

Risk Assessment of Acoustic Toys



- This course will give you an introduction to risk assessment of acoustic toys.
- The course takes the perspective of a market surveillance authority and presents the way a market surveillance authority would carry out such a risk assessment.



Disclaimer



- This course arises from the Joint Market Surveillance Action on GPSD Products - JA2016, which received funding from the European Union in the framework of the ‘Programme of Community Action in the field of Consumer Policy (2014-2020)’.
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To note . . .

- Click on the “Resources” button to view some documents which are related to this course.

Try out the “search” function (right-hand side) to find text from within any part of this course.



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- Click on the subjects that you are interested in:

Part I - Acoustic Requirements

Part II - Background Considerations

Part III - Risk Assessment

Part IV - A Worked Example



PART I

Acoustic Requirements of Toys within EN71-1:2014



Introduction

- ❑ The EN 71-1:2011+A2:2013 standard has been harmonised under the Toy Safety Directive 2009/48/EC and published in the [OJEU](#) on 31 October 2013. There was a transitional period until 30 September 2014. This revision included various changes to acoustic requirements of toys.
- ❑ This means that as from 31-10-2013 onwards, this standard can be used to demonstrate compliance with the safety requirements in acoustics under the Toy Safety Directive (TSD) - 2009/48/EC.
- ❑ Additionally, as from the 30-09-2014 there is no longer any presumption of conformity for products manufactured according to the superseded standard.



European Standard EN 71-1:2014

- ❑ The current European standard, EN 71-1:2014, was published in the OJEU on 13-03-2015 and the date of cessation of presumption of conformity of the superseded standard EN 71-1:2011+A3:2014 is 29-02-2016.
- ❑ It is important to note that the requirements are related to toys that are clearly designed to produce sound. This means that only those sounds within a toy that are designed and intended by the manufacturer fall within such requirements.
- ❑ These sounds may be **continuous, impulsive** or a **combination of both** in character.



European Standard EN 71-1:2014

- The new requirements defines 11 types of toys and for each of them, continuous (time-averaged emission) and impulsive (peak) sound pressure levels are defined.
- Three exposure categories are defined for each of the 11 types of toys. These specify the duration of the sounds the toy is able to emit and the ease with which the sound event can be activated by children playing with the toy.






Product Type of Toys

From September 30, 2014, all toys intentionally producing sound are now required to be assessed. Toys emitting sounds have been categorized into 11 product types:




- Close-to-the-ear toys
- Table-top or floor toys
- Hand-held toys
- Toys using headphones or earphones
- Rattles

- Squeeze toys
- Pull-along or push toys
- Percussion toys
- Wind toys
- Cap-firing toys
- Voice toys



Brief Explanation - Product Category of toys

	Description of Products	Related Examples from EN71-1	PHOTOS
Close-to-the-ear toys	Toy clearly designed to emit sound, <i>intended to be used within 2.5cm of the ear</i> (Clause 3.10 of EN71-1)	Toy telephones, toy rifles with a loudspeaker in the stock	
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	
Hand-held toys	Toy clearly designed to emit sound, intended to be held in the hand <i>but excluding</i> 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	



Brief Explanation - Product Category of toys

	Description of Products	PHOTOS
Toys using headphones or earphones	Toys using headphones or earphones	
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)	
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)	


Brief Explanation - Product Category of toys

	Description of Products	Related Examples from EN71-1	SOME PHOTOS
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	
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	

Brief Explanation - Product Category of toys

	Description of Products	Related Examples from EN71-1	SOME PHOTOS
Cap-firing toys	Toy clearly designed to emit sound caused by discharge of a percussion cap (Clause 3.7 of EN71-1)	Cap guns	
Pull-along or push toys	Toy <u>on which movement is imparted by the user for example by pulling it by a cord or pushing it</u> by means of a rigid extension (Clause 3.48 of EN71-1)	<p>Examples of pull-along or push toys <u>that emit sound only as a result of movement imparted on the toy</u>, include toys making intentional mechanically excited sound when the axles/wheels are rotating.</p> <p>Pull-along or push toys that produce sound which is NOT dependent on the energy imparted by the user, for example electronic sound, are instead tested as <i>hand-held</i> or <i>table-top</i> or <i>floor toys</i> (Clause 4.20.2.8 of EN71-1)</p>	

Brief Explanation - Product Category of toys

	Description of Products	Related Examples from EN71-1	SOME PHOTOS
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)	

Exposure Categories

Acoustic requirements are based not only on the sound levels produced by the toy, but also on the daily exposure time. Three exposure categories take into account that the length of time a sound is emitted from a toy is variable.

Category 1: Toys emitting sound during time periods typically longer than 30 s after each initiation and other toys emitting sound typically during more than 1/3 of the playing time.

Category 2: Toys emitting sound during time periods typically shorter than 30 s but longer than 5 s after each initiation and other toys emitting sound typically during less than 1/3 and more than 1/10 of the playing time.

Category 3: Toys emitting sound during time periods typically shorter than 5 s after each initiation and other toys emitting sound typically during less than 1/10 of the playing time.

