Joint Market Surveillance Actions on GPSD Products - JA 2015
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Assessment of Risks from Acoustic Toys

1 Introduction

The purpose of this document is to provide guidance to market surveillance authorities in assessing the risk from acoustic toys that emit too high sounds. It covers the 11 types of acoustic toys from the standard.

The document is based on work carried out by the JA2014 Toys Activity Group with support from a professor in audiology, Stig Arlinger from Sweden. (Stig Arlinger was active as an expert in CEN/TC52/WG3, responsible for the revision of the acoustic requirements in EN 71-1, on behalf of the Swedish Consumer Agency. As professor of technical audiology at Linköping university in Sweden, he has been extensively involved in research concerning noise-induced hearing disorders and hearing protection. He was also project leader within ISO/TC43 for the 2013-revision of ISO 1999 “Estimation of noise induced hearing loss”. During nine years he was the convenor of CEN/TC159 Hearing protectors.)

Stig Arlinger prepared a report "Acoustic toys and risks for impaired hearing" for the Toys Activity Group. It explains how to assess the risk posed by acoustic toys that produce too loud sounds. At the end of the report is a table that gives an indication of the risk associated with excessive sound pressure levels taking into account the three exposure categories and the limit values given in the standard for each of the 11 types of toys.

The full report is included in annex 1 of this document.

2 Background

The risk for suffering hearing injuries due to excessive sound levels depends upon the sound pressure level, the duration, the type of sound (continuous or impulse), the distance to the sound emitting source, and the pattern of use. These parameters are interlinked; if the sound pressure level is low, but the source is close to the ear, it may be more risky than a source producing a higher sound pressure level at a greater distance. Likewise, the pattern of use influences the distance between the source and the ear and the duration of the exposure.

Sound pressure level measurement distinguishes between continuous sounds and impulsive sounds. Continuous sound pressure level (LpA - A-weighted time-averaged emission sound pressure level) is measured in dB(A). Impulsive sound pressure level (LpC Peak - C-weighted emission peak sound pressure level) is measured in dB(C).

EN 71-1:2014, clause 4.20 lists the sound pressure level limit values that will give presumption of conformity with the Toy Safety Directive's safety requirements for acoustics. These limit values only apply to toys that are designed to emit sound, i.e. toys with sound-producing features such as electric or electronic devices, percussion caps, rattling components, etc.

The standard defines 11 types of acoustic toys:

- Close-to-the-ear toys
- Table-top or floor toys
- Hand-held toys
- Rattles
- Squeeze toys
- Pull-along or push toys

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- Percussion toys
- Wind toys
- Cap-firing toys
- Voice toys
- Toys using headphones or earphones

For each of them limit values are given for LpA and LpC peak. In addition, three exposure categories are defined for each type of toy. These specify the duration of the sound emission and how easily the child can activate the sound production when playing with the toy.

3 Measurement Uncertainty

If an accredited test laboratory measures the sound pressure level of a toy, according to EN 71-1:2014, it will classify the toy according to the 11 types defined in the standard as well as its exposure category. The laboratory should also inform about the measurement uncertainty that applies to the specific test.

The JA2014 Acoustic Toys Working Group developed the following approach to dealing with the measurement uncertainty for toys:

- Risk assessment

  It is recommended that the risk assessor uses the measured sound pressure level without considering the measurement uncertainty.

  The rationale is that the "correct sound pressure level" is known to be somewhere in the range from the measured value minus the measurement uncertainty to the measured value plus the measurement uncertainty. It is impossible to tell where, it could be below or above the actual test results measured by the laboratory. From the perspective of consumers, one would tend to add the measurement uncertainty to the test results, whereas from the perspective of the economic operators, one would tend to subtract the measurement uncertainty from the test results. Taking the measured values without considering the uncertainties is seen as a pragmatic and median approach between the two perspectives.

- Risk management

  It is recommended that the authority uses the measured sound pressure level minus the measurement uncertainty and that measures are only taken if this value is still above the limit value given in the standard.

  In borderline cases, where the measured value is above the limit value and the reduced value (i.e. the measured value minus the measurement uncertainty) is below the limit value, it is recommended that the market surveillance authority requests the economic operator to prove that the toy complies with the Toy Safety Directive for instance by asking for the declaration of conformity and the risk assessment performed by the economic operator. If the economic operator is unable to produce these, action should be considered.

This approach is recommended by the 16 European market surveillance authorities that took part in the JA2014 Acoustic Toys Activity. More information can be found in the final technical report from the Activity at PROSAFE's website (www.prosafe.org) under the topic "Joint Action 2014" or via the direct link http://www.prosafe.org/index.php/joint-action-2014/acoustic-toys.

4 Risk Assessment

Table 1 and table 2 give a summary of how the risk arising from excessive sound power levels produced by acoustic toys is assessed using the method described by Stig Arlinger in his report. The method considers both continuous sounds (LpA) and impulsive sounds (LpC Peak) and it recommends injury severity levels and probability factors for each of the 11 types of acoustic toys. Table 1 recommends injury severity levels. Table 2 recommends estimated probability factors (primarily based on the average distance between the toy and the child's ear during play).

