# Note to the Advisory Forum on the EFSA Strategy 2020 Implementation Plan

## 1. Objective of the meeting

With regards to the Strategy 2020 initiative, the objective of the December 2015 Advisory Forum meeting is as follows:

- Present and discuss a draft list of actions implementing the strategic objectives, as well as their upstream expected outcomes at the level of the operational objectives, with a particular focus on Member State cooperation elements;
- Capture the AF feedback in view of the further definition of the implementation plan before its final submission for adoption by the EFSA Management Board in March 2016.

## 2. Scope of the document

Since the previous discussion with the Advisory Forum on the EFSA Strategy in October, further work has been undertaken on:

- EFSA Strategy document: collection of inputs from the EFSA EXPO conference, summary compilation of comments received from the public consultation and engagement activities internally in EFSA (e.g. a series of info-sessions with EFSA staff, etc);
- Strategy implementation plan: progress in the definition of the actions that will be implemented by 2020 (on-going and new) to develop the necessary capabilities and realise EFSA's strategic objectives, first estimations of the underlying resource needs (FTEs and budget), development of an integrated, performance-based approach for the monitoring and review of the Strategic plan, as well as the development of Key Performance Indicators (KPI) to be used.

The document attached to this note contains elements of the strategy implementation plan, specifically a draft list of implementing actions and their expected outcomes at the level of the defined operational objectives, and is aimed at providing the basis for the discussions to be held at the meeting.

## 3. Next steps

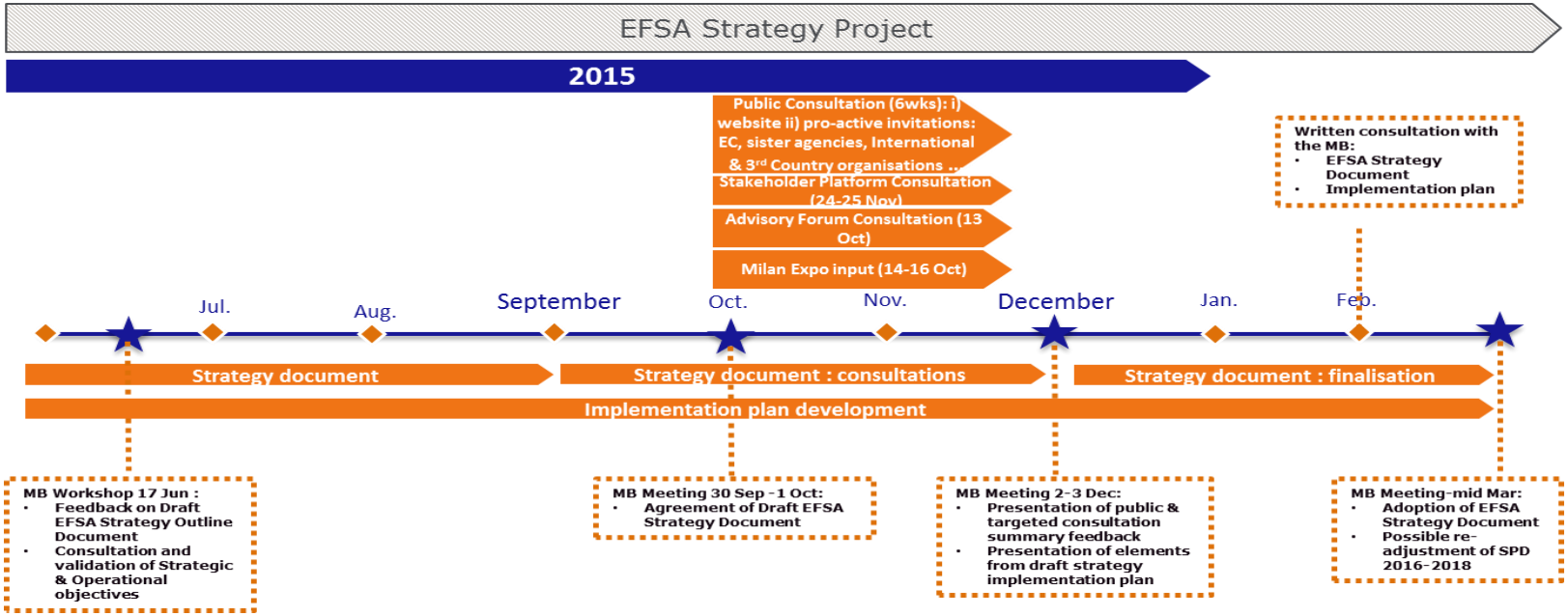
The graphic below presents the key next steps and their timing to finalise the strategy document and the implementation plan by March 2016. This includes the following main activities:

