

The Director General

Maisons-Alfort, 1 June 2021

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

on the "health effects associated with exposure to virtual and/or augmented reality technologies"

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 published on its website. This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 1 June 2021 shall prevail.

On 19 April 2017, ANSES issued an internal request to conduct the following expert appraisal: "health effects associated with exposure to virtual and/or augmented reality technologies".

1. BACKGROUND AND PURPOSE OF THE REQUEST

The rapid development of new audiovisual technologies using virtual reality (VR) and/or augmented reality (AR) techniques, their growing availability to the general public and their increasing use in the workplace are surrounded by questions about their possible health effects. These questions, which had already been raised in the conclusions of ANSES's 2014 opinion on the health effects of stereoscopic audiovisual technologies in 3D (commonly referred to simply as 3D), called for a specific expert appraisal to be conducted on this topic.

After an opinion of ANSES's Scientific Board, the Agency therefore issued an internal request to assess the potential health effects associated with exposure to virtual and/or augmented reality technologies.

Virtual and/or augmented reality techniques have now been in use in the workplace in various sectors (e.g. automotive, healthcare, etc.) for several decades. Virtual reality has recently been

given a new lease of life with the increasing availability and rapid spread of headsets intended for the general public. In their instructions for use, most headset manufacturers warn users about possible discomfort (e.g. eye strain, nausea, dizziness, etc.) and even advise against the use of these devices by children under 12 or 13 years of age. However, their precautions are not based on any scientific arguments, nor are there any studies to back up the warnings.

Virtual reality and/or augmented reality refer to specific forms of human-computer interaction. In the case of virtual reality, users are immersed in an entirely computer-generated virtual world by means of sensorimotor interfaces with which they interact. With augmented reality, interaction with computer-generated virtual images enhances the information obtained from real objects and the environment.

2. ORGANISATION OF THE EXPERT APPRAISAL

This expert appraisal falls within the sphere of competence of the Expert Committee (CES) on "Physical agents, new technologies and development areas". The Agency mandated the Working Group on "Health effects associated with exposure to virtual and/or augmented reality" to conduct this expert appraisal under the leadership of the CES.

2.1. Working Group

The Working Group was formed following a public call for applications. The experts in this group were selected for their scientific and technical skills in the areas of virtual and/or augmented reality technologies, ophthalmology, neurosciences, psychosocial sciences and ergonomics. Set up in March 2018, the Working Group held 27 plenary sessions between March 2018 and December 2020.

2.2. External contributions

To make up for the lack of data on the characterisation of exposure to virtual and augmented reality technologies, two studies were funded by ANSES.

Survey of the general population

A study was commissioned from OpinionWay with a view to surveying the general population in order to collect exposure data on virtual and augmented reality technologies (population concerned, type of application used, frequency of use and content type).

Physical measurements on headsets and telephones

A research and development agreement was signed between ANSES and the French Scientific and Technical Centre for Building (CSTB), with the aim of clarifying exposure to the different types of physical agents emitted by virtual reality devices. The study sought to characterise the electromagnetic field emissions of several types of virtual reality devices (headsets and telephones), as well as the composition and temporal modulation of the light emitted by the screens.

2.3. Collective expert appraisal

The methodological and scientific aspects of the expert appraisal work were regularly submitted to the CES. The report produced by the Working Group takes account of the observations and additional information discussed with CES members. This expert appraisal

work was therefore conducted by a group of experts with complementary skills. It was carried out in accordance with the French Standard NF X 50-110 "Quality in Expertise Activities".

Interests declared by the experts were analysed by ANSES before they were appointed and throughout their work in order to prevent risks of conflicts of interest in relation to the points addressed in the expert appraisal. The experts' declarations of interests are made public via the ANSES website: <u>http://www.anses.fr</u>.

2.4. Questions addressed

With a view to gaining a better understanding of the potential risks to the population of these technologies, ANSES's expert appraisal began by describing them through:

- a classification of the possible applications and contexts of use;
- a presentation of the different virtual and/or augmented reality devices and interfaces available (visual interfaces, auditory devices, haptic interfaces¹);
- a presentation of the content that can be visualised via the devices and its characteristics (scenes and stimuli, user experience, ways of interacting with the device).

These aspects are described in Chapter 2 of the expert appraisal report.

In order to better understand the potential adverse effects of virtual and augmented reality on human health, the physiological mechanisms involved in human interaction with these technologies were described. These mechanisms particularly concern the visual and vestibular systems and their interactions, and involve effects not only on the central nervous system but also on the autonomous (peripheral) nervous system.

