

FINAL PHASE IMPLEMENTATION PLAN TO AN “OPEN EFSA”

NOTE TO THE MANAGEMENT BOARD

With this document EFSA informs its Management Board on the progresses made by the Transparency and Engagement in Risk Assessment (TERA) Project since the last update provided in December 2015. It presents the final implementation plan regarding the 35 measures aimed at increasing transparency and engagement at each step of the risk assessment workflow, identified following a wide-ranging stakeholder’s consultation. The outcome of the Impact Assessment study that supports the choice of the implementation options is also reported.

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1. Introduction

At the [March 2015 Management Board meeting](#), EFSA pledged to follow up on several proposals put forward by its stakeholders following a wide-ranging consultation and concerning the introduction at different steps of its risk assessment workflow of a number of measures aimed at increasing transparency and engagement.

Several measures, proposed at the time, were considered particularly challenging to implement because of a potentially imbalanced impact on EFSA's different stakeholder groups, the possible change of the nature of one or more steps in the risk assessment cycle and/or because of an expected high resource requirement. The Management Board, therefore, asked EFSA to evaluate their potential impact before deciding on their deployment.

In July 2015, the Transparency and Engagement in Risk Assessment (TERA) project was launched to carry out the impact assessment of the most challenging measures identified and to follow up on their implementation in a concerted way with other on-going parallel initiatives at EFSA. In October 2015, the impact assessment study was commissioned.

In December 2015, an update on the TERA project was presented to the Management Board. Progress was reported on the implementation of measures that had already been planned or were underway in EFSA's portfolio as part of the continuous improvement of its processes. The Board also had an update on the Impact Assessment Study that EFSA carried out to predict the expected effects of the implementation of the most challenging measures.

Finally, in March 2016 the new stakeholder engagement approach was presented to the Board, outlining the results of the review carried out by EFSA in recent years to offer a new methodology for further engaging with stakeholders during the scientific assessment process.

2. Impact Assessment of the measures aimed at increasing transparency and engagement in EFSA's risk assessment cycle – Methodological aspects

In October 2015, EFSA commissioned an impact assessment of 35 measures aimed at increasing transparency and engagement in EFSA's risk assessment process. The 35 measures were identified through a wide-ranging consultation intended to promote trust and confidence in EFSA's risk assessment process. The assessment required the development of an impact assessment methodology that could be applied to the measures identified by EFSA and its stakeholders before conducting a full impact assessment on a sub-set of prioritised measures.

Firstly, 35 different measures were defined in detail following desk research (41 face-to-face and telephone interviews with EFSA staff members). In a second phase, a preliminary assessment of the 35 proposed measures was carried out followed by a full impact appraisal for a sub-set of 10 measures (prioritised according to predefined criteria, e.g. demand by different stakeholders, the distribution and diversity of benefits, risk of not delivering, no previous implementation experience).

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The 10 measures were assessed using Multi-criteria Mapping (MCM) and information gathered via 50 interviews with: EFSA staff, Management Board members, Scientific Committee and Panel Members, Member State representatives, industry representatives, non-governmental organisation (NGO) and consumer group representatives and academics.

The assessment was done through analysing the respective strengths and weaknesses of each measure. The criteria used were ‘transparency’, ‘use of evidence’, and ‘cost’ as pre-defined by the study team.

Box: What is Multi-Criteria Mapping¹

MCM is a form of multi-criteria analysis that was used to identify quantitative and qualitative impacts of the measures and allows issues that are important to stakeholders to be raised and robustly assessed and compared to others. It is a software-assisted technique used to appraise different ‘options’, in this case the measures that underwent in-depth assessment.

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. The result of 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.

The 10 measures were finally compared and mapped according to the overall convergence (alignment of views) or divergence (difference of views) amongst respondent group assessments of each measure, whether optimistic or pessimistic, against the evaluation criteria and the extent to which respondent groups agreed or disagreed on the implementation approach (see Figure 1).

Based on the outcome of the Impact Assessment Study (May 2016) including the definition of the 35 measures, their preliminary impact appraisal and the full Impact Assessment for the 10 prioritised measures, EFSA was able to complete its implementation plan, addressing all the measures proposed by its stakeholders. The summary report of the impact assessment can be found [here](#).

¹ Key relevant references and weblinks for Multi Criteria Mapping (MCM):

www.multicriteriamapping.com: providing a range of documents and other resources

www.sussex.ac.uk/Users/prfh0/Pamphlets.pdf: providing some popular briefing

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3. Impact Assessment of the measures aimed at increasing transparency and engagement in EFSA’s risk assessment cycle – Outcome

Based on the preliminary Impact Assessment, choices regarding the implementation modalities were elaborated for all the measures not undergoing a full Impact Assessment.

For some measures (n = 5), the introduction of new features in the concerned steps of the risk assessment cycle was foreseen and included in the implementation plan. Nonetheless, all of these measures are planned to be implemented within one year.

