

Dear Contributor,

Thank you for participating in the public consultation of the ICNIRP draft guidelines.

Please note that it is important that ICNIRP understands exactly the points that you are making. To facilitate our task and avoid misunderstandings, please:

- be concise
- be precise
- provide supporting evidence (reference to publication, etc.) if available and helpful.

Please provide your details below as per the online form and the provision of the privacy policy

Last name, first name: Roth-Delgado, Olivia	Email address:	Affiliation (if relevant): ANSES					
If you are providing these comments officially on behalf of an organization/company, please name this here: ANSES - French Agency for Food, Environmental and Occupational Health & Safety							
⊠ I hereby agree that, for the purpose of the public consultation, my comments along with my identity (last and first names, affiliation and organization where relevant) will be published on the ICNIRP website after the consultation phase.							

<u>Please complete the comments table</u>: Please use 1 row per comment. If required, please add extra rows to the table.



	Document (Guidelines, App A, App B)	Line Number #	Type of comment (General/ Technical/ Editorial)	Comment. Proposed change. Context.
1	Guidelines	16-17	General	It is unclear whether the ICNIRP 2018 publication will fully replace the ICNIRP 1998 publication or not. In the ICNIRP 2018 publication, for example, there are insufficient references to justify the choice of 4 W/kg as the lowest exposure level leading to adverse health effects on animals. Insert your proposed change. Explain the context of your comment.
2	Guidelines	23-41	Technical	The ICNIRP guidelines exclude electromagnetic compatibility issues and refer explicitly to compliance with standard 60601-1-2. There have been changes to the limits in the 100 kHz – 10 MHz band, and measuring methods have considerably evolved. The ICNIRP 2010 recommendations are more nuanced on this point even if they cited the same references. Moreover, by approaching implants from the point of view of electromagnetic compatibility, the thermal effects on passive implants appear to be hidden. What other effects are there besides those generated by electrical equipment? Are they excluded? Or are they included in the notion of an object or medical act? Insert your proposed change. Explain the context of your comment.
3	Guidelines	43-53	Technical	ICNIRP should give a more detailed definition and evidence-based justification for the following categories (preferably in a table): (i) biological effects, (ii) health effects, (ii) adverse health effects, (iv) substantiated adverse health effects. These definitions are necessary to apprehend the summary conclusions at the end of Appendix B sections, which are currently very assertive. Insert your proposed change. Explain the context of your comment.
4	Guidelines	49-53	Technical	The weight of evidence for the methodology used to determine harmful effects to human health is not sufficiently described and needs to be made more transparent. How many times must an effect be replicated to be considered as sufficient? How many studies are required? How is "sufficient scientific quality" assessed by ICNIRP? Which indicators are needed? The scientific basis of "scientifically substantiated" should be made more explicit. Insert your proposed change. Rigorous methods to assess the weight of evidence for issues related to electromagnetic fields have been developed over time (e.g. by ANSES and Health Canada). A detailed description in the core guidelines document and appendices of the weight of evidence approach taken by ICNIRP is needed and should be more thorough and transparent.



5	Guidelines	49-50	General	The part of the sentence which says "explicable more generally within the context of the scientific literature" should be clarified. Insert your proposed change. Explain the context of your comment.
6	Guidelines	54-59	Technical	The concept and definition of "operational threshold" is new in the ICNIRP rationale. A more detailed explanation of this concept is needed. Insert your proposed change. Explain the context of your comment.
7	Guidelines	60	Technical	What exactly does "more-general" knowledge mean? Insert your proposed change. Explain the context of your comment.

Add further rows if needed. For this copy the above row.

And paste it here.

