M. Olivér VÁRHELYI
Health commissioner
European Commission
rue de la Loi 200,
1049 Bruxelles, Belgique

Paris, 21st of February 2025

<u>Subject:</u> Request for rejection of the SCHEER "*Opinion on the need of a revision of the annexes in the Council Recommendation 1999/519/EC and Directive 2013/35/EU, in view of the latest scientific evidence available with regard to radiofrequency (100kHz – 300Ghz)*"

Dear Commissioner,

The applicants to this request hereby wish to alert the European Commission about the lack of conformity with European law and the lack of scientific reliability of the "*Opinion on the need of a revision of the annexes in the Council Recommendation 1999/519/EC and Directive 2013/35/EU, in view of the latest scientific evidence available with regard to radiofrequency (100kHz – 300Ghz)* (hereafter, "the SCHEER Opinion") adopted by the Scientific Committee on Health, Environmental and Emerging Risks ("SCHEER" hereafter) on the 18th of April 2023.

The applicants acknowledge this Opinion was requested by the European Commission, and that it presents the views of the individual members of the Ad Hoc expert committee, and therefore does not necessarily reflect the views of the European Commission.

However, as stated in the Opinion, the role of the SCHEER is to review new information that may influence the assessment of risks to human health in this matter, and to provide regular updates on the scientific evidence base to the Commission.

The European Commission's decision on establishing Scientific Committees in the field of public health, consumer safety and the environment of August 7th, 2015 (hereafter, the Commission's Decision), specifically states that "*The work of the Committees effectively contributes to improving public health and protecting citizens and the environment. <u>This is achieved by evaluating the latest available scientific data to provide the Commission with sound and timely evidence-based risk assessment and scientific advice for the development and monitoring of Union policies and legislation relating to public health, consumer safety and environmental risks.</u> (…) The work of the Scientific Committees should be based on the principles of high level of expertise, independence, and transparency. It must be organised in conformity with best practice and principles of risk assessment that is independent from risk management and decision making. The Committees' members should be highly qualified, specialised and independent experts, working in the public interest.*"

As the opinion was requested by the European Commission to assess the need for a revision of the current European regulatory framework on exposure to radiofrequency and electromagnetic fields (hereafter "RF EMF"), the applicants would like to express their concerns about the lack of conformity of the opinion with the Committee's Rules of Procedure and thus the reliability of the opinion.

In this Opinion, the SCHEER states that it "c*ould not identify moderate or strong level of evidence for adverse health effects resulting from chronic or acute RF EMF exposure from existing technology at levels below the limits set in the annexes of Council Recommendation 1999/519/EC and Directive 2013/35/EU. The SCHEER advises positively on the need of a technical revision of the annexes in Council Recommendation 1999/519/EC and Directive 2013/35/EU with regard to radiofrequency electromagnetic fields (100 kHz to 300 GHz), because there is a need to recognize the recently introduced dosimetric quantities and establish limits for them*."

<u>The failure to identify and establish the numerous adverse health effects resulting from chronic or acute exposure to radiofrequency below the established limits is a foreseeable consequence of the lack of adherence to the basic principles of risk assessment. In particular, the consequence of lack of independence and lack of excellence of the experts is that the assessment is unreliable - and in fact severely biased.</u>

Furthermore, the opinion is in stark contradiction with the position of the majority of the independent scientific community on the subject. Indeed, a large number of studies show the evidence of biological and health effects far below the limits set by the International Commission on Non-Ionising Radiation Protection on which the 1999 Council Recommendation is based (hereafter "ICNIRP"). Moreover, several appeals from the majority of the scientific community have stated that the limits are far too lenient to prevent adverse health effects.

According to the applicants, the SCHEER has produced a flawed scientific opinion which does not reflect the scientific consensus on the adverse health effects of chronic or acute RF-EMF exposure. The European Commission should not consider it as a reliable opinion in view of the composition of the working group and its flawed methodology (**1**), leading to an underestimation of the adverse health effects of RF-EMR exposure, both for human health and for the environment (fauna and flora are not even considered) (**2**).

In light of the above, the applicants request the rejection of the SCHEER opinion and that a new opinion on the matter should be issued by an independent body, free of any conflict of interest and links to the telecommunications industry (**3**).

1. The malfunctioning of the Scientific Committee and its flawed methodology

1.1. The malfunctioning of the Scientific Committee

- **<u>The composition of the Committee</u>**

The purpose of the SCHEER is to bring together the most qualified and independent experts on the subject under consideration, in order for them to review new information that may influence the assessment of risks to human health and the environment.

Article 4 of the Commission's 2015 Decision provides as follows:

> *"The members of the Scientific Committees shall be appointed by the Director General of the Directorate General for Health and Food Safety on the basis of the proven scientific expertise*

and of experience demonstrated by the candidates for the defined range of disciplines, having regard to the need to ensure:

(a) balanced representation of expertise in one or more of the fields of competence of the relevant Committee, in order to collectively cover the widest possible range of disciplines relevant for that Committee to fulfil its mission and to reflect the diversity of scientific problems and approaches;

(b) independence and absence of conflict of interest;

(c) balanced geographical origin representation; (d) balanced gender representation. "

Annex I of the Rules of Procedure specifies:

"2. Access to the best experts

The Committees should strive to involve or to consult the most qualified experts on the issue considered, while ensuring compliance with independence requirements. Experts should be selected taking also into account pluralism of views and multi-disciplinarily and, as far as possible, geographical origin distribution and gender balance."

At the time of the Opinion, the members of the SCHEER were the following : Professor Thomas BACKAUS (University of Gothenburg, Sweden), Doctor Teresa BORGES (Ministry of Health, Lisbon, Portugal), Doctor Wim DE JONG (Retired from RIVM, Bilthoven, the Netherlands), Professor Pim DE VOOGT (KWR Watercycle Research Institute, Nieuwegein, the Netherlands), Professor Raquel DUARTE-DAVIDSON (UKHSA, UK), Professor Peter HOET (Medical Faculty, Leuven, Belgium), Professor Ion RODICA-MARIANA (ICECHIM, Bucharest, Romania), Doctor Renate KRATKE (Federal Institute for Risk Assessment, Berlin, Germany), Professor Domesthenes PANAGIOTAKOS (Harokopio University, Athens, Greece), Professor Ana PROYKOVA (University of Sofia, Bulgaria), Doctor Theodoros SAMARAS (Aristotle University, Thessaloniki, Greece), Professor Marian SCOTT (University of Glasgow, Scotland), Doctor Emanuela TESTAI (Department of Primary Prevention Mechanism of Toxicity Unit, Rome, Italy), Professor Marco VIGHI (IMDEA Water Institute, Madrid, Spain) and Professor Sergej ZACHAROV (General University Hospital, Prague, Czech Republic).

