



# Annual Quality Management Review 2020

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## List of abbreviations

<b>AF</b>	EFSA Advisory Forum
<b>AQMR</b>	Annual Quality Management Review
<b>ART</b>	Architecture Transformation Programme
<b>BAU</b>	Business as usual
<b>BUS</b>	Business Services Department
<b>CORSER</b>	EFSA Corporate Services Unit
<b>DEV</b>	Development
<b>DG SANTE</b>	Directorate-General for Health and Food Safety
<b>DG ENV</b>	The Directorate-General for Environment
<b>ECDC</b>	European Centre for Disease Prevention and Control
<b>ED</b>	Executive Director
<b>EFSA</b>	European Food Safety Authority
<b>ENCO</b>	EFSA Engagement and Cooperation Unit
<b>EPA</b>	EFSA Process Architecture
<b>FEED</b>	EFSA Feed Unit
<b>FIN</b>	EFSA Finance services Unit
<b>FIP</b>	EFSA Food Ingredients and Packaging Unit
<b>FTE</b>	full-time staff equivalent
<b>FP</b>	Focal points
<b>GMO</b>	Genetically Modified Organism / EFSA GMO Unit
<b>GPS</b>	EFSA Global performance services Unit
<b>HUCAP</b>	EFSA Human Capital Services Unit
<b>IMS</b>	Integrated Management System
<b>IPCHEM</b>	Information Platform for Chemical Monitoring
<b>KPI</b>	Key performance indicator
<b>LA</b>	EFSA Legal and Regulatory Affairs Unit
<b>L&amp;D</b>	Learning & Development
<b>MB</b>	EFSA Management Board
<b>MFF</b>	Multiannual Financial Framework
<b>MS</b>	Member States
<b>MT</b>	Management Team
<b>NUTRI</b>	EFSA Nutrition Unit
<b>PII</b>	Process improvement initiative
<b>PIs</b>	Process indicators
<b>PRES</b>	Pesticide residues Unit
<b>PREV</b>	Pesticide peer review Unit
<b>RA</b>	Risk assessment
<b>RASA</b>	EFSA Risk Assessment and Scientific Assistance Department
<b>QC</b>	Quality Circle
<b>QMS</b>	Quality Management System
<b>REPRO</b>	EFSA Scientific Evaluation of Regulated Products Department
<b>SCER</b>	EFSA Scientific Committee and Emerging Risks Unit
<b>SPOC</b>	Single point of contact
<b>SO</b>	Strategic Objective

<b>SOP</b>	Standard Operating Procedure
<b>ToRs</b>	Terms of reference
<b>TR</b>	Transparency Regulation
<b>TS</b>	Transformation Services
<b>WINS</b>	Working instructions
<b>WG</b>	Working Group

## Foreword

EFSA's mission is to actively contribute to the safety of the EU food chain by providing scientific advice to risk managers, by communicating on risks to the public, and by cooperating with Member States, Institutional partners and other parties to ensure a coherent, trusted food safety system in the EU. As clearly outlined in the EFSA's Quality Policy, having in place a sound quality management system helps EFSA to foster a culture of continual improvement, increasing the organisation's performance with a focus on customers and stakeholders' expectations and satisfaction.

The EFSA Quality Management System (QMS) was awarded in 2016 the ISO 9001:2015 certification, providing evidence that the organisation has a solid basis for the provision and communication of scientific advice via its scientific excellence, independence, openness, innovation, and cooperation. In alignment with ISO 9001:2015 requirements, EFSA performs a yearly review of its Quality Management System (QMS) to ensure its ongoing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization. This report covers all relevant provisions for the annual review

In 2019, the European Union adopted a regulation on the transparency and sustainability of EU risk assessment in the food chain based on the proposal of the European Commission in response to the "fitness check" of the General Food Law and the EU citizens' initiative "Ban glyphosate". This new Transparency Regulation, aiming at significantly increasing the transparency of the EU risk assessment in the food chain, will come into force in March 2021 bringing with it a significant number of challenges and changes that will have a large impact on EFSA's QMS. Further changes will also take place as a result of the Quality Roadmap development in alignment with the new Strategy 2027. All these developments and updates to our current processes, procedures and way of work will need to be captured by a well-documented, well-monitored and controlled QMS.

## 1.0 Executive Summary

In 2020, EFSA continued towards further strengthening its QMS, with all Annual Quality Management Systems objectives being entirely or partially delivered.

The first surveillance audit of EFSA's second cycle of **ISO 9001:2015 certification** had a positive outcome confirming its operational implementation on processes according to the requirements of the standard, to the applicable internal procedures, and confirming EFSA's commitment to support and maintain its QMS.

The **2020 Internal Quality Audit** plan was carried according to the newly approved WIN, which establishes the use of a risk-based approach when selecting the activities to be audited during the year. It was also the first time that the audits took place remotely, and despite some initial setbacks due to fewer auditors available, all the audits were completed on time before the external ISO 9001:2015 audit.

With regards to the **Customer Feedback interviews** with SANTE, as in previous years, the positive communication and collaboration between EFSA Units and SANTE was praised. The current exchanges to align on the terms of references before a mandate is sent are very useful for both sides, and the need to use them effectively was seen as vital. The readiness of both parties to discuss and negotiate deadlines, highlighting a mutual understanding of priorities and workload was also considered very beneficial.

The QMS was effectively updated in line with the **Transparency Regulation measures** and ongoing strategic needs. This resulted in the review of the EPA architecture (EPA2 to EPA2.5), in line with the new and revised processes. Our current documentation also underwent many changes, most of which will come into force in line with the new Transparency Regulation on March 27th. This review provided a good opportunity to streamline and optimise our process documentation ensuring that it continues to be fit for purpose and relevant, adjusting to the many changes that the organisation is facing.

Considering the impact of the SARS-CoV-2 outbreak, the overall **performance of EFSA processes was satisfactory**.

Looking at EFSA’s core business, the Authority’s scientific production system was able to close 697 scientific questions, less than the initial plan of 780 but in line with the forecast.

In terms of compliance with the deadlines for the scientific production, the overall timeliness stood at 83%, a small reduction compared to 2019 (86%) but it can still be considered a positive result, given the circumstances. However, in the area of regulated products, the index decreased by around 7 percentage points year-on-year (from 83% to 76%).

Very positive was the performance in the area of communication of findings, with the index measuring the timeliness of publication on the EFSA Journal at 88%, above the target and in line with the results from 2019.

The effect of the pandemic was particularly evident in the result achieved in the Strategic Objective 4, as development activities were deprioritised to safeguard the business as usual, and also the Strategic Objective 3 registered some disruption, also due to the nature of the work carried out. The remaining SOs, instead, registered positive or unchanged performance year-on-year.

Several activities were carried out during the year to achieve the further **integration of management systems**. Most notable was the EFSA-led interagency framework contract with a **single external certification body** provider covering all management standards. This will allow a more harmonised overview of external audits, audit plans, audit reports, findings, and recommendations getting the organisation one step closer to full **integration of its management systems**.

A **Process Improvement Initiative on the Integration of EFSA’s Management System** was kicked off in November 2020 to develop and start implementing a roadmap for the further integration. This activity will run throughout 2021 and possibly continue in 2022.

The **continuous improvement process** ran as a BAU process for the first time in 2020 after the successful completion of the pilot the previous year. The process delivered several successful PII’s and steered the rolling out of the LEAN capability in the organisation via training and communication activities.

The following objectives and actions have been identified for 2021, to address identified areas of improvement as well as the changes and evolutions to EFSA’s external and internal environment which could have an impact on EFSA’s QMS.

