



RISK ASSESSMENT & SCIENTIFIC ASSISTANCE DEPARTMENT

CALL FOR PROPOSALS

SIMPLIFIED FORM OF GRANT - FINANCING BASED ON ACHIEVEMENT OF RESULTS $^{\rm 1}$

Call reference: GP/EFSA/ALPHA/2021/09

Call title: Survival of African swine fever virus in feed, bedding materials and mechanical vectors and their potential role in virus transmission Project/Process code: ALPHA-04 Budget line: 3210

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.

¹ Article 125.1(a) FR





INDICATIVE PROCEDURE TIMETABLE

Milestone	Date ²	Comments			
Launch date	31/10/2021	Date of call publication on EFSA's website.			
Deadline for applicants to raise clarification questions to EFSA	13/01/2022	 If, after having read this Call for proposals and guide for applicants, you have any questions, you may address them to <u>EFSAProcurement@efsa.europa.eu</u> by indicating the Call reference. 			
Deadline for EFSA to reply to clarification questions	17/01/2022	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 proposals Any proposal posted after the final deadline will automatically be rejected.	21/01/2022	 You can submit your proposal: either by post (registered mail) or by courier not later than 21/01/2022, 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 21/01/2022 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 Mrs Raffaella Rovesti, 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/ALPHA/2021/09 - 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	March 2022	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.			

 $^{^{2}\,}$ All times are in the time zone of the country of the EFSA.





Provide EFSA with feedback:

If you considered applying to this call for proposals but finally decided not to do so, your feedback and reasoning for such a decision would be very much appreciated. Please address it to: <u>EFSAProcurement@efsa.europa.eu</u>. EFSA will process any feedback confidentially in order to improve the quality of its future grant calls.





1. GRANT OPPORTUNITY AND CONDITIONS

1.1 LEGAL FRAMEWORK

Article 36 of the Regulation (EC) 178/2002³ 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 projects⁴, 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 Regulation (EU, Euratom) 2018/1046⁵ 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 2021 Work Programme for grants and operational procurements as presented in Annex XIa of the Programming Document 2021 – 2023, available on the EFSA's website⁶.

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

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

⁵ <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1046&from=IT</u>

⁶ <u>https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp2123.pdf</u>





SIMPLIFIED FORM OF GRANT - FINANCING BASED ON ACHIEVEMENT OF RESULTS

Financing based on achievement of results as opposed to financing based on cost is a new type of grant introduced in the EU financial Regulation 2018. This type of grant gives advantages on an administrative level to both EFSA and the beneficiaries. The below table illustrates the main changes.

- Co-financing principle is not applicable
- No-profit principle is not applicable
- Estimated budget is not requested
- The concept of eligible/non eligible costs is no longer relevant
- Payments are done based on approval of deliverables. No need for EFSA to calculate the final grant amount based on spending and no need for the beneficiary to submit supporting documents for incurred costs.





1.2 BACKGROUND AND MAIN OBJECTIVE OF THE CALL

BACKGROUND

ASF is a notifiable viral disease of members of the Suidae family, including domestic pigs, wild boar and African wild suid species. It is endemic in sub-Saharan Africa where it is transmitted in an ancient sylvatic cycle among warthogs and soft ticks of the genus *Ornithodoros*. This cycle is not accompanied by overt disease or mortality in warthogs and the infection would probably go unnoticed. However, any introduction of the disease into the domestic pig sector via ticks or fomites leads to a severe multi-systemic disease that can resemble a viral haemorrhagic fever with exceptionally high lethality (Penrith, 2009). Over the last decade, ASF has gained international impact and has truly gone pandemic. In 2007, the disease was introduced into Georgia. Subsequently, the virus spread in the Trans-Caucasian region and reached the Russian Federation. From Russia, the virus moved further and reached the European Union in 2014. In August 2018, the disease reached China, and it is still spreading to new countries in Asia and the Pacific.

Among the reasons for its continuous and expanding spread is the high survival of the causative agent, ASF virus (ASFV) (Plowright and Parker, 1967, Mebus et al., 1993, Petrini et al., 2019). Even though oral infection requires much more virus particles than that required for parenteral transmission of ASFV (McVicar, 1984), the tenacity of the virus has led to discussions of virus transmission through feed, water and fomites. These transmission routes have been implicated in transmission in affected countries (Olsevskis et al., 2016; Boklund et al., 2020; EFSA 2020; EFSA 2021). Despite commercially traded crops, vegetables, hay, straw and other plant material (grasses, woods, roots, seeds, leaves, etc) are considered to have a low risk of containing and maintaining infectious ASFV (EFSA 2021, Strategic approach to the management of African Swine Fever for the EU, Working Document SANTE/7113/2015), a high level of uncertainty is observed in affected regions and application of a strict precautionary principle may have led to hardship for arable crop farmers.