The SCHEER Opinion 2023 was written by an Ad Hoc working group of eight persons, appointed for this particular task. The Ad Hoc group comprised **5 SCHEER members** (Doctor Teresa BORGES (Ministry of Health, Lisbon, Portugal), Professor Domesthenes PANAGIOTAKOS (Harokopio University, Athens, Greece), Professor Ana PROYKOVA (University of Sofia, Bulgaria), Doctor Theodoros SAMARAS (Aristotle University, Thessaloniki, Greece), Professor Marian SCOTT (University of Glasgow, Scotland)), and **3 external experts**: Clemens Dasenbrock, Heidi Danker-Hopfe and Olga Zeni.

The Ad hoc working group does not fulfill the criteria lined out in Article 4:

Half of the working group's members are not experts on RF EMR health effects, thus not representing the excellence in the field (main criterium of Article 4).

The other four experts have conflicts of interests, thus not fulfilling the criteria of independence (Article 4, b). These four members have ties to the industry in terms of research funding, membership of an industry organization, or possessing shares in companies with business related to this issue.

Furthermore, these four scientists have all previously expressed opinions favourable to upholding the prevailing exposure limits, stressing the one-sided representation of experts in the field (detail below).

In contrast, none of the majority of experts advocating for better protection through lowering the limits for RF-EMF exposure were selected for Ad Hoc working group.[1]

Therefore, and in the case at point, the Commission has failed to include representatives from the majority of the scientific experts in the matter. The composition of the Ad Hoc working group does not fulfill the criterium in Article 4.

- **The guiding principles of independence, commitment, and transparency**

The SCHEER is governed by a set of guiding principles, of which independence, commitment and transparency are paramount.

As set out in Article 16 of the Commission's Decision in Rule of Procedure III. b.:

> *"b. Independence*
>
> *9. The scientific advice must not be influenced by any consideration other than the scientific assessment of the risks in question.*
>
> *10. This principle implies in particular, independence from any external economic or political interests, but also from bias related to political, economic, social, philosophical, ethical or any other non-scientific considerations.*
>
> *11. The principle of independence refers to the organisation and results of the process, including in particular the independence criteria and conditions and arrangements for the participation of members and experts."*

Regarding the rules and procedures relating to independence, Rule V. specifies:

> *"17. Members and experts shall undertake to act independently from any external influence. They shall ensure that they do not directly or indirectly delegate their responsibilities to any other person or allow themselves to be influenced in any way during the execution of their duties.*
>
> *18. For this purpose, members and experts shall make in writing a Declaration of Interests (see Annex II) at the beginning of their mandate and then annually. Ad hoc experts shall make in writing a Declaration of Interests before the meeting to which they are invited.*
>
> *19. A Declaration of Interests shall not be required in relation to observers, since they do not have voting rights and do not participate in the formulation of recommendations or advice.*
>
> *20. Members and experts shall be in a position to show beyond question that they can act independently. They are under a continuing duty to declare before undertaking any activity, situation, circumstance or other fact potentially involving an interest, as indicated in Annex II, in order to enable the Scientific Committee and/or the Commission services to identify those interests which might be considered prejudicial to their independence.*
>
> *21.Declarations of Interests shall be published on the Scientific Committees' website and in the Register of Commission expert groups and other similar entities3. They must be complete and updated accordingly with any relevant additional or new information.*

1 Kelley, Blank, Lai, Moskowitz, "*International Appeal: Scientists call for protection from non-ionizing electromagnetic field exposure*" December 2015, European Journal of Oncology, Volume 20 (n. 3/4): pp. 180-182.

22. Members and experts participating in meetings of the Scientific Committees or in a working group, or in any other activity, shall declare at the beginning of each meeting or event any activity, situation, circumstance or other fact potentially involving an interest, as indicated in Annex II, in order to enable the Scientific Committee and/or the Commission services identify those interests which might be considered prejudicial to their independence in relation to the items on the agenda for that meeting or event. This declaration shall be made in writing or verbally, following a request of the Chair or the Secretariat and should be noted in the minutes of the meetings.

23. The Secretariat, the Chairs and the Committees shall ensure that the principles of independence of members and experts are complied with at all times. Members shall draw the Committee's and the Secretariat's attention through the Chair to any factual matter that could undermine credibility of Committee's work. The Committee's discussions of the matter shall be recorded.

24. The Secretariat shall draw the Commission services' attention to all cases where it appears that a member or expert might have ceased to fulfil the requirement to act independently from any external influence and address the measures to be taken, included as appropriate, the revocation of his/her appointment.

25. Any member or expert who, in accordance with his/her Declaration of Interests, or according to the opinion of the Scientific Committee, the working group or the Commission services, may not be able to act independently, shall be excluded from the activities considered or may only be allowed to participate to the extent and in a way compatible with the objective to preserve the process from any undue influence. In such case, the member or expert may not act as a Chair or rapporteur in relation to the specific matter and may not have voting rights. The extent of the concerned individual's participation in the Committee's work shall be decided by the Chair in consultation with the Committee or working group members and in agreement with the Commission services, within the framework of these Rules of Procedure. Measures may include the physical withdrawal from the meeting for the point under discussion, or limited participation.

26. Conclusions and decisions taken in relation to the Declarations of Interests, as well as their rationale, shall be recorded. In the case of declarations made at the meetings, the records shall be part of the minutes.

27. Members or experts contacted by third parties in connection with their participation on a specific question in Committee meetings, a working group or any other activity of the Scientific Committee shall inform the Secretariat and refer the third party to the Secretariat.

