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European Food Safety Authority

Implementation Plan – First Phase Transformation to an "Open EFSA"

Management Board, 18 - 19 March 2015

European Food Safety Authority

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1. Scope of the document

This document identifies how EFSA will further embed transparency and openness into its scientific processes, following public consultation on its discussion paper "Transformation to an Open EFSA"[1].

It describes the principles and phases of the approach that will support ranking and prioritisation of the "measures" identified by EFSA and/or suggested by stakeholders.

The document explains the method developed for assessing the cost-effectiveness of measures to support further transparency and openness at EFSA. It is aimed primarily at EFSA's Management Board and EFSA's stakeholders.

2. EFSA's response to public feedback: the list of measures

In 2013, EFSA started an initiative aimed at re-framing how it runs its scientific operations exploiting the opportunities offered by the latest institutional, technological and societal developments.

EFSA carried out a consultation and organised a workshop with its interested parties,[2] which allowed the Authority to identify stakeholders' needs and perceived benefits of the transparency and openness of EFSA's scientific advice.

These findings were then reflected in a paper with the aim of triggering further discussions on how to put in place an effective process based on full transparency and dialogue with the public on the questions, the data, the methodologies used and the outcomes of EFSA's scientific processes.

During the third quarter of 2014, EFSA consulted the public on the ideas put forward in this paper, gathering contributions from stakeholders and institutional partners.

Based on comments and suggestions, a *list of measures* has been drawn up and is detailed in paragraph 6 of this document. It contains:

- initiatives as initially identified by EFSA or refined after public feedback; and
- new ideas suggested by the public, omitting proposals conflicting with regulatory constraints and issues related to the management of expert's interests. The latter is the subject of a separate policy review scheduled for later in 2015 and 2016.

3. Implementing the measures: a two-tiered approach

The measures have been classified into two categories:

- **Category 1**: measures that the Authority considers can be reached by 2017 due to actions already delivered or planned in its portfolio of projects and programmes. These are part of the continuous improvement of EFSA processes and are subject to ex-ante evaluation activities undertaken by EFSA.
- **Category 2**: measures that do not fall under the previous category and:
  - *improve services and outcomes for stakeholders and risk managers* – EFSA will construct 'value models' based on measurable operational and stakeholder benefits (lower cost, quicker response, higher quality or satisfaction, increased public scrutiny, etc.); or
  - *significantly change the nature of one or more steps* of the scientific decision making process – since 'value models' cannot be meaningfully applied here, high level targets with frequent milestone reviews will be evaluated, as well as pilots and "early wins".

[1] European Food Safety Authority, Discussion Paper Transformation to an "Open EFSA", available online at http://www.efsa.europa.eu/en/corporate/doc/openefsadiscussionpaper14.htm

[2] EFSA Stakeholder conference - Transparency in Risk Assessment, held in Parma on 3 October 2013, whose programme, presentation and minutes are available online at http://www.efsa.europa.eu/it/events/event/131003.htm.

4. Category 1: implementing and monitoring

Measures that impact the transparency and openness of EFSA core business, will be consolidated into three multi-annual programmes to coordinate and align all the projects handling (1) methodologies, (2) expertise and (3) information in EFSA to facilitate attainment of the vision.

Quarterly reviews of the portfolio will ensure that programmes stay aligned with the promised benefit delivery and transparency and openness strategic objectives.

5. Category 2: assessing and prioritising

The assessment will be rolled out in three steps:

5.1.1. Step 1: design the technical approach

Objective and activities: define a technical guide that will detail the approach to be used and design the value decision tree that will allow applying the cost benefit analysis, and in particular:

- measures for which EFSA will focus on a fully-fledged cost benefit analysis,
- measures for which no early attempt to link to return on investment or hard targets will be made.

Deadline: Q2 2015

5.1.2. Step 2: re-shaping the Risk Assessment process

Objectives and activities: select measures that maximize benefits, unless the EFSA Founding Regulations requires another regulatory approach, by:

- defining at what level of expected benefit a measure may be worth implementing,
- quantifying measures, to the extent that these can be reasonably estimated,
- comparing costs and benefits all along the implementation plan,
- prioritising measures that compete for EFSA public resources.

The assessment results and its outputs will be used as a decision support tool in all matters related to transparency and openness.

Deadline: Q4 2015

5.1.3. Step 3: monitoring the results

Objectives and activities: update the assessment to show whether a measure is achieving its promised benefits.

If a measure fails to meet expectations, EFSA can redesign or, in some cases, stop delivery and reallocate efforts to better performing measures. Measures will be considered from a range of perspectives, including qualitative feedback, strategic contribution to transparency and openness, capacity to deliver, alongside the Cost Benefit Ratio.

