Joint Action 2014 GPSD

Joint Market Surveillance Action co-funded by the European Union Agreement No: 666174 - GPSD

Final Technical Report, ACOUSTIC TOYS

Covering the period May 2015 - Feb 2017







Disclaimer

This report arises from the Joint Market Surveillance Action on GPSD Products - JA2014, 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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Executive Summary

This report presents the work done in relation to <u>Acoustic Toys</u>, as part of "Joint Market Surveillance Action on GPSD Products - JA2014". The Action is co-funded by the European Union under Grant Agreement No. 666174 - GPSD.

Number of Market Surveillance Authorities

The market surveillance activity, which was coordinated by PROSAFE, was undertaken by 16 countries from the European Economic Area. 14 different EU Member States: Austria, Belgium, Cyprus, Czech Republic, Estonia, Finland, Germany, Latvia, Lithuania, Luxembourg, Malta, Portugal, Romania, The Netherlands and 2 EFTA countries: Iceland and Norway, took part in this activity.

Type of Acoustic Toy Groups Inspected

From 1 October 2014 onwards, all toys intentionally producing sound are required to be in line with the revised acoustic requirements of the European standard (EN 71-1:2011+A2:2013). The working group decided to follow the classification defined in the standard itself. For this reason, toys emitting sounds have been categorised into 11 product types: Close-to-the-ear toys, Tabletop 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 and Voice toys.

Basic Statistics on Sampling & Testing

Around **2,190 different models of acoustic toys** were inspected, out of which **371 samples** were tested at a laboratory.

98% of all samples were taken directly from distributors or importers and the rest were extracted directly from local EU manufacturers. The authorities had also extracted samples form online sales and some with assistance from Customs.

10% of the tested acoustic toys were found non-compliant. The acoustic toy group with the highest non-compliance was cap-firing toys - 28%, followed by close-to-the-ear toys - 20% and wind toys - 14%. Hand-held toys, percussion toys, voice toys and rattles have a percentage of non-compliance of less than 6%.

The declaration of conformity

For each of the samples tested, the market surveillance authorities tried to collect the declaration of conformity (DoC), however only 63% of the DoCs from all the samples sent were provided.

Risk Assessment

According to the risk assessment made, the most critical risks were found in:

- Cap-firing toys (100% of all the non-compliant samples had a serious risk)
- Wind Toys (70% had a serious risk and the remaining 30% were classified as "high risk")
- Close-to-the-ear toys (50% had serious risk, 37% had a high risk and 12.5% had a medium risk)



- Hand-held toys (70% had a high risk and 30% had a medium risk)

Measures taken by the Market Surveillance Authorities

Market surveillance authorities issued 3 recalls, 30 sales-bans and/or withdrawals from the market and 26 RAPEX alerts were notified or are in the process of notification.

Liaisons & lessons learnt

The working group cooperated with Commission representatives as well as with the TOY-ADCO members and external stakeholders. It is expected that more involvement of Customs will take place by the next Joint Market Surveillance Action on toys.

The working group was able to draw lessons at both technical and administrative levels and these are listed in the report.

Caution!

Statistics shown in this report need to be used and interpreted with caution. The scope of such projects is not to determine the percentage level of safe products within the respective parts of the Single Market, but rather to ensure that any dangerous products are completely removed as quickly as possible, through effective collaboration between market surveillance authorities and economic operators, for the ultimate benefit to consumers.

The testing results shown in this report are based on products that were sampled from the markets in the participating countries by experienced market surveillance inspectors that were looking for non-compliant and potentially unsafe products. As in any routine market surveillance activity, the results represent the targeted efforts that authorities undertake to identify unsafe products. They do not give a statistically valid picture of the market situation.



Introduction

This is the final technical report prepared for the Acoustic Toys Activity of the Joint Market Surveillance Action 2014 on GPSD Products - JA2014. The Joint Action received funding from the European Union in the framework of the 'Programme of Community action in the field of Consumer policy (2007-2013)'.

This report gives an overview of the market surveillance activities on acoustic toys performed by the 16 Member States involved in this joint action. It gives an outline of the number of samples extracted from the market as well as the type of tests carried out. Risk assessment is also discussed at a later stage, including the type of action taken by the respective market surveillance authorities.

1 Background Information

This chapter presents a short extract of the project description. The full description can be found in the Grant Agreement [1] (Refer to Chapter 7 for the appropriate reference).

1.1 Title of the Activity

The name of the Activity is "Toys 3" and it deals with "acoustic toys". It is marked as number "3" since it is the third activity on toys being coordinated by PROSAFE. The activity was part of Joint Market Surveillance Action on GPSD Products - JA2014.

The European Commission supported the Joint Action financially under Grant Agreement No. 666174-GPSD.

1.2 Participating Member States

The activity was undertaken by 16 market surveillance authorities from 16 different countries from within the European Economic Area: (Austria, Belgium, Cyprus, Czech Republic, Estonia, Finland, Germany, Iceland, Latvia, Lithuania, Luxembourg, Malta, Norway, Portugal, Romania & The Netherlands) and coordinated by PROSAFE.

Furthermore, DGCCRF from France (which was outside the financial scheme) took part in one of the joint action meetings in order to cross-share information with each other on acoustic toys. This was done during the meeting at the laboratory where all the test results and risk assessment strategies were discussed.

The applicant body that also took overall responsibility for the Joint Action was PROSAFE.

1.3 Overview of Key Staff in the Activity

The Activity Leader was Corine Postma-Koolen from NVWA, The Netherlands, who was supported by the PROSAFE consultant, Noel Toledo.

1.4 Main Objectives

The general objectives of the Activity were to continue to create conditions whereby Member States could cooperate successfully on market surveillance activities and to co-ordinate a number of product activities exposing the results of the activities to the largest number of Member States national authorities possible.



The main objectives of this activity were:

- ✓ To develop best practices and exchange experience with carrying out market surveillance activities for toys.
- √ To detect dangerous toys on the marketplace and take action against them.
- ✓ To update the priority-list for toys to be targeted in future joint actions.

1.5 The volume of the activity

Although the Grant Agreement envisaged around 250 samples of acoustic toys that had to be tested, it resulted that due to better prices achieved through joint tendering, a total 389 samples were sent for testing.

In turn, a total of 450 tests were carried out on these toys. However, it was found that 4 out of the non-compliant toys were placed on the market prior to 1st October 2014 and these were compliant to the previous version of the European Standard and therefore no direct enforcement action could be taken. More details can be found about the tests in chapter 3.

1.6 The Phases of the Activity

The Activity was a market surveillance action that followed these phases:

- Deciding on sampling criteria
 - The Activity decided on how the Member States should carry out sampling, i.e. how many samples would be taken by each authority; when would the sampling take place; should sampling take place in one or more rounds; what criteria would be applied when selecting the specific samples; and how many items should be taken of each product.
- Sample products
 - The Member States would collect products according to the sampling criteria. This implied that the market surveillance authorities would visit manufacturers, importers, wholesalers and retailers to collect products. This was coordinated and reported back to the Activity.
- Test products at a laboratory
 - The Activity would issue a call for tender and selected an appropriate laboratory and the Member States were instructed on how to send their products for testing. The products were shipped and the laboratory submitted test reports after the testing had taken place. The Joint Action shared all test reports with the participants.
- Risk assessment
 - The participants developed a common approach to the application of the RAPEX risk assessment guideline for the particular product to assure that the resulting assessments were harmonised to the extent possible. An expert in acoustics was asked to assist this working group in developing a special report on risk assessing acoustic toys. The Member States then assessed the risk for the products applying the agreed approach and any relevant national conditions.
- Follow-up on non-compliant products and exchange information on follow-up activities.
 The Member State authorities followed up towards the economic operators in their countries, i.e. consulted the economic operators on the results from the risk assessment; agreed on appropriate measures and followed-up to ensure that these were properly implemented. The resulting measures were reported to the Joint Action and shared with all participants.

