# Joint Action 2015 GPSD

Joint Market Surveillance Action co-funded by the European Union Grant Agreement No: 705 038 - GPSD



## Final Technical Report, Child Care Articles 5, Soothers and Soother Holders

Covering the period April 2016 - May 2018





#### Disclaimer

This report arises from the Joint Market Surveillance Action on GPSD Products - JA2015, 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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#### **Table of Contents**

Ove	rview of	f tables	4
Ove	rview of	f Figures	4
Abbı	reviatio	ns	5
Exec	cutive S	ummary	6
1	Introd	uction	7
	1.2 Pa 1.3 Ov 1.4 Ma 1.5 Bu 1.6 Th	ackground Information articipating Market Surveillance Authorities verview of Key Staff in the Activity ain Objectives udgeted Activities ne Phases of the Activity	7 8 8 8
2	Settin	g up the Product Activity	10
		endering Process for Test Laboratories	
3	Testin	g	13
	3.2 Re	ne Testing Program	15
4		ssessment & Action Taken	
	4.2 Th 4.3 Ac 4.4 RA	ne Risk Assessment Method	30 31 33
5	Liaiso	ns	36
		volvement of Customs	
6	Evalua	ation, Lessons Learned	37
	6.1 Lc	poking Ahead	37
7	Biblio	graphy	38
Anne	ex 1 - E	xamples of Press Releases or Media Releases	39
Δnne	-x 2 - F	xamples of Press Coverage Obtained	46

## Overview of tables

Table 1 The types of soothers and soother holders targeted by the Child Care Articles 5 Activity	 
Table 7 The risk level associated with the identified non-compliances for soothers (all 73 samples) 30 Table 8 The risk level associated with the identified non-compliances for traditional soother holders (77 samples)	)
Table 10 Overview of measures taken against the non-compliant soothers (all 73 samples)	2
Overview of Figures	
Figure 1 Country of Origin for all 195 soothers and soother holders sampled	Ó
were applicable to all 73 soother samples	)
The generally high number of non-compliant soother holder samples encouraged the participants to examine the following 2 aspects further: the country of origin for all non-complying samples (the results of which can be seen in Figure 9 below) and the number of soother holders that demonstrated multiple non-compliances according to the laboratory testing (see Figure 10).	
Figure 10 Country of origin for those 95 soother holders that were non-compliant to EN 12586	



## **Abbreviations**

A11 Article 11 RAPEX Notification
A12 Article 12 RAPEX Notification

ANEC The European consumer voice in standardisation CA Consumer Agency (Neytendastofa), Iceland

CAS Customs Authorities
CCA Child Care Articles

CCA5 Child Care Articles 5 (the fifth Joint Action on child care articles managed

by PROSAFE, this time focusing on soothers and soother holders)

CCP Commission for Consumer Protection, Bulgaria

CPS Consumer Protection Service, Cyprus
CEN European Committee for Standardization

CEN TC 252 WG 5 European Committee for Standardization - Feeding, Drinking, Sucking and

Similar Functions Committee

Chafea Consumers, Health and Food Executive Agency
CRPC Consumer Rights Protection Centre, Latvia

DG JUST European Commission, Directorate-General Justice and Consumers,

responsible for EU policy on justice, consumer rights and gender equality

DSTA Danish Safety Technology Authority, Denmark

EEA European Economic Area

EFTA European Free Trade Association
EN 12868:2000 European Standard for nitrosamines
EN 12586:2007 + A1:2011 European Standard for soother holders

EN 1400:2013 + A1:2014 European Standard for soothers EN 71 European Standard for toys

ENPC European Nursery Products Confederation

EU European Union

FPSE Federal Public Service Economy, Belgium

GPSD General Product Safety Directive

ICSMS Information & Communication System for Market Surveillance

IDB European Injury Database

JA2015 Joint Market Surveillance Action coordinated by PROSAFE with an

implementation time-frame of April 2016 up to June 2018

MDC Ministry of Development and Competitiveness, Greece

MEBW Ministry of Environment, Climate Protection and the Energy Sector of

Baden-Wuerttemberg, Germany

MFR Regierung von Mittel Franken, Germany

MCCAA Malta Competition Consumer Affairs Authority, Malta

MS Market Surveillance

MSA Market Surveillance Authority

NACP National Authority for Consumers' Protection, Romania

NVWA The Netherlands Food and Consumer Product Safety Authority, The

Netherlands

PROSAFE Product Safety Forum of Europe

RAG European Commission's Risk Assessment Guidelines tool SCRPA State Consumer Rights Protection Authority, Lithuania

TARIC A code used by Customs Authorities to establish the type of product being

traded and confirms the various rules applying to the specific product



## **Executive Summary**

This report presents the activities undertaken and the results achieved in the Product Activity Child Care Articles 5 of the "Joint Market Surveillance Action on GPSD Products 2015 - JA2015", co-funded by the European Union under the Grant Agreement No. 705 038. The project was carried out by 35 MSAs from 27 Member States of the European Union and the European Economic Area, under the coordination of PROSAFE.

The present Child Care Articles Activity focussed on **soothers and soother holders** and its primary goals were to:

- Build on the work undertaken within previous Joint Actions on Child Care Articles, e.g. baby bath tubs and wheeled conveyances, highchairs, cots and safety barriers, thereby increasing the safety of such products;
- Ensure that soothers and soother holders are safe in use;
- Continue to support the harmonisation of market surveillance across the EEA within this product sector.

Thirteen participating Market Surveillance Authorities (MSAs) were involved in this specific Activity under PROSAFE's coordination. These were Belgium, Bulgaria, Cyprus, Denmark, Germany (x 2 MSAs), Greece, Iceland, Latvia, Lithuania, Malta, The Netherlands and Romania.

