INTEGRATED MANAGEMENT SYSTEM REVIEW 2023

efsa
EUROPEAN FOOD SAFETY AUTHORITY

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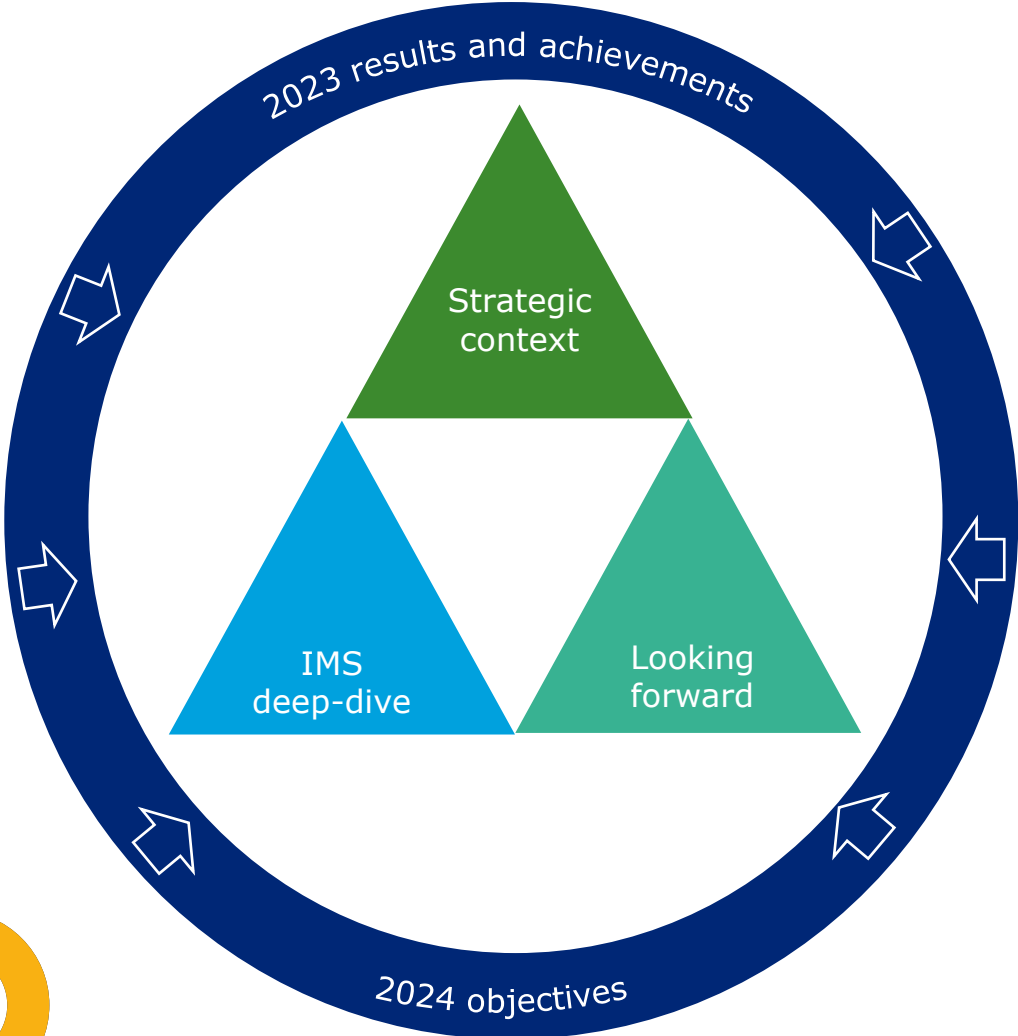
2024 objectives

IMS strategic context
❑ Reporting on results & implementation plan
❑ Changing context
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❑ Updated risk register

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STRATEGIC CONTEXT

YEAR OF GROWTH

Risk assessment production

Budget execution and partnerships

New processes, new roles, new organisation

Core business performance

	INPUT		PERFORMANCE			
	Budget	FTEs	Volume	Timeliness	Stock	Satisfaction
2023	56.9 M	261	660	84.6%	1581	69%
2022	52.5 M	243	582	84.3%	1512	73%
YoY	+8%	+7%	+13%	-	+5%	-4%

Strengthen the Risk Assessment Production

Progresses in **the identification of main bottlenecks** in EFSA's RA workstream (speed of RA initiative, SWOT analysis of panel system, …), which will inform improvement initiatives from 2024 onwards.

IT tools becoming more stable and moved from DEV (RASE project) to BAU. However, enhancements are still expected to take place in 2024.

Optimise budget execution and partnerships

Business as Usual (BAU) — Development Activities (DEV) — TOTAL

- 2018: € 7.5 (5.2 €, 2.3 €)
- 2019: € 7.9 (5.2 €, 2.7 €)
- 2020: € 11.9 (7.1 €, 4.8 €)
- 2021: € 24.5 (13.2 €, 11.3 €)
- 2022: € 34.9 (12.1 €, 22.9 €)
- 2023: € 35.9 (20.3 €, 15.5 €)
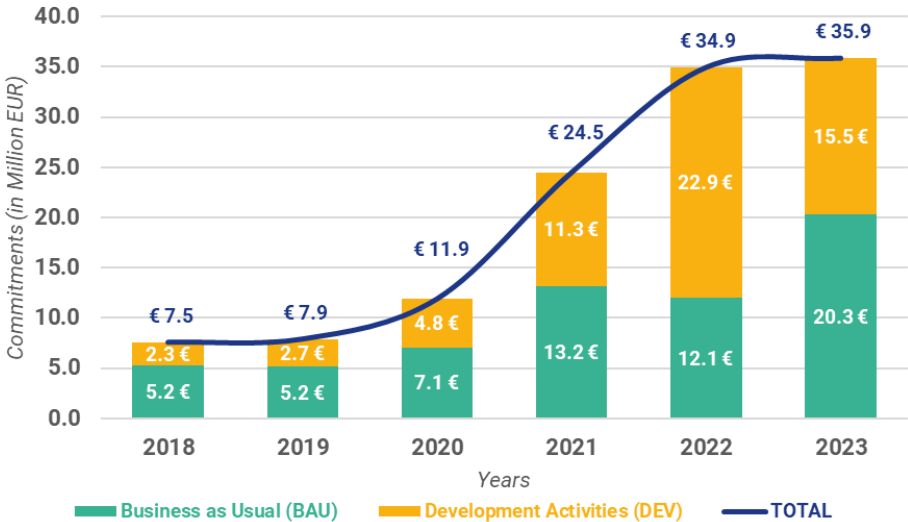
Ensure a smooth and efficient running of new processes, new roles, and new organisation
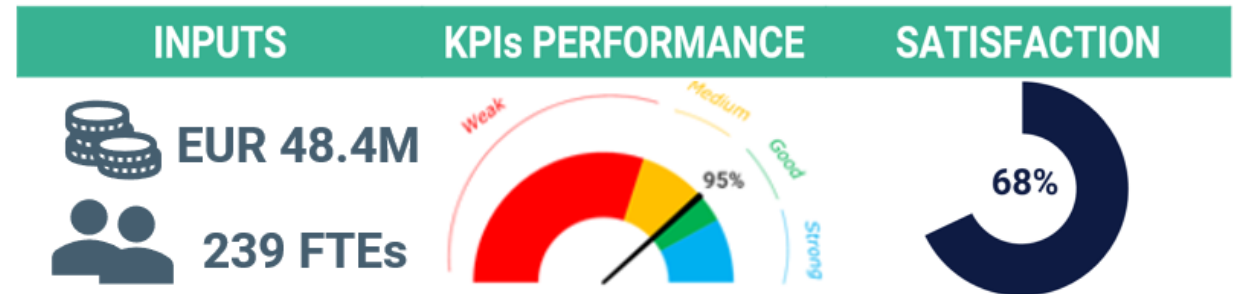
- **DMF 2.0** rolled out
- **Product management** implemented
- **EPA 3.0** documentation finalised
- **IMS** strengthened and **integrated ISO** audit successfully passed

