COMMUNICATION, ENGAGEMENT & COOPERATION DEPARTMENT

CALL FOR PROPOSALS

and guide for applicants

Call reference: GP/EFSA/ENCO/2020/02

Call title: Thematic grants: Preparedness for future challenges in specific areas of EFSA`s work

Lot 1: Evaluating the impact on/by gastro-intestinal (GI) tract microbiomes (human and domestic animal) in assessments under EFSA's remit;
Lot 2: Evaluating the impact on/by environmental microbiomes (plants, wildlife, soil) in assessments under EFSA's remit
Lot 3: Hotspots for plant-pests introductions: an integrated analysis to better prepare for pests' invasions

Project/Process code: E08.01.06

Budget line: 3210

European Food Safety Authority
Via Carlo Magno 1A – 43126 Parma, Italy
Tel. +39 0521 036 111 | www.efsa.europa.eu

INDICATIVE PROCEDURE TIMETABLE

Milestone	Date[1]	Comments
Launch date	16/03/2020	Date of call publication on EFSA's website.
Deadline for applicants to raise clarification questions to EFSA	~~19/06/2020~~ 15/07/2020	If, after having read this Call for proposals and guide for applicants, you have any questions, you may address them to EFSAProcurement@efsa.europa.eu by indicating the Call reference.
Deadline for EFSA to reply to clarification questions	~~24/06/2020~~ 17/07/2020	Replies will be provided on EFSA's webpage where this Call is published and which the applicants are requested to consult regularly.
Deadline for submission of proposals Any proposal posted after the final deadline will automatically be rejected.	~~30/06/2020~~ **24/07/2020**	Applicants can submit proposals: - either by post (registered mail) or by courier not later than ~~30/06/2020~~ **24/07/2020**, in which case the evidence of the date of dispatch shall be constituted by the postmark or the date of the deposit slip, to the address indicated below. The applicant submitting a proposal by post or by courier is requested to send an informative e-mail to EFSAProcurement@efsa.europa.eu. - or delivered by hand **not later than 12.30 hours (Italian time) on** ~~30/06/2020~~ **24/07/2020** to the address indicated below. In this case, a receipt must be requested from EFSA as proof of submission, signed and dated by the staff member in EFSA Post Office who accepted the delivery. The EFSA Post Office is open from 8.30 to 12.30 Monday to Friday. It is closed on Saturdays, Sundays and EFSA holidays. Submission by post, courier or hand to this address: *European Food Safety Authority - EFSA* *For the attention of – Georgiana Guga, Finance Unit (Procurement Team)* *Via Carlo Magno 1/A, I – 43126 Parma, Italy* Proposals must be submitted using the double envelope system. The outer envelope should be sealed with adhesive tape, signed across the seal and carry the following information: - *"CALL FOR PROPOSALS GP/EFSA/ENCO/2020/02 – NOT TO BE OPENED BY THE INTERNAL MAIL DEPARTMENT".* - name of the applicant - **the posting date should be legible on the outer envelope**
Notification of the evaluation results	End September 2020	Estimated. **Attention:** outcome of the present call will be communicated to all applicants to the e-mail address indicated in their proposal. Accordingly, applicants who have submitted proposals under the present call are strongly invited to check regularly the inbox in question.
Grant agreement(s) signature	October 2020	Estimated

[1] All times are in the time zone of the country of the EFSA.

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ANNEXES:

1. GRANT OPPORTUNITY AND CONDITIONS[2]

1.1 LEGAL FRAMEWORK

Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002[3] establishing the European Food Safety Authority, lays down the general principles and requirements of food law and sets out procedures in matters of food safety.

Article 36 of the above-mentioned Regulation describes networking of scientific organisations in Member States, operating in the fields within EFSA's mission. It also called for the establishment of a List of Competent Organisations designated by Member States. The eligibility criteria for designation to the List of Competent Organisations are set out in the implementing rules (Regulation (EC) No 2230/2004) and Member States designate eligible organisations with support from their national EFSA Focal Point. EFSA's Management Board regularly updates the List of Competent Organisations based on input from Member States.

Article 5 of the Commission Regulation (EC) 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of the European Parliament and Council Regulation (EC) 178/2002 with regard to the network of organisations operating in the fields within the EFSA's mission specifies that the financial support to the networking organisations shall take the form of subsidies (grants) awarded in accordance with the EFSA's financial regulation and implementing rules.

The present Call for proposals and guide for applicants (hereinafter referred to as "the Call") is procedurally governed by Title VIII of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012.

This call is based on EFSA's 2020-2022 draft Work Programme for grants and operational procurements as presented in Annex IX of the Programming Document 2020 – 2022, available on the EFSA's website[4].

1.2 BACKGROUND & MAIN OBJECTIVE

This call for proposals is divided into three specific lots:

Lot 1: Evaluating the impact on/by gastro-intestinal (GI) tract microbiomes (human and domestic animal) in assessments under EFSA's remit;

[2] The applicant is reminded that this Call and guide for applicants contains a selection of the most important conditions for the grant implementation. For the full set of conditions the applicant is invited to consult the draft grant agreement attached to this Call.

[3] As amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain.

[4] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp2022.pdf

Lot 2: Evaluating the impact on/by environmental microbiomes (plants, wildlife, soil) in assessments under EFSA's remit;

Lot 3: Hotspots for plant-pests introductions: an integrated analysis to better prepare for pests' invasions

BACKGROUND TO LOTS 1 & 2

Microbiome refers collectively to communities of microorganisms and their genome in a defined environment (Marchesi and Ravel, Microbiome (2015)3:31). Microbiomes (incl. Bacteria, Viruses, Archaea, and Eukarya such as protists, fungi and algae) are found in humans, plants, and animals as well as in terrestrial and marine environments, providing benefits to the planet as a whole and everything that lives on it. Due to their ubiquitous metabolic potential, microbiomes occupy a central position in the "One Health" framework, which approaches human, animal and plant health from a new integrated perspective. Many recent research projects have offered new insights into the associations between microbiomes and a wide range of human diseases. Ongoing studies are demonstrating that microbiome structures and dynamics across the food system (from soils and aquatic habitats to plants, animals and the foods produced from them) can have both direct and indirect effects on human/animal microbiomes and health, in addition to their obvious impact on food quality, safety and sustainability (CNBBSV concept paper, 2019).

In the absence of explicit legal requirements to account for microbiomes in risk assessment, there are no guidance nor methodology in place to systematically account for possible effects on microbiomes or effects by microbiomes on human/animal/plant health. So far, potential effects on microbiomes are mentioned under various activities across EFSA: e.g. (1) EFSA outsourced in the past a project to monitor information on the potential impact on gut microbiota during the re-evaluation of specific food additives; (2) Under the health claim legislation novel foods, such as probiotics, are assessed for modulating the gut microbiome; (3) Antimicrobial resistance is one of the areas being investigated in EFSA as a broad thematic area. Also, in other areas of EFSA microbiomes play an important role for the subjects under risk assessment: e.g. soil and plant microbiomes (such as rhizobiome and leaf biota) have relevance for plant protection products (PPP), GMOs and Plant health; Animal microbiomes are relevant for feed additives, contaminants and animal health and welfare.

MAIN OBJECTIVE OF LOTS 1 & 2

The main objective of lots 1 and 2 is to build capacity for (1) evaluating the impact on microbiomes by various modulators under EFSA's assessments, and (2) evaluating the impact of microbiomes on human, animal and plant health, in order to determine whether microbiomes can be included in risk assessments under EFSA's remit or not. Proposals from applicants for this grant should allow EU Member States Authorities and EFSA to share knowledge, data and methods relevant for risk assessment, in a coordinated and effective manner. As microbiome assessment lies at the intersection of chemical and biological risk assessment, it will provide opportunities for experts on these two disciplines to collaborate and foster mutual understanding on their respective risk evaluations. The proponents should present their proposal to achieve the main objective, elaborating on the specific expertise needed, the contacts built to address this wide topic and the methodologies that are useful in a regulatory context. The proposal should aim at providing evidence-based advice. This implies that where current evidence is not existing or not sufficient, proposals may include data generation initiatives. The same for technologies and models.

BACKGROUND TO LOT 3

To bring forward pest risk assessment, new approaches, methods and tools need to be developed and validated in cooperation across EU Member States and EFSA. The analysis of EU "hotspots" for plant pests[5] introductions[6] to better prepare for new plant pest invasions, and the development of a more advanced integration of spatial and landscape aspects in quantitative pest risk assessment[7] is at the forefront of EFSA's current methodological needs. The new EU Plant Health Law, Regulation (EU) 2016/2031, establishes the rules to determine the phytosanitary risks posed by any species, strain or biotype of pathogenic agents, animals or parasitic plants injurious to plants or plant products ('pests') and the measures to reduce those risks to an acceptable level. To support the EU plant health regulatory framework, EFSA conducts risk assessment and contributes to the EU preparedness to new plant health threats by horizon scanning[8] and by supporting Member States surveillance[9]. To do so, EFSA has developed a quantitative methodology for pest risk assessment[10,11]. Pest risk assessment provides the scientific basis for the evaluation of risks posed to cultivated and wild plants by plant pests and the science-based evidence to inform decision-making by risk managers. Risk assessment comprises the systematic synthesis of knowledge and characterisation of risks by estimating the potential for introduction (entry, transfer and establishment) and spread of plant pests and the subsequent impacts to crops and plants in the wider environment (FAO, 2017a). The assessment of the effectiveness of risk reduction options can inform risk management decision-making and helps risk managers to identify appropriate strategies against quarantine plant pests. In this area, EFSA has pioneered the development of quantitative methodologies, allowing the effectiveness of risk reducing options to be quantitatively assessed as an integral part of the assessment framework. For quantitative risk assessments it is essential to have powerful analytical tools and, accordingly, a deep understanding not only of the biology of the pests and their epidemiology, but also of all the factors that determine their geographic distribution and temporal and spatial evolution. In this latter case, understanding how landscape features determine and shape pests occurrence is a fundamental part of it. Similarly, a reliable and scientifically sound identification of prime monitoring areas across different agro- and forest-ecosystems and production schemes is needed to tailor effective phytosanitary responses.