The approach was typical in that the participating MSAs undertook to:

- Study their national markets for soothers and soother holders;
- Use this data to make decisions on sampling;
- Visit manufacturers/importers/wholesalers/retailers/e-tailers to inspect and collect products;
- Test all the selected samples at an appropriately skilled and accredited laboratory in Europe;
- Carry out harmonised risk assessments;
- Undertake follow-up actions and/or appropriate administrative activities on non-compliant products;
- Report on the follow-up actions taken (in order to improve safety for consumers).

In total, 195 products were sampled and tested: 73 soothers and 122 soother holders. 77 of the 122 soother holders were traditional soother holders (comprised of a strap with a soother holding device at one end and the garment clip at the other), and the remaining 45 also contained a toy/play element (i.e. were either regarded as a toy or considered to have significant play value and therefore required to also meet the requirements of the Toy Safety Directive). 29% of the 73 soothers and 78% of the 122 soother holders were considered to be non-compliant by the participating MSAs.

The test results were subject to risk assessments using the European Commission's Risk Assessment Guidelines tool<sup>1</sup>. Following the results of this exercise, the participating MSAs took enforcement actions on many of the models tested. Detailed feedback concerning the standard was also conveyed to the relevant CEN Working Group (TC 252/WG 5 for Feeding, Drinking, Sucking and Similar Functions Committee), as a number of queries arose as a result of this project.

Overall, it can be concluded that the goals of the Action were met.

#### Caution!

The above results 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.

The samples were tested at an accredited laboratory. The test focussed on those safety requirements that have the largest impact on consumer safety.

<sup>1</sup> https://ec.europa.eu/consumers/consumer-safety/rag/



D8.6 - Final Technical Report, Child Care Articles 5, Soothers and Soother Holders

## 1 Introduction

This is the final technical report prepared for the Soothers and Soother Holders Activity of the Joint Market Surveillance Action on GPSD Products 2015 - JA2015, which was co-funded by the European Union under Grant Agreement No. 705038.

Funding for the testing of soothers and soother holders was granted due to the number of reported accidents that involved children aged between 0-4 years. IDB (EU Injury Database) data indicates that approximately 44 injuries per year involving soothers and/or soother holders are serious enough to require a visit to the emergency department. The most serious problems associated with such products are suffocation risks, choking on small parts/lack of removal device/lack of ventilation holes and chemical risks.

The current European standard for soothers EN 1400:2013+A1:2014 was published in April 2014. The current European standard for soother holders EN 12586:2007+A1:2011 was published in January 2011. Consequently, Market Surveillance Authorities from the twelve participating EEA countries wanted to check that products were being manufactured according to the legislation, that the standards and clauses therein covered the foreseeable risks and lastly to examine whether 'soothers and soother holders are safe in use' (as stated in the Grant Agreement).

### 1.1 Background Information

This chapter presents a short extract of the project description. The full description can be found in the Grant Agreement.

#### 1.2 Participating Market Surveillance Authorities

The CCA5 activity was undertaken by PROSAFE and 13 Market Surveillance Authorities from 11 Member States of the EU (Belgium, Bulgaria, Cyprus, Denmark, Germany (x 2), Greece, Latvia, Lithuania, Malta, The Netherlands and Romania) and Iceland.

- BE Belgian Federal Public Service Economy (FPSE)
- BG Bulgarian Commission for Consumer Protection (CCP)
- CY Cyprus Consumer Protection Service (CPS)
- DK Danish Safety Technology Authority (DSTA)
- GR Greek Ministry of Development and Competitiveness, General Secretariat for Industry (MDC)
- IS Icelandic Consumer Agency (CA)
- DE German Ministry of Environment, Climate Protection and the Energy Sector of Baden-Wuerttemberg (MEBW)
- DE German Regierung von Mittel Franken (MFR)
- LV Latvian Consumer Rights Protection Centre (CRPC)
- LT Lithuanian State Consumer Rights Protection Authority (SCRPA)
- MT Malta Competition and Consumer Affairs Authority (MCCAA)
- NL Netherlands Food and Consumer Product Safety Authority (NVWA)
- RO Romanian National Authority for Consumers' Protection (NACP)

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 Sarah Jacques, Belgium, FPSE.

The Activity Leader was supported by the PROSAFE Activity Coordinator, Rebecca Morrison.



#### 1.4 Main Objectives

The general objectives of the overall JA2015 project were to continue to create conditions whereby MSAs 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 MSAs possible.

The general objectives of the product activities were to ensure that products on the EU market were safe and carried the appropriate warnings and instructions. The following specific objectives were identified for JA2015 CCA5:

- To build on the work undertaken during CCA1, 2, 3 & 4 and thereby increase the safety of products within this product category;
- To ensure that soothers and soother holders are safe in use;
- To continue to support harmonisation of market surveillance across the EEA within this product sector;
- Further update the CCA Priority List for future Joint Actions;
- Take actions if and where necessary;
- To undertake market surveillance with some involvement from Customs Authorities;
- Coordinate with stakeholders ANEC, ENPC and CEN.