The measures that have already been successfully implemented as of June 2016 (n = 17) were also reported and described in the final implementation plan (see all details in Table 1). Although these measures are currently available in the respective risk assessment steps, in some cases EFSA has foreseen to further strengthen their deployment by introducing technical improvements or extend their application.

Two measures are not recommended for implementation: 6.6 *Review of language regime* was considered too costly in terms of translation to extra languages and partly satisfied by the recent professionalization of editing service (Wiley); 4.13 *Q&A document comprising the questions posed during the stop the clock mechanism* was assessed as too resource intensive and partially covered by the recent introduction of new services to applicants. In addition, measure 4.9 *Put in place external peer-review system* was not considered to be effective as such to improve scientific quality in the particular context as the one of EU regulatory agencies providing scientific and technical advice²;

The final outcome of the 10 measures undergoing MCM is illustrated in Figure 1. Five measures were consistently assessed optimistically amongst different groups of interviewees. They are: 1.1 *Public consultation on framing of the mandate*; 3.1 *Consultation on the risk assessment methodologies*; 4.1 *Consultation on missing data to be considered by EFSA*; 4.5 *Plenary meeting minutes reflecting the discussion and decisions taken*; 4.10 *Increased transparency through the weight of evidence approach*. The introduction of specific solutions or the strengthening of current provisions (e.g. through the definition of criteria to increase consistency of use and provide more predictability), were anticipated in these cases.

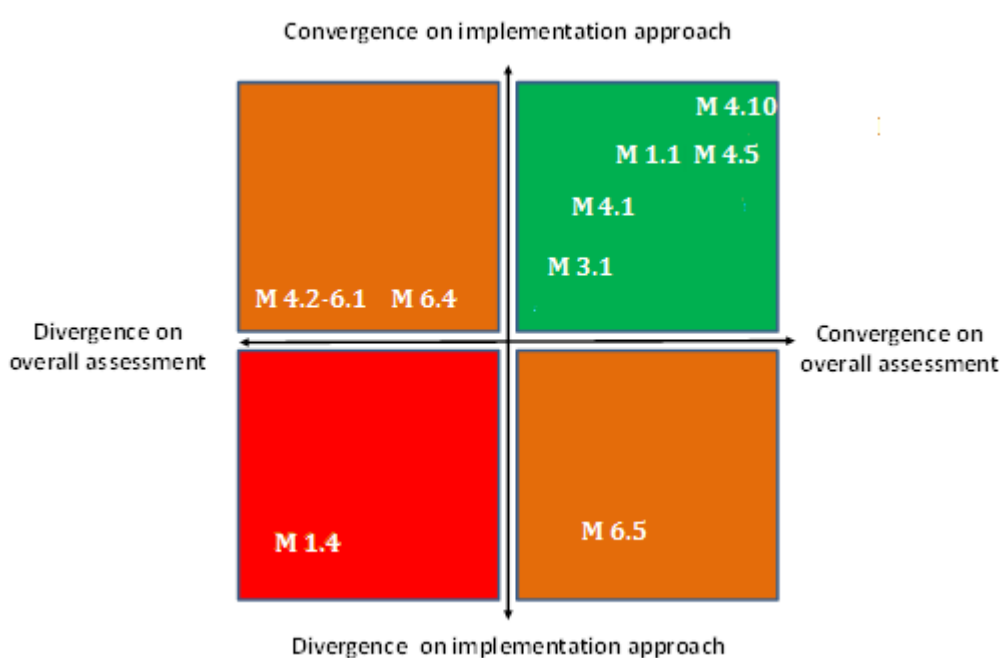
Measures 4.2 *Proactive release of data* and 6.1 *Publication of data used/discarded* (for generic opinions respectively during and after risk assessment) and 6.4 *Publication of data/information received from applicants’ (except commercially sensitive information)* could contribute to improvements in the ability of the public to scrutinise how EFSA reaches its conclusions. All were supported by most respondent groups but industry stakeholders considered that this measure would perform poorly in terms of increasing transparency and enhance use of evidence compared to the

² Peer review’ by EU-ANSA Agencies: A reflection paper: <http://bookshop.europa.eu/en/-peer-review-by-eu-ansa-agencies-pbTE0215981/>

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other measures. Overall these measures were considered to imply moderate costs to EFSA and the extent to which benefits outweigh costs will also depend on how data ownership issues are resolved. Measure 6.5 *Possibility to post comments on opinions* was considered to increase transparency and use of evidence, but there was no agreement on the implementation approach. EFSA could conduct a feasibility study for this measure. Measures 1.4 *Pre-submission engagement with applicants* received widely divergent views both about implementation and likely impacts and its implementation was considered appropriate only for groups of applicants, e.g. multiple industry representatives from the same sector.

Figure 1 Outcome of the full Impact Assessment through Multi Criteria Mapping (MCM)



4. Final implementation plan of the measures aimed at increasing transparency and engagement in the risk assessment cycle

The outcomes of the Impact Assessment were translated in a detailed implementation plan by EFSA. An overview of the core benefits expected by introducing the selected provisions are illustrated in the text below and an exhaustive description of the implementation features, including related extent, frequency and timelines is reported in Table 1 below.

