CALL FOR PROPOSALS

AND GUIDE FOR APPLICANTS

Call reference: GP/EFSA/PREV/2023/03
Call title: Partnership with EFSA on the retrospective Cumulative Risk Assessment of dietary exposure to pesticide residues

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: The main objective of the call is to conclude Framework Partnership Agreements with multiple organisations belonging to the Article 36 list that will support EFSA in producing retrospective CRAs in the next 4 years. Two lots (hazard assessment and exposure assessment) are proposed.

INDICATIVE PROCEDURE TIMETABLE

Milestone	Date[1]	Comments
Launch date	28/04/2023	Date of call publication on EFSA's website.
Deadline for applicants to raise clarification questions to EFSA	21/06/2023	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	23/06/2023	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.	**30/06/2023**	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 –Muriel Pesci, 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/PREV/2023/03 – 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 USB key of all documents, including the technical proposal.**
Notification of the evaluation results	09/2023	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	09/2023	Estimated

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

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Annexes:

Annex 1: Draft Framework Partnership agreement monobeneficiary and multibeneficiaries
Annex 2: Estimated budget template (for information only, not to be completed with application)
Annex 3: Financial statement template (for information only, not to be completed with application)

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 specific data in response to a common priority, in particular the Community priorities contained in the Authority's work programmes, and in cases where the Authority's scientific assistance is urgently needed by the Commission, especially in the context of the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002;
2. 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;
3. 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;

[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.

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 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 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[6].

1.2 BACKGROUND AND OBJECTIVES OF THE CALL

1.2.1 Background

Human and ecological risk assessment of combined exposure to multiple chemicals poses challenges to researchers, risk assessors and risk managers, and the development of harmonised methodologies for the assessment of multiple chemicals has been identified as a key priority area for EFSA. Furthermore, in the area of pesticide residues, Article 14 of Regulation (EC) No 396/2005[7] stipulates that decisions on applications concerning the setting, modifying and deletion of maximum residue levels (MRLs) shall take into account the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances, and their known cumulative and synergistic effects, when the methods to assess such effects are available.

The PPR Panel therefore elaborated methodologies to carry out cumulative risk assessment (CRA) of pesticide residues and recommended in 2009 a tiered approach for CRA[8] where the first tier consisted of a deterministic assessment while the second tier consisted of a probabilistic assessment. In 2012, A Guidance on the Use of Probabilistic Methodology for Modelling Dietary Exposure to Pesticides[9] was adopted. Finally, in 2013, the PPR panel adopted opinions on the establishment of cumulative assessment groups (CAGs) of pesticides[10] and on the relevance of dissimilar mode of action[11] in this context.

1.2.2 Article 32 of Regulation (EC) No 396/2005

Article 32 of Regulation (EC) No 396/2005 requires EFSA to assess chronic and acute risks to the health of consumers from pesticide residues, based on the results of official controls carried out by Member States. For completeness, this assessment should consider the risks resulting from the combined exposure to pesticide residues (i.e., by performing retrospective CRAs).

1.2.3 First CRAs performed by EFSA

Upon the development of the methodologies described in Section 1.2.1, EFSA started in 2016 a pilot phase for implementation of retrospective CRA. The first assessments that were conducted concerned

[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:379:0064:0067:EN:PDF
[6] https://www.efsa.europa.eu/sites/default/files/2022-01/amp2325.pdf
[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32005R0396&qid=1675874964689
[8] https://www.efsa.europa.eu/en/supporting/pub/en-40
[9] https://www.efsa.europa.eu/en/efsajournal/pub/2839
[10] https://www.efsa.europa.eu/en/efsajournal/pub/3293
[11] https://www.efsa.europa.eu/en/efsajournal/pub/3472

the acute effects of pesticide residues on the nervous system and their chronic effects on the thyroid. Final reports[12], [13], [14], [15], [16], [17] were published in 2019 and 2020. Later, EFSA finalized additional reports[18],[19] in 2021 and 2022 on the cumulative dietary risk assessment of chronic acetylcholinesterase inhibition and of craniofacial alterations, respectively.

1.2.4 Implementation of CRA from 2022 onwards

Based on the experience acquired, EFSA is now intending to proceed with a wider and faster implementation of CRA of pesticides. Indeed, in its report to the European Parliament and the Council on the evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market[20] and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides, the European Commission highlights the need to continue methodological development for CRA in order to further strengthen consumer protection and calls for speeding up the process and allocating sufficient resources by EFSA and Member States.

In first instance, to ensure an optimal use of resources, EFSA is developing a prioritisation method which will allow the identification of pesticides and organ systems of relevance for dietary CRA. In 2023, EFSA will issue a scientific report identifying active substances which, on the basis of their health-based guidance values for acute and chronic risk assessment and on their residues in food commodities reported in the EFSA annual reports, exceed a certain level of risk and therefore need to be considered in the context of CRAs. This report will also identify organs/systems that will require a comprehensive CRA, when, for these organs/systems, the hazard index (HI) calculated with pesticides affecting them will have been shown to be higher than 1. On the longer term, the implementation of the prioritisation method is intended to be repeated every three years.

In the EFSA-SANTE Action Plan on CRA for pesticides residues[21], it is estimated that between 8 and 15 organ/systems will require such comprehensive CRA, starting with the establishment of CAGs. In the minimum estimation (8 organ/systems requiring comprehensive CRA), all CAGs are expected to be established by 2026. In the maximum estimation (15 organ/systems requiring comprehensive CRA), all CAGs are expected to be established by 2030.

To meet the objectives of this action plan, EFSA is seeking, through this call, the cooperation of competent organisations in Member states. For a good understanding of the modalities of this cooperation, Section 1.2.5 describes in detail all the different steps of the CRA process, while Section 1.3 explains how the carrying out of these steps will be distributed between EFSA and the organisations that will be awarded.

1.2.5 The CRA process

For each prioritised organ/system, CRAs will be performed following a stepwise process covering the three usual modules of risk assessment, i.e., hazard identification and characterisation, exposure assessment and risk characterisation. This process is described and commented in Figure 1~~Figure 1~~.

12 https://www.efsa.europa.eu/en/efsajournal/pub/5800
13 https://www.efsa.europa.eu/en/efsajournal/pub/5801
14 https://www.efsa.europa.eu/en/efsajournal/pub/5764
15 https://www.efsa.europa.eu/en/efsajournal/pub/5763
16 https://www.efsa.europa.eu/en/efsajournal/pub/6087
17 https://www.efsa.europa.eu/en/efsajournal/pub/6088
18 https://www.efsa.europa.eu/en/efsajournal/pub/6392
19 https://www.efsa.europa.eu/en/efsajournal/pub/7550
20 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R1107&qid=1675876013817
21 https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_cum-risk-ass_action-plan.pdf

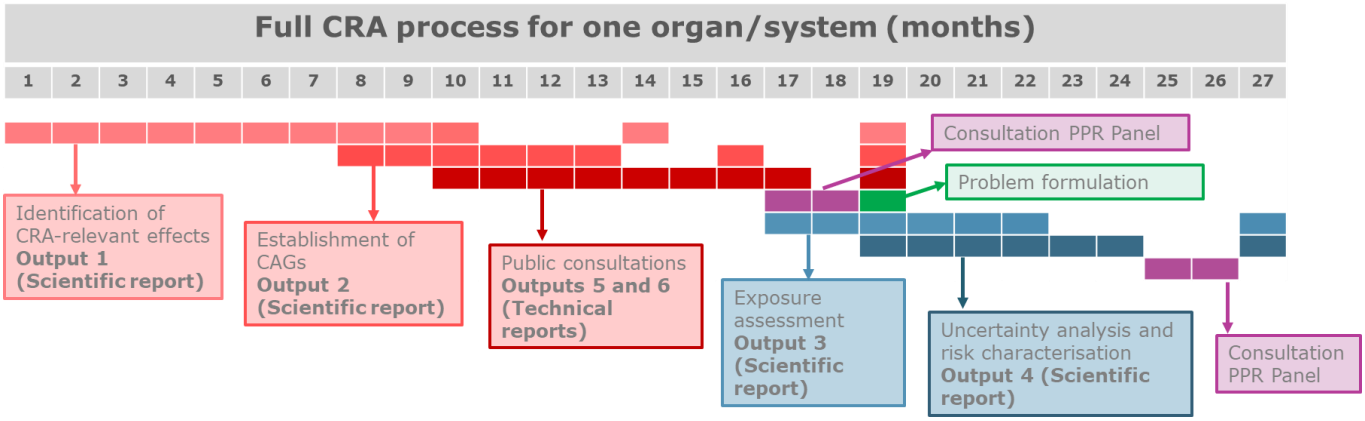

Figure 1 Flowchart of the CRA for an organ or system (the production of Outputs 2 and 3 are the subject of the present call for proposal)

