Discussion Paper
Transformation to an **"Open EFSA"**

Public Consultation, 17 July - 15 September 2014

efsa
European Food Safety Authority

Executive Summary

This discussion paper sets forth a conceptual framework, a step-by-step methodology and a plan for the transformation of the European Food Safety Authority (EFSA) into an Open Science organisation over the next five years. Transparency (access to data, information and documents) and openness (engagement) have been key values for EFSA since its creation in 2003. Adherence to these values helps to legitimise EFSA's work and ensure accountability to society. The Open EFSA initiative aims to explore how EFSA can better meet society's expectations now in EFSA's second decade as the EU food safety system's scientific risk assessor. It also aims to understand the implications that increased openness and transparency could have for the Authority's organisational set up. The Open EFSA initiative will follow three key steps: by the end of 2014, EFSA will finalise a list of possible actions that should be subject to a cost/benefit analysis; from 2015, as and when each cost/benefit analysis is completed EFSA will develop a plan to prioritise each action considering their added value; finally, from 2016 onwards, EFSA will roll out the actions as and when possible.

This paper is designed to promote a discussion and to seek the input of EFSA's partners and stakeholders as well as experts and practitioners in the field of open government and open science, on these specific points:

- Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with or would you suggest additional ones that the paper does not capture?
- How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction?
- How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established?
- How can EFSA foster even further an environment of creative debate amongst its experts by striking the appropriate balance between availability and quality of information?
- Would you identify any other strategic drivers, contextual elements or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA?

Interested parties and the public at large are invited to submit written comments, via the dedicated page on the EFSA website, by 15 September 2014.

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1. Introduction

This document aims at strengthening the implementation by EFSA of Openness and Transparency principles.

Openness and Transparency have been systematically identified as key elements in bringing citizens closer to the European Union, and the Union closer to its citizens. In this context, Openness is meant as an enabler for citizens to participate more closely in the decision-making process, and transparency as the quality of being clear, obvious and understandable without doubt or ambiguity, thereby contributing to increased understanding of the actions of Union administrations.[1] Together these values help to legitimise decisions taken in the public interest and enhance accountability of the concerned actors.

Decentralised agencies of the Union need to be particularly attentive to the need for openness, and of their operations being understandable and accountable to Union citizens and interested parties. EFSA is an agency of the European Union established to provide scientific advice and scientific and technical support on all direct or indirect risks related to the food chain. It is required to do so while operating to high standards of openness, transparency and scientific excellence. Since its creation, the Authority has placed great emphasis on these principles.

The benefits of public engagement

In EFSA's context, openness and transparency allow civil society to be informed about EFSA's internal processes, to have access to and understand its outputs, and to engage in EFSA's scientific decision-making process in the appropriate consultative fora. This engagement is intended to result in scientific outputs that should be more comprehensive, more understandable to those who contributed to their development and more relevant to the intended recipients. This, in turn, is more likely to address the requirements of Union risk managers and increase the accountability of institutional actors, such as EFSA, that perform technical tasks. The proactive and committed adherence to openness and transparency values by the Authority facilitates an informed debate, both among experts and the public, on scientific issues within EFSA's remit. Thereby this represents a prerequisite for constructive and informed dialogue between the agency and any interested organisation or individual.

For these reasons, upon its establishment, EFSA implemented measures designed to ingrain these concepts in its activities, adopting several corporate documents regulating the Authority's working practices,[2] and policies aimed at enhancing EFSA's openness to its institutional partners and other interested parties.[3] In recent years, building on the measures already taken, EFSA has developed additional policies raising the bar for the implementation of these principles.[4] For instance, since EFSA was created it has organised more than 100 public consultations on its draft outputs, in 2012, it created an Application Desk as a point of reference for interaction with applicants, and in 2013, EFSA opened up its Scientific Committee and Panel meetings to observers.

1 Recital 2 of Regulation (EC) N° 1049/2001; outlining the same concepts also see Joined Cases C-92/09 and C-93/09, *Volker und Markus Schecke/Hartmut Eifert v Land Hessen*, [2010] ECR I-11063; Case T-233/09, *Access Info Europe v Council* [2011] ECR II-1073 and Professor P. Nikiforos Diamandouros, European Ombudsman, Transparency, Accountability, and Democracy in the EU', Lecture by the European Ombudsman at the School of Advanced International Studies of the Johns Hopkins University, Bologna, Italy, 17 October 2006.