The main instrument through which EFSA will increase engagement with its stakeholders at all steps of the risk assessment cycle will be through consultation at different steps of the RA workflow: a) on the definition of the mandate, to reach a mutual understanding of the issues to be addressed and/or to potentially adjust the risk assessment questions; b) during the definition of methodology/evidence

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needs; c) during the preparation of advice to allow for inclusion of broader views and inputs and d) after adoption to extend such interactions and maintain an open dialogue.

To make the most effective use of consultation tools, EFSA will further facilitate interaction to stakeholders and use a professional technological platform for consultations, including scope for live commenting. Other means for consultations will be physical/virtual meetings, webinars, digital collaboration tools etc. A twelve-month plan for upcoming public consultations is already available on EFSA's website.

Further improvements to forecasting and consistency on the use of consultations (hence further transparency) will be supported by the development of an *EFSA decision on Public Consultation*, setting criteria for triggering consultations as well as the goals and means of the consultation and their follow up (e.g. comments analysis and inclusion, post consultation meeting, etc.).

Dedicated dialogue with applicants will also continue through the various services already established such as the high-level sectoral meetings with industry representatives and via progressive improvement of the accessibility of the guidance documents that describe how to prepare and submit application dossiers.

In addition, the dialogue with the European Commission will be deepened by gradually introducing the systematic discussion and agreement on the mandate Terms of Reference before the request is formally sent to EFSA (currently being piloted with mandates addressed to 5 panels). Also, consultation meetings with Member States will take place more often, with the aim of exchanging views on draft scientific opinions.

Further transparency on the scientific meetings and their outcomes will be achieved by providing faster and more detailed information through panel meeting minutes and “flash reports” at the end of the plenaries. Contribution to the scientific assessment by stakeholders will be further reflected through formal acknowledgement in the published scientific opinion.

Publication of the Panel members' Curriculum Vitae, now includes employment records with a plan to extend such information requirements to Working Group experts. The documentation concerning the selection of Working Group experts, has been also enhanced and criteria determining when the inclusion in the scientific discussion of hearing experts is necessary will be established.

Transparency on the use of evidence and choice of methodology is at the core of the Promoting Methods for Evidence Use in Scientific Assessments (PROMETHEUS) project and of a number of guidances being developed by the scientific Committee (e.g. Weight of Evidence, Uncertainty, Biological relevance). All will build on EFSA's existing experience and provide by 2018 further transparency and clearness on choice and use of evidence as well as a systematic, consistent and accessible method for weighing it up.

EFSA is extensively investing in a multi-annual Information Management Programme coordinating, supervising, steering and monitoring 16 projects to handle EFSA information. Insight on the evidence used and the methodology applied by EFSA, is an initiative that goes beyond transparency and has the

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ambitious aim of fostering data re-use and promoting collaborative platforms that ultimately promote innovation.

In line with the roll-out of this initiative, the data, information and methodologies applied in the scientific assessment will be available after publication of the output, in a readable and reusable format on EFSA’s website taking into account data confidentiality and security. Summaries of data are instead being already made progressively available, once an application dossier has been formally accepted by EFSA.

Meanwhile, EFSA will continue to collect data via open (continuous /ad hoc) or targeted calls to support its risk assessments, e.g. the continuous collection of chemical contaminants and residues data in food and feed included in monitoring and control programmes. In these data collections, Member States, research institutions, industry, academia and any other stakeholders are invited to submit data for inclusion in the EFSA Data Warehouse and used in future EFSA scientific opinions and reports.




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Table 1. Final implementation plan of the TERA measures applicable to the different steps of the risk assessment cycle

<div style="text-align: center;">  <p>RISK ASSESSEMENT CYCLE</p> </div> <div>MEASURE</div> <div>Outcome (scope)</div>	IMPLEMENTATION FEATURES	<div>SINCE/BY</div> <div> <div style="background-color: #2e8b57; width: 15px; height: 15px; display: inline-block;"></div> = IN PLACE <div style="background-color: #90ee90; width: 15px; height: 15px; display: inline-block;"></div> = IN PLACE WITHIN 1 YEAR <div style="background-color: #ffa500; width: 15px; height: 15px; display: inline-block;"></div> = IN PLACE IN 2 YEARS <div style="background-color: #ff4500; width: 15px; height: 15px; display: inline-block;"></div> = IN PLACE IN 3 YEARS <div style="background-color: #6a5acd; width: 15px; height: 15px; display: inline-block;"></div> = POSTPONED </div>	REMARKS
1.1 - 1.5 CONSULTATION (MEETINGS) ON FRAMING OF MANDATES AND RELATED QUESTIONS (C2) <i>Potentially adjusted risk assessment question/s, mutual understanding of question to be addressed (Scientific outputs, except application assessments)</i>	<ul style="list-style-type: none"> EFSA engages on framing of the mandate with targeted SHs and/or openly (in parallel), according to established criteria Consultation applies to self-task (including guidances)/controversial issues/emerging science mandates. Public consultations/physical meetings/other means, are used as appropriate³ 	Q1 2017	Implementation times dictated by establishment of a new EFSA decision on Consultations
	<ul style="list-style-type: none"> The “Mandate WG”, as foreseen in the new Stakeholder Engagement Approach, is formalized 	Q2 2017 	Development aligned with new Stakeholder Engagement Approach

