European Food Safety Authority

QUALITY MANAGEMENT

REPORT OF THE QUALITY MANAGER 2010

Summary

2010 saw the accomplishment of the follow-up to the External Review with the launch of a call for expanding the reserve list of the External Review Working Group, the implementation of eight SOPs in the area of EFSA's scientific activities and business continuity, and the introduction of the concept of Work Instructions with 4 implementations. In addition, Quality Mangement prepared a vision paper for an Integrated Quality Management System (Annex 1) at EFSA for the coming 5 years, ultimately aiming at ISO 9001 certification.

While EFSA has been aiming at developing a Quality manual and implementing a continuous improvement approach, EFSA should now plan for the future by evolving to a more integrated system which should take EFSA to the next level.

This report further outlines the achievements in Quality Management in 2010, i.e. developing SOPs, managing EFSA's review process, and changing the approach to Quality Management to prepare for the future.

1. Development of Standard Operating Procedures as foundation of EFSA's Quality Management System

EFSA started to implement its Quality Management in 2008 by developing a Quality Policy (Annex 2) to promote a culture of continuous improvement and to ensure consistency through EFSA's internal processes, procedures, guidelines and a common methodology.

To successfully apply its Quality Management System, EFSA has been:

- Identifying and documenting the processes needed for the Quality Management System and key processes critical for the realization of EFSA's mission, strategy and policies
- Determining quality objectives and requirements from regulations, partners, stakeholders and others for the output of EFSA's services and deliverables

- Determining, documenting, analysing and evaluating the risks related to these processes and introduce and implement control measure to determine or mitigate the risks
- Determining and documenting criteria and methods needed to ensure that both the operation and the control of these processes are effective
- Ensuring that the internal controls cover the policies and procedures established, documented, implemented and maintained by EFSA's management and that there is documented evidence that the output of the service or the deliverable meet the requirements
- Determining required verification, validation, monitoring, quality control, compliance and test activities specific to the output and the criteria for output acceptance (e.g. deliverables agreed in a framework contract)
- Ensuring the allocation of appropriate resources and the availability of information necessary to support the operation and monitoring of the processes, allocate available resources according to the prioritization resulting from the risk analysis, and document and communicate the risks related to the unavailability of adequate resources
- Implementing actions necessary to achieve the planned results and continual improvement of the processes.

The implementation of the above is helping EFSA to find opportunities for improvement; reinforce our strengths; steer the improvement process; learn by staff involvement; enhance performance and satisfaction; measure progress over time; achieve outstanding practice; ensure consistency; and identify clear roles and responsibilities.

The main focus for developing SOPs was on harmonizing and documenting best practice in the areas of EFSA's scientific and communications activities, and business continuity.

In addition, EFSA has introduced Work Instructions (WIN) in its Quality Management System. WIN are used to describe step-by-step instructions for the accomplishment of a task by one person or team and are retained in the Directorate or Unit where the work is performed.

2. EFSA's review process

2.1 Introduction

Based on a proposal from the Scientific Committee (Annex 3), EFSA decided to develop and implement a proposal for a review system for the quality and consistency of EFSA's scientific activities. These reviews are intended to contribute to improving the quality, clarity and consistency of the scientific advice provided by EFSA in its scientific outputs and ensuring that best scientific practice is followed.

The self review and internal review were developed and launched in 2008, with improvements being made in 2009. The first external review was carried out in 2009.

2.2 Self review

2.2.1 Methodology

The questionnaire with 30 questions (Annex 4) covers the entire process from developing a scientific document to the delivery and follow-up. The questions relate, amongst others, to: clarity of the Terms of References (ToR), (renegotiated) deadline, identification of conflicts of interests and actions taken, composition of Working Groups, collection, completeness and compliance of data, assessment of studies, addressing of data uncertainties, minority opinions, quality of the summary, actions for follow-up.

2.2.2 Results

Out of 17 units submitting a total of 469 self-review reports, the (re)negotiations of deadlines (n=172) and the delays in deadlines (n=94) were most often mentioned (14 out of 17 Units identified at least one of these issues as an area for improvement).

Over the past years, EFSA has been paying special attention to deadline (re)negotiations, taking into account the complexity of the dossier, the workload of the Panel, Network or Working Group. In order to further improve this, EFSA has already initiated the formalisation agreements on any new deadlines for output delivery with the EC, and has established a roadmap with the expected workload, including the timetable.
However, for the applications, where legal provisions determine the deadlines, (re)-negotiations are only possible in certain instances, good planning and prioritization of the overall work is therefore critical as well as good collaboration with the requestors.

Upon processing the experts' declarations of interest, 7 out of the 17 Units identified a potential conflict of interest (n=32) and handled these by either not inviting the expert, or inviting them as a hearing expert, or excluding them from the discussion or signing a waiver for the expert.

2.3 Internal review

2.3.1 Methodology

Randomly selected scientific outputs were reviewed by EFSA, i.e. 2 scientific internal reviewers and 1 communications specialist anonymously and independently addressing a set number of questions (Annex 5). The Head of Unit formulated a reply to the comments of the 3 reviewers in line with SOP 0002 – Self and Internal Review. In 2010, a total of 15 outputs were internally reviewed.

2.3.2 Results

Overall, the internal reviewers' feedback was positive and constructive. The 15 scientific outputs were perceived as being well-written, concise and transparent. Most of the outputs had unambiguous objectives, easy to read and understand, with a clear separation between risk manager and risk assessor in the assessment.

More specifically, the share of the negative comments (C and D scores) out of the 511 scores received, was with a mere 2.7% very low. The questions for which these comments were made most often, were questions 1, 3, 8, 11 and 12, i.e. if the ToRs were adequately addressed (7% of total of replies for question 1), if any assumptions, limitations and uncertainties were adequately addressed and reported (4.8% of total of replies for question 3), if all the conclusions were substantiated in the main body of the text (4.7% of total of replies for question 8), if the summary adequately reflects the context of the question and the content of the output (7% of total of replies for question 11), and, if the summary was adequately informative and clear for the risk managers (4.7% of total of replies for question 12).

The higher scores (A and B) were received for questions 2, 5, 6 and 9, i.e. respecting the boundaries between risk assessment and risk management (100 % of total of replies for question 2), the data/information being adequately presented (97.6% of total of replies for question 5), having a right balance between major and minor findings (97.7% of total of replies for question 6), and the conclusions being coherent with and supported by the main content of the scientific output (95.5% of total of replies for question 9).

The questions for which "not applicable" was replied, was mainly for question 10 on minority opinions (40.5% of all replies received for question 10).