Efficient working environment dimension

19%, 40%, 19%, 15%, 5%, 2%
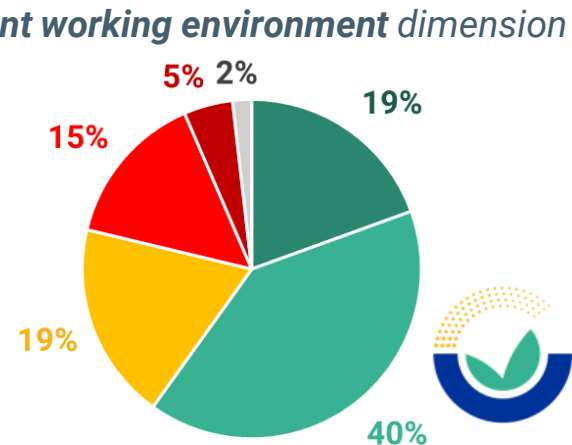
OVERVIEW OF EXPECTED OUTCOME 1.1

SCIENTIFIC ADVICE

OVERALL PERFORMANCE

INPUTS	KPIs PERFORMANCE	SATISFACTION
EUR 48.4M 239 FTEs	95%	68%

HIGHLIGHTS

- **Citations of EFSA' s scientific outputs** over target
- Good performance overall in **RA of applications** (questions closed, stock, timeliness)
- Positive stakeholders' perception on **EFSA's impartiality**

ATTENTION AREAS

- **Pesticides** (questions closed, stock, timeliness) and **Generic RA** (timeliness) performance
- Small decrease in **satisfaction rate** (timeliness, applicants' support)

OVERVIEW OF EXPECTED OUTCOME 1.2

COMMUNICATION

OVERALL PERFORMANCE

INPUTS	KPIs PERFORMANCE	SATISFACTION
EUR 8.5M	101%	69%
22 FTEs		

HIGHLIGHTS

- Continuous growth of **EFSA's multilingual policy**
- Good performance of **EFSA's campaigns**
- Survey's respondents satisfied with **EFSA's clarity of communication**

ATTENTION AREAS

- **Social media interactions** below target
- Small decrease in **satisfaction rate** (reach of communication)

OVERVIEW OF EXPECTED OUTCOME 2.1

PREPAREDNESS FOR FUTURE RISK ANALYSIS NEEDS

OVERALL PERFORMANCE

INPUTS	KPIs PERFORMANCE	SATISFACTION
EUR 56.1M	101%	74%
145 FTEs		

HIGHLIGHTS

- Resources allocated to **BAU outsourcing above target**, and higher than foreseen **number of organisations contributing to EFSA's work programme**
- **Methods and Data preparedness** to address RM's requests exceeding targets
- Positive feedback from **external survey**

ATTENTION AREAS

- **Project performance** slowed down in the areas of harmonisation

OVERVIEW OF EXPECTED OUTCOME 3.1

EMPOWER PEOPLE AND ENSURE ORGANISATIONAL AGILITY

OVERALL PERFORMANCE

| INPUTS	KPIs PERFORMANCE	SATISFACTION
EUR 42.3M	Weak · Medium · Good · Strong — 105%	84%
182 FTEs		

HIGHLIGHTS

- Excellent **occupancy rate**
- Excellent **staff engagement and management indexes**, and good **feedback from external survey**
- Positive outcomes of **ISO and ECA audits**
- **Budget execution** in line with targets
- Overall **positive process and project** performance