Against this background, the competent authorities request science-based recommendations for action and detailed handouts on inactivation procedures and other risk mitigation strategies. The current strategic approach considers mitigation concepts if locally harvested grass and straw is considered to present a risk under the local prevailing conditions. These measures include the ban of feeding fresh grass or untreated grains to pigs. Regarding bedding, the use of straw for pigs is discouraged unless an inactivating treatment or storage for at least 90 days before use is applied. However, no detailed information is available regarding the survival of ASFV on several crops, or on the inactivation procedures used and their implementation and supervision.

Recently, EFSA has assessed the ability of different matrices (both plant-derived feed, feed of animal origin, and bedding) to transmit African swine fever in an opinion based on published scientific evidence and Expert Knowledge Elicitation (EKE) (EFSA, 2021).





African swine fever virus in feed

Feed of animal origin

A widely used product of animal origin is spray dried porcine plasma (SDPP). In a study funded by the European Association of Blood Products Producers (EAPA), Blázquez et al. (2018) studied the survival of ASFV in spray-dried 0.5 kg samples of liquid concentrated porcine plasma (28% solid) inoculated with ASFV (strain BA-71) (final TCID₅₀ concentration of $10^{5.77}$ per mL of liquid concentrated plasma) in a laboratory spray dryer at an inlet temperature of 200°C and at 80°C outlet temperature. Virus titration results showed that the spray drying had inactivated 4.11 ± 0.20 log10 TCID₅₀/mL of the inoculated ASFV. This study is in line with a recent study by Fischer et al. (2020) that showed that heavily recontaminated SDPP stored at room temperature displayed a distinct ASFV titre reduction after one week and complete inactivation after two weeks.

Moreover, commercially collected liquid porcine plasma mixed with low doses of the serum from an ASFV experimentally infected pig was not sufficient to infect susceptible animals when fed for 14 consecutive days.

It can be assumed that hydrolysed proteins, gelatine, collagen, calcium phosphate, and rendered fats for use in feed are processed in a way that ASFV is inactivated (see Chapter III of Annex IV of Regulation 142/2011). However, dedicated data could not be found in the literature review (EFSA, 2021).

Plant derived feed

Based on laboratory tests, it can be assumed that ASFV can be transmitted by natural consumption of ASFV contaminated plant-based feed or liquids by swine, especially after repeated consumption (Niederwerder et al., 2019). With regard to ASFV survival, Dee et al. (2018) showed that re-contaminated dried distiller's grains that were stored at varying temperatures did not contain infectious ASFV after 30 days. Heavily re-contaminated soy oil cake and soybean meal remained positive for virus isolation for 30 days (Stoian et al., 2019, Dee et al., 2018). The same was true for compound feed and choline (feed additives). On the other hand, Fischer et al. (2020) showed that a two-hour drying already inactivates ASFV on dry wheat, barley, rye, triticale, corn, and peas.

Compound feed contaminated with ASFV was positive for virus isolation for less than 5 days at room temperature, less than 40 days cooled, but at least 60 days when frozen (Sindryakova et al., 2016)

No data exist for roots, legumes other than peas (see above), other seeds or forages (EFSA, 2021).

ASFV survival in bedding

So far, no data exist on the survival of ASFV in saw dust, wood chips, turf or hulls/husks of rice or other cereals. However, Olesen et al. (2018) showed a very short time window for transmission via a contaminated stable environment. This outcome could change with different temperatures.





ASFV survival in mechanical vectors

Outbreaks of African swine fever virus (ASFV) continues to occur on European farms and affect both farms with and without biosecurity measures (EFSA, 2014; EFSA, 2015). While wild boar are infected throughout the year, with a declining incidence in summer and increasing incidence in autumn and winter, ASF outbreaks on large pig production farms with biosecurity measures enforced are strongly clustered within the summer season (EFSA, 2017a). There may be several explanations for this pronounced seasonality of ASF in pig farms, but one hypothesis is that blood-feeding arthropods that are absent during the winter season may be driving this incidence pattern. Species of soft ticks act as reservoir for AFSV and may play an important role in transmission and as reservoirs in areas where they are endemic. However, no soft tick species are present in the Baltic area, where the seasonal incidence was first reported in the European Union.

ASFV spreads among wild boar populations and among domestic pig populations by direct and indirect contact, and there is no indication that mechanical vector transmission plays any relevant role. However, pigs in stables with good biosecurity are effectively isolated from wild boar populations, and in such herds, vectors may play an important role in transmitting the virus from wild boar to a single pig in a stable on a farm. Mechanical transmission of pathogens by blood-feeding vectors is potentially an effective mechanism and several pathogens are adapted to this type of transmission, e.g. Lumpy skin disease and Equine infectious anaemia.

