ANSES Opinion
Request No 2014-SA-0253

The Director General

Maisons-Alfort, 5 April 2019

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

on the "effects on human health and the environment (fauna and flora) of systems using light-emitting diodes (LEDs)"

On 19 December 2014, ANSES received a formal request from the Directorate General for Health, Directorate General for Labour, Directorate General for Risk Prevention and Directorate General for Competition, Consumer Affairs and Fraud Control to undertake an expert appraisal assessing the effects on human health and the environment (fauna and flora) of systems using light-emitting diodes (LEDs).

1. BACKGROUND AND PURPOSE OF THE REQUEST

The objective of the expert appraisal undertaken by ANSES was to update knowledge on the health effects related to exposure to lighting systems using LEDs. The request focused more specifically on assessing the risks associated with exposure to LED systems for the general population and workers, distinguishing between the different types of applications of LED lighting systems and objects (domestic lighting, professional uses, vehicle lights, toys, screens, etc.) and taking into account real situations of exposure. Moreover, a review of the potential environmental risks associated with these systems throughout their life cycle was requested.

Pursuant to Directive 2005/32/EC on the eco-design of energy-using products, known as the "EuP" Directive, the planned withdrawal of incandescent lamps (spread out between 2009 and 2012) and conventional halogen lamps (set for September 2018) from the lighting market has led to a sharp increase in LED lighting systems on the consumer market, thus increasing the population's exposure to lighting systems using this technology. The scope of LED systems has expanded: it now includes not only a large number of applications for professional use, but also applications for public use including displays and signs, as well as certain objects and devices (toys, decorative objects, etc.), backlighting in screens (mobile telephones, tablets, televisions, etc.) and indoor and outdoor lighting.

When publishing its first Opinion on the health effects associated with LEDs (ANSES's collective expert appraisal report published in 2010[1]), the Agency drew attention to the retinal toxicity of blue light. Indeed, LEDs are unique in that they emit light rich in short wavelengths: this is known as blue-rich light. On this occasion, ANSES issued recommendations relating, among other things, to the placing on the market of LEDs and the provision of information to consumers.

The potential health effects associated with exposure to the light emitted by LEDs are now better documented. Since the Opinion issued by the Agency in 2010, new experimental data, obtained in animals in particular, have been published regarding the phototoxicity associated with long-term exposure to blue light. New data have also been published relating to the disruptive effects of blue light on the biological clock, glare, and the health effects associated with temporal light modulation (light-intensity fluctuations in lighting that may be visually perceived depending on frequency). Regarding the possible effects on the environment, there are data that raise questions about potentially induced imbalances in ecosystems, which may have consequences for fauna and flora as well as for humans and human health.

Adding or substituting artificial light to/for natural sunlight raises the issue of the potential health effects this may cause, due to the accumulation or modification of the lighting environment. Over the past few decades, humans have considerably increased their exposure to blue light in the evening with artificial lighting and backlights rich in blue light. Previously, the lighting systems used had tended to be yellow-orange in colour (candles, incandescent lamps).

The update of the expert appraisal considered all of the effects on human health and the environment (fauna and flora) that could be associated with exposure to the light of LED lamps.

2. Organisation and methodology 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 a Working Group of experts, entitled "Health effects of LED systems", to undertake this expert appraisal under the leadership of the CES.

Working Group

The Working Group was formed following a public call for applications issued on 28 April 2015. The experts in this group were selected for their scientific and technical skills in the areas of physics, optical radiation metrology, vision, ophthalmology, chronobiology, biology, the environment and lighting regulations. The Working Group was created in September 2015. It met 25 times in plenary sessions between September 2015 and May 2018.

[1] https://www.anses.fr/fr/system/files/AP2008sa0408.pdf.

External contributions

To make up for the lack of data relating to the characterisation of exposure to LED systems, three studies were financed by the Agency.

Characterisation of the artificial lighting systems available on the French market

First of all, a research and development agreement was drawn up between the Agency and the French National Consumer Institute (INC) in order to conduct an updated comparative study of the technical properties of various lighting systems available on the market.

Documentation of exposure to light in populations

The implementation of a second study was entrusted to the French Scientific and Technical Centre for Building (CSTB), in order to characterise the population's exposure to various artificial lighting and LED systems, in real conditions of exposure. A software program developed to that end enabled light exposure to be assessed for several exposure scenarios (children, workers, elderly people, etc.).

Assessment of blue-light protection systems intended for the general public

A third study was undertaken with the CSTB to assess the blue-light filtration capacities of protective devices intended for the general public (screen filters, treated lenses, blocking glasses, software protection).

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 the CES members. This expert appraisal 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 have been made public via the ANSES website: http://www.anses.fr

Expert appraisal methodology

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 was thus undertaken for the period from January 2010 to July 2017.

The results of the studies financed by ANSES to supplement knowledge of protective devices and exposure to artificial light in populations were taken into account in the expert appraisal.

The Working Group also interviewed external experts and figures, as well as representatives from the lighting industry and environmental protection associations, inviting them to contribute information and data supplementing the data available for the expert appraisal.

Assessment of the level of evidence for health effects

For each studied health effect, the results of the available studies undertaken in humans on the one hand and animals on the other hand were considered separately to characterise the evidence provided regarding the connection between exposure to LED light, in particular blue-rich light, and the occurrence of the health effect. In the end, the evidence for humans and animals was combined in order to establish an overall assessment of the level of evidence for the health effect of exposure to LED light, classifying it into one of the following categories:

- proven effect;
- probable effect;

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

Characterisation of exposure

The lack of literature data dealing with the population's exposure to LED technologies led ANSES to finance specific measurement campaigns, in particular to describe the type and quantity of light emitted by LED systems used on a daily basis (e.g. lamps, objects featuring LEDs, vehicle headlamps, and computer, tablet and mobile telephone screens). Exposure to blue-rich light, especially via LED systems, was assessed as part of life scenarios, thanks to measurements taken *in situ* in specific environments.

Table 1 in the Annex summarises the main physical quantities used in particular to quantify emissions and exposure in the area of lighting.

Assessment of risks to human health

By combining the assessment of the level of evidence for health effects obtained from the analysis of the scientific articles and the data from the exposure scenarios, the expert appraisal sought to characterise the potential risks to humans associated with exposure to systems using LEDs. Thus, the Working Group classified risks of occurrence of health effects in humans into four levels as defined below:

- high risk;
- moderate risk;
- low risk;
- no predictable risk.

The collective expert appraisal report describes the methodology used to assess the level of evidence for the studied effects as well as the qualitative assessment of the related risks.

3. ANALYSIS AND CONCLUSIONS OF THE CES

The Expert Committee on “Physical agents, new technologies and development areas” adopted the collective expert appraisal work and its conclusions and recommendations as described in this summary at its meeting of 23 November 2018 and informed the ANSES General Directorate accordingly.

3.1 Specific characteristics of the light emitted by LED lamps

The specific characteristics of LEDs are related to the type of radiation emitted on the one hand and to the physical properties of the lamps using this technology on the other hand.