In this sense, the identification of spatial clusters, or invasion "hotspots", for plant pests is becoming increasingly recognized as an essential component for prioritising the efforts to reduce the introduction of alien plant pests and their impact on EU crops and vegetation. Hotspots can be defined as areas with an elevated occurrence or prevalence of plant pests due to a combination of factors that result in higher rates of pest entry, establishment, spread and ultimately impact on agriculture and forest production, (functional) biodiversity and/or ecosystem services. The

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5 According to the Glossary of phytosanitary terms - International Standards for Phytosanitary Measures ISPM 5 (https://www.ippc.int/static/media/files/publication/en/2019/06/ISPM_05_2019_En_Glossary_2019-06-26_PostCPM-14-Fixed.pdf), a pest (or a plant pest) is defined as "Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.

6 According to the Glossary of phytosanitary terms - International Standards for Phytosanitary Measures ISPM 5, introduction (of a pest) is defined as "the entry of a pest resulting in its establishment [FAO, 1990; revised ISPM 2, 1995; IPPC, 1997]

7 See section 9.2 on plant health risk assessment strategies and challenges in the minutes of the 82nd plenary meeting of the Scientific Panel on Plant Health (https://www.efsa.europa.eu/sites/default/files/event/190925-m_1.pdf)

8 For more details, please see the EFSA Journal virtual issue on Horizon scanning for plant health (https://efsa.onlinelibrary.wiley.com/doi/toc/10.2903/(ISSN)1831-4732.Horizon-scanning-for-plant-health)

9 For more details, please see the EFSA Journal virtual issue on the Toolkit for plant pest surveillance in the EU (https://efsa.onlinelibrary.wiley.com/doi/toc/10.1002/(ISSN)1831-4732.toolkit-plant-pest-surveillance).

10 EFSA PLH Panel (EFSA Panel on Plant Health), Jeger M, Bragard C, Caffier D,Candresse T, Chatzivassiliou E, Dehnen-Schmutz K, Gregoire J-C, Jaques Miret JA, MacLeod A, NavajasNavarro M, Niere B, Parnell S, Potting R, Rafoss T, Rossi V, Urek G, Van Bruggen A, Van Der Werf W,West J, Winter S, Hart A, Schans J, Schrader G, Suffert M, Kertesz V, Kozelska S, Mannino MR,Mosbach-Schulz O, Pautasso M, Stancanelli G, Tramontini S, Vos S and Gilioli G, 2018. Guidance on quantitative pest risk assessment. EFSA Journal 2018;16(8):5350, 86 pp. (https://doi.org/10.2903/j.efsa.2018.5350).

11 See the EFSA Journal virtual issue on Quantitative Pest Risk assessment (https://efsa.onlinelibrary.wiley.com/doi/toc/10.2903/(ISSN)18314732.Quantitative-pest-risk-assessments)

underlying factors determining the location and properties of such hotspots are resulting from the global trade network of plant commodities, climatic conditions, land-use and cover, landscape structure, production systems, and cultural practices; the so called "risk factors" in risk based surveillance.

A spatial-explicit mapping of hotspots for plant pests at local, regional and national levels in the EU together with an in depth analysis of the environmental conditions and factors that define such hotspots is a crucial for setting long-term plant health priorities, as well as for development of spatially and landscape based quantitative pest risk assessments methodologies and to support risk based surveillance for plant pests.

MAIN OBJECTIVE OF LOT 3

The main objective of Lot 3 is to develop a methodological framework for the identification of hotspots for plant pests introduction and the subsequent analysis and identification of factors that determine their occurrence; by doing this, the vulnerability of different regions of the EU and the underlying factors for such vulnerability can be revealed. Accordingly, this approach will allow developing and integrating novel methods of spatial-explicit analysis in current quantitative pest risk assessments (based on EFSA guidance for Quantitative pest risk assessments)[12]. The identification of hotspots and the underlying factors should be considered in a holistic way, i.e. going beyond single pests or single crops and taking into account the complexity, the diversity of the EU landscapes and putting forward the vulnerability of EU geographical regions at different scales and agro- and forest production ecosystems. The choice of target pest groups and agro- and forest ecosystems by the applicant should consider the likelihood of the pests to enter, establish and spread but also the potential threat in terms of impact on agricultural and forest production, biodiversity and ecosystem services. Proposals should make an inventory and mapping of the hotspots for plant pest introductions, render evidence-based methods that describe the factors that determine these hotspots, and develop a methodology for the inclusion of hotspot analysis in quantitative pest risk assessment.

1.3 SPECIFIC OBJECTIVES OF EACH LOT

SPECIFIC OBJECTIVES OF LOT 1: Evaluating the impact on/by gastro-intestinal (GI) tract microbiomes (human and domestic animal) in assessments under EFSA's remit

The proposals for Lot 1 should focus on the possible exposure to modulators of the GI microbiome via dietary pathway and their effect on human/domestic animal health. The scope of Lot 1 is EFSA wide, meaning that the proposal for Lot 1 needs to cover for possible risk/benefit[13] assessments relevant for EFSA's panels: FAF, CONTAM, BIOHAZ, FEEDAP, GMO, NDA, PPR, AHAW and SC (http://www.efsa.europa.eu/en/science/scientific-committee-and-panels). Therefore, the required expertise needs to be broad, incl. systems biology. For the specific objectives 1 below, it is acknowledged that the distinction between the various points raised under a – d and in particular between a and b, is not always strictly possible and that overlap exists.

1. **Reviewing the state of the art and appraising critically the evidence, technologies and models (in vitro/in silico/in vivo) for**

[12] https://doi.org/10.2903/j.efsa.2018.5350
[13] Includes efficacy assessment

a. accounting for intra and inter individual baseline variations according to human and domestic animal target populations and accounting for temporal change

Understanding the baseline can be considered the most important objective as it currently represents the initial step from where risk assessment could start.

As background information for this point (with respect to humans) it might be useful to mention that human studies have shown that intestinal microbial communities are inherently dynamic and can fluctuate between different states of eubiosis over time. These fluctuations are closely linked to the person's path through life and the communities maintain a mutualistic relationship with their human host that is essential for homeostasis and health. Recent extensive surveys and meta-analyses exploring variations in the human gut microbiome in health and disease revealed that even microbiome dysbioses are highly personalized and follow distinctive temporal changes. Studies characterizing the gut microbiome in thousands of people, in parallel with covariates assessing health status, diet, lifestyle, medication, biomedical parameters and genetics (Falony et al., Science 2016, Wang et al., Nature Genetics 2016; Rothschild et al., Nature 2017), have demonstrated that these determinants explain only a small fraction of the total gut microbiome variation and that we are still missing important covariates when assessing drivers of this variation. (CNBBSV concept paper, 2019) All those factors and others—such as socioeconomic status, geography, pregnancy status and environmental exposures—appear to play roles in shaping the composition and function of microbial communities. (NASES 2018).
The same may apply to the different domestic animal species and various rearing or environmental conditions to which they are exposed to.

Proposals should assess available data on the baseline gut microbiome profiling of healthy humans and/or healthy domestic animals of different age groups and with different lifestyles. The aim is to enhance the understanding of the role of population variation in the gut microbiome and susceptibility to effects of modulators.

A starting point could also be to map the knowledge gained by studies on ruminants and review the method used in that area of research.

Proposals should attempt to generate evidence looking into new determinants/drivers from animal, plant and environmental domain possibly impacting variation in human and domestic animal gut microbiomes.

Although the greatest part of current knowledge on microbiome concerns bacteria, proposals could also consider other microorganism such as archaea, virus and fungi and their possible effect on host/bacteria interaction.

b. characterising the structure and functional effects of microbiomes in human and domestic animal gastrointestinal tract.