Risk Assessment



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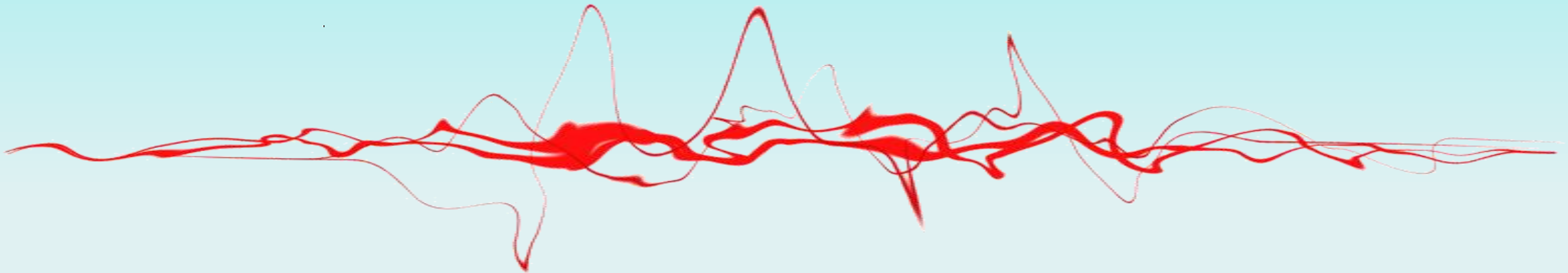
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PART II

Background Considerations



Basic Information

- ❑ A DECIBEL (dB) is a scale to measure the sound pressure level (SPL). This was first devised by telephone pioneer Alexander Graham Bell
- ❑ It is a *logarithmic* scale
 - ❑ Every increase of 10dB on the scale is equivalent to a 10-fold increase in sound intensity (which broadly corresponds with a doubling in loudness).
 - ❑ A sound of 20dB is 10 times more intense than a sound of 10dB and a 30dB sound is 100 times more intense.



The Decibel Scale

Generic Descriptions

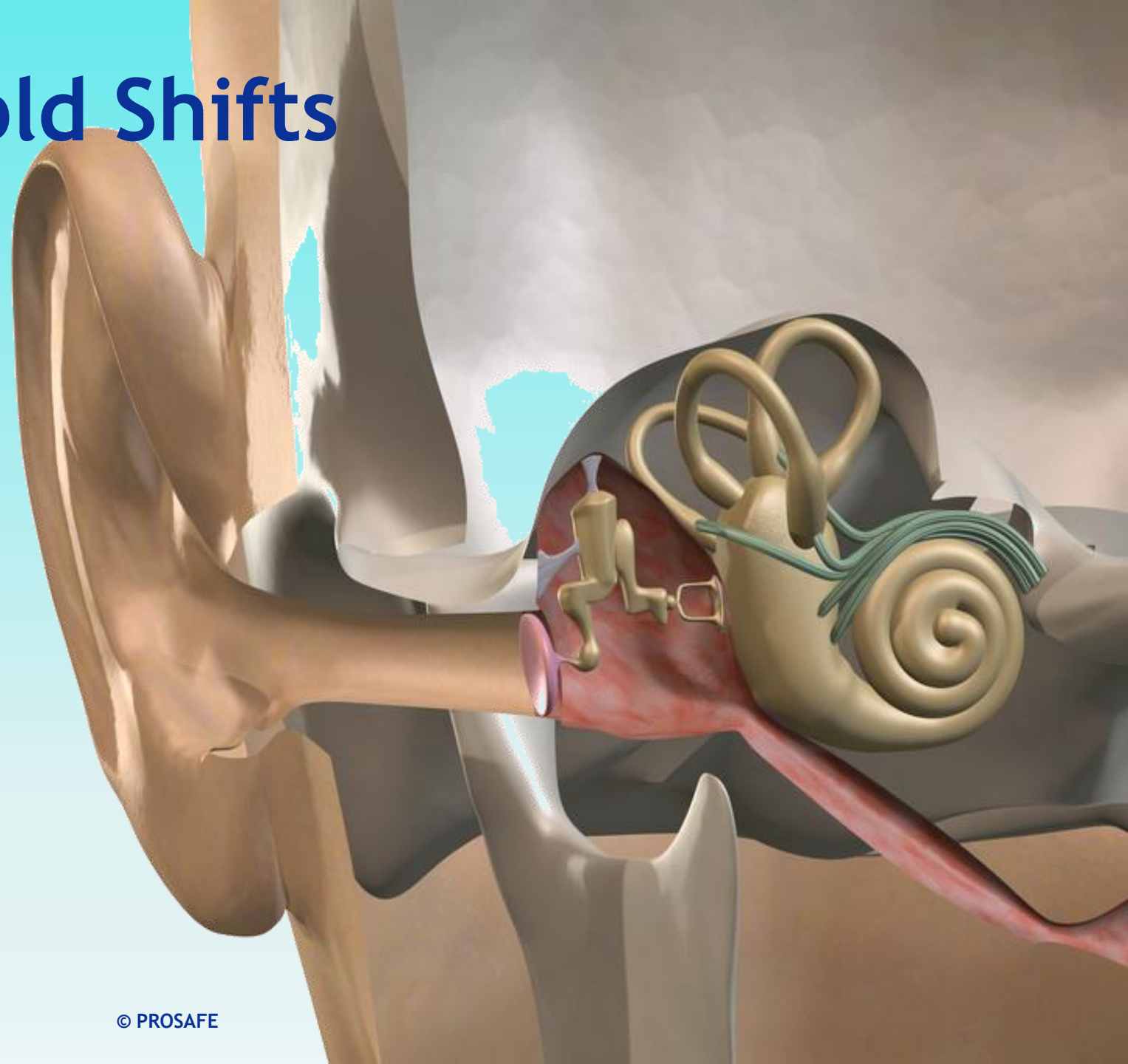
Level in decibels	Everyday example	Times more intense	Times louder
10dB	Rustling or falling leaves.	1	1
20dB	Watch ticking.	10	2
30dB	Birds flying by.	100	4
40dB	Quiet conversation.	1,000	8
50dB	Louder conversation.	10,000	16
60dB	Quiet traffic noise.	100,000	32
70dB+	Louder traffic	1 million	64
80dB+	Loud highway noise at close range	10 million	128
85dB	Hearing damage after about 8 hours.		
100dB	Jackhammer (pneumatic drill) at close range	1 billion	512
100dB	Hearing damage after about 15 minutes.		
110dB+	Jet engine at about 100m	10 billion	1024
120dB	Threshold of pain. Hearing damage after very brief exposure.		