#### 1.5 Budgeted Activities

The total testing budget for the CCA5 Soothers and Soother Holders Activity allowed the testing of 195 samples as follows:

73 soothers - tested to the mechanical and product information clauses of EN 1400:2013+A1:2014<sup>2</sup> 12 of the 73 soothers above were also tested to the chemical clauses of EN 1400:2013+A1:2014

122 soother holders - tested to the mechanical and product information clauses of EN 12586:2007+A1:2011<sup>3</sup>

12 of the 122 soother holders were also tested to the chemical clauses of EN 12586:2007+A1:2011 45 of the 122 soother holders, which contained a toy element or component considered to be of play value were also tested to the relevant clauses of EN 71-1:2014 Safety of toys<sup>4</sup>

#### 1.6 The Phases of the Activity

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

#### • Deciding on sampling criteria

Each of the 13 MSAs presented information on those types of soothers and soother holders that were present in their economies, alongside details of issues, complaints, accidents, etc. This overview helped to deliver a snapshot of the types of soothers and soother holders currently being sold on the markets of the MSAs and provided a basis for the sampling criteria within the scope of the Action. It was finally agreed that MSAs would sample:

- ✓ Traditional soothers with silicone teats
- ✓ Traditional soothers with latex teats
- ✓ Traditional soothers (either teat type) that were also supplied with teat protectors
- ✓ Traditional soother holders

<sup>&</sup>lt;sup>4</sup> For the remainder of this report, most references to the test standard EN 71-1:2014 Safety of toys has been shortened to EN 71



D8.6 - Final Technical Report, Child Care Articles 5, Soothers and Soother Holders

 $<sup>^2</sup>$  For the remainder of this report, most references to the test standard EN 1400:2013+A1:2014 has been shortened to FN 1400

<sup>&</sup>lt;sup>3</sup> For the remainder of this report, most references to the test standard EN 12586:2007+A1:2011 has been shortened to EN 12586

✓ Soother holders that were also regarded as a toy or those that included a play element and were therefore also subject to the Toy Safety Directive

#### Sample products

Using the data gathered above, the MSAs decided on how they should carry out sampling, i.e. how many and what type of soothers and soother holders would be taken by each authority, when the sampling would take place, and how many samples should be taken of each product, etc. This implied that the market surveillance authorities would visit manufacturers, importers, wholesalers, retailers and use the internet to collect products. This phase was coordinated and reported back to the Activity.

#### Test products at a laboratory

The Activity issued a call for tender and selected an appropriate laboratory. MSAs were instructed how to send their products for testing. The soothers and soother holders were shipped and the laboratory submitted test reports after the testing had taken place.

#### Risk assessment

The participants developed a common approach to the application of the RAPEX risk assessment guidelines for each particular product to ensure that the resulting assessments were harmonised to the greatest extent possible. The MSAs then assessed the risk for the products applying the agreed approach and any relevant national conditions.

Follow-up on non-compliant products and exchange of information on follow-up activities.

The MSAs followed up with the economic operators in their countries, i.e. consulted the economic operators on the results from the risk assessment, agreed on appropriate measures and ensured that these were properly implemented. The resulting measures were reported to the Joint Action and shared with all participants.

### 1.7 Timeline for Activity

April 2016	JA2015 start date
April 2016	JA2015 Launch Meeting
May 2016	CCA5 Kick Off Meeting (with stakeholders) and Planning of Activity for soothers and soother holders was undertaken
September 2016	CCA5 Meeting 2
November 2016	Expression of Interest for testing soothers and soother holders, tender documents sent
January 2017	CCA5 Meeting 3, market surveillance/sampling undertaken, lab appointed and contract signed
March 2017	Samples to lab, testing begins
July 2017	Testing completed and test reports circulated. CCA5 Meeting 4 (at test lab), risk assessments performed
November 2017	CCA5 Meeting 5, Follow up actions discussed
January 2018	CCA5 Meeting 6 with stakeholders present. MSAs to present the results of the JA
April 2018	Activity Leader attended CEN TC 252 WG 5 Meeting. JA2015 Final Conference, final actions completed
May 2018	Final Technical Report delivered



## 2 Setting up the Product Activity

#### 2.1 Tendering Process for Test Laboratories

A list of potential testing laboratories from within the EEA was drawn up by the participants and the Activity Coordinator. An 'Expression of Interest' for the testing of soothers and soother holders was prepared and sent to a total of 33 laboratories, of which eight replied detailing their experience of testing soothers and soother holders, relevant accreditations and their relationships with manufacturers.

A call for tender was then prepared by the Activity Coordinator in association with all the MSAs involved and sent to four of the responding labs (the remaining 4 laboratories were not accredited for testing to EN 1400 and/or EN 12586 so were excluded from the remainder of the tendering process). In addition, the call was publicised via Twitter (@PROSAFE\_ORG), placed on the PROSAFE website<sup>5</sup> and the European Commission was informed about the open call.

A total of three laboratories replied. These responses were evaluated at length together with the participating MSAs, and the contract was then awarded to the lab offering the best value for money.

The purpose of the testing was to check that the soothers and soother holders sampled by the MSAs met all tests within the current standards - EN 1400 and EN 12586.

#### 2.2 Selecting Products, Sampling

The Child Care Articles activity under JA2015 focussed on soothers and soother holders. These products had been selected using the annual Priority List task that has been in place and updated annually since JA2011, whereby each country within the EU and EFTA is asked to propose those CCA products that are causing them the most concern. Their responses are then ranked in order to determine the priority products that the Joint Actions should focus on.

According to the Grant Agreement, the primary goal of the Child Care Articles Activity was to focus the group's work upon soothers and soother holders. The work undertaken was to include surveillance activities, product testing, risk assessment of the products tested and eventual action needed to be taken. The proposal envisaged a joint market surveillance activity where the participants would carry out coordinated market surveillance in their national markets. Therefore, the testing of such products was a requirement for the Action.

The Activity Coordinator sent a memo to all the participating MSAs giving pictorial examples of which types of soothers and soother holders to sample - see Table 1 overleaf.

http://prosafe.org/index.php/news-items/38-news-and-events/news-items/241-ja2015-safety-barriers-call-for-tender.



Table 1 The types of soothers and soother holders targeted by the Child Care Articles 5

Activity



Thereafter, the Activity discussed how the target of 195 samples would be divided amongst the 13 MSAs and what combination of products would be sampled. As a result, each participant was provided with a number of models to obtain from their market; this number being based on the available budget (as per the Grant Agreement) for testing being shared between the participating MSAs.