This information provided the basis for the assessment of the health risks associated with the use of virtual and augmented reality, using the evidence available on exposure of the population and on the harmful health effects.

A debate was also held on the ethical questions raised by the use of these technologies, drawing on the available literature.

2.5. Expert appraisal method

Literature search and analysis

The collective expert appraisal was mainly based on a critical analysis and summary of the data published in the scientific literature (articles, reports, etc.). The literature search covered the period from January 2010 to January 2020. This is because virtual and augmented reality technologies have evolved rapidly in recent years, limiting the relevance of scientific publications prior to 2010.

The results of the studies financed by ANSES supplemented the knowledge of population exposure to virtual and augmented reality technologies, and were taken into account in the expert appraisal.

The Working Group also interviewed external scientific experts and other individuals (representatives of the union of leisure software publishers) in order to add to the information and data available for the expert appraisal.

¹ A haptic interface is a force feedback system. It enables the user to interact with a software application or virtual object through the sense of touch.

Assessment of the level of evidence for health effects

This expert appraisal only investigated the potential adverse effects; the therapeutic effects of virtual and/or augmented reality devices were not assessed. For each adverse health effect studied, the results from the selected studies were considered in order to characterise the levels of evidence for the link between exposure to virtual and/or augmented reality technologies and the occurrence of that effect.

The experts ultimately arrived at an overall assessment of the level of evidence for a health effect associated with exposure to virtual and/or augmented reality according to one of the following categories:

- proven effect;
- probable effect;
- possible effect;
- not possible to conclude from the available data as to whether or not there is an effect;
- probably no effect.

Characterisation of exposure

Exposure of the general and occupational populations was characterised by a description of the users (adults and children), the frequency and duration of use, and also by the type of content viewed. In addition, exposure to the physical agents (blue light, temporal light modulation, noise and electromagnetic fields) emitted by different types of devices was also studied.

3. ANALYSIS AND CONCLUSIONS OF THE CES

3.1. Exposure to virtual and/or augmented reality

Few data are available on the exposure of populations to virtual and/or augmented reality, despite the fact that these technologies are increasingly being used outside the workplace, in the private sphere and by the general public. Only a few studies on the subject were identified. The expert appraisal therefore focused on generating data to document this aspect with the help of a cross-sectional survey. The results of this survey were combined with data from the available studies, in order to clarify the characteristics of virtual and/or augmented reality users in France and make initial assessments of exposure in the occupational, private or public spheres, in terms of exposure time, content viewed and devices used.

In general, whether it concerns augmented reality or virtual reality, the average duration of a session exceeds one hour for almost all uses, with the median duration being one hour for both adults and children.

Adult users are more often men (57%) with an average age of 40, from higher socioprofessional categories (43%) and with a good command of technological tools. Among children, there is a slight predominance of boys (55%), and the average age is 12.7 years. Overall, the most represented age groups are 9-11 years and 12-14 years.

In the private sphere, virtual reality is used more than augmented reality. The main application is for video games, especially among children. The smartphone is the primary medium used by adults, while games consoles are more common among children. However, both adults and

children use three types of interfaces on average, the most cited being smartphones, dedicated headsets and games consoles.

In occupational settings, use of the two technologies is fairly similar. The main purpose is for training, healthcare or stock management, and smartphones are used less than computers and headsets.

3.2. Adverse health effects associated with exposure to virtual and/or augmented reality

The objective of the expert appraisal was to assess the level of evidence for the potential adverse health effects reported in the scientific literature. It should be noted that the selected studies on adverse health effects were conducted exclusively in humans, and not in animals. This is because animal studies are rare and were not considered relevant.

Studies on the beneficial health effects, assessed in therapeutic trials, were not taken into account if there were no results on adverse side effects. Nevertheless, their importance for better understanding the mechanisms behind the occurrence of health effects will be examined at the end of this section.

The following health effects are documented in the scientific literature:

- effects related to the ergonomics of virtual and/or augmented reality interfaces (musculoskeletal disorders, accidents², effects due to the hygiene of the interface and to noise levels);
- cybersickness (virtual reality sickness): nausea, vomiting, headaches, general discomfort, vision effects, physiological effects (cardiac, gastric, respiratory, dermal, etc.), vestibular effects (dizziness);
- impaired sensorimotor coordination caused by exposure;
- psychological and psychosocial effects such as emotional risks, derealisation (detachment from one's surroundings), dependency on the interface and content, content-related effects (violence, relationship to sexuality, etc.), social isolation;
- effects that alter self-image (through avatars);
- effects related to physical agents emitted by virtual and/or augmented reality devices (blue light and temporal light modulation³, electromagnetic fields);
- neurological effects (epileptic seizures);
- effects on development (emotional, cognitive) of the visual and auditory systems.

