

National Research Programme for Environmental and Occupational Health "Radiofrequencies and Health"

2019 Call for Projects

<u>Deadline for submitting letters of intent: 5 February 2019</u> Deadline for submitting the complete proposals: 21 May 2019

Please note that should any discrepancies be found between the English and the French version, the latter shall prevail.

I. OVERVIEW OF THE PROGRAMME

The French National Research Programme for Environmental and Occupational Health (PNR-EST) is financed by ANSES with funds from the Ministries of the Environment, Agriculture and Labour, and also involves several co-funding partners, including ADEME, and ITMO Cancer from the AVIESAN alliance as part of the Cancer Plan. It also benefits from funds under the ECOPHYTO Plan.

The French National Research Programme for Environmental and Occupational Health (PNR-EST) promotes the production of knowledge in support of public policymaking for environmental and occupational health and safety, and disseminates this knowledge to stakeholders. This programme has a leading role in fostering interactions within the scientific community, which helps ANSES mobilise researchers for its collective expert assessments of health risks.

This programme organises calls for research projects. Two calls will be funded: the present call, dedicated to the theme "Radiofrequencies and health", and the second which covers a wide area (excluding radiofrequencies).

II. OVERVIEW OF THE CALL FOR PROJECTS

This call for Research Projects (CRP) on "Radiofrequencies and health" was issued following the ANSES reports on the same subject published since October 2013¹. The CPR is aiming to create new knowledge, especially to fill gaps or remove doubts that have been highlighted in the reports. In addition, it aims to expand the size of the research community involved in the field of radiofrequencies and health. During the selection process, a strong emphasis will be

¹ <u>http://www.anses.fr/fr/documents/AP2011sa0150Ra.pdf</u> <u>https://www.anses.fr/fr/system/files/AP2012SA0091Ra.pdf</u> <u>https://www.anses.fr/fr/system/files/AP2011SA0150Ra.pdf</u>



placed on the quality of the projects' methodologies², insofar as they are intended to be used in future assessments. Particular interest is given to research subjects whose results can be used rapidly by public policymakers.

III. SCOPE OF THE CALL FOR PROJECTS

The call for projects deals mainly with the assessment and analysis of risks related to radiofrequencies, to human health, in the general population and in the workplace. The themes covered by this CRP are provided in Annex 1 as a list of research questions.

IV. PROPOSAL CHARACTERISTICS

Proposals of research projects will have clearly identified goals. This excludes projects that may only appear as contributions to larger research programmes and projects without specific deliverables identified under the terms of the work.

These research projects may be conducted by a single team or a consortium involving several partners. Each team shall have a clearly identified scientific leader. The project shall be presented as a single proposal, with its manager being the scientist in charge of one of the teams. Funding is requested to complete the study or project. The rules are set out in Annex 2.

Two types of research projects are expected in 2019 :

Feasibility studies:

Their purpose is to explore an innovative approach whose feasibility has not been established.

- Funding shall not exceed €50,000.
- The maximum duration for such a study is 2 years.

Complete projects:

These are research projects which rely on an established methodological approach so that there is a reasonable level of assurance that the objectives will be met.

- Financial support will lie between €40,000 and €200,000. It can exceed these limits if this is required by the project's nature, and provided the request is justified. This should be justified, for instance for projects on radiofrequencies involving large consortia set up to tackle all issues from engineering to biology. In all cases the budget request may not exceed €400,000.
- The duration for a complete project is between two and three years.

V. SELECTION PROCEDURE

The selection procedure relies on two committees:

² In the October 2013 report, page 341 mentions "ensure the methodological quality of the experimental protocols and the rigour of the analysis and interpretation of data from in vitro and in vivo studies by research teams both on the RF exposure part (exposure characterisation, signal shape, justification for the choice of the type of exposure, etc.) and on the part relating to biological experimentation (blind experiment, appropriate positive and negative controls, allowing the interpretation of the amplitude of changes related to RF exposure, identification of false positives, repetition of experiments, sufficient statistical power, etc.)....."



- The research programme's scientific committee (RPSC). It is composed of renowned researchers. The RPSC assesses the scientific value of the submitted projects and establishes a list.
- The programme's steering committee. It is made up of ministries involved in the scope covered by the call. The steering committee chooses the projects to be funded from the list established by the RPSC.

The selection process will be divided into two stages as defined below:

- an initial selection on the basis of letters of intent,
- a second selection based on complete applications, from among the shortlisted letters of intent.

The submission timetable and procedures are described in Section IX.