It is known that the biting fly *Stomoxys calcitrans* may efficiently act as a mechanical vector of ASFV under laboratory conditions, when blood feeding on naive pigs after having fed on infectious blood several hours before (Mellor et al., 1987). However, it is not known if this mechanism plays any epidemiological role under field conditions. Blood-feeding arthropods may also be able to spread ASFV by transporting not fully digested blood meals that may still contain viable ASFV. If the blood-fed arthropods are accidentally ingested by a pig, by e.g. falling to the feed or if the insect is crushed on the pig and released blood containing infectious virus is ingested, this may result in infection. It has been shown in laboratory experiments that insects and ticks containing a virus contaminated blood meal may lead to infection in pigs if swallowed in a meal (Olesen et al., 2018a; Pereira et al., 2020). It has been also demonstrated that ASFV remains detectable and viable for several hours in *S. calcitrans* after blood feeding, although the effect of temperature on virus survival in the insects remains unknown (Olesen et al., 2018b).

With the limited evidence in mind, this call for research proposals is intended to generate or expand baseline data on the survival of the virus on various crops, plant-derived feeds and bedding materials to adjust risk assessments and deduce inactivation protocols and put them to practice.

In addition, as successful introduction of ASFV from wild boar to production animals inside biosecurity provided stables is likely to be a rare event; it is difficult to prove or even detect this phenomenon from observational field studies or epidemiological data. However, if quantitative data on virus survival in vectors at different temperatures (natural temperature range in the field) and importantly in different potential vector insect groups (with different physiology and different blood meal sizes) are obtained, then the probability of ASFV vectordriven introduction to production farms may be estimated. If these probabilities could then combined with quantitative data for movements of blood-fed insects between wild boar areas





and indoor pigs, it may indirectly be used to estimate the daily risk of mechanical vectors introducing an infectious dose of ASFV to an indoor pig environment.

MAIN OBJECTIVES OF THE CALL

There are two main objectives of this call:

- **1.** Assess the duration of ASFV survival in feed and bedding material (plantbased material)
- Assess the survival of ASFV in feed through laboratory survival tests
 - Plant based feed focussing on major grains (e.g. wheat, barley, rye, triticale, oats), legume seeds (e.g. rapeseed), tubers (e.g. sugar beet, fodder beet), and fresh grass and others (rushes, leaves, roots).
- Assess the survival of ASFV in bedding and roughage through laboratory survival tests

 Straw, hay, woodchips, peat, silage, barks.
- Explore concepts of risk mitigation in proof-of-concept approaches (e.g. heat treatment, citric acid treatment)

2. Assess the role of mechanical vectors in ASFV transmission

Two objectives exploring ASFV transmission by different groups of blood feeding insects are proposed:

- Determine in a laboratory setting for how long ASFV can be detected in an infected insect blood meal from different species of insects (selected among *Culicoides*, Culicidae, Phlebotominae, Tabanidae and *Stomoxys*) at different temperatures ranging from 10° C to 30 °C.
- Determine in a laboratory setting if different species of *Culicoides* and Culicidae after feeding on ASFV infected blood are able to successfully infect naïve pigs via oral intake or insects' bites.

1.3 SPECIFIC OBJECTIVES OF THE CALL

For each of the specific objectives, the applicant is requested to develop a detailed research protocol, which is building on the proposed methods and study designs. The applicant may deviate from the proposed methods and study design, providing appropriate argumentation in their proposal.

Specific objective 1: Assess the duration of ASFV survival in feed or bedding materials (plant-based material)

<u>Methods</u>

• Assess survival on artificially contaminated feed materials such as hay and crops, and bedding materials.





- At least the storage at different ambient conditions should be evaluated, i.e. -20°C, 4°C, 10°C, 18-22°C, and 37°C. If possible, other variables such as % humidity rate can also be included in the protocol.
- Detection of ASFV by qPCR and virus isolation (the latter is mandatory).

Study design

- Use representative ASFV strains that are currently circulating in the EU (preferably genotype II), proof-of-concept could be done with fluorescent marker to facilitate first analyses
- Mirror natural conditions using biological materials (blood, organ suspensions) rather than culture supernatants (except for the first proof-of-concept, see above). The use of biological suspensions ensures surface behaviour and wetting that can be extrapolated to field conditions.
- To ensure statistical validity, two to three independent runs should be carried out. These runs should be performed with an appropriate number of technical replicates (e.g. three test aliquots).
- Storage should be done for at least 6 months with shorter sampling intervals in the first four weeks, e.g. daily for the first week, weekly thereafter for one month and then twice monthly.
- Mitigation concepts should be explored as proof-of-concept (small scale). These concepts could include e.g. acid treatment or heat or any other treatment that may reduce the risk of ASFV transmission.