1.7 Timeline for Activity

Six physical meetings were organised throughout the lifetime of this project. Further details can be found within Figure 1.



A summary of these meetings is shown in Figure 1 below for easy reference:

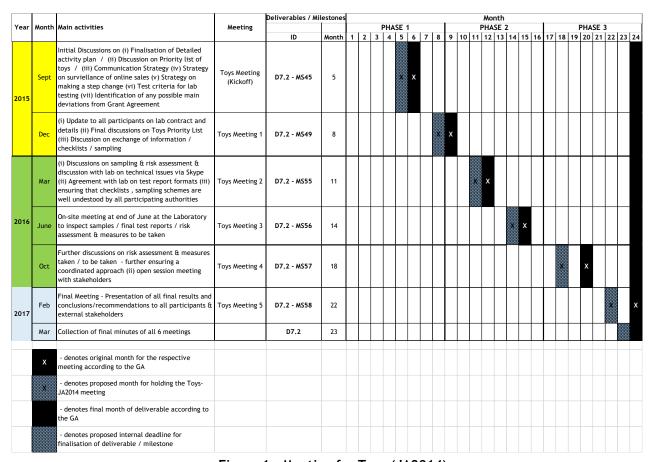


Figure 1 - Meeting for Toys (JA2014)

The final meeting, which took place in February 2017, was utilised to specifically inform everyone about the results of this project. Stakeholders were invited and discussion time was available to better explain these results and also get any final input / recommendations from market surveillance authorities and external stakeholders too. The recommendations were included in this final version of the report.

Workshops & Final Conference

Besides the six main meetings, PROSAFE organised periodic workshops and seminars as part of the events surrounding all the activities within JA2014. The Task Leader and/or Task Coordinator (Consultant) of this working group took part in all these workshops in order to update the rest of the participants and also to encourage the sharing of best practices between various other product-specific activities organised within JA2014.

TOY-ADCO Meetings

Strong liaison with the TOY-ADCO Members continued throughout the lifetime of the project. Nowadays, there is a standing agenda point related to activities coordinated by PROSAFE on Toys for every TOY-ADCO meeting that is organised. This shows the on-going cooperation and collaboration which exists between the respective parties.

Main Activities

The main activities have been divided into three main phases.



PHASE 1 - Preparation stage - (*around 8 months*) - this involved finalisation of the detailed activity plan, preparing guidance to the participating authorities in the form of checklists, sampling schemes and other related guidance. The Toys Priority list has also been updated during this initial phase. Additionally, the test criteria, call for tenders of lab testing and adjudication were also prepared in this phase.

An important aspect in this phase was the decision to get external expertise in the area of risk assessment of acoustic toys. An expert was appointed for this task and this served to develop for the first time a more in-depth approach to risk assessment of acoustic toys. More information can be found in chapter 4 on risk assessment.

PHASE 2 - Implementation stage - (around 6 months) - This involved the actual inspections, sampling and testing of acoustic toys. Sampling activities were held between mid-February to end of April 2016. Checklists were utilised to help zoom in on those particular acoustic toys which already showed signs of non-compliances. 389 samples were sent for testing.

PHASE 3 - Final Results & Follow-up - (*around 10 months*) - This involved the discussion of non-compliances found, risk assessment implicated and the actual implementation of measures and follow-up action taken by the respective market surveillance authorities. It also included the finalisation of statistics and the eventual development of this Final Technical Report.

1.8 Other background information

Online Sales

This working group also tried to see whether it could perform a certain level of inspection on online sales of acoustic toys. Some Member States managed to perform inspections and in total 90 toy models were inspected online by 9 different Member States, out of which 44 samples were sent for testing by 6 of the Member States.

Customs

Although it was not expected that Customs would be involved directly in this particular project, the individual Member States were free to decide on their own if they wished to involve Customs in picking up some of the samples.

The Lithuanian authority managed to inspect 4 importers at the Customs border with the help of Customs authorities. 20 samples were checked, out of which <u>4 samples</u> were sent for testing. The rest of the market surveillance authorities did not involve Customs for this particular project.

Priority List for Toys

The Toys Priority List produced during JA2013 was re-discussed; fine-tuned and agreed upon. It was agreed that two lists had to continue to be developed from now onwards:

- (i) one dealing with mechanical aspects of toys and various other aspects;
- (ii) the other dealing with just chemical aspects of toys.

For JA2015, it was also confirmed by the previous working group on toys that "Chemicals in plasticised toys" had to be focused. On the other hand, this group re-confirmed that the next priority group to be considered within JA2016 would be "electrical toys".



2 Setting up the Product Activity

2.1 Tendering Process for Test Laboratories

A tender was issued for testing of acoustic requirements of these toys. In view that the revised standard was relatively recent (the standard EN71-1:2011 was superseded on 30th September 2014, at which point the presumption of conformity with the harmonised legislation were no longer applicable after that date), one could still find toys which complied with the older version of the standard or which complied with the new standard, depending on when they were placed on the market. For this reason, it was agreed to ask for prices, not only for testing in line with clause 4.20 of EN 71-1:2011+A2:2013 or later versions of the standard, but also prices for testing in line with clause 4.20 of the superseded standard - EN71-1:2011.

The call was published on the PROSAFE website on the 18th October 2015 and all respective emails and contact with the Secretary of the Toys Notified Body Group was done on the same day in order to alert as many laboratories as possible. The deadline for submitting the tenders was the 16th November 2015. Six laboratories sent a tender by the required deadline. After the adjudication process, one laboratory was identified for the testing of these acoustic toys.

2.2 Selecting Products, Sampling

It is important to note that the market surveillance authorities focused their attention on toys that are <u>clearly designed to emit sound</u>, as described within the European standard and that they fell within the requirements of this standard.

Certain toys which were possibly in "a grey area" were discussed in detail during the meeting at the laboratory (held in June 2016) in order to ascertain whether those particular toys were considered by the whole group as a toy or not.

From 1st October 2014, all toys intentionally producing sound were required to be in line with the revised acoustic requirements of the European standard. The working group decided to categorise the acoustic toys in line with the categories already defined in the standard. For this reason, toys emitting sounds have been categorised 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

A brief description of each of these acoustic toy categories is shown in the next two pages (refer to Figure 2-Part I and Figure 2-Part2).

It is worth noting that the market surveillance authorities found it very hard to find any acoustic toys falling into the category "toys using headphones or earphones". Indeed, only one sample was found by the 16 market surveillance authorities and this was sent for testing and found to be compliant with the acoustic requirements.



Additionally, some samples were tested for more than one category by the laboratory, in view that the particular toy could be considered to fall under two or more categories. Some others were tested according to different exposure levels too. Indeed, this is why 450 tests were carried out in total (refer to Figure 4 on page 15 of this report).

	Description of Products	Related Examples from EN71-1		s	
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 EN71-1:2011+A3:2014)	Toy telephones, toy rifles with a loudspeaker in the stock	105 Jacor		
Table-top or floor toys	Toy clearly designed to emit sound, intended to be used on a table, floor or another large surface (Clause 3.60 of EN71-1:2011+A3:2014)	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 <u>but excluding</u> close-to-the-ear toys, rattles, squeeze toys, cap-firing toys, wind toys, voice toys and percussion toys (Clause 3.31 of EN71-1:2011+A3:2014)	Clicking toys, Toy Tools, toy guns	AMEL .		

