by Scientific Committee and Panel Members under an optimistic scenario (60 base points). The relatively greater range of uncertainty expressed by Member State and NGO and Consumer Group representatives indicates that the measure may not perform well under sub-optimal conditions, and indeed overall this measure had one of the highest average degrees of uncertainty and relative ambiguity for Member State representatives of all the measures, as well as NGO and consumer group representatives.

Targeted rather than open calls for expert input were the most likely approach to ensure that the consultation would yield useful results due to the highly technical issues involved. Focus groups and physical meetings would be the mostly likely approach to implement this measure. A tiered approach could also be considered by first launching an expert consultation and then opening up the process to all interested stakeholders. EFSA should consider implementing the measure on an ad hoc basis for issues of high public interest or areas of emerging science.

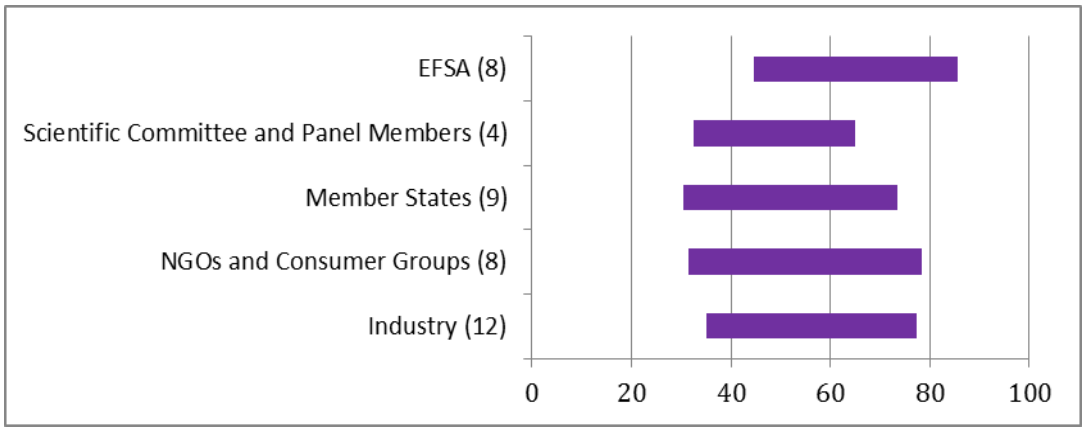


**Figure 4: Measure 3 (M3) overall assessment under all evaluative criteria**

This measure would be most effective at improving the use of evidence and ensuring that EFSA draws on the latest and the best expertise available for risk assessment methods. A discussion on the most appropriate risk assessment methodologies at the beginning of the working group is likely to add scientific value and robustness to the rest of the process. The measure could contribute to increased transparency under the condition that EFSA documents the criteria for experts selected to participate in a targeted consultation, the outcome and the justification and criteria for accepting comments.

This measure would be limited to particular cases and so would not be used frequently and the groups of people who would contribute would be small. Costs for attending expert meetings would most likely be borne by EFSA. Potential cost savings may arise in the long run if the most appropriate methods are used and accepted by stakeholders. The extent to which benefits outweigh costs will depend on EFSA's ability to target the most relevant experts to participate in the consultation. Benefits should outweigh costs if EFSA can ensure that they capture the most relevant expertise and ensure transparent and well-documented consultation processes for non-participants.

External stakeholders identified potentially low costs for themselves to engage in and contribute to a consultation on methodologies. Member States identified staff time as the highest cost associated with the measure. NGOs and consumer groups assessed the measure the lowest due to the relatively fewer resources available to contribute to a call compared with other groups.

## 3.4. Measure 4: Consultation on data

The fourth measure considered during the MCM analysis involves consultation on missing data when a gap has been identified during the work of the working groups to prepare the scientific advice. EFSA conducts ad hoc consultations when a gap in evidence has been identified. EFSA is considering whether to publish calls for data and information in those cases where a gap has been identified in order for the working group to complete the risk assessment. EFSA could publish an open or targeted call for data with details available on its website. The consultation and its outcomes could be published on EFSA's website.

Consultation on missing data was assessed similarly, and positively, across all six groups of respondents. The rankings show a significant amount of overlap, particularly at the positive end of the assessment, across all six respondent groups. The measure was most optimistically assessed among EFSA representatives and Member State respondents (more than 85 base points) and second highest among Scientific Committee and Panel Members and industry representatives (more than 70 base points) (Figure 5).