ATTENTION AREAS

- **Leadership index** below target

GRANTS AND PROCUREMENTS EVOLUTION 2018-2023

Execution

100%
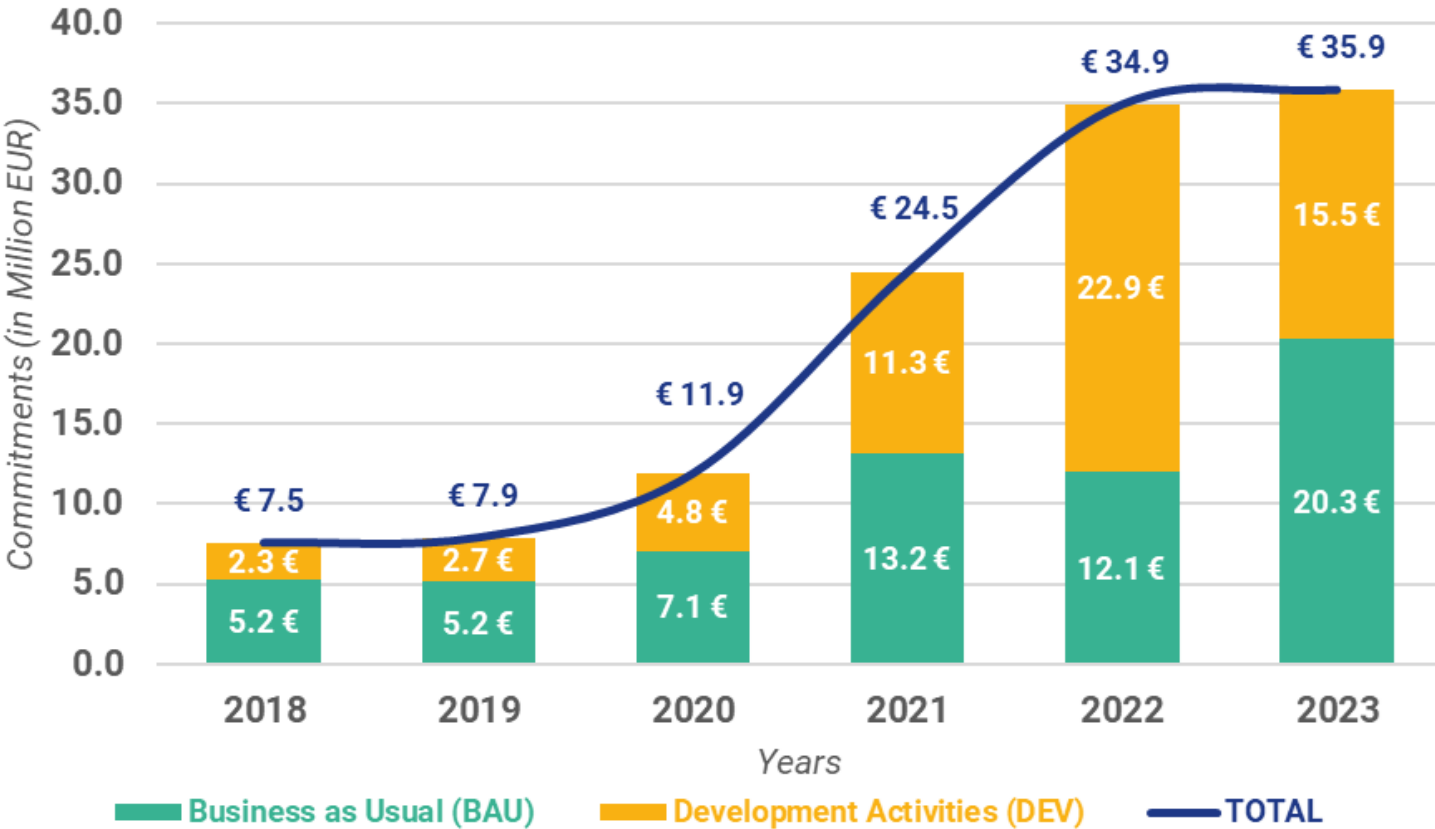
Commitment

€ 155.5M

Target met

100%

Diff. payment
€27.9M

Target met

89%
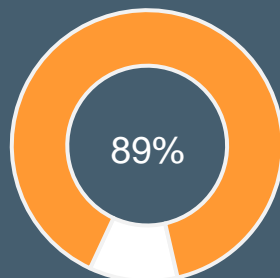
Non-diff. payment
107.0€M

1% below the target of 90%

Transfers

€ 1.2M

€ 0.02M

€ 2.7M

€ 1.1M

€ 0.03M

Title III
OPERATIONS,
74.5M, 48%

Title I STAFF,
67.1M 42%

Title II
INFRASTRUCTURE,
13,8M 10%
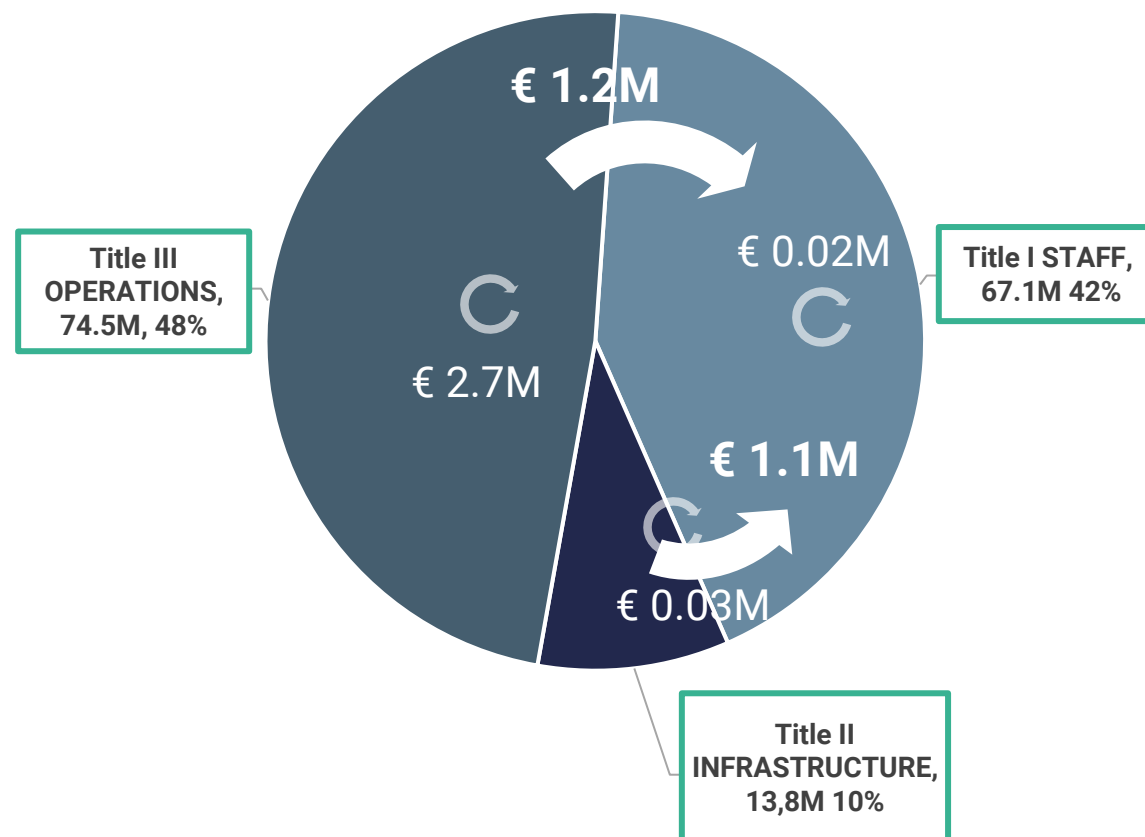
Internal transfers
between chapters