	Description of Products	SOME PHOT	os
Toys using headphones or earphones	Toys using headphones or earphones		*
	Toy, intended for <u>children who are too young</u> <u>to sit up unaided</u> , that is clearly designed to emit sound when shaken or activated by the child or another person (Clause 3.50 of EN71-1:2011+A3:2014)		60 0
Squeeze toys	Pliable toy, intended for <u>children who are too</u> <u>young to sit up unaided</u> , 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 3.56 of EN71-1:2011+A3:2014)		53/2014

Figure 2 (Part I) - Description of Acoustic Toy Groups



	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 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 3.49 of EN71-1:2011+A3:2014)	Examples of pull-along or push toys that emit sound only as a result of movement imparted on the toy, only include toys making intentional mechanically excited sound e.g. when the axles/wheels are rotating. 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 hand-held or table-top or floor toys	NALKER PARTY OF THE PARTY OF TH
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 3.69 of EN71-1:2011+A3:2014)	Telephones, walkie-talkies, voice recording toys, sing-along microphones and electronic bull horns (toy megaphones)	

	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 3.44 of EN71-1:2011+A3:2014)	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 3.70 of EN71-1:2011+A3:2014)	Trumpets and toy whistles	

Figure 2 (Part I) - Description of Acoustic Toy Groups

Around <u>2,190 different models of acoustic toys</u> were inspected by the respective 16 market surveillance authorities, out of which <u>389 samples were sent for testing at the laboratory</u>.



Figure 3 below gives a breakdown of the samples according to whether they were directly taken from manufacturers of the respective EU Member States; whether they were extracted directly from importers; or whether they were extracted from distributors.

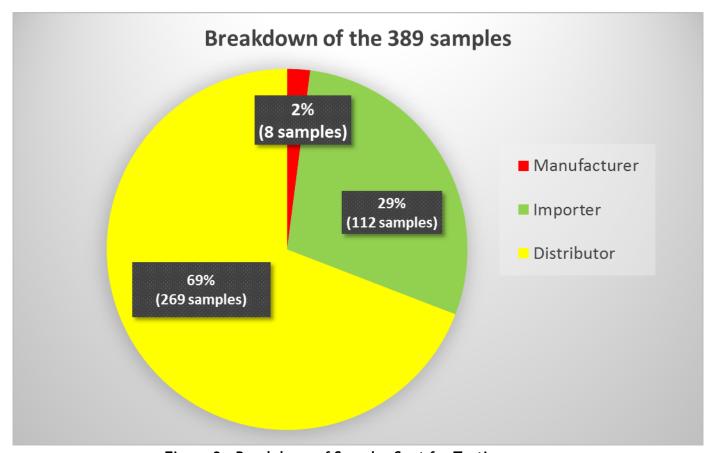


Figure 3 - Breakdown of Samples Sent for Testing

The majority of the samples were taken directly from distributors or importers. Together they represent around 98% of all samples taken from the market. Only 2% were extracted directly from the local EU manufacturers.

Additionally, it may be worth noting that 44 samples were extracted directly via online sales and another 4 with assistance from Customs.



3 Testing

3.1 The Test Program

The original amendment to EN 71-1 on acoustic requirements was published by CEN on 31 Oct 2013 - EN 71-1:2011+A2:2013. From that date onwards, this standard could be used to demonstrate compliance with the safety acoustic requirements under the Directive 2009/48/EC the Toy Safety Directive (TSD) - [4]. Additionally, as from 1st October 2014, there is no longer any presumption of conformity for toys manufactured according to the superseded standard (EN 71-1:2011).

Tests were first carried out according to the acoustic requirements (EN 71-1:2011+A3:2014). It is worth noting that the acoustic requirements for amendments A2 and A3 are the same. EN 71-1:2011+A3:2014 was the harmonised standard until 29.02.2016. (published in the OJ EU) on the dates when samples were sent for testing. If they failed this test, the laboratory had to perform the test according to the superseded "older" version of the acoustic requirements - pending that these were relevant. However, it is important to note that the tests only focused upon acoustic requirements. Additional analysis was carried out by the Member States themselves, as can be seen in section 3.3 below.

The new requirements define 11 types of toys and time-averaged emission and peak sound pressure levels are defined for each of them. Additionally, 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. The tests were performed in a hemi-anechoic room. The associated environmental factor is lower than 2 dB (class 2).

3.2 Results

As explained earlier on, 389 samples were sent for testing. However, <u>one</u> sample was not considered an acoustic toy by the laboratory and therefore was not tested, thus actually having 388 samples initially to be tested.

When it came to actual testing, one needs to also remember that the initial intention was to perform 467 tests as indicated in the left column of Figure 4.

However, it resulted that <u>seven</u> other samples were found to be broken either during transportation, assembly or just before performing the particular test. <u>Three</u> other samples were considered by the laboratory as non-functional. Additionally, <u>seven</u> voice toys were found to be undetermined. More information will be given later on about these particular seven samples since it could be of particular interest to CEN.

To conclude and as seen in Figure 4, 450 tests (467-7-3-7=450) were ultimately carried out on the acoustic toy samples. Additionally, this also means that the total number of SAMPLES actually tested was 371, as per explanation shown below:

Initial number of samples sent for testing	389 samples
One sample not recognised by lab as an acoustic toy	1
Samples found to be broken	7
Samples found to be non-functional	3
Samples (voice toys) with undetermined results	7



ACOUSTIC TOYS WITH FULL TEST RESULTS BY THE LABORATORY								
Category	N° of tests required on acoustic toys*	Broken Toys not tested	Non- funtional toys	Undetermined test results	TOTAL Number of Tests Performed			
1 - Close to the ear toy	40				40			
2 - Table-top or Floor-toy	70	2			68			
3 - Hand-held toy	155	3			152			
4 - Rattle	23				23			
5 -Squeeze toy	13				13			
6 - Pull along or push toy	4				4			
7 -Percussion toy	40	1			39			
8 -Wind toy	72	1			71			
9 - Cap-firing toy	18				18			
10 - Voice toy	31		3	7	21			
11 - Toy using headphones or earphones	1				1			
TOTAL	467	7	3	7	450			

* Not including the one sample which was not considered by LNE as an acoustic toy

Figure 4 - Testing of Samples

Acoustic Toy Categories

Looking closely again at Figure 4, one can determine that the category with the highest number of tests was hand-held toys (152 tests), followed by wind toys (71 tests), table-top /floor-toys (68 tests), close-to-the-ear toys (40 tests), percussion toys (39 tests), and various other toy categories as can be seen within this Figure.

The differences in the number of tests between the categories are mainly due to the amount of type of acoustic toys found in the market. Thus, in the case of "Toy using headphones", only one sample was tested, since only one market surveillance authority from all of the 16 Member States managed to find one in their market. However, there is also another element worth noting and this is related to the fact that the inspectors were asked to focus on those acoustic toys which possibly already showed signs of some kind of non-compliance. Therefore, one needs to remember that the sampling is not representative of the actual market only, but also takes into account the type of non-compliant elements found within certain acoustic toys.

Uncertainty values of tests carried out

Unfortunately, the expanded uncertainty values for all tests carried out by the laboratory were rather high, measuring +/- 7.6 dB and therefore not as precise as the authorities would have expected. This meant a variance of more than 15 dB which made the assessment by the market



surveillance authorities rather difficult. In view that this is a logarithmic scale, the difference in sound pressure levels can be considered substantial.