For each of the health effects listed above, and according to the availability of data from scientific publications of sufficient quality, the experts assessed the level of evidence for the health effect associated with exposure to virtual and/or augmented reality and detailed the associated mechanisms. The results of this assessment are presented below.

² Accidents are defined here as falls or collisions caused by, for example, poor lighting or the concealment or cluttering of the surrounding area.

³ Temporal light modulation is a variation over time of the luminance of the light object at a frequency that may or may not make this phenomenon visible to the human eye. Temporal modulation may not be detected by the eye but may still be associated with health effects.

3.2.1. Sufficiently documented health effects

For virtual reality, some health effects were sufficiently documented to enable the Working Group to identify them and assess the associated level of evidence:

- cybersickness, which is the subject of the vast majority of publications identified, and which includes effects on the central and peripheral (autonomous and somatic) nervous systems, including effects on posture and balance, as well as vision effects;
- effects occurring only after exposure (changes in sensorimotor and perceptual abilities);
- effects related to physical agents: blue light, temporal light modulation (headaches, eye strain, etc.), electromagnetic fields emitted by devices.

The intensity of these effects depends on the exposure devices (interface) and content offered, but also on each person's individual susceptibility.

Cybersickness

Symptoms and physiological measurements

Cybersickness (virtual reality sickness) encompasses a group of symptoms that can be experienced during exposure to virtual reality: pallor, discomfort, vision disorders, disorientation, headaches, fatigue, dizziness and postural instability, nausea, vomiting, tachycardia and hypersalivation. Cybersickness affects between 30 and 50% of users, depending on the type of population (see the OpinionWay survey for ANSES), and can occur very rapidly after the start of a session (in less than 5 minutes). The chance of cybersickness occurring depends heavily on the content (rollercoaster ride or calm landscape, etc.), the field of vision involved (the wider it is, the more intense the symptoms may be), and the visual interface and mode of interaction.

Visual symptoms, which are common in cybersickness, may include eye strain, oculomotor disorders, migraines and headaches, blurred vision during and after exposure, visual discomfort, dry eyes, eye burning and watering. These symptoms are usually temporary and disappear within minutes or hours of exposure.

Some studies show an increase in postural instability during or after exposure to virtual reality, which can go as far as loss of balance when the content is particularly likely to provoke a reaction (i.e. rollercoaster). Although the risk of loss of balance decreases very quickly even during exposure, the persistence of postural instability after exposure is still poorly documented.

Virtual reality experiences also induce effects on the central and peripheral nervous systems, according to mechanisms that are still relatively unknown. A combination of subjective (via scales or questionnaires) and objective (physiological measurements) means are used to assess the severity of the cybersickness symptoms experienced during a virtual reality session. There is a correlation between the subjective severity of the symptoms and their physiological manifestation (cardiac, neurological, sensory, dermal, digestive or respiratory variables, etc.). In general, the effects increase with the exposure time and/or provocative nature of the content (virtual situation, speed or direction of navigation, etc.), but decrease with repeated sessions, i.e. habituation.

Contexts favouring the occurrence of cybersickness

The analysis of the identified studies found both technological and individual factors associated with an increased risk of developing cybersickness, although the mechanisms are not yet

understood. The diversity of the factors taken into account, the exposure times and conditions and the use of different questionnaires (e.g. during exposure, before and after, after only) limit the ability to reach a conclusion as to the conditions under which cybersickness occurs.

Among the technological factors, the method of navigation (walking, driving, flying, etc.) is often cited as a causal factor, but no conclusion on its direct involvement could be drawn from the evidence provided by the available studies. On the other hand, a properly ventilated environment, pleasant music or perfume can reduce the intensity of cybersickness.

The way in which the user receives the visual information may also increase the severity of the symptoms experienced. The use of a headset, for example, is associated with more pronounced cybersickness (in terms of symptom severity), although it is not possible to distinguish the roles played by stereoscopic rendering, active head movement, or the type of control over the visual environment.

Lastly, few studies have looked at technological factors other than visual ones that may contribute to the occurrence of cybersickness. For example, it has been shown that the auditory rendering of movement while the user is static can cause cybersickness.

Individual susceptibility is due to a wide variety of factors. In general, the susceptibility of people aged 12 to 50 may be explained by the greater acuity of their sensory systems. Other vulnerable groups include people prone to postural instability, motion sickness, anxiety and migraines. A higher susceptibility to cybersickness has also been reported for women who are pregnant or in the middle of their menstrual cycle. Conversely, experience using these technologies seems to decrease the intensity of cybersickness symptoms.

