The Director General

Maisons-Alfort, 19 October 2010

OPINION
OF THE FRENCH AGENCY FOR FOOD, ENVIRONMENTAL AND OCCUPATIONAL HEALTH & SAFETY

in response to the internally-solicited request entitled "Health effects of lighting systems using light-emitting diodes (LEDs)"

ANSES's public health mission involves ensuring environmental, occupational and food safety as well as assessing the potential health risks they may entail.

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

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1. PRESENTATION OF THE QUESTION

The European Eco-design Directive (2005/32/EC), known as "EuP" for Energy-using Products, aims to improve the energy efficiency of certain consumer goods. This Directive was transposed into national law by the Member States of the European Union in 2007 and came into force between 2008 and 2010.
On 18 March 2009, in application of the EuP Directive, the European Commission decided in favour of a gradual ban on the sale of the most energy-consuming lamps, scheduled for implementation from 1 September 2009 to 1 September 2016. Compact fluorescent or "low-energy" lamps, or other sources of energy-saving lighting such as light-emitting diodes, are destined to replace them eventually.
Light-emitting diodes are light sources that are currently undergoing rapid technological and financial development. They have been used for several years in electronics as weak, monochromatic light sources for indicator or warning lights and are now commonly used as normal light sources in lighting systems.
The first visible spectrum LED was created in 1962 and emitted only very low intensity light. The blue diode was invented in 1990, followed by the development of the white diode that made it possible for new and important applications to be adopted, mainly for lighting, television and computer screens. The first white LEDs appeared on the market gradually and are now increasingly powerful[1] (consuming from a few Watts to a few tens of Watts). The most widely-used procedure for producing white light couples a blue LED and a yellow phosphor.

[1] Source – ADEME: "Low-power LEDs (i.e. lower than 1 Watt) are used as indicator lights on domestic appliances, for example. High-power LEDs (i.e. higher than 1 Watt) can withstand stronger currents (up to 1500 mA) and supply more light (135 lm/W)".

The French company OSYRIS[2] expressed concern in a letter addressed to the French Institute for Public Health Surveillance (InVS), dated 27 December 2007, about the possible impact on the retina of light from LEDs. The letter underlined the possible link between exposure of the eye to shortwave radiation, close to ultraviolet light (characteristic of the light spectra of LEDs) and the risk of macular degeneration, an eye disease. The InVS forwarded the OSYRIS letter to the French Agency for Environmental and Occupational Health Safety (AFSSET[3]) in a letter dated 14 January 2008.
Simultaneously, the question of the impact of LEDs on occupational health was raised during informal discussions between AFSSET and the Directorate-General for Labour (DGT), the latter having recently been alerted by projects for the use of indoor LED lighting for buildings. The development of this type of lighting solution is likely to accelerate mainly due to cost considerations, for applications involving both general and professional populations.

2. Scientific context and applicable standards

In France, lighting accounts for 10% of total electricity consumption, or 350 kWh per year and per household[4]. LEDs consume far less energy than other types of lighting and have much longer lifetimes.
The luminous efficacy of incandescent lamps is of the order of 10 to 15 lumens[5] per Watt (lm/W), for halogen lamps it is from 15 to 30 lm/W and for compact fluorescent lamps it is in the range of 50 to 100 lm/W. Some of the latest LEDs achieve an efficacy of up to 100 to 150 lm/W, with predictions in the region of 200 lm/W for 2020[6].
There is as yet no standard definition of the lifetime of an LED. Estimates for current LEDs, however, predict considerable lifetimes, up to 50,000 hours[7], or 50 times longer than incandescent lamps and 3 to 5 times longer than compact fluorescent lamps.
The technology behind LEDs, which have certain advantages over other types of lighting, (energy efficiency and lifetime), is constantly changing. They are used in a wide variety of fields: public, domestic and workplace lighting, sports facilities, as indicator lights (toys, signage, etc.), vehicle lights and light therapy products. However, the quality of the light (colour temperature[8], colour rendering index[9]) emitted by these lamps does not always achieve the same level of performance as other sources of lighting.

There are currently three methods for creating a light-emitting diode that emits white light:

[2] A French company specialising in lasers and their application in medicine and industry.

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

[4] Source: ADEME 2010.

[5] The lumen is the unit used to quantify luminous flux and expresses the total quantity of light emitted by a source. The candela is the unit used to express the quantity of light emitted in a given direction. The quantity of light received on a surface is expressed in lux.

[6] The theoretical limit for the luminous efficacy of light sources is set at 683 lm/W.

[7] Source: ADEME 2010

[8] The colour temperature of a white light is used to define its hue, which can be warm or cold; lights with warm hues tend towards yellow-orange and have colour temperatures below 3000 K. Higher colour temperatures correspond to “colder” hues.

[9] The Colour Rendering Index (CRI) runs from 0 to 100 and defines the aptitude of a light source to reproduce the different colours of the objects on which its light falls, compared to a reference source. Sunlight has a CRI of 100, while some low-pressure sodium-vapour lamps (used in road tunnels, for example) have a CRI of 20. In shops, schools and offices, the CRI should always be greater than 80.

- *1*: by combining a short wavelength-emitting diode (blue) with a yellow luminophore;
- *2*: by using a diode emitting in the near-ultraviolet, coupled with one or more luminophores;
- *3*: by using at least three visible wavelength-emitting diodes that combine to give a white light.

At the moment, the most economic and widely used is Method 1. The conclusions presented in this Opinion concern LEDs using this first method. They cannot therefore be extrapolated to cover LEDs created using other methods for producing white light.

Strong components in the blue part of the spectrum of light emitted by the LEDs, as well as the associated intensity of the radiation, raise the issue of new health risks related to these sources of lighting.
Some scientific studies [Dawson *et al.*, 2001[10], Ueda *et al.*, 2009[11]], based on laboratory experiments with blue LEDs conducted on monkeys, give reason to suspect a danger for the retina related to exposure to light-emitting diodes.
A study by Altkorn [Altkorn *et al.*, 2005] investigated the health impact of LEDs by reviewing the current debate on the position of LEDs with regard to standards: should they be rated, in terms of photobiological risk, according to the same standards as those applied to lasers or according to the standards applied to incoherent light sources? Indeed, until 2008, LEDs were considered in the same way as laser sources. Since January 2008, the NF EN 60825-1 'Lasers' standard has recommended using, for LED devices, the CIE[12] S009:2002 'Photobiological safety of lamps and lamp systems' photobiological safety standard concerning incoherent sources, which became a French standard (NF EN 62471) in December 2008.