However, EFSA and Member State respondents also expressed the greatest degree of ambiguity for this measure against all the others, reflecting differences in the conditions under which individuals in the group thought this measure might perform well or not. NGO and consumer group respondents assessed the measure the lowest among the different groups, as seen by both the lowest optimistic

assessments (70 base points) and the lowest pessimistic assessment (29 base points). This is due to the pessimistic assessment on the use of evidence and cost. Academic representatives assessed this measure relatively high but showed the greatest range of uncertainty about the performance of the measure.

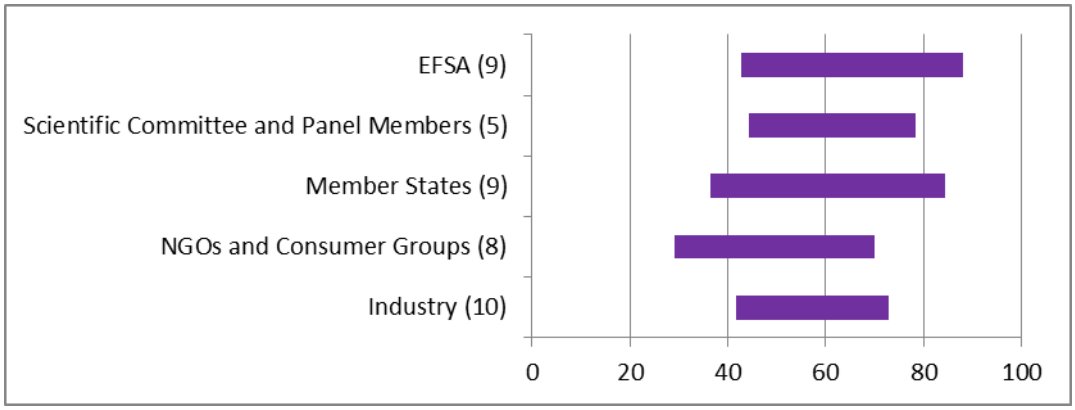


**Figure 5: Measure 4 (M4) overall assessment under all evaluative criteria**

Targeted rather than open calls for data were the most likely approach to ensure that data gaps are closed due to the specific data required. Open calls may be appropriate in specific cases, and could be decided on an ad hoc basis. A tiered approach could be considered, that is, applying a targeted call first and then extending to an open call if the targeted approach does not yield the required data.

The measure would improve EFSA's access to, and use of, evidence by improving and widening the evidence-base used in risk assessments. The measure could help to avoid inconclusive opinions and make opinions more robust. EFSA would need to consider how to implement procedures that would engender trust in the source and quality of the data received and that the data received through the call would be structured in a useful way that would facilitate the risk assessment and not delay it. Transparency would also improve with the measure, at a minimum by disclosing data gaps, regardless of the results of the call. Transparency could be greater if EFSA disclosed the data source and how data were assessed and used.

Benefits should outweigh costs if EFSA can have a relatively high degree of trust in the data and use the data efficiently in the risk assessment process, without having to spend considerable time on data cleaning, checking and transformation. Stakeholders identified potentially high costs for data collection, cleaning, transformation and evaluation in cases where a call was applicable to their own areas of interest/research, or for Member States where they collect data on a relevant issue. Academics, NGOs and consumer groups have relatively fewer resources at their disposal to contribute to a call compared with other groups.

## 3.5. Measure 5: Proactive release of data

The fifth measure assessed by the study team involves the proactive release of data used in the general scientific risk assessment during or after the preparation of scientific advice by the EFSA working groups. Disaggregated data and information used in the preparation of advice is not publicly available. EFSA is considering whether to publish all information used in the risk assessment during the evidence assessment. The data and information could be made available to all stakeholders through EFSA's website or to a sub-set of stakeholders through EFSA's Data Warehouse.

Proactive release of data received a wide range of scores across the six groups of respondents. The measure was most optimistically assessed by Member State, NGO and consumer group, and EFSA representatives, with all three optimistic assessments exceeding 80 base points (Figure 6). This measure was one of the most positively assessed under optimistic conditions for all three groups. Industry assessed this measure the lowest overall (range of 16 base points to 36 base points) with a

small range of uncertainty (20 base points). In addition, the measure was the most pessimistically assessed across all measures for Scientific Committee and Panel Members, with a pessimistic normalised assessment of 22 base points, although this group expressed a greater range of uncertainty than industry indicating that the measure could potentially perform well under the right conditions. Overall, there was a relative lack of synergy between the assessment of those in industry and those in the other respondent groups. With the exception of the Scientific Committee and Panel Members and to a lesser extent, academics, there was very little overlap between the measure assessments. This pattern of rankings is not often seen in an MCM assessment; the lack of overlap is unusual because common ground between perspectives is brought out in the assessment.