A full CRA process investigating the risks related to the possible effects that can result from the combined exposure to pesticide residues on a defined organ or system may take 27 months. It consists of a sequence of steps which are described in Table 1~~Table 1~~, with their respective indicative timelines.

Table 1 The successive steps of the CRA for an organ or system

Step	Month	Content description
1	1 to 10	Hazard identification: Definition of the specific effects of relevance for CRA The task consists in the identification and unambiguous definition of the specific effects of relevance for CRA for the organ/system under consideration, in consistency with the hazard-driven criteria described in the guidance document of the EFSA Scientific Committee on scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals[22]. For each specific effect, respective relevant indicators (i.e., toxicological endpoints identifiable in toxicological studies reflecting the specific effect) are defined. To prepare Step 2, the conditions triggering the inclusion of active substances in each CAG to be established, and the principles of their characterisation for the respective specific effects, are also defined. Where relevant, also the lines of evidence to be considered in the assessment of the CAG-membership probability (i.e., the probability that a substance included in a CAG is actually causing the respective specific effect) are defined. A first draft scientific report on the identification of the specific effects for the organ/system under consideration will be prepared by month 10.
2	8 to 13	Hazard characterisation: Establishment of CAGs For each of the specific effects defined in Step 1, a CAG will be established.

22 EFSA Scientific Committee, More SJ, Bampidis V, Benford D, Bragard C, Hernandez-Jerez A, Bennekou SH, Halldorsson TI, Koutsoumanis KP, Lambré C, Machera K, Naegeli H, Nielsen SS, Schlatter JR, Schrenk D, Silano V, Turck D, Younes M, Benfenati E, Crépet A, Te Biesebeek JD, Testai E, Dujardin B, Dorne JLCM and Hogstrand C, 2021. Guidance Document on Scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals. EFSA Journal 2021;19(12):7033, 37 pp. https://doi.org/10.2903/j.efsa.2021.7033

		The task first consists in collecting all the indicators of the specific effects concerning the active substances prioritised by the prioritisation method (see Section 1.2.4) and causing effects on the organ/system under consideration, as well as any further information needed to implement efficiently the principles of the hazard characterisation defined in step 1 (e.g., details on the study design needed to allow the combination of studies for the characterisation of substances) or the uncertainty analysis in step 11 (e.g., data allowing the assessment of the dose-response relationship). These data are collected from Draft Assessment Reports, Renewal Assessment Reports and their addenda generated by Rapporteur Member States in the context of Regulation (EC) No 1107/2009, as well as from other sources of similar nature (e.g., JMPR evaluations), in a predefined format/template . A robust quality check procedure of the data collection needs to be put in place. Secondly, the collected data are assessed to decide which active substance is to be included in the CAG(s), using the conditions of inclusion defined in Step 1. Finally, all the substances included in the CAGs are characterised for the respective specific effects, using the characterisation principles defined in Step 1. A first draft scientific report on the establishment of CAGs for the organ/system under consideration is prepared by month 13.
3	10 to 19	<u>Public consultations</u> Two public consultations are conducted. The first public consultation is launched at month 10 and concerns the draft scientific report on the identification of the specific effects. The second public consultation is launched at month 14 and concerns the draft scientific report on the establishment of the CAGs. Both public consultations are initiated by EFSA and take place on the EFSA website for a 2-month period. Technical reports covering the 2 public consultations are prepared during month 17 and submitted to the internal EFSA approval during month 19 (**Outputs 5 and 6**). These technical reports describe the results of the public consultation and provide answers to each submitted comment.
4	14	<u>Hazard identification (update)</u> A second draft scientific report on the identification of the specific effects for the organ/system under consideration is prepared, based on the outcome of the public consultation, for submission to the PPR panel.
5	16	<u>Hazard characterisation (update)</u> A second draft scientific report on the establishment of CAGs for the organ/system under consideration is prepared based on the outcome of the public consultation, for submission to the PPR panel.
6	17 to 18	<u>PPR panel consultation</u> The PPR panel is consulted for the endorsement of the second draft scientific report on the identification of the specific effects for the organ/system under consideration and the second draft scientific report on the establishment of CAGs for the organ/system under consideration.
7	19	<u>Hazard identification (finalisation)</u>

		The final scientific report on the identification of the specific effects for the organ/system under consideration (**Output 1**) is prepared, based on the outcome of the consultation of the PPR panel and submitted to the internal EFSA approval during month 19.
8	19	Hazard characterisation (finalisation) The final scientific report on the establishment of CAGs for the organ/system under consideration (**Output 2**) is prepared, based on the outcome of the consultation of the PPR panel submitted to the internal EFSA approval during month 19.
9	19	Problem formulation After establishment of the CAGs for the organ/system under consideration, the assessment questions (i.e., the precise health effects for which a cumulative risk assessment needs to be performed) to be addressed in the following steps of the process (exposure assessment, uncertainty analysis and risk characterisation) are defined. The number of assessment questions per organ/system is not necessarily the same as the number of identified specific effects. If this does not impair the protectiveness of the CRA for the organ/system under consideration, the number of assessment questions can be smaller than the number of CAGs. The scope (e.g., commodities, consumer populations) and type of assessment (e.g., acute, chronic) related to each assessment question are also defined.
10	17 to 22	Cumulative exposure assessments Cumulative exposure assessments are performed by probabilistic modelling. These assessments meet the following conditions: • They are conducted with the MCRA software[23] • Indicatively, they are performed for the up to about 30 populations of adults, children and toddlers in different EU Member States • Indicatively, they use monitoring data from the latest available 3-year cycle of the Member States monitoring programmes on up to about 40 raw primary commodities,, some of their processed products and on commodities intended for infants and children. • Inner loop execution is performed in accordance with the harmonised technical approach on the parameters governing retrospective cumulative exposure assessment of the European commission[24], for the Tier II scenario. • Sampling uncertainties affecting the occurrence and consumption data are quantified by outer loop execution where the inner loop execution is repeated 100 times. Prior to each execution, new consumption and occurrence data sets of the same size are generated from random sampling with replacement from the original data sets. • Sensitivity analyses are performed to explore the impact of sources of uncertainty on the results. At least the following sensitivity analyses are performed: a) Sensitivity with left-censored data imputed at 1/2 LOQ on commodities for which the use of the active substance is authorised b) Sensitivity analysis with all left-censored data imputed at zero c) Sensitivity analysis assuming that residues will not be present in any processed food d) Sensitivity analysis excluding samples obtained through a selective sampling strategy e) Sensitivity analysis assuming that samples are not subject to unit-to-unit variability (acute effects only) f) Sensitivity analysis assuming that no residues are present in drinking water g) Sensitivity analysis excluding non-compliant samples (i.e., samples in which residues of at least one pesticide exceeds the MRL multiplied by 2)

[23] https://mcra.rivm.nl/Select

[24] https://ec.europa.eu/food/plant/pesticides/max_residue_levels/cumulative_risk/technical-annex_en