#	Objective	Actions
1	<b>Maintained ISO 9001:2015 certification</b>	Prepare for and run surveillance audit
		Implement an internal quality audit cycle
		Customer feedback interviews with SANTE Customer/stakeholder survey
		Close gaps on process documentation (SOPs/WINs) and LEAN documentation
2	<b>EFSA’s QMS updated in line with TR measures and strategic needs</b>	Update of EPA (EPA III) for the 2021 planning cycle with inputs from DEV and lessons learnt from the past
		Update Quality roadmap in line with the Strategy 2027
		Adopt Quality Policy
3	<b>Integration of management systems</b>	Accountability policy by year-end (LA)
		EFSA’s integration of management systems roadmap: In line with PII IMS timeline and deliverables

		Hierarchy of Norms implementation: In line with the PII HoN timeline and deliverables
		Integrated indicators framework: Review of KPIs and PIs in line with the strategy
4	<b>Implement Continuous Improvement Process</b>	Run PIIs (Lean), communicate results achieved
		Deploy L&D plan on process management and lean

## 2.0 Extent to which 2020 Quality Management Objectives have been met

In 2020, the below were identified as Quality management objectives. They have all been entirely or partially addressed:

#	Objective	Status	Actions
1	<b>Maintained ISO 9001:2015 certification</b>		Prepare for and run surveillance audit
			Implement an internal quality audit cycle
2	<b>EFSA's QMS updated in line with TR measures and strategic needs</b>		Advise DEV on criteria/checklist for new process design, and for the process transition from DEV to BAU
			<b>Update of EPA (EPA III)</b> for the 2020 planning cycle with inputs from DEV and lessons learnt from the past
			Finalise assessment of <b>change management</b> effectiveness and update processes
			Strengthen scientific output quality via the <b>rolling-out concept of "scientific value"</b> in science processes, including outsourcing
		<b>Update Quality roadmap</b> in line with the <b>Strategy 2027</b>	
3	<b>Integration of management systems</b>		<b>Quality policy</b> , including quality of science, and <b>Records management policy integrated to Accountability policy</b> by year end
			<b>Additional measures in collaboration with Assurance</b> , and overall Process and Performance Management
4	<b>Further strengthened process management capability<sup>1</sup></b>		<b>Close gaps on process documentation</b> (SOPs/WINs)
			Develop " <b>metafiches<sup>2</sup></b> " for PIs and <b>close gaps for PIs</b> (ISO 9001 audit recommendation)
			<b>Deploy lean</b> for process improvement and communicate results achieved
			Finalise process management handbook and deploy L&D plan (process management, process metrics, lean)
		Create a visual process map	

During 2020 several activities were de-prioritised (in red above) due to the impact of the SARS-CoV-2 and the decision to safeguard resources to deliver on EFSA's core business and the mandatory Transparency Regulation preparations. Despite this, the key activities that had to be performed to maintain a reliable and fit-for-purpose Quality Management System were effectively implemented.

<sup>1</sup> The objective "perform process maturity for all process" has been postponed until 2021 after further discussions

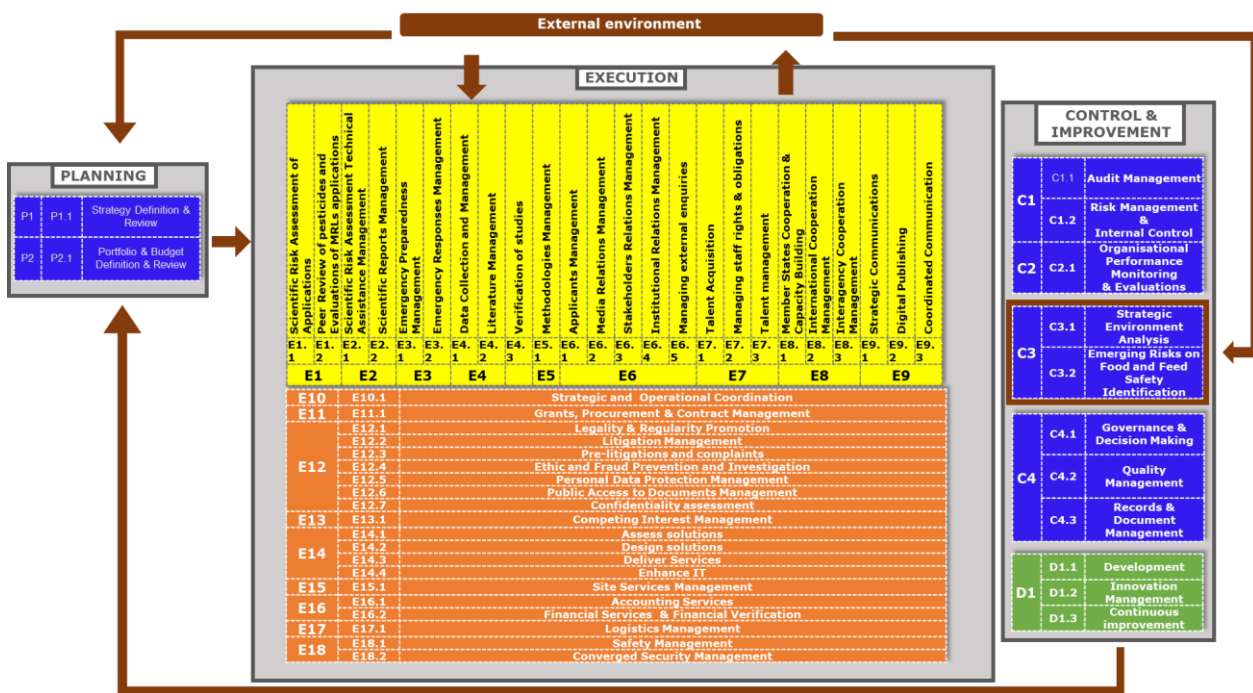
<sup>2</sup> The KPI's fact sheet, which is the document that contains information on the rationale of the indicator, the methodology to measure it, the data source(s), ...

The preservation of the **ISO 9001:2015 certification was achieved** by the organisation after the external audit confirmed that the QMS was compliant with the standard. To achieve this, EFSA satisfactorily addressed the recommendations for improvement made during the previous re-certification audit, particularly with advances in reporting on process performance (already begun in the 2019 Annual Quality Management Review).

The **Internal Quality audit programme** was carried out as expected in 2020, the difference being that audits took place virtually. This was the first year the exercise was carried out in this way and, overall, it can be deemed a success.

During 2020 many changes came about due to the ART programme implementing the transparency regulation. To ensure a smooth transition from the outputs of the projects, guidance was produced with the requirements needed for a process to become part of the business as usual. This checklist also supported the development of the new process charters and the completion of process elements such as performance indicators.

With these changes, the EFSA **process architecture** also had to be adapted to reflect the new/updated process. Due to the re-prioritisation mentioned above, the full review of the architecture was not possible during the year, so an intermediate approach was adopted with the development of the **EPA 2.5**, which integrated all new mandatory processes stemming from the Transparency Regulation as well as the three *end-to-end* science processes. This was used for the 2020 planning cycle exercise and will guide the organisation's activities through the upcoming year. Further changes are expected in 2021, when the EPA 3.0 will be developed and adopted.



The new **Quality Policy** was shared with colleagues in SANTE early in the year and some preliminary feedback was received. The concepts explained in this document are fully embedded in the end2end science process designs and will be rolled out during 2021 with their implementation. The policy was also endorsed by EFSA's Management Team (MT), and it is being integrated in EFSA's new Strategy 2027, and it is pending the official approval from the Management Board (MB) as part of the overarching Accountability Policy under development.

Efforts continued to **integrate the various management systems** and their documentation, with the drafting of the Information Management Policy which merged the **Records Management Policy** and the **Information Security Policy**. The final approval of this document is pending the development of the integrated Accountability Policy.



Another significant step towards integration was the conclusion of the EFSA-led Interagency framework contract with a **single external certification body** provider covering all Management Standards. This will allow a more harmonised overview of external audits, audit plans, audit reports, findings, and recommendations. This will provide EFSA staff greater clarity of the various audits and activities that are going on in the organisation and will make it easier for the various management systems owners to harmonise and coordinate their work.

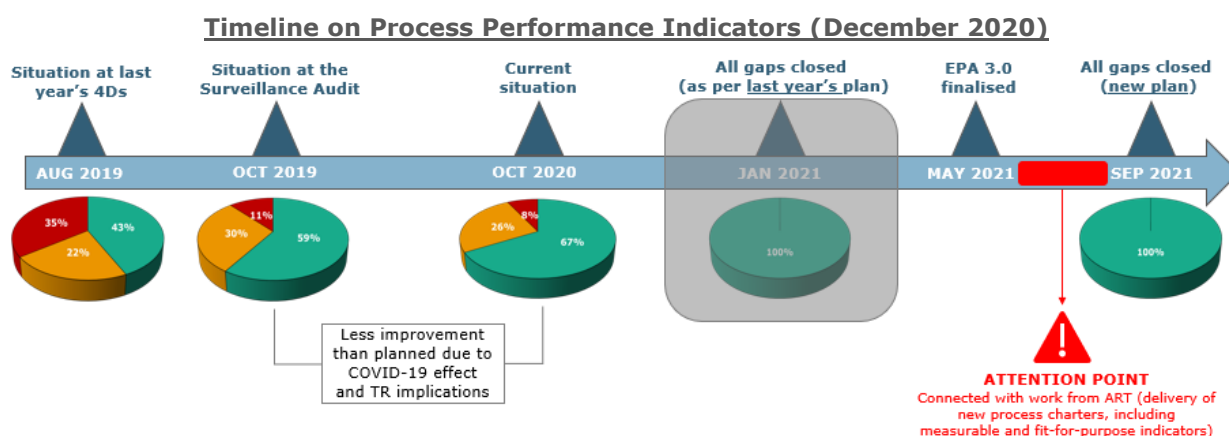
A **Process Improvement Initiative on the Integration of EFSA's Management System** was kicked off in November 2020 to develop and start implementing a roadmap for the further integration. This activity will run throughout 2021 and possibly continue in 2022.