³ The new EFSA decision on Consultation, will set criteria for when/what/who/how to consult (endorsed by beginning of 2017) providing process consistency and predictability

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1.2 SIMPLIFICATION OF REQUIREMENTS TO TAKE ACTIVE ROLE IN PUBLIC CONSULTATIONS <i>Ensure contribution of stakeholders in public consultation (All public consultations by EFSA)</i>	<ul style="list-style-type: none"> Process recently enhanced, allowing for submissions of additional information to support comments. Dedicated mailbox established, monitored and closed at the end of the consultation 	In place (2015)	
	<ul style="list-style-type: none"> EFSA moves to a professional public consultation tool 	Q1 2017 	
1.3 PRE-NOTIFY INTERESTED PARTIES OF FORTHCOMING PUBLIC CONSULTATION <i>Ensure regular and ahead-of-time information to stakeholders (All public consultations by EFSA)</i>	<ul style="list-style-type: none"> Calendar of upcoming Consultations is available on EFSA’s website, indicating consultation subject/timeframe (i.e. launch/closing dates) and updated each quarter 	In place (2015)	
	<ul style="list-style-type: none"> Automatised continuous updates are introduced 	Q1 2017 	Development aligned with roll-out of Information Access Management project
1.4 PRE-SUBMISSION MEETINGS WITH APPLICANTS IN THE AREA OF REGULATED PRODUCTS <i>Clarification of data requirements (Draft applications in the area of regulated products)</i>	<ul style="list-style-type: none"> High-level pre-submission scientific meeting with groups of applicants/multiple industry representatives from the same sector are included in ApDesk Catalogue of Services 	Q2 2017	
	<ul style="list-style-type: none"> More user friendly guidance documents on the preparation and presentation of applications are available in ALL areas 	Q4 2018 	In line with Guidance Review roll-out
2.1 PUBLISH FULL BIOGRAPHIES (C1) <i>Ability of public to scrutinise experts backgrounds (Experts working with EFSA)</i>	<ul style="list-style-type: none"> Panels’ expert Curriculum Vitae now include previous employment records and are available on EFSA’s website 	In place (2015)	

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	<ul style="list-style-type: none"> The same level of documentation is available for Working Group experts 	Q2 2018	Developments aligned with Expertise Management Programme
2.2 -2.3 ENHANCED DOCUMENTATION OF THE CRITERIA FOR SELECTION OF WORKING GROUP MEMBERS AND HEARING EXPERTS <i>Auditability of expert selection process (Experts working with EFSA/Expertise not available in Working Groups)</i>	<ul style="list-style-type: none"> Working Group Terms of Reference are available on the website Selection procedure and criteria are re-defined and detailed in SOP; documentation and record keeping requirements for each step in the process are strengthened to facilitate auditing 	In place (2015)	
	<ul style="list-style-type: none"> Criteria on need for inclusion of scientific hearing experts are established Decision on their inclusion is recorded in Plenary/WGs meeting minutes 	Q1 2017	
3.1 CONSULTATION ON THE RISK ASSESSMENT METHODOLOGIES APPROACH (C2) <i>Improve scientific quality and ownership (Scientific outputs except application assessments)</i>	<ul style="list-style-type: none"> EFSA consults on its guidances (often in more stages) 	In place	
	<ul style="list-style-type: none"> EFSA consults on risk assessment approaches on issues of high public interest/emerging science/controversial subjects. Open/targeted/focus groups (involving selected experts) consultations, to be opened in subsequent stages to any interested stakeholders (tiered approach) ⁴ are carried out 	Q1 2017	Implementation time aligned with establishment of a new EFSA Decision on Consultations

⁴ Measure already in place but through the new EFSA decision on Consultation, set criteria for when/what/who/how to consult (endorsed by beginning of 2017) will provide further process consistency and predictability

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	<ul style="list-style-type: none"> Work is in progress, with further pilots in 2016 involving all panels to test the implementation of Promoting Methods for Evidence Use in Scientific assessments (PROMETHEUS) and collect lessons learned. A decision on its final implementation is taken 	Q4 2017 	Developments aligned with Promoting Methods for Evidence Use in Scientific Assessments project
3.2. OPENED AND/OR TARGETED CALL FOR EVIDENCE (C2) <i>Widen EFSA's evidence base (scientific outputs)</i>	<ul style="list-style-type: none"> EFSA consults through open calls (continuous/ ad hoc) or tiered approach or with targeted call for data first and then extending to an open call, as need be³ 	Q1 2017	Implementation times aligned by establishment of a new EFSA decision on Consultations
	<ul style="list-style-type: none"> Formalisation of Discussion Groups with SHs dedicated to Data collection/exchange 	Q3 2016 	Development aligned with new Stakeholder Engagement Approach
3.3 CONSULTATION ON THE FORMAT OF THE CALL FOR DATA (C2) <i>Clarity on requested data (calls for data/information)</i>	<ul style="list-style-type: none"> Consultations on the format of data to be collected continue to be carried out on ad-hoc basis when standard format are not available 	In place (2007)	