Scientific basis - regarding risks for hearing impairment by exposure to loud sounds

- There is no scientific evidence that the sensitivity of children in relation to auditory hazard by exposure to loud sounds is significantly different from that of adults.
- The 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 focused on long-term effects - mainly focusing 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.

Hearing Threshold Shifts

- ✓ Hearing threshold shifts 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 or permanent.



Auditory effects of noise exposure

- There are two types of hearing threshold shifts:
 - **Temporary threshold shift (TTS).** Hearing thresholds return to to pre-exposure levels after hours-weeks. Daily exposure levels not exceeding 75-80 dB(A) are unlikely to produce significant TTS.
 - **Permanent threshold shifts (PTS).** When TTS after a single exposure reaches 30-40 dB, the risk for PTS is considered real.



Tinnitus

- ❑ Tinnitus is an auditory perception of sound without the presence of a corresponding external physical signal.
- ❑ 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 exposure causing permanent tinnitus.



Hidden hearing loss

- ❑ 'Hidden hearing loss' represents 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. The same type of damage is likely to occur also in humans.
- ❑ It has been estimated that a noise exposure resulting in TTS of less than 20 dB represents negligible risk for such permanent effects on inner hair cells and/or auditory nerve fibers.
- ❑ This type of damage causes increased problems understanding speech in noisy environment, and is likely to cause tinnitus.

Exposure to continuous noise

- ❑ Emission sound pressure levels fulfilling the requirements of EN 71-1:2014 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.



Exposure to impulse noise

- Peak sound pressure levels fulfilling the requirements of EN 71-1:2014 are safe.
- Exceeding the requirement by 5 dB may introduce a risk for permanent effects on inner hair cells and auditory nerve cells - 'hidden hearing loss'.
- Exceeding the requirement by 10 dB may represent risk for immediate permanent hearing loss, PTS.





Additional Information

More information can be found in the various attached documents and links.

Click on “Resources” to access a number of presentations, interesting documents and even the Final Technical Report developed by the JA2014 Toys Working Group (GA 666174).

The risk assessment is based on the study conducted by Dr Stig Arlinger on acoustic toys as commissioned by the JA2014 Toys group - “Acoustic toys and risks for impaired hearing - November 2016” - (shown as an Annex to this Final Technical Report).

Risk Assessment



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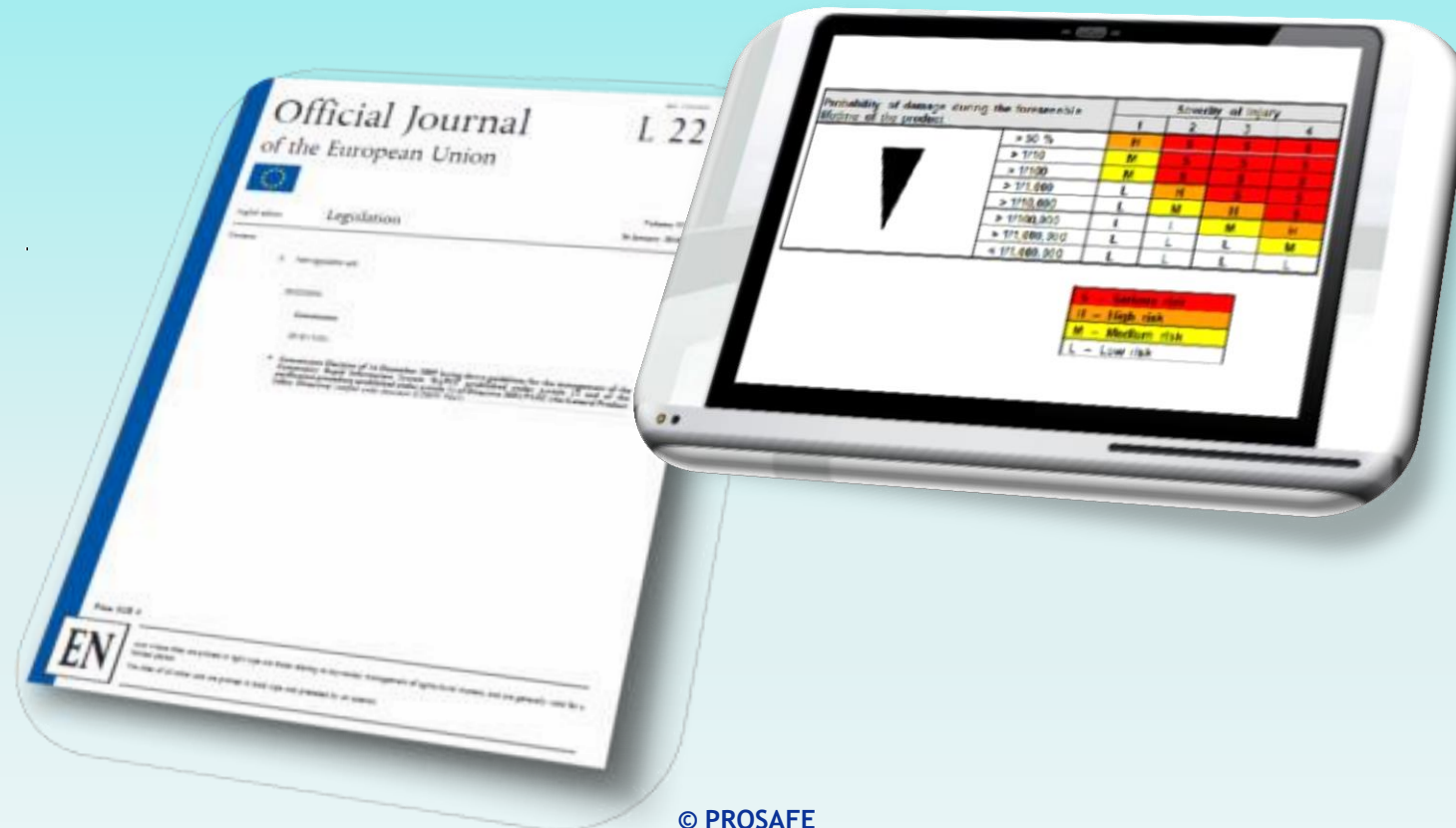
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PART III

