

The Director General

Maisons-Alfort, 1 October 2013

OPINION

of the French Agency for Food, Environmental and Occupational Health & Safety

concerning the update of the “Radiofrequency electromagnetic fields and health” expert appraisal

ANSES undertakes independent and pluralistic scientific expert assessments.

ANSES primarily ensures environmental, occupational and food safety as well as assessing the potential health risks they may entail.

It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

It provides the competent authorities with all necessary information concerning these risks as well as the requisite expertise and scientific and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).

Its opinions are made public.

On 14 June 2011, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) issued an internal request for an update of the “Radiofrequencies and health” expert appraisal published by the Agency on 14 October 2009.

1. BACKGROUND AND PURPOSE OF THE REQUEST

Radiofrequency (RF) electromagnetic fields have been the subject of health and environmental concerns in France and abroad for several years, and this situation prompted the Agency¹ to publish opinions and collective expert reports in 2003, 2005 and 2009, in response to requests from the authorities.

In its most recent opinion concerning RF fields, published on 14 October 2009, the Agency highlighted the need to implement continuous surveillance for any new scientific work published in this field, which is constantly changing. In this context, ANSES issued an internal request on this topic on 14 June 2011 (Internal request No. 2011-SA-0150) in order to set up a permanent working group (WG) on the subject of “Radiofrequency electromagnetic fields and health”.

The working group’s missions are to:

- regularly update the collective expert appraisal on health effects potentially related to exposure to RF fields;

¹ AFSSA (French Food Safety Agency) and AFSSET (French Agency for Environmental and Occupational Health Safety) merged on 1 July 2010 to form the French Agency for Food, Environmental and Occupational Health & Safety (ANSES).

- answer questions raised by the development of new technologies using RF fields, and respond to requests that the Agency may receive for expert appraisals in this area;
- make annual recommendations for avenues of research intended to support the Agency's call for research projects specifically concerning RF fields;
- inform stakeholders of the results of new research and thus contribute to public debate on this topic.

Wireless technology applications using RF fields are constantly changing. Mobile devices are used in new ways, and new technologies are developed (LTE² and fourth generation mobile communication technology (4G)), but it is not always possible to observe or to foresee the precise impact these changes may have on exposure of the general population or in occupational settings.

Furthermore, scientific articles dealing with the effects of RF fields or assessing possible mechanisms of action have been published at a steady rate since 2009, despite the completion of major national research programmes, especially in Europe. France is however an exception since permanent funding has been allocated to research on the health effects of RF fields, following the Agency's recommendation in 2009, and subsequently included in the Government's budget since the 2011 Finance Act.

2010 and 2011 were marked by two important events with the publication of the combined results of the Interphone epidemiological study which examined the association between use of mobile phones and onset of brain tumours [*The Interphone Study Group, 2010*], and then in 2011, the classification of radiofrequency electromagnetic fields as "Possibly carcinogenic to humans" (2B) by the International Agency for Research on Cancer (IARC).

Lastly, the experiments carried out in France by the COMOP and subsequently by the COPIC Steering Committees³ set up to study the feasibility of lowering exposure to electromagnetic waves emitted by base-station antennas while maintaining coverage and service quality, have recently produced data enabling the characterisation of population exposure to radiofrequency radiation (Report of 31 July 2013, published after completion of the ANSES Working Group's expert appraisal).

There are many issues concerning the health risks related to RF fields which merit future study and expert appraisals, particularly hypersensitivity to electromagnetic waves, or exposure of children and other special population groups, such as workers. Considering on the one hand the number of recent publications and the expected publication of results from on-going studies, and on the other, the need to grant particular attention to the issue of hypersensitivity to electromagnetic waves, ANSES decided to postpone assessment of this issue, to be dealt with in a special report by the Working Group.

2. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal was carried out in compliance with Standard NF X 50-110 "Quality in expertise activities – general requirements of competence for an expertise activity (May 2003)".

² LTE: *Long-term evolution*, technology preparing 4G.

³ The COPIC was formed from the operational committee (COMOP) on models and experiments concerning exposure and attempting to reach a concerted approach to issues raised by mobile telephony. It was set up in 2009 as a result of the commitments made at the "Grenelle des Ondes" consultation, following the roundtable discussions on "Radiofrequencies, health and the environment" held between 23 April and 25 May

The appraisal fell within the competence of the Expert Committee (CES) on Physical agents, new technologies, and development areas, and was undertaken by the Working Group (WG) on Radiofrequency electromagnetic fields and health.

This WG was set up following a public call for applications from experts issued on 1 December 2010. The experts were recruited on the strength of their expertise in the fields of metrology and dosimetry of electromagnetic fields, epidemiology, medicine, biology, and the human and social sciences. Sixteen independent experts were appointed on 30 June 2011 for a period of three years.

In all, the WG held 13 plenary sessions (15 days⁴) between 21 September 2011 and 26 June 2013, and 20 sessions for its subgroups. During these meetings, nine hearings were held to obtain contributions from stakeholders and other scientists. In addition to these hearings, the Working Group also requested written contributions from the French Telecommunications Federation on more specific issues. The "Radiofrequency and health" Dialogue Committee⁵ set up by the Agency was kept regularly informed of the progress of the expert appraisal.

Work was presented nine times to the CES, then adopted in September 2013, concerning both methodological and scientific aspects.

Method: review of scientific literature and evaluation of levels of evidence

Review of scientific literature

As for the previous report (AFSSET, 2009), the ANSES Working Group decided to focus on the health effects potentially related to the wavelengths used by new or developing technologies, i.e. those between 8.3 kHz and 6 GHz (mobile telecommunications, TV and radio broadcasting, etc.). Since most of the articles published concern effects of the signals characteristic of mobile telecommunications, the report deals principally with this area.

The WG aimed to evaluate all the potential health effects of radiofrequency electromagnetic fields, whether non-carcinogenic, such as effects on the brain, foetal development or sleep for instance, or carcinogenic.

The literature review was as comprehensive as possible and covered the period from 1 April 2009 (end of the assessment period for the literature review in the previous Agency report) to 31 December 2012.

Scientific publications (original articles, reports, grey literature, etc.) were identified with the help of several specialised search engines (PubMed, Scopus, etc.), as well as the bibliography lists from other expert reports, and those supplied by certain members of the "Radiofrequency and health" Dialogue Committee. The large-scale search provided more than 1000 publications for review.

Analysis of publications

The experts of the Working Group pooled their expertise to carry out a collective analysis of the studies on the effects of RF fields in biological models including *in vivo* and *in vitro* studies, and in epidemiological and clinical studies. Each *in vitro*, *in vivo* or clinical study

⁴ The WG met 11 times for a one-day session, and twice for sessions lasting two consecutive days.

⁵ ANSES's "Radiofrequency and health" Dialogue Committee is a forum for discussion, reflection and information on scientific issues related to the potential health effects of radiofrequencies and associated risk assessments. It was set up in June 2011 in the light of the experience acquired by the "Health and Radiofrequency" Foundation. It includes representatives of associations, labour unions, mobile phone operators and broadcasters, institutions, local authorities and elected officials, with a view to achieving a balance between interest groups.

was analysed at least by a physicist and two biologists (or a biologist and a medical doctor), and each epidemiological study by two epidemiologists. Those concerning societal considerations and risk management aspects were analysed by a sociologist and a psychosociologist.