As background information to this point, it may be useful to mention that the microbial ecosystem most explored is most probably the microbiome of the human gut. This microbial community interacts constantly and extensively with the host at the intestinal mucosal surface and plays fundamental roles in several aspects of its physiology that are instrumental to the maintenance of metabolic and immunological homeostasis. There is mounting evidence on the role of the gut microbiome in a number of enteric and systemic disorders in humans such as metabolic and cardiovascular disorders, cancer, neurodegenerative disorders and inflammatory chronic diseases. (CNBBSV concept paper, 2019)

The profile and functions of the microbiome in food-producing animals have been investigated in several species. Although different species seem to partly share their microbiota (Milani et al., ISME J 2017), monogastric (e.g. pigs, chicken), ruminant (e.g. dairy cows, sheep) and lagomorph (e.g. rabbits) animals have well distinguished ecosystems that have co-evolved with their own microbiota and are characterized by species-specific enterotypes. This is due to their different food sources (e.g. herbivorous vs. omnivorous), different anatomy and physiology, and feeding behaviours.
Animal microbiomes can be manipulated for a more sustainable production of high-quality foods by modulating animal growth, controlling their physiological development, boosting their defences against pathogens, improving their nutrient quality and controlling resistance to stress. Available data suggest that the livestock microbiota plays a significant part in the ultimate health, production efficiency and behaviour of animals. Several studies of rumen microbiota (Wallace et al. BMC Genomics 2015; Ben Shabat et al. ISME J 2016) have investigated their evident symbiosis with ruminants and their role in greenhouse gas production. However, there seems to be less information on pigs and poultry, and no significant relationship between the gut microbiome and animal phenotypes has yet been established (Stanley et al., Appl Microbiol Biotechnol 2014; Yuliaxis Ramayo-Caldas et al., ISME J 2016).

Proposals should focus on the relationships between microbiome structure and health. They should assess available data to characterise the structure and function of microbiomes in human and animal gastrointestinal (GI) tract. Multiple functional effects of the microbiome have already been linked to the health status of the host. Focus should be given to how compositional structure differences in GI microbiome due to exposure of modulators within EFSA's remit translate to a functional effect in humans and animals. The focus should be on the proof of causality with the modulators under assessment of EFSA (e.g., substances added/used to/in food and/or feed, environmental contaminants). The proposal should aim to address the range of possible microbiome specific end points.

Proposals can complement this aspect with the elaboration of particular case studies that might be proposed to address it in a more concrete way. For example: to study the effects of using feed additives on the animal gut microbiome (preferably during different life stages, e.g. before and after weaning) and how this translates to an effect on the animal. There are already studies showing effects of for instance organic acids on the intestinal microbiome of pigs but it is not clear how this is linked with the health status of the animal.

EFSA would be interested to focus on the various functions of the GI microbiome and to establish criteria to distinguish between background modulation and adversity. EFSA also sees a link to the work on biological relevance of the EFSA Scientific Committee (https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4970) to discuss/propose what are natural variations according to time and environment and what is a healthy microbiome for the context of EFSA.

As examples, EFSA would be interested in proposals that start to explore from the diseases that are linked with impaired microbiomes via dietary exposure and check if the current animal models (or test systems) are adequate to account for this. Since it may be still unclear if the disease is the cause or the effect of microbiome alterations, proponents may also opt to not start from the disease but link the various metabolic pathways to particular groups of microbiomes. A further practical idea might be to check first omics generated databases linked to disease status and study effects and role of the genes by in vitro experiments.

c. for assessing the impact of potential chemical and biological modulators on the microbiomes in human and domestic animal GI tract via dietary exposure pathway.

One way that interactions between the microbiome and a chemical modulator can influence host health is through direct chemical-induced changes in the microbiome. Such changes can be detected by assessing changes in community membership, relative abundance of existing members, spatial organization of the community, microevolution within particular member species, gene expression, or activity of particular metabolic pathways. It is well established that microbiomes of specific composition can have distinct causal effects on host biology. If exposure to a chemical modulator or any other factor leads to alterations in microbiome composition, the altered microbiome itself might have distinct direct effects on the host, although not all changes will contribute causally to host phenotype. (NASEM 2018)
The capacity of chemical modulator to induce microbiome changes in animals has been demonstrated with a variety of pesticides, metals, artificial sweeteners, and drugs (Patterson and Turnbaugh 2014; Claus et al. 2016). Most studies have relied on analysis of microbial community composition. It has also be shown that the effects of chemical modulators on the composition of host-associated microbiomes can be modulated by the host. (NASEM 2018)
The same may apply to various biological modulators and may be worthwhile investigating.

Although several reports have shown that a chemical challenge can be sufficient to alter host physiology and microbiome composition the reported experiments alone do not clearly distinguish between direct causal effects of the chemical on the microbiome and indirect effects of the chemical acting first on the host and altering selective pressures on the microbiome that change microbiome composition. (NASEM 2018)

Proposals should focus on the evidence providing a direct causal relationship between any kind of induced change via dietary exposure in the microbiome and host phenotype.

Proposals should address this aspect from a broad theoretical perspective, as well as with the elaboration of particular case studies within EFSA's remit that might be proposed to address it in a more concrete way.

d. or assessing the metabolism of chemicals by the gut microbiome via dietary exposure pathway

Research has indicated that the human microbiome can modulate exposure to environmental chemicals. The idea that microbiota in the host can contribute to host metabolism is deeply rooted in the field of drug metabolism.
It is critical to investigate how the activities encoded by the human microbiome influence the dose of toxicologically active chemicals at the ultimate target site (tissue, cell, or macromolecule). Knowledge of how the human microbiome modulates the pharmacokinetics and metabolism of environmental chemicals generally lags behind knowledge of how the microbiome modulates drugs. Still, there is compelling evidence on gut microbiome involvement in the metabolic transformation of environmental chemicals in broad chemical classes, including metals, polycyclic aromatic hydrocarbons (PAHs), pesticides and persistent organochlorines, nitroamines and aromatic amines, and other toxicant classes. Research suggests that the human microbiome might modulate the dose–response relationships of environmental chemicals through a few general mechanisms, which might directly or indirectly influence the pharmacokinetics of the chemicals. The mechanisms include direct metabolic transformation of environmental chemicals and various secondary transformations such as deconjugation of host-generated metabolites; regulation of epithelial-barrier permeability with implications for transport or excretion of chemicals, and regulation of the expression or activity of endogenous host metabolic pathways (for example, in the host liver) via signalling processes that involve microbial products. (NASEM 2018)

Proposals should contribute to enhance the understanding of the toxicologic significance of microbiome – mediated metabolism of chemicals and propose strategies that include the microbiome as an integrated part of a multiorgan host response.

Proposals should address this aspect from a broad theoretical perspective, as well as with the elaboration of particular case studies that might be proposed to address it in a more concrete way.

2. Drafting a roadmap to advance research to address risk assessment needs to account for effects on/ by gut microbiomes in humans and domestic animals

Whether interactions between modulators and the gut microbiome have adverse health consequences cannot be known without new research. NASEM (2018) suggest focussing on the following elements among others: (1) The extent to which harm to the microbiome is incorporated into or detectable in conventional animal testing. (2) The extent to which microbiomes differ substantially among animal strains and species and between humans and animals. (3) Characterization of the degree to which microbiomes can recover from insult or adapt to continuing insult. Additional considerations to guide chemical-microbiome research from a risk assessment perspective are provided by Rodricks et al. (2019).

Proposals should summarize first the risk assessment needs for each relevant area within EFSA's remit (: CONTAM, BIOHAZ, FEED, GMO, NUTRI, PRAS, FIP, AHAW and SCER.) and then recommend for each need related research. Proposals should highlight the most urgent needs to advance risk assessment.

Proposals should include establishing a network with relevant experts and international risk assessment bodies to probe the proposed roadmap.

SPECIFIC OBJECTIVES OF LOT 2: Evaluating the impact on/by environmental microbiomes (plants, wildlife, soil) in assessments under EFSA's remit

The proposals for Lot 2 should focus on the possible exposure to modulators of the environment microbiomes and their effect on plant/wildlife/soil condition. Such exposure is relevant for EFSA's work on Plant Health and Animal Health and Welfare (for wildlife animals). Such exposure is also relevant for regulated products (that are released into the environment) and subject to EFSA's assessments on plant protection products, GMOs or Feed/Food additives. The scope of Lot 2 is therefore to cover for environmental risk/benefit[14] assessments in relevant EFSA Panels: PPR, GMO, FEEDAP, FAF, CEP, PLH, AHAW, BIOHAZ, CONTAM, NDA and Scientific Committee. (http://www.efsa.europa.eu/en/science/scientific-committee-and-panels). The various microbiomes in the environment to be included within the scope of the proposal are soil and sediment microbiome, plant microbiome (incl. rhizobiome), marine sediment and seawater ecosystems, GI microbiome in wildlife animals. Therefore, the required expertise needs to be broad, incl. systems biology. For the specific objectives 1 below, it is acknowledged that the distinction between the various points raised under a – d, is not always strictly possible and that overlap exists.

1. **Reviewing the state of the art and appraising critically the evidence, technologies and models (in vitro/in silico/in vivo) for**

    a. **establishing baselines for selected microbiomes in the environment.**

Understanding the baseline can be considered as the most important objective as it currently represents the initial step from where risk assessment could start. Given the enormous natural

[14] Includes efficacy assessment

variations, clarity is needed on what are the natural modulations according to time and environment and what is a healthy microbiome for the context of EFSA. Therefore, proposals should attempt to address the question of what is considered a normal, healthy baseline for environmental microbiomes. The soil microbiomes (incl. rhizobiomes) may be prioritized if needed. Also, specific cases might be used to address this objective. Where this specific objective is not feasible due to knowledge gaps or technical constraints, it might be addressed by new data generation or database compilation if useful to advance risk assessment where needed.

b. characterising the structure and function of the microbiomes in the environment.

