Integrated Management Systems Review 2021

Trusted science for safe food

efsa
European Food Safety Authority

Table of contents

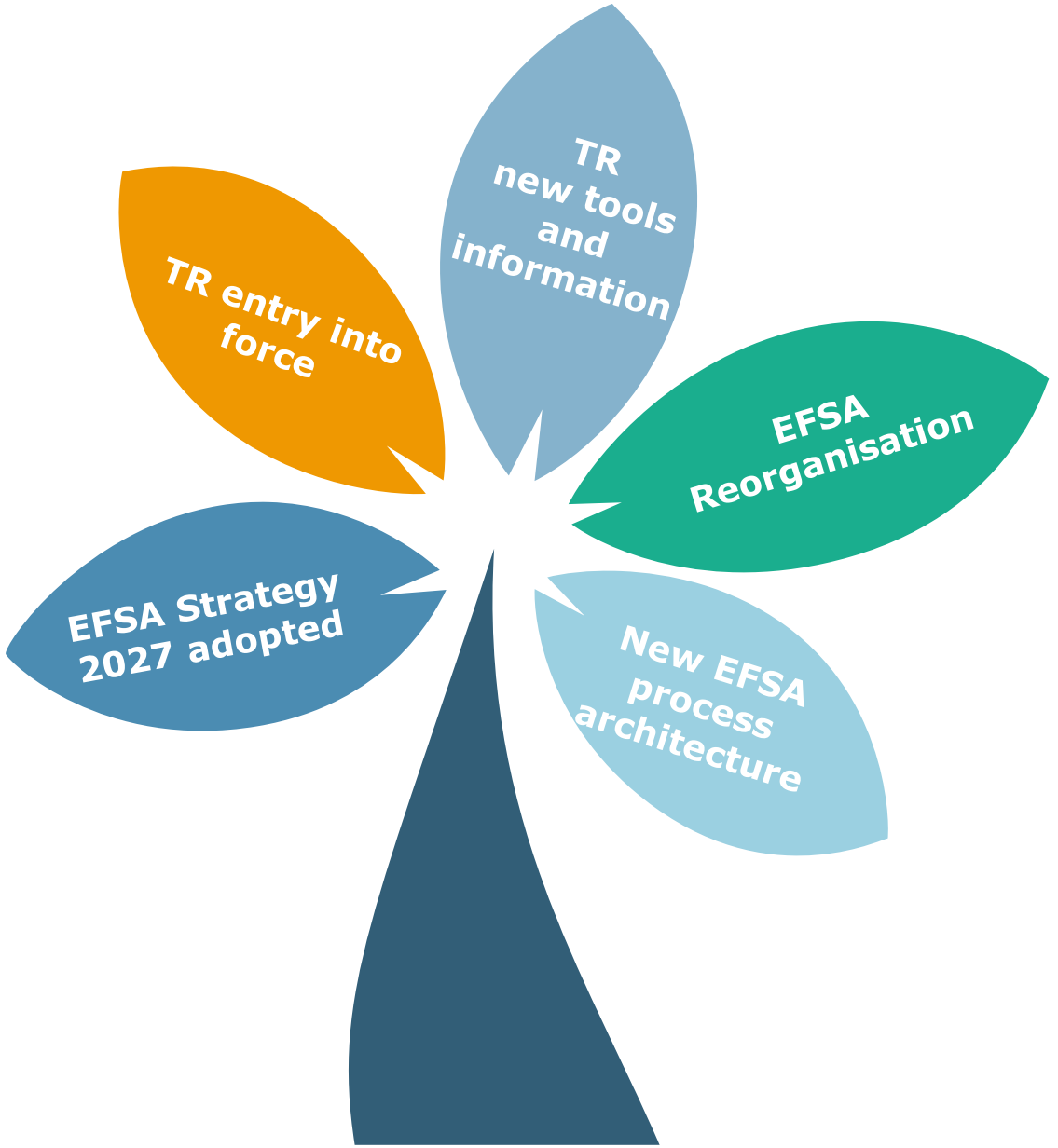
Integrated management systems annual review

2021 reporting and 2022 and multiannual objectives/roadmap

2021 results and achievements

2022 objectives

General context – Major developments in 2021



EFSA Integrated Management System

Scope of IMS Process Improvement Initiative

Delivered*

Phase I (2021)

- Define and map EFSA's Management Systems
- Develop a roadmap for IMS implementation
- Implement some IMS roadmap actions
- Identify opportunities for the individual MS

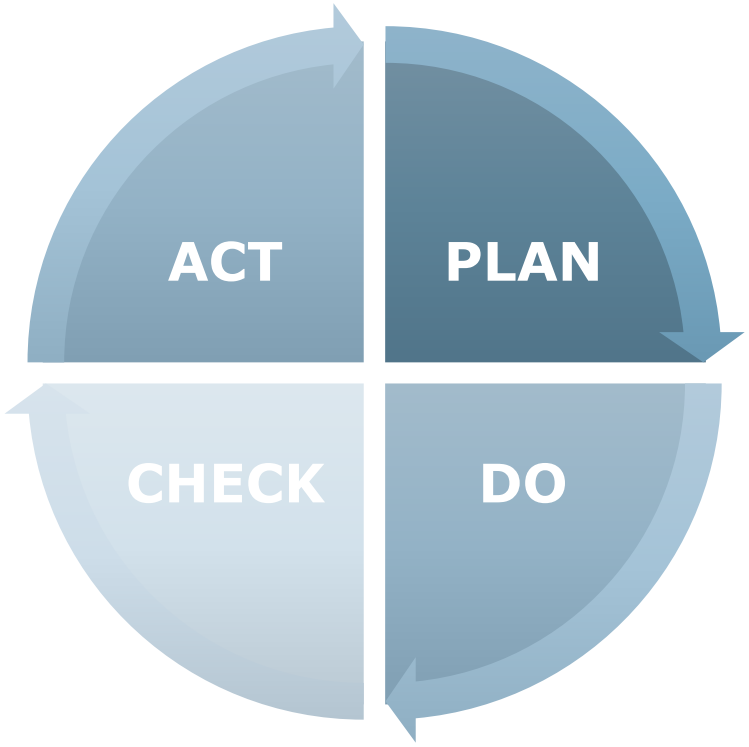
Phase II (2022-2023)

- Identify and implement additional actions at more granular level
- Implement the IMS roadmap

Introduction on Management Systems and Integrated Management System

A **Management System** (MS) is considered a **set of policies**, **processes and procedures utilized** by an organization **to ensure the fulfilment of tasks required to achieve its objectives**. In particular, the objectives can be related to several topics such as legality and regularity, quality of products and services & organisational performance, environmental performance and health and safety in the workplace.

MS standards are designed to be **applicable across all economic sectors** and to **organizations operating in diverse geographical areas** with **different cultural** and **social conditions**.



Plan-Do-Check-Act Approach

One fundamental principle is that **all standards can work together**.

For this reason, **management standards have been structured** utilizing the **same high-level structure**. In particular, Management Systems are based on the 4-element **Plan-Do-Check-Act** (PDCA) **approach**, which represents a **dynamic process cycle** used by organizations to **achieve continual improvement**.

The abovementioned approach combines **planning, implementing, controlling** and **continual improvement**, as the organization learns from the resolution of any issue it may encounter. Below an overview of each element:

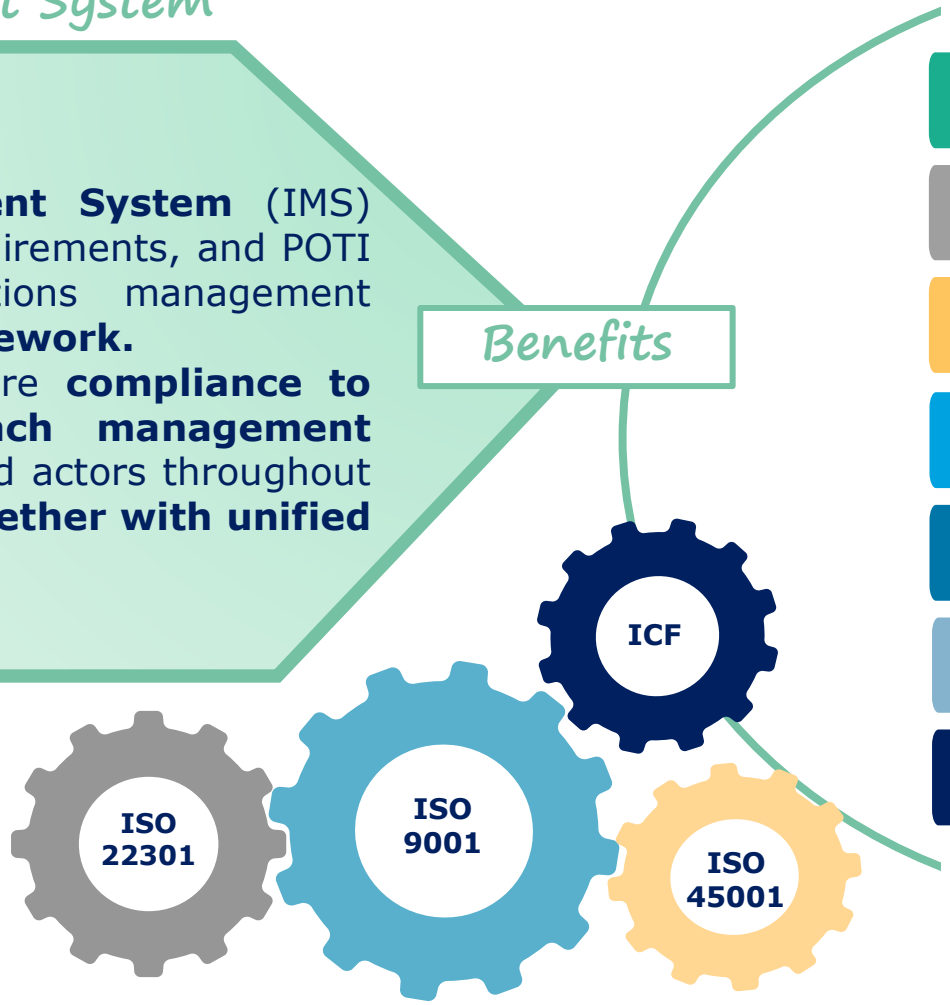
1. **Plan:** establish objectives and process;
2. **Do:** implement the process as planned and ensure their operation;
3. **Check:** monitor and review processes and activities with regards to the policy and the objectives set;
4. **Act:** take actions to continually improve the performance of MS.

Most importantly, the PDCA approach aims at **supporting the organizational performance** in achieving MS objectives.

Introduction on Management Systems and Integrated Management System

Integrated Management System

An **Integrated Management System** (IMS) integrates all objectives, requirements, and POTI elements of an organisations management standards into a **single framework.**
Having an IMS should ensure **compliance to the requirements of each management standard** and allow units and actors throughout the organization to **work together with unified objectives and efficiency**.



- **Improved Performance**
- **Streamlined process/Eliminating Redundancies**
- **Reduction in documentation**
- **Consistent objectives and KPIs across multiple systems**
- **Improved clarity to the organization**
- **Reducing Management Systems Maintenance**
- **Integrated follow up of improvement actions**

Introduction on Management Systems and Integrated Management System

Below an illustration of the **building blocks of an IMS** with an explanation of the **meaning of each block:**

MANAGEMENT STANDARDS, OBJECTIVES AND REQUIREMENTS

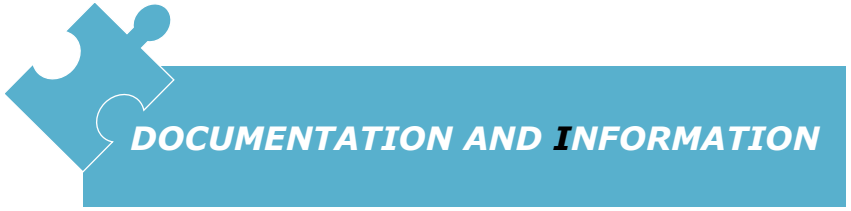
ICF and ISO standards that set out requirements aimed at **supporting** an organization in **achieving MS objectives**.

GOVERNANCE AND ORGANIZATION

Entities (Units)/Actors responsible for **managing part of the IMS** and for ensuring accountability and transparency.

PROCESSES, PROCESS CHECKS & CONTROLS

Processes related to the IMS for which common elements (e.g. integrated/coordinated audit) **could be combined to create synergies**. **Checks and controls to be performed** based on the relevant management systems.



DOCUMENTATION AND INFORMATION

Process Charters, EFSA's Repository of governance documents (which includes IMS Policies, Manual, SOPs, WINs) **and records** (including the ones encompassing checks and controls) to support and enable the implementation of management standards.

TOOLS & IT TOOLS

Registers (Risk Register, Register of findings /recommendations, actions, etc.) and **other instruments** that support the achievement and the implementation of the IMS.
Software tools that enable to run correctly, oversight and manage the implementation and maintenance of the IMS.

EFSA Management System Integration| **Standards & integrated objectives**

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Standards *(objectives)*

EU/MS REGULATIONS, ICF

1) effectiveness, efficiency and economy of operations;
2) reliability of reporting;
3) safeguarding of assets and information;
4) prevention, detection, correction and follow-up of fraud and irregularities; and
5) adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the multiannual character of programmes as well as the nature of the payments concerned.

ISO MSs

Quality Management
(ISO 9001)

Consistently meeting customers' expectations through the products and services provided

HSSE

OH&S Management (ISO 45001: 2018): eliminating and minimizing OH&S risks, while improving the performance

Business Continuity Management (ISO 22301: 2019): increasing ability to respond to and recover from disruptive events

Environmental Management (ISO 14001: 2015 & EMAS): managing organization's environmental responsibilities

Information Security Management (ISO 27001: 2017): safeguarding data security from security risks, threats and impacts

Methodologies

Better regulation guidelines
Programme/project management PM2, COSO

Hierarchy of Documents & Repository of EFSA's governance documents (internal)*

***More details from slide 15**

EFSA Management System Integration| **Lines of accountability**

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Standards

EU (FR, staff, Founding) /MS REGULATIONS, ICF

ISO MSs

Quality Management (ISO 9001)

HSSE

- **OH&S Management**
- **Business Continuity Management**
- **Environmental Management (ISO 14001 & EMAS)**
- **Information Security Management**

Objectives

- **LEGALITY AND REGULARITY** *(ICF n. 4 and 5)*
- **QUALITY AND PERFORMANCE** *(ICF n. 1 and 2 - ISO 9001)*
- **SAFETY AND SECURITY** *(ICF n. 3; ISO 45001, 14001, 22301, 27001, EMAS)*

3rd Line of accountability (overall assurance, meta analysis/synthesis)

External audits

Audit & RMIC

2nd Line of accountability (specific controls)

Quality Management

Safety and Converged Security

- Financial, contract mgt (G&P and staff), competing interests, PAD, confidentiality
- Workplan/strategy planning and monitoring, Budget/resources (ftes/posts/competences)
- Physical and information security, safety, business continuity...

