

Advisory Forum
April 1st 2020

Partnerships for RA now and in the future

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evaluation of regulated products

Trusted science for safe food

General Food Law-options for collaborative RA production

(EC) No 2230/2004 implementing rules for Reg (EC) No 178/2002



Art 4

■ Allows tasks to be entrusted to organisations on the **article 36 list**

- ❑ disseminating best practices and improving methods of collecting and analysing scientific and technical data, particularly for the purposes of **facilitating comparability and producing a Community-level summary**;
- ❑ **collecting and analysing specific data in response to a common priority**, in particular the Community priorities contained in the Authority's work programmes, and in cases where the Authority's scientific assistance is urgently needed by the Commission, especially in the context of the general plan for **crisis management** referred to in Article 55 of Regulation (EC) No 178/2002;
- ❑ **collecting and analysing data with a view to facilitating risk assessment by the Authority, including assessment tasks** in the field of human nutrition in relation to Community legislation, especially the compiling and/or processing of scientific data on any substance, treatment, food or feed, preparation, organism or contaminant which may be linked with a health risk, and the collection and/or analysis of data on the exposure of Member States' populations to a health risk associated with food or feed;
- ❑ **producing scientific data or works contributing to the risk assessment tasks, including assessment tasks** in the field of human nutrition in relation to Community legislation, for which the Authority is responsible; this type of task must correspond to precise problems identified in the course of the work of the Authority, and in particular that of its Committee and permanent Scientific Panels, and must not duplicate Community research projects or data or contributions which it is the industry's duty to provide, especially in the context of authorisation procedures;
- ❑ **preparing the Authority's scientific opinions, including preparatory work relating to the assessment of authorisation dossiers**;
- ❑ preparing the **harmonisation of risk assessment methods**;
- ❑ **sharing data** of common interest, e.g. the establishing of databases;
- ❑ the tasks referred to in Articles 6 and 18(3)(b) of Regulation (EC) No 1829/2003.

Art 5

■ Allows for **financial support** for performing such tasks to be given through **grants**.

Art 6&7

■ Set out **strict quality criteria, implementing conditions** and **performance monitoring** required to ensure that entrusted tasks are performed to high scientific and technical standards.

The TR (2019/1381) amending Reg (EC) No 178/2002, introduces at Article 28, a new para. 5(e) *Applicable as of 06/2022*

“the Authority shall support the tasks of the Scientific Committee and Scientific Panels by organising their work, in particular the preparatory work to be undertaken by the Authority's staff or by designated national scientific organisations referred to in Article 36, including by organising the possibility for preparing scientific opinions to be peer-reviewed by the Scientific Panels before they adopt them”.

Title 3 - Operational expenditure increases from 32% in 2019 to > 50% from 2022 onwards

	2019 budget		2020 budget		2021 draft budget		2022 plan		2023 plan	
	€	%	€	%	€	%	€	%	€	%
Title 1 – Staff expenditure	44.1	55%	48.6	45%	53.6	42%	56.0	37%	58.0	38%
Title 2 – Infrastructure expenditure	10.4	13%	13.4	12%	16.6	13%	15.6	10%	15.7	10%
Title 3 – Operational expenditure	25.4	32%	46.0	43%	58.6	45%	78.1	52%	77.7	51%
Total EFSA	79.9		108.0		128.8		149.7		151.5	

Towards a new partnership model supporting pan-EU RA

■ PHASE 1

- Strengthening existing collaborations
- Identifying new ones
- Urgent support to be launched **June 2020** + support to be included in **2021 portfolio**

We need to start now !

■ PHASE 2

- New TR provisions allow development of extensive partnerships for RA
- A **partnership model** needs to be put in place
 - Processes
 - Tools
 - Quality management system (also guarantee consistency)
 - Guarantee confidentiality/independence
 - Partnership relation management

Under development !