2 European Food Safety Authority, Decision concerning access to documents, MB 16.09.2003 – adopted; European Food Safety Authority, Decision of the Management Board of the European Food Safety Authority concerning implementing measures of transparency and confidentiality requirements - MB 10.03.2005 – 10; European Food Safety Authority, "Openness, transparency and confidentiality", MB 16.09.2003 – 13 – Agreed.

3 For example, with the establishment of a Consultative Stakeholders Platform and the creation of sectoral Networks to enhance cooperation with National Competent Authorities.

4 European Food Safety Authority, Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority, mb 15 12 11 – Policy on independence and scientific decision making process – ADOPTED; Id., Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision Making Processes regarding Declarations of Interests, EFSA/2012/05/LRA; Id., EFSA's approach on Public Consultations on scientific outputs; Id., Science Strategy 2012 – 2016; Id., EFSA's Communications Strategy: 2010 – 2013 perspective, mb 16 12 10 item 4 doc 3 – Adopted; Id., Guidelines for observers of 16 December 2013.

2. Drivers of change

Since the founding elements of EFSA's Openness and Transparency approach were laid down, society and technology has evolved substantially.

Societal trends

In 2002, when EFSA was founded, social media was in its infancy, and the potential that openness and transparency could deliver had not yet been fully grasped. Crowd sourcing and open innovation initiatives were still far to the future.

Technological advances

The development and growth of global Information Technology networks has granted rising numbers of users more reliable and faster access to information and opinions on the Internet. Breaking down previous barriers to engagement (distance, knowledge, means of interaction), this change has allowed the gradual and steady growth in users' interest, involvement and participation in projects beyond their traditional spheres of influence.

Opportunities

To exploit these developments, public organisations have put in place Open Government initiatives pushing transparency in the public sector to new heights.[5] Collective intelligence available globally via the Internet is capable of elaborating and digesting enormous quantities of data. The concept of citizen scientist[6] or collaborative projects such as Wikipedia or the Human Genome Project, have shown the potential benefits of collaborative approaches. Public agencies make available pollution, health and enforcement data from countless business operators in public programs where the analysis of the resulting aggregated data could have substantial additional benefits for society.[7] So called e-science is essential for meeting the scientific challenges emerging in the twenty-first century, where the analysis of big data is becoming a fundamental feature of scientific research.[8] This is especially relevant for Union agencies such as EFSA, set up as networking actors to connect national competent authorities at European level. These agencies are charged with creating knowledge communities of professionals and serving as "information hubs" for regulatory decision-making often carried out elsewhere.

Challenges

The societal and technological developments outlined in the previous paragraphs provide both opportunities and challenges for regulatory bodies possessing sizeable quantities of granular and aggregated data that are continuously fed into its scientific decision-making processes.

Greater transparency and openness imply considerable resource investments, both in financial and human capital terms, linked to the obligation to ensure fair and equal treatment to all interested parties and adequate and efficient processing of the information and data received. Transparency and openness should therefore be result driven and not a goal *per se*, to ensure that EU citizens obtain value for the money invested in the EU project. Furthermore, greater involvement and participation could also hide potential risks, such as disproportionate influence of a limited number of actors or loss of control by the Authority over the content of a document.

On a different level, in line with the *EU 2020* policy goals,[9] investments in product development and innovation must be protected by Union actors to justify the financial risk accepted by investors and to promote the competitiveness of the EU as innovative region. In this respect, there may be negative consequences from the different ways of using the information and data offered. This in turn could trigger the need to put in place appropriate data protection and confidentiality protocols for commercially sensitive information and personal data.

Legal framework

Over the years, the EU has formalised its vision of a European society aspiring to grow based on advanced democratic principles.

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5 See e.g., European Commission, The Digital Agenda for Europe, COM(2010) 245 final/2; *Id.*, Communication on scientific information in the digital age COM(2008) 56; Id., Communication on ICT infrastructures for e-Science COM(2009) 108; G8 "Open Government Partnership", U.K. "Opening Up Government" and U.S.A. "Open Government Initiative", or the Research Data Alliance. More information is available on the websites of each initiative.