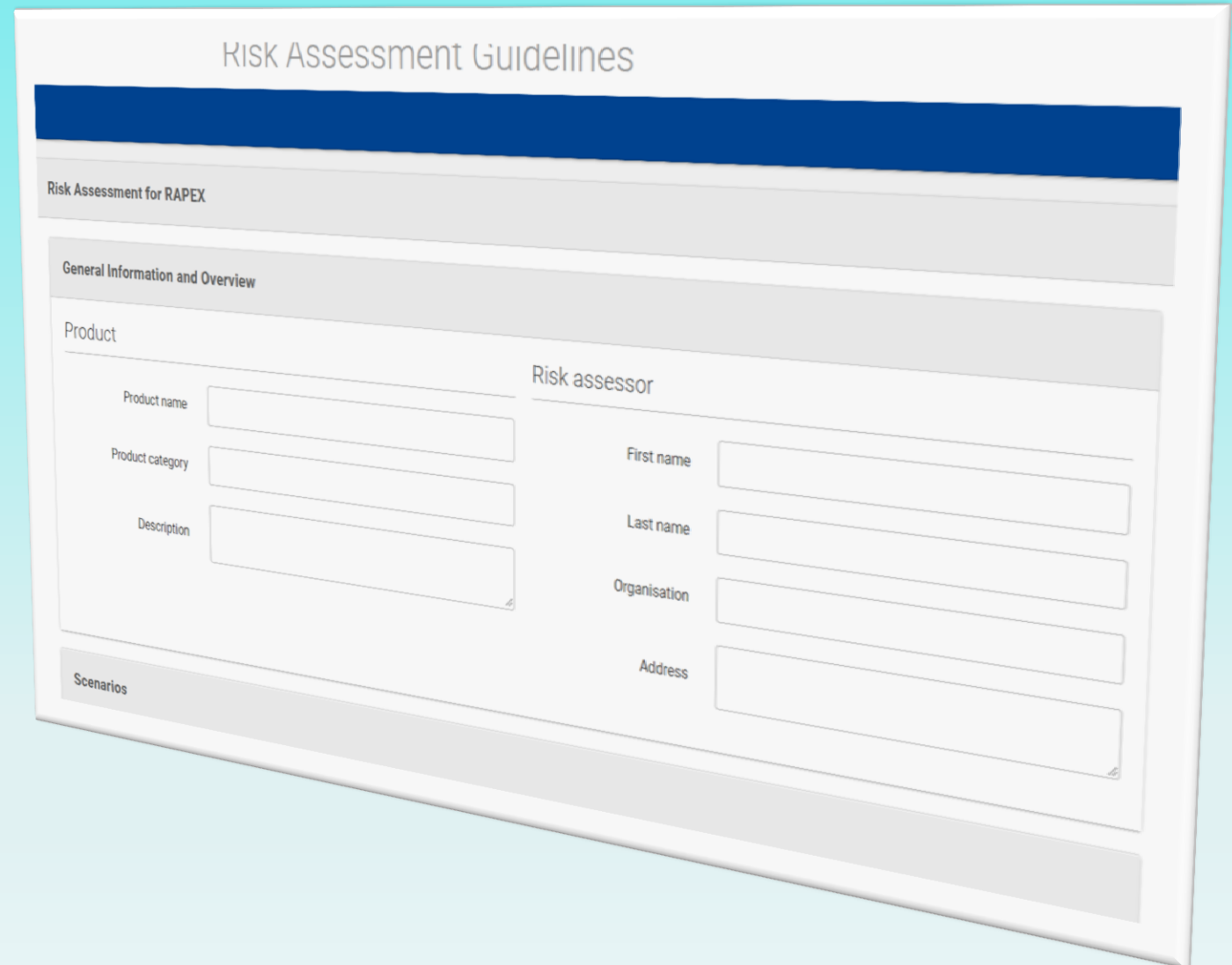
Risk Assessment



The Risk Assessment Guidelines (RAG) Website

The RAG Website, developed by the European Commission in line with the Guidelines 2010/15/EU, is utilised for this purpose.

<https://ec.europa.eu/consumers/consumer-safety/rag/>



Risk Assessment Guidelines

Risk Assessment for RAPEX

General Information and Overview

Product

Product name

Product category

Description

Risk assessor

First name

Last name

Organisation

Address

Scenarios

To note . . .