- December Management Board meeting until March Management Board meeting:
    - Collection of feedback by AF members until 21/12/2015;
    - Revision of Strategy document: integration of feedback received during

the consultations, from the MB and the AF

- Finalisation of the implementation plan: integration of feedback received by the Board and the AF in December to elaborate and complete the strategy Implementation Plan.

- February 2016: written consultation with the Management Board on the Strategy and Implementation Plan documents.
- March Management Board meeting: the final draft of the EFSA Strategy document (including layout) and its Implementation Plan will be presented for adoption by the Management Board.


EFSA Strategy Project
2015
Public Consultation (6wks): i) website ii) pro-active invitations: EC, sister agencies, International & 3rd Country organisations ..
Stakeholder Platform Consultation (24-25 Nov)
Advisory Forum Consultation (13 Oct)
Milan Expo input (14-16 Oct)
Written consultation with the MB:
• EFSA Strategy Document
• Implementation plan
Jul.
Aug.
September
Oct.
Nov.
December
Jan.
Feb.
Strategy document
Strategy document : consultations
Strategy document : finalisation
Implementation plan development
MB Workshop 17 Jun :
• Feedback on Draft EFSA Strategy Outline Document
• Consultation and validation of Strategic & Operational objectives
MB Meeting 30 Sep - 1 Oct:
• Agreement of Draft EFSA Strategy Document
MB Meeting 2-3 Dec:
• Presentation of public & targeted consultation summary feedback
• Presentation of elements from draft strategy implementation plan
MB Meeting-mid Mar:
• Adoption of EFSA Strategy Document
• Possible re-adjustment of SPD 2016-2018

## 4. EFSA Strategy 2020 Implementation Plan

Below a first indication of the **expected outcomes** and corresponding **implementing activities** by Strategic and Operational Objectives is presented. This is important to note that this is still work in progress. After discussion, the activities list will be further developed, road mapped and prioritised as necessary.

# SO1: Prioritise public engagement in the process of regulatory science.

| Expected outcomes | Implementing activities |
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| **OO 1: Ensure that mandates capture societal needs** | |
| Prioritised EFSA mandates are framed considering stakeholder inputs. EFSA's self-tasking initiatives are planned and implemented taking into account societal needs. Clear guidance is provided by EFSA to applicants for regulated products on the relevant mandates and on issues related to the preparation of application dossiers. | Ex-ante impact assessment (feasibility, costs and benefits) to inform the implementation of measures in EFSA's risk assessment workflow towards increased transparency and engagement (TERA project)<br><br>Targeted social science research, evaluation and monitoring to inform engagement activities |
| | Implementation of measures towards ensuring that mandates capture societal needs:<br><br>• Simplification of requirements to take active role in Public Consultation<br>• Pre-notification of interested parties of Public Consultation<br><br>Implementation of measures towards ensuring that mandates capture societal needs. pending the results of the impact assessment:<br><br>• Public Consultation of framing mandates<br>• Pre-submission meetings with applicants to ensure clarification of data requirements<br>• Meetings with Stakeholders to ensure mutual understanding of question to be addressed |
| | Further develop the customer-oriented approach for applications of Regulated Products, by strengthening support (info-sessions and guidance) to applicants at the pre-submission phase. |

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| | Strengthening the liaison office in Brussels to maximise engagement and communication effectiveness |
| **OO 2: Make documentation on information gathering and the evaluation process available** | |
| All documentation and information relevant to the production of EFSA scientific outputs is accessible to the public and linked to the outputs, allowing their re-use and dissemination. Confidentiality of documents and data has been defined, agreed with relevant parties, and is respected. The submission and management of application dossiers and the information contained in them has been automated. | Implementation of measures to make documentation on information gathering and the evaluation process available (TERA project):<br>• Publish full biographies enabling the public to scrutinise experts backgrounds<br>• Documentation of the criteria of selection of WG members enabling the auditability of expert selection process<br>• More feedback on the extent and on the reasons why certain data were/were not used to empower the public to scrutinise EFSA work<br>• Minutes reflecting the flow of the discussions towards clarity of the decision making<br>• Increase transparency of the weight of evidence approach towards a harmonized way of evidence integration<br>• Consistent decision making on confidentiality of application dossiers (+ right to be heard), ensuring legal certainty<br>• Transparency on key studies identification and reasons to discard studies on harmful effects, empowering the public to scrutinise EFSA work<br>• Acknowledge the role of SHs contribution into EFSA's work, ensuring transparency of the engagement process<br><br>Implementation of measures to make documentation on information gathering and the evaluation process available, pending the results of the impact assessment:<br>• Documentation of the criteria of the selection of Hearing experts enabling the auditability of the expert selection process<br>• Proactive release of data/information in a readable/reusable format to empower the public to scrutinise EFSA work<br>• Increased accessibility to key data packages of MSs to build knowledge community<br>• Q&A document (also covering stop the clock), towards establishing good administrative practice<br>• Consistent approach to allow applicants addressing all issues during stop clock window to ensure clarity to applicants on study requirements<br>• Flash summary/abstract after the plenary meeting adopting an opinion to increase process predictability |

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| | Development of an electronic workflow to automate and make more efficient the submission and management of application dossiers for regulated products (MATRIX project) |
| **OO 3: Foster an engaged scientific debate** | |
| Stakeholders and citizens can participate regularly in defined check-points throughout the development of scientific outputs, including for regulated products. | Implementation of measures to foster an engaged scientific debate (TERA project):<br>• Consultation on missing data/information to be considered by EFSA to widen EFSA's evidence base<br>• Open Panel plenary meetings extended by half a day/year/panel towards increased public engagement<br><br>Implementation of measures to foster an engaged scientific debate, pending the results of the impact assessment:<br>• Consultation on the RA methodologies to improve scientific quality and ownership<br>• Open and/or targeted call for data/information to widen EFSA's evidence base<br>• Consultation on the call for data/information format to ensure clarity on requested data<br>• Public consultation on draft opinions to improve scientific quality and ownership<br>• Post public consultation technical hearings to increase the likelihood of convergent opinions<br>• Pre public consultation meetings with MSs to increase the likelihood of convergent opinions<br>• Structured process allowing to post comments on opinions, empowering the public to scrutinise EFSA work |
| | Further develop the customer-oriented approach for applications of regulated products, by an increased engagement with applicants throughout the life-cycle of applications (e.g. webinars, applicant hearings, targeted support to SMEs) |
| **OO 4: Ensure clarity in the communication of findings** | |

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| The visibility and use of the EFSA Journal has been increased, a fit for purpose peer review system is in place, the outputs published in the Journal include links to underlying data and metadata (documents and methods used), engagement post-publication is made possible, messages are tailored for the general, international audience according to the needs | Implementation of measures to ensure clarity in the communication of findings, , pending the results of the impact assessment (TERA project):<br>• Put in place external peer review system to ensure scientific and communication quality<br>• Publication of data/information used and discarded in a readable format, empowering the public to understand, re-use and scrutinise EFSA work<br>• Publication of applied assessment methodologies, empowering the public to understand, re-use and scrutinise EFSA work<br>• Publication of information on applications (except sensitive data) including gaps where they exist, empower the public to understand and, scrutinise the outcome of scientific outputs and re-use the underlying data<br>• Post-adoption follow-up meetings towards clarity on outcome of risk assessments<br>• Review language regime of outputs, to increase reach of EFSA's scientific outputs |
| | Targeted communications research, evaluation and monitoring to inform communication activities |
| | Build a global network on risk communication to internationalise messages. |

## SO2: Widen EFSA's evidence base and maximise access to data.

| Expected outcomes | Implementing activities |
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| **OO 1: Adopt an Open Data approach** | |
| EFSA scientific data (structured and unstructured) are accessible to the outside world insofar as possible. Agreements with data owners and providers are in place and appropriate data security is implemented. Confidentiality and security of data have been defined, agreed with relevant parties, and are respected. New scientific knowledge is generated by external parties re-using EFSA data. | Development of a Data Warehouse, a central repository of structured data (currently without data from application dossiers) used in EFSA's outputs with a user interface and tools to access the data at different levels of access for EFSA's stakeholders in accordance with the EFSA DWH Access Rules (DWH) |
| | Development of a system to assign DOIs (Digital Object Identifiers) to data, allowing the linking of data used in EFSA outputs and tracing of data re-use (DOI) |
| | EFSA's Data Collections metadata are published in the EU Open Data Portal in accordance with the EFSA DWH Access Rules, and EFSA fosters initiatives promoting the re-use of EFSA's data, e.g. through innovation campaigns (EU Open Data Portal) |
| | Develop the Virtual Library, a repository for peer and non-peer reviewed documents and metadata (from EFSA projects, MS reports, models and software), and a portal with advanced search functionalities, to offer better access to unstructured data and literature underpinning EFSA's scientific outputs (Open SCAIE) |
| **OO 2: Improve data interoperability to facilitate data exchange** | |
| EFSA has formed partnerships and has set up data sharing/exchange mechanisms with a wider pool of scientific and regulatory bodies ensuring a wider coverage of data. EFSA has set-up a framework and respects and promotes the use of common standards for semantic | Introduction of a framework for information access management, centralising the management of Users and Users Groups accessing and retrieving all EFSA information and adoption of metadata standards across the different IT applications and business needs |

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| | interoperability. | Formation of a data exchange/open data networking group towards widening EFSA's evidence base; participation in European and/or international interoperability working groups/initiatives with data providers (e.g. EU agencies, JRC, FVO, Member States, International bodies), ensuring interoperability, where feasible, with existing or new data collections in the EFSA's scope. |
| **OO 3: Migrate towards structured scientific data** | | |
| | EFSA receives and provides pertinent scientific data in structured and agreed formats. EFSA fosters the submission and re-use of structured data to foster innovation and new methods in risk assessment. | Definition of a structure for the application dossier data including the definition of harmonised structured sections of dossiers. Foster the submission of structured data and implement a tool to transfer into the SDWH end-points used in the risk assessments and develop a reporting and data mining tool to retrieve regulated product data including end points validated by EFSA (Matrix project) |
| | | Identify scientific data that could be harmonised using a structured format (i.e. currently unstructured or new data collections), building on existing international standards. Improve on-line access to validated and consolidated structured scientific data, providing support for their re-use, e.g. for in silico, bio-informatics and simulation methods, within EFSA remit; |

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

| Expected outcomes | Implementing activities |
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| **OO 1: Set up and implement a common risk assessment and research agenda with Member States, in collaboration with international partners** | |
| A common risk assessment and a common research agenda have been set-up, in cooperation with EU and International partners. Implementation actions have been planned and are regularly reviewed. Their implementation is ongoing via prioritised activities. EFSA's cooperation fora and grant/procurement schemes work in synergy and are instrumental to ensure capacity sharing and capacity building among the Member States and international/3rd country bodies in addressing core business needs, as well as the risk assessment and research agendas. This avoids duplication of activities and provides solutions to resource bottlenecks in EU risk assessment. | Set up, coordination and implementation of a common risk assessment agenda: i) common priorities, ii) their planning and implementation, (iii) role/task allocation among EU and, where relevant, International partners. |
| | Establish clusters with other EU Agencies to identify, plan, implement and review research priorities and establish close collaboration with DGs JRC, R&I and Agri as well as with the EU reference laboratories for the funding of key research projects and the monitoring of their early results. Identify the areas for integration in the clusters with International partners. |
| | Streamline, optimise and integrate operations of EFSA's cooperation fora to maximise impact at national, EU and international level. Strengthen selected cooperation fora (e.g. with new partners or in new areas) and develop new ones (e.g. with EU Agencies or in the international sphere). Move from bilateral to multilateral fora in the area of international cooperation. |
| | Further develop and implement innovative schemes (e.g. grants and procurements) enabling the evolution from cooperation to partnerships, capacity sharing and capacity building in addressing core business needs as well as the risk assessment and research agendas. |
| **OO 2: Foster the EU and international risk assessment community** | |
| EFSA, Member States and International partners are cooperating closely to foster the EU and international risk assessment | Develop and implement an attraction package in cooperation with Member States to attract and retain the best scientific assessment scientists for EU risk |

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| community: the necessary competences are identified and regularly reviewed, actions are in place to foster the development of the necessary expertise and capabilities, bottlenecks and incentives for attracting experts for EU risk assessment have been identified and are addressed; the sourcing with multidisciplinary risk assessment expertise has been improved. | assessment (experts and staff). |
| | Define EFSA's framework for risk assessment competency management, from the mapping of technical and behavioural competencies in a European perspective, to its use for selection purposes. |
| | Cooperate with Member States to foster a risk assessment talent pool: assess the availability of needed competencies in the market and establish measures to continuously develop them, spanning from young to senior scientists. |
| | Foster the continuous development of key, interdisciplinary competencies and capabilities for scientific assessment in the remit of EFSA, spanning young to senior scientists. Strengthen: existing and set up and implement new dedicated mobility schemes (e.g. PhD exchanges, guest scientists), a fellowship programme and a coordinated scheme for scientific training, in close link with the generation of new capabilities and methodologies. |
| | Further develop, streamline and focus events and campaigns to support the attraction package and the networking between experts, national bodies and other Centres of Expertise, as well as relevant stakeholders. |
| **OO 3: Review and further develop EFSA's scientific assessment model** | |
| EFSA has taken stock of best practises and has optimised its workforce model under the current regulatory regime, making best possible use of available capacities, getting timely access to the necessary expertise, and ensuring clarity in the roles and responsibilities of the different actors. EFSA is proactive in proposing and finding solutions with regards to its expertise needs and is prepared to address future challenges and opportunities. | Review the available capacity, roles and tasks of Panels, working groups, EFSA staff and networks within the scientific evaluation process and coordinate initiatives towards a more effective and efficient model. Assess EFSA's workforce needs and develop a model and a tool for workforce (staff & experts & other contributors) planning. |
| | Explore, pilot and start using new ways of increasing risk assessment capacity:<br>• Crowdsourcing<br>• Cognitive Computing |

## SO4: Prepare for future risk assessment challenges.

| Expected outcomes | Implementing activities |
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| **OO 1: Strengthen EFSA's preparedness to anticipate and respond effectively to food safety risks** | |
| EFSA is prepared for the future. Priority areas and actions for preparedness are proactively and timely identified, in collaboration with key partners and stakeholders. Self-tasking is coordinated and structured, fully integrated with the emerging risks identification and crisis preparedness processes. EFSA is at the forefront of addressing new scientific issues and is proactive rather than reactive, enabling a constructive dialogue with stakeholders. EFSA is widely seen as a key and active guardian of EU food safety. | Develop a process for the identification, planning and implementation of prioritised preparedness actions and possible integration in the risk assessment and research agendas |
| | Further strengthen the capability on emerging risks screening and preparedness:<br>• Develop web based monitoring tools, horizon scanning, early identification and rapid response in the area of Plant hazards for emerging risks in general.<br>• Data collection, surveillance, risk profiling for introduction and spread of vector borne animal diseases |
| | Further develop the "toolbox" for crisis preparedness and management, with focus on:<br>• Trace-back and trace forward methodologies<br>• New multi-year training programme, improving collaboration and exchange of best practices with external partners |
| | Develop capabilities in chemical risk assessment. Integrate new approaches in chemical risk assessment towards addressing toxicology in the absence of data, reducing uncertainty, 3Rs, addressing complex questions:<br>• Endocrine disruptors and non-monotonic dose response<br>• Integration of epigenetics in risk assessment<br>• Chemical mixtures and cumulative risk assessment<br>• Nanotechnology<br>• Update on read-across approaches such as TTC<br>• Modelling human variability (genetic, microbiota) in metabolic, toxicokinetic and toxicodynamic processes<br>• Human biomonitoring |

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| | • Developmental Neurotoxicity Testing Strategy (focus on pesticides)<br>• Optimising control experiments in regulatory risk assessment of pesticides |
| | Further development of environmental risk assessment capabilities:<br>• Develop a holistic approach to the risk assessment of bee health<br>• Develop a coordinated framework for environmental risk assessment towards landscape-based environmental/ecological risk assessment, usable in Guidance documents and compatible with modelling activities<br>• Further developments in ecotoxicology and environmental fate and behaviour for pesticides assessment |
| | Develop a coordinated approach across EFSA Panels and in collaboration with sister agencies for the development of a holistic approach on anti-microbial resistance |
| | Further develop approaches for biological risk assessment<br>• Integrate the knowledge from different areas (PLH, BIOHAZ, GMO, PPR) in predictive modelling for biological risks.<br>• Microorganisms used as plant protection products<br>• Development of a framework for relevant scientific information and criteria for suggestion of Microbiological Criteria<br>• Application and use of whole genome sequencing for risk assessment<br>• Investigations to fill in the gaps regarding the epidemiology of food born viruses (Hepatitis E epidemiology and Norovirus)<br>• Methodology and impact of current and new methods for controlling Campylobacter from farm to fork<br>• Quantitative pathway analysis of plant pest introduction with commodities<br>• Research and data generation of introduction, spread and disease of key plant pests, e.g. Xyllela |
| | Further develop capabilities in animal welfare risk assessment on animal-based indicators of animal welfare |
| | Develop EFSA's capability in exposure assessment by moving towards a holistic approach in exposure assessment and further developing methodologies for the estimation of non-dietary (combined) exposure to chemicals; use the above in developing combined exposures from the dietary and non-dietary routes |

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| | Develop tools and approaches supporting food inspections, with regards to:<br>• Risk ranking of biological and chemical (contaminants) hazards<br>• Surveys design towards risk-based inspection<br>• Plant health surveillance as a harmonized and coordinated approach to survey planning and a risk based surveillance |
| | Develop a process for the identification, planning and implementation of prioritised actions in view of the updating opinions (e.g. availability of new data) |
| **OO 2: Support the development and use of harmonised methodologies for risk assessment across the EU and internationally** | |
| EFSA scientific assessment methodologies are fully mapped with respect to the established guidance documents, gaps have been identified and prioritisation of actions for addressing these gaps is completed. A long term plan for guidance development and review is being implemented, taking into account international developments. All EFSA guidance documents are fully implemented within EFSA. MS, EU and International agencies are aware of all EFSA guidance documents which are seen as world leaders. This results in fewer divergences of opinion and increased transparency | Develop and maintain EFSA scientific assessment methodologies framework:<br>• Mapping of EFSA scientific assessment methodologies and respective guidance documents (cross-cutting and sectoral) and gap identification<br>• Establishment and implementation of a process for the maintenance and updating of EFSA's methodologies framework i.e. for new guidance or for revision of existing guidance and monitoring of their implementation in cooperation with Member States and International partners |
| | Continue developing (through revision of existing guidance documents and the establishment of new guidance documents) cross-cutting guidance in prioritised areas, including:<br>• Benchmark dose<br>• Biological relevance for toxicological risk assessment<br>• Harmonised methodologies for the characterisation of uncertainties<br>• Weight of evidence<br>• Population subgroups<br>• Guidance on extrapolation of data from lab animals to farm species<br>• Equivalence testing,<br>• Implementation of new methodologies to support systematic review process<br>• Data representativeness,<br>• Critical appraisal tools |
| | Continue developing (through revision of existing guidance documents and the establishment of new guidance documents) sectoral guidance in a more coordinated manner across the different areas. Assess synergies and overlaps in the planned development of guidance across the different areas, and prioritise their development, in close cooperation with the |

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| | | cross guidance development |
| **OO 3: Become an international hub in methodologies and tools for risk assessment** | | |
| | All tools and methods used for EFSA scientific assessment are available online and instruction on their use is easily accessible. Commonly used scientific assessment tools can be linked to through EFSA resources such as the website. Greater transparency is achieved, the EFSA hub becomes an international reference. | Develop a platform to host methodologies and tools used in EFSA on EFSA's website and making them available to the public. |
| | | Explore the creation of a hub for linking to others' methods and tools in cooperation with Member States and international partners. |

## SO5: **Create an environment and culture implementing EFSA's values.**

| Expected outcomes | | Implementing activities |
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| **OO 1: People: build a culture that puts EFSA's values into practice** | | |
| | EFSA staff, experts and partners demonstrate a shared understanding of EFSA's mission, as well as accountability and adherence to EFSA's values in their daily activities and regular practises; EFSA's managerial community leads by example. EFSA has aligned performance management and people development to EFSA Strategy 2020 values and objectives and to this end has put in place a set of reward practises. | Develop leadership awareness, establish a leadership pipeline and a managerial community that sets the example and reinforces behaviours that put into practice EFSA's values. Introduce standards and related indicators to set expectations and measure managerial performance. |
| | | Establish, operationalise and embed reputation management in the culture of organisation and the daily practices of managers, staff and experts. Reinforcing internal communication capacity to enable strategic transformation to staff and experts |
| | | Align performance management and people development to EFSA Strategy 2020 values and objectives: define standards, monitoring scheme, development practices and reward system, also via exploring innovative approaches towards the promotion and |

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| | maintenance of a reward culture for EFSA staff |
| | Putting innovation into practice: frame innovation under the innovation priority of the EC, implement a process for the identification, award and implementation of innovative ideas by EFSA staff as well as from the public at large. |
| **OO 2: Organisation and process: develop an environment focused on improving organisational performance and capabilities** | |
| EFSA has established an operational framework to put in practise its values and ensure delivery of strategic objectives 1-4:<br>• An integrated governance framework, enabling decision making.<br>• An integrated business process architecture and capability building approach<br>• A decision making process that ensures objectivity<br>• Innovative collaboration and engagement spaces (physical and virtual) for staff, experts, stakeholders, and the general public, used regularly for engagement and cooperation.<br>• An environment fostering staff wellbeing<br>• An enabling technological environment | Definition of an integrated EFSA Governance framework, based on a coherent, consistent and harmonised business process architecture, enabling decision-making. |
| | Establish an integrated capability building approach, based on a business process architecture, and use it to ensure coherence in the implementation of EFSA's Strategic plan.<br>• Establish an effective corporate business control function, controlling effective performance management and strategic execution<br>• Link EFSA's strategic objectives impact to its capabilities, processes, organisation structure and technology, and coordinate the implementation or necessary alignments, ensuring in all organisational changes appropriate change management initiatives.<br>• Streamline EFSA's initiatives in compliance and controlling of risks, quality and continuous improvement. Ensure appropriate certification (ISO9001) |
| | From independence to objectivity: putting in place a decision making process that ensures objectivity |
| | Development of cooperation and engagement platforms and tools (digital and physical) for internal and external (experts, Member States) collaboration as well as for public engagement |
| | Further developments with regards to site management (office spaces, social spaces, towards appropriate certifications (OSHAS, EMAS) |
| | Put in place and maintain a business continuity system |