To reduce the risk of symptoms during exposure, therefore, these people should avoid viewing fast, multi-dimensional movements (i.e. those in more than two directions, with accelerations, both forwards and backwards) and avoid using headsets. Curbing body movements, for example by sitting on a chair with a backrest, also helps limit symptoms. Limiting movement and using breathing techniques also help reduce the severity of symptoms in people susceptible to cybersickness.

According to the Working Group and the CES, there is sufficient evidence in human experimental studies to conclude that there is a link between exposure to virtual reality and the occurrence of cybersickness. Cybersickness is therefore a proven effect of exposure to virtual reality. The symptoms seem to be reversible, but there are not enough data in the literature to assess whether or not they persist.

Effects occurring only after exposure

The expert appraisal highlighted the existence of adverse effects (changes in sensorimotor and perceptual abilities) occurring after exposure to virtual and/or augmented reality, linked to sensory incongruence⁴ during exposure.

The Working Group and the CES concluded that exposure has a proven effect on sensorimotor and perceptual abilities. These effects may persist for several hours after exposure and the return to pre-exposure performance may depend on the type of incongruence experienced.

⁴ Poor adaptation of signals to each other.

Effects associated with physical agents

A campaign of measurements on virtual reality headsets⁵ was undertaken during this expert appraisal. It was used to document electromagnetic field emissions and characterise the temporal modulation of the light emitted by the headsets.

With regard to the electromagnetic fields emitted by virtual reality devices, these are generated by their radiofrequency transmitters (for communications such as Wi-Fi, Bluetooth, 4G, 5G, etc.) and by electromagnetic interference that may come from the circuits, sensors and electronic equipment built into the headsets. The levels of electromagnetic fields measured on virtual reality headsets are low and the resulting exposure is well below the regulatory limits. The most recent expert appraisals carried out by ANSES have not demonstrated any causal link between exposure to low levels of electromagnetic fields and the occurrence of health effects.

Similarly, the luminance levels of the light emitted by the displays of the virtual reality devices tested were low. However, they can contain high levels of blue light, whose effect on the disruption of circadian rhythms and sleep has been proven (ANSES, 2019⁶). Furthermore, the consequences on the retina of long-term exposure at short distances from the eyes remain to be determined. Regarding children, adolescents and young adults, the still maturing lens has very poor filtering ability for blue light, making them more susceptible to all blue-light-emitting devices.

Lastly, all the headsets tested exhibited very high temporal light modulation, with rates of around 100% (which is never the case with the normal screens of tablets, smartphones, TVs, computers, etc.), in a frequency range from 70 to 90 Hz. The Working Group reiterates that ANSES's 2019 expert appraisal on the health effects of LEDs had concluded that "the effect of temporal light modulation (in the frequency range of 1 to 80 Hz) on the triggering of seizures in people with epilepsy was proven", and "the effect of temporal light modulation (in the frequency range of 50 to 120 Hz) on eye strain, the triggering of headaches and migraines was possible".

3.2.2. Adverse health effects for which no conclusion could be drawn (lack of data)

The lack of data in the scientific literature (absence of or too few studies, depending on the effect) meant that it was not possible to conclude as to whether or not there are any adverse health effects from virtual and/or augmented reality, for the following effects:

- ergonomics-related, e.g. musculoskeletal disorders, occurrence of accidents (no studies on virtual reality, too few studies on augmented reality with a focus on mobile augmented reality alone);
- psychological and psychosocial (too few studies);
- on self-image in the virtual world (too few studies);
- neurological (no studies);
- on development (no longitudinal studies).

With regard to ergonomics-related effects, the few studies available have methodological limitations. Focusing on augmented reality in mobile situations, they report a low prevalence

⁵ Only headsets with integrated displays were tested, and not headsets using smartphones.

⁶ ANSES Opinion of 2019 on the effects on human health and the environment (fauna and flora) of systems using light-emitting diodes (LEDs).

of musculoskeletal disorders, similar to that observed for other forms of light to moderate physical activity performed outdoors. The few summaries on virtual or augmented reality provide qualitative data on the variety of physical impairments, but no information on their prevalence. They include injuries, fractures and tendon damage. Another dimension examined is the impact on workload (information overload).