6 See e.g. European Commission, Background document for the Public consultation on "Science 2.0: Science in transition

7 See e.g. Envirofacts and Enviromapper websites created by the U.S.A. Environmental Protection Agency

8 European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Open data. An engine for innovation, growth and transparent governance, COM(2011) 882 final of 12.12.2011, 4

9 Communication of the Commission, Europe 2020. A strategy for smart, sustainable and inclusive growth, COM(2010) 2020 final, 3 March 2010, and following communications and reports on the same subject available at http://ec.europa.eu/europe2020/index_en.htm.

Treaty on European Union, maintains the fundamental principle according to which the "ever closer union among the peoples of Europe" takes decisions "as openly as possible".[10] In the "Lisbon Treaty", this is directly linked to the section on democratic principles, thereby acknowledging the imperative that openness (and transparency) be considered a pillar of the EU "democratic principle".[11]

These high level ambitions have been translated in EFSA's Founding Regulation with a strong transparency drive defined by the Legislator as it sought to ensure that the Authority undertakes its risk assessments in an independent, objective and transparent manner[12] and required that EFSA publishes its scientific documents, background information, minutes of its scientific meetings, etc.[13]

The legal framework challenges and empowers EFSA to set out on an innovative pathway to offer EU citizens open and transparent scientific decision-making processes. It is up to the Authority to decide on the actual degree of openness it wants to implement. [14]

3. Vision and goals

Vision: "Society engages in EFSA's scientific work and gains trust in the EU food safety system"

This document aims to lay down the principles and the plan for the creation of an Open EFSA. Yet, openness and transparency *per se* are not an aim. They are instruments used to achieve predetermined policy goals of sound public policy and legitimate decision-making. EFSA's mission is to provide transparent and independent scientific advice to underpin the policies and decisions of risk managers in the European Commission, European Parliament and Member States, to provide effective and timely communication on all risks associated with the food and feed chain to a wide audience, including the public and all interested parties, and to promote coherence in risk communication in cooperation with the Commission and Member States.[15]

"Society engages in EFSA's scientific work and gains trust in the EU food safety system"

Open EFSA goals

Drawing on the Authority's mission and its medium-term planning, the vision of creating an Open EFSA seeks to achieve two primary policy goals within the next five years:

- Improving the overall quality of available information and data used for its outputs
- Complying with normative and societal expectations

3.1 Improving the overall quality of available information and data used for EFSA's outputs

At its core, science is the pursuit and application of knowledge and understanding of the natural and social world following a systematic methodology based on evidence. The field of scientific risk assessment in which EFSA operates does not differ substantially from its parent subject in this respect.

More accessible data means higher quality data

Data have been described as "the lifeblood of the knowledge economy" and of a proper e-science,[16] or "Science 2.0".[17] In the context of its operations EFSA amasses a sizeable quantity of datasets by procuring scientific studies, receiving data contained in application dossiers submitted by commercial operators, awarding grants for the development of scientific projects and publications, literature

10 Article 1, Consolidated Version of the Treaty on European Union, Official Journal C 83/13, 30.3.2010.
11 Articles 10(3) TEU and 11 TEU. More detailed provisions are laid down in Article 15 of the Treaty on the Functioning of the European Union and Article 298 TFEU and Article 41 of the CFREU.
12 Articles 6(2) of Regulation (EC) No 178/2002.
13 Article 38 of Regulation (EC) No 178/2002.
14 This is also confirmed in the Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies, and related Common Approach on decentralised agencies, 19 July 2012, at page 14.
15 Programming Document of the European Food Safety Authority 2014-2016 incorporating Annual Management Plan 2014 and Multiannual Plan 2014-2016 European Food Safety Authority, mb 19 12 13 – EFSA programming document 2014-2016 – ADOPTED, p. 5.
16 See e.g. European Commission, The Digital Agenda for Europe, COM(2010) 245 final/2; *Id.*, Communication on scientific information in the digital age COM(2008) 56; Id., Communication on ICT infrastructures for e-Science COM(2009) 108.
17 See European Commission, Background document for the Public consultation on "Science 2.0: Science in transition.

reviews, analysis of data, and by receiving data from Member States in the context of their monitoring activities. EFSA's potential as a data provider to communities of professionals interested in its work is therefore vast. This potential should be exploited to the greatest extent possible without losing the trust of its partners, individuals and applicants (that is, groups and individuals who submit dossiers to EFSA for scientific evaluation).