1st Line of accountability

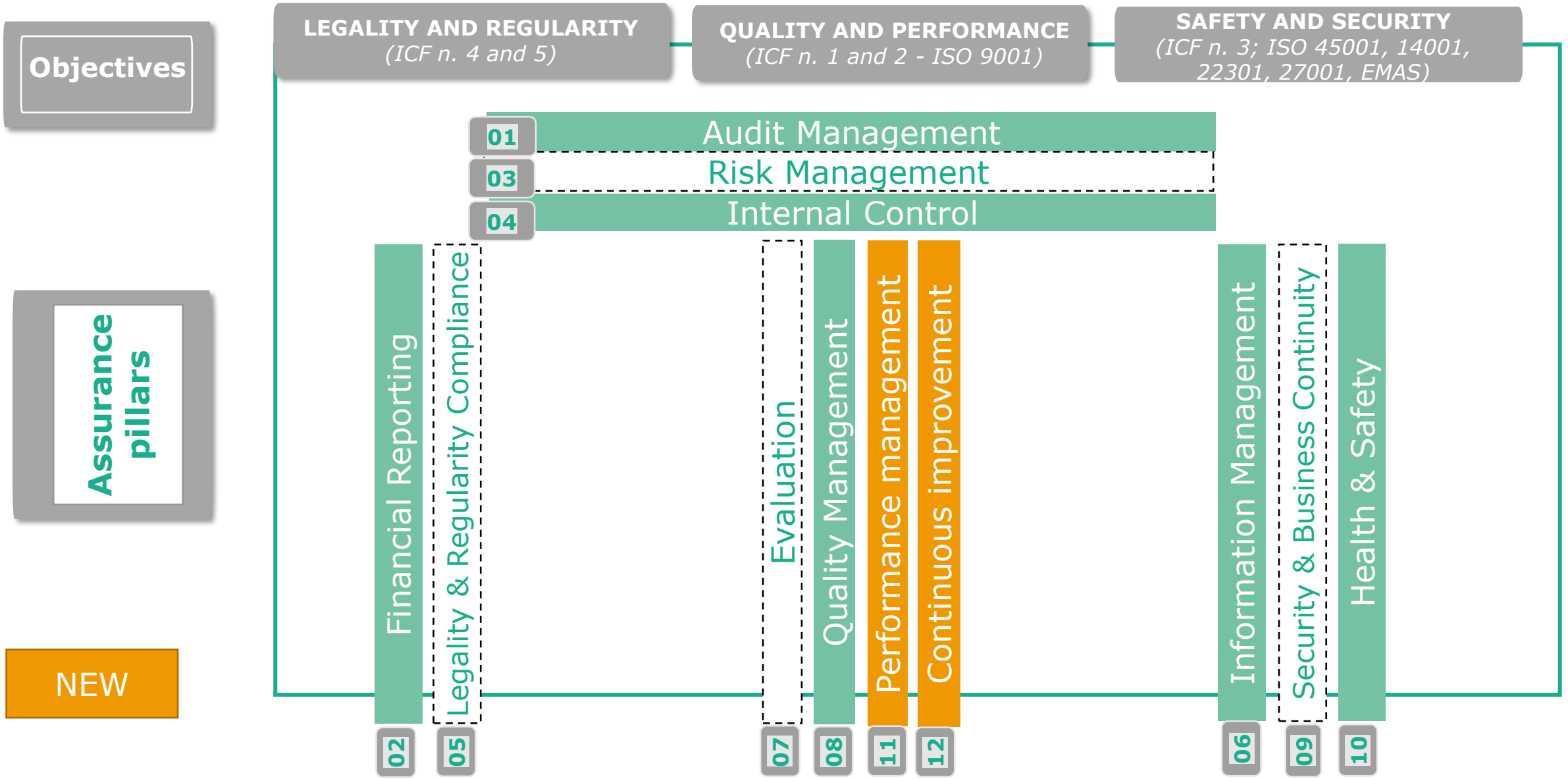
All EFSA Processes, all process architects, owners, managers on their own processes

MB Audit Committee

Accountability Council – chaired by the ED/Empower HoD

IMS Committee – chaired by the Audit & RMIC Process Manager

Objectives & Assurance Pillars reporting



Roadmap for the implementation| **EFSA's Integrated Management System**

Single external ISO auditing body,
HSSE integration
Risk based internal quality audits
Surveys/feedback integration

- Nov. 2021 — *Internal Audit using integrated audit checklist*
- Dec. 2021 — *IMS integration in new process charters*
- Dec. 2021 — *Recording of findings, recommendations & actions*
- Dec. 2021 — *Corrective/ Preventive Actions*
- Jan. 2022 — *GAP Analysis*
- Jan. 2022 — *Full implementation of the Hierarchy and repository of docs*
- Jan. 2022 — *SOP on IMS*
- Feb. 2022 — *Management Review Meeting*
- Mar. 2022 — **IMS Manual & Objectives**
- Jun. 2022 — *IMS Coordinator and IMS governance*
- Jun. 2022 — *IMS Process Implementation*
- Dec. 2022 — *Accountability Policy IMS Register and workflow*
- Jan. 2023 — **Awareness Training**
- May-June 2023 — *Integrated pre-certification*
- Oct. 2023 — ***Integrated External Audit***

EFSA Management System Integration| **Actions/opportunities**

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Standards

EU Regulations & ICF MS

ISO MSs

Quality Management (ISO 9001)

HSSE

- **OH&S Management**
- **Business Continuity Management**
- **Environmental Management** (ISO 14001 & EMAS)
- **Information Security Management**

Objectives

LEGALITY AND REGULARITY | **PERFORMANCE AND QUALITY** | **SAFETY AND SECURITY**

Integration roadmap

- Integrated MS Map
- Integrated documentation & single hierarchy of documents process (Quality management)
- Integrated indicators framework
- Integrated decision-making bodies (council & committee)
- Harmonized follow-up action template and non-conforming reporting in ERW
- Integrated Policy (accountability)
- Definition of a common SOP
- IMS Coordinator
- Management Review Meeting
- Awareness training sessions
- Integrated findings, recommendations, and actions register
- IMS Manual & Objectives

- EPA integration of quality, risk management and business continuity, data protection
- Integrated risk-based planning for the internal quality audit programme
- Single auditing body
- Integrated audit templates
- Integrated audit documentation
- Conversion of the documents from other management systems into the QMS format
- Integrated internal and external audits

Some items identified at this level will require further analysis to see whether they need to be integrated at a higher level (ISO or ICF)
For a more detailed analysis, please refer to the IMS MS Map

- Quality Policy
- Surveys alignment/centralisation
- Annual alignment of EPA, Organization design, enterprise architecture, L&D plan
- Further, competence – based linking of EPA charters with Department/Unit Charters and resource management with post management

- Policies and Handbooks
- Form to record internal and external factors
- Register for the assessment of the internal and external factors
- Register of the interested parties
- Register containing the analysis of the needs and expectations of interested parties
- Internal Documents register

Actions currently to be commenced/ongoing

Maintain the IMS|
Annual Cycle 2022 (IMS SOP)

Below it is provided an overview of the **main checks described in the IMS Standard Operating Procedure** that are recurring in the view of continuous **improvement:**

February

Overview of main outcomes of the previous year, risk register update and objective setting for the year for the Integrated Management System. Internal and external IMS audit plan and controls discussed and agreed.
Formalisation of the Management Review meeting utilizing the Management Review Report with Accountability Council

01

January- February

Review/Update of Hierarchy/Repository of documents is done - ensuring that the documentation of each Management System is in compliance with EPA and any recommendations/findings from audits. Relevant committee members + owners of Document process.

02

April-May

Check and approval of EPA, Org Design in time for the planning cycle n+1 and plan for related POTI architeture/standars updates to be performed (e.g. EPA, OrgDesign/DMF..). Changes approved by Accountability Council end May.

03

June- September

As part of the annual planning cycle, **Process Managers review their respective EPA Charters. Risk management exercise is performed**. **IMS Committee Coordination performs a quality check**.)

04

September

Status of the IMS to be presented to the Accountability Council prior to external audits. This ensures management that IMS is in compliance with all standards. Approval of EFSA's corporate risks, to be integrated in the SPD.

05

December

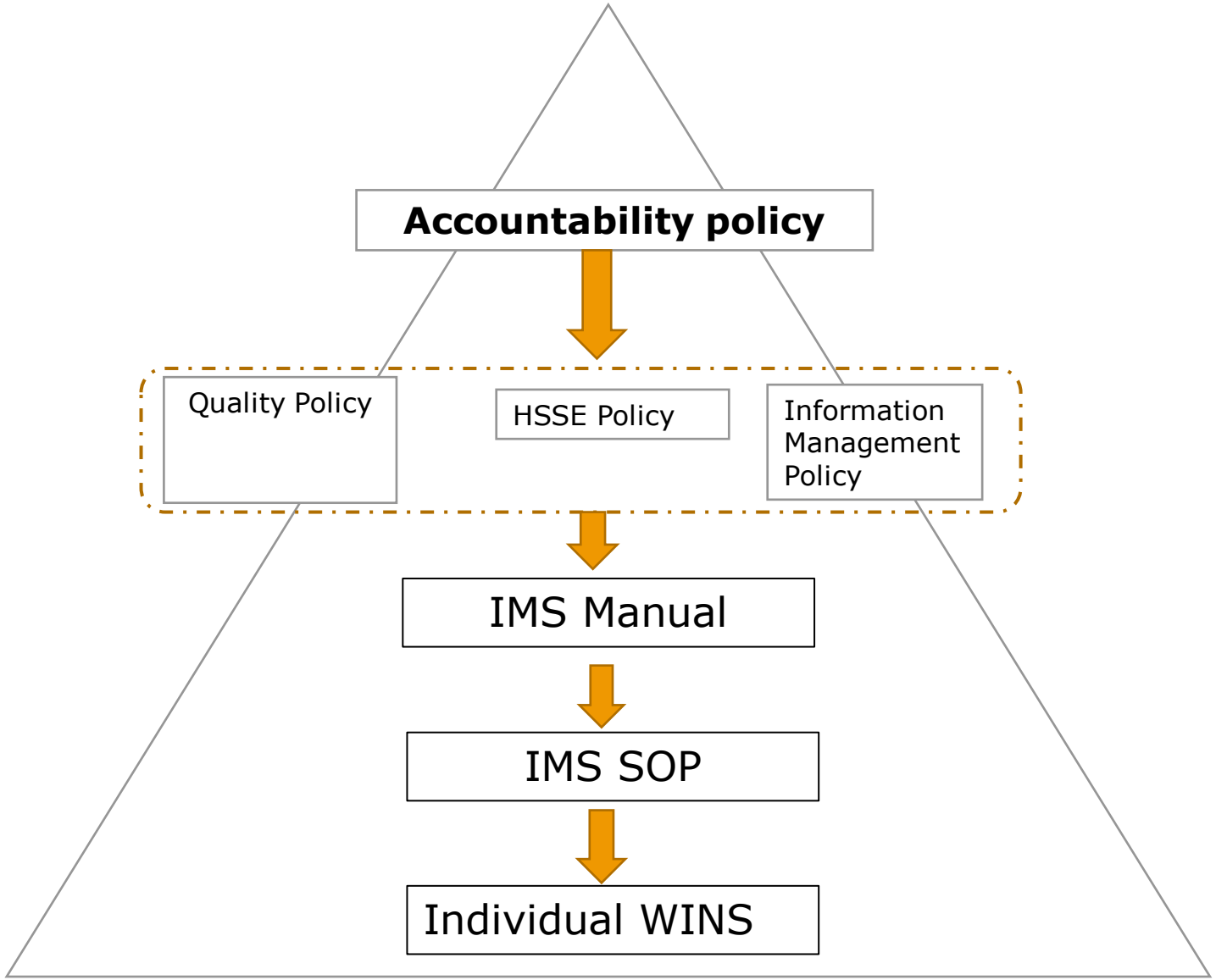
IMS Committee meets to discuss outcome of completed audits (internal/external), discuss non-conformities etc in preparation for Management review meeting with Council in Feb. Needs for trainings on IMS are discussed/agreed**.**

06

IMS Committee

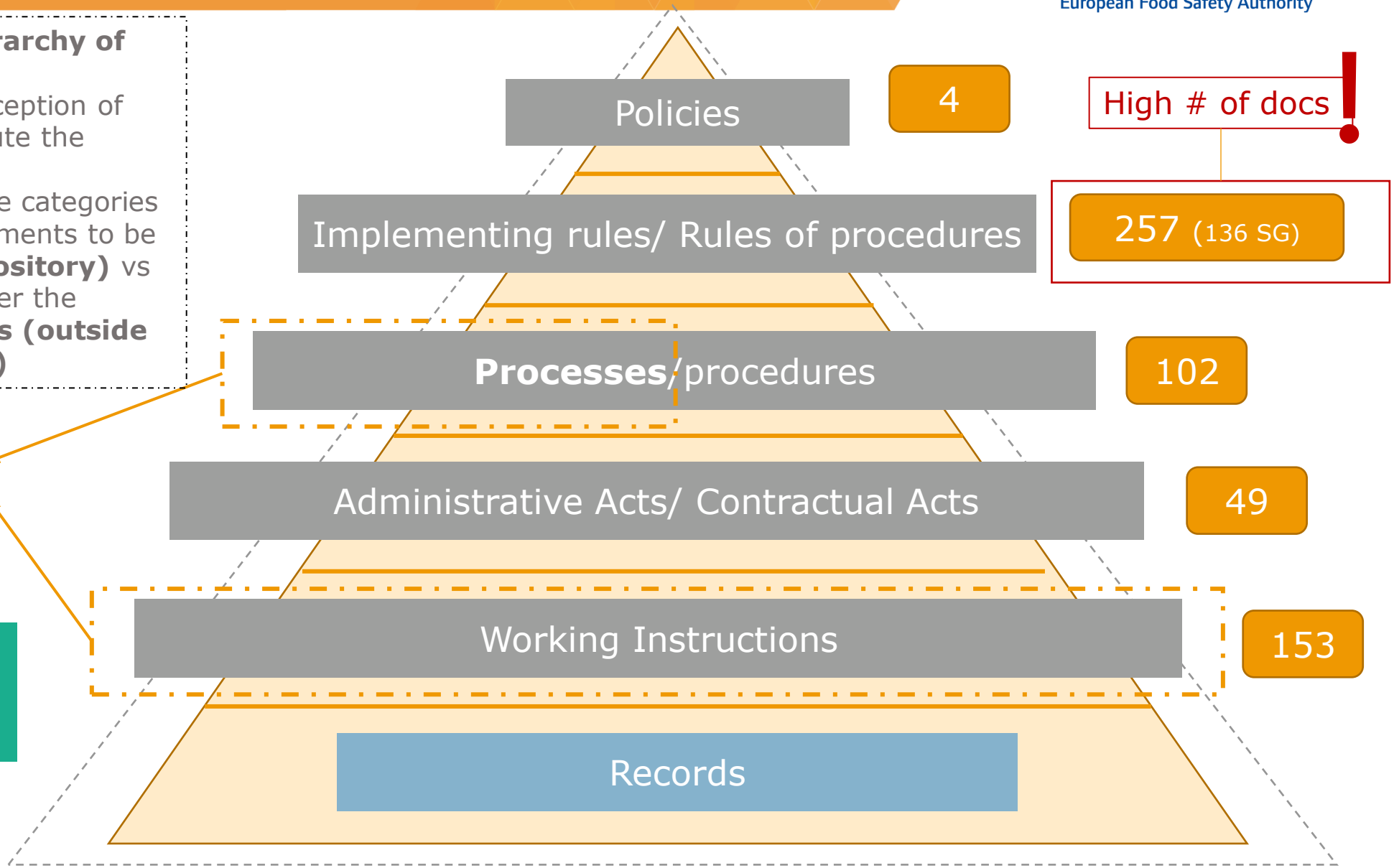
Accountability Council and IMS Committee involved

