EXECUTIVE DIRECTOR

New grant procedure in two steps

CALL FOR PROPOSALS
and guide for applicants

Call reference: GP/EFSA/ED/2022/01
Call title: NAM projects in the areas of AOP development and transcriptomics for risk assessment
Project/Process code: EPA13.02-ED-21
Budget line: 3210

Restricted to the list of competent organisations adopted by EFSA Management Board according to Article 36 of European Parliament and Council Regulation (EC) No 178/2002

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INDICATIVE PROCEDURE TIMETABLE

Milestone	Date[1]	Comments
FIRST STEP		
Launch date	04/7/2022	Date of call publication on EFSA's website.
Deadline for applicants to raise clarification questions to EFSA	~~18/9/2022~~ 30/09/2022	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	~~20/9/2022~~ 04/10/2022	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 outline proposals (step 1) Any proposal posted after the final deadline will automatically be rejected.	~~**26/9/2022**~~ **10/10/2022**	Applicants can submit the outline proposals: - either by post (registered mail) or by courier not later than ~~**26/09/2022**~~ **10/10/2022**, in which case the evidence of the date of dispatch shall be constituted by the postmark or the date of the deposit slip, to the address indicated below. The applicant submitting a proposal by post or by courier is requested to send an informative e-mail to EFSAProcurement@efsa.europa.eu. - or delivered by hand **not later than 12.30 hours (Italian time) on** ~~**26/09/2022**~~ **10/10/2022** 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 –Giorgia Ciani, 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/ED/2022/01– NOT TO BE OPENED BY THE INTERNAL MAIL DEPARTMENT".* - name of the applicant - **the posting date should be legible on the outer envelope**
Notification of the evaluation results with proposals shortlisted and invitation to submit full application	~~October~~ November 2022	Estimated. *Attention: outcome of the 1st step evaluation 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.*
SECOND STEP		
Deadline for applicants to raise clarification questions to EFSA	Indicated in the letter inviting applicants to step 2	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	Indicated in the letter inviting applicants to step 2	Replies will be provided on EFSA's webpage where this Call is published and which the applicants are requested to consult regularly.

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

Deadline for submission of full application (step 2)	Indicatively 2 months from notification of results for step 1 (the exact date will be indicated in the letter inviting applicants to the step 2)	Applicants can submit full applications: - either by post (registered mail) or by courier not later than **the date indicated in the letter inviting applicants to the step 2**, in which case the evidence of the date of dispatch shall be constituted by the postmark or the date of the deposit slip, to the address indicated below. The applicant submitting a proposal by post or by courier is requested to send an informative e-mail to EFSAProcurement@efsa.europa.eu. - or delivered by hand **not later than 12.30 hours (Italian time) on the date indicated in the letter inviting applicants to the step 2** 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 –Giorgia Ciani, 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/ED/2022/01– NOT TO BE OPENED BY THE INTERNAL MAIL DEPARTMENT".* - name of the applicant - **the posting date should be legible on the outer envelope**
Notification of the evaluation results	January 2023	Estimated.
Grant agreement(s) signature	End February 2023/March 2023	Estimated.

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1. GRANT OPPORTUNITY AND CONDITIONS[2]

1.1 LEGAL FRAMEWORK

Article 36 of the Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety foresees the possibility to financially support networking of organisations operating in the fields within the EFSA's mission.

In particular, Article 36 (1) 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, the development and implementation of joint projects[3], the exchange of expertise and best practices in the fields within the Authority`s mission.

On the 19th December 2006 the Management Board, acting on a proposal from the Executive Director, drew up a list of competent organisations designated by the Member States which may assist EFSA, either individually or in networks, with its mission. This list is regularly updated by EFSA's Management Board.

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

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

This call is based on EFSA's 2022 Work Programme for grants and operational procurements as presented in Annex XII of the Programming Document 2022 – 2024, available on the EFSA's website[4].

This call follows a 2-step submission procedure. The procedure requires applicants to submit an outline proposal (step 1) and full application (step 2). For details on the procedure and on the documents necessary for the two steps refer to section 2 below.

1.2 BACKGROUND AND MAIN OBJECTIVE OF THE CALL

BACKGROUND

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

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

[4] https://www.efsa.europa.eu/sites/default/files/event/mb-20211216/C05.SPD-2022-2024-4.mb211216-a2.pdf

In 2021 EFSA commissioned by ways of procurement a roadmap for actions on new approach methodologies (NAMs) in risk assessment. The main conclusions from this roadmap for action are in line with EFSA's view that toxicological studies performed in whole animal studies are not readily suited to provide mechanistic and molecular understanding of the toxicological events leading to adversity[5]. In contrast, NAMs, using the combination of human-relevant *in vitro* methods and computational (*in silico*) approaches have the potential to fill this gap. The shift away from whole animal studies for chemical risk assessment and their eventual replacement by NAMs, is emphasized in the EFSA Strategy 2027[6] and the European Commission's EU's Chemicals Strategy for Sustainability[7]. The aim of integrating NAMs in chemical risk assessment is not only to enlarge the palette or catalogue of scientific assessment options but to also contribute to a more robust and trusted mechanism to enhance the speed, precision and quality of the assessments and to decrease the uncertainty in chemical RA for food and feed safety. However, the adoption and integration of NAMs into an enhanced risk assessment process (i.e. Next Generation Risk Assessment (NGRA)) poses a number of challenges that need to be taken into account in order to realise this paradigm shift, including their acceptability, recognised robustness and confidence in their use by risk assessors.

