ANSES Opinion
Request No 2022-SA-0193
Related Request Nos 2014-SA-0253 and 2019-SA-0139

The Director General

Maisons-Alfort, 8 July 2024

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

on "consideration in the regulatory framework of the effects on children's health of LEDs[1] contained in toys"

ANSES undertakes independent and pluralistic scientific expert assessments.
ANSES primarily ensures environmental, occupational and food safety as well as assessing the potential health risks they may entail.
It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.
It provides the competent authorities with all necessary information concerning these risks as well as the requisite expertise and scientific and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).
Its opinions are published on its website. This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 8 July 2024 shall prevail.

On 25 October 2022, ANSES received a formal request from the Directorate General for Health and the Directorate General for Enterprise to conduct an expert appraisal on the 2020 update of Standard NF EN IEC 62115 on the safety of electric toys. ANSES was asked to verify whether this update provided an adequate response to its recommendation not to place on the market toys containing LEDs classified in a photobiological risk group higher than 1, which could harm children's health[2]. It was also asked to analyse whether the standard took sufficient account of children's clearer crystalline lenses, which make them more sensitive than adults to blue light.

1. BACKGROUND AND PURPOSE OF THE REQUEST

On 14 May 2019, ANSES published an opinion on the health effects of exposure to light emitted by LED lamps, highlighting the toxicity of blue light and its disruptive effect on biological rhythms. In its conclusion, the Agency stated that the exposure limits for blue light applicable

[1] LED: Light-emitting diode
[2] Reference is made here to Standard NF EN 62471 "Photobiological safety of lamps and lamp systems"

to the general population were not sufficiently protective against phototoxic risks. Children were identified as a particularly sensitive population as they have a clearer crystalline lens and smaller eyeball than adults, leading to higher retinal illuminance (ANSES, 2019, p. 128). At the time, ANSES recommended restricting the sale of LED systems (lamps, luminaires, objects and especially toys) to the general public to those in photobiological risk group 1 or lower[3].

Since this expert appraisal was published, the regulatory context has evolved with the 2020 update of Annex E of Standard NF EN IEC 62115 on the safety of electric toys, applicable from 2022.

The purpose of this formal request is therefore to verify the extent to which this new version of Standard NF EN IEC 62115 provides an adequate response to ANSES's recommendations on photobiological safety.

This formal request comes at a time when LEDs have become widespread in everyday objects. A variety of different toys can potentially incorporate LEDs, including cuddly toys, interactive electronic toys (interactive dolls, "educational" robots, etc.) and creative toys (drawing tablets, illuminated construction sets, science kits, etc.). Toys incorporating LEDs are on sale for all age groups: infants and toddlers, young children (aged 2 to 5), school-age children (aged 6 to 12) and adolescents. However, the target age groups can vary considerably depending on the type of toy and its level of complexity.

2. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal was carried out in accordance with French Standard NF X 50-110 "Quality in Expert Appraisals – General requirements of Competence for Expert Appraisals (May 2003)".

It falls within the sphere of competence of the Expert Committee (CES) on "Physical agents and new technologies". ANSES entrusted the expert appraisal to the Working Group on "Toys and blue light". The methodological and scientific aspects of the work were regularly presented to the CES between 26 January 2023 and 30 April 2024. This work was adopted by the CES on "Physical agents and new technologies" on 30 April 2024.

The expert appraisal mainly consisted of a detailed examination of Standard NF EN IEC 62115 and the source data on which it is based.

Hearings were also held to analyse the process and reasons for updating the standard, the regulatory context for placing toys on the market and the procedures for verifying toy conformity.

This Working Group therefore held hearings with:

- the European Committee for Electrotechnical Standardization (CENELEC);
- the French Federation of Toy and Childcare Industries (FJP);
- the Directorate General for Health (DGS);

[3] The standards for assessing photobiological safety (CIE S009, IEC 62471 and NF EN 62471) refer to the ICNIRP limit values and propose classifying lamps into risk groups: risk group 0 "no risk", risk group 1 "low risk", risk group 2 "moderate risk" and risk group 3 "high risk".

- the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF);
- the Directorate General for Enterprise (DGE);
- the Directorate General for Customs and Indirect Taxation (DGDDI).

ANSES analyses interests declared by experts before they are appointed and throughout their work, in order to prevent risks of conflicts of interest in relation to the points addressed in expert appraisals.

The experts' declarations of interests are made public via the website: https://dpi.sante.gouv.fr/.

3. ANALYSIS AND CONCLUSIONS OF THE WG AND THE CES

3.1. Health effects of light, limit values and a reminder of ANSES's work in this area

In 2013, the International Commission on Non-Ionizing Radiation Protection (ICNIRP) published a revision of its initial guidelines, drawn up in 1997, aimed at defining exposure limits for visible, infrared and ultraviolet optical radiation (ICNIRP, 2013). However, the ICNIRP's proposed exposure limits for blue light, which remained the same as those established in 1997, only concerned acute exposure (single, continuous exposure for less than eight hours). Nevertheless, these values are regarded as global benchmarks, and have been included, for example, in European Directive 2006/25/EC on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (artificial optical radiation)[4].

ANSES opinions on LED lighting systems, published in 2010 and 2019

Since 2010, ANSES has carried out several expert appraisals on the risks associated with the blue light emitted by LEDs. In 2010, it issued an internal request to assess the potential risks posed by LED lighting. In its conclusions, it highlighted the toxicity of blue light for the retina and recommended regulatory changes to ensure better protection of public health. Following this opinion in particular, the safety standards for lamps and luminaires were revised to include a requirement for photobiological safety, based on the risk groups as defined in Standard NF EN 62471:2008 on photobiological safety. These requirements now apply to devices subject to European Directive 2014/35/EU[5], known as the Low Voltage Directive (in particular all mains-powered "domestic" electrical appliances).

In 2019, following a formal request from the Directorate General for Health and the Directorate General for Risk Prevention to update its expert appraisal on the effects of LEDs on human health and the environment, ANSES confirmed the toxicity associated with blue light and in particular the harmful effects on the retina and its consequences such as age-related macular

[4] Directive 2006/25/EC of the European Parliament and of the Council 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) (19th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:114:0038:0059:EN:PDF

[5] Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

degeneration (AMD). ANSES therefore recommended developing information campaigns on the phototoxic effects of the light emitted by certain LED lighting devices (hand-held torches, head torches, toys, vehicle headlights, blue-light decorative string lights) available on the market, especially for the most sensitive population groups such as children. It also recommended restricting the sale of LED systems (lamps, luminaires, objects and especially toys) to the general public to those in photobiological risk group 1 or lower. Lastly, it recommended updating the exposure limits for blue light, as these did not take account of the specific situation of children, whose crystalline lenses filter blue light less effectively than those of adults and the elderly.

In addition to the toxic effects, ANSES emphasised that exposure to blue light in the evening or during the night, even at low intensity, disrupts biological rhythms and sleep. To prevent this, it recommended limiting exposure to blue light, particularly before bedtime and during the night, by reducing the use of LED screens.

ANSES opinion on blue-light exposure limits, published in 2020

In 2020, at the request of the French Directorate General for Health, ANSES issued an opinion detailing the scientific arguments underlying its recommendation to update the blue-light exposure limits issued by the ICNIRP and take better account of young populations (whose crystalline lenses do not sufficiently filter blue light).

In this opinion, ANSES emphasised that the ICNIRP's recommendations were based on the results of experiments carried out in the 1980s. Phototoxicity detection techniques at the time were not very sensitive and could not detect retinal lesions with potential short- or long-term functional consequences. Current techniques can detect retinal damage caused by exposure to blue light at an earlier stage. Recent studies on rodents have thus suggested that the retinal doses considered by the ICNIRP as being thresholds for acute toxicity are overestimated. As a result, the exposure limits set by the ICNIRP are too high.

ANSES has also indicated that the development of exposure limits, currently based on acute exposure situations, should also take into account:

- the cumulative effect of long-term exposure;
- increased sensitivity of the retina at night;
- the spectral composition of light;
- the amount of red light, which could have photoprotective effects.

3.2. Regulatory context for the placing of toys on the market

Toys are a major part of children's lives. To ensure they are safe to use, their placing on the market in France is governed by regulations.

According to the definition in Decree No. 2010-166 of 22 February 2010, a toy is "*a product specifically designed or clearly intended for use by children under the age of 14 for the purpose of play*". This includes a vast range of objects incorporating LEDs, such as dolls, miniature cars, construction sets, cuddly toys, board games, etc.

At European level, Directive 2009/48/EC is the harmonised regulation governing toy safety. It entered into force throughout the European Union on 20 July 2009. This directive aims to ensure that toys placed on the market in the European Union meet essential safety requirements, particularly regarding the materials used, mechanical and physical properties, stability, flammability, chemical risks and risks associated with electromagnetic radiation, such

as light emitted. It also sets out the standards enabling manufacturers to demonstrate the conformity of toys with these essential requirements (list published by Commission Implementing Decision in the Official Journal of the European Union, in its Annex 3).