With regard to the effects of self-image in the virtual world (avatar), this subject has only recently started to be investigated due to recent technological advances in headsets, realistic rendering and computing power. The studies are very fragmented and mainly focus on situations where the avatar's characteristics are imposed on the user. Nevertheless, they appear to indicate that the feeling of embodiment in a virtual human (avatar) does have an influence. This influence, which is not simply related to pleasure or realism criteria, seems to be very real and is reflected in possible behavioural changes during and after exposure. While the studies mainly show behavioural changes regarded as "positive" (improved social behaviour, less sensitive to gender or racist stereotypes), the mechanisms leading to these changes could just as easily produce "negative" changes, although for ethical reasons this has not been studied directly. The results of these studies are enough to underline the need for vigilance.

With regard to other psychological or psychosocial effects, the experts identified a very limited group of studies assessing the potentially harmful psychological effects attributed to virtual reality. Research has focused in particular on the possibility of an altered relationship with reality. The few studies assessing paranoid ideations after exposure to virtual reality cannot be used to rule on a possible adverse effect specific to virtual reality. Although one study showed that virtual reality can induce symptoms equating to derealisation, these may not necessarily be harmful and could even contribute to the person's well-being. The issue of exposure to violent content was also discussed, but it was impossible to distinguish effects of the violent content from effects of the virtual reality device.

There are no data on the possible adverse neurological effects of exposure to virtual or augmented reality.

Concerning harmful effects on development, there are no longitudinal studies available to assess the long-term effects of exposure to virtual or augmented reality. Nevertheless, the Working Group examined the effects of exposure to virtual and/or augmented reality during childhood or adolescence on development (in all its dimensions: psychological, visual, sensorimotor, etc.).

3.3. Susceptible population groups

The CES emphasises that through the studies analysed, the Working Group identified population groups that are particularly vulnerable and likely to develop adverse effects following exposure to virtual and/or augmented reality.

- populations that are in principle more susceptible to cybersickness, because of their physiological state and the destabilising conditions associated with virtual and/or augmented reality, due to difficulties with multi-sensory integration:
 - o pregnant women;
 - people with vestibular disorders (otolith disorders, abnormal vestibulo-ocular reflex, especially at medium and fast frequencies);
 - people prone to motion sickness;

- people suffering from static postural and/or dynamic balance anomalies with proprioception disorders (cervical disorders, major osteoarticular disorders, people suffering from Parkinson's disease, the elderly, etc.);
- people susceptible to oculomotor disorders such as strabismus, convergence insufficiency, anisophoria, anisometropia (unequal refractive error), relative amblyopia (difference in visual perception between the two eyes), uncorrected ametropia; people suffering from eye diseases or anomalies;
- migraine sufferers;
- o people with an anxious temperament or who suffer from panic attacks.
- populations that are more susceptible to the light radiation emitted by the devices, due to their age or state of health:
 - children, adolescents and young adults (clear lens); aphakic (no lens) and pseudophakic (artificial lens) individuals; people suffering from eye diseases or anomalies;
 - people suffering from sleep disorders;
 - people suffering from photosensitive epilepsy.

Virtual and augmented reality are however used on some of these susceptible populations for therapeutic re-education within a medical framework where there is awareness of the risks. In this context, special attention needs to be paid to these populations.

In addition, the CES and the Working Group draw attention to the possibility that the effects of virtual or augmented reality on the autonomous nervous system may aggravate pre-existing conditions in certain population groups. These include people suffering from certain heart diseases (angina, heart failure, rhythm disorders, uncontrolled cardiac conduction disorders) or primary or secondary neuropathic disorders linked to metabolic disorders, uncontrolled high blood pressure, etc.

3.4. Ethical aspects of exposure to virtual and/or augmented reality

A specific literature review was conducted to examine studies raising ethical questions about user exposure to virtual and augmented reality devices, or about the effects on others and on society.

This literature varies widely in terms of its scientific legitimacy. Many publications simply assert, without proof, a number of hypotheses that generally stem from an ideological position (e.g. technophobia). In brief, few studies are based on either a field approach or rational argumentation or demonstration.

Several fundamental questions emerge, however, on which it would be worth conducting a more in-depth and concerted reflection with all the actors involved (designers, financiers, distributors, prescribers, professional and individual users).

Is it ethically acceptable for virtual or augmented environments to evade ethical questioning on the grounds that they are not part of the real environment? To put it another way, should the ethical precepts that guide the choices and actions of the actors involved (from the designer through to the end user) in the real environment also serve as a reference framework for their decisions and actions in virtual or augmented reality? This question can obviously be extended to the possibility of letting users make choices in virtual worlds in line with their personal

philosophy, and not forcing them to decide between two eventualities that in their eyes are equally reprehensible (for example, during an escape sequence in a game, a companion is slowing me down: I have the choice between abandoning him or killing him, as helping him to walk is not an option offered by the game designer).