To meet these challenges, the roadmap consortium identified potential EFSA priorities regarding the incorporation of NAMs into regulatory hazard and risk characterisations of chemicals in food and feed[8]. To this end, seven key areas were identified requiring further scientific development and a number of activities were recommended to fill some of the identified knowledge gaps which in turn would enable the implementation of NAMs in EFSA's scientific assessment process. Accordingly, EFSA is in the process of developing a multi-annual plan to address the recommendations of the roadmap in accordance with EFSA´s business needs. A number of NAM case studies have already been initiated, including case studies pertinent to the area of neurodegeneration and nanomaterial kinetics.

MAIN OBJECTIVE OF THE CALL

This call is aimed at inviting proposals for NAM-based case studies in areas that have been identified in the NAM roadmap as needing further scientific development. In line with EFSA's vision the proposed case studies should have the potential to improve the speed, precision and predictability of chemical risk assessment related to food safety by enabling the integration of mechanism-based data while at the same time reducing the need for animal bioassays. This call focuses specifically at addressing the following two areas (Lots) identified:

Lot 1: "Development of AOPs/AOP networks"

Lot 2: "NAM transcriptomics for toxicology specific pathway analysis to predict target organ toxicity".

Applicants are invited to submit project proposals that address one or more missing key element(s) for the implementation of NAMs in EFSA's scientific assessment process for improved regulatory decision making in the areas of food and feed. A detailed description of the two lots is provided under section 1.3.

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[5] Escher SE, Partosch F, Konzok S, Jennings P, Luijten M, Kienhuis A, de Leeuw V, Reuss R, Lindemann K-M, Hougaard Bennekou S, 2022. Development of a Roadmap for Action on New Approach Methodologies in Risk Assessment. 153 pp. doi:10.2903/sp.efsa.2022.EN-7341

[6] https://op.europa.eu/webpub/efsa/strategy-2027/en/" \l "chapter2

[7] ec.europa.eu/environment/strategy/chemicals-strategy_en

Applicants are invited to submit proposals that address the objectives outlined below using their judgement as to how to best address the objective(s) with the most appropriate methodological and scientific approaches available in order to promote the use of NAMs in food and feed human health risk assessment while guarantee scientific excellence and maximum impact for EFSA.

Important: Applicants should note that this will be a **2-step procedure**, with the first step consisting in submitting an **Outline Proposal (step 1)** that, if shortlisted, will lead to the applicant being invited to submit a **Full Application (step 2)**. For details on the procedure and on the documents necessary for the two steps refer to section 2 below.

1.3 LOTS

This call for proposals is in two Lots, described below. Lot 1 is divided in 4 specific areas (A,B,C,D). Applicants may apply for one or two lots.
For Lot 1, applicants may apply for one or more specific areas.

Applicants are reminded that each lot or specific area (for lot 1) needs a separate application through an Outline Proposal (details are provided under section 5 – submission of proposal).

Applicants are encouraged to take into consideration past and current experience from EU-funded research projects addressing NAMs (e.g. EU-ToxRisk, ASPIS clusters, PARC) to enhance the translation of scientific findings into regulatory acceptance.

LOT 1: Development of AOPs/AOP networks (AOPs)

Adverse Outcome Pathways (AOPs) can greatly facilitate the use of NAMs together with existing *in vivo* animal data and human observational data by integrating them into a mechanistic framework. Moreover, AOPs can guide the prioritisation of development and fit-for-purpose validation of NAMs that measure Key Events (KEs) and that could ultimately facilitate the full replacement of *in vivo* data. AOP knowledge is considered a backbone not only for single substance assessments also for grouping of substances for mixture risk assessments (ref EFSA MixTox2).
It is recognised that there are many efforts ongoing in the development of AOPs for several target organ toxicities, such as for certain pathways leading to hepatotoxicity or neurotoxicity, through EU-funded projects such as within the ASPIS cluster[9] and within PARC.[10] However, the following target organ toxicities have been identified as of regulatory relevance and of importance to EFSA. Proposals to prioritise AOP development and supporting NAMs for testing and providing appropriate case studies in one or more of the areas below are invited. The submitted proposals should include means for the verification of the AOP/AOP network(s) and support the integration of NAM-based *in vitro* data with *in vivo* data or clinical/epidemiological evidence for regulatory purposes:

> **A. Specific area: Developmental neurotoxicity:** Proposals with relevance to the work of EFSA are invited to be submitted to develop AOPs/AOP networks and supporting NAMs that specifically address toxicity to glial cells in the context of developmental sensory or motor neurotoxicity. The proposals should include a series of case studies that support both the AOP/AOP network and the NAMs developed/identified to test and verify relevant MIEs/KEs and

[9] https://aspis-cluster.eu/
[10] https://www.anses.fr/en/content/european-partnership-assessment-risks-chemicals-parc#:~:text=The%20European%20Partnership%20for%20the,for%20the%202021%2D2027%20period

biological parameters for their integration with *in vivo* data or clinical/epidemiological evidence for regulatory purposes.

B. Specific area: Framework for metabolic syndrome: Proposals with relevance to the work of EFSA are invited to be submitted in the area of metabolic syndrome and insulin resistance. Human epidemiological and *in vivo* animal studies have linked endocrine disrupting activities of chemicals acting through nuclear receptors (such as the oestrogen and androgen receptors) with the induction of metabolic syndrome(s) leading to obesity or type 2 diabetes. Proposals are invited for the development of a conceptual framework of AOPs/AOP network(s) that links the action of this group of compounds to a metabolic syndrome and identify KEs that contribute to the development of metabolic syndrome and insulin resistance. The proposals should also devise NAM approaches and conduct appropriate case studies with relevance to the work of EFSA that can be used to frame and test for the relevant nodes leading to metabolic syndrome and insulin resistance.