Step 1: Selection based on the letters of intent

Letters of intent that do not meet the eligibility criteria defined in Section VI will not be evaluated. The RPSC will assess the letters of intent. This will take into account the selection criteria defined in Section VII. Members of the steering committee can be also consulted regarding criterion 3 and the closeness of the project to their priorities. Special attention should be paid to the quality of the letters of intent, which need to contain enough information, in a small amount of space, to allow the RPSC to evaluate the relevance of the proposal. Only proposals whose letters of intent are shortlisted will be eligible to submit a complete application.

Step 2: Selection based on the complete applications

To be eligible, complete proposals must meet all of the eligibility criteria described in Section VI. Applications that do not meet all of these criteria will not be evaluated. Eligible projects will then go through the following selection process:

- 1. Collective scientific assessment of the projects by the RPSC: on the basis of the opinions of at least two independent experts per project, according to the criteria described in Section VII. A list of projects will be submitted to the steering committee.
- 2. Collective opinion of the steering committee on the projects selected by the RPSC, according to the criteria described in Section VII. This collective opinion also takes into account the available funds and priorities of sponsors. The steering committee can also give advice on appropriateness of requested funds with regard to the planned tasks. Under exceptional circumstances, it may recommend project modifications or even consolidation to incorporate several approaches or disciplines likely to improve the project's overall quality and relevance in relation to the programme's objectives.
- 3. The final decision to support a project is made by the steering committee. The list of selected projects and the sponsor's identity is published at the end of the selection process on the ANSES website.



VI. ELIGIBILITY CRITERIA

A project's eligibility will be examined at both selection stages, firstly through the letter of intent and secondly through the complete application, on the basis of the information that is available at each stage. Research projects must meet the same conditions at each stage:

Proposal characteristics

- 1. The projects must lie within the research domain covered by the call for projects as defined in Section III.
- 2. The proposals' characteristics must be compatible with those listed in Section IV.
- 3. The project must not contain actions that have already been funded under another call for projects. If there is any ambiguity, project managers should describe which parts of the project interact with other sources of funding.

Conditions regarding the participating teams

- 1. The partnership must be clearly identified at the letter of intent stage.
- 2. This call for projects is open to all research teams, irrespective of the institution to which they belong³ (higher education and research establishments, research organisations, other public establishments with a research mission, technical centres, private establishments with R&D activity, etc.). Partners other than research teams are welcome insofar as their added value in the project has clearly been established.
- 3. The project must involve one French academic partner (higher education and research establishments, research organisations, other public establishments with a research mission).
- 4. The call for research projects is open to foreign teams or to teams from international organisations.
- 5. An RPSC member cannot hold any management role in a project (scientific leader of any team involved in the research project).

Administrative conditions

- 1. Letters of intent and complete applications must be submitted in accordance with the procedures listed in Section IX. They must contain all of the requested information and be submitted by the deadline.
- 2. The project must be authorised by the institutional leader of the coordinating research team and signed by the manager of each partner team.

³ Regarding the eligibility of ANSES teams, refer to the recommendation of its Ethics Committee <u>https://www.anses.fr/fr/system/files/DEON-Ft-2013003.pdf</u>



VII. CRITERIA FOR THE SCIENTIFIC ASSESSMENT OF PROJECTS

A project will be examined at both selection stages, through a letter of intent and then a complete application, on the basis of the information that is available at each stage. The selection criteria are as follows:

Letter of intent stage

Letters of intent are reviewed according to the following criteria:

- 1) Scientific significance of the subject for the topic of radiofrequencies and health in the general population or at work. Impact on French public policies.
- 2) Scientific novelty: proposals shall be justified with regard to research undertaken at French, European and international levels. When the aim of the project is to reproduce a study, originality will be assessed on the method used to maximise the quality of the results of this second study.
- 3) Connection to research questions. The considerations mentioned in the "Research questions" annex will play an important role in the prioritisation of projects, particularly by the steering committee.
- Methodological quality and scientific feasibility: the approaches must be detailed and the methods described to enable the project's feasibility to be evaluated, particularly at the full application stage.