Various criteria were used to assess study quality, including study protocol validity. Each expert completed an evaluation sheet for each analysed publication, with the support of the scientific coordinators at ANSES. These analyses were then discussed in subgroups in order to evaluate the methodological quality of the publications, irrespective of the results and conclusions.

Assessment method for levels of evidence

For the present expert appraisal, the experts focused on developing an appropriate method to assess the level of evidence for each potential health effect studied.

This was achieved by taking into account both work published since April 2009 and the conclusions of the previous report (AFSSET, 2009), so that the assessment process became an integral part of the accumulation of knowledge.

The terminology defined by the WG to evaluate the studied effects is strongly influenced by that used by the IARC to study an agent's carcinogenic potential.

For each effect analysed, data supporting the existence of the effect taken from studies using biological models (*in vivo* animal or *in vitro* studies), and data from clinical or epidemiological studies, were classified as: "sufficient", "limited" or "inadequate", or alternatively "suggesting a lack of effect"⁶.

The level of evidence indicating the existence of the studied effect in humans was then analysed overall, in view of all available data, and was placed in one of the following categories:

Proven effect on humans

This category is used only when *sufficient evidence* is available supporting the existence of the effect in epidemiological or clinical studies. In exceptional cases, an effect can be placed in this category if evidence from epidemiological or clinical studies is not quite sufficient, but there is *sufficient evidence* of the existence of the studied effect in animal models, and it is highly likely that RF fields act through a recognised mechanism.

Probable or possible effect on humans

This category includes effects for which there is as a *maximum, almost sufficient evidence* supporting existence of the effect from epidemiological or clinical studies, and as a *minimum*, no epidemiological or clinical data are available but *sufficient evidence* supporting the existence of the effect has been found in animal models. These effects are classified as either *probable effects on humans* or *possible effects on humans* on the basis of epidemiological or experimental findings, mechanism data or other relevant data. The terms *probable effect* and *possible effect* have no quantitative value and are only used to indicate different levels of suspected existence of the effect in humans, with *probable effect* indicating a higher level of suspected existence than *possible effect*.

Probable effect on humans

This category is used when there is *limited evidence supporting the existence of the studied effect* from epidemiological or clinical studies and *sufficient evidence* in animal models. In certain cases, the studied effect may be placed in this category if there is *inadequate evidence* from epidemiological or clinical studies, but *sufficient evidence* from animal models and it is highly likely that the effect is related to a mechanism of action that is also present in humans.

⁶ See details in Annex.

In exceptional cases, the studied effect may be placed in this category solely on the basis of *limited evidence* supporting existence of the effect from epidemiological or clinical studies.

Possible effect on humans

This category covers effects for which there is *limited evidence* from epidemiological or clinical studies, and *inadequate evidence* in animal models. It can also be used when there is *inadequate evidence* from epidemiological or clinical studies, but *sufficient evidence* in animal models.

In certain cases, this category may also cover effects for which there is *inadequate evidence* from epidemiological or clinical studies, and no *sufficient evidence* from animal models, corroborated by mechanism data and other relevant findings.

An effect can be placed in this category solely on the basis of solid evidence from mechanism data or other findings.

Effect for which the level of evidence is inadequate to conclude that there is an effect on humans

This category mainly includes studied effects for which evidence supporting the effect is *inadequate* from epidemiological or clinical studies, and *inadequate* or *limited* in animal models.

Exceptionally, studied effects that have *inadequate evidence* from epidemiological or clinical studies, but *sufficient evidence* from animal models may be placed in this category when it is highly likely that the mechanism of action in animals does not operate in humans.

This category also includes effects that cannot be placed in another category.

Use of this category does not indicate that there is no effect or overall safety. It often shows that more research is needed, especially when data on the studied effect can be interpreted in different ways.

Probably no effect on humans

Studied effects in this category have *evidence suggesting the absence of an effect* from epidemiological or clinical studies, and from animal models, in a wide range of conditions or exposure settings. It is very difficult to demonstrate the absence of an effect.

In some cases, effects can be placed in this group when *evidence supporting the existence of the studied effect* in epidemiological or clinical studies is *inadequate*, but *evidence suggesting the absence of an effect* is available in animal models, consistently and strongly corroborated by a large amount of mechanism data and other relevant findings.

The general framework for assessing evidence levels for a given effect is shown in Figure 1.

Evidence for the existence of the effect studied in models

		Sufficient	Limited	Inadequate	Lack of effect
<i>Evidence for the existence of the effect studied in humans</i>	Sufficient	Proven effect on humans			
	Limited	Probable effect on humans	Possible effect on humans		
	Inadequate	Possible effect on humans	Level of evidence inadequate to conclude on an effect		
	Lack of effect				Probably no effect on humans

Figure 1: Assessment of the level of evidence for a given effect depending on the evidence supporting the existence of an effect in humans and animals

Biological and health effects

Biological effects are changes of a biochemical, physiological or behavioural nature induced in cells, tissues or in the body, in response to external stimuli. A biological effect, that is usually reversible, falls within the internal regulation mechanisms of the body, i.e. homeostasis.

Observation of a biological effect, especially in experimental conditions, does not necessarily mean that it causes damage, let alone that it results in an effect on health. The human body is constantly subjected to a variety of internal and external stimuli and a biological effect may simply manifest the normal adaptive response of the cell, tissue, or body, to this stimulation.

An effect on health is only possible when the biological effect exceeds the adaptive capabilities of the given biological system. The effect then goes beyond adaptive physiological responses, and homeostasis, under the influence of the external agent.

3. ANALYSIS AND CONCLUSIONS OF THE EXPERT COMMITTEE

Results of the collective expert appraisal

Changes in exposure to radiofrequency energy

The development of new wireless communication technologies is associated with constant changes in the radioelectric signals used to carry information, such as voice, data, and so on. Use of these technologies and the characteristics of the signals (modulations, frequency bands, form, and power levels) determine the impact these new technologies have on individual exposure levels.

The deployment of fourth generation mobile telecommunications technology, along with the various former systems still in place, is likely to lead to increased exposure of the population. Recent research carried out by the COPIC testing committee has provided data on changes in expected exposure levels.

The form and uses of communication devices are changing particularly rapidly. As an example, digital tablets are connected to the mobile telephone network or to Wi-Fi access points, and are used in the hands or on the knees. Protocols for measuring exposure to electromagnetic fields are therefore constantly being challenged.

Finally, consumption of mobile services is evolving at a high pace, both in terms of number of users, with a 112% penetration rate in France on 1 March 2013⁷, and behaviours, with more than 51 billion text messages (SMS) sent in France in the first quarter of 2013, i.e. 241 on average per month per active client.

Evaluation of evidence levels for each studied effect of radiofrequency electromagnetic fields on human health

The Working Group used the methodology described above to classify the various potential effects of radiofrequencies on human health and assessed three major areas: effects on the central nervous system (CNS), other non-carcinogenic effects, and carcinogenic effects.