C. Specific area: Stress response and altered glucocorticoid production caused by altered hypothalamic and pituitary control: The hypothalamic–pituitary–adrenal (HPA) axis plays a key role in adaptation to environmental stresses. The secretion of hormones from the hypothalamic paraventricular nucleus is coupled to the secretion of pituitary adrenocorticotropic hormone (ACTH) which in turn regulates the secretion of glucocorticoids and dehydroepiandrosterone (DHEA) and its sulphate DHEAS by the adrenal gland cortex. The glucocorticoids trigger the metabolic, immune, neuromodulatory, and behavioural changes needed to cope with the effect of stressors. The adrenal gland cortex is often identified as a target organ in experimental toxicity studies. Proposals with relevance to the work of EFSA are invited to be submitted to develop AOPs/AOP networks and supporting NAMs that specifically address toxicity to the HPA axis, and in particular on the adrenal gland cortex. Using appropriate case studies, the integration of the NAM data with *in vivo* data or clinical/epidemiological evidence should be demonstrated.

D. Specific area: qAOP/s having oxidative stress as a node: qAOP models could be used for quantitative risk assessment of chemicals. However, so far very limited number of qAOPs exist. A critical aspect of building qAOP is defining the threshold for inducing an effect. Along this lines, oxidative stress endpoints and response to conditions of oxidative stress have been related to several organ toxicities and related to exposure to chemicals. However, the threshold for inducing each specific effect needs to be understand in order to integrate this evidence and use it for regulatory purposes. Oxidative stress can be measured with several endpoints in human observational studies, in in vivo and also using NAMs. Proposals with relevance to the work of EFSA are invited to be submitted to develop qAOPs/AOP networks that identify oxidative stress as a common/shared node and supports NAMs for testing in AOP networks dealing with neurotoxicity and DNT adverse outcomes.

LOT 2: NAM transcriptomics for toxicology specific pathway analysis to predict target organ toxicity

Toxicity arises from the perturbation of cellular homeostatic and signalling pathways and can be identified through specific endpoint measurements (e.g. biomarker expression) that reflect MIEs/KEs or that reflect apical events such as cell proliferation or cell death. A complementary approach is to interrogate the transcriptomic profile which can provide evidence on biological responses elucidating important information on the type of adversity elicited by the chemical (e.g. cell proliferation, cell stress response, inflammatory response) by mapping gene expression. The application of

transcriptomics to NAMs can be done high-throughput and has recently generated some promising results.

Proposals with relevance to the work of EFSA are invited to develop a battery of cellular models where the transcriptomics response can be mapped to specific toxicity responses and target organ toxicities. The proposals should include efforts to integrate and map the transcriptomics response to specific adverse outcomes, differentiating early and late MIEs and KEs, as well as concepts to link such data to AOP/AOP network(s) in a qualitative and quantitative way that has the potential to produce evidence for mechanistic-based hazard identification/characterisation and thus risk assessment, taking into account similar Calls already initiated by EFSA.[11]

1.4 ELIGIBLE ORGANISATIONS

To be eligible, applicants must be on the list of competent organisations designated by the Member States in accordance with Article 36 of Regulation (EC) 178/2002 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/.

Proposals can be submitted by **one eligible organisation or by a consortium of eligible organisations.** In case of a consortium, one of the partners must be identified in the proposal as the consortium leader (coordinator). The applicant is responsible for identifying consortium partners, all of whom must be on the Article 36 list of competent organisations.

1.5. ROLES AND RESPONSIBILITIES

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

A) Proposals submitted by consortium:

- **The Applicant** submits the outline proposal (step 1) and the full application (step 2) to EFSA on behalf of the consortium. The applicant is the leading entity of the consortium. There can be only one applicant in project proposal/grant application;

- **The Partner** is the other entity in the consortium. There can be a minimum of one partner or more partners.

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

As soon as the grant agreement is signed, the applicant becomes the Coordinator and partner/s become co-beneficiary/ies. The coordinator and co-beneficiary/ies are referred to as the beneficiaries. The beneficiaries are jointly and severally liable for the technical implementation of the project as described in the full application 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:

[11] https://etendering.ted.europa.eu/cft/cft-display.html?cftId=10539

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

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

The other beneficiary/ies:

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

B) Proposals submitted by a sole applicant:

- **The Applicant** submits the outline proposal (step 1) and the full application (step 2) to EFSA. There can be only one applicant in the proposal/grant application.

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

The beneficiary:

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

1.6. POSSIBILITY OF IMPLEMENTING CONTRACTS AND SUBCONTRACTING

Implementation contracts:
Where the implementation of the project requires the award of procurement contracts (implementation contracts), e.g. purchase of services and/or goods or equipment necessary for the implementation of the action, the beneficiary must award the contract to the entity offering the best

value for money or the lowest price (as appropriate), avoiding conflicts of interests. The beneficiary is expected to clearly document the tendering procedure and retain the documentation for the event of an audit.

Entities acting in their capacity as contracting authorities within the meaning of Directive 2014/24/EU[12] must comply with the applicable national public procurement rules.

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

- Subcontracts must be awarded to the entity offering best value for money or the lowest price (as appropriate), avoiding conflicts of interests;
- Subcontracting must only cover the implementation of a limited part of the action;
- Recourse to subcontracting is justified having regard to the nature of the project and what is necessary for its implementation;
- Tasks to be subcontracted and the corresponding estimated costs must be identified in the estimated budget (to be submitted in step 2) and approved by EFSA before the signature of the grant agreement;
- Recourse to subcontracting during project implementation, if not envisaged from the outset in the proposal, is subject to prior authorisation in writing by EFSA, and must be formalised via an amendment to the grant agreement. Approval may be granted as long as it does not entail a change to the grant agreement which would call into question the decision awarding the grant or be contrary to the equal treatment of applicants;
- The conditions applicable to the beneficiaries under Articles II.6 (*Confidentiality*), II.7 (*Processing of Personal Data*), II.8 (*Visibility of Union Funding*) of the grant agreement are also applicable to the subcontractor;
- **Core tasks such as coordination of the project and core experimental data generation must not be subcontracted**. Only ancillary and assistance tasks can be subcontracted.