28. Members and experts shall inform the Secretariat of any relevant contacts they might have with petitioners, special interest groups, other stakeholders or other Union or international bodies in relation to the fields of work undertaken by the Committees (including Working Groups). The Secretariat, in consultation with the Scientific Committee in question, shall advise on any action to be taken if and when necessary should there be any possibility of a potential conflict of interest."

According to Rule III. d.:

"d. Commitment

13.The members and experts shall commit themselves to act independently, in the public interest and to contribute actively to the work of the Scientific Committees. They shall set an exemplary conduct in all activities related to the Scientific Committees.

d. Transparency

14. The meaning of the scientific advice, the way conclusions were drawn, the limits of their validity and the relevant uncertainties must be clear and understandable for users, relevant stakeholders, and the public. Equally, the organization and process leading to the scientific advice, as well as their rationale, must be presented in a clear and understandable manner. Openness, dialogue, and collaboration with other bodies and third parties should also contribute to transparency."

In this regard and based on Articles 18 and 19 of the Commission's Decision, Rules VII and VIII specify:

"VII. *Rules and procedures related to commitment*

(...) 35. Members and experts are expected to contribute actively to the discussion and deliberations on subjects within their field of competence during meetings of the Committees and the working groups and, when requested, with written comments. They shall take into account that meetings, in general, involve preparatory work and that requested contributions (e.g. studies, reports or drafting opinions) shall be provided in due time. (...)

VIII. *Rules and procedures related to transparency*

43. The Scientific Committees shall operate in accordance with the high level of transparency, without prejudice to legitimate requests for confidentiality or the need to safeguard the freedom and scientific integrity of the scientific debate and the independence of members and experts vis-à-vis external influence.

44. Requests for access to documents will be handled in accordance with the provisions of Regulation 1049/20016.

45. The following documents of the Scientific Committees shall be published on the Scientific Committees' website without undue delay by the Secretariat, subject to respect of confidentiality requirements as well as protection of personal data:

- *Draft agendas of plenary meetings of the Committees, and meetings of the Inter-Committee Coordination Group established in accordance with Chapter X point m.*
- *Minutes of plenary meetings and meetings of the Inter-Committee Coordination Group and working groups,*
- *Requests for opinions (mandates),*
- *Preliminary opinions published for public consultation and final opinions, including minority opinions and the names of the participants in the working groups that contributed to the opinion concerned. Minority opinions shall be attributed to the members concerned,*
- *Declarations of Commitment and Confidentiality of members and experts,*
- *Declarations of Interest of members and experts who participated in working groups; declarations of interest made in relation to items on the agendas of plenary meetings and working groups shall be published as part of meeting minutes,*

- *The names of the members of the Scientific Committees and experts, together with their brief CVs,*

- *Scientific Committee reports clarifying contentious issues as a result of a substantive divergence over scientific issues with other Union bodies (Article 13(3) of the Decision),*

- *Rules of Procedures,*

- *Stakeholder dialogue activities (consultations on mandates, calls for information, calls for experts, calls for hearings, public consultations on preliminary opinions etc.).*

Annex 1 of the Rules of Procedure specifies:

> *"1. Transparency of processes*
>
> *Both the processes applied and the opinions themselves must have a high degree of transparency. As far as the process is concerned, this requirement applies in particular to the way in which the relevant expertise is identified and organised, including the procedures for the identification and selection of experts in the Committees and working groups, the procedures for the identification and acquisition of the relevant data and information, the weight of evidence, the role of the different actors intervening in the process, the consultations held and the decision making procedures."*

In the case, at hand:

- Proof of lack of transparency, commitment, and independence

Journalists from Investigate Europe uncovered how a close-knit circle of pro-ICNIRP scientists, "the ICNIRP Cartel", some with documented ties to telecom interests, sat on all major official science review boards and referenced each other, thus creating an illusion of scientific consensus of no-risk from wireless technology products.

The SCHEER working group forms part of this closed circle of a few self-referencing expert groups. The SCHEER opinion report repeatedly refers to other reports from scientist groups within this closed circle. At the center of this circle is the officially sounding International Commission on Non-Ionizing Radiation Protection, or ICNIRP for short. ICNIRP is in fact a private invitation-only club.

The SCHEER report ignores a number of scientific reviews because the authors claim these have a "high risk of bias" (page 20). However, as we shall see below, 50% of the authors have themselves a high risk of bias due to ties and funding from industry and pro-industry organizations. Furthermore, they have made prior statements that are clearly in favor of the ICNIRP limits and thus to the telecommunications interests:

Theodoros Samaras: Associate member of IEEE/ICES. IEEE has also sponsored several of his publications. He is a former employee of and advisor to IT'IS Foundation, an organization funded by major telecom companies, and a shareholder of Tessaloniki Software solutions. He was also member of SCENIHR 2015 working group, which manufactured doubt about the evidence for harmful effects and then concluded that there were no adverse health effects.

Clemens Dasenbrock: Has received funding for research from Swiss Research Foundation for Electricity and Mobile Communication (FSM) that receives funding from telecommunications companies. He has also been a member of ICNIRP (SEG) and of SSM (Swedish Radiation Safety Authority) expert group for several years. SSM's report published in 2021 concluded that there is "no reason to change any reference levels or recommendations in the field".

Heidi Danker-Hopfe: Has received funding for research from the Swiss Research Foundation for Electricity and Mobile Communication (FSM) since 2016. FSM receives funding from telecommunications companies. She is also a member of the SSM (Swedish Radiation Safety Authority) expert group since many years and the German SSK (Strahlenschutz-kommission) expert group. The Swedish SSM 2021 report concluded that there is "no reason to change any reference levels or recommendations in the field" and the German group adopted a report in December 2021 concluding in line with the industry beneficial narrative that "there is currently no reliable evidence for health risks from exposures of persons below" the ICNIRP limits. She was also member of SCENIHR 2015 working group, concluding that there was no evidence for health effects.

Olga Zeni: Previously funded by Telecom Italia, Italy (wireless industry). She was also a member of SCENIHR 2015 working group, concluding that there is no evidence for health effects and the WHO 2014 expert group drafting sections. She has previously expressed opinions in favour of ICNIRP limits.