Continue numbering	Guidelines	95	Technical	The key issue which requires attention in the guidelines is whether the foetus is a more sensitive population within the general public or not.
				Insert your proposed change.
				The foetus, children, pregnant women and ill people are often considered to be part of a sensitive population. Furthermore, in its Opinion (ANSES, 2016), ANSES notes that children are more exposed to radiofrequencies than adults, for self-explanatory anatomical reasons. These observations had already led the Health Council of the Netherlands, in 2011, and Health Canada, in 2015, to reconsider the reference levels to protect the health and safety of the general population, and more particularly of children.
Continue	Guidelines	100	Technical	Regretfully the "presumed exposure scenarios" are not described in the document.
numbering				Insert your proposed change.
				Explain the context of your comment.
Continue numbering	Guidelines	122	Technical	If ICNIRP considers temperature elevation, nerve stimulation, dielectric breakdown of biological membranes or electroporation as health effects, brain parameter disorders such as EEG parameter changes during sleep should also be discussed. Insert your proposed change.
				Explain the context of your comment.



Continue numbering	Guidelines	134	Technical	Could ICNIRP justify the 6 GHz cut-off, because it does not match a biological cut-off. Furthermore, the IEEE sets the limit at 3 GHz, considering that it offers better health protection (based on Hirata <i>et al.</i> , 2013) Insertyourproposed change. Explain the context of your comment.
Continue numbering	Guidelines	146, 156 Table 1.	Technical	The symbol for transmitted energy, Htr, is similar to the symbol for magnetic field strength, H. This may be misleading for the reader. We suggest changing the symbol for transmitted energy, e.g. T _r . Explain the context of your comment.
Continue numbering	Guidelines	169	Technical	Nerve stimulation, membrane permeabilization and temperature elevation are here described as the "three primary biological effects", and this rise in temperature is used to derive exposure limits. This appears to be in contrast with appendix B (line 48), where the distinction between biological and adverse health effects is explained, and it is said that "only adverse health effects require limits for the protection of humans". Insert your proposed change. Explain the context of your comment.
Continue numbering	Guidelines	179-183	General	There are several references on thermal physiology in the literature. The document should therefore include more references on thermal physiology and a more detailed description of the thermally-based operational adverse health effects/threshold. Insert your proposed change. Explain the context of your comment.
Continue numbering 9	Guidelines	226-228	General	In which cases does ICNIRP consider lower temperatures on which to base limits? Insertyourproposedchange. Explain the context of your comment.
Continue numbering	Guidelines	255	Technical	The term "mild hyperthermia" should be more precisely explained. Insert your proposed change. Explain the context of your comment.
Continue numbering	Guidelines	260	Editorial	Reference to ACGIH 2017 should be changed to ACGIH 2018a,b Insert your proposed change. Explain the context of your comment.
Continue numbering	Guidelines	272	General	The "recent theoretical models" should be referenced. Insert your proposed change. Explain the context of your comment.



Continue numbering	Guidelines	276	General	An ambient temperature of 28°C cannot actually be considered as "moderate", considering that the thermoneutral environment for the human body is about 21°C. Or should it be so? In which case it should be fully justified? Insert your proposed change. Explain the context of your comment.
Continue numbering	Guidelines	334	Technical	The ICNIRP 1998 Guidelines stipulate that "The hypothalamus is considered to be the control center for normal thermoregulatory processes, and its activity can be modified by a small local temperature increase under conditions in which rectal temperature remains constant" and they refer to a study by Adair et al. (1984) where "altered thermoregulatory behaviour starts when the temperature in the hypothalamic region rises by as little as $0.2 - 0.3$ °C". In the ICNIRP 2018 Guidelines, the operational adverse health effect threshold for brain tissues is 2°C, assigned as a Type 2 tissue. Therefore, the 2°C temperature elevation in the brain is 10 times higher than found by Adair's study. ICNIRP should add references about the effects of an increase in brain temperature up to 2°C and explain the inconsistency between the 2018 and 1998 ICNIRP Guidelines concerning this particular issue. Explain the context of your comment.
Continue numbering	Guidelines	364-366	Technical	These sentences are confusing: "Further, ICNIRP assumes realistic exposures (such as from radio-communications sources). This method provides for higher exposures in the limbs than in the head and torso." This should be clarified. Insert your proposed change. Explain the context of your comment.
Continue numbering	Guidelines	366	General	On which study is the choice of 20 W/kg for the head and torso, or 40 W/kg for the limbs based? Insert your proposed change. Explain the context of your comment.
Continue numbering	Guidelines	370	Technical	ICNIRP should be more explicit as to why the 6-minute average closely matches the thermal time constant for local exposure. Insertyourproposedchange. Explain the context of your comment.
Continue numbering	Guidelines	406-414	Technical	More explanation and references should be added to understand the origin and basis of the equations. Insert your proposed change. Explain the context of your comment.
Continue numbering	Guidelines	410	Technical	The rationale of the SA formula should be made explicit and described. Insert your proposed change. Explain the context of your comment.