Besides filling in the “product hazard” & “consumer type”, a good description needs to be given within the “injury scenario” - including:

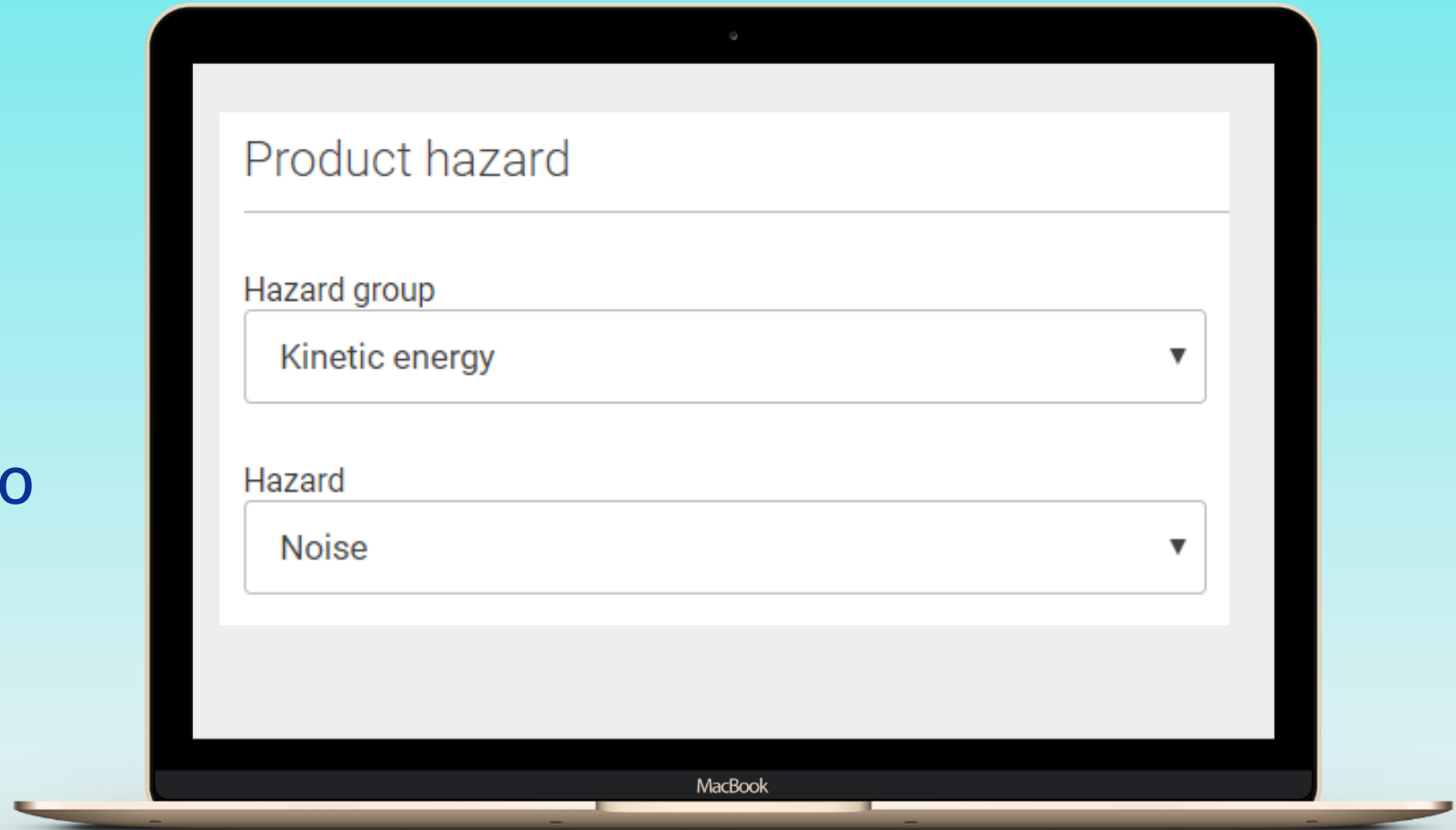
- Which of the 11 “type” of toys is the child playing with?
- What level of exposure category does the toy have?
- Indicate amount in dB over the EN71-1:2014 limits for continuous sound pressure level (SPL) or impulse SPL or both.
- For further information, please refer to the Final Technical Report developed by the Toys working group.



Product Hazard

The first step in the RAG tool is to determine the **product hazard**.

The hazard group to be considered is “kinetic energy” and the hazard to be chosen is “noise”.



Severity of injury

The RAPEX Guideline defines 4 degrees of severity of injury. With regard to hearing injury the following severity levels are can be found as shown in the picture.

Your injury

Hearing injury, foreign body in ear ▼

Select below a severity level (1 to 4)

- 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 of injury

- ❑ 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.
- ❑ 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 71-1:2014.



Severity of injury

- ❑ Severity level 3, 'partial loss of hearing', may occur as tinnitus, 'hidden hearing loss', or permanent threshold shift, PTS.
- ❑ Severity level 4, 'complete loss of hearing in both ears', is impossible to cause with any type of loud sound from a toy.



Severity of injury

- Tinnitus and ‘hidden hearing loss’ may occur if the requirements for **time-averaged 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 time-averaged emission sound pressure levels are exceeded by 20 dB or if the requirements for peak sound pressure level are exceeded by 10 dB.