IMS|
ISO IMS **Hierarchy**



IMS wide|
Hierarchy & repository of EFSA documents

Entire triangle is the **Hierarchy of Documents**.
All the levels with the exception of **Records*** will constitute the **Repository.**
Further distinction within the categories can be made between documents to be **managed centrally (Repository)** vs the ones that are under the **responsibility** of the **Units (outside the Repository)**

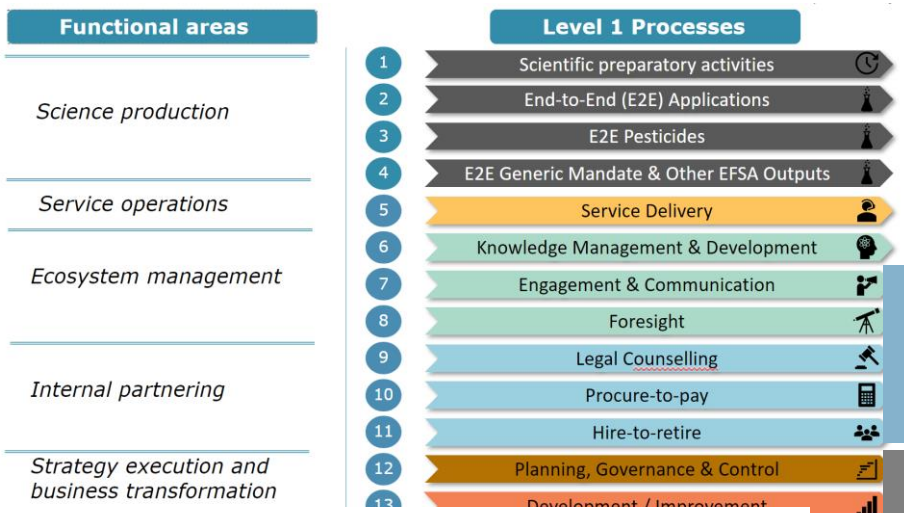


New in the Repository

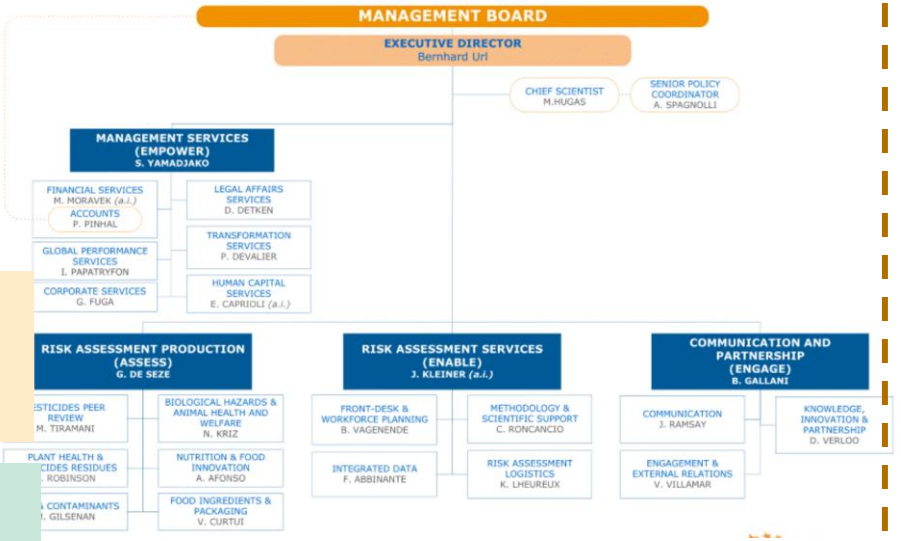
101 docs cleaned from Repository (outdated, duplication etc)

Architectures

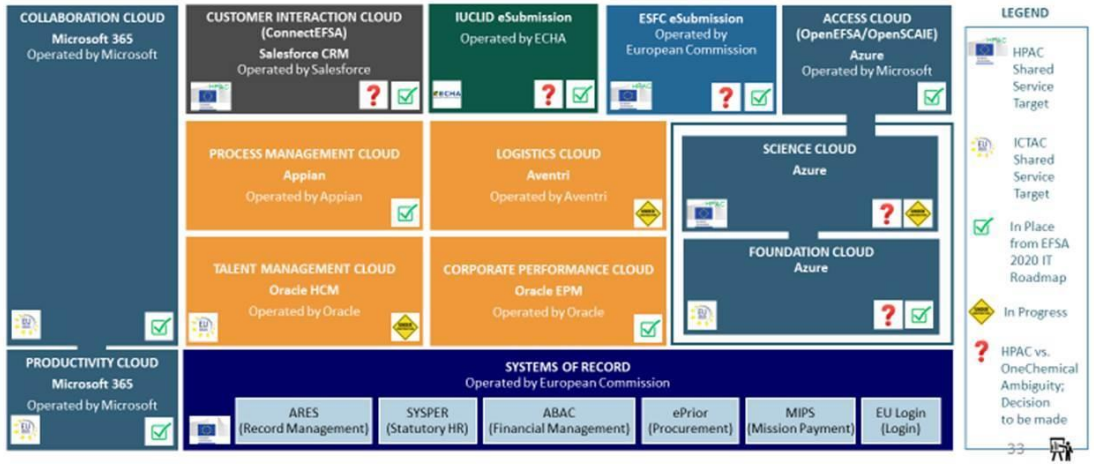
EPA3



New Organigramme



Technology Architecture



P O T I

Work ongoing

Maintenance, updating and alignment of EFSA's Architectures to be part of the **IMS** and piloted in **2022**

IMS 2021|Results and achievements
Audits overview

IAS Audit on Procurement and Grant Award Processes | ECA Financial, Legality & Regularity Audit

0 critical / 1 very important observation
3 important recommendations*

All EFSA's ISO certification's were confirmed in 2021

ISO 9001:2015 Quality Management

Surveillance Audit

0 non-conformities

0 findings

ISO 45001: 2018 OH&S Management

Surveillance Audit

0 non-conformities

ISO 22301: 2019 Business Continuity Management

1st Re-Certification

5 Minor non-conformities

ISO 14001: 2015 & EMAS Environmental Management

Surveillance Audit

0 non-conformities

*More info on slide 13

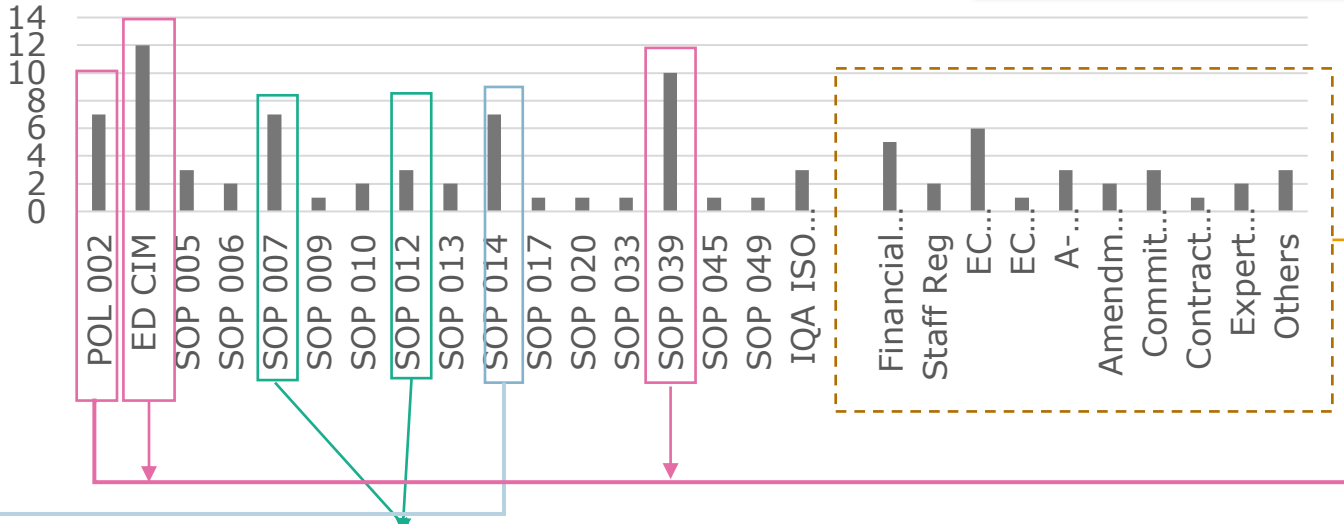
Internal control| **Nonconformities**

During 2021, EFSA recorded 81 deviations

16 ex-ante

65 non-conformities

A proactive approach has been adopted: for recurring issues, NCs have been inserted in the workflow by Unit/Department following general or specific scenarios, in order to better identify and follow up on the mitigating actions



L&R
ECA 2021 recommendation: Omission to register the late publication of contract award notice in the ERW (Financial, Legality and Regularity Audit)
Internal Control Framework Principle 12

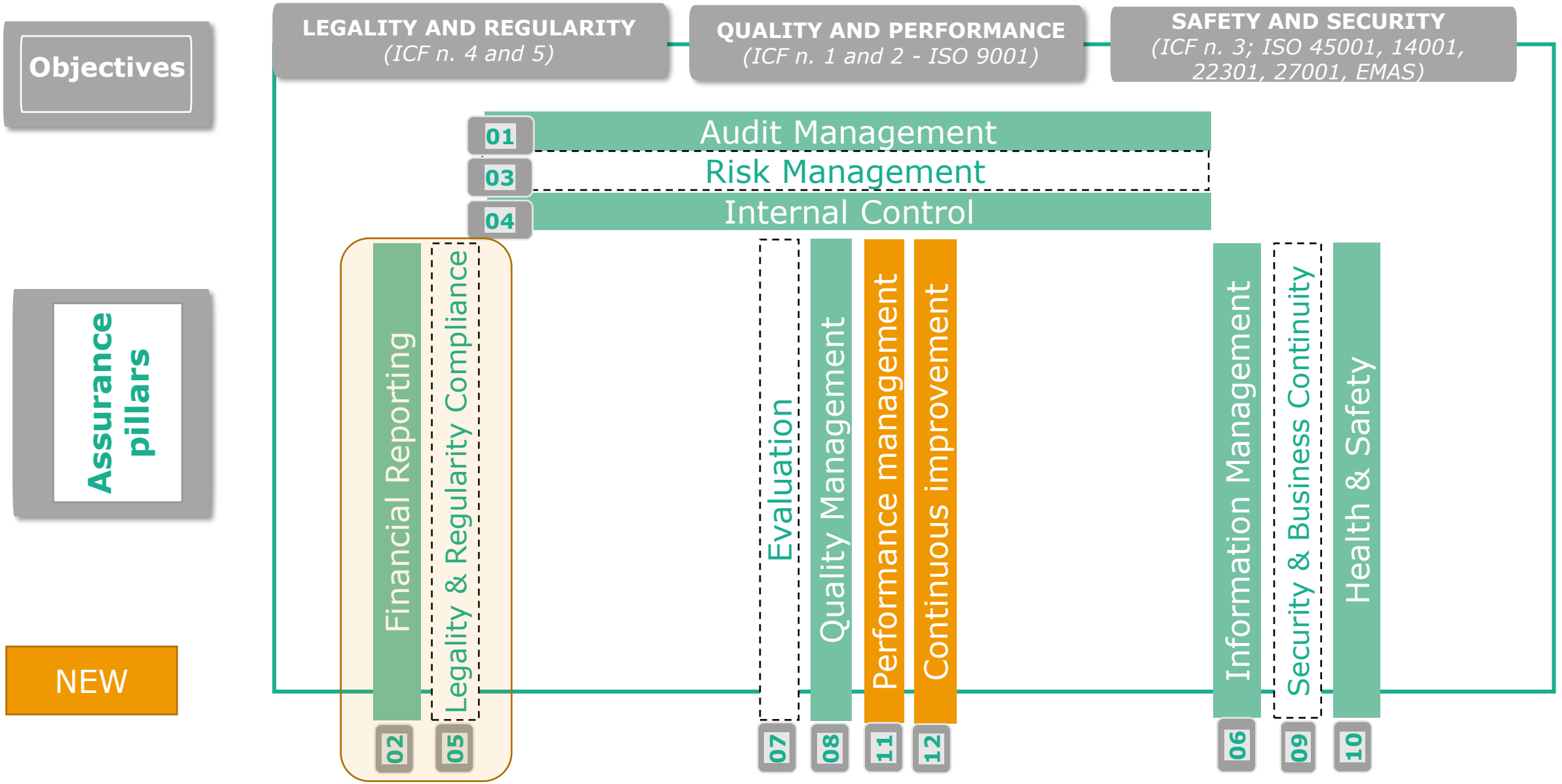
SOP 007 Risk Assessment of Generic Mandates and SOP 012_Risk Assessment of applications: Linked to the unfeasibility of recording tollgates for the pre-Transparency mandates/dossiers on the Case Management tool

SOP_014_Publishing a scientific output in the EFSA Journal- Updated as a result of the high number of non-conformities around the 14WD after adoption to be sent to EFSA Journal

Opportunity: HSSE non-conformities overview reported separately since currently not inserted in ERW

EFSA Policy on Independence, **ED on Competing Interest Management** and **SOP 039_Management of Competing Interests**:
15 NCs related to DoIs' submission and assessment were detected, due to the malfunctioning of the new DoI IT tool
WG on Independence set up. IMPRUL_110_CIM 28 09 2021 temporary processing of Declaration of Interest in contingent exceptional circumstances

Objectives & Assurance Pillars reporting



Legality and Regularity|
Internal Control Assessment | 2021 Achievements

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Internal Control Assessment Sources

1. Audit
2. Monitoring Criteria
3. Control Activities
4. Continuous Monitoring (Exception reporting)

Audits & Certifications

- ECA Financial, Legality and Regularity Audit *0 critical observations*
- IAS Audit on Procurement and Grant Award *0 critical/very important observations*
- IAS Internal Audit Plan 2022-2024
- Follow-up on very important outstanding recommendations *Action plans on track or ready for review*
- EFSA Audit Plan 2022-2024
- Single provider Certification audits *driver for integration*
- ISO certifications *All ISO certifications confirmed in 2021*