In France, this European directive was transposed into national legislation by Decree No. 2010-166 of 22 February 2010 and its Implementing Order of 24 February 2010. This decree sets out the procedures for implementing European toy safety regulations in France. It stipulates additional requirements specific to France, mainly with regard to toy labelling, marketing conditions, penalties in the event of non-conformity, and market surveillance procedures. Toy manufacturers, importers and distributors are responsible for ensuring that their products comply with the requirements in force before placing them on the market. In particular, Standard NF EN IEC 62115 on the safety of electrical toys serves to verify compliance with requirements relating to the risks associated with LEDs in toys.

3.3. Reminder of the definitions of optical quantities

Various concepts are used throughout this opinion to characterise and measure light emissions. Their definitions are given below.

Emission quantities (independent of distance)

- **Radiant flux** is a measure of the power of the optical radiation emitted by a light source in all directions. It is expressed in watts (W).
- **Luminous flux** characterises the luminous power of a light source, weighted by the sensitivity curve of the human eye under photopic conditions (daylight vision). It is expressed in lumens (lm) and is essential for assessing light emission.
- **Radiant intensity** in a given direction measures the radiant flux emitted by a light source per unit solid angle centred on that direction. The unit is the watt per steradian ($W.sr^{-1}$).
- **Luminous intensity** in a given direction measures the luminous flux emitted by a light source per unit solid angle centred on that direction. The unit is the candela (cd).
- The **radiance** of an element of a light source in a given direction measures the radiant flux emitted by this element, per unit solid angle and per apparent area of this source in this direction. The unit is the watt per square metre per steradian ($W.m^{-2}.sr^{-1}$).
- The **luminance** of an element of a light source in a given direction measures the luminous flux emitted by this element, per unit solid angle and per apparent area of this source in this direction. The unit is the candela per square metre ($cd.m^{-2}$).

Exposure quantities (distance-dependent)

- **Irradiance** is given by the radiant flux received by a surface, wherever it comes from, per unit area. The unit is the watt per square metre ($W.m^{-2}$).
- **Illuminance** is given by the luminous flux received by a surface, wherever it comes from, per unit area. The unit is the lux (lx). Illuminance depends on distance.

Exposure limits, such as those established by the ICNIRP, correspond to levels of exposure to light below which no adverse health effects are observed. Exposure limits are used as benchmarks to assess the level of radiation emitted by these devices.

According to Standard NF EN IEC 62115, "***Accessible Emission Limits*** *(**AELs***) [...] *ensure that optical radiation from electric toys (during normal use and under foreseeable misuse) does not exceed the exposure limits recommended by the International Commission on Non-Ionizing radiation Protection (ICNIRP). These limits are the maximum levels of exposure that are not expected to result in adverse health effects*".

3.4. Presentation of Standard NF EN IEC 62115 on the electrical safety of toys and its changes

3.4.1. Purpose of Standard NF EN IEC 62115 and reasons for updating it

Standard NF EN IEC 62115 defines the safety requirements for toys powered by electrical energy sources, such as batteries or mains adapters. Use of this standard is intended to guarantee that electrical toys placed on the market are safe for use by children. This standard replaces the approved Standard NF EN 62115 of December 2005 and its amendments of 2011, 2013 and 2018, which remained in force until February 2022. The remainder of this opinion deals strictly with annexes E, F, G and H of this standard (annexes relating to the ocular safety of toys containing sources of optical radiation).

According to the information gathered by ANSES during its hearings, there were two main reasons for updating Standard NF EN IEC 62115 in 2020:

- the widespread use of LEDs in toys, replacing other light sources: because LEDs are small and available in different colours, they can be easily integrated into toys;
- difficulties in applying the previous version of the standard: the limit values expressed as a function of the radiant flux were dependent on the geometry of the source, which made practical verification of compliance difficult, according to manufacturers. Updating the standard was therefore intended to make it easier for toy manufacturers to assess the safety of the optical radiation, by moving from a measurement of radiant flux to an assessment based on radiant or luminous intensity values taken from the technical specifications of LED manufacturers.

3.4.2. Main changes to Standard NF EN IEC 62115 between its 2005 and 2020 versions

The Working Group studied the two versions of Standard NF EN IEC 62115, and summarises below the main changes made in 2020.

- **References for light emission limits**

Although laser diodes and LEDs operate according to different physical principles, also leading to different light characteristics, they were initially considered to be identical in terms of safety (ICNIRP, 2000). LEDs were therefore treated as sources of coherent[6] radiation (like lasers, for example, in Standard IEC 60825-1), before being considered as sources of incoherent

[6] A coherent light source is one whose emitted light waves are in phase, with the same frequency, direction of propagation and polarisation. Conversely, an incoherent light source is one in which the emitted light waves are not in phase. For example, the light from an incandescent lamp is an incoherent source, because the light waves emitted by the various heated atoms are in phase with each other for a brief moment, but they quickly lose their coherence due to collisions between the atoms. The light from a laser is a coherent source, because the light waves emitted by the stimulated atoms are in phase.

radiation[7]. Light exposure limits have been defined by the ICNIRP for coherent radiation (ICNIRP, 2000) and incoherent radiation (ICNIRP 1996, 1997, 2013). The 2005 version of Standard NF EN 62115 referred to exposure limits for coherent sources such as lasers, whereas the 2020 version of the standard now refers to limit values for incoherent light sources. In 2020, the ICNIRP published a technical guide that applies specifically to LED safety (ICNIRP, 2020).

Exposure limits are determined by considering the photobiological risks for exposed individuals. Standard NF EN 62115 defined accessible emission limits (AELs) applicable directly to the light sources, based on the ICNIRP exposure limits and a method taken from the publication by Higlett *et al.* (2012).

- **Physical measurements**

Both the 2005 and 2020 versions of the standard took the entire optical spectrum into account, from ultraviolet to infrared. However, it is essential to note that the physical quantities to be measured have been modified in the latest version.

In the 2005 version:

- the standard recommended measuring the radiant flux of light sources in order to assess the amount of energy emitted by LEDs in toys;
- in practice, radiant flux measurements were carried out at a distance of 100 mm from the light source (vision with the naked eye), with the possibility of reducing this distance to 14 mm (to represent vision using an optical instrument);
- radiant flux measurements were carried out on the bare LED[8].

With the 2020 version:

- radiant or luminous intensities, which do not depend on the distance from the light source, must now be used. Toy manufacturers can therefore refer directly to the technical data sheet for the LEDs, which specifies the radiant or luminous intensity. This eliminates the need for physical measurements and simplifies the process of verifying toy conformity.

The 2020 version of the standard also refers to an ICNIRP recommendation concerning sources of incoherent radiation to introduce a luminance threshold value of 10,000 cd/m² for toys containing LEDs (see Annex H of the standard).

- **Sensitive populations taken into account**

In the 2005 version of the standard, toys were considered in the same way regardless of the age group they were intended for. In 2020, a significant change was made by introducing a weighting coefficient that reduced the exposure limits for children under 3 years of age (by a factor of 10) for UV-A radiation and for visible light with a wavelength of less than 440 nm.

- **Measurement conditions**

In the 2005 version of the standard, the maximum radiation emitted by the LED had to be measured on the bare LED. In the 2020 version, the measurement must first be carried out on

[7] From 2007 (IEC, International Electrotechnical Committee) or 2008 (NF), Standard 60825-1 on the safety of laser products recommended application of publication S009 from the International Commission on Illumination (CIE). This CIE publication S009 was transcribed into Standard IEC 62471.

[8] The LED and associated electronics are extracted from the toy and the assembly is tested under worst-case electrical conditions.

the bare LED, and then if the LED exceeds the AEL, the measurement is carried out with the LED integrated in the toy. As a result, the 2020 version of the standard does not take into account unsafe use or deterioration of the toy, such as if the position of the LED in the toy were changed.

In addition, the measurement must be taken once steady state has been established, at least 60 seconds after the LED is switched on (no time is specified in the 2005 version), meaning that it is not possible to measure the maximum intensity that may appear immediately after the LED is switched on.

Table 1 summarises the changes to Standard NF EN IEC 62115 between 2005 and 2020.

Table 1: Summary of changes to Standard NF EN IEC 62115 in the 400 to 700 nm spectral range

	Version 2005	**Version 2020**
Quantities assessed	Radiant flux expressed in watts (W)	Radiant intensities expressed in W per steradian (W/Sr) or luminous intensities expressed in candela (cd)
References for exposure limits considered	ICNIRP, 1997	ICNIRP, 2013
AEL reference	Standard NF EN 60825-1	Publication by Higlett *et al.*, 2012
Exposure scenarios	Not applicable	Two exposure scenarios at a distance of 100 mm for 100 s ("*foreseeable misuse*") and 200 mm for 10,000 s ("*worst-case condition*") are described in the annex to the standard and explained in the article by Higlett *et al*. The scenario involving exposure at a distance of 200 mm for 10,000 consecutive seconds was chosen by the authors to define AELs
Measurement distances	100 mm from the source To simulate assessment of the source with an optical instrument, this distance can be reduced to 14 mm.	If the LED manufacturer's luminous intensity data are available in the technical specifications, no further measurements are required. The manufacturer carries out these measurements in accordance with Standard CIE 127. If the manufacturers' measurements are unavailable, a luminous intensity measurement will be carried out. In practice, the measurement is carried out at 200 mm.
Measurement conditions	Measurements carried out on the bare LED; the maximum radiation level must be measured.	Measurements on the bare LED, then on the toy if necessary. Measurement from 60 seconds after establishment of steady state.
Luminance threshold	Not applicable	Adoption of the ICNIRP threshold at 10,000 cd/m²
Sensitive populations taken into account	No age distinction	Weighting coefficient for children under 3 years of age

3.5. Impact of the update of Standard NF EN IEC 62115 on the consideration of health risks: reduced protection of health

3.5.1. Analysis of the scientific article behind the standard: emission limits not sufficiently protective

The 2020 version of Standard NF EN IEC 62115 drew on the scientific publication[9] *Safety of light emitting diodes in toys* (Higlett *et al.*, 2012) for the choice of accessible emission limits (AELs). This publication sought to propose a simplified method[10] based on an examination of luminous and radiant intensities using the ICNIRP limit values for incoherent radiation. However, this desire for simplification led to the elimination of any consideration of the size of the source, contrary to the ICNIRP's recommendations on coherent and incoherent sources.