3. Organisation of the expert appraisal

At its meeting on 23 September 2008, the AFSSET Expert Committee (CES) on "Physical agents, new technologies and development areas" discussed the impact of LEDs on human health. The CES judged the subject to be a matter of some concern and decided that the Agency should investigate the question on its own initiative.
The Scientific Council issued an Opinion, on 29 September 2008, in favour of AFSSET investigating on its own initiative the health consequences of exposure to lighting systems using light-emitting diodes. The expert appraisal was entrusted to the CES on "Physical agents, new technologies and development areas". At the suggestion of the CES, the Agency set up a Working Group with a mandate to carry out the expert appraisal. After a public call for applications from 12 December 2008 to 12 March 2009, the Working Group was formed with experts in ophthalmology, dermatology, lighting and optical radiation physics.
The Working Group convened ten times in plenary session between 13 May 2009 and 26 March 2010. It also interviewed French and international scientific experts, and representatives of the French Lighting Association (*Association Française de l'Eclairage* – AFE) in order to obtain all relevant information for carrying out the investigation. To conduct its appraisal, the Working Group carried out a broad review of the international

[10] Dawson, *et al*, *Local fundus response to blue (LED and laser) and infrared (LED and laser) sources*, Exp. Eye Res., 73(1):137-47 2001
[11] Ueda *et al*, *Eye damage control by reduced blue illumination*, Exp. Eye Res, 89(6):863-8. 2009
[12] CIE: International Commission on Illumination

scientific literature alongside its interviews with leading scientists. At the group's request, the French Environment and Energy Management Agency (ADEME) submitted a written contribution on the French and European market for lighting systems and the recycling of lamps.
The bibliographical analysis carried out by the 'LED' Working Group was as thorough as possible. The scientific studies taken into account in the report were all published in international, English-language, peer-reviewed journals.
The methodological and scientific aspects of the work were regularly submitted by the Working Group to the CES. The report produced by the Working Group takes account of observations and additional information supplied by the members of the CES.
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" to ensure compliance with the following points: competence, independence and transparency, while at the same time ensuring traceability.

4. RESULT OF THE COLLECTIVE EXPERT APPRAISAL

The work of the experts was based on five main themes:
- a review of the current situation regarding lighting;
- a presentation of the technology behind LEDs;
- an analysis of the way light interacts with biological systems (the eyes and skin);
- a summary of the standards currently applicable to LEDs;
- an analysis of the potential health effects of LEDs.

A special feature of this study concerned the calculations and measurements conducted by the members of the Working Group in their respective laboratories (CSTB[13], INRS[14], LNE[15]) to assign some examples of LED lighting systems to specific Risk Groups in accordance with the photobiological standard applicable to LEDs (NF EN 62471).

The CES on "Physical agents, new technologies and development areas" adopted the collective expert appraisal together with its conclusions and recommendations at its meeting on 3 June 2010 and informed the Agency's General Directorate.

5. OPINION AND RECOMMENDATIONS

This Opinion is based on the collective expert appraisal of the 'LED' Working Group and the CES on "Physical agents, new technologies and development areas". It restates the conclusions and recommendations in the report and the summary of the collective expert appraisal by the CES, and makes supplementary proposals for risk management.

CONCLUSIONS OF THE COLLECTIVE EXPERT APPRAISAL

As a result of the analysis of the existing scientific literature and the information collected during the additional hearings, potential health issues related to the use of LEDs were identified. Those of greatest concern, due to both the severity of the corresponding

[13] CSTB: *Centre Scientifique et Technique du Bâtiment* (French Scientific and Technical Centre for Construction)
[14] INRS: *Institut National de Recherche et de Sécurité pour la prévention des accidents du travail et des maladies professionnelles* (National Research and Safety Institute)
[15] LNE: *Laboratoire National de Métrologie et d'Essais* (the Metrology Institute and Reference Laboratory for French Industry)

dangers and the probability of their occurring as a result of the increasingly widespread use of LEDs, relate to the photochemical effects of blue light on the eye and the glare phenomenon. They result from:

- the spectral imbalance in LEDs (high proportion of blue light in white LEDs)
- the very high luminance[16] of LEDs (high brightness density per surface unit emitted by these very small sources).

Risks related to blue light

The photochemical risk is associated with blue light, and depends on the accumulated dose to which the person has been exposed, which is generally the result of low intensity exposure repeated over long periods. There is a high level of proof of such a risk.

Evidence from human observation and experimental studies on cell cultures and various animal species has converged to demonstrate the specific toxicity of shortwave (blue) light to the retina. Blue light is therefore recognised as being harmful and dangerous to the retina, as a result of cellular oxidative stress.

There is a strong suspicion that blue light aggravates age-related macular degeneration (ARMD), based on converging observations on experimental models. Epidemiological studies carried out up to now have proved inconclusive as a result of their lack of precision in assessing exposure and the data concerning individual predisposition.

Three population groups have been identified as being either especially sensitive to the risk or highly exposed to blue light:

- children (because of the transparency of their crystalline lens) and both aphakics (with no crystalline lens) and pseudophakics (with artificial crystalline lenses) who consequently either cannot or can only insufficiently filter short wavelengths (particularly blue light);
- population groups which are already light-sensitive: patients suffering from certain eye (e.g. ARMD) and skin diseases, patients taking photosensitising substances, etc., for whom blue light may aggravate their condition;
- population groups highly exposed to LEDs (certain categories of workers: those installing lighting systems, theatre and film industry professionals, etc.) which are subjected to high-intensity lighting, and are therefore likely to be exposed to large quantities of blue light.

Risk related to glare

In indoor lighting, it is generally agreed that luminance higher than 10,000 cd/m²[17] causes visual discomfort irrespective of the position of the lighting unit in the field of vision. Because the emission surfaces of LEDs are highly concentrated point sources, the luminance of each individual source can be 1000 times higher than the discomfort level. The level of direct radiation from this type of source can therefore easily exceed the level of visual discomfort, far more than is the case with "traditional" lighting (halogen and low-energy lamps).

[16] Luminance is the unit used to quantify the light emitted by a non-point source, per surface unit, in other words, the light density. It is expressed in candela per square metre (cd/m^2) and defines the brilliance of a light source as perceived by the human eye. It can therefore be used to measure glare.

[17] This value is generally quoted as being the upper limit beyond which subjects experience discomfort from glare in indoor lighting. The French NF X 35 103 standard: *Principes ergonomiques visuels applicables à l'éclairage des lieux de travail* (Ergonomic principles applicable to the lighting of workplaces for visual comfort) mentions admissible luminance of 2000 cd/m² for a small source on the working surface.

Other risks related to exposure to LEDs

The experts considered other potential risks such as disruption of circadian rhythms (biological clock) and stroboscopic effects (visually imperceptible fluctuation of the intensity of light).

There is very little risk of thermal effects, associated with burns to the retina and generally resulting from short-term exposure to very intense light, from the normal uses of LEDs.

LED technology can lead to the emission of electromagnetic fields insofar as such systems are combined with a power and voltage transformation device. Because of the low levels of exposure generated, the Working Group did not undertake a specific study of potential associated risks.

Assessment of the photochemical risks of LEDs

There is currently little information about human exposure to lighting, whether for systems using LEDs or other types of light sources. The Working Group was only able to present quantified risk assessments for exposure to blue light, under the terms of the NF EN 62471 standard for photobiological safety. This standard, which concerns the photobiological safety of lamps and devices using lamps, recommends exposure limits for radiation from these light sources. It provides a system of classification based on radiance and actual irradiance. The standard considers all of the photobiological hazards that may affect the eye (thermal and photochemical hazards) for ultraviolet to infrared wavelengths and defines four risk groups: Risk Group 0 (no risk), Risk Group 1 (low risk), Risk Group 2 (moderate risk), Risk Group 3 (high risk).

Due to the lack of information on exposure, the Working Group asked certain national laboratories to take radiance measurements. These readings were taken as an exploratory measure and were not intended to be exhaustive. Furthermore, as the standard was not designed to cover LED systems, these experiments are inadequate for a rigorous assessment of the photobiological risks related to LEDs, and are intended simply to determine the risk group of these new lighting systems in comparison to those for traditional lighting.