2.4 External review

2010 saw the launch of a call for expression of interest to extend the reserve list of the External Review Working Group (deadline for applications was 15 December). The evaluation and selection of these applicants will take place in 2011. The External Review Working Group was firstly set up in 2009, however, the reserve list needed to be extended due to experts being involved in other EFSA activities and due to the fact that EFSA wanted to include more non-EU experts.

The next external review cycle will occur in 2011 for scientific outputs adopted between 1 January and 31 December 2010.

3. Activities planned for 2011 and beyond

In addition to having an External Review exercise in 2011, EFSA's Quality Management will also focus on :

a. Revision of EFSA's Quality Policy

As EFSA has now a solid back bone of harmonized and documented process and procedures, we are in a position to take the next step and start mapping the road to certification in the overall context of an Integrated Quality Management System (IQMS). EFSA would need to revise and update its Quality Policy in light of this development, paying particular attention to the systematic management of non-conformity, complaints, corrective actions and preventive actions.

b. Establishment, implementation and maintenance of a comprehensive IQMS

An IQMS is a single integrated system used by an organization to manage the totality of its processes in order to meet the organisation's objectives and to satisfy its staff, beneficiaries and other stakeholders.

a. Further development of QMS manual as backbone of the system

EFSA should ensure that the IQMS documentation is understood, implemented and maintained at all levels in the organization. To this extent, a user-friendly electronic system should be further developed to ensure that it can be readily accessed from each desktop at EFSA, the correct document is available at the correct version, at the right place and at the right time. Each SOP should also be linked to the related process maps, templates and supporting documentation.

In addition, Quality Management should also continue to make an inventory and map existing processes in the remaining areas of EFSA and continue developing Work Instructions for those areas where a specific task needs to be described, such as processing of MRL and data collection.

b. Benchmarking/networking for IQMS and best practices

EFSA should consider establishing a benchmarking programme addressing the most important factors for the successful implementation of its IQMS, i.e. by comparing systems and processes and agreeing on the best practices in a cost-effective way. Several other EU agencies, services in the EC, national authorities and stakeholders have experience with the implementation of an IQMS, whereas others might like to benefit from the experience already gathered.

c. Risk management approach

Considering that risk management is part of IQMS, EFSA is to monitor and mitigate risks. EFSA has already conducted 2 High Level Risk Assessment workshops, but also at process level, EFSA is to regularly perform risk analyses. The risks identified at these 2 levels could be merged into a Risk Register whereby risks could be ranked according to priority (e.g. based on their likelihood and on the severity of their consequences). In

addition, EFSA should also determine risk prevention methods in order to mitigate the risk.

d. Internal audits and opportunities for improvement

In order to achieve continual improvement, EFSA started to conduct internal audits in relation to its SOPs in 2010. As internal audits and the resulting action plans are very valuable for the implementation and improvement of the IQMS, it is suggested to further develop this function.

c. Self-Assessment and Certification

For the purpose of certification, EFSA would need to demonstrate conformity with the requirements of ISO 9001:2008. In preparation of this, EFSA will embark on a self-assessment exercise, identifying findings and learnings. EFSA staff will be at the core of this exercise which will give them an opportunity to express what is working well and what needs improving. EFSA can then develop a system Designed to Value (based on Risk Benefit) and move to an explicit integrated Quality Management System.

End

ANNEXES

Annex 1 – Vision paper for an Integrated Quality Management System

Annex 2 – EFSA's Quality Policy

Annex 3 – Summary of the Scientific Committee's proposal for a review system

Annex 4 - Questionnaire for self-review

Annex 5 – Questionnaire for internal review

Annex 1

European Food Safety Authority

Subject : EFSA's Integrated Quality Management System 2010-2015

1. Introduction and purpose of this note

This note describes the achievements in Quality Management (QM) of the past couple of years and to make suggestions in relation to the vision of QM up to 2015. This note also looks at the responsibilities and key actors in an Integrated Quality Management System (IQMS).

2. Achievements 2008-2010

1. EFSA's Quality policy

EFSA started to implement its Quality Management in 2008 by developing a Quality Policy to promote a culture of continuous improvement and to ensure consistency through EFSA's internal processes, procedures, guidelines and a common methodology. The Quality Policy described the main activities and tasks in QM as follows:

- Establish, document, implement and maintain the first part of a Quality Management System in line with EFSA's founding regulation, financial regulations, staff regulations, relevant management documents adopted by the Management Board and Executive Director and the internal control standards.
- Continually improve the effectiveness of the Quality Management System through the use of a quality policy, quality objectives, improvement actions (Plan-Do-Check-Act) and audit results.

Furthermore, EFSA's QM is underpinned by the following guiding principles :

- Leadership and Constancy of Purpose

In order to maximize EFSA staff's commitment and effectiveness, to have a clear sense of direction and to align all activities, the behaviour of EFSA's management should create clarity and unity of purpose and an environment in which its staff could excel.

- Management by Processes and Facts

EFSA should systematically co-ordinate and manage its activities and make decisions and plan improvements using reliable information (for example, focusing on desired outcomes, maximizing the use of the people and resources, setting realistic goals and strategic direction)

- People Development and Involvement

In order to reach maximized participation of the staff, a positive attitude and morale, effective sharing of knowledge, creating an opportunity for people to learn and develop new skills, EFSA should encourage the involvement of everyone by sharing values and a culture of trust and empowerment.

- Partnership/stakeholder/supplier Development

EFSA should have mutually beneficial relationships built on trust and sharing of knowledge with its partners, stakeholders and suppliers. This would create value for all parties and create a synergy in terms of resources and costs.

- Continuous Learning, Innovation and Improvement

EFSA's performance would be maximized when it is based on the management and sharing of knowledge within a culture of continuous learning, innovation and improvement. This would lead to organizational agility, reduction of expenses/costs, identification of opportunities, optimization of performance and prevention-based improvement activities within the daily work.

- Customer Orientated

EFSA is ultimately part of the European system for the development of food law and provides the important first step in the process. It needs to be able to deliver value and insight into the process of the developing measures to mitigate against risks in the areas within its remit.

- Consumer Focus

The European consumer is the main ultimate beneficiary of EFSA's service and output. EFSA should have a clear understanding of how to deliver value to the consumers and to retain their trust and confidence.

- Public Responsibility

The long-term interest of EFSA and its staff are best served by adopting an ethical approach and by meeting the expectations of the European consumers. By doing so, EFSA would increase its public awareness and its trust and confidence. It would also enhance its credibility, performance and value to the consumer.

- Good Governance

EFSA should further apply the principles of good governance, i.e. openness, participation, accountability, effectiveness and coherence. EFSA's policies and decisions should be prepared, implemented and enforced in an inclusive way.