Specific Objective 2A: Survival time of ASFV in infected insect blood meals at different temperatures

<u>Methods</u>

Laboratory experiments assessing how long ASFV in an infected insect blood meal from different species of insects can be detected at different temperatures.

Study design:

At least one species of wild trapped or laboratory reared insects belonging to Culicoides, Culicidae, Tabanidae and Stomoxys are fully fed on naturally ASFV infected blood (or blood spiked with a realistic concentration of virus) and stored at 10° C, 20° C and at 30° C for 0, 2, 4, 8, 16 and 24 hours, after which individual insects are analysed for ASFV with qPCR and by isolation in cell culture (e.g. Olesen et al., 2018b). The number of insects in each analysed batch needs to be sufficiently high to show a significant decay of virus over time.

Specific Objective 2B. Assess possible transmission of ASFV from infected vectors to pigs via oral intake or mechanical transmission.

Methods:

Laboratory experiments assessing possible transmission to pigs of ASFV through infected vectors via oral intake or mechanical transmission





Study design:

At least one insect species of wild trapped or laboratory reared insects belonging to *Culicoides* or Culicidae are fully fed on naturally ASFV infected blood (or blood spiked with a realistic concentration of virus) and stored for two hours, after which individual *Culicoides* or Culicidae are orally fed to pigs under experimental conditions. Five pigs are fed with 1, 2, 4, 8 and 16 individual *Culicoides*, respectively, and five pigs are fed with 1, 2, 4, 8 and 16 Culicidae, respectively. The 10 pigs are followed for two weeks, and antibodies and clinical manifestations are monitored daily. Preferably, if laboratory conditions allow, transmission of ASFV though mechanical transmission can be studied.

1.4 ELIGIBLE ORGANISATIONS

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

To be eligible, the applicant and in case of a consortium the partner/s 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. You may consult the list on EFSA's website at http://www.efsa.europa.eu/en/networks/art36.htm. It is sufficient to be on the Art. 36 list at the moment of entry into force of the legal commitment, i.e. the signature of the grant agreement. We however strongly suggest that you apply to the Art. 36 list before expiry of the application deadline for this call for proposals.

1.5. ROLES AND RESPONSIBILITIES

A) If the proposal is submitted by a consortium:

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

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

Once the grant is awarded the grant agreement is signed between EFSA, the applicant and all partners. However, the partners do not sign themselves the grant agreement. They give to the applicant, if they agree so, a mandate (template will be provided by EFSA), where they authorise the applicant to sign the grant agreement, and any possible amendments to it, also on their behalf. This facilitates the signature process where only two signatures need to be collected, one from EFSA and one from the applicant. As soon as the grant agreement is signed the applicant becomes **the Coordinator** and its partner/s become **the Co-Beneficiary/ies**. The coordinator and co-beneficiary/ies are together 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 will become annex 1 of the grant agreement. If a beneficiary fails to implement its part of the project, the other beneficiaries become responsible for implementing its part.





Regarding **the coordinator**, please note also the following important roles:

- Take part in implementing the project;
- Monitors that the action is implemented properly;
- Act as the intermediary for any communication between the consortium and EFSA;
- Receive and answers all claims EFSA might have in relation to the implementation of the project;
- Request and review any documents or information required by EFSA and verify their completeness and correctness before passing them on to EFSA;
- Inform EFSA and the partner/s of any event that is likely to substantially affect the implementation of the project;
- Submit the deliverables and reports to EFSA;
- Request and receive payments from EFSA and distribute 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.

Regarding **the other beneficiary/ies**, please note also the following important roles:

- Take part in implementing the project;
- Forward to the coordinator the data needed to draw up the reports 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) If the proposal is submitted by a sole applicant:

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

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

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

Regarding **the beneficiary**, please note also the following important roles:

- Take part in implementing the project;
- Monitors that the action is implemented properly;
- Communicate with EFSA;
- Receive and answer all claims EFSA might have in relation to the implementation of the project;
- Request and review any documents or information required by EFSA and verify their completeness and correctness before passing them on to EFSA;
- Inform EFSA of any event that is likely to substantially affect the implementation of the project;
- Submit the deliverables and reports to EFSA;

Request and receive 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 an equipment, the beneficiary/ies must award the contract to the entity offering the best value for money or the lowest price (as appropriate), avoiding conflicts of interests, and retain the documentation for the event of an audit.

Entities acting in their capacity of contracting authorities in the meaning of applicable public procurement directive shall abide by the applicable national public procurement rules.