The radiance[18] measurements show that certain LEDs currently on sale to the general public and potentially used in domestic lighting situations, for signage and guide lights, fall into Risk Group 2, whereas all the other light sources currently on sale to the public fall into either Risk Groups 0 or 1. The safe exposure limit times implied by placing these items in Group 2 vary from a few seconds for certain royal blue LEDs to a few tens of seconds for certain cold white LEDs.

Furthermore, it seems that the NF EN 62 471 standard is unsuited to lighting systems using LEDs:

- the maximum exposure limits defined by the ICNIRP[19] and used to define the Risk Groups are not appropriate for repeated exposure to blue light as they were calculated for exposure of one 8-hour day and do not take into account the possibility of exposure over an entire lifetime;
- it contains ambiguities concerning the measurement protocols for allocating Risk Groups: the same LED could be assigned to different Risk Groups if considered

[18] The readings taken were of the radiance (which depends on the wavelength) weighted by the degree of phototoxicity of the blue light.

[19] ICNIRP: International Commission for Non-Ionising Radiation Protection.

individually or if integrated in a lighting system, as the evaluation distance imposed by the standard could be different;

- it does not take into account the sensitivity of certain specific population groups (children, aphakics, pseudophakics, etc.).

It is important to emphasise that other widely-used sources of lighting, particularly high-pressure gas discharge lamps (metal-halide lamps for outdoor lighting), are also in Risk Group 2. However, this last example is intended for clearly identified uses and can only be installed by professionals who are required to limit the exposure level for the population.
With the arrival on the domestic lighting market of LEDs, light sources falling into Risk Group 2 thus become available to the general public, without details of the risk incurred appearing on the labelling.
The methodology adopted in this report enabled the experts to evaluate the photobiological risks related to LEDs producing a luminous flux close to the mean of LEDs found on the market at the time of writing this document. At present and in the next few years it seems unlikely that technological progress will yield LEDs that can be classified in Risk Group 3. On the other hand, with the increase in both luminous flux and radiance, there is no doubt that more and more LEDs will fall into Risk Group 2.

Compliance with standards concerning glare

With regard to glare-related risks, the standards lay down certain references[20] covering visual ergonomics and safety. In LED lighting systems available on the market, the LEDs are often directly visible in order to avoid attenuating the level of brightness produced. This could lead to non-compliance with the requirements laid down in the standards.

RECOMMENDATIONS

The purpose of the following recommendations is to protect both the general public and working populations exposed to LED lighting in the workplace.

Concerning regulations and standards

Directive 2001/95/EC concerning general product safety applies to all products classified in sectors not covered by specific legislation (toys, etc.). The “EC” label, which is mandatory on all electrical devices sold in Europe, is a ‘self-declaration’, indicating that the manufacturer considers that the product complies with all the EU conditions for use of the label.
Where LED lighting is concerned, EC labelling ensures that the product complies with the essential requirements of the following European Directives: “Low voltage” (2006/95/EC), “Electromagnetic compatibility” (2004/108/EC) and “Eco-design” (for Energy-using Products) (2005/32/EC), concerning product safety, power consumption and emissions (noise, vibrations, radiation, electromagnetic fields), recycling potential, etc.
To satisfy these requirements, products must comply with specific standards, known as harmonised standards, published in the Official Journal of the European Union (e.g. NF EN 62311 concerning electromagnetic fields and NF EN 62471 concerning the photobiological safety of lamps). Furthermore, the Government Decree 2010-750 of 2 July 2010,

[20] The text refers to the French standard NF X 35-103: ‘*Ergonomie : Principes d´ergonomie visuelle applicables à l´éclairage des lieux de travail*’ (Ergonomics: Ergonomic principles applicable to the lighting of workplaces for visual comfort), the European standards NF EN 12464-1: ‘Lighting of workplaces – Part 1: indoor workplaces’, NF EN 12464-2: ‘Lighting of workplaces – Part 2: outdoor workplaces’, and the series of standards NF EN 13201: ‘Street Lighting’ and NF EN 12193: ‘Sports Lighting’.

transposing Directive 2006/25/EC into French law, stipulates the measures to be applied to ensure that workers are protected against the risks of exposure to artificial optical radiation.

Considering:

- the health risks related to blue light emitted by LED lighting systems falling into Risk Groups higher than 1 (according to the NF EN 62 471 standard);
- the significant risks of glare induced by LED lighting systems;
- the need to protect the general and working population from excessive radiance produced by LED systems and any risk of glare associated with the different uses of these new lighting systems;
- the marketing of LED products intended for light therapy, comfort or well-being purposes;

ANSES recommends:

- limiting the sale of LEDs for domestic use or for the general public to LEDs falling into Risk Groups equal to or less than 1 (when assessed at an observation distance of 200 mm);
- regulating the installation of LED lighting systems falling into Risk Groups greater than 1, by limiting them to professional uses, under conditions in which risks can be prevented;
- encouraging manufacturers and integrators of LED lighting systems to:
  - design lighting systems in which beams of light emitted by LEDs cannot be seen directly, to avoid glare. In particular, ANSES recommends the use of optical devices that reduce the intensity of light perceived directly or by reflection and to make the sources of LED light more diffuse;
  - take account of the progressive wear of phosphor layers in white LEDs, which in time could lead to devices moving to a higher photobiological risk group.
- assessing the safety and compliance of devices for light therapy, comfort or well-being and regulating their use.

Considering:

- that the standards in force for designing LED-based lighting installations are not always applied by professionals (electricians, lighting technicians and designers);
- that current photobiological safety standards seem unsuited to lighting systems using LEDs;

ANSES recommends:

- obliging professionals designing lighting systems using LEDs to apply all standards concerning the quality of lighting:
  - NF X 35-103 (‘Ergonomics: Ergonomic principles applicable to the lighting of workplaces for visual comfort’);
  - NF EN 12464-1 (‘Lighting of workplaces – Part 1: indoor workplaces’);
  - NF EN 12464-2 (‘Lighting of workplaces – Part 2: outdoor workplaces’);

  - the series of NF EN 13201 standards (‘Street Lighting’);
  - NF EN 12193 (‘Sports Lighting’).
- adapting the NF EN 62 471 standard (‘Photobiological safety of lamps and lamp systems’) to cover lighting systems using LEDs. It is essential to make it easier for manufacturers to take this standard into account and remove any ambiguity concerning how it should apply to LED systems. ANSES therefore recommends:
  - specifying in the NF EN 62 471 standard the conditions for measuring and evaluating LED systems;
  - publishing a guide to applying this standard, geared exclusively to LED systems;
  - determining the risk group for the worst case of observation (at a distance of 200 mm from the system) that will thus constitute the most unfavourable risk group;
  - adapting the standard to cover children and aphakic or pseudophakic individuals, taking into account the phototoxicity curve of the relevant type of light published by the ICNIRP;
  - considering proposing sub-groups for each risk group that would allow the risk to be assessed more precisely as a function of exposure time;
  - in the case of risk groups greater than 0, evaluating safe distances (at which observation corresponds to Risk Group 0) and indicating these explicitly on products intended for consumers (for devices for the general public) or for professionals responsible for installing lighting systems.
- introducing photobiological safety requirements in all safety standards concerning LEDs. This mainly concerns the following standards:
  - the NF EN 60 598 series of standards ‘Luminaires’;
  - NF EN 62 031: ‘LED modules for general lighting. Safety specifications’;
  - IEC 62 560: ‘Self-ballasted LED lamps for general lighting services by voltage > 50 V – Safety specifications’;
  - draft IEC standard 62 663-1 ‘Non-ballasted single capped LED lamps for general lighting – safety requirements’.