2. Introduction of SOPs as foundation of Quality Management System

To successfully apply its Quality Management System, EFSA has been:

- Identifying and documenting the processes needed for the Quality Management System and key processes critical for the realization of EFSA's mission, strategy and policies
- Determining quality objectives and requirements from regulations, partners, stakeholders and others for the output of EFSA's services and deliverables
- Determining, documenting, analysing and evaluating the risks related to these processes and introduce and implement control measure to determine or mitigate the risks
- Determining and documenting criteria and methods needed to ensure that both the operation and the control of these processes are effective
- Ensuring that the internal controls cover the policies and procedures established, documented, implemented and maintained by EFSA's management and that there is documented evidence that the output of the service or the deliverable meet the requirements
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- Ensuring the allocation of appropriate resources and the availability of information necessary to support the operation and monitoring of the processes, allocate available resources according to the prioritization resulting from the risk analysis, and document and communicate the risks related to the unavailability of adequate resources
- Implementing actions necessary to achieve the planned results and continual improvement of the processes.

The implementation of the above is helping EFSA to:

- find opportunities for improvement
- reinforce our strengths
- steer the improvement process
- learn by staff involvement
- enhance performance and satisfaction
- measure progress over time
- achieve outstanding practice
- ensure consistency
- identify clear roles and responsibilities

One of EFSA's core activities is the provision of independent scientific advice regarding food and feed safety. Therefore EFSA decided to firstly map and start documenting the procedures in relation to its scientific activities. An inventory of existing processes, procedures and other documentation was made with all Units in RA, SCA and SCAF. This inventory provided an overview of what was already in place at EFSA. The Risk Assessment workflow, i.e. a description of the flow of activities from the moment a mandate is received until the publication of the scientific output, was developed and published on EFSA's website.

The Risk Assessment workflow was used as the basis to identify risks (the areas which are most probable to present threats and challenges), processes and activities in the area of organising the work internally and providing scientific support to the external experts contributing to the work of EFSA, where a clear documentation and description of the work processes could lead to enhanced transparency and consistency in the way EFSA produces its scientific output. Once these work processes and activities were identified, a prioritization was done and the Standard Operating Procedures (SOP) developed and implemented.

A documented procedure is to be established to define the controls needed to:

- Approve documents for adequacy prior to implementation
- Review and update as necessary and re-approve documents
- Ensure that changes and the current revision status of documents are identified
- Ensure that relevant versions of applicable documents are available for everyone
- Ensure that documents remain legible and readily identifiable
- Ensure that documents of external origin are identified and their distribution controlled
- Prevent the unintended use of obsolete documents
- Apply suitable identification to all documents

At least 2 Units in RA and SCA were asked to take the responsibility in the drafting of the text. Upon initial agreement of the draft, the SOP was consequently discussed in one or more scientific meetings and circulated for consultation to other relevant Units and/or Directorates. This approach was considered as being efficient and effective as the staff members dealing with the content of the SOP were empowered. Each SOP has an owner, i.e. the person who carries the main responsibility in relation to the purpose of the SOP, and an approver, i.e. the reporting officer of the SOP owner.

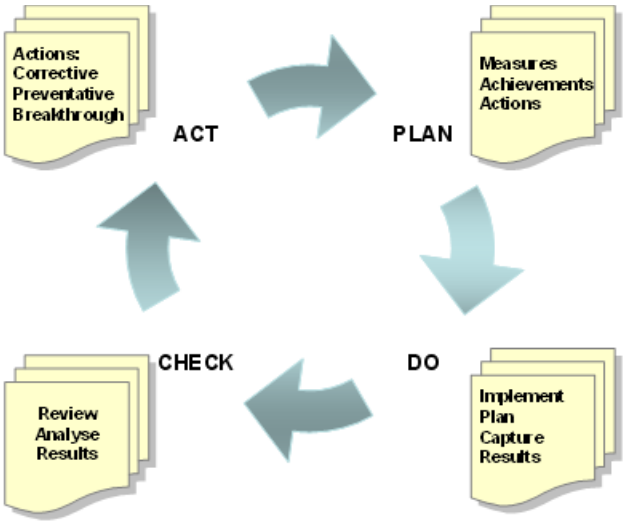
As for SOPs that have been developed in the Administration and Communications Directorates, the QM identified the need for an SOP or the Directorate raised the need with the QM. The SOP was then further developed in line with SOP001 on Developing and Approving a new Standard Operating Procedure.

Between 2008 and mid-2010, the main focus was on harmonizing and documenting best practice in the areas of :

- *Organising scientific meetings* : targeted to staff members in EFSA's Science Directores and Units. Enabling the organisation (from the decision to the follow-up) of a scientific (Committee, Panel, Network or Working Groups) meeting.
- *Adopting an opinion* : this SOP includes adoption of the opinion in the SC/Panel plenary or by written procedure, the editing of the opinion and preparing the opinion for publication.
- *Establishing a WG under the SC, a Panel and a Network* : enables the establishment and the updating of a WG, including the selection of WG experts (at the establishment of and during the WG), the review of their declarations of interest and the invitation of the selected WG experts.
- *Science internal project* : enables the encoding, recording and updating of EFSA science internal projects in the Risk Assessment Workflow system.

- *Monthly reporting* : intended to provide comprehensive information about EFSA's scientific activities for both internal use and dissemination to the Management Board and the European Commission.
- *Checking the completeness, validating and managing an application :* this SOP has been designed to enable the Units in EFSA's RA and SCA Directorates to check the completeness, validate and manage the applications in a consistent way.
- *Conducting a survey for data collection* : targeted to those staff members who are involved in (1) the drafting of and/or analysis of a survey, (2) the drafting of and/or analysis of a call for data, and (3) a survey organized by a third party.
- *Archiving* : this SOP gives an overview of the archiving process from the time the decision has been taken to archive a record up to storage and destruction of the record. The documentation also includes EFSA's Policy on Archiving and guidelines on what, who, when, etc. to archive.
- *Incoming mail* : this SOP enables all EFSA staff to register and process non-confidential incoming mail in a harmonised and consistent manner across all Directorates and Units.
- *Press releases and webstories* : the procedure steps in this SOP facilitates the drafting, approval, pre-notification, publication and dissemination of corporate and scientific press releases and web stories.
- *Correcting published scientific outputs* : targeting all members of staff in EFSA's RA and the Scientific Committee and Advisory Forum Unit (SCAF) dealing with correcting published scientific documents, this SOP has been developed to enable the correction of any relevant already published EFSA scientific output in a consistent and transparent way by the use of the procedural steps.
- *Planning Communications activities* : the aim of this SOP is to explain the cycle of the calendar for communication activities and how it interacts with the different planning processes at EFSA.
- *Preparing a scientific output for publication* : this SOP applies to all staff in EFSA's Communications, RA, SCA and SCAF who deal with preparing and publishing an EFSA scientific output.
- *Conducting a self review and internal review for EFSA's scientific outputs* : provides EFSA with the means to comprehensively review the quality of all its scientific activities. This procedure is designed to give continuing feedback to EFSA about the quality of its work.
- *Developing and approving a procedure and its review* : One SOP enables the preparation, development, presentation and approval of a SOP at EFSA in a consistent way. Another SOP aims to harmonize and standardize the process to review an EFSA SOP in a timely manner.