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To use the tables properly, the risk assessor needs to have a test report for the toy that states the measured sound power levels (LpA and LpC Peak), the limit values from the standard, the type of toy (from the 11 types defined by the standard) and the exposure category as defined by the standard.

	Measured sound power level	Injury severity level	Additional condition
Continuous sound (LpA)	0 – 10 dB(A) over limit value	2	-
	>= 10 dB(A) over limit value	3	If the measured sound power level is more than 15 dB(A) over the limit value, the probability is increased by a factor of 10.
Impulsive sound (LpC Peak)	0 – 5 dB(C) over limit value	2	-
	>= 5 dB(C) over limit value	3	If the measured sound power level is more than 10 dB(C) over the limit value, the probability is increased by a factor of 10.

Table 1: Recommended injury levels

Type of toy	Definition (EN 71-1:2014)	Clause	Recommended probability
Cap-firing toys	Toys clearly designed to emit sound caused by discharge of a percussion cap.	3.7	>= 1/1.000
Close-to-ear-toys	Toy clearly designed to emit sound, intended to be used within 2,5 cm of the ear.	3.10	>= 1/10.000
Handheld toys	Toy clearly designed to emit sound, intended to be held in the hand but excluding close-to-the-ear toys, rattles, squeeze toys, cap-firing toys, wind toys, voice toys and percussion toys.	3.31	>= 1/100.000
Percussion toys	Toy clearly designed to emit sound when struck with a beater, such as a drumstick, or by the hand.	3.43	>= 1/100.000
Pull-along or push toys	Toy on which movement is imparted by the user for example by pulling it by a cord or pushing it be means of a rigid extension.	3.48	>= 1/1.000.000
Rattles	Toy, intended for children who are too young to sit up unaided, that is clearly designed to emit sound when shaken or activated by the child or another person.	3.49	>= 1/100.000
Squeeze toys	Pliable toy, intended for children who are too young to sit up unaided, incorporating a noise-making feature activated by forcing air through an opening, clearly designed to emit sound when flexed or squeezed by the child or another person.	3.55	>= 1/100.000
Table top or floor toys	Toy clearly designed to emit sound, intended to be used on a table, floor or another large surface.	3.59	>= 1/1.000.000

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Type of toy	Definition (EN 71-1:2014)	Clause	Recommended probability
Toys using headphones or earphones	(none)	-	>= 50%
Voice toys	Toy clearly designed to emit sound by electronically amplifying or distorting the voice and where the output sound level depends on the input sound level of the voice.	3.68	>= 1/10.000
Wind toys	Toy clearly designed to emit sound when actuated by the blowing action of the child or another person.	3.69	>= 1/1.000

Table 2: Recommended probabilities

5 Example

This example shows how the risk assessment method summarised in the two tables works in the online RAG risk assessment tool.

The example considers an toy trumpet.

According to EN 71-1:2014 a toy trumpet is a wind toy.

A laboratory test has shown that it can produce a continuous sound power level (LpA) that exceeds the limit values from the standard with 12 db(A). The peak sound power level (LpC Peak) is within the limit laid down in the standard.

The first step in the RAG tool is to determine the product hazard. The hazard group is “kinetic energy” and the hazard is “noise”, figure 1:

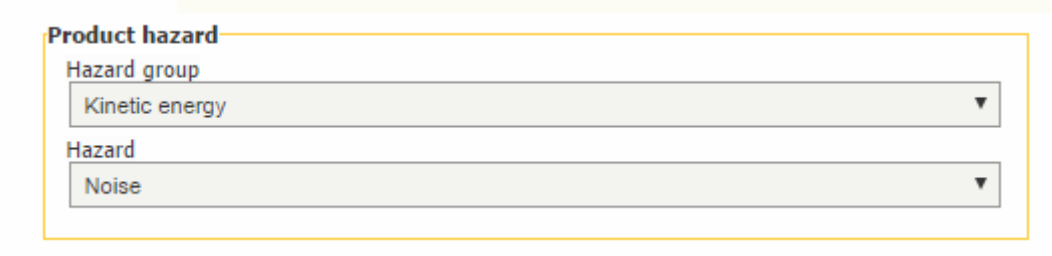

Figure 1: Hazard group and hazard for an acoustic toy

Next, the consumer type must be identified and an appropriate injury scenario must be described to explain how the hazard causes the injury.

Then the risk assessor must decide on the type of injury from the drop-down list. In the case of high sounds from acoustic toys, the appropriate injury is “Hearing injury, foreign body in ear”, figure 2.