Firstly, the light spectrum emitted by LEDs can be richer in blue light (there are lamps with very high colour temperatures[2] of above 6000 K, supplying extremely blue-rich light) and poorer in red light than most other natural and artificial light sources. The additional blue light in the LED spectrum compared to other light sources (spectral imbalance) raises the issue of the effects of light from LED lamps on the retina (phototoxic effects) and on circadian rhythms and sleep (melanopic effects). The lack of red light in LEDs may also deprive individuals of the potential photoprotective effects of this

[2] Colour temperature is a way to characterise light sources in comparison with an ideal material emitting light only under the influence of heat. The temperature of the black body whose visual appearance is closest to that of the light source is expressed in Kelvins (a unit of the international system whose symbol is K).

radiation, especially during the physiological emmetropisation[3] process that takes place during childhood.

Secondly, due to their high luminance[4] and small emission areas, LED lights can produce more glare than light emitted by other technologies (incandescent, compact fluorescent, halogen lamps, etc.). This can especially be the case with LED matrices (small LED aggregates on the same base), LED spotlights, vehicle lights and hand-held lamps.

Lastly, LEDs are highly reactive to current fluctuations. Thus, variations in light intensity can appear depending on the quality of the power supply. These phenomena are grouped under the term “temporal light modulation”. Humans can suffer from the negative effects of these variations, whether or not they are visually perceptible.

3.2 Changes in regulations and standards since 2010

3.2.1 Regulations and standards relating to the phototoxicity of light

- *Exposure limits*

Regarding exposure to optical radiation and photobiological safety in particular, the International Commission on Non-Ionizing Radiation Protection (ICNIRP) published new guidelines on exposure to visible and infrared optical radiation in 2013 (ICNIRP, 2013)[5]. The blue-light exposure limits, which remained the same as those proposed in 1997, only involved acute exposure (single, continuous exposure for less than eight hours).

- *Regulatory texts governing uses of devices, lighting products and artificial optical radiation applicable to LEDs in particular*
  - General population

The European “Low Voltage” Directive (2014/35/EU) aims to ensure that the electrical equipment on the European market meets requirements providing a high level of protection of health and safety. Manufacturers can rely on their products’ compliance with harmonised standards to meet the essential requirements of this directive.

However, portable lighting systems (hand-held lamps, head torches) do not fall within the scope of the Low Voltage Directive. Nevertheless, they use LED sources that can have very high light intensities.

Similarly, for vehicle lighting (exterior lamps), there are no regulations intended to guarantee photobiological safety, for example by limiting the emission intensities of lamps or human exposure.

The case of toys using LEDs is not adequately covered by the European Directive on the safety of toys (2009/48/EC), since it refers, for health-related risks, to the standard on the safety of laser products (IEC 608251-1), which is not suited to LED lighting. This standard also does not consider the fact that the eyes of children are more sensitive to blue light due to a clearer lens.

  - Workers

European Directive 2006/25/EC of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (artificial optical radiation - AOR) includes risk related to blue light. For this specific risk, it relies on the ICNIRP guidelines

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[3] Emmetropisation is the process of normal ocular development leading to the formation of a sharp image on the retina.

[4] Luminance is a quantity corresponding to the perceived brightness of an area. A very bright area has high luminance, while a completely black area has zero luminance.

[5] ICNIRP Guidelines on Limits of Exposure to Incoherent Visible and Infrared Radiation, published in: Health Physics 105(1):74-96;2013.

published in 1997. In France, the AOR Directive was transposed into the Labour Code by decree in 2010[6]. A ministerial order from 2016[7] defines risk assessment methods based on European standards relating to human exposure to optical radiation.

- Standards

The standards relating to the assessment of photobiological safety (CIE S009, IEC 62471 and NF EN 62471) refer to the ICNIRP limit values and propose that lamps be classified into risk groups: risk group 0 (no risk), risk group 1 (low risk), risk group 2 (moderate risk) and risk group 3 (high risk).

In 2014, a technical report (IEC TR 62778:2014) accompanying the NF EN 62471 standard was published by the International Electrotechnical Commission (IEC). This report describes a method for assessing the photobiological risk group in the case of blue light. It includes several of ANSES's recommendations, in particular a procedure for transferring the risk group of an individual LED to an LED module and a finished product (luminaire), as well as the specification of a minimum viewing distance for people exposed to light sources in risk group 2 or higher.

Since 2015, harmonised lighting standards have included photobiological safety requirements[8] limiting the possible effects of radiation on eyes and skin. A distinction is made between lamps on the one hand and luminaires[9] powered by the electrical grid (non-portable luminaires) on the other hand. Regarding lamps, the requirements consist in limiting the photobiological risk group to level 0 or 1 in accordance with the NF EN 62471 standard. Regarding non-portable luminaires, there are no limits on the risk group; there is merely an obligation to inform consumers in the event of a risk group of 2 or higher[10].

3.2.2. Regulations and standards relating to other health effects

There are currently no specific regulations dealing with effects related to circadian rhythm disruption, glare, or temporal light modulation.

- *Circadian rhythm disruption*

In 2004, the International Commission on Illumination (CIE) published a document, updated in 2009 (CIE, 2009)[11], defining spectral sensitivity curves for melanopsin[12]-containing retinal ganglion cells.

- *Glare*

The standards relating to glare have not changed since 2010. The lighting industry uses the glare ratings, in particular the Unified Glare Rating (UGR), defined by the CIE. The UGR formula was initially developed for interior luminaires equipped with fluorescent tubes. The validity of extending the use of the UGR to LED lighting systems is questionable. The CIE's 2013 publication, "Review of

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6 Decree no. 2010-750 of 2 July 2010 concerning the protection of workers from risks due to artificial optical radiation, JORF no. 0153 of 4 July 2010, page 12149, text no. 11.

7 Ministerial Order of 1 March 2016 concerning methods for assessing risks resulting from occupational exposure to artificial optical radiation, JORF no. 0066 of 18 March 2016, text no. 30.

8 These requirements are specified in Standard NF EN 62560– Self-ballasted LED-lamps for general lighting services by voltage > 50 V – Safety specifications, and Standard NF EN 60598-1 Luminaires – Part 1: General requirements and tests (general part common to all luminaires).

9 A luminaire is a combination of a lamp and a decorative element or a combination of several lamps.

10 For non-portable luminaires belonging to risk group 2, the safety standards (for example, Standard NF EN 60598-1 on general requirements for luminaires) require the labelling of the threshold distance and the following statements: *"the luminaire should be positioned so that prolonged staring into the luminaire at a distance closer than x m is not expected"* and *"do not stare at the light source".*

11 CIE 158:2009: Ocular Lighting Effects on Human Physiology and Behaviour.

12 Melanopsin is a photopigment contained in the retina and photosensitive ganglion cells.

Lighting Quality Measures for Interior Lighting with LED Lighting Systems" (CIE 205:2013), concluded that a new assessment system for glare was necessary for LED lighting.

- *Health effects related to temporal light modulation*

Since 2015, most standardisation organisations have produced new standards and technical documents or updated those already existing to describe phenomena involving temporal light modulation. However, there are no European or French regulations limiting the temporal modulation of the light emitted by lamps and luminaires. The regulations on lighting (in terms of eco-design and labelling) are currently being revised by the European Commission; aspects involving temporal light modulation are expected to appear in the text.

3.3 Human health risks associated with exposure to LED light

The human health risks associated with exposure to LED light are mainly due to the spectral composition of the light on the one hand and temporal light modulation on the other hand.

Of the health effects of LEDs, those related to blue light, such as phototoxicity and circadian rhythm disruption, are highly dependent on the exposed person's age. Indeed, the lens acts as a blue-light filter in the eye and its transmittance changes considerably with age. Children are born with a clear lens, letting through all blue light, and reach an optimum filtration rate around the age of 20. A person over the age of 60 has a blue-light filtration rate around twice that of a 20-year-old.