Most of the work on **process documentation** in 2020 was focused on the new or updated processes coming from the ART programme as a result of the TR. This activity saw approx. **14 SOPs and 40 WINS** updated or completely redrafted. These new SOPs have provided great opportunities for leaning our documentation, e.g. two end-to-end science WINS implementing the tollgates in the areas of generic mandates and applications, will replace approx. 20 Unit specific WINS. In the area of BUS Services, all services covered by the SPOC have developed a corresponding WIN ensuring that there are no documentation gaps in these areas. These cut across the whole organisations, with science SOPs and Business Services WINS being the most affected. Most of these documents will come into effect as of March 27<sup>th</sup>, 2021.

In BAU mode **one new SOP** was drafted to cover the activities of the EU summary reports, **whilst 23 WINS** were developed/updated to cover existing gaps (e.g. AMU Library services, Process and communication activities for the production of joint ECDC-EFSA Rapid Outbreak Assessments), to harmonise existing documentation (Control of non-conformities and corrective actions- developed by RASA/REPRO) or to document newly established processes (e.g. Feedback Collection Mechanism) With this final effort, and a few other documents in their last stages just pending approval, in 2021 the organisation will be in a good shape regarding documentation coverage.

One area of attention flagged during the 2019's ISO 9001:2015 re-certification Audit was to continue pushing on the definition of **process performance indicators**.

Due to the reprioritisation of tasks that took place as a consequence of the SARS-CoV-2 pandemic, EFSA descoped the work planned on closing the gaps on the current set of indicators, targeting quick wins in those processes that were not to impacted by the intermediary EPA 2.5 architecture, and to the completely new processes (e.g. notification of studies) leading to an updated timeline (see below).



A more comprehensive review will be carried out in the context of the new EPA 3.0 and also in synergy with the EFSA 2027 Strategy.

Regarding the *meta-fiches*, the entire work was postponed to 2021, also in this case to ensure synergy with EPA 3.0 and the new Performance Framework.

The template to store this information was developed in line with the teachings of the training on process performance indicators that was rolled out in 2019 and 2020, and the approach was piloted within some processes of the GPS units.

The **continuous improvement process** ran as a BAU process in 2020 with a total of 20 improvement initiative being carried out across the organisation, either via the PII umbrella or via the projects led by training attendees of the Lean Six Sigma training. This year also saw in fact the process centrally manage the LEAN capability, by organising a LEAN six-sigma green belt training delivered to key actors in the organisation which will become LEAN ambassadors in their respective Units. The 20 improvement initiatives cover 22% of EFSA processes (36% of macroprocesses).

The process management handbook was drafted and is pending final validation. This document will cover in one single document the entire life cycle of a process in EFSA, from birth to integration and run in BAU. It also provides information for process managers and other key actors on how to identify suitable performance indicators and process maturity metrics.

For 2021 the process is expected to continue to run as planned, providing support for EFSA staff on PIIs and enhance the LEAN capability.

## 3.0 Performance of the QMS

### 3.1 AQMR 2019 Improvement actions

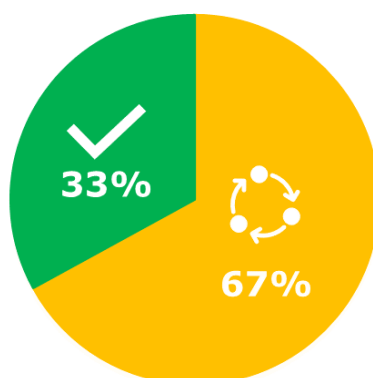
In the 2019 AQMR several improvement actions were identified from triggers spanning non-conformities, internal quality audits, performance deviations etc, to be implemented in 2020.

The opportunities for improvements were split in two categories, those to be implemented at the corporate level steered by the central QM function, which were reflected in the 2020 objectives and explored in section 2 –“Extent to which 2020 Quality Management Objectives have been met”.

Those opportunities for improvement that were identified by the process managers as part of the end of year reporting assessment, or that had an impact on specific/targeted processes were managed at Unit level. The implementation of these improvement actions was monitored throughout the year, and out of a total of 88 opportunities approx. a third have been addressed/closed, with the remaining ongoing via LEAN initiatives or under the various ART projects. With the issues faced during the year, many Units had to deprioritise those activities that were “nice to have”, to concentrate on “must-have” deliverables. Despite this, a considerable effort was made to address those opportunities for improvement deemed key for the processes to run as needed.

The LEAN six-sigma green belt training projects tackled processes/activities which benefited from the LEAN methodology to address improvement opportunities spanning performance issues (e.g. Peer review process - Optimisation and reduction of time to deliver), addressing customer feedback (e.g. Reducing total process length in setting up new WGs, Simplification of Performance Reports) and improvement actions to address changes in process demand/influx (e.g. LEAN of SOP lifecycle: from development to inclusion in Repository, Management of ad hoc GPS Analysis).

#### **Status of opportunities for improvement AMOR 2019**



Out of the 88 identified opportunities for improvement about 1/3 have been completely addressed (green in the pie chart above). Most of the improvement actions were in SO1 and were developed to

address issues raised from our customer feedback activities (survey interviews with SANTE). Some examples of the actions that were completed in SO1 were the documentation of the process on EU annual summary reports preparation (both SOP and corresponding WINs), the leaning project in PRES to support the staff to deliver efficiently and timely the requested scientific outputs, ensuring their quality and "fit-for-purpose". The Customer/Stakeholder bi-annual survey has been also updated to include questions targeted to applicants, which will replace the current feedback approach.

In SO2, actions addressing the low satisfaction related to DATA re-use in the 2019 Customer/Stakeholder were developed. Most prominent was the partnership with the JRC and DG ENV on the IPCHEM portal, which greatly improved the discoverability of European chemical monitoring data for re-use by interested parties with some 200 million analytical records in the public domain on the IPCHEM portal. EFSA also continued carrying out communication activities (e.g.: on social media) regarding the uploads in the Knowledge Junction platform, to raise awareness on these activities.

Improvement actions in the area of SO3 were performed to address the previously reported low awareness of cooperation tools and to enhance cooperation with MS in the 2019 Customer/Stakeholder survey. In 2020, planned calls of thematic and partnering grants were launched in time (in March) as originally planned. There was more focus on MS cooperation also due to the increased budget, which has enabled to launch of both types of `cooperation tools` calls in the same year. The role of MS/AF/FP in promoting and linking the content of these calls with their national priorities was an important element of the successful update of these calls by MS organisations.

The completed actions in SO4 mainly covered the dissemination, implementation, and awareness-raising of EFSA methodologies by implementing the new Methodologies Management process. To this end, a WIN on dissemination and capacity building activities for the implementation of EFSA cross-cutting GDs was developed and approved. The process for the production and communication activities of joint ECDC-EFSA Rapid Outbreak Assessments was also reviewed, documented, and described in a WIN.

Some completed actions under SO5 included the implementation of the performance management for experts process, the rolling out of further activities in the portfolio management solution which led to several efficiencies obtained compared to previous years and the continuous training on contract management and drafting of tender specs that have been provided to EFSA staff. There were also significant steps taken in the enhancement of the continuous improvement process and PII approach which was complimented by Lean Six Sigma capability building activities (training, awareness campaigns, etc.) aimed at refining the quality of improvement initiatives being run by EFSA, and to establish an on-going, self-maintained and sustainable CI practice.

### **3.2 Customer/Stakeholder feedback**

EFSA gathers feedback from its external and internal customers and stakeholders using four main mechanisms:

1. Customer Feedback exercise with SANTE
2. Reputation Barometer
3. Customer/stakeholder feedback survey
4. Customer feedback mechanism process

EFSA implemented the first two: the annual exercise with SANTE aiming at looking at the satisfaction of our main customer with our scientific processes and outputs, and gathering feedback of key EFSA's stakeholders on a series of key areas important to EFSA's reputation. The 4<sup>th</sup> activity was the conclusion of a pilot of the Customer feedback mechanism process aiming at having a coordinated approach to collecting customer feedback (internal and external) across the organisation.