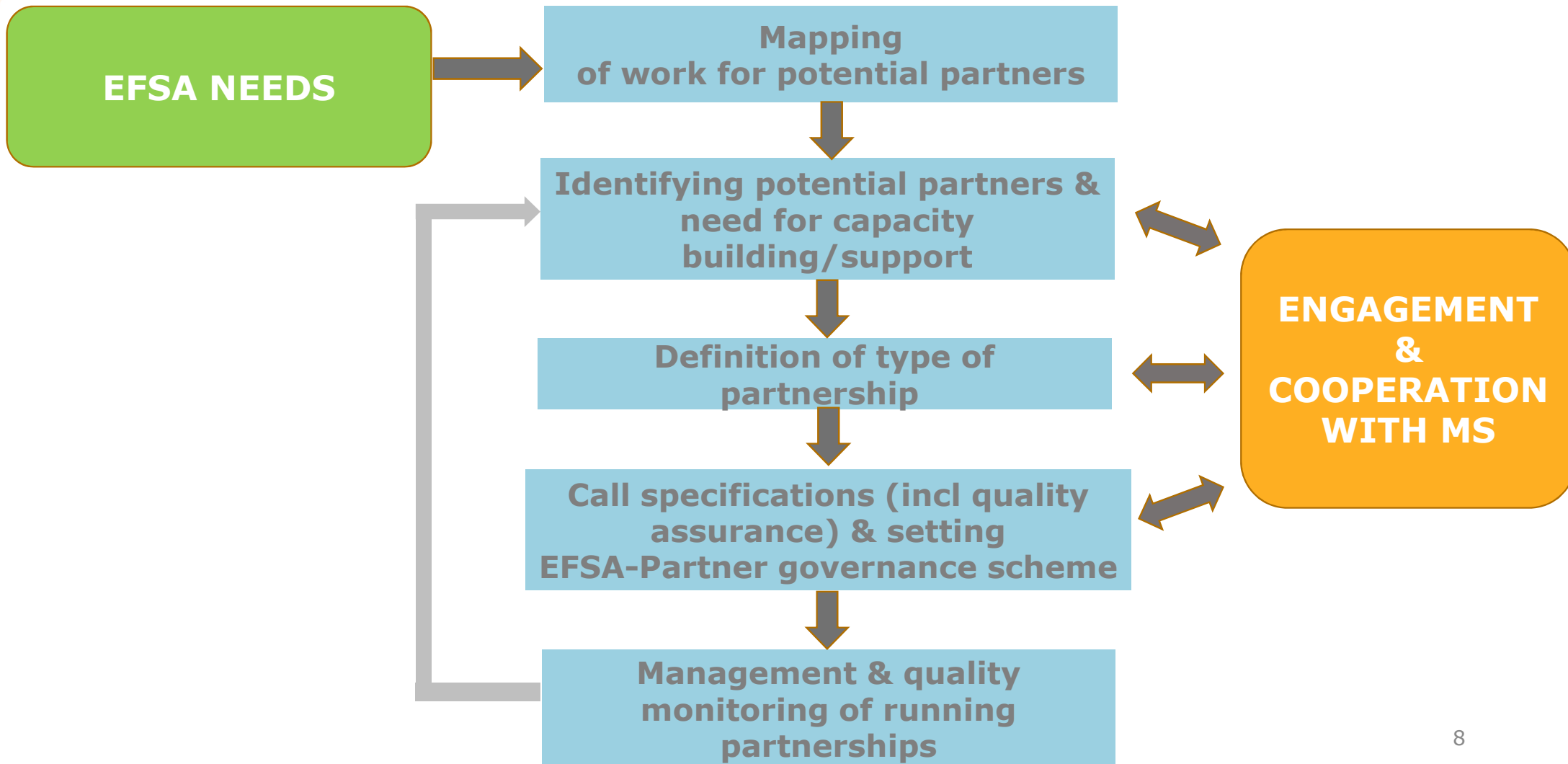
PHASE 1

PHASE 2

PHASE 2: remit of partnership model

- **Future Partnership model**
- **RA and scientific advice 'production' (Business as usual - BAU)**
 - Preparatory work for RA advice/opinions
 - RA to be peer reviewed by EFSA panels
- **Methods and Tools Development (DEV)**
 - Methodology, tools and guidance to be implemented in RA on *SHORT TERM* (< 1 yr – 2 yrs)
- **New – Longer term scientific studies and projects ('SPIDO')**
 - Big multi-partner thematic projects, results to be implemented in the RA on *LONG TERM* (> 2 yrs)

PHASE 2: Basic steps of a partnership model



PHASE 2: From reactive to proactive partnership building

1. **Early communication of outsourcing needs to MS** -> enabling early engagement / interest / networking of MS organisations
2. **New tools / mechanism for partner identification & engagement** -> through use of Art36 tool and competence mapping tool
3. **Fit-for-purpose Art36 list** -> ensuring, with the support of MSs, the list is kept up-to-date with the most relevant/competent organisations (for grants)
4. **Standardised mechanisms to define the most adequate type of partnership** -> e.g. grant vs procurement, open call vs monopoly scheme
5. **Enhanced dialogue with partner(s) when drafting agreements / contracts** -> for refining the partnership model, including tailored provisions that avoid unnecessary administrative burden