It is remarkable how the four appointed SCHEER working group members with expertise on RF biological effects, have all over the last years expressed positions that benefit continued adherence to the ICNIRP limits, in conflict with the majority of experts in the field. Furthermore, three of them were also on the SCENIHR 2015 working group (Samaras, Danker-Hopfe, Zeni). Consequently, it is no surprise that the SCHEER opinion takes the same position as the SCENIHR opinion 2015 in its attitude. Two of the experts are also on the Swedish SSM expert group, where a majority of the experts always have been members or consulting experts of ICNIRP. Several of them also receive funding from the telecommunications industry. Consequently, SSM reports have consistently concluded in favor of ICNIRP limits. In 2011, it was revealed that a prominent member of SSM and previous member of ICNIRP 1996-2008 and SCENIHR 2009/2007 (Anders Ahlbom) was a member of the board in his brother's telecom lobbying company in Brussels. Furthermore, the brother had previously been a lobbyist for the largest Swedish telecom operator, Telia, in Brussels.

The outcome of the SCHEER report can be said to be predetermined, merely by the choice of experts on the working group. The result is given by design.

Nordhagen and Flydal (2022) analyzed the composition of authors behind the reports on which the ICNIRP 2020 guidelines are based. Their analysis, published in 2022, shows that the authors of the ICNIRP 2020 guidelines paper are referring to themselves and their co-authors in a small circle of ICNIRP-affiliated co-authors, with only 17 researchers at its core: "Our analysis shows that ICNIRP 2020 itself, and in practice all its referenced supporting literature stem from a network of co-authors with just 17 researchers at its core, most of them affiliated with ICNIRP and/or the IEEE, and some of them being ICNIRP 2020 authors themselves. Moreover, literature reviews presented by ICNIRP 2020 as being from independent committees, are in fact products of this same informal network of collaborating authors, all committees having ICNIRP 2020 authors as members."

Journalists from Investigate Europe did an investigation of ICNIRP's influence on expert panels in 2019. Their report showed the influence of ICNIRP on other important health protection organizations and concluded that there was an ICNIRP cartel of experts that influenced SCENIHR/SCHEER and the WHO and other health agencies' conclusions on the topic.

Being a member of ICNIRP is a potential conflict of interest when acting on behalf of another organization, according to a decision by the ethical council of the Karolinska Institute. This opinion was based on an analysis of Anders Ahlbom, member of both ICNIRP (1996-2008), SCENIHR (2009 and 2007) and SSM (2002-2011).

Regarding Annex 1, transparency of weighing of the evidence. There is not transparence with regard to the selection of evidence and weighing of the evidence:

The Ad Hoc Group in outset only consider new meta-analysis and in some scientific reviews. The criteria for including reviews is not clear, as some major important recent scientific reviews are omitted. Furthermore, the Ad Hoc group choose to include other studies when they find it "relevant". There is no transparency as to why consider some studies "relevant" whereas a large number of high quality scientific studies are not considered to be relevant.

Finally, the Ad Hoc group do not consider the fact that a large part of the studies that are not showing effect, have used a type of radiation (pure sinus waves, i.e., non-modulated waves or information carrying waves) that is very different from the radiation from RF-EMF communication devices (highly modulated). They do not substantiate why they do not consider this especially important quality /relevance criterium - despite the fact that they reference one scientific review which demonstrate the importance of modulation. This bias explains the no-effect finding in a sizeable proportion of the studies that do not find effect. Nevertheless, the Ad Hoc group gives high weight to studies that are biased in this regard, even without discussing this issue.

When "weighing the evidence" the Ad Hoc group claims to follow the procedure described in the SCHEER memorandum. However, the opinion report shows many inconsistencies in this regard. It clearly does not follow the methodology lined out in the memorandum. The Ad Hoc group does not include all relevant research or other relevant lines of research when weighing the evidence.

In section 5.3.3, the Ad Hoc group even invents a category "*strong overall weight of evidence that the effects are not caused by RF exposure*" which does not exist in the memorandum (methodology), simply because it is highly unscientific. The common pattern of all the methodologic errors is a bias towards creating doubt regarding the evidence showing effect and substantiating the (biased) claims that there is no sufficient evidence of hazards from the exposure.

- **The scope of the Scientific Committee's mandate**

The SCHEER's activities are supposed to be limited by the terms of reference of its mandate, which limit and clearly define its activities and prerogatives.

According to **Rule I.2.** of the Rules of Procedure of the Scientific Committees, based on Article 2 of the Commission's Decision:

> "*2. The Scientific Committees support the European Commission in evidence-based policy making by providing risk assessment and scientific advice on matters related to public health, consumer safety and the environment.*"

According to **Rule X. c.** of the Rules of procedure:

> "*64. Requests for scientific opinions (mandates) shall be submitted by Commission services to the Secretariat.* ***The terms of reference of the mandate shall be limited to risk assessment.*** (…)
>
> *All mandates shall be reviewed by the Secretariat before submission to a Committee, for conformity with the applicable template, clarity and completeness, relevance in relation to the fields of competence of the Committee, appropriateness of the terminology and* ***absence of risk management aspects in the questions proposed****. (...)"*

Annex I, B, 15. Specifies:

> *"15. Avoidance of risk management statements*

Both the questions posed in a mandate and the replies provided in the opinion, shall not address risk management aspects. The opinions shall not recommend risk management measures.

Nevertheless, if so requested in a mandate, an opinion may assess (including comparatively) the effectiveness of specified measures in terms of risk reduction."

However, in the case at point:

- Proof of the SCHEER exceeding the terms of the mandate.

The main task of SCHEER is to assist in risk management. SCHEER is part of the political system under the Commission, but the rules from 2016 allow SCHEER also to perform risk assessment. This mixture of risk assessment and risk management is against fundamental principles laid down in the WHO and the EU the purpose of which is to protect the public and the environment.

The European agencies were created in recognition of the fact that a clear separation between the European policy system (risk management) and the organization providing the scientific advice (risk assessment) is crucial, in order to obtain objective risk assessment as a basis for policy making in the EU. When risk assessment is performed by the SCHEER, i.e., in a department under the EU Commission, it is a violation of the arm-length principle, and the principle of separation of risk assessment and risk management.