In 2020, the Customer/Stakeholder survey (3 above) was not launched as it is planned bi-annually. Some lessons learnt from these activities will be used in 2021 by exploiting synergies and tailoring them better. This includes continuing the dialogue with SANTE on the selection and format of the customer feedback exercise according to changing needs and priorities, and exploring further alignments and complementarities between the external surveys, such as the Reputation Barometer and

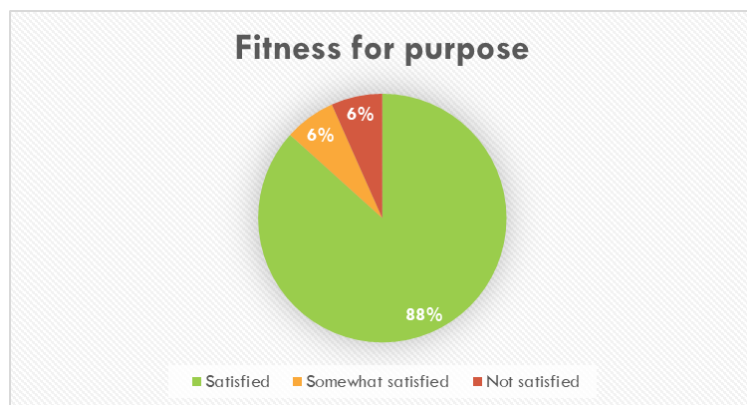
Customer/Stakeholder, but also other ad hoc ones, ensuring that the results of one can be used to refine another, and eventually merging to the extent possible.

### 3.2.1 Customer Feedback exercise with SANTE

During the 2019/2020 exercise, the interviews covered a mix of randomly selected opinions (5) and some (10) targeted by SANTE or EFSA in view of opportunities for improvement.

As per previous exercises, the overall feedback received was positive, with some areas for improvement identified by SANTE. Praise was given by both sides to the good collaboration and communication which contributes to the delivery of high-quality scientific opinions.

The readiness of both parties to discuss and negotiate deadlines, highlighting a mutual understanding of priorities and workload was also considered very beneficial.



This section of the interview looked concretely at the following aspects:

- The extent to which the opinion adheres to and provides a clear answer to the terms of reference
- The extent to which the opinion allows for a full understanding of the uncertainties, assumptions, and weight of evidence
- The extent to which the opinion provides a clear basis for regulatory action

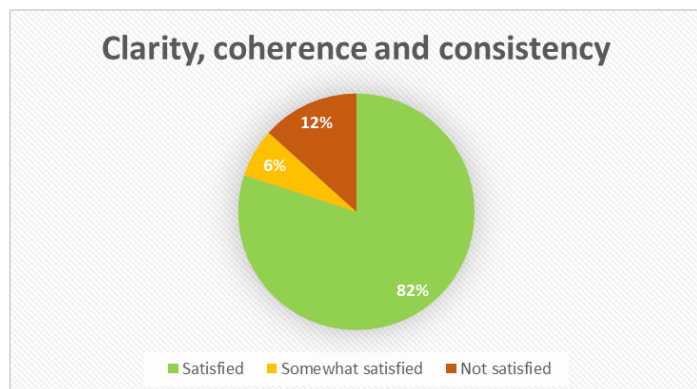
Out of 15 opinions that were discussed, SANTE was fully satisfied with 13 which were deemed fit for purpose by SANTE colleagues.

The importance of effectively using the Terms of Reference mandate negotiation process, applicable to the general risk assessment mandates (requests under Regulation 178/2002 and 396/2005 (Art. 43)) to have a mutual understanding of the expectations and therefore fully meet the ToRs was highlighted during some of the interviews.

Overall, the opinions allowed for a full understanding of the uncertainties, assumptions, and weight of evidence even in cases where there were significant data gaps

Most opinions provided a clear basis for regulatory action, despite some of them not having been used yet at the time of the interview due to them being adopted quite recently in the previous months.

There were two opinions where SANTE highlighted that they faced some challenges when using them for regulatory action.



Regarding the clarity, coherence and consistency of the scientific opinion, the satisfaction was also high, with 12 out of the 15 opinions receiving positive feedback.

This part of the interview covered the following:

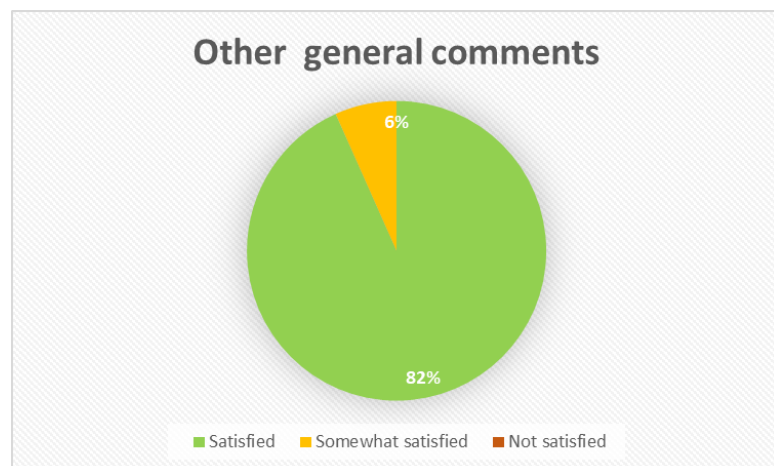
- The extent to which the conclusions are consistent with the evidence and methods presented in the opinion
- The extent to which the summary responds to the terms of reference

- The extent to which the summary is consistent with the main body of the text of the opinion
- The extent to which the level of clarity and detail in the opinion facilitate risk management

The conclusions were consistent throughout with the evidence and methods presented in the opinions.

The level of detail was generally appreciated, opinions are overall very comprehensive and provide the risk manager with a defensible opinion and enough detail on which to base their risk management decisions on

On the other hand, SANTE colleagues highlighted that sometimes providing extensive detail on aspects that are not key to the opinion can be seen as slightly exceeding the ToRs and could be summarised in the future (e.g. "Risk assessment of African swine fever in the south-eastern countries of Europe")



Most comments in this section highlighted the very good collaboration of SANTE and the EFSA Units, which was seen as very positive across the Board. There was also a general satisfaction with the timeliness and length of the scientific opinions. Only in one case there was general dissatisfaction with some specific aspects of the opinion (FIP Unit Food Contact Materials opinion - see below for targeted areas for improvement -).

Following up on a recommendation from the previous exercise, a more streamlined approach was agreed with SANTE for the

2020/2021 exercise, mainly to address workload and availability issues: only a few opinions selected by EFSA or SANTE would be discussed in an interview style, whilst for the rest (all randomly selected ones, and the ones where issues were minor), the feedback would be provided via written procedure.

This approach ensured the coverage of approximately the same number of opinions as per previous years but minimising the effort from both sides.

The exercise is still ongoing and the report will be finalised and followed up during 2021.

### 3.2.2 Reputation Barometer

With the bi-annual Customer/Stakeholder feedback survey being planned for 2021, in 2020 EFSA gathered feedback from their stakeholders using the Reputation Barometer, a study that EFSA carried out for the second time this year (after the 2017 edition).

The study consisted of a survey that was sent to representatives of 5 of EFSA's stakeholder's groups (Member States; European Commission; businesses, farmers and primary producers; consumers and thematic organisations; as well as the scientific community) and gathered feedback on EFSA's reputation using 12 attributes:

1. EFSA's approach to providing scientific advice
2. The quality of EFSA's risk assessment opinions
3. The efficiency of EFSA in producing risk assessments
4. The identification and characterisation of emerging risks by EFSA
5. EFSA's work to harmonise risk assessment methods
6. EFSA's independence and objectivity
7. The level of transparency at EFSA
8. How EFSA communicates risks
9. EFSA's Engagement with external partners
10. EFSA's provision of scientific and technical assistance to Member States for crisis management
11. The quality of EFSA's governance
12. EFSA's innovativeness

Overall, 359 invites were sent out, with a response rate of 33%.