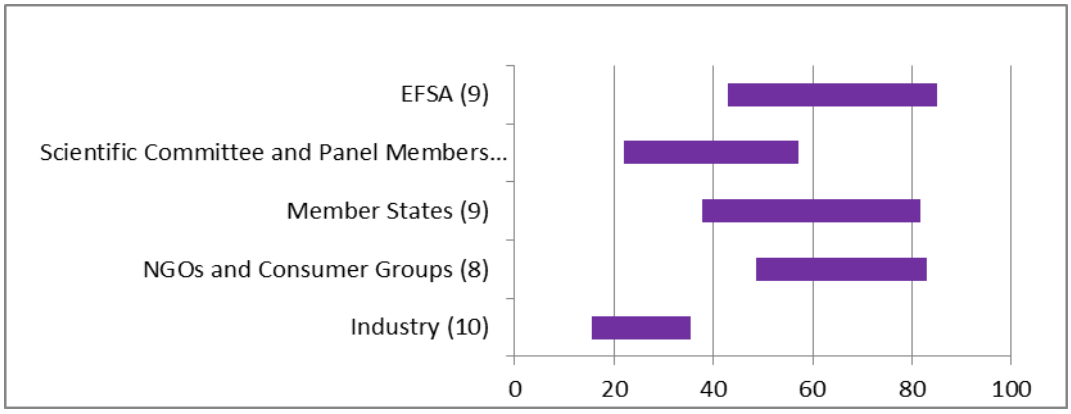


**Figure 6: Measure 5 (M5) overall assessment under all evaluative criteria**

There are two main ways that EFSA could consider implementing this measure: making the data available to a sub-set of stakeholders either through the Data Warehouse project or through the EFSA website. There was little overlap among stakeholders on the optimistic and pessimistic conditions for implementation. EFSA is not the data owner of the majority of the data used in general risk assessments and therefore the implementation options need to take into consideration permission to publish the data from owners and consider issues regarding industry confidentiality.

There were divergent views on the measure's potential contribution to improved transparency and use of evidence among respondent groups. The measure could contribute to improvements in the ability of the public to scrutinise how EFSA reaches its conclusions under the condition that data are made available publicly. Improved transparency would also depend on whether data were accompanied by explanatory notes and background information.

This measure is likely to imply moderate costs to EFSA under the condition that the release of data can be implemented in an automated way. The extent to which benefits outweigh costs will depend on how data ownership issues are resolved. Member State representatives identified potential high indirect economic impacts if national data were misused. Industry identified potential indirect economic impacts associated with this measure due to concerns about competition and market distortion.

## 3.6. Measure 6: Publishing information received from applicants

The sixth measure assessed by the study team involves publishing information received from applicants, except commercially sensitive data. Application dossiers for market approval include data and information to support the application. EFSA neither proactively nor systematically releases any data or information received from applicants at any stage in the market authorisation process. EFSA is considering whether to publish all information received from applicants (except commercially sensitive data) as standard practice. This could include identification of gaps in evidence where they exist. Information from applicants could be published at different stages during the risk assessment process. For example, information could be published after completeness checks, or following a market authorisation decision.

This measure was positively assessed by all stakeholder groups with the exception of industry respondents. All other groups found that the proactive release of data would be a favourable measure with optimistic assessments exceeding 70 base points and most pessimistic assessments exceeding 40 base points (Figure 7). Most respondent groups also expressed similar ranges in their assessments (20–40 base points).[6] Overall, and again with the exception of industry's perspective, this measure was viewed as one of the most favourable of all the measures assessed.

EFSA, Member State, Scientific Committee and Panel Member, and NGO and consumer group representatives viewed this measure favourably based largely on its potential to improve transparency in the risk assessment process for regulated products. The main argument given for this positive assessment related to the potential contribution of the measure to establish trust and confidence in EFSA's risk assessment and in the conclusions reached.