1.7 DURATION, MEETINGS AND REPORTING

The maximum duration of projects under this Call is **four (4) years**.

The following **meetings** with EFSA are foreseen:

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

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

2. **Interim Meetings:** Regular interim tele-meetings will be held during the course of the project (approximately 2 meetings per year, depending on the interim reports to be submitted to EFSA). The purpose of these meetings is to discuss the interim reports as well as any issues or difficulties (technical or financial) encountered during the project. Minutes of the meetings shall be taken and provided to EFSA by the beneficiary. The exact number of meetings to be held will be agreed with EFSA at the start of the project.

3. **Regular check-point Meetings:** The beneficiary will be asked to include in its work plan indicatively a 2-hour tele-meeting every 2nd month throughout the entire duration of the contract to allow to discuss on the progress of the tasks/deliverables; any issues or risks should be highlighted during these meetings.

4. **Final meeting (physical meeting, held at EFSA premises, or tele-meeting) will be held one month before the end of the project:** The purpose of this meeting is to discuss the final report/deliverables as well as any problems or difficulties (technical or financial) encountered during the project.

The following **reports** are foreseen and must be drafted in UK Standard English language and may be subject to publication at EFSA's discretion.

1. At least one interim report per year, the exact number of interim reports will be agreed with EFSA and defined at the kick-off meeting.

2.Draft final report: to be submitted 2 weeks in advance of the final meeting.

3. Final report: to be submitted prior to the expiry of the grant agreement and no later than 1 month after the final meeting and incorporating any feedback suggested by EFSA during that final meeting. The coordinator shall submit the Final Report to EFSA. The final report will include an analysis for the potential impact resulting from the completion of the proposed project in regulatory science.

Please note that all reporting, minutes, outcome of the discussions could be made available at EFSA's discretion to EFSA's Panel and WG members and other relevant partners (e.g. Member States, other EU Agencies).

1.8 PAYMENTS

The following payment scheme will be applied:

- **pre-financing payment**, upon the entry into force of the grant agreement, without need for payment request, **between 10% and 40% of the maximum grant amount**; the aim of the pre-financing is to provide the beneficiaries with a float; it remains the property of the EU until the payment of the balance. The exact percentage amount of pre-financing will be determined at the time of grant award;

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

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

1.9 GRANT PRINCIPLES

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

- **Co-financing**: In accordance with Article 190 of the Financial Regulation, grants shall involve co-financing. The resources necessary to carry out the project /action shall not be provided entirely by the grant. The project costs not covered by the EFSA grant must be financed from the applicant and partner/s resources. The applicant and its partner/s must therefore contribute financially to the project. Additionally, there may be also a financial contribution from another entity, but such an entity may be only a public body. Contributions from the private sector are not permitted.
- **No-profit**: In accordance with Article 192 of the Financial Regulation, grants shall not have the purpose or effect of producing a profit within the framework of the project for the applicant or partner. Profit is defined as a surplus of the receipts over the eligible costs incurred by the beneficiaries, at the time of request for payment of the balance. The receipts shall be limited to income generated by the project, as well as financial contributions specifically assigned by donors to the financing of the eligible costs. Where a profit is made, EFSA shall be entitled to recover a part of it in line with procedure foreseen in the Grant agreement. The verification of the non-profit rule does not apply to low value grants (</= 60.000 €) or grant in the form of financing not linked to costs pursuant to article 125(1)(a) of the Financial Regulation.
- **Non-retroactivity**: A grant may be awarded for a project which has already begun only where the applicant can demonstrate in the grant application the need to start the action before the grant agreement is signed. In accordance with Article 193 of the Financial Regulation, costs eligible for financing may not have been incurred prior to the date of submission of the grant application. No grant may be awarded retrospectively for a project already completed.
- **Non-cumulative**: In accordance with Article 191(3) of the Financial Regulation, in no circumstances shall the same costs be financed twice from the EU budget. In no circumstances shall the same costs be financed twice by the Union budget. To ensure this, the applicant shall indicate the sources and amounts of Union funding received or applied for the same project or part of the project or for its functioning during the same financial year as well as any other funding received or applied for the same project.

1.10 EFSA GRANT CONTRIBUTION

The form of grant awarded under this Call is grant based on reimbursement of a specified proportion of the total eligible project costs actually incurred (EU Financial Regulation, Article 125.1(f)).

The **maximum amount** of EFSA funding **for each Lot is 5,000,000.00 €** (five million euro).

The project/s to be supported under each Lot is/are co-financed by EFSA at maximum **90% of the total eligible project costs**.

In other words, the grant has double ceiling: the maximum amount of EFSA contribution per Lot and the reimbursement rate applied on the total eligible project cost.

However, EFSA reserves the right:

- not to award all the funds available at any cost, e.g. if the quality of submitted proposals will not be satisfactory.
- To reject at any step of the procedure proposals which present ethics issues.
- not to award any grant and/or to cancel the whole grant procedure at any time before the signature of the grant agreement without any compensation to be paid to the applicant.
- to transfer funds available under one Lot to the other Lot, depending on the projects ranked in the reserve list to be financed under each lot
- to award more grants in cumulative value above 5.000.000,00 EUR per Lot in case additional funds will be made available in EFSA budget in the financial year 2022 and/or 2023. In such case, EFSA reserves the right to allocate the additional funds to the next ranked proposal(s) on the reserve list.