Concerning use, information and traceability

ANSES recommends that consumer information about health risks related to the use of LED lighting systems be made available immediately pending the implementation of an appropriate regulatory framework.

Considering:

- the proven risk resulting from acute exposure to blue light and the uncertainty surrounding the effects of chronic exposure at low doses, together with the uncertainty concerning the effects on the biological clock and diminished pupil contraction;
- that certain populations are sensitive to light in general (children, aphakics, pseudophakics, patients suffering from certain eye and skin diseases, patients taking photosensitising treatments, etc.);

ANSES recommends:

- avoiding the use of light sources emitting cold white light (light with a strong blue component) in places frequented by children (maternity wards, nurseries, schools, leisure centres, etc.) or in the objects they use (toys, electronic display panels, game consoles and joysticks, night lights, etc.);
- informing patients taking photosensitising drugs about the risks related to exposure to light with a strong blue component.

Considering:

- that there are populations of workers likely to be exposed to bright LED lighting systems;

ANSES recommends:

- developing appropriate means of protection (such as safety goggles specifically to protect against exposure to LEDs) for workers highly exposed to LED lighting systems.

Considering:

- the lack of information available to the public concerning the LED lighting systems on the market;

ANSES recommends:

- ensuring that manufacturers and integrators of LEDs carry out quality controls and qualify their products with regard to the different Risk Groups;
- setting up a clear, easy-to-understand labelling system for consumers, particularly concerning the technical characteristics of the lighting and any potential health effects;
- mandatory indication of the photobiological safety Risk Group on the packaging of LED products, after assessing the product at a distance of 200 mm. For light sources falling into Risk Group 1, the labelling should also indicate the safety distance beyond which the risk moves down to Group 0;
- mandatory indication of the photobiological safety Risk Group for all types of lighting.

CONCERNING STUDIES AND RESEARCH THEMES

Considering the lack of data about exposure of the general and working populations to artificial light, ANSES recommends:

- enriching the available documentation on exposure of the population to artificial light in both occupational and general environments;
- defining a suitable index for evaluating the intensity of glare produced by an LED source, as the Unified Glare Rating used for other types of lighting is unsuitable for LEDs, which are sources of low-angle light.

Concerning studies and research on the health effects of LED lighting systems, ANSES recommends:

- developing clinical research to define maximum exposure limits for blue light and, for this purpose:
  - studying the cumulative medium- and long-term effects of exposure to blue light;
  - carrying out prospective and retrospective studies of populations undergoing light therapy with the use of blue LEDs;
- undertaking research to improve characterisation of the effects of artificial light, and in particular light emitted by LED systems, on biological rhythms. ANSES therefore recommends:
  - further studies to improve characterisation of the spectra of action of the mechanisms by which light regulates the human biological clock;
  - quantifying the impact of exposure to cold artificial lights on circadian rhythms and pupil contraction;
  - in general, studying how health is affected by light pollution (linked with possible disruption of the biological clock) and systematic installation of LED lighting systems;
- studying the triggering or aggravation of photodermatoses caused by LED lighting;
- organising measurement campaigns to characterise the electromagnetic fields generated by LED lighting systems.

Concerning studies and research to be carried out on LED technology to prevent potential health risks, ANSES recommends:

- encouraging research for the development of new emissive materials coupled with optimised luminophores, to obtain a high quality white light, with the highest possible luminous efficacy;
- developing research into the design of lighting units adapted to LEDs with a view to reducing luminance, by applying optical solutions;
- studying the mechanisms that cause the degradation of the phosphor layers in white LEDs, potentially leading to an increase in the amount of blue light emitted.

The Director General

Marc Mortureux

afsset

EXPERT COLLECTIVE APPRAISAL: SUMMARY AND CONCLUSIONS

concerning the internally-solicited request entitled "Health effects of lighting systems using light-emitting diodes (LEDs)"

This document summarises the work of the Expert Committee and the Working Group

Presentation of the question

The European Eco-design Directive (2005/32/EC), known as "EuP" for Energy-using Products, aims to improve the energy efficiency of certain consumer goods. This Directive was transposed into national law by the Member States of the European Union in 2007 and came into force between 2008 and 2010.
On 18 March 2009, in application of the EuP Directive, the European Commission decided in favour of a gradual ban on the sale of the most energy-consuming lamps, to be implemented from 1 September 2009 to 1 September 2016. Compact fluorescent or "low-energy" lamps, or other sources of energy-saving lighting such as light-emitting diodes, are destined to replace them eventually.
Light-emitting diodes are currently undergoing rapid technological and financial development. They have been used for several years in electronics as weak, monochromatic light sources for indicator or warning lights and are now commonly used as normal light sources in lighting systems such as traffic lights, portable lighting, vehicle lights and domestic room-lighting.

The first visible-spectrum LED was created in 1962 and emitted only very low intensity light. The blue diode was invented in 1990, and was followed by the development of the white diode that made it possible for new and important applications to be adopted, mainly for lighting and for television and computer screens. The first white LEDs appeared on the market gradually and have now become increasingly powerful[1] (attaining several Watts). The most widely-used procedure for producing white light couples a blue LED and a yellow phosphor.

The French company OSYRIS[2] expressed concern in a letter addressed to the French Institute for Public Health Surveillance (InVS), dated 27 December 2007, about the possible impact on the retina of light from LEDs. The letter underlined the possible link between exposure of the eye to shortwave radiation, close to ultraviolet light (characteristic of the light spectra of LEDs) and the risk of age-related macular degeneration, an eye disease. The InVS forwarded the OSYRIS letter to the French Agency for Environmental and Occupational Health Safety (AFSSET) in a letter dated 14 January 2008.
Simultaneously, the question of the impact of LEDs on occupational health was raised during informal discussions between AFSSET and the Directorate-General for Labour (DGT), the latter having recently been alerted by the projected use of indoor LED lighting for buildings. The development of this type of lighting solution is likely to accelerate, mainly due to cost considerations.

[1] Source - ADEME: "Low-power LEDs (i.e. lower than 1 Watt) are used as indicator lights on domestic appliances, for example. More energy-consuming LEDs (i.e. higher than 1 Watt) can withstand stronger currents (up to 1500 mA) and supply more light (135 lm/W)".
[2] A French company specialising in lasers and their application in medicine and industry.

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Scientific context and applicable standards

In France, lighting accounts for 10% of total electricity consumption, or 350 kWh per year and per household[3]. LEDs consume far less energy than other types of lighting and last much longer.

The luminous efficacy of incandescent lamps is of the order of 10 to 15 lumens[4] per Watt (lm/W), for halogen lamps it is from 15 to 30 lm/W and for compact fluorescent lamps it is in the range of 50 to 100 lm/W. Some of the latest LEDs achieve an efficacy of up to 100 to 150 lm/W, with predictions in the region of 200 lm/W for 2020[5].

There is as yet no standard definition of the lifetime of an LED. Current LEDs have considerable lifetimes (estimated at up to 50,000 hours[6], or 50 times longer than incandescent lamps and 3 to 5 times longer than compact fluorescent lamps).

The technology behind LEDs, which have certain advantages over other types of lighting, (energy efficiency and lifetime), is constantly changing but the quality of the light (colour temperature[7], colour rendering index[8]) emitted by these lamps is not always as high as for other types of lighting. At present, LEDs have a greater impact on the environment than other types of lighting.