There is a distinction between light sources (or light objects) emitting blue light and objects that have a blue colour. In the first case, the light spectrum received by the eye is (often) enriched with blue light. The amount of light received by the retina in the blue band can be large and have phototoxic effects on the eye and a disruptive effect on biological rhythms. In the second case, the blue colour of the objects and surrounding materials, with conventional lighting, is due to the reflection of part of the spectrum and ends up absorbing some of the light. The intensity of the light source is diminished overall, and the perception of colour can have soothing effects.

3.3.1. Circadian rhythm disruption, sleep disruption, and effects on cognitive performance and vigilance levels

3.3.1.1 Hazard characterisation

- *Circadian rhythm disruption*

The light received by the retina has two main effects: it enables the formation of images (visual effect) and gives the body an idea of the time of day (non-visual effect). This non-visual effect involves melanopsin-containing retinal ganglion cells (mRGCs) that have specific spectral sensitivity: they are strongly stimulated by blue light, with peak sensitivity around 480 nm. These mRGCs send their messages to the suprachiasmatic nuclei of the hypothalamus, the seat of the central circadian clock. This central clock distributes the message to the rest of the body, in order to synchronise all of its biological functions with the day/night cycle. Thus, the adequate regulation of mRGC activity is essential for keeping the biological rhythms of organisms synchronised with their environment. The "melanopic" wavelength band (turquoise blue, 480-490 nm) is thus related to effects on circadian rhythmicity.

The central biological clock determines the production of a hormone, called melatonin, whose secretion begins in the evening, around two hours before bedtime, and then reaches a peak towards the middle of the night before returning to very low and even undetectable levels in the morning and for the rest of the day. Thus, the daily rhythm of circulating melatonin concentrations is a reliable indicator of the biological clock's activity and disruptions.

The effective synchronisation of the central circadian clock, and thus of the biological functions that depend on it, in particular wake/sleep rhythms, requires high light intensity during the day and total darkness at night. Current lifestyle habits, especially in urban environments, are increasingly tending to disrupt the natural daily light/dark cycle, with time spent indoors during the day (accompanied by a decrease in light intensity) and exposure to multiple light sources (lighting, screens) in the evening and at night.

There have been many different publications studying the disruption of circadian rhythms related to exposure to light in the evening or at night. The results of several experimental studies conducted in humans, during which people were subjected to blue-rich light from artificial lighting or screens (computers, telephones, tablets, etc.), were consistent and indicated that nocturnal melatonin synthesis was delayed or inhibited even by very low exposure to blue-rich light.

The degree of circadian disruption seems to depend on the light intensity, the time and duration of exposure, and the individual's history of exposure to light during the day. However, a value of around 10-40 lux or lower (a very low level that can be largely exceeded with domestic lighting) is sufficient to observe an impact on the circadian clock (illustrated by the suppression of nocturnal melatonin secretion).

In conclusion, in light of the sufficient evidence provided by studies undertaken in humans, circadian rhythm disruption induced by exposure to blue-rich light during the evening or at night is considered as proven.

Furthermore, experimental studies in animals have demonstrated that circulating melatonin in a mother crosses the placental barrier and enters the foetal circulation, which possesses melatonin receptors. Thus, maternal melatonin can impact foetal development, in particular the establishment of the circadian system. At night, maternal exposure to light modifies melatonin levels and induces a prenatal effect that appears to have consequences lasting into adulthood (effects on circadian rhythms, metabolic effects, etc.). It can reasonably be assumed that in humans, the effects of modern lighting at night on maternal melatonin secretion negatively impact *in utero* foetal development.

The disruption of circadian rhythms is also associated with other health effects[13] (disruption of sleep quality and quantity, metabolic disorders, increased risk of cancer - especially breast cancer, cardiovascular diseases, effects on mental health). However, the direct connection between exposure to blue-rich light in the evening or at night and the occurrence of these health effects, while strongly suspected, has not been proven to date in humans.

- *Sleep disruption*

Most of the available scientific studies show that blue light alters sleep regulation via circadian disruptions. The evidence provided by studies undertaken in humans is sufficient to conclude that exposure to blue-rich light during the evening has a proven effect on sleep onset latency and the duration and quality of sleep.

- *Effects on vigilance levels and cognitive performance*

Several studies have shown that exposure to blue light (from LEDs in particular) in the day or at night improves cognitive performance and enhances vigilance levels. A number of studies have focused on the effects of lighting, especially blue light, on the performance of night workers. The objective has been the short-term optimisation of vigilance and the reduction of sleepiness in order to reduce industrial and traffic accidents and enhance performance and productivity. These are major challenges for modern societies. However, the issue of potential health effects, due to a possible increase in the phototoxicity of light at night, has yet to be defined.

[13] Assessment of the health risks associated with night work, ANSES collective expert appraisal report, June 2016.

3.3.1.2 Characterisation of LED light sources and exposure

Exposure to blue light was studied in the “melanopic” band (turquoise blue, 480-490 nm) for effects on melatonin and circadian rhythms.

The quantity of blue light emitted by an LED object can be estimated based on its colour temperature, expressed in Kelvins (K), and its level of illuminance on a surface, expressed in lux (especially at the plane of the eye).

Measurement campaigns undertaken to describe the type and quantity of light emitted by LED systems showed that light emitted by screens of televisions, computers, mobile telephones or tablets had a low level of illuminance but was rich in blue light. LED computer screens had colour temperatures ranging from 4500 K to 6900 K and illuminance values at the plane of the eye ranging from 20 to 60 lux. For the LED screens of smartphones and electronic tablets, colour temperatures ranged from 4100 K to 7000 K and illuminance values at the plane of the eye from 2 to 10 lux. As for domestic lighting, the LED lamps available on the market can offer colour temperatures ranging from 2500 K (low level of blue light) to 6900 K (very high level of blue light).

Regarding human exposure to blue light in the melanopic band, no data were identified in the scientific literature. The light exposure scenarios developed for this expert appraisal, representing typical living conditions for various populations, showed that exposure in the melanopic band was similar with LED lighting with moderate levels of blue light (colour temperatures ranging from 2700 K to 4000 K), compact fluorescent lamps and halogen lamps. Nevertheless, with life scenarios including “worst case” situations (LEDs with very high levels of blue light, colour temperatures of around 6500 K), exposure in the melanopic band was higher compared with other lighting technologies, regardless of the population in question. Moreover, the use of LED screens and objects is likely to increase exposure to blue light in the melanopic band.

3.3.1.3 Health risk assessment

Based on the available data, the risk of circadian rhythm disruption or sleep disruption related to exposure to LEDs cannot be precisely quantified. Nevertheless, in light of the above and based on a qualitative approach, the Working Group's experts consider that the risk of circadian disruption associated with exposure to blue-rich LED lights in the evening or at night is high.

In particular, exposure before bedtime to LED lighting or screens from televisions or communication technologies enriched with blue light is likely to adversely affect sleep duration and quality and impact cognitive functions.

3.3.1.4 Susceptible population groups

The available studies have shown even stronger effects of delayed bedtimes, due to the impairment of non-visual functions, in particular melatonin suppression, in children, adolescents and young adults (before the age of 20). An obvious factor is the higher lens clarity of young people, causing more light to pass through than for adults. In addition to the widespread use of devices with LED screens by adolescents, the behavioural, hormonal and circadian changes occurring in this phase of life (increase in the endogenous period of the circadian cycle) are probably also involved.