For each area, summary tables on the classification of effects are provided following an overview of research on mechanisms (see below).

Studies chosen for the evaluation of evidence levels for effects of RF fields on human health were those in which experimental exposure conditions could not induce direct effects related to an increase in the macroscopic temperature of tissues or of cell models.

A total of 308 original scientific articles published between April 2009 and December 2012 dealing specifically with the effects of RF fields in the scope of this expert appraisal were analysed. Two thirds of these studies of sufficient quality to contribute to evaluation of the level of evidence were retained according to the criteria explained in this report, to determine classifications and reach conclusions on the studied effects. Evaluation of the levels of evidence for the effects was also based on the analyses and conclusion of the expert appraisal prepared in 2009.

Non-carcinogenic effects on the central nervous system (CNS)

Studies on mechanisms of neurotoxicity

In the experimental conditions tested in mechanistic studies on the CNS (*in vitro*, *in vivo* or clinical), no neurotoxic effects of exposure to RF fields were demonstrated on:

⁷ Source: French postal and electronic communications authority (ARCEP): *Observatoires/Services mobiles* - <http://www.arcep.fr/index.php?id=35>

- cellular responses in the brain:
 - o no change in the expression of various heat shock proteins, *in vitro* or *in vivo*;
 - o no effects on brain plasticity;
 - o no adverse effects such as oxidative stress including heat shock proteins, either *in vitro* or *in vivo*, whether for acute or semi-chronic/chronic exposure⁸ (Arendash *et al.* even showed that chronic exposure to RF fields could have a beneficial effect on various oxidative stress markers, an effect related specifically to improved mitochondrial function and cognitive performance in certain mice);
 - o no effects on autophagy (cell degradation system) involving chaperone proteins following acute exposure (on the basis of a single *in vitro* study);
 - o no *in vitro* effects on cell death (apoptosis);
 - o no effects on inflammation (markers of glial activation or production of pro-inflammatory cytokines) following acute exposure;
- the blood-brain barrier (BBB), irrespective of the biological models tested;
- glutamatergic neurotransmission following acute exposure (on the basis of a single *in vivo* study);
- expression of early-immediate genes or proto-oncogenes (such as *c-fos* or *c-jun*), whether *in vitro* or *in vivo*, following acute or chronic exposure (on the basis of a limited number of studies);
- cerebral blood flow and/or cerebral energy metabolism. Although both mechanisms appear to increase or to decrease on exposure to RF fields, the results are discrepant, or even contradictory depending on the various measurement techniques used. As indicated in several publications, these variations can be considered to fall within physiological fluctuation levels.

However, following exposure to RF fields, the following effects have been observed:

- various effects on neuronal cell death depending on the type of study (*in vitro* or *in vivo*): changes (increase or decrease) in the total number of neurones and increase of cells in apoptosis following chronic exposure *in vivo* (in a limited number of studies);
- an effect on the astrocyte marker (GFAP) related to inflammation (probably transient effect) following chronic exposure *in vivo*;
- an oxidative stress-type effect following prolonged exposure to radiofrequencies on mitochondrial DNA in neurones (on the basis of a single *in vitro* study). Mitochondrial DNA is particularly sensitive to oxidative stress due to a lack of histone-type protective proteins, a reduced repair ability, and proximity of the respiratory chain in the mitochondrial inner membrane. This could explain the discrepant results here compared to most studies that did not target this type of DNA;
- changes in electrical activity in the brain (especially the power of *alpha* rhythm).

Of note, the conclusions of studies on neurotoxicity mechanisms induced by exposure to RF fields differ depending on the analytical techniques used for experimental results. The biological effects observed warrant further study through additional research specifically

⁸ For information, in rodents, acute toxicity was studied following exposure of a few hours (sometimes a few minutes), subacute toxicity by repeated exposure for a few days (up to 28 days), subchronic toxicity (or semi-chronic) by exposure for 90 days, and chronic toxicity through repeated exposure for more than 90 days and generally for a duration of one year.

involving a larger number of test animals for *in vivo* studies, or by conducting studies in humans. In any event, it is not currently possible to establish a causal relationship between these biological effects and resulting potential health effects.

Moreover, biological effects have been observed at specific absorption rates (SARs) greater than or equal to 4 W/kg, probably related to thermal effects, and in particular:

- an inflammatory response-type effect for an SAR of 6 W/kg;
- an effect on brain plasticity for an SAR of 10 W/kg.

Evidence levels for non-carcinogenic health effects on the CNS

The evidence level for the existence of each studied effect on the CNS in humans is presented in Table 1.

Table 1: Classification of evidence levels in humans for non-carcinogenic effects on the central nervous system (CNS)

Studied effect	Evidence supporting the existence of the studied effect in animal and/or cell models <i>(Number of studies of high quality taken into account in the 2009 + 2013 assessments)</i>	Evidence supporting the existence of the studied effect in human clinical and epidemiological studies <i>(Number of studies of high quality taken into account in the 2009 + 2013 assessments)</i>	Classification of the level of evidence in humans
Cognitive function	Limited in terms of cognitive performance and memory (improvement) <i>(No previous studies + 4 studies)</i> → <i>The 4 studies conducted by the Arendash et al. group on metabolism, cerebral blood flow and cognitive function suggest that chronic exposure to RF fields may result in improved cognitive function and memory, particularly in very old mice. These results merit further study.</i>	Inadequate <i>(2 meta-analyses + 11 studies)</i>	Inadequate evidence to conclude
	Inadequate in terms of anxiety and locomotor activity <i>(No previous studies + 5 studies)</i>		
Sleep	Limited <i>(No previous studies + 1 study)</i> → <i>A single analysed study shows an increase in the number of periods of REM sleep (Pelletier et al., 2012). These results merit further study. Investigations should be pursued and a full 24-hour period studied.</i>	Inadequate data concerning the electrical macrostructure of nocturnal sleep, subjective changes to sleep, and disruptions of cognitive tasks associated with polysomnographic recordings <i>(1 + 8 studies)</i>	Inadequate evidence to conclude on the existence of a short term pathological effect on sleep. Absence of data on long-term effects

Studied effect	Evidence supporting the existence of the studied effect in animal and/or cell models <i>(Number of studies of high quality taken into account in the 2009 + 2013 assessments)</i>	Evidence supporting the existence of the studied effect in human clinical and epidemiological studies <i>(Number of studies of high quality taken into account in the 2009 + 2013 assessments)</i>	Classification of the level of evidence in humans
		Sufficient data to demonstrate an increase in the spectral power of the electroencephalogram in the frequencies of sleep spindles (short-term physiological effect) <i>(1 meta-analysis + 3 studies)</i>	
Circadian rhythms	Inadequate <i>(No previous studies + 1 study)</i>	Absence of quality data	Inadequate evidence to conclude