In conclusion, EFSA has been aiming at continuous improvement and long-term goals in line with the Plan-Do-Check-Act approach whereby its processes are regularly evaluated and improved in the light of their efficiency, effectiveness and flexibility. EFSA has also been focusing on satisfying staff & stakeholders/beneficiaries and manages by processes and facts whereby the related activities are systematically measured and monitored.



3. INEX project

Based on a proposal from the Scientific Committee, EFSA decided to develop and implement a proposal for a review system for the quality and consistency of EFSA's scientific activities. These reviews are intended to contribute to improving the quality, clarity and consistency of the scientific advice provided by EFSA in its scientific outputs and ensuring that best scientific practice is followed.

The self review and internal review were developed and launched in 2008, with improvements being made in 2009. The first external review was carried out in 2009.

A Standard Operating Procedure on the self and internal review was implemented in April 2008 in order to ensure harmonization across all scientific Units. In addition, an SOP on the external review is being developed.

The main findings, areas for improvements and recommendations have been covered in the Report of the Quality Manager 2008 and 2009, and in the INEX report 2008 and 2009 (for internal use only)

3. Vision 2010-2015

d. Revision of EFSA's Quality Policy

As EFSA has now a solid back bone of harmonized and documented process and procedures, we are in a position to take the next step and start mapping the road to certification in the overall context of an Integrated Quality Management System (IQMS). EFSA would need to revise and update its Quality Policy in light of this development, paying particular attention to the systematic management of non-conformity, complaints, corrective actions and preventive actions.

e. Establishment, implementation and maintenance of a comprehensive IQMS

An IQMS is a single integrated system used by an organization to manage the totality of its processes in order to meet the organisation's objectives and to satisfy its staff, beneficiaries and other stakeholders.

a. Further development of QMS manual as backbone of the system

EFSA should ensure that the IQMS documentation is understood, implemented and maintained at all levels in the organization. To this extent, a user-friendly electronic system should be further developed to ensure that it can be readily accessed from each desktop at EFSA, the correct document is available at the correct version, at the right place and at the right time. Each SOP should also be linked to the related process maps, templates and supporting documentation.

EFSA's Quality Management, together with the Management Team and EFSA staff, should continue to build EFSA's IQMS and develop and promote the implementation of any remaining SOPs which were identified as a priority in the area of:

- Processing and approving declarations of interest
- Reporting performance indicators
- Preparing and launching public consultations
- Sharing scientific data between EC and EU agencies
- Security of confidential information in the area of international agreements
- Business Continuity and emergency response plans
- Appointing and replacing experts to the Scientific Committee and Panels
- Finalising, endorsing and publishing other scientific outputs of EFSA
- Preparing and conducting an external review
- Conducting ad-hoc data collection to support EFSA's opinions

In addition, Quality Management should also continue to make an inventory and map existing processes in the remaining areas of EFSA and will introduce Work Instructions (WIN) for those areas where a specific task needs to be described, such as processing of MRL and data collection.

In order to identify the results and areas for improvement of its performance, EFSA should continue or initiate to:

1. Apply suitable methods for monitoring, and where applicable, measure the processes, procedures, cost, resources and outputs
2. Take corrective and preventive actions when the planned results are not achieved
3. Document evidence of the monitoring, measurement and the applied corrective and preventive actions
4. Control the non-conformity processes, procedures and outputs. Any non-conformity to requirements should be identified in order to prevent unintended use or release. Records about non-conforming processes, procedures and outputs, including the subsequent actions, should be kept
5. Analyse data providing information related to partner/stakeholder/consumer satisfaction, conformity to requirements, opportunities for preventive and improvement actions, risk analysis and risk mitigation

6. Continually improve the effectiveness of the IQMS through the use of the quality policy and objectives, internal and external audit results, analysis of data, improvement actions and management review.

b. Suggestion for key roles and functions in EFSA's IQMS

Executive Director	EFSA's ED champions and is committed to the IQMS. The ED ensures that the IQMS is established in order to achieve EFSA's objectives.
Management Team	Each EFSA's MT member fulfills the role of process owner for one or more processes. The process owner is responsible for managing the process so that it meets user requirements and delivers the output. This includes responsibility for implementing the process, for defining, implementing and using performance measures, for maintaining the process and for ensuring that the process is aligned with EFSA's policies and objectives.
Quality Manager	The QM coordinates, implements, maintains and improves the IQMS. The QM also provides leadership and guidance on quality issues. The QM is also responsible for supporting the Directorates in continuously improving the services and functioning of their processes and identifying areas for improvement. The QM oversees, upon request of the process owner, the development of the processes and procedures.
SOP Champions	Representatives of each RA Unit and SCAF who meet on a monthly basis in order to (1) coordinate, together with the HoU or deputy HoU , the best methods for the implementation of SOPs within their units and the best way to archive relevant information, (2) regularly monitor the status quo of EFSA SOPs and to communicate to their Units the latest news on SOP implementation (newly approved SOPs, SOPs currently under revision, etc.), (3) collect the Units comments on SOPs under development or on the ones under revision, (4) be the contact point for SOP Audit and pre-audits exercises.
Quality Circle	The comments/areas for improvement on an SOP are suggested to be taken into consideration by a Quality Circle (3 reps from

	RA, 1 from SCAF, reps from SCA, chaired by the QM) who would propose a revised SOP to the SOP owner. The Quality Circle has to be created. The members should be SOP Champions and should have a particular interest in/knowledge of QM. Should the Quality Circle prove to be efficient and effective, QM will suggest the implementation of this practice in those areas which are not Science-related.
EFSA staff	Middle managers and other staff members support the Directors in performing their duties. All staff are potential IQM actors and should contribute to the system's implementation and continual improvement.

c. Benchmarking/networking for IQMS and best practices

EFSA should consider establishing a benchmarking programme addressing the most important factors for the successful implementation of its IQMS, i.e. by comparing systems and processes and agreeing on the best practices in a cost-effective way. Several other EU agencies, services in the EC, national authorities and stakeholders have experience with the implementation of an IQMS, whereas others might like to benefit from the experience already gathered.

d. Risk management approach

Considering that risk management is part of IQMS, EFSA is to monitor and mitigate risks. EFSA has already conducted 2 High Level Risk Assessment workshops, but also at process level, EFSA is to regularly perform risk analyses. The risks identified at these 2 levels could be merged into a Risk Register whereby risks could be ranked according to priority (eg based on their likelihood and on the severity of their consequences). In addition, EFSA should also determine risk prevention methods in order to mitigate the risk.

e. Internal audits and opportunities for improvement

In order to achieve continual improvement, EFSA started to conduct internal audits in relation to its SOPs in 2010. As internal audits and the resulting action plans are very valuable for the implementation and improvement of the IQMS, it is suggested to further develop this function.