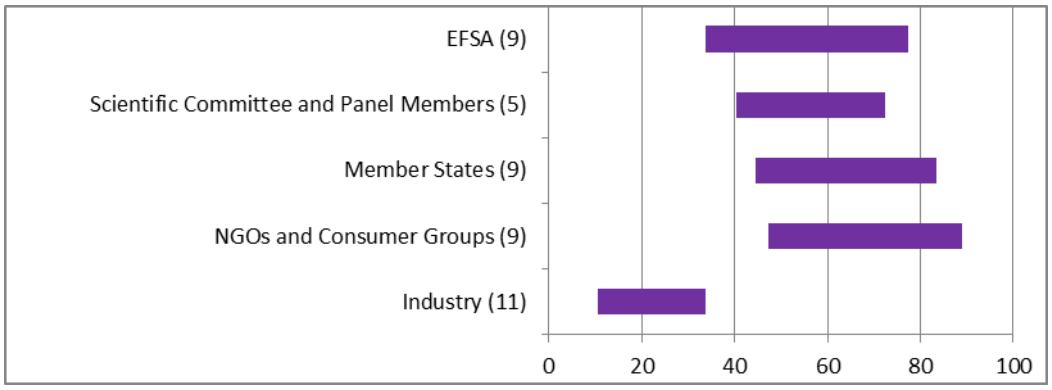


**Figure 7: Measure 6 (M6) overall assessment under all evaluative criteria**

However, industry respondents assessed this measure least favourably overall out of all the measures, and, notably, there was no overlap between the assessment of industry and any other perspectives. As explained for Measure 5, this lack of overlap is relatively rare in an MCM assessment, because despite divergent perspectives being provided, there is usually common ground between perspectives – something that is brought out in the assessment. In this case, however, industry respondents viewed this measure as highly unfavourable (fewer than 40 base points under an optimistic assessment) because they foresaw unresolvable confidentiality issues and potential economic impacts if sensitive commercial data were released accidentally. There was low ambiguity across the group in this assessment (indicating similar scores were used across respondents), although there was a relatively high degree of average uncertainty expressed for this measure by this group.

EFSA will need to consider the extent to which different stakeholders should be able to access data and in which format. This could involve a tiered approach with re-usable data accessible only through request, data available for review in a physical reading room at EFSA premises, or data publicly available through EFSA's website. EFSA should also consider at which point in the risk assessment process data should be released; that is, immediately after submission, prior to a potential commenting period[7] or after opinion adoption. There was no agreement on the most optimistic or pessimistic conditions among respondents.

This measure was positively assessed by all stakeholder groups with the exception of industry respondents. It would be most effective at improving transparency in EFSA's risk assessment process related to regulated products and thereby establish trust and confidence in the conclusions reached. Performance under this criterion will depend on how commercially sensitive data will be defined and redacted. The measure could also help to contribute to the better use of evidence by allowing for greater data availability, which may spur innovation and scientific progress.

[6] The one perspective with a much higher range of uncertainty was academics; however, as noted earlier there were only two individuals in this respondent group and this must be taken into consideration when analysing the quantitative data associated with their assessments.

[7] Depending on the process set out in the legislative framework.

This measure is likely to imply higher costs to EFSA than Measure 5 due to the need to go through application data to remove only data that should be considered confidential and ensure that no confidential data is accidently released. The extent to which benefits outweigh costs will depend on how EFSA resolves issues related to the confidentiality of application data. Benefits should outweigh costs if EFSA can ensure that the applicant's right to confidentiality is balanced with other stakeholder groups' request for transparency. Industry identified potentially high costs for themselves and potential indirect economic impacts associated with this measure due to competition and market distortion concerns.

## 3.7. Measure 7: Commenting on opinions

The final measure that underwent MCM analysis involves the opportunity for stakeholders to comment on EFSA scientific opinions after they have been published. The measure is related to the final stage in the risk assessment process when a scientific opinion (or other output) is adopted or a decision is made on market authorisation. After adoption, there is no opportunity for the public to comment on the final version of the scientific output or decision. EFSA is considering whether to allow stakeholders to post comments on its opinions for issues of high public interest and for decisions on market authorisation. EFSA could publish the adopted opinion or decision and allow the public to comment. In accordance with Better Regulation guidelines, the comment period would be open for 12 weeks. EFSA could respond to the comments received.