Sub-contracting:

It is a subgroup of the implementation contracts, hence must satisfy the above conditions. Subcontractors are not consortium partners. They are not part of the grant agreement. They don't have a contractual relationship with EFSA. Subcontractors are entities contracted by the applicant and/or its partner/s to carry out some specific tasks. Subcontracting is allowed under these conditions:

- Subcontracting only covers 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;
- The tasks intended to be subcontracted and the corresponding estimated costs must be approved by EFSA before the signature of the grant agreement;
- Any recourse to subcontracting while the project is in progress, if not envisaged from the outset in the proposal, is subject to prior authorisation in writing by EFSA, and shall be formalised via an amendment of the grant agreement.
- The conditions applicable to the beneficiaries under Article II.7 of the grant agreement are also applicable to the subcontractor.
- Core tasks, such as project coordination, cannot 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 **18 15** months years (after the kick-off meeting).

MEETINGS

Below mentioned meetings with EFSA are foreseen:

- 1. Kick off meeting (web-meeting): The kick-off meeting is regarded as the start of the project and takes place no later than **1 month** after the signature of the grant agreement. At this meeting, details of the project will be discussed and the objectives, the reports structure 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.
- 2. Progress monitoring web-meetings will be held first 2 months, and then every 4 months after the kick-off meeting: The purpose of these meetings is to discuss the progress of the research activities as well as any difficulties encountered during the project and agree on possible solutions. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.





3. Final meeting (web-meeting) will be held one month before the end of the project. The purpose of this meeting is to discuss the results of the studies and the draft final report. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.

All data, reports and minutes shall be uploaded on a dedicated sharepoint site, created by EFSA and shared with the contractors, which will allow co-editing of the documents.

DELIVERABLES

Deliverable 1 - ASFV survival in plant material

- **Deliverable 1.1. Detailed research protocol**: <u>1,5 months</u> after the start date of the project (the kick-off meeting) a detailed research protocol must be submitted to EFSA. The protocol must describe in detail the research activities proposed to study the duration of ASFV survival in plant materials, including a detailed planning of the research activities, eventual modifications from the proposal, further elaborations or specifications agreed during the kick-off meeting and the envisaged statistical analysis.
- Deliverable 1.2. Final report: at latest 17 14-months after the start date of the project (after the kick-off meeting) a draft report on the study of the duration of the survival of ASFV in plant material must be submitted to EFSA and latest 18 15 months after the start date of the project (after the kick-off meeting) a final report should be submitted. The final report will comprise the integration of the research protocol, results, discussion and conclusions of the study. The dataset generated in the study shall also be delivered to EFSA as a Microsoft Excel database, as part of the final report. The report should be compiled in a format that would allow publication as an External Scientific Report in the templated provided by EFSA without additional editing. They must include abstract, introduction, materials and methods, results, mitigation measures. Besides, the publication of the study results in a scientific journal is encouraged.

Deliverable 2 - Role of mechanical vectors in ASFV transmission

- Deliverable 2.1. Detailed research protocol: <u>1,5 months</u> after the start date of the project (the kick-off meeting) a detailed research protocol must be submitted to EFSA. The protocol must describe in detail the research activities proposed to study the duration of ASFV survival in blood meals of different insect species. The research protocol should include a detailed planning of the research activities, eventual modifications from the proposal, further elaborations or specifications agreed during the kick-off meeting and the envisaged statistical analysis.
- Deliverable 2.2. Final report: latest 17 14 months after the start date of the project (after the kick-off meeting) a draft report on the study of the duration of the survival of ASFV in insect blood meals must be submitted to EFSA and latest 18 15 months after the start date of the project (after the kick-off meeting) a final report should be submitted. The final report will comprise the integration of the research protocol, results, discussion and conclusions of the study. The dataset generated in the study shall be also delivered to EFSA as a Microsoft Excel database, as part of the final report. The report should be compiled in a format that would allow publication on as an External Scientific Report of EFSA in the template provided by EFSA without additional editing. They must include abstract, introduction, materials and methods, results, conclusions and future perspectives. The report shall also include possible concepts of





risk mitigation measures. Besides, the publication of the study results in a scientific journal is encouraged.

