European Food Safety Authority

QUALITY MANAGEMENT

ANNUAL QUALITY MANAGER'S REPORT 2013

Quality Management Vision: *To create a pre-eminent, fit-for-purpose quality management system that is fully integrated into the organisation's Management Standards, focused on customer service and dedicated to achieving excellence through continuous improvement.*

Summary

2013 saw further progress on implementing a Quality Management System (QMS) for EFSA with the following highlights (for details see full text):

- Completion of EFSA outputs review by the ERWG (External Review Working Group);
- Filling the remaining gaps in ISO 9001:2008 compatibility for the science areas;
- Completion of the Repository of Governance and Management Documents for the whole organisation;
- Set up of a customer feedback mechanism for science;
- Start of the roll-out of quality management to Resources & Support (RESU) and Communications (COMMS) Departments.

In 2014 activities will focus on progressing the roll-out of a QMS to the RESU and COMMS parts of the organisation, further development of the Repository of Governance and Management Documents, evolution of the ERWG and, finally, consolidating the move towards getting things "right first time" and evidence based continuous improvement.

The target is to achieve a fully integrated ISO-compatible QMS for the whole organisation by the end of 2016.

2013 Progress

1. EFSA's External Review process

EFSA established the ERWG in 2009 to review the quality of scientific outputs in areas covered by EFSA's scientific units, its Scientific Committee and its Advisory Forum Unit. The ERWG completed reviews in 2009, 2011 and 2012 affording a critique of a random sample of outputs that generated a series of recommendations for both EFSA activities and for future ERWG reviews. This is a rolling programme with the recommendations from one year being addressed during the next year, in parallel with that year's review.

1.1 2013 Review of Scientific Outputs and Procured Reports published in 2012

The 2013 Review was carried out using the same three-step process as previously described in the Annual Quality Manager's Report 2012. Using a process of random selection, a total of 24 scientific outputs generated by 16 Science Units were reviewed along with, for the first time, 25 reports procured by EFSA as part of the grants and procurement process. These outputs and reports were allocated by the ERWG chairman to the reviewers with each being evaluated independently by two reviewers. Each output and report was evaluated using a pre-determined template that includes a clear set of criteria and guidance for the scoring.

The principal message from the review was that the majority of the scientific outputs and procured reports were well constructed, transparent and easily understandable. The key recommendation is to ensure that the best practice demonstrated in the majority of cases is extended across the whole organisation. For details of the recommendations and EFSA's response see Annex 1.

1.2 Implementation of the recommendations from 2012 Review

In the ERWG's 2012 report a total of 17 recommendations were made. During 2013 EFSA either completed or made significant progress to resolution against 12 of them, 3 recommendations did not require action from EFSA and no progress was made against only 2 recommendations (i.e. 1. EFSA to split terms of reference where an opinion is long; 2. the Chair of the ERWG to join Panel meetings). For details of the recommendations and EFSA progress see Annex 1.

2. Deepening implementation in Science

In December 2012 a benchmarking exercise was carried out by an internationally recognised certification organisation to determine the current level of compatibility with the ISO9001:2008 quality management standard in the science areas. This activity was called the Science Health check. The degree of compatibility was determined as over 70%. In the Health Check 5 main areas for improvement and 4 lesser areas for improvement against the ISO standard were identified. The Quality Management project plan for 2013 was developed to address these areas.

At the end of 2013, using the AS/NZO 1SO9001:2008 self assessment checklist, the EFSA Quality Management team reviewed progress against areas for improvement identified in the 2012 Science Health check. Against the 5 main areas for improvement, progress has been made against 4 areas with the remaining one being included in the activities for 2014. Against the 4 lesser areas for improvement progress has been made against 3 (for details of progress, see below). Finally, deployment of the project management approach developed in 2013, essential for the operation of a Quality Management system, will also continue in 2014.

2.1 Management review

In the past EFSA carried out a significant piece of work by mapping its scientific processes and aligning Standard Operating Procedures (SOPs) against these. In 2013 both the content of the SOPs as well as their completeness were reviewed and resulted in 6 SOPs out of 18 being redrafted, 6 SOPs being corrected and 1 new SOP being drafted.