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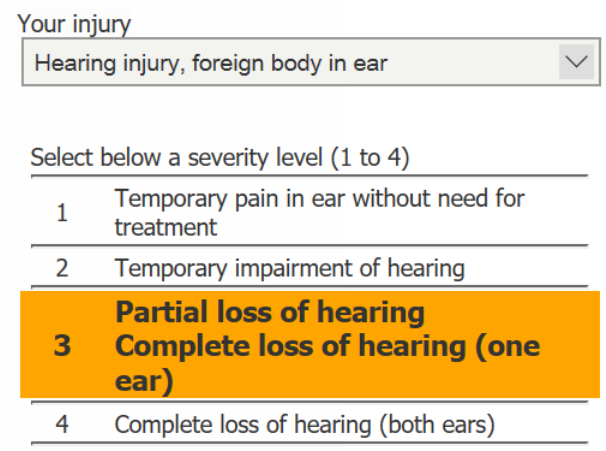

Figure 2: Type of injury and possible injury levels for hearing injuries

Once the option "Hearing injury, …" is selected as the injury type, the table below the field shows that there are four injury severity levels to choose from, ear", figure 2.

The risk assessor should then consult the above table 1 and select the entry for "Continuous sound (LpA)" that exceeds the limit value with more than 10 dB(A). The table shows that the recommended injury level is 3. Figure 2 shows that this option has been selected.

The measured level exceeds the limit value with less than 15 dB(A) so table 1 also shows that no additional conditions apply (last column).

The next step is to estimate the probability. The risk assessor should consult table 2 for this purpose and look up the type of toy in the table. A toy trumpet is a wind toy, which is found in the final row of the table. The table shows that the recommended probability is >= 1/1.000. This value is entered in the appropriate field in the RAG tool.

The final step is to determine the risk. It is calculated automatically by the RAG tool. The result ("Serious risk") is shown in figure 3.

Severity of injury level	Calculated probability	Overall probability	Risk of this scenario
3	0.001000000	= 1/1,000	Serious risk

Figure 3: Resulting risk level

6 Concluding remarks

This document presents guidance and should be applied as such. Every case must be assessed carefully on its own allowing fully for the specific characteristics of the particular case.

The risk assessor should document all considerations and rationales carefully in the risk assessment report so others can understand the lines of thinking. Such explanations will also help the risk assessor if he has to explain the case at a later stage – for the economic operator or in a court case.

The documentation should also include the conclusions from a sensitivity analysis to show how sensitive the resulting risk level is to changes in the input parameters; how much can the probabilities change before the resulting risk level changes.

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Annex 1: Report from Professor Stig Arlinger

Acoustic toys and risks for impaired hearing

Report to the PROSAFE Project TOYS-JA2014

by Stig Arlinger

Professor Stig Arlinger was active as an expert in CEN/TC52/WG3, responsible for the revision of the acoustic requirements in EN71-1, on behalf of the Swedish Consumer Agency. As professor of technical audiology at Linköping university, Linköping, Sweden, he has been extensively involved in research concerning noise-induced hearing disorders and hearing protection. He was also project leader within ISO/TC43 for the latest revision of ISO 1999 (2013) "Estimation of noise induced hearing loss". During nine years he was the convenor of CEN/TC159 Hearing protectors.

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Disclaimer

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Acoustic toys and risks for impaired hearing

Report to PROSAFE project TOYS-JA2014
by Stig Arlinger,

1. Introduction

A number of market surveillance authorities involved in the product safety of acoustic toys took part in a joint market surveillance activity called 'TOYS-JA2014'. This project, coordinated by PROSAFE and funded by the European Union, was implemented between 2015 – 2016. In view that the surveillance authorities were mainly going to test the products in line with the latest acoustic requirements as found within the standard EN 71-1:2011+A3:2014, I was asked by this working group to see if some form of guidance could be given in relation to risk assessment of these acoustic toys in line with this revised standard.

One needs to first and foremost explain that this report should only be considered as generic guidance and ultimately one needs to ascertain the final level of risk on a case-by-case basis in line with the guidance given within this report and after fully considering all the aspects associated with that particular toy.

The European Standard EN 71-1:2011+A3:2014 specifies requirements on maximum sound pressure levels from toys that are clearly designed to produce sound. The sounds may be continuous, impulsive or a combination of both in character. Eleven different types of toys are defined in the standard, mainly related to their design and the ways in which children are assumed to play with them.

As yet there exists no scientific evidence that the sensitivity of children with relation to auditory hazard by exposure to loud sounds is significantly different from that of adults. The absolutely dominating scientific knowledge about noise as a hazard to human hearing is based on studies on adult human subjects. Most studies have focused on occupational noise exposure, but also to some extent on exposure to loud sounds in free-time activities such as listening to music. Studies have concerned retrospective analyses after exposures over longer time periods with focus on effects in terms of permanent hearing loss, but also short term effects have been studied, recording temporary changes in auditory function after well-defined exposures.