Strong components in the blue part of the light spectrum emitted by LEDs, as well as the intense radiation of what are highly concentrated point sources, raise concern about new potential health risks.

Some scientific studies [Dawson *et al.*, 2001[9], Ueda *et al.*, 2009[10]] based on laboratory experiments with blue LEDs conducted on monkeys, have concluded that the retina is in danger of being damaged by exposure to light-emitting diodes.

Another study by Altkorn [Altkorn *et al.*, 2005] investigated the health impact of LEDs by reviewing the current debate on the position of LEDs with regard to standards: should they be rated, in terms of photobiological risk, according to the same standards as those applied to lasers or according to the standards applied to incoherent light sources? Indeed, until 2008, LEDs were treated in the same way as laser sources. Since January 2008, the NF EN 60825-1 'Lasers' standard has recommended using, for LED devices, the CIE[11] S009:2002 'Photobiological safety of lamps and lamp systems' standard, which became a French standard (NF EN 62471) in December 2008.

Organisation of the expert appraisal

At its meeting on 23 September 2008, the AFSSET Expert Committee (CES) on "Physical agents, new technologies and development areas" discussed the impact of LEDs on human

[3] Source ADEME 2010

[4] The lumen is the unit used to quantify luminous flux

[5] The theoretical limit for the luminous efficacy of light sources is set at 683 lm/W.

[6] Source ADEME 2010

[7] The colour temperature of a white light is used to define its hue, which can be warmer or colder; lights with warm hues tend to yellow-orange and have colour temperatures below 3000 K. Higher colour temperatures correspond to "colder" hues.

[8] The Colour Rendering Index (CRI) runs from 0 to 100 and defines the aptitude of a light source to reproduce the different colours of the objects on which its light falls, compared to a reference source. Sunlight has a CRI of 100, while some low-pressure sodium-vapour lamps (used in road tunnels, for example) have a CRI of 20. In shops, school premises and offices, the CRI should always be greater than 80.

[9] Dawson, et al, *Local fundus response to blue (LED and laser) and infrared (LED and laser) sources*, Exp. Eye Res., 73(1):137-47 2001

[10] Ueda et al, *Eye damage control by reduced blue illumination*, Exp. Eye Res, 89(6):863-8. 2009

[11] CIE: *Commission Internationale de l'Eclairage* (International Commission on Illumination)

health. The CES judged the subject to be a matter of some concern and decided that an internally-solicited request should be made to investigate the issue.

The AFSSET Scientific Council issued an Opinion, on 29 September 2008, in favour of AFSSET itself investigating the health consequences of exposure to lighting systems using light-emitting diodes. AFSSET mandated the CES on “Physical agents, new technologies and development areas” to conduct the expert appraisal. At the suggestion of the CES, the Agency then set up a Working Group to carry out the expert appraisal. After a public call for applications from 12 December 2008 to 12 March 2009, the Working Group was formed with experts in ophthalmology, dermatology, lighting and optical radiation physics.

The Working Group coordinated by AFSSET held 10 plenary sessions between 13 May 2009 and 26 March 2010. It also interviewed leading French and international scientists and also representatives of the French Association of Lighting Professionals (*Association Française de l’Eclairage* – AFE) in order to obtain all relevant information for carrying out the investigation. To conduct its appraisal, the Working Group carried out a broad review of the international scientific literature alongside its interviews with leading scientists. At the group’s request, the French Environment and Energy Management Agency (ADEME) submitted a written contribution on the French and European market for lighting systems and the recycling of lamps.

The bibliographical analysis carried out by the ‘LED’ Working Group was as thorough as possible. The scientific studies taken into account in the report had all been published in international, English-language, peer-reviewed journals.

The Working Group’s ongoing appraisal was submitted to the CES at regular intervals, regarding both its methodological and scientific aspects. The report produced by the Working Group takes account of feedback and additional information from the members of the CES.

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” to ensure compliance with the following points: competence, independence and transparency, while at the same time ensuring traceability.

Result of the collective expert appraisal

The work of the experts was based on five main approaches:

- a review of the current situation regarding lighting;
- a presentation of the technology behind LEDs;
- an analysis of the way light interacts with biological systems (the eyes and skin);
- a summary of the standards currently applicable to LEDs;
- an analysis of the potential health effects of LEDs.

A special feature of this study concerned the calculations and measurements conducted by the members of the Working Group in their respective laboratories (CSTB[12], INRS[13], LNE[14]) to assign some examples of LED-based lighting systems to specific Risk Groups in accordance with the photobiological standard applicable to LEDs (NF EN 62471).

[12] CSTB: *Centre Scientifique et Technique du Bâtiment* (French Scientific and Technical Centre for Construction)
[13] INRS: *Institut National de Recherche et de Sécurité pour la prévention des accidents du travail et des maladies professionnelles* (National Research and Safety Institute).
[14] LNE: *Laboratoire National de Métrologie et d’Essais* (the Metrology Institute and Reference Laboratory for French Industry).

The CES on "Physical agents, new technologies and development areas" adopted the collective expert appraisal, together with the conclusions and recommendations in this summary, at its meeting on 3 June 2010 and informed AFSSET's General Directorate.

Conclusions of the expert appraisal

As a result of its analysis of the existing scientific literature and the information collected during the additional hearings, the Working Group identified potential health issues related to the use of LEDs.

Characteristics of LEDs relevant to risk assessment

The technology behind light-emitting diodes is based on the polarisation of a semiconductor by applying a voltage that causes photons to be emitted in the form of quasi-monochromatic radiation, whose wavelength depends on the semiconductor used. There are no semiconductors capable of emitting white light on their own. There are, however, currently three different ways of producing white light indirectly with an LED. Given the technological constraints and the imperatives concerning electrical efficiency, currently the most widely-used method for producing white light uses a yellow luminophore to transform part of the light from a blue diode.

- ***Spectral imbalance within the blue***

The light spectrum from white LEDs is largely made up of very weak emissions ranging between blue and yellow, but with a high proportion of blue light (a blue spike in the spectrum). These characteristics are highly specific to LEDs, and are not found in other, traditional types of lighting.

- ***High luminance***[15]

LEDs are point sources of light that can be aggregated in lighting units to achieve high luminous flux. Because the emission surfaces of LEDs are highly concentrated point sources, the luminance of each individual source produces very high luminance, at least 1 000 times higher (10^7 cd/m²) than that from a traditional lighting source.

- ***Stroboscopic effect***

Depending on their architecture, the electrical power supplied to LED lighting systems can vary, causing fluctuations in the intensity of the light produced that are barely perceptible to the naked eye. These fluctuations have not yet been characterised in any detail[16]. The frequency of these effects can vary from a few Hertz to several hundred Hertz[17] for those LEDs that have already been studied.

[15] Luminance (expressed in candela per square meter, or cd/m²) is the unit used to quantify the light emitted by a non-point source, per surface unit. It defines the brilliance of a light source as perceived by the human eye. It can therefore be used to measure glare.

[16] Both the frequency and the modulation rate (the ratio between the amplitude of the fluctuation and the mean value of the light) depend heavily on the type of supply. For a power supply in direct current (rectified and filtered), the frequency of fluctuation is 100 Hz and the modulation rate can attain values from 2% to 20% depending on the quality of filtering. For a Pulse Width Modulation (PWM) power supply, the frequency is of the order of tens of kilo-Hertz and the modulation rate can vary, and may even exceed 50%. Lastly, for the new technology by which LEDs are powered by alternating current, the frequency of fluctuation is 100 Hz and the modulation rate can reach 100 %.

