

Scoping Paper Summary

Strategic Partnership with Member States for Data Quality (Pilot project)

1. Background

Data are an element of utmost importance in the risk assessment process. EFSA has for many years established and supported a process for collecting data from EU data providers with harmonised model and transmission protocol. The EU Member States' competent authorities are by far the major data providers to EFSA.

Since 2007 EFSA awarded to Member States' organisations involved in data collection 4 M€ to support data harmonisation and electronic transmission of data to EFSA (28 grants and 31 procurements).

These contracts/grants were mainly focused on supporting the implementation of the electronic transmission of data in one specific domain at time (i.e. zoonoses, occurrence of chemical contaminants, additives, pesticides residues and veterinary drug residues). No provisions were made in these contracts/grants for maintaining the systems developed in the funded projects. These contracts/grants did not include any measuring, monitoring or rewarding of the quality of data provided. Finally, these contracts/grants were of limited duration. Finally, although in-bound checks of formal correctness are automatically performed by the EFSA data collection system, the contracts/grants were mainly focusing on the delivery of structured data to EFSA rather than on ensuring and improving the quality of the data content and on promoting the systematic resolution of data quality issues.

A need for a more continuous and structured funding from EFSA was highlighted several times by the data providers through the specific scientific networks, particularly for those data collections where a clear legal framework does not exist. Many countries claim that this prevents the assignment of dedicated resources to deliver quality data to EFSA. The current contracts are helping to mitigate this issue but only for the duration of the contract, while the major data quality work is needed once the harmonised data collection and transmission system enters the 'production' phase. In addition, EFSA was supporting different data domains with separate contracts. This approach did not encourage the development of strong data governance at national and European level.

Therefore, in the context of re-shaping the support to Member States on data collection, an innovative proposal has been developed.

2. Objectives

The proposed approach aims to develop the engagement of Member States in data transmission to EFSA, by building a solid long-term partnership with data suppliers (MSs). The partnership is expected to allow long-term planning on both sides, to clarify responsibilities and sharing of tasks and costs between EFSA and MSs and to deliver a tangible improvement of the data collection process both in terms of data quality and national governance. The main objectives are therefore:

- Ensuring data quality (**innovation for data**);
- Improving the governance of the entire process and streamlining the overall coordination (**innovation for scientific cooperation**);
- Ensuring simplified long-term co-funding of data providers at national level (**innovation for EFSA grant outsourcing scheme**).

The proposed project is directly linked to EFSA's Strategic objective 2 - "Widen EFSA's evidence base and optimise access to its data".

In summary, the project will help countries (EFSA Advisory Forum members) to maintain a national overview on data collection activities via the co-ordination role of Focal Points. In parallel, co-founding data providers at national level will improve the processes of reporting data to EFSA and the quality of the data delivered.

1. Key Benefits

- Co-ordination and structure at MS level:
 - Clarity at MS level on data transmitted to EFSA;
 - Clear data governance;
 - Clear contact point for data access.
- Update standards:
 - Ensure stable resources for the standards updating process;
 - Guarantee up-to-date data models and validation rules.
- Data quality:
 - Dedicated contact point at MS level for data stewarding activities;
 - Improved data quality KPIs;
 - Capacity of monitoring data quality.

2. Main components of the partnership agreements

One 4-year direct framework partnership agreement (FPA) customised to address, where possible, MS specificity. The general components of the framework partnership agreement will be:

- Framework support for **updating existing standards** (Standard Sample Description, Standard Sample Description ver.2, zoonoses and other data models defined in the remit of EFSA data collection activities):
 - Agreed lump sum/unit cost per domain for each MS, forecasting the costs for updating existing standards. The lump sum/unit cost will be calculated based on the complexity of the data standard. The sum for the data collection maintenance will be co-financed by EFSA and the MS.
- Framework support for **data quality stewarding**:
 - Agreed lump sum/unit cost per domain for each MS, forecasting the costs for supporting and enhancing data quality. The lump sum/unit cost will be calculated based on the amount of data to manage for each data domain and includes the activity of the data quality responsible person (data steward). The sum for the data quality support will be co-financed by EFSA and the MS.