2. Auditory effects of noise exposure

Three main types of effects after noise exposure are known:

1.1 Hearing thresholds shifts. Hearing thresholds, tested using pure tones in the frequency range from 125 to 8.000 Hz, represent the sensitivity of the auditory organ. Physiologically they are mainly determined by the state of the outer hair cells in the human inner ear. Threshold shifts may be temporary in character – **Temporary Threshold Shifts, TTS**. Directly after an exposure a loss of sensitivity can be

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recorded at one or several test frequencies, usually most pronounced in the range 3-6 kHz. After a sufficiently long recovery time – from hours to a few weeks – the hearing thresholds return to pre-exposure levels. Daily exposure levels not exceeding 75-80 dB(A) are unlikely to produce significant TTS.

1.2 In case of sufficiently long and loud exposure, hearing thresholds may never recover, but a permanent hearing loss is present – **Permanent Threshold Shift, PTS**. This situation is assumed to reflect permanent damage of outer hair cells, but other structures in the inner ear may be damaged as well. When TTS after a single exposure reaches 30-40 dB, the risk for PTS is considered real, i.e. the hearing thresholds will never return to pre-exposure levels.

2. Tinnitus is an auditory perception of sound without the presence of a corresponding external physical signal. The sound may be heard as a tone, a whistling or a buzzing sound. The most likely explanation for tinnitus is some type of damage to the inner ear and/or auditory nerve. Tinnitus may occur also when no measureable hearing loss is present. No clear evidence exists for critical exposure values with regard to noise causing permanent tinnitus. However, indirect evidence makes tinnitus as a consequence of "hidden hearing loss" very likely (Schaette & McAlpine, 2011).

3. "Hidden hearing loss" is a term that has been suggested to represent damage that has occurred to inner hair cells in the inner ear and/or to nerve fibers in the auditory nerve, leading from the inner ear to the brainstem. Animal studies have shown that such damage may occur after noise exposure that gives rise to TTS without leaving any PTS. These studies were performed on mice and guinea-pigs with exposures that gave rise to TTS of around 40 dB measured 24 hours after the exposure (Kujawa & Liberman, 2009; Furman et al, 2013). Prell et al (2012) estimates that a noise exposure resulting in TTS of less than 20 dB represents negligible risk for permanent effects on inner hair cells and/or auditory nerve fibers.

3. The noise at work directive

As explained in section A.25 of the EN 71-1 standard, the limit values of the standard are based on the lower action values found in directive 2003/10/EC (2003), commonly referred to as the "noise at work directive".

This Directive specifies the following concepts with regard to occupational exposure to noise in Article 3, clause 1:

(a) exposure limit values: $L_{EX,8h}$ = 87 dB(A) and p_{peak} = 200 Pa, corresponding to 140 db (C) in relation to 20 uPa, respectively;

(b) upper exposure action values: $L_{EX,8h}$ =85 dB(A) and p_{peak} = 140 Pa, corresponding to 137 dB (C) in relation to 20 uPa, respectively;

(c) lower exposure action values: $L_{EX,8h}$ = 80 dB(A) and p_{peak} = 112 Pa, corresponding to 135 dB (C) in relation to 20 µPa, respectively.

These limit values are related to the position(s) normally occupied by the head of the person who is affected by the noise.

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Further, in Article 6 on hearing protectors is stated:

(a) where noise exposure exceeds the lower exposure action values, the employer shall make individual hearing protectors available to workers;

(b) where noise exposure matches or exceeds the upper exposure action values, individual hearing protectors shall be used;

And in Article 7, Limitation of exposure, is stated:

1. *Under no circumstances shall the exposure of the worker as determined in accordance with Article 3(2) exceed the exposure limit values.*

4. Exposure to continuous noise

The International Standard ISO 1999 (2013), "Acoustics — Estimation of noise-induced hearing loss" provides data that allows calculation of the statistical risk for permanent noise-induced hearing loss after exposure to noise at various sound pressure levels. Figure 1 below illustrates the degree of permanent hearing loss, PTS, in decibel (dB) after 10 years of daily exposure for the 10 percent of the exposed population most affected by the noise. This figure shows that the lower action level for continuous noise of 80 dB(A) implies a very low risk for PTS at the most vulnerable frequencies 3-4 kHz even after many years of daily exposure.