Each of the 13 participating authorities supplied a mix of soothers and soother holders as set out in Table 2 below:

Table 2 Number of samples selected by the MSAs regarding the differing soothers and soother holders

	BE	BG	CY	DK	DE MEBW	DE MFR	GR	IS	LV	LT	МТ	NL	RO	TOTAL
SOOTHERS	6	6	6	6	6	1	6	6	6	5	6	6	6	72
TRADITIONAL SOOTHER HOLDERS	4	10	9	10	2	4	10	5	5	4	8	3	4	78
SOOTHER HOLDERS WITH A PLAY ELEMENT	7	0	1	0	8	5	0	5	5	5	2	7	0	45
TOTAL	17	16	16	16	16	10	16	16	16	15	16	16	10	195

The methodology of the selection for the soother and soother holder samples varied from country to country. The number of online inspections was high, as the Market Surveillance Inspectors in some instances used the internet to seek out products that could be visually seen to demonstrate a cause for concern e.g. very low-cost items, craft made products, soother holders of beaded design, etc. Of the 195 products sampled in total, 26 were identified using the internet. Of the 160 (of 195) inspections that were reported:

- 63 soothers and soother holders were seen in-store and sampled in the store;
- 71 obtained directly from producer/importer/distributor/etc.;
- 8 identified on-line, then sourced from producer/importer/etc.;
- 14 seen on-line, sampled in-store;
- 2 identified on-line, then sourced from e-shop/their warehouse;
- 2 found and sampled on-line.

The MSAs also recorded detail regarding the Country of Origin for the 195 sampled soothers and soother holders as detailed in Figure 1 below:

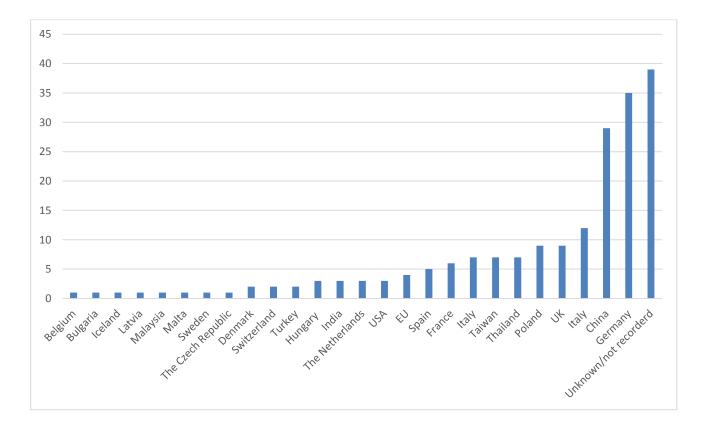


Figure 1 Country of Origin for all 195 soothers and soother holders sampled

As can be seen above, 102 samples (or 52%) were manufactured in Europe. The remainder were marked as being from outside the EU (28%), or of unknown/unrecorded origin (20%).



## 3 Testing

#### 3.1 The Testing Program

Testing is required to establish the extent to which a product represents a safety risk to users and this is usually undertaken in accordance with the applicable safety standard - EN 1400 for the 73 soothers that were examined and EN 12586 for the 122 soother holders (plus some relevant tests from EN 71-1 for the 45 soother holders that contained a toy/play element).

Regarding the mechanical clauses within EN 1400 - tests were conducted in the order set out within the standard. A total of 12 identical soothers (i.e. preferably from the same batch) were required for each product being examined. These soothers were prepared (boiled, then placed in a conditioned atmosphere) prior to testing.

For the 12 soothers that were also tested according to the chemical clauses of EN 1400, an additional 8 (i.e. 20 identical soother samples in total) were needed. The samples were prepared in a similar way as noted above and tested according to the schedule detailed within the standard.

All 122 soother holders were similarly conditioned and then tested to the mechanical clauses of EN 12586. As mentioned above, testing was carried in the the order set out in the standard. 12 of the 122 soother holders were also tested to the chemical clauses. Furthermore, 45 of the 122 soother holders were considered also to be subject to the Toy Safety Directive, so were additionally tested to the relevant clauses of EN 71-1.

Unless otherwise specified in this report, all tests were carried out in the order listed within the relevant standards. Whenever a failure occurred during testing, tests continued unless the failure rendered the product unusable.

Once all tests were completed, the laboratory prepared one test report for each product sample. The report included the test results obtained and indicated any non-conformities to the particular clauses. Also included were supporting photographs, as well as comments or other relevant clarifications.

In addition to the lab's results, each of the MSAs also undertook their own examinations regarding product information, marking and instructions for use, in particular to check that the information supplied with/on the product was correct and in the correct language(s).

#### 3.1.1 Testing based on EN 1400:2013+A1:2014

The mechanical tests taken from EN 1400 for soothers were applied as follows:

To check all samples supplied for duplicates

To check all samples are 'Soothers' and fall under the EN 1400 standard

- 6.3.1 Pre-treatment
- 6.3.2 Boiling
- 6.3.3 Conditioning
- 8.1 General
- 8.2 Teat
- 8.3 Shield
- 8.4 Shield ventilation
- 8.5 Ring
- 8.6 Plug
- 8.7 Knobs, plugs and/or covers made from non-flexible materials
- 8.8 Rings, knobs, plugs and/or covers made of flexible materials
- 8.9 Openings
- 9.1.2 Impact resistance
- 9.7.2.2 Tensile test along the major axis
- 9.2.2.1 Puncture resistance of teat
- 9.3.2.1 Tear resistance of teat
- 9.7.2.2 Tensile test at right angles to the major axis