- **Deliverable 2.3. Detailed research protocol**: <u>1,5 months</u> after the start date of the project (the kick-off meeting) a detailed research protocol must be submitted to EFSA. The protocol must describe in detail the research activities proposed to study the possible transmission of ASFV from infected vectors to pigs via oral intake or mechanical transmission. The research protocol should include a detailed planning of the research activities, eventual modifications from the proposal, further elaborations or specifications agreed during the kick-off meeting and the envisaged statistical analysis. The study protocol will need to be approved by the relevant ethical committee and this ethical committee approval will need to be <u>delivered to EFSA</u> before the study involving animals can be carried out.
- Deliverable 2.4. Final report: latest 17 14 months after the start date of the project (after the kick-off meeting) a draft report on the study of the possible transmission of ASFV from infected vectors to pigs via oral intake or mechanical transmission must be submitted to EFSA and latest <u>18 15-months</u> after the start date of the project (after the kick-off meeting) a final report should be submitted. The final report will comprise the integration of the research protocol, results, discussion and conclusions of the study. The dataset generated in the study shall be also delivered to EFSA as a Microsoft Excel database, as part of the final report. The report should be compiled in a format that would allow publication on as an External Scientific Report of EFSA in the template provided by EFSA without additional editing. They must include abstract, introduction, materials and methods, results, conclusions and future perspectives. The report shall also include possible concepts of risk mitigation measures. Besides, the publication of the study results in a scientific journal is encouraged.

The above mentioned deliverables must be drafted in UK standard English language. Please also note that all reporting, minutes, outcome of the discussions could be submitted at EFSA's discretion to EFSA's Panel and WG members.

Time from signature of the Grant agreement	Month 1	Month 2	Month 3	Month 5	Month 9	Month 13	Month <mark>17 14</mark>	Month <mark>18 15</mark>
Deliverables		Research	Web	Web	Web	Web	Draft	Final
		protocols	meeting	meeting	meeting	meeting	Final	Reports
			minutes	minutes	minutes	minutes	report	
Meetings	Kick-off		Progress	Progress	Progress	Progress	Final	Final
	meeting		monitorin	monitorin	monitorin	monitorin	Meeting	Meeting
			g web	g web	g web	g web		
			meetings	meetings	meetings	meetings		

Foreseen planning of meetings and deliverables





Foreseen milestones and corresponding project completion rate

Milestones	Project completion rate %		
Approval of Deliverable 1.1	5%		
Approval of Deliverable 1.2	25%		
Approval of Deliverable 2.1	5%		
Approval of Deliverable 2.2	25%		
Approval of Deliverable 2.3	5%		
Approval of Deliverable 2.4	35%		
Approval of all Deliverables	100%		

1.8 PAYMENTS

The following payment scheme will be applied to the signed grant agreement:

- **pre-financing payment**, upon grant agreement entry into force, without need for a request for payment, between 10% and 20% of the maximum grant amount set out in the grant agreement; 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. Please note the exact amount of pre-financing will be determined at the time of awarding the grant;
- **interim payment**, based on the request for interim payment, up to 30% of the maximum grant amount set out in the grant agreement. The interim payment is subject to the approval by EFSA of the Research protocols (D1.1, D2.1 and D2.3).
- **final payment (payment of the balance)**, the amount due as the balance payment is calculated by EFSA by deducting from the final EFSA grant amount the total amount of prefinancing and interim payments already made. The payment is subject to the approval of the final reports 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**: Not applicable
- **No-profit**: Not applicable
- **Non-retroactivity**: A grant may be awarded for a project which has already begun provided that the applicant can demonstrate the need for starting the action prior to signature of the grant agreement. In such cases, costs eligible for financing shall 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**: A project may only receive one grant 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 grant will take the form of a financing not linked to costs amounting to maximum 400 000 euro. Payment will be conditioned on the achievement of the results described in section 1.7 above.

During the course of the implementation of the project, the main indicators used by EFSA to evaluate the implementation of the action would be:

- Degree of compliance with <u>methods</u> and <u>study design</u> as described in sections 1.3 and 1.7 above.

In case the action is not implemented in line with the project, EFSA will reduce the maximum contribution initially estimated, in line with the actual implementation of the action taking into consideration the project % completion rate indicated in the milestone table available above in section 1.7 above.

EFSA intends to fund one proposal following this Call. However, EFSA reserves the right not to award all the funds available at any cost, e.g. if the quality of submitted proposals will not be satisfactory. Please note that EFSA has also the right not to award any grant and 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.

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

1.11 PUBLICITY

The beneficiary/ies is/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.

1.12 PROTECTION OF PERSONAL DATA IN RELATION TO GRANT PROCEDURES

Processing your application in the context of this grant procedure, will involve the recording and processing of personal data (i.e. the name, any CV and contact details and/or financial details of individuals contained in your application) pursuant to Regulation (EC) N° 2018/1725⁷.

⁷ 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.





Unless indicated otherwise, the questions and any personal data requested are required to evaluate the application in accordance with the specifications of the Call and the data will be processed solely for that purpose.

Detailed information on the processing of personal data in the context of grant award procedures of EFSA is given in the <u>Privacy Statement</u> available on the EFSA website. This on-line privacy statement details the following:

- the legal basis, purpose and controller of the personal data processing;
- what personal information EFSA is collecting and/or further processing;
- to whom personal data is disclosed;
- what technical means are applied for data processing and way in which EFSA secures the information;
- how data subjects can access, modify and delete their information;
- how long EFSA keeps the personal data;
- the contact details for data subjects to exercise their rights;
- the right of recourse to the European Data Protection Supervisor.