Deadline: Q4 2016

6. Detailed implementation plan

	SCIENTIFIC DECISION MAKING WORKFLOW	MEASURES	SCOPE	CORE OUTCOMES	CATEGORY	DELIVERY DATE
1	**Define the mandate**	1.1 Public consultation of framing of mandates and related questions	1.1 Scientific outputs, except application assessments	1.1 Potentially adjusted risk assessment question(s)	C2	
		1.2 Simplification of requirements to take active role in public consultations	1.2 All public consultations by EFSA	1.2 Increased engagement rate	C1	Q4 2016
		1.3 Pre-notify interested parties of forthcoming public consultation	1.3 All public consultations by EFSA	1.3 Increased planning capacity of the public	C1	Q4 2015
		1.4 Pre-submission meetings with applicants in the area of regulated products	1.4 Draft applications in the area of regulated products	1.4 Clarification of data requirements	C2	
		1.5 Meetings with stakeholders	1.5 Scientific outputs, except application assessments	1.5 Mutual understanding of question to be addressed	C2	
2	**Define expertise**	2.1 Publish full biographies	2.1 Experts working with EFSA	2.1 Ability of public to scrutinise experts backgrounds	C1	Q4 2016
		2.2 Documentation of the criteria of selection of Working Group members	2.2 Experts working with EFSA	2.2 Auditability of expert selection process	C1	Q4 2015
		2.3 Documentation of the criteria of the selection of Hearing experts	2.3 Expertise not available in Working Groups	2.3 Enlarged pool of expertise available; auditability of expert selection process	C2	
3	**Define risk assessment methodology and evidence**	3.1 Consultation on the risk assessment methodologies	3.1 Scientific outputs except application assessments	3.1 Improve scientific quality and ownership	C2	
		3.2 Open and/or targeted call for data/information	3.2 Scientific outputs	3.2 Widen EFSA's evidence base	C2	

SCIENTIFIC DECISION MAKING WORKFLOW		MEASURES	SCOPE	CORE OUTCOMES	CATEGORY	DELIVERY DATE
		3.3 Consultation on the format of the call for data/information	3.3 Calls for data/information	3.3 Clarity on requested data	C2	
4	**Prepare draft advice**	4.1 Consultation on missing data/information to be considered by EFSA	4.1 Scientific outputs	4.1 Widen EFSA's evidence base	C1	Q2 2016
		4.2 Proactive release of data/information in a readable/reusable format	4.2 Information linked to the risk assessment decision making process, except commercially sensitive one	4.2 Empower the public to scrutinise EFSA work	C2	
		4.3 Increased accessibility to key data packages of Member States	4.3 Member States data	4.3 Build knowledge community	C2	
		4.4 More feedback on the extent and on the reasons why certain data were or were not used	4.4 Scientific outputs	4.4 Empower the public to scrutinise EFSA work	C1	Q4 2016
		4.5 Minutes reflecting the flow of the discussions	4.5 Panel meetings	4.5 Clarity of the decision making	C1	Q3 2015
		4.6 Public consultation on draft opinions	4.6 Scientific outputs, except application assessments	4.6 Improve scientific quality and ownership	C2	
		4.7 Post public consultation technical hearings	4.7 Scientific outputs, except application assessments	4.7 Increase likelihood of convergent opinions	C2	
		4.8 Pre public consultation meetings with Member States	4.8 Scientific outputs, except application assessments	4.8 Increase likelihood of convergent opinions	C2	
		4.9 Put in place external peer review system	4.9 Scientific outputs	4.9 Improve scientific quality	C2	

SCIENTIFIC DECISION MAKING WORKFLOW		MEASURES	SCOPE	CORE OUTCOMES	CATEGORY	DELIVERY DATE
		4.10 Increase transparency of the weight of evidence approach	4.10 Scientific outputs	4.10 Harmonized way of evidence integration	C1	Q4 2016
		4.11 Ensure consistent decision making on the confidentiality of application dossiers, including right to be heard	4.11 Applications dossiers	4.11 Ensure legal certainty	C1	Q4 2015
		4.12 Transparency on the identification of key studies and detailed reasons to discard studies which document harmful effects.	4.12 Scientific outputs	4.12 Empower the public to scrutinise EFSA work	C1	Q2 2016
		4.13 Q&A document comprising the questions posed during the stop the clock processes	4.13 Application dossiers	4.13 Establishment of good administrative practice	C2	
		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.	4.14 Application dossiers	4.14 Clarity to applicants on study requirements	C2	
5	**Discuss and adopt advice**	5.1 Open Panel plenary meetings extended by half a day/year/panel	5.1 Open Panel plenary meetings	5.1 Increased public engagement	C1	Q4 2015
		5.2 Decisions available via flash summary/abstract after the plenary meeting	5.2 Scientific outputs	5.2 Increase process predictability	C2	
		5.3 Acknowledge the role of stakeholders' contribution into EFSA's work	5.3 Scientific outputs	5.3 Foster engagement	C1	Q4 2016

SCIENTIFIC DECISION MAKING WORKFLOW		MEASURES	SCOPE	CORE OUTCOMES	CATEGORY	DELIVERY DATE
6	**Communicate advice**	6.1 Publication of data/information used and those discarded in a readable format	6.1 Scientific outputs	6.1 Empower the public to scrutinise EFSA work	C2	
		6.2 Publication of applied assessment methodologies	6.2 Scientific outputs	6.2 Empower the public to scrutinise EFSA work	C2	
		6.3 Post-adoption follow-up meetings	6.3 Scientific outputs	6.3 Clarity on outcome of risk assessments	C2	
		6.4 Publication of all information received from applicants (except commercially sensitive data) and mention of gaps where they exist	6.4 Scientific outputs for application assessments	6.4 Empower the public to scrutinise the outcome of scientific outputs	C2	
		6.5 Possibility to post comments on opinions; structured process allowing for such an interaction	6.5 Scientific outputs	6.5 Empower the public to scrutinise EFSA work	C2	
		6.6 Review language regime of publication of output	6.6 Scientific outputs	6.6 Increase reach of EFSA's scientific outputs	C2	
7	**Update advice**	7.1 Make publicly available all documents linked to a decision on whether to update a scientific output	7.1 Scientific outputs	7.1 Empower the public to scrutinise EFSA work	C2	