		Additional sensitivity analyses might be performed following the analysis of the detailed results of the calculations and/or according to needs identified during the uncertainty analysis process (step 11 below). The results of cumulative exposure calculations are expressed as total margin of exposure (MOET). 95% confidence intervals (incl. central estimate) are reported for P50, P90, P95, P99 and P99.9 of the exposure distribution at least. Violin plots of the confidence intervals at the threshold for regulatory consideration (i.e., P99.9) are presented for the selected population groups. Detailed information on the input data and output data are formatted and reported in a way similar to the recent EFSA scientific reports on CRA regarding chronic AChE inhibition[25] and craniofacial alterations[26]. A draft scientific report on the cumulative exposure assessment is prepared by month 22. For each CAG, this report includes one Excel workbook containing the input data for the exposure assessment (see https://zenodo.org/record/7143238#.Y1FeXHZBzD4 for guidance on the content) and one excel workbook containing the output data concerning the Tier II exposure assessment (see https://zenodo.org/record/7143238#.Y1FeXHZBzD4 for guidance on the content)
11	19 to 24	Uncertainty analysis and risk characterisation An uncertainty analysis is conducted according to the stepwise process described in the recent EFSA scientific reports on CRA regarding chronic AChE inhibition and craniofacial alterations. It includes the following steps: • Step 11.1: Identification of sources of uncertainty and collection of information supporting the assessment of their impact. • Step 11.2: Evaluation of the individual impact of all sources of uncertainty. • Step 11.3: Evaluation of the combined impact of uncertainties relating to exposure on one hand, and relating to toxicology on the other hand. • Step 11.4: 1-D Monte Carlo simulations to combine distributions quantifying uncertainties related to exposure and toxicology with the uncertainty distribution for the MOET at the 99.9th percentile of exposure generated by the exposure model. • Step 11.5: Accounting for dependencies and differences between populations. This uncertainty analysis aims at quantifying the probability of the MOET at 99.9th percentile of the exposure distribution being less than 100 for all populations under consideration, which is the final expression of the cumulative risks. It is supported by Expert Knowledge Elicitation, following the EFSA guidance[27]. At least 6 independent experts are involved in each area of scientific expertise necessary for the elicitation process (toxicology and dietary exposure). The process is supported by technical notes which document the impact of uncertainties, and by ad-hoc sensitivity analyses. These can include recalculation of the cumulative exposure after Benchmark Dose modelling for the substances which contribute the most to the cumulative risk. When this is required, the principles described in the guidance of the EFSA Scientific Committee on the use of the benchmark dose approach in risk

[25] EFSA (European Food Safety Authority), Anastassiadou M, Choi J, Coja T, Dujardin B, Hart A, Hernandez-Jerrez AF, Jarrah S, Lostia A, Machera K, Mangas I, Mienne A, Schepens M, Widenfalk A and Mohimont L, 2020. Cumulative dietary risk assessment of chronic acetylcholinesterase inhibition by residues of pesticides. EFSA Journal 2021;19(2):6392. 161 pp. doi:10.2903/j.efsa.2021.6392

[26] EFSA (European Food Safety Authority), Anagnostopoulos C, Anastassiadou M, Castoldi AF, Cavelier A, Coja T, Crivellente F, Dujardin B, Hart A, Hooghe W, Jarrah S, Machera K, Menegola E, Metruccio F, Sieke C and Mohimont L, 2022. Scientific Report on retrospective cumulative dietary risk assessment of craniofacial alterations by residues of pesticides. EFSA Journal 2022;20(10):7550, 255 pp. https://doi.org/10.2903/j.efsa.2022.7550

[27] EFSA (European Food Safety Authority), 2014. Guidance on Expert Knowledge Elicitation in Food and Feed Safety Risk Assessment. EFSA Journal 2014;12(6):3734. 278 pp. doi:10.2903/j.efsa.2014.3734

		assessment[28], including its updates, are applied and the corresponding EFSA platform for BMD analysis is used. Step 11.5 is also facilitated by simulations testing the impact of dependencies and the effect of downshift/upshift of the MOET distribution on the probability of the MOET at 99.9th percentile being below 100. Hearings of stakeholders in possession of particular data or knowledge informing the uncertainty analysis can be organised. A draft scientific report on the uncertainty analysis and the risk characterisation is prepared by month 24.
12	25 to 26	PPR Panel consultation The PPR panel is consulted on the draft scientific report on the cumulative exposure assessment and on the draft scientific report on the uncertainty analysis and the risk characterisation.
13	27	Cumulative exposure assessment (finalisation) The final scientific report on the cumulative exposure assessment (**Output 3**) is prepared based on the outcome of the consultation of the PPR panel.
14	27	Uncertainty analysis and risk characterisation (finalisation) The final scientific report on the uncertainty analysis and the risk characterisation (**Output 4**) is prepared based on the outcome of the consultation of the PPR panel.

As indicated in the above table, for each organ/system, the outcome of the entire process will be reported by the following outputs:

- **Output 1**: Scientific report identifying the specific effects of relevance for CRA and defining the relevant indicators, criteria for inclusion in CAGs, hazard characterisation rules and lines of evidence for eventual assessment of the CAG-membership probability
- **Output 2**: Scientific report establishing the CAG, covering the data collection, the identification of substances causing the effect and their characterisation by a point of departure
- **Output 3**: Scientific report on the cumulative exposure assessment for the (critical) specific effects defined in output 1
- **Output 4**: Scientific report on the uncertainty analysis and the risk characterisation for the specific effects addressed in output 3
- **Outputs 5 and 6**: Technical reports on the public consultation on draft outputs 1 and 2.

All outputs will be approved by EFSA before publication. Outputs 1 to 4 will be submitted to the PPR Panel for endorsement/advice as part of the approval process.

These CRAs should be repeated on a periodic basis because the use of pesticides and the scientific knowledge on their toxicological properties are continuously changing. Every three years, the CAGs should therefore be updated to include new substances emerging from the prioritisation method, if appropriate, and to update the toxicological characterisation of active substances already included if new information has been made available to EFSA after the initial establishment of the CAGs. After update of the CAGs, new CRAs should be conducted using up-to-date information (most recent monitoring data, consumption surveys, processing factors…)

[28] EFSA Scientific Committee, Hardy A, Benford D, Halldorsson T, Jeger MJ, Knutsen KH, More S, Mortensen A, Naegeli H, Noteborn H, Ockleford C, Ricci A, Rychen G, Silano V, Solecki R, Turck D, Aerts M, Bodin L, Davis A, Edler L, Gundert-Remy U, Sand S, Slob W, Bottex B, Abrahantes JC, Marques DC, Kass G and Schlatter JR, 2017. Update: Guidance on the use of the benchmark dose approach in risk assessment. EFSA Journal 2017;15(1):4658, 41 pp. doi:10.2903/j.efsa.2017.4658

1.2.6 OBJECTIVES OF THE CALL

The main objective of the call is to conclude Framework Partnership Agreements (FPA – see Section 1.4.1) with multiple organisations belonging to the Article 36 list that will support EFSA in producing CRAs in the next 4 years, according to the process described above in Section 1.2.5.

This would contribute to the achievement of the EFSA-SANTE action plan and, at the same time, optimise the experience sharing in EU and contribute to the achievement of the EFSA strategic objective 'Building the EU's scientific assessment capacity and knowledge community'.

1.3 LOTS, TASKS, DELIVERABLES, TIMELINES, COORDINATION MEETINGS AND PAYMENTS

1.3.1 Lots

This call includes 2 lots:

- Lot 1: Establishment of CAGs
- Lot 2: Cumulative exposure assessments

Interested organisations can submit proposals for the 2 lots, or for one lot only.