More generally, several population groups were identified as being more specifically susceptible to the risk of circadian and sleep disruption associated with exposure to LEDs:

- infants, children, adolescents and young adults (due to a clear lens); aphakic (with no lens) and pseudophakic (with an artificial lens) individuals;
- pregnant women (potential health effects on the unborn child);
- night workers[14];

[14] Night workers are particularly susceptible since their exposure to LED lighting is potentially high.

- people with ocular diseases or anomalies, and people with sleep disorders.

3.3.2 Ocular effects and diseases

3.3.2.1 Hazard characterisation

Phototoxicity is a mechanism of light-induced cellular damage that can lead to cell death. Exposure to intense and acute light is phototoxic since it causes the irreversible loss of retinal cells, which can lead to partial and permanent (scotoma[15], decrease in visual field, reduced resolution) or total (blindness) vision loss. Chronic exposure to low-intensity phototoxic lights speeds up the ageing of retinal tissues, potentially leading to vision loss and degenerative diseases such as age-related macular degeneration (ARMD).

Regarding the toxic effects of blue-rich light on the eye, the available data show that:

- the retinal phototoxicity of acute (for less than eight hours) exposure to blue-rich light is proven;
- the contribution of chronic (for several years) retinal exposure to blue-rich light to the occurrence of ARMD is proven; since the long-term ocular effects of artificial lighting have not been studied to date, these conclusions are based on epidemiological studies taking into account exposure to sunlight (blue-rich light);
- in addition to the received phototoxic dose, the time of exposure plays a major role. Some experimental studies, currently limited to animals, have demonstrated increased retinal vulnerability to phototoxicity at night, due to a daily photosensitivity rhythm and disruptive effects on the endogenous retinal clock.

Numerous studies have shown that the exposure limits (ELs) selected by ICNIRP for the retinal toxicity of light are not sufficiently protective. Some authors (Hunter *et al.*, 2012)[16] have considered that to be protective, these ELs would need to decrease by a factor of 20. In addition, the expert appraisal provided an opportunity to highlight that these ELs are only proposed for acute exposure (for less than eight hours) and ignore the issue of long-term exposure. The experts also mentioned the existence of new UV-LED systems[17] that may pose phototoxic risks.

Furthermore, the review of the scientific literature on myopia and Sjögren syndrome[18] led to the following conclusions:

- the effect of blue-rich light on myopia is possible (whether positive or negative);
- the effect of blue-rich light on the occurrence of Sjögren syndrome is possible.

3.3.2.2 Characterisation of LED light sources and exposure

Exposure to blue light was studied in the “phototoxic” band (deep blue, 450-470 nm).

The physical measurements taken as part of this expert appraisal showed that some of the tested LED lighting devices (hand-held lamps, head torches, toys and certain vehicle lights - especially dipped-beam headlamps, etc.) emit blue-rich light (devices classified in risk group 2, maximum anticipated exposure duration of less than 100 s, according to the exposure limits defined by

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[15] A break in the field of vision due to insensitive retinal areas.

[16] Hunter, Jennifer J., Jessica I. W. Morgan, William H. Merigan, David H. Sliney, Janet R. Sparrow, and David R. Williams. 2012. The Susceptibility of the Retina to Photochemical Damage from Visible Light. Progress in Retinal and Eye Research 31 (1): 28-42.

[17] New generation of LEDs whose blue-light peak is shifted to the ultraviolet region (around 410 nm).

[18] Sjögren syndrome involves lacrimal system dysfunction causing dryness on the surface of the eye (cornea, conjunctiva, etc.). This syndrome is characterised by ocular discomfort with tingling sensations or an impression of a foreign body in the eye.

ICNIRP). Some telephone screens and electronic tablets using LED technology emit fairly low-intensity but systematically blue-rich light. It should also be noted that decorative blue LEDs have emerged on the market and that LEDs are being used in a growing number of applications (e.g. in agricultural lighting systems, to light up aquariums, etc.).

Adding artificial lighting to natural lighting is likely to modify the ocular doses received by the cornea and retina in the phototoxic band (up to a 50% increase). Comparing the contributions of LED lighting systems and other lighting technologies to overall human exposure according to defined scenarios produced the following results:

- in general, LED lighting systems increase the imbalance in wavelengths in favour of blue light compared to red light, in comparison with other lighting systems, at the same colour temperature;
- exposure in the phototoxic band is even higher when colour temperature is high (blue-rich light), regardless of the lighting technology (LED or otherwise).

Regarding the phototoxic dose received by the retina, the results of the examination of exposure scenarios showed that LEDs were only different from other technologies in the “worst case” scenario, in which the LED lighting systems used had very high levels of blue light (high colour temperatures of around 6500 K). Even so, the experts underline that this “worst case” scenario can correspond to the situations of certain people with very low exposure to natural light who are subjected to blue-rich lighting in their workplace (for example, in the winter, it is dark out in the morning when leaving home and in the evening when returning home, and the daytime is spent in an environment lit exclusively by artificial blue-rich lighting).

The Working Group's experts would like to point out the significant commercial development of small bare decorative LEDs emitting blue light (string lights, ambient lighting, etc.). These LEDs can increase exposure in the phototoxic band, even at low luminance levels. Indeed, the photons of blue light have higher energy than the photons associated with longer wavelengths. They can therefore induce photochemical reactions similar to those caused by ultraviolet radiation. Moreover, human visual perception is less sensitive to blue light. High energy levels in blue light can therefore be received by the retina without creating a strong visual sensation. Since this blue-coloured light does not necessarily create glare, it can be stared at over a long period, especially by children.

3.3.2.3 Health risk assessment

Based on the available data, the risk of ocular diseases occurring in relation to exposure to LEDs cannot be precisely quantified. However, in light of the above and based on a qualitative approach, the experts consider that the risk of acute toxicity associated with “warm white” (low colour temperature) LEDs for domestic use is low.

It should be noted that lighting devices belonging to risk group 2 (hand-held lamps, head torches, toys and certain vehicle lights) are available on the market. The risk of ocular diseases occurring in relation to exposure to these devices is higher, especially for susceptible population groups. Similarly, objects specifically emitting blue light (e.g. decorative LEDs), even at low intensities, can increase exposure in the phototoxic band.

Due to the lack of data on the chronic effects of low-dose exposure to cool light (screens, for example), the risk level associated with chronic exposure to blue-rich LEDs cannot currently be assessed.

3.3.2.4 Susceptible population groups

Regarding the risk of ocular diseases, several susceptible population groups were identified based on the data from the literature:

- infants, children, adolescents and young adults (clear lens); aphakic (no lens) and pseudophakic (artificial lens) individuals;

- people with ocular diseases (dry eye, ARMD, glaucoma, retinopathy, etc.); people with motor or cognitive disorders reducing their avoidance or decision-making capacities in the event of overly intense light; people taking photosensitising medications or exposed to photosensitising pollutants;
- night workers[19] and any other professionals with potentially high exposure to LED lighting (surgeons, dentists, lighting professionals, lighting distributors, performing artists, people working in sport facilities, people working in agri-food facilities using LEDs (greenhouses, aquaculture), etc.).