Monitoring Criteria

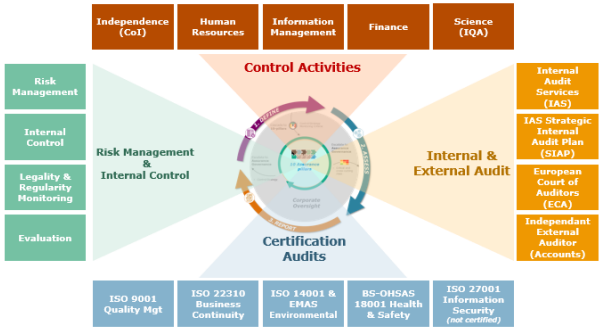
- 2019 Discharge granted
- ECA's clean audit opinion on reliability of the accounts and legality & regularity of transactions
- Anti-Fraud Strategy *New EFSA Anti-Fraud Strategy and Implementing Rules*
- No transmission or follow-up of any suspicion of fraud to OLAF
- Risk Management exercise *Carried out against newest EPA 3*
- Number of exceptions and non-conformities *within target*
- EDPS inspections and follow-up *on track*
- CERT-EU implementation of recommendations *on track*
- Managerial onboarding programs *Ongoing*

Control activities

- **Independence** *No Conflict of Interest identified*
- **User Access Rights Management**
  - Access rights granted in ABAC *in line with delegations*
  - Annual review DMS Access Rights *extended scope*
- **Finance**
  - Public Procurement Committee *Recognized in grant procurement and award process by IAS*
  - Financial verification on mass payments *within threshold*

Continuous monitoring (Exception reporting)

- Exception register | Outcome ECA review IUCLID exception



Legality and Regularity|
Internal Control Assessment | 2021 Weaknesses

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Internal Control Assessment sources

1. Audits
2. Monitoring Criteria
3. Control Activities
4. Continuous Monitoring (Exception reporting)

Audits & Certifications

- ECA Financial, Legality and Regularity Audit 2021 *1 very important recommendation*
- IAS Audit on Procurement and Grant Award 2021 *3 important recommendations*
- Follow-up ECA *one outstanding difference in opinion from 2017 position Accounting Officer*
- Follow-up IAS four important recommendations not implemented within agreed timelines Documentation of the monitoring of grant and procurement procedures (*IAS 2021) Action plan behind schedules*
  - Documentation of grant and procurement procedures
  - Two recommendations on the EFSA staff DoI Management
  - Implementation of the Oracle Fusion Performance management tool

Monitoring Criteria

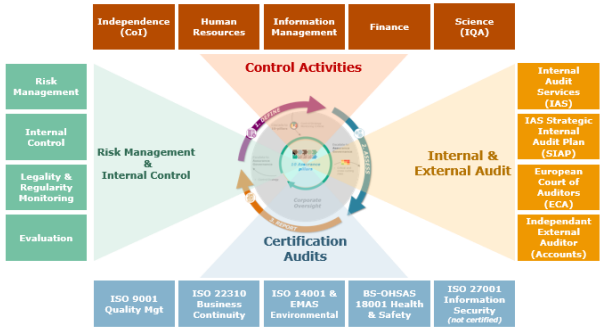
- Mandatory training *Attendance rate*
- Financial impact of exception NCs *Above threshold*

Control Activities

- **Independence** One Competing Interest Management Compliance & Veracity Check in 2021
- **Human Resources**
  - Monitoring time and leave management *Reporting tool not available*
  - Remuneration cap for outside activities *Ongoing*

Continuous monitoring (Exception reporting)

- **Independence**
  - Expert Declaration of Interest *Technical issues IT solution*
  - EFSA Staff Declarations of Interest
- **Finance**
  - IUCLID SLA between EFSA and ECHA *Financial impact*
  - Omission to register the late publication of contract award notice *ECA*



Legality and Regularity | IAS/ECA 2021 recommendations overview

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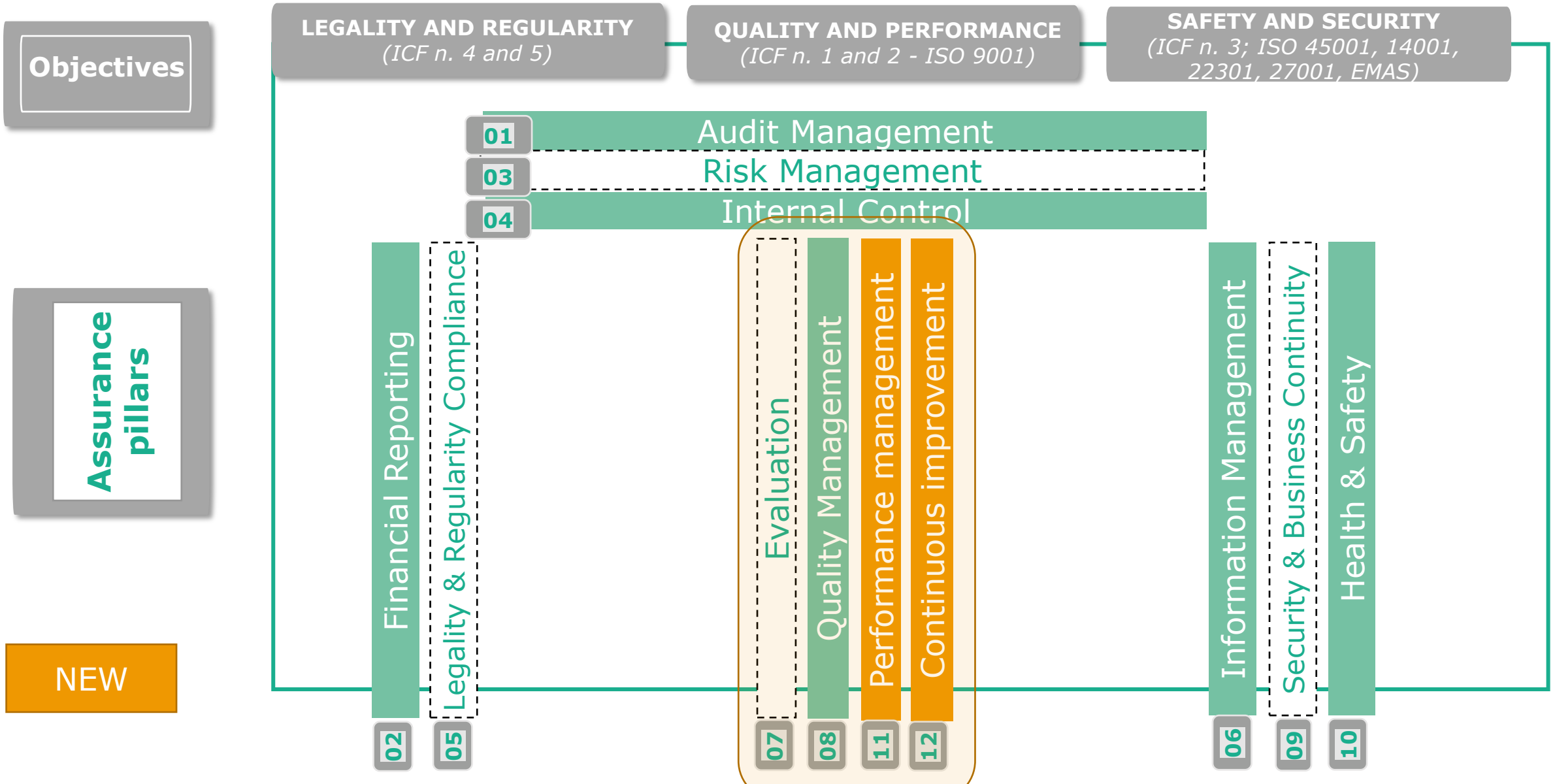
	RATING	AUDIT RECOMMENDATION	INITIAL TARGET	REVISED TARGET	OWNER	STATUS
2021	**Very important**	1. DURATION TEMPORARILY OCCUPATION MANAGERIAL POSTINGS (ECA)	Q2 2022	NA	FIN	Open
2020		2. ACCUMULATED BATCHES OF WORK OF THE RE-EVALUATION OF SAFETY OF FOOD ADDITIVES AND ENZYMES (IAS)	Q4 2021	NA	FIP	Ready
2019		3. WEAKNESSES IN THE TIME MANAGEMENT PROCESS (IAS)	Q4 2020	NA	HuCap/LA/ TS	Ready
2021	Important	**4**. DOCUMENTATION OF THE MONITORING OF GRANT AND PROCUREMENT PROCEDURES (IAS)	Q4 2021	**Q2 2022**	FIN	***Open***
		5. TIMING OF CONTRACT SIGNATURE AND DECLARATION OF HONOUR (IAS)	Q3 2021	NA	FIN	Ready
		6. PROCEDURE AND DOCUMENTATION DECLARATION ABSENCE CONFLICT OF INTEREST AND CONFIDENTIALITY IN THE PROCUREMENT AND GRANT AWARD PROCESS (IAS)	Q3 2021	NA	FIN	Ready
2020		7. STAFF EXPERTISE, BACKUP ARRANGEMENTS AND TRAINING (IAS)	Q4 2021	NA	FIP/HuCap	Ready
		8. MONITORING (IAS)	Q4 2021	NA	FIP/GPS	Ready
		9. ACCESS RIGHTS AND PUBLIC INFORMATION (IAS)	Q4 2021	NA	ISO/DMO/ ART	Ready
		10. FOLLOW UP AND APPROVAL OF DECLARATIONS OF INTEREST FROM EFSA STAFF (IAS)	Q4 2021	**Q2 2022**	LA	***Open***
2019		**11. WEAKNESSES IN APPRAISAL AND PROMOTION EXERCISE (IAS)**	Q4 2020	**Q4 2022**	HuCap/TS	***Open***
		12. MONITORING REMUNERATION CAP OUTSIDE ACTIVITIES AND MANAGEMENT OF CONFLICT OF INTEREST (IAS)	Q2 2020	**Q2 2022**	LA	***Open***

The summary table shows the state of play of all outstanding audit recommendations.

All are ready for review or on track except for four recommendations that will not be implemented within agreed timelines.

Out of these, two recommendations are still open beyond 6 months from the initial target deadline of implementation and these will be reported as such in the Annual Activity Report.

Objectives & Assurance Pillars reporting



Quality and performance| **Status of 2021 QMS objectives**

2021 Objectives- Status

#	Objective	Status	Actions
1	Maintained ISO 9001:2015 certification		Prepare for and run surveillance audit
			Implement internal quality audit cycle
			Customer feedback interviews with SANTE / Customer/stakeholder survey
			Close gaps and lean process documentation (SOPs/WINs)
2	EFSA's QMS updated in line with TR measures and strategic needs		Update of EPA (EPA III) for the 2021 planning cycle
			Update Quality roadmap in line with the Strategy 2027
			Adopt Quality Policy
3	Integration of management systems		Adopt Accountability policy by year end
			Develop and implement EFSA's integration of management systems roadmap
			Operationalise hierarchy and repository of normative documents implementation
			Integrated indicators framework: review of KPIs and PPIs in line with strategy
4	Implement Continuous Improvement Process		Run Process Improvement Initiatives (Lean), communicate results achieved
			Deploy L&D plan on process management and lean

Achieved/on track | Partially achieved | Deprioritised/postponed

Quality and performance| Customer Feedback

DG SANTE Feedback: 2021 overview

A mix of written procedure and interviews was employed in order to cover the same number of opinions, whilst minimizing the effort

Positives

Good collaboration of SANTE and EFSA Units

General satisfaction with the timeliness and length of opinions

Continuous alignment between EFSA and SANTE on items opinion's template was highlighted as very useful

EFSA's willingness and availability to answer questions, clarify doubts and present information to interested parties

Areas for attention:

Specific Actions for improvements were identified for 7 out of 14 outputs

General point for attention:

The importance of having a strong leadership and guidance from the EFSA Panels' chairs was highlighted.

This has been an observation that has come up in previous years, and for which some closer monitoring is needed.

DG SANTE Feedback 2022

The interview template has been updated for the current cycle to receive feedback on the "Abstract" at the request of EFSA Journal. This addition was welcomed by SANTE colleagues

EFSA Strategy Reputation Survey 2022

Customer/stakeholder survey to be merged with the Reputation barometer
The new EFSA Strategy Reputation survey to become one single annual survey as of 2022.
To be launched in the first half of the year

Quality and performance | **Internal Quality Audits**

2021 overview

- **Mix approach for auditing based on interviews and document check type audit in order to minimize burden on Units.**
- **Number of interview style audit: 8**
- **Number of document check audit: 4**
- **New IMS template used**
- 12 process variants audited
- 5 Non-Conformities, 15 Opportunities for improvement, and 7 Best Practices found

Most of the non-conformities identified cover issues detected in the **EPA Process Charters**: missing **risk identification** on respective **Process Risk Registers**, lack of risk rating and mitigating actions adopted.

2022 selection approach

Unit's to be audited have been selected avoiding those that will be potentially audited externally (ISO or otherwise).

Should this approach be continued, or should the Internal Quality Audits be used as prep for other audits?