- 9.4.2 Knob, plug and/or cover retention
- 9.5.2 Bite endurance of elastomeric components
- 9.7.2.2 Tensile test at right angles to the major axis
- 9.7.2.3 Tensile tests for single components and pairs of components
- 9.7.2 Integrity
- 9.2.2.2 Puncture resistance of knob made of flexible materials (if relevant)
- 9.3.2.2 Tear resistance of knob made of flexible materials (if relevant)
- 9.7.2.2 Tensile test at right angles to the major axis (if relevant)
- 9.5.2 Bite endurance of elastomeric components (if relevant)
- 9.7.2.2 Tensile test at right angles to the major axis (if relevant)
- 9.6.2 Rotation endurance (if relevant)
- 9.7.2.2 Tensile test along the major axis (if relevant)
- 12 Consumer packaging
- 13 Product information

The chemical tests taken from EN 1400 for soothers were applied to 12 samples as follows:

- 10.1 General Chemical requirements
- 10.2 Materials
- 10.3 Migration of certain elements
- 10.4 Determination of N-Nitrosamines and N-Nitrosatable substances release
- 10.5 2 Mercaptobenzothiazole (MBT), Antioxidant and Formaldehyde release
- 10.6 Bisphenol A release
- 10.7 Colour Fastness
- 10.8 Volatile compounds content

#### 3.1.2 Testing based on EN 12586:2007+A1:2011

The mechanical tests taken from EN 12586 for all soother holders were applied as follows:

To check all samples supplied for duplicates

To check all samples are 'Soother Holders' and fall under the EN 12586 standard

- 6.1.1 Preparation
- 5.1.3 Visual and tactile
- 5.1.4.1 Finger traps
- 5.1.5 Decoration
- 5.1.6 Length
- 5.1.7 Strap width
- 5.1.8.1 Cord thickness
- 5.1.8.2 Exposed cord length
- 5.1.9 Maximum size of press studs, touch-and -close and similar devices
- 5.2.1 Impact resistance
- 5.2.2 Durability of the garment fastener
- 5.2.3 Tensile strength
- 5.1.10 Permanent fasteners/5.1.11 Detachable fasteners/5.1.12 Supplementary components
- 5.1.4.2 Ventilation holes
- 7 Consumer packaging
- 8 Product information

The chemical tests taken from EN 12586 for soother holders were applied to 12 samples as follows:

- 5.3.1 General Chemical requirements
- 5.3.2 Requirements by material
- 5.3.3 Migration of certain elements
- 5.3.4 Nickel
- 5.3.5 Colour fastness
- 5.3.6 Formaldehyde
- 5.3.7 Phthalate content
- 5.3.8 Colourants
- 5.3.9 Primary aromatic amines



- 5.3.10 Monomers
- 5.3.11 Wood preservatives

For those soother holders that contained a toy or play element, a second sample was tested to the following clauses of EN 71-1:2014 as follows:

- 5.1 General requirements
- 5.2 Soft-filled toys and soft-filled parts of a toy (if applicable)
- 5.8 Shape and size of certain toys
- 5.10 Small balls

#### 3.2 Results

#### 3.2.1 Results of testing 73 soothers to EN 1400

Table 3 gives an overview of the non-compliances found within the 73 samples that were tested to the current version of the EN standard for soothers. Further analysis undertaken by the MSAs involved showed that 16 of 60 samples (or 26%) failed clauses 11 and/or 12 of EN 1400 - which relates to the consumer packaging and product information part of the standard (marking, purchase information, instructions for use).

Table 3 Distribution of non-compliant soother samples based on tests to EN 1400

Clause	Title	Number of tested samples	Number of non- compliant samples	Failure rate
6	General	73	0	0%
7	Printing and decals	73	0	0%
8	Construction properties	73	6	8%
9	Mechanical properties	73	6	8%
10	Chemical requirements	12	0	0%
11 & 12	Consumer packaging and product information	60	17	26%
6 - 12	All clauses	73	21	29%

The table above, combined with figure 2 below, demonstrates the distribution of non-compliant samples according to the sampling MSAs.

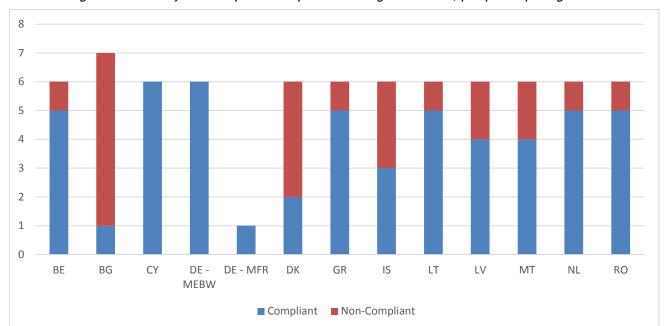


Figure 2 Details of non-compliant samples according to EN 1400, per participating MSA

Table 4, below, provides a detailed breakdown of the test failures to EN 1400 where 52 of the 73 samples (71%) passed all of the laboratory tests.

Table 4 Number of failures attributed to particular test clauses (all 73 samples)

Clause	Requirement	Number of non- compliant samples	Number of samples tested	Failure rate
6.	Conditioning	0	73	0%
7.	Printing and decals	0	73	0%
8.1	General	0	73	0%
8.2	Teat	1	73	1%
8.3	Shield	3	73	4%
8.4	Shield ventilation	3	73	4%
8.5	Ring	1	57	2%
8.6	Plug	0	9	0%
8.7	Knobs, plugs and/or covers made from non-flexible materials	1	9	11%
8.8	Rings, knobs, plugs and/or covers made of flexible materials	0	9	0%
8.9	Openings	0	9	0%
9.1.2	Impact resistance	4	73	5%
9.7.2.2	Tensile test along the major axis	3	73	4%
9.2.2.1	Puncture resistance of teat	0	73	0%