KEY ACTIONS STATUS / BY EOR − QUALITATIVE ASSESSMENT

❑ Good progress (details in annex):

o N.27 (31%) finalised the set-up and are running rather stable with continuous improvements (achieved)

o N.56 (65%) in progress, i.e. relevant improvements/developments ongoing (in progress)

o N.3 (3%) are yet to start (to start)

❑ Opportunity for consolidation: all key actions in progress present synergies/overlaps
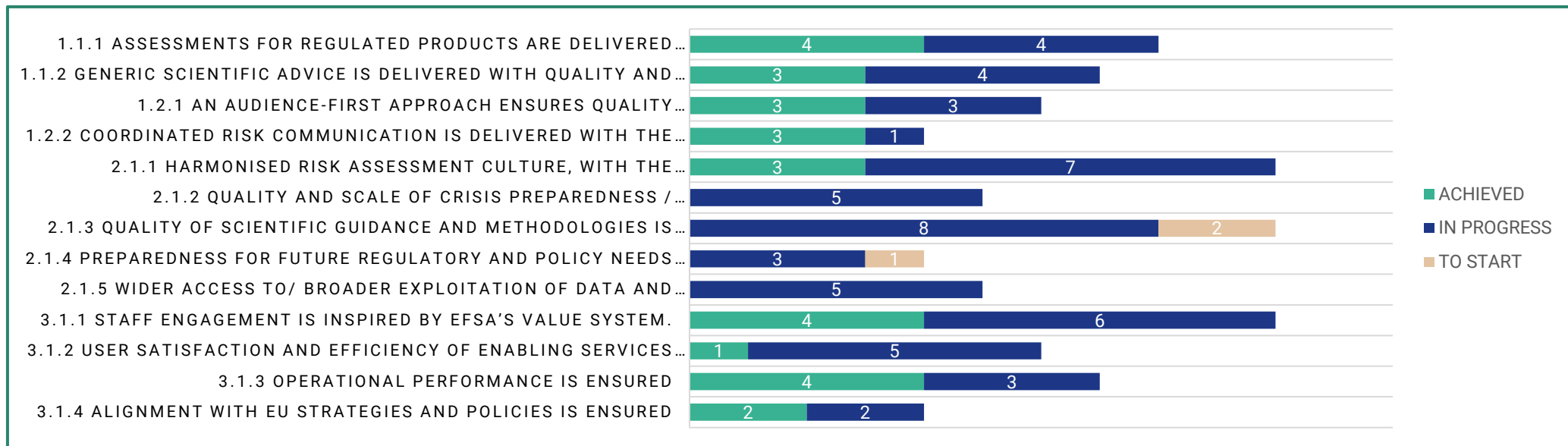
TRANSPARENCY REGULATION MEASURES STATUS – QUALITATIVE ASSESSMENT

Transparency			Sustainability		
	Content dossier disclosure	Fully implemented		MS and NGOs in EFSA MB	Fully implemented
	Management of confidentiality content	Fully Implemented, close scrutiny		New experts' selection process	Fully implemented
				New experts' indemnity regime	Fully implemented
	Notification of studies	Fully implemented		Outsourcing / insourcing of preparatory work	Partially implemented, activities in progress
	Pre-submission advice	Fully implemented			
Reliability	Public consultations	Fully implemented	Communication	Coordinated communication between Risk Assessors and Risk Managers	Fully implemented, activities in progress
	Commission audits	Fully implemented		Proactive communication Scientific literacy actions Wider use of social media	Fully implemented, activities in progress
	Commission verification studies	Fully implemented, activities in progress		Increased communication analysis and social science	Fully implemented, activities in progress
				Increased public and stakeholder engagement	Fully implemented, activities in progress

CHANGING CONTEXT 2024-2027

Core Business
SO1 - Deliver trustworthy scientific advice and communication of risks from farm to fork

Sustaining and Developing Core Business
SO2 – Ensure preparedness for future risk analysis needs

Managing and Enabling Core Business
SO3 – Empower people and ensure organisational agility