In addition, EFSA could train its SOP Champions in accordance with ISO 10011 on planning and performing quality audits.

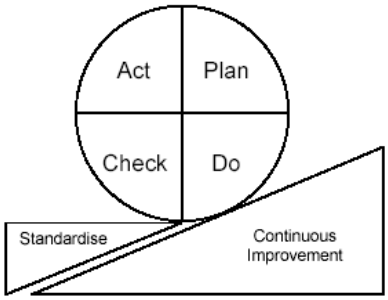
f. <u>Certification</u>

Certification or accreditation is the written recognition by an independent third party that a service, product or system meets a certain level of quality. Certification is generally based on a standard, such as :

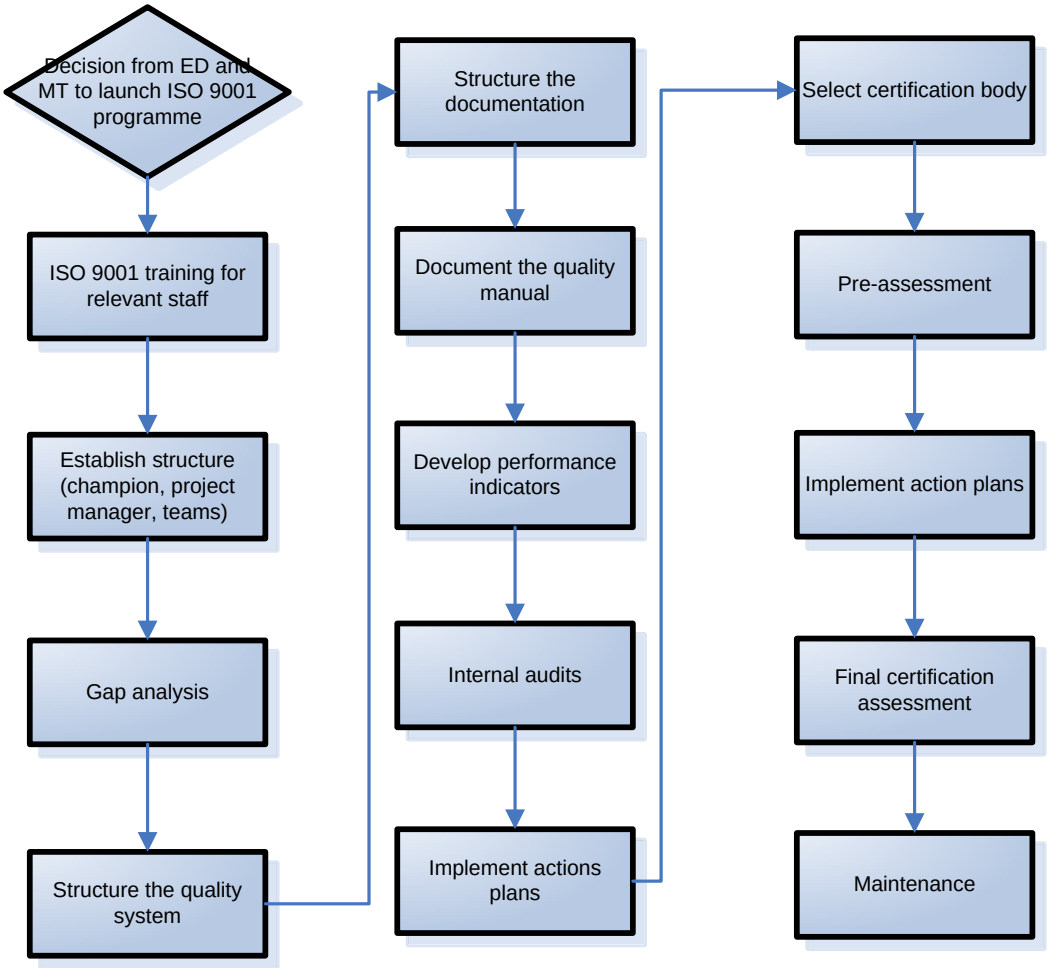
a. The ISO 9000 family of standards
b. EFQM (European Foundation for Quality Management)

a. ISO 9001

ISO 9001 is one of the the world's most established quality framework and sets the standard not only for quality management systems, but management systems in general. It helps an organization to succeed through improved customer satisfaction, staff motivation and continual improvement, and would provide a framework to monitor and improve EFSA's performance.



The main steps on the roadmap to ISO 9001 certification would be :

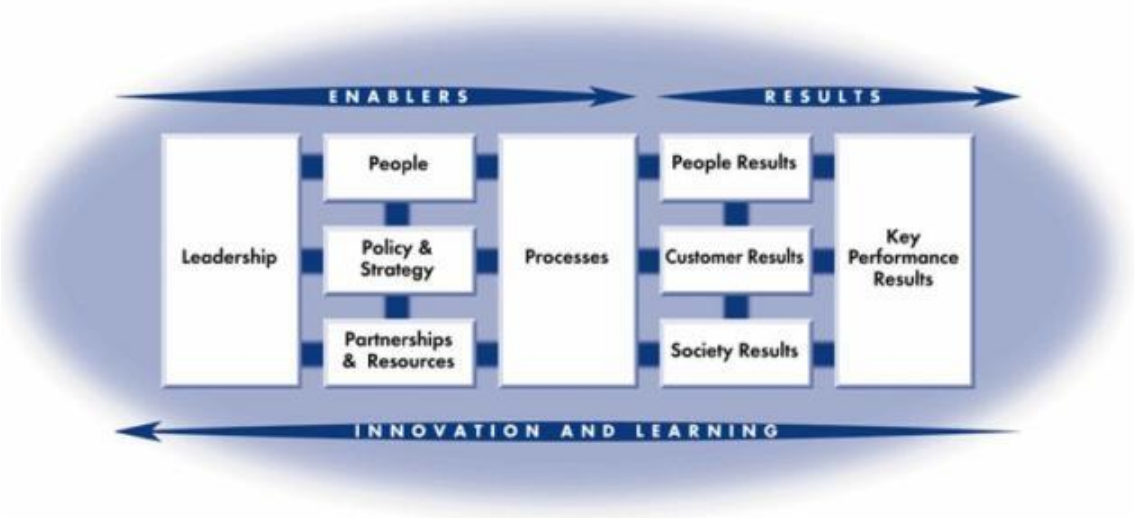


For the purpose of certification, EFSA would need to demonstrate conformity with the requirements of ISO 9001:2008 by providing evidence of the implementation of :

