

**NOTE TO THE DIRECTOR OF THE SCIENCE STRATEGY AND COORDINATION AND TO  
THE DIRECTOR OF RESOURCES AND SUPPORT**

**TYPE OF THE MANDATE: INTERNAL MANDATE PROPOSED BY EFSA TO THE SCIENCE  
STRATEGY & COORDINATION DIRECTORATE AND THE LEGAL &  
REGULATORY AFFAIRS UNIT FOR A POLICY RELATED TO INFORMATION  
ACCESS IN THE SCIENTIFIC DECISION MAKING PROCESS**

**TITLE OF THE MANDATE: EFSA TRANSPARENCY PROGRAMME 2013 -2016: – PROJECT FOR  
DEVELOPMENT OF A NEW POLICY RELATED TO INFORMATION ACCESS  
IN THE SCIENTIFIC DECISION MAKING PROCESS**

**MANDATE IS REPLACING INTERNAL SCIENCE PROJECT DESCRIPTION ON NEW TRANSPARENCY  
INITIATIVE (P-2013-00015/26/02/2013)**

**BACKGROUND:**

In EFSA's context transparency is defined as the extent to which interested parties have legitimate access to information to meet their needs to understand the basis of EFSA's scientific decision-making process and its related outputs. Openness is defined as the extent to which interested parties are enabled to participate in EFSA's decision making processes. Openness and transparency are recognised as two of the principles available to the European Union, whose implementation may contribute to legitimise its existence and administrative action *vis-à-vis* the European citizens and taxpayers. This also holds true for Union agencies and transparency is one of EFSA's core organisational value together with openness, scientific excellence and independence. In this context EFSA's Management Board adopted in 2003 EFSA's approach to "openness, transparency and confidentiality" and in 2005 it issued a decision concerning implementing measures of transparency and confidentiality. EFSA's Scientific Committee issued in 2006 and 2009 two opinions on transparency in risk assessment one related to procedural aspects and the other related to scientific aspects.

EC Regulation 1049/2001 provides the legal framework on public access matters and applies to all documents held by an institution, that is to say, documents drawn up or received by it and in its possession, in all areas of activity of the European Union.

Over the years the environment in which EFSA operates and the framework applicable to openness and transparency have evolved and there is a growing demand from interested parties for more transparency of the scientific decision-making process. In order to appropriately act on these demands there is a need for EFSA to further reflect on and to define a clear and updated framework, which lays down EFSA's policy and approaches to:

1. Information access related to the scientific decision-making process.
2. Engagement of stakeholders at the initiation of, during and after the scientific decision-making process.
3. Better understanding of the scientific decision-making process.

The current project will deal with the first aforementioned point.

## **OBJECTIVES:**

The objectives of the transparency programme, in general, is to provide clarity on EFSA's policy and approaches towards openness and transparency underlying the scientific decision-making process and thereby promoting confidence, legitimacy, accountability and participation in the work of the Authority among all interested parties.

The objectives of the current project, in particular, is to develop the EFSA policy related to disclosure of information in the risk assessment process.

## **TERMS OF REFERENCE:**

1. In a first step, EFSA is asked to develop a new policy related to information access, as follows:
  - Access to documents to enhance the EFSA's implementation of the EC Regulation 1049/2001 on public access to documents and to strengthen and centralise EFSA's procedure aimed at harmonising the handling of specific access requests.
  - Extent to which information underlying the scientific decision-making process should proactively be made available to the public, and at what time of the process, including open meetings, for different categories of documents (e.g. application dossiers, draft opinions).

The sharing of Member States owned data should be addressed separately and to be included in a data warehouse access rules to be developed by EFSA.

## **KEY STAKEHOLDERS OF THE PROJECT:**

1. EFSA staff
2. EFSA scientific experts
3. EFSA Management Board
4. EFSA Stakeholders (Institutional, non institutional) and media

## **SCOPE IN EFSA'S WORK AND OUTSOURCING PROGRAMME:**

The transparency programme is part of EFSA's continued efforts and commitment to safeguard its core values and to build trust in its work. The transparency programme addresses the recommendations made by the EFSA Management Board (December 2012). Transparency in the scientific decision-making process touches on many important aspects such as selection of independent high qualified experts, data warehouse access rules, quality management, and communication roadmap which are also addressed in other EFSA programmes to safeguard EFSA's core values.

## **PROJECT GOVERNANCE:**

Project sponsor: Juliane Kleiner

Project manager: Dirk Detken

Management Team: ED, Science and Communication Directors, HoU LRA, HoU EXO

Consultative Forum: Joint Science meeting members

## **IT IMPACT (NO/YES - IF APPLICABLE PLEASE EXPLAIN THE RESOURCE IMPACT):**

Yes, the transparency programme part 1 may have an IT impact however at the moment the resource impact is not quantifiable as it will depend on the extent to which meetings will be recorded/web streamed and documents to be proactively released on the website (analysis currently underway). An IT impact, if any, will be relevant for 2015, since the policy is expected to be adopted in December 2014. An informed estimate of this impact can be done in time within 2014.

## TIMELINE AND EXPECTED DELIVERABLES:

Milestones for Part 1 of transparency programme: Policy on openness and transparency focusing on information access and open Plenary meetings.