Known tools for critical appraisal could include typical microbiology cultivation approaches (which may underestimate (soil) microbial diversity), and culture-dependent or independent molecular approaches including Sequencing (e.g. 16S RNA, metagenomics). A map of functions of the microbiome would also be of particular interest of EFSA. It is noted that micro-organisms groups other than Bacteria (e.g. Archaea, Viruses and Eukarya such as protists fungi and algae) are also relevant and would be to be addressed. Furthermore, it would be interesting to link metabolic pathways to subgroups and their functionality. For this objective, there is a potential overlap with points c and d below, since the potentiality of the microbiome to react on antropogenic inputs could be linked to certain metabolic pathways and genomes present. The aim is to focus on the relationships between microbiome structure and health.

The soil microbiomes (incl. rhizobiomes) may again be prioritized if needed. Also, specific case studies might be used to address this objective. Where this specific objective is not feasible due to knowledge gaps or technical constraints, it might be addressed by new data generation or database compilation if useful to advance risk assessment where needed.

c. for assessing the impact of exposure to potential chemical and biological modulators on the environmental microbiomes.

Proposals should focus on the evidence providing a direct causal relationship between a chemical/biologicals-induced change in the microbiome. Proposals should address this aspect from a broad theoretical perspective, but it would be preferred that the proposal should aim to address the range of possible microbiome specific endpoints. If more feasible, the elaboration of particular case studies (particular modulators) might address this objective in a more concrete way. The focus should then be on the proof of causality with the modulators under assessment of EFSA (e.g., substances added/used to/in food and/or feed, environmental contaminants). EFSA is interested to know if computational models could be a start for assessing effects that are direct (through metabolism) or indirect (through composition change); and how toxicodynamic-toxicokinetic (TDTK) implications can be informative.

d. for assessing the impact (adverse/beneficial) of environmental microbiomes on the health of their host

Multiple effects have already been linked to the health status of the environment and wildlife organisms living in it (plant and/or wildlife animals). However, this specific object has to be focussed on the causality with the modulators under assessment of EFSA (see above) and the host phenotype. The range of effects addressed under this objective might benefit from ranking according to severity or likelihood of occurrence. The proposal could also elaborate on the protection goals for risk assessment, based on biodiversity and ecosystem services (EFSA SC Guidance, 2016). A starting point could also be the interpretation of toxicological studies and the observed effect. Subsequently it would need to be addressed 'what are the metabolic functions of microbiomes of test animals and how do they compare to those of wildlife animals?'

As examples, EFSA would be interested in proposals that start to explore from the diseases that are linked with impaired microbiomes of the environment and check if the current animal models (or test systems) are adequate for this. Since it may be still unclear if the disease is the cause or the effect of microbiome alterations, proponents may also opt to not start from the disease but link the various metabolic pathways to particular groups of microbiomes. A further practical idea might be to check omics generated databases for genes that are involved in the effects and study effects by in vitro experiments e.g. that could screen for enzymatic activities of genes that are not yet annotated. Furthermore, proponents might support the AOP approach. Such proposals might then search for the key events that are responsible for the adverse outcome (which are several diseases) and discuss the direction towards a mechanistic RA.
For addressing the question, 'When does the change becomes adverse?', one idea is to document what is seen in tox studies and map the changes to build up a database and a knowledge base to start understanding the modulation versus adversity. EFSA would also be interested to focus on functionality and to establish criteria between modulation and adversity. EFSA also sees a link to the work on biological relevance of the EFSA Scientific Committee (https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4970) to discuss/propose what are natural variations, what are the natural modulation according to time and environment and what is a healthy microbiome for the context of EFSA.

2. **Drafting a roadmap to advance research to address risk assessment needs to account for environmental microbiomes**

Whether interactions between modulators and the environmental microbiome have adverse consequences cannot be known without new research. For soil, it can be suggested to focus on the following elements among others: (1) Improved culturing strategies for bacteria even if we have genomic information available for several microorganisms. There is a gap in understanding their functional attributes. Genomic data can be exploited to identify conditions for the effective cultivation and isolation of recalcitrant microorganisms. (2) Viruses and their role in the soil microbiome as they can kill a large percentage of the microbial cells they are known to have an important action in shaping the bacterial community; (3) Focus on the importance of horizontal gene transfer of antibiotic resistance traits, xenobiotic degradation, heavy metal detoxification, plant symbioses etc.

For microbiomes of wildlife organisms, direction for further research can be (1) the extent to which harm to the microbiome is incorporated into or detectable in conventional animal testing. (2) The extent to which microbiomes differ substantially among animal strains and species. (3) Characterization of the degree to which microbiomes can recover from insult or adapt to continuing insult. Additional considerations to guide chemical-microbiome research from a risk assessment perspective are provided by Rodricks et al. (2019).

Proposals should summarize first the risk assessment needs for each relevant EFSA Panels: PPR, GMO, FEEDAP, FAF, CEP, PLH, AHAW, BIOHAZ, CONTAM, NDA and Scientific Committee. (http://www.efsa.europa.eu/en/science/scientific-committee-and-panels) and then recommend for each need related research. Proposals should highlight the most urgent needs to advance risk assessment.

Proposals should entail establishing a network with relevant experts and international risk assessment bodies to probe the proposed roadmap.

SPECIFIC OBJECTIVES OF LOT 3: Hotspots for plant-pests introductions: an integrated analysis to better prepare for pests' invasions.

1. **Identification of hotspots for plant health:** analysis and identification of factors determining pest introductions, establishment and spread across European agro- and forest ecosystems. The proposed studies should be developed under different scenarios (e.g. trade and transportation networks, commodity pathways, human movement, landscape, climate, and pest, crop and forest management, etc) for the different groups of pests, crops and agro- and forest production systems. By doing this, the vulnerability for pest introduction, establishment and spread of certain regions and agro- and forest production system across the EU can be revealed.

2. **A detailed hotspots mapping by means of geographic (GIS) and factor analyses of areas/sites prone to the occurrence of plant pests coupled to the identification of the factors that shape, influence and determine the characteristic of these hotspots.** This detailed mapping should render: 1) and inventory of the main hotspots for plant pest's introduction in the EU; and 2) a clear identification of risk factors that could be used in prioritising and planning pest surveillance and in the identification of suitable risk reduction options.

3. **Producing tools for quantitative pest risk assessment that allow forecasting in time and space how variations in hot-spot properties (environmental, landscape features and other factors) affect the importance and evolution in time and space of hotspots** i.e. entry, establishment, spread and impact of plant pests under different scenarios, considering pests, agriculture and forestry production systems. In consequence, proposals should envisage the development of methodological spatially explicit analytical tools that can be integrated and implemented into the current EFSA's quantitative pest risk assessment methodology. As a result, the quantitative pest risk assessment can provide not only a quantitative estimation of the risk associated with a particular pest or group of pests in different ecosystems but also make predictions of the potential geographical distribution and spread under different scenarios (landscapes, environmental and climatic scenarios, production systems, management, etc).

Proposal should consider as an overarching specific objective to support a plan for transferring the developed methodology and results to the EU and MSs risk assessors, risk managers and plant health scientists (e.g. via workshops, summer schools and joint publications).

1.4 ELIGIBLE ORGANISATIONS

To be eligible, applicants must be on the list of competent organisations designated by the Member States in accordance with Article 36 of Regulation (EC) 178/2002[15] and Commission Regulation (EC) 2230/2004. This list is regularly updated by EFSA Management Board and is available for consultation by accessing this link[16].

In order to achieve the main objective of the call, proposals can be submitted by **one eligible organisation or by a consortium of eligible organisations, although consortium are strongly encouraged.** In case of a consortium, one of the partners must be identified in the proposal as the consortium leader. The applicant is responsible for identifying consortium partners.

[15] As amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain.

[16] https://efsa.force.com/competentorganisations/s/recordlist/CompetentOrganisation__c/00B1v000009LqfIEAS

1.5 ROLES AND RESPONSIBILITIES

For proper understanding of this call it is important to have clarity on the terminology regarding involved organisations and their roles.

A) Proposals submitted by consortium:

- **The Applicant** submits the proposal/grant application to EFSA on behalf of the consortium. The applicant is the leading entity of the consortium. There can be only one applicant in project proposal/grant application;
- **The Partner** is the other entity in the consortium. There can be a minimum of one partner or more partners.

Once the grant is awarded, the grant agreement is signed between EFSA and the applicant. Partners do not sign the grant agreement directly but instead sign a mandate (template provided by EFSA) authorising the applicant to sign the grant agreement and any future amendments on their behalf.

As soon as the grant agreement is signed, the applicant becomes the Coordinator and partner/s become co-beneficiary/ies. The coordinator and co-beneficiary/ies are referred to as the beneficiaries. The beneficiaries are jointly and severally liable for the technical implementation of the project as described in the proposal which becomes annex 1 of the grant agreement. If a beneficiary fails to implement its part of the project, the other beneficiaries become responsible for implementing that part.