The study generated an EFSA reputation score for each of the stakeholder groups selected. Scores were calculated on a scale from -100 to +100 with intervals of "negative", "neutral" and "positive" reputation:

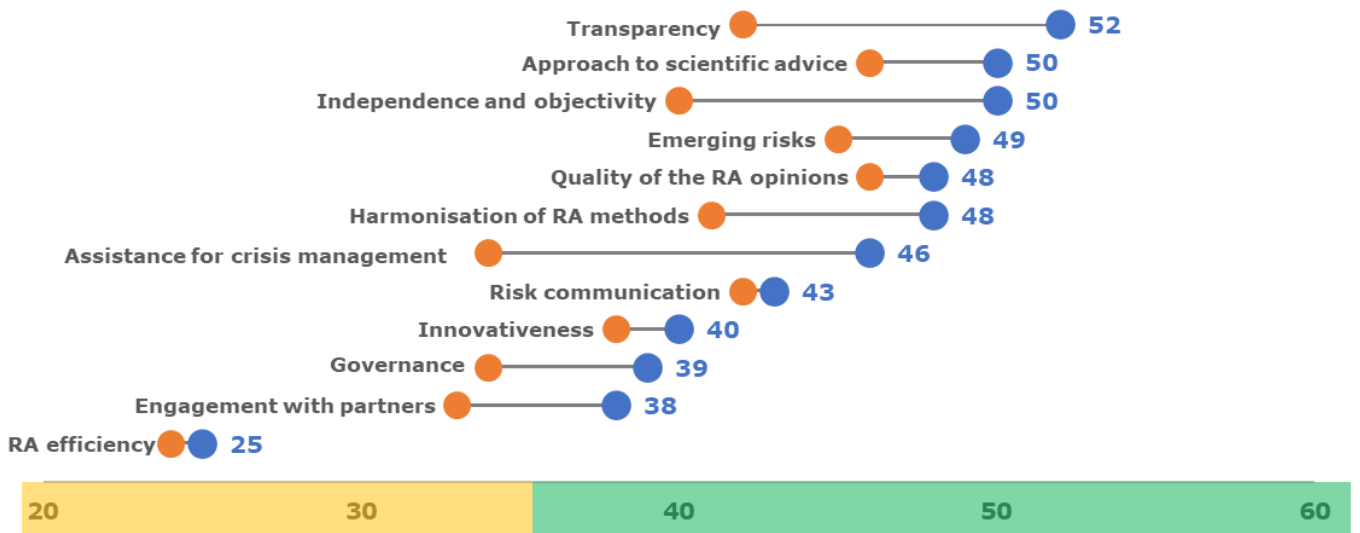
Year	Member State Authorities	European Commission	Business, farmers and primary producers	Consumers and thematic organisations	Scientific community
2017	46	33	20	3	42
2020	52	44	23	12	54

Negative					Neutral					Positive										
-100	-90	-80	-70	-60	-50	-40	-30	-20	-10	0	10	20	30	40	50	60	70	80	90	100

EFSA’s reputation largely improved across stakeholder groups and attributes between 2017 and 2020. The highest improvements were registered for the scientific community, European Commission and consumers and thematic organisations.

**Reputation Barometer scores by attribute (2017 vs 2020)**



The attributes where an increase in score was most notable were *harmonisation of risk assessment methods*, *transparency*, *independence and objectivity*, and *assistance for crisis management*. On the other hand, the attribute of *RA efficiency* was stable when compared to 2017, scoring lowest among most stakeholder groups.

Moreover, most of the attributes moved into the positive area (score higher than 35 points).

Despite the Reputation Barometer and the Customer/Stakeholder Feedback Survey having had a different focus, targeted a different stakeholders’ mix, and employed a different methodology, some of the results remain comparable, showing similar results year-on-year:

- In the macro-area of **Fitness-for-Purpose** (*Approach to scientific advice*, *Quality of RA opinions*, *RA Efficiency*, *Transparency*, *Assistance for crisis management*), EFSA similarly scored positive results to what emerged in the 2019 Customer/stakeholder feedback survey. The only dimension that is in the neutral area in 2020 is the “*RA Efficiency*”, and this is somewhat coherent with the 2019 results in the question “*To what extent do you consider the scientific advice provided by EFSA to be timely?*”, which registered a result below the average of the dimension
- The macro-area of **Harmonisation** (*Harmonisation of RA methods*) remained one of the highest-scoring dimensions in both survey (2<sup>nd</sup> out of 10 dimensions in 2019 vs 5<sup>th</sup> out of 12 dimensions in 2020)
- The macro-area of **Communication** (*Risk Communication*) is in the positive area in both surveys.

### 3.2.3 Customer/Stakeholder Feedback Survey

Despite 2020 being an idle year for the comprehensive Customer/Stakeholder feedback survey (which is run every two years), EFSA has already started the preparation of the 2021 edition.

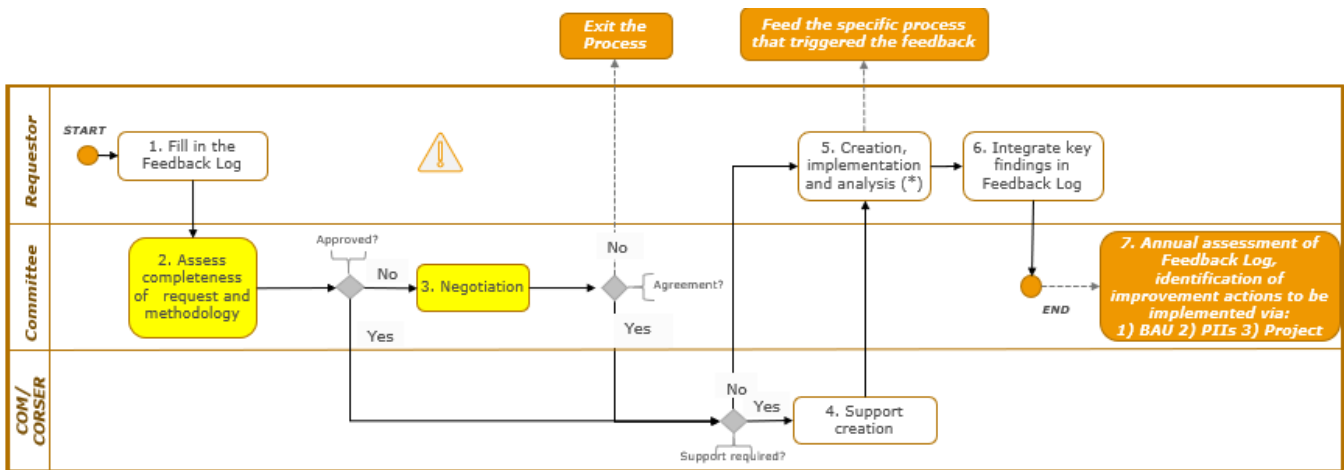
In particular, the involvement of EFSA’s social science function has already been planned, to continue improving the fitness-for-purpose of the survey.

The survey will be run considering the opportunities for improvement that were put forward in last year’s AQMR as well as the ones coming from the Reputation Barometer.

Moreover, and addressing one of the suggestions coming from the latest surveillance ISO 9001:2015 audit, it has been foreseen to incorporate ADPEK’s feedback requests into the general survey, with a set of questions already identified and agreed upon between the Unit and the Quality function.

### 3.2.4 Customer Feedback mechanism process

A streamlined **process to collect customer feedback** was developed aimed at better coordinating feedback requests to (i) avoid high volumes of surveys leading ultimately to respondent fatigue, (ii) optimise the timing of and avoid duplications and overlaps between different requests, and (iii) ensure results are readily available (through a log) to maximise the use of insights and business intelligence. This activity was kicked off towards the end of 2019 and it was piloted throughout 2020.



\* It can be carried out by external contractors

In 2020, EFSA administered 45 requests for feedback, mainly through surveys, more to internal stakeholders (meaning EFSA staff, either in full or a targeted group) compared to external stakeholders (see table below).

Through this process, EFSA was not only able to monitor the frequency of the feedback requested (internally/externally) but was also able to increase the quality of the surveys sent out (through the methodological and technical support given by the committee managing the process) and to avoid, in a couple of instances, the launch of unnecessary surveys (since similar data were already available elsewhere).

**Survey requests – 2020**

Type of feedback	Number	Internal audience (all staff and targeted)	External audience
<b>Surveys</b>	<b>41</b>	<b>24</b>	<b>17</b>
<b>Interviews</b>	<b>2</b>	<b>-</b>	<b>2</b>
<b>Focus groups</b>	<b>1</b>	<b>-</b>	<b>1</b>
<b>Other</b>	<b>1</b>	<b>-</b>	<b>1</b>
<b>TOT</b>	<b>45</b>	<b>24</b>	<b>21</b>

The collection of the feedback needs for 2021 was launched at the end of 2021 ensuring an overview and early planning of the year ahead.