Quality and performance|
Overall EFSA performance 2021

5 Strategic Objectives

SO1. *Prioritise public and stakeholder engagement in the process of scientific assessment*

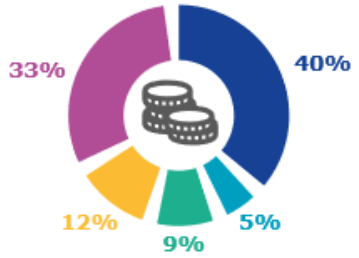
SO2. *Widen EFSA's evidence base and optimise access to its data*

SO3. *Build the EU's scientific assessment capacity and knowledge community*

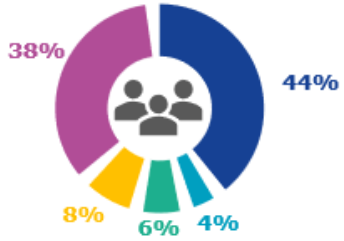
SO4. *Prepare for future risk assessment challenges*

SO5. *Create an environment and culture that reflect EFSA's values*

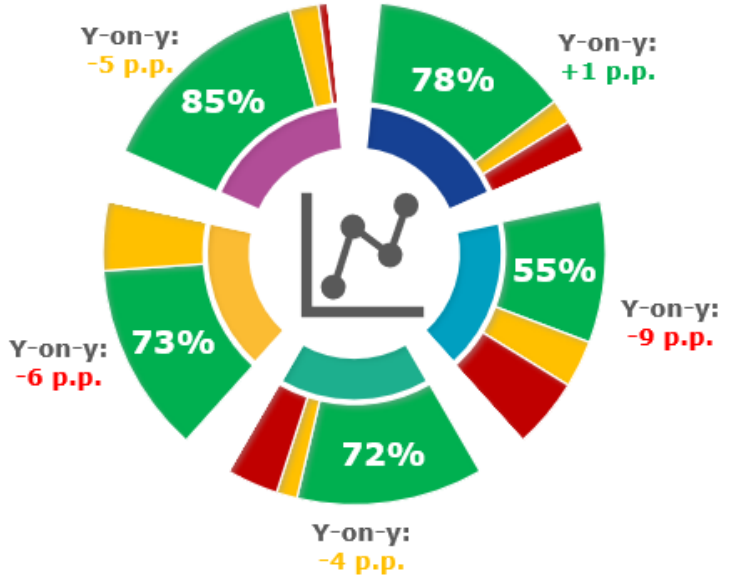
EUR 129.1 M budget



538 FTEs



Overall Performance

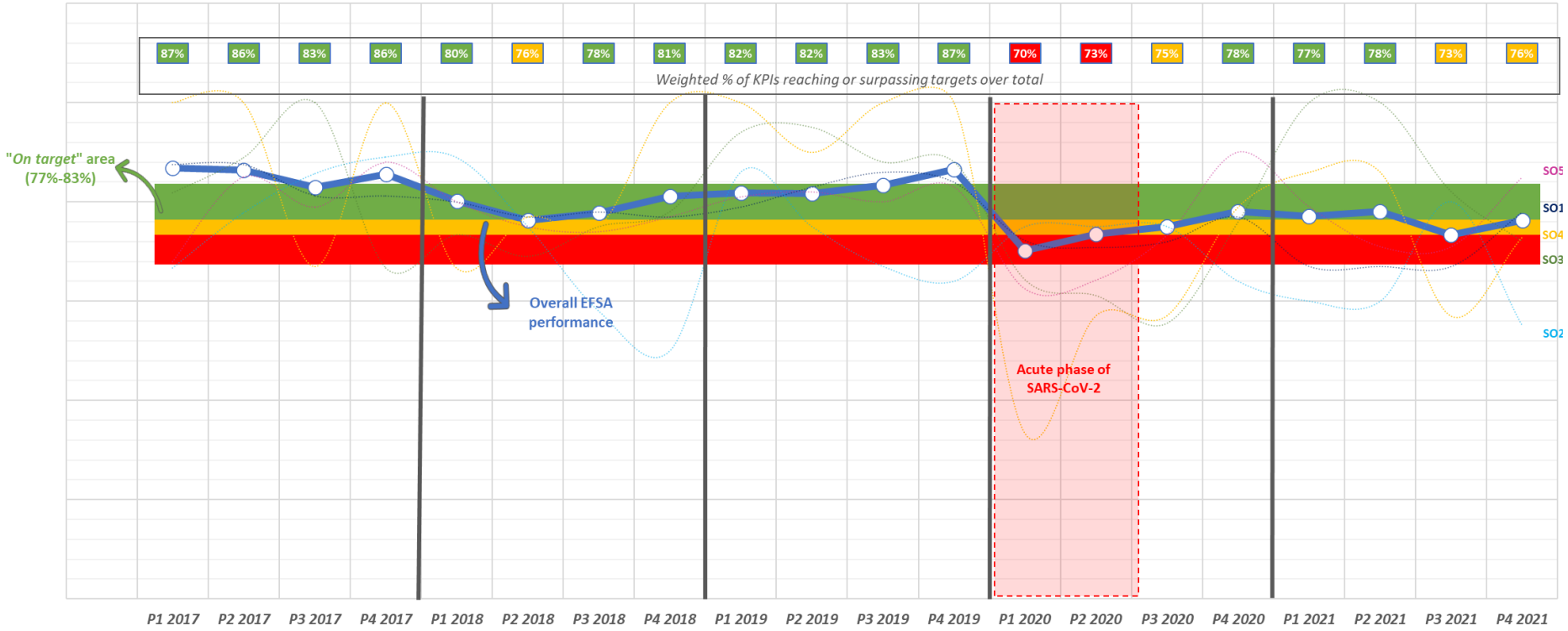


KEY METRICS

704 scientific questions closed *(81 less than planned but in line with 2020 result of 697)*
***Overall timeliness of adoption of scientific questions:* 85%** *(2 p.p. more than 2020)*
***Timeliness of publication of scientific questions:* 94%** *(6 p.p. more than 2020)*
64,121 ***citations of EFSA scientific questions*** *(higher-than-planned increase)*
100% budget execution, *despite budget increase of 19% (to EUR 129 M)*

Using the % of KPIs reaching or surpassing target as mean of analysis, **EFSA registered a performance in line with the previous year**. In particular, **SO1 registered the same performance as last year** (with even an almost identical # of questions closed, 704 vs 697), whilst the other SOs registered some minor deviations (around 5 p.p.), with the exception of SO2 (-9 p.p., mainly due to overplanning in terms of # of questions closed).

Quality and performance|
Overall EFSA performance (2017-2021)



Performance within the ***"on target"* area (77%-83%) between 2017 and 2019. A drop emerges in P1 2020**, due to the impact of the SARS-CoV-2 pandemic, with also P2 2020 registering similar results. These two periods can be considered being the "*acute phase*" of the pandemic. Since **September 2020, the performance moved away from the red area** but it remained behind the 2019 levels, also due to the impact of the TR on EFSA's operations (resources needed to implement the provisions, effect of the adaptation to new tools/procedures, delay of the efficiency gains expected from the ART programme).

To be noted that:

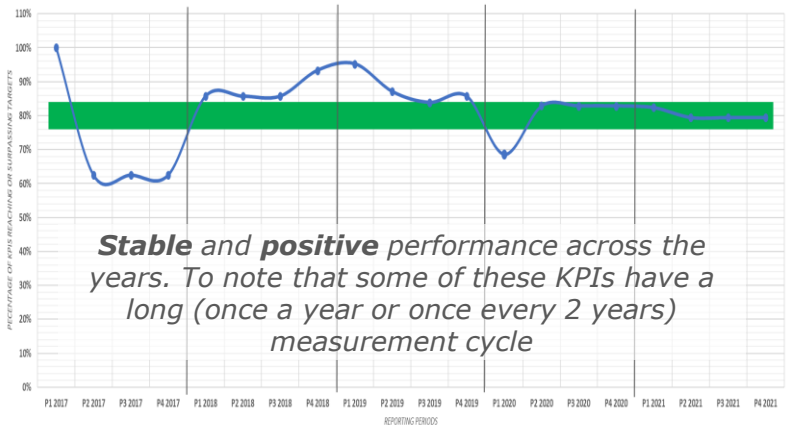
- despite the recent challenges and hurdles, **SO1 and SO5 were safeguarded**, with their performance at the end of 2020 (*SO1:77%; SO5:90%*) and 2021 (*SO1:78%; SO5:85%*) within the "*on target*" area and in line with the average performance registered within the strategic cycle (*80% and 83%, respectively*).
- **SO3 and SO4** registered a positive average performance but a drop can be seen in the past two years, also due to consequence of the re-prioritisation of activities to react to the SARS-CoV-2 pandemic.
- **SO2** saw the least positive average performance (68%). To be noted that this areas has very few indicators, and this can affect the robustness of the analysis

Graph is showing the % of KPIs reaching or surpassing targets over total, weighted by average amount of resources (budget+FTEs) spent in each SO between 2017-2021. Dotted lines represent the performance of each SO over the reporting periods. Some adjustments have been carried out to minimise the impact of different measurement cycles among the various KPIs

Quality and performance|
EFSA performance by type of KPI

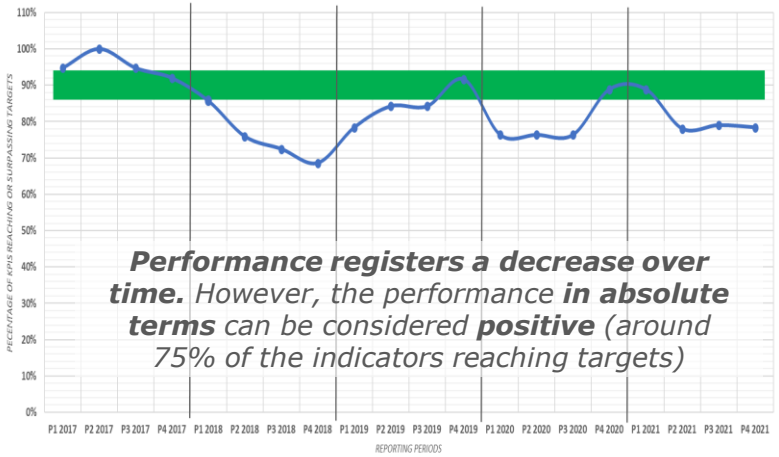
European Food Safety Authority

INTERMEDIARY IMPACT KPIs



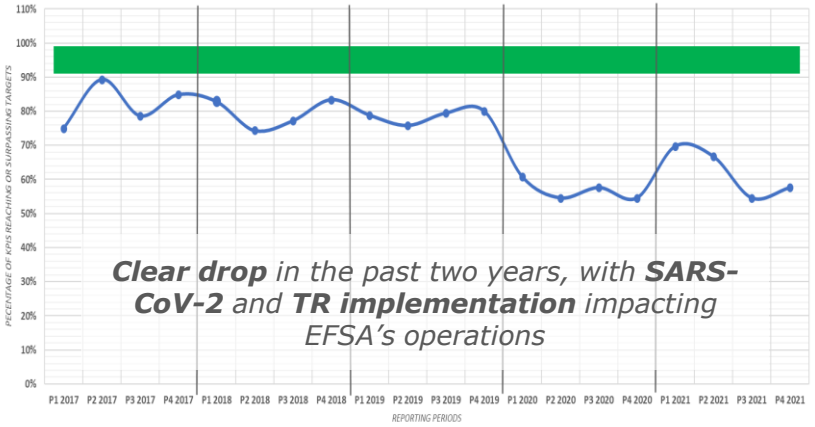
***Stable** and **positive** performance across the years. To note that some of these KPIs have a long (once a year or once every 2 years) measurement cycle*

OUTCOME KPIs



***Performance registers a decrease over time.** However, the performance **in absolute terms** can be considered **positive** (around 75% of the indicators reaching targets)*

OUTPUT KPIs



***Clear drop** in the past two years, with **SARS-CoV-2** and **TR implementation** impacting EFSA's operations*

Graphs are showing the % of KPIs reaching or surpassing targets over total. Some adjustments have been carried out to minimise the impact of different measurement cycles among the various KPIs. Green bar shows the expected performance as per targets in the SPD (80% for Intermediary Impact KPIs, 90% for Outcome KPIs, 95% for Output KPIs, which were stable targets over the years).

Quality and performance|
Resources Management - Budget

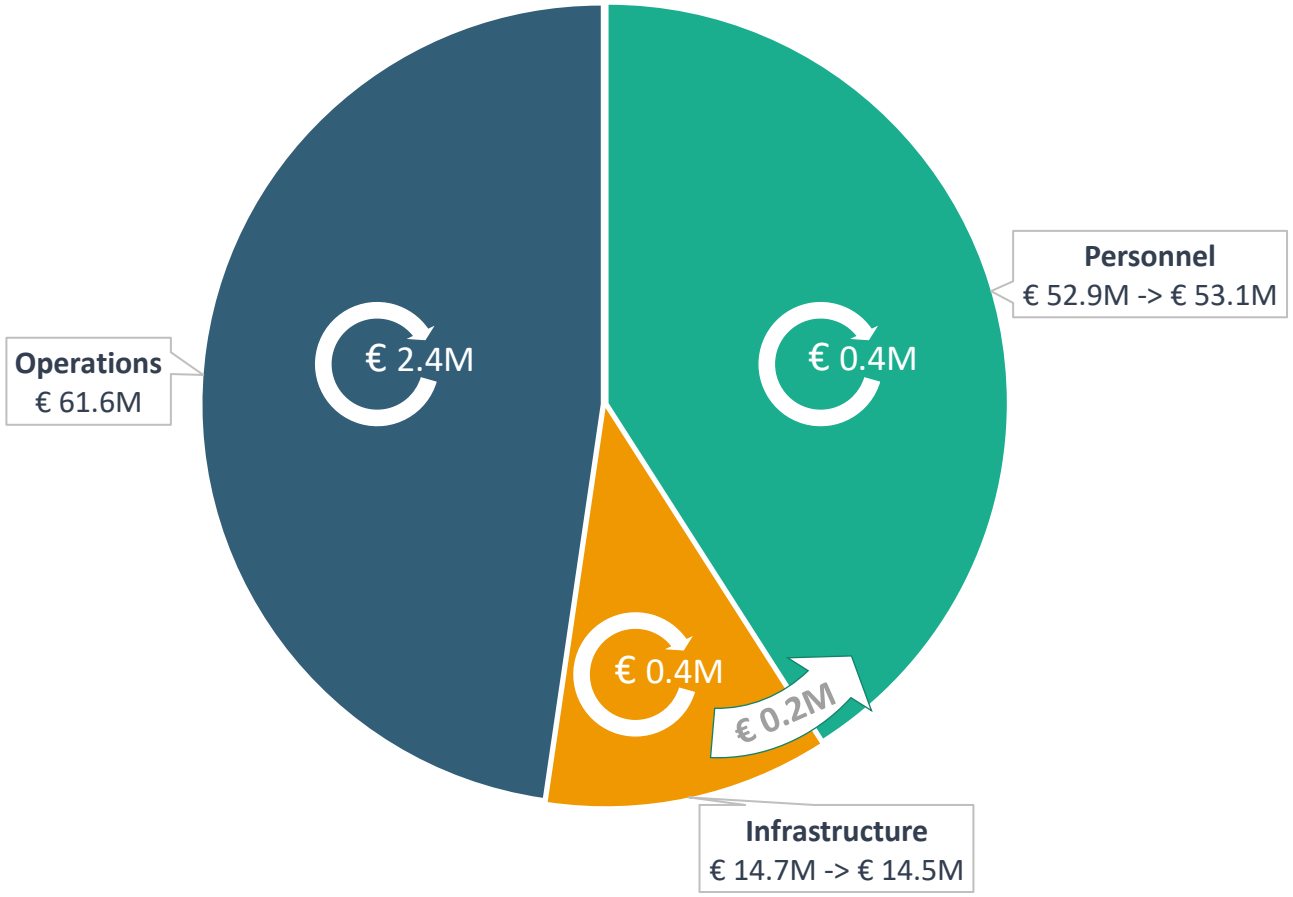
Commitment execution:
€ 19.1M (100%, target 100% met)

Payment execution:
€ 106.8M (89%)
- Non-differentiated credits: € 91.3M (87% out of target 90%)
- Differentiated credits: € 15.5M (100%, target 100% met)*

Carry forward to 2022
(C1 non-differentiated credits): € 13.7M (13%, out of target <=10%)

Cancellation of C8 credits
(non-differentiated credits carried forward from 2020): 4%