The total amount of estimated eligible costs, as presented by the applicant in the estimated budget (Annex 3) (see also part 1.11), and which serves as a basis for calculation of the initial EFSA grant, will be verified by EFSA during the evaluation of full applications (step 2). EFSA reserves the right to implement the necessary adaptations to the estimated eligible costs in case the Rules on eligibility of costs (Annex 1) were not correctly applied by the applicant.

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

1.11 ESTIMATED BUDGET AND ELIGIBLE COSTS

The full application (step 2) must be accompanied by the estimated budget (Annex 3) which must be established in line with the Rules on eligibility of costs (Annex 1). The estimated budget must show all the costs and income which the applicant considers necessary to carry out the project.

Estimated budget must be:

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

Estimated budget – cost side:[13]

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

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

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

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

Estimated budget – income side:

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

1.12 APPROVED ESTIMATED BUDGET

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

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

An overestimation or underestimation of costs, or missing justification of the costs, missing details, or detected inconsistency with the technical description of the project in the full application will have a negative impact on the evaluation score under the award criterion 4 (step 2).

If EFSA regards the estimated budget described in the full application as realistic, consistent with the technical description of project, sufficiently detailed, well justified and established in accordance with the Rules on eligibility of costs (Annex 1) and no modification is needed, it will become the approved estimated budget and the EFSA grant may correspond to the applicant's request. In some cases, the

analysis of the estimated budget could result in EFSA suggesting reductions, e.g. need to correct the costs in line with the Rules on eligibility of costs. After the proposed modifications are agreed by the applicant and EFSA, the estimated budget, as modified, will become the approved estimated budget for the project.

1.13 INITIAL EFSA GRANT

Having agreed the approved estimated budget, and provided the proposal is selected for grant award, EFSA will establish the amount of the initial EFSA grant, having regard to the limits set out in part 1.10 of this call. The initial EFSA grant will be expressed as an amount in Euro and also as a percentage (EFSA max. 90% co-financing rate) of the total eligible project cost. This amount will be indicated in the grant agreement as the maximum grant amount.

1.14 FINAL EFSA GRANT

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

1.15 PUBLICITY

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

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

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

1.16 PROTECTION OF PERSONAL DATA IN RELATION TO GRANT PROCEDURES

Processing of personal data by EFSA (data controller)
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.[14]

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

[14] 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

(Annex 2) as a data processor of EFSA. These rules shall be observed also by any subcontractor involved for specific task implementation under the awarded grant.

In addition, the beneficiary and any subcontractor shall adhere to the declarations and the details on any processing of personal data as part of the implementation of activities under the grant, to be provided in the relevant questionnaires contained in the template for outline proposal (Annex 4).

1.17 PUBLIC ACCESS TO DOCUMENTS

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

1.18 OPEN ACCESS AND PUBLICATION OF THE OUTPUTS

EFSA is committed to the publication of grant outputs in the Knowledge Junction[15] 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.

The publication by the beneficiary of the output resulting from the action under this grant in scientific journals is also encouraged, following prior consultation and agreement with EFSA and subject to the requirements of Article II.8 of the FPA.

2. SELECTING PROPOSALS

This call for proposal is a **2-step procedure**, with the first step consisting of submitting an **Outline Proposal (step 1)** that, if shortlisted, will lead to the applicant being invited to submit a **Full Application (step 2)**.

The Evaluation Committee will evaluate the outline proposal (step 1) and the full application (step 2) according to the procedure and requirements described in sections 2.1 and 2.2. below.

2.1 Step 1

To meet the requirements for step 1, the applicant must submit an **outline proposal** (suggested max 5 pages) for the relevant Lot/s and/or area of expertise for Lot 1 within the specified deadline following the **template** attached to this call (Annex 4).

The Evaluation Committee will evaluate the submitted outline proposals as follows:

1. Verification of submission requirements (section 3.1 below)
2. Eligibility criteria (section 3.2 below)
3. Verification of ethics declarations and ethics self-assessment if applicable (3.3 below)
4. Award criteria to assess outline proposals to be shortlisted (3.4 below)

If the outline proposal fails at any of the above-mentioned evaluation stages, 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.

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

At the end of step 1, outline proposals which passed all the above-mentioned evaluation stages and quality thresholds (detailed under section 3.4) will be included in a shortlist and will be invited to submit a full application.

Outline proposals that have failed any of the above-mentioned evaluation stages will be rejected and the applicants informed in writing.

2.2 Step 2

Applicants whose outline proposal is included in the shortlist will be invited to submit a full application (deadline will be indicated in the letter inviting applicants to the step 2). In the letter inviting applicants to step 2, the Evaluation committee may specify suggestions for fine tuning the proposed projects in view of the submission of the full application.

Full applications received within the specified deadline will be evaluated as follows:

1. Verification of submission requirements (4.1)
2. Eligibility criteria (4.2)
3. Verification of ethics issues (4.3)
4. Selection criteria: (4.4)
5. Award criteria (4.5)
6. Exclusion criteria (4.6)
7. Selection criteria: Professional conflicting interests-DoI assessment (4.8)

At the end of step 2, full applications passing the above-mentioned evaluation stages and quality thresholds detailed under section 4.5 will be ranked in the final reserve list of projects to be funded under each Lot.

Full applications not passing the above-mentioned evaluation stages will be rejected and the applicants informed in writing.