3.3.3 Glare and visual comfort

3.3.3.1 Hazard characterisation

Glare corresponds to viewing conditions in which a person experiences discomfort or is less capable of perceiving details or objects, due to an unfavourable luminance distribution or an extreme contrast. A distinction should be made between disability glare, which reduces the subject's visual capacities and performance, and discomfort glare, which causes the subject to experience a sensation of discomfort but does not cause a decline in visual performance.

Several factors modulate glare-related disability. These include the quantity of light sent into the eye by the source itself as well as the distance from the glare source and the observer’s age. However, the spectral composition of light does not modify the disability glare phenomenon.

It appears that the multiple visible point sources in luminaires (LED matrices) considerably increase discomfort. All studies have consistently shown that (1) non-uniform sources produce more glare than uniform sources, even with moderate luminance, and (2) the higher the contrast, the greater the sensation of discomfort. Moreover, since the scattering of light in ocular environments increases with age, discomfort also increases. Regarding both LED sources and “conventional” light sources, colour temperature does not seem to be a determinant of visual comfort. However, at the same colour temperature, the spectral composition and especially the blue-light enrichment of the spectrum has probable consequences on visual discomfort.

The long-term effects of repeated glare are not known to date. Furthermore, there is a high level of inter-individual variability in the general population as to the assessment of glare situations.

3.3.3.2 Characterisation of LED light sources and exposure

Luminance (expressed in cd/m^2 [20]), measured when directly viewing a light source from a short distance, enables the level of glare potentially produced by that light source to be assessed. The LED lamps tested for this expert appraisal had disparate luminance levels; some of them, especially those in LED spotlights, produced a very high level of glare.

Another aspect of visual comfort is related to colour rendering. The colour rendering index (CRI) represents a light's capacity to faithfully render a colour. A CRI of 100 refers to an optimum light, and it is recognised that a CRI is deemed acceptable above 80. LED lamps do not yet offer the capacities of halogen lamps, which have CRIs close to 100, but their performance is similar to that of compact fluorescent lamps, sometimes with measured CRIs greater than 80. Compared to the context of ANSES's previous expert appraisal published in 2010, LED technology now offers higher-quality colour rendering.

3.3.3.3 Health risk assessment

Based on the available data, the risk of visual discomfort or disability glare related to exposure to LEDs cannot be precisely quantified. However, in light of the above and based on a qualitative approach, the experts consider that certain lighting devices including LEDs (hand-held lamps,

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[19] Night workers are particularly susceptible since their exposure to LED lighting is potentially high.

[20] cd/m^2: candela per square metre.

vehicle lights, LED spotlights, LED matrices, etc.) can pose a high risk of glare. Moreover, while certain LED lamps have better colour rendering than they did a few years ago, this can still be improved.

3.3.3.4 Susceptible population groups

Age is a factor aggravating the risk of glare associated with LEDs, both during the day and at night. Deterioration of vision accelerates after the age of 60, at varying rates depending on the individual. The stray light generated around sources increases considerably with age, lowering the perception of object contrast and therefore visual performance.

Subjects with migraine seem to be specifically susceptible to the glare caused by certain irregularities in the spectral distribution of light energy.

3.3.4 Skin effects

3.3.4.1 Hazard characterisation

Blue light may have adverse effects on the skin, accelerating ageing and delaying healing processes, whereas exposure to wavelengths of 590 to 700 nm (red light) appears to have opposite effects. The experts conclude that the effect of exposure to blue-rich light on the occurrence of skin diseases is possible.

Moreover, the delayed carcinogenic effect (melanoma induction) induced by blue-light LED phototherapy used for the treatment of neonatal jaundice should be given special attention. Of the five studies undertaken to assess the risk of developing benign or malignant melanocytic lesions following blue-light neonatal phototherapy, three showed an increased number of common or atypical naevi in exposed children.

3.3.4.2 Characterisation of LED light sources and exposure

There are no exposure data specifically dealing with the skin effects of blue-light emissions. Nevertheless, the photobiological risk group provides an idea of the quantity of blue light emitted by LED lighting (see § on the characterisation of exposure for ocular diseases).

3.3.4.3 Health risk assessment

Based on the available data, the potential risks to the skin related to exposure to LEDs cannot be quantified. Based on a qualitative approach and considering the exposure levels associated with the domestic use of LED lighting as well as the limited skin penetration depth of blue-light optical radiation, the experts consider that the risk of skin diseases occurring in relation to exposure to blue light from LEDs is low.

3.3.4.5 Susceptible population groups

The experts identified some potentially susceptible population groups:

- newborns in the event of blue-light LED phototherapy prescribed to treat neonatal jaundice;
- people with certain skin diseases (epithelial lesions, wounds, etc.); these people appear to have an increased risk of skin lesions developing or worsening during exposure to blue light.

3.3.5 Other disorders (migraines, headaches, visual fatigue, accidents, epilepsy attacks)

3.3.5.1 Hazard characterisation

The temporal modulation of a lighting system is primarily characterised by its modulation frequency and the corresponding modulation rate, expressed as a percentage of the light intensity (values ranging from 0% to 100%). Depending on its frequency, this modulation may or may not be perceptible by the human visual system. Three separate visual effects (conscious perception of modulation) have been described: flicker, the stroboscopic effect and the phantom array effect. Health effects can be directly induced by these visual effects or occur with no conscious perception of any modulation. The health effects that can result from the conscious or unconscious perception of modulation are epilepsy attacks, traffic accidents, accidents related to the use of machines, migraines, headaches and visual fatigue.

Effects such as headaches, migraines and visual fatigue can be associated with temporal modulation frequencies between 80 and 120 Hz. The related evidence provided by studies is limited for humans.

Phenomena such as the stroboscopic effect (apparent immobility or slowing of a moving object) and the phantom array effect (persistence of an image during a visual saccade) can occur at high modulation frequencies (greater than around 80 Hz). In an industrial or domestic context, it is likely that the stroboscopic effect could affect safety during the use of machines or tools.

Temporal light modulation can also be associated with the triggering of attacks in people with epilepsy. However, the modulation frequencies of the LED lamps and luminaires available on the market are too high to trigger attacks in these individuals. Nevertheless, there is a possibility of attacks being triggered in the population of epileptic subjects during exposure to LED lamps or luminaires with abnormal temporal modulation (defective products or incompatibility with the controller).

Moreover, certain self-contained lighting devices on bicycles (recharged by magnetic induction) are very strongly modulated (100% modulation) at frequencies varying with the cyclist's speed. At certain speeds, the temporal modulations are located around 15 Hz, in the most critical band for the triggering of epilepsy attacks.

In all of these situations, temporal light modulation is associated with visual discomfort and a decrease in visual efficiency, especially at workstations in occupational settings.

3.3.5.2 Characterisation of LED light sources and exposure

Results from the scientific literature dealing with the temporal modulation of LED lamps were aggregated with measurements taken in the context of this expert appraisal; of the 53 tested lamps:

- 18 lamps (around 34%) had very low temporal modulation (of less than 1%);
- 12 lamps (around 23%) had temporal modulation between 1% and 15%, similar to that of halogen and compact fluorescent lamps;
- 14 lamps (around 26%) had modulation between 12% and 70%; their values were significantly higher than those of halogen and compact fluorescent technologies;
- nine lamps (around 17%) had very high modulation, exceeding 70% and even reaching 100%.

It is estimated that around 43% of LED lamps for domestic use have degraded temporal modulation performance (modulation rate greater than 15% at 100 Hz) compared to halogen and compact fluorescent technologies.