This meant that an acoustic toy having the limit exceed by 7.5 dB could not be considered as "non-compliant" since when you reduce the amount of 7.6 dB it would be considered as "compliant". The main outcome from this fact is that the number of non-compliant samples would have been more if the uncertainty level was less than the above-mentioned figures. Up to 67 additional samples fell into this category, all of these 67 samples would have been considered as also not complying to the standard if no uncertainty value were considered. If the uncertainty level would have been in the region of 3 dB, about 27 samples would have fallen in this category.

From information acquired by this working group, it seems that the uncertainty level is not usually this high in most of the laboratories. However, the working group is not sure whether this high level of uncertainty could also be found in other laboratories. In view of this experience, it is suggested to market surveillance authorities that such information should be requested prior to any testing, so that the market surveillance authority is fully aware of the level of uncertainty.

Undetermined Test Results in Voice Toys

When the laboratory tried to perform the test on certain voice toys according to the required standard specifications, the results were considered to be "undetermined", as can be seen from Figure 4, meaning that results could NOT be established. This situation concerns such voice toys where the microphone and the loudspeaker cannot be separated, but are fixed together. Of course, this was only the case in 7 out of a total of 31 voice toys. However, it was the only category where such a problem occurred. The main reason for this is that the measuring result was dependent of the loudness of the child's voice. Therefore, if the child had a loud voice the result could be too loud and vice-versa.

The Test Results

As can be seen from Figure 5, a total of 450 tests were initially carried out as per EN71-1:2011+A2:2013. However, out of the non-compliant toys, there were 4 acoustic toys which were placed on the market prior to 1st October 2014 and which conformed to the previous standard EN71-1:2011.

In the case of these 4 particular samples, the economic operators were contacted by the market surveillance authorities so that they are aware of the test results and in order to ensure that no new consignments of such acoustic toys are placed on the Single Market.

It is worth noting that the acoustic toy group with the highest non-compliance was cap-firing toys - 27.8%, followed by close-to-the-ear toys - 20% and wind toys - 14.1%. Hand-held toys had a non-compliance of 6.6% and in the case of percussion toys it was 5.1%. In the case of voice toys and rattles, these have a percentage non-compliance of less than 5%.

It is also worth noting that in the case of squeeze toys, although 13 samples were tested, they were all found to be compliant. Similarly, in the case of pull-along / push-along toys, although only 4 samples were tested, all of them complied the acoustic requirements.

When it comes to determining the **overall percentage of non-compliance**, one needs to remember that earlier on, we mentioned that 371 samples (with 450 tests) were initially carried



out. Therefore, the overall percentage non-compliance on all samples tested was found to be 10.3% (38/371= 10.3).

TOTAL NON-COMPLIANCES FOUND AS PER EN 71-1:2011+A2:2013 were ini be non-c were			Acoustic Toys which were initially found to be non-compliant BUT were found to be placed on the market	RESULTANT NON-COMPLIANT TOYS				
Category	N° of tests performed	N° of Non- compliances	prior to 1st Oct 2014 & conforming to EN71- 1:2011	Category	N° of tests performed	N° of Non- compliances	% of Non- compliance	
1 - Close to the ear toy	40	8		1 - Close to the ear toy	40	8	20.0%	
2 - Table-top or Floor-toy	68	1		2 - Table-top or Floor-toy	68	1	1.5%	
3 - Hand-held toy	152	12	2	3 - Hand-held toy	152	10	6.6%	
4 - Rattle	23	1		4 - Rattle	23	1	4.3%	
5 -Squeeze toy	13	0		5 -Squeeze toy	13	0	0.0%	
6 - Pull along or push toy	4	0		6 - Pull along or push toy	4	0	0.0%	
7 -Percussion toy	39	2		7 -Percussion toy	39	2	5.1%	
8 -Wind toy	71	12	2	8 -Wind toy	71	10	14.1%	
9 - Cap-firing toy	18	5		9 - Cap-firing toy	18	5	27.8%	
10 - Voice toy	21	1		10 - Voice toy	21	1	4.8%	
11 - Toy using headphones or earphones	1	0		11 - Toy using headphones or earphones		0	0.0%	
TOTAL	450	42	4	TOTAL 450 38		38		

Figure 5 - Non-compliance found within each Acoustic Toy Group

3.3 Additional Analysis by the Member States

It was agreed from the beginning of the project that besides testing for acoustic requirements according to the European standard, that the market surveillance authorities would also perform checks on labelling/markings and warnings and in particular on the declaration of conformity. The results are shown below.

The declaration of conformity

Each market surveillance authority was asked to collect the respective declaration of conformity (DoC) for each of the samples tested. The result is shown in Figure 6 below, whereby the market surveillance authorities managed in total to collect 63% of the DoCs from all the samples sent for testing.



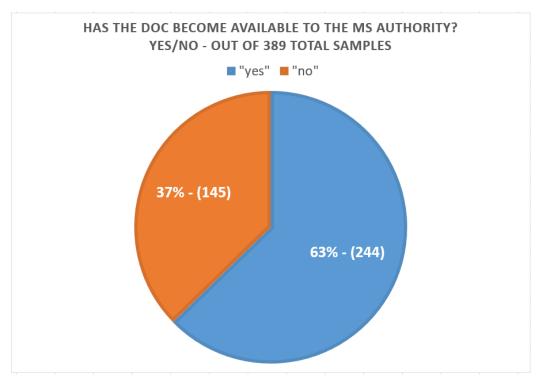


Figure 6 - Availability of Declaration of Conformity

These figures show the availability of the DoC for all 389 toys from the 16 market surveillance authorities. When one analyses the actual level of availability of these DoCs at Member State level, the results give a very different situation.

Looking at Figure 7 below it immediately becomes apparent that 4 out of the 16 market surveillance authorities did not manage to collect 50% of the DoCs, with one of them only managing to collect 25% of all the DoCs.

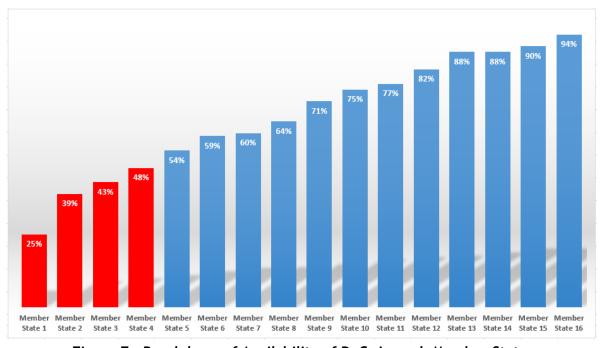


Figure 7 - Breakdown of Availability of DoCs in each Member State



On the other hand, 5 other authorities managed to collect over 80% of the DoCs, with one managing to collect 94% of all the DoCs. The rest of the authorities were somewhere in between.

There is no easy and simple reason for this huge disparity. It would be very interesting to understand why there was such a huge difference in the level of availability of such DoCs. However, this goes beyond the scope of this report. What can be said is that the market surveillance authorities were notified about the respective statistics.