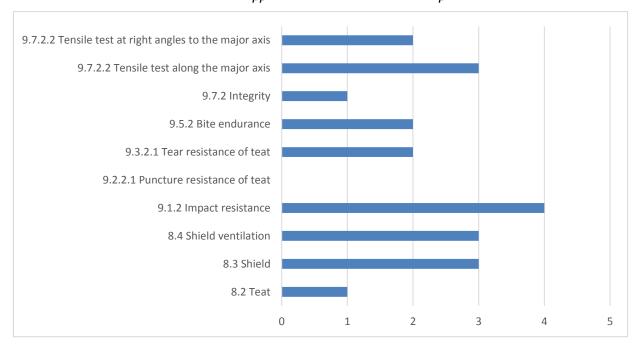
9.3.2.1	Tear resistance of teat	2	73	3%
9.7.2.2	Tensile test at right angles to the major axis	2	73	3%
9.4.2	Knob, plug and/or cover retention	1	65	2%
9.5.2	Bite endurance of elastomeric components	2	73	3%
9.7.2.2	Tensile test at right angles to the major axis	2	73	3%
9.7.2	Integrity	1	73	1%
9.2.2.2	Puncture resistance of knob made of flexible materials (if relevant)	0	1	0%
9.3.2.2	Tear resistance of knob made of flexible materials (if relevant)	0	1	0%
9.7.2.2	Tensile test at right angles to the major axis (if relevant)	0	1	0%
9.5.2	Bite endurance of elastomeric components (knob made of flexible material) (if relevant)	0	2	0%
9.7.2.2	Tensile test at right angles to the major axis (knob made of flexible material) (if relevant)	0	2	0%
9.6.2	Rotation endurance (if relevant)	0	0	0%
9.7.2.2	Tensile test along the major axis (if relevant)	0	0	0%
10.1	General Chemical requirements	0	12	0%
10.2	Materials	0	12	0%
10.3	Migration of certain elements	0	12	0%
10.5 2	Mercaptobenzothiazole (MBT), Antioxidant and Formaldehyde release	0	12	0%
10.6	Bisphenol A release	0	12	0%
10.7	Colour Fastness	0	12	0%
10.8	Volatile compounds content	0	12	0%
11	Teat protectors	7	17	41%
12	Consumer Packaging	15	60	25%
13	Product Information	17	60	28%

Table 4 above gives an overview of the results of all samples according to EN 1400 and examines the different types of failures seen. When looking at the overall picture, one immediately notices that the level of non-compliances relating to consumer packaging, product information and teat protectors is noticeably higher.

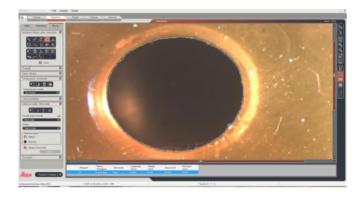
This report will now examine the mechanical failures seen with soothers in more detail. Figure 3 below analyses the types of failures seen under test clauses 8 and 9 of EN 1400 (but only those tests that were applicable to all 73 samples). It shows the highest rate of non-compliances related to impact resistance.



Figure 3 Number of non-compliant samples according to the tests within clauses 8 and 9 of EN 1400 that were applicable to all 73 soother samples



Regarding clauses 8.3 Shield and 8.4 Shield ventilation, 3 soothers (or 4%) failed each of these tests (it is interesting to note that no single soother failed both these clauses relating to the shield but were in fact 6 separate non-compliant samples). Clause 9.1.2 for Impact resistance had the highest number of failures (4 soothers or 5%), which were widely regarded as being of serious risk to a consumer as small parts resulted, which are in turn regarded as a choking hazard. Some examples of non-compliances to these clauses are shown below:



Picture 1: Failure for 8.4 Shield ventilation The ventilation holes are too small



Picture 2: Failure for 9.1.2 Impact test The shield broke and small parts were generated

Further examples of non-compliances to other tests within clauses 8 & 9 of EN 1400 are shown below:



Picture 3: Failure for 9.3.2.1 Tear Resistance of teat



Picture 4: Failure for 9.4.2 Knob, plug and/or cover retention



Picture 5: Failure for 9.5 Bite endurance endurance

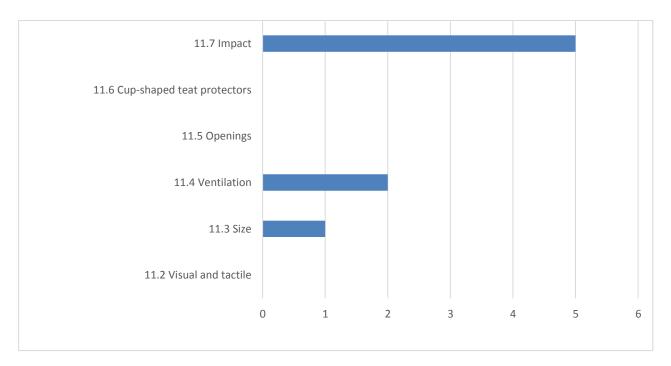


Picture 6: Failure for 9.5 Bite

Finally, the MSAs examined the correlation between those samples that were non-compliant to clauses 8 and/or 9 of EN1400 (testing mechanical and physical function of the soother) versus the teat type i.e. latex or silicone - to determine whether one material performed better than the other. Of the 73 samples tested, 58 had silicone teats and 15 had latex teats. 7 of the 58 silicone teat soothers failed under clauses 8 and/or 9 (or 12%) and 2 of the 15 latex teat soothers failed the same clauses (or 13%).

As stated above, 17 of the 73 soother samples were supplied with a teat protector (which was contained within the same package as the soother). Teat protectors are marketed by some manufacturers to protect the teat of the soother while it is not being used by the child. Where present, these teat protectors were subject to the tests set out under clause 11 of EN 1400. Four main hazards are examined: the overall size (potential choking hazard); size of ventilation holes where required (potential suffocation hazard); small parts generated from an impact test (choking hazard); and the exact shape and size of cup-shaped teat protectors (suffocation hazard). The results are given in figure 4 below, which details 8 non-compliances to clause 11 from a total of 7 teat protectors.