[17] *A Review of the Literature on Light Flicker: Ergonomics, Biological Attributes, Potential Health Effects, and Methods in Which Some LED Lighting May Introduce Flicker*, IEEE Standard P1789 (2010)

Identified health issues

The main health risks associated with LED-based lighting systems result from their high luminance (i.e. the high brightness density per surface unit emitted by these very small sources) associated with the unusual emission spectrum of white LEDs, which have a high proportion of blue (shortwave) light. Other potential effects are raised in the report, such as disturbance to circadian rhythms and stroboscopic effects.

With regard to the many potential health effects identified (photochemical effect, glare, etc.), there is currently little information on human exposure to lighting to enable us to quantify the corresponding health risks adequately, whether for systems using LEDs or other types of light sources.

The Working Group was therefore only able to make quantified risk assessments for exposure to blue light, under the terms of the NF EN 62471 standard for photobiological safety. However, this standard is unsuited to lighting systems using LEDs. In the light of current knowledge, the maximum exposure limits given in this standard do not take account of daily exposure to LEDs.
In the following description of the risks identified by the Working Group, the effects on the eye, both thermal and photochemical, have been dealt with separately from the other effects particularly related to disturbance of circadian rhythms.

<u>Effects on the eye</u>

- **Risk related to the thermal effect of light**

The risk of thermal effects is related to burns to the retina, generally resulting from short-term exposure to a very intense light. This type of danger concerns all wavelengths, from ultraviolet to infrared and the entire visible spectrum. This type of risk, usually associated with lasers, is unlikely in conventional uses of LEDs.

- **Risk related to the photochemical effects of blue light**

The risk of photochemical effects is related to human exposure to blue light and the risk level depends on the accumulated dose to which the person is exposed. It therefore generally involves repeated, low-intensity exposure over long periods.

  - ***Characterisation of the risk***

Evidence from human observation and experimental studies on cell cultures and various animal species has converged to demonstrate the specific toxicity of shortwave (blue) light to the retina.

Blue light can cause photochemical damage. Lesions occur on the outer retina (photoreceptors and cells of the pigment epithelium) and appear after some time has passed. The lesions may not be visible via ophthalmoscopy. Two types of photochemical lesions have been described: those resulting from interaction with visual pigments, which affect the photoreceptors, and those related to interaction with the lipofuscin, which affect the cells of the pigment epithelium.

These interactions lead to the production of high doses of cytotoxic free radicals. The photoreactive pigments (lipofuscin) in the epithelium accumulate with age, increasing the risk of oxidative stress. Cellular death has functional consequences which are particularly significant as they concern the macular region (central vision).

There is no current consensus as to whether accumulated lesions resulting from low doses of oxidative stress could, over long periods, accelerate premature aging of the retina and favour macular degeneration.

At the moment there are no appropriate animal models of age-related macular degeneration (ARMD), as all the models use rodents, whereas only primates and certain birds have maculae. The necessary follow-up times for these species are not compatible with the experimental protocols.
In humans, repeated exposure to very bright sunlight can cause irreversible macular lesions close to those observed in age-related maculopathies, but the epidemiological studies carried out in this field have not all identified exposure to sunlight as a risk factor for ARMD.

Following converging observations on experimental models, there is a strong suspicion that blue light aggravates ARMD. Epidemiological studies in humans have never clearly shown such effects, as a result of difficulties in evaluating the exposure and individual predisposition.

In adults, the crystalline lens (which, as it turns yellow, partly absorbs blue radiation) and the macular pigments partially protect against this toxicity through their capacity to absorb blue light. These protective mechanisms are weaker in children (whose crystalline lenses are transparent), aphakics (with no crystalline lenses) and pseudophakics (with artificial crystalline lenses). There is also less protection available in cases of reduced macular pigment, as observed during certain macular pathologies (e.g. ARMD).

- ***Exposure to LEDs***

There is currently no information about human exposure to lighting, whether for systems using LEDs or other types of light sources.

- ***Photobiological safety standards***

<u>Description of the NF EN 62471 standard and risk groups</u>

The NF EN 62471 standard concerning the photobiological safety of lamps and devices using lamps suggests maximum exposure limits for radiation from light sources commonly used for lighting, and provides a method of classification based on radiance and actual irradiance together with a method for measuring these values. This standard covers all photobiological hazards for the eye (thermal and photochemical hazards), for ultraviolet to infrared wavelengths.

The standard defines four Risk Groups:
- Risk Group 0 (no risk): the product involves no photobiological risk;
- Risk Group 1 (low risk): the product involves no risk in terms of maximum exposure limits under normal conditions of use;
- Risk Group 2 (moderate risk): the product involves no risk in terms of aversion response to very bright light sources or due to thermal discomfort;
- Risk Group 3 (high risk): the product may involve a risk even during momentary or short exposure periods.

Gaps and inadequacies in the standard

- *Maximum exposure limits unsuitable for repeated exposure to blue light*

  The maximum exposure limits for the general public designed to avoid acute lesions to the retina have been put forward by the ICNIRP[18,19] and used in the NF EN 62 471 standard and in European Directive 2006/25/CE concerning artificial optical radiation.

  These maximum exposure limits were calculated for exposure to a light source in the field of vision for one 8-hour working day. They were calculated from experimental data weighted by a reduction factor of 5 to 10 times the energy necessary to produce observable lesions.

  In practice, experiments on animals have established the energy thresholds for inducing lesions to the ocular fundus that can be observed macroscopically by ophtalmoscopy after a single exposure to light. These lesions take the form of a whitening of the neural retina, as a result of an oedema of the superficial retinal layers.

  In the light of current knowledge, the maximum exposure limits in force do not allow evaluation of daily chronic exposure limits to blue light. The classification of lamps by these values does not take account of the long-term risk resulting from accumulated exposure. This means that repeated and prolonged exposure could induce an accumulated risk potentially greater than that assessed using the maximum exposure limits.

- *Ambiguity in measurement distances*

  For the most common lighting lamps, the NF EN 62 471 standard requires the risk group to be evaluated at the distance at which they produce a brightness of 500 lx. For other types of lamps, the risk group must be determined for the worst observation case, i.e. a distance of 200 mm.
  The risk group for any lighting system using LEDs can be determined using either of these measurement protocols, leading to very different classifications (evaluation at 500 lx always gives a lower value than evaluation at 200 mm). There is therefore ambiguity concerning the distance at which these measurements should be taken.

- *Failure to take into account population groups sensitive to blue light*

  To assess the risk related to blue light, the NF EN 62 471 standard recommends using the phototoxicity curve for blue light suggested by the ICNIRP. This curve is only suitable for adults. The standard includes no specific recommendations for population groups whose natural mechanisms for filtering blue light are diminished (children, aphakics and pseudophakics), or who are more sensitive to blue light as a result of retinal diseases. In fact, the ICNIRP gives a different phototoxicity curve for blue light for aphakics. The current standard does not take account of the situation of population groups sensitive to blue light.