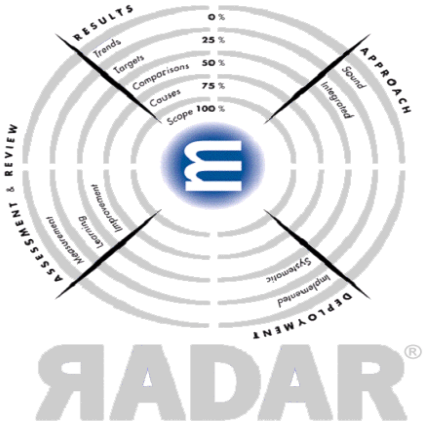
- General requirements (eg developing and documents a QMS)
- Management requirements (eg showing commitment to Quality, focusing on customers, carrying out QMS planning)
- Resource requirements (eg ensuring and meeting competence of workers, providing the necessary infrastructure and a suitable work environment)
- Realization requirements (eg design and development, supplier and purchasing processes)
- Remedial requirements (eg monitoring and measurement customer satisfaction, planning and performing regular internal audits, preventing occurrence of non-conformities)

b. EFQM

The EFQM Excellence Model is a non-prescriptive framework based on 9 criteria. 5 of these are "Enablers" (what an organization does) and 4 are "Results" (what an organization achieves).

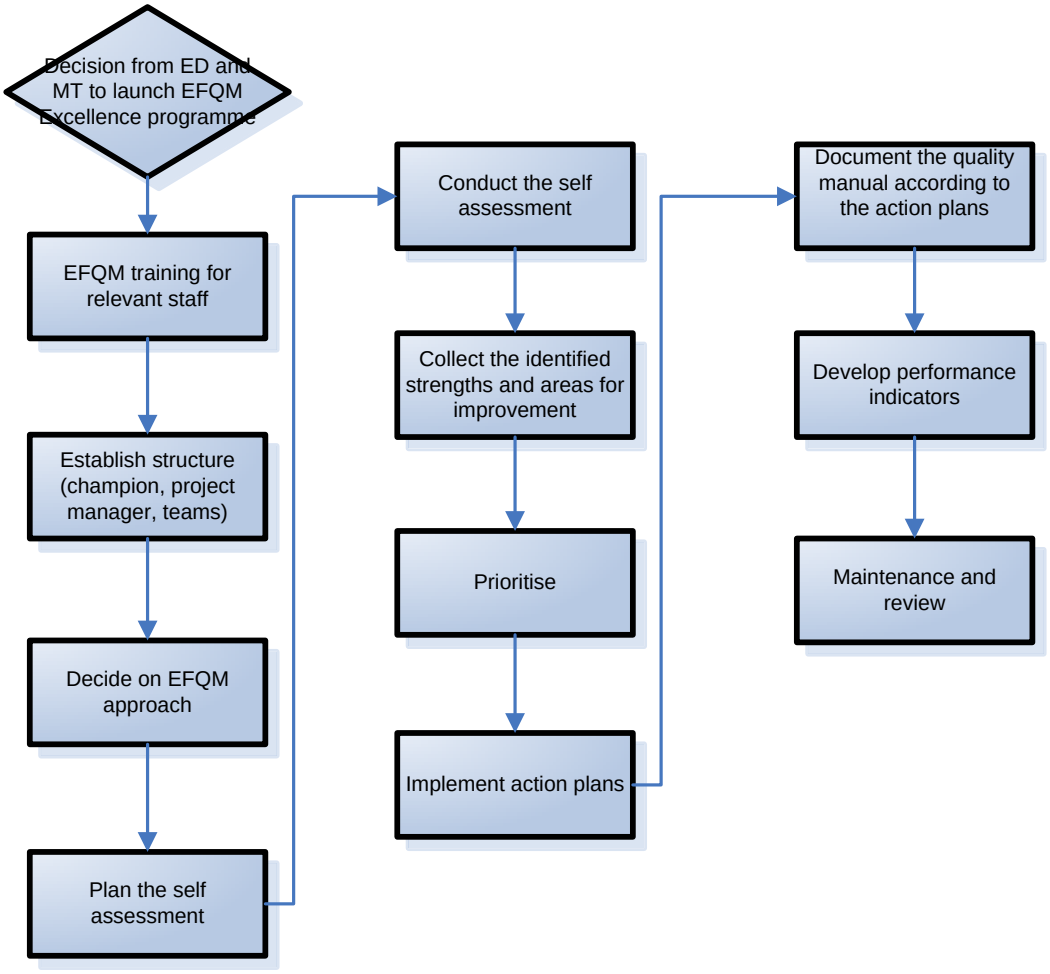


At the heart of the EFQM Model lies the logic RADAR, consisting of Results, Approach, Deployment, Assessment and Review :



The EFQM provides different approaches to perform an assessment, i.e. a questionnaire approach, a matrix chart approach, a workshop approach, a pro-forma approach, etc. In order to identify which approach would be most suitable for EFSA, we would need to look at EFSA's maturity and the desired outcome.

The main steps on the roadmap to Excellence would be :



An organization can become an EFQM member and join a network of European private and public organizations in order to benchmark and share good practices. Membership provides access to EFQM services, knowledge base, support and training. Each year, EFQM recognizes organizations for Excellence and awards the EFQM Excellence Award, which is Europe's most prestigious award for organizational excellence, in different categories.

g. <u>INEX project</u>

Following an analysis of the self and internal review in 2008 and 2009, and the external review in 2009, Quality Management, in cooperation with the Science Directorates, will identify and implement the necessary corrective actions in order to further improve the process.

The next external review cycle will take place in the first half of 2011 for scientific outputs adopted between 1 January and 31 December 2010. A call for expression of interest to expand the current reserve list of the the ERWG will be prepared and launched in September 2010.

END

Annex 2

European Food Safety Authority

QUALITY MANAGEMENT

EFSA'S QUALITY POLICY

4. Introduction to EFSA's Quality Management System

EFSA is a young and fast growing organisation with a high public profile. In order to execute its tasks in a cost-effective way, to satisfy its staff, stakeholders and beneficiaries, to meet requirements in a timely manner and to continually improve its effectiveness in line with EFSA's founding regulation, the financial regulations, the staff regulations and the internal control standards, EFSA will need to manage its processes, people, resources and information. Effectively managing these is a tool to achieving EFSA's organizational goals. The collective effort of all members of staff, Directorates and Units drive the organisation as a whole to achieve its desired objectives.