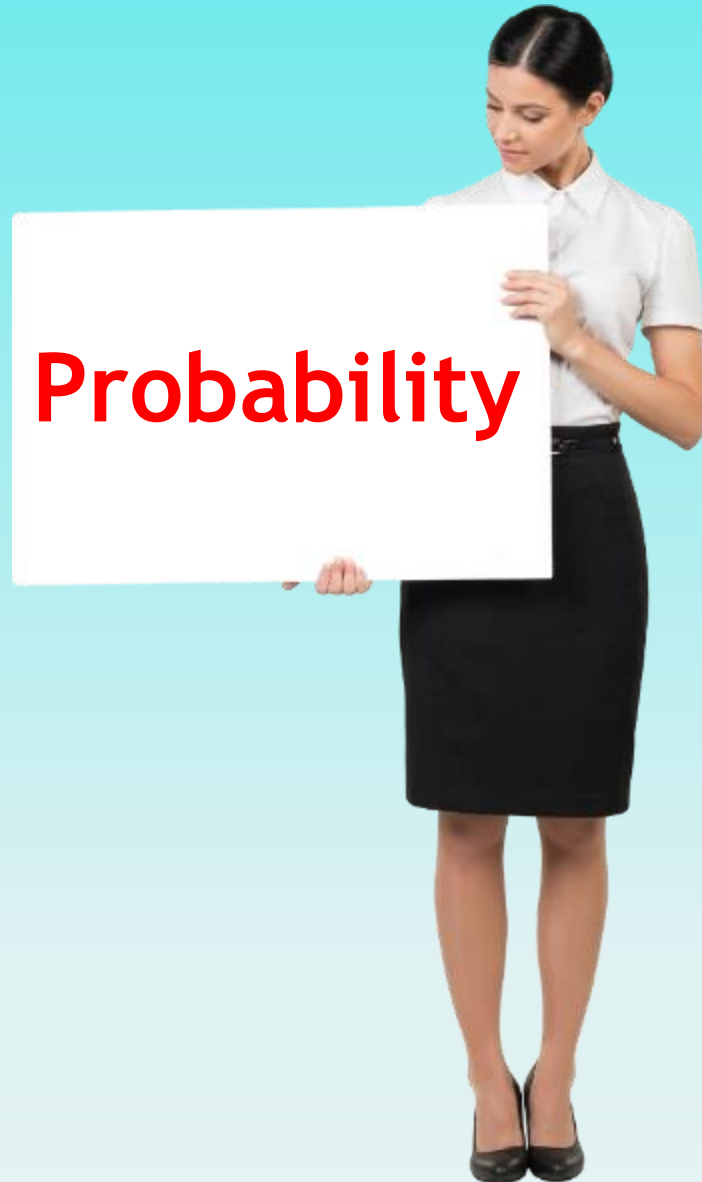


Severity of injury

- It is not easy to state in general terms that one or the other of these three types of injury (i.e. tinnitus, 'hidden hearing loss', or PTS) is a worse burden for the affected person.
- However, it is reasonable to state that:
 - When the limits within EN 71-1 for **time-averaged emission SPL** is exceeded by **less than 10 dB** and/or for **peak emission SPL** by **less than 5 dB** there is a risk of injury of **Severity Level 2 (TTS)**.
 - exceeding the limits within EN 71-1 for **time-averaged emission SPL by 10 dB or more** and/or exceeding the requirements for **peak emission SPL by 5 dB or more** - represents the risk of injury of **Severity Level 3 (permanent effects)**.

Probability of Injury

- ✓ The standard EN71-1:2014 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.
- ✓ **Distance of the toy from the ear is critical in such cases.** For short distances even small changes in distance may have a large effect on the sound level reaching the ear.



Probability of Injury

- ✓ 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.
- ✓ Therefore, toys that are intended to be used close to the ear or can easily be moved to such positions represent the highest probability of damage.



Probability

Probability Estimates

- Table-top or floor toys & 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 $\geq 1/1,000,000$.
- Hand-held toys are sometimes relatively small and therefore easily placed close to an ear. The probability of damage is estimated to be $\geq 1/100,000$.
- 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 $\geq 1/100,000$.



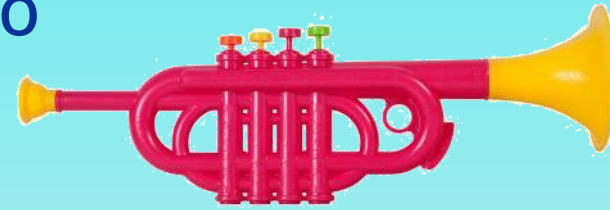
Probability Estimates

- Rattles & Squeeze Toys may be activated relatively close to a small child's ear, 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 $\geq 1/100,000$.
- 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 $\geq 1/10,000$.
- 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 $\geq 1/10,000$.



Probability Estimates

- Wind toys may relatively easily be activated close to another child's ears. The probability of damage is estimated to be $\geq 1/1,000$.
- Cap-firing toys may easily be fired close to another child's ear. The probability of damage is estimated at $\geq 1/1,000$.
- Toys using headphones or earphones are by definition placed on the child's ears. Thus, the probability is $\geq 1/2$.



Probability Estimates

□ IMPORTANT FINAL NOTE

When the requirements for time-averaged emission sound pressure levels are exceeded by 15 dB or more and/or the requirements for peak sound pressure level are exceeded by 10 dB or more,

- the probability of injury shall be increased by a factor of 10 and the risk levels adjusted accordingly.



BRIEF SUMMARY



The table below gives a summary of how risk assessment is calculated.