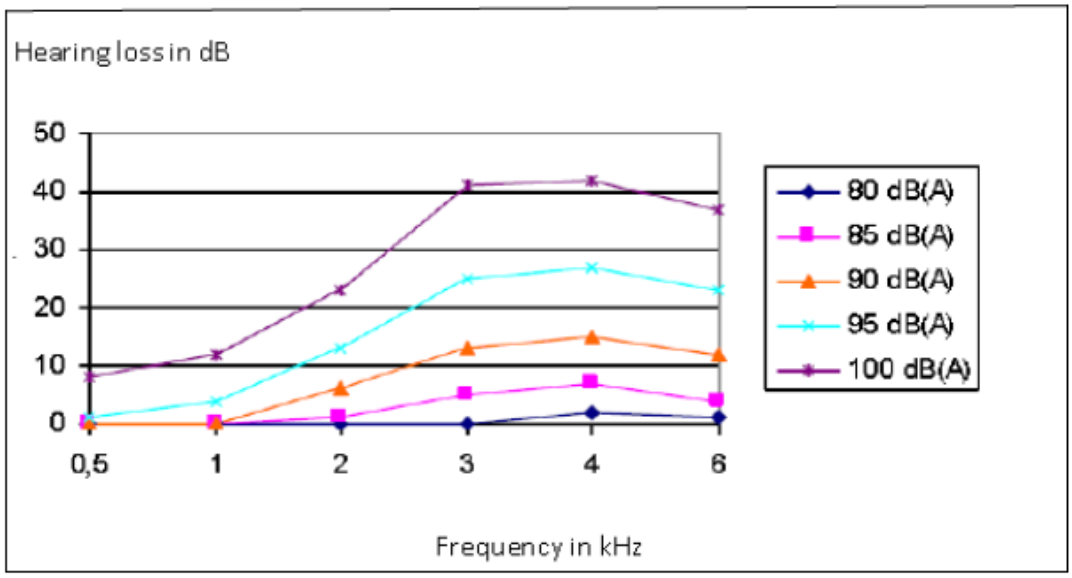

Fig. 1. Noise-induced permanent hearing loss after 10 years in occupational noise in levels between 80 and 100 dB(A) (8h/day) - 10-percentiles according to ISO1999.

With regard to temporary threshold shift, TTS, a number of laboratory studies have been published. Exposures to noise at 105 dB(A) for 10 min was used by one group in several studies, resulting in mean TTS at 3-4 kHz of between 7 and 18 dB with individual cases exceeding 20 dB. This exposure corresponds to approximately 88dB(A) during 8 hours. Based on 8 hours exposure duration, Mills et al (1981) estimated average TTS as a function of noise level. A noise level of 80 dB(A) resulted in a TTS of 6 dB, 85 dB(A) produced

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13 dB, and 90 dB(A) gave rise to a TTS of 21 dB. Above approximately 85 dB, TTS increased by 1,7 dB for each dB increase in noise level. Melnick (1991) estimates that a broadband noise of 78 dB(A) may give rise to a TTS of approximately 8 dB. According to Ward et al (1961) noise-induced TTS increases in proportion to the logarithm of time, i.e. average TTS increases by 3 dB when exposure time is doubled.

As explained in section A.25 of EN 71-1:2011+A3:2014 the effective daily playing time for toys with continuous sound generation is assumed to be 2 hours, allowing a maximum emission sound pressure level of 86 dB (rounded to 85 dB), corresponding to 80 dB during 8 hours exposure time. Such an exposure might thus give rise to an average TTS of approximately 5-6 dB. There is no evidence to assume that such an exposure would give rise to any permanent effect on the exposed person.

A noise level of 90 dB(A) for an 8 hour exposure would according to Mills et al (1981) give rise to an average TTS of approximately 20 dB. Exceeding this amount of TTS might involve a risk of permanent effects in terms of damage to inner hair cells or auditory nerve cells, the "hidden hearing loss". Converted to 2 hours exposure time, this corresponds to 96 dB(A) – conveniently rounded to 95 dB(A). A further increase in noise level by 10 dB is likely to involve a certain risk of permanent effects on hearing thresholds, PTS.

The EN-standard divides toys into three different categories, depending on assumed effective daily operating time of 120 minutes (category 1), less than 40 minutes (category 2), and less than 12 minutes (category 3). Due to the shorter exposure times for the two latter categories, the maximum permitted emission sound pressure levels are 5 and 10 dB higher, respectively.

Concluding this section on exposure to continuous noise from toys the following recommendations for all three categories of toys seem reasonable:

- Emission sound pressure levels fulfilling the requirements of EN 71.1:2011+A3:2014 are safe.
- Exceeding the requirement by 10 dB may introduce a risk for a TTS of 20 dB or more and permanent effects on inner hair cells and auditory nerve cells – "hidden hearing loss".
- Exceeding the requirement by 20 dB may represent risk for immediate permanent hearing loss, PTS.

5. Exposure to impulse noise

C-weighted peak sound pressure level, independent of impulse duration, is the parameter used in the noise at work directive as well as in EN 71.1:2011+A3:2014. This is what has to be accepted, although several studies have shown that the peak sound pressure level is a rather simplistic measure of impulse noise with regard to risk for hearing impairment.

Ward et al (1961) found that 25 impulses delivered during one minute at 140 dB gave rise to a TTS of approximately 10 dB. Coles et al (1968), assessing earlier experiences from military exposures, proposed a criterion based on a combination of peak sound pressure level and impulse duration. For a 1 msec duration the limit was approximately 160 dB(C) and for 10 msec the limit was 152 dB(C) for 90% of exposed subjects showing a TTS of maximum 20 dB. A detailed NATO-study (2003) reconsidered all available studies with focus on exposure

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to military weapons. For rifles a limit of approximately 153 dB (C) peak sound pressure level was assumed to limit TTS 2 minutes after exposure to less than 25 dB in 95% of the exposed population. Pfander et al (1980) identified a maximum peak sound pressure level of 148 dB (C) which would be acceptable also for impulses of very long duration. Their criterion for safe exposure was based on less than 5% of the exposed population to have a measureable TTS 24 hours after the exposure.