The appointment of experts without the required excellence in the field and experts with ties to the industry is also indicative of a violation of the arm-length principle.

Furthermore, the opinion does not even fulfill the basic requirements for risk assessment. Indeed, all relevant available scientific evidence must be considered in a risk assessment, not only a subjective selection of the evidence published within a short period of time. It should be added that "latest available scientific data" mentioned in the EC Decision, means all scientific data available as close as possible to the evaluation process.

- **<u>Cooperation with other scientific bodies and diverging opinions</u>**

The SCHEER is supposed to be proactive in seeking scientific collaboration and coordinating work with other experts in the field, especially when divergent opinions emerge. It has failed to do so.

In accordance with Rule XI. a:

"*Each Scientific Committee shall assist the Commission services and contribute in identifying, resolving or clarifying at an early stage potential or actual divergence between their scientific opinions and the scientific opinions of Union, national or international bodies carrying out similar tasks, on general or specific risk assessment issues. Each Scientific Committee shall assist and contribute in identifying needs and possibilities for coordination of work and collaboration, in particular the need for a joint opinion and/or a joint working group or exchange of experts as members of a working group.*

132. When a substantive divergence is identified with a Union risk assessment body, the Scientific Committee concerned shall, on the request of the Commission services, cooperate with the body concerned.

To this end, the Commission services may convene a meeting between the Scientific Committee and the scientific organs of the bodies concerned. The Scientific Committee shall designate a rapporteur.

133. When it is not possible to resolve divergent opinions, a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data shall be submitted to the Secretariat. This document shall be made public.

134. In order to help identifying, preventing or managing divergences over scientific opinions, the Secretariat shall seek to agree with Union bodies involved in risk assessment appropriate arrangements which may take the form of common guidelines".

Annex I of the Rules of procedure points out:

> *"3. Proactive search for scientific collaboration*
>
> *As far as reasonably feasible and appropriate in light of the objectives of the consultation and time constraints, consultation and collaboration with other scientific organisations dealing with the subject addressed by a Committee should be proactively sought. In particular, risk assessments available on the subject addressed should be looked for and the results duly considered."*

In the case at point, the SCHEER's Opinion is in striking contrast with the 2023 ANSES Opinion on the matter.

In its conclusion and recommendations (page 19), the ANSES states that it had already found, in its 2013 assessment and with the limited evidence at the time, several effects relating to:

- In animal models: sleep, male fertility and cognitive performance;
- In humans: gliomas in intensive users and neuroma of the vestibulo-acoustic nerve in epidemiological studies and, with sufficient evidence, a short-term physiological change in brain activity during sleep.

Specifically for children, the ANSES concluded in 2013 that radiofrequency might have an effect on:

- Cognitive functions: the results showing acute effects are based on experimental studies with well controlled methodology;
- Well-being

The ANSES stated that it will carry out methodological work on the establishment of exposure limits in the field of electromagnetic fields with the aim of proposing an appropriate method and new exposure limits, taking into account in particular the above-mentioned effects according to the level of evidence.

It concluded by stressing the importance of continuing to monitor exposure to electromagnetic fields and of adapting technical standards for measuring exposure to technological developments.

Thus, there seems to be a strong contrast between the SCHEER opinion and the ANSES assessment, which once again illustrates that the SCHEER opinion is not scientifically representative, as it does not take into account divergent opinions on the issue of RF-EMF exposure.

<u>Significantly, whilst adverse health effects have undeniably been demonstrated in animal studies, and whilst toxicity from other pollutants tested in animals is strictly accepted as composing a risk to humans, in the case of EMFs, the SHEER unilaterally discarded the relationship between animal and human risk.</u>

In opposition, the SCHEER could have investigated for a mechanism that aligns animal exposure dosing methodology with the simulation of human harm so that animal studies would have been transferable to humans and accepted as sufficient evidence of human harm.

The Opinion also conflicts with the majority of field experts on the matter.

The majority composed of 259 scientists from this field of research, with more than 2000 peer reviewed studies between them, have signed a joint statement (EMF-Scientist Appeal) demanding better protection through lowered limits for RFR exposure in link with the growing evidence of harmful effects of exposures below the ICNIRP limits : *"It is our opinion that, because the ICNIRP guidelines do not cover long-term exposure and low-intensity effects, they are insufficient to protect public health"*.

In October 2022, a group of 16 world leading scientists within the independent International Commission on the Biological Effects of Electromagnetic Fields (ICBE-EMF) published a peer reviewed paper providing evidence that the ICNIRP limits endorsed by the EU Commission are based on outdated and since disqualified assumptions. Hence, it demonstrated that the ICNIRP limits do not offer sufficient protection against harmful effects. This paper also concluded that the exposure limits must be lowered, and that the 5G roll-out must be halted:

"The past 25 years of extensive research on RFR demonstrates that the assumptions underlying the FCC's and ICNIRP's exposure limits are invalid and continue to present a public health harm".

In addition, the 5G Appeal, signed by over 433 scientists and medical doctors, concludes that 5G will lead to "potential serious health effects" and a "massive increase of mandatory exposure" to radiofrequency radiation. The 5G Appeal has repeatedly been communicated to the EU Commission. The first two studies on health effects in humans from 5G base station radiation published in 2023 (case studies) supported that 5G increase radiation exposure massively, indicating that 5G can rapidly cause symptoms historically known as the microwave syndrome although the levels were below the ICNIRP limits.

In 2016, a group of European medical doctors published the EUROPAEM EMF guidelines. In this publication it is recommended that exposure to RF should not exceed between 0.000001% to 0.001% of ICNIRP limit during extended exposure (at least 4 hours a day) to frequencies between GSM 900 to Wi-Fi 5,6 GHz, depending on sensitivity, night-time, or daytime exposure. Thus, very much lower maximum levels than the ICNIRP 2020 levels of 10 million microwatts per square meter averaged over 6 or 30 minutes.

1.2. The misapplication of rules, procedures, and methodology

According to **Rule III.6,** "*the Scientific Committees shall perform their tasks in compliance with the principles of excellence, independence, confidentiality, commitment and transparency, in accordance with Articles 16-19 of the Decision."*

In this case, the SCHEER opinion is shown to have inadequate, partial and unscientific methodology.