The coordinator has the following important roles:

- Takes part in implementing the project;
- Monitors the action is implemented properly;
- Act as intermediary for communication between the consortium and EFSA;
- Receives and answers all claims EFSA might have in relation to implementation of the project;
- Requests and reviews any documents or information required by EFSA and verifies their completeness and correctness before passing them to EFSA;
- Informs EFSA and the partner/s of any event that is likely to substantially affect implementation of the project;
- Submits the deliverables and reports to EFSA;
- Requests and receives payments from EFSA and distributes the funds to partner/s without unjustified delays;

The coordinator may not delegate the above-mentioned tasks to the co-beneficiary/ies or subcontract them to any third party.

The other beneficiary/ies:

- Take part in implementing the project;
- Forward to the coordinator the data needed to draw up reports, financial statements and other documents required under the grant agreement;
- Inform the coordinator of any event or circumstances likely to substantially affect or delay the implementation of the project.

B) Proposals submitted by a sole applicant:

- **The Applicant** submits the proposal/grant application to EFSA. There can be only one applicant in the proposal/grant application.

As soon as the grant agreement is signed, the applicant becomes the beneficiary. The beneficiary is liable for the technical implementation of the project as described in the proposal which becomes annex 1 of the grant agreement.

The beneficiary:

- Takes part in implementing the project;
- Monitors the action is implemented properly;
- Communicates with EFSA;
- Receives and answers all claims EFSA might have in relation to the implementation of the project;
- Requests and reviews any documents or information required by EFSA and verifies their completeness and correctness before passing them to EFSA;
- Informs EFSA of any event that is likely to substantially affect the implementation of the project;
- Submits the deliverables and reports to EFSA;
- Requests and receives payments from EFSA;

1.6. POSSIBILITY OF IMPLEMENTING CONTRACTS AND SUBCONTRACTING

Implementation contracts:
Where the implementation of the project requires the award of procurement contracts (implementation contracts), e.g. purchase of services and/or goods or equipment necessary for the implementation of the action, the beneficiary must award the contract to the entity offering the best value for money or the lowest price (as appropriate), avoiding conflicts of interests. The beneficiary is expected to clearly document the tendering procedure and retain the documentation for the event of an audit.

Entities acting in their capacity as contracting authorities within the meaning of Directive 2014/24/EU[17] must comply with the applicable national public procurement rules.

Sub-contracting:
Sub-contractors are not consortium partners and are not party to the grant agreement. They do not have any contractual relationship with EFSA. Subcontractors are entities contracted by the beneficiary to carry out some specific tasks or activities. Subcontracting is allowed under these conditions:

- Subcontracts must be awarded to the entity offering best value for money or the lowest price (as appropriate), avoiding conflicts of interests;
- Subcontracting must only cover the implementation of a limited part of the action;
- Recourse to subcontracting is justified having regard to the nature of the project and what is necessary for its implementation;
- Tasks to be subcontracted and the corresponding estimated costs must identified in the estimated budget and approved by EFSA before the signature of the grant agreement;

[17] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65-242)

- Recourse to subcontracting during project implementation, if not envisaged from the outset in the proposal, is subject to prior authorisation in writing by EFSA, and must be formalised via an amendment to the grant agreement. Approval may be granted as long as it does not entail a change to the grant agreement which would call into question the decision awarding the grant or be contrary to the equal treatment of applicants;
- The conditions applicable to the beneficiaries under Articles II.6 (*Confidentiality*), II.7 (*Processing of Personal Data*), II.8 (*Visibility of Union Funding*) of the grant agreement are also applicable to the subcontractor;
- **Core tasks must not be subcontracted**. Only ancillary and assistance tasks can be subcontracted.

1.7 DURATION, MEETINGS AND REPORTING

FOR LOTS 1 & 2

Duration: The maximum duration of projects under lots 1 & 2 is **2.5 years (30 months) from the kick-off meeting**.

Meetings with EFSA:

1. **Kick off meeting (physical meeting, held at EFSA premises or virtual meeting to be held online in the event of travel restrictions/limitations on access to EFSA's premises due to COVID-19)**: The kick-off meeting is regarded as the start of the project and must take place no later than **one month** after the signature of the grant agreement. At this meeting, details of the project will be discussed and the objectives, the final report structure, deliverables and timeframe will be clarified. In particular, the beneficiary will explain their proposal. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.

   The presence at kick-off meeting of a beneficiary's staff member responsible for administrative/finance issues of the project is advised as this will facilitate understanding by the beneficiary of the grant principles, related financial reporting requirements (declaration and documentation of incurred costs) and significantly ease the financial management of the grant agreement, both for EFSA and the beneficiary.

2. **Interim meetings via tele/video conference every 2 months following the kick-off meeting**: The purpose of these meetings will be to discuss progress as well as any problems or difficulties (technical or financial) encountered during the project. Minutes of the meetings shall be taken and provided to EFSA by the beneficiary.

3. **Interim physical meeting at EFSA's premises or virtual meeting to be held online in the event of travel restrictions/limitations on access to EFSA's premises due to COVID-19 halfway through the total project duration**: The purpose of this meeting is to discuss progress as well as any problems or difficulties (technical or financial) encountered during the project. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.

4. **Final meeting (physical meeting, held at EFSA premises or virtual meeting to be held online in the event of travel restrictions/limitations on access to EFSA's premises due to COVID-19) will be held one month before the end of the project:** The purpose of this meeting is to discuss the draft final report and deliverables as well as any

problems or difficulties (technical or financial) encountered during the project. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.

Reporting:
The following reports are foreseen and must be drafted in UK Standard English to a level which does not require further proof reading by EFSA.

1. **Kick-off / inception report 1 month after the kick-off meeting** must be submitted to EFSA. The content and format for the written kick-off / inception report will be agreed during the kick-off meeting.

2. **Interim reports every 6 months after the kick-off meeting** must be submitted to EFSA. The content and format for the written interim reports will be agreed during the interim tele/video meetings. Other possible interim deliverables (e.g. databases, evidence or models) shall also be provided.

3. **Draft final report: 1 month before the final meeting. The draft final report to be submitted to EFSA** will comprise the integration of the inception report, the interim reports, an overall summary, conclusions and discussions for the whole project. The draft final report should also include an impact assessment. The draft final report will be discussed at the final meeting which will take place 1 month before the end of the project.

4. **Final report: No later than 1 month after the final meeting. The final report to be submitted to EFSA** will comprise the integration of the inception report, the interim reports, an overall summary, conclusions and discussions for the whole project. The final report should also include an impact assessment and incorporate any feedback provided by EFSA on the draft final report. Other possible deliverables such as databases, evidence or models also have to be provided in their final format.

FOR LOT 3

Duration: The maximum duration of projects under lot 3 is **3 years (36 months) from the kick-off meeting**.

Meetings with EFSA:

1. **Kick off meeting (physical meeting, held at EFSA premises or virtual meeting to be held online in the event of travel restrictions/limitations on access to EFSA's premises due to COVID-19)**: The kick-off meeting is regarded as the start of the project and must take place no later than **one month** after the signature of the grant agreement. At this meeting, details of the project will be discussed and the objectives, the final report structure, deliverables and timeframe will be clarified. In particular, the beneficiary will explain their proposal. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.

   The presence at kick-off meeting of a beneficiary's staff member responsible for administrative/finance issues of the project is advised as this will facilitate understanding by the beneficiary of the grant principles, related financial reporting requirements (declaration and documentation of incurred costs) and significantly ease the financial management of the grant agreement, both for EFSA and the beneficiary.

2. **Interim meetings via tele/video conference every 2 months following the kick-off meeting:** with project coordinator and other relevant scientific staff. The purpose of these meetings will be to discuss progress as well as any problems or difficulties (technical or

financial) encountered during the project. Short minutes of such meetings shall be taken and provided to EFSA by the beneficiary.

3. **Interim physical meeting at EFSA's premises or virtual meeting to be held online in the event of travel restrictions/limitations on access to EFSA's premises due to COVID-19 halfway through the total project duration**: The purpose of this meeting is to discuss progress as well as any problems or difficulties (technical or financial) encountered during the project. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.

4. **Final meeting (physical meeting, held at EFSA premises or virtual meeting to be held online in the event of travel restrictions/limitations on access to EFSA's premises due to COVID-19) will be held one month before the end of the project:** The purpose of this meeting is to discuss the draft final report and deliverables as well as any problems or difficulties (technical or financial) encountered during the project. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.

Reporting:
The following reports are foreseen and must be drafted in UK Standard English to a level which does not require further proof reading by EFSA.

5. **Kick-off / inception report 1 month after the kick-off meeting** must be submitted to EFSA. The content and format for the written kick-off / inception report will be agreed during the kick-off meeting.

6. **Interim report 15 months after the kick-off meeting** must be submitted to EFSA. The content and format for the written interim report will be agreed during the interim tele/video meetings. Other possible interim deliverables (e.g. databases, evidence or models) shall also be provided.

7. **Draft final report: 1 month before the final meeting. The draft final report to be submitted to EFSA** will comprise the integration of the inception report, the interim reports, an overall summary, conclusions and discussions for the whole project. The draft final report should also include an impact assessment. The draft final report will be discussed at the final meeting which will take place 1 month before the end of the project.