Figure 4 Non-compliances related to clause 11 of EN 1400 for teat protectors (all 17 samples)



As can be seen from the chart above, 5 of the 7 non-compliant teat protectors failed the impact test. The photos below give 2 examples of the resulting damage seen. Where the impact test resulted in small parts (picture 7), the soother was regarded as presenting a serious risk to consumers.



Picture 7: Failure for 11.7 Impact resistance



Picture 8: Failure for 11.7 Impact resistance

The MSA participants also checked whether the information provided with or on the soothers complied with the requirements. The results for 60 (of 73) soothers are shown in Figure 5 below.

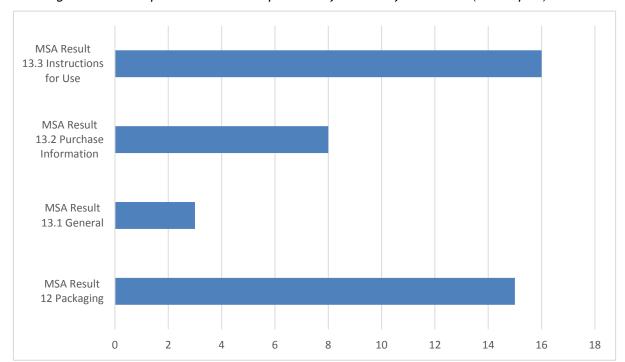


Figure 5 Non-compliances related to product information for soothers (60 samples)

In total 17 non-compliant samples for marking/purchase information/packaging were identified. In many cases, the correct language was missing (i.e. the native language of the area/country where the product was being sold) or the normative warnings were not displayed correctly.

#### 3.2.1 Results of testing 122 soother holders to EN 12586:2007+A1:2011

Table 5 gives an overview of the non-compliances found for all the 122 samples that were all tested to the current version of the EN standard for soother holders. The table clearly demonstrates that high levels of failures in relation to the general requirements of EN 12586 (mainly dimension checks) were identified - 86 soother holders (or 70%) failed one or more of the mechanical/dimensional test clauses. Analysis undertaken by the MSAs involved also showed that 53 of the 109 samples checked (49%) failed clauses 7 and/or 8 of EN 12586 - which relates to the product information part of the standard (marking, purchase information, instructions for use). Of the 45 soother holders that contained a toy or play element and were therefore also subject to EN 71-1:2014 (part 5) 31 of 45 (69%) were not compliant.

Number of non-Number of Clause Title Failure rate compliant tested samples samples 5.1 General requirements 122 86 70% 5.2 122 54 44% Mechanical requirements 5.3 Chemical requirements 0 0% 12 7 & 8 Consumer packaging 109 54 50% and product information EN 71-1 (part 5) Toys 45 31 69% All clauses 122 95 **78**%

Table 5 Distribution of non-compliant samples based on tests to EN 12586



The table above, combined with Figure 6 below, demonstrates the effectiveness of the sampling activities - that inspectors were able to select potentially non-compliant products when they chose the soother holders for testing.



Figure 6 Details of non-compliant samples according to EN 12586, per participating MSA

Table 6, below, provides a breakdown of the test failures to EN 12586 where only 27 of the 122 samples (22%) passed all of the tests.

Table 6 Number of failures attributed to particular test clauses of EN 12586 and EN 71-1 (all 122 samples)

Clause	Requirement	Number of non- compliant samples	Number of samples tested	Failure rate
6.1.1	Preparation	0	122	0%
5.1.3	Visual and tactile	7	122	6%
5.1.4.1	Finger traps	1	122	1%
5.1.5	Decoration	0	122	0%
5.1.6	Length (to CEN Interpretation Document 1510)	54	122	44%
5.1.7	Strap width	0	122	0%
5.1.8.1	Cord thickness	3	44	7%
5.1.8.2	Exposed cord length	10	24	42%
5.1.9	Maximum size of press studs, touch-and -close and	2	20	10%



	similar devices			
5.2.1	Impact resistance	25	122	20%
5.2.2	Durability of the garment fastener	6	122	5%
5.2.3	Tensile strength	6	122	5%
5.1.10	Permanent fasteners	9	122	<b>7</b> %
5.1.11	Detachable fasteners	1	4	25%
5.1.12	Supplementary components	29	41	71%
5.1.4.2	Ventilation holes (to CEN Interpretation Document 639)	48	122	39%
5.3.1	General Chemical requirements	0	12	0%
5.3.2	Requirements by material	0	12	0%
5.3.3	Migration of certain elements	0	12	0%
5.3.4	Nickel release	0	12	0%
5.3.5	Colour fastness	0	12	0%
5.3.6	Formaldehyde	0	12	0%
5.3.7	Phthalate content	0	12	0%
5.3.8	Colorants	0	12	0%
5.3.9	Primary aromatic amines	0	12	0%
5.3.10	Monomers	0	12	0%
5.3.11	Wood preservatives	0	12	0%
EN 71-1:2014 - 5.1	General requirements	11	45	24%
EN 71-1:2014 - 5.2	Soft-filled toys and soft- filled parts of a toy (if applicable)	0	45	0%
EN 71-1:2014 - 5.8	Shape and size of certain toys	30	44	68%
EN 71-1:2014 - 5.10	Small balls	1	20	5%
7	Consumer Packaging	48	109	44%
8	Product Information	54	109	50%

Table 6 above gives an overview of the results of all samples according to EN 12586 and EN 71-1. When looking at the overall picture, for all 122 samples, one immediately notices the level of the non-compliances, in particular those related to soother holder length, ventilation holes and consumer packaging/product information. Regarding the 45 soother holders also tested to the Toy Safety Directive, it is similarly concerning to note the non-compliances for the shape and size of certain toys.