Complete application stage

Projects are assessed based on the following criteria:

- 1) Scientific significance of the subject for the topic of radiofrequencies and health in the general population or at work. Impact on French public policies.
- 2) Scientific novelty: proposals shall be justified with regard to research undertaken at French, European and international levels. When the aim of the project is to reproduce a study, originality will be assessed on the method used to maximise the quality of the results of this second study.
- 3) Connection to research questions. The considerations mentioned in the "Research questions" annex will play an important role in the prioritisation of projects, particularly by the steering committee.
- 4) Methodological quality and scientific feasibility, particularly the relevance of the choice of methods: the approaches must be detailed and the methods described to enable the project's feasibility to be evaluated, particularly at the complete application stage.
- 5) Organisational and partnership excellence (the project must include a provisional project timetable).
- 6) Consortium excellence. Scientific output of the requesting parties. Distribution of activities among teams: the skills necessary for the project must be clearly presented.
- 7) Appropriateness of the project length and allocated resources (financial request, human investments). Quality of the supervision of non-permanent staff.
- 8) For projects that could be a subject of scientific controversy, measures adopted to ensure the quality of the results (e.g. traceability of data, presence of information that could be used to reproduce experiments or analyse data, inter-partner trials, multiple points of view held by partners, involvement of stakeholders in methodological design, participatory sciences, etc.)



VIII. AGREEMENT

The funding terms for the selected projects will be specified in the agreement between ANSES and a "coordinator" establishment. This establishment will in most cases be the one to which the project manager's team belongs. The main rules are listed in Annex 2. In exchange for financial support, the research teams shall:

- Commit to participate in actions to promote the results obtained during and/or at the end of the project (publications in peer-reviewed journals, presentations at conferences organised by the sponsor, contribution to summary reports, etc.).
- For complete projects, supply a mid-term report and, in all cases, at the end of the project, a final report that includes a publishable scientific summary. The final report can be used by ANSES in its missions.
- Mention the support provided by the National Research Programme for Environmental and Occupational Health on appropriate occasions, in particular in publications.

Considerable importance is attached to the rigour with which the scientific project manager leads the project, which means that the contractual commitments for the timing of deliverables should be fully respected.

IX. PROJECT SUBMISSION TERMS

Letters of intent must be submitted online by the scientific project managers no later than **Thursday 5 February 2019 at noon (12:00)**, French time. Projects shall be submitted using the **Research and Scientific Watch ("Recherche et Veille") platform** available via the ANSES website. The platform will be operational in **December 2018**.

Important: The project manager should carefully read the eligibility rules listed in this call for projects, including at the letters of intent stage.

All compulsory sections must be completed before the deadline. Incomplete applications will not be considered. Applicants are therefore advised to prepare in advance.

The letters of intent will then be evaluated and the project manager will be informed of the result ("authorised to submit a complete project or not").

For those whose letters of intent are shortlisted, complete applications must be submitted by the scientific project managers. For the radiofrequencies theme, it is desirable that the text is written in English to allow evaluation on a broader scale. The file should be transmitted:

 Online, on the same platform, no later than 21 May 2019 at noon (12:00), French time. Acknowledgement of receipt of electronic applications will be automatically sent to the project managers.



2) By sending ANSES the certificate published online after the application has been submitted. One printed copy⁴ of this certificate, with all the required signatures, must be sent by post no later than 25 June 2019 at midnight (00:00), to the following address:

> ANSES APR EST RF 2019 ACI-COP-2-028 14 rue Pierre et Marie Curie F-94701 MAISONS-ALFORT Cedex France

Provisional key dates

November 2018	Opening of the call
December 2018	Opening of the online application for letters of intent
5 February 2019 at	Deadline for submitting letters of intent
noon	
April 2019	Dissemination of the first selection results, based on the letters of
	intent, to project managers
21 May 2019 at noon	Deadline for submitting the complete proposals
25 June 2019 at	Deadline for returning certificates
midnight	
October 2019	Transmission of the steering committee's results on final selection to
	the scientific project managers.

X. CONFIDENTIALITY

Members of the research programme's Scientific Committee (RPSC), as well as experts consulted for the scientific evaluation of projects, are subject to strict confidentiality regarding the content of the projects submitted to the call.

Sponsors and state agencies serving on the programme steering committee are bound to strict confidentiality on the content of submitted projects. For mapping purposes or to manage multiple funding requests, however, they may share information on the laboratories or organisations active in the research topics covered by this call for projects.

For projects not selected for funding, the files will remain confidential.

⁴ Coordinators are advised to gather all signatures on a single certificate. Nevertheless, one copy per signature will be accepted, in the event of difficulty. <u>Scanned signatures are not accepted.</u>



For projects selected for funding, the research content will be kept confidential. However, ANSES will publish the summary of the project as submitted to this call for projects, and the name of the partners. In addition, each funding organisation may use this work for its internal needs according to the terms defined in the agreement signed with the project manager. Finally, the scientific reports issued on completion of the work will be submitted to the reviewers, who therefore have access to their content.

In accordance with the rules on intellectual property (literary and artistic property and industrial property), and the confidentiality rules inherent in research, all publications resulting from funded projects will be deposited on an open archive platform as required in the long term by national guidelines on open science. This will be specified as necessary in the agreement.