The Working Group conducted an in-depth analysis of this publication, in which it identified some errors and confusion[11] (see Annex 4), listed below:

- two exposure scenarios, one defining a worst-case condition of normal use (distance of 200 mm for a duration of 10,000 s) and the other a situation of foreseeable misuse (distance of 100 mm for a duration of 100 s), were used to define the AELs for visible light. An error in reasoning led the authors to conclude that the "misuse" scenario would lead to exposure 2500 times lower than under the "worst-case" condition of normal use. This error led the authors to eliminate the misuse exposure scenario (distance of 100 mm) when in reality it leads to exposure that is four times higher. If this scenario had been adopted, it would have led to AELs four times lower than those chosen by the authors, considering this source of error alone;
- the ICNIRP guideline value for incoherent light sources (visual luminance threshold of 10,000 cd/m² to guarantee the absence of photobiological risk for broad-spectrum sources) was incorrectly taken into account, leading to an AEL that was too high. As an example, for LEDs with a diameter of 2 mm, the AEL determined by the Higlett *et al*. publication in candela is too high by a factor of 1000 compared with the correct AEL;
- the conversion of weighted radiant intensities for the risk associated with blue light into luminous intensities and then into (unweighted) radiant intensities is marred by a calculation error of a factor of 10. The corresponding AELs, expressed in $W.sr^{-1}$, are therefore overestimated by a factor of 10.

Overall, these errors led the authors to propose accessible emission limits that are higher than they should be, meaning that these limits are not sufficiently protective[12].

---

[9] The publication by Higlett *et al.* (2012) is cited in the bibliographic references of Standard NF EN IEC 62115.

[10] This simplified method is an alternative to the assessment methods derived from Standard NF EN 62471 and to the classification according to photobiological risk groups defined in this standard.

[11] Link to the preprint of the scientific article detailing the analysis of the errors identified: https://www.preprints.org/manuscript/202403.0170/v2

[12] ***Contact with the authors of the publication by Higlett et al. (2012)***

In view of the errors found in the publication by Higlett *et al*. (2012), ANSES undertook to contact its authors on several occasions between June and August 2023, to invite them to a discussion with the aim of clarifying the points raised by the Working Group. The authors declined this invitation, explaining that they had been involved in this area of research for more than ten years, and that they no longer had the necessary resources to re-examine this subject at the present time.

Technical details for the scientific community

A detailed "letter to the editor" was drafted by the experts of the Working Group for the editor of the *Journal of Radiological Protection* (published jointly by the Institute of Physics Publishing (IOPP) and the Society of

3.5.2. Illustration using measurement data obtained from toys

The Working Group assessed the impact of the update of Standard NF EN IEC 62115 on photobiological safety. To do this, it compared assessments of acceptable limit values according to the 2005 and 2020 versions of the standard on 10 toys featuring red, green, blue or white LEDs. At ANSES's request, the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) provided reports of tests carried out recently according to the 2020 version of the standard, during inspection campaigns on the toy market. ANSES also funded a measurement campaign to assess the conformity of these 10 toys with the 2005 version of the standard.

It is important to remember that the assessment of accessible radiation differs between these two versions of the standard. For the 2005 version, this assessment was expressed in terms of radiant flux (in watts), whereas for the 2020 version, it was expressed in terms of radiant intensity (in watts per steradian – $W.sr^{-1}$).

In order to compare the results obtained using the 2005 and 2020 versions of the standard, the Working Group calculated the ratio between the accessible radiation level and the limit value in force (referred to here as the "protection ratio"). A value for this ratio greater than 1 indicates that the regulatory limit has been exceeded. This indicator is used in the field of optical radiation safety mainly to assess the transmission of the protective filter that would need to be installed to reduce the radiation level and bring it below the limit value.

For the 2005 version of the standard, in the case of LEDs emitting in the 400 to 700 nm wavelength range, two types of limit need to be considered, corresponding to the thermal and photochemical risks, respectively. The Working Group selected the highest ratio value between these two types of risk.

The test results are shown in Figure 1. With a sample of 19 LEDs found in the 10 toys, the conformity tests showed that when the LEDs were tested according to the 2005 version of the standard, eight of them did not comply with the limit value, whereas when they were tested according to the 2020 version of the standard, only one of them was not compliant[13] (see Table 2). The 2020 version of the standard is therefore much more permissive than the 2005 version.

Radiological Protection (SRP)), in which the paper by Higlett *et al*. had been published. This letter highlighted the specific points of the Higlett *et al*. study that were the subject of criticism and concern on the part of the Working Group. Its aim was to draw this journal's attention to these key issues and request an in-depth assessment of the scientific validity of the study's conclusions in relation to the points raised. The letter to the editor was submitted on 13 September 2023 and rejected on 1 February 2024. The experts of the Working Group had pointed out to the publisher (the IOPP) that the peer review had not been carried out with integrity and was marred by a conflict of interest. The IOPP acknowledged this point and the letter to the editor was resubmitted for publication on 7 March 2024. The letter was again rejected on 28 March 2024 on the basis of a peer review carried out by the editor and justified by a lack of response from the authors and the difficulty in finding another expert to assess the content.

[13] The 2005 and 2020 versions of Standard NF EN IEC 62115 are based on the same exposure limit value established by the ICNIRP.

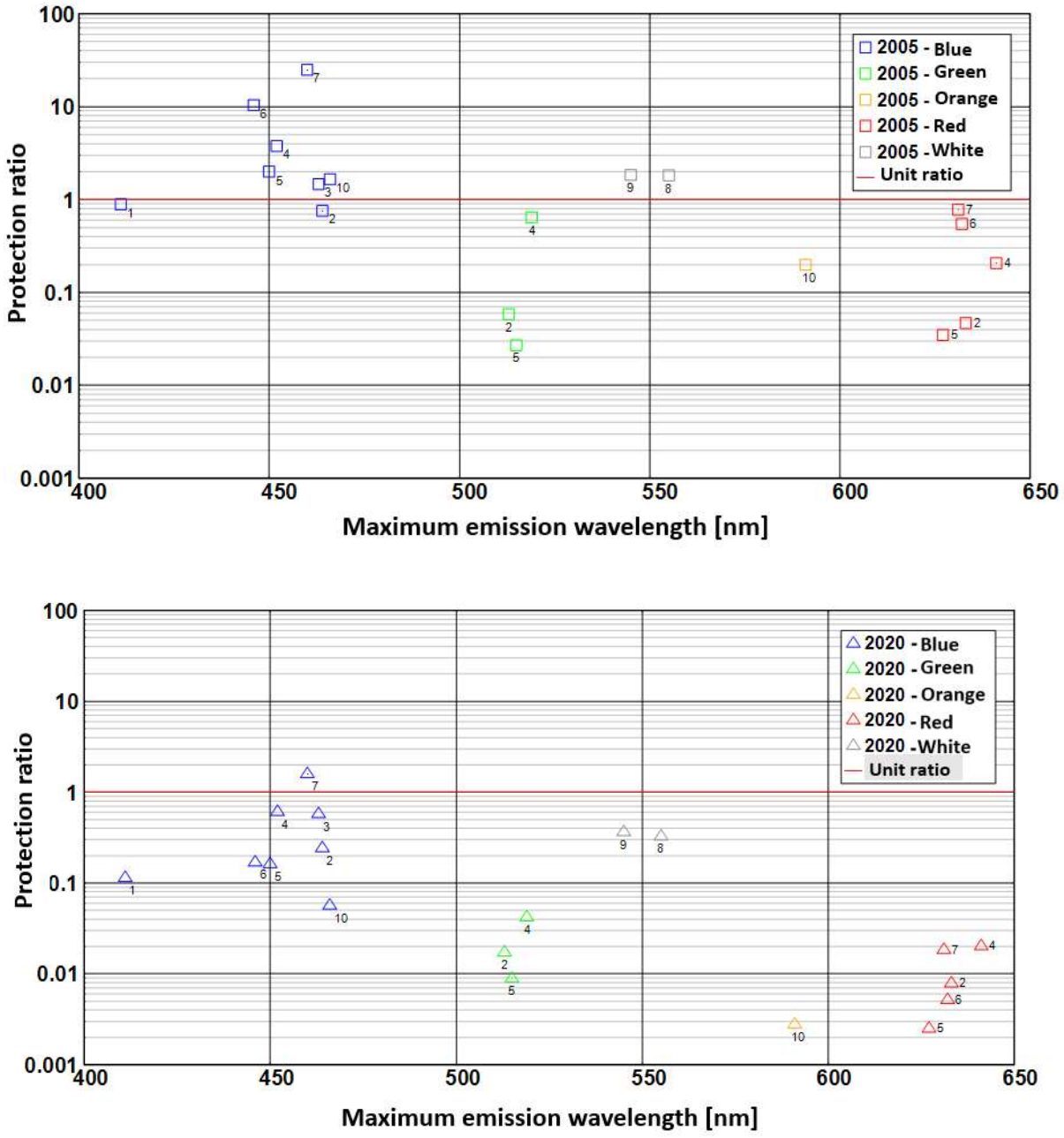

Figure 1: Ratios between the accessible radiation level and the limit value considered for the 19 LEDs contained in the 10 toys tested (2005 version of the standard above, 2020 below)