This Final Report will now examine the failures for soother holders in more detail. Figure 7 below analyses the types of failures seen under Clauses 5.1 and 5.2 of EN 12586 only (but only those tests that were applicable to all 122 samples), which relate to the physical construction of the soother holders. It clearly



demonstrates that the highest rate of non-compliances is related to the length of the soother holders. This was followed by ventilation holes and impact resistance.

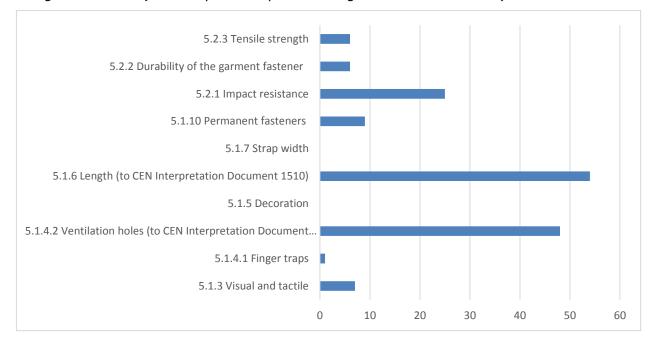
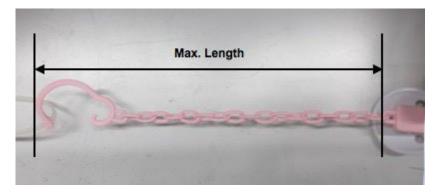


Figure 7 Number of non-compliant samples according to clauses 5.1 and 5.2 of EN 12586

Regarding clause 5.1.6 Length specifically, 54 samples (or 44%) failed this test (according to CEN Interpretation Document 639). It is concerning to note that this clause had the highest number of failures, as limiting the length of soother holders was the main reason for the EN 12586 standard in the first place. Soother holders that are too long pose a strangulation risk to consumers, so the rationale behind this test is to check for exactly that. The test is undertaken with the soother clip in the open position, in order to determine the maximum length of the product (see Picture 9 below). It should be noted that whilst some soother holders were only slightly longer than allowed (220mm  $\pm$  3.7mm), some were much longer and therefore posed a serious risk to consumers (the longest measured was 496mm, more than twice the 220mm permitted).



Picture 9: How clause 5.1.6 Length is applied

High levels of non-compliances to clause 5.1.4.2 Ventilation holes (according to CEN Interpretation Document 1510) was also seen, with 48 soother holders (39%) failing to meet the standard. The idea behind this test clause is to prevent an infant from choking whilst laying on the floor with the soother holder in its mouth. Pictures 10 and 11 show non-compliances for supplementary components in the form of beads (they are un-ventilated). Pictures 12 and 13 show non-compliant garment fasteners, where the



ventilation holes are either too small (Picture 12) or a 25mm diameter area remains un-ventilated (Picture 13).



Picture 10: Failure to 5.1.4.1 Ventilation (supplementary beads)



Picture 12: Failure to 5.1.4.1 Ventilation (ventilation holes are too small)



Picture 11: Failure to 5.1.4.1 Ventilation (supplementary beads)



Picture 13: Failure to 5.1.4.1 Ventilation (un-ventilated area exceeding 25mm)

25 samples (or 20%) of the soother holders failed for impact resistance. When a test weight was dropped onto them, the products broke in some way. Any and all breakages are regarded as a failure to the standard, but the MSAs then tested the broken parts that resulted in the 'small parts cylinder' (a standard piece of test equipment used throughout EN standards for children's products). When any broken part fitted fully inside the test cylinder, the product was rated 'serious risk' as choking could result. See Pictures 14 to 17 below for examples.

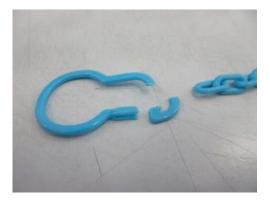


Picture 14: Failure to 5.2.1 Impact



Picture 15: Failure to 5.2.1 Impact





Picture 16: Failure to 5.2.1 Impact



Picture 17: Failure to 5.2.1 Impact

Further examples of non-compliances to other tests within clause 5.1 and 5.2 of EN 12586 are as follows:



Picture 18: Failure for 5.1.3 Visual inspection



Picture 19: Failure for 5.1.4.1 Finger entrapment



Picture 20: Failure for 5.2.2 Garment fastener test fastener



Picture 21: Failure for 5.2.3 Tensile

As with soothers above, the MSA participants also checked whether the information provided with or on the products complied with the requirements. The results are shown in Figure 8 below.

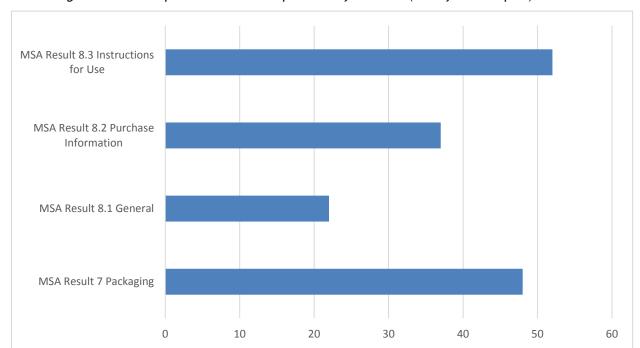


Figure 8 Non-compliances related to product information (109 of 122 samples)

Again, a high percentage of non-compliances were seen. 52 of the 109 examined (or 48%) failed for instructions for use alone. It is frustrating for the MSAs to see such a high volume of non-compliances in relation to these test clauses, as it should be simple for manufacturers to meet the standard in these regards.

The generally high number of non-compliant soother holder samples encouraged the participants to examine the following 2 aspects further: the country of origin for all non-complying samples (the results of which can be seen in Figure 9 below) and the number of soother holders that demonstrated multiple non-compliances according to the laboratory testing (see Figure 10).

