

Annual Quality Manager's Report 2016



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EFSA has been working over the past years to set up, and constantly improve, its Quality Management System (QMS) so as to ensure that the organisation has a solid basis for scientific excellence, independence, openness, innovation and cooperation.

The QMS is aligned with EFSA's Founding Regulation, the Financial Regulations, the Staff Regulations, the Internal Control Standards and requirements as set out in the Quality Management Standard ISO 9001:2015.

1. Summary

In 2016 EFSA made great progress towards implementing a robust QMS in the organisation. Highlights included:

- obtaining the ISO 9001:2015 certification;
- again very positive feedback from the European Commission (DG SANTE) on the quality of EFSA's scientific outputs (defined by the criteria "fitness for purpose" and "clarity in communication"); this notion was also received from the Member State feedback exercise;
- continuously improving and strengthening the QMS across EFSA.

2. QMS Operation – progress made in 2016

2.1. *Quality Circle*

The Quality Circle (QC), composed of one quality correspondent (and one alternate) per unit, continued its monthly meetings. The aim of these meetings is to exchange information, share best practices and ensure the effective and harmonised implementation of the Plan-Do-Check-Act cycle.

The members of the QC have expanded their role to become "ISO satellites" as well as central points of information on Quality-related matters in their respective units.

10 members of the QC also took on the role of Internal Quality Auditors and audited each unit in EFSA. The final reports of these audits are confidential; however, the key findings are used by Quality Management (QM) as a source for continuous improvement. The Internal Quality Auditors received specific training to support them in their new role.

2.2. *External review*

After the dissolution of the External Review Working Group (ERWG), EFSA needed to implement a new system to assess the quality of the work done by external providers. The third-party supplier feedback pilot project was developed to fill this gap. Feedback received so far from this pilot suggests that the overall quality of the external reports is good, albeit there is room for improvement.

The development of the Quality Assurance System for Science was a necessary step forward to move EFSA to the next level of maturity. This project is almost finalised, with only some minor issues still ongoing. With this project coming to an end, EFSA needed to take the next step, moving from Quality Control to Quality Assurance. To do this, the ex-ante Quality Review pilot project was developed together with targeted staff members.

The outcome of this pilot project will be assessed in June 2017. It will then be discussed with the Quality Circle and the Joint Science Meeting (JSM) in order to decide whether to formalise it.

2.3. Customer feedback

The collection of customer feedback is an essential element of EFSA's QMS and the ISO 9001:2015 standard.

For science, EFSA's customers have been identified as DG SANTE, the European Parliament and the Member States.

The customer feedback exercise with DG SANTE was first carried out in 2014 and has been repeated every year since.

At the beginning of 2016, the third customer feedback exercise was kicked off, during which – based on a previous agreement between DG-SANTE and EFSA – outputs from all 10 panels were reviewed. In May 2016 the outputs were randomly selected, with the possibility to change them for outputs giving a more reliable view of EFSA's work. The interview approach was the same as in the previous two exercises, as were the criteria: "fitness for purpose" and "clarity in communication".

Overall, the feedback received during the interviews was well prepared by DG SANTE staff (with specific examples given), balanced and self-critical. The quality of EFSA's work was rated as high by all DG SANTE staff members interviewed. In most cases, the selected outputs have been used to support Risk Management (RM) decisions.

There is a strong desire, by both EFSA and DG SANTE, to repeat the exercise in 2017.

In 2016, EFSA also started a pilot for receiving feedback on its work from our other main customer, EU Member States. The exercise is still in early days but initial feedback is positive, and it has been confirmed that the pilot will be extended in 2017, when further Member States will become involved in order for EFSA to have a more comprehensive feedback.

2.4. ISO certification audit

The objective of the Stage 2 assessment was to assess the current status of EFSA's QMS so as to confirm its operational implementation for processes according to applicable internal procedures, the ISO 9001:2015 requirements, and to confirm EFSA's commitment to support and maintain its QMS.

No major or minor non-conformities were identified, but some improvements have been suggested.

Based on the results of the Stage 2 assessment audit, "the EFSA QMS can be considered robust, well established and in compliance with ISO 9001:2015 requirements".

Moreover, there is ample evidence of retained documented information related to the monitoring, analysis and evaluation of the QMS performance that demonstrates a suitable EFSA capability to control, maintain and review, as necessary, its QMS to ensure that it is continuously fit for purpose.

Based on the above considerations, it has been recommended that EFSA is awarded the certification according to the ISO 9001 2015 scheme, and the certificate was signed on 11 November 2016.

3. QMS Operation – next steps for 2017

3.1. Surveillance audit

In light of the outcome of the ISO 9001:2015 certification audit, EFSA will devise an implementation plan to address any improvement areas identified.

All improvement actions will need to be developed and established by autumn, when the next audit is expected to take place.

3.2. Finalising the implementation of the Quality Assurance System for Science

After the dissolution of the ERWG, EFSA needs to find an effective replacement for the work carried out by the group.

In 2016, EFSA initiated a number of pilot projects to close this gap. The efficiency of these ongoing initiatives will be assessed in the course of 2017.

3.3. Quality Circle

EFSA will continue to empower the role of QC members as ISO satellites in their units. They will be provided with further training so they can carry out their roles and responsibilities in the best way possible.

The Internal Quality Auditors will continue with their role and will receive further training to improve their skills as auditors. The Internal Quality Auditor team will be expanded to increase EFSA's capacities in this area and continue meeting this ISO requirement.

3.4. Further system harmonisation

As EFSA has a robust and well established customer feedback mechanism with DG SANTE for science, the focus for 2017 is to develop a feedback mechanism for the RESU and COMMS departments as well.

In early 2016, a workshop was organised to discuss and identify who are the customers for RESU and COMMS. The departments have used the resulting information to develop a rudimentary feedback mechanism, which has not yet been implemented, however.

The goal for 2017 is to have a solid mechanism for these two departments in place by the end of the year.

4. Conclusion

Looking at the work carried out in the area of Quality throughout 2016, EFSA can be proud of what it has achieved. The hard work must continue, however, in 2017 in order to meet the ISO 9001:2015 requirements, and maintain our cycle of continuous improvement.

By the end of 2017, QM will draft the QM Plan for 2018 and present the outcomes of the current year.