	Severity Level 2 (SL2)	Severity Level 3 (SL3)	SL3 Additional Condition	Probability	Risk Assessment
LpA (A-weighted time-averaged emission SPL)	< 10 dB over the limit specified in EN 71-1: 2011+A3:2014	>= 10 dB over the limit	IF >=15 dB over the limit ⇒ Increase probability by a factor of 10	<p>Toys using headphones / earphones >= 1/2</p> <p>Wind Toys, Cap-firing Toys >= 1/1,000</p> <p>Close-to-ear Toys, Voice Toys >= 1/10,000</p>	Calculate final RA.
LpC Peak (C-weighted emission peak SPL)	< 5 dB over the limit specified in EN 71-1: 2011+A3:2014	>= 5 dB over the limit	IF >=10 dB over the limit ⇒ Increase probability by a factor of 10.	<p>Hand-held toys, Rattles, Squeeze Toys, Percussion Toys >= 1/100,000</p> <p>Tabletop or Floor Toys, pull-along / push-along toys, >= 1/1,000,000</p>	

Risk Assessment



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PART IV

A Worked Example

Non-Compliant Acoustic Toy Trumpet

This example is used to better explain the risk assessment methodology explained in Part III.

The example is about a non-compliant acoustic toy trumpet (wind toy) with LpA of 12 dB over the limit and LpC under the limit as determined by the EN 71-1 standard.



The first step

The first step within the RAG Tool (The Risk Assessment Guidance Tool), is to determine the product hazard itself. The hazard group is “kinetic energy” and the hazard itself is “noise” as shown below:

Product hazard

Hazard group

Kinetic energy ▼

Hazard

Noise ▼

The next step

Once the consumer type is identified, a proper scenario description is given how the hazard causes the injury.

An example is shown to the right hand side. This will be inputted in the area requested within the RAG tool.

Your injury scenario: Describe it!

The child is playing the trumpet and creating sounds, resulting in damage to hearing in the form of tinnitus and/or 'hidden hearing loss' due to high continuous sound pressure levels (LpA of 12 dB over the limit as specified within EN 71-1:2014). The probability of damage to hearing is estimated to be $\geq 1/1,000$.

The Severity of Injury

Once a proper scenario description is given, the level of the severity of injury is identified.

One would then have to choose the type of injury, in this case, “Hearing injury, foreign body in ear”. One can also conclude that there is a “Severity Level 3” since it is over the limit by 10 dB.

Your injury

Hearing injury, foreign body in ear ▼

Select below a severity level (1 to 4)

1) Temporary pain in ear without need for treatment

2) Temporary impairment of hearing

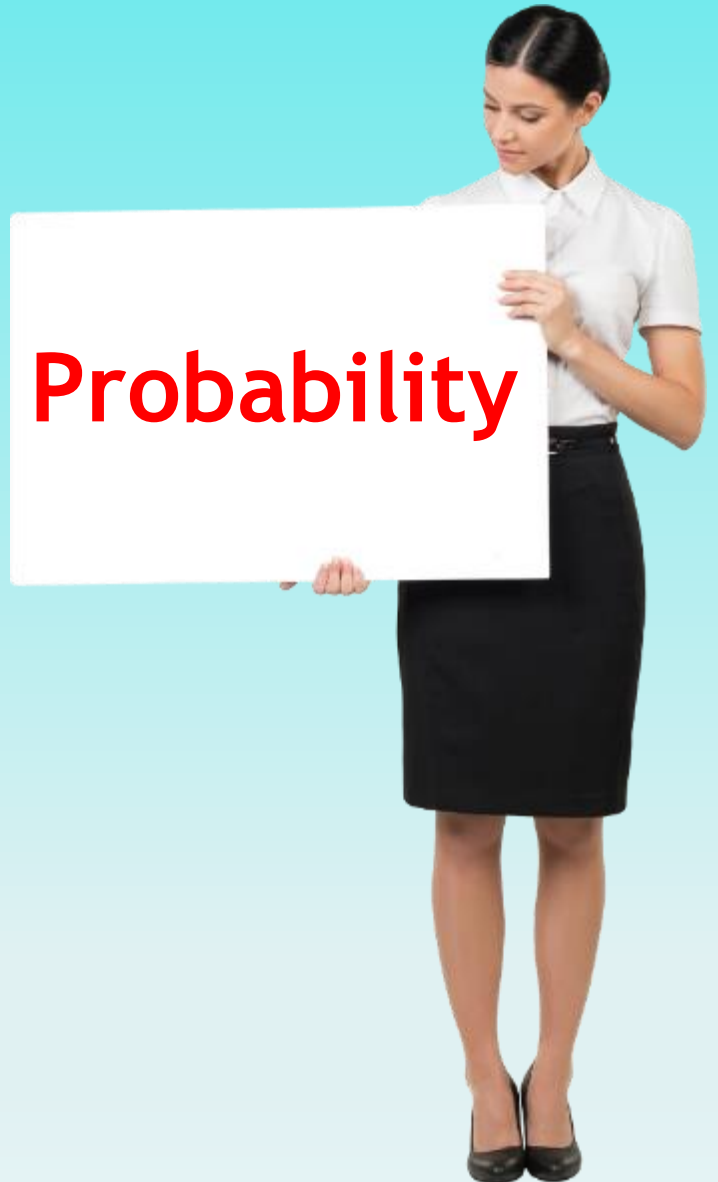
3) Partial loss of hearing
Complete loss of hearing (one ear)

4) Complete loss of hearing (both ears)

Probability Estimate

The next step is to calculate the probability. Wind toys may relatively easily be activated close to another child's ear.

Therefore, the probability of injury scenario has been estimated to be $\geq 1/1000$.



Risk Assessment Result

Severity of injury level

3

Calculated probability

0.001

Overall probability

= 1/1000

Risk of this scenario

Serious risk

The final step is determining the risk itself.

This is calculated automatically within the RAPEX risk assessment website as shown below, indicating that the risk is a “serious risk”.