EFSA is therefore likely to gain from making data sharing at EU level more open, systematic and transparent, by receiving further input through its interaction with society.

Increasing public scrutiny

EFSA's model of gathering or sourcing scientific evidence and expertise usually rests on the contributions of a combination of external experts, internal scientific resources (such as staff), and outsourcing via the processes set down in the Agency's financial regulations.[18] All these working methods are mostly based on a logic of self-contained scientific expertise, which largely excludes the public, professionals outside EFSA's scientific groups, and also the Authority's stakeholders, with the notable exception of public consultations or hearings.

Enhanced openness to interested parties and external knowledge communities will contribute to enhanced scientific scrutiny, and therefore better quality outputs, by facilitating their active contribution to EFSA's scientific processes and by creating the conditions to make EFSA's assessments more reproducible by others. Ultimately, this would support EFSA's goal of producing complete, meaningful and high quality outputs, in accordance with the EU's *Europe 2020* policy objectives[19]. Such outputs provide EU risk managers with the most complete scientific picture possible thereby further enabling them to take informed decisions.

Exchanging knowledge

Finally, in addition to alignment with the *Europe 2020* strategy and its related initiatives,[20] an increased reliance on open scientific methods should also be supportive of the EU's "Fifth Freedom", the free movement of knowledge.[21] EFSA already endeavours to foster sharing of scientific approaches and literature reviews as its contribution to the development and support of the European Research Area (within the limits of EFSA's institutional remit and in cooperation with its national and international partners). An Open EFSA model can further stimulate and enhance such exchanges.

3.2 Complying with normative and societal expectations

Increasing trust

One of the prime factors for the establishment of EFSA was to regain the confidence of Europe's and third countries' citizens in the EU's ability to address food safety challenges.

Trust in EFSA as a reliable partner and public institution and in its scientific outputs was recognised as one of three strategic objectives in the Authority's Single Programming Document 2014-2016.[22] Transparency is fundamental to achieving and maintaining trust in a public body.

Democratising science

Adopting an open mode of working, guided by a proactive Open Government model,[23] is likely to gradually make processes for developing regulatory science available to a larger part of the public. This is due to the enhanced availability of information (through technological innovation) and the widespread acceptance of an open data culture.

An open model of scientific discussion also grants individuals access to raw datasets or earlier versions of an output, allowing concerned citizens, if they wish, to monitor the progress of an output prior to adoption so as to be potentially ready to contribute, or simply be reassured that the work is being delivered. This increased empowerment of interested groups and citizens would ultimately lead to an enhanced sense of ownership over the process for delivering the final output. Ideally, this secures greater understanding of the outputs and support for their accuracy and reliability, ultimately contributing to increased trust in EFSA's work.

18 These may be either procurement or the award of grants.
19 European Commission, COM(2011) 882 final, *supra* footnote n. 11, 4; *Id.,* A Reinforced European Research Area Partnership for Excellence and Growth, COM(2012) 392 final.
20 European Commission, COM(2011) 882 final and more recently, N. Kroes, Stockholm.
21 Speech of J. Potocnik, European Commissioner for Science and Research, The EU's Fifth Freedom: creating free movement of knowledge, Informal Competitiveness Council, Würzburg, 26 April 2007.
22 European Food Safety Authority, Programming Document of the European Food Safety Authority 2014-2016, supra footnote nr. 1, at 5.
23 European Commission, COM(2011) 882 final and more recently, N. Kroes, Opening up Scientific Data, speech given on 18 March 2013 on the occasion of the launch of the research Data Alliance in Stockholm

Protecting privacy and commercially sensitive information

While being as transparent and open as possible, the Authority is also obliged, and committed, to ensure that information, documents or data entitled to protection from use, reuse or disclosure is handled in the most appropriate manner. This safeguards and satisfies the legitimate interests and expectations of concerned individuals in this context.

For instance, this includes the need to secure the agreement of the data owner, such as Member State competent authorities, for the disclosure of a relevant dataset when this is not already provided for in the relevant legal framework.