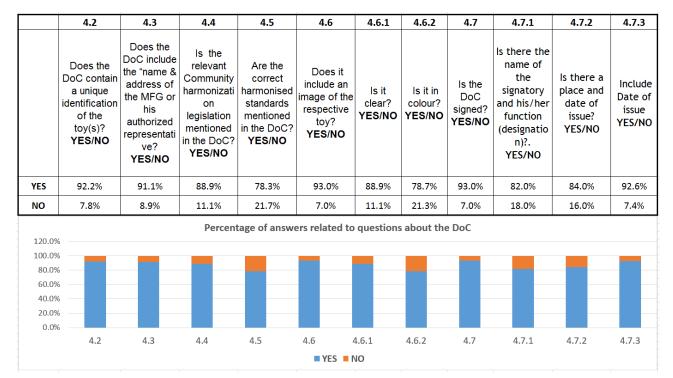


Figure 8 - Percentage of Correct Answers related to the content of the DoC

Of particular interest is Figure 8, showing the type of questions asked in relation to the actual DoCs collected.

It is very positive to see that the manufacturers, being themselves responsible for issuing the DoC, seem to know what needs to be included within the declaration of conformity, since the percentage of correct responses is quite high in this case.

However, when it comes to the actual mentioning of the standard itself within the DoC (refer to question 4.5 within Figure 8), this was not as high as expected. The same thing is true when it comes to the photos of the toy that need to be in colour (refer to question 4.6.2 of Figure 8). The name of the signatory and designation, as well as the place and date of issue are also sometimes missing (refer to question 4.7.1 & 4.7.2 of Figure 8).



3.4 Conclusions

The overall testing and the checks performed on hundreds of acoustic toys were found to be a very positive exercise since this process not only removed from the market a number of non-compliant products but also helped the market surveillance authorities to learn from each other's experiences gained throughout this joint market surveillance activity.

The information gathered in relation to the declaration of conformities was also quite interesting and, the fact that there are currently quite significant differences between the level of availability of the DoCs made some market surveillance authorities think whether they might need to perform some work in the form of awareness campaigns amongst economic operators, so that the level of availability of such DoCs may increase in certain Member States.

Of particular importance is the experience gathered in risk assessing these acoustic toys. In view of the particular importance attributed to risk assessment, this will be described in more detail in Chapter 4.



4 Risk Assessment & Action Taken

4.1 Introduction

One needs to appreciate that having a number of non-compliances related to the respective standard does not automatically mean that the particular product is completely unsafe. Although Member States are obliged to ensure that there are no non-compliances, proportionate action needs to be taken based on the level of risk associated with that particular product.

Risk assessment has to be performed by the respective market surveillance authorities in order to determine the level of risk and, hence, the level of risk management needed for each particular case. This working group tried to find some previous documents and reports associated with risk assessment of acoustic toys. Unfortunately, in view that the standard was just (relatively) recently updated, no documents or information could be found specifically dealing with risk assessing acoustic toys.

During the first meeting of this working group, it was agreed that an expert on acoustics was required to help better determine how to perform risk assessment of these acoustic toys. Professor Stig Arlinger was appointed to assist this group for this particular purpose.

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.

The European standard itself already takes into account various scenarios, since it has different limits related to different acoustic toy groups and also depending on the level of exposure (three different levels of exposure are specified within the standard) to the ear of the child.

Based on all of this, a special report dealing with risk assessment of acoustic toys was prepared by Prof Arlinger after listening to what this working group needed, and also after explaining to him the principles behind risk assessment for consumer products that are laid down in part IV.5 of Commission Decision 2010/15/EU (the RAPEX Guidelines) [2].

The report has been found to be very useful and helped the whole working group to determine the risk level associated with non-compliances found in continuous and/or peak sound pressure levels as determined by the respective standard.

4.2 How was it done

The report by Prof Arlinger can be found as an annex to this Final Technical Report. It tries to give a logical way of how to assess acoustic toys in line with the deviations found from the limits determined by the test report of that particular toy.

It is not the scope of this Final Technical Report to carry on explaining the details of the report produced by Prof Arlinger. This will take too long and will be outside the scope of this report. A presentation was also given during the last Risk Assessment Seminar organised by PROSAFE on 1st December 2016, whereby there seemed to be a good level of acceptance on how the risk assessment is being performed. A similar presentation was also given to the TOY-ADCO group on 21-22 February 2017.



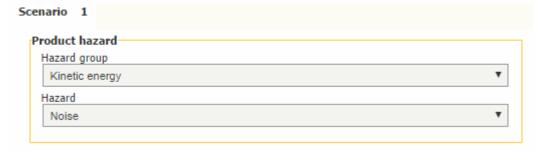
Figure 9 gives a basic summary of how acoustic toys can be risk assessed using the report by Professor Arlinger. The report itself tries to make a distinction between the deviation from the limits associated with LpA measure (A-weighted time-averaged emission sound pressure level) and the LpC Peak measure (C-weighted emission peak sound pressure level) - for each of the respective 11 acoustic toy groups. The respective severity levels have been explained in the report and a probability factor is also given for each of the 11 product types of acoustic toys, mainly based on the average distance between the toy and the ear of the child when the child is playing with the toy. The result is the table shown below (which is a summarised version of the conclusions made by the report produced by Professor Arlinger).

	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	Toys using headphones / earphones >= ½ Wind Toys, Cap-firing Toys >= 1/1,000 Close-to-ear Toys, Voice Toys >= 1/10,000	Calculate
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.	Hand-held toys, Rattles, Squeeze Toys, Percussion Toys >= 1/100,000 Tabletop or Floor Toys, pull- along / push-along toys, >= 1/1,000,000	final RA.

Figure 9 - Summary of how to determine the level of risk of acoustic toys

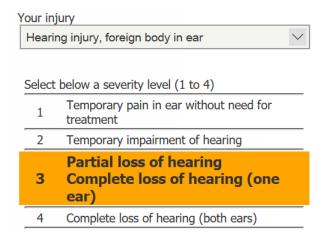
An example is given below in order to better explain the risk assessment methodology shown in Figure 9 and how it relates to the RAPEX risk assessment method. Taking for example an **acoustic toy trumpet (wind toy)** with LpA of 12 db over the limit but with an LpC under the limit as determined by the EN 71-1 standard;

The first step within the RAPEX risk assessment method, for which a practical tools is available at https://ec.europa.eu/consumers/consumer-safety/rag/, is to determine the product hazard itself. The hazard group is "kinetic energy" and the hazard itself is "noise" as shown below:





Once the consumer type is identified, a proper scenario description is given how the hazard causes the injury. One would then have to choose the type of injury, in this case, "Hearing injury, foreign body in ear". Ultimately, there are four severity levels to choose from:



Looking at Figure 9 above, one can conclude that there is a "Severity Level 3" since it is over the limit by 10 dB. The report by Prof Arlinger indicates that partial loss of hearing may occur as tinnitus, "hidden hearing loss" if the requirements for emission sound pressure levels are exceeded by 10 dB. Therefore, Severity level 3 is chosen from the 4 options.

The next step is to calculate the probability. In this case, Figure 9 shows that the probability of this occurring is >= 1/1000 in the case of wind toys. The report by Prof Arlinger makes reference to the intrinsic aspects within the standard itself, whereby 11 toy types are defined, 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 the 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. Wind toys may relatively easily be activated close to another child's ear. Therefore, the probability of injury scenario has been estimated within the report to be >=1/1000.

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".