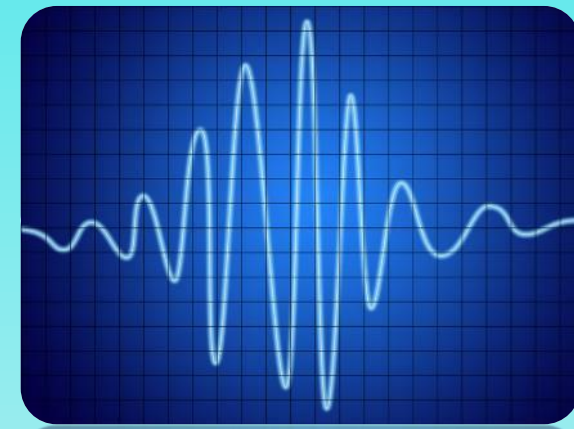


Some further tips

Level of Uncertainty in acoustic testing

It is suggested that uncertainty values are asked for from the respective laboratories prior to any testing of such acoustic toys so that the market surveillance authority is fully aware of the level of uncertainty in these respective tests.

It is important for the market surveillance authority to be aware of such levels of uncertainties. However, when dealing with risk assessment, it is suggested to consider using the measured sound pressure level **WITHOUT** considering the measurement uncertainty. **Why is this?**



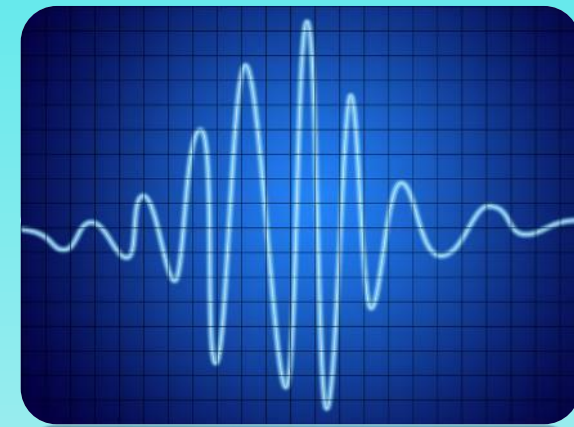
Some further tips

Level of Uncertainty in acoustic testing

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.

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.

It is only when considering risk management that such uncertainties should be taken into consideration.



Some further tips

Sensitivity Analysis - how sensitive is the resulting risk level to uncertainties in probability?

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. If the measurement of uncertainty is high, it seems reasonable to check if the result will change if you increase or decrease the sound pressure level corresponding to the measurement of uncertainty.

Including all this information within the final risk assessment report will ensure that if your risk assessment decision is challenged, you have enough documentation to explain and show how you have arrived at your final conclusion.



Concluding Remarks

One needs to remember to risk assess each product on a case-by-case basis, taking into consideration any information available and specific characteristics of that particular product.

The risk assessor should document all considerations and rationales carefully in the risk assessment report so others can understand the lines of thinking, including also a sensitivity analysis to show how sensitive the resulting risk level is to changes in the input parameters.



Well DONE !

You have finished this course. Please answer the final questions to complete this course.



FINAL QUESTIONS

Complete
the quiz . . .

CORRECT - The aim of risk assessment is to analyse the risks that a non-compliant product poses to the users. This in particular also addresses the question whether a risk is serious or not.

What is risk assessment ?

A

The process whereby the risk level of a given product is determined



The process whereby the appropriate measure against a non-compliant product is determined



The process where a producer checks whether the product complies with standards and legal requirements

► Click [here](#) for the next question

FINAL QUESTIONS

Complete the quiz . . .

CORRECT - Article 10 of the Toy Safety Directive , 2009/48/EC, refers to the safety requirements within Annex II. Within this Annex, paragraph 10 refers to the general acoustic requirements for toys, which in turn are further elaborated within the voluntary standard EN 71-1:2014.

Where can you find acoustic requirements for toys?



Acoustic Requirements are found within the General Product Safety Directive



For products sold in the European Economic Area, the acoustic requirements are referred to within The Toy Safety Directive and in turn are further described in EN 71-1:2014.



There are no specific acoustic requirements for toys

► Click [here](#) for the next question

FINAL QUESTIONS

Complete
the quiz . . .

CORRECT - Three exposure categories are defined for each of the 11 types of toys. These specify the duration of the sounds the toy is able to emit and the ease with which the sound event can be activated by children playing with the toy.

How many exposure levels are defined in EN 71-1:2014?



None. There are only 11 different toy types described in the European Standard EN 71-1.



There are 11 exposure categories.



There are 3 exposure categories.

► Click [here](#) for the next question

FINAL QUESTIONS

Complete
the quiz . . .

CORRECT - Hearing threshold shifts 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 or permanent.

What are hearing threshold shifts?



They are the limits associated within the standard.

B

Hearing threshold shifts represent the sensitivity of the auditory organ.



These shifts can be either continuous, impulsive or a combination of both in character.

▶ Click [here](#) for the next question

FINAL QUESTIONS

Complete
the quiz . . .

CORRECT - The European Standard, EN 71-1:2014 stipulates the exact limits for both continuous and peak level sound pressure levels. The A-weighted time-averages sound pressure level limits, LpA, the C-weighted emission peak sound pressure level limits, LpC and their respective distances are specified for each of the 11 toy types.

Where can you find the limits associated with continuous and impulsive (peak) noise levels?



Within the Toy Safety Directive, 2009/48/EC



There are no particular limits and only generic guidance is available.



Within the European Standard EN 71-1:2014

► Click [here](#) for the next question

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