Studied effect		Evidence supporting the existence of the studied effect in animal and/or cell models (Number of studies of high quality taken into account in the 2009 + 2013 assessments)	Evidence supporting the existence of the studied effect in human clinical and epidemiological studies (Number of studies of high quality taken into account in the 2009 + 2013 assessments)	Classification of the level of evidence in humans
Auditory function	Evoked potentials	Inadequate (5 + 2 studies) → Studies showing an effect of radiofrequencies on auditory function were all conducted in rabbits (Budak et al., 2009; Kaprana et al., 2011). The results should be taken into account with reservations.	Inadequate (15 + 5 studies on evoked potentials) → The only study showing a decrease in amplitude and an increase in cochlear action potential latency [Colletti et al., 2010] is not representative of a real situation (exposure of deep structures during craniotomy and anaesthesia)	Inadequate evidence to conclude on the existence of a short-term pathological effect on auditory function Absence of long-term data
	Tinnitus	Absence of quality data	Inadequate (No previous studies + 2 studies)	
Neurological disorders	Multiple sclerosis	Absence of quality data	Inadequate (No previous studies + 1 study)	Inadequate evidence to conclude
	Amyotrophic lateral sclerosis	Absence of quality data	Inadequate (No previous studies + 1 study)	Inadequate evidence to conclude
	Epilepsy	Inadequate (No previous studies + 1 study)	Inadequate (No previous studies + 1 study)	Inadequate evidence to conclude
	Alzheimer's disease	Inadequate (No previous studies + 4 studies)	Absence of quality data	Inadequate evidence to conclude

Other non-carcinogenic effects, excluding CNS effects

Studies on mechanisms of action

Analysis of publications concerning studies on radiofrequency-related mechanisms of action and non-carcinogenic effects, excluding the CNS, provided the following conclusions:

- no significant effect of acute exposure to RF fields on gene expression (some low level and/or transient changes have however been described, but have no impact on final protein concentrations in cells (no transcriptional response) and therefore probably have no harmful effect);
- exposure to RF fields may lead to increased oxidative stress or disrupt cellular protection systems. However, results appear to depend on the model used and no data in humans has been published.

In any event, it is not possible at present to establish a relationship between these biological effects, a mechanism of action, and resulting effects on health.

Evidence level for the studied non-carcinogenic health effects, excluding those on the CNS

The level of evidence for an effect on humans, for each studied non-carcinogenic effect (excluding the CNS) is shown in Table 2.

Table 2: Classification of evidence levels in humans for non-carcinogenic effects excluding the central nervous system

Studied effect		Evidence supporting the existence of the studied effect in animal and/or cell models <i>(Number of studies of high quality taken into account in the 2009 + 2013 assessments)</i>	Evidence supporting the existence of the studied effect in human clinical and epidemiological studies <i>(Number of studies of high quality taken into account in the 2009 + 2013 assessments)</i>	Classification of the level of evidence in humans
Reproduction and development	Male fertility	Limited <i>(2 + 9 studies)</i> → <i>Results to be confirmed with a more robust methodology: Falzone et al. (2012); Kesari and Behari 2010</i>	Absence of quality data	Inadequate evidence to conclude
	Female fertility	Inadequate <i>(No previous studies + 1 study)</i>	Absence of quality data	Inadequate evidence to conclude
	Sexual behaviour	Absence of quality data	Absence of quality data	As quality data are lacking, impossible to evaluate the effect
	Height, weight and viability of descendants	Inadequate <i>(1 + 4 studies)</i>	Absence of quality data	Inadequate evidence to conclude
	Teratogenic effects and <i>in utero</i> development	Inadequate <i>(4 + 14 studies)</i>	Absence of quality data	Inadequate evidence to conclude
	Immune system	Inadequate <i>(8 + 6 studies)</i> → <i>Results of investigations carried out in identical conditions by the teams of Grigoriev and Poullétier de Gannes appear to be discrepant</i>	Inadequate <i>(1 + 0 studies)</i>	Inadequate evidence to conclude
Endocrine system	Absence of quality data	Inadequate <i>(2 + 0 studies)</i>	Inadequate evidence to conclude	

Studied effect		Evidence supporting the existence of the studied effect in animal and/or cell models <i>(Number of studies of high quality taken into account in the 2009 + 2013 assessments)</i>	Evidence supporting the existence of the studied effect in human clinical and epidemiological studies <i>(Number of studies of high quality taken into account in the 2009 + 2013 assessments)</i>	Classification of the level of evidence in humans
Cardio-vascular system	Haematological parameters	Absence of quality data	Absence of quality data	As quality data are lacking, impossible to evaluate the effect
	Vasomotricity of blood vessels	Inadequate <i>(No previous studies + 1 study)</i>	Absence of quality data	Inadequate evidence to conclude
	Heart rate	Absence of quality data	Inadequate <i>(5 + 4 studies)</i>	Inadequate evidence to conclude
	Blood pressure	Absence of quality data	Inadequate <i>(2 + 0 studies)</i>	Inadequate evidence to conclude
Well-being and reported health		Absence of quality data	Inadequate <i>(0 + 11 studies)</i> → <i>Indications of an association between perceived symptoms and the distance to the base-station antenna assessed by residents, rather than actual measured distance</i>	Inadequate evidence to conclude concerning an effect on the general population
Overall health (all-cause mortality)		Inadequate <i>(0 + 1 study)</i>	Absence of quality data	Inadequate evidence to conclude

Carcinogenic effects

Studies on mechanisms of carcinogenicity

Concerning experimental test conditions in *in vitro*, *in vivo* or clinical mechanistic studies on carcinogenesis, an analysis of publications provided the following conclusions:

- it is not possible to rule out the fact that RF fields in certain conditions, particularly with exposure to modulated signals, may:
 - o promote DNA oxidation. Changes observed on the oxidative state of guanine (in only two studies) were correlated with an increase in oxidative stress in the cell or body;
 - o induce DNA breakage (clastogenic effect). However, breaks are often low level (close to natural background levels);
- nonetheless, no permanent effect of RF fields on loss of DNA integrity has been demonstrated at low exposure levels:
 - o no mutagenic or co-mutagenic effect of RFs has been observed;
 - o no data appear to indicate that exposure to RF fields induces chromosome segregation abnormalities on mitosis (no aneuploidy);

As a result, the observed changes of DNA oxidation and a clastogenic effect appear to be rapidly repaired. They probably have no consequences on chromosomal integrity;

- there are no convincing data on changes to the cell cycle that could be involved in tumour development;
- the available studies on a possible co-carcinogenic effect of RF fields do not provide any evidence that electromagnetic energy potentiates the effects of known genotoxic agents (no co-carcinogenic effect). A single *in vivo* study demonstrated a possible co-carcinogenic effect of RFs in a specific cancer model in offspring. The results of this study merit further research;
- the *in vivo* studies on tumour development analysed (15 studies in the 2009 AFSSET report and 3 subsequently) do not provide any evidence of increased incidence or worsening of cancer, particularly in the event of chronic and semi-chronic exposure to RFs.

The biological effects observed warrant further study through additional research, specifically in relation to modulated signals. It is not currently possible to establish a relationship between these biological effects, a mechanism of action, and resulting effects on health.

Evidence levels for the studied carcinogenic health effects

The evidence level for the existence of effects on humans for each studied carcinogenic effect is presented in Table 3.