The FPA will involve a consortium of national organisations responsible for data provision and coordination in each specific country. It will have a simplified implementation mode: low value lump sum/unit cost specific grants, no verification of costs; co-financing rate from EFSA up to 50%. Given that the FPA involves different country organisations responsible for data provision, a national coordination function is also needed. In summary, the above described initiative involves in terms of expertise two different roles: **Data Stewards** and a **National Coordinator**. The role of Data Steward is entirely new and covered by the new financial agreement. Data Stewards must have in depth data knowledge, and for this reason they need to be allocated for each data domain. The National Coordinator has exclusively a communication and interface role at MS level. The Focal Points are probably seen as the best candidates to fulfil this role; this is due to the

compatibility of their tasks, described in the existing “Multi-Annual Focal Point Grant Agreement”, with the consortium co-ordinator role envisaged by the FPA. The tasks envisaged for the two roles are detailed in the following sections.

3. Role of Focal Points

The FPA on Data Quality will foresee a consortium co-ordination role, supported with specific co-funding; as anticipated, the Focal Points are probably considered the best candidates to support this role. The specific activities to be carried out are described below and structured in line with the current main FP tasks.

Focal Points Main tasks	Proposed FP activities on Data Quality
Coordination of EFSA's Scientific Networks at national level	<ul style="list-style-type: none"> • Support the creation of a consortium identifying at national level Article 36 organisations involved in the remit of the data collections in the scope of the FPA on Data Quality. Coordination of the consortium. Encourage organisations who are data providers to enroll as Article 36 organisations, in not yet on the List. Where not possible, exemption will be possible through subcontracting of tasks under the Focal Points' organisation, which is in the Article 36 List. • Maintain an overview on MS data providers that are transmitting data to EFSA and inform the Advisory Forum member regularly. This includes, for example, the monitoring of the progress of the data collection reporting; and as well the overall quality of the performance of national data providers through the use of web reports available through the EFSA scientific data warehouse. To facilitate this task, graphical interactive reports will be made available (EFSA will first present them and provide training on their interpretation to FPs in order for them to best perform this activity).
Networking and raising the visibility of EFSA and of its role in the EU food safety system	<ul style="list-style-type: none"> • Promote EFSA's Data Warehouse at country level and projects aiming at data exploitation. • Be the contact point for requests to authorize access to the EFSA's Data Warehouse for MS governmental organisations. • Promote EFSA's data collection exercise involving all bodies contributing to data generation at country level.
Cooperation through Article 36 and databases or networks of scientific experts	<ul style="list-style-type: none"> • Be the contact point at national level decisions regarding data submitted by the MSs to EFSA, for data transmission and access (Data governance). <p>Within the annual activities report provided by FPs, an annex should be included listing the national data transmitted to EFSA.</p>
Training opportunities in risk assessment	<ul style="list-style-type: none"> • Convey to EFSA need for training from national data managers/data stewards involved in data processing and data submission to EFSA. • Inform to data managers/data stewards involved in data processing and data submission to EFSA information on trainings available in EFSA.
Exchange of scientific information	<ul style="list-style-type: none"> • Promote widening access to data submitted to EFSA.
International Cooperation	<ul style="list-style-type: none"> • Be the contact point for sharing data collected by EFSA with international organisations.

4. Role of Data Stewards

While Focal Points have a co-ordination and communication (interface) role that does not require data management expertise, the Data Stewards must have a profound knowledge of the data and the data management process used to submit data to EFSA. For the specific data domains under their remit, the data stewards must:

- Have knowledge at country level of the data flows, document them and keep the documentation up-to-date and shared with EFSA;
- Be responsible for accepting/rejecting the validation reports prepared by EFSA when data is received in the EFSA system;
- Be responsible for the monitoring and achievement of the agreed thresholds for the data quality KPIs included in the FPA;
- Be responsible for the allocation of the relevant resources at national level according to the FPA;
- Be responsible for resolving or clarifying data quality issues in their specific domain and to re-submit updated data to EFSA within the timeframe defined in the FPA;
- Be the data domain experts for questions and issues cascaded down through the Coordinator;
- Be the direct contact point for any data technical related communication with EFSA;
- Be the contact point for training on data transmissions to EFSA at country level for their specific data domain, through the Coordinator.