Opinion commenting was assessed favourably compared with other measures, but there were many points of disagreement within and between respondent groups about the way in which the measure should be implemented, which were obscured in the aggregate scores. The measure was assessed most positively by Scientific Committee and Panel Members compared with other measures evaluated by this group in the MCM and also compared with other respondent groups on the measure itself (Figure 8). However, this group of respondents also expressed widely differing views and conditions about the performance of the measure, which are illustrated in the wider range of uncertainty shown in the figure below, as well as in a relatively high average degree of uncertainty that was used by respondents in this group.

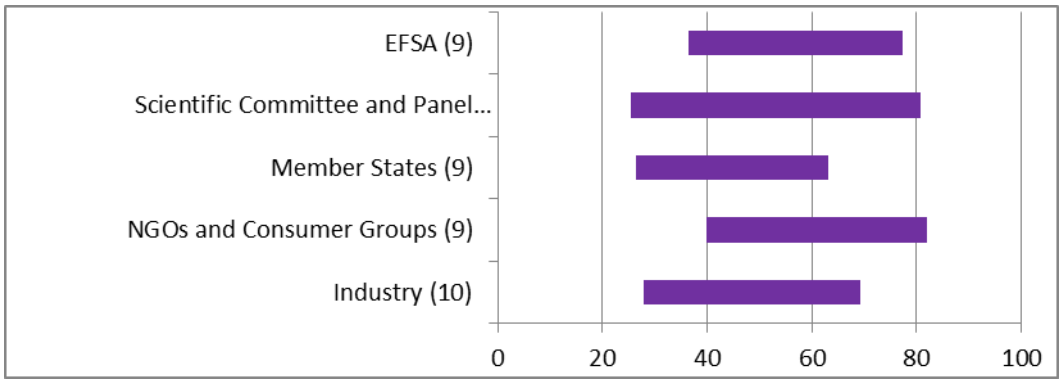


**Figure 8: Measure 7 (M7) overall assessment under all evaluative criteria**

The measure was favoured in an optimistic scenario by NGO and consumer group representatives, receiving an assessment of 80 base points. EFSA representatives (77 base points) and academics were also positive about the measure under an optimistic scenario. This was the least preferred measure for Member State representatives in the MCM exercise overall, with an optimistic assessment of 61 base points and a pessimistic assessment of 26 base points.

This measure could be implemented in different ways, and the chosen approach will affect its impacts for different groups. Once the opinion is published, commenting could be used to reopen an opinion if new evidence emerges, or it could be used just as a way of identifying potential improvements to the risk assessment process in the future (for other opinions). There was neither convergence on a preferred approach overall, nor among respondents in particular groups. There was no agreement on

whether commenting should be allowed by anyone who wished to comment, or only by selected groups (e.g. registered stakeholders and/or applicants).

Nevertheless, there were points of agreement regarding other aspects of implementation, including the need to have clear criteria for accepting comments and an approach to weighting comments for response by EFSA. There was also more support for a limited period to comment on an opinion post-adoption (e.g. 12 weeks) rather than leaving the comment period open indefinitely.

The measure could improve transparency generally where EFSA provided an organised response to comments; simply providing an opportunity for comments would be insufficient for improving transparency without engagement from EFSA. The measure could also improve EFSA's use of evidence where commenting identifies gaps, uncertainties and/or errors or inaccuracies in the opinion. The measure could also improve future risk assessments through learning from the comments on previous opinions.

The potential costs to EFSA from this measure are high, particularly as the measure is likely to be most supported where EFSA engages with the comments in a structured way. There is a high degree of divergence among respondent groups about the best approach to implementation and, as a result, uncertainty about the degree to which it could improve transparency and use of evidence. Consequently, no conclusion can be drawn about the efficiency of the measure.

## 3.8. Light-touch assessment

The following two measures were subject to a light touch assessment, which was applied in cases where anticipated costs were considered moderate to low in the preliminary impact assessment.

### 3.8.1. Measure 8: Publishing meeting minutes

The first measure assessed using the light-touch approach was publishing meeting minutes after Scientific Committee and Panel meetings. During the preparation of scientific advice, EFSA publishes limited minutes after Scientific Committee and Panel meetings outlining the scientific topic(s) discussed. EFSA is considering whether to publish more extensive meeting minutes. EFSA could publish non-attributable minutes reflecting the flow and outcomes of the discussion or minutes stating the outcome of the discussion. The minutes would be published on EFSA's website.