The stroboscopic effect is particularly visible with LED lamps and luminaires having high temporal modulation at 100 Hz.

Some LED lamps and luminaires have high enough modulation levels that the phantom array effect is perceptible, especially when driving a car.

3.3.5.3 Health risk assessment

For people with epilepsy, based on the available data, it is not possible to quantify the risk of attacks being triggered in relation to the temporal modulation of an LED lighting system.

Moreover, the experts consider that due to the limited number of exposure data, the risk associated with effects (headaches, migraines, visual fatigue) occurring in the frequency range (80-120 Hz) associated with LED exposure is not known.

Based on the scientific data, it is not possible to conclude as to whether or not the perception of the stroboscopic or phantom array effect has an impact on accidents occurring when handling machines or tools, or on traffic accidents.

3.3.5.4 Susceptible population groups

Studies dealing with the maturation of the visual contrast perception system in humans indicate that maximum temporal contrast sensitivity is reached during adolescence and young adulthood. These are therefore population groups particularly sensitive to modulated light.

Epidemiological studies showing an association between modulated light and the triggering of migraine refer to migraine patients as a population group sensitive to modulated light.

Work undertaken using older-generation fluorescent tubes showed that certain individuals had heightened sensitivity to temporal light modulations at the frequency of 100 Hz. In addition, studies have shown that some individuals visually perceive flicker at 100 Hz.

Thus, with regard to certain health effects related to temporal light modulation, several susceptible population groups were identified:

- regarding headaches, migraine and visual fatigue:
    - children, adolescents and young adults;
    - migraine sufferers;
- regarding the risk of accidents related to the stroboscopic effect or phantom array effect:
    - machine and tool operators and vehicle drivers;
    - people with motor or cognitive disorders reducing their avoidance or decision-making capacities;
    - children, adolescents and young adults;
- regarding the triggering of epilepsy attacks: people with epilepsy.

3.4 Effectiveness of protective devices

There are various solutions claiming to reduce or suppress the effects of blue light: these include filters built into computer screens or into the lenses of prescription glasses, as well as programmable lighting systems that modulate the quantity of melanopic light (wavelength of around 480-490 nm) depending on the time of day.

According to the measurements taken for this expert appraisal:

- specific blue-light-blocking glasses were more effective at filtering than treated ophthalmic lenses. However, neither of these two systems was effective enough to be considered as personal protective equipment[21] (PPE) regarding the risk of acute retinal phototoxicity resulting from prolonged exposure to a very high-intensity LED source;
- depending on the tested protective device, the capacity to filter blue radiation in the melanopic band was highly variable: it was very low or even non-existent for treated lenses, despite the claims made by manufacturers and distributors of these products. It cannot be said that this filtration is sufficient to prevent the decrease in melatonin secretion induced by exposure to light in the evening and the related effects of sleep onset delay;
- for the tested screens claiming to limit blue-light emissions, no real effectiveness was observed. However, reducing the colour temperature (switching to warm white) and brightness of the screens was somewhat effective at reducing the quantity of blue light in the spectrum.

[21] There are currently no standards specifying test methods and performance requirements for PPE with regard to blue light.

3.5 Environmental impact of LEDs

3.5.1 Threat to biodiversity

The diversity of the living world is reflected in the wide variety of metabolic, physiological and behavioural responses to light observed in fauna and flora. Thus, what might be an advantage for a given plant or animal species may prove to be a disadvantage for another. Changes in the (daily and annual) biological rhythms, orientation, geographical distribution and migration of species can thus be observed following exposure to artificial light. There can also be indirect effects (in the medium and long term) on these populations and their ecosystems.

Research into the impact on the living world of the light emitted by LEDs at night still heavily relies on that dealing with artificial light in general. Moreover, it still involves a very limited number of species. Regardless of the studied ecosystem, the general long-term trend as observed in the scientific literature appears to be an increase in mortality and a decline in the diversity of the animal and plant species studied in environments lit at night, including by LED lighting systems.

According to the scientific literature, the effects of light at night, especially from LED lighting, on fauna and flora and ecosystems are proven for all of the species studied. Overall, these effects correspond to those of night-time lighting. It is important to distinguish those that could be specifically related to the particular characteristics of LEDs (intensity, spectral composition). These effects are combined with other anthropogenic pressures (chemical pollution, geographical barriers, shrinking habitats, overexploitation, etc.). The continuous extension of human, industrial and leisure activities in addition to physical and chemical nuisances combined with the effects of climate change are all factors that certain animal and plant populations will probably be incapable of coping with, which will speed up the decline in biodiversity. However, data involving the combined action of these multiple disruptive factors are still extremely scarce.

3.5.2 Light pollution

The collective expert appraisal report associated with this summary includes an assessment of the effects of LED deployment (outdoor display and lighting sources in particular) on light pollution. Various aspects have been considered, such as effects on the sky glow, nuisances for humans (intrusive light, light trespass, glare, circadian rhythms) and nuisances for ecosystems and biodiversity.

According to the Working Group's experts, the change in lighting technologies due to LEDs could either increase or reduce light pollution, depending on the choices made for public and indoor lighting, architectural and landscape enhancement, etc. The categories of LED lighting systems that may be responsible for the greatest increases in light pollution are as follows: illuminated signs, billboards and advertising, as well as lighting for commercial, agricultural (including horticultural greenhouses), aquaculture and industrial zones. This also encompasses lighting for outdoor car parks in these zones. In these categories, the trend is towards an increase in the number and intensity of points of light.

Replacing lamps for street lighting and indoor lamps with LEDs could contribute to reducing light pollution, by better targeting areas to be illuminated (and thus limiting diffusion) and modulating the quality (wavelength) and intensity of the light emitted, as enabled by LED technology, provided that the number of points of LED light is not increased compared to the number of replaced points of light.

Despite the results highlighted above, it is difficult to assess the overall impact of the transition from current lighting systems to LEDs on light pollution.

3.5.3 Impacts related to the life cycle of LED lamps and luminaires

Several categories of environmental impacts are defined when analysing the life cycle of a product: energy consumption, the amount of hazardous waste produced, the amount of water used, the impact on global warming, toxic effects on human health, etc. The results of the life-cycle analyses (LCAs) undertaken for the analysed light sources show that LED lamps and luminaires have the lowest environmental impacts compared to other lighting technologies. This is due to the higher light efficiency of LED lighting compared to other sources. However, the content of the LCA studies dealing with lamps and luminaires varied, especially in terms of the analysed products and chosen methods (the functional unit, impact categories and life-cycle stages included). Despite major differences in the LCA methods, the analyses generally led to very similar results: the LED use phase was primarily (70% to 99%) responsible for the environmental impacts observed, due to the energy consumption of this technology. Manufacturing was responsible for most of the other impacts.

The CES notes that one limitation of the LCAs was the lack of a methodology for assessing the impacts of light on human health and the environment (fauna and flora).

Recommendations of the CES

Based on the Working Group's conclusions and recommendations, the CES is issuing the following recommendations aiming to better protect human health (general population and workers) and the environment from effects related to exposure to LED systems. These recommendations are intended to limit harmful effects related to exposure to LEDs by developing information for the general population and in the workplace and by improving the normative and regulatory frameworks governing the use of LEDs. Lastly, the CES highlights the efforts to be made in terms of research.