Organisations submitting an offer for Lot 1 are in addition invited to indicate the toxicological domains in which they would wish to be involved. The toxicological domains that are intended to be addressed during the period of validity of the FPAs are:

- Nervous system toxicity (Developmental toxicity excluded)
- Developmental neurotoxicity
- Thyroid toxicity
- Kidney toxicity
- Liver toxicity
- Developmental toxicity
- Reproductive toxicity
- Haematopoietic system toxicity
- Craniofacial alterations
- Female reproductive system toxicity
- Male reproductive system toxicity
- Mammary glands toxicity
- Adrenal glands toxicity

Interested organisations can indicate interest for all domains, some of them or one only.

1.3.2 Tasks distribution between EFSA and the organisations awarded for Lot 1 and Lot 2, deliverables, timelines and coordination meetings

For each organ or system for which a CRA will be undertaken, a partnership between EFSA, one organisation awarded for Lot 1 and one organisation awarded for Lot 2 will be formally established through Specific Agreements. Under this partnership, the lead of the different steps described in Table 1~~Table 1~~ will be typically distributed as follows:

- EFSA: Steps 1, 3, 4, 6, 7, 9, 11, 12 and 14
- Organisation awarded for Lot 1: Steps 2, 5, 8,
- Organisation awarded for Lot 2: Step 10 and 13

However, as there is a high degree of interdependency between the steps of the process, mutual support between the 3 actors will be necessary in many of these steps. Table 2, Table 3 and Table 4 describe in detail the tasks and deliverables that will be expected in the different steps from the

organisations awarded for Lot 1 and Lot 2. These tables also give insight into the workload associated to the tasks, based on the experience acquired by EFSA in earlier CRAs. The indicative timelines of execution of these tasks are given in Table 1~~Table 1~~.

Table 2 Tasks foreseen under Specific Agreements related to Lot 1 for a first CRA

Step	Task expected form organisations awarded for lot 1	Outcome/Deliverables	Estimated workload
Step 1	Preparation of and participation as WG member to the meetings of the EFSA WG on Cumulative Risk Assessment dedicated to organ/system under consideration	Active contribution to the meetings of the EFSA WG	15-25 days
Step 2	Collection of data	Data collection template filled. 1st draft scientific report on the establishment of CAGs for the organ or system under consideration	2-4 days/substance
	Establishment of CAGs (identification of the substances to be included and characterisation of these substances by an overall NOAEL and an overall LOAEL for the respective specific effect)		2.5-5 days/CAG
	Preparation of a 1st draft scientific report on the establishment of CAGs for the organ or system under consideration		20 days + 3-5 days/CAG
	Internal coordination		25 days + 3-5 day/CAG
	Quality control		10-20 days + 2-4 days/CAG
	Coordination meetings with EFSA		20 days
Step 3	Preparation of replies to submitted comments in relation to step 2	Replies to submitted comments in relation to step 2	0.2-0.4 days/substance and CAG
	Coordination meetings with EFSA		14 days
Step 4	Coordination meeting with EFSA	None	2 days
Step 5	Preparation of the 2nd draft scientific report on the establishment of CAGs for the organ or system under consideration. Major changes may be needed in case public comments trigger modifications of the specific effects	2nd draft scientific report on the establishment of CAGs for the organ or system under consideration	5 to 50 days
	Coordination meetings with EFSA		2 to 10 days
Step 6	Coordination meeting with EFSA	None	1.5 days
Step 7	No task foreseen	None	
Step 8	Preparation of the final scientific report on the establishment of CAGs for the organ or system under consideration	Final scientific report on the establishment of CAGs for the organ or system under consideration (Output 2 of the full CRA process described in section 1.2.5)	5 to 10 days
	Coordination meeting with EFSA		2 days
Step 9	Coordination meeting with EFSA	None	2 days
Step 10	No task foreseen	None	-
Step 11	Step 11.1: collection of information regarding uncertainties in Step 2 (e.g., lines of evidence supporting the assessment of CAG-membership probabilities of risk drivers, assessment of CAG-membership probabilities, uncertainties affecting the characterisation of substances included in the CAG), drafting of the respective technical notes. Additionally, collection of data for BMD modelling for risk drivers and performance of BMD modelling might be required (when this is the case, the principles to be applied in the data collection and in the BMD-modelling will be defined in consultation with EFSA).	Technical notes documenting the uncertainties affecting Step 2. When BMD modelling is performed, one of these technical notes will consist in a BMD-modelling report elaborated following the principles of reporting of the BMD analysis given the guidance of the EFSA Scientific Committee[29].	10 days + 5 days/CAG (without BMD modelling) to 20 days + 10 days/CAG (with BMD modelling) days
	Step 11.2: Preparation and participation of 2 experts to the EKE 1 session		4 days/CAG

[29] EFSA Scientific Committee, Hardy A, Benford D, Halldorsson T, Jeger MJ, Knutsen KH, More S, Mortensen A, Naegeli H, Noteborn H, Ockleford C, Ricci A, Rychen G, Silano V, Solecki R, Turck D, Aerts M, Bodin L, Davis A, Edler L, Gundert-Remy

Step	Task expected form organisations awarded for lot 1	Outcome/Deliverables	Estimated workload
	Step 11.3: Preparation and participation of 2 experts to the EKE 2 session	Active participation of 2 experts in the EKE sessions	2 days/CAG
	Step 11.5: Preparation and participation of 2 experts to the EKE 3 session		4 days/CAG
Step 12	No task foreseen	None	
Step 13	No task foreseen	None	-
Step 14	No task foreseen	None	-

Table 3 Tasks foreseen under Specific Agreements related to Lot 1 for a CRA repetition

Step	Task expected form organisations awarded for lot 1	Outcome/Deliverables	Estimated workload
Step 1	Preparation of and participation as WG member to the meetings of the EFSA WG on Cumulative Risk Assessment dedicated to organ/system under consideration	Active contribution to the meetings of the EFSA WG	10-20 days
Step 2	Collection of data	Data collection template filled. Draft scientific report on the establishment of CAGs for the organ or system under consideration	2-4 days/substance
	Establishment of CAGs (identification of the substances to be included and characterisation of these substances by an overall NOAEL and an overall LOAEL for the respective specific effect)		2.5-5 days/CAG
	Preparation of a 1st draft scientific report on the establishment of CAGs for the organ or system under consideration		20 days + 3-5 days/CAG
	Internal coordination		25 days + 3-5 day/CAG
	Quality control		10-20 days + 2-4 days/CAG
	Coordination meetings with EFSA		20 days
Step 3	No task foreseen	None	-
Step 4	No task foreseen	None	-
Step 5	No task foreseen	None	-
Step 6	Coordination meeting with EFSA	None	1.5 days
Step 7	No task foreseen	None	-
Step 8	Preparation of the final scientific report on the establishment of CAGs for the organ or system under consideration	Final scientific report on the establishment of CAGs for the organ or system under consideration (Output 2 of the full CRA process described in section 1.2.5)	5 to 10 days
	Coordination meeting with EFSA		2 days
Step 9	Coordination meeting with EFSA	None	2 days
Step 10	No task foreseen	None	-
Step 11	Step 11.1: collection of information regarding uncertainties in Step 2 (e.g., lines of evidence supporting the assessment of CAG-membership probabilities of risk drivers, assessment of CAG-membership probabilities, uncertainties affecting the characterisation of substances included in the CAG), drafting of the respective technical notes. Additionally, collection of data for BMD modelling for risk drivers and performance of BMD modelling might be required (when this is the case, the principles to be applied in the data collection and in the BMD-modelling will be defined in consultation with EFSA).	Technical notes documenting the uncertainties affecting Step 2. When BMD modelling is performed, one of these technical notes will consist in a BMD-modelling report elaborated following the principles of reporting of the BMD analysis given the guidance of the EFSA Scientific Committee[30].	10 days + 5 days/CAG (without BMD modelling) to 20 days + 10 days/CAG (with BMD modelling) days
	Step 11.2: Preparation and participation of 2 experts to the EKE 1 session		4 days/CAG