Note: Each LED was evaluated according to the 2005 (squares, measurements taken in 2024) and 2020 (triangles, measurements taken in 2022) versions of the standard. The red line (ratio equal to 1) indicates the compliance limit – Note how this limit is exceeded for blue LEDs (blue squares) and white LEDs (grey squares) with a calculation based on the 2005 standard. Of the 19 toy LEDs assessed, 11 complied with the 2005 version of the standard and 18 complied with the 2020 version.

Table 2: Compliance of each LED assessed according to the 2005 and 2020 versions of the standard

Toy N°	Tested LED Color	Evaluation according to NF EN 62115:2005	Evaluation according to NF EN 62115:2020
1	Blue	Compliant	Compliant
2		Compliant	Compliant
3		NON COMPLIANT	Compliant
4		NON COMPLIANT	Compliant
5		NON COMPLIANT	Compliant
6		NON COMPLIANT	Compliant
7		NON COMPLIANT	NON COMPLIANT
10		NON COMPLIANT	Compliant
2	Green	Compliant	Compliant
4		Compliant	Compliant
5		Compliant	Compliant
10	Yellow-orange	Compliant	Compliant
2	Red	Compliant	Compliant
4		Compliant	Compliant
5		Compliant	Compliant
6		Compliant	Compliant
7		Compliant	Compliant
8	White	NON COMPLIANT	Compliant
9		NON COMPLIANT	Compliant

3.5.3. Case of blue LEDs that are prohibited in lighting (NF EN 62471:2008) but compliant for toys (NF EN IEC 62115:2020)

The Working Group noted that certain LEDs can be classified in risk group 2 according to the standard for photobiological safety of lamps (NF EN 62471), while complying with the 2020 version of the standard for safety of electric toys (NF EN IEC 62115:2020).

This can be explained by an incorrect transposition of the graph in Figure 9 of the article by Higlett *et al.* to Table E.3 of Standard NF EN IEC 62115:2020. More specifically, the intensity limit of 0.046 $W.sr^{-1}$, which separates the risk groups RG0/RG1 from risk group RG2 in Standard NF EN 62471:2008, has been rounded up to 0.05 $W.sr^{-1}$ in Standard NF EN IEC 62115:2020. Consequently, for certain blue LEDs, whose maximum emission is between 428 nm and 455 nm, and for certain radiant intensity values that comply with Standard NF EN IEC 62115:2020 (see Figure 2 below), the risk group RG2 is obtained according to the standard for photobiological safety (i.e. LEDs that would not be authorised to be placed on the market for consumer lighting). This is an additional shortcoming of the 2020 version of the toy standard.

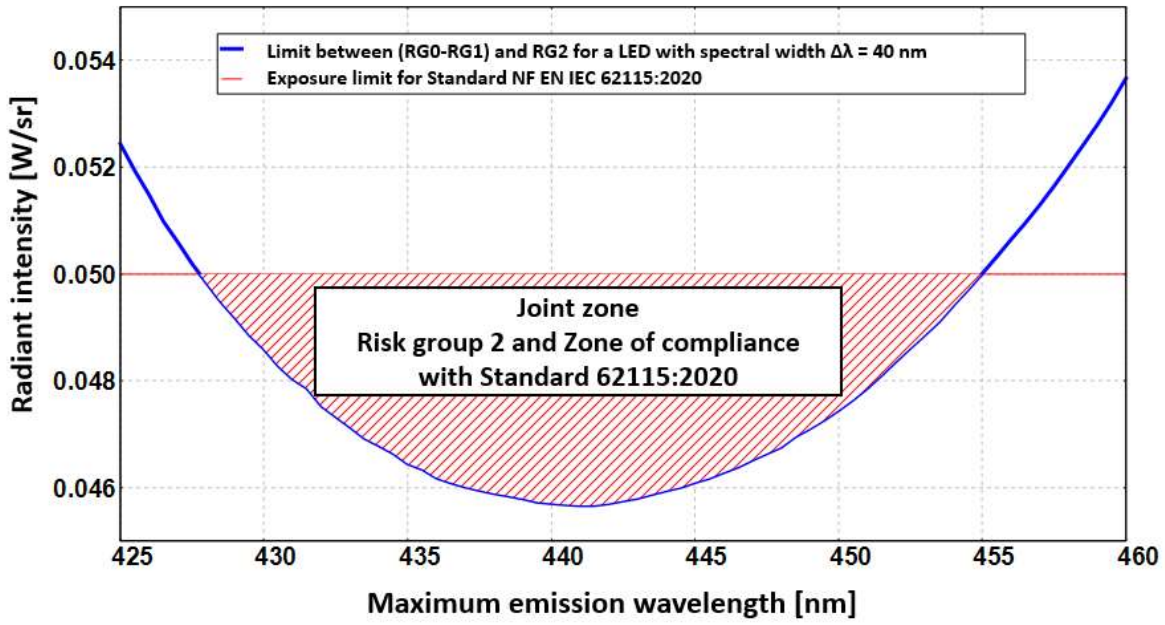

Figure 2: Superimposition of the limit between risk groups RG0/RG1 and RG2 and the limit value of Standard NF EN IEC 62115:2020

Note: For an LED with a spectral width of 40 nm generating a weighted radiant intensity of 0.04 $W.sr^{-1}$.

3.6. Potential health effects resulting from exposure of children to high-intensity LEDs

The above findings show that when using electrical toys that comply with the current electrical safety standard, children may be exposed to higher intensity LEDs than previously. As ANSES emphasised in its 2010 and 2019 opinions (ANSES, 2010 and 2019), such exposure can have both short- and long-term consequences. It can cause temporary loss of vision (saturation glare) and persistent after-images in the field of vision due to transient impairment of retinal photoreceptor functioning. Moreover, the exposure dose can exceed the limit for photochemical damage to the retina by a factor of four, increasing the risk of acute effects such as photoretinitis.

Retinal damage is potentially cumulative. In adulthood, it could lead to eye diseases suspected of being due to repeated exposure to light sources and intense glare, such as age-related macular degeneration (AMD) or glaucoma.

The risks posed by high-intensity LEDs can only be mitigated by children's aversion reflex (i.e. their tendency to look away). However, this aversion reflex may not be fully developed in young children with immature retinas. In addition, children's eyes have a shorter focal length than those of adults, resulting in greater exposure of the retina for the same amount of corneal illuminance. Furthermore, children are likely to handle their toys at a short distance from their eyes, generally less than the 200 mm chosen by Higlett and colleagues to define the LED intensity limits.

In older children, the aversion reflex may be intentionally ignored for play purposes, as described in recent case reports of macular damage in children exposed to a hand-held high-intensity LED light (Zhang *et al*., 2023) or a laser pointer during games (Swatch *et al*., 2022). In addition, LEDs emitting pure blue light are not perceived as being very bright, due to the lower sensitivity of vision in this spectral range, even when the radiant intensity is high. In this case, in the absence of a high luminosity signal, the aversion reflex is very limited or even non-existent.

3.7. Conclusion and recommendations of the Working Group and the CES

Considering:

- the different errors in the publication by Higlett *et al*. (2012) – the article used as a basis for the ocular safety assessment of toys incorporating sources of optical radiation in Standard NF EN IEC 62115:2020;
- the insufficient consideration of the specific characteristics of children, in physiological (clarity of the crystalline lens), morphological (size of limbs) and behavioural terms (actual use of toys);

the Working Group and the CES conclude that:

- the update of Standard NF EN IEC 62115 does not follow ANSES's recommendations on limiting the placing on the market of objects that could be hazardous due to the phototoxicity of the blue light they emit;
- the errors identified and reported above may have an impact on the safety of toys using LEDs, even when they have been declared compliant with the essential health and safety requirements. Indeed, Standard NF EN IEC 62115:2020 is unable to prevent light emissions from LEDs in toys from exceeding the exposure limits for the risk associated with blue light (NF EN 62471:2008). Nor does this 2020 version of the standard help avoid the intense glare associated with exposure to luminance levels that can far exceed the threshold of 10,000 $cd.m^{-2}$.