Table 3: Classification of evidence levels in humans for carcinogenic effects

Studied effect		Evidence supporting the existence of the studied effect in animal and cell models <i>(Number of studies of high quality taken into account in the 2009 + 2013 assessments)</i>		Evidence supporting the existence of the studied effect in clinical and epidemiologic al studies <i>(Number of studies of high quality taken into account in the 2009 + 2013 assessments)</i>	Classification of the level of evidence in humans
		Animal data	Mechanistic data		
Brain tumours	Glioma	Absence of specific quality data	Inadequate general data on the genotoxic mechanisms and on the development of tumours <i>in vivo</i>	Inadequate in the general population Limited for "intensive" users , i.e. with over 1640 hours of cumulative exposure <i>(15 + 10 studies)</i>	Inadequate evidence to conclude on the risk of glioma associated with environmental exposure to radiofrequencies. However, possible effect for "intensive" users , i.e. with over 1640 hours of cumulative exposure. An increased risk of glioma cannot be ruled out, with the following characteristics: 1) slightly higher incidence of gliomas (less than 20%); 2) limited to small subgroups of users (highly intensive users for example); 3) associated only with one or more rare types of glial tumours; 4) for induction periods greater than 15 years (no data are available beyond this limit).
	Meningioma	Absence of specific quality data			Inadequate <i>(10 + 4 studies)</i>
	Acoustic neurinoma	Absence of specific quality data		Limited <i>(13 + 4 studies)</i> → <i>The results of the study by Benson et al. (2013), published after the end of the literature review period were taken into account.</i>	Limited evidence <i>The Benson et al. study (2013) appears to leave open the hypothesis of an increased risk of acoustic neurinoma in long-term users of mobile phones.</i>
	Salivary gland tumours	Absence of specific quality data		Inadequate <i>(3 + 2 studies)</i>	Inadequate evidence to conclude

Studied effect	Evidence supporting the existence of the studied effect in animal and cell models <i>(Number of studies of high quality taken into account in the 2009 + 2013 assessments)</i>		Evidence supporting the existence of the studied effect in clinical and epidemiological studies <i>(Number of studies of high quality taken into account in the 2009 + 2013 assessments)</i>	Classification of the level of evidence in humans
	Animal data	Mechanistic data		
Leukaemia	Absence of specific quality data		Inadequate <i>(No previous studies + 2 studies)</i>	Inadequate evidence to conclude
Melanoma	Cutaneous	Absence of specific quality data	Inadequate <i>(No previous studies + 1 study)</i>	Inadequate evidence to conclude
	Ocular		Inadequate <i>(No previous studies)</i>	Inadequate evidence to conclude
Cancer incidence and mortality (all types)	Absence of specific quality data		Inadequate <i>(No previous studies + 2 studies)</i>	Inadequate evidence to conclude

Regulatory considerations

The expert appraisal published by the Agency in 2009 details the applicable regulatory limit values based on the recommendations of the International Commission on Non-Ionising Radiation Protection (ICNIRP), and the scientific data that led to establishment of these recommended limits.

The main changes in French regulations concern the planning laws known as “Grenelle” 1 and 2. They aim primarily to improve control and monitoring of exposure of the public and to protect children.

European Directive 2013/35/EU⁹, which establishes minimal health and safety requirements for workers exposed to electromagnetic fields, was published in the Official Journal of the European Union on 29 June 2013. It must be transposed into national legislation of Member States before 1 July 2016.

⁹ Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC.

Risks related to radiofrequency electromagnetic fields from the human and social sciences perspective

The historical aspects of the public controversy on this subject in France were discussed in the 2009 report. A future update could include an analysis of the consequences of publication of this report and of classification of radiofrequency electromagnetic fields as category 2B in 2011 by the IARC, and also study the contribution of ANSES's Dialogue Committee on Radiofrequency and Health or the consequences of the studies carried out by COPIC.

A total of 23 articles in the areas of the human and social sciences published between 2009 and 2012 were analysed, presenting research on the perception and representation of risk, and on risk management.

The expert report proposes a critical overview of the articles discussing the psychosociological aspects of perception and representation of the risks related to RF fields. This overview shows that users have little technical knowledge concerning mobile telecommunications, and as a result, their exposure to RF fields. The variability of information and communication on the risks tends to reinforce the initial perceptions of the public. It would be beneficial to assist users in assessing their individual exposure more clearly, by providing suitable information.

Concerning risk management, it should be noted that the various articles retained for evaluation follow varying approaches but all call for greater participation of the public in risk assessment and in decision-making. The focus is often on the precautionary principle, but the four other principles highlighted during the roundtable on "Radiofrequency, health and the environment" of 2009, i.e. transparency, attention, democratic deliberation and consistency of public action, appear to be as important in dealing with the risks related to RF fields.

Lastly, the report offers a synopsis of articles dealing with the relevance and conditions of application of the precautionary principle in the area of risks associated with RF fields.

Conclusions of the collective expert appraisal

Analysis of the results of the expert appraisal and consideration of the data in the previous appraisal (AFSSET, 2009), gives rise to the following conclusions.

Many studies in the fields of biology and epidemiology have been published since the 2009 report. Among the biology studies, many well-conducted investigations show no effects. Some studies have found biological effects in pathways that have not been well evaluated to date, and the results need to be validated (mitochondrial DNA, co-carcinogenicity, modulated signals, etc.). Until now, most of the effects appear to be transient or involve basic biological variation, demonstrating the ability of biological systems to repair or restore homeostasis. It is therefore impossible to conclude that the observed biological effects have effects on health.

Concerning the study of non-carcinogenic effects, studies on the central nervous system (CNS) are dealt with separately from the others.

Regarding studies of CNS effects, in the tested experimental conditions on cellular or animal models or in clinical studies, the level of evidence is inadequate to conclude that exposure to RF fields has an effect in humans (see Table 1) on:

- cognitive function;
- sleep in the short-term (following acute exposure);
- circadian rhythms (on the basis of a limited number of studies);
- auditory function in the short-term (following acute exposure);

- neurodegenerative disorders (amyotrophic sclerosis and Alzheimer's disease, in particular) and on other neurological diseases (e.g. multiple sclerosis and epilepsy) (on the basis of a limited number of studies).