U, Sand S, Slob W, Bottex B, Abrahantes JC, Marques DC, Kass G and Schlatter JR, 2017. Update: Guidance on the use of the benchmark dose approach in risk assessment. EFSA Journal 2017;15(1):4658, 41 pp. doi:10.2903/j.efsa.2017.4658

[30] EFSA Scientific Committee, Hardy A, Benford D, Halldorsson T, Jeger MJ, Knutsen KH, More S, Mortensen A, Naegeli H, Noteborn H, Ockleford C, Ricci A, Rychen G, Silano V, Solecki R, Turck D, Aerts M, Bodin L, Davis A, Edler L, Gundert-Remy U, Sand S, Slob W, Bottex B, Abrahantes JC, Marques DC, Kass G and Schlatter JR, 2017. Update: Guidance on the use of the benchmark dose approach in risk assessment. EFSA Journal 2017;15(1):4658, 41 pp. doi:10.2903/j.efsa.2017.4658

	Step 11.3: Preparation and participation of 2 experts to the EKE 2 session	Active participation of 2 experts in the EKE sessions	2 days/CAG
	Step 11.5: Preparation and participation of 2 experts to the EKE 3 session		4 days/CAG
Step 12	No task foreseen	None	-
Step 13	No task foreseen	None	-
Step 14	No task foreseen	None	-

Table 4 Tasks foreseen in specific actions related to Lot 2 for a first CRA and for a CRA repetition

Step	Task expected form organisations awarded for lot 2	Outcome/Deliverables	Estimated workload
Step 1	No task foreseen	None	-
Step 2	No task foreseen	None	-
Step 3	No task foreseen	None	-
Step 4	No task foreseen	None	-
Step 5	No task foreseen	None	-
Step 6	No task foreseen	None	-
Step 7	No task foreseen	None	-
Step 8	No task foreseen	None	-
Step 9	Coordination meeting with EFSA	None	2 days
Step 10	Nominal simulations and default sensitivity analyses with MCRA	Draft scientific report on cumulative exposure assessments One Excel workbook containing the input data for the exposure assessment (see https://zenodo.org/record/7143238#.Y1FeXHZBzD4 for guidance on the content) One Excel workbook containing the output data concerning the Tier II exposure assessment (see https://zenodo.org/record/7143238#.Y1FeXHZBzD4 for guidance on the content)	15 days/CAG
	Ad-hoc sensitivity analyses		3 days/sensitivity analysis and CAG
	Preparation of the draft scientific report on cumulative exposure assessments		30 days + 3-5 days per CAG
	Internal coordination		10 days + 3-5 day/CAG
	Quality control		15 days + 2-4 days/CAG
	Coordination meetings with EFSA		5 days
Step 11	Step 11.1: collection of information regarding sources of uncertainty directly related to the exposure calculations conducted in Step 10, drafting of the respective technical notes	Technical notes documenting the uncertainties affecting Step 10. Active participation of 2 experts in the EKE sessions.	10 days + 5 days/CAG
	Step 11.2: Preparation and participation of 2 experts to the EKE 1 session		4 days/CAG
	Step 11.3: Preparation and participation of 2 experts to the EKE 2 session		2 days/CAG
	Step 11.5: Preparation and participation of 2 experts to the EKE 3 session		4 days/CAG
Step 12	Coordination meeting with EFSA		1.5 days
Step 13	Preparation of the final scientific report on the cumulative exposure assessments	Final scientific report on cumulative exposure assessments (Output 3 of the full CRA process described in section 1.2.5)	5 to 10 days
Step 14	No task foreseen	None	-

Important notes:

- Step 10 requires the use of the MCRA software. As part of the ongoing agreement GP/EFSA/DATA/2021/04-01/2022 – SA01 between EFSA and RIVM for open MCRA, RIVM will provide ad hoc support to organisations awarded for Lot 2 where needed for a smooth performance of the tasks requested by the specific agreements.

The tasks described above do not include the preparation of the data. The data required to execute the calculations will be prepared by EFSA in a format that can be uploaded directly in MCRA.

The indicative timelines to perform the tasks mentioned in tables 2 to 4 under the successive steps of the process are given in table 1.

Coordination meetings between EFSA and the organisations performing the specific actions will take place regularly (e.g., on biweekly basis).

1.3.3 Payments

No.	Payments	Linked to EFSA approval of deliverable No.
	The payment modalities applicable to each specific agreement are detailed in articles 4 and 5 of the **draft specific agreement** published under the framework partnership agreement (Annex 1 of the call for Proposals).	NA

Deliverables must be drafted in English.

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).

1.4INFORMATION ON THE GRANT AGREEMENT

Applicants should note that the draft Framework Partnership 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 question, 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 Framework Partnership Agreements (FPA)

This Call for proposals aims to conclude long-term Framework Partnership Agreements (FPA) with multiple organisations for the performance of the tasks described in these specifications. An FPA sets out the framework conditions and is subsequently implemented through Specific Agreements. The specific agreements will set out the specific conditions for performing the respective assignments.

This Call is divided into two lots with financial ceilings available for specific agreements under each lot as follows:

Lot 1 Establishment of CAGs: Ceiling 2.900.000 €.
Lot 2 Cumulative exposure assessments: ceiling 1.100.000€.

The costs under Specific Agreements are co-financed by EFSA at maximum 90% of the total eligible costs.

The maximum duration of these Framework Partnership Agreements is 4 years.

The duration of the specific agreements will be typically 24 months for lot 1 and 11 months for lot 2. The FPA continues to apply to specific agreements after its expiry. The services relating to such specific

agreements must be performed no later than 24 months for Lot 1 and no later than 11 months for Lot 2 after the expiry of the FPA.

Multiple FPAs are envisaged for each lot. Applicant may submit a proposal for one lot only or for the 2 lots. The proposal should indicate clearly for which lot the application is submitted, and in case of application for lot 1, the toxicological domain(s) of interest of the applicant. In case of application for the 2 lots, 2 separate proposals must be provided. Proposals for each lot will be individually evaluated by EFSA according to the award criteria indicated in section 2.5.

The below forecast of specific agreements is to be considered as indicative. EFSA reserves the right to shift budget over the period of the FPA and award Specific Agreements as and when needed according to the actual timing of the tasks where support is required.

	Year 1	Year 2	Year 3	Year 4	Total
Lot 1	- Liver toxicity (1st CRA) - Reproductive toxicity (1st CRA) - Developmental neurotoxicity (1st CRA) - Nervous system toxicity (repetition)	- Developmental toxicity (1st CRA) - Haematopoietic system toxicity (1st CRA) - Craniofacial alterations (repetition)	- Female reproductive system toxicity (1st CRA) - Male reproductive system toxicity (1st CRA) - Kidney toxicity (repetition)	- Mammary glands (1st CRA) - Adrenal glands (1st CRA) - Liver toxicity (repetition)	13
Lot 2	- Liver toxicity (1st CRA) - Thyroid toxicity (repetition)	- Reproductive toxicity (1st CRA) - Developmental neurotoxicity (1st CRA) - Nervous system toxicity (repetition)	- Developmental toxicity (1st CRA) - Haematopoietic system toxicity (1st CRA) - Craniofacial alterations (repetition)	- Female reproductive system toxicity (1st CRA) - Male reproductive system toxicity (1st CRA) - Kidney toxicity (repetition)	11
Total	6	6	6	6	24

EFSA further reserves the right not to award Specific Agreements under the FPAs without any compensation to be paid to the applicants. EFSA reserves the right to allocate unused funds from a specific lot to a different lot in case of operational need during the course of FPA implementation.

The total amount of estimated eligible costs, as presented by the applicant in the Estimated Budget (Annex 2), and which serves as a basis for calculation of the initial EFSA specific grant, will be verified by EFSA before signature of the Specific Agreement. EFSA reserves the right to implement the necessary adaptations to the estimated eligible costs in the case the **Rules on eligibility of costs** were not correctly applied by the applicant.