Recommendations for the public authorities to protect the population and the environment

The CES recommends developing actions and information regarding:

- the need to limit exposure to blue-rich light (from LEDs and other technologies), by favouring the use of warm-coloured lighting (colour temperature below 3000 K) before going to bed and during the night, especially for certain population groups: children, adolescents and pregnant women (see lists by health effect in Section 3). In particular, the CES recommends not using blue-rich night-lights for infants and children and limiting the exposure of children and adolescents to blue-rich light sources (computer, tablet, mobile telephone screens, etc.) at night and before going to bed;
- the importance of enhancing the light contrast between daytime and night-time by increasing exposure to natural light during the day and limiting exposure to artificial light before bedtime and at night;
- the phototoxic effects of light associated with exposure to certain LED lighting devices (hand-held lamps, head torches, toys, vehicle lights, blue-light decorative string lights) available on the market, especially for the most susceptible population groups such as children;
- the widely varying effectiveness of the protective devices currently proposed with regard to the adverse health effects associated with exposure to LEDs.

In order to protect against the harmful effects of light pollution on humans and their environment, the CES recommends:

- undertaking actions to limit intrusive light in homes and thus reduce the risk of circadian disruption;

- limiting the number of illuminated outdoor facilities, keeping the surface areas of illuminated zones to a minimum, improving control of their directivity and promoting their sound management;
- conducting, wherever lighting is necessary, a study of its impact on the local ecosystem in natural and suburban areas;
- creating protected spaces, without any artificial lighting.

Recommendations for employers and occupational physicians to protect workers

- considering the phototoxic effects of blue light and the potential effects of temporal light modulation, the CES reiterates the obligation to limit the exposure of workers to these light sources and inform them of the related hazards;
- moreover, given the effects observed on foetal development in animals related to maternal exposure to light at night, the CES recommends limiting the exposure of pregnant women to light during the night.

Recommendations regarding the regulatory and normative frameworks with the aim of protecting human health and the environment

At national level:

the CES recommends enforcing the regulations on the switching-off of interior lighting with exterior emission and the illumination of building façades (Ministerial Order[22] of 25 January 2013 on the nocturnal lighting of non-residential buildings in order to limit light pollution and energy consumption) as well as those on the switching-off of advertising signs (Decree no. 2012-118[23] on outdoor advertising and signs).

At European level:

regarding normative changes to be made, the CES recommends:

- revising the exposure limits for optical radiation proposed by ICNIRP, so as to make them sufficiently protective against phototoxic risks. They should take into account chronic exposure and consider other indicators, especially those relating to infra-clinical toxicity[24];
- creating an effectiveness index and requiring its labelling on devices providing protection against blue light (accounting for the attenuation rate);
- developing a metrological standard, at European level, specifying conditions for measuring temporal modulation and calculating the related indices;

regarding regulatory changes to be made, the CES recommends:

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[22] "The interior lighting of premises for professional use must be switched off one hour after these premises have been vacated. Building façade lighting must be switched off at 1 am at the latest. Store window lights and window display lights must be switched off at 1 am at the latest or one hour after these premises have been vacated, whichever occurs later".

[23] "Illuminated advertisements must be switched off at night, between 1 am and 6 am, except for airports and urban units with more than 800,000 inhabitants, for which the mayors shall set out the applicable rules. Illuminated signs shall comply with the same rules".

[24] For example, there can be cell death in the retina without this being visible when examining the back of the eye.

- requiring the labelling of the photobiological risk group (assessed according to Standard NF ISO 62471) for domestic lighting as well as for LED objects;
- restricting the sale of LED systems (lamps, luminaires, objects and especially toys) to the general public to those in risk group 1 or lower;
- harmonising the regulatory framework by amending the regulations specific to LED systems other than lamps and luminaires, in order to take into account the photobiological risk, in particular:
    - Directive 2009/48/EC on the safety of toys;
    - UNECE[25] (United Nations Economic Commission for Europe) Regulations R112 and R113 on prescriptions for light sources from vehicles.
- limiting the luminance of vehicle lights (without necessarily reducing the overall flux and therefore the range of vision);
- taking into account, in the regulations, the specific characteristics of bare LED strips and matrices in devices sold to the general public (bare LED aggregates on the same base);
- establishing, at European level, limits for temporal light modulation, in order to limit the biological and health effects associated with the light emitted by LED lamps and luminaires;
- amending the current regulations in order to take into account the risks associated with temporal modulation, in particular:
    - Directive 2006/25/EC of the European Parliament on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (artificial optical radiation);
    - the UNECE regulations, requiring a minimum modulation frequency of around 2 kHz when the lamps (front lamps and rear lamps) of vehicles are used in pulse width modulation[26] (PWM) mode. This recommendation will limit the visibility of the phantom array effect, which is a source of proven visual disturbances;
- introducing the option to automatically lower the colour temperature (switch to warm white) and brightness of mobile telephone and tablet screens before bedtime.

Research recommendations

While numerous data are available on the health effects of light, especially blue light, the scientific data are still incomplete with regard to the specific effects of LEDs depending on their geometry and spectral quality. Therefore, the CES insists on the need to improve the quantitative assessment of the impact of a general shift to LED technology on human health and the environment.

The CES encourages the implementation and intensification of research into light-induced circadian rhythm disruption and the resulting effects on vigilance, sleep, mood, well-being, cognition and health. Two aspects for which there is still little documentation should particularly be taken into account in humans and diurnal animal models:

- the impact of the maternal light environment on foetal development;

[25] The UNECE Sustainable Transport Division provides secretariat services to the World Forum for Harmonization of Vehicle Regulations.

[26] PWM mode is a duty-cycle modulation. Light is modulated at a fixed frequency and the change in the duty cycle modifies the average light intensity.

- for children and adolescents, the impact of the light environment, depending on the period (day, night), on biological rhythm synchronisation and health, particularly considering higher light transmission due to a clearer lens and a more open pupil.

Since potentially beneficial effects of a strong light contrast between daytime and night-time have been described in the scientific literature, it will be necessary to:

- confirm the effects of exposure to sufficient daytime light intensities on quality of life, sleep, well-being and health, especially for people with circadian rhythm disorders (elderly subjects, hospitalised patients, people with dementia, etc.);
- improve knowledge of the ability of exposure to blue light in the morning to correct circadian desynchronisation and assess the associated ocular risks;
- for night workers, study the relevance of favouring exposure to certain wavelengths depending on the time of day, to promote vigilance on the one hand and recovery on the other hand while minimising the negative side effects.

The CES recommends improving the assessment of the risk of eye dryness and ocular diseases occurring in relation to exposure to light in the phototoxic range, especially in the long term. Special attention should be paid to certain susceptible population groups (children, adolescents, people with ocular diseases, aphakic individuals, etc.). The CES also recommends studying the factors that may be involved in the phototoxicity of light, such as the time of exposure, the possible associated temporal modulation, and risk factors related to ocular diseases. It would also be advisable to study to what extent phototoxicity results obtained in rodents can be extrapolated to humans.

Since temporal light modulation appears to be a major flaw of certain LEDs and LED systems, the CES recommends improving knowledge of its visual, biological and health effects. In particular, it recommends conducting:

- studies to better identify inter-individual variations in sensitivity to temporal contrasts and better understand the prevalence and incidence of effects related to temporal light modulation in the general population;
- studies enabling the risk of accidents arising from exposure to a stroboscopic effect or phantom array effect to be quantified.