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4.1 CONSULTATION ON MISSING EVIDENCE TO BE CONSIDERED BY EFSA (C1) <i>Widen EFSA evidence base (scientific outputs)</i>	<ul style="list-style-type: none"> EFSA consults on missing evidence through tiered approach, with targeted call for data first and then extending to an open call, as need be⁵ 	Q1 2017	Implementation times aligned with establishment of a new EFSA decision on Consultations
	<ul style="list-style-type: none"> EFSA establishes transparent work processes to define criteria outlining the reasons for including/excluding evidence and how to communicate this to the public Work is in progress, with further pilots in 2016 involving all panels to test the implementation of Promoting Methods for Evidence Use in Scientific assessments (PROMETHEUS) and collect lessons learned. A decision on its final implementation is taken 	Q4 2017 	Developments aligned with Promoting Methods for Evidence Use in Scientific Assessments project
	<ul style="list-style-type: none"> Discussion Groups with SHs, dedicated to Data collection/exchange are formalised 	Q3 2016 	Development aligned with new Stakeholder Engagement Approach
4.2 PROACTIVE RELEASE OF EVIDENCE IN A READABLE/REUSABLE FORMAT DURING THE SCIENTIFIC ASSESSMENT	<ul style="list-style-type: none"> Discussion Group of the Electronic Management of Regulated Products Applications project agrees on the definition of commercially sensitiveness of data (including legal aspects) 	Q4 2017 	Development aligned with Information Management

⁵ Measure already in place but through the new EFSA decision on Public Consultation, set criteria for when/what/who/how to consult (endorsed by beginning of 2017) will provide further consistency and predictability


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Empower the public to scrutinize EFSA work <i>(Information linked to the risk assessment decision making process, except commercially sensitive one)</i>	<ul style="list-style-type: none"> Summaries of applicant's data are available through EFSA website following dossier acceptance (currently already available for NUTRI Health claims Art. 14, FEED, GMO, and Pesticides) 	Q4 2018 	Programme, and: <ul style="list-style-type: none"> Electronic Management of Regulated Products Applications Lifecycle project Information Platform for Chemical Monitoring project Scientific Data Warehouse Data Collection Framework Open Scientific Advance Information and Evidence Hub Information Access management
	<ul style="list-style-type: none"> A coordinated approach to collect, store and access monitoring data on chemicals and chemical mixtures, in humans and in the environment (involving MSs and other EU agencies) is established 	Q4 2018 	
	<ul style="list-style-type: none"> Access to data collected by EFSA in support of its risk assessment process and in accordance with agreed access rules to different categories of stakeholders is granted (currently already granted to 150 registered users). EFSA data collection process and tools are improved according to the Reference Terminologies and Management system 	Q4 2016 	
	<ul style="list-style-type: none"> A central repository for data, models/methods and a dedicated portal is made available to allow both storage and user-friendly retrieval of the EFSA's inputs to its risk assessment 	Q2 2018 	
	<ul style="list-style-type: none"> An enhanced infrastructure for managing and control access to Information is established 	Q2 2017 	
4.3 INCREASED ACCESSIBILITY TO KEY DATA PACKAGES OF MSs Build knowledge community (Member States data)	<ul style="list-style-type: none"> A 'User community' is established among 16 Member States with significantly extended access through EFSA's Data Warehouse to each other's raw data under defined conditions of a 'Circle of Trust' The Circle of Trust and possible use of data by MSs is extended to more MSs members 	In place (2015) 	

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	<ul style="list-style-type: none"> The introduction of “Data Quality Steward” in MSs is piloted 	Q2 2017	
4.4 MORE FEEDBACK ON THE EXTENT AND ON THE REASONS WHY CERTAIN DATA WERE/WERE NOT USED <i>Empower the public to scrutinise EFSA’s work (Scientific outputs)</i>	<ul style="list-style-type: none"> The new guidelines on the structure and content of EFSA’s scientific opinions and statements are established 	In place (2015)	
	<ul style="list-style-type: none"> Work is in progress, with further pilots in 2016 involving all panels to test the implementation of Promoting Methods for Evidence Use in Scientific assessments (PROMETHEUS) and collect lessons learned. A decision on its final implementation is taken 	Q4 2017 	Developments aligned with Promoting Methods for Evidence Use in Scientific Assessments project
4.5 MINUTES REFLECTING THE PLENARY DISCUSSIONS (C1) <i>Clarity of the decision making (Panel meetings)</i>	<ul style="list-style-type: none"> Meeting minutes reflects the plenary discussion and the decisions taken The minutes are published within 10 working days 	Q4 2016 	
4.6. PUBLIC CONSULTATION ON DRAFT OPINIONS (C2)	<ul style="list-style-type: none"> EFSA consults on its draft outputs 	In place (2006)	