8. **Final report: No later than 1 month after the final meeting. The final report to be submitted to EFSA** will comprise the integration of the inception report, the interim reports, an overall summary, conclusions and discussions for the whole project. The final report should also include an impact assessment and incorporate any feedback provided by EFSA on the draft final report. Other possible deliverables such as databases, evidence or models also have to be provided in their final format.

Applicable to all lots
The final report will be published on the EFSA website using the template of EFSA external scientific report. In the event that data generation, new methodologies or databases are created under the grant, such tools must also be published in the Knowledge Junction (ref. below point 1.18).

Applicants should note that all reporting, minutes, outcome of the discussions could be submitted at EFSA's discretion to EFSA's Panel and WG members.

1.8 PAYMENTS

The following payment scheme will be applied:

- **pre-financing payment**, upon the entry into force of the grant agreement, without need for payment request, 40% of the maximum grant amount; the aim of the pre-financing is to provide the beneficiaries with a float; it remains the property of the EU until the payment of the balance. The exact percentage amount of pre-financing will be determined at the time of grant award;

- **interim payment**, in the middle of the project, based on the request for interim payment, up to 30% of the maximum grant amount set out in the grant agreement or 90% of actually incurred costs declared for the reporting period, whichever is lower; interim payment is subject to the approval by EFSA of the interim report with the corresponding deliverables and approval of the statement of actual costs incurred by the beneficiaries;

- **final payment (payment of the balance)**, after the final EFSA grant amount has been determined (in line with Article II.25 of the grant agreement); the amount due as the balance payment is calculated by EFSA by deducting from the final EFSA grant amount the total amount of pre-financing and interim payments already made; if the total amount of earlier payments is greater than the final EFSA grant amount, the payment of the balance takes the form of a recovery; if the total amount of earlier payments is lower than the final EFSA grant amount, EFSA will pay the balance; payment is subject to the approval of the final report by EFSA.

1.9 GRANT PRINCIPLES

The financial help provided by EFSA under this Call is a grant governed by the EU Financial Regulation referred to in part 1.1. Accordingly, the grant awarded following this Call must comply with the following principles:

- **Co-financing**: In accordance with Article 190 of the Financial Regulation, grants shall involve co-financing. The resources necessary to carry out the project /action shall not be provided entirely by the grant. The project costs not covered by the EFSA grant must be financed from the applicant and partner/s resources. The applicant and its partner/s must therefore contribute financially to the project. Additionally, there may be also a financial contribution from another entity, but such an entity may be only a public body. Contributions from the private sector are not permitted.
- **No-profit**: In accordance with Article 192 of the Financial Regulation, grants shall not have the purpose or effect of producing a profit within the framework of the project for the applicant or partner. Profit is defined as a surplus of the receipts over the eligible costs incurred by the beneficiaries, at the time of request for payment of the balance. The receipts shall be limited to income generated by the project, as well as financial contributions specifically assigned by donors to the financing of the eligible costs. Where a profit is made, EFSA shall be entitled to recover a part of it in line with procedure foreseen in the Grant agreement. The verification of the non-profit rule does not apply to low value grants (</= 60.000 €) or grant in the form of financing not linked to costs pursuant to article 125(1)(a) of the Financial Regulation.

- **Non-retroactivity**: A grant may be awarded for a project which has already begun only where the applicant can demonstrate in the grant application the need to start the action before the grant agreement is signed. In accordance with Article 193 of the Financial Regulation, costs eligible for financing may not have been incurred prior to the date of submission of the grant application. No grant may be awarded retrospectively for a project already completed.
- **Non-cumulative**: In accordance with Article 191(3) of the Financial Regulation, in no circumstances shall the same costs be financed twice from the EU budget. In no circumstances shall the same costs be financed twice by the Union budget. To ensure this, the applicant shall indicate the sources and amounts of Union funding received or applied for the same project or part of the project or for its functioning during the same financial year as well as any other funding received or applied for the same project.

1.10 EFSA GRANT CONTRIBUTION

The form of grant awarded under this grant Call is based on reimbursement of a specified proportion of the total eligible project costs actually incurred (EU Financial Regulation, Article 125 (1a)).

The projects to be supported under this Call are co-financed by EFSA at maximum **50% of the total eligible project costs**. In addition, the maximum possible amount of EFSA grant for each project awarded a grant **500,000 €.** In other words, the grant has double ceiling: the maximum amount and the reimbursement rate applied on the total eligible project cost.

EFSA's maximum grant amount per project:
Overall, EFSA has 1.500.000 Euro available under this Call. EFSA intends to fund **3 proposals (one per lot)** following this Call. The currently available amount of 1.500.000 Euro shall be sufficient to co-finance one successful project per lot (maximum 500.000 Euro per lot). However, EFSA reserves the right:

- not to award all the funds available at any cost, e.g. if the quality of submitted proposals will not be satisfactory i.e. if the submitted proposals do not meet the set award criteria thresholds (2.5 Award Criteria). In such case EFSA reserves the right to re-distribute funds from one lot to another lot that has more than one successful proposal (i.e. proposals which have satisfied the quality thresholds and are ranked in a reserve list). If more than one proposal is proposed for award under a given lot, the evaluation committee should assess and confirm that there is no duplication of scope;
- to award more grants in cumulative value above 1.500.000 Euro in case additional funds will be made available in 2020 EFSA budget. In such case EFSA reserves the right to distribute the additional funds to the lot(s) that has/have more than one successful proposal(s) (i.e. proposals which have satisfied the award criteria thresholds and are ranked in a reserve list). In case more than one lot has more than one successful proposal then the highest ranked proposal(s) across all lots will be proposed for award. If more than one proposal is proposed for award under a given lot, the evaluation committee should assess and confirm that there is no duplication of scope.

EFSA reserves the right not to award any grant and/or to cancel the whole grant procedure at any time before the signature of the grant agreement without any compensation to be paid to the applicant.

The total amount of estimated eligible costs, as presented by the applicant in the estimated budget (Annex 3) (see also part 1.11), and which serves as a basis for calculation of the initial EFSA grant, will be verified by EFSA during the evaluation of proposals. EFSA reserves the right to implement the

necessary adaptations to the estimated eligible costs in case the Rules on eligibility of costs (Annex 1) were not correctly applied by the applicant.

If the amount granted is lower than the funding sought by the applicant, it is up to the applicant to find supplementary financing or to reduce the total cost of the project without diluting either the objectives or the content.

1.11 ESTIMATED BUDGET AND ELIGIBLE COSTS

The proposal must be accompanied by the estimated budget (Annex 3) which must be established in line with the Rules on eligibility of costs (Annex 1). The estimated budget must show all the costs and income which the applicant considers necessary to carry out the project.

Estimated budget must be:

- sufficiently detailed to permit identification, monitoring and checking of the costs;
- balanced, i.e. total income and total project costs must be equal;
- consistent with the work plan;
- expressed in Euro.

Estimated budget – cost side:[18]

- ***Eligible direct costs:***
  1. Costs of personnel;
  2. Travel costs and subsistence allowances;
  3. Depreciation costs of equipment or other assets;
  4. Consumables and supplies;
  5. Workshops, seminar, conferences;
  6. Subcontracting;
  7. Eligible VAT;
  8. Miscellaneous costs are costs arising directly from the requirements imposed by the grant agreement.

The above categories represent an exhaustive list of possible eligible direct costs. However, if, for example, the project does not foresee costs for workshops / seminars / conferences, then this category of costs can be left empty in the estimated budget.

- ***Eligible indirect costs*** incurred in carrying out the project are eligible for a flat-rate funding capped at not more than 10% of the total eligible direct costs. If a beneficiary (partner in the consortium) already receives an operational grant from the EU budget its indirect costs are not eligible under the present call.

Estimated budget – income side:

- ***Mandatory incomes:***
  1. Grant requested from EFSA;
  2. Applicant's financial contribution;
  3. Partners financial contribution;
- ***Optional incomes:***
  4. Financial contributions from other public bodies;
  5. Income generated by the project.

[18] For more details refer to the Rules on eligibility of costs in Annex 1.

1.12 APPROVED ESTIMATED BUDGET

The estimated budget submitted with the proposal is analysed by EFSA, as part of evaluation process, in order to assess whether:

- it is realistic;
- it is consistent with the proposed project;
- the estimated budget is sufficiently detailed;
- the cost items are reasonably justified;
- to eliminate cost items which cannot be accepted according to the Rules on eligibility of costs (Annex 1).

An overestimation or underestimation of costs, or missing justification of the costs, missing details, or detected inconsistency with the technical description of the project will have a negative impact on the evaluation score under the award criterion 6.

If EFSA regards the estimated budget as realistic, consistent with the technical description of project, sufficiently detailed, well justified and established in accordance with the Rules on eligibility of costs (Annex 1) and no modification is needed, it will become the approved estimated budget and the EFSA grant may correspond to the applicant's request. In some cases, the analysis of the estimated budget could result in EFSA suggesting reductions, e.g. need to correct the costs in line with the Rules on eligibility of costs. After the proposed modifications are agreed by the applicant and EFSA, the estimated budget, as modified, will become the approved estimated budget for the project.