Speed of risk assessment

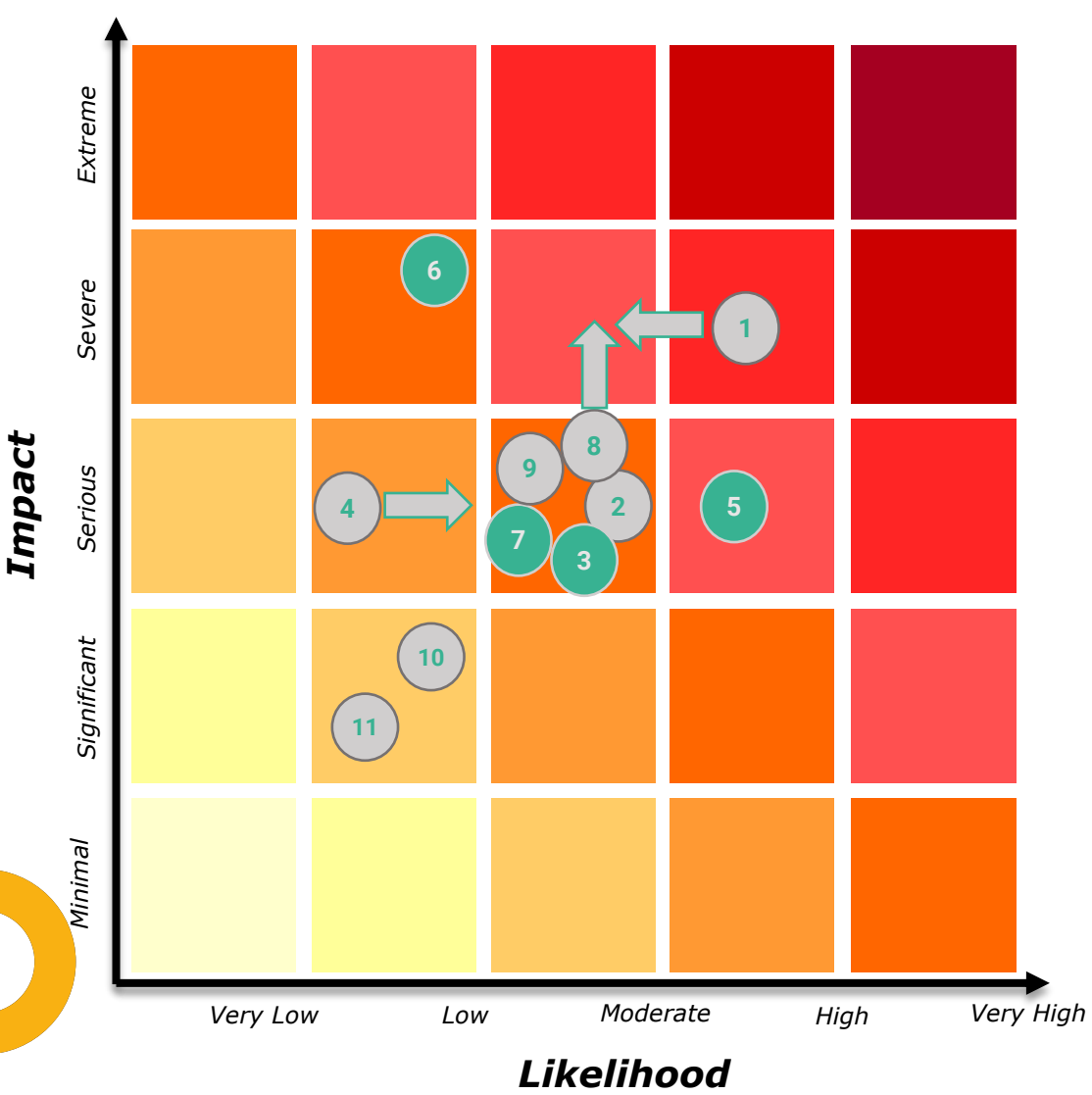Readiness of risk assessment approaches

Digital partnerships

INTERNAL CONTEXT

- *Closure of 1st phase of strategy 2027 focusing on TR implementation– processes/tools/organization stability – IMS integration*
- *Changing remit: new tasks, new mandates, new partnerships, across Agencies process integration, new resources, digitalisation/AI*
- *E2E risk assessment: increased quality expectations, backlog/stock persists, delay of partnership model, guidance updating attention, new panels*
- *Operational budget "reduced"*
- *New Executive Director*

EXTERNAL CONTEXT

- *Evolving policy/regulations: farm to fork - one substance one assessment – GMO – FCM - one health – horizon Europe - cybersecurity*
- *– new EU Parliament and Commission*
- *Geopolitical changes with inflation (staff and utilities)*

Impact (vertical axis): Extreme, Severe, Serious, Significant, Minimal

Likelihood (horizontal axis): Very Low, Low, Moderate, High, Very High

Risk identified for 2023	Update/reviewed risk
1-Risks related to the external environment	
Transparency Regulation, Confidentiality assessment 4 - High 4- Severe (1)	The risk is still present in 2024 but the rating has been adjusted to 3-Moderate 4- Severe
Crisis preparedness & response 3 – Moderate 3 - Serious (2)	Risk remains in 2024. Risk rating confirmed. Mitigating actions ongoing
Inflation 3 – Moderate 3 - Serious (3)	**NEW** risk for 2024. Mitigating actions defined.
2. Risks related to planning, processes and systems	
IT Security & Data Protection 2 – Low 3 - Serious (4)	The risk is still present in 2024 but the rating has been adjusted to 3 – Moderate 3 – Serious New mitigating actions put in place for 2024.
Speed of risk assessment 4– High 3 - Serious (5)	**NEW** risk for 2024. Mitigating actions defined
Quality of risk assessment 2 – Low 4 - Severe (6)	**NEW** risk for 2024. Mitigating actions defined
Readiness for regulatory and scientific developments 3 – Moderate 3 - Serious (7)	**NEW** risk for 2024. Mitigating actions defined

Risk identified for 2023	Update/reviewed risk
3- Risks related to people and the organization	
Scientific Expertise 3 – Moderate 3 - Serious (8)	Risk remains in 2024. Risk rating upgraded. 3– Moderate 4 – Severe New mitigating actions put in place for 2024.
Independence 3 – Moderate 3 - Serious (9)	Risk remains in 2024. Risk rating confirmed. Mitigating actions ongoing
4. Risks related to legality and regularity aspects	
Fraud 2 – Low 2 - Significant (10)	Risk remains in 2024. Risk rating confirmed. Mitigating actions ongoing
Grants & Procurement 2 – Low 2 - Significant (11)	Risk remains in 2024. Risk rating confirmed. Mitigating actions ongoing

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OPERATIONAL CONTEXT

KEY IMS OBJECTIVES 2023 | STATUS

IMS common objectives

LEGALITY AND REGULARITY OBJECTIVES
all achieved

- **Discharge** is granted

- **IMS 2022** Reporting is **endorsed** by Accountability Council

- Coordination, clearance & follow-up internal and external audits

- Coordination risk process, risk map and risk register

- **IC control monitoring** criteria defined, monitoring internal audit/control activities and **IC control** assessment performed

- Coordination Audit Committee meetings

QUALITY AND PERFORMANCE OBJECTIVES
mostly achieved – details in upcoming slides

- Define and implement the **IMS register and workflow**

- **IMS roadmap** implementation: **common** calendar, Certification approach, IQA approach, documentation approach

- **Hierarchy of documents** - first review of all repository documentation (including scientific guidances)

- **Accountability policy** integration with IMS and DMF

- Finalisation of the pending **process documentation** for new and impacted processes

- **POTI governance:** further define Information & Technology and align with Process and Organisation

- Prepare and run **surveillance ISO 9001 internal and external audits**

- Optimise and run **Customer feedback activities**

- **BIKE 2**: foundation work (E2E science, Dept/unit dashboards) and action plan for lean managing by numbers and corporate reporting

- **Evaluations:** TR measures evaluations in 2023 and ex-post and ex-ante quality checks on selected DEV projects

- Stimulate Dept./Units in the regular identification of **continuous improvement** initiatives following PDCA

HSSE OBJECTIVES
all achieved- details in upcoming slides

ENVIRONMENT ISO 14001 - EMAS

- **Energy diagnosis** of EFSA to understand how energy is used and which interventions can be done to reduce energy consumption

- **New contract** for travel agency services including green criteria

- **ISO 14001 and EMAS maintenance**

SAFETY ISO 45001

- **New on-line** refresh course

- **Two Emergency drills**

- **ISO 45001 certificate maintenance**

SECURITY ISO/IEC 27001 and ISO 22301

- **Aligned** EFSA processes with ISO/IEC 27001 requirements

- **Performed disaster recovery** exercise

- **ISO/IEC 27001 FIRST** certification and **ISO 22301 certificate maintenance**

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EFSA CONTROL ENVIRONMENT

1.Process control activities

6.Internal control monitoring criteria

2.External/Internal evaluations

3.Internal audits

5.External EU audits (ECA/IAS)
Stable. Overview in the detail plan

4.External certification audits (ISO)