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<i>improve scientific quality and ownership (scientific outputs, except application assessments)</i>	<ul style="list-style-type: none"> Consultation applies to self-tasks (including guidances)/emerging science/controversial opinions. Public consultations/physical meetings/other means, are used as appropriate⁶ 	Q1 2017	Implementation times aligned with establishment of a new EFSA decision on Consultations
	<ul style="list-style-type: none"> EFSA moves to a professional public consultation tool 	Q1 2017 	
4.7 DURING AND POST PUBLIC CONSULTATION TECHNICAL HEARING (C2). <i>Increase likelihood of convergent opinions (Scientific outputs, except application assessments)</i>	<ul style="list-style-type: none"> EFSA carries out during and post-public consultation technical hearings on an ad hoc basis Upon request, the meetings are organized in Brussels in order to make them accessible to the greatest number of stakeholders as possible 	In place (2009)	
	<ul style="list-style-type: none"> Technical hearings are organized consistently according to defined criteria⁵ Webinars might be introduced to facilitate access 	Q1 2017	Implementation times aligned with establishment of a new EFSA decision on Consultations
4.8. CONSULTATION MEETING WITH MSs (C2) <i>Decrease likelihood of divergent opinions (Scientific outputs, except application assessments)</i>	<ul style="list-style-type: none"> EFSA organises meetings with interested authorities in the Member States prior/during public consultation to exchange views on a draft scientific opinion/ scientific issue. Issues are identified by the Advisory Forum (AF) through discussion in a standing agenda item at AF meetings, or through written notification in between meetings, indicating an interest for pre-consultation. 	Q1 2017	



⁶ Measure already in place but through the new EFSA decision on Consultation, set criteria for when/what/who/how to consult (endorsed by beginning of 2017) will provide further consistency and predictability

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	<ul style="list-style-type: none"> EFSA makes the meeting minutes publicly available on its website, including positions attributed to the Member State expressing the opinion Meeting options are physical meeting (in BXL or not)/virtual (eg. webinars) 		
4.9 PUT IN PLACE EXTERNAL PEER-REVIEW SYSTEM (C2) <i>Improve scientific quality (scientific outputs)</i>	<ul style="list-style-type: none"> For controversial opinions an external-review is carried out through target consultation on drafts, with a detailed report on comments received and how they were taken on board⁷ 	Q1 2017	Implementation times aligned with establishment of a new EFSA decision on Consultations
4.10 INCREASE TRANSPARENCY THROUGH THE WEIGHT OF EVIDENCE APPROACH (C1) <i>Harmonized way of evidence integration (scientific outputs)</i>	<ul style="list-style-type: none"> The guidance document taking into account national and international developments as well as other relevant guidance (eg. biological relevance and uncertainty) is adopted by the SC 	Q4 2017 	Developments aligned with adoption of SC guidance on Weight of Evidence
4.11 CONSISTENT DECISION MAKING ON CONFIDENTIALITY OF APPLICATION DOSSIERS <i>Ensure legal certainty (Applications dossiers)</i>	<ul style="list-style-type: none"> A standardised procedure on confidentiality, harmonising the way EFSA processes, assesses and decides on confidentiality claims filed by applicants is in place 	In place (2014)	
4.12. TRANSPARENCY ON THE IDENTIFICATION OF KEY STUDIES AND DETAILED REASONS TO DISCARD STUDIES WHICH DOCUMENT	<ul style="list-style-type: none"> The new guidelines on the structure and content of EFSA's scientific opinions and statements are established 	In place (2015)	

⁷ Through the new EFSA decision on Consultation, criteria for when/what/who/how to consult (endorsed by beginning of 2017) will provide further consistency and predictability