Personal data may be registered in the Early Detection and Exclusion System (EDES) if you are in one of the situations mentioned in Article 136 - 140 of the Financial Regulation. For more information see the Privacy Statement on:

http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm).

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 the Grant Agreement (Annex 1)** as a data processor of EFSA.

1.13 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.

1.14 OPEN ACCESS

EFSA is committed to the publication of grant outputs in the <u>Knowledge Junction</u>⁸ 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.

⁸ Learn more at <u>http://www.efsa.europa.eu/en/press/news/161114</u>





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 (see 2.1)
- 2. Eligibility criteria (see 2.2)
- 3. Exclusion criteria (see 2.3)
- 4. Selection criteria (see 2.4)
- 5. Award criteria (see 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:

- The proposal was submitted within the deadline for submission of proposals.
- The proposal is submitted on the EFSA application form (Annex 2).
- The proposal is duly signed by the authorised representative of the applicant.
- The proposal is complete and includes all the supporting documents.

2.2 ELIGIBILITY CRITERIA

The following will be verified:

- The applicant and in case of consortium also its partner/s 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
 proposals for this call.
- 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.

Documents to be provided:

- **LEGAL ENTITY FORM (Annex 3)** (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 this legal entity form should be provided together with a copy of the resolution or decision establishing the public body, or other official document establishing that public body. For a private body an extract from the official journal, copy of articles of association, extract of trade or association register, certificate of liability to VAT (if, as in certain countries, the trade register number and VAT number are identical only one of these documents is required).
- **FINANCIAL IDENTIFICATION FORM (Annex 4)** (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.

The following is applicable only if the applicant is a consortium:

• **PARTNERSHIP STATEMENT**: it is required that the applicant and partner/s provide EFSA with this statement in which they indicate their technical and financial involvement. The applicant and partner/s must sign this partnership statement. No template is provided by EFSA.

2.3 EXCLUSION CRITERIA

The applicant and partner/s must sign a declaration on their honour certifying that they are not in one of the exclusion situations referred to in the Articles 136-140 of EU Financial Regulation as listed therein.

Documents to be provided:

• **THE DECLARATION ON HONOUR FOR EXCLUSION CRITERIA (Annex 5)**: template is published together with this Call; to be completed/signed individually by the applicant and by each of the partners.

2.4 SELECTION CRITERIA

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:

1) Professional requirements

A **team of experts** involved in the project must be composed of experts with this minimum expertise:

- <u>Profile 1</u>: 1 expert with at least 5 years of experience in virology and diagnostic tools for the detection of *African swine fever*.
- <u>Profile 2</u>: 1 expert with at least 5 years of experience in entomology.
- <u>Profile 3</u>: 1 expert with at least 5 years of experience in international project management and a very good level of written and spoken English. For non-native speakers, this should be demonstrated by an Official certificate of English proving a C1 level OR at least 3 years of





work/study in an English-speaking environment or least 3 years of experience working in international projects where English is the working language.

• <u>Profile 4</u>: 1 expert with at least 5 years of experience in statistical analysis of biological studies, to support in the development of the research protocol and analysis of the results.

One expert may cover more than 1 profiles above.

2) Technical requirements

The applicant must have **access to the laboratory facilities** that allow the studies to be carried out, including the minimum safety requirements necessary to carry out experiments on ASFV infected pigs and vectors. The presence of the necessary technical equipment and experience with African swine fever diagnostic tools (Virus isolation and PCR tests) is a prerequisite.

Documents to be provided by the applicant:

- <u>Generic evidence:</u> THE DECLARATION ON HONOUR ON SELECTION CRITERIA (Annex 6).
- <u>Generic evidence</u>: Additional document for private bodies only: to be submitted only if the grant requested from EFSA is > 60.000 €: SIMPLIFIED FINANCIAL STATEMENT (Annex 7) (template available at EFSA's website, published together with this Call) completed for at least last 2 closed financial years.
- Evidence requested for the Operational Capacity:
- a) THE INSTITUTION PROFILE for all institutions involved in the project as coordinator, member of the consortium or subcontractor. The institution profile must contain the list of major relevant projects and/or publications related to objectives of this call carried out and/or published in the course of the past 5 years.
- b) A summary table and THE CURRICULUM VITAE, preferably in Europass format, of the experts and other staff to be involved in the project, or, if the individual members not yet assigned for the proposed project, at least staff profiles necessary for the project, including for each member a brief summary of the relevant expertise, and a list of publications relevant to the project;
- c) At least 5 relevant peer reviewed scientific paper(s) (and/or laboratory/institution report(s)) on laboratory experiments identifying African swine fever virus in different matrices or insects, and/or on transmission of viruses by insects, co-authored/co-produced by the experts involved in the project.
- **d)** A statement that the applicant will have **access to the technical facilitates** described in this section under point 2) Technical Requirements above this table.
- <u>Generic evidence (if applicable)</u>: LETTER OF COMMITMENT: applicable only in the case when other public body financially contributes to the project (body other than EFSA, applicant or in case of consortium, its partners); to be signed by the contributing public body; it serves to confirm its commitment to financially contribute to the project; no template is provided by EFSA.
- Institutional and Individuals declaration of interests available <u>here</u> EFSA will request Institutional and Individuals DoIs only from the awarded beneficiary, prior to the signature of the grant agreement. The requirement to submit Institutional and Individual DoIs will be specified in the award letter and will have to be provided and assessed by the EFSA Authorising Officer before and as a condition of grant agreement signature. <u>Institutional and Individual DoIs do not need to be</u> provided with your proposal at this stage.

In case of a consortium and/or in case of subcontracting, such declarations will need to be completed separately and submitted for each partner and for each identified





subcontractor and for each individual member of the project team coming from consortium partners or subcontractors. Please refer to <u>EFSA's policy on independence</u> and the <u>Decision of the Executive Director</u> <u>on Competing Interest Management</u> for more detailed information.

1.5 AWARD CRITERIA

The award criteria serve to assess the quality of the proposals submitted in the light of the objectives and priorities set and of the expected results and make it possible to award the grant to the action which, in accordance with Article 199 of the Financial Regulation, maximises the overall effectiveness of the Union funding.

A) QUALITY AWARD CRITERIA

- 1. The extent to which the proposal **achieves the main objectives of this call** and is likely to deliver outputs (OVERALL **MAX 40 POINTS, with max 20 points for each objective**):
 - Objective 1: Assess the duration of ASFV survival in plant materials
 - Objective 2: Assess the role of mechanical vectors in ASFV transmission
- The extent to which the project is described in detail, as well as to <u>which the proposed</u> <u>methodology is well described</u> and of high quality with particular reference to the two main objectives (OVERALL MAX 40 POINTS, with max 20 points for each objective):
 - Objective 1: Assess the duration of ASFV survival in plant materials
 - Objective 2: Assess the role of mechanical vectors in ASFV transmission
- 3. **Project programme description clarity**, including phases, clear timelines for the project tasks completion, detailed milestones per task (e.g. via a project Gantt chart), expected outcomes and deliverables: **MAX 10 POINTS**.
- 4. <u>Feasibility of the proposed project execution</u>: feasibility of the proposed methodology; description of identified risks and proposed mitigating actions; proposed contingency plan in case of deviations from the project programme: **MAX 10 POINTS**.

The sum of all quality award criteria gives a maximum possible total of 100 points.

Applicants must provide a detailed technical proposal addressing all points in this call for proposals and each of the quality award criteria. Repetition of mandatory requirements in the call for proposals without providing further detail will only result in a very low score.

Proposals must score a minimum of 70 points out of maximum possible 100.

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 or not on the reserve list.

EFSA reserves the right to invite the 1st ranked applicant on the reserve list, to adapt its proposal based on the evaluators' comments.

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

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

3. SUBMITTING PROPOSALS

3.1 APPLICATION FORM

The proposal must be submitted using the **EFSA APPLICATION FORM (Annex 2).** The application form is published together with this call and must be:

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

Please note that, by submitting the proposal, the applicant and in case of consortium also its partner/s accept/s the procedures and conditions as described in this Call and in the documents referred to in it.

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

3.2 LANGUAGE OF THE PROPOSAL AND THE SUPPORTING DOCUMENTS

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

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





3.3 SUBMISSION MODALITIES

Proposals can be submitted as indicated in the second page of this document in the Indicative procedure timetable (Call for Proposals and guide for Applicants).

3.5 EXPECTED DURATION OF PROCEDURE

Information on expected duration of procedure – time to grant:

- Applicants will be informed on the decision regarding their application at the latest by 6 months since the deadline for submission of proposals.
- Signature of the grant agreement will take place at the latest by 3 months since the successful applicant/s has/have been informed on the decision on their application.





ANNEXES:

- Annex 1: Draft grant agreement
- Annex 2: Application form
- Annex 3: Legal entity form (download template here)
- Annex 4: Financial identification form (download template here)
- Annex 5: Declaration on honour for exclusion criteria
- Annex 6: Declaration on honour for selection criteria
- Annex 7: Simplified financial statement (download template <u>here</u>)
- Annex 8: Institutional and Individual declarations of interests (download template <u>here</u>)