- **The guiding principle of excellence**

According to Rule III. a.:

> *"7. The scientific advice must represent the best information and guidance on the assessment of the risks considered that science can provide at the time of adoption of the opinion under the conditions and deadlines imposed. It shall be based on the best data, scientific knowledge and methodology available at the time of preparation of an opinion.*
>
> *8. The principle of excellence refers to the performance and outcome of the entire process. It refers in particular to the intrinsic scientific quality of the opinion, its adequacy in relation to the aims of the mandate, its clarity, completeness and transparency. It also refers to the*

effective communication of the contents and conclusions of the opinions and the actual and perceived credibility of the process."

In this case, the assessment falls short of the principle of excellence as the Committee members lack documented expertise in the field. It also omits distinguished scientists and involves others with industry ties and conflicts of interest.

- **Methodology, weight of the evidence and uncertainties**

The methodology employed by SCHEER is meant to be governed by a set of specific rules that encompass scope, evidence weighing, data usage, and risk assessment. In the case in question, the methodology rules were not followed.

In accordance with Annex I, B:

"7. Definition of objectives and scope

The scope and objectives of the risk assessment should be clearly defined in the mandate, in collaboration between the requesting Commission service and the Committee.

8. Transparency of opinions

Transparency should be ensured on all aspects of an opinion, including data and methods used and calculations and assumptions made, in such a way that the risk assessment performed and its conclusions are understandable and reproducible.

9. Use of best data

The risk assessment should be based on the best reasonably obtainable data and information at the time of the consultation. Limitations related to the data used, in particular due to time or other practical constraints, must be explained. Strategies and procedures for identifying and acquiring data and information shall be documented and sources of data shall be clearly identified in the opinion.

10. Best practice methodological approach

Risk assessment methods and procedures applied shall correspond to best international practices and accepted standards. In cases where a Committee considers it appropriate to use novel or non-validated methodological approaches in the development of an opinion, the Committee shall ensure that it clearly documents and explains the reasons/benefits for using such a method as well as its potential limitations.

Specific guidelines on the methodological approach to be used, (e.g., how to weight evidence, or assess uncertainties), may be elaborated by the Committee in the form of memoranda or notes of guidance that shall take into consideration best practices used for risk assessment. (…)

12. Qualitative and quantitative assessment

Risk assessment should be, as far as relevant and scientifically and practically possible, quantitative. When qualitative assessment is made, the narrative assessment should provide an unequivocal description and characterisation, of the nature, extent, probability, and magnitude of the risk.

In particular, ranges (or bounds) and scenario/sensitivity analyses may be used as rather simple ways to provide information about the uncertainty of the measured risks. (…)

17. Expression of risks

Risks should be expressed quantitatively as far as scientifically and practically feasible, account taken of the data and knowledge available. Uncertainty and variability of the risk estimate should be presented contextually. Expression of risks includes its nature, scope and distribution, probability, and magnitude.

Framing risks, if appropriate, in particular referring to notions of acceptability of certain risks using terms like "acceptable risk", "normal risk", "serious risk", "safe" etc. should be avoided and preference should be given to descriptive terms deriving from the results of the risk assessment (i.e., versus the margin of safety, probability and severity of effects etc.). Notions of ranking or acceptability of risks should only be introduced based on an approach and criteria that have been previously agreed with the risk managers."

More specifically and concerning the weighing of evidence, Annex I B. 11 of the Rules of Procedure specifies the following:

"11. Clarity on weight of evidence

The development of a scientific opinion ought to be the result of the critical evaluation of data/evidence and expert judgement. It is therefore essential that both the evidence and the expert judgement are properly presented, explained, and documented in each opinion.

The specific criteria (quantity, quality, strength, relevance, etc.) for critically evaluating data and scientific information that have led to decisions on whether to include or exclude them, or partially take them into account by attributing to them a certain weight, shall be clearly explained. Their application in the specific case considered shall also be documented and explained in the opinion.

The criteria used for attributing a weight to the various streams of evidence in order to determine the existence of risks, and characterise them, and to draw conclusions, as well the application of those criteria should also be explained.

In a similar manner, the expert judgement should be properly explained and documented to clearly demonstrate the contribution of evidence and of expert judgement in the opinion and its conclusions."

The rules governing the weight of evidence and uncertainties are exposed in the 2018 Memorandum of Weight of evidence and uncertainties, adopted by the SCHEER in 2018.

The latter states that the three main steps are the following:

"2. Identification, collection and selection of the possible sources of evidence

3. Assessment and weighing of individual lines of evidence

4. Integration of different lines of evidence".

The SCHEER Opinion consistently contravened the guidelines for evaluating evidence, as they are outlined in the 2018 Memorandum.

This critical analysis exposes several partial approaches, including the hand-picking of reports that predominantly align with the interests of the ICNIRP Cartel.

Another issue identified by the applicants is the evaluation of the included studies: it tends to draw biased conclusions. For instance, section 5.3.3.1 claims a "strong overall weight of evidence that such effects are not caused by RF exposure," despite the existence of evidence supporting the effects. Furthermore, the claim is scientifically non-sense, as (claimed) insufficient evidence cannot be evidence of a different causal relation, and the claim is in clear conflict with the 2018 memorandum.

Additionally, the report states that "effects are uncertain," even though there is robust evidence for adverse health effects. This inconsistency challenges the objectivity of the findings.

The SCHEER consistently omits pertinent lines of research that are crucial for assessing the evidence, as outlined in the methodology document.

It is also crucial to consider all pertinent scientific evidence, whereas SCHEER's selection of evidence is biased and only includes recent materials.