In addition, there are strong arguments that open access to scientific publications available to EFSA as part of application dossiers for the evaluation of substances, products, processes, claims or organisms, would contribute to breaking down barriers that hinder access to research data. However, unilateral action by EFSA in this sense could be inappropriate and overstepping its mandate, and ultimately damaging to concerned owners and authors.[24]

In this respect, when it discloses its scientific documents and relevant background documentation, EFSA is bound to comply with the requirement set out in its Founding Regulation to safeguard confidential information and personal or regulatory data protected by EU law. This is an obligation EFSA cannot ignore.[25]

In its enhanced openness drive, EFSA is also expected to protect personal data of the individuals who are directly or indirectly mentioned in studies, documents or exchanges in EFSA's possession.[26]

4. Squaring the circle

The rationale for the *gradual* structuring of the Authority as an Open EFSA is threefold:

- Maximising added-value from the resources available inside and outside the Authority
- Enhancing the efficiency of the agency by shifting the focus to proactive disclosure
- Tapping into the possibilities of citizen scientists and information through innovative use of Information Technology tools.

However, opening up EFSA also presents important challenges. EFSA must consider the appropriate level of interaction with, and support from, third parties that submit information or data (or comments on information or data EFSA holds). The Authority must also assess the costs and the benefits related to the processing of an increasing amount of information and data. Furthermore, it is critical to balance a substantial opening in terms of openness – the ability of the external world to contribute to the development of EFSA's outputs – with procedural guarantees granting EFSA's experts the necessary room for creative discussion and debate.

4.1 Transparency

EFSA's default position on data, information and documents it holds is that they should be made accessible and available to the public, unless one of the few exceptions provided in the relevant legal framework applies. Transparency, therefore, concerns the extent to which information is available on a timely and non-discriminatory basis to allow for increased understanding from interested individuals and communities. Interested parties and concerned individuals should be able to monitor the development of EFSA's outputs, from the moment a request is received by EFSA to the moment the relevant output is published.

This means increased transparency in all the relevant phases of EFSA's scientific and institutional decision-making processes, specifically: a) the preparatory phase of an output; b) the evaluation phase; c) the adoption phase; and d) the communication phase.

24 COM(2012) 401 final, at 7.
25 Respectively Articles 38 and 39 of Regulation (EC) No 178/2002.
26 Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, Official Journal L 008, 12.1.2001, p.1.

Safeguarding free discussion

Yet, EFSA's scientific governance as laid down in the institutional and legal framework is mostly founded on the concept of its Scientific Committee and Scientific Panels, which are the only bodies delegated by law to adopt EFSA's scientific opinions. When assessing the level of openness and transparency to be achieved, EFSA must investigate whether a complete and unchecked opening up of scientific meetings is likely to diminish the qualitative and quantitative level of the scientific discourse. Science and regulatory science are not definitive disciplines. Total transparency may inhibit actors in these challenging sectors, preventing the correct recourse to "trial and error" processes, hindering creativity, the formulation of dissenting opinions or even of basic questions, and favouring entrenchment in mainstream thinking.

In sum, if EFSA fails to protect its experts' views, the Authority could paradoxically stimulate self-censorship and endanger frank and open scientific discussion. To prevent this, EFSA should consider how to best balance implementation of an Open EFSA with the need to maintain the appropriate "room to think".

4.2 Openness

In this context, openness means EFSA's ability to allow for, and benefit from, the participation of a wide range of parties, such as fellow institutional partners, individual professionals, national authorities, industrial or professional associations, academic operators, individual undertakings or Union citizens, who possess knowledge relevant to EFSA's operations. To make enhanced openness real, the content of the information made available must be sufficient, reliable and relevant to issue under discussion.

Principle of reusability

As a Union agency, EFSA is part of the broader EU policy trend to implement the vision set out in Europe 2020 growth strategy. The European Commission has adopted a Decision regulating use and re-use of its data and documents, which includes a general principle on open data and reusability.[27] Although not directly applicable to the Authority, this important legal act sets the course EFSA should follow. EFSA should implement a presumption of reusability and lay down clearly the conditions when, or processes where, the principle should be validly applied while avoiding unnecessary administrative burdens for interested parties and the Authority itself.