5. Cost model design

The cost model will be organised to cover the two main aspects of the proposal:

- **Updating the reporting standards and electronic data collection-transmission system at MS level**

The MSs, in order to receive co-funding related to the updating of reporting standards, need to prove that they have in place and use on routine basis an electronic system to prepare, convert and submit data to EFSA. This co-funding will be used by MSs to achieve the following objectives:

- Keeping the data collections up-to date/in line with the evolving data models and validation rules;
- Guaranteeing a stable long term investment on the technical infrastructure to support quality data collection at MSs level;
- Maintaining at MS level a stable data management framework.

The proposed cost model foresees a fixed cost based on the complexity of the data collection; the costs are independent from the number of records the data collection contains. The reason for this choice is linked to the fact that the maintenance costs of the system including the update of the validation rules is not linked to the size of the database but only to the complexity of the database structure. The costs will be also adjusted to each country cost of living using the result of the pilot as baseline and by applying the cost of living index per country as available from Eurostat.

- **Enhancing and guaranteeing data quality**

The MSs, in order to receive co-funding related to the enhancement and monitoring of data quality must:

- Allocate a dedicated data steward per data domain at MS level;
- Monitor, achieve and improve data quality KPIs;

The costs of the process of enhancing and guaranteeing data quality will depend on the volume of data that have to be managed for the specific data domain. The costs will be also adjusted to each country cost of living using the result of the pilot as baseline and by applying the cost of living index per country as available from Eurostat.

6. The Data Quality KPIs and penalties/bonus

The FPA will clarify the service provided by EFSA to support data provision, but will also clarify the responsibility of MSs as data supplier, since these will subscribe the agreement and be paid for providing this service. These responsibilities will be translated in reaching specific data quality objectives, which means specific thresholds for certain data quality key performance indicators (KPIs). Both KPIs and thresholds will be decided jointly by MSs and EFSA (e.g. delivery on time before deadline of 95% datasets, 99% of selected data elements filled in with semantically relevant values, 99% limit of quantification reported). Meeting/not meeting the requirements may be supported either by an incentive system or by a penalty system, respectively. The two methods will have the same maximum target budget.

7. The pilot

A number of MS expressed availability to participate in the pilot, as proposed by their AF Members during their 59th AF meeting on 8-9 March 2016 (Austria, Croatia, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, The Netherlands, Norway, and Slovak Republic). These countries will be contacted during June – July 2016 to confirm their interest to participate and further refine the proposal to try to meet the specific needs of the data collection arrangements in their country. In case the financial amount necessary to support the countries available to participate exceeds the budget available for the pilot (budget of 500,000€ was estimated to support up to 5 countries), EFSA will select participating countries using country size and geographical distribution as selection criteria. During the September 2016 AF meeting, the pilot proposal will be discussed and agreed upon, with pilot contracts being signed at the beginning of 2017.

The pilot will run during 2017. In 2018 the results of the pilot will be collated, analysed and presented to EFSA management and to the AF for a final “go”/“no-go” decision to be taken. In case of a “go” decision, implementation of the project will start in 2019.

8. Timeline

- Pilot phase 1 year:
 - FPA preparation and signature with consortium co-ordinator (preferred candidate is Focal Point): Sep. 2016 – Dec. 2016;
 - Pilot Grant Agreements signature: Jan. 2017 – Feb. 2017;
 - Pilot Grant Agreements duration: Jan. 2017 – Dec. 2017;
 - Preparation of pilot results with pilot countries: Jan. 2018 – Mar. 2018;
 - Presentation to EFSA management of pilot results: Mar. 2018;
 - Presentation to AF meeting: Mar. 2018;
 - Decision for full implementation: Jun. 2018;
 - Framework contracts preparation and signature Jul 2018 – Dec 2018.
- Full implementation (if agreed):
 - Up to 20 countries at regime: 2019 (Participation to the FPA is not mandatory);
 - Up to all countries at regime: 2020 (Participation to the FPA is not mandatory)

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Document history

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