Furthermore, 2013 saw the initiation of a new project to collect all of the documents supporting the SOPs, so-called Working Instructions (WINs). The result was the identification of 80 WINs. These were aligned against the relevant SOPs and published internally.

2.2 Verification and Non-conformity reporting

As part of a programme of continuous improvement and learning by doing, the members of the Quality circle[1] were trained in verification (a process used to check that what you presume is being done is actually carried out in practice). During 2013 the implementation in all units

[1] The Quality circle includes representatives from each unit and its role is to support Quality management at all stages (Plan, Do, Check, Review) of the continuous improvement cycle

of 2 SOPs was verified for at least one output per unit. The activity has been useful in both driving implementation, as a learning by doing exercise and for sharing best practice. The degree of implementation in the units of the 2 SOPs was very high, with no deviations from process or record keeping observed. The activity will continue in 2014.

During 2013 the reporting of non-conformities (non-conformities are defined as deviations from SOPs or where quality requirements have not been met) and the resulting actions to correct them has been implemented. Non-conformities are not the result of a Quality Management activity looking at a sample, but can be spotted by anyone inside the organisation. This process was also aligned with the non-compliance reporting required by the Internal Control Standards.

Since implementation, 50 non-conformities across all SOPs, outputs and reports have been reported by EFSA staff. A detailed analysis of the reported non-conformities and the root causes as defined in the current SOPs has been carried out. In summary 86% of reported non-conformities related to editorial or formatting errors in published outputs – nearly all of which resulted in republication. The remaining 14% of non-conformities related to missing Declarations of Interest (DoIs) – all of which where subsequently submitted and approved (this represents between 0.1 - 0.2% of the DoIs requiring assessment). No other deviations from process or failure to meet quality standards (non-conformities) were reported. The fact that deviations from process are being spotted and reported also confirms the high degree of implementation of the SOPs as observed in the verification activity as described above.

2.3 EFSA Governance Documents

EFSA requires a mechanism for managing documents that govern its operations i.e. ensuring that these are up to date and complete. This need has resulted in the development of the EFSA Repository of Governance and Management Documents (the Repository).

The Repository was launched and a first version is now available to all EFSA staff.

2.4 Customer Feedback

The collection of customer feedback is an essential part of any continuous improvement programme and a requirement of the ISO9001:2008 standard which EFSA is using as the basis for its own QMS. The objective is to collect the feedback in a pragmatic way to minimise the effort required, whilst providing the most useful information to drive continuous improvement in EFSA.

In conjunction with the main customer for our science outputs (DG SANCO), agreement has been reached on a customer feedback mechanism covering EFSA's scientific outputs. This mechanism will be implemented in 2014.

3. Roll-out to RESU and Communications Departments

Initial work on rolling out an ISO 9001:2008 compatible system to the RESU and COMMs parts of the organisation was begun in 2013. Work has focused on the same approach used successfully for science. As a result, a Health Check process has been initiated to understand what is already in place and working and where the potential areas for improvement lie. The results of this Health Check will be known in early 2014 and will form the basis for the development of the work programme for the following two years.

Plan for 2014

Even though the main elements of a QMS for science compatible with ISO 9001:2008 are in place, the principles of continuous improvement mean that work will still be required in this area.

1. Science

1.1 ERWG

The role of the ERWG and its relationship to EFSA is continuing to evolve. The group is entering into the second year of its current three-year mandate and, as such, this is an appropriate time for EFSA to consider how the remit of the ERWG might be updated. A Task Force has been established to consider the future role of the ERWG; conclusions will be reached at the end of 2014.

1.2 ISO Standard on Scientific Assessment

An international, independent and auditable management standard that could provide a framework for the carrying out of scientific assessments would be of benefit to organisations like EFSA. Adherence to such an independently developed, internationally recognised and independently auditable standard, could be an effective tool to further raise the quality of EFSA's scientific processes and might help to better answer questions e.g. about EFSA's independence and transparency in the decision-making process.

Initial discussions have been held to explore this further and will continue in 2014. If successful, it would form the basis for a QMS to support the core business of delivering scientific advice.

2. RESU and Communications roll-out

The detailed work plan for 2014 can be developed only once the results of the Health Check are available in March. However, it can be envisaged that the QMS will adhere to the overarching principles of "fit-for-purpose" and continuous improvement. The approach is likely to broadly follow that taken for science with SOPs being developed based on processes, supported by WINs.