ISO 9001 QUALITY

17 Process/products were audited

12 Number of interview style audits

5 Number of document check audits

7 End2end science processes/products

2.2 **RA Applications:** 2 products (Food additives and food additives re-evaluation)
3.2 **RA Pesticides:** 3 products (Basic substances, active substances, new active substances)
4.2 **RA Generic Mandates:** 2 products (Animal Health and animal welfare)

Results

8 minor non – conformities
15 observations
13 opportunities for improvement
2 best practices

- # of **Internal Quality Auditors** have decreased since 2020 > Training and expertise to be built within GPS to expand the audit teams, and reduce need for outsourcing
- Continuation of 2023, in depth end2end audits to be performed
- Audit processes not processed in 2023
- **RISK:** Possible overlaps between internal/external ISO 9001 and IAS audits

ENVIRONMENT ISO 14001- EMAS

2023

Internal audit exercise carried out in April 2023 resulted in the following:

- 0 non-conformities
- 2 observations concerning the update of 2 documents

Evaluation of compliance with European regulations and Italian environmental legislation carried out in April 2023 resulted in the following:

- 0 non-conformities

SAFETY- ISO 45001

2023

Internal audit exercise carried out in May 2023 resulted in the following:

- 0 non-conformities
- 5 observations

BUSINESS CONTINUITY- ISO 22301

2023

Internal audit exercise carried out in October 2023 resulted in the following:
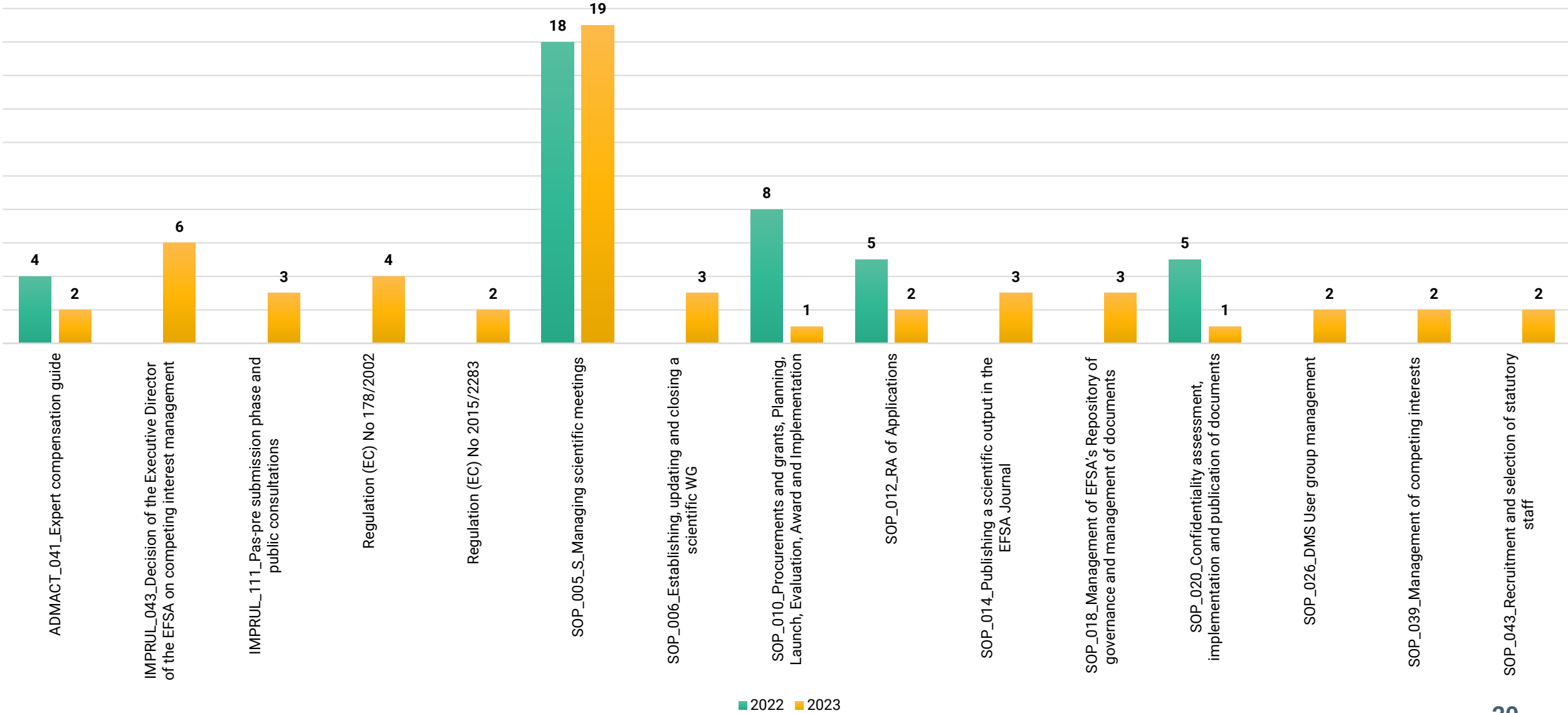
- 0 non-conformities