Considering the numerous corrections and changes to be made to Annexes E, F, G and H of the 2020 version of Standard NF EN IEC 62115 to make it sufficiently protective for children, the Working Group and the CES recommend:

- working on a new standard tailored to children that takes better account of their specific needs;
- for the foreseeable future, using the 2005 version of the standard on safety of electrical toys to assess their conformity.

In addition, to ensure greater safety and protection of children from the risks associated with artificial light, the Working Group and the CES:

- reiterate their recommendation for light exposure limits to be updated in view of the latest research data;
- recommend that lighting devices to which children may be exposed (night-lights, hand-held torches, illuminated clothing, decorative lamps, etc.) be subject to the same ocular safety assessment as toys, in accordance with an updated standard.

Pending the development of standards that are more protective of children's ocular health, the Working Group and the CES recommend that parents and educators be informed of the potential hazards of LED toys.

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

The use of light-emitting diodes (LEDs) has become widespread in everyday objects, particularly lighting. LEDs are now also incorporated in toys and can be found, for example, in cuddly toys, interactive electronic toys and creative toys.

Directive 2009/48/EC aims to ensure that toys placed on the market in the European Union meet essential safety requirements, particularly regarding the risks associated with electromagnetic radiation, such as light emitted. The harmonised European standard on the safety of electrical toys (NF EN IEC 62115) is designed to enable manufacturers to demonstrate compliance with the essential requirements, particularly regarding the risks associated with LEDs in toys. This standard, whose first version was published in 2005, was last revised in 2020. One of the main reasons for updating this standard, which entered into force in 2022, was to make it easier for toy manufacturers to assess the safety of the optical radiation, by enabling compliance to be verified on the basis of parameters supplied by LED manufacturers, instead of measurements.

The Directorate General for Health and the Directorate General for Enterprise formally asked ANSES to assess whether this update of the standard on safety of electrical toys takes into account the Agency's recommendations on protecting children's health, set out in its opinions on LED lamps (ANSES, 2010, 2019, 2020).

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

ANSES's collective expert appraisal was based firstly, on an analysis of the new version of the standard on safety of electrical toys (NF EN IEC 62115, 2020 version), including the scientific publication on which it is based (Higlett *et al.,* 2012) and secondly, on a comparison of a sample of toys whose conformity was assessed comparatively with the old and new versions of the standard.

ANSES concluded that errors in the original scientific publication led to emission limits that are not sufficiently protective for users of LED toys. It therefore took action to contact the publisher of the article. The expert appraisal also showed that this version of the toy standard could lead to LED toys with a photobiological risk group greater than 1 being placed on the market. Lastly, this version of the standard does not help avoid glare from very high luminance levels, which could lead to accidents. Children and users are therefore exposed to short- and long-term risks to their eyesight.

Consequently, to ensure the protection of children's ocular health, ANSES recommends suspending application of the current version of Standard NF EN IEC 62115 (2020) and provisionally using its 2005 version to assess the conformity of toys with the essential safety requirements, even if this version did not make any distinction according to the targeted users.

With the aim of defining a protective regulatory framework for children, the Agency recommends that work be undertaken without delay to revise the sections on ocular safety in the standard on safety of electrical toys, taking greater account of the specific biological and

physiological characteristics of children. This revision should take account of the latest knowledge in the field of ocular safety.

The results of the analysis of the two versions of the standard and the assessments conducted on a sample of toys with both standards indicate that toys placed on the market may comply with the 2020 version of Standard NF EN IEC 62115, without complying with the 2005 version. For such toys, ANSES concludes that ocular safety has not been demonstrated and that there is a strong presumption of non-conformity with the requirements of Directive 2009/48/EC.

Pending these changes to the standards, which are essential for children's ocular health, the Agency recommends that parents and childcare professionals be informed of the potential hazards of LED toys.

The Agency also points out that certain LED objects (night-lights, hand-held torches, illuminated clothing, decorative lamps, etc.) may be intended for children, without being covered by Standard NF EN IEC 62115. It recommends examining the possibilities for better regulation of the placing on the market of these other luminous devices, in terms of the photobiological risk.

Pr. Benoit VALLET

KEY WORDS

Jouet, LED, lumière bleue, phototoxicité, enfant, éclairage, sécurité oculaire

Toy, LED, blue light, phototoxicity, child, lighting, ocular safety

REFERENCES

AFNOR. 2005. NF EN IEC 62115 Electric toys - Safety, 2005.

———. 2020. NF EN IEC 62115 Electric toys - Safety, 2020.

ANSES. 2010. ANSES Opinion and Report on the formal request entitled "Health effects of lighting systems using light-emitting diodes (LEDs)", 2010.

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

———. 2020. ANSES Opinion on "blue-light exposure limits for the general population", 2020.

Boyce, Peter Robert. 2014. *Human Factors in Lighting*. 3rd ed. Boca Raton: CRC Press. https://doi.org/10.1201/b16707 .

Boyce, Peter Robert. 2022. "Light, lighting and human health". 2022. https://journals.sagepub.com/doi/10.1177/14771535211010267.

International Electrotechnical Commission. 2014. "IEC 60825-1 Safety of laser products – Part 1: Equipment classification and requirements", 2014.

DiLaura, David L., ed. 2011. *The Lighting Handbook: Reference and Application*. Tenth edition. New York, NY: Illuminating Engineering Society of North America.

Higlett, M. P., J. B. O'Hagan, and M. Khazova. 2012. "Safety of Light Emitting Diodes in Toys". *Journal of Radiological Protection* 32 (1): 51. https://doi.org/10.1088/0952-4746/32/1/51.

International Commission on Non-Ionizing Radiation Protection (ICNIRP). 1996. "Guidelines on limits of exposure to laser radiation of wavelengths between 180 nm and 1,000 mm. Health Phys. 71:804 – 819", 1996.

———. 1997. "Guidelines on Limits of Exposure to Broad-Band Incoherent Optical Radiation (0.38 to 3 microM). International Commission on Non-Ionizing Radiation Protection". *Health Physics* 73 (3): 539-54.

———. 2000. "ICNIRP Statement on Light-Emitting Diodes (LEDS) and Laser Diodes: Implications for Hazard Assessment. International Commission on Non-Ionizing Radiation Protection". *Health Physics* 78 (6): 744-52. https://doi.org/10.1097/00004032-200006000-00020.

———. 2013. "ICNIRP Guidelines on Limits of Exposure to Incoherent Visible and Infrared Radiation". *Health Physics* 105 (1): 74-96. https://doi.org/10.1097/HP.0b013e318289a611.

International Commission on Non-Ionizing Radiation Protection (ICNIRP), Gunde Ziegelberger, Sharon A. Miller, John O'Hagan, Tsutomu Okuno, Karl Schulmeister, David Sliney, et al. 2020. "Light-emitting diodes (LEDS): Implications for safety". *Health Physics* 118 (5): 549-61. https://doi.org/10.1097/HP.0000000000001259.

Kim, Su Hwan, Young Kook Kim, Young In Shin, Goneui Kang, Seong Pyo Kim, Hajoung Lee, In Hwan Hong, et al. 2024. "Nighttime Outdoor Artificial Light and Risk of Age-Related Macular Degeneration". *JAMA Network Open* 7 (1): e2351650. https://doi.org/10.1001/jamanetworkopen.2023.51650.

Lotmar, W. 1976. "A Theoretical Model for the Eye of New-Born Infants". *Albrecht Von Graefes Archiv Fur Klinische Und Experimentelle Ophthalmologie. Albrecht Von Graefe's Archive for Clinical and Experimental Ophthalmology* 198 (2): 179-85. https://doi.org/10.1007/BF00410018.

Osborne, Neville N., Claudia Núñez-Álvarez, Susana Del Olmo-Aguado, and Jesús Merrayo-Lloves. 2017. "Visual Light Effects on Mitochondria: The Potential Implications in Relation to Glaucoma". *Mitochondrion* 36: 29-35. https://doi.org/10.1016/j.mito.2016.11.009.

Swatch, Priya, Annie Chang, and Raman Bhakhri. 2022. "Laser Pointer Retinopathy: A Case Report and Review". *CRO (Clinical & Refractive Optometry) Journal* 33 (1). https://doi.org/10.57204/001c.33792.

Zhang, Li, Chun-Yan Lei, Zhi-Cheng Zhang, Jin-Yue Gu, and Mei-Xia Zhang. 2023. "Accidental macular injury from short-term exposure to a handheld high-intensity LED light". *Heliyon* 9 (8): e18705. https://doi.org/10.1016/j.heliyon.2023.e18705.

SUGGESTED CITATION

ANSES. (2024). ANSES opinion on "consideration in the regulatory framework of the effects on children's health of LEDs contained in toys" (Request No 2022-SA-0193). Maisons-Alfort: ANSES, 32 p.

ANNEX 1: PRESENTATION OF THE PARTICIPANTS

PREAMBLE: The expert members of the Expert Committees and Working Groups or designated rapporteurs are all appointed in a personal capacity, *intuitu personae*, and do not represent their parent organisation.