One such example of biased evaluation is the clear and consistent evidence for increased risk of brain tumors in mobile phone users with more than 10 years of exposure in the heaviest user group. This has been the result of repeated meta-analysis of available epidemiological studies. In this case SCHEER chose to create doubt about the solid evidence, by referring to “significant criticism” from two letters to the scientific journal editor of one of these meta-analyses. The two letters were each coauthored by members of ICNIRP, thus propagating the ICNIRP cartel biased view. In conflict with the methodology document, SCHEER also fails to mention that the evidence of cancerous effects is consolidated by the solid evidence of oxidative stress and DNA damage caused by the radiation (i.e., evidence for the mechanism) and further the cancerous effects found in the largest animal studies. Other experts conclude: “When the cumulative body of evidence is assessed, the overall picture on low intensity nonthermal levels of RFR [radiofrequency radiation] shows a clear and consistent pattern of adverse effects that form the basis of the mechanisms whereby RFR can cause the cancers seen in human populations.”

Further, regarding studies that do not find effects, SCHEER fails to analyze whether it has failed because of poor study design, e.g., irrelevant exposure. In contrast, irrelevant criteria are used to discard a large body of studies that finds effects, e.g., the strict demands for dosimetry, where this criterium it is not relevant or pertinent.

There is evidence that effects from exposure is highly dependent on the modulation of the radiation as well as duration of the exposure, some of which is even referenced by SCHEER. Nevertheless, in weighing the evidence, SCHEER repeatedly fails to acknowledge importance of modulation and duration. It also <u>falsely claims</u> that lack of effects from exposure with pure sinus-waves (un-modulated) or very short exposure is “conflicting evidence”, with regard to evidence of effects from strongly modulated radiation (as from the wireless communication technologies) and long-term exposure.

In addition, SCHEER fails to specify whether their conclusions are based on studies on short-term exposure or long-term exposure, although this is clearly an important factor.

Part 1 conclusion:

In summary, the SCHEER's primary responsibility is to aid the EU Commission in risk management. However, the European Commission has given the SCHEER mandate to perform risk assessment under certain conditions, listed in this document. In its Opinion, the SCHEER provides both risk management advice, which is subjective, and risk assessment, which involves identifying potential hazards. However, when the SCHEER attempts to execute both risk assessment and risk management, it merges two different competencies, contravening the principle of a clear separation between the two.

As per the Terms of Reference (TOR) for the SCHEER to provide risk management support, it is recommended that independent bodies conduct the prior risk assessment to prevent conflicts of interest from influencing the risk assessment.

2. Leading to an underestimation of the adverse health effects of RF EMF exposure

Due to the aforementioned (1), the SCHEER's Opinion on RF-EMF exposure significantly underestimates the negative health impacts it has on both human health (2.1) and the environment (2.2).

2.1. The underestimation of the harmful effects of RF EMR on human health

The SCHEER Opinion finds that they "*Could not identify moderate or strong level of evidence for adverse health effects resulting from chronic or acute RF EMF exposure at levels below the limits set in the annexes of Council Recommendation 1999/519/EC and Directive 2013/35/EU*".

The conclusion is based on a severely biased assessment, which does not adhere to the methodology document. Among others, the majority of the evidence is excluded, the selection of evidence is biased, and the weighing of the evidence is unscientific as important errors in non-effect studies are not considered.

This Opinion strongly contrasts with the majority of experts on the matter, who agree that the limits allow exposure to harmful levels of radiation and should be stricter.

Among the effects that have been documented to occur below the threshold of the EU Commission endorsed ICNIRP limits are: Negative effects on the brain and the nervous system, behavioural effects (symptoms such as headache, dizziness, and sleep disturbances), DNA-damage, oxidative stress, harmful effects on sperms and increased risk of cancer. Alone, the formation of reactive oxidative species (ROS) and the resulting oxidative stress has been evidenced in more than 200 scientific papers and is a probable cause of many other of the observed effects, as ROS interfere with basic cellular functions.

During the last two decades, scientific evidence showing harmful effects from Radiofrequency electromagnetic radiation (RF radiation) has grown and accumulated to a substantial amount of straightforward evidence showing harmful effects on humans and animals from exposure below the ICNIRP exposure limits recommended by the EU Commission in 1999. This RF radiation is emitted into the environment from ubiquitous wireless technologies, such as 2G, 3G, 4G, 5G, Wi-Fi, et cetera.

Already in 1999, the very year the EU adopted ICNIRP guidelines, scientific evidence showed DNA-damage, brain damage and increased risk of cancer from exposure levels below those thermal exposure limits. There was also evidence of increased risk of various symptoms such as sleep disturbances, headache, dizziness caused by chronic exposure to RF at non-thermal levels. In 2009, the European Environmental Agency stated that there was sufficient evidence for health effects (DNA damage and cancer) below the ICNIRP guidelines to warrant the implementation of the precautionary principle. This was ignored by the EU Commission.

Scientists in this research field have, since the start of this millennium, repeatedly called for better protection of the public and the environment against the many health and environmental effects associated with long term exposure below the ICNIRP thermal-based limits. As of today, a majority of the scientists in the field (259), have signed the EMF Scientists Appeal demanding better protection:

- Due to the growing evidence of harmful effects well below the ICNIRP exposure limits: *"It is our opinion that, because the ICNIRP guidelines do not cover long-term exposure and low-intensity effects, they are insufficient to protect public health."*

433 scientists and medical doctors have signed the 5G Appeal asking for a moratorium of the 5G roll out due to potential serious health consequences and the massive increase of mandatory exposure.

In 2012, the BioInitiative Report which was prepared by 29 scientists from ten countries was published. It concluded that, already by then, harmful effects were "clearly established" at exposure intensities well below the ICNIRP limits, and further, "public safety limits for electromagnetic and radiofrequency fields (ICNIRP) remain thousands of times higher than exposure levels that health studies consistently show to be associated with serious health impacts. Based on toxicological principles, the BioInitiative group in 2012 recommended an exposure limit for RFR radiation of 30-60 µW/m2, and even lower for sensitive persons and children, and 3-6 µW/m2 for the protection against all known health effects. These recommended thresholds for protection against health effects from long term exposure are of an order of 1 million below the ICNIRP thresholds for protection against short term heating. In 2022 BioInitiative scientists wrote:

"When the cumulative body of evidence is assessed, the overall picture on low-intensity non-thermal levels of RFR [radiofrequency radiation] shows a clear and consistent pattern of adverse effects that form the basis of the mechanisms whereby RFR can cause the cancers seen in human populations. Of 261 studies looking at oxidative effects from RFR exposure, 240 (91%) showed damage. Of 346 studies on effects of RFR on genes, 224 (65%) reported genetic damage. Oxidative stress and genetic damage are the major mechanisms leading to cancer. In addition, RFR exposure causes effects on brain and behaviour. Of 336 studies published on RFR neurological effects, 73% reported effects, and only 27% showed no effect."