Following their ranking on the final reserve list, EFSA reserves the right to invite applicants to adapt the proposed project in response to the evaluators' comments.

The number of applicants invited to adjust their project and ultimately awarded an EFSA grant will be based on the ranking of the grants against 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/s will be signed.

In case an applicant fails to adapt the proposed project, EFSA reserves the right to reject it. The budget made available in this way may be used for projects of next applicants on the reserve list. EFSA may repeat the adaptation process until the available budget of the call is assigned to other applicants on the reserve list.

3. EVALUATION OF STEP 1

All the evaluation stages for step 1 will be assessed by the evaluation committee on the basis of the outline proposal submitted according to template in Annex 4. No additional supporting document is required for step 1.

3.1 VERIFICATION OF SUBMISSION REQUIREMENTS

The following will be verified:

- Outline proposal was submitted within the deadline for submission of proposals;
- Outline proposal is submitted according to the EFSA template (Annex 4);
- Outline proposal is duly signed by the authorised representative of the applicant;
- Outline proposal is complete.

3.2 ELIGIBILITY CRITERIA

The following will be verified:

- The applicant and in case of consortium also its partner/s must be 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. Applicants or partners not currently on the list may apply to be included but they must be formally accepted and included on the Art 36 list by the EFSA Management Board before the deadline for submitting outline proposals for step 1 of this call.

3.3 VERIFICATION OF ETHICS DECLARATIONS AND ETHICS SELF-ASSESSMENT IF APPLICABLE

The ethics declarations and the ethics self-assessment, if applicable, submitted according to the template for the outline proposals in Annex 4 will be assessed by the Evaluation Committee. Based on the information provided in the outline proposal (Part A, section 5 "ethics" in Annex 4) EFSA reserves the right to reject the outline proposals which do not comply with the ethical requirements or, if applicable, to propose adjustments to the outline proposals related specifically to ethics in the event that outline proposals are included in the shortlist for step 2.

3.4 AWARD CRITERIA FOR STEP 1: OUTLINE PROPOSAL

The award criteria for step 1 serve to assess the quality of the outline proposal in relation to the objectives of the Call for proposal in order to establish the shortlist of proposals which will pass to step 2.

The following award criteria **for step 1** are applicable in this Call:

1. The extent to which the outline proposal demonstrates EFSA's needs in the relevant Lot/specific scientific area for Lot 1 applied for and has the capacity to address the scope of the lot(s) within this Call and, for Lot 1, the relevant specific area(s) - **max 30 points**;

   Please refer to outline proposal (Part B): Section 1, I and II: the problem and the solution: scope of proposal

2. Potential for providing a relevant, state of the art solution for more efficient (e.g. faster and more precise) risk assessment - **max 30 points**;

   Please refer to outline proposal (Part B): Section 1, III: the solution: approach and methodology)

3. Potential impact of the proposed work and its outcomes on regulatory science[16] and the scientific quality of the proposal - **max 30 points**;

   Please refer to outline proposal (Part B): Section 1, IV and V: the impact

4. Project management - **max 10 points**.

   Please refer to Outline proposal (Part B): Section 2

In order for an Outline Proposal to be shortlisted leading to EFSA inviting the applicant to submit a full application, the Outline proposal must score a **minimum of 70 points out of maximum possible 100 points.**

4. EVALUATION OF STEP 2

The evaluation stages for step 2 will be assessed by the evaluation committee on the basis of the full application and supporting documents listed below.

4.1 VERIFICATION OF SUBMISSION REQUIREMENTS

The following will be verified:

- Full application was submitted within the deadline for submission of proposals;
- Full application is submitted on the EFSA application form (Annex 5);
- Full application is duly signed by the authorised representative of the applicant;
- Full application is complete and includes all the supporting documents.

4.2 ELIGIBILITY CRITERIA

The following will be verified:

- Applicant and in case of consortium also its partner/s correspond to the ones indicated in the outline proposal in step 1;
- Applicant and in case of consortium also its partner/s participate in the project financially;
- Applicant and in case of consortium also its partner/s are involved in the execution of the project;
- Subcontracting, if any, is justified in the proposal and indicated in the estimated budget.

Documents to be provided:

- **LEGAL ENTITY FORM (Annex 6)** (download template here)
  to be completed and signed by the applicant and in case of consortium also by its partner/s. For a public body the legal entity form should be provided together with a copy of the resolution or decision establishing the public body, or other official document establishing that public body. For a private body an extract from the official journal, copy of articles of association, extract of trade or association register, certificate of liability to VAT (if, as in certain countries, the trade register number and VAT number are identical only one of these documents is required).

[16] Regulatory Science: Transdisciplinary scientific information, including risk/safety assessments, methods, tools, models and scientific advice, to support sound and transparent science-based policies

- **FINANCIAL IDENTIFICATION FORM (Annex 7)** (download template here)
  to be completed only by the applicant and in case of consortium only by the coordinator.

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

Only applicable if the applicant is a consortium:

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

4.3 VERIFICATION OF ETHICS ISSUES

The full applications will be verified to confirm their compliance with ethics issues and the declarations provided in the outline proposal (Part A, section 5 "ethics" in Annex 4). Based on the information provided in the full application, EFSA reserves the right to reject the full application if it does not comply with the ethical requirements or, if applicable, to propose adjustments to the projects related specifically to ethics.