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



4.3 The Risk Assessment Results

TOTAL TESTS CARRIED OUT & RESPECTIVE NON-COMPLIANCE IN EACH PRODUCT GOUP				RISK ASSESSMENT					
Category	N° of tests performed	N° of Non- compliances	Medium (out of non-		No. of High Risk	Percentage of High Risk (out of non- compliant samples)	No. of Serious Risk	Percentage of Serious Risk (out of non- compliant samples)	
1 - Close to the ear toy	40	8	20.0%	1	12.5%	3	37.5%	4	50.0%
2 - Table-top or Floor-toy	68	1	1.5%	1	100.0%	0	0.0%	0	0.0%
3 - Hand-held toy	152	10	6.6%	3	30.0%	7	70.0%	0	0.0%
4 - Rattle	23	1	4.3%	0	0.0%	1	100.0%	0	0.0%
5 -Squeeze toy	13	0	0.0%	0	0.0%	0	0.0%	0	0.0%
6 - Pull along or push toy	4	0	0.0%	0	0.0%	0	0.0%	0	0.0%
7 -Percussion toy	39	2	5.1%	1	50.0%	1	50.0%	0	0.0%
8 -Wind toy	71	10	14.1%	0	0.0%	3	30.0%	7	70.0%
9 - Cap-firing toy	18	5	27.8%	0	0.0%	0	0.0%	5	100.0%
10 - Voice toy	21	1	4.8%	1	100.0%	0	0.0%	0	0.0%
11 - Toy using headphones or earphones	1	0	0.0%	0	0.0%	0	0.0%	0	0.0%
TOTAL	450	38		7		15		16	

Figure 10 - Risk Assessment of Non-Compliant Samples

Figure 10 shows the risk assessment performed by the market surveillance authorities in line with Professor Arlinger's report. It is to be noted that all the market surveillance authorities have utilised this approach to come up with their final risk assessment of the non-compliant acoustic toys. This ensured a consistent approach amongst all 16 market surveillance authorities.

It is worth noting that the 38 non-compliances indicated in Figure 10 also represent the actual number of non-compliant <u>samples</u>. The risk assessment percentages shown on the right-hand side of the table are based on these 38 non-compliant <u>samples</u>.

Looking again at Figure 10, one can recognise that the most critical risks were found in:

- Cap-firing toys (100% of all the non-compliant samples had a serious risk)
- Wind Toys (70% had a serious risk and the remaining 30% were classified as "high risk")
- Close-to-the-ear toys (50% had serious risk, 37% had a high risk and 12.5% had a medium risk)
- Hand-held toys (70% had a high risk and 30% had a medium risk)

In the case of **rattles**, there was only one sample which was not compliant and the risk was classified as high risk. Similarly, in the case of **percussion toys**, only two samples were non-compliant and these were classified as 50%-high risk and 50%-medium risk.

With regards to **voice toys**, again only one sample was found to be non-compliant and this was classified as medium risk. However, one needs to remember that some of the tests could not be



concluded effectively by the laboratory since no test results could be determined for some of these toys.

4.4 Action & Measures taken

Figure 11 shows the type of action / measures taken by the respective market surveillance authorities. The data is classified according to the type of risks found within the 38 non-compliant samples.

Therefore, out of 16 non-compliant samples having a serious risk, there were 15 of them which were notified (or in the process of being notified) within RAPEX. Three of them were recalled with the absolute majority having performed a sales-ban and/or a withdrawal.

In the case of 15 non-compliant samples having a high risk, 11 were also notified (or in the process of being notified) within RAPEX. 13 out of the 15 samples had a sales-ban and/or withdrawal performed by the respective market surveillance authorities.

MEASURES TAKEN BY MARKET SURVEILLANCE AUTHOITIES									
Category	Non-compliant Products	Recalls	Salesban and/or withdrawal	Minor Action	In progress	RAPEX Alert Issued / To be Issued			
Serious Risks	16	3	12		1	15			
High Risks	15		13	1	1	11			
Medium Risks	7		5		2	0			
TOTAL	38	3	30	1	4	26			

Figure 11 - Measures taken by market surveillance authorities on non-compliant samples

In the case of the 7 samples having a medium risk, none of them were notified in RAPEX and 5 of them either had a sales-ban and/or withdrawal performed by the market surveillance authorities.

Additional action

One needs to remember that there were a number of samples which could be considered as borderline cases. This means that these types of samples were initially found to be non-compliant before reducing the uncertainty value from the respective test results.

In such cases, the market surveillance authorities tried to take some kind of administrative action by at least initially informing the respective economic operators about the specific test results and whether the economic operator could give to the authorities some additional proof in terms of test results and/or other technical documents which could better validate the safety acoustic requirements of the toys in question.

In the case where the economic operator could not produce any documentation whatsoever about the respective acoustic toys, it was agreed that action was taken by the competent authorities to stop the sales where necessary of these toys.



Declaration of Conformity

As indicated earlier on in this report, the authorities tried to collect the declaration of conformity of all the samples sent for testing. Those economic operators which did not produce the respective declaration were assessed by the authorities after taking into consideration the test results, the labelling on the product and risk assessment results. Action was taken accordingly and in a proportionate manner.

It was emphasized and agreed by all the market surveillance authorities that the checking of the declaration of conformity was meant to raise a certain level of awareness amongst economic operators about the importance of being able to produce these documents to the respective market surveillance authorities. As can be seen from section 3.3 of this report, the market surveillance authorities only managed in total to collect 63% of the DoCs from all the samples sent for testing. However, the actual percentage availability in all the 16 Member States taking part in this joint action varied tremendously from just 25% to 94%. Additionally, in certain cases, the actual content of the DoC in question was not completely correct.

Other labelling checks

The market surveillance authorities also performed some additional labelling checks. However, it is not the scope of this report to refer to all the information for each and every check done by the respective authorities. The most important aspects have already been included in this Final Technical Report.



5 Liaisons

5.1 Involvement of stakeholders

Similar to previous joint market surveillance activities on toys coordinated by PROSAFE, the participating authorities within this joint surveillance activity wished to involve as many stakeholders as possible. Open sessions for external stakeholders were organised for various meetings and in view that TOYS-JA2014 and TOYS-JA2015 are running simultaneously, it was agreed between the respective Task Leaders to update the stakeholders on both activities in alternate meetings and, at the same time, reduce the number of open session meetings to stakeholders, thus becoming more efficient and focused in the approach taken.

The following stakeholders actively participated in these meetings:

☐ ANEC, the European Consumer Voice in Standardisation,

ANEC is the European consumer voice in standardisation. Their membership is open to representatives of national consumer organisations from 33 countries (EU, EFTA and accession countries).

☐ CEN - The European Committee for Standardisation

More than 50.000 technical experts from industry, associations, public administrations, academia and societal organizations are involved in the CEN network that reaches over 600 million people. 33 National Standards Bodies make up the CEN membership and they represent CEN in their country, besides various other affiliates.

The CEN TC 52 Chairman was also directly updated throughout this activity too.

☐ EUROCOMMERCE

EuroCommerce is the voice for around six million retail, wholesale, and other trading companies. Their members include national commerce federations in 31 countries, Europe's 27 leading retail and wholesale companies, and federations representing specific sectors of commerce.

☐ TIE - Toy Industries for Europe

Toy Industries of Europe (TIE) is the trade association for the European toy industry. Members of TIE include corporate companies as well as national associations from Bulgaria, France, Germany, Italy, the Netherlands, Spain, Sweden, the UK, Denmark and Sweden.

☐ Toys Notified Body Group

The Member States, EFTA countries (EEA members) and other countries with which the EC has concluded Mutual Recognition Agreements (MRAs) and Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products (PECAs) have designated Notified Bodies, established per directive. The Notified bodies' assessment of products' conformity with the EU directives is extremely important not only for manufacturers but also for market-surveillance activities.

5.2 Customs

Although there was no extensive cooperation with Customs authorities, the market surveillance authority from Lithuania actually not only involved customs but also managed to extract 4



samples for testing from border controls. It is expected that more involvement of customs will take place during the next joint market surveillance action on toys.