Based on the above data and considering the lack of data for impulse noise exposure that is not related to firearms, the following conclusions are drawn:

- Peak sound pressure levels fulfilling the requirements of EN 71.1:2011+A3:2014 are safe.
- Exceeding the requirement by 5 dB, i.e. 140 dB (C) peak sound pressure level, may introduce a risk for permanent effects on inner hair cells and auditory nerve cells – "hidden hearing loss".
- Exceeding the requirement by 10 dB, i.e. 145 dB (C) peak sound pressure level, may represent risk for immediate permanent hearing loss, PTS.

6. Severity of injury

The RAPEX Guideline defines 4 degrees of severity of injury. With regard to hearing injury the following severity levels are listed (page 63):

1. Temporary pain in ear without need for treatment.
2. Temporary impairment of hearing.
3. Partial loss of hearing. Complete loss of hearing (one ear)
4. Complete loss of hearing (both ears)

Severity level 1, 'temporary pain in ear', may occur as a reaction to a very loud sound. Such an experience will invariably give rise to some kind of defense reaction, making the exposure to the particular sound very short in time and unlikely to be repeated.

With reference to section 2 of this document it is obvious that severity level 2 or severity level 3 may occur.

Severity level 2, 'temporary impairment of hearing', i.e. TTS, may occur for any exposure that exceeds the requirement for emission sound pressure levels according to EN 71-1:2011+A3:2014.

Severity level 3, 'partial loss of hearing', may occur as tinnitus, "hidden hearing loss" or permanent threshold shift, PTS. Tinnitus and "hidden hearing loss" may occur if the requirements for emission sound pressure levels are exceeded by 10 dB or if the requirements for peak sound pressure level are exceeded by 5 dB. Immediate PTS may occur if the requirements for emission sound pressure levels are exceeded by 15 dB or if the requirements for peak sound pressure level are exceeded by 10 dB.

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It is not easy to state in general terms that one or the other of these three types of injury is a worse burden for the affected person. Therefore, it is reasonable to state that exceeding the requirements for emission sound pressure level by 10 dB or exceeding the requirements for peak sound pressure level by 5 dB represent the risk of injury of severity level 3.

Severity level 4, 'complete loss of hearing in both ears', is impossible to cause with any type of loud sound from a toy.

7. Probability of damage

The risk for injury is defined as a combination of severity of injury and probability of damage during the lifetime of the product. The standard defines eleven toy types which differ in size and in the way children are assumed to play with them. These aspects affect the probability that a toy may emit its sound close to the ear of a child, be it the child who is handling the toy in question or another child. When the distance between a sound source and a child´s ear decreases, the sound level reaching the ear increases. By a first approximation this increase is 6 dB for each halving of the distance. This means that for short distances even small changes in distance may have a large effect on the sound level reaching the ear. Therefore, toys that are intended to be used close to the ear or can easily by moved to such positions represent the highest probability of damage.

Close-to-the-ear toys are by definition intended to be used close to a child´s ear. If the child manages to place the toy in such a way as to produce a closed coupling to the ear, this is likely to increase the sound pressure entering the ear. The probability for this is estimated at e 1/10 000.

Table-top or floor toys are typically relatively large and unlikely to be close to a child´s ears during play. The probability of damage is estimated to be e 1/1 000 000.

Hand-held toys are sometimes relatively small and therefore easily placed close to an ear. Examples are clicking toys or toy guns that may generate high impulse sounds at short distances. The probability of damage is estimated to be e 1/100 000.

Pull-along or push toys are typically relatively large and unlikely to be close to a child´s ears during play. The probability of damage is estimated to be e 1/1 000 000.

Voice toys may in some cases be close to a child´s ear when activated by another child. The probability of damage is estimated at e 1/10 000.

Toys using headphones or earphones are by definition placed on the child´s ears. Thus, the probability is e 50%.

Rattles may be activated relatively close to a small child´s ears but more likely the activation takes place at a longer distance, with the intent to allow the child to see the movements that activate the rattle. The probability for damage is estimated to be e 1/100 000.

Squeeze toys may be activated relatively close to a small child´s ears but more likely the activation takes place at a longer distance, with the intent to allow the child to see the

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movements that activate the toy. The probability for damage is estimated to be e 1/100 000.

Percussion toys are normally relatively large in size and therefore unlikely to be activated when close to a child's ear. However, for example tambourines, belonging to this group, may be used relatively close to an ear. The probability of damage is estimated to be e 1/100 000.

Wind toys may relatively easily be activated close to another child's ears. The probability of damage is estimated to be e 1/1 000.

Cap-firing toys may easily be fired close to another child's ear. The probability of damage is estimated at e 1/1 000.

8. Risk level

When the requirements according to EN 71-1:2011+A3:2014 are met the risk level for any hearing injury is very low.