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HARMFUL EFFECTS (C1) <i>Empower the public to scrutinize EFSA work (scientific outputs)</i>	<ul style="list-style-type: none"> Work is in progress, with further pilots in 2016 involving all panels to test the implementation of Promoting Methods for Evidence Use in Scientific assessments (PROMETHEUS) and collect lessons learned. A decision on its final implementation is taken 	Q4 2017 	Developments aligned with Promoting Methods for Evidence Use in Scientific Assessments project
4.13 Q&A DOCUMENT COMPRISING THE QUESTIONS POSED DURING THE STOP THE CLOCK PROCESSES (C2) <i>Establishment of good administrative practice (Application dossiers)</i>	<ul style="list-style-type: none"> Measure already partly addressed by measure 4.14. Very resource intensive 	Postponed	
4.14 ENSURE A CONSISTENT APPROACH FOR HIGHLIGHTING MAJOR WEAK POINTS OF A GIVEN APPLICATION IN ORDER TO MAKE IT POSSIBLE FOR THE APPLICANT TO ADDRESS ALL ISSUES DURING THAT STOP CLOCK WINDOW (C2) <i>Clarity to applicants on study requirements (Application dossiers)</i>	<ul style="list-style-type: none"> Applicants can request a teleconference to clarify a request from EFSA for additional information or clarifications as described in (EFSA's Catalogue of support initiatives during the lifecycle of applications for regulated products) Applicants are invited upon request as applicants hearing to WG and Panel meetings (physical/via teleconference) to answer questions and to clarify outstanding issues about their submitted information 	In place (2015)	
	<ul style="list-style-type: none"> Approach consistency is further strengthen by the adoption of the “Code of Good Administrative Practice” by ApDesk 	Q4 2016 	
5.1 OPEN PANEL PLENARY MEETINGS EXTENDED BY HALF A DAY/YEAR/PANEL <i>Increased public engagement (Open Panel plenary meetings)</i>	<ul style="list-style-type: none"> In 2015, the meeting format was extended to allow for exchange of views between experts and observers In 2016, all the Panels and the Scientific Committee are holding open plenary meetings in Brussels Future enhancement will consider the use of e-tools (e.g. web streaming, interactive webinars, etc.), facilitating greater participation of observers while minimising costs 	In place (2016)	



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5.2 DECISIONS AVAILABLE VIA FLASH SUMMARY/ABSTRACT AFTER THE PLENARY MEETING (C2) <i>Increase process predictability (scientific outputs)</i>	<ul style="list-style-type: none"> Video-casted “flash reports” following open plenaries, are published just after the meeting is concluded. 	In place (2016)	
	<ul style="list-style-type: none"> Flash summaries reporting the outcome of plenary meetings are available on EFSA website at the end of the plenary. 	Q4 2016 	
5.3. ACKNOWLEDGEMENT OF THE ROLE OF THE SHS CONTRIBUTION INTO EFSA'S WORK (C1) <i>Foster engagement (scientific outputs)</i>	<ul style="list-style-type: none"> The role of SHs is acknowledged in the opinions SHs are engaged according to their expertise, at different steps in the R.A. workflow 	Q4 2016 	Development aligned with new Stakeholder Engagement Approach
6.1- 6.4 PUBLICATION OF EVIDENCE USED AND THOSE DISCARDED IN A READABLE FORMAT AND MENTION OF GAPS WHERE THEY EXIST (C2) <i>Empower the public to scrutinise EFSA work (scientific outputs and application assessments)</i>	<ul style="list-style-type: none"> The data and information is made available in a readable and reusable format to all stakeholders through EFSA's website/ EFSA's Data Warehouse with access rules after publication of the opinion. 	Q4 2018 	Development aligned with Information Management Programme , and: <ul style="list-style-type: none"> Electronic Management of Regulated Products Applications Lifecycle project Information Platform for
	<ul style="list-style-type: none"> Discussion Group of the Electronic Management of Regulated Products Applications project agrees on the definition of commercially sensitiveness of data (including legal aspects) 	Q4 2017 	
	<ul style="list-style-type: none"> Summaries of applicant's data are available through EFSA website following dossier acceptance (currently already available for NUTRI Health claims Art. 14, FEED GMO, and Pesticides) 	Q4 2018 	

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	<ul style="list-style-type: none"> A coordinated approach to collect, store and access monitoring data on chemicals and chemical mixtures, in humans and in the environment (between MSs and other EU agencies) is established 	Q4 2018 	Chemical Monitoring project <ul style="list-style-type: none"> Scientific Data Warehouse Open Scientific Advance Information and Evidence Hub Information Access management
	<ul style="list-style-type: none"> Access to data collected by EFSA in support of its risk assessment process and in accordance with agreed access rules to different categories of stakeholders is granted (currently already granted to 150 registered users). EFSA data collection process and tools are improved according to the Reference Terminologies and Management system 	Q4 2016 	
	<ul style="list-style-type: none"> A central repository for data, models/methods and a dedicated portal is made available to allow both storage and user-friendly retrieval of the EFSA’s inputs to its risk assessment 	Q2 2018 	
	<ul style="list-style-type: none"> An enhanced infrastructure for managing and control access to Information is established 	Q2 2017 	
6.2 PUBLICATION OF APPLIED METHODOLOGIES <i>Empower the public to scrutinise EFSA work (Scientific outputs)</i>	<ul style="list-style-type: none"> The new guidelines on the structure and content of EFSA’s scientific opinions and statements are established 	In place (2015)	
	<ul style="list-style-type: none"> Work is in progress, with further pilots in 2016 involving all panels to test the implementation of Promoting Methods for Evidence Use in Scientific assessments (PROMETHEUS) and collect lessons learned. A decision on its final implementation is taken 	Q4 2017 	Developments aligned with Promoting Methods for Evidence Use in Scientific Assessments project