The expert appraisal gives rise to the following findings:

- o in humans, a short-term physiological effect has been observed on sleep. The effect involves an increase in spectral power on the electroencephalogram (EEG) in the frequency of sleep spindles, with modulation around 14 Hz. This effect is reproducible, but the underlying mechanism is not known and needs to be investigated. In addition, significant decreases in the duration of stage 2 sleep and increases in the duration of REM sleep in the third quarter of the night have been observed (an increase in the number of periods of REM sleep has also been reported in a single study in rats). Neither of these physiological changes are accompanied by subjective alterations in sleep, nor by disruptions of cognitive tasks associated with polysomnographic recordings. This suggests that the effect probably has no pathological consequences in the short term;
- o in animals, the four studies conducted by the Arendash *et al.* group in normal mouse and transgenic mouse models for Alzheimer's disease included measurement of oxidative stress, mitochondrial function, cerebral blood flow, and cognitive function. These studies confirm earlier findings demonstrating that chronic exposure to RF fields may result in improved cognitive performance and memory, specifically in very old mice. These results should be validated and evaluated in humans;

Concerning other non-carcinogenic effects other than CNS effects, the level of evidence is inadequate to conclude that exposure to RF fields has an effect in humans (see Table 2) on:

- male fertility;
- height, weight and viability of descendants (on the basis of a limited number of studies);
- teratogenesis and *in utero* development;
- the immune system;
- the endocrine system (on the basis of a limited number of studies);
- the cardio-vascular system, particularly haematological parameters, vasodilation, heart rate and blood pressure (on the basis of a limited number of studies);
- well-being (in the general population);
- overall health (all-cause mortality, on the basis of two studies);
- the visual system (on the basis of a limited number of studies, all analysed in the 2009 AFSSET report);

Only one article of sufficient quality aimed to evaluate a possible effect of RF fields on female fertility.

Two remarks can be made following analysis of the literature published since 2009:

- Most *in vitro* data on human spermatozoa and *in vivo* data in rats do not show an effect on male fertility. The experts however attributed a limited evidence level on the basis of two studies that raise questions. More research should be conducted in this area. Ultimately, available evidence indicating the existence of an effect on male fertility in animals is limited, and does not enable definitive evaluation of this potential effect;
- Certain well-being studies in the general population have demonstrated an association between perceived symptoms and the distance from base-station

antennas assessed by residents, rather than the actual exposure level, which appears to point to a nocebo effect.

Concerning the potential carcinogenic effects of radiofrequencies, the evidence level is inadequate to conclude that exposure has an effect in humans (see Table 3) on development of:

- gliomas in the general population;
 - meningiomas;
 - salivary gland tumours;
 - pituitary tumours (adenomas) (on the basis of two studies analysed in the 2009 AFSSET report);
 - leukaemia (on the basis of a limited number of studies);
 - cutaneous (on the basis of a limited number of studies) and ocular melanomas;
- and on cancer incidence and mortality (all types).

Analysis of articles published since 2009 leads to the following comments:

- the level of evidence is limited to conclude on the risk of glioma associated with RF fields for intensive users of mobile phones, i.e. those with more than 1640 hours of cumulative exposure. An increased risk of glioma with the following characteristics cannot be ruled out:
 - 1) slightly higher increase in risk (less than 20% increase in incidence of gliomas);
 - 2) limited to small subgroups of users (e.g. highly intensive users);
 - 3) associated only with one or more rare types of glial tumours;
 - 4) for induction periods greater than 15 years (no data are available for longer periods);
- the level of evidence is limited to conclude on the risk of acoustic neurinoma, on the basis of a recent study (Benson *et al.*, 2013).

Recommendations of the collective expert appraisal

Recommendations for studies and research

Biological studies on cell or animal models

Specifically in view of:

- methodological deficiencies concerning the characterisation of exposure in experimental conditions in many studies;
- the need to better document the possible effects of chronic exposure to radiofrequencies,

the Expert Committee (CES) emphasises the relevance of the recommendations made in the previous Agency report (AFSSET, 2009) concerning the importance of ensuring the methodological quality of experimental protocols and the need to perform studies on several generations of animals, specifically on reproduction and development.

The CES adopts the recommendations detailed in the 2013 report issued by the Working Group on Radiofrequency and health, and emphasises the need to:

- study the long-term effects of RF fields, particularly on fertility, reproduction, development, and carcinogenesis;
- supplement available sleep EEG data, particularly during chronic exposure;
- study combined exposure to RF fields with other chemical and physical agents, for which the known mechanisms of action could have a potentiating or inhibitory action on the studied effect;
- specifically consider modulated signals.

The CES recommends that new studies with a rigorous methodology be carried out on some of the effects discussed in this report. These include certain biological effects (oxidative stress, number of neurones in the brain), physiological effects (number of periods of REM sleep, or auditory evoked potentials, for instance), effects on reproduction, and improvement in cognitive performance.

Epidemiological studies

Specifically in view of:

- the difference between biological effects and health effects in the human population;
- the many methodological shortcomings regarding characterisation of human exposure;
- continued uncertainty regarding the possible carcinogenic risk related to exposure to RF fields, and the almost complete lack of epidemiological studies on neurodegenerative disorders,

the CES emphasises the relevance of the recommendations made in the Agency's previous report (AFSSET, 2009) concerning the importance of improving characterisation of exposure of studied populations, and of studying the potential effects of RF fields on the health of highly exposed populations, in particular in the occupational setting.

The CES adopts the recommendations detailed in the report issued by the Working Group on Radiofrequency and health (ANSES, 2013), specifically emphasising the need to monitor the possible effects of RF fields on potentially susceptible populations including children, pregnant women, the elderly, epileptic subjects, etc.

Social effects of new technology usage patterns

The CES recommends:

- that the impact of use of new wireless technologies on stress, fatigue, burn-out syndrome, addiction, etc., be studied more closely, in the general and occupational populations;

Recommendations concerning characterisation of exposure

Characterisation of exposure in experimental studies

The CES adopts the recommendations detailed in the 2013 report issued by the Working Group on Radiofrequencies and health, and emphasises specifically:

- the benefit of a precise, reproducible measurement framework for exposure to electromagnetic fields, including for example a time measurement for the incident electric field at the location of the exposure models and in their absence;
- the need to ensure that the exposure system and associated measurement parameters are valid, and to document the various exposure conditions in scientific publications.

Characterisation of exposure to electromagnetic environments

Specifically in view of:

- the development of new telecommunications technologies using new types of signals;
- the utility of in-depth knowledge and characterisation of individual exposure from multiple sources, including continuous long-term exposure,

the CES emphasises the relevance of the recommendations made in the Agency's previous report (AFSSET, 2009) concerning the importance of suitability of measurement protocols to technological changes, and the description of exposure in highly exposed populations (highest environmental levels, certain professions, etc.).

The CES adopts the recommendations detailed in the report of the Working Group on Radiofrequency and health, and emphasises in particular the need to:

- take into account new exposure conditions related to new devices, such as tablets, through detailed modelling of the hand for instance, since homogenous human body models show limitations for these exposure conditions;
- access certain internal functions of mobile phones to determine the actual power emitted by the devices, with the aim of developing measurement techniques for research and for providing information to the public.

Recommendations concerning reduction of exposure levels

Specifically in view of:

- the strong development of technologies using RF fields which could increase exposure levels;
- the fact that part of the population (see work by the COPIC¹⁰) wants to reduce exposure levels to RF fields, and the available technical means enabling this reduction for devices such as mobile phones, baby monitors, DECT wireless telephones, etc.;
- calls for reduction in exposure levels related to base-station antennas for mobile telecommunications, with no change in coverage, to a value that has no scientific

¹⁰ Led by the Operational Committee for Radio Waves, a study on the lowering of exposure levels has been initiated. It aims to reduce the radiofrequencies emitted by base-station antennas and to evaluate the impact on the quality of services, network coverage, and the number of antennas. The work of the Committee will help to improve local debate on the installation of antennas and to propose new information procedures (<http://www.developpement-durable.gouv.fr/Actions,13259.html>).