Cascade mechanism: The points awarded in the evaluation will constitute the ranking in order to establish a cascade of beneficiaries. EFSA will consult the beneficiary ranked first in order to conclude a specific agreement for work to be carried out.

The beneficiary should confirm their acceptance of the terms described in the specific agreement within 15 calendar days from the day after the request is sent by EFSA. Where requested, the CVs and Individual Declarations of Interest of staff members fulfilling the expertise requirements should be submitted within 30 calendar days from the day after the request is sent by EFSA. In case the beneficiary does not to accept the terms described in the specific agreement, they should reply within 15 calendar days. In case of negative reply EFSA will contact the second beneficiary in the cascade and the above timescales for replying would be applicable.

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 **a single eligible organisation or by a consortium of eligible organisations. The establishment of consortia is however not recommended because it implies an unnecessary level of coordination of the specific agreements.** 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[31] must comply with the applicable national public procurement rules.

Subcontracting is not permitted under this call for proposals (i.e. staff members working in the project must be employed by organisation awarded the grant).

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:

[31] 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)

The form of grant awarded under this Call is grant based on a combination of the forms of grant in accordance with Article 125(1)(f) EU FR. Specifically, reimbursement of a specified proportion of the total eligible project costs actually incurred (Article 125 (1)(b), Unit costs for certain cost headings (Article 125(1)(c) and flat rate financing (Article 125(1)(e).

- **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 must be 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 €).
- **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. 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.

1.9 ESTIMATED BUDGET AND ELIGIBLE COSTS

For the submission of a proposal under this Call for proposals, leading to the signature of an FPA, **no estimated budget is required**.

Budget estimations will be necessary only before the signature of the Specific Agreement, and will be tailored to the magnitude of the workload necessary to achieve the objective of the Specific Agreement. The estimated budget must show all the costs and income which the applicant considers necessary to carry out the tasks. The Estimated budget will be in practice prepared in close cooperation with EFSA's operational and finance units. To facilitate budget estimations, Tables 2 and 3 include data of the workload associated to each task falling under the Specific Agreements, which are based on the experience acquired so far by EFSA when performing similar CRAs. The estimated budget must be established in line with the Rules on eligibility of costs.

Estimated budget prepared before signature of each Specific Agreement will have to be:

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

- expressed in Euro.

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

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.[32]

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 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.

[32] 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

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 participate in the project financially; • Applicant and in case of consortium also its partner/s are involved in the execution of the project; •
	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, and • participate in its funding.
	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:
	Requirement 1. The applicant or in case of a consortium, the consortium as a whole, must have the professional resources, competencies and qualifications necessary to complete specific actions in the field of the lot for which it applies.
	Requested evidence:
	Evidence 1: The applicant is required to demonstrate a corporate experience by at least one of the following modalities: • Information, in the form of legal documents or links to webpages, demonstrating that the remit/mission of the applicant includes the scientific area of the lot it applies for; • Demonstration of a prominent role of the applicant in at least one national or international scientific activity/project in the scientific area of the lot it applies for; • Corporate reports/scientific publications of the applicant in the scientific area of the lot it applies for. Evidence 2: The applicant is required to demonstrate its capacity to build a team dedicated to specific agreements for the lot(s) applied for, through the submission of CURRICULUM VITAE of 3-5 scientists with at least 3 years of relevant experience in the scientific area of the lot it applies for.

	Evidence 3: The applicant is required to demonstrate its capacity to select a coordinator for specific agreements with at least 5 years of experience in project management, including staff management/team leadership. Evidence 4 (applicants for Lot 2 only): The applicant is required to demonstrate that one of the members of the team dedicated to specific agreements has at least 3 years of experience in probabilistic modelling of dietary exposure. In the context of Evidence 1 and Evidence 2 above, the 'scientific area of the lot applied for' needs to be understood as 'hazard characterisation of pesticides or other chemicals for which the available toxicological data package is similar to that of pesticides' in case of Lot 1 and 'exposure assessment of pesticide residues' in case of Lot 2. Furthermore, it is desirable, but not mandatory that applicants: • Submitting a proposal for Lot 1 provide evidence, in the form of a signed statement, that they have access to unsanitised version of Draft (Renewal) Assessment Reports of EU Member States prepared in the context of the possible inclusion of active substances in Annex I of Council Directive 91/414/EEC or Regulation (EC) No 1107/2009, and to the original study reports • Submitting a proposal for Lot 2 provide evidence, in the form of a signed statement or adequate certificate, that they have access to the MCRA software and have been trained for its use. • **INDIVIDUAL DECLARATION OF INTERESTS** Template available here. ~~Individual DOIs will be requested from each member of the proposed project team, (including staff of partners in the consortium) in advance of the signature of each specific agreement~~. Individual DOIs may be requested for members of the project team having influence and/or control over scientific outputs, in advance of the signature of each specific agreement. Please refer to EFSA's policy on independence and the Decision of the Executive Director on Competing Interest Management for more detailed information. **Individual DoIs do not need to be provided with your proposal at this stage.**

2.5 AWARD CRITERIA

The organisation submitting a proposal shall provide corporate outputs (e.g., reports of finalised projects, risk assessment reports, scientific papers, etc…) in English that it considers to be representative of its capacity to perform the tasks anticipated in case of a Specific Agreement. These outputs will be assessed by EFSA on whether they:

1	Clearly describe their objective and scope (Max 10 points, threshold 5 points)
2	Adequately address the source, nature and quality of the data and properly describe the assessment methods, assumptions, limitations and uncertainties (Max 50 points, threshold 25 points)

3	Present conclusions that are coherent with the main content (Max 10 points, threshold 5 points)
4	Are relevant as regards the submitted proposal (Max 30 points, threshold 15 points).

Points 1 to 3 will be evaluated in reference to the Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA[33].

With respect to point 4, the assessment of the relevance of the outputs provided in support of proposals for Lot 1 will consider the extent to which they deal with hazard identification and characterisation of chemicals in general, and in particular in the toxicological domain(s) for which the applicant has indicated interest. The assessment of the relevance of the outputs provided in support of proposals for Lot 2 will consider the extent to which they deal with dietary exposure to chemicals in general, and in particular with probabilistic modelling.

In order to be considered for award for the given lot, the proposal must score a minimum of 60 points out of maximum possible 100 points, and in addition, score at least half of the points attributed to each criterion.

For each lot, proposals which have satisfied these thresholds will be ranked according to points obtained in order to form the cascade of beneficiaries to whom an FPA will be awarded. In lot 1, one cascade of beneficiaries will be defined for each of the toxicological domains listed in Section 1.3.1.

The applicant(s) will be notified, once the evaluation has been finalized, whether they are eligible for FPA with EFSA. FPA will specify for which lot it applies and the ranking obtained by the organisation for the respective combination(s).

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.

Following their ranking on the reserve list, EFSA reserves the right to invite applicants to adapt their proposal based on the evaluators' comments, in accordance with article 200(5) EU FR. 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. EFSA may repeat the adaptation process until the available budget of the call is assigned to other applicants on the reserve list.

[33] Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. Part 2: General Principles. The EFSA Journal (2009) 1051, 1-22.

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).

In particular, the applicant will clearly indicate for which lot(s) its application is submitted. Furthermore, if the application is related to Lot 1, the applicant should specify for which of the following toxicological domains its application is valid:

- Nervous system toxicity (Developmental toxicity excluded)
- Developmental neurotoxicity
- Thyroid toxicity
- Kidney toxicity
- Liver toxicity
- Developmental toxicity
- Reproductive toxicity
- Haematopoietic system toxicity
- Craniofacial alterations
- Female reproductive system toxicity
- Male reproductive system toxicity
- Mammary glands toxicity
- Adrenal glands toxicity

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.
☐	**AWARD CRITERIA:** Technical proposal covering award criteria, see part 2.5 of the call.