Two-way interaction

To enhance the level of openness at EFSA, the Authority commits in general terms to put potential contributors in a position to provide meaningful and relevant input on the data and studies the Authority generates and owns. Further, EFSA aims to develop a system allowing proactive and unsolicited input from interested parties and qualified individuals at all phases of its internal decision-making process, and ideally also after finalisation of its outputs.

For this to become possible, EFSA must ensure that the information and data it makes available are in a format that allows EU citizens and interested parties to use and re-use them to reproduce and verify EFSA's outputs, or to advance science further.

27 Commission Decision of 12 December 2011 on the reuse of Commission documents (2011/833/EU) Official Journal L 330/39, 14.12.2011. For Member States, see also Directive 2003/98/EC of the European Parliament and of the Council of 17 November 2003 on the re-use of public sector information, Official Journal L 345 , 31/12/2003, p. 90 as last amended.

5. Rolling out the change

Preparing EFSA for enhanced transparency, crowd sourcing data and information through innovative use of Information Technology tools requires a detailed plan. This must follow a transparent and open process which comprehensively addresses the opportunities and challenges analysed above. This process must take into account the relevant factors, including input resulting from a thorough consultation of EFSA's stakeholders and other interested parties.

Therefore, EFSA developed a methodology structured on the Authority's scientific workflow to identify which 'Open EFSA' actions proposed by the Authority can be delivered and if so, the implications of such action. The methodology splits EFSA's scientific decision-making workflow into nine main steps, represented in the chart below (see Image 1)

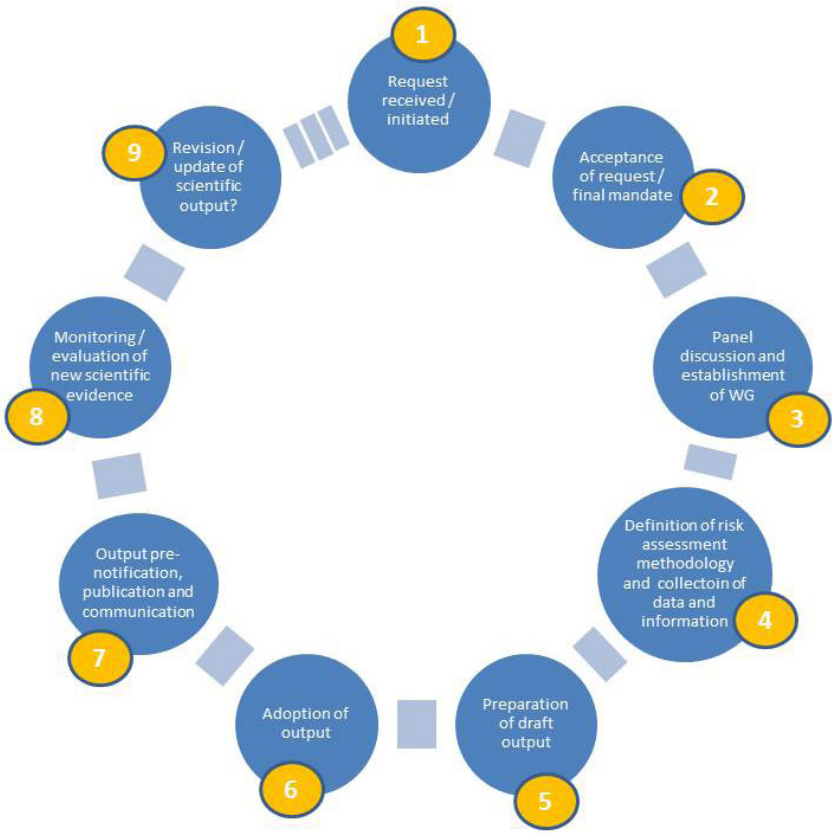

Image 1: Steps in EFSA's scientific workflow

EFSA then applied the following three phases of the methodology (see Image 2):

Phase 1 – Identifying Critical Success Factors

At each step, EFSA identified Critical Success Factors related to the achievement of the two general goals of this document (Section 2 above).

Phase 2 – Policy options and legal checks

EFSA then identified different options at its disposal for meeting the critical success factors, including a legitimacy check to ensure that it complies with application of the institutional and legal frameworks. This Phase implies a judgment call on EFSA's part outlining how and when the actions should unfold.