5.3 Other Liaisons

At Commission level, both DG-JUST and DG-GROW continued to be involved from the beginning of this activity. This ensured that the Commission was being kept fully up-to-date with all the respective activities. Representatives from both DGs were invited for each meeting, ensuring that related information was cross-shared between market surveillance authorities and the Commission.

This activity was mainly done by the direct participation of 16 EEA Countries. However, it was again decided from the beginning that this working group had to continue to closely liaise with all the TOY-ADCO members so that the information is cross-shared with a much wider network of market surveillance authorities. For this reason, updates and presentations were given during each TOY-ADCO meeting.

Besides all the above, the autumn and spring market surveillance workshops coordinated directly by PROSAFE were used as a basis for further discussion with all the participants of the whole Joint Action - JA2014. One needs to remember that although this activity involved the direct participation of 16 EEA Countries, the whole joint action involved a much larger number of market surveillance authorities from various different countries within the European Economic Area. This ensured that the good practices and experiences, including challenges related to this activity, were all discussed and shared with a much wide group across Europe.

The Risk Assessment group within JA2014 served to assist this working group to initially develop a plan of action on how to perform risk assessment of acoustic toys. In turn, this working group on acoustic toys (JA2014), by means of experience gathered throughout this project, was able to provide valid input to the Risk Assessment group (JA2015) and a presentation was given on 1st December 2016 on how risk assessment of acoustic toys has been performed with the assistance of an acoustics expert.



6 Evaluation, Lessons Learned

Looking back at this two-year activity, there are some lessons which could be derived from this project.

At a technical level:

- ✓ One needs to be careful how to interpret data and statistics. Market surveillance authorities, in order to be more efficient, will continue to zoom in on those products which are possibly non-compliant. Therefore, any statistics need to be evaluated with certain caution.
- ✓ The report developed by Professor Arlinger was found to be extremely useful as a generic guidance to market surveillance authorities on how to perform risk assessment of acoustic toys. This was also discussed with the Risk Assessment Working Group coordinated by PROSAFE who in turn also found the document quite useful.
- ✓ More coordination isneeded with Customs in order to involve them more in such joint activities. The next toys activity within JA2015 is trying to be more innovative in this approach and will probably be able to involve customs authorities to a much higher degree.
- ✓ More awareness is needed in ensuring the proper availability of declaration of conformities to market surveillance authorities. Although in some Member States this is already quite high, in others more effort may be needed in this area.
- ✓ 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.
- ✓ A few of the market surveillance authorities have found the use of sound meters useful as a preliminary screening tool to identify possibly non-compliant acoustic toys. More indepth analysis may be needed in this regard to determine to what extent such screening tools can be helpful to market surveillance authorities.
- ✓ Input from stakeholders during the meetings, including in particular technical input due to their expertise and experiences, proved to be useful to the whole group, ensuring that the activity is more focused.
- ✓ Market surveillance authorities who are interesting to perform a market surveillance project on acoustic toys should ideally first refer to the Commission's guidance N°10 on musical instruments. http://ec.europa.eu/growth/sectors/toys/safety/guidance/

At an administrative level;

- ✓ Joint tendering for testing of samples continued to prove itself advantageous for market surveillance authorities, since larger amounts of samples tested meant better test prices for surveillance authorities. This also meant that the working group could perform higher numbers of tests and focus on a much larger number of samples.
- ✓ The involvement of the TOY-ADCO group, in particular, by updating them continuously on the activities being coordinated by PROSAFE in the area of toys, was found to be quite useful and positive to all parties concerned.



7 Bibliography

Related quotes and references in the text are stated with a number in brackets, e.g. [1]. The full list of references is given below.

- 1. "Grant Agreement for an Action Multiple Beneficiaries, Agreement Number 2011 82 01". Grant Agreement 2011 82 01 GPSD JA.
- 2. "Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive [GPSD])". Published in the Official Journal of the European Union L22/1.
- 3. Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety
- 4. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.



Annex 1: Report from Professor Stig Arlinger

1

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.





November 2016



Disclaimer

This report arises from the Joint Market Surveillance Action on GPSD Products - JA2014, which received funding from the European Union in the framework of the 'Programme of Community Action in the field of Consumer Policy (2007-2013)'.

The report reflects only the views of the author. *The Consumers, Health and Food Executive Agency (Chafea)* cannot be held responsible for any use, which may be made of the information contained therein.



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 <u>Hearing thresholds shifts.</u> 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



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. <u>Tinnitus</u> 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: $L_{EX,8h} = 85 \text{ dB}(A)$ and $p_{peak} = 140 \text{ Pa}$, corresponding to 137 dB (C) in relation to 20 uPa, respectively;
- (c) lower exposure action values: $L_{EX,8h} = 80 \text{ dB}(A)$ and $p_{peak} = 112 \text{ Pa}$, corresponding to 135 dB (C) in relation to 20 μ Pa, respectively.

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



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:

 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.

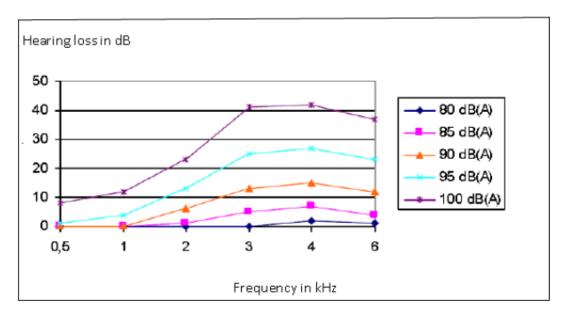


Fig. 1. Noise-induced permanent hearing loss after 10 years in occupational noise in levels between 80 and 100 dB(A) (8h/day) - 10-percentiles according to ISO1999.

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



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



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.
- Temporary impairment of hearing.
- 3. Partial loss of hearing. Complete loss of hearing (one ear)
- 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.



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



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	Н
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	Н	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.



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.