In 2016, European scientists and physicians published recommendations (The EUROPAEM EMF guidelines) for maximum exposure to RF radiation of 10-1 000 µW/m2, at night-time down to 1-100 µW/m2, and even lower for sensitive persons: 0.1-10 µW/m2.

In October 2022, a group of 16 world-leading scientists within the International Commission on the Biological Effects of Electromagnetic Fields (ICBE-EMF) published a peer reviewed paper, "Scientific evidence invalidates health assumptions underlying the FCC and ICNIRP exposure limit determinations for radiofrequency radiation: implications for 5G." The scientist provide evidence that the ICNIRP limits are based on false and outdated assumptions, do not protect against harmful effects, and conclude that the exposure limits must be lowered, and that the 5G roll-out must be halted: "ICNIRP's exposure limits are invalid and continue to present a public health harm."

In November 2022, a former long-time member of ICNIRP, Professor James C. Lin, concluded in a peer-reviewed article: "there are consistent indications from epidemiological studies and animal investigations that RF exposure is probably carcinogenic to humans. The principle of ALARA—as low as reasonably achievable—ought to be adopted as a strategy for RF health and safety protection."

The Opinion also ignores the lack of studies on 5G millimetre waves. The ICNIRP 2020 paper gives an all clear for the telecom industry to roll out 5G at very high frequencies never used before on entire populations. If adopted, the telecom industry can expose entire populations to high levels of microwave and millimetre waves up to limits that only protect against the outdated paradigm that there are only thermal effects. SCHEER fails to address possible health effects from these higher frequencies, that will be added to those frequencies already in use for 5G (3.5 GHz) in combination with 4G. The telecom industry plan is to add very high frequencies (24 GHz- 56 GHz) called FR2 or 5G step 2, that according to SCHEER "requires positioning 5G base stations every few hundred meters in dense urban areas".

Scientists agree that there are no studies investigating the effects on humans or living beings in the environment from exposure to these additional frequencies. The SCHEER Opinion paper will give the EU Commission an all clear to adopt the outdated ICNIRP 2020 limits, which ICNIRP falsely claims will protect everybody from any health effects: There is no science to back up the claim, neither for the 3.5 GHz frequencies (FR1) and, even more importantly, nor for the frequencies above 24 GHz. This is an unacceptable negligence that might even be considered scientific misconduct.

Health Council of the Netherlands Report (2020) even recommended not to use 26 GHz band for as long as the potential health risks have not been investigated:

"There has been almost no research into the effects of exposure to frequencies around 26 GHz…. The committee recommends not to use the 26 GHz frequency band for 5G for as long as the potential health risks have not been investigated."

Whereas which SCHEER refer to the same report from the Health Council of the Netherlands repeatedly on many topics through the Opinion report, SCHEER choose to ignore this conclusion on the technology using millimetre waves, which is not in favour of the industry. This further adds to the severe SCHEERs severe negligence.

2.2. The failure to include the environmental effects of RF-EMF on flora and fauna

In its 2023 Opinion (n°2021-SA-0192), the ANSES highlights the need to further study the possible effect of radio frequencies on fauna and flora, in addition to the effects observed on human health due to environmental exposure. The ANSES states that such information could be considered when setting the recommended limits of exposure.

Conclusion of Part 2:

The European Commission is responsible for planning, preparing, and presenting new legislative proposals. The legislative acts it proposes must defend the interests of the Union and its citizens.

If the Commission were to rely on the Opinion in determining whether to revise the legislation on prescribed exposure limits to RF-EMF, malpractice would ensue since the decision would not be based on reliable and unbiased scientific assessment and would be in breach of the Rules of Procedure.

3. The applicant's requests

The applicants urge the Commission to acknowledge the numerous inadequacies of the SCHEER's Opinion and thereby disqualify it.

They further call for the institution to direct a qualified entity to undertake a reliable and impartial assessment of the matter in question.

Since the basis for the judgments are pertinent for the validity of the risk assessments, it is a main obligation to ensure that the scientific assessors are independent, i.e., not disqualified due to political and economic interests.

In 2009, the EEA called for the implementation of the precautionary principle to protect the human populations against possible health effect from RF radiation from telecommunication devices:

"The evidence is now strong enough, using the precautionary principle, to justify the following steps: 1. For governments, the mobile phone industry, and the public to take all reasonable measures to reduce exposures to EMF, especially to radio frequencies from mobile phones, and particularly the exposures to children and young adults who seem to be most at risk from head tumours."

This recommendation was since repeated by the EEA, e.g., in the report "Late Lessons from Early Warnings" in 2013: *"Precautionary actions now to reduce head exposures, as pointed out by the EEA in 2007, and many others since, would limit the size and seriousness of any brain tumour risk that may exist. Reducing exposures may also help to reduce the other possible harms…."* The warnings and recommendations from the EEA have been ignored by the EU Commission.

In view of the large amount of science on the effect of EMF published in the past decade, the EU commission should request a full risk assessment from a competent independent scientific expert group under an authority which is independent from any political system (risk management).

Conclusion

To conclude, it has been shown that the SCHEER Opinion presents a partial and untrustworthy scientific assessment regarding the adverse health impacts of RF-EMF exposure below the prescribed limits and, hence, should not be considered by the European Commission for the above-mentioned reasons.

It would be malpractice for the European Commission to rely on this opinion to assess the need for new legislation in this area, as the opinion lacks a satisfactory and qualitative risk assessment of the issue.

Therefore, the applicants respectfully request that the European Commission acknowledge the numerous insufficiencies found within SCHEER's Opinion and disregard it. They further request that an impartial and reliable scientific evaluation be conducted, in order to assess the potential health and environmental hazards posed by exposure to RF-EMF below the set limits.

The assessment should be conducted by qualified experts free of any conflicts of interest or ties to the industry.

We look forward to your reply and remain
Yours Sincerely.

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