Is it ethically acceptable for the actors involved to fail to take account of the (proven and/or potential) effects of exposure to a virtual or augmented environment that may occur following this exposure? Does their responsibility end at the spatial and temporal "borders" of the virtual or augmented environment, or should it extend beyond (into the real environment, during and after exposure)? If so, how should this responsibility be limited in space and time and to whom should it be assigned?

Furthermore, the ideological positions (e.g. technophiles versus technophobes) disseminated in the media, in certain works and present in public discourse contribute to the cacophony around the benefit/risk ratio of virtual and/or augmented reality. The idea that exposure to virtual reality devices may cause dependency and addiction has not been backed up by any scientific evidence to date. An ethic of scientifically based information is needed to ensure that the actors' decisions can be framed by ethical precepts. These decisions include those by designers who create environments that prescribe ethically questionable actions, professionals who enable the public to use devices without informing them of the possible adverse effects, and users whose behaviour is ethically questionable.

3.5. Conclusions of the CES and of the Working Group

In conclusion, the CES draws attention to the sufficiently documented health effects detailed above, in particular cybersickness and post-exposure effects involving changes to sensorimotor and perceptual abilities. These appear to be reversible, although the duration of their persistence is unknown. This expert appraisal also stresses that certain devices used in virtual and augmented reality may be responsible for health effects associated with the light emitted, whether due to its blue component or its strong temporal modulation.

In addition to these well-documented effects, there are still numerous uncertainties about the possible harmful consequences of using virtual and/or augmented reality. The CES notes that there is a lack of data on the possible adverse effects of virtual and/or augmented reality, some of which have not yet been studied by the scientific community.

Virtual and augmented reality technologies are now widely used for therapeutic purposes, with claims of effectiveness. Although this effectiveness was not analysed in this expert appraisal, it does suggest that these technologies can have a lasting effect on humans, on their psychology, memory, physiology, etc. An understanding of the mechanisms involved in the use of virtual and augmented reality technologies in this therapeutic context could help identify any adverse effects that have not yet been documented or foreseen.

3.6. Recommendations of the CES and of the Working Group

The CES reiterates the recommendations of the Working Group concerning provision of information about the health effects of virtual and augmented reality, regulation of the uses in order to protect users, and improving knowledge of the potentially harmful health effects of exposure to these technologies.

Recommendations to inform users about the proven health effects

Insofar as the Working Group has identified proven health effects, users (professionals and individuals) should be informed by appropriate means that the use of virtual and/or augmented reality can:

- lead to the occurrence of cybersickness and related symptoms, some of which may persist after exposure;
- have sensorimotor consequences (e.g. impaired manual dexterity or ability to orientate the body) after exposure;
- lead to the disruption of circadian rhythms (difficulty falling asleep, sleep time, etc.) when users are exposed to the light emitted by the devices;
- induce epileptic seizures in susceptible individuals.

Recommendations to inform users about health effects for which no conclusion could be drawn

In addition, the CES and the Working Group draw attention to the insufficiently documented health effects about which users should also be informed:

- if an avatar is used, behavioural repercussions during and after exposure;
- ergonomics-related effects, e.g. musculoskeletal disorders, occurrence of accidents (no studies on virtual reality, too few studies on augmented reality with a focus on mobile augmented reality alone);
- psychological and psychosocial effects (too few studies);
- neurological effects (no studies);
- developmental effects (no longitudinal studies).

In this context, users should be informed about the necessary precautions:

- take a rest after exposure, especially before driving a vehicle or using tools or machinery;
- cease exposure immediately if symptoms appear, except when used in an assisted therapeutic or professional context;

Lastly, people – especially those identified as susceptible – should be advised to limit their exposure.

Recommendations to regulate or supervise uses in order to protect people by limiting the occurrence of effects:

- protect the most susceptible populations (see above) through mandatory provision of information to them and limiting exposure times, or even limiting access to these technologies in the public sphere;
- regulate the use of technology (apart from in the private sphere) by:
 - using suitable premises, including a room where users can rest after exposure to limit the risk of accidents due to temporary difficulties re-adapting to the real environment;
 - having experienced people supervise the risks to ensure that users are not a danger to themselves or to others (virtual reality room, sufficient space, etc.);
 - allowing users to cease exposure at any time, insofar as the virtual and/or augmented reality experience may affect a person's well-being;

 providing information on the recommended age ranges for the content offered (e.g. using the European PEGI⁷ rating system).