For all questions or requests for administrative or scientific information, please contact the CRP unit:

Scientific issues Administrative issues

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ANNEX 1: Research questions

These questions are focused on the effects of radiofrequencies, defined in this call for projects as frequencies in the range from 8.3 kHz⁵ to 300 GHz. In the case of projects on electromagnetic hypersensitivity, taking a broader frequency range (extended to the lower frequencies) into account can be useful to understanding the phenomenon and is thus authorised. The effects of electromagnetic fields can be studied for these fields alone or in combination with a cofactor.

In addition to the signals corresponding to current exposure, project managers are invited to address new sources of exposure and the associated signals (such as connected objects) and the effect of various modulations used for mobile communication.

For these projects, the selection criterion "methodological quality and scientific feasibility" of Section VII includes: characterisation of the exposure of target populations, implemented exposure protocols (frequency, duration, etc.) or exposure situations for observational studies (e.g. operator data), in particular the electromagnetic sources, applicators or antennas used, the exposure environment (space, Faraday cage, etc.) and the means for measuring the exposure (sensor type, bandwidth, frequency etc.).

Research on mechanisms of action of radiofrequencies at the cellular level

1. *In vitro, in vivo* or clinical studies on the mechanisms of action of radiofrequencies on living organisms at the cellular and molecular levels, taking into account changes in frequency use linked to new uses and new communication technologies.

Research on the physiological responses to or health effects of radiofrequencies

This research will have to take into account the evolution of the electromagnetic environment: deployment of connected objects, new generations of mobile phones (4G, 5G), changes in uses and therefore of exposure situations, etc.

- 1. In vivo or clinical studies on physiological responses to radiofrequencies, in particular:
 - on sleep (relying for humans on objective criteria such as the ones defined by the American Academy of Sleep Medicine);
 - on circadian rhythms;
 - on the immune system;
 - on metabolism (metabolomics analysis);
 - on reproduction and development over several generations of animals;
 - on the autonomous nervous system (analysis of ortho/parasympathetic balance from heart-rate variability and other exploration techniques);

⁵ Value set by the International Telecommunication Union



- on functional and brain development, according to age (*in utero*, juvenile, adult and elderly), by undertaking longitudinal studies in animals to identify possible sensitivity/vulnerability time windows;
- on cognitive function (memory, reasoning, executive functions and attention) in humans: by conducting challenge studies with adults and children at different ages of development, in situations with or without exposure to radiofrequencies, using properly calibrated psychometric instruments, brain imaging techniques and/or records of brain electrical activity (EEG) (including evoked potentials) in basal conditions or stimulation (cognitive tasks);
- Epidemiological studies⁶ on possible effects of RF energy on health, including cancer, fertility disorders, neurodegenerative diseases, circadian rhythms and long-term effects of physiological changes in sleep related to radiofrequencies. In particular, studies involving populations that are more vulnerable to radiofrequencies (epileptic patients, children, etc.) or less well documented (women, pregnant women, the elderly) or particularly subject to exposure (workers);
- 3. Study of the effects of co-exposures, approximating actual exposure situations and enabling analysis of the combined effects of RF and other environmental factors (physical or chemical) on the body;
- 4. Study of the effects of electromagnetic fields on living organisms in frequency bands that have not yet been widely studied, particularly above 6 GHz, potentially associated with emerging uses concerning communicating objects;
- 5. Additional studies to assess the health and psychosocial impact of the use of mobile communication technologies by children, due in particular to addictive phenomena, sleep disorders, etc.;
- 6. Study of the effects of radiofrequencies on the environment, including animal behaviour.

⁶ Particular care will be taken to consider confounding factors in particular connected with the use of radio equipment.