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[18] ICNIRP (International Commission for Non-Ionising Radiation Protection), "*Guidelines on limits of exposure to broad-band incoherent optical radiation (0.38 to 3 μm)"* (1997)
[19] ICNIRP (International Commission for Non-Ionising Radiation Protection), "*ICNIRP statement on light-emitting diodes (LED) and laser diodes : implication for hazard assessment"* (2000)

- ***Measurements taken by the Working Group***

The Working Group made risk assessments defined according to the NF EN 62 471 standard for different lighting systems, in order to compare LEDs with other types of lighting.
It seems that certain LEDs that are very widely used in lighting, signage and guide lights fall into Risk Group 2, whereas all other light sources currently on sale to the public fall into either Risk Group 0 or 1. The maximum exposure times implied by placing these items in Group 2 vary from a few seconds for certain royal blue LEDs to a few tens of seconds for certain cold white LEDs.
LEDs and LED-base lighting systems can be classified in different Risk Groups depending on their radiance and hue (cold white, warm white, etc.), thus increasing the difficulty of preventing this risk.

- ***Sensitive or highly exposed population groups***

Three population groups have been identified as being either especially sensitive to the risk or highly exposed to blue light:

  - children (because of the transparency of their crystalline lens) and both aphakics (with no crystalline lens) and pseudophakics (with artificial crystalline lenses) who consequently either cannot or can only insufficiently filter short wavelengths (especially blue light);
  - population groups which are already light-sensitive: patients suffering from certain eye and skin conditions and patients taking treatments one of whose side-effects is to increase photosensitivity, etc., for whom blue light can be an aggravating factor for their condition;
  - population groups highly exposed to LEDs (certain categories of workers: those installing lighting systems, theatre and film industry professionals, etc.) which are subjected to high-intensity lighting, and are therefore susceptible to exposure to large quantities of blue light.

- ***Conclusions concerning the risk related to blue light***

It is important to emphasise that other widely-used sources of lighting, particularly high-pressure gas discharge lamps (metal-halide lamps for outdoor lighting), also fall into Risk Group 2. However, these lamps are intended for use in clearly-identified applications and can only be installed by professionals who are required to limit the exposure level for the population.

The arrival of LEDs on the lighting market for the general public is an unprecedented development: it is the first time that sources classified in Risk Group 2 have become accessible to the general public, for use in the home and, most importantly, with no indication of the risk.

The same LED considered individually or integrated in a lighting system could be assigned to different Risk Groups depending on the evaluation distance imposed by the NF EN 62 471 standard.
As the technology behind LED lighting evolves over the next few years, lighting performance is likely to improve considerably. The risks associated with exposure to LED-based lighting systems are therefore likely to increase as the radiance increases.

The methodology adopted in this report enabled the experts to evaluate the photobiological risks related to LEDs producing a luminous flux close to the mean of LEDs found in the range of fluxes available on the market at the time of writing this document. At present and for the next few years it seems unlikely that technological progress will yield LEDs that can be classified in Risk Group 3. On the other hand, with the increase in both luminous flux and radiance, there is no doubt that more and more LEDs will fall into Risk Group 2.

- **Risks related to glare**

There are two types of glare: discomfort glare and disability glare.

Discomfort glare produces a disagreeable sensation, without necessarily impairing the vision of objects. It is related to the luminance of the lighting unit and to contrast differences. It is associated with a momentary reduction in visual performance.

Disability glare perturbs the vision of objects (veiling luminance) without necessarily causing a disagreeable sensation. It is related to the quantity of incident light on the eye and the luminance of the lighting unit. It can cause accidents in the home (either slip-and-trip falls or falls from heights), in traffic (collisions) and elsewhere.

In indoor lighting, it is generally agreed that luminance higher than 10,000 cd/m² causes visual discomfort irrespective of the position of the lighting unit in the field of vision. This value is commonly cited for discomfort glare in indoor lighting as being the value above which subjects are bound to suffer the effects of glare.

The French NF X 35 103 standard for visual ergonomics gives a limit value of 2,000 cd/m² for discomfort glare, for the case of a small source located in the central area of the field of vision.

Because the emission surfaces of LEDs are highly concentrated point sources, the luminance of each individual source can be at least 1000 times higher than the luminance from traditional lighting sources. The level of direct radiation from this type of source greatly exceeds the level of visual discomfort.

The Working Group recorded luminances of more than 10,000,000 cd/m² for certain LEDs with an electrical power of 1 W (in devices on public sale for domestic use).

In LED lighting systems available on the market, the LEDs are often directly visible in order to avoid attenuating the level of brightness produced. This leads to non-compliance with the requirements laid down in the standards (visual ergonomics and safety requirements) for lighting intended to avoid excessive luminance in the field of vision.

Other effects

- ***Risk of deregulating the biological clock and pupil contraction***

In humans, the biological clock and pupil contraction are regulated by wavelengths close to 480 nm which suppress the production of melatonin (a hormone participating in the regulation of the biological clock and therefore the circadian cycle).

The spectrum produced by LEDs differs fundamentally from that of natural light, with a very low proportion near 480 nm. This could expose subjects to a risk of deregulation of their biological clocks and, in consequence, of their circadian rhythms. These risks are exacerbated by high-temperature colours (cold white and blue), which are frequently found in LED-based lighting systems.

Deregulation of the biological clock can affect the metabolism, the thymus (depression, mood swings), the waking/sleeping rhythm, etc.
Furthermore, the pupil contraction reflex is induced in strong light by these same wavelengths. It could be reduced under LED lighting, which could lead to stronger light falling on the retina and an increase in the risks associated with blue light.

- **Risk related to flicker in the light emitted by LEDs**

As a consequence of the manner in which they are powered electronically, the light emitted by LEDs may be subject to rapid fluctuation of great amplitude. This fluctuation, combined with the fact that LEDs have very low remanence, is usually imperceptible to human vision. In situations involving movement or in confined spaces with periodic variations in contrast, it can be responsible for stroboscopic effects. Although such stroboscopic effects have never been studied in depth, they can have a direct impact on health (epileptic seizures for subjects at risk), visual performance and safety. A recent publication[20] showed that LEDs can produce fluctuations in light at frequencies known to produce effects on health (from 3 to 60 Hz for visible fluctuations and from 120 à 150 Hz for non-visible fluctuations).

Recommendations

The following recommendations apply to both lighting systems using LEDs already on the market and future LED-based systems.

Concerning health risks related to exposure to LEDs,

Considering:
the health risks related to blue light emitted by LED lighting systems in products available to the public despite belonging to Risk Groups higher than 1 (according to the NF EN 62 471 standard);

the CES recommends:

- banning the sale to the public of lighting systems falling into Risk Groups higher than 1, evaluated at an observation distance of 200 mm;
- reserving LEDs falling into Risk Groups higher than 1 for applications designed to be installed safely by professionals.

Considering:
the health risks created by LED lighting systems, related to very high luminance and substantial glare;

the CES recommends that manufacturers and integrators**:**

-in order to protect the population against excessive luminance from LED systems and strong glare,

- design lighting systems such that the beams emitted by LEDs are not directly visible. In particular, the CES recommends the use of optical devices that reduce the intensity of

[20] *A Review of the Literature on Light Flicker: Ergonomics, Biological Attributes, Potential Health Effects, and Methods in Which Some LED Lighting May Introduce Flicker*, IEEE Standard P1789 (2010)

light perceived directly or by reflection and to make the sources of LED light more diffuse;

- take account of the progressive wear of phosphor layers in white LEDs, which in time could lead to devices moving to a higher photobiological risk group.