5. Quality Statement

EFSA is committed to providing independent risk assessment and scientific advice on existing and emerging risks in relation to food and feed safety, plant health and protection, animal health and welfare and nutrition, by fostering a culture of trust, teamwork, responsibility, high expectations and open and clear communications with staff members, institutional partners, stakeholders particularly consumers and. National European and international bodies operating within the same field as EFSA

EFSA understands the value of continual improvement – Setting goals and objectives throughout the organization to ensure that we are meeting stakeholders' and consumers' expectations, accountable within the European system of food law.

EFSA ensures that the Quality Policy and associated processes and procedures are understood by its staff members through the empowerment of the staff in the Quality Policy initiatives and through the ongoing review of the goals, objectives and requirements that have been established.

6. Scope, purpose, objectives and activities of EFSA's Quality Management System

3.1 Scope

This policy is the highest-level description of EFSA's Quality Management System and sets out the framework for ensuring the effectiveness and efficacy of the System.

This policy applies to all staff and all processes.

3.2 Purpose

Promoting a culture of continuous improvement by implementing a Quality Management system to ensure consistency through EFSA's internal processes, procedures, guidelines and a common methodology.

3.3 Overall objective

To implement a Quality Management System at EFSA in order to continuously improve its effectiveness and efficiency in EFSA's daily work.

3.4 Main activities and tasks

- Establish, document, implement and maintain the first part of a Quality Management System in line with a quality model or regulatory framework (to be decided), EFSA's founding regulation, financial regulations, staff regulations, relevant management documents adopted by the Management Board and Executive Director and the internal control standards.
- Continually improve the effectiveness of the Quality Management System through the use of a quality policy, quality objectives, improvement actions (Plan-Do-Check-Act) and audit results.

7. Guiding principles of EFSA's Quality Management System

4.1 Leadership and Constancy of Purpose

In order to maximize EFSA staff's commitment and effectiveness, to have a clear sense of direction and to align all activities, the behaviour of EFSA's management should create clarity and unity of purpose and an environment in which its staff could excel.

4.2 Management by Processes and Facts

EFSA should systematically co-ordinate and manage its activities and make decisions and plan improvements using reliable information (for example, focusing on desired outcomes, maximizing the use of the people and resources, setting realistic goals and strategic direction)

4.3 People Development and Involvement

In order to reach maximized participation of the staff, a positive attitude and morale, effective sharing of knowledge, creating an opportunity for people to learn and develop

new skills, EFSA should encourage the involvement of everyone by sharing values and a culture of trust and empowerment.

4.4 Partnership/stakeholder/supplier Development

EFSA should have mutually beneficial relationships built on trust and sharing of knowledge with its partners, stakeholders and suppliers. This would create value for all parties and create a synergy in terms of resources and costs.

4.5 Continuous Learning, Innovation and Improvement

EFSA's performance would be maximized when it is based on the management and sharing of knowledge within a culture of continuous learning, innovation and improvement. This would lead to organizational agility, reduction of expenses/costs, identification of opportunities, optimization of performance and prevention-based improvement activities within the daily work.

4.6 Customer Orientated

EFSA is ultimately part of the European system for the development of food law and provides the important first step in the process. It needs to be able to deliver value and insight into the process of the developing measures to mitigate against risks in the areas within its remit.

4.7 Consumer Focus

The European consumer is the main ultimate beneficiary of EFSA's service and output. EFSA should have a clear understanding of how to deliver value to the consumers and to retain their trust and confidence.

4.8 Public Responsibility

The long-term interest of EFSA and its staff are best served by adopting an ethical approach and by meeting the expectations of the European consumers. By doing so, EFSA would increase its public awareness and its trust and confidence. It would also enhance its credibility, performance and value to the consumer.

4.9 Good Governance

EFSA should further apply the principles of good governance, i.e. openness, participation, accountability, effectiveness and coherence. EFSA's policies and decisions should be prepared, implemented and enforced in an inclusive way.

8. Implementation of Quality Management System

5.1 Developing a Quality Management System

To successfully apply its Quality Management System, EFSA should:

- Identify and document the processes needed for the Quality Management System and key processes critical for the realization of EFSA's mission, strategy and policies[1]
- Determine quality objectives and requirements from regulations, partners, stakeholders and others for the output of EFSA's services and deliverables[2]
- Determine, document, analyse and evaluate the risks related to these processes and introduce and implement control measure to determine or mitigate the risks[3]
- Determine and document criteria and methods needed to ensure that both the operation and the control of these processes are effective[4]
- Ensure that the internal controls cover the policies and procedures established, documented, implemented and maintained by EFSA's management and that there is documented evidence that the output of the service or the deliverable meet the requirements[5]
- Determine required verification, validation, monitoring, quality control, compliance and test activities specific to the output and the criteria for output acceptance (e.g. deliverables agreed in a framework contract)[6]
- Ensure the allocation of appropriate resources and the availability of information necessary to support the operation and monitoring of the processes, allocate available resources according to the prioritization resulting from the risk analysis, and document and communicate the risks related to the unavailability of adequate resources[7]
- Implement actions necessary to achieve the planned results and continual improvement of the processes.

The implementation of the above would help EFSA to:

- find opportunities for improvement
- reinforce our strengths
- steer the improvement process
- learn by staff involvement
- enhance performance and satisfaction
- measure progress over time
- achieve outstanding practice
- ensure consistency
- identify clear roles and responsibilities

5.2 Documenting the Quality Management System

[1] ICS nr 15
[2] ICS nr 7
[3] ICS nr 11
[4] ICS nr 24
[5] ICS nrs 12-13-14-18-24
[6] ICS nr 17
[7] ICS nrs 9-11-12

EFSA should ensure that the Quality Management System documentation is understood, implemented and maintained at all levels in the organization. To this extent, a user-friendly system should be developed to ensure that it can be readily accessed, the correct document is available at the correct version, at the right place and at the right time[8].

A documented procedure is to be established to define the controls needed to:

- Approve documents for adequacy prior to implementation
- Review and update as necessary and re-approve documents
- Ensure that changes and the current revision status of documents are identified
- Ensure that relevant versions of applicable documents are available for everyone
- Ensure that documents remain legible and readily identifiable
- Ensure that documents of external origin are identified and their distribution controlled
- Prevent the unintended use of obsolete documents
- Apply suitable identification to all documents

Records established and maintained provide evidence of compliance with regulations, conformity with requirements and the internal control standards, and the effective operation of the Quality Management System[9].