WORKING GROUP

Members

Ms Francine BEHAR – University Professor-Hospital Practitioner in Ophthalmology at the AP-HP – Paris Cité University

Mr Olivier ENOUF – Metrology Engineer, Expert in optical radiation regulations – National Metrology and Testing Laboratory (LNE)

Mr Christophe MARTINSONS – Research and Expertise Engineer – Head of the Lighting and Electromagnetic Fields Division – French Scientific and Technical Centre for Building (CSTB)

Ms Alicia TORRIGLIA – Doctor, Director of Ophthalmology Research, Cordeliers Research Centre, French National Institute for Health and Medical Research (INSERM)

RAPPORTEUR

Ms Françoise VIÉNOT – Professor Emeritus – Centre for Research on Conservation (CRC), National Museum of Natural History, National Centre for Scientific Research (CNRS), Ministry of Culture, 36 rue Geoffroy Saint Hilaire, 75005 Paris, France

EXPERT COMMITTEE

The work covered in this report was monitored and adopted by the following Expert Committee (CES):

- CES on "Physical agents and new technologies"

Chair

Ms Anne PEREIRA DE VASCONCELOS – Research Manager, French National Institute for Health and Medical Research (INSERM), Laboratory of Cognitive and Adaptive Neurosciences – UMR 7364, French National Centre for Scientific Research (CNRS) – University of Strasbourg

Members

Ms Valentina ANDREEVA – Lecturer at Sorbonne Paris Nord University, Nutritional epidemiology research team

Mr Serge BOARINI – Associate Professor of Philosophy, Bourgoin-Jallieu

Ms Anne BOURDIEU – Occupational Physician, Expert in the Unit for Physical and Psycho-social Risks, field of ionising and non-ionising radiation, INRS, Medical Studies and Assistance Department, Paris

Mr Jean-Marie BURKHARDT – Director of Psychology and Cognitive Ergonomics Research at Gustave Eiffel University (formerly IFSTTAR) – Psychology and Applied Ergonomics Laboratory

Mr Thomas CLAUDEPIERRE – Professor in Neurosciences at the University of Lorraine

Mr Pierre DEGAUQUE – Professor Emeritus at the University of Lille, Institute of Electronics, Microelectronics & Nanotechnology (IEMN – UMR CNRS 8520), Telecommunications, Interference & Electromagnetic Compatibility (TELICE) Group

Mr Thierry DOUKI – Researcher/Doctor Engineer in Chemistry, French Alternative Energies and Atomic Energy Commission (CEA)

Mr Didier DULON – Neuroscience Research Director at INSERM, Hearing Institute, Institut Pasteur, Paris

Mr Guillaume DUTILLEUX – Professor of Environmental Acoustics at the Norwegian University of Science and Technology, Trondheim, Department of Electronic Systems

Mr Jack FALCÓN – Emeritus Researcher at the National Centre for Scientific Research (CNRS), specialising in animal chronobiology, Biology of Aquatic Organisms and Ecosystems (BOREA), CNRS 7208, National Museum of Natural History

Mr Nicolas FELTIN – Head of the Materials Department at the National Metrology and Testing Laboratory, Department for Scientific and Industrial Metrology, Paris

Mr Luc FONTANA – Professor of Medicine and Occupational Health at Jean Monnet University, Faculty of Medicine, occupational and environmental disease consultation centre, Saint-Etienne

Mr Pierre-Marie GIRARD – Research Manager at the National Centre for Scientific Research (CNRS) in radiation biology, Institut Curie – Research Centre – UMR3347, University Centre, Orsay

Ms Irina GUSEVA-CANU – Epidemiologist, University Professor, University of Lausanne

Ms Frédérique MOATI – Lecturer in Biophysics and Nuclear Medicine at Paris Sud XI University / Hospital Practitioner / Radiopharmacist / Biologist, AP-HP Bicêtre Hospital, retired

Mr Jean-Luc MOREL – Research Manager at the National Centre for Scientific Research (CNRS), Institute of Neurodegenerative Diseases, Bordeaux

Ms Catherine MOUNEYRAC – Vice-Rector for Research and Valorisation at the Catholic University of the West (UCO)

Ms Anne-Lise PARADIS – Research Manager at the National Centre for Scientific Research (CNRS)

Ms Marie-Pierre ROLS – Research Director at the National Centre for Scientific Research (CNRS)

Ms Valérie SIMONNEAUX – Research Director in Neurobiology of Rhythms at the National Centre for Scientific Research (CNRS)

Ms Alicia TORRIGLIA – Doctor, Director of Ophthalmology Research, Cordeliers Research Centre, French National Institute for Health and Medical Research (INSERM)

Ms Françoise VIÉNOT – Professor Emeritus – Centre for Research on Conservation (CRC), National Museum of Natural History, National Centre for Scientific Research (CNRS), Ministry of Culture, 36 rue Geoffroy Saint Hilaire, 75005 Paris, France

ANSES PARTICIPATION

Scientific coordination

Ms Dina ATTIA – Scientific Project Manager – ANSES

Scientific contribution

Ms Dina ATTIA – Scientific Project Manager – ANSES

Mr Olivier MERCKEL – Head of the Unit for assessment of risks related to physical agents – ANSES

Ms Aurélie NIAUDET – Deputy Head of the Unit for assessment of risks related to physical agents – ANSES

Administrative secretariat

Ms Sophia SADDOKI – ANSES

HEARINGS WITH EXTERNAL PERSONS

Pr. Françoise VECCHIERINI, 28 February 2023

Hôtel-Dieu de Paris – Paris Centre University Hospitals – Sleep and Vigilance Centre.

French Federation of Toy and Childcare Industries (FJP), 17 April 2023

Mr Martial DOUMERC – Safety, Quality and Environment Manager

European Committee for Electrotechnical Standardization (CENELEC), 17 April 2023

Mr Nicolas DIMIER, Coordinator of the joint IEC (International Electrotechnical Commission) and CENELEC working group on technical committees for the safety of electric toys (IEC/EN 62115)

Directorate General for Health (DGS), 15 May 2023

Ms Alice KOPEL, Bureau for the external environment and chemical products (EA1), Sub-directorate for prevention of risks associated with the environment and food

Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF), 15 May 2023

Ms Hélène HERON, Bureau 5A "Industrial Products"

Ms Karine SIMBELIE, Bureau 5A "Industrial Products"

Ms Nathalie MICHEL, Bureau 5A "Industrial Products"

Directorate General for Enterprise (DGE), 15 May 2023

Mr Blaise SOURY-LAVERGNE, Head of the Product Standardisation and Regulation Division

Mr Ludovic DEFFAIN SQUALPI, Product Standardisation and Regulation Division

Ms Frédérique SANDEAU, Product Standardisation and Regulation Division

Directorate General for Customs and Indirect Taxation (DGDDI), 15 May 2023

Ms Sophie BERNERT, Bureau JCF2 – Control Policy

Ms Doris ESSAYAG, Bureau JCF2 – Control Policy

Mr Patrick AGRAL, Bureau JCF2 – Control Policy

ANNEX 2: FORMAL REQUEST LETTER

2022-SA-0193

GOUVERNEMENT

Liberté
Égalité
Fraternité

Direction générale des entreprises
Direction générale de la santé

Paris, le 25 OCT. 2022

Direction générale des entreprises
Sous-direction de la normalisation, de la réglementation des produits et de la métrologie
Pôle normalisation et réglementation des produits

Direction générale de la santé
Sous-Direction de la prévention des risques liés à l'environnement et l'alimentation
Bureau Environnement extérieur et produits chimiques

Nos réf. : I.22-005201

Le Directeur général des entreprises
Le Directeur général de la santé

à

Monsieur le Directeur général
de l'Agence nationale de sécurité sanitaire
de l'alimentation, de l'environnement et du
travail

Objet : Saisine relative à la prise en compte dans la réglementation de la recommandation de l'Anses sur la restriction de la mise à disposition des objets à LED auprès du grand public à ceux de groupes de risques photobiologiques 0 ou 1 dans le cas des jouets.

Dans son avis du 5 avril 2019 relatif aux effets sur la santé humaine et sur l'environnement (faune et flore) des systèmes utilisant des diodes électroluminescentes (LED), l'Anses recommande de restreindre la mise à disposition des objets à LED auprès du grand public à ceux de groupes photobiologiques 0 ou 1.

Cette recommandation a notamment inspiré le plan national santé environnement n° 4, publié en mai 2021, qui comprend une action 9 « Réduire les nuisances liées à la lumière artificielle pour la santé et l'environnement ». En particulier, la troisième partie de cette action « Prévenir les risques liés à la lumière bleue » prévoit qu'en application des recommandations de l'Anses, la France interdira les LED de groupe de risque supérieur à 1 dans les articles à destination des enfants et dans les lampes torches, sous réserve de compatibilité de cette mesure avec le droit européen.

Or, depuis les travaux d'expertise conduits par l'agence, la norme EN 62115 de sécurité pour les jouets électriques, notamment son annexe E « Sécurité des jouets électriques comportant des sources de rayonnement optique », a évolué, avec notamment l'ajout d'exigences concernant la sécurité des LED afin de minimiser le risque de blessures oculaires.

Afin de répondre à l'objectif de l'action n° 9 du PNSE4, il est nécessaire de vérifier si l'évaluation de la conformité des jouets via la norme EN 62115 actualisée en 2020 garantit que les jouets déclarés conformes sont dans un groupe de risque photobiologique inférieur ou égal à 1, tel que défini dans la norme de sécurité photobiologique.