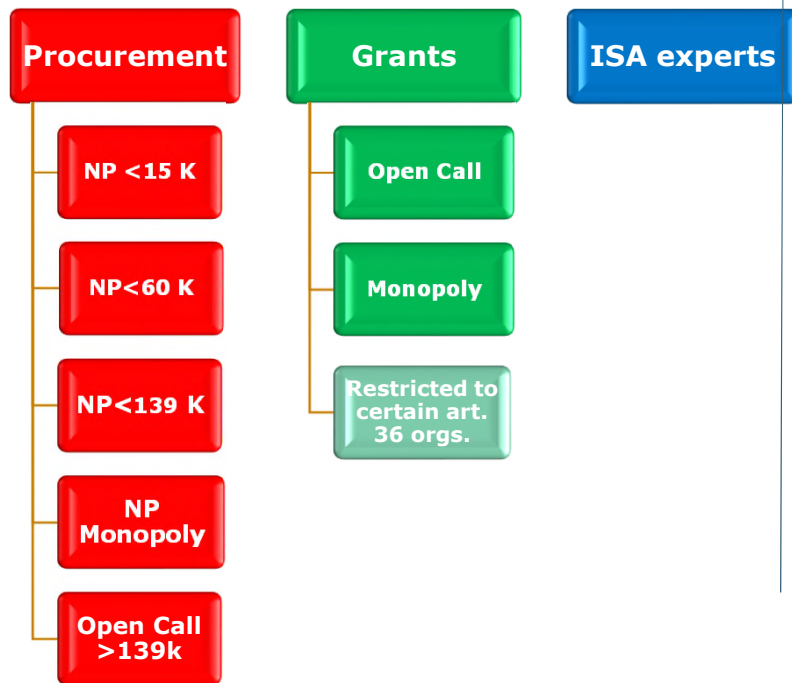
PHASE 1

PHASE 2


PHASE 1: Catalogue of tools for outsourcing

Limited by EU Financial Regulation to Procurement (Title VII), Grants (Title VIII), External Remunerated Experts (Art. 237)

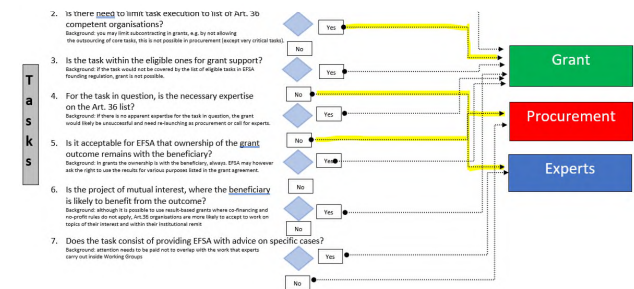
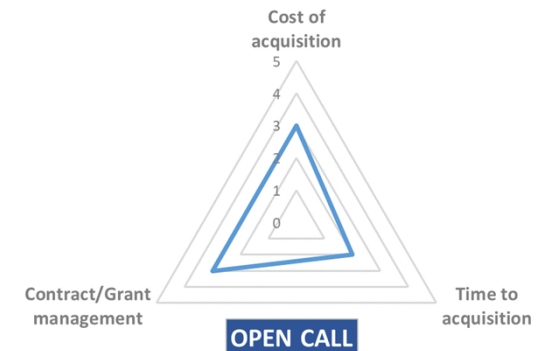
1 - Overview



2 - Description

-  **How does it work?**
-  **Pros and Cons**
-  **How long will it take?**
-  **Typically used for**

3 - Diagrams



PHASE 1: Some topics of interest for partnership in support of BAU 2020/2021

- 1st identification exercise performed
 - **Systematic literature search and data extraction/classification in preparation of RA in all areas** (examples (gene)tox studies, endpoints, ADME (adsorption, distribution, metabolism and excretion), characterisation of chemicals (NMR, Mass spectroscopy, characterisation of complexes, analysis of nano-materials,...) compositional data, nutritional assessment,....)
 - **Support with the writing up of scientific reports, including the interpretation of summary data, tables and figures in an epidemiological context**
 - **Summary reports** (TSE, zoonoses, contaminants,...)
 - **Statistical expertise for study design**

Introducing 2 partnership case studies



Cooperation on enzymes risk assessments



Framework partnership agreement on sharing tools and knowledge for crisis preparedness, uncertainty in risk assessment, models and tracing.

Challenges for successful partnerships applying EFSA standards



- Quality assurance
 - Integration with existing QMS
 - Consistency between experts (in and outside EFSA)

- Independency
 - Guarantee independence of everyone involved, partners and their collaborators

- Confidentiality
 - Full control of exchanged information and related security

- Partner relationship management
 - Invest in a dedicated process

Thinking about future partnership: your input

- 1 -2 April AF: first discussion on future partnership opportunities
- MSs analysis of existing partnerships
- Bilateral discussion with MSs on specific cooperation opportunities (expression of interests)
- 18 June MB: discussion on sustainable RA in EU
- 1-2 July AF: discussion on future partnership opportunities
- Piloting new partnership initiatives
- June 2022: entry into force Art. 28 para. 5(e). Before an amendment of Implementing Regulation 2230/2004 would be needed

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