Continue	Guidelines	414	General	The clarity of this paragraph should be improved.
numbering				Insertyourproposedchange.
				Explain the context of your comment.
Continue numbering	Guidelines	429	General	"To be compliant with the present guidelines, exposure cannot exceed any of the restrictions described below, nor those for the 100 kHz – 10 MHz range of the ICNIRP (2010)"
				Insertyourproposedchange.
				2010 ICNIRP's guidelines are established in order to limit exposure to low-frequency electromagnetic fields (1 to 100 kHz) and some guidance is extended to 10 MHz. However, the most restrictive values at e.g. 1 MHz can be extracted from ICNIRP's 2010 guidelines but are not in ICNIRP's 2018 guidelines.
Continue numbering	Guidelines	450, 467	General	The document needs to include a cross-check of the reduction factors (with specific attention given to consistency) with the other reduction factors, e.g. local exposure). It looks as if ICNIRP does not intend to change the basic restrictions issued in 1998.
				Insert your proposed change.
				Explain the context of your comment.
Continue	Guidelines	461	Technical	What are the scientific references to justify the choice of a 30-minute average?
numbering				Insertyourproposedchange.
				Explain the context of your comment.
Continue	Guidelines	487	General	Health effects associated with the local and centrally-mediated thermoregulatory process should be named.
numbering				Insertyourproposedchange.
				Explain the context of your comment.
Continue numbering	Guidelines	682	Technical	For a frequency of 100 kHz, reference levels could refer to ICNIRP 2010 or ICNIRP 2018 guidelines. However, values do not match, whether for electrical or magnetic fields (e.g. at 100 kHz 12,200 V/m (2018) vs. 170 V/m (2010) for workers).
				Even ICNIRP's 2010 guidelines do not apply to frequencies above 100 kHz; reference levels are given in the table. Between 0.1 MHz and 10 MHz, the limit values are not harmonized with ICNIRP 2010 LF Guidelines (e.g. at 10 MHz 122 V/m (2018) vs. 170 V/m (2010). This could be confusing.
				Insert your proposed change.
				Explain the context of your comment.
Continue numbering	Guidelines	601, 718 Table 3, Table 6	Technical	The definition of <6 min is not sufficient. For example, for a repeated pulsed radiation (e.g. 1 ms pulse) which lasts more than 6 min, how should we interpret the SA? In some working conditions, workers can be exposed to highly varying short-term exposure levels; how can the exposure be defined? Explain the context of your comment.