Electromagnetic hypersensitivity⁷

- Clinical characterisation of functional symptoms (sleep disorders, headache and migraine, digestive disorders) experienced by people declaring themselves "EHS" (by measurements or using detailed questionnaires that are internationally recognised or, failing this, carefully optimised with respect to the investigated symptoms). People declaring themselves "EHS" can be their own controls (with and without exposure), or they can be compared with non-EHS people.
- 2. Investigation of tools to characterise subjects declaring themselves "EHS", physiological markers, biological markers, specific genetic markers.
- 3. Investigation of mechanisms that could explain electromagnetic hypersensitivity (for instance production of neurotransmitters, study of cryptochromes, etc.).
- 4. Investigation of links between certain characteristics of electromagnetic fields and the symptoms experienced by persons declaring themselves "EHS" (challenge experiments that take into account, in particular, the diversity and evolution of the electromagnetic environment, continuous exposure measurements and collection of symptoms, etc.).
- 5. Investigations to explain the relationship between EHS and multiple chemical sensitivity, migraine, tinnitus, fibromyalgia, and medically unexplained syndromes more generally.
- 6. Investigation of vulnerability factors (for example comparative studies using control populations and populations with medically unexplained syndromes).
- Research on the use, effectiveness and possible side effects of therapeutic measures (management of symptoms such as tinnitus, migraine) for subjects declaring themselves "EHS", treatments used.
- 8. Investigation on metabolism and cerebral blood flow, the blood-brain barrier (using high-resolution imaging techniques) for people declaring themselves "EHS".
- 9. Research on the effects of an MRI test (tolerance) on individuals declaring themselves "EHS", compared with control subjects.
- 10. Sociological studies to understand the caregiver-patient relationship for people declaring themselves "EHS".
- 11. Sociological comparison of subjects declaring themselves "EHS" in different countries.

⁷ Or idiopathic environmental intolerance to electromagnetic fields.



Characterisation of exposure

- 1. Research on the characterisation of how different radio devices are used by children (types of devices, frequency and duration of use, depending on age, etc.).
- 2. Research on the actual exposure of children to radiofrequencies when using radio devices (tablets, telephones, etc.).
- 3. Research on the characterisation of human exposure in the context of cumulative exposure: PLC, new communication technologies, connected objects, autonomous and connected transport, etc.).



ANNEX 2: Chargeable expenses

I. ELIGIBLE EXPENSES

Chargeable expenses should correspond to actual expenditure and be strictly linked to the project's execution, exclusive of any profit margin. In particular, only expenses incurred between the start and the end of the project, as stipulated in the agreement, will be taken into account. It should be possible at any time to prove the genuine nature of the expenses incurred. Receipts and all documents justifying the expenditure incurred under the project shall be kept by the beneficiaries for four years and submitted to ANSES if requested.

Personnel expenses

The only expenses accepted are: wages of fixed-term contract personnel and professional fees, including social contributions and taxes on wages.

With the exception of permanent personnel whose salaries come from the French state budget, the other personnel expenses are taken into account in the amount of the financial contribution made by ANSES.

Overhead expenses and small-equipment expenses

The following expenses are accepted, including non-recoverable VAT:

- laboratory costs (procurement of products or consumables),
- office supplies,
- purchase of patents or licences,
- publication costs,
- travel expenses of permanent or temporary personnel assigned to the project, particularly for participation in ANSES communication and dissemination events,
- conference registration fees related to the project,
- outsourced work (photos, computing, etc.),
- maintenance of equipment purchased for the project,
- procurement of small equipment whose unit cost is less than €1,600 excl. tax.
- allowances for trainees.

Equipment expenses

Equipment expenses are regarded as expenses incurred for equipment whose unit value is greater than €1,600 excl. tax. ANSES will take into account:

- all or part of the cost of purchasing this equipment, if it is not reusable after the project's completion (which should generally be the case);
- the share of depreciation calculated pro rata to the period of use if the equipment is reusable after the project's completion, unless an exception is made by ANSES.

General management fees



Part of the general administrative fees linked to the project can count as expenses. These fees are limited to 4% of total expenses, unless an exception is made by ANSES on the express request of the recipient, with justification.

Service provision

Regardless of their legal status, recipients can contract work to or lease equipment from entities outside of the project. The cost of this work shall remain marginal in relation to the programme's total cost (less than 30% of this total cost), unless an exception is made by ANSES on the express request of the recipient, with justification. The costs of these services shall appear individually as overhead expenses.

ANSES does not enter into commitments with service providers, who therefore have no grounds upon which to make any claim to ANSES if the recipient of a grant fails to comply with its obligations. Services are provided exclusively for and under the supervision of the grant's recipient. In accordance with the rules in force, the recipient must pay for services as they are delivered, irrespective of the date of the payment expected from ANSES.

Internal invoicing case:

These expenses must be related to services traceable in accounting, carried out by another entity (department) of the grant recipient (coordinator or partner of the project). The costs of these services must be identified analytically.

In addition, these services must be proportionate to their actual use for the purposes of the project and must not have been taken into account in the structural costs and/or management fees. They must be invoiced exclusive of any profit margin.

These expenses must comply with the eligibility rules described in this Annex.

II. NON-ELIGIBLE EXPENSES

The following expenses cannot be paid by ANSES:

- Financial fixed assets and routine expenses to replace equipment;
- Expenses related to marketing, sales and distribution fees;
- Expenses related to land and buildings.