### 3.3 Satisfaction of external providers

To assess the performance of the external providers contributing to EFSA’s core activities, scientific officers are asked to fill in a quality check form for each external scientific report delivered during the year. From the forms filled in this year, we can see an improvement in the rating of the reports, in particular areas that have performed lower in previous years such as “*Has satisfactory quality of the deliverable been achieved without significant effort from EFSA staff?*”.

#### Satisfaction of external providers – quality form results

Year	Were the objectives as defined in the Terms of Reference achieved in the final deliverable?	Was the method followed as proposed in the offer?	Is the deliverable useful for EFSA’s work?	Has satisfactory quality of the deliverable been achieved without significant effort from EFSA staff?	Is the deliverable clearly structured?	Do language and style of the deliverable meet EFSA requirements?
2020	4.0	4.0	3.95	4.0	4.0	4.0
2019	3.9	3.9	4.0	3.6	4.0	3.8
2018	3.7	3.9	3.9	3.3	3.9	3.9

Ratings go from 1 (lowest) to 4 (highest)

The improvement in the scores on the quality of the external scientific reports can be linked to the continuous training on contract management and drafting of tender specifications to scientific officers, rolled out throughout 2019 and 2020 by the FIN Unit as a follow-up action from the 2018 AQMR. Continuous support provided by procurement colleagues at various stages of the contract, especially when they anticipate delays on deliverables or the quality falls short of what was established in the tender specifications continues to be also crucial in ensuring that the expected quality is met.

Although useful in providing insights on the performance of external providers, as previously reported there are shortcomings with the quality check form. This check is perceived as a burden for some scientific officers and it is not consistently filled in for every scientific report (out of 41 published in 2020, only 24 completed the quality check form, those Units that did not complete it will be requested to enter a non-conformity in the workflow).

The introduction of the “toll gates” from 27<sup>th</sup> March 2021 will provide an opportunity for a more consistent way to do this assurance check on the reports delivered by external providers. To embed this check into our QMS, the current *SOP\_009\_S Approving supporting publications* has been updated to reflect the toll gate principle and provide further guidance on evaluating the quality of an external scientific report (the updated SOP will come into effect on the 27<sup>th</sup> March). This will help us evolve from a quality control perspective into a quality assurance one i.e. whilst the process is ongoing, not only at the end after publication.

With more outsourcing of activities linked to our core processes becoming a reality soon, a close eye will need to be kept to evaluate if the new process delivers a reliable way of measuring satisfaction of the work done by external providers.

### 3.4 Managing non-conformities (SOPs)

In 2020, there were a total of 50 (up to October) non-conformities and ex-ante deviations registered in the exception request workflow. Out of these, 30 were against SOPs, 6 against ED Decisions, while the remaining 14 were registered against other binding documents such as policies and MB decisions.

For the non-conformities, actions preventing their reoccurrence have been put in place, such as:

- Update of documentation (e.g. *WIN\_SOP014\_06 FIP Procedure for outputs publication*)



- Update of templates (e.g. FEED template for Renewal opinions)
- Strengthening the Unit's internal quality checks with the continuous support and communication of Quality Circle Correspondents

The SOPs that registered the highest number of non-conformities are listed below:

- *SOP\_005\_S Managing scientific meetings*: Following the same trend as in previous years, this SOP registered the highest number of non-conformities with a total of 8. The majority were concerning the publication of meeting minutes 15WD after the meeting. The SOP\_005\_S has been reviewed to align with the new end2end science processes, however, it was concluded that the timely publication of minutes is a must, particularly considering other transparency measures taking place. The publishing of the minutes will become less burdensome with new tools coming into force in 2021
- *SOP\_014\_S Publishing a scientific output in the EFSA Journal*: There were 6 non-conformities primarily against the requirement of publishing a scientific output within 28 days after adoption. In most cases, this deviation could not have been avoided, however a proposal to review the SOP to add a "clock-stop" in the period of 28 days in case of delays caused by external parties is being considered
- *SOP\_015\_S Correction of a published scientific output*: There were 7 Correction Type Erratum republications registered and closed. In 2021 we will review the way that this type of deviations is reported (to be linked to the quality of the output)

A summary of the registered non-conformities is presented in the table below.

SOP (n)	SOP name	NCs (n)	Units	Status
SOP_005_S	<i>Managing scientific meetings</i>	8	BIOCONTAM, SCER, FIP, FEED	<b>Closed</b>
SOP_006_S	<i>Establishing, updating and closing scientific WGs</i>	1	FIP (ex-ante exception)	<b>Closed</b>
SOP_008_S	<i>Data collection and validation</i>	1	DATA (ex-ante exception)	<b>Closed</b>
SOP_012_S	<i>SOP_012 Adopting a scientific opinion, statement or guidance of the Scientific Committee/Scientific</i>	2	FEED, FIP	<b>Closed</b>
SOP_014_S	<i>Publishing a scientific output in the EFSA Journal</i>	6	FEED, PREV	<b>Open</b>
SOP_015_S	<i>Correction of a published scientific output</i>	7	BIOCONTAM, PRES, FEED, FIP	<b>Closed</b>
SOP_023_A	<i>Control of Non-Conformities to SOPs and Corrective actions</i>	1	PRES (+ 1 FEED IQA not yet in ERW)	<b>Closed</b>
SOP_039_M	<i>Management of competing interests</i>	3	BIOCONTAM, DATA	<b>Closed</b>
SOP_045_A	<i>Performance Management of Statutory Staff at EFSA</i>	1	HUCAP	<b>Closed</b>

In 2021, with new SOPs and processes coming into effect, a rise in non-conformities is to be expected whilst the organisation adapts to the new ways of working. This should not be taken as a weakness of the QMS but rather as an expected side effect of change.

We should nevertheless pay close attention to recurring non-conformities, particularly in newly designed processes since this may signal that the process needs to be revised.

An ex-ante request was registered to cover specific exceptions during the deployment of the new SOPs throughout 2021 (mainly relevant for the period January to March).

### 3.5 Risk management

Risk management is a continuous, proactive, and systematic process of identifying, assessing, and managing risks to provide reasonable assurance towards the achievement of objectives. At EFSA, the methodology is aligned at process, project and programme level and integrated in EFSA's process management.

As part of EFSA's planning cycle, risks and mitigating actions are identified at process level and captured in the EFSA Process Architecture (EPA) process charter. The critical and cross-cutting risks that could potentially impact the achievement of EFSA's objectives, and respective mitigating actions and controls that reduce the risks to acceptable levels are outlined in EFSA's Programming Document. The analysis of these controls can be found in the Assurance Report, which concluded that in general all the Internal Control components are present and functioning.

### 3.6 Internal quality audits

The internal quality audits were carried out using the ISO 9001:2015 standard as their backbone and ensuring that all the requirements laid out in clause 9.2 Internal Audit have been met.

The internal quality audit programme has been designed to sample critical processes within the organisation to provide top Management with enough evidence that the Quality Management System:

- a) Conforms to:
  - 1) the organisation's own requirements for its quality management system
  - 2) the requirements of the ISO 9001:2015 standard
- b) Is effectively implemented and maintained.

2020 internal audit goal:

*"Do processes comply with the organisation's QMS and the relevant ISO 9001:2015 standard? Are processes planned, monitored and measured and deviations from performance documented and used to improve the QMS?"*

All EFSA's processes and their variants were mapped against several criteria to understand which processes should be selected for this auditing cycle.

Further mapping was done with the Assurance Advisor to have an overview of those processes that were covered by other types of internal control activities, and which were filtered out from the selection. The aim was to minimise the effort required in a year challenged with the SARS-CoV-2.

Early in the year, the audits had to be moved to a virtual setting to ensure that we were fully able to implement our audit plan within the agreed timeline. In total 23 process variants were audited, all covering 9 EFSA's science units. A total of 2 minor Non-Conformities (FEED, PREV), 25 Opportunities for improvement and 4 Best Practices were found.

The Units showed that they had addressed prior audits non-conformities and had made considerable steps to implement any previously identified opportunities for improvement. In general, all processes audited were compliant with the requirements of the standard.

Using the lessons learnt from the 2019 audits, the WIN for Internal Quality Audits was updated and approved in 2020.