The various health effects of LEDs mentioned above make it necessary to improve the assessment of exposure in populations. The CES recommends taking precise measurements of luminance distribution, spectral energy distributions and temporal modulation for a wide range of LED devices to which the population is exposed.

The CES recommends better taking account of the environmental impact of a general shift to LED technology, by improving knowledge regarding the effects of light pollution on fauna and flora and the ecosystem as a whole.

Lastly, the CES recommends considering the entire life cycle of LEDs, in particular:

- accessing detailed data on the products used in the manufacture of LEDs (raw materials, manufacturing processes) and those released into the air, water and soil during the manufacture of LEDs;
- documenting end-of-life for LEDs: recovery and sorting of used products, recovery of raw materials, recycling of certain LED components, treatment of final waste.

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

ANSES endorses the conclusions and recommendations of its Expert Committee on “Physical agents, new technologies and development areas”, set out in Section 3 of this Opinion.

An initial expert appraisal on the health effects of exposure to LED lamps was published by ANSES in 2010, when this technology was just starting to be deployed on a large scale and other lighting technologies (incandescent in particular) were beginning to be gradually withdrawn from the market at the same time. This expert appraisal had underlined the retinal toxicity of the blue light contained in LED lighting systems and their high capacity for glare.

Long contained mainly in specific applications (signage, electronic objects, etc.), LED technology is increasingly being used in automotive vehicles (lamps, etc.) and has become essential in domestic and public lighting as well as in light objects and screens (telephones, computers, televisions). The artificial light to which the population and its environment are exposed, which was previously rich in yellow-orange shades, is now richer in blue light than it was 10 years ago due to the now predominant use of LEDs in industrial and consumer applications.

This expert appraisal sought to update the state of knowledge since 2010 on the various health effects likely to be associated with exposure to blue-rich light as well as other characteristics of LED lighting. To do so, it used a methodology for assessing the levels of evidence associated with the health effects in question.

Moreover, due to the lack of literature data dealing with the population's exposure to LED technologies, the Agency financed specific measurement campaigns, in particular to describe the type and quantity of light emitted by LED systems used on a daily basis (lamps, objects featuring LEDs, vehicle headlamps, computer, tablet and mobile telephone screens, etc.).

The new scientific data examined corroborated the findings of 2010 relating to phototoxicity and enabled the experts to establish that the retinal phototoxicity of acute exposure to blue-rich light is proven. The long-term contribution of blue-rich light to the occurrence of age-related macular degeneration (ARMD) is also proven.

The Agency confirms that some of the tested lighting devices (hand-held lamps, vehicle lamps, LED spotlights, LED matrices, etc.) can produce high levels of glare.

In 2010, the Agency had suggested the possibility of biological clock disruption induced by exposure to LEDs. The update of the expert appraisal showed that the disruption of circadian rhythms (biological clocks) induced by exposure to blue-rich LED light in the evening or at night is proven. Children and adolescents, exposed from a very early age to screens in particular (tablets, game consoles, mobile telephones, etc.), constitute a particularly susceptible population group.

Regarding the temporal modulation of the light emitted by LEDs, the data examined showed that a high proportion of the tested LED lamps had degraded performance (high temporal modulation). Although the health risks associated with exposure to this modulation have not been determined, some people (children, adolescents, young adults, machine operators and vehicle drivers, etc.) may be more susceptible to the potential health effects of this light modulation: headaches, visual fatigue, risk of accidents, etc.

Regarding the impacts of light on the environment and biodiversity in particular, the available studies show an increase in mortality and a decline in the diversity of the animal and plant species studied in environments lit at night, including by LED lighting systems.

The Agency's recommendations

Advance knowledge

Regarding the assessment of risks related to exposure to LEDs, ANSES underlines the need to better quantify the risk levels associated with the identified effects. It thus recommends initiating additional research aiming to:

- improve knowledge of exposure for the general population, workers and the environment;
- better characterise the health effects associated with the temporal modulation of the light from LEDs in addition to long-term phototoxicity;
- clarify the exposure-response relationship between exposure and the occurrence of health effects (especially those involving circadian disruption, phototoxicity, etc.).

Lastly, to respond to the potential health effects associated with exposure to LED phototherapy devices, the Agency advises the public authorities to have a risk-benefit assessment of these devices undertaken by a competent organisation.

Adapt the regulations and improve information

In light of the newly available experimental data concerning phototoxicity mechanisms, ANSES underlines the need to update the exposure limits (ELs) for blue light, especially to take into account the specific situation of children, whose eye lens filters blue light much less efficiently than that of adults and elderly people. These ELs are used to verify the compliance of LED systems with the essential health and safety requirements set out in European directives.

Considering the results of the risk assessment undertaken as part of the collective expert appraisal, ANSES recommends adapting the regulatory framework applicable to LED systems, in order to:

- restrict the sale of LED objects to the general public to those in photobiological risk group 0 or 1;
- limit the light intensity of vehicle lamps, while guaranteeing road safety;
- establish, at European level, limits minimising the temporal modulation of the light emitted by all light sources (lighting systems, screens, LED objects), all while improving the characterisation of the related health effects.

Pending changes to the regulations, ANSES recommends raising awareness in the population and encouraging people, children in particular, to limit their exposure to:

- blue-rich light before bedtime and during the night (LED screens: mobile telephones, tablets, computers, etc.);
- blue-rich lighting, i.e. “cool white” lamps and luminaires, by favouring indirect lighting or using diffusers;
- direct light from LED objects in risk group 2 or higher (hand-held lamps, toys, vehicle lamps, etc.).

ANSES also draws attention to the varying levels of effectiveness of the current devices providing protection against the phototoxicity of blue light (treated lenses, protective glasses, specific screens, etc.). It also notes their lack of significant action on the preservation of circadian rhythms for which, in the case of LED screens, exposure can only be limited by reducing the brightness and colour temperature of screens. It encourages the establishment of standards defining performance criteria for personal protective equipment in relation to blue light.

Regarding the environment and biodiversity, although it is difficult to assess the overall health and environmental impacts of the transition from current lighting technologies to LEDs, ANSES recommends strengthening the prevention of light pollution. The Agency thus underlines the need to enforce the current regulations and adapt them, in particular by limiting the number of points of light and reducing light pollution, all while taking care to ensure the safety of people.

Dr Roger Genet

Keywords

Lumière bleue, LED, éclairage artificiel, phototoxicité, rythmes circadiens, modulation temporelle de la lumière, biodiversité, pollution lumineuse.

Blue light, LED, artificial lighting, phototoxicity, circadian rhythms, temporal light modulation, biodiversity, light pollution.

Annex

Table 1: Main physical quantities used in the area of lighting

Quantity	Unit	Description
Luminance (*L*)	Candela per square metre (cd/m²)	Amount of visible light emitted by a light surface or an object, for example the luminance of a computer screen: around 200 cd/m²
Illuminance *(E)*	Lux (lx)	Amount of light received on a surface. For example: 500 lux on a desk
Colour temperature *(T)*	Kelvin (K)	Specifies the shade of a white light: a "warm" light will have a low temperature (yellowish colour, T < 3000 K), while a "cool" light will have a high temperature (bluish colour, T > 5000 K)
Colour rendering index (CRI)	No unit	Ability of a light to faithfully render the colour of objects. A highly faithful light will have a CRI of 100, while a moderate-quality light will have a CRI below 80
Luminous efficacy	Lumens per watt (lm/W)	Defines the energy efficiency of a light source