And more specifically for professional uses:

- impose alternatives to virtual reality for susceptible people;
- encourage the creation of training courses for users of virtual and/or augmented reality devices.

Recommendations for studies and research

In general, in order to be able to make better use of research results when assessing health risks associated with exposure to virtual and/or augmented reality, the reproducibility of studies and the description of technological devices and procedures in scientific publications should be improved (characterisation of exposure, devices used, exposure time, etc.).

The CES recommends encouraging the generation of knowledge and documentation of the mechanisms involved in therapeutic effects.

Better documentation is also needed on the health effects for which no conclusion could be drawn, along with a clearer understanding of the associated mechanisms of occurrence:

- investigate the psychological and psychosocial risks associated with the use of virtual and/or augmented reality; the effects of exposure on children's development; the potential neurological effects, problematic uses and addiction;
- better understand the effects of embodiment in an avatar;
- better document effects caused by exposure or occurring after exposure;
- identify more precisely the technical factors (interfaces, duration of exposure, context and type of use, etc.) and individual factors involved in the occurrence of the various harmful health effects;
- clarify the effects related to ergonomics (risk of falling, accidents, etc.);
- analyse the virtual reality content available to the general public in order to assess the incongruence experienced and the possible effects occurring after exposure.

More specifically, with regard to cybersickness, further studies should be carried out to:

- better document the individual factors that may contribute to the occurrence of cybersickness;
- investigate the mechanisms of occurrence of cybersickness and its persistence after exposure, and their relationship with the different technological parameters;
- examine the possibility of conducting tests to measure postural organisation and spontaneous body sway prior to exposure, with the aim of predicting whether or not a person will be susceptible to cybersickness.

It would also be worthwhile studying the health effects of co-exposure to virtual and/or augmented reality and other risk factors such as tobacco, psychotropic substances, alcohol, etc.

⁷ PEGI: Pan European Game Information. The rating consists of two sets of logos, the first indicates the minimum age of the player with a number, and the second indicates the content type (e.g. violent or offensive content) by means of a picture and/or word.

Lastly, the long-term consequences of repeated exposure should be investigated, in particular the potential aggravation of pre-existing conditions, as well as all the proven and suspected adverse effects.

In terms of exposure, efforts should be made to obtain a better characterisation of exposed populations and uses:

- gain a better understanding of the uses in order to assess the associated risks in a more meaningful way;
- gain a better understanding of the population involved and the duration of their exposure;
- better document exposure of the population to different physical agents (blue light, temporal modulation, sound, radiofrequency electromagnetic fields) when using a mobile telephone as a virtual and/or augmented reality device.

Ethical aspects should also be taken into account:

- conduct an in-depth and concerted reflection with the actors involved on the ethical issues raised by exposure to virtual and augmented reality;
- initiate a debate on the legal provisions that could govern the use of virtual and augmented reality devices.

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

The areas of application of virtual and/or augmented reality technologies have now gone beyond the professional domain, flourishing in recent years in a variety of uses (educational, therapeutic, recreational, informational, etc.) that now reach a wider, more diversified and particularly younger audience.

This development has gone hand in hand with the appearance in the scientific literature of reports of various symptoms (nausea and dizziness, eye strain, general fatigue, etc.) by headset users, associated with possible sensorimotor inconsistencies (e.g. delay between when the user moves their head and when the image in the headset is updated).

These findings led ANSES to issue an internal request, in order to analyse in detail the possible health effects associated with the use of virtual and augmented reality.

Virtual reality and augmented reality technologies are also used in a therapeutic context for effects regarded as positive for humans, in the treatment of certain disorders (e.g. phobias, addiction, etc.). However, these beneficial aspects were not examined in this expert appraisal.

The French Agency for Food, Environmental and Occupational Health & Safety endorses the conclusions and recommendations of its CES on "Physical agents, new technologies and development areas".

With regard to potential harmful effects, the analysis of the available scientific literature showed that exposure to virtual reality can:

 disrupt the sensory system and lead to symptoms (such as nausea, dizziness, sweating, pallor, etc.) that are grouped together under the term "cybersickness". These symptoms can occur very rapidly upon exposure in susceptible people. These symptoms appear to be reversible, but their possible persistence is insufficiently documented; • also, after exposure, lead to changes in sensorimotor and perceptual abilities.

In addition, headsets and mobile telephones (which can be integrated into headsets) use LED screens rich in blue light at only a short distance – a few centimetres – from the eyes. In its 2019 expert appraisal⁸, ANSES had shown that exposure to blue light in the evening or at night can lead to the disruption of circadian rhythms. Furthermore, exposure to blue light may induce toxic effects on the retina in the long term. Lastly, exposure to the temporal modulation of the light emitted by these LED screens can trigger epileptic seizures in susceptible individuals.