Year	Non-conformity	Target	Owner	Status
2020	NC (minor) against the requirement of SOP 023,	P3 2021	FEED	<b>ONGOING</b>

	step 4, to predefine the deadline and the relevant staff member for the corrective actions of any identified non-conformity. Refers to the one FEED NC registered in 2020	Compliance to be checked during IQA 2021		A detailed cross-cutting WIN providing guidance on how to implement SOP_023_M Control of non-conformities and corrective actions has been drafted and approved
2020	NC (minor) against ISO 9001:2015 clause 6.1.2. The risks for the process variant E02.02.11 (new code number: E02.01.15) have been identified, however mitigation actions to address these risks are not described, as required by the standard	N/A	PREV	<b>CLOSED</b> The EPA process charters had not been uploaded properly at the time of the audit, thus this was registered as a non-conformity. This was corrected soon after and the correct documents were made available

To address issues regarding workload and the availability of fewer internal quality auditors, the 2021 audit programme will concentrate on key new processes, to have a closer look at how they have been implemented and transitioned from DEV to BAU. This audit programme will be available in the next months and as in previous years it will be drafted using a risk-based approach with the support of the Assurance Advisor.

Further support will be sought during the year for carrying out the internal quality audits, with the possibility of using external consultants for parts of the process, being explored.

### 3.7 ISO 9001:2015 Surveillance audit

In 2020, EFSA underwent its first Surveillance audit of its second cycle of ISO 9001:2015 certification, where approximately half of the organisation was audited.

To successfully maintain its certification, EFSA had to address the recommendations for improvement made during the previous audit, which were included as part of the 2020 Annual Quality Review objectives. The recommendations and the actions to address them can be found below:

Recommendations	Actions
When revised processes (Transparency Regulation) are available check for possibilities of streamlining the process documentation	<ul style="list-style-type: none"> <li>- Possibilities for streamlining already being explored under ART with the development of end2end SOPs.</li> <li>- Hierarchy of Norms PII will also look at reviewing current documentation and identify any overlaps</li> </ul>
Ensure a better overview of the performance of a process across all dimensions (Volume, Time, Cost, Quality, Customer Satisfaction)	All performance indicators integrated in one single reporting tool, Hyperion. Due to SARS-CoV-2 reprioritisation (which impacted the EPA 3.0 plan), revision of indicators for science units is ongoing (starting with RA processes), revision of indicator of COMCO units expected to be finalised by year-end, whilst for BuS units existing indicators are being streamlined (and gaps reduced)

Further strengthen the process performance section (based on indicators) in the Annual Quality Management Review	As part of the 2019 AQMR, Units were asked to give an overview of their process performance captured in the End-of-year reporting doc where deviations and possible improvements were identified
Performance deviations should be managed similarly to non-conformities, linking an identified improvement action to its root cause	The end-of-year reporting file aimed at tackling this issue, by ensuring performance deviations and their corresponding improvement actions were linked to an identifiable trigger. The same approach has been used for the identification of LEAN initiatives, PIIs etc

These improvement actions were presented to the auditor during the re-certification audit which took place remotely on the 12th of October (GPS) and on the 22/23rd of October (HUCAP, TS, ENCO, AMU, SCER, APDESK, FIP, GMO, PREV, BIOCONTAM). After reviewing all our actions to address the previous recommendations and extensively auditing half of EFSA’s organisational Units and processes, the auditor recommended that EFSA’s certification should be confirmed.

The audit report concluded that EFSA’s QMS has allowed the organisation to plan suitable actions to drive enhancements and improvements and to react to planned changes in the context i.e. the implementation of transparency regulation, as well as unforeseen circumstances, like the effect of lockdown and implications on the way of working.

The certification was confirmed with 0 non-conformities and two general areas for improvement:

- To identify the most optimal process performance indicators to measure process performances and trends
- Reflect on how to improve the tools available to effectively monitor large numbers of recommendations/improvement actions across the QMS

Actions to address the recommendations above will be explored in 2021.

**3.8 Process performance, monitoring and measurement of results**

In line with 2019, also in 2020 EFSA continued improving their process performance framework. At the beginning of the year, three training sessions were delivered to provide the needed knowledge to identify, develop, monitor, and use fit for purpose indicators, as well as to disseminate a common language and understanding on the matter across the organisation. The training sessions were targeted towards the actors with process quality responsibility within the organisation, i.e. process owners, process managers and quality circle representatives.

The training supported EFSA in improving the quantity and the quality of the indicators used at the process variant level, in line with the recommendation received in the 2019’s ISO 9001:2015 re-certification audit, as well as in ensuring that a common language is used and understood within the organisation.

Due to the impact of the SARS-CoV-2 pandemic on EFSA’s operation, a complete review of the indicators at the process level was postponed to 2021, alongside the revamp of the EFSA Process Architecture, and the initial plan on the work on Process Performance Indicators set out in 2019 was changed to take into account the new situation. Nevertheless, quick wins were targeted in 2020, aiming at reducing the gaps and improving the fitness-for-purpose of the indicators in some processes (*the ones not affected by the changes brought in by EPA 2.5*).

## ISO 9001:2015 preparation: Recommendations

### Possible area for attention: PPIs

A) "...but not in all cases the entire KPI spectrum (Volume, Time, Cost, Quality, Customer Satisfaction) has been yet covered as required by the EPAs. It is recommended not to loose momentum via keeping pushing on identification of any additional KPI that could improve performance"

B) "...to include in the QMS management review a dedicated session to discuss about them in order also to check their appropriateness"

2019

2020

1. **"End of Year report"** piloted in December (Process managers asked to **sum up** 2019 performance, as well as **identify opportunities for improvement**, some of which were carried out in 2020), **to tackle recommendation B.**
2. **Three additional sessions of the training on Performance Indicators** were carried out, further 45 people trained
3. **Initial plan (as per AQMR)** to close remaining gaps and develop **metafiches**, as well as use a new IT tool (Hyperion) to carry out reporting of performance
4. **New tool was introduced** (as of January)
5. **Impact of COVID-19** (and consequent re-prioritisation of tasks) and **TR affected** also **this plan** (metafiches preparation postponed, and delays in the agreement on the new process structure)
6. **3-way approach was developed, targeting improvements that could have been used already in 2020 but also in 2021**, avoiding to carry out "stop-gap" activities but **to still ensure progress for recommendations A and B:**
  - > In BuS, to improve the current set of indicators in the processes that were not impacted by EPA 2.5, **aiming at reducing existing gaps** and streamlining current indicators (e.g.: merging/removing low-value PIs from the same dimension)
  - > In COMCO, to continue with **their own project** to close gaps/increase the fitness for purpose of indicators as of 2021
  - > In Science (RASA/REPRO), to support the ART Programme in the creation of a set of **cross-cutting indicators for RA processes** (also taking into account the new tools to be used in 2021)

Completely new TR processes to develop PPIs by the end of 2020. Other impacted and pending processes by end 2021 (EPA3 and Strategy)
7. **Process Performance reporting was safeguarded** (August and December)
8. **Metafiches approach piloted** in GPS
9. **End of year report planned** to be carried out

LEGEND: ● Original plan ● New plan ● Issue

5

After the positive introduction of the "End of Year Report" in 2019, also at the end of 2020 process managers were asked to provide an assessment of the performance of their processes covering measurement of indicators, non-conformities, audit results, customers/stakeholder feedback, and lessons learnt. The performance analysis was provided by the process managers as a self-assessment on how their activities went in 2020.

The vast majority of processes (80%) met the revised targets set after the re-prioritisation of tasks agreed in May to counter the negative effects (direct and indirect) of the SARS-CoV-2 pandemic on EFSA's operations (including the postponement of some deliverables as well as of descoping/reduction of targets). 11% of the processes registered some deviations, which were assessed via a root-cause analysis but their performance remained in the positive spectrum, reporting deviations only in some areas. The remaining 9% of the processes were not assessed, either because they were not expected to run in 2020 (e.g.: Decision making) or because they were not triggered (e.g.: Assessment of Decontamination dossiers).

The results from the End of Year Reporting exercise are in line with those stemming from the monitoring of EFSA's workplan, where around 90% of the measured deliverables/metrics listed were completed during the year on updated targets).

The results also show how the re-prioritisation exercise was effective in safeguarding resources to deliver on prioritised objectives.