Aussi, nous sollicitons votre agence afin de procéder à un examen de la nouvelle version de la norme EN 62115 publiée en 2020 et applicable depuis février 2022 et de vérifier :

- d'une part, si cette nouvelle version permet de répondre de manière adéquate à la recommandation de l'Anses en partie reprise dans l'action n° 9 du PNSE4 visant à ne pas mettre à disposition des jouets comprenant des LED de groupe de risque supérieur à 1 ;
- d'autre part, si cette nouvelle norme prend suffisamment en compte la spécificité des enfants (qui sont plus sensibles à la lumière bleue en raison d'un cristallin plus clair).

Nous vous remercions de bien vouloir nous transmettre, dans les meilleurs délais, votre proposition de contrat d'expertise. Celle-ci comprendra notamment les modalités de traitement et de restitution des travaux, dont le rendu final est attendu pour le 31 décembre 2023.

Le directeur général des entreprises

Thomas COURBE

Le directeur général de la santé

Jérôme SALOMON

61 boulevard Vincent-Auriol - Télédoc 131 - 75703 Paris Cedex 13 - www.economie.gouv.fr/fr
14 avenue Duquesne – 75350 Paris 07 SP - Tél. 01 40 56 60 00 - www.social-sante.gouv.fr

ANNEX 3: HARMONISED STANDARDS APPLICABLE TO TOYS

The table below shows all the standards used to establish conformity with the essential requirements of Directive 2009/48/EC on the safety of toys:

Table 3: harmonised standards applicable to toys, list published by Commission Implementing Decision in the Official Journal of the European Union (OJEU) on 31 May 2021

No	Reference of the standard		
1.	EN 71-1:2014+A1:2018 Safety of toys — Part 1: Mechanical and physical properties		
2.	EN 71-2:2011+A1:2014 Safety of toys — Part 2: Flammability		
3.	EN 71-3:2019 Safety of toys - Part 3: Migration of certain elements		
4.	EN 71-4:2013 Safety of toys — Part 4: Experimental sets for chemistry and related activities		
5.	EN 71-5:2015 Safety of toys — Part 5: Chemical toys (sets) other than experimental sets		
6.	EN 71-7:2014+A3:2020 Safety of toys — Part 7: Finger paints — Requirements and test methods		
7.	EN 71-8:2018 Safety of toys — Part 8: Activity toys for domestic use		
8.	EN 71-12:2016 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances Informative note: The limit values in point a) of Table 2 of clause 4.2 of standard 'EN 71-12:2016 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances' are lower than the limit values to be complied with set in point 8 of part III of Annex II to Directive 2009/48/EC. In particular those values are as follows:		
	Substance	Standard EN 71-12:2016	Directive 2009/48/EC
	N-nitrosamines	0.01 mg/kg	0.05 mg/kg
	N-nitrosatable	0.1 mg/kg	1 mg/kg
9.	EN 71-13:2014 Safety of toys — Part 13: Olfactory board games, cosmetic kits and gustative games		
10.	EN 71-14:2018 Safety of toys - Part 14: Trampolines for domestic use		
11.	EN IEC 62115:2020 Electric toys — Safety EN IEC 62115:2020/A11:2020		

ANNEX 4: ANALYSIS OF THE PUBLICATION BY HIGLETT *ET AL*., 2012

The preprint analysis of the article by Higlett *et al*. (2012), written by the Working Group and ANSES, has been available since 13 March 2024 via the following link: https://www.preprints.org/manuscript/202403.0170/v1

Analysis of Intensity Limits for Light Emitting Diodes Used in Toys and Consequences for Children's Visual Health

Christophe Martinsons (*), *Centre Scientifique et Technique du Bâtiment (CSTB), Acoustics, Vibrations, Lighting, and Electromagnetism Division, Saint Martin d'Hères, France.*

Olivier Enouf, *Laboratoire National de Métrologie et d'Essais (LNE), Photonics Department, Trappes, France.*

Francine Behar-Cohen, *Centre de Recherche des Cordeliers, Sorbonne Université, INSERM UMR S1138, Université de Paris, Physiopathologie des maladies oculaires, OphtalmoPôle, AP-HP, Cochin Hospital, Paris, France*.

Alicia Torriglia*, Centre de Recherche des Cordeliers, INSERM UMR S1138, Paris, France.*

Françoise Viénot, *Muséum National d'Histoire Naturelle (MNHN), Paris, France*

Dina Attia, *French agency for food, environmental and occupational health & safety (ANSES)*, *Risk Assessment Department, Physical Agents Risk Assessment Unit, Maisons-Alfort, France*.

(*) corresponding author:

christophe.martinsons@cstb.fr
Tel. +33 616 54 59 25

Abstract

The analysis of the current safety standards for electric toys showed that the normative intensity limits for visible light emitted by LEDs integrated in toys are overestimated. These limits were originally set in a scientific article published in 2012 that was adapted into the international safety standard published in 2017, and into the subsequent European and national standards, all published in 2020. The overestimation of the intensity limits results from several errors made in the original article. Accordingly, the current normative intensity limits for visible light used in toys do not protect the children's eyes against adverse effects of exposure to high intensity LEDs which may compromise their visual health. Updating the safety

standards for electric toys using a method based on robust scientific data is recommended to protect children's visual health and ensure their long-term well-being.

Introduction

Light-emitting diodes (LEDs) are energy-efficient light sources with a wide range of intensities and spectral distributions. Their versatility, ease of operation, and low cost have made them widely used in toys in which they fulfill various functions, such as simple indicators or sophisticated color-changing pattern projectors.

Ensuring the safety of toys equipped with LEDs is crucial as light transmittance is higher in children's eyes, increasing the risk of phototoxicity compared to adults.[1] Given the small size of LEDs, even a modest radiant flux can result in very high radiance and luminance values.[2] The potential risks of light exposure for the eyes are described in the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines.[3] In the visible range, an acute exposure to visible light in the blue part of the spectrum may cause retinal photochemical damage, which may irreversibly alter vision.

The latest international safety standard for electric toys was published in 2017.[4] It defines luminous and radiant intensity limits to ensure the optical safety of the LEDs incorporated in toys. This standard was adopted in 2020 as a European standard,[5] then transposed to national standards in 34 countries.

The intensity limits defined by the currently approved standards are based on an assessment method described in a scientific article published by Higlett and colleagues in 2012.[6] The limits were established for LEDs emitting in the visible and in the ultraviolet spectral ranges. While radiant intensity limits in the ultraviolet range were correctly derived in this paper, the determination of intensity limits in the visible spectrum, which concerns most of the LEDs used in toys, was, in our opinion, erroneous.

Because of these errors, which are detailed below, the luminous and radiant intensity limits for visible light emitted by LEDs in toys are largely overestimated in the safety standards. These limits fail to protect the eyes of children against retinal hazards and the consequences of repeated exposures to the intense glare caused by high intensity LEDs.

Analysis of the intensity limits for LEDs used in toys

Higlett and colleagues described an assessment method for determining the optical radiation safety of light-emitting diodes (LEDs) used in toys.[6] They determined accessible emission limits in terms of radiant or luminous intensity. These specifications are usually provided in the

technical datasheet of the LEDs. Therefore, the toy manufacturer can select compliant LEDs without performing specific optical safety tests.

The analysis of the article of Higlett and colleagues revealed errors in the sections concerning the determination of limits for visible light. The three errors are the following:

- Incorrect assessment of the foreseeable misuse exposure scenario
- Incorrect derivation of luminous intensity from luminance
- Numerical errors in the computation of radiant intensity limits

Firstly, Higlett and colleagues incorrectly assessed the retinal photochemical hazard in the foreseeable misuse exposure scenario (exposure at a distance of 100 mm during 100 s). They did not consider the spatial averaging process across the effective acceptance angle recommended by the International Commission on Non-Ionizing Radiation Protection (ICNIRP)[3] to account for involuntary eye movements. As a result, Higlett and colleagues concluded that this scenario was not restrictive in comparison with the worst-case condition of normal use at 200 mm during 10 000 s. They rejected the foreseeable misuse scenario. Due to this error, the safety limits concerning the retinal effects of short wavelength optical radiation (blue and violet light) were overestimated by a factor of 4.

Secondly, Higlett and colleagues incorrectly calculated luminous intensity from a luminance value of 10 000 cd m^{-2}, a threshold defined as a simple guideline by the ICNIRP to avoid complex measurements of white light sources.[3] Their calculation ignored the apparent size of the LED, leading to largely overestimate the luminous intensity limits, expressed in unit cd. The error factor is about 1 000. The consequence of this error is that LEDs used in toys can be extremely bright, with luminance values that may exceed 10^7 cd m^{-2}.

Thirdly, a numerical error was identified in the computation of the radiant intensity limits by Higlett and colleagues, resulting in values 10 times higher than the true radiant intensity limits, already overestimated due to the error reported above. Consequently, when referring to emission limits expressed in unit of W sr^{-1}, LEDs can have luminance values which may be around 10^8 cd m^{-2}.

Greater detail concerning the three errors can be found in the Appendix.