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.

4. RULES ON ELIGIBILITY OF COSTS

1. GENERAL PRINCIPLES

The eligible costs of the project receiving an EFSA grant must be shown in detail in an estimated budget. EFSA will take the final decision on the nature and amount of the costs to be considered as eligible.

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.

Costs eligible for an EFSA grant are those that are:

- incurred during the duration of the project, with the exception of costs relating to audit certificates;
- indicated in the estimated budget of the project;
- necessary for the implementation of the project which is the subject of the grant;
- identifiable and verifiable, in particular being recorded in the accounting records of the beneficiary and determined according to the applicable accounting standards of the country where the beneficiary is established and according to the usual cost accounting practices of the beneficiary;
- complying with the requirements of applicable tax and social legislation;
- reasonable, justified, and comply with the principle of sound financial management, in particular regarding economy and efficiency.

Estimated budget – cost side:

- ***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 **not applicable;**
  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.

To be eligible, costs need to be incurred during the duration of the project, i.e. from the grant agreement entry into force and project deadline.

The eligible costs presented in the estimated budget must be as realistic as possible, except for eligible indirect costs which are a flat rate.

Once the project is implemented all the eligible actually incurred direct costs must be justified by supporting documents, e.g. invoices, timesheets, evidence of travel or presence at a meeting etc. EFSA reserves the right to ask any supporting document in order to verify that the costs declared as eligible were actually incurred and paid.

2. ELIGIBLE COSTS

2.1 ELIGIBLE DIRECT COSTS

"Direct costs" of the project are those specific costs which are directly linked to the implementation of the project and can therefore be attributed directly to it. They may not include any indirect costs[34]. To be eligible, direct costs shall comply with the conditions of eligibility set out above in point 1.

2.1.1 COSTS OF PERSONNEL – Estimated Budget Excel, Sheet A.1

The costs of personnel working under an employment contract with the beneficiary or an equivalent appointing act and assigned to the project are considered eligible costs (comprising actual salaries plus social security contributions and other statutory costs included in the remuneration).

In line with the EU Financial Regulation, the salary costs of public officials will be considered as a direct cost of the beneficiary to the extent that they relate to the cost of activities which the relevant public authority as beneficiary would not carry out if the project concerned was not undertaken.

The costs of natural persons working under a contract with the beneficiary other than an employment contract may be assimilated to costs of personnel, provided that the following conditions are fulfilled:

- the natural person works under the instructions of the beneficiary;
- the result of the work belongs to the beneficiary

If the above conditions are not met, the amounts paid to the natural person shall be presented under the category "subcontracting".

IMPORTANT:

[34] Indirect costs are explained in section 2.2 below.

Staff assigned to the project must be classified in one of the four categories Manager, Researcher/Teacher/Trainer, Technical, Administrative. EFSA will check the correctness of the assigned category of each staff member from the CV's which will be provided by the beneficiary.

UNIT COSTS for personnel are shown in the table below. These costs are calculated based on EUROSTAT data, EFSA historical data, information received from other EC services and considering the annual labour costs per country. An annual revision of unit costs is done based on the application of the national inflation rates as published by Eurostat. **Last revision entered into force on 16 August 2022.**

The **UNIT COSTS** per day for staff **must** be used when establishing the estimated budget and when declaring the incurred costs. **THE NUMBER OF DAYS** spent on the project (one day is composed of 8 working hours according to working day duration at EFSA) is to be indicated when establishing the estimated budget and when declaring the incurred costs.

The rate of the country in which the partner organisation is registered should be applied, independently of where the tasks will be executed (i.e. a staff member of an organisation of Country A working fully or partly in Country B will be budgeted on the basis of the rates of Country A).

The beneficiary must be able to justify the personnel costs at the end of the project by providing supporting documents (e.g. timesheets), if requested by EFSA.

The beneficiary shall ensure that CVs for all profiles (including technical and administrative staff) inserted in the budget are submitted together with the proposal for **direct** agreements. This will allow EFSA to check the correctness of the assigned role of each staff member. For those profiles for which the applicant reserves the right to recruit staff after the communication of the outcome of the call, CVs need to be provided to EFSA for checking the correctness of the assigned role as soon as the recruitment is complete.

UNIT COST PER DAY IN EUROS (August 2022)

Country	Manager	Researcher Teacher Trainer	Technical	Administrative
Austria	500	337	272	216
Belgium	471	382	269	240
Bulgaria	73	66	50	34
Croatia	225	203	163	103
Cyprus	322	240	149	101
Czech Republic	198	127	92	67
Denmark	589	416	291	261
Estonia	118	90	69	49
Finland	441	271	209	173
France	468	378	277	217
Germany	499	339	252	222
Greece	207	145	103	93
Hungary	127	102	77	52
Ireland	410	340	248	184
Italy	477	313	212	183
Latvia	100	75	58	43
Lithuania	134	79	54	39
Luxembourg	544	383	309	241
Malta	129	107	83	62
Netherlands	462	374	236	187
Poland	150	98	75	56
Portugal	274	192	130	82
Romania	143	109	85	54
Slovakia	135	109	96	78
Slovenia	257	195	156	98
Spain	344	227	174	125
Sweden	398	335	276	212
Iceland *(EEA Country)*	393	358	309	199
Liechtenstein *(EEA Country)*	492	331	267	213
Norway *(EEA Country)*	516	430	364	280
Switzerland *(EFTA Country)*	657	471	411	325

2.1.2 TRAVEL COSTS AND SUBSISTENCE ALLOWANCES – Estimated Budget Excel, Sheet A.2

All travel costs for missions, workshops/seminars/conferences must be included under Sheet A.2:

MISSIONS: travel costs and related subsistence allowances of staff and other persons taking part in the project are eligible. Kick-off, interim, final meetings and field trips (if any) are part of this category.

WORKSHOP/SEMINAR/CONFERENCE: travel costs for external participants and speakers (not staff employed by coordinator or partners) are eligible. As subsistence allowances are not foreseen for the participation of external participants in workshops/seminars/conferences, meals and accommodation for workshops must be inserted under the category "Miscellaneous" – Sheet A.6.
The daily subsistence allowances and travel costs of EFSA representatives shall not enter in the estimated budget because these costs are paid by EFSA directly to the staff concerned.

Travel costs
These unit costs must be applied when establishing the estimated budget and when declaring the incurred costs:

UNIT COSTS

Type of transport	Distance in road Km	Travel Unit cost
Car	Any distance	**0.33 €/Km**
Train	Any distance	**0.40 €/Km**
Flight	Any distance	**500 €**

If two or more staff members travel together sharing a car, the cost should be calculated only one time for the entire group of people. Insert the number of km for only one of the staff travelling by car and insert "shared" for all other staff traveling together.

Inter-continental flights are not included. They should be estimated on a case-by-case basis and declared on real incurred cost of flight ticket. The most economical fares must be sought (i.e., non-flexible economic class).

Daily subsistence allowances (DSA)

The DSA applies only for a mission to a place more than 50 km from the normal place of employment.

For travels related to workshops, the DSA is not applicable because costs of hotel accommodation and meals (lunch and dinner) are to be declared under item Miscellaneous costs (see article 2.1.5).

The amounts presented in the below table are calculated to cover the following expenses during a day of mission: accommodation, meals, local transport to reach airport/train station at the place of residence/employment and within the place of mission (car, parking, taxi and/or public transport), and sundry expenses, such as telecommunications costs (fax, internet).

The DSA is to be calculated according to the length of the mission: from the time of departure of the means of transport used until the arrival at the place of employment or home.

- </= 24 hours: full DSA;
- > 36 hours </= 48 hours: 2 x DSA, etc.

Missions to countries not mentioned in the below table shall be submitted to EFSA for an ex-ante agreement.