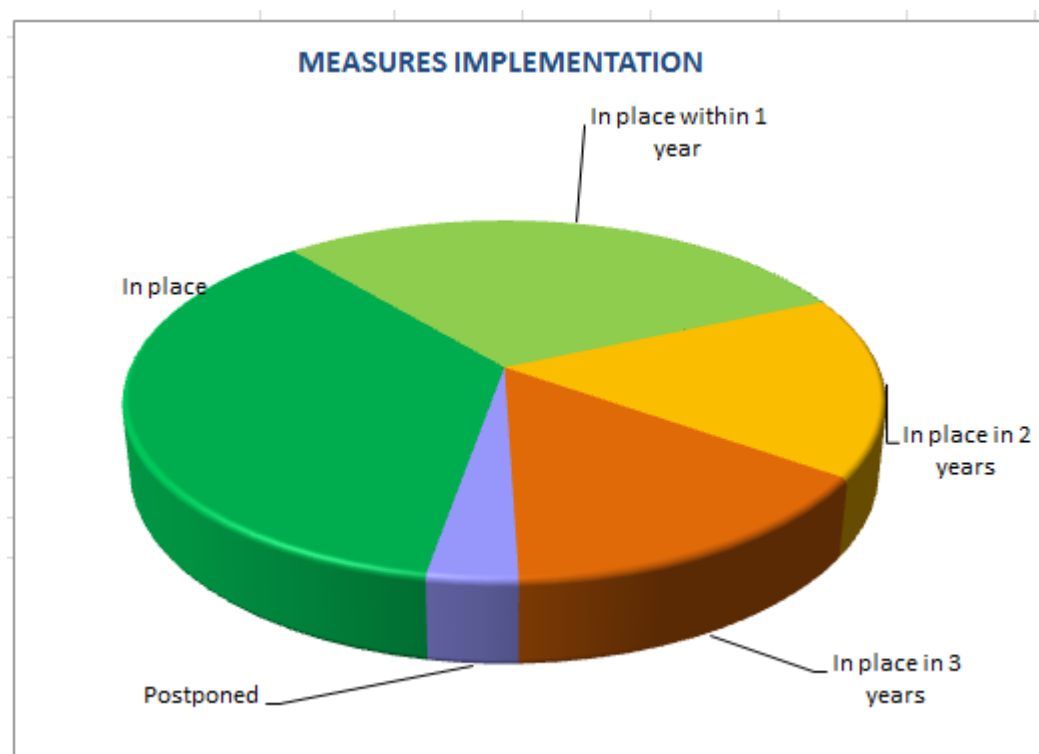
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6.3 POST-ADOPTION FOLLOW-UP MEETINGS (C2) <i>Clarity on outcome of risk assessments (Scientific outputs)</i>	<ul style="list-style-type: none"> Post-adoption teleconference with individual applicants receiving negative and/or inconclusive opinion described in EFSA’s Catalogue of support initiatives during the lifecycle of applications for regulated products are available upon request (shortly to be extended to any finalized and published output) The outcome is followed-up by an EFSA’s letter including the main points of the discussion 	In place (2015)	
6.5 POSSIBILITY TO POST COMMENTS ON OPINIONS; STRUCTURED PROCESS ALLOWING FOR SUCH AN INTERACTION <i>Empower the public to scrutinise EFSA work (Scientific outputs)</i>	<ul style="list-style-type: none"> The Scientific Committee (SC) guidance on re-opening of opinions is established and includes criteria for posting comments during the re-opening process and how these will be addressed by EFSA 	Q2 2017 	Developments aligned with adoption of SC guidance on opinion re-opening
6.6 REVIEW LANGUAGE REGIME <i>Increase reach of EFSA’s scientific outputs (Scientific outputs)</i>	<ul style="list-style-type: none"> EFSA scientific outputs are (heavy/light) edited by Wiley in consistent manner. For issues of high public interest, EFSA publishes lay-audience summaries (English-language only) 	In place (2016)	
	<ul style="list-style-type: none"> Further implementations (ie. 24 languages translation) very resource intensive, return on investment not expected 	Postponed	
7.1 MAKE PUBLICLY AVAILABLE ALL DOCUMENTS LINKED TO A DECISION ON WHETHER TO UPDATE A SCIENTIFIC OUTPUT (C2) <i>Empower the public to scrutinise EFSA work (Scientific outputs)</i>	<ul style="list-style-type: none"> The Scientific Committee (SC) guidance on re-opening of opinions is adopted and specifies the evidence and documentation that is required for decision-making 	Q2 2017 	Developments aligned with adoption of SC guidance on opinion re-opening

5. NEXT STEPS

The deployment of the TERA project responds to EFSA’s Strategy 2020 (and in particular Strategic Objective 1). The proposed implementation plan will be translated in resource requirements and introduced in EFSA Single Programming Document and yearly work plans according to the agreed timelines (see Figure 2).

Figure 2. TERA measures implementation timelines



However, it has to be acknowledged that the measures as currently foreseen by the TERA project are the results of a consultation that was carried out in 2014. EFSA will have to keep abreast of new developments in “Open Science” and continue to respond to societal demand for further transparency and engagement. In addition, EFSA will remain vigilant on technological developments that might offer new tools and further facilitate the Authority ambitions.