A documented procedure defines the controls needed for the identification, storage, protection, retrieval, retention time and disposal of records[10] and defines the rules for public access to EFSA's documents. It also determines the classification of, i.e. public, restricted, internal, confidential documents.

5.3 Monitoring, measurement, analysis and improvement

In order to identify the results and areas for improvement of its performance, EFSA should:

7. Apply suitable methods for monitoring, and where applicable, measure the processes, procedures and outputs
8. Take corrective and preventive actions when the planned results are not achieved[11]
9. Document evidence of the monitoring, measurement and the applied corrective and preventive actions[12]
10. Control the non-conformity processes, procedures and outputs. Any non-conformity to requirements should be identified in order to prevent unintended

[8] ICS nr 15
[9] ICS nrs 14-15-18-20
[10] ICS nr 13
[11] ICS nr 17
[12] ICS nr 13

use or release. Records about non-conforming processes, procedures and outputs, including the subsequent actions, should be kept[13]

11. Analyse data providing information related to partner/stakeholder/consumer satisfaction, conformity to requirements, opportunities for preventive and improvement actions, risk analysis and risk mitigation
12. Continually improve the effectiveness of the Quality Management System through the use of the quality policy and objectives, internal and external audit results, analysis of data, improvement actions and management review

End

[13] ICS nrs 13-18-20-24

Annex 3

Summary of the Scientific Committee's proposal for a review system

A Review System for EFSA's Scientific Activities

Scientific Advice of the Scientific Committee

(Question No EFSA-Q-2007-060)

Adopted on 3 August 2007

SUMMARY

The European Food Safety Authority asked its Scientific Committee to develop a proposal for a review system to assess the quality of EFSA's scientific work. The proposal developed by the Scientific Committee is comprised of the following four components:

1. Self-review: During the development of each opinion or other scientific document the compliance with best scientific practice should be checked.
2. Internal scientific review: A sample of EFSA draft opinions or other scientific documents should be reviewed by senior scientific staff and/or members of a Scientific Panel or Committee, not involved in the preparation of the opinion, before adoption by the relevant Scientific Panel(s) or Committee.
3. External scientific review: A number of EFSA adopted opinions, or other scientific documents should be reviewed by independent scientists.
4. The appreciation of EFSA's scientific work by the intended users should be assessed.

This proposal offers a strategy that should provide EFSA with the means to comprehensively review the quality of its scientific activities, both by internal review and by independent, external review processes, together with additional consultations with institutional and non-institutional stakeholders. The strategy is designed to give continuing feedback to the Authority about the quality of its work.

The strategy should be updated in due course, taking into account the experiences gained with these proposals. Contacts should also be made with other European and international organisations to draw on any experience they may have with similar reviews of their scientific activities.

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Annex 4

Questionnaire for self-review

1. Is there a common understanding between the experts and the originator of the request of what is needed and expected (clarity of terms of reference)?
2. Has a realistic time frame been discussed with the originator of the request with respect to the priority and complexity of the question?
3. , when necessary, appropriate external experts have been involved for addressing the particular question (e.g. composition of working groups)?
4. Have the Declarations of Interests of Scientific Panel and Committee members, working groups or other external experts been obtained and checked by the secretariat for potential conflicts of interest before their involvement in the Scientific Panel or Committee and/or its working groups?
5. Where potential conflicts of interest have been identified, have correct procedures for dealing with them, as set out in EFSA guidance, been correctly followed?
6. Have any cross-cutting issues been identified and, if so, have other relevant Panels or internal and external expert groups been appropriately involved?
7. Has any need for external consultation been considered prior to the adoption of the document (especially for guidance documents)?
8. Where necessary, have risk communicators been alerted by the secretariat sufficiently early in the process to ensure appropriate and timely communication?
9. Where data have been provided by outside parties, have the dossiers been checked for completeness and compliance with any relevant guidelines for data submission (e.g. adequacy for addressing the question, compliance with GLP, up-to-date, inclusion of unpublished data and comprehensive literature search)?
10. Where primary and/or additional data have been collected by the SC/P or their WGs (e.g. literature searches, consultation of external experts or national authorities, identification of relevant unpublished data, identification of any previous risk assessments on the same or similar topic by EFSA or other expert bodies) how was it ensured that the dataset was comprehensive enough and up-to-date?
11. Have the data been properly described in the document?
12. Are the sources of information used properly described in the document?
13. Has a check been made that all scientific data have been properly referenced (within the text and in the reference list)?
14. Where relevant, have key studies for the assessment been properly identified and were reasons given for their selection as key studies?
15. Have the implications of potentially contradictory/conflicting data been discussed?
16. Have opinions of other expert bodies been discussed and, if relevant, the reasons for any diverging views been explained?
17. Have significant data gaps been identified and discussed?
18. Have the underlying assumptions, limitations and uncertainties in the data been discussed?14
19. Have existing relevant EFSA guidance documents on risk assessment

practices/methodologies been followed?
20. Is the approach followed broadly in accordance with internationally agreed guidance on risk assessment procedures?
21. Does the assessment adequately address the terms of reference?
22. Are the conclusions coherent with the main content of the opinion?
23. Are any assumptions, limitations and uncertainties adequately addressed?
24. In the case of a minority opinion, has it been clearly expressed and reported?
25. In the case of a provisional/interim conclusion, is there a clear indication of what further research or information may be needed and is there a timeline for follow-up?
26. Does the assessment respect the boundaries between risk assessment and risk management?
27. Is the summary adequately informative and clear for the target audience?
28. Does the summary adequately reflect the context of the question and the content of the opinion, including the conclusions and any recommendations?
29. Has the document been delivered on time? If not, please specify.
30. What means are in place for follow-up of the documents, if relevant?

Annex 5

Questionnaire for internal review

1. Depending on the type of scientific output : a. Does the assessment adequately address the terms of reference? or b. Are the objectives of the report/analyses clearly specified and stated?
2. Does the assessment respect the boundaries between risk assessment and risk management?
3. Are any assumptions, limitations and uncertainties adequately addressed and reported?
4. Are the applied statistical and other analyses methods appropriate and fit for purpose?
5. Is the information (data) adequately presented?
6. Is there a right balance between major and minor findings?
7. In the case of any provisional/interim conclusion, is there a clear indication of what further research or information may be needed and a timeline for follow-up?
8. Are all conclusions substantiated in the main body of the text?
9. Are the conclusions coherent with and supported by the main content of the scientific output?
10. In the case of any minority output, has it been clearly expressed and reported?
11. Does the summary adequately reflect the context of the question and the content of the output, including the conclusions and, if any, recommendations?
12. Is the summary adequately informative and clear for the risk managers?