Country	€
Austria	234
Belgium	250
Bulgaria	192
Croatia	185
Cyprus	228
Czech Republic	194
Denmark	297
Estonia	185
Finland	255
France	282
Germany	225
Greece	194
Hungary	184
Iceland (EEA country)	245
Ireland	267
Italy	246
Latvia	189
Liechtenstein (EEA country)	175
Lithuania	186
Luxembourg	246
Malta	226
Netherlands	269
Norway (EEA country)	220
Poland	183
Portugal	184
Romania	198
Slovakia	174
Slovenia	201
Spain	216
Sweden	304
Switzerland (EFTA country)	220

2.1.3 DEPRECIATION COSTS OF EQUIPMENT OR OTHER ASSETS – Estimated Budget Excel, Sheet A.3

These costs are eligible if:

- the acquisition is strictly necessary for the performance of the project;
- those costs are recorded in the accounting statements of the beneficiary;
- the asset has been purchased in accordance with Article II.10 of the Grant agreement and it is written off in accordance with the international accounting standards and the usual accounting practices of the beneficiary.
- **Important:** The depreciation costs of equipment/software bought before the submission of the proposal can be taken into account in the estimated budget and when declaring the incurred costs but only for the portion covered by the period of the implementation of the proposed action. The percentage and the period covered by the depreciation costs should comply with the usual accounting practices of the beneficiary.

EFSA reserves the right to verify the correct application of the usual accounting practices of the beneficiary. In case the depreciation periods are not clearly indicated in those practices the following rules will be applied by EFSA:

- computer equipment (hardware) is written off over a period of 3 years,
- office furniture and equipment (photocopiers, fax, etc.) over 5 years, and
- specific computer software (not common software which is supposed to be covered by indirect costs) is covered in full.

The costs of rental or lease of equipment or other assets are also eligible, provided that these costs do not exceed the depreciation costs of similar equipment or assets and are exclusive of any finance fee.

Only the portion of the equipment's depreciation corresponding to the duration of the project and the rate of the actual use for the purposes of the project can be considered by EFSA as eligible. Consult the call for proposals for the maximum allowed duration of the project.

2.1.4 CONSUMABLES AND SUPPLIES – Estimated Budget Excel, Sheet A.4

The costs of consumables and supplies are eligible if:

- they are purchased in accordance with Article II.10 of the Grant agreement;
- they are directly assigned to the project.

Unlike the equipment, these are "consumables[35]", i.e. items that are not entered as fixed assets in the accounts (or inventory) of the beneficiary and are not written off. The term "directly assigned to the project" is important in order to avoid reimbursing the same cost twice by way of indirect costs. The nature of the project and the fact that the costs are specific to the project are key factors justifying direct cover of these costs.

All other items that are not "consumables" are to be inserted under "miscellaneous" (e.g. publication fees).

2.1.5 SUBCONTRACTING – Estimated Budget Excel, Sheet A.5 – NOT APPLICABLE

Costs entailed by subcontractors within the meaning of Article II.11 of the Grant agreement are eligible, provided that the conditions laid down in that Article and in the Call for proposals are met.

[35] For example: laboratory material, reagents, gloves, medicines, etc.

The costs of natural persons working under a contract with the beneficiary other than an employment contract and which cannot be assimilated to costs of personnel, as indicated in part 2.1.1, are to be declared in this section.

Core tasks[36] may not be subcontracted. Only ancillary and assistance tasks may be subcontracted.

2.1.6 MISCELLANEOUS COSTS– Estimated Budget Excel, Sheet A.6

GENERAL MISCELLANEOUS COSTS: These might be the costs arising directly from requirements imposed by the Grant agreement, e.g. dissemination of information, specific evaluation of the project, audits, translations, printing/copying, including the costs of any requested financial guarantees, provided that the corresponding services are purchased in accordance with Article II.10.

MISCELLANEOUS COSTS RELATED TO WORKSHOPS, SEMINARS, CONFERENCES: This category of eligible costs is intended to cover costs linked to the organisation of a workshop, seminar or conference, in particular:

1. hire of premises;
2. hire of equipment;
3. interpretation (interpreters and hiring of booths);
4. translation costs in connection with workshop/seminar/conference;
5. catering (lunch and dinner) and accommodation costs for external participants and speakers
6. external speaker fee (intended for an expert coming from outside of beneficiary/consortium), max 500 € per speaker per day;
7. other costs (e.g. printing costs for documentation to be distributed to participants, various supplies, reception staff).

In case a contract is to be awarded within the context of a workshop, e.g. translation or preparation of documents, these services or supplies must be purchased in accordance with Article II.10 of the Grant agreement.

2.1.7 ELIGIBLE VAT

Duties, taxes and charges paid by the beneficiary, notably value added tax (VAT), are eligible, provided that they are included in eligible direct costs.

VAT is accepted as an eligible cost if it is not recoverable, and so declared on honour by the beneficiary in the estimated budget.

The eligible VAT cost should be declared in the same heading of the estimated budget in which the related cost is declared.

2.2 ELIGIBLE INDIRECT COSTS – Estimated Budget Excel, Summary sheet

"Indirect costs" of the project are those costs which are not directly linked to the implementation of the project and can therefore not be attributed directly to it. They may not include any costs identifiable or declared as eligible direct costs.

To be eligible, indirect costs shall represent a fair apportionment of the overall overheads of the beneficiary and shall comply with the conditions of eligibility set out in point 1.

[36] For example coordination of the grant

Unless otherwise specified, eligible indirect costs shall be declared on the basis of a flat rate of 10% of the total eligible direct costs. Eligible indirect costs may not include any eligible direct costs. The formula in the Summary of the estimated budget excel automatically calculates the eligible indirect costs at 10% of the inserted eligible direct costs.

The indirect costs are frequently of an administrative, technical and logistical nature, are cross-cutting for the operation of the beneficiary's various activities and cannot therefore be booked in full to the project for which the grant is awarded because this grant is only one part of those activities. Indirect costs comprise costs connected with infrastructures and the general operation of the organisation such as renting or depreciation of buildings and plant, water/gas/electricity, maintenance, cleaning, insurance, supplies, small office equipment such as toner, paper, stationary, communication and connection costs (phone, internet, fax, etc.), postage, and costs connected with horizontal services such as administrative and financial management, human resources, training, legal advice, documentation, IT, etc.

3. INELIGIBLE COSTS

In addition to any other costs which do not fulfill the conditions set out for eligible costs, the following costs shall not be considered eligible:

- return on capital;
- debt and debt service charges;
- provisions for losses or debts;
- interest owed;
- doubtful debts;
- exchange losses or costs of conversion;
- costs of transfers from the Authority charged by the bank of the partner;
- costs declared by the beneficiary in the framework of another action receiving a grant financed from the Union budget (including grants awarded by a Member State and financed from the Union budget and grants awarded by other bodies than the Authority for the purpose of implementing the Union budget); in particular, indirect costs shall not be eligible when the beneficiary already receives an operating grant financed from the Union budget during the period in question;
- contributions in kind from third parties;
- excessive or reckless expenditure;
- deductible VAT.

The ineligible costs, if any, must be declared in the Estimated Budget excel, Summary Sheet.

4. FLEXIBILITY WITH APPROVED ESTIMATED BUDGET

After the estimated budget of the project has been approved by EFSA (corrections are possible during the evaluation of the proposal) it becomes the approved estimated budget, and it will be attached to the Grant agreement. The approved estimated budget is based on estimates, and therefore it is normal that during the project implementation there might be a need to adjust it to reality or any unforeseen events.

The approved estimated budget may be adjusted by making transfers provided that such adjustments do not affect the basic purpose and the completion of the project is not jeopardised. No amendment is necessary for these transfers.

If the beneficiary wishes to replace a staff member by another employee, e.g. because of dismissal, maternity leave, long term sick leave of original staff member, a prior approval of EFSA should be sought and the new CV and individual declaration of interest (if DoIs are applicable) shall be provided. No amendment is necessary for these changes.