4.4 SELECTION CRITERIA

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

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

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

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

Requirements for Lot 1:

A.Requirements for the organisation

The applicant must have proven experience in:

- Developing and executing experiments in the field of *in vitro* toxicology and NAMs
- Chemical risk assessment methodologies and regulatory procedures
- Reporting and evaluating scientific results for regulatory use

B.Requirements for the team of experts

1) Team composition: The team should include at least three experts;
   - one senior expert with minimum 6 years of experience in the field of *in vitro* toxicology and NAMs acting as project/team coordinator and at least three of the six years in managing scientific projects in the field of *in vitro* toxicology and NAMs;
   - 2 additional experts with a post graduate level degree (minimum master's degree) and at least 3 years of professional experience in the field of *in vitro* toxicology and NAMs.

2) The team overall (any of the experts mentioned under point 1, above) should have:
   a) Expertise (of minimum 3 years) in developing and implementing proposals for using new methods and innovative approaches in the field of *in vitro* toxicology and NAMs
   b) Justified expertise for conducting the proposed experimental studies (of minimum 3 years)
   c) Experience in writing scientific reports and publications (of minimum 3 years)

For the senior expert (also acting as the point of contact with EFSA): an excellent level of spoken and written English (evidenced either by a certificate demonstrating at least level B.2 of the Common European Framework of References for Languages; or evidence of having worked for at least 2 years in a working environment where English is used for meetings, communications and producing written reports and scientific publications).

Requirements for Lot 2:

A. Requirements for the organisation

The applicant must have proven experience in:
- Developing and executing experiments in transcriptomics in the field of *in vitro* toxicology
- Chemical risk assessment methodologies and regulatory procedures
- Reporting and evaluating scientific results for regulatory use

B. Requirements for the team of experts

1) Team composition: The team should include at least three experts;
- one senior expert with minimum 6 years of experience in the use of transcriptomics in the field of *in vitro* toxicology, acting as project coordinator and at least three of the six years in managing scientific projects in transcriptomics in the field of *in vitro* toxicology;
- 2 additional experts with a post graduate level degree (minimum master degree) and at least 3 years of professional experience in transcriptomics in the field of *in vitro* toxicology

2) The team overall (any of the experts mentioned under point 1, above) should have:
   a) Expertise (of minimum 3 years) in developing and implementing proposals for using new methods and innovative approaches in transcriptomics in the field of *in vitro* toxicology
   b) Justified expertise for conducting the proposed experimental studies (of minimum 3 years)
   c) Experience in writing scientific reports and publications (of minimum 3 years)

For the senior expert (also acting as the point of contact with EFSA): an excellent level of spoken and written English (evidenced either by a certificate demonstrating at least level B.2 of the Common European Framework of References for Languages; or evidence of having worked for at least 2 years in a working environment where English is used for meetings, communications and producing written reports and scientific publications).

Documents to be provided by the applicant:

- **DECLARATION ON HONOUR – Section B (Annex 8);**
  to be completed by the applicant or in case of consortium by the coordinator;

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

- **<u>Evidence requested for requirements 1 and 2</u>:**

  Table in Annex 5A (Lot 1) and/or 5B (Lot 2) completed with evidence (e.g. scientific reports or publications) of at least two recently finalised projects (within the last 5 years) and of at least one new or ongoing project relevant to the topics of the Lot(s) applied for.

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

  LIST OF PROJECT TEAM MEMBERS NAMES – in addition to the CV's, table in Annex 5A (Lot 1) and/or 5B (Lot 2) completed with the names and relevant profiles and expertise covered.

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

4.5 AWARD CRITERIA

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

1. **UNDERSTANDING OF THE ASSIGNMENT AND SCOPE OF THE CALL; max 10 points – minimum threshold 70%.:** The extent to which the full application is in line with the outline proposal submitted under step 1 and a detailed description is provided with regards to demonstrating EFSA's needs in the relevant Lot/specific scientific area applied for and how and why the proposed project has the capacity to address the scope of the lot(s) within this Call and, for Lot 1, the relevant specific area(s).

2. **METHODOLOGY PROPOSED FOR IMPLEMENTATION; max 60 points - minimum threshold 70%**: The extent to which the methodology in the full application is well-described and in detail, and shows the capacity to address the specified objectives, including convincing justification for the choice of the proposed methodology highlighting the expected impact and relevance on regulatory science: More specifically the applicant should provide:
   a. a well-structured step by step explanation of the proposed methodology; substantiated with convincing justification for the methodology choice (including advantages and disadvantages) (**25 points**)

b. a detailed description for the potential impact of the proposed project on regulatory science (**25 points**)
c. a detailed justification that the project will deliver a relevant, state of the art solution for more efficient (e.g. faster) risk assessment (**max 10 points**);

3. **PROJECT MANAGEMENT AND ORGANISATION; RISK MANAGEMENT & QUALITY ASSURANCE; max 20 points – minimum threshold 60%**
   a. Clear and detailed information on distribution of the tasks among the project team; in case of joint offer & subcontractors, clarity on who does what, when and why (justify why the partner/subcontractor is proposed to do the particular task/work-package); **max 10 points**
   b. Quality of communication, internal within the team (and in case of joint offers & subcontractors also the communication between joint offers partners and subcontractors) and external with EFSA; **max 5 points**
   c. Quality of risk management identification/mitigation and measures for quality assurance proposed for this particular project (including role of team leader / leading partner in quality assurance); **max 5 points**

4. **TECHNICAL AND FINANCIAL CONSISTENCY OF THE PROPOSAL; max 10 points:** consistency between the proposed project and its estimated budget, e.g. how it reflects the task distribution/role of partners.

In order to be considered for the reserve list, the full application must:

- for criteria 1 and 2, score at least 70% of the points attributed to that criteria
- for criterion 3, score at least 60% of the points attributed to that criterion
- overall score a minimum of 70 points out of maximum possible 100 points;

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

4.6 EXCLUSION CRITERIA

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

Documents to be provided:

- **THE DECLARATION ON HONOUR – Section A (Annex 8)**: template is published with this Call; to be completed/signed individually by the applicant and in case of consortium by each partner.