Implications for Children's Visual Health

While using electric toys complying with the current safety standards, children may be exposed to high intensity LEDs at short distances, causing repeated temporary losses of vision (saturation glare) and afterimages persisting in the visual field because of the photobleaching of the retinal photoreceptors.[7] Furthermore, the exposure dose may exceed the limit for

photochemical retinal damage by a factor of 4,[3] increasing the risk of acute effects such as photoretinitis.

Damage to the retina is potentially cumulative, leading to eye pathologies during adulthood suspected to be linked with repeated exposures to bright sources and intense glare, such as age-related macular degeneration (AMD)[8] or glaucoma.[9]

The risks presented by high intensity LEDs can only be mitigated by the aversion response of children. However, the aversion reaction may not be fully developed in young children whose retina is immature. Furthermore, the eyes of infants younger than two years of age have a shorter focal length,[10] which implies that they are likely to manipulate their toys at short distances, typically less than the distance of 200 mm that was chosen by Higlett and colleagues to define the intensity limits of LEDs.

With older children, the aversion response can be intentionally ignored for playing purposes as described in recent case reports of macular injuries in children exposed to a hand-held high intensity LED device[11] or to a laser pointer[12] during games. Besides, LEDs emitting pure blue light are not perceived as being very bright due to the lower sensitivity of vision in this spectral range, even when radiant intensity is high.[13] In this case, without high brightness cue, the aversion response is very limited, or non-existent. [1,14]

Safety Standards

The errors found in the article of Higlett and colleagues[6] were integrally transposed into the international safety standard for electric toys, into the equivalent European standard, and into 34 national standards. The overestimation of the safe intensity limits for visible light emitted by LEDs prevents the current standards from providing adequate protection against the harmful effects of high intensity LEDs incorporated in toys.

Conclusion

It is recommended to revise the normative intensity limits of LEDs used in toys to correct the existing errors and ensure adequate protection of children's visual health. Regulatory agencies and health authorities should take action to update these standards.

Funding

This study was funded by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), Maisons-Alfort, France.

References

1 ICNIRP. Light-Emitting Diodes (LEDS): Implications for Safety. *Health Physics* 2020; **118**: 549–61.

2 Behar-Cohen F, Martinsons C, Viénot F, *et al.* Light-emitting diodes (LED) for domestic lighting: Any risks for the eye? *Progress in Retinal and Eye Research* 2011; **30**: 239–57.

3 ICNIRP. ICNIRP Guidelines on limits of exposure to incoherent visible and infrared radiation. *Health Physics* 2013; **105**: 74–91.

4 International Electrotechnical Commission (IEC). IEC 62115:2017 Electric Toys - Safety. 2017.

5 European Committee for Electrotechnical Standardization (CENELEC). EN IEC 62115:2020 Electric Toys - Safety. 2020.

6 Higlett MP, O'Hagan JB, Khazova M. Safety of light emitting diodes in toys. *J Radiol Prot* 2012; **32**: 51–72.

7 Boyce PR. Human factors in lighting, Third edition. Boca Raton: CRC Press, Taylor & Francis Group, 2014.

8 Kim SH, Kim YK, Shin YI, *et al.* Nighttime Outdoor Artificial Light and Risk of Age-Related Macular Degeneration. *JAMA Netw Open* 2024; **7**: e2351650.

9 Osborne NN, Núñez-Álvarez C, Del Olmo-Aguado S, Merrayo-Lloves J. Visual light effects on mitochondria: The potential implications in relation to glaucoma. *Mitochondrion* 2017; **36**: 29–35.

10 Lotmar W. A theoretical model for the eye of new-born infants. *Albrecht Von Graefes Arch Klin Exp Ophthalmol* 1976; **198**: 179–85.

11 Zhang L, Lei C-Y, Zhang Z-C, Gu J-Y, Zhang M-X. Accidental macular injury from short-term exposure to a handheld high-intensity LED light. *Heliyon* 2023; **9**: e18705.

12 Swatch P, Chang A, Bhakhri R. Laser Pointer Retinopathy: A Case Report and Review. *CRO Journal* 2022; **33**. DOI:10.57204/001c.33792.

13 DiLaura DL, Houser KW, Mistrick RG, Steffy GR. The Lighting Handbook (10th edition): Reference and Application. New York, NY: Illuminating Engineering Society, 2011.

14 Boyce P. Light, lighting and human health. *Lighting Research & Technology* 2022; **54**. DOI:10.1177/14771535211010267.

Appendix: explanations of the errors identified in the original article of Higlett and colleagues: Higlett MP, O'Hagan JB, Khazova M. Safety of light emitting diodes in toys. *J Radiol Prot* 2012; 32: 51–72.

Error 1: incorrect assessment of the foreseeable misuse scenario

Two exposure scenarios were used by the authors to define the accessible emission limits (AELs) for visible light (page 54 of the original paper):

- Scenario 1 corresponding to a worst-case condition of normal use at 200 mm from the eyes for 10 000 s,
- Scenario 2 corresponding to a foreseeable misuse scenario at a viewing distance of 100 mm for 100 s.

In the first scenario (page 55), Higlett and colleagues used the blue light hazard exposure limit of 100 W m^{-2} sr^{-1} (B-lambda weighted radiance) defined by the International Commission for Non-Ionizing Radiation Protection (ICNIRP) in their guidelines. They used the ICNIRP effective size of source of 0.11 rad (acceptance angle corresponding to a solid angle of 0.01 sr), leading to an exposure limit of 1 W m^{-2} (B-lambda weighted irradiance) at the eye and a corresponding AEL of (0.04 × Ω) W in terms of B-lambda weighted flux emitted by the LED, where Ω is the solid angle of the LED beam.

Surprisingly, Higlett and colleagues used a different method for evaluating the AEL in the second scenario (page 55). They correctly used the ICNIRP exposure limit of 10 000 W m^{-2} sr^{-1} (B-lambda weighted radiance) corresponding to an exposure of 100 s, but they multiplied it by the solid angle Ω of the LED beam and by the square of the viewing distance, thereby ignoring the ICNIRP acceptance angle. Their calculation gave an AEL of (100 × Ω) W, a value which is 2 500 times higher than the AEL of Scenario 1. They thus rejected Scenario 2 as they judged that it was not restrictive for optical safety, in comparison with Scenario 1.

Should Higlett and colleagues have used the ICNIRP acceptance angle as they did for the first scenario (for an exposure of 100 s, it is 0.011 rad, which is equivalent to a solid angle of 0.0001 sr), they would have found an AEL of (0.01 × Ω) W. Scenario 2 is actually 4 times more restrictive than Scenario 1. Scenario 2 should have been the one to consider in the assessment of optical safety.

Error 2: incorrect consideration of the ICNIRP luminance threshold of 10 000 cd m^{-2}

The luminance threshold of 10 000 cd m^{-2} was considered by Higlett and colleagues on page 56 of the original paper to establish safe limits for visible optical radiation, following the ICNIRP

guidelines stating that below this indicative value, retinal exposure limits for the blue light hazard and thermal injury would not be exceeded in the case of light sources with a broad spectrum. [3]

Higlett and colleagues calculated the luminous intensity value corresponding to a luminance of 10 000 cd m^{-2} using Equation 3 on page 56 of the article. This equation contains a parameter named *Area*. Higlett and colleagues defined this parameter as being the area of the beam at the eye. This is incorrect because luminous intensity is the product of the luminance and the apparent source area, which is usually much smaller than the area of the beam at the eye. For instance, if an LED of 10 000 cd m^{-2} has an apparent area of 4 mm², its luminous intensity is 0.04 cd.

In the paper, the luminous intensity values corresponding to a luminance of 10 000 cd m^{-2} can reach 38.4 cd, as shown in Figure 7 (page 58 of the original article). Unfortunately, this luminous intensity value corresponds to LEDs having a very high luminance that may reach more than 1 000 times the ICNIRP guideline of 10 000 cd m^{-2}. For example, an LED of 38.4 cd with a typical apparent area of 4 mm² has a luminance of about 10 000 000 cd m^{-2}, far beyond the 10 000 cd m^{-2} threshold considered by Higlett and colleagues to limit the luminance of LEDs.

Error 3: incorrect determination of emission limits expressed in unit of radiant intensity

A threshold of 0.76 W sr^{-1} was used by Higlett and colleagues to provide a limit to the AEL curves expressed in unit of radiant intensity, as shown in Figure 9 (page 59 of the article). This value corresponds to luminous intensities that may largely exceed the limit of 38.4 cd, which was already overestimated due to Error 2. Based on our own calculations, we can conclude that Higlett and colleagues made an error of a factor of 10 in establishing the radiant intensity threshold.

To illustrate this error, we can consider a white LED having a radiant intensity of 0.76 W sr^{-1} and a correlated colour temperature of 5 410 K. The corresponding luminous intensity is 250 cd, a value that exceeds the limit of 38.4 cd previously derived by the Higlett and colleagues. The combination of Error 2 and Error 3 would lead to wrongly considering that this white LED is safe for the eyes. If this white LED has an apparent area of 4 mm², its true luminance is 62 500 000 cd m^{-2}. Again, this value is far beyond the 10 000 cd m^{-2} threshold considered by Higlett and colleagues as a limit to the luminance of LEDs.