Phase 3 – Cost/Benefit Analysis

Finally, EFSA devises a timeframe in which to carry out a Cost/Benefit Analysis of each option, determining how suitable they are to EFSA's needs and achievable in view of the available resources.

Each Cost/Benefit Analysis will comprise consideration of costs, effectiveness and proportionality, together with broader reflections on the expected financial perspective for the following years, a comparison of the result and expected benefit from each measure and, where possible, availability of less expensive alternative measures.

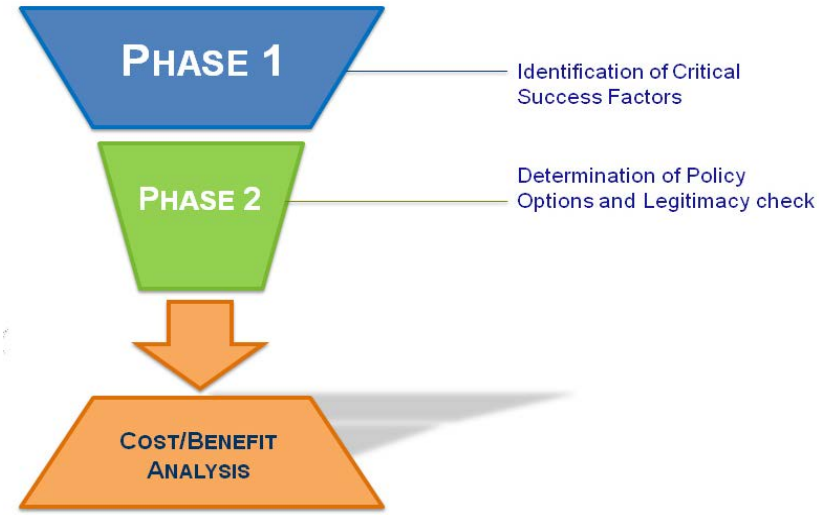

Image 2: Open EFSA methodology

Information technology needs

To be truly effective, an enhanced approach to transparency or open innovation or collaborative projects implies a *de facto*, and not merely formal, enhanced availability of information, data or documents. Such an approach presupposes that all interested parties are in a position to access, and understand, the relevant tools and data. Also to prevent enhanced data openness hampering intellectual accessibility data should be identifiable, easily located and supported by contextualising metadata that allow both professionals and non-specialists to understand and use them.

An ambitious programme like the one outlined in this document, aiming at establishing and fostering an Open EFSA, requires Information Technology infrastructure, which allows the assembling, exploring and sharing of large datasets with a potentially undefined number of users. This system must also be able to gather and keep track of the feedback or input resulting from this sharing process, ultimately transforming EFSA into a data and information hub that identifies inherent relationships and exploits the growing potential of linked data technologies.[28]

EFSA acknowledges that implementation of the approach outlined in this document is dependent on appropriate Information Technology infrastructure and has therefore already earmarked resources for some of the actions stemming from it.[29]

The Open EFSA Options table

The Open EFSA Options table presents the outcome of Phases 1 and 2 of this exercise. This table lists a number of concrete options that EFSA will assess against the relative costs and benefits.

This table paints a stepwise evolution towards gradually achieving Open EFSA, insofar as compatible with legal and regulatory constraints outlined above.

In terms of Transparency of EFSA's processes and outputs, the practical, midterm objective is to make the work carried out by EFSA reproducible by interested parties, bearing in mind the implications for data quality, intelligibility, accessibility and clarity of the output.

Concerning Openness, the actions identified in the table aim at actively seeking data from stakeholders in a more systematic and regular manner. The long-term view is to consider the feasibility of establishing a system allowing the empowerment of citizen scientists within the boundaries of the applicable legal framework and to clarify the extent to which data entrusted to the Authority could be made available to stakeholders, be reused for purposes other than those originally envisaged and/or by individuals other than those empowered by the relevant legal provisions.

28 See *e.g.* Article 33 of Regulation (EC) No 178/2002.
29 European Food Safety Authority, Programming Document of the European Food Safety Authority 2014-2016, supra footnote nr. 2, § 2.3 and ff.