Budget transfers

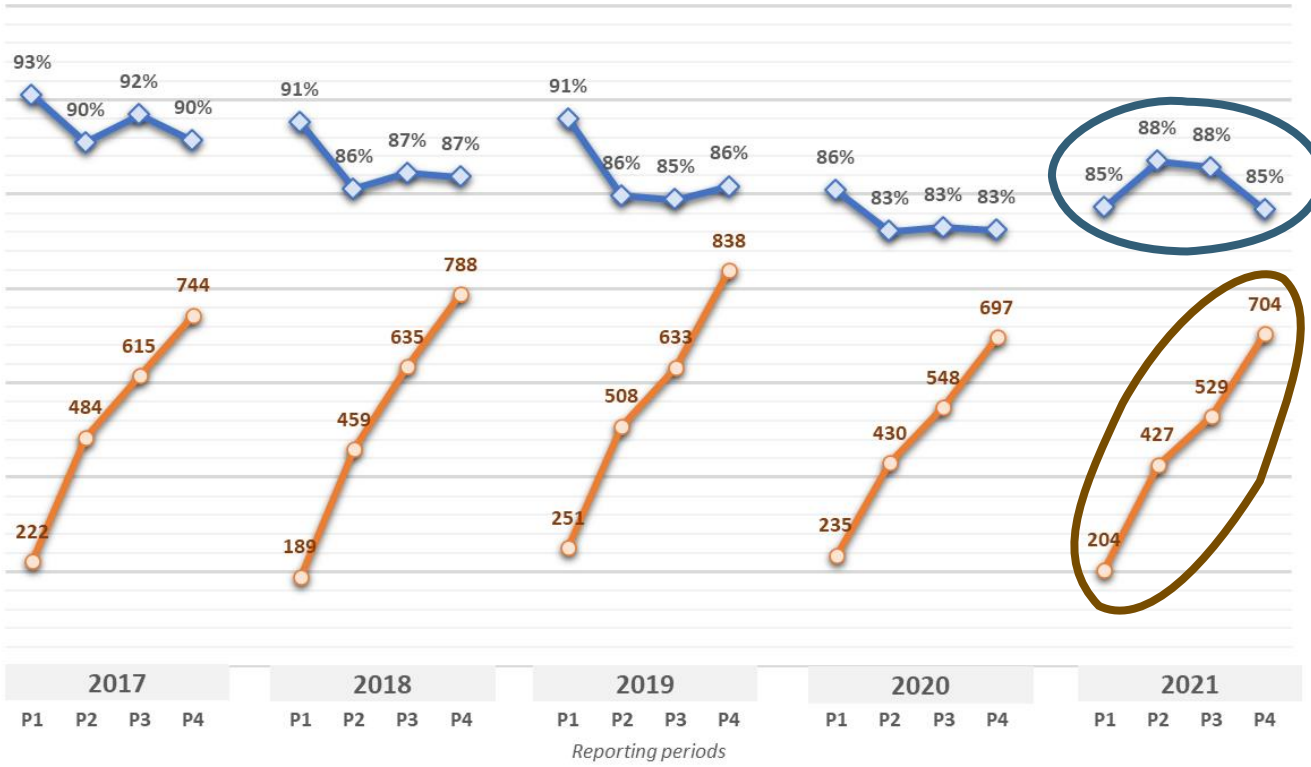


Internal transfers between chapters

* Differentiated payment budget has been increased following budget amendment (€ 1.5M) and transfers in from non-differentiated credits

Quality and performance|
Deep dive – RA main indexes

Timeliness of adoption and number of questions closed – Performance over the years

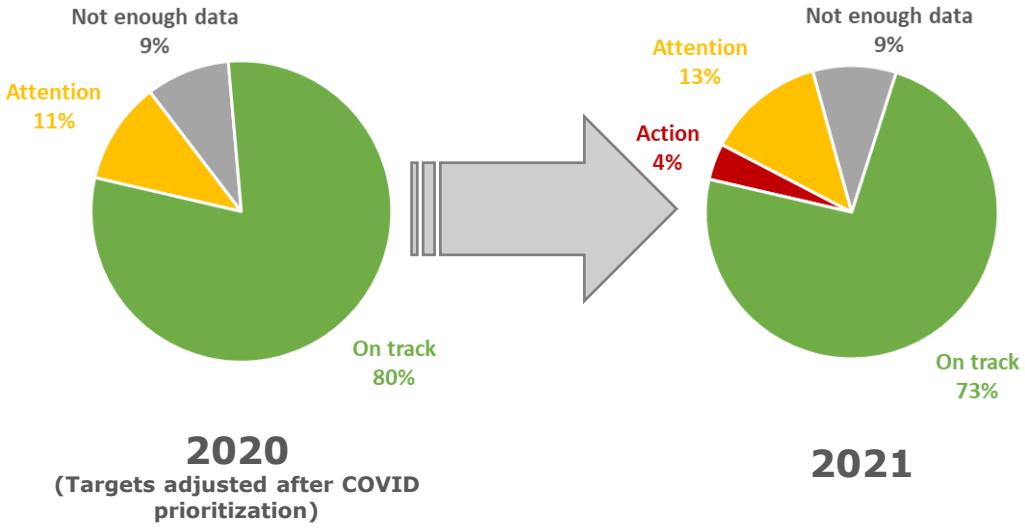


The overall (all SOs) timeliness of adoption showed a **decrease over the years**, due to the issues of increased workload (*large batches of work and the arrival of several new tasks since 2017*) and increased complexity of EFSA's Risk Assessment. However, **in 2021 an increase y-on-y was registered**, mainly due to the fact that COVID-related issues that emerged in 2020 were not registered in 2021. The drop in P4 2021 is due some late adoptions mainly in the areas of flavourings and MRLs

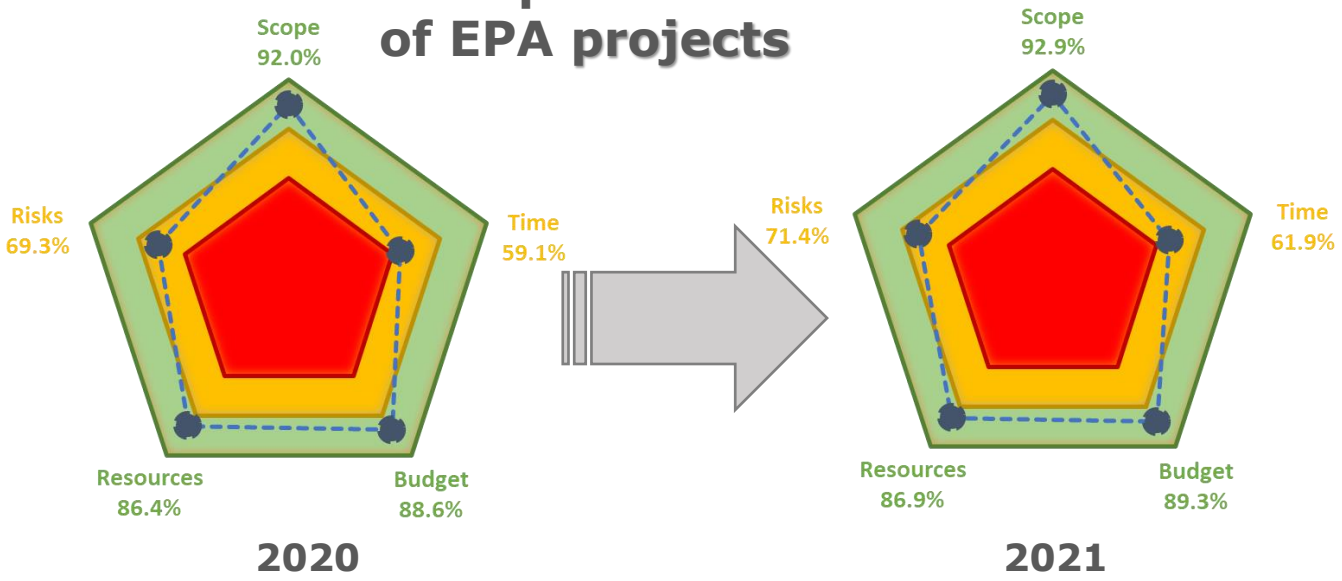
2021 performance **10% below target** (785) but **in line with 2020** figures. Compared to pre-COVID years, however, there is a **decline in terms of finalisation of outputs**, with the impact of the **pandemic** (in 2020) and the **changes brought by TR** (in 2021) adding up on the issues of increased complexity and increased workload mentioned above.

Quality and performance|
Process and Project Performance

Overall performance of EPA processes



Overall performance of EPA projects



Process performance in 2021 showed some deteriorations compared to 2020. The delta y-on-y is mainly explained by ***teething issues*** **in the new/enhanced activities impacted by TR** (foreseen volumes/timelines not in line with actuals) and impacts of **other changes** (such as adaptation to new tools/procedure/providers). Moreover, last year's assessment was done taking into account the targets after COVID, which also contributes to explain the deterioration y-on-y.
The 9% of grey processes refers to processes part of the EPA 2.5 framework that were not active in 2021 (either because not fully defined or not triggered).

The project performance, instead, shows minor improvements in all the dimensions, with the issues connected to **delays** in finalization of projects and **risks** (mainly related to implementation, especially for the science-related development activities)

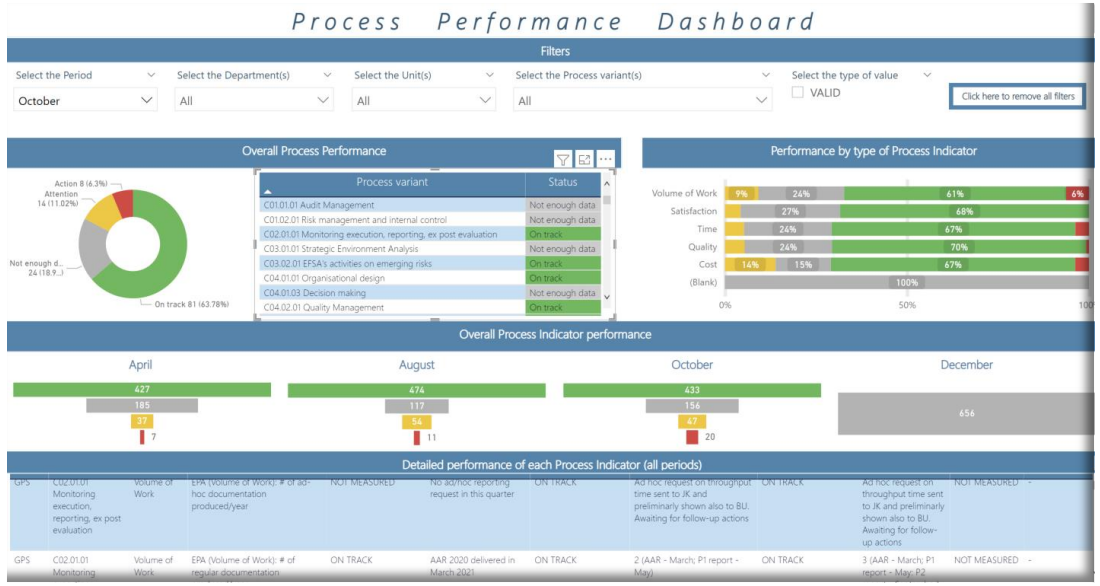
Quality and performance | **Performance**

European Food Safety Authority

Activities carried out in 2021

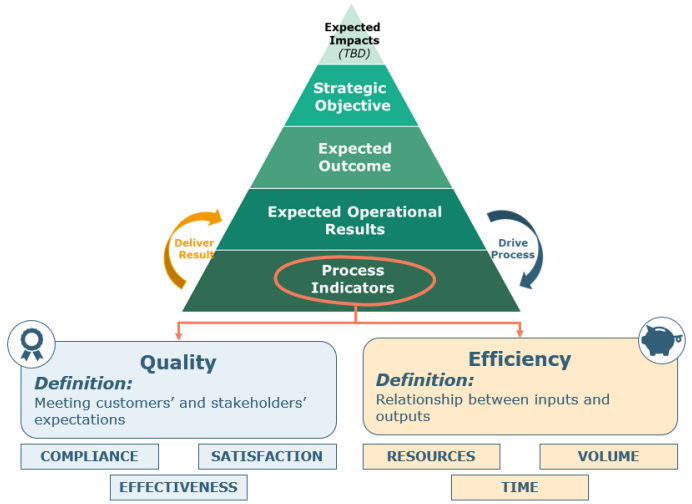
Run

- Central insertion of **all process metrics** related to EPA 2.5 **in units' workplans** to facilitate a more regular measurement
- **Creation** of an interactive **dashboard** on process metrics for units to have an *at a glance* overview of their process performance / as a tool to support the ISO 9001:2015 audit



Development

- Revision of the **EFSA Performance Framework** and **revision of all process metrics** to align them with EPA 3.0 processes



On average, **6 metric/process** have been put forward, with stronger control in the area of RA (9 metrics/process).
When applicable, **synergies with Strategy KPIs** have been created.

In the context of the new Performance Framework, we have also created (albeit the work is not finalized yet) **dedicated *fiches* per each metric** to capture elements like scope and measurement method. The aim is to **systematize knowledge** and increase the likelihood of a **stable measurement** over the years.

Quality and performance|
Performance of external providers

Contract terminations, reduction in payment & application of liquidated damages for delay

	2020	2021
Termination	2	3
Liquidated damages	4 cases = 6,667 EUR	3 cases = 6,633 EUR
Payment reduction	3 cases = 92,087 EUR	8 cases = 176,756 EUR

There was overall good performance in line with previous years, any performance deviations did not have any considerable impact when looking at the whole EFSA budget.