4.7 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. 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.

4.8 SELECTION CRITERIA: PROFESSIONAL CONFLICTING INTEREST

EFSA will request Institutional and Individuals DoIs only from the awarded beneficiary/ies, prior to the signature of the grant agreement. The requirement to submit Institutional and Individual DoIs will be specified in the award letter and will have to be provided and assessed by the EFSA Authorising Officer before and as a condition of grant agreement signature. **Institutional and Individual DoIs do not need to be provided with your proposal in either step 1 or step 2.**

In case of a consortium and/or in case of subcontracting, such declarations will need to be completed separately and submitted for each partner and for each identified subcontractor and for each individual member of the project team coming from consortium partners or subcontractors.
Please refer to EFSA's policy on independence and the Decision of the Executive Director on Competing Interest Management for more detailed information.

5. SUBMITTING PROPOSALS

5.1 APPLICATION FORMS

Step 1: Outline Proposal

The outline proposal must be submitted using the **template for OUTLINE PROPOSAL (Annex 4).** The template is published together with this call. The template must be:

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

The applicant should provide enough detail to ensure the outline proposal is well described.

By submitting an outline 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 outline proposal, the applicant must submit the outline proposal 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.

Step 2: Full application

The full application must be submitted using the **EFSA FULL APPLICATION FORM (Annex 5).** The full application form is published together with this call. The application form must be:

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

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

By submitting a full application, 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 full application, the applicant must submit the application also on 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.

5.2 LANGUAGE OF THE OUTLINE PROPOSAL AND FULL APPLICATION (INCLUDING SUPPORTING DOCUMENTS)

Outline proposals (step 1) and full applications (step 2) 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 for the full application some supporting documents are required. These supporting documents are an integral part of the full application. For more information on the relevant supporting documents to be submitted, please refer to step 2 of this Call (section 4 above). 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.

5.3 SUBMISSION MODALITIES

Outline proposals (step 1) and full applications (step 2) are to be submitted as indicated in the second page of this document in the Indicative procedure timetable.

5.4 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 2 months of the deadline for submission of outline proposals **(step 1)**;
- All applicants shortlisted following step 1 will be informed of the decision regarding their application within 4 months of the deadline for submission of full application **(step 2)**;
- 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 full application.

ANNEX 5A - ORGANISATION, TEAM AND EXPERTISE REQUIREMENTS FOR LOT 1 (as stated under section 4.4 of the call for proposal) – step 2

A. Requirements for the organisation

Requirement	List of scientific reports or publications of at least two recently finalised projects (within the last 5 years) and of at least one new or ongoing project relevant to Lot 1 [17]
Proven experience in developing and executing experiments in the field of *in vitro* toxicology and NAMs	
Proven experience in chemical risk assessment methodologies and regulatory procedures	
Proven experience in reporting and evaluating scientific results for regulatory use	

B. Requirements for the team of experts

Team composition

Expert profile required	Expert's name and link to CV	Proof of English level at least level B.2 of the Common European Framework of References for Languages
1 senior expert with minimum 6 years of experience in the field of *in vitro* toxicology and NAMs acting as project/team coordinator and at least three of the six years in managing scientific projects in the field of *in vitro* toxicology and NAMs		
2 **additional experts** with a post graduate level degree (minimum		n/a

[17] Note = the same project/publication can be listed to demonstrate several requirements.

master's degree) and at least 3 years of professional experience in the field of *in vitro* toxicology and NAMs.		

Expertise for the team overall

Requirement	**Indicate the name of the expert(s) meeting the expertise requirement and the link to the CV**
a) Expertise (of minimum 3 years) in developing and implementing proposals for using new methods and innovative approaches in the field of *in vitro* toxicology and NAMs	
b) Justified expertise for conducting the proposed experimental studies (of minimum 3 years)	
c) Experience in writing scientific reports and publications (of minimum 3 years)	

ANNEX 5B - ORGANISATION, TEAM AND EXPERTISE REQUIREMENTS FOR LOT 2 (as stated under section 4.4 of the call for proposal) – step 2

A. Requirements for the organisation

Requirement	List of scientific reports or publications of at least two recently finalised projects (within the last 5 years) and of at least one new or ongoing project relevant to Lot 2 [18]
Proven experience in developing and executing experiments in transcriptomics in the field of *in vitro* toxicology	
Proven experience in chemical risk assessment methodologies and regulatory procedures	
Proven experience in reporting and evaluating scientific results for regulatory use	

C. Requirements for the team of experts

Team composition

Expert profile required	Expert's name and link to CV	Proof of English level at least level B.2 of the Common European Framework of References for Languages
one senior expert with minimum 6 years of experience in the use of transcriptomics in the field of *in vitro* toxicology, acting as project coordinator and at least three of the six years in managing scientific projects in transcriptomics in the field of *in vitro* toxicology		
2 additional experts with a post graduate level degree (minimum master degree) and at least 3 years		n/a

[18] Note = the same project/publication can be listed to demonstrate several requirements.

of professional experience in transcriptomics in the field of *in vitro* toxicology		

Expertise for the team overall

Requirement	**Indicate the name of the expert(s) meeting the expertise requirement and the link to the CV**
a) Expertise (of minimum 3 years) in developing and implementing proposals for using new methods and innovative approaches in transcriptomics in the field of *in vitro* toxicology	
b) Justified expertise for conducting the proposed experimental studies (of minimum 3 years)	
c) Experience in writing scientific reports and publications (of minimum 3 years)	