The abovementioned findings need to be considered having the following observations in mind:

- Some processes do not have good coverage of indicators, thereby having only a partial view of their performance. This was an issue already present last year
- Some processes reported a good performance without any indicators/facts to back their evaluations. This was less of an issue compared to 2019, which is probably due to the increased familiarity with the task, and the decision to monitor the process indicators in the Hyperion Workplan
- There were only few links with the inputs required to run the process (*phasing out Sciforma for monitoring FTEs consumption at process level may have played a role*), and few mentions of stakeholders' perception (*also due to the fact that the bi-annual Customer/Stakeholder Feedback Survey was not planned in 2020*), with the focus remaining on the delivery of activities. This was an issue already present last year

With the complete revamp of the EPA structure, a new Strategic cycle, and a new Organisational Design expected to be ready by 2022, there is an opportunity to increase the quality and the fitness-for-purpose of the indicators used, and to keep reinforcing the links of process performance with the activities of portfolio, corporate monitoring, and continuous improvement.

### **3.9 Adequacy of resources<sup>3</sup>**

EFSA has been suffering from limited staff in recent years, which has challenged its ability to deliver, particularly when faced with (i) increased workload, (ii) more complex work and (iii) a need for greater transparency and engagement with society. Moreover, in 2020 EFSA faced additional challenges, linked to the additional costs incurred for preparing for the implementation of the TR, and with the disruption caused by SARS-COV-2 pandemic.

#### **SARS-COV-2**

The resource gap for the year 2020 was higher than initially estimated mainly because of the SARS-COV-2 crisis and of the effort for preparing for TR mandatory measures as of March 2021. Concerning the SARS-COV-2 crisis, EFSA has estimated that the crisis has caused a 5% reduction of the workforce during the year 2020 and that the change in the ways of working (exclusively remotely), together with external causes (e.g. contractors delivery delays, applicants missing data provision delays, etc.) has caused a global 6% internal inefficiency.

#### **Increased cost for TR preparation**

For what refers to the preparatory work for the implementation of the TR measures, in particular the ones to be run from March 2021, the effort in the year 2020 has demonstrated to be higher than the additional human resources assigned to EFSA in the same year. In particular, the development projects (including FSCAP, Iuclid, Appian 108, Process re-design, etc.) have absorbed around 55 FTEs. In parallel, extra effort was necessary in the areas of talent selection, procurement, engagement and communication estimated for the year 2020 at around 12 FTEs.

The gap in human resources for the year 2020 is therefore estimated at around 71 FTEs.

To counterbalance the increase of demand in resources and the reduction by 10% of the number of posts between 2013-2018, EFSA has put in place several measures:

- Process re-engineering (centralisation and streamlining of procurement, contract management and business control functions, optimisation and outsourcing of the services to support experts meeting organisation and execution)
- Improved capability across the organisation in process management, focusing on customer satisfaction and on continuous improvement via incremental initiatives
- Digitalisation of working practices and effective knowledge sharing for increasing productivity (e.g. the NWOW and digital collaboration projects)
- Fostering synergies and avoiding duplication with Member States and other EU bodies (e.g. molecular typing, Information Platform for Chemical Monitoring (IPCHEM), EU risk assessment agenda (EU RAA), interagency framework contract on cloud services)

In 2020, additional efficiencies estimated at 6.5 FTEs have been generated by the centralisation of mission support (5 FTEs), the deployment of centralised corporate planning and reporting solutions (0.5 FTE) and the deployment of the NWOW project (1 FTE).

EFSA also improved its occupancy rate (from 93.8% in 2014 to 97.6% in 2019) improving the recruitment process and optimising the use of interim resources for covering long-term absences.

As the capacity improvements were not able, already in previous years, to counterbalance the increase in demand, EFSA received in 2019 an additional EUR<sup>9</sup>0.22 million and six (6) contract agent (CA) posts to address the increased workload in the area of novel food applications and plant health high-

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<sup>3</sup> Further details are available in the EFSA's Annual Activity Report 2020 and Single Programming Document 2021-2023

risk commodities applications. Nonetheless, demand and availability remained unbalanced, including in 2020, with a resource shortfall initially estimated at around 23 FTEs.

For 2021, the above drivers will continue to challenge EFSA's demand-capacity balance, with the foreseen gap of resources amounting to approximately 80 FTEs. In view of the above, and the imminent risks of accumulating workload, risk assessment evaluations backlogs, and performance deterioration, EFSA has put forward a request to the budgetary authorities for flexibility in the use of the assigned budget. In particular, to accommodate in its budget envelope (as included in the draft MFF 2021-27) an increased number of 30 Contract Agents for a period of five years (from the year 2022 to the year 2026), allocated to the processes of a significant temporary capacity shortage (Animal feed, Food ingredients and packaging, Nutrition, Pesticides peer review, Human resources).

### **3.9.1 Adequacy of resources for maintaining and running EFSA's QMS**

In 2020 a total of 4 FTE across the organisation were planned to carry out essential quality management activities. These activities included, but were not limited to:

- Central QM function (GPS)
- Quality circle participation (all units)
- Drafting of QMS documentation (all units)
- Internal Quality audits 9001 preparation and attendance (all units)
- Process documentation maintenance/update/development (EPA charters) (all units)
- Performance analysis and deviations reporting (PI's development, non-conformity reporting) (all units)

Moreover, quality-related tasks are integrated throughout the organisation in the execution of the processes and projects, such as in the roles of process/project/programme sponsors, owners, and managers.

To further develop the capabilities of the available resources to run the QMS, several training sessions were provided in 2020 (e.g. training on process performance indicators, performance and result-based management; LEAN six-sigma green belt) to the main actors across the organisation on key activities central to the management system. For such capability improvements to be sustainable, and particularly to drive continuous improvement, an increase in resource investments will be required. The ongoing SARS-CoV-2 and Transparency Regulation implementation investments will pose continuous challenges on resource availability also in 2021. To address this shortfall, a combined approach based on less-ambitious planning, outsourcing, and reviews for de-prioritisation, is being followed.

### **3.10 Opportunities for improvements 2021**

Following the analysis of all feedback streams (process performance, customer feedback, non-conformities, internal quality audits, etc), several opportunities for improvement across all strategic objectives have been identified for 2021.

As per previous years, the opportunities for improvement that affect the QMS will be managed at corporate level by the QM function and are reflected in the 2021 objectives. These include follow-up to external ISO 9001 audit general recommendations, and any other activity that has an impact on the overall structure/performance of the QMS (process changes, documentation etc).

In 2021, there will be a stronger focus on rolling out the already developed processes and documentation that will allow EFSA to implement the activities required by the Transparency Regulation. This may result in fewer process improvements being implemented. Despite this, during the end-of-year reporting exercise a total of approx. 80 opportunities for improvement for 2021 were identified across all departments, of which around half are directly addressing deviations coming from customer feedback, non-conformities, audits, and performance deviations. Most of the other opportunities not directly triggered by a deviation have been identified to address other challenges such as increased workload and the need for faster delivery of outputs. Several opportunities for automation have also been identified.

Improvement opportunities that have been identified on specific processes will be monitored throughout the year via the Quality Circle.

### 3.11 QM Objectives 2021

Considering the performance and progress made in 2020, and EFSA's strengths, weaknesses, challenges and opportunities, the following quality management objectives are proposed for 2021:

#	Objective	Actions
1	<b>Maintained ISO 9001:2015 certification</b>	Prepare for and run surveillance audit
		Implement an internal quality audit cycle
		Customer feedback interviews with SANTE Customer/stakeholder survey
		Close gaps on process documentation (SOPs/WINs) and LEAN documentation in line with EPA 3.0 and integration of management systems
2	<b>EFSA's QMS updated in line with TR measures and strategic needs</b>	Update of EPA (EPA III) for the 2021 planning cycle with inputs from DEV and lessons learnt from the past
		Update Quality roadmap in line with the Strategy 2027
		Adopt Quality Policy
3	<b>Integration of management systems</b>	Accountability policy by year-end
		EFSA's integration of management systems roadmap: In line with PII IMS timeline and deliverables
		Hierarchy of Norms implementation: In line with PII HoN timeline and deliverables
		Integrated indicators framework: Review of KPIs and PIs in line with strategy and EPA 3.0
4	<b>Implement Continuous Improvement Process</b>	Run PIIs (Lean), communicate results achieved
		Deploy L&D plan on process management and lean

## 4.0 Conclusion and next steps

Analysing the achievements of EFSA's Quality Management throughout 2020, we are confident that we have consolidated the foundations of our QMS in alignment with ISO 9001:2015 requirements and are on track for a successful 2nd surveillance audit in 2021. We are looking forward to entering this new period of change, whilst maintaining our cycle of continual improvement, aimed at increasing the performance of the organisation and its processes, in line with customers' needs and stakeholders' expectations.

To ensure that the content of this report is effectively used, we will:

- Internally communicate its content with the organisation via the QC
- Publish it on the EFSA website for transparency vis-à-vis our customers/stakeholder