The overall increase in number (8 compared to 3 cases in 2021) is linked to take-over of IT services by a new contractor, for which three separate cases of payment reduction were registered, albeit for low amounts, due to quality issues in the first months of take-over and implementation. The high EUR amount overall for payment reduction is linked in particular to three specific cases:

- 1 payment reduction of 75k in a grant for benchmark dose analysis where, despite the methodology described in the specifications, the beneficiary insisted to apply their own methodology using only analogous models in the model averaging framework. This was not in compliance with the specifications, nor acceptable to EFSA
- 1 payment reduction of 63k due to quality issues in the data migration under a specific contract under the previous IT FWC.
- 1 payment reduction of 17k due to non-delivery of data under EU menu FWCs which was attributable to low quality issues of the contractor

Quality and performance| **Evaluations**

European Food Safety Authority

a) ***external*** *(third party)* ***evaluation of EFSA*** *as described in its Founding Regulation;*

b) ***external*** *(third party)* ***evaluations*** *for areas of work which entail significant spending and/or organisational implications, whether individual (e.g.,* ***project****) or* ***cluster*** *(e.g., EFSA strategy) activities;*

c) ***internal evaluations*** *for EFSA's "development" activities (projects), covered* ***ex-ante*** *by project charters and* ***ex-post*** *by project closing reports.*

EFSA Strategy 2027

3rd external evaluation - *MB recommendation*

Mid term strategy 2020 evaluation

Ex-post evaluation - STEP 2018

Ex-ante PCO/ex-post end of project reports

Project

Ad Hoc external evaluations: Closing programmes

Programmes

Recommendations and findings

To be integrated into IMS

Highlights 2021

Closing STEP 2018 open recommendations:

- *Centralisation - harmonise and streamline the role of the DBC vis-à-vis the coordinators across the departments*
- *Enabling the Strategy to provide long-term benefits: Strategy (& work-programme) performance monitoring (streamlining the number of KPIs and linking benefits to strategic results)*

To be carried out from 2022 onwards:

- ***Third party external evaluations*** *are envisioned to take place in 2023 (on closed programmes)*
- *The next* ***external evaluation****, to be carried out by the EC, is planned to be finalised by March 2026.*
- ***Mid term evaluation*** *2027 Strategy in 2024*

Quality and performance| **Continuous Improvement Overview**

Impact: 16 improvement projects in scope

Cycle Time reduction	Customer satisfaction	Risk mitigation	Efficiency
We re-design processes and/or remove obstacles to be faster	*We simplify processes and services to better meet customer needs*	*We identify critical control points in the process and mitigate associated risk*	*We find ways to do more with less*
Food Enzyme experts identification: Identified 13 additional experts (+130%)	**GPS SPoC set up and pilot phase 1:** Target is to increase customer satisfaction by 30% (based on survey analysis)	**PAD - Deadlines calculation system:** Formalised opportunity scope and problem statement. Set up of working team	**APDESK FTES and KPIs:** • Established current projects / processes / FTE baseline and reviewed FTEs needed. Identified tasks to be outsourced. • Root cause analysis and suggestions for the improvement of the management of tasks and the distribution of workload • Developed detailed KPI reporting tool
Feed expert identification: Achieved minimum number of suitable experts per WG between 6 and 10 (+20/30%)	**EU FORA Digital Platform:** The implementation has been sourced to a supplier and it is expected to be implemented and operative during 2022's H1. The initial sizing will be for 120 users, and it is foreseen a yearly increase of 30-35 users		**Business Impact Analysis:** From 5 working days to 1 (-80%)
SOP lifecycle optimization: Time taken from SOP dev to inclusion in repository from 162 to 92 days (-43%)	**Hierarchy of Norms:** Number of documents decreased from 514 to 415 (-19%)		**Staff onboarding:** Defined new-comer self service mode leading to an improvement of FTE consumption
Optimization Time Allocation Drafting Reasoned Opinion (RO) Art 12 Lead time to draft RO from 108 to 57 days (-47%)	**Integrated Management System:** Delivered the roadmap for the integration of the EFSA management system; e.g. ISO standards, ICF, Regulations,...		**Strategic Sourcing - centralised inventory of sourcing needs/ opportunities:** Defined sourcing model and high-level process to feed sourcing processes in the EPA 3.0 with relative governance
Expert selection: 100% selections < 250 days. "Mean time to hire" has reduced from 55 to 23 days (-58%)			**Food Enzyme Risk assessment - dossier evaluation process:** A PII in 2018 and LSS in 2020 have been taken to improve the dossier evaluation process. The Nr of scientific opinions adopted per plenary meeting passed from 9 in 2017 to 24 in 2021 (+167%)
PLH 2020-2026 mandate: # expert days per opinion from 5 to 4.50 (-10%)			

Started in 2021 | Started in 2020 | Closed

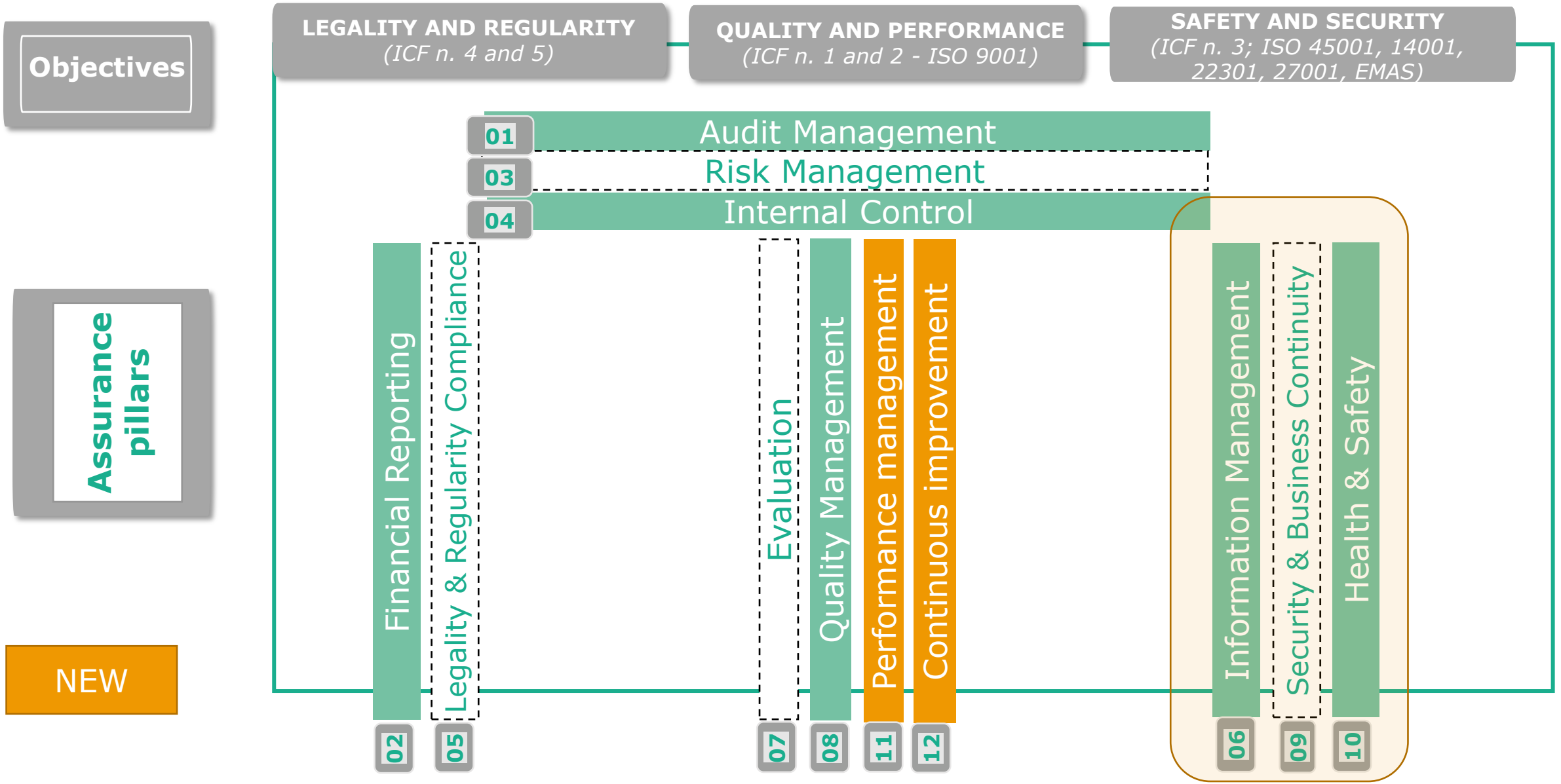
Managed in 2021

- ✓ **(9) FTEs** saved on the Science Area (improvement of the Food Enzyme Risk assessment dossier evaluation process and optimization of the time allocated in drafting Reasoned Opinion Art. 12,) vs **0.42 FTEs allocated**; i.e. 0.1 GPS and 0.32 Process Owners and other stakeholders
- ✓ **23** person days to hire experts (- 58%)
- ✓ **92** days for SOP dev. to inclusion in repository (-43%)
- ✓ **13** days to write performance report (-38%)
- ✓ **205** days GMO applications cycle time (-13%)
- ✓ **4.5** expert days per opinion (-10%)
- ✓ **New strategic sourcing** process and model
- ✓ **New onboarding** process for newcomers

Enlarge scope of CI process
Opportunity: collecting and managing all EFSA improvement opportunities in the IMS improvement register

New CI partners
Opportunity: leveraging on LSS skilled employees to build up a CI partnership approach per Dep.

Objectives & Assurance Pillars reporting



HSSE|
Status of 2021 objectives

Domain	Objective description	Status
Health and Safety ISO 45001	Biological, Chemical Risk monitoring	Achieved
	Electric System Inspection	Achieved
	Contractors activities monitoring	Partially achieve
Environment ISO 14001 - EMAS	Purchase of electric energy 100% produced from renewable sources	Achieved
	Awareness campaign on environmental sustainability	Partially achieved (due to the COVID pandemic)
	Planning and organization of events according to environmental sustainable criteria	Partially achieved (due to the COVID pandemic)
Business Continuity ISO 22301	Transition to ISO norm version 2019	Achieved
	Integration with Corporate MS	Postponed
	Significant IT Disaster Recovery exercise	Partially achieved

Achievements: Information security and Records Management Policy consolidated and merged into **Information Management Policy**

HSSE| Non-conformities

Description of minor non conformity	Solution already implemented or to be implemented in 2022
The autonomy of power generator is not consistent with RTO	Increase the generator fuel tank capacity (ongoing, to be completed in 2022)
It is missing a dedicated process that determines what aspects of BC are considered relevant and therefore to be monitored and measured	Define the process and improve the monitoring already performed (ongoing, to be completed in 2022)
Combustible material present in the data-centre	Remove combustible material and plan and execute periodical thorough checks (done, and checks on going)
The "restore phase" of the IT Disaster Recovery is weak	Review of the "restore phase" of the IT Disaster Recovery and test it (ongoing, to be completed in 2022)
The organisation does not control effectively the ICT supply chain	Implement IT suppliers audit – with particular regards to those that are critical (ongoing, to be completed in 2022 and re-run periodically in future)

Risk Management| EFSA Corporate Risks 2022

Risk areas identified in 2022:
- **Budget execution**
- **IT tools and organization**
- **Remaining pending EPA3.0 processes and organisation**

Way-forward: to be cascaded down to the EFSA risk register
Mitigating actions: to be discussed with relevant Process Owners (some started)

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Objectives	Risks	Mitigating actions
LEGALITY AND REGULARITY *(ICF n. 4 and 5)*	Transparency Regulation	• ART programme
	Fraud consideration	• Anti-fraud strategy
	Grants and Procurement	• EFSA grants and procurement policies and guidelines • Dedicated trainings on grants and procurement processes • Control activities for grant agreements, procurement procedures and mass payments • Annual financial, legality and regularity audits performed by the European Court of Auditors
QUALITY AND PERFORMANCE *(ICF n. 1 and 2 - ISO 9001)*	Brexit	• Preparedness for the UK withdrawal • Identification of areas of EFSA's operations likely to be affected by Brexit
	SARS-CoV-2	• Monitoring of developments • Assessment preparation on the impact of the changing context on EFSA's operations and EFSA's corporate services
	Independence	• EFSA Independence Policy: clear framework for the way in which the Authority manages the interests of its scientific experts and others with whom it works in the course of its activities • Processes and guidelines detailing how to declare, assess and publish relevant interests • Committee on conflict of interest advises on issues related to competing interests • Mandatory training on ethics and integrity • Annual compliance and veracity checks carried out by EFSA on a sample of declarations of interest
	Scientific Expertise	• Expertise Management programme (EMP) • Guidelines to govern the process of selection of external experts • External review of the evaluation of experts for panel renewal • EFSA staff policies and guidelines
SAFETY AND SECURITY *(ICF n. 3; ISO 45001, 14001, 22301, 27001, EMAS)*	Information Management	• Information Management Programme (IMP) coordinating all projects related to EFSA's information at 360 degrees • Information Security Policy focusing on EFSA's approach to information security management • Dedicated trainings on Information Security Awareness
	IT Security	• EFSA's business continuity plan is based on a business impact analysis defining dependencies and recovery times for IT systems

Risk management | Way forward
Integration with performance management

External/Top down

IAS Strategic Internal Audit Plan 2022-2024 *(example)*

Risk area identified:

- **2. End to end risk assessment process**
- 1. Risk of **ineffective processes for the provision of general risk assessment** based on mandates and **ineffective application of the agreed methodology**
- 3. Risks of **insufficient engagement with stakeholders** and society **in different parts of the risk assessment process**

Process Risk Registers

Risk 1:

- EPA3 4.1 Generic Mandates: Risk partially addressed

Risk 3:

- EPA 2.5 (New process design ongoing) E06.03.03 Public consultation: MINOR RISK IDENTIFICATION

Are these risks identified in the respective process charters?

Are these risks monitored by process metrics?

Process Performance

Measurements:

Feedback **interview with SANTE**
Risk 1: Fitness for purpose/Timeliness
Risk 3: Engagement

KPIs
Risk 1:
- Timeliness of adoption
- Timeliness of publication
- Methods preparedness to address RM's questions
- Up-to-date scientific guidance documents

Risk 3:
- Public consultation
- Customers/Partners/Stakeholders satisfaction on risk assessment

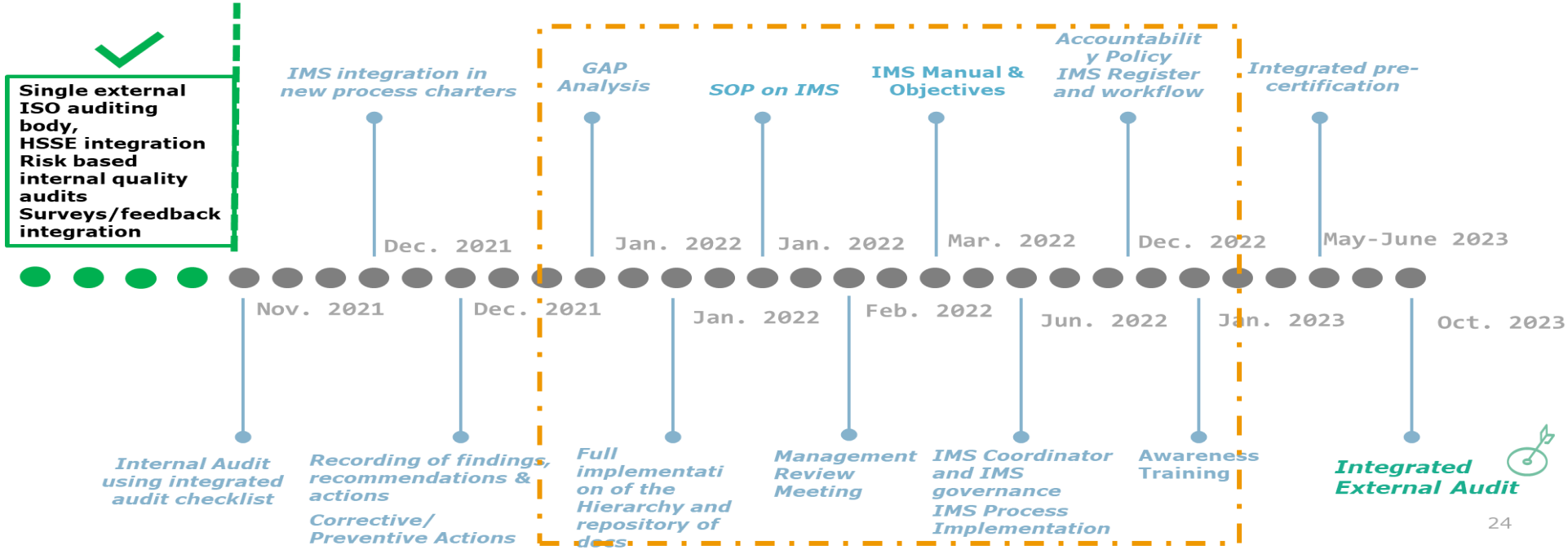
PPIs
Risk 1:
- Throughput time, Timeliness of adoption (4.1)
- Usability of cross-cutting guidance documents by relevant Panels, # of ad-hoc requests for advice on cross-cutting guidance implementation addressed (6.1)