Milestone	Timeline
Meeting record of input from interested parties via first meeting of Stakeholder Consultative Forum Discussion Group on information access and process transparency: <i>focus on information access</i> <sup>1</sup>	Done
Input from interested parties via scientific conference on openness and transparency.	Done
Meeting record of input from interested parties via a second meeting of Stakeholder Consultative Forum Discussion Group on information access and process transparency: <i>focus on process transparency</i> <sup>1</sup> .	Done
EFSA's internal analysis on the extent to which information can be proactively disclosed, including participation as observers to Plenary meetings <sup>2</sup> .	January 2014
Drafting of policy on openness and transparency focusing on reactive and proactive information release and approval by EFSA's Management team.	April 2014
Public consultation of draft policy on openness and transparency.	May – June 2014
Revised draft policy taking into account comments received during public consultation.	October 2014
Submission of draft Policy to EFSA's Management Board for possible adoption.	December 2014
Publication of policy together with technical report addressing comments received during the public consultation.	December 2014

## PUBLICATION PLAN (IF APPLICABLE):

Policy on openness and transparency and the technical report addressing comments received during the public consultation to be published on the web in December 2014.

<sup>1</sup> See also TOR of EFSA Stakeholder Consultative Platform Discussion Group on Process transparency and information access)

<sup>2</sup> A relevant internal mandate from EFSA to SCISTRAT P&M Team, approved on 12 December 2013, on "the attendance of observers at EFSA SC/Panel meetings" will feed into this.

Production of scientific outputs			Consultation Mechanisms			Resource and Timing Impact			
Panel	WG	EFSA Staff	Network meetings	Workshops Seminar	Public Consultation	Other Financial Resources (excl. Art.36, Procurement)	Duration of execution	IT Costs	Total cost (incl. Art.36, Procurement)
No	No	1.6	No	YES 1 stakeholder conference 2 Stakeholder Consultative Forum Discussion Group	No	No	24 months	TBC	42,000€

#### FTE (2013-2014)

SCISTRAT: 0.5 FTE  
 LRA: 0.5 FTE  
 REPRO: 0.3 FTE  
 RASA: 0.1 FTE  
 COMMS: 0.1 FTE  
 EXO: 0.05 FTE  
 CORSER: 0.05 FTE

#### PROGRAMME MANAGEMENT LAYER

#### OTHER PROJECTS UNDER THE TRANSPARENCY PROGRAMME 2013 – 2016:

In view of the horizontal nature of the core value transparency at EFSA and the number of projects that are included under the umbrella of the transparency programme (see Annex I), it is crucial to continue monitoring this linkage over the next years. It is suggested that the management team of this project pays special attention to the coordination of communication among the project teams for a lean integration of the parts and successful completion of the programme.

[SIGNED]  
Bernhard Url

## ANNEX I

Other projects under the EFSA Transparency programme 2013 -2016:

- A. EFSA will also lay down approaches for its engagement with stakeholders at the initiation of, during and after the risk assessment process. The final outcome of the project(s) should lay down EFSA's principles for but not be limited to:
- Involvement of interested parties at the initiation of the risk assessment process, e.g. public consultation of new drafted mandates of specific public interest, or the organisation of public hearings at the beginning of the risk assessment process.
  - Extent to which advice can be given to business operators before submitting an application for an assessment by EFSA.<sup>3</sup>
  - Extent to which feed-back is given to applicant business operators during the risk assessment process.
  - Public consultation of draft opinions other than Guidance Documents.
  - Extent to which feed-back should be given after a scientific output is published.
- B. EFSA will further promote the understanding and transparency of the scientific decision-making process and the fit for purpose of EFSA's scientific output via various projects. Projects should address but not be limited to:
- Update the format for scientific opinions to ensure that the information content of all opinions is as complete as appropriate in the interest of full transparency.
  - Gather feed-back from institutional customers on whether EFSA's scientific outputs are fit-for-purpose and to provide a proposal to the Executive Director on how the customers feed-back can be translated into concrete actions.
  - Provide a framework for a harmonised and transparent approach in searching and appraising the scientific evidence (SC and EFSA).
  - Redesign of EFSA's website to enhance its user-friendliness.
  - Laymen summary for certain opinions.
- C. EFSA will develop a separate policy on the sharing of Member States owned data via a project which will provide data warehouse access rules.

---

<sup>3</sup> An internal mandate proposed by EFSA to the APDESK Unit for a Project on "interactions with stakeholders – development of a customer oriented approach" should feed into this second step of the transparency programme.

**INDICATIVE TIMEFRAME FOR OTHER PARTS OF THE TRANSPARENCY PROGRAMME:**

<b>Activity</b>	<b>Timeline</b>
Revised format for EFSA's scientific opinions (self mandate of the Scientific Committee).	2014
Proposal to the Executive Director on how the institutional customers feed-back on the utility and fit-for-purpose of EFSA's scientific advice can be translated into concrete actions (EXO).	2014
Data warehouse access rules (LRA and DATA).	2015
Framework for searching and appraising the scientific evidence (AMU, Scientific Committee and SCER).	2015
EFSA approaches for its engagement with stakeholders at the initiation of, during and after the risk assessment process (SCISTRAT, APDESK and LRA).	2016
Redesign of EFSA website (Communication).	2015