- justification, a call expressed specifically at the roundtable on “Radiofrequency, health, and the environment” held from 23 April to 25 May 2009¹¹ ;
- the intention expressed by some cities in France to test exposure levels lower than regulatory limit values,

The CES adopts the recommendations detailed in the report issued by the Working Group on Radiofrequency and health, and specifically emphasises the need to:

- provide users with information on maximum exposure levels (Specific Absorption Rate (SAR), for example) caused by individual devices using RF fields (DECT telephones, tablets, baby monitors, etc.), like the regulatory requirements in place for mobile phones;
- propose simple measures enabling users of communication devices to reduce their exposure, if they so wish;
- study, on the basis of information provided by the COPIC, the consequences, on human exposure to radiofrequency fields from mobile phones, of a possible increase in the number of base-station antennas, with the aim of reducing environmental exposure levels.

The CES also notes that according to results of investigations presented in the expert appraisal, the tested "anti-wave" devices have not demonstrated their usefulness in terms of exposure reduction.

4. CONCLUSIONS AND RECOMMENDATIONS OF THE AGENCY

The Agency recognises the important work carried out by the Working Group on Radiofrequencies and health aimed at objectively assessing the level of evidence for the possible effects of radiofrequencies on human health. This pioneering work is based on a structured analysis of study protocols and the results of the scientific studies evaluated on the basis of the method used by the IARC as a guide to assess the carcinogenicity of an agent.

Thanks to a broad review of the scientific literature, this expert appraisal constitutes an update to the report and Agency's Opinion published in 2009.

Previous work carried out by the Agency suggested the existence of biological effects related to radiofrequency exposure mainly from *in vitro* studies concerning cellular mechanisms of action. This update of the Agency's appraisal has once again found these effects, in particular on apoptosis and oxidative stress, in certain experimental conditions. The 2013 expert appraisal also points out an effect of RF fields on the electrical activity of the brain associated with mobile telephone exposure, in line with the results published in 2009.

The 2009 report also described radiofrequency-related effects on learning and memory in animals. This type of effect was again reported in the 2013 expert appraisal, with a limited level of evidence.

However, the effects observed on cerebral blood flow mentioned in 2009 were not confirmed by the new studies analysed.

The 2013 expert appraisal has demonstrated various effects, with limited evidence:

- in animal models: on sleep, male fertility and cognitive performance;

¹¹ Feedback report, J.F. Girard, <http://www.ladocumentationfrancaise.fr/var/storage/rapports-publics/094000240/0000.pdf>.

- in humans, on glioma for intensive users and on acoustic neurinoma in epidemiological studies, and with a sufficient level of evidence, a short-term physiological change in cerebral activity during sleep.

The Agency also found studies that do not demonstrate effects associated with radiofrequency exposure on: tinnitus, the immune system, the endocrine system, blood pressure, salivary gland tumours, leukaemia, melanoma, and meningioma for latency periods less than 15 years.

The Agency emphasises however that it is not possible to conclude concerning certain studied effects in the absence of data in humans, specifically on circadian rhythms, Alzheimer's disease, reproduction and development, haematological parameters, and vasomotricity of blood vessels.

All the studies showing effects were carried out at exposure levels comparable to those induced by mobile phone use, with one exception¹² conducted at environmental exposure levels. Nonetheless, the impact of the type of signal used in communication protocols (2G, 3G, 4G) on the potential effects appears to be poorly documented.

Biological effects can be observed below the exposure limit values defined at the international level (European Council Recommendation 1999/519/EC). However, the Agency's experts were not able to establish a causal relationship between the described biological effects on cells or animal models, or in humans, and possible resulting effects on health.

De facto, no available data makes it possible to propose new exposure limit values for the general population.

Epidemiological studies published since 2009 that focus on the relationship between exposure to mobile telephones and development of glioma indicate, with a limited level of evidence, that the risk, if any, would be low in intensive mobile phone users. To date, no mechanism of action has been identified.

Furthermore, the Agency notes the massive development of technologies using RF fields that leads to extensive exposure of the population, including the most susceptible individuals, and that the population cannot avoid this exposure. Although recent investigations at the national level have shown, in the studied geographic areas, that overall exposure is low in terms of current reference values, they also demonstrate that there are areas with much higher exposure, in which exposure could be reduced by technological means. In this context, even though mobile telephones probably remain the primary source of exposure, it seems that a description of environmental exposure of the population and its variations over time are only partially documented.

The French Agency for Food, Environmental and Occupational Health & Safety adopts the conclusions and recommendations of the Expert Committee (CES) on Physical agents, new technologies and development areas. Additional conclusions and recommendations are given below and it should be noted that on-going studies, concerning specifically electro-hypersensitivity and children, may result in new conclusions in the short term.

Regarding studies and research

The Agency underlines the specific funding made available for research in the area of the potential effects of radiofrequency electromagnetic fields on health in France. The

¹² Concerning changes in specific sleep parameters.

research programme provides annual funding for structural projects as part of the expert appraisals carried out by ANSES's working group.

Considering the methodological shortcomings in the characterisation of exposure or in the experimental protocols observed in many of the studies, the Agency recommends initiating a debate with a view to drawing up methodology guidelines for carrying out experimental studies on the potential effects of radiofrequencies, based on the experience of the many reports of expert appraisals published in different countries.

Considering the constant progress in wireless communications technologies, the Agency recommends stepping up studies of the effects of electromagnetic fields on living organisms in those wavebands that have not been extensively studied to date, especially those above 6 GHz, potentially associated with emerging uses concerning communication devices "smart objects").

Considering the continuing uncertainties in the results of research into the possible long-term health effects of radiofrequency fields, the Agency adopts the recommendations of the Working Group in order to:

- facilitate the access of research teams to data held by mobile telephony operators, to improve the characterisation of exposure of humans and, more generally, to be able to quantify the actual exposure of populations as precisely as possible in epidemiological studies;
- undertake new studies and continue those currently underway on the possible long-term effects of exposure to RF fields, especially regarding mobile telephones;
- encourage large-scale cohort studies in the general population, international if possible, collecting validated data on exposure in order to study the possible long-term effects of RF fields;
- monitor trends in disease development over time and investigate aggregated spatial and temporal data from validated sources, such as cancer registers.

Furthermore, the Agency recommends reinforcing identification of population groups potentially more susceptible to electromagnetic fields generated by radiofrequencies (children, pregnant women, etc.), as well as extending our knowledge of the effects of exposure on these groups.

Considering the significant lack of harmonisation among research studies carried out to explore the biological and health effects of RF fields (regarding experimental models tested, systems and levels of exposure, types of signal used, etc.), the Agency recommends encouraging a consistent approach for studies with discussions at the international level to define guidelines for coordinated research, taking into account what has been acquired, current uncertainties and gaps in current knowledge.