SECURITY - ISO 27001

2023

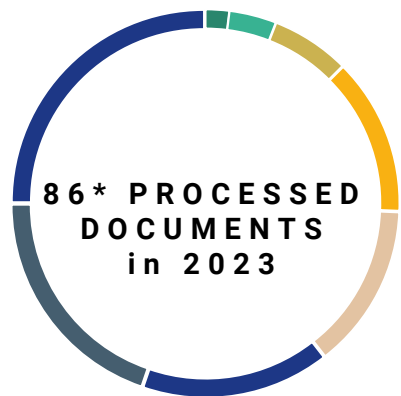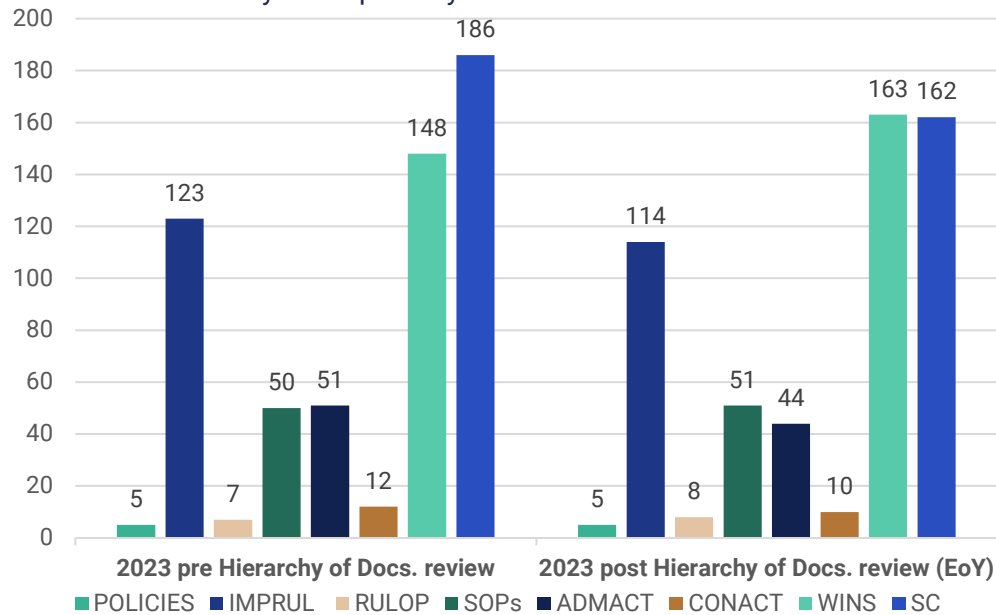Internal audit exercise carried out between December 2022 and February resulted in the following:

- 16 observations, mainly related to documents' publication

INTERNAL CONTROLS AND INTERNAL AUDITS | NON-CONFORMITIES 2023

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Hierarchy and repository of documents review exercise 2023

86* PROCESSED DOCUMENTS in 2023

out of which 9 IMPRUL, 1 RULOP, , 18 SOPs, 12 ADMACTs, 2 CONACTs, 44 WINs

Removal of outstanding and overlapping documentation

Harmonized central check point to ensure compliance

Centralized catalogue of documents/processes & governance

IMS integration i.e., post RASE tool manuals & CORSER documentation

Clarity for the organization & flexibility of updating for relevance

Review and revision of cross-cutting and sectorial guidance documents with 24 documents flagged as obsolete

*out of which 162 Scientific Guidances, 114 IMPRUL, 8 RULOP; ** EPA charters are stored in the Repository*

Positive developments & benefits

Pyramid:
- 5 — POLICIES
- 284* — IMPLEMENTING RULES/ RULES OF PROCEDURE
- 51 / 52** — PROCESSES/ PROCEDURES
- 44 / 10 — ADMINISTRATIVE ACTS/ CONTRACTUAL ACTS
- 163 — WORKING INSTRUCTIONS
- RECORDS

IMS

INTERNAL CONTROLS AND INTERNAL AUDITS | HSSE | SPECIFIC MANAGEMENT REVIEWS & OUTCOME

Accountability Council

HSSE Management Review: outcome of the **HSE Committee** and the **Agency Security Committee**

Health & Safety and Environmental Committee

Specific **HSE Management Review** including considerations requested by the standards (ISO 45001: 2018, ISO 14001: 2015 & EMAS)

ISO 14001 – EMAS	ISO 45001
Purchase of electricity produced 100% from renewable sources	Fourth year with zero injuries
Carbon footprint assessment of EFSA (reference year 2022)	On-line training courses for all staff (OHS First Course and OHS Refresh)
New contract for shuttles services including green criteria	E.R.T. training
Energy diagnosis (analysis of EFSA's energy consumption and plant efficiency)	Emergency drills
New contract for bar, catering and canteen services including green criteria	ISO 45001 certificate maintenance
ISO 14001 maintenance and annual update of EMAS registration	

Agency Security Committee (ASC)

Specific **IS and BC Management Review** including considerations requested by the standards (ISO/IEC 27001: 2022, ISO 22301: 2019)

ISO 22301	ISO 27001
Ongoing integration with Corporate MS and other MS	Ongoing integration with Corporate MS and other MS
ServiceNow BC and SecOps modules have been implemented as pilot	Obtain ISO 27001 certification
DR Tests were carried out in 2023	Maintain alignment with upcoming EU security regulations
BCMS documents have been reviewed and updated.	Develop in collaboration with Safety the adaptation of the Emergency response management to the new EFSA working environment (hybrid/teleworking)
Results of BIA were confirmed and IT systems supporting critical and scientific processes have a proper RTO and RPO.	Collaborate with EFSA stakeholders (DW, TS, DPO, DMO, etc) to address high priority recommendations stemming from 2022 security assessments, address IAS recommendation and consolidate Security by Design processes
ISO 22301 certification maintenance	

EXTERNAL AUDITS AND EVALUATIONS | EXTERNAL AND CERTIFICATION AUDITS RESULTS

ECA Financial, Legality & Regularity Audit

No critical, very important or important audit recommendations

European parliament Discharge

Discharge 2021 granted. 4 recommendations have been implemented, and the remaining (9) in the process of being fully addressed.

All EFSA's ISO certifications were confirmed in 2023

ISO 9001:2015 Quality Management

0 non-conformities

0 opportunities for improvement

ISO 45001: 2018 OH&S Management

1 minor non-conformity

6 opportunities for improvement

ISO 22301: 2019 Business Continuity Management

2 minor non-conformities

0 opportunities for improvement.

ISO/IEC 27001: 2013 Information Security Management

3 minor non-conformities

3 opportunities for improvement.

ISO 14001: 2015 & EMAS Environmental Management

0 non-conformities

6 opportunities for improvement.

EXTERNAL AUDITS AND EVALUATIONS | EVALUATIONS

External Evaluations

[MB recommendation](#) from Third External Evaluation addressed and closed during the 2023 June MB meeting

4th External Evaluation will be kicked-off in the course of 2024 by the EC to be finalized by March 2026

Review of the policy of Independence

Dec 2023: MB endorsed the independence sub-group recommendations on the revision of the policy of independence (following ex-post evaluation)

Jun 2024: Revised Independence policy will be presented to the MB for adoption.