1.13 INITIAL EFSA GRANT

Having agreed the approved estimated budget, and provided the proposal is selected for grant award, EFSA will establish the amount of the initial EFSA grant, having regard to the limits set out in part 1.10 of this call. The initial EFSA grant will be expressed as an amount in Euro and also as a percentage (EFSA max. 50% co-financing rate) of the total eligible project cost. This amount will be indicated in the grant agreement as the maximum grant amount.

1.14 FINAL EFSA GRANT

Maximum grant amount set out in the grant agreement was calculated based on the estimated eligible costs. **The final EFSA grant** will naturally have to be determined based on actually incurred costs. The final EFSA grant is determined by EFSA in line with Article II.25 of the grant agreement.

1.15 PUBLICITY

All beneficiaries are expected to follow the rules on visibility of EFSA funding set out in Article II.8 of the grant agreement.

According to Article 38 of the EU Financial Regulation EFSA is bound to publish information on recipients of its grants at its website. Such publication shall take place no later than 30 June of the year following the financial year in which the grants were awarded and shall cover these data of the beneficiaries:

- name of the beneficiary,

- address of the beneficiary,
- subject of the grant,
- amount awarded.

1.16 PROTECTION OF PERSONAL DATA IN RELATION TO GRANT PROCEDURES

Processing of personal data by EFSA

Information on the processing of personal data by EFSA in the context of this grant procedure is available in the Privacy Statement on the EFSA website as well as in Article II.7 of the draft grant agreement. Any personal data included in the Agreement (i.e. the name, any CV and contact details and/or financial details of individuals contained in your application) must be processed by EFSA in accordance with Regulation (EU) No 2018/1725.[19]

Applicants should note that personal data as applicant or selected beneficiary may be registered in the Early Detection and Exclusion System (EDES) if you are in one of the situations mentioned in Article 136 of the Financial Regulation. For more information see the Privacy Statement on: http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm#BDCE).

Processing of personal data by the beneficiary

In case the implementation of activities under an awarded grant entails the processing of personal data, the beneficiary shall comply with the relevant rules in Article II.7.2 of the Grant Agreement (Annex 2) as a data processor of EFSA.

1.17 PUBLIC ACCESS TO DOCUMENTS

In the general implementation of its activities and for the processing of grant procedures in particular, EFSA observes Regulation (EC) N° 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

1.18 OPEN ACCESS

EFSA is committed to the publication of grant outputs in the Knowledge Junction[20] in order to improve transparency, reproducibility and evidence reuse. The Knowledge Junction runs on the EU-funded Zenodo research-sharing platform where uploaded items receive a unique Digital Object Identifier to make them citable. Any part of the output resulting from the action under this grant may be published (at EFSA's discretion) on the Knowledge Junction with attribution to the beneficiary.

[19] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC

[20] Learn more at http://www.efsa.europa.eu/en/press/news/161114

2. SELECTING PROPOSALS

The Evaluation Committee established by EFSA specifically for this call will evaluate the submitted proposals in five steps:

1. Verification of submission requirements (2.1)
2. Eligibility criteria (2.2)
3. Exclusion criteria (2.3)
4. Selection criteria (2.4)
5. Award criteria (2.5)

If the proposal fails at any step it is automatically excluded from further evaluation. EFSA may contact the applicant during the evaluation process if there is a need to clarify certain aspects or for the correction of clerical mistakes.

2.1 VERIFICATION OF SUBMISSION REQUIREMENTS

The following will be verified:

- proposal was submitted within the deadline for submission of proposals;
- proposal is submitted on the EFSA application form (Annex 4);
- proposal is duly signed by the authorised representative of the applicant;
- proposal is complete and includes all the supporting documents.

2.2 ELIGIBILITY CRITERIA

The following will be verified:

- The applicant and in case of consortium also its partner/s are on the list of competent organisations designated by the Member States in accordance with Art 36 of Regulation (EC) 178/2002 and Commission Regulation (EC) 2230/2004. This list is regularly updated by EFSA Management Board. Organisations which are not currently on the list of competent organisations designated by the Member States may apply for the award of a grant under this call for proposals but must provide evidence (see box below) of having taken the necessary steps for inclusion on the article 36 list prior to the deadline of this call for proposals. Award and eventual signature of the grant agreement is conditional upon the inclusion of the organisation on the article 36 list.
- Applicant and in case of consortium also its partner/s participate in the project financially;
- Applicant and in case of consortium also its partner/s are involved in the execution of the project;
- Subcontracting, if any, is justified in the proposal and indicated in the estimated budget.

Documents to be provided:

- **LEGAL ENTITY FORM (Annex 5)** (download template here)
  to be completed and signed by the applicant and in case of consortium also by its partner/s. For a public body the legal entity form should be provided together with a copy of the resolution or decision establishing the public body, or other official document establishing that public body. For a private body an extract from the official journal, copy of articles of association, extract of trade or association register, certificate of liability to VAT (if, as in

certain countries, the trade register number and VAT number are identical only one of these documents is required).

- **FINANCIAL IDENTIFICATION FORM (Annex 6)** (download template here)
  to be completed only by the applicant and in case of consortium only by the coordinator.

Please note that there is no need to submit these forms if they have already been submitted under another EFSA procurement or grant procedure and provided that these forms are still valid. In this case simply indicate in the application form the reference of the call under which the form/s were submitted to EFSA.

Only applicable if the applicant or partner/s are not already included on the Art 36 list of competent organisations:
Evidence that an organisation has taken the necessary steps for inclusion in the Art 36 List of competent organisations prior to the deadline of the call is constituted by the creation of the "initial Assessment Request" by the "Admin Contact Person" of the organisation in the online CompOrg-tool before the call deadline. Practically to reach that stage the interested applying organisation must complete the following 3 steps:

1. contact EFSA national Focal Point (FP) and provide it with the requested information for assessment of their compliance with the criteria for inclusion in the List;
2. answer (if any) additional request(s) for information from the respective FP;
3. access actively the newly created profile/account of the organisation in the online tool and specifically:
   a. insert the **contact details** of the organisation (also per competences)
   b. generate the "**initial Assessment Request"**, which brings the workflow in the tool to the FP level.

Step 3 can only be performed when access has been granted to a nominated individual within the applicant organisation, a so called "Admin. Contact Person", who is assigned licence/user access credentials to the tool (initiated by Focal Point, via EFSA Service Desk). Applicants should initiate this procedure as early as possible to allow completion of all 3 steps by the call deadline.

Only applicable if the applicant is a consortium:

- **PARTNERSHIP STATEMENT**:
  The applicant and partner/s must provide EFSA with a statement indicating their technical and financial involvement. The applicant and partner/s must sign the partnership statement. No template is provided by EFSA.

For British applicants:

As a consequence of the UK withdrawal from the European Union on 31 January 2020 and entry into force of the Withdrawal Agreement ratified by the UK and the European Union, the UK will have a special status with the European Union until the end of the Transition Period (31 December 2020). Until the end of the Transition Period, the UK organisations already on the List of competent organisations shall remain on the article 36 list and may apply for EFSA's grants. As of 31st January 2020, no new UK organisations may be placed on List of competent organisations. The Transition Period based on the Withdrawal Agreement may be extended once up to two years. A decision on Transition Period extension shall be taken by the UK and the European Union before July 2020.

Please be aware that in case of grant award, the eligibility criteria must be complied with for the entire duration of the grant. This implies that after the expiry of the Transition Period, UK beneficiaries will no longer be eligible to receive EU grant funding.

2.3 EXCLUSION CRITERIA

The applicant and partner/s must sign a declaration on their honour certifying they are not in one of the exclusion situations referred to in the Articles 136 of EU Financial Regulation.

Documents to be provided:

- **THE DECLARATION ON HONOUR FOR EXCLUSION CRITERIA (Annex 7)**: template is published with this Call; to be completed/signed individually by the applicant and in case of consortium by each partner.

2.4 SELECTION CRITERIA

The purpose of the selection criteria is to verify the financial and operational capacity of the applicant and in case of consortium also of its partner/s.

Financial capacity:
The applicant and in case of consortium also its partner/s must have stable and sufficient financial resources to:

- maintain their activity throughout the period during which the project is being carried out, and
- participate in its funding.

Operational capacity for each lot:
The applicant or in case of a consortium, the consortium as a whole, must have the professional resources, competencies and qualifications necessary to complete the proposed project:

For lot 1:
The applicant must demonstrate they have access to an experienced, multidisciplinary team of experts in the field of microbiome which comprises at least one senior scientist (10 years post doctorate experience) being specialist in studying human and/or domestic animal gut microbiome and at least one senior scientist (10 years post doctorate experience) in safety evaluations of human and/or domestic animal health in the context of risk assessment.

For lot 2:
The applicant must demonstrate they have access to an experienced, multidisciplinary team of experts in the field of microbiome which comprises at least one senior scientist (10 years post doctorate experience) being specialist in studying environmental microbiomes) and at least one senior scientist (10 years post doctorate experience) in environmental risk assessment.

For lot 3:
The applicant must demonstrate they have access to an experienced, multidisciplinary team of experts in the field of pest risk assessment which comprises at least one senior scientist (10 years post doctorate experience) being specialist either in landscape or spatial ecology (with experience in spatially explicit analysis/GIS) in the context of agriculture and/or forestry and at least one senior scientist (10 years post doctorate experience) in either plant pathology and/or entomology and/or pest risk assessment.

Documents to be provided by the applicant for each lot:

- **DECLARATION ON HONOUR ON SELECTION CRITERIA (Annex 8);**

- **SIMPLIFIED FINANCIAL STATEMENT (Annex 9)**
  only required for private bodies if the grant requested from EFSA is >60.000 €. The template published with the Call should be completed for at least the last two closed financial years;

- **Evidence requested for operational capacity for each lot:**
  CURRICULUM VITAE of the experts and other staff to be involved in the project, including a brief description of the expertise and a list of publications relevant to the project for each person proposed. If individual team members are not yet assigned for the proposed project, applicants should provide details of the staff profiles necessary for the project;

- **LETTER OF COMMITMENT:**
  applicable only in the case when other public body financially contributes to the project (body other than EFSA, applicant or in case of consortium, its partners); to be signed by the contributing public body; it serves to confirm its commitment to financially contribute to the project; no template is provided by EFSA;

- **INSTITUTIONAL AND INDIVIDUALS DECLARATION OF INTERESTS**
  Template available here. EFSA will request Institutional and Individuals DoIs only from the awarded beneficiary, prior to the signature of the grant agreement. The requirement to submit Institutional and Individual DoIs will be specified in the award letter and will have to be provided and assessed by the EFSA Authorising Officer before and as a condition of grant agreement signature. **Institutional and Individual DoIs do not need to be provided with your proposal at this stage.**
  In case of a consortium and/or in case of subcontracting, such declarations will need to be completed separately and submitted for each partner and for each identified subcontractor and for each individual member of the project team coming from consortium partners or subcontractors.
  Please refer to EFSA's policy on independence and the Decision of the Executive Director on Competing Interest Management for more detailed information.

2.5 AWARD CRITERIA FOR EACH LOT

The award criteria serve to assess the quality of the proposals in relation to the objectives of the Call. The following award criteria are applicable in this call:

AWARD CRITERIA FOR LOTS 1 & 2

1. Extent to which the proposal achieves the objectives of this call for lots 1 & 2 and is likely to deliver output that will be useful; **(MAX 30 POINTS)**

2. Extent to which the project is described in detail, as well as the proposed methodology is well described and of high quality; **(MAX 30 POINTS)**

3. Project management clarity, including phases, clear timelines for the project tasks completion, detailed milestones per task (e.g. via a project Gantt chart), expected outcomes and deliverables, proposed contingency plan in case of deviations from the

project programme and clear description of task distribution among the consortium (if applicable); **(MAX 10 POINTS)**

4. Extent to which the proposal is likely to boost scientific cooperation between EFSA and MS's, and at EU level. Points will be awarded for proposals submitted as a consortium, regardless of consortium size; considering the extent to which formation of a consortium supports meeting of the specified objectives, e.g. multidisciplinary; **(10 POINTS)**

5. Description of specific quality assurance measures proposed for the project to guarantee high quality of deliverables; **(MAX 5 POINTS)**

6. Technical and financial consistency of the proposal: consistency between the proposed project and its estimated budget, e.g. how it reflects the task distribution/role of partners if applicable: **(MAX 15 POINTS)**

AWARD CRITERIA FOR LOT 3

1. Extent to which the proposal achieves the three specific objectives of this call for lot 3 and is likely to deliver output that will be useful; **(MAX 30 POINTS)**

2. Extent to which the project is described in detail, and level of detail of the spatial analysis (mapping), as well as the proposed methodology is well described and of high quality and applicable in quantitative pest risk assessment; **(MAX 30 POINTS)**

3. Project management clarity, including phases, clear timelines for the project tasks completion, detailed milestones per task (e.g. via a project Gantt chart), expected outcomes and deliverables, proposed contingency plan in case of deviations from the project programme and clear description of task distribution among the consortium (if applicable); **(MAX 10 POINTS)**

4. Extent to which the proposal is likely to boost scientific cooperation between EFSA and MS's, and at EU level. Points will be awarded for proposals submitted as a consortium, regardless of consortium size; considering the extent to which formation of a consortium supports meeting of the specified objectives, i.e. is multidisciplinary and shows a holistic approach by focussing on multiple pests and/or multiple crops and/or multiple agro- and forest ecosystems (vs. regional/one country/one pest/one crop) **(MAX 10 POINTS)**

5. Description of specific quality assurance measures proposed for the project to guarantee high quality of deliverables; **(MAX 5 POINTS)**

6. Technical and financial consistency of the proposal: consistency between the proposed project and its estimated budget, e.g. how it reflects the task distribution/role of partners if applicable: **(MAX 15 POINTS)**

FOR ALL LOTS

In order to be considered for a reserve list for lot 1, 2 and 3, each lot, the proposal must:

- score a **minimum of 70 points** out of maximum possible 100 points; and
- for criteria 1 and 2 score at least half of the points attributed to that criterion.

Proposals which satisfied these quality thresholds will be ranked in a reserve list.

2.6 PROCESS FOLLOWING THE ASSESSMENT AGAINST AWARD CRITERIA

The applicant(s) will be notified, once the evaluation has been finalized, whether they are placed on the reserve list for each lot or not.

As described in section 1.10 of this call for proposals, EFSA intends to fund **3 proposals (one per lot)** following this Call. The currently available amount of 1.500.000 Euro shall be sufficient to co-finance one successful project per lot (maximum 500.000 Euro per lot). However, EFSA reserves the right:

- not to award all the funds available at any cost, e.g. if the quality of submitted proposals will not be satisfactory i.e. if the submitted proposals do not meet the set award criteria thresholds (2.5 Award Criteria). In such case EFSA reserves the right to re-distribute funds from one lot to another lot that has more than one successful proposal (i.e. proposals which have satisfied the quality thresholds and are ranked in a reserve list). If more than one proposal is proposed for award under a given lot, the evaluation committee should assess and confirm that there is no duplication of scope;
- to award more grants in cumulative value above 1.500.000 Euro in case additional funds will be made available in 2020 EFSA budget. In such case EFSA reserves the right to distribute the additional funds to the lot(s) that has/have more than one successful proposal(s) (i.e. proposals which have satisfied the award criteria thresholds and are ranked in a reserve list). In case more than one lot has more than one successful proposal then the highest ranked proposal(s) across all lots will be proposed for award. If more than one proposal is proposed for award under a given lot, the evaluation committee should assess and confirm that there is no duplication of scope.

Following their ranking on the reserve list for each lot, EFSA reserves the right to invite applicants to adapt their proposal based on the evaluators' comments. The number of applicants invited to adjust their proposals and ultimately awarded an EFSA grant will be decided based on the value of grants requested compared to the overall available budget of EFSA for this Call.

Following the successful conclusion of the adaptation phase, the award decision will be taken by EFSA. Subsequently, the grant agreement will be prepared.

In case some applicants fail to adapt the proposal, EFSA reserves the right to reject the proposal. The budget made available in this way may be used for projects of next applicants on the reserve lists for each lot. EFSA may repeat the adaptation process until the available budget of the call is assigned to other applicants on the reserve list for each lot.

3. SUBMITTING PROPOSALS

3.1 APPLICATION FORM

The proposal must be submitted using the **EFSA APPLICATION FORM (Annex 4).** The application form is published together with this call. The application form must be:

- duly completed in all its parts;
- supported with all the requested annexes;
- signed by a duly authorised legal representative of the applicant.

The applicant should be precise and provide enough detail to ensure the proposal is well described in the application form.

By submitting a proposal, the applicant and in case of consortium also partner/s accept/s the procedures and conditions described in this Call and in the documents referred to in it.

In addition to a full paper version of the application, the applicant must submit the application also on a CD or USB. The electronic version must be identical to the paper version. In case of any discrepancies between the electronic and paper version, the latter will prevail. All documents presented by the applicant become the property of EFSA and are deemed confidential.

3.2 LANGUAGE OF THE PROPOSAL AND THE SUPPORTING DOCUMENTS

Proposals may be submitted in any official language of the European Union. However, as EFSA`s working language is English, the submission of proposals in English would speed up the evaluation process.

Please note that some supporting documents are required. These supporting documents are an integral part of the proposal. For more information on the relevant supporting documents to be submitted, please refer to part 2 of this Call. If these supporting documents are in a language other than English, in order to facilitate and speed up the evaluation, it would be appreciated if a reliable translation of the relevant parts of the documents into English is provided with the proposal.

3.3 SUBMISSION MODALITIES

Proposals are to be submitted as indicated in the second page of this document in the Indicative procedure timetable.

3.4 EXPECTED DURATION OF PROCEDURE

In accordance with Article 194(2) of the Financial Regulation, the maximum time-limits for the procedure are as follows:

- All applicants will be informed of the decision regarding their application within 6 months of the deadline for submission of proposals;

- Signature of the grant agreement will take place within 3 months from the date the successful applicant/s has/have been informed of the decision on their application.