To avoid their occurrence, therefore, uses and exposure should be adapted, and the Agency particularly recommends:

- ceasing exposure as soon as symptoms of cybersickness appear, in order to limit the risk of accidents (linked to possible disruption of the vestibular system);
- observing a rest period after any exposure;
- ceasing use two hours before bedtime (especially for the most susceptible populations such as children and adolescents) in order to avoid exposure to blue light from virtual and/or augmented reality technology screens;
- advising against the use of virtual and/or augmented reality technologies by epileptics.

The Agency recommends that clear information on these effects be made available to the various users:

- professionals, through dedicated training or materials and guides;
- the general public (both private sphere and public places), through labelling, posters, etc.

The Agency recommends increasing awareness among occupational health stakeholders and in particular considering the proven effects in order to protect worker health (including information on the risks of virtual/augmented reality in the "single document" on occupational risk assessment, the need to offer alternatives to virtual and/or augmented reality technologies, monitoring of exposure in occupational settings, consideration of individual sensitivities in conjunction with occupational medicine, etc.).

With regard to exposure, the Agency points out that very few data on the occupational and general populations are currently available. The study it conducted of a representative sample of the general population showed relatively high average use times, with sessions lasting an average of one hour. Given the variety of environments in which virtual/augmented reality is used, developments in use and exposure should be documented by including exposure to virtual reality in major studies on living conditions (for example, via the CREDOC survey on the Living conditions and aspirations of the French, or the annual SUMER⁹ and Working conditions surveys conducted by DARES).

The analysis of the available data showed that many aspects have not yet been sufficiently investigated and documented, in particular the understanding of long-term effects associated with repeated exposure. Regarding this, ANSES wishes to stress that:

 cybersickness is the best described health effect in the scientific literature – apart from the question of its persistence – although there is a clear lack of data for other suspected adverse health effects (behavioural and developmental effects);

⁸ ANSES expert appraisal report, published in 2019, on the "effects on human health and the environment (fauna and flora) of systems using light-emitting diodes (LEDs)" ⁹ SUMER: A survey reporting on medical surveillance of employees' exposure to occupational risks

⁹ SUMER: A survey reporting on medical surveillance of employees' exposure to occupational risks

- the long-term effects of exposure to virtual and/or augmented reality technologies need to be considered, particularly those related to cybersickness (effect on the visual system) and the effects of repeated exposure;
- the available studies tend to focus on use, and their primary purpose is not to assess the health effects. It is therefore important to encourage research whose primary purpose is to assess the possible adverse effects of virtual and/or augmented reality. Moreover, it would be beneficial to better exploit studies on positive health effects in order to gain a better understanding of the underlying mechanisms to help understand the adverse health effects.

The expert appraisal also led to the identification of ethical questions on the use of virtual and/or augmented reality technologies. Three categories of effects that raise ethical questions were identified:

- effects on users: infringement of their freedom and/or safety, privacy, addiction, identity disorders, disrupted inhibitions, de-socialisation and discrepancies between moral judgement and actions;
- effects on others (e.g. infringement of the freedom of others, infringement of their safety or physical integrity due to violent behaviour);
- societal effects: pressure on social values, exacerbation of a paranoid representation
 of social interactions, "gamification" of culture, existence of social inequalities in training
 and tools intended for healthcare professionals and patient care, and possible
 instrumentalisation of virtual and/or augmented reality devices by healthcare
 practitioners for commercial purposes.

ANSES therefore considers that an in-depth debate should be conducted by and with the actors involved on the ethical issues raised by exposure to virtual and/or augmented reality. Given the diversity of uses (professional, health, leisure, etc.) and the types of actors involved (software publishers, hardware developers, application designers, etc.), the Agency recommends establishing an explicit ethical framework for each occupational category.

Beyond the effects associated with the use of virtual and/or augmented reality devices, the health effects of digital tools in the broader sense appear to depend on many factors and in particular the media used (telephones, tablets, etc.), the content, the times, places and contexts of use (daytime or evening, with the family, assisted or alone, etc.), the purpose of the use or individual vulnerabilities (social or biological). In this context, ANSES has undertaken an expert appraisal of the effects of digital tools on the health of children and adolescents. Through an analysis of the scientific literature on this topic, this should provide some answers and opportunities for better understanding the possible adverse effects, identifying ways of preventing them and recommending how to regulate their use.

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