Evaluation of the EFSA Networks

First evaluation of the EFSA networks will be delivered in Q2 2024 (to gather recommendations on on the possible continuation or discontinuation of each network or sub-group)
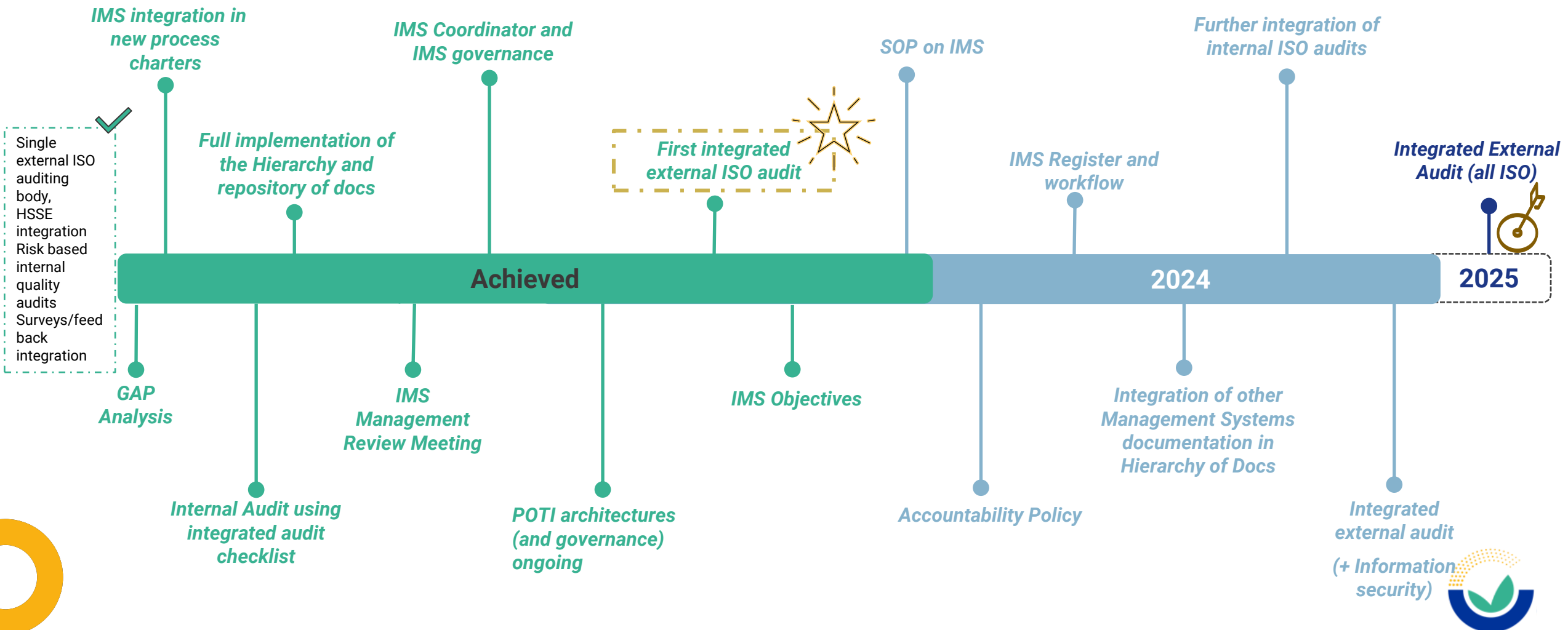
Out of **41** monitoring criteria, **only 6** are registering a minor deviation under the principles **highlighted, without** however **posing any concerns** on the functioning of the internal control principles.

Internal Control Principles	
1. EFSA demonstrates a commitment to integrity and ethical values.	10.EFSA selects and develops control activities that contribute to the mitigation of risks to the achievement of objectives to acceptable levels.
2.The Management Board demonstrates independence from management and exercises oversight of the development and performance of internal control through the Audit Committee monitoring assurance activities, audit results and the outcome of the Discharge procedure.	11. EFSA selects and develops general control activities over technology to support the achievement of objectives
3. Management establishes, with over-sight, structures, reporting lines and appropriate authorities and responsibilities in the pursuit of objectives.	12. EFSA deploys control activities through corporate policies that establish what is expected and in procedures that put policies into action.
4. EFSA demonstrates a commitment to attract, develop and retain competent individuals in alignment with objectives	13. EFSA obtains or generates and uses relevant quality information to support the functioning of internal control.
5. EFSA holds individuals accountable for their internal control responsibilities in the pursuit of objectives.	14. EFSA internally communicates information, including objectives and responsibilities for internal control, necessary to support the functioning of internal control.
6. EFSA specifies objectives with sufficient clarity to enable the identification and assessment of risks relating to objectives.	15. EFSA communicates with external parties about matters affecting the functioning of internal control.
7. EFSA identifies risks to the achievement of its objectives across the organisation and analyses risks as a basis for determining how the risks should be managed	16. EFSA selects, develops and performs ongoing and/or separate assessments to ascertain whether the components of internal control are present and functioning
8.EFSA considers the potential for fraud in assessing risks to the achievement of objectives.	17. EFSA assesses and communicates internal control deficiencies in a timely manner to those parties responsible for taking corrective action, including senior management and the Management Board, as appropriate
9.EFSA identifies and assesses changes that could significantly impact the internal control system.	

LOOKING FORWARD|
IMS 2024 UPDATED IMS ROADMAP

IMS integration in new process charters

IMS Coordinator and IMS governance

SOP on IMS

Further integration of internal ISO audits

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

Full implementation of the Hierarchy and repository of docs

First integrated external ISO audit

IMS Register and workflow

Integrated External Audit (all ISO)

Achieved	2024	2025

GAP Analysis

IMS Management Review Meeting

IMS Objectives

Integration of other Management Systems documentation in Hierarchy of Docs

Internal Audit using integrated audit checklist

POTI architectures (and governance) ongoing

Accountability Policy

Integrated external audit (+ Information security)

LOOKING FORWARD|
IMS KEY OBJECTIVES 2024 – DEVELOPMENTS

IMS management reviews covering all MS (ISOs and ICF)

IMS roadmap implementation : Information security audit added to **integrated external ISO audit**

IMS roadmap implementation : further **integration of internal audits**

IMS roadmap implementation : delivery of **IMS register and workflow**

IMS roadmap implementation : Hierarchy of documents **– complete integration of HSSE docs** including scientific guidances)

Integration of IMS report in AAR

Accountability policy integration with IMS and DMF in collaboration with EMPOWER Office

Revised **Independence policy**

Revised **Information Management policy**

Evaluations: evaluation of networks

Evaluations: contribute to EFSA external evaluation

Evaluations: internal mid term strategy review and TR measures evaluation

IAS end2end audit

Updating of the **carbon footprint** assessment of EFSA (reference year 2023)

Contract for travel agency services including green criteria

Garden revamping (increased biodiversity and visual impact)

On-line training courses for all personnel (OHS First Course and OHS Refresh)

Cybersecurity ensured and aligned with new regulatory framework