Regarding characterisation of exposure

Considering the complex and rapidly changing nature of the electromagnetic environment, and also the substantial work carried out recently by the COPIC, the Agency recommends:

- continuing to improve the characterisation of public exposure to various sources of surrounding electromagnetic fields, especially for the purpose of monitoring any changes over time, in the indoor and outdoor environments;
- undertaking work comparing a spatial description of the levels of electromagnetic fields with the geographical distribution of the population, with a view to providing an initial characterisation of residential exposure.

Regarding information and control

Considering that:

- Decree No. 2002-775 of 3 May 2002 on exposure limits for the general public to electromagnetic fields emitted by equipment used in telecommunication networks or by radioelectric facilities does not concern radiation emitted by other sources of electromagnetic fields to which the general public may be exposed;
- the Decree is based in particular on Recommendation 1999/519/EC¹³ by the Council of the European Union of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz);
- the aforementioned Recommendation 1999/519/EC by the Council of the European Union specifies that:
 - *(7) Actions on limiting the exposure of the general public to electromagnetic fields should be balanced with the other health, safety and security benefits that devices emitting electromagnetic fields bring to the quality of life, in such areas as telecommunications, energy and public security;*
 - *(11) Such basic restrictions and reference levels should apply to all radiations emitted by electromagnetic fields with the exception of optical radiation and ionising radiation [...];*
 - *(19) The Member States should take note of progress made in scientific knowledge and technology with respect to non-ionising radiation protection, taking into account the aspect of precaution, and should provide for regular scrutiny and review with an assessment being made at regular intervals in the light of guidance issued by competent international organisations, such as the International Commission on Non-Ionising Radiation Protection;*
- regulatory requirements for displaying the SAR (Decree No. 2010-1207 dated 12 October 2010) only concern mobile telephones intended for use in networks open to the public;

ANSES recommends, without prejudice to the need to respect reference values in force concerning electromagnetic compatibility, that:

- current regulations concerning exposure of the general population to electromagnetic fields emitted by equipment used in telecommunications networks or by radioelectric installations (Decree No. 2002-775 of 3 May 2002) be extended to cover other artificial sources of emissions of radiofrequency radiation for which compliance with exposure limit values cannot be established *a priori*;
- devices emitting electromagnetic fields intended for use near the body (DECT telephones, tablet computers, baby monitors, etc.) display the maximum level of exposure generated (SAR, for example).

Regarding control of exposure levels

Considering the current or future deployment of new mobile communication technologies (LTE, 4G, etc.), in parallel with the existing services, and the uncertainties concerning the long-term effects of exposure to radiofrequencies, the Agency emphasises the need for these technological developments to go hand in hand with limitation of individual exposure, whether exposure is environmental or related to devices.

¹³ 1999/519/EC: Council Recommendation, of 12 July 1999, on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz), *Official Journal No. L 199 of 30/07/1999 p. 0059 – 0070*.

ANSES recommends:

- reducing the exposure of children by encouraging only moderate use of mobile phones, ideally with hands-free kits and mobile terminals with the lowest SAR values;
- for adults with intensive use of mobile phones (in talk mode) to use a hands-free kit and mobile terminals with the lowest SAR values;
- carrying out an in depth study of the effects of an increase in the number of base station antennas (in order to reduce environmental exposures) on personal exposures to radiofrequency fields from mobile phones;
- that the development of new network infrastructures be subject to prior studies concerning the characterisation of exposures, taking into account the accumulation of existing levels with those that would be generated by new installations, in order to favour concerted discussion regarding new installations or modifications of transmitters;
- documenting the conditions pertaining to existing installations that cause the highest exposure of the public, and investigating to what extent these exposures can be reduced by technical means.

The Director General

Marc Mortureux

KEY WORDS

Radiofrequency electromagnetic fields, health, exposure, risk assessment, telecommunications, mobile telephony, Wi-Fi, 4G.

ANNEX

Evaluation of evidence for each studied effect

The categories presented below only concern evidence for the studied effect indicating that a specific exposure has or does not have an effect, and not the extent of the effect nor the underlying mechanisms.

1/ Study of the effects of radiofrequencies in animal and cell models

Data concerning the studied effects in animal models are classified according to the following categories:

Sufficient evidence supporting the existence of the studied effect: the WG considers that a cause-effect relationship has been established between exposure to radiofrequency electromagnetic fields under assessment and the studied effect, a) in two or more animal species, or b) in two or more separate studies in the same species, carried out at different times or in different laboratories, or following different protocols.

Limited evidence supporting the existence of the studied effect: available data appear to show that there is an effect, but they are limited and do not enable definitive evaluation of the effect because, a) evidence of the effect is limited to a single investigation, or b) questions remain concerning the relevance of the protocol, conduct of the study, or interpretation of results, or c) the incidence of the observed effect may be naturally high in certain microbiological strains.

Inadequate evidence supporting the existence of the studied effect: study results cannot be interpreted as proof of the existence or absence of a studied effect because, a) they do not demonstrate an effect, b) they have serious qualitative or quantitative shortcomings, or c) there are no available data on the studied effect in animal models.

Evidence supporting the absence of an effect: there is a sufficient number of studies in two or more species showing, in a consistent manner, within the limits of the investigations carried out, that the RF fields tested do not have an effect. When the information obtained suggests a "lack of effect", this conclusion can only be applied to the studied effect, to the tested RF fields, in the conditions and levels of exposure, and for the duration of observation used in the available studies.

2/ Study of the effects of radiofrequency electromagnetic fields in humans

Data concerning the studied effect from epidemiological or clinical studies in humans are classified according to the evidence in favour of existence of an effect, in one of the following categories:

Sufficient evidence supporting the existence of the studied effect: the WG considers that a cause-effect relationship has been established between exposure to the RF fields under assessment and the studied effect in humans. In other words, a positive relationship has been established between exposure and onset of an effect, in studies in which random, bias, and confounding factors have been ruled out with sufficient certainty (see Bradford-Hill criteria [Bradford-Hill, 1965]).

Limited evidence supporting the existence of the studied effect: a positive association has been established between exposure to the RF fields under assessment

and onset of an effect and the WG considers that a causal interpretation for this association is credible, but it was not possible to rule out with sufficient certainty that random, bias, or confounding factors did not play a role.

Inadequate evidence supporting the existence of the studied effect: available studies a) do not show an effect, b) do not have sufficient quality, consistency or statistical power to conclude on the existence or absence of a cause-effect relationship between exposure to the RF fields under assessment and the studied effect, or c) no data are available on the studied effect in humans.

Evidence supporting the absence of an effect: there are several sufficient studies covering all exposure levels known to concern humans with converging results that do not point to a positive association between exposure to the RF fields under assessment and the studied effect, irrespective of the level of exposure examined. The results of these studies, alone or in combination, must have narrow confidence intervals, with an upper limit close to nil (for example a relative risk of 1.0). Bias and confounding factors must be ruled out with reasonable certainty, and follow-up should be sufficiently long. When available information suggests an "absence of effect", this conclusion can only be applied to the studied effect, to the tested RF fields, in the conditions and levels of exposure, and for the duration of observation used in the available studies. Moreover, the possible existence of a very slight risk at the studied exposure levels can never be ruled out.