- in order to protect the drivers of vehicles, pedestrians, cyclists and motorcyclists from the risk of glare related to excessive luminance emitted by LED headlights,

- only be authorised to install LED-based lighting systems from Risk Groups 0 or 1 for motor vehicle headlights by day or night, given that daytime running lights will be mandatory for all new cars from February 2011 (European Directive on daytime lighting 2008/89/EC);

Considering:

- the proven risks resulting from acute exposure to blue light and the uncertainty surrounding the effects of chronic exposure at low doses, together with the uncertainty concerning the effects on the biological clock and pupil contraction;
- that certain population groups are sensitive to light in general (children, aphakics, pseudophakics, patients suffering from certain eye and skin diseases, or who are taking photosensitising drugs, etc.);
- that there are populations of workers susceptible to exposure to bright LED lighting systems;

the CES makes the following recommendations:

- specifically to protect population groups at risk, such as those sensitive to light and those highly exposed to LEDs. The CES thus recommends:

  - for children, avoiding the use of sources emitting a cold white light or blue light in places frequented by children (maternity wards, nurseries, schools, recreation centres, etc.) or in the objects they use (toys, electronic display panels, game consoles and joysticks, night lights, etc.).
  - developing appropriate means of protection (such as safety goggles specifically to protect against exposure to LEDs) for workers highly exposed to LED lighting systems;
  - informing patients taking medicines one of whose side-effects is to increase photosensitivity about the risks related to exposure to cold light and particularly light emitted by LEDs, even those classified as belonging to Risk Group 0; informing health workers of the existence of this risk;
  - employing caution in the use of devices to increase the effective size of LEDs, even if such devices do not increase the luminance (such as optical collimators and multichip assemblies of LEDs). Indeed, the use of these devices leads to shorter maximum exposure times to blue light than in the case of single chip LEDs without additional optics. A higher Risk Group may then be appropriate.

Considering:
that LED-based products for light therapy, comfort and well-being are available on the market, the CES recommends evaluating the safety and compliance of these devices.

Concerning standards relative to the lighting quality and the photobiological safety of LEDs,

Considering:

- o that the standards in force for lighting installations are not always applied by professionals (electricians, lighting specialists, designers of lighting systems) in the case of LED systems;
- o that the standards related to photobiological safety might prove to be ill-adapted to LED lighting systems;

the CES makes the following recommendations:

- That professionals installing LED-based lighting systems be obliged to apply all standards relative to lighting quality:

- French standard NF X 35-103 ('*Ergonomie : Principes d´ergonomie visuelle applicables à l´éclairage des lieux de travail*' – Ergonomics: Ergonomic principles applicable to the lighting of workplaces for visual comfort);
- NF EN 12464-1 ('Lighting of workplaces – Part 1: indoor workplaces');
- NF EN 12464-2 ('Lighting of workplaces – Part 2: outdoor workplaces');
- the series of NF EN 13201 standards ('Street Lighting');
- NF EN 12193 ('Sports Lighting').

- Adapting the NF EN 62 471 standard ('Photobiological safety of lamps and lamp systems') to cover lighting systems using LEDs. It is essential to make it easier for manufacturers to take this standard into account and remove any doubt as to how it should apply to LED systems. The CES therefore recommends:

- specifying in the NF EN 62 471 standard the conditions for measuring and evaluating LED systems;
- publishing a guide to applying this standard, exclusively for LED systems;
- determining the risk group for the worst case of observation: at a distance of 200 mm from the system, thus giving the most unfavourable Risk Group;
- adapting the standard to cover children and people who are either aphakic or pseudophakic, taking into account the phototoxicity curve of the relevant type of light published by the ICNIRP;
- proposing sub-groups for each risk group that would allow the risk to be assessed more precisely as a function of exposure time;
- in the case of risk groups greater than 0, evaluating safe distances (distance at which observation corresponds to Risk Group 0) and for these to be indicated explicitly on products intended for consumers (the case of devices for the general public) or for professionals responsible for installing lighting systems.

- To reinforce the photobiological safety aspect in the requirements for upgrading existing lighting systems to bring them into compliance with standards:

- introducing photobiological safety requirements into all safety standards covering LED lamps, LED modules and LED lighting units. This mainly concerns the following standards:
  - o the NF EN 60 598 series of standards: 'Luminaires';
  - o NF EN 62 031: 'LED modules for general lighting. Safety specifications';
  - o IEC 62 560: 'Self-ballasted LED lamps for general lighting services by voltage > 50 V – Safety specifications';
  - o draft IEC standard 62 663-1 'Non ballasted single capped LED lamps for general lighting – safety requirements'.

Concerning information for consumers, traceability and the quality and labelling of LEDs,

Considering*:*

- the lack of information available to the public concerning LED-based products;

the CES makes the following recommendations:

- That consumers be informed of the quality and performance of the lighting systems they choose to buy. That consumers be given easy access to information about the characteristics of the products they buy. The CES recommends:

- ensuring that manufacturers and integrators of LEDs carry out quality and traceability controls on LEDs; apart from the quality in terms of lighting, it is essential that they ensure that their products comply with their assigned Risk Group;
- considering a labelling system that will be comprehensible for consumers and contain all relevant information (power, voltage, colour temperature, luminous flux, etc.);
- making it mandatory to indicate the photobiological safety Risk Group on the packaging of LED products, after assessing the product at a distance of 200 mm. For light sources falling into Risk Group 1, the labelling should also indicate the safety distance beyond which the risk moves down to Group 0;
- making it mandatory to indicate the photobiological safety Risk Group for all types of lighting;
- considering the creation of a quality label (reproducibility, ecolabelling, etc.).

Recommendations for studies and research themes

Considering the lack of data on exposure of the general public and the working population to artificial light, the CES makes the following recommendations:

- Characterising and studying the exposure of the population to artificial light.

- Defining a suitable index for evaluating the intensity of glare produced by an LED-based source, as the Unified Glare Rating (UGR) used for other types of lighting is not appropriate for LEDs, which are sources of low-angle light.

Concerning studies and research on the health effects of LED lighting systems, the CES recommends:

- Developing clinical research to obtain information for defining exposure limit values for blue light. The CES therefore recommends:

  - studying the cumulative medium- and long-term effects of exposure to blue light;
  - carrying out prospective and retrospective studies of subjects undergoing light therapy with blue LEDs;
  - implementing experimental protocols for evaluating the consequences of prolonged and accumulated exposure at levels inferior to the exposure limit values.

- Undertaking research to improve characterisation of the effects of artificial light, and particularly the light emitted by LED systems, on biological rhythms. The CES therefore recommends:

- further studies to improve characterisation of the spectra of action of the mechanisms by which light regulates the human biological clock;
- quantifying the impact of exposure to cold artificial lights on circadian rhythms and diminished pupil contraction;
- in general, studying how health is affected by light pollution (linked with possible disruption of the biological clock) and systematic installation of LED lighting systems.

- Systematically studying the triggering and/or aggravation of photo-dermatoses caused by LED lighting.

Concerning studies and research to be carried out on LED technology to prevent health risks, the CES makes the following recommendations;

- Improving LED technology. The CES therefore recommends:

- encouraging research for the development of new emissive materials coupled with optimised luminophores, to obtain a high quality white light, with the highest possible luminous efficacy;
- developing research into the design of lighting units adapted for LEDs (small size and considerable luminous flux) with a view to reducing luminance, by applying optical solutions;
- studying the mechanisms that cause the degradation of white LEDs, potentially leading to a drift towards the blue end of the visible spectrum in the light emitted.

Maisons-Alfort, 03/06/2010

On behalf of the experts of the CES “Physical agents, new technologies and development areas”,

Chairperson of the CES, Jean-François Doré