There were several different approaches to implementation of this measure discussed by interviewees. These included providing more extensive meeting minutes, which could include more documentation on the outcome than they currently do (e.g. the rationale for the choice of risk assessment method), or that could go beyond summarising the outcome and include a description of the flow of discussion as well. Another possibility is to provide live web-streaming or audio recordings after the meeting, specifically for plenary meetings (but not for all meetings, since many of these would include the discussion of commercially sensitive information).

Overall, the measure is relatively uncontroversial, although there are a few considerations for EFSA to make if it chooses to implement the measure. First, Panel Members may feel that they are unable to express their views freely and they may be less willing to express divergent views compared with the current situation. Second, EFSA will need to take any commercially sensitive information discussed into account and ensure that this information is not conveyed through the minutes.

### 3.8.2. Measure 9: Transparency of the weight of evidence approach

The second measure assessed under the light touch approach involves transparency through the weight of evidence[8] approach. EFSA does not have a standardised or systematic approach to document the weight of evidence used in its scientific outputs. EFSA is considering developing an

[8] There is no standard definition of the weight of evidence approach. According to the European Chemicals Agency, the weight of evidence is defined as 'an evidence based approach which involves an assessment of the relative values/weights of different pieces of the available information that have been retrieved and gathered in previous steps.' See: ECHA, 2010.

approach to document each step in the research process for scientific staff to use throughout the course of the risk assessment. EFSA could develop and introduce a template including standard elements common across risk assessments in different scientific areas, but allowing researchers flexibility in documentation.

Respondents did not identify different implementation options for this measure, but rather focused on the likely effectiveness and efficiency of the measure. Overall, the implementation of this measure is uncontroversial and is supported by the respondents consulted.

## 3.9. Convergence and divergence on the measures and their implementation

As a final stage of analysis, the measures were further compared according to the overall convergence (alignment of views) or divergence (differences of views) among respondent group assessments of each measure, whether optimistic or pessimistic, against the evaluative criteria and the extent to which respondent groups agreed or disagreed on the implementation approach. The measures were mapped by the study team using a qualitative judgement based on consideration of each of these issues to identify those measures that are characterised by different features of convergence or divergence. Figure 9 shows the mapping of the measures on each dimension. There is no quantitative basis for the figure (including the scale); rather, the measures mapped onto each of the quadrants shows relative convergence or divergence of views.

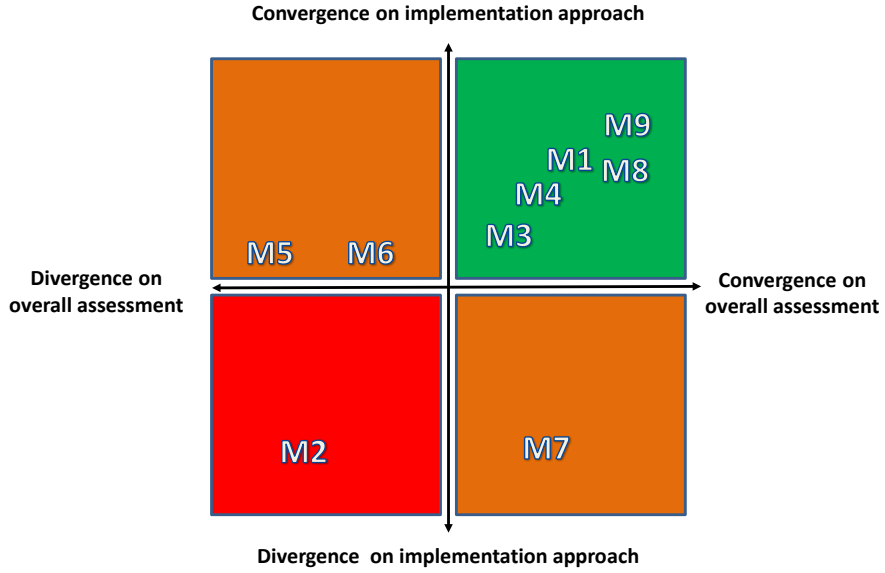


**Figure 9: Convergence of the measures overall and on the implementation approach**

The mapping is strictly based on the nature of convergence about the assessment of the measure (whether optimistic or pessimistic) and implementation approach. Those measures for which there was convergence on both dimensions were generally assessed as having benefits that outweighed the costs (Measures 1, 3, 4, 8 and 9) compared with those for which there was divergence on either or both dimensions (Measures 5, 6 and 7). The measure for which there was more relative divergence both overall and regarding the implementation approach (Measure 2) was also the measure for which the respondents identified the most negative potential impacts. Divergence on the approach to implementation means that EFSA would find it challenging, if not impossible, to offset the negative impacts for one or more groups through adaptations to the measure.