8	ustic Levels as determin	Acoustic Levels as determined by EN71-1:2011+A2:2013															
3000	PRODUCT GROUP	Description as specified within EN71-1	Related Exemples from EN71-1			•	weighted time	-weighted time averaged emission sound pressure level LpA	nssaud punos	are level LpA				C-weighted peak emission sound pressure level LpCpeak	emission sov el LpCpeak	aunssaud pun	Comments
				Test Measurement	Category 1: Toys emitting sound during time periods typically longer than 30 s after each initiation	Category 1: sound during t ger than 30 s a initiation	time periods after each	Category 2: Toys emitting sound during inne periods typically shorter than 30 s but longer than 5 s after each initiation	Category 2: tting sound during tim torter than 30 s but los s after each initiation		Category 3: Toys emitting sound during time periods typically shorter than 5 s after each initiation	Category 3: sound during ti than 5 s after o	ime periods each initiation				(info in this column still to be confirmed)
						Medium Risk	Max Limit: 69 dB		Medium Risk	Wax Limit: 74 dB	-	edum štík A	Max Limit: 79 dB		Att mubak	Max Limit: 114 dB	
쁑	Close-to-the-ear toys	Toy clearly designed to error sound, intended to be used within 2.5cm of the gor (Cleare 3.10 of EN71-1)	Toy telephones, toy rifles with a loudspeaker in the stock	Measurement at 50cm	Shall not exceed	High Risk	Win Limit: 70 dB	shall not exceed 65dB	High Risk	Min Limit: 75 db	shall not exceed	Egn Risk	Win Limit: 80 dB	shall not exceed 110dB	High Risk	Win Limit: 115 dB	Old Standard: LpA - 80dB / LpCpeak - 115dB
						Serious Risk	Win Limit:75 dB		Serious Risk M	Win Limits 80 dB	. wi	erious Risk A	Win Limit: 65-db		yig irope	Win Umit: 120 dB	
		Toy clearly designed to emit sound,			-	Wedlum Risk	Win Limit:75 dB		Wedtun Risk W	Win Limit-100 dB	-	Wedom Stok	Wn Umit:115 dB		Wedom Stok	Win Limit: 120 dB	
Ħ	Table-top or floor toys	intended to be used on a table, floor or another large surface (Cleans 3.59 of	Toy cars, mechanical animals, and large and builty toys	Measurement at 50cm	Shall not exceed	High Risk	Max Limit: NR	shall not exceed 854B	म अध्य प्रवेश	Max Limits NR	shall not exceed H	Sgn Flick A	Wax Limit: NR	shall not exceed 110dB	Magn Plate	Max Limit: NR	Old Standard: LpCpeak - 115dB
		D471-1)			***	Serious Risk	Max Limit: HR		Serious Risk: M	Wax Limit: NR	ari	erious Risk A	Max Limit: NR		Serious Risk	Max Limit: NR	
L		Toy clearly designed to emit sound, intended to be held in the hand but			1	Wedlam Risk	White 90 db		Medium Ride	Win Limit: 95 dB	1	Aedum Stik A	Win Limit: 100 dB		Medium Stick	Min Limit: 115 dB	
Ŧ	Hand-held toys	excluding class-to-the-ear tops, rattlen, squeeze tops, cap-firing tops, whol tops,	Clicking toys, Toy Tools, toy gura	Measurement at 50cm	Shall not exceed	High Risk	We Limite's di	shall not exceed 85dB	High Risk M	Win Limit-100 dB	shall not exceed H	Sgn Risk A	Wn Limit:105 dB	shall not exceed 110dB	High Risk	Win Limit: 120 dB	0ld Standard: LpCpeak - 115dB
		voice toys and percussion toys (Clause 3.31 of EV71-1)				Serious Bisk	Max Limit: HR		Serious Bids: 14	Max Limits NR	. M	erious Risk A	Wax Limit: NR		yeg mopes	Max Limit: NR	
		Toy on which movement to imparted by			*	Wedlam Risk	Win Limit:95 dB		Medium Risk M	Win Limit-100 dB	-	Wedom Risk A	Win Limite 115 dB		Wedom Stok	Win Limit: 120 dB	
ž	Pull-along or push-along toys	the user for example by pulling it by a cond or pushing it by means of a rigid		Measurement at 50cm	Shall not exceed	High Risk	Max Limit: NR	shall not exceed 8548	High Risk M	Max Limit: NR	shall not exceed H	Name of the Asset	Wax Limit: NR	shall not exceed 110dB	With Risk	Max Limit: NR	Old Standard: LpCpeak - 115dB
		extension (Clause 3.48 of EV71-1)				Serious Risk	Max Limit: NR		Serious Blak	Max Limits NR	. w	erious Risk A	Wax Limit: NR		Serious Risk	Max Limit: NR	
		Toy clearly designed to emit sound by	Telephones, walkie-talkies, volce		*	Wedlum Risk	Max Limit: 89 dB		Medium Risk M	Wax Limit: 94 dB	4	Wedom Risk A	Wax Limit: 99 dB		Wedum Bisk	Max Limit: 114-dB	
5	Voice toys	electronically amplifying or obtorting the voice and where the output tound level depends on the input tound level of the		Measurement at 50cm	Shall not exceed	High Risk	Win Limit: 90 dB	shall not exceed 85dB	High Risk	Win Limit: 95 dB	shall not exceed 11	High Risk A	Win Limit: 100 dB	shall not exceed 110dB	High Risk	Win Limit: 115 dB	Old Standard: Levels - 77
		voice (Clause 3.68 of Di71-1)	horm (by megaphones)			Serious Risk	Win Limit: 95 dB		Serious Risk: M	Win Limit-100 db	. M	Vertous Blok A	Win Limit: 105 dB		Serious Risk	Win Limit: 130 dB	
					=	Wedlam Risk	Max Limit: NR								Medium Bitk	Max Limit: NR	
뽀	Toys using headphones or earphones			Measurement at a	Shall not exceed	High Risk	Max Limit: NR							shall not exceed 135dB	High Risk	Max Limit: NR	Old Standard: LpA - 90dB / LpCpeak - 115dB
						Serious Risk	Max Limit: 89 dB								Serious Risk	Max Limit: 139 dB	
		Toy, intended for children who are too							Medium Risk M	Min Limit: 95 dB					yay ungew	Win Limit: 115 dB	
2	Rattles	designed to entit cound when shaken or activated by the child or another person		Measurement at 50cm				Shall not exceed 85dB	High Plak	Win Limit-100 dB				shall not exceed 110dB	Migh Risk	Win Limit: 120 dB	Old Standard: LpA - 85dB / LpCpeak - 110dB
		(Clause 3.49 of EK71-1)							Serious Risk M	Wax Limits NR					Serious Risk	Max Limit: HR	
		Pliable toy, intended for children wite, are too young to all up andded,							Medium Risk	Win Limit: 75 dB					Medium Stick	Win Limit: 115 dB	
ե	Squeeze toys	activisted by forcing air through an opening, clearly designed to emit sound		Measurement at 50cm				Shall not exceed 85d8	High Risk	Win Limit-100 dS				shall not exceed 110dB	High Risk	Win Limit:120 dB	Old Standard: LpA - 85dB / LpCpeak - 110dB
		when flexed or squeezed by the child or another person. (Clease 3.55 of ER71-1)							Serious Risk	Water Liferities NR					Serious Risk	Max Limits NR	
									Medium Ride M	Win Limit: 95 dB					Medium Stok	Win Limit:135 dB	
į.	Percussion toys	10y clearly designed to errit sound when struck with a beater, such as a drumstick, or be the hand ifflence 3,4% of PATI-11	Druma, xylophones and tambourines	Measurement at 50cm				Shall not exceed 85dB	High Risk	Win Limit-100 dS				shall not exceed 130dB	Majn Risk	Win Limit:140 dB	
									Serious Blak	Wax Limits NR					Serious Risk	Max Limit: NR	
		Toy clearly designed to emit sound when							Medium Risk M	Wax Limits NR	4	Adum Bitk A	Wax Limit: NR		Att mubak	Max Limit: NR	
¥	Wind toys	actuated by the blowing action of the child or another person (Clause 3.00 of	Trumpets and tay whittles	Measurement at 50cm				shall not exceed 85d8	High Risk M	Wax Limit: 94 dB	shall not exceed	Bgh Risk	Wax Limit: 99 dB	shall not exceed 110dB	High Risk	Max Limit: 114 dB	
		D671-1)							Serious Risk.	Min Limit: 95 dB	47	erious Risk A	Win Limit: 100 dB		Serious Risk	Win Limit: 115 dB	
		Toy clearly designed to emit your									4	edum Ritk	Was Unit: NR		Medium Risk	Max Limit: NR	
5	Cap-firing toys	caused by discharge of a percussion cap (Clause 3.7 of EA71-1)	Cup guns	Measurement at 50cm							Shall not exceed 11 90dB	Spr No.	Wax Limit: 99 dB	shall not exceed 125dB	High Risk	Max Limit: 129 dB	Old Standard: LpCpeak - 125dB
											50	erious Risk	Min Limit: 100 dB		Serious Risk	Min Limit: 130 dB	



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