WAY FORWARD FOR INTEGRATION

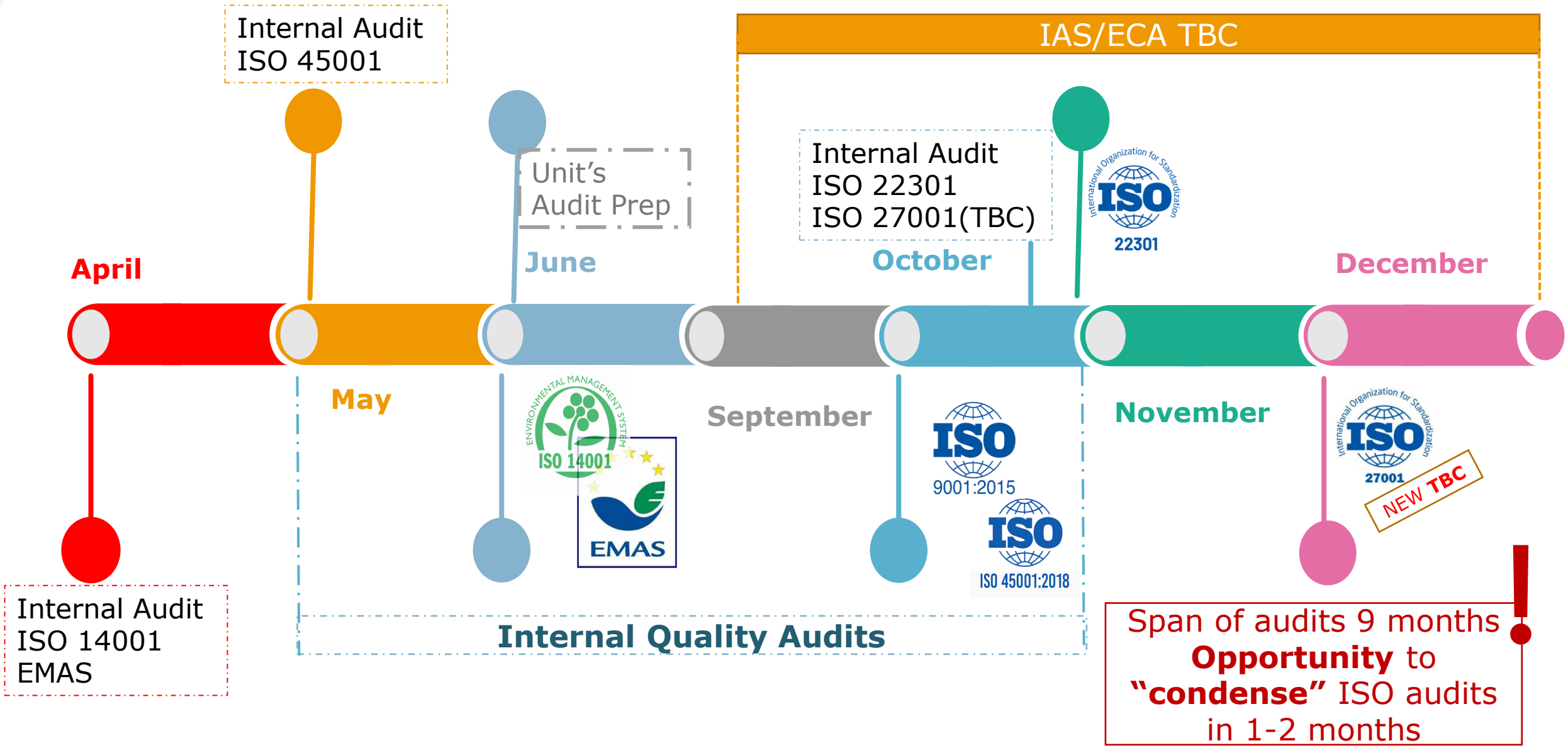
- Link between **objective setting** and **risk reflection** is currently missing
- **KPI's** and **risk reflection** should be set **at same time** in planning cycle
- **Integrated Process Documentation** (integration of process risk registers and charters)
- Roles and responsibilities, **validation** at unit and department level

IMS wide| 2022 Objectives

#	Objective	Action
0	Integration of management systems	Draft and finalise common documentation in line with roadmap(such as common SOP, development of IMS manual, Accountability Policy)
		Implement IMS-wide MT review meetings and report
		Implementation of Hierarchy of documents
		Common IMS register & workflow
		Coordination Audit Committee meetings
		Coordination risk process, risk map and risk register



IMS wide|
Audits overview (dates)



IMS wide|
Audits- process overview (2022)

European Food Safety Authority

ECA Financial, legality & regularity audits | IAS audit | External ISO Audit* | Internal ISO audit

* Entire ISO 9001 audit plan to be defined in March 2022

5. Services Delivery
- 5.1 Services to applicants
- 5.2 Support to managing RA evidence
- 5.3 People services
- 5.4 Logistics services
- 5.5 Site & Facility services
- 5.6 Digital services
- 5.7 Financial Services
- 5.8 Public Access to Documents
- 5.9 Content Sanitization

6. Knowledge Management & Development
- 6.1 Methodology management
- 6.2 Strategic competencies
- 6.3 Knowledge Organization
- 6.4 Capacity building
- 6.5 Data management

7. Engagement & Communication
- 7.1 Partnerships
- 7.2. Community management
- 7.3. Strategic engagement
- 7.4. Social research & Comm. planning
- 7.5 Digital channels management
- 7.6 Coordinated comm. development
- 7.7 Internal communication

8. Foresight
- 8.1 Environment scanning
- 8.2 Inn&Transf agenda definition

9. Legal Counselling
- 9.1 Decisions review management
- 9.2 Legal partnering / advice

10. Procure-to-Pay
- 10.1 Strategic outsourcing decisions
- 10.2 Outsourcing launch, evaluation and award
- 10.3 Contract management
- 10.4 Accounting

11. Hire-to-Retire
- 11.1 Talent pools
- 11.2 Onboarding
- 11.3 Competency development
- 11.4 Competing interest management
- 11.5 Performance management

1. Scientific preparatory activities
- 1.1 Generic Pre-submission Advice
- 1.2 Renewal Pre-submission Advice
- 1.3 Notifications of Study
- 1.4 Sc. Workforce planning

2. E2E Applications
- 2.1, 3.1 Dossier Intake
- 2.2, 3.2, 4.2 Risk Assessment
- 2.3, 3.3, 4.3 Confidentiality Assessment
- 2.4, 3.4, 4.4 Sc Output publication

3. E2E Pesticides

4. E2E Generic Mandates

12. Planning, Governance & Control
- 12.1 Strategy, Planning, Analysis
- 12.2 Audit & RMIC
- 12.3 Quality Management
- 12.4 Safety & Converged Security
- 12.5 External governance actors coordination (MB etc)

13. Develop & Improve
- 13.1 Enterprise Architecture
- 13.2 Innovation Implementation
- 13.3 Continuous improvement

IMS wide|
Internal quality audits & support proposal

European Food Safety Authority

Internal Quality Audit **Interviews**

Performed by:
Internal quality auditors

- 2.1 Applications Dossier Intake
- 2.2 RA of Applications(FEEDCO)
- 2.2 RA of Applications (NIF)
- 3.2 Peer-review of Pesticides / Assessment of MRLs (PLANTS)
- 4.1 RA of Generic Mandates (BIOHAW)
- 4.1 RA of Generic Mandates (MESE)
- 5.1 Services to Applicants
- 6.1 Methodology mgmt.
- 6.4 Capacity Building

New processes

Document checks/self assessment

Performed by:
Relevant Unit & QM

- 1.4 Scientific workforce planning
- 6.2 Strategic Competencies
- 6.3 Knowledge organisation
- 7.1 Strategic Partnership & Community building
- 7.2 Community Management
- 7.3 Strategic Engagement
- 8.1 Environmental scan
- 8.2 Innovation & Transformation agenda definition
- 11.1 Talent Pools
- 13.1 Enterprise Architecture
- 13.2 Innovation Implementation

External Audit preparation

Advised by:
GPS

ECA (Financial, legality & regularity audits)

- 5.7 Financial services
- 10.1 Strategic Outsourcing Decisions
- 10.2 Outsourcing Launch, Evaluation & Award
- 10.3 Contract Management
- 10.4 Accounting

IAS audit

- 6.5 Data management

ISO 9001:2015

- TBC

IMS wide| Hierarchy of documents

Rolling out Hierarchy of documents in 2022:

- New classification of docs
- Harmonised naming convention
- Updated templates
- 1 Catalogues with overview of all document levels
- NEW/Updated SOP to be finalised

The process may need to be implemented gradually due to limited resources between GPS/LA

Repository Team suggested composition

GPS
Coordinates/advices/ reviews

LA
Advices/reviews

MESE
Maintains Scientific guidances catalogue

Repository Team:
Responsible for maintaining the integrity of the Repository. Involved in all layers of the HoD (except Records). Their involvement is foreseen from the moment a need for a new document arises.

- When a need for a new document is identified, the team is responsible for identifying the nature of the document (level)
- Checking whether there is any other existing documentation, and if so, if there is a need for further documentation
- Ensuring the correct naming conventions/templates are being used
- Maintaining the various "catalogues" up-to-date to ensure that staff have access to the latest up to date documentation

2022 objectives|
IMS specific objectives & actions

European Food Safety Authority

Legality & Regularity

1	Internal Control	Definition of Internal control monitoring criteria, coordination control activities and internal control assessment performed
		Perform a control environment review (ex-ante and ex-post) for IT financial, vendor management and G&P expenditure
2	Audit Management	Coordination, clearance and follow-up annual ECA financial, legality and regularity audits, ECA Special Reports and Horizontal topics
		Coordination, clearance and follow-up IAS audits on Information Security & Disaster Recovery and Enterprise Data Governance and Management

HSSE

1	Maintain HSSE ISO standards certification ISO 14001, ISO 45001, EMAS, ISO 22301	Prepare and run internal and surveillance audit
2	Implement ISO 27001	Develop MS and implement the first cycle of ISO 27001
3	Ensure MS effectiveness	Design and run coordinated Cybersecurity and Business Continuity test/exercises
4	Implement continuous improvements	Cover the minor non conformities to improve the compliance with the norm
		Ensure integration among MS procedures to ensure a more agile management
		Consolidate "Benefits and achievement reporting

Quality & Performance

1	Maintained ISO 9001:2015 certification	Prepare and run surveillance audit, Implement internal quality audit cycle
		Run customer feedback activities and integrated survey
2	EFSA's Quality Management System updated in line with the EPA3 process finalisation and RFCs	Definition of the new processes including their documentation (Process charters (including PPIs), SOPs/WINs) and the pending organisational evolutions (e.g. IT organisation)
3	Finalise the definition of EFSA'sperformance framework	Finalisation of KPIs and cascading to processes
		Finalisation of the new programmes & IT roadmap and new agile approach for handling DEV and PII
		Create the basis for aligning IT tools with performance framework
		Improve and streamline the integration of the end to end performance management in EFSA (covering workplan, FTEs/posts, Budget), and reinforce the PDCA cycle
4	Strengthen evaluations	Develop and implement fit for purpose annual/multiannual evaluations plan
5	Consolidate continuous improvement	L&D- Continuing developing the capability of continuous improvement and support/partner with staff to enforce process management and continuous improvement knowledge and responsibility
		Consolidate "Benefits and achievements reporting"

Quality and performance| **Performance – moving forward**

a) Align IT tools with performance framework

Reason why:
Both at KPIs and at process metric level there is the opportunity to invest to have more **automatic measurement**. This is obviously a source of efficiency (less FTEs spent, more harmonization, less manual mistakes) and frees more time for analysis. Also the reporting side (dashboards,…) can be enhanced.

Create a stronger P-D-C-A cycle

Reason why:
Establish a **codified process to handle deviations (compliance/performance)** that integrated all the needed processes/actors, and **establish a stronger links** between the various elements (such as between **performance monitoring and risks management**, integrating register and process).
Performance deviations to be **regularly escalated to Process Sponsor/PCO/Assurance/Continuous improvement** functions in case of consecutive moderate deviations (*does the process have a sub-optimal design?*), or relevant deviation (*is the execution at risk?).*

Create a measurement (and improvement) **culture**

Reason why:
This was a suggestion also coming from the FIP Lean Six Sigma exercise done some years ago.
Differentiate what is **measuring** (we need to measure what we do, ideally done with an increased degree of automatisation) and what is **reporting** (report only what's important/what's concerning/what's scrutinised). This should be, however, **a pull and not a push** (clarify role of central control bodies and process hierarchy roles). Good examples from CI can help in this regard.

Risk of not acting: Lack of efficiency generation, Sub-optimal use of Performance monitoring

Quality and performance | **Continuous improvement**

EPA 13.3 Continuous Improvement
Process scope enlarged

Collected from all sources of improvement actions

NEW Exception request workflow tool to be used as central register (mid-2022)

ID	DEPARTMENT	UNIT	EPA PROCESS 3.0	IMPROVEMENT DESCRIPTION	SOURCE	IMPROVEMENT TYPE
48	ASSESS	Nutrition & Food Innovation	2.2 RA of Applications	Consider to redesign the process since the current one has reached his maximum productivity in his current form and the current demand of work from the team and the working group is not anymore sustainable as already indicated in previous reports	EoYR	PII
56	ASSESS	PREV	3.2 Peer-review of Pesticides / Assessment of MRLs	Format for the assessment of basic substances should be changed in order to provide a more "fit-for-purpose" product. However clear and consistent guidelines should be given by and agreed with SANTE. The general limited database provided by the applicants for these active substances requires an action to increase their awareness on why the dossier preparation is crucial to avoid several data gaps. Implementing for basic substances a similar approach to the Conclusions template which indicate the "weight" of data gap for the final risk assessment may be useful.	2020 DG SANTE-EFSA Customer Feedback exercise	BAU
59	EMPOWER	GPS	12.3 Quality Management	It was noted that SOPs 9 & 10 are linked, in that they both deal with the approval process of the final deliverables, but that SOP 9 is not mentioned in SOP 10 - creating a misunderstanding about the steps to be taken. Lead authors of the SOPs 009_S & 010_S to propose more integration between both applicable procedures in the process. The lack of integration caused the **Non-compliance event 76**	EFSA Exception Register 2021	BAU

Process Leader suggests/indicates Improvement type in liaison with relevant Unit