Continue numbering	Guidelines	709	Editorial	Typing error: 6 GHz instead of 66 GHz Insert your proposed change. Explain the context of your comment.
	Guidelines	825,828, 836,837, 840,849, 856,864	Technical	How is frequency "i" defined within a given frequency range? Insert your proposed change. If one considers RF power measurement, a resolution bandwidth is defined in order to have consistent and repeatable measurements. Discrete summations can give a value >1 even for communication channels that are "off" (noise) if a high number is considered!
Continue numbering	Appendix A	none	General	ICNIRP states that studies should be independently replicated in order to be taken as evidence, but most studies showing a temperature rise in the organs are authored by A. Hirata, member of the Icnirp RF guidelines project group. Insertyourproposedchange. Explain the context of your comment.
Continue numbering	Appendix A	190	Technical	"There is no data on body core temperature elevation for whole body exposure to radiofrequency EMF above 6 GHz." Having said that, the guidelines may therefore be highly uncertain about core temperature elevation above 6 GHz. The data from IR exposure is not able to replace data from microwave exposure. Insert your proposed change. Explain the context of your comment.
Continue numbering	Appendix A	210	General	Reference to be checked: Hirata et al. (2008b) seems to examine whole body SAR in the nine-month-old infant model, not a three- year-old child model. Insertyourproposedchange. Explain the context of your comment.
Continue numbering	Appendix A	230	Technical	It is questionable to extend the data on the temperature rise in a foetus up to 6 GHz from the data between 40-500 MHz. Local SAR/temperature hot spots in the foetus could be generated due to RF exposure above 500 MHz and up to 6 GHz. Insert your proposed change. Explain the context of your comment.
Continue numbering	Appendix A	334	Editorial	Takei et al, : already publishedInsert your proposed change.Explain the context of your comment.



Continue numbering	Appendix A	456	Editorial	Reference to be checked (see doi: 10.1186/s12938-017-0432-x) Explain the context of your comment.
Continue numbering	Appendix B	all	General	In all chapters, the references should be extended. Explain the context of your comment.
Continue numbering	Appendix B	23	General	Note that the WHO report is a draft document. Insertyourproposedchange. Explain the context of your comment.
Continue numbering	Appendix B	48	General	The difference between biological and adverse health effects is not clear. Temperature elevation is a biological effect, but it is considered as the critical effect used to derive limit values. Insert your proposed change. Explain the context of your comment.
Continue numbering	Appendix B	78	General	ICNIRP should provide a reference to justify "SAR>4 W/kg for non-human primates, exposures which correspond to an increase in body core temperatures of approximatively 1°C" Insertyourproposedchange. Explain the context of your comment.
Continue numbering	Appendix B	92-115	General	ICNIRP should provide references. Insertyourproposedchange. Explain the context of your comment.
Continue numbering	Appendix B	161-176	General	Cataracts and other effects on the eye may be included in section 3, "Auditory, vestibular and ocular function" Insert your proposed change. Explain the context of your comment.
Continue numbering	Appendix B	189	Technical	"The most recent report has provided (Roschmann, 1991)". This reference is old and only one publication is referred to here. This section needs more references. Insert your proposed change. Explain the context of your comment.



Continue numbering	Appendix B	200	General	What is the meaning of "changes to normal sensory processing"? Insert your proposed change. Explain the context of your comment.
Continue numbering	Appendix B	216	General	The rationale and scientific basis of "robust changes" should be clarified. Insertyourproposedchange. Explain the context of your comment.
Continue numbering	Appendix B	220	General	ICNIRP should provide references for "daily exposure to mobile phone signals does not impact plasma levels of melatonin or melatonin metabolism"
Continue numbering	Appendix B	226	General	The references of these epidemiological studies should be given. Does this mean that people's melatonin levels can vary just by them thinking that they are exposed?
Continue numbering	Appendix B	211 & 232	General	Is there a sound reason why the chapters on the neuroendocrine system and neurodegenerative diseases are not included in the chapter "brain physiology and function"?
Continue numbering	Appendix B	275	Editorial	The phrase "these are serious adverse health effects that need to be avoided" talking about death and thermal breakdown is awkward. Insertyourproposedchange. Explain the context of your comment.
Continue numbering	Appendix B	346	General	The NTP reports are currently draft documents. Insertyourproposedchange. Explain the context of your comment.
Continue numbering	Appendix B	378-386	General	An effect could be observed for higher cumulative call time groups even if there were no trends observed for any of the lower cumulative call time groups. This result may be interpreted carefully.
Continue numbering	Appendix B	406	General	"In Summary, no effects of radiofrequency EMF on Cancer have been substantiated" may sound like a contradiction with IARC's conclusion in its monographs (Non Ionizing Radiations, Part 2: Radiofrequency electromagnetic Fields) "Radiofrequency Electromagnetic Fields are "possibly Carcinogenic to Humans (group 2B)""