OPEN EFSA OPTIONS TABLE

	SCIENTIFIC DECISION MAKING WORKFLOW	CRITICAL SUCCESS FACTORS	POLICY OPTIONS
1	A request is received or initiated (draft)	Mandate captures societal needs	1. Public consultation if a self task or issue of high public interest 2. Pre-submission meetings (in case of regulated products) or 3. Meetings with main stakeholders and NGOs (in case of general RA's)
2	The request is accepted (final mandate)	Mandate captures societal needs	The mandate is published and explained in the context of previous work (if appropriate)
3	Panel discussion and establishment of Working Group	Reassurance that the selection process reflects expertise needed to address mandate and that selection process is objective and unbiased	1. Publish biographies and Annual Declarations of Interests 2. Documentation on the criteria of selection of WG available in the final output 3. Open calls for hearing experts if appropriate
4	The risk assessment methodology is defined and data/information collection is performed	4.1 Methodology/data/information meets EFSA's and international standards 4.2 Documentation on the methodology/data/information used 4.3 Ensuring reproducibility of the Risk Assessment	1. Public consultation, e.g. statistical data models for analysis, if applicable 2. Consultation reports, including inclusion/exclusion criteria 3. Open and/or targeted call for data/information 4. Pre-publication of the methodological approach chosen or reference to a given guidance document upon which the assessment will be based
5	The draft output is prepared	5.1 An informed and constructive scientific debate is ensured 5.2 Substantiation/traceability of decisions of Working Group/Panel should be available	1. Consultation on possible missing data/info to be considered by EFSA 2. Proactive release of information used in a readable format 3. Proactive release of information not used in a readable format 4. Minutes representing collegial discussions and eventual diverging opinions (Article 30) 5. Public meetings on Expert knowledge elicitation (EKE) 6. Public consultation on draft opinions, 7. Technical hearings in dedicated consultative meetings. 8. Consultative meetings with Member States
6	The output is adopted	Substantiation/traceability of discussions of WG/panel available	1. Open plenary meetings 2. Main decisions available shortly after the plenary meetings 3. Publication of a flash summary/abstract immediately after the plenary meeting
7	The output is pre-notified, published and communicated)	7.1 Concerned parties are prepared for potential impact 7.2 Clarity and understanding of the output's findings as well as EFSA's contribution/role	1. Pre-notification 2. Publication in EFSA Journal a. Publication of the output/decision b. Publication of data/info used and discarded c. Publication of methodology used (i.e. analysis models) 3. Broad array of communications channels depending upon target audience 4. Follow-up meetings 5. Consultation reports, including inclusion/exclusion criteria
8	Monitoring / evaluation of new scientific evidence	Documentation on the information gathering and evaluation process is available	The updated 'file' is publicly available
9	Revision / update of scientific output	Document the need (or not) for a revised risk assessment	New (self) mandate accompanied by contextual risk communications

Undeniably in this process the cost effectiveness evaluation will be particularly important at a time of budget restraints and public spending reviews. EU citizens and taxpayers cannot be expected to willingly finance disproportionate investments in openness and transparency initiatives for the sake of increasing EU institutions' credibility; they are entitled to benefit from concrete gains resulting from activities financed through the EU budget. Therefore, EFSA will focus its resources wisely on must-have and high value-added initiatives.[30]

30 European Food Safety Authority, Programming Document of the European Food Safety Authority 2014-2016, *supra* footnote nr. 2.

6. Open EFSA: the way ahead

"Society engages in EFSA's scientific work and gains trust in the EU food safety system" is EFSA's vision on the path to an Open EFSA.

This document consults the public on this path, and presents a list of policy options that will be assessed by the Authority in terms of costs and benefits. Based on the outcome of this consultation, by 2014 EFSA will adopt a Policy outlining Cost/Benefit Analysis timelines for the implementation of a culture in line with Open Government principles. From 2015, as each cost/benefit analysis is completed, EFSA will develop an action plan to prioritise each action considering their added value. From 2016 onwards, EFSA will roll out the agreed actions in line with the Authority's strategic priorities.

European Food Safety Authority

Via Carlo Magno 1A
43126 Parma
ITALY

Tel. +39 0521 036 111
Fax +39 0521 036 110
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