3. EFSA's Repository of Governance and Management Documents

A high-level framework will be developed setting out the documents the organisation will deploy in the areas of Governance and Management. The use of vocabulary across the document types will be harmonised against an agreed set of definitions. The current documents will be re-organised within the framework, using the definitions for each document type within the structure. A mechanism will be created to ensure key elements, of both scientific and administrative guidance, are employed in a harmonised way across the organisation, and, finally, gaps identified in the existing documents will be filled.

Annex 1 External Review Working Group

1.0 Recommendations from the ERWG in 2012 and EFSA's progress in 2013

A total of 17 recommendations were made by the ERWG. In 2013 EFSA either completed or made significant progress to resolution against 12 of them. Three recommendations did not require action from EFSA and no progress was made against only 2 recommendations. The

full detail is given below with the ERWG recommendation quoted first in italic and the EFSA response or progress in normal text.

1.1 Regarding EFSA's scientific outputs

1.1.1 EFSA should further implement project management procedures to drive accountability and responsibility in a move from quality control to quality assurance.

EFSA has implemented a project management approach covering a limited number of projects. It has implemented a Project Co-ordination Office. EFSA has committed to having implemented a project management approach to all activities by the end of 2014.

1.1.2 EFSA should revisit the peer review and editorial process as a small number of documents persistently have typographical or grammatical errors.

The chair of the ERWG has raised the issue with the Editorial Board of the EFSA Journal. A proposal has been made to include the Chair of the ERWG as a permanent member of the Editorial Board. All re-publications are now captured as part of the non-conformity reporting. The operation of the EFSA Journal has been transferred to the Channels unit in communications and a strategic review commissioned.

1.1.3 EFSA should introduce additional SOPs where necessary. In the case of errata, what are the criteria for an output to be republished? For example, should an output be republished if a table was omitted?

The review of the relevant SOP was unfortunately delayed due to the re-organisation of the EFSA Journal. Working on this has been included in the work programme for 2014.

1.1.4 Low quality outputs may arise from low quality inputs. A more prospective proforma should be supplied to companies before they provide supporting evidence and reports.

A review of procurement procedures has been launched. The process now includes an additional requirement prior to payment that a self declaration is required from the contractor that all Quality Assurance processes promised in the original contract have been adhered to.

1.1.5 It is recommended to split terms of reference where an opinion is very long.

Terms of reference for our opinions are set by our customers (the EU Commission, EU Parliament and Member States). We have recognised that customer feedback on how best to present our outputs is an area for improvement. As such we have implemented new customer feedback mechanisms. It is hoped that this will further improve the degree to which out outputs meet the customer needs.

1.1.6 Efforts should be made to make the outputs (for each class) homogenous and to ensure that there is consistent use of RA terminology, using the Scientific Opinion on Risk Assessment Terminology (OP 2664) as a guide.

EFSA has instigated a review of its risk assessment guidelines. This review will be completed in 2014.

1.1.7 In some cases, much greater efforts are needed when the summary section of the output is drafted in order to synthesise the key information of the output, rather than simply repeating large sections of text from the body of the output.

Work is ongoing to redraft the relevant guidance document. However, EFSA is also encouraging the consistent use of wording across the different sections of text within outputs.

1.2 Regarding the operations of the ERWG

1.2.1 The role of the ERWG and its relationship to EFSA is continuing to evolve. This would be an appropriate time for EFSA to consider how the remit of the ERWG might be updated alongside the move from a quality control to a quality assurance approach.

A Task Force has been established to consider the future role of the ERWG.

1.2.2 It was agreed that the consensus approach was wholly beneficial, although this was not always reached in line with journal peer review experiences. In some cases there were issues with deadlines in both directions between the ERWG and EFSA. It is anticipated that this situation will improve when an electronic board is adopted.

All ERWG timings were adhered to this year. Analysis of the consensus between the two ERWG reviewers reached this year indicates that it has remained steady compared to last year. EFSA requests that the ERWG carry out an evidence-based review to identify areas for improvement.

1.2.3 Move ERWG to use Sciencenet in procedural form.

All activities and documents were successfully supported on the Sciencenet Platform in 2013.