When the requirements for emission sound pressure levels are exceeded by less than 10 dB and for peak sound pressure level by less than 5 dB there is a risk of injury of severity level 2 (TTS).

When the requirements for emission sound pressure levels are exceeded by 10 dB or more and the requirements for peak sound pressure level are exceeded by 5 dB or more there is a risk of injury of severity level 3 (permanent effects). Related to the estimated probabilities for damage according to section 7, the following risk levels are estimated as shown in Table 1:

Toy category	Risk level regarding injury level 2	Risk level regarding injury level 3
Close-to-the-ear toy	M	H
Table-top or floor toy	L	L
Hand-held toy	L	M
Pull-along or push toy	L	L
Voice toy	M	H
Toy using headphones or earphones	S	S
Rattle	L	M
Squeeze toy	L	M
Percussion toy	L	M
Wind toy	H	S
Cap-firing toy	H	S

Table 1: Estimated risk levels for injury levels 2 or 3. L=Low, M=Medium, H=High, S=Serious risk

When the requirements for emission sound pressure levels are exceed by 15 dB or more and/or the requirements for peak sound pressure level are exceeded by 10 dB or more, the probability of damage shall be increased by a factor of 10 and the risk levels adjusted accordingly.

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Table 2 below indicates the maximum emission sound pressure levels and peak sound pressure levels for the different toy categories with respect to the estimated risk levels. Where risk of a certain level is not relevant for a specific type of toy, i.e. the risk level in question is assumed to never occur, this is indicated by NR = Not Relevant.

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Acoustic Levels as determined by EN71-1:2011+A2:2013