# 4. Conclusions and Recommendations

An immediate general finding from the MCM analysis can be seen in the pattern of the performance of the measures. Measures 1 (framing the mandate), 3 (consultation on risk assessment methods) and 4 (consultation on data) can be seen in some ways to perform relatively better, overall, across all perspectives, as evidenced by a relatively higher median assessment across respondent groups. These measures could be pursued by EFSA.

Measure 7 (commenting on opinions) could result in increased transparency and use of evidence, but there was no agreement on the implementation approach. EFSA could conduct a feasibility study for this measure to further assess the potential implementation approaches and associated resource requirements. Measure 6 (publishing application information), and to some extent Measure 5 (proactive release of data), are supported by most respondent groups but industry stakeholders expected this measure to perform poorly compared with the other measures. There will likely be a high degree of opposition from this group if EFSA pursues these measures.

Measure 2 (pre-submission engagement with applicants) received widely divergent views about implementation and likely impacts. Non-industry stakeholders largely opposed the measure and many respondents identified potential risks to EFSA's reputation by appearing biased to industry, which could outweigh any benefits to EFSA through cost effectiveness gains in the application process. Guidance documents were identified as potentially unhelpful by industry representatives and may be a waste of EFSA resources. EFSA should investigate this issue through active engagement with industry to determine whether there is sufficient support to warrant the expenditure.

Both of the light touch measures were assessed positively by interviewees. Measure 9 (transparency of the weight of evidence approach) was supported by respondents consulted and there was convergence on the implementation approach. Measure 8 (publishing meeting minutes) was also supported by respondents, but there were questions about the best approach to take to implementation, which EFSA will need to take into consideration. EFSA could pursue both measures.

MCM is based on the premise that there is not one single 'best' option for science policy issues, but rather multiple ways forward that could, and should, be explored simultaneously. Indeed the measures assessed in this study are not necessarily mutually exclusive and were therefore assessed according to the trade-offs, different viewpoints, implications and potential areas of synergy between the measures and the different stakeholders that will be affected by them.

There are advantages and disadvantages to using MCM to evaluate the entire set of 35 measures that EFSA is considering under the TERA project. The advantages can be observed in the assessment within this report. MCM is a method with core values of inclusion, openness, participant agency and transparency. These principles of inclusiveness, reflexivity in elicitation and analysis, engagement, transparency and openness are those that EFSA also promotes. Therefore, using a method to evaluate future measures that itself embodies these principles provides a strong signal of EFSA's commitment to the wider TERA project agenda. Furthermore, the method allows for transparent and open assessment of participant views on the measures in a way that is not constrained and allows issues that are of importance to stakeholders to be raised. Finally, using a qualitative method that is guided by quantitative assessments provides robustness in the approach that makes it easy to implement across a range of issues.

However, the MCM process is also time-consuming and requires appropriate resources. The assessment of just seven measures by 50 interviewees took a team of analysts and support from EFSA to accomplish. These interviews are important to conduct in a robust and detailed fashion in order to elicit the qualitative information that drives the analysis. EFSA would need to think carefully about how to implement a more detailed process across a larger set of measures and the study team recommends that EFSA prioritises those measures that merit a more detailed assessment. In addition, a grouping exercise would be advised, so that participants evaluate similar types of measures and do not evaluate too many in a single exercise. Seven core measures was a large number in this study and the study team would not recommend more than that being done for any one exercise.

Overall, the information and data elicited using MCM provided a rich and highly nuanced picture for EFSA of the different conditions and framings that are likely to affect performance of the measures, should they be implemented. It allows EFSA to appreciate the different views and perspectives that affect the potential impact of the measures, and take into account these views when considering how to implement them in order to become a more transparent and open organisation.

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## Abbreviations

| | |
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| EC | European Commission |
| EFSA | European Food Safety Authority |
| MCM | Multicriteria Mapping |
| NGO | Non-governmental organisation |
| TERA | Transparency and Engagement in Risk Assessment project |