1.2.4 Extend ERWG remit to include raw material (e.g. company reports) sent to EFSA where appropriate.

Review of procured reports was included in the ERWG review programme for 2013 and successfully completed. However, EFSA feels there is still room for improvement and the ERWG is invited to consider further proposals.

1.2.5 A verbal report from the ERWG Chair to the EFSA Heads of Units may be useful.

The chair of the ERWG has verbally reported to the Editorial Board of the EFSA Journal.

1.2.6 Clarification of timeline issues remain owing to lack of access of ERWG members to some data held by EFSA. This issue needs to be revisited.

Review of the timeliness evaluation criteria has been included in the customer feedback evaluation and this will be trialled in 2014.

1.2.7 Some ERWG reviewers may find it difficult to distinguish the quality of science versus clarity in communication. The role of the ERWG is not to challenge the assessments contained in individual outputs but to ensure the quality of those outputs. The ERWG must remain mindful of this distinction.

EFSA urges the ERWG to stick to its remit.

1.2.8 ERWG should adhere to templates with a uniform input format – and not alter format (landscape etc).

No Comment.

1.2.9 The ERWG review would benefit from more involvement with and feedback from EFSA panels, perhaps with the ERWG Chair sitting in on an EFSA panel meeting.

A schedule of open panel meetings is available.

1.2.10 Issues remain with a single ERWG evaluation template for very different output classes; ambiguity remains in the interpretations of 'A' and 'B' scores in the ERWG template.

Discussion of these points was included on the agenda of the first meeting in 2014 in line with recent practice and the templates and criteria modified, although work will continue in this area in line with the principles of continuous improvement.

2.0 2013 Recommendations from the ERWG and EFSA's response to them

2.1 Regarding EFSA's scientific outputs and procured reports

2.1.1 In line with moving to a Quality Assurance approach, standard operating procedures should be introduced to support the project management approach being introduced.

EFSA is currently drafting SOPs to support the implementation of the project management approach.

2.1.2 Peer reviewing should be revisited to ensure that the minority of problematic outputs are identified and corrected prior to publication.

EFSA QM has made the following proposal which is being considered by the organisation:

i/ Panel Chairs should be made formally aware that they have a role equivalent to a sub-editor of the EFSA Journal when it comes to the adoption process.

ii/ The process of proof reading should be harmonised across the whole organisation and this has been included in the recent review of the functioning of the EFSA Journal.

2.1.3 Low score patterns should be analysed.

EFSA introduced the process of analysing scores at the end of 2012. This process has been repeated in 2013 and the results have been sent to the Directors and the Chair of the ERWG. This process is carried out in line with the overarching objective of keeping the process at an organisational level.

2.1.4 Consideration could be given to the introduction of a more iterative process between the risk managers and the risk assessors during the development of a mandate.

EFSA is currently working on this proposal as part of the current RASA re-organisation.

2.1.5 It would be useful to follow standard Journal policy and include key dates on publications (e.g. outputs could include date of receipt of mandate, acceptance date, output adoption date).

EFSA will consider the feasibility of this recommendation and report back to the ERWG in due course.

2.1.6 EFSA should harmonise across the organisation the content of report sections (i.e. output summaries should have the same "feel"). In addition, EFSA should avoid the use of cut and paste between different sections in the same document (i.e. the summary should not be a cut and paste of the introduction or conclusions).

EFSA agrees on the need to improve clarity on the requirements for each section of an output and this is currently being reviewed by the Scientific Committee. However, the consistent use of wording through the document is also being encouraged with the objective of discouraging the use of different ways of saying the same thing.

2.1.7 Greater use of illustrations and diagrams could be used to improve clarity of the message.

Feedback will be sought from customers regarding this suggestion.

2.1.8 EFSA should implement a customer feedback mechanism aimed at improving areas for communication.

As previously reported this has been developed and will be implemented in 2014.

2.2 Regarding the operations of the ERWG

2.2.1 EFSA should allow the Chair of the ERWG to provide a verbal report to panels on the ERWG's activities and findings along with possibly allowing the chair of the ERWG to participate in some panel meetings as an observer.

EFSA QM will write to the HoU and ask for their feedback on this proposal.

2.2.2 The issue of the ERWG evaluating timeliness should be revisited.

The item will be placed on the agenda for discussion at the first ERWG meeting of 2014.