CODE	PRODUCT GROUP	Description as specified within EN71-1	Related Examples from EN71-1	A-weighted time averaged emission sound pressure level LpA									C-weighted peak emission sound pressure level LpCpeak			Comments
				Test Measurement	Category 1: Toys emitting sound during time periods typically longer than 30 s after each initiation			Category 2: Toys emitting sound during time periods typically shorter than 30 s but longer than 5 s after each initiation			Category 3: Toys emitting sound during time periods typically shorter than 5 s after each initiation						*(info in this column still to be confirmed)*
CE	Close-to-the-ear toys	Toy clearly designed to emit sound, *intended to be used within 2.5cm of the ear* (Clause 3.10 of EN71-1)	Toy telephones, toy rifles with a loudspeaker in the stock	Measurement at 50cm	Shall not exceed 60dB	Medium Risk	Max Limit: 69 dB	shall not exceed 65dB	Medium Risk	Max Limit: 74 dB	shall not exceed 70dB	Medium Risk	Max Limit: 79 dB	shall not exceed 110dB	Medium Risk	Max Limit: 114 dB	Old Standard: LpA - 80dB / LpCpeak - 115dB
						High Risk	Min Limit: 70 dB		High Risk	Min Limit: 75 dB		High Risk	Min Limit: 80 dB		High Risk	Min Limit: 115 dB	
						Serious Risk	Min Limit:75 dB		Serious Risk	Min Limit: 80 dB		Serious Risk	Min Limit: 85 dB		Serious Risk	Min Limit: 120 dB	
TF	Table-top or floor toys	Toy clearly designed to emit sound, intended to be used on a table, floor or another large surface (Clause 3.59 of EN71-1)	Toy cars, mechanical animals, and large and bulky toys	Measurement at 50cm	Shall not exceed 80dB	Medium Risk	Min Limit:95 dB	shall not exceed 85dB	Medium Risk	Min Limit:100 dB	shall not exceed 90dB	Medium Risk	Min Limit:115 dB	shall not exceed 110dB	Medium Risk	Min Limit:120 dB	Old Standard: LpCpeak - 115dB
						High Risk	Max Limit: NR		High Risk	Max Limit: NR		High Risk	Max Limit: NR		High Risk	Max Limit: NR	
						Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR	
HH	Hand-held toys	Toy clearly designed to emit sound, intended to be held in the hand but excluding close-to-the-ear toys, rattles, squeeze toys, cap-firing toys, wind toys, voice toys and percussion toys (Clause 3.31 of EN71-1)	Clicking toys, Toy Tools, toy guns	Measurement at 50cm	Shall not exceed 80dB	Medium Risk	Min Limit: 90 dB	shall not exceed 85dB	Medium Risk	Min Limit: 95 dB	shall not exceed 90dB	Medium Risk	Min Limit: 100 dB	shall not exceed 110dB	Medium Risk	Min Limit: 115 dB	Old Standard: LpCpeak - 115dB
						High Risk	Min Limit:95 dB		High Risk	Min Limit:100 dB		High Risk	Min Limit:105 dB		High Risk	Min Limit:120 dB	
						Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR	
PA	Pull-along or push-along toys	Toy on which movement is imparted by the user for example by pulling it by a cord or pushing it by means of a rigid extension (Clause 3.48 of EN71-1)		Measurement at 50cm	Shall not exceed 80dB	Medium Risk	Min Limit:95 dB	shall not exceed 85dB	Medium Risk	Min Limit:100 dB	shall not exceed 90dB	Medium Risk	Min Limit:115 dB	shall not exceed 110dB	Medium Risk	Min Limit:120 dB	Old Standard: LpCpeak - 115dB
						High Risk	Max Limit: NR		High Risk	Max Limit: NR		High Risk	Max Limit: NR		High Risk	Max Limit: NR	
						Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR	
VT	Voice toys	Toy clearly designed to emit sound by electronically amplifying or distorting the voice and where the output sound level depends on the input sound level of the voice (Clause 3.68 of EN71-1)	Telephones, walkie-talkies, voice recording toys, sing-along microphones and electronic bull horns (toy megaphones)	Measurement at 50cm	Shall not exceed 80dB	Medium Risk	Max Limit: 89 dB	shall not exceed 85dB	Medium Risk	Max Limit: 94 dB	shall not exceed 90dB	Medium Risk	Max Limit: 99 dB	shall not exceed 110dB	Medium Risk	Max Limit: 114 dB	Old Standard: Levels - ??
						High Risk	Min Limit: 90 dB		High Risk	Min Limit: 95 dB		High Risk	Min Limit: 100 dB		High Risk	Min Limit: 115 dB	
						Serious Risk	Min Limit: 95 dB		Serious Risk	Min Limit:100 dB		Serious Risk	Min Limit: 105 dB		Serious Risk	Min Limit: 120 dB	
HE	Toys using headphones or earphones			Measurement at *a*	Shall not exceed 85dB	Medium Risk	Max Limit: NR							shall not exceed 135dB	Medium Risk	Max Limit: NR	Old Standard: LpA - 90dB / LpCpeak - 115dB
						High Risk	Max Limit: NR								High Risk	Max Limit: NR	
						Serious Risk	Max Limit: 89 dB								Serious Risk	Max Limit: 139 dB	
RA	Rattles	Toy, intended for *children who are too young to sit up unaided* , that is clearly designed to emit sound when shaken or activated by the child or another person (Clause 3.49 of EN71-1)		Measurement at 50cm				Shall not exceed 85dB	Medium Risk	Min Limit: 95 dB				shall not exceed 110dB	Medium Risk	Min Limit: 115 dB	Old Standard: LpA - 85dB / LpCpeak - 110dB
									High Risk	Min Limit:100 dB					High Risk	Min Limit:120 dB	
									Serious Risk	Max Limit: NR					Serious Risk	Max Limit: NR	
ST	Squeeze toys	Pliable toy, intended for *children who are too young to sit up unaided* , incorporating a sound-making feature activated by forcing air through an opening, clearly designed to emit sound when flexed or squeezed by the child or another person. (Clause 3.55 of EN71-1)		Measurement at 50cm				Shall not exceed 85dB	Medium Risk	Min Limit: 95 dB				shall not exceed 110dB	Medium Risk	Min Limit: 115 dB	Old Standard: LpA - 85dB / LpCpeak - 110dB
									High Risk	Min Limit:100 dB					High Risk	Min Limit:120 dB	
									Serious Risk	Max Limit: NR					Serious Risk	Max Limit: NR	
PT	Percussion toys	Toy clearly designed to emit sound when struck with a beater, such as a drumstick, or by the hand (Clause 3.43 of EN71-1)	Drums, xylophones and tambourines	Measurement at 50cm				Shall not exceed 85dB	Medium Risk	Min Limit: 95 dB				shall not exceed 130dB	Medium Risk	Min Limit:135 dB	
									High Risk	Min Limit:100 dB					High Risk	Min Limit:140 dB	
									Serious Risk	Max Limit: NR					Serious Risk	Max Limit: NR	
WT	Wind toys	Toy clearly designed to emit sound when actuated by the blowing action of the child or another person (Clause 3.69 of EN71-1)	Trumpets and toy whistles	Measurement at 50cm				shall not exceed 85dB	Medium Risk	Max Limit: NR	shall not exceed 90dB	Medium Risk	Max Limit: NR	shall not exceed 110dB	Medium Risk	Max Limit: NR	
									High Risk	Max Limit: 94 dB		High Risk	Max Limit: 99 dB		High Risk	Max Limit: 114 dB	
									Serious Risk	Min Limit: 95 dB		Serious Risk	Min Limit: 100 dB		Serious Risk	Min Limit: 115 dB	
CF	Cap-firing toys	Toy clearly designed to emit sound caused by discharge of a percussion cap (Clause 3.7 of EN71-1)	Cap guns	Measurement at 50cm							Shall not exceed 90dB	Medium Risk	Max Limit: NR	shall not exceed 125dB	Medium Risk	Max Limit: NR	Old Standard: LpCpeak - 125dB
												High Risk	Max Limit: 99 dB		High Risk	Max Limit: 129 dB	
												Serious Risk	Min Limit: 100 dB		Serious Risk	Min Limit: 130 dB	

PROSAFE Joint Actions Best Practice

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