CALL FOR PROPOSALS
AND GUIDE FOR APPLICANTS

Call reference: GP/EFSA/PLANTS/2023/04
Call title: Develop a stepwise approach for a fit for purpose risk assessment, in particular for low-concern active substances and uses

Restricted to **the list of competent organisations** established by the Authority's Management Board in application of article 2 the Commission Regulation (EC) No 2230/2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the Authority's remit.

Brief description of the call objectives: This call aims at developing an harmonised tiered approach for appropriate risk assessment of pesticides of potential low concerns. This approach shall include problem formulation, science-based criteria for not submitting experimental data and fit-for-purpose risk assessment methods, including exposure and hazard assessment.

INDICATIVE PROCEDURE TIMETABLE

Milestone	Date[1]	Comments
Launch date	19/06/23	Date of call publication on EFSA's website.
Deadline for applicants to raise clarification questions to EFSA	6/09/23	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	8/09/23	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.	**15/09/23**	Applicants can submit proposals: - either by post (registered mail) or by courier, 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 advance e-mail to EFSAProcurement@efsa.europa.eu. - or delivered by hand **not later than 12.30 hours (Italian time) on the deadline for submission of proposals** 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 Ms R. De Bon 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/PLANTS/2023/04 – NOT TO BE OPENED BY THE INTERNAL MAIL DEPARTMENT".* - name of the applicant - **the posting date should be legible on the outer envelope** **The application submission must contain one original unbound paper version and one USB key of all documents, including the technical proposal.**
Notification of the evaluation results	10/2023	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	11/2023	Estimated

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

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Annex:

Annex 1: Draft grant agreement

1. GRANT OPPORTUNITY AND CONDITIONS[2]

1.1 LEGAL FRAMEWORK

Article 36 (1) of the Regulation (EC) 178/2002[3] of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, stipulates that the Authority shall promote the European networking of organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects[4], the exchange of expertise and best practices in the fields within the Authority's mission. The list of competent organisations designated by the Member States, which may assist EFSA with its mission, is approved and regularly updated by EFSA's Management Board. The full list of Article 36 organisations can be found here.

EFSA's founding regulation was 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.

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 in Article 4 that tasks may be entrusted by the Authority to organisations on the list of competent organisations.

The present call specifically focuses on the below tasks defined in Article 4(3):

1. collecting and analysing data with a view to facilitating risk assessment by the Authority, including assessment tasks in the field of human nutrition in relation to Community legislation, especially the compiling and/or processing of scientific data on any substance, treatment, food or feed, preparation, organism or contaminant which may be linked with a health risk, and the collection and/or analysis of data on the exposure of Member States' populations to a health risk associated with food or feed;
2. producing scientific data or works contributing to the risk assessment tasks, including assessment tasks in the field of human nutrition in relation to Community legislation, for which the Authority is responsible; this type of task must correspond to precise problems identified in the course of the work of the Authority, and in particular that of its Committee and permanent Scientific Panels, and must not duplicate Community research projects or data or contributions which it is the industry's duty to provide, especially in the context of authorisation procedures;

Article 5(2) of the Commission Regulation (EC) 2230/2004[5] of 23 December 2004 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

[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 in Annex 1 of this Call.

[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF

[4] Project is frequently referred to in this Call as "action", in line with EU Financial Regulation terminology.

[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:379:0064:0067:EN:PDF

Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union.

This call is based on EFSA Founding regulation[6] and EFSA's 2023 Work Programme for grants and operational procurements as presented in Annex XII of the Programming Document 2023 – 2025, available on the EFSA's website[7].

1.2 BACKGROUND AND OBJECTIVES OF THE CALL

Plant protection products in EU are regulated by Regulation (EC) No 1107/2009[8]. Data requirements are laid down in Regulation (EU) No 283/2013[9] (active substance) and Regulation (EU) No 284/2013[10] (plant protection product).
According to the Regulation (EC) No 1107/2009, pesticide active substances to be approved shall not have any harmful effect on human or animal health or any unacceptable effects on the environment. For this purpose, applicants have to submit an application dossier, containing a data package investigating various aspects for a specific active substance. The dossier is submitted to a "rapporteur" Member State (RMS) that evaluates the dossier submitted, carries out an initial risk assessment and prepares an assessment Report. The European Food Safety Authority (EFSA) is responsible for coordinating the peer-review by all MSs of the risk assessment performed by the RMS.
Studies to investigate the fate and behaviour of the active substance and potential effects on non-target organisms allowing to perform some aspects of the risk assessment, are detailed in the data requirements (see above) and should be included in the dossiers submitted by applicants.

In the last years, the Green Deal[11] and the Farm to Fork Strategy[12] introduced measures to reduce the use of chemical plant protection products, as well as to stimulate the use of non-chemical alternatives and plant protection products of low concern. For some of these products, it might be expected *a priori* that there will be lower effect when comparing with a conventional chemical product. In addition, the current requirements for risk assessment might not be fit for purpose for some active substances or uses, in particular innovative active substances. How plant protection products impact the environment or human/animal health depends on their intrinsic properties and use, and a low effect can be expected either because the substance is not hazardous and/or the exposure is low. While data requirements are the same for all active substances falling under the scope of the Regulation (EC) No 1107/2009, it is acknowledged in Regulations (EU) No 283/2013 and 284/2013

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

[7] https://www.efsa.europa.eu/sites/default/files/2022-01/amp2325.pdf

[8] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. *OJ L 309, 24.11.2009, p. 1–50*

[9] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance. *OJ L 93, 3.4.2013, p. 1–84*

[10] Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance, *OJ L 93, 3.4.2013, p. 85–152*

[11] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

[12] https://ec.europa.eu/food/horizontal-topics/farm-fork-strategy_en

that some of the data requirements may not be needed if adequately justified, as indicated in the respective introductions in their Annexes (point 1.5):

"*The information shall include a full and unbiased report of the studies conducted as well as a full description of them. Such information shall not be required, where one of the following conditions is fulfilled:*

(a) it is not necessary owing to the nature of the product or its proposed uses, or it is not scientifically necessary;

(b) it is technically not possible to supply.

In such a case a justification shall be provided."

Point (a) might be applied to substances expected to be of low effect such as for example some botanical active substances and pheromones, simplifying the dossiers, speeding up the assessment process, and facilitating the placing on the market of products containing such active substances. Harmonised criteria would be helpful for defining the scientific justification, as they would also streamline the peer reviews foreseen in the regulatory process.

Specific EU Guidance Documents[13,14] have been developed for plant extracts/botanical active substances and pheromones aiming to provide practical solutions on how procedures and data requirements can be applied to facilitate the risk assessment of these type of substances. However, they give limited guidance for performing risk assessment. Nevertheless, these Guidances[13,14] mention the possibility to make use of alternative extrapolation methods such as QSARs (Quantitative structure–activity relationship models[15]), Read-across[16] or more generally non-testing methods when justified and possible. Although the use of alternative methods is in principle applicable to any kind of chemicals, little use is made of them, because of a lack of guidance. Therefore, there is a need to further investigate the use of alternative methods for pesticide risk assessment, including for low-concern active substances.

In addition, the current Environmental Risk Assessment (ERA) as reflected in numerous guidance documents is mainly conceived for traditional spraying applications and is not sufficiently flexible to cover other type of applications, in particular applications of low-concern substances with other techniques (e.g. brush/paste/dispenser applications). It is also not conceived for active substances of particular nature (e.g. volatile chemicals, substances with physical mode of action) or for new modes of action (e.g., RNAi, peptides and antibodies). Therefore, there is a need for a more flexible and fit for purpose risk assessment which would follow a need-to-know approach, based on a problem formulation that implies that the risk assessment can adapt to particular properties of the active substances or particular ways of use.

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13 SANCO/11470/2012– rev. 8, Guidance document on botanical active substance used in Plant Protection Products, 2014

14 SANTE/12815/2014 rev. 5.2, Guidance document on semiochemicals active substances and Plant Protection Products, 2016

15 Structure-activity relationship (SAR) and quantitative structure-activity relationship (QSAR) models - collectively referred to as (Q)SARs - are mathematical models that can be used to predict the physicochemical, biological and environmental fate properties of compounds from the knowledge of their chemical structure. These models are available for free or as commercial software.

16 Read-across and grouping', or 'read-across', is one of the most commonly used alternative approaches for data gap filling in registrations submitted under the REACH Regulation. Read-across involves the use of relevant information from analogous substance(s) (the 'source' information) to predict properties for the 'target' substance(s) under consideration.

Recent developments involving Member States, EFSA and the European Commission at the Standing Committee on Plants, Animals, Food and Feed[17], cover inter alia the development of a method to conduct an explicit problem formulation, which would allow to simplify the environmental risk assessment and identify the environmental fate and ecotoxicological studies needed in the ERA of a representative use on which the risk assessment is based. This method presented an added value for uses with low environmental effects and application methods like indoor uses, precision application techniques, localised applications or drip irrigation. In addition, a compendium of conditions of use, including pesticide application techniques which lead to a reduced exposure and risk from plant protection products is under development. These recent developments should be taken in consideration, as well as other published relevant scientific information.

It is also to note that some active substances may be subject to other regulatory frameworks, e.g. used as food, food additives, or in food processes or occur naturally. This implies that exposure may need to be contextualised with other routes or already occurring levels of the respective substance.

In this context, it is relevant to have harmonised science-based **criteria for justifications** to implement point 1,5 of the Annex to Regulations 283/2013 and 284/2013, and fit-for-purpose risk assessment methods including **exposure** and **hazard** assessment for substances of **potential low concern,** i.e., where there might be an expectation *a priori* to have a low environmental effect (or as defined by the Regulation (EU) No 1107/2009 "*they shall not have any unacceptable effect on the environment*"). This might be expected for example for pheromones, certain botanical active substances, or other biological origin materials. In the table 1 a non-comprehensive list of the kind of active substances for which such justifications might be considered is reported. The criteria and/or fit-for-purpose risk assessment methods to be developed in this call should cover at least substances like botanical active substances[18], semiochemicals, inorganics and other biological materials or biological similar materials as defined below.

Table 1: Kind of active substance that should be considered within this project

Semiochemicals SANTE/12815/2014 rev.5.2 May 2016	Semiochemicals are substances or mixtures of substances emitted by plants, animals, and other organisms that evoke a behavioural or physiological response in individuals of the same or other species.
Botanical active substances	Active substances obtained from plant material. A 'botanical active substance' consists of one or more components found in plants and obtained by subjecting plants or parts of plants of the same species to a process such as pressing, milling, crushing,

- [17] Mentioned in the following PAFF meeting report: : January 2023, point A.16 Working Group on environmental relevant topics in the context of Regulation (EC) No 1107/2009, https://food.ec.europa.eu/system/files/2023-04/sc_phyto_20230125_ppl_sum.pdf
- October and July 2022: point A.16 Working Group on environmental relevant topics in the context of Regulation (EC) No 1107/2009 (case studies) https://food.ec.europa.eu/system/files/2023-01/sc_phyto_20221013_ppl_sum.pdf https://food.ec.europa.eu/system/files/2022-09/sc_phyto_20220714_ppl_sum.pdf
- May 2020: Point A.08 Defining Specific Protection Goals for Environmental Risk Assessment, in particular Report on the Workshop on 3-4 February 2020 and way forward: https://food.ec.europa.eu/system/files/2020-07/sc_phyto_20200518_ppl_sum.pdf.
- Regular update will be published on the following website: https://food.ec.europa.eu/horizontal-topics/committees/paff-committees/phytopharmaceuticals_en

[18] Whilst the term "Plant extracts" is the term used in regulation Regulations (EU) No 283/2013, the term "Botanicals actives substance" is preferred in the EC guidance.

SANCO/11470/2012-re.8 20 March 2014 Also called plant extracts in other regulatory documents; plant derived material	distillation and/or extractions. The process may include further concentration, purification and/or blending, provided that the chemical nature of the components is not intentionally modified/ altered by chemical and/or microbial processes.
Other Biological material	Active substances obtained from animals, from micro-organisms or fermentation, e.g. blood, animal oil, urea, RNAs, proteins (including antibodies), sugars, lipids…
Inorganics	Inorganics including minerals and non-carbon-based molecules and ions, essential elements with physical mode of action.
Others	Any other non-hazardous other substances of natural origin which is not covered by the previous categories

OBJECTIVES OF THE CALL

The main objective of the call is to develop a harmonised stepwise approach for a fit for purpose risk assessment of active substances that are falling under Part A of the Data Requirements (Regulation 283/2013) and that are potentially of low concern. The aim shall primarily be to support the identification of situations where some or all data are not required due to the 'nature' of the active substance and its proposed uses or because 'not scientifically necessary' (according to the abovementioned point 1.5 in the Annex of Regulations 283/2013 and 284/2013). As second objective, a fit-for-purpose ERA accounting for the specificities of these type of substances shall be developed.

The stepwise approach shall include a clear definition of the problem formulation, science-based criteria for justification for not requiring standards studies and fit-for-purpose risk assessment methodology. Hazard properties, fate and behaviour and exposure routes should be considered for identifying the harmonised criteria. Where needed, methods of pesticide application specific to these potential low concern active substances could be identified and shall be considered (e.g., burrows, brush, dispensers, etc.). However, precision application techniques, if not specific to these potential low concern active substances, are not in the scope of this project.

The work shall be carried out taking into consideration ongoing developments currently being discussed at the Standing Committee on Plants, Animals, Food and Feed, e.g. supporting the definition of flexible approach for environmental risk assessment and compiling pesticide application techniques. EFSA will provide to the beneficiary of this grant all the updated information that will be available.

The outcome of this grant may support the development of a specific technical guidance.

Three main situations shall be considered:

- situations where it might be scientifically justified that some specific data are not necessary owing to the nature of the active substance or the product (according to point 1.5 of Annex of Regulation 283/2013 and 284/2013)
- situations where it might be scientifically justified that some specific data are not necessary owing to the proposed representative use(s) (according to point 1.5 of Annex of Regulation 283/2013 and 284/2013)
- fit-for-purpose risk assessment methodologies shall be developed, depending on the kind of data which would be needed under the different scenarios.

The beneficiary should develop the following sub-objectives:

Sub-objectives	Description
Sub-objective 1	Make proposals for criteria that would allow to identify and group low-concern active substances, such as physico-chemical properties, mode of action against target organisms, human, non-target organisms, as well as environmental fate and behaviour, including fast degradation or natural background levels.
Sub-objective 2	For both hazard and exposure, identify harmonized and science-based criteria for justifying the non-submission of guideline studies specified in both active substance and plant protection product data requirements.
Sub-objective 3	In conjunction to the criteria identified in sub-objective 2, investigate the potential use of alternative methods to testing for the hazard assessment of the substance expected to be of low-concern.
Sub-objective 4	In conjunction to the criteria identified in sub-objective 2, investigate the potential use of fit-for-purpose approaches for the exposure assessment of the substances expected to be of low concern, when the standard exposure assessment is not applicable.
Sub-objective 5	Based on sub-objectives 1 to 4, suggest a stepwise approach starting from problem formulation, for fit-for-purpose risk assessment methodologies.
Sub-objective 6	Adapt the methodology from EFSA (2011)[19], which is based on the data requirements, to describe how to perform a proper and fit-for-purpose literature search to support the scientific justification considering sub-objectives 2, 3 and 4 when searching for available literature data for the different group of low concern substances e.g., by indicating fit for purpose search terms and inclusion/exclusion criteria.
Sub-objective 7	Identify knowledge gaps to allow for further investigation in the future

By applying to this call, the applicant shall describe how he will address sub-objectives 1, 2, 3, 4, 5, 6, 7 in terms of methodological approach, timelines, roles and responsibilities.

1.3 TASKS, DELIVERABLES, TIMELINES, MEETINGS AND PAYMENTS

To achieve the objectives described in Section 1.2, the beneficiary shall perform the following tasks:

Task 1: Categorisation of substances (linked to Sub-objective 1)

- Develop a methodological approach for categorising low-concern substances and their grouping to achieve the outcome needed to fulfil sub-objective 1
- Identify a list of case studies on the basis e.g. Commission database for pesticide active substances (https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database_en), available EFSA conclusion, US EPA assessment, PMRA (Canada) assessment, and European Member states assessment in the context of authorisation of plant protection products. The case studies should be used to identify and develop the criteria. Case study from previous work carried on by the European Commission[17] should also be considered, where needed.

Task 2: Identification of the scientific criteria (linked to Sub-objective 2)

- Collect and collate information to support the identification of the scientific criteria or threshold in order to justify as set out in point 1.5 of the Regulation (EU) No 283/2013 that in some

[19]Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal, 9(2):2092 https://doi.org/10.2903/j.efsa.2011.2092

cases, in the area of toxicology, ecotoxicology and environmental fate, guideline studies are not needed (e.g. under which limit of solubility a chemical would not be bioavailable). Identify criteria or categories of substances or substances that would be considered a-priori incompatible with being low-concern substances. Where relevant, values of measured properties shall be proposed, and uncertainties described. Criteria shall be identified for both hazard and exposure. Previous work performed at the European Commission level should be considered, as previously mentioned[17].

Task 3: Identification of alternative methods to *in vivo* toxicity testing (linked to Sub-objective 3)

- Based on the grouping performed under sub-objective 1, collect and collate information to identify alternative methods to *in vivo* toxicity testing, including extrapolation (i.e. *in silico*, *in vitro*, embryo test...) that could be used for the assessment of potential low-concern substance/product, and their applicability. Uncertainties of using alternatives methods shall be described.

Task 4: Fit-for-purpose approach for the exposure assessment (linked to Sub-objective 4)

- Based on the grouping performed under sub-objective 1, identify specificities that should be accounted for in the exposure assessment. Once identified, solutions shall be proposed to allow for a more fit-for-purpose and accurate exposure assessment. This shall consider all types of exposure assessments for non-target organisms but could be grouped into exposure via plants, food items in addition to plant organs, soil, surface water, or spray droplets via drift (in the case of non-target terrestrial plants). Background levels of exposure, or contextualisation of exposure which can be expected via other routes, shall be taken into consideration.

Task 5: Fit-for-purpose approach for the risk assessment (linked to Sub-objective 5)

- Develop risk assessment schemes applying a tiered approach. Solutions shall be proposed to allow for a more fit-for-purpose and accurate tiered risk assessment for the various categories of low-concern substances identified. It shall be based on a structured WoE approach, should include problem formulation, Expert Knowledge Elicitation (EKE) (EFSA, 2014)[20] and uncertainty analysis, and shall consider all types of non-target organism groups covered in Regulation (EU) No 283/2013.

Task 6: Methodological approach (linked to Sub-objective 6)

- Propose a methodology for adapting the EFSA 2011[19], to perform the collection and collation of information to be included in the dossier, including amongst other the question formulation, the source of data that will be checked, and inclusion/exclusion criteria and the acceptability of the extracted data.

Task 7: Workshop organisation

- Develop the agenda and prepare the material for a workshop in which the proposed categorisation of substances, scientific criteria, and fit-for purpose methods and approach identified to perform the hazard, exposure and risk assessment of these low concern active substances will be discussed and agreed with Member states and other relevant stakeholders.

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[20] Guidance on Expert Knowledge Elicitation in Food and Feed Safety Risk Assessment, 2014. EFSA Journal, 12(6), https://doi.org/10.2903/j.efsa.2014.3734

Task 8: Final report

- Draft a final report which, on the basis of the outcome of the above tasks, to describe the stepwise approach for the evaluation of the ERA of the active substances of low concern that has been developed. The stepwise approach shall include a clear definition of the problem formulation to implement the identified criteria and to select the proper ERA method for each category.

Tasks	Deliverables	Deadline
Overarching task: Develop an outline describing in detail the methodology to address sub-objectives 2, 3, 4, 5.	**Inception report:** This report shall include: - The protocol outlining the methodology to address objectives 2, 3, 4, 5. - The planning of the Workshop organisation in terms of timeline and task (Task 9)	3 months from kick-off meeting
Task 1 - Categorisation of substances: Development of a methodological approach for categorising low-concern substances and identification of case studies	**Deliverable 1 - Interim report 1:** The first interim report shall include (Task 1): - A suggestion on how to categorize low-concern substances - A proposal of substance representative for each category, to be used as case-study to fine-tune the criteria	3 months from kick-off meeting
Task 2 - Identification of the scientific criteria: Collect and collate information to support the identification of science-based criteria based on hazard and exposure.	**Deliverable 2 - Interim report 2**. The second interim report shall include for the substance categories agreed in deliverable 1 a draft proposal for: -Science-based criteria for not submitting regulatory studies for low-concern active substance based on hazard and exposure (Task 2) - Categories of substances or substances that would be considered a-priori incompatible with being low concern substances, e.g. hazardous inorganics or botanical components from poisonous plants (Task 2). - Identify the relevant alternative methods (*in silico*, *in vitro* testing) that could be used in the hazard assessment of each type of active substance of low-concern identified in deliverable 1 (Task 3), - Fit-for-purpose and accurate exposure assessment alternative (Task 4)	9 months from kick-off meeting
Task 3 - Identification of alternative methods to *in vivo* toxicity testing: Collect and collate information to identify alternative methods to *in vivo* toxicity testing.		
Task 4 – Fit-for-purpose approach for the exposure assessment: Fit-for-purpose and accurate exposure assessment shall be proposed, considering all types of exposure assessments for non-target organisms.		

Task 5 – Fit-for-purpose approach for the risk assessment: Based on tasks 3, 4, 5, fit-for-purpose risk assessment methodologies shall be proposed to allow for a more tailored and accurate risk assessment for low-concern substances	- Fit-for-purpose and accurate risk assessment approach for low-concern substance (Task 5) -A tailored methodological approach for data collection and collation (Task 6) In Annex to the report, the methodology developed for data collection and collation should be reported. The interim report 2 shall be used as a background document in the workshop discussion to refine the case studies and discussion point to be addressed in the workshop.	
Task 6 - Methodological approach for data collection and collation: A tailored methodology (adaptation of EFSA 2011), shall be developed to perform the collection and collation of information to be included in the dossier.		
Task 7 – A **Workshop** shall be organised, to discuss with MS/other stakeholder the proposed scientific criteria, the proposed alternative methods and approach identified to perform the hazard, exposure and risk assessment	**Deliverable 4: Workshop** organisation, including relevant stakeholders. EFSA can support in organising the workshop, however the beneficiary shall organise the agenda, the background documents, and take the minutes from the workshop.	11 months from kick-off meeting
	Deliverable 5: Interim report 3 - Outcome of the workshop. This interim report shall report the outcome of the workshop discussion.	12 months from kick-off meeting
Task 8 - Based on the previous work, a final report shall be drafted	**Deliverable 6: Final report version 1.** Based on the previous deliverables 1, 3 and 5, a final external report shall be submitted describing a tiered approach according to science-based criteria for: - identifying when a substance is not of low concern - carrying out appropriate risk assessment of the various categories of low-concern active substances. This approach might include problem formulation, criteria for data waiver and alternative methods risk assessment, including specific approaches for exposure and hazard assessment for low-concern substance. This final deliverable shall also include a description on how to do a proper and fit-for-purpose literature search to support the scientific justification when searching for available literature data for low concern substances, and shall identify knowledge gaps, to allow for further investigation in the future. A first draft shall be provided within 16 months from the kick-off meeting, to allow for revision by the end of the contract. A fine-tunned final version of deliverable 6 shall be submitted by month 18.	16 months from kick-off meeting (final report version 1) 18 months (final version)

Subcontracting is allowed for non-core tasks only such as using Experts Knowledge Elicitation (EKE) approach.

Deliverables must be drafted in English and may be subject to publication at EFSA's discretion.

Please note that all reporting, minutes, outcome of the discussions could be submitted at EFSA's discretion to EFSA's Panel and Working Group members. For the purpose of alignment of the various activities on this topic, the beneficiary can be involved in EFSA's Panel and Working Group developing tasks that have affinity with the current grant. In addition, EFSA might provide to the beneficiary materials relevant to perform the task of this grant, in particular regarding the on-going developments at the Standing Committee on Plants, Animals, Food and Feed. Use of the grant deliverables may be subject to publication, subject to the terms and conditions set out in the draft grant agreement (Annex 1 of the call for proposals).

No.	Meetings	Deadline for finalisation
1	**Kick-off meeting:** One day[21] teleconference 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. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary. The presence at the 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 and significantly ease the financial management of the grant agreement, both for EFSA and the beneficiary.	One month after entry into force of agreement (M1)
2	**Interim meeting 1** – This Teleconference aims at discussing deliverable 1 and 2, in particular the following shall be agreed on: - The proposal for the low-concern PPP categorisation - The selection of low-concern PPP to be used as case-studies - The protocol outlining the methodology to address objectives 2, 3, 4, 5 - The planning of the Workshop organisation	4 months from kick-off meeting
3	**Interim meeting 2** – This teleconference aims at discussing deliverable 3, and shall take place before the workshop.	Within 2 weeks from receipt of deliverable 3
4	**Additional interim meetings:** Bi-monthly teleconference, as needed. The purpose of these meetings is to discuss the progress made, the potential issues or difficulties encountered, and the organisation of the workshop (deliverable 3). Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.	Every 2 months from kick-off meeting to the workshop (i.e. M3, M5, M7, M9)
5	**Interim meeting 3 :** This last Interim meeting (teleconference) aims at discussing the deliverable 5 (Final report version 1) and any related issues.	16 months after the kick-off meeting
No.	**Payments**	**Linked to EFSA approval of**

[21] One day = 8 hours, half day = 4 hours

		deliverable No.
1	**Pre-Financing payment** as specified in articles I.4.1 and I.5.2 of the draft grant agreement (Annex 1 of the call for Proposals) up to 30%	1
2	**Interim payment**, as specified in articles I.4.3 and I.5.3 of the draft grant agreement (Annex 1 of the call for Proposals) 40% against deliverable 1, 2, 3, 4, 5	2
3	**Payment of the balance** as specified in article I.4.4 and I.5.4 of the draft grant agreement (Annex 1 of the call for Proposals) 30% at the end of the contract.	3

Deliverables must be drafted in English and may be subject to publication at EFSA's discretion.

Please note that all reporting, minutes, outcome of the discussions could be submitted at EFSA's discretion to EFSA's Panel and Working Group members. Use of the grant deliverables may be subject to publication, subject to the terms and conditions set out in the draft grant agreement (Annex 1 of the call for proposals).

1.4 INFORMATION ON THE GRANT AGREEMENT

Applicants should note that the draft grant agreement is published with the call for proposals. If any applicant should have specific comments on the provisions of the draft grant agreement, these must be raised in a clarification, prior to the deadline for receipt of proposals so that a clear and transparent reply may be published for the benefit and information of all applicants.

1.4.1 Direct Agreement

This Call for proposals aims to conclude a Direct Agreement for the performance of the tasks described in these specifications for a fixed duration. The Agreement can be signed between the Authority and one or several partners.

The budget EFSA has available is 500,000.00 €.

The maximum duration of this Direct Agreement is 18 months from the kick-off meeting.

EFSA intends to fund one proposal following this Call. 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.

Please note that 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.

1.5 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 and Commission Regulation (EC) 2230/2004. This list is regularly updated by EFSA Management Board and is available for consultation using this link https://efsa.force.com/competentorganisations/s/.

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.** In case of a consortium, one of the partners must be identified in the proposal as the consortium leader. The applicant (consortium leader) is responsible for identifying consortium partners.

1.6 ROLES AND RESPONSIBILITIES

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

Proposals submitted by a sole applicant:

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

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:

- 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.

Proposals submitted by consortium:

- **The Applicant** submits the proposal to EFSA on behalf of the consortium. The applicant is the leading entity of the consortium.

- **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 (leading entity of the consortium).

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.

1.7 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[22] 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:

- **Core tasks must not be subcontracted**. Only ancillary and assistance tasks can be subcontracted.
- 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 must be justified having regard to the nature of the project and what is necessary for its implementation;

- Tasks to be subcontracted must be identified in the proposal and be approved by EFSA before the signature of the grant agreement;
- 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

[22] 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)

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.

1.8 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:

The form of grant awarded under this Call is based on financing not linked to the costs of the relevant operations in accordance with Article 125 (1)(a) of the EU Financial Regulation. Grants financed in this way require the fulfilment of conditions set out in sector specific rules of Commission decisions or the achievement of results measured by reference to previously set milestones or through performance indicators.

The present call for proposals comes with an innovative and simplified grant management, where the grant amounts paid to the partner are based on the pre-defined sums which are not linked to the actual costs of the action. This means there is no need for co-financing from the partner, and no need for completion of estimated budgets or timesheets to record the work. The agreed sums are set at a level designed to stimulate the mutually convenient partnership creation. The payment of agreed sums from EFSA will be carried out based on the acceptance by EFSA of the delivered work. If you have questions on this grant form, during the application period, please raise any clarification questions to EFSAProcurement@efsa.europa.eu.

The financial support 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 certain grant principles established in the EU Financial Regulation, specifically:

- **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. The tasks entrusted by EFSA should not be performed before the signature of the grant Agreement.

Article 180(3) of the EU Financial Regulation specifically states that **the following grant principles are NOT applicable** where the grant takes the form of financing not linked to the costs pursuant to article 125(1)(a):

- **Co-financing**: In accordance with Article 190 of the Financial Regulation, grants shall involve co-financing.
- **No-profit**: In accordance with Article 192(3)(d) 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.
- **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.

1.9 ESTIMATED BUDGET AND ELIGIBLE COSTS : NOT APPLICABLE TO FNLC

1.10 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

With regards to publications of EFSA outputs that are integrating the preparatory work delivered in the context of this grant, the beneficiary could be mentioned in authorship lists indicating the affiliation to its organisation.

1.11 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 must be processed by EFSA in accordance with Regulation (EU) No 2018/1725.[23]

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 the grant agreement resulting from this call entails the processing of personal data, the beneficiary shall comply with the relevant rules in Article II.7.2 of the Grant Agreement (Annex 1) as a data processor of EFSA.

1.12 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.

1.13 OPEN ACCESS

EFSA is committed to the publication of grant outputs in the Knowledge Junction 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

[23] 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

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.

1.14 HUNGARIAN PUBLIC INTEREST TRUSTS ESTABLISHED UNDER HUNGARIAN ACT IX OF 2021

Following the Council Implementing Decision (EU) 2022/2506, as of 16th December 2022, no legal commitments (including the grant agreement itself as well as subcontracts, purchase contracts, financial support to third parties etc.) can be signed with Hungarian public interest trusts established under Hungarian Act IX of 2021 or any entity they maintain.
Affected entities may continue to apply to calls for proposals. However, in case the Council measures are not lifted, such entities are not eligible to participate in any funded role (beneficiaries, affiliated entities, subcontractors, recipients of financial support to third parties).
In this case, co-applicants will be invited to remove or replace that entity.

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;
- administrative data for grant application form is duly signed by the authorised representative of the applicant;
- proposal is complete and includes all the supporting documents.

2.2 ELIGIBILITY CRITERIA

Criterion No. 2.2	Requirements and requested evidence
1	**Eligibility criteria**
	The following requirements will be verified:
	• At the day of deadline for submission of proposals, 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; • 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.
	Requested evidence:
	• **Administrative data for grant application (including Legal Entity and Financial Identification Forms):** available here • **LEGAL ENTITY FORM:** available 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:** available 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 the Legal entity and Financial information 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 administrative data for grant application form the reference of the call under which the form/s were previously submitted to EFSA. **Only applicable if the applicant is a consortium:** • **PARTNERSHIP STATEMENT**: The applicant and partner/s must provide EFSA with a statement indicating their involvement in the action. The applicant and partner/s must sign the partnership statement. No template is provided by EFSA.

2.3 EXCLUSION CRITERIA

Criterion No. 2.3	Requirements and requested evidence
2	**Exclusion criteria**
	The following requirements will be verified:
	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 136-140 of EU Financial Regulation.
	Requested evidence:
	THE DECLARATION ON HONOUR – Section A, available here: to be completed/signed individually by the applicant and in case of consortium by each partner.

2.4 SELECTION CRITERIA

A) Financial capacity

Criterion No. **2.4A**	Requirements and requested evidence
1	**Financial capacity**
	The purpose of the selection criteria is to verify the financial capacity of the applicant and in case of consortium also of its partner/s.
	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.
	Requested evidence:
	Documents to be provided by the applicant: • **DECLARATION ON HONOUR – Section B,** available here to be completed by the applicant or in case of consortium by the coordinator. • **SIMPLIFIED FINANCIAL STATEMENT** available here 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. • **LETTER OF COMMITMENT:** applicable only when another 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;

B) Professional and operational capacity

Criterion No. **2.4.B**	Requirements and requested evidence
1	**Professional and operational capacity:**
	Requirements:
	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: **1. Requirements for the organisation:** The beneficiary must provide evidence of expertise (at least 5 years during the last 10 years) in the field of the environmental safety assessment of pesticides, including pesticides of low-concern such as inorganics, semio-chemicals, botanical active substances or other type of biological materials used as plant protection products. Preferably, they should also have experience in performing an EKE in the above fields. **2. Requirements for the team of experts:** Experts involved in the tasks should have a relevant University degree at post-graduate level. The minimum number of experts shall be at least four experts, of which at least two senior experts and one acting as project coordinator. One expert can cover more than one of the profiles listed below, but the team of experts must have experience in the following fields: a. Project management b. Plant protection products regulatory assessment framework c. Pesticides phys-chem properties d. Environmental fate and exposure e. Modes of action in target organisms, humans and non-target organisms f. Alternative methods to chemical testing g. Risk assessment methodology for chemicals, including WOE approach.

	The senior experts must have at least five years of experience at least in one of the above fields while the junior experts must have at least three years of experience at least in one of the above fields. Or, alternatively, they must give evidence of relevant projects (for subobjectives identified above or listed in points a, b, c, d, e and or f hereabove; for example, regulatory assessment report), i.e. three projects or publications for the senior experts, one for the junior experts. Experts shall have a level of English of at least B2 of the European common language framework
	Requested evidence:
	• **EVIDENCE REQUESTED FOR REQUIREMENT 1:** A list of projects carried out during the last 10 years in the field of environmental risk assessment of plant protection products indicating the respective starting and end dates and a description of the most relevant projects performed (not more than 3). • **EVIDENCE REQUESTED FOR REQUIREMENT 2:** **CURRICULUM VITAE** of the experts and other staff to be involved in the project, including a brief description of the expertise, dates and duration of the relevant working experience and/or short description of the relevant projects carried out in the course of the past 10 years. Either a language certificate at level B2, 2 years work or education experience in an English speaking environment or publications in English where they are listed as author are required. • **LIST OF PROJECT TEAM MEMBERS NAMES** – in addition to the CV's, the applicant should also summarise on one page, the names of the individual project team members. • **INDIVIDUAL DECLARATION OF INTERESTS** Template available here. EFSA may request Institutional DoIs only for subcontractors not included in the Art.36 list (where applicable) and Individuals DoIs for members of the project team having influence and/or control over scientific outputs (for staff of leader, partners in the consortium and/or subcontractors), will be requested prior to and as a condition of grant agreement signature. The requirement to submit 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. **DoIs do not need to be provided with your proposal at this stage.** 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

Criterion No. **2.5**	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
1	The extent to which the proposal **achieves the objectives of this call** and is likely to deliver the required output **(10 points)**
2	**Project description and organisation (25 points – minimum threshold 60%)** • Clear description of the project and organization of project into work packages/task 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; **5 points** • Clear and detailed information on distribution of the tasks among the project team; in case of consortium partners, clarity on who does what, when and why (justify why the partner/subcontractor is proposed to do the particular task/work-package); **10 points** • The internal team communication; in case of joint offers & subcontractors also the communication between joint offers partners and subcontractors; **5 points** • The communication with EFSA (who, how, when); **5 points**
3	**Proposed methodology (40 points - minimum threshold 60%)** Particular attention will be given to the justification of the choice of proposed methodology and to the step by step explanation of methodology, with particular reference to the following: • **Methodology for the development of a tiered approach** starting from problem formulation, for alternative risk assessment methodologies for the various identified categories of low-concern active substances by developing a structured WoE (weight of evidence) approach including uncertainty analysis **15 points** • **Methodology to identify the science-based criteria** for justifying the data waiving for the various type of low-concern substance, based on hazard and exposure, including the source of data to be searched **5 points** • **Methodology for investigating the potential use of alternative methods** to in vivo testing for the hazard assessment of active substances expected to be of low-concern (in vitro testing, in silico, etc…), including the source of data to be searched **5 points** • **Methodology for identifying solutions** to allow for a more fit-for-purpose and accurate exposure assessment, including the source of data to be searched **5 points** • **Methodology for the workshop organisation** (expertise identification, how to get input from the experts during both the preparation and running phase of the workshop) **10 points**
4	**Risk management (10 points)** Description of **identified risks** and proposed mitigating actions, : • Risk identification; **5 points** • Proposed risk mitigation actions and their likely effectiveness; **5 points**
5	Description of **quality assurance measures** proposed for the project to guarantee high quality of deliverables (**15 points):** • Role of team leader / leading partner in quality assurance; **10 points** • Special additional measures for quality assurance proposed for this particular project; **5 points**

In order to be considered for a reserve list, the proposal must:

- score a minimum of 70 points out of maximum possible 100 points; and
- for criteria 2 and 3, score at least 60% of the points attributed to that criterion.

Proposals which have satisfied these quality thresholds will be ranked in a reserve list. The reserve list will be valid for six months from signature of the feedback letter.

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 or not.

EFSA reserves the right to invite the 1st ranked applicant on the reserve list, to adapt its proposal based on the evaluators' comments in accordance with article 200(5) EU FR.

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

If the 1st ranked applicant fails to adapt its proposal, EFSA reserves the right to reject the proposal. The budget made available in this way may be used for a project of the next ranked applicant on the reserve list.

3. SUBMITTING PROPOSALS

3.1 SUBMISSION COMPLETENESS CHECKLIST

The proposal must be submitted along with all the requested annexes and the administrative data for grant application form signed by a duly authorised legal representative of the applicant.

The applicant should be precise and provide enough detail to ensure the technical proposal is well described (free format).

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 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.

The below checklist is designed to help the applicant to collect the documents in a structured way before submission of the proposal/application to EFSA.

APPLICATION SUBMISSION COMPLETENESS CHECKLIST	
☐	**ELIGIBILITY CRITERIA:** for details of which documents are needed see part 2.2 of the call: Administrative data forms signed (including Legal Entity and Financial Identification Forms) available here. Partnership Statement (only for consortium)
☐	**EXCLUSION CRITERIA:** for details of which documents are needed see part 2.3 of the call: Declaration on honour section A, available here.
☐	**SELECTION CRITERIA:** for details of which documents are needed see part 2.4 of the call: • Declaration on honour section B, available here. • Simplified Financial Statement, available here only for private bodies if the grant requested from EFSA is >60.000 €. • Letter of commitment applicable only when another public body financially contributes to the project • **EVIDENCE REQUESTED FOR REQUIREMENT 1:** A list of projects carried out during the last 10 years in the field of environmental risk assessment of plant protection products indicating the respective starting and end dates and a description of the most relevant projects performed (not more than 3). • **EVIDENCE REQUESTED FOR REQUIREMENT 2:** **CURRICULUM VITAE** of the experts and other staff to be involved in the project, including a brief description of the expertise, dates and duration of the relevant working experience and/or short description of the relevant projects carried out in the course of the past 10 years. Either a language certificate at level B2, 2 years work or education experience in an English speaking environment or publications in English where they are listed as author are required. • **LIST OF PROJECT TEAM MEMBERS NAMES** – in addition to the CV's, the applicant should also summarise on one page, the names of the individual project team members.

☐	**AWARD CRITERIA:** Technical proposal covering award criteria, see part 2.5 of the call Estimated budget in excel and signed pdf

3.2 SUBMISSION MODALITIES

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

3.3 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.

3.4 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.