



PARTNERSHIPS FOR RISK ASSESSMENT

NOTE TO THE MANAGEMENT BOARD

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1. Introduction

1.1. Outline of the item

Background

The setting of the present item in the agenda is a **result of the discussions** in the 94th Management Board meeting in March 2023. There, some members asked EFSA's senior management about the increased financial investment in scientific cooperation, following the entry into force of Regulation (EU) 1381/2019 (the "Transparency Regulation"). In the same meeting, the Executive Director gave a snapshot of the evolution of grants and procurement as part of the presentation of the Annual Activity Report 2022, emphasizing the need for EFSA to boost scientific cooperation further by promoting partnership arrangements with competent organisations¹ in Member States to support the preparation of risk assessment opinions. A more in-depth discussion in the following Management Board meeting was promised.

Rationale

In 2018, at the Council's Working Party in charge of examining the legislative proposals which a few months later led to the adoption of the Transparency Regulation, EFSA's representatives indicated that approximately 65% of the budget increase foreseen by the new regulation (i.e. approx. EUR 40.6 million out of EUR 62.5 million) would be "**redistributed to Member States**", mainly via the reimbursement to panel and working group experts (EUR 10,6M) and by means of increased grants and procurement (EUR 30 million).

The consolidated figures for 2022, included in this note, show that **EFSA has increased** expenditure in cooperation, but has not yet reached the target set at the time.

Most cooperation happens via grants and procurement. Of that budget, almost two thirds went to investments on **preparedness**, research, new capabilities, data and methods, while the rest were dedicated to **preparatory tasks** for EFSA's risk assessment opinions.

It is also important to note that most of the latter still takes place in the form of **ad-hoc** contracts/agreements, often transactional, one-off and limited in time, scope and number of parties involved.

In this regard, EFSA's **aim** is threefold:

- further **increase cooperation** activities overall;
- **invert the balance** and increase the cooperation activities directly supporting the preparation of risk assessment advice, thus helping to increase speed and sustainability of EFSA's operations;
- move from ad-hoc cooperation to long-term, structured **partnerships** with (groups of) competent organisations in Member States.

¹ Competent organisations include institutes, research centres, national agencies and other bodies designated by the Member States, on the basis of criteria covering scientific and technical competence, efficiency and independence, pursuant to article 36 of [Regulation \(EC\) 178/2002](#)



The Management Board members, in their diversity of institutional profiles, could act as **advocates** with national and European authorities and help steering a common effort to facilitate partnerships.

Objectives

- Present and discuss the **state of play** of EFSA's scientific cooperation and the opportunities for risk assessment partnerships.
- Discuss the **role** of the Management Board to help build partnerships
- Discuss the advocacy **approaches** needed by Management Board members, considering the specificities of different Member States

1.2. The challenges for risk assessment cooperation

The European food safety system, a shared project built over the past two decades, has consistently provided the highest standards of food safety to EU consumers. The realm of regulatory science, in general, and food safety risk assessment, in particular, face a multitude of challenges that call for **renewed efforts in boosting scientific cooperation and developing partnership solutions**.

The **big picture** is complex and includes new emerging risks, climate change, demographic shifts, new political priorities and societal expectations. These global and European contexts result in increased pressure on the timely and fit-for-purpose production of scientific advice by EFSA and its health and food safety ecosystem.

Firstly, EFSA **needs to enhance responsiveness** to requests for scientific advice from EU risk managers and policy makers. This would avoid bottlenecks in a market in need of swift but thorough assessment of innovative products and processes. Plus, the implementation of several current ambitious policies in the EU, such as the Farm to Fork Strategy, the Biodiversity Strategy and the Chemicals Strategy for Sustainability needs the scientific advice and technical support from actors like EFSA.

Furthermore, the **complexity of mandates** is increasing. The questions have a stronger transdisciplinary dimension, as One Health approaches gain relevance in food safety, recognizing the interconnection between the health of people, animals, plants, and their shared environment. The degree of novelty, scarcity or overabundance of data in diverse formats, acceptable levels of uncertainty, and the breadth of Terms of Reference are other factors contributing to the complexity of the risk assessment process.

To deal with a bigger and more complex workload and keep up with **the rapid evolution of science**, risk assessment must develop new methodologies and integrate new disciplines, enlarge the pool of experts and actors available to conduct and support the work and exploit the opportunities offered by new technologies.

The above challenges are exacerbated as they compound with the **multiplicity and diversity of actors** and interests characterising the food safety environment. This includes the traditional Risk Assessment community comprising EU agencies, EC services, Member States' national organisations working on food safety risk assessment or risk management bodies and, overall, competent organisations in Member States. However, the ecosystem also includes actors and groups that go beyond the aforementioned parties, such as stakeholders, professional groups,



research institutes and academia, the industry, non-governmental bodies, citizens and citizen scientists, etc. These challenges are amplified by the pervasiveness and speed of real-time interaction and information sharing via the net and social media.

The **Transparency Regulation** answered partly to these challenges by enabling more transparency of risk assessment data and processes, by prompting more engagement with stakeholders and by fostering joint/coherent risk communication at EU and national level. It also paved the way for further enhancing cooperation and partnership between EFSA and competent organisations in Member States, which is in fact a key strategic objective of EFSA (and the focus of this paper).

It is evident that furthering interaction and engagement between actors can **open the door to new possibilities** in the collection, processing, interpretation, use and sense-making of information in support of risk assessment needs. It can also optimize processes and workflows and minimize divergences among risk assessors, essential to guarantee that regulatory science is responsive and fulfils its role in a timely manner.

To **move ahead** requires among others alignment of work programs, harmonization of methodologies, standardization of data, integration of new technologies, capacity building and common management of knowledge and expertise among organisations. But first and foremost, it requires will and determination at political level.



2. Cooperation to date

2.1. The framework for scientific cooperation

Since its establishment, cooperation has been a **core value** and feature of EFSA. By design its operating model leverages expertise from across the EU and beyond, gathering and integrating knowledge from a wide range of scientists, academics, institutes, national risk assessment authorities.

Expertise mobilisation by EFSA broadly occurs in three ways:

1. **At individual level:** experts employed by other organisations dedicate part of their time to carry out specific risk assessment tasks for EFSA (e.g. collection of data, appraisal of evidence, integration of results) in the context of preparation and adoption of scientific opinions. These experts include members of Panels and Working Groups (approx. 700), members of Scientific Networks (approx. 600) and so-called Individual Scientific Advisors (ISA, approx. 80 in 2022).
2. **At organisation level:** institutes and bodies in Member States (approx. 400), provide clearly specified services (preparatory tasks such as collation of data, literature review, hazard assessment etc..) in the framework of contractual arrangements with EFSA (see below).
3. **Specific for pesticide active substances** (special assessment process defined by EU pesticides legislation): one or more rapporteur Member State(s) prepare(s) a draft assessment report which is then peer reviewed by scientific experts nominated by Member States and coordinated by EFSA.

Relations with **individual experts** are regulated by EFSA's financial regulation, internal rules and contractual arrangements which set out conditions and compensations for their time as well as their expenses. EFSA has over the years consolidated and expanded the pool of scientists from which it selects panel and working group members. It has also developed new contractual solutions (the ISA scheme) whereby individual experts can be chosen for particular assignments, thus allowing to fill expertise gaps in an agile way.

Cooperation with **organisations** (n. 2 above) is provided for by EFSA's Founding Regulation² and is regulated by EU/EFSA financial rules. EFSA has since 2002 implemented these provisions through calls for grants or procurement (see below for more details), resulting in contracts and agreements with hundreds of organisations from all Member States. Despite the diversity of forms, the prevailing model of cooperation until present has been limited in timeframe and scope, mostly configured in ad-hoc transactional basis and involving individual organisations or relatively small consortia.

Even so, along the years, **cooperation has been essential for** EFSA's to fulfil its mandate. In this direction, the Transparency Regulation emphasized the need for increased cooperation to secure the "sustainability of the EU risk assessment in the food chain", providing increased resources for it. Critically, it also provided the margin for broadening the scope of the work that can be entrusted to competent organisations in Member States by specifying that the latter may

² [Regulation \(EC\) 178/2002](#), Art. 22, complemented by implementing rules under Commission Regulation (EC) 2230/2004.



be asked to prepare scientific opinions to be peer-reviewed by the Scientific Panels before adoption³.

EFSA integrated this **ambition** in its Strategy 2027⁴ and has undertaken a review of its cooperation model towards a more systemic and strategic approach. EFSA also adjusted its organisational structure to fit these ambitions by allocating the responsibility to a newly set up unit (KNOW) and by organizing the relevant tasks within a specifically designed process integrated in EFSA's Process Architecture.

Financial instruments for cooperation

EFSA's legal framework allows for **two main types** of instruments to cooperate with organisations:

- **Procurement.** Following general procurement rules from the European Commission, EFSA puts out contracts for the "purchase of services, goods and works" to public tender. All economic operators established in the EU can bid and compete on the basis of quality and price.
- **Grants.** This preferential scheme is foreseen by Article 36 of EFSA's Founding Regulation to enable the close cooperation between EFSA and Member States. EFSA puts out calls for proposals for the performance of risk assessment or capacity building tasks. Only organisations designated by Member States and included in the so-called Art. 36 List (currently 317) can apply and grants are awarded to proposals offering highest quality.

Procurement and grants procedures **result** in direct contracts/grants (fixed duration and contribution) or framework contracts/agreements (cooperation for a maximum of 4 years, with specific orders placed periodically).

The **choice** between one type or the other depends on the case. Grants are generally chosen when EFSA knows there are organisations in the article 36 list with the **capabilities** to deliver the work, whilst procurement is used to access a bigger market, with public advertisement of the calls.

The **confidentiality** and sensitivity of dossiers and potential conflicts of interest are also decisive factors for restricting or broadening the calls.

As for the contractual relation, in procurement EFSA is the **owner of the work**, as sole funder. Instead, grants give more margin for co-ownership, co-design and co-investment. This nature, coupled with the possibility to have framework/long-term agreements, makes grants more likely to help reach win-win situations for EFSA and the other organisations in a longer run, and hence, better fit **to build and solidify partnerships**, as they will be explained later.

2.2. Financial investment in cooperation

As requested at the last Management Board meeting, one of the objectives of this document is to provide the financial state of play of cooperation with Member States, particularly with regard to the ambition set for the implementation of the Transparency Regulation. At the time, EFSA

³ [Regulation \(EU\) 2019/1381](#), Art. 5e.

⁴ [EFSA Strategy 2027](#).



envisaged that roughly two thirds of the EUR 62.5 million provided by the legislation (that is, approximately EUR 40 million) would be **redistributed to Member States**.

Since 2019, EFSA’s expenditure in cooperation through reimbursement to individual experts and grants and procurement has grown by EUR 31.5 million (as per the 2023 forecast). Therefore, there is still a gap to close, which can be attributed to various factors. First, EFSA’s budget has had to respond to challenges from its external context, like the Covid-19 pandemic and the rapid virtualization of work and expert meetings, and inflation and the subsequent adjustments and reallocations among budget titles (e.g., increased incidence of salaries and energy bills). Second, and more relevant to this note, the target presented in 2019 was a long-term one. EFSA has advanced in this transition, making progress to overcome blockers and strengthen incentives (see learnings in point 2.3), but scientific cooperation is not yet at its full potential.

Evolution of grants and procurement

The bulk of EFSA’s scientific cooperation occurs within the frame of grants and procurement. The expenditure via these mechanisms is therefore a **key indicator** to assess the state of cooperation and project its development.

This envelope had been stable in the years prior to the Transparency Regulation, with an average of EUR 9 million between 2014 and 2019. Since the entry into force of the legislation, the **expenditure has grown steadily** (see Figure 1), doubling between 2020 and 2021 and reaching EUR 34.9 million in 2022.

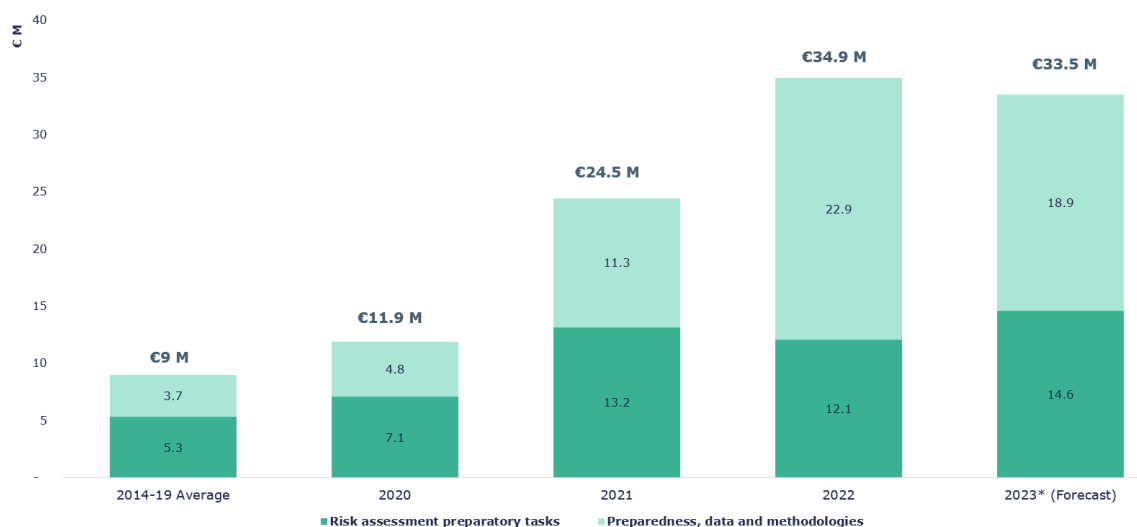


FIGURE 1 GRANTS AND PROCUREMENT EXPENDITURE PER CATEGORY, 2014-2023

Figure 1 apportions expenditure into the **two main categories** structuring EFSA’s work programme. Cooperation in preparedness, research, new capabilities, data and methods accounted for 65% of the expenditure in 2022 (EUR 22.9 million), whilst cooperation for supporting the preparation of question-driven risk assessment opinions was smaller in volume, accounting for the remaining 35% in 2022 (EUR 12.1 million). The evolution shows that the bulk of the budget increase has flowed into projects that support preparedness but don’t immediately help EFSA’s core business (e.g., roadmaps for action in New Approach Methodologies or Artificial Intelligence). By contrast, expenditure in preparatory tasks for risk assessment opinions has grown at a smaller rate. EFSA aims to invert this balance and concentrate cooperation efforts in the latter category, as a key to boost speed and sustainability of risk assessment. In fact, the



current forecast for 2023, besides its slight overall decrease, already presents a shift of proportions in this direction.

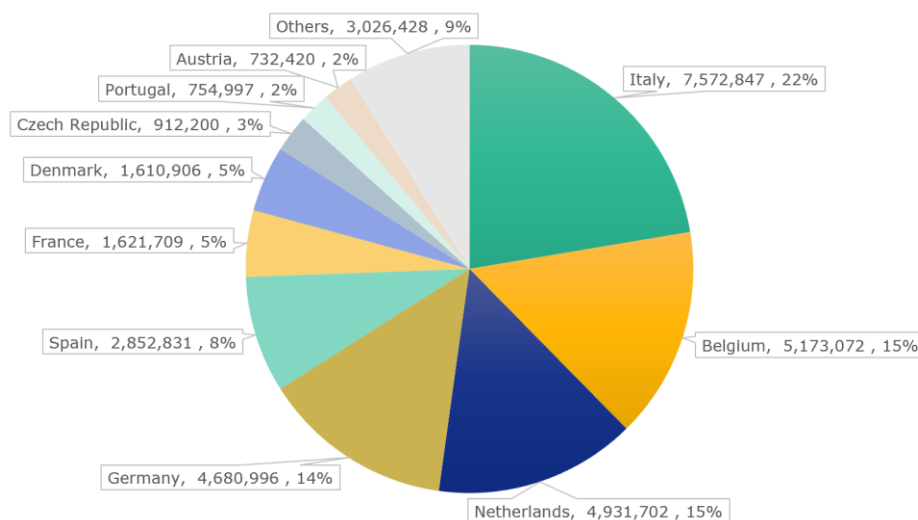


FIGURE 2 TOP 10 RECIPIENT COUNTRIES BY G&P EXPENDITURE IN 2022

As for the distribution of EFSA’s grants and procurement budget **among Member States**, drawing a clear-cut picture is not possible, since consortia do not disclose information on how EFSA’s payments are partitioned among their members. Figure 2 shows a repartition allocating the entire payment to the main recipients, based on the country of entities acting as consortium leaders or sole contractor of the calls. The percentages have to be read with care, but they show how organisations from certain countries take a more active or leading role in engaging with EFSA’s calls.

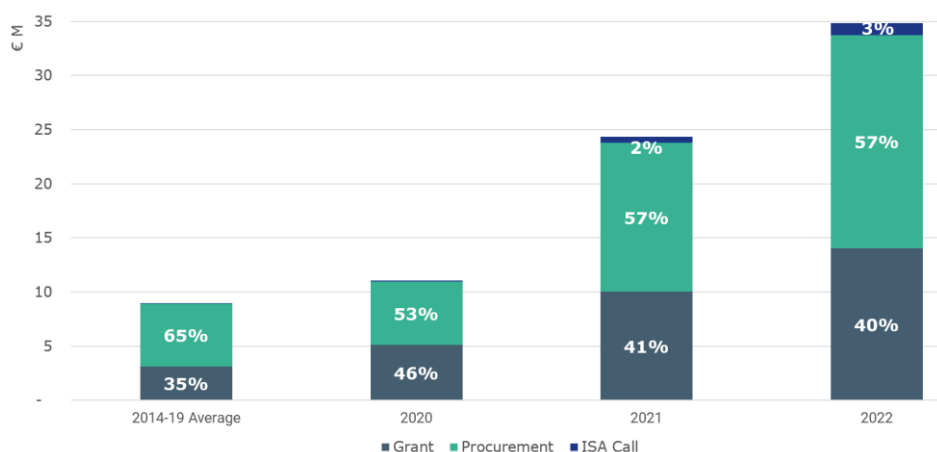


FIGURE 3 EXPENDITURE 2014-2022 PER INSTRUMENTS

As explained in point 2.1, the instruments used for cooperation (grants, procurement and the recently established ISA scheme), vary depending on the cases. Figure 3 shows that in 2022 a bigger budget was spent via procurement (EUR 19.7 million) than grants (EUR 14 million) in 2022, following the trend observed in recent years. With views to the evolution of the cooperation model towards structured and long-term partnerships (see below), it is in the interest of EFSA to invert such balance to **give way for more grants**, with a bigger component of co-design and co-investment.



2.3. Learnings for enhancing cooperation

Despite the increased attention and priority, EFSA's calls **don't always come to fruition**, for instance, they might receive too few applications or harvest suboptimal results.

The experience to date brings many relevant **lessons** for the success of current cooperation and the evolution of its model⁵, which EFSA has been addressing over the years by continuous improvement efforts.

For instance, some **financial conditions** of calls have been reported as not sufficiently attractive for applicants. The reimbursement rate, in some cases, has been felt as insufficient, particularly in countries where cost of expertise is higher. Applicants have also encountered legal hurdles such as tax issues or other regulatory restrictions. Besides these, **procedures** have sometimes been seen as complex and time-consuming, and deadlines tight.

Predictability, with earlier information on upcoming calls and more precise specifications, is also a major factor for organisations to plan and mobilise resources and/or seek partners for building consortia. Precisely, the **lack of available (eligible) staff** very often hinders the possibilities of cooperation, as organisations may find it hard to replace the expertise needed for EFSA.

In response, EFSA has implemented **operational improvements** such as digitalisation and simplification of processes, increase of co-financing rate and unit costs (with new grant funding schemes which allow for profit), better planning, enhanced communication, as well as support and info sessions for applicants.

On substance, a key challenge for EFSA has been **finding relevant scientific expertise**, familiar with EFSA's risk assessment methodologies and capable of matching speed and quality expectations in the deliverables. This might compound with an insufficient organizational capability to execute complex projects, difficulties in meeting transparency or conflict of interest standards, the lack of opportunities for authorship recognition, or the absence of strategic interest or political steering towards EU cooperation.

Capacity building and systematic training for/among certain organisations and/or in certain countries (as well as follow-up mechanisms to effectively capitalize on them) are essential to deal with this problem. On its side, EFSA has incremented resources for these activities, now a prominent part of EFSA's work planning.

Enlarging the article 36 list and/or further involving its members, i.e. reaching out to the many experts' organisations still unfamiliar with EFSA, can also help covering certain areas with a lack of identified actors and improving the dissemination of calls. EFSA is therefore engaged on fostering networking and improving knowledge of expertise in the market (including through its Focal Points in Member States). It is also working towards setting up a more structured repository of previous calls to better inform intelligence.

In fact, keeping up with **scientific development**, information sharing or visibility are expressed by competent organisations as some of the main incentives to work with EFSA.

⁵ EFSA has collected internal and external feedback on cooperation from EFSA staff and competent organisations (see e.g. [presentation](#) to the Advisory Forum).



Experience also shows that the key to bridging the gap and promote cooperation with organisations is to align EFSA’s needs with their **areas of strategic interest**, or to **co-design** relevant work and initiatives. Organisations are more likely to participate if they can implement their own programme whilst also working for EFSA. This has been highlighted to be more important than the actual economic value of transactions.



3. From cooperation to partnerships

3.1. The concept of partnership

The arguments and considerations presented in the previous chapter provide clear evidence that, to increase volume, consistency and impact of cooperation, and hence the sustainability of the EU risk assessment system, a **new approach is needed**, privileging broader and long-term partnership arrangements.

EFSA has since its inception worked on enhancing its **cooperation framework**, hence forward-looking concepts like structural and strategic approaches, mutual benefit, multiannual perspective, common risk assessment agenda have been under discussion for long time. The concept of partnerships was first formalised in 2016, in the context of EFSA Strategy 2020. The Transparency Regulation and subsequently EFSA strategy 2027 have established a clear link between EFSA's long term sustainability and the evolution of scientific cooperation in the direction of partnerships.

Partnerships have been at the centre of discussions in **EFSA's Advisory Forum**, with a document summarizing the partnership concept and suggesting a number of intervention areas to support the development of partnerships.

Partnership is **defined** there as a long-term, trust-based cooperation, built on common values and goals, with attractive win-win elements, primarily between EFSA and competent organisations in Member States, EU Agencies, EC Services, where risks and benefits are shared and that generate, among others, tangible outputs.

Partnerships that correspond to the aforementioned concept are **not intended to eliminate *ad hoc* cooperation**, i.e. transactional, one-off and scope limited (as prevailing thus far). Beyond its practical value and utility to support risk assessment, such cooperation could in fact pave the way for partnership, by helping the parties discovering the potential for mutual benefits and areas of strategic alignment, as well as developing familiarity and mutual trust.

Partnerships can cover a potentially unlimited **variety of activities** and topics ranging from EU and national open-ended research projects to the production of question-driven risk assessment opinions. Examples of research partnership are numerous, as this practice is well consolidated as a modality to implement research programs. EFSA has in recent years increased its engagement as active participants in research partnerships such as PARC (chemical risk assessment) or One Health AMR. On top of this, EFSA has been engaged in promoting and financing (thanks to Transparency Regulation funds) new partnerships in the context of large development programs on new capabilities, data and methods, e.g. in the areas of environmental risk assessment, new approach methodologies and artificial intelligence. This explains the sharp increase of the relevant portion of expenditure via grants and procurement in the category 'preparedness, data and methods' (see Figure 1).

In contrast, as shown in the previous chapter, partnerships for preparatory tasks for risk assessment opinions have proven to be more difficult to establish in particular with regard to identifying common incentives and objectives, aligning work planning cycles and organising and sharing resources and capabilities. Figures reported above illustrate how cooperation and partnership activities in this area **lag behind** in percentage terms. This represents a clear opportunity since the ability of collaboratively producing risk assessment opinions across the



different EU regulatory risk assessment organisations is what ultimately defines a successful EU risk assessment model.

3.2. Making partnerships for preparatory tasks for risk assessment happen

Operational considerations

Partnerships are intended to help implementing work programs and to respond to questions raised by risk managers. They become particularly relevant when there are recurring needs of similar nature or **persistent risk assessment issues** that need to be addressed (e.g. in the area of regulated products) and when there are challenges, e.g. facing **new risk assessment needs** (e.g. assessing urgent authorisations of plant protection products), which are best addressed by pooling of knowledge and expertise in competent organisations.

Entrusting a partnership to produce substantial parts of or even the entire draft scientific opinion, can be organised in **different ways**, depending on the characteristics of the tasks at hand (repetitiveness, resources needed). For instance, work on a mandate can be entrusted end-to-end (from protocol development to draft opinion) to a single partnership or can be broken down into unit-tasks (e.g. data collection, hazard characterization) that can be distributed across partner organisations and then assembled separately.

In this vein, partnerships shall include contractual elements on quality and delivery terms and other cooperation modalities. To the extent that partnerships contribute to scientific opinions of EFSA, it is essential they clearly set out the **required standards** for scientific quality, independence, transparency, confidentiality, and cybersecurity.

Naturally, they also **require resources** to operate. From EFSA's side, those resources will come through EFSA's grants and procurement funding, as well as by – among others – providing (digital) platforms for experts to cooperate, facilitating networking and development of communities and supporting capacity building initiatives. Competent organisations in Member States and national authorities are also expected to commit (additional) resources as appropriate.

Governance considerations

As explained earlier, a considerable factor for the success of partnerships is the ability to **tackle common interests** and priorities with Member States. EFSA's framework foresees three organs through which relations with Member States are governed, i.e. the Management Board, the Advisory Forum and the Focal Points.

The **Advisory Forum** is de facto the **community of EU risk assessors** as it includes EFSA and Member States' responsible agencies and bodies. It has a central role in **coordinating** scientific cooperation and partnership. Its members are nicely placed to enable joint planning of risk assessment work as well as to stimulate the participation in partnerships of competent organisations in their country (with whom they also cooperate at national level). The Advisory Forum has established tools that can support joint planning of work (database of forthcoming risk assessment activities, regular discussions and partnership focussed sessions at meetings, increased role by members in defining the agenda). This has helped aligning programmes and initiatives occasionally, but structured processes are still missing.



EFSA's **Focal Points**, being the **interface between EFSA and competent organisations** in Member States also play a significant role in **supporting and facilitating** the implementation of partnerships. Their mandate has recently expanded to enable them (including on self-initiative) to disseminate information to competent organisations, promote initiatives (data, capacity building, knowledge management, risk-communication) facilitate the joint planning of work, identify cooperation and partnership opportunities, and foster networking and outreach towards organisations who currently don't work for EFSA.

The new **Management Board**, since 2022 including **national government representatives**, can play a decisive role to **connect and advocate**, thus helping partnership opportunities to further develop. First, they are the highest governance body of EFSA, in a position to appreciate the strategic importance of partnership for EFSA's long term sustainability and to steer management actions accordingly. Secondly, as representatives of national governments, they can help liaise with Member States' risk managers and policy masters, encouraging them to consider the opportunity for joining forces at EU level when defining political priorities and providing political instructions and funding to national risk assessors.

The main challenge is how to make this happen in different Member States to a comparable level, considering their very **diverse institutional set-up** (e.g. different national and regional organisations dealing respectively with hygiene and food safety, veterinary services and animal health, pesticides, plant health etc.). Also, the diversity of roles and affiliations of Management Board members in their home may require different advocacy approaches.



4. Partnership opportunities

The benefit of implementing new partnership initiatives across the various food safety areas, specifically to sustain the preparation of risk assessment opinions, is clear. The examples below have been selected to illustrate more in depth the background and current situation in **some critical areas** for risk assessment where there are more evident needs to enhance responsiveness towards innovation and/or emerging risks, to support environmental sustainability, to integrate the One Health approaches, or to promote further knowledge.

This selection does not intend to be comprehensive, but to provide a further, concrete stimulus for discussion.

4.1. Pesticides

Pesticides have traditionally attracted **political attention**, which increased in recent years along with health and sustainability issues and related societal concerns. An evolving regulatory framework (EU Farm to Fork and Chemical strategies), constant innovation and One Health constraints keep bringing new demands to EU risk assessors.

EFSA's operating model in the area of pesticides is **different from the other areas** (food safety, plant health, animal health and welfare, nutrition), as it does not comprise panels and working groups. Long-standing structured cooperation between EFSA and Member States is mandated by EU legislation, with Member State(s) (so called "rapporteurs") in charge of preparing a draft assessment report of active substances, to be peer reviewed by scientific experts nominated by national governments and coordinated by EFSA. EFSA also assesses risks associated with pesticides' residues. Member States then evaluate and authorize the plant protection products at national level.

The model has **worked relatively well** over the years, providing for a structured sharing of work between the EU and national level, as well as reducing the scope for divergencies between EFSA and national risk assessors.

However, there are some **shortfalls**: the process is slow, the risk assessment capacity is concentrated in the rapporteur Member States, the peer review often needs to update its expertise to deal with emerging issues (e.g. endocrine disruptors). A reinforced participation of Member States is therefore desirable to increase timeliness and responsiveness within the current EU procedure.

Over the years, EFSA has **complemented** the working model above by a number of ad hoc cooperation initiatives, mobilising resources and expertise at national level. Some of them have progressively acquired partnership status.

One example of **partnership supporting the preparation** of risk assessment advice is based on the framework agreement (grant) under the title *Preparatory tasks falling within the mission of the EFSA Pesticides Peer Review and Pesticides Residues and Application Desk units*⁶, supported by competent organisations from FR, GR, IT and NL. Cooperations so far was much appreciated, yet the resource capacity made available by those organisations does not match

⁶ [GP/EFSA/PREV/2021/01](#). Duration: 2022-2026. Budget: EUR 1,765 million



the volume of work that needs to be processed. Other Member States should therefore engage and build capacity to be able to participate.

Other “intended” partnership examples, supporting knowledge evolution on emerging issues, should build as a result of two recently launched calls inviting competent organisations to work with EFSA on **cumulative risk assessment** of dietary exposure to pesticide residues⁷ and on the development of a protocol for the **evaluation of emergency authorisations** of pesticides⁸.

4.2. Novel food

Novel food⁹ is often the result of **innovation** and, as such, it is associated with offering additional options to the consumer, contributing to industry competitiveness and, in several cases, improving sustainability performance. New fermentation technologies, edible insects, and the use of nanotechnology in food formulations are relevant examples.

EFSA’s **workload for assessing novel food** applications has continuously increased since the entry into force of the new EU regulatory framework (2018), which centralised the assessment process under EFSA’s responsibility (currently around 50 new applications received per year). For producing scientific opinions, EFSA relies largely on the work of its staff and of panel and working group experts. These resources have come under strain. EFSA has so far been able to respect the strict legal deadlines for concluding its assessments but the forecast is that the situation will become increasingly challenging in the coming years.

Cooperation projects have been launched to **provide support to EFSA** in the novel food work. In 2021, EFSA concluded framework agreements¹⁰ with competent organisations from AT, BE, ES, GR, IT and SK, to carry out risk assessment tasks as part of the evaluation of novel food dossiers. So far competent organisations have contributed to certain tasks alone (product characterization, ADME and toxicology studies’ evaluation) which do not correspond to the entire risk assessment process. However, experience so far indicates that their capacity has not been fully exploited, hence cooperation can potentially expand in volumes, range of tasks and level of integration of the different assessment parts.

4.3. Food enzymes, food additives, flavourings, feed additives

Food and feed additives, enzymes and flavourings are areas of **rapid innovation rate** and, as such, they all contribute to the competitiveness of the sector and can improve performances with regards to sustainability (e.g., by helping achieve improved shelf-life and, hence, limit food waste, limit methane emissions by animals). EFSA provides scientific advice as part of the EU authorisation process, mostly relying on the support from panel and working group experts.

Workload on evaluating existing and new substances **has grown significantly**, especially concerning enzymes and feed additives. Regarding enzymes, EFSA had invested significant time and efforts in exploring potential for establishing a partnership with Member States to support

⁷ [GP/EFSA/PREV/2023/03](#). Closing date for applications 30 June 2023. Financial ceiling: EUR 2.9 million for Lot 1 and EUR 1.1 million for Lot 2.

⁸ [GP/EFSA/PLANTS/2023/02](#). Closing date for applications 21 August 2023. Financial ceiling: EUR 1 million.

⁹ New foods, food from new sources or food produced with different processes and technologies or with new substances, which was not consumed significantly in the EU prior to 1997

¹⁰ [GP/EFSA/NUTRI/2021/01](#). Duration: 2021-2026. Budget: EUR 400,000.



preparatory tasks for risk assessment, but finding the right format, modalities, and level of engagement of various actors had proven particularly challenging.

Eventually, EFSA decided to **broaden the framework** for the intended partnerships, including tasks pertaining to the risk assessment of all food and feed additives, thereby exploiting the similarities of evaluation processes in these areas. An all-embracing call for proposals¹¹ was launched which attracted good interest from a wider range of organisations across Europe. As a result, framework agreements are being concluded to cover the entire set of tasks for dossiers evaluation and preparation of draft opinions concerning **food additives, flavourings, food enzymes and feed additives**.

These agreements are set to provide the basis for a very **comprehensive partnership effort** with competent organisations from AT, BE, DE, DK, ES, FR, GR, IT, NL, NO, PT and SE. All these players have been involved in extensive preparatory discussions. Despite time-consuming, these exchanges allowed to develop a scheme that fits on the one hand the operational requirements of competent organisations, and on the other the rigid framework EFSA must adhere to.

The partnership scheme foresees that risk assessment work is divided in a series of small, well-defined tasks to be allocated to different partners, which when **put together correspond to a draft scientific opinion**. The latter will then be peer reviewed by the responsible Scientific Panel of EFSA. This approach makes it easier to share the work across many actors, yet at the cost of a higher coordination/overhead effort. It will be an interesting **piloting experience**, which could potentially be extended to cover other neighbouring areas (e.g. novel food).

4.4. Animal health

Preventing and managing animal diseases is critical for protecting animal and human health and the environment (**One Health**), as well as protecting **food security**. The **risk assessment** work (comprising ad hoc, generic opinions) is carried out relying mainly on panel and working group experts. Long-lasting mandates on **monitoring and surveillance** are instead carried out by EFSA staff with important support from Member States authorities.

Preparedness, including timely availability of data is crucial for successful delivery of scientific advice in this area. EFSA has therefore developed over time several important **cooperation activities on data** with Member States, including projects such as VectorNet¹² (vectors and pathogens in vectors, joint EFSA/ECDC project, coordinated by NL) and EnetWild¹³ (distribution/density of wild species and their pathogens, coordinated by IT). These have contributed to the delivery of many scientific advices, e.g. on the re-emergence of Rift Valley Fever in Mayotte (France), SARS-COVID-19 in minks and the One Health approach for cross-border pathogens. A successful new system for the collection of standardised data on animal diseases (SIGMA project)¹⁴ has been implemented for African Swine Fever (involving affected Member States) and will be implemented for surveillance on avian influenza (involving all Member States). The latest development is a project that aims to develop a tool for 'living online risk assessments' (coordinated by SE and NL) available to EFSA and Member States alike.

¹¹ [GP/EFSA/FIP/2022/01](#). Duration: 2023-2027. Budget: EUR 3.5 million.

¹² Project initiated in 2014. Budget: EUR 5 million to date

¹³ Project initiated in 2016. Budget: EUR 2.5 million to date.

¹⁴ Project initiated 2018. Budget: EUR 600,000 to date



There are also other initiatives to close important knowledge gaps. A recent example is the more comprehensive **partnership effort on African swine fever**¹⁵. Its objective is to study the survival of the virus in feed, bedding materials and mechanical vectors, to analyse their potential role in virus transmission and to explore mitigation concepts.

While successful, these initiatives are **still limited** on geographical coverage: in several Member States data harmonisation is still lacking and/or organisations/stakeholders are not engaged in providing data. Furthermore, more involvement of national authorities in the development of risk assessment tools would ensure these **tools have the potential to be used both at national and EU level**.

4.5. Plant health

Identifying plant pest risks at an early stage and assessing the efficacy of phytosanitary measures to mitigate such risks is **key to biosecurity** (One Health), and to ensure the protection of **food safety and food security, environment and landscape**. EFSA risk assessment aims to prevent or reduce the risk of entry and spread of new plant pests. This includes providing support to Member States' plant health surveillance by developing and making available online tools and datasheets.

For delivering its scientific advice and support to crisis preparedness, EFSA has built a high throughput production system, supported by Panel and Working Group experts and with a **strong involvement of Member States** competent organisations.

Since 2017, EFSA has awarded 15 framework agreements and several direct grants¹⁶, to support the **categorisation** of large taxonomic and crop groups, **surveillance and horizon scanning**, other individual pest categorisation, climate suitability and **commodity risk assessments**. This has resulted in a close partnership effort with a core group of competent authorities and organisations from approximately 10 Member States.

However, despite some slight increase over time, participation is **still limited** in number and geographical coverage, especially when facing the wide range of the advice areas (mentioned above) and the need to keep up with **innovation and new assessment methodologies**. It is therefore important to **extend the scope** of partnership beyond the core group and reach out also to academics, universities and applied research institutes across Member States.

4.6 Other opportunities

Many other areas suitable for developing new partnerships initiatives are identified, including for example:

- **Aquatic diseases, animal and fish welfare**: these are new or growing food/feed safety areas for which certain national organisations could develop as 'expertise hubs', to support risk assessment by EFSA and by other national authorities.
- **Data mapping and retrieval**: EFSA and the Advisory Forum have identified several avenues for launching partnership initiatives aiming at the development and operation of innovative information systems and tools.

¹⁵ [GP/EFSA/ALPHA/2021/09](#). Duration: 2022-2023. Budget: EUR 400,000.

¹⁶ Overall budget: EUR 7.6 million.



- **Common tasks in the risk assessment:** expertise on recurrent tasks (e.g. chemical exposure, toxicology, allergenicity etc.) which typically form part of risk assessment under different regulatory frameworks could be pooled within 'expertise hubs' (comprising large consortia of organisations) to support EFSA and Member States' work.
- **Capacity building:** EFSA and organisations in Member States could develop platforms for knowledge transfer and make them available to the entire EU risk assessment community.
- **Trainings:** developing competences and expertise on harmonised cross-cutting and sectoral risk assessment methodologies is a must-have to ensure the sustainability of the EU risk assessment system.



5. Summary and conclusions

The arguments developed in this note show the need for EFSA to **further invest** in developing and expanding partnership initiatives with Member States, in particular to support preparatory tasks for risk assessment. This requires that policy makers, risk managers and risk assessors at EU and national level **intensify and coordinate** their efforts and commitment.

EFSA has identified a set of **principles and concepts** towards expanding partnership initiatives, which are submitted to the Management Board for consideration:

- *EFSA's **vision** for partnerships is key to ensuring the sustainability of the EU risk assessment system.*
- *EFSA shall prioritise its **actions** in this area with particular focus on preparatory tasks for risk assessment.*
- *Partnerships should be mainly based on **grants**, which allow selected organisations to co-design, co-invest and co-own risk assessment tasks. Use of this tool should be facilitated as much as possible.*
- ***Engagement** with national risk assessment authorities and competent organisations in Member States should be expanded, by promoting strategic alignment, coordinated planning, joint deployment of resources and capacity building. When relevant, the Art. 36 list should be enlarged.*
- ***Political will** and steering are essential to make partnerships a structural part of EU risk assessment work.*
- *Management Board Member States' representatives can play an active role at political level, **connecting** to national governments and EU institutions and **advocating** that:*
 - *Risk managers consider cooperation with EFSA when mandating national risk assessors to work on food safety issues.*
 - *Policy makers instruct national risk assessors to coordinate with EFSA on work-planning and budgeting with a view to allocating resources for partnership initiatives (complementing EFSA's contributions).*
- *Advocacy **approaches** by Management Board Member States' representatives may differ based on their positions in national administrations and the diverse set-up in each member state's food safety administration.*
- *Close **interaction** between Management Board members, Advisory Forum members and Focal Points at national level is necessary to jointly steer, coordinate, facilitate the taking up of partnership initiatives by competent organisations in Member States.*

In order to structure the discussion at the Management Board meeting, the following **questions** are proposed for consideration:

1. Are there any **considerations** Management Board members wish to make on the opportunity of expanding efforts for partnership initiatives in preparatory tasks for risk assessment?
2. How can the different Management Board members (national representatives, EU institutions, stakeholders) individually contribute to **advocating** for partnerships and how can EFSA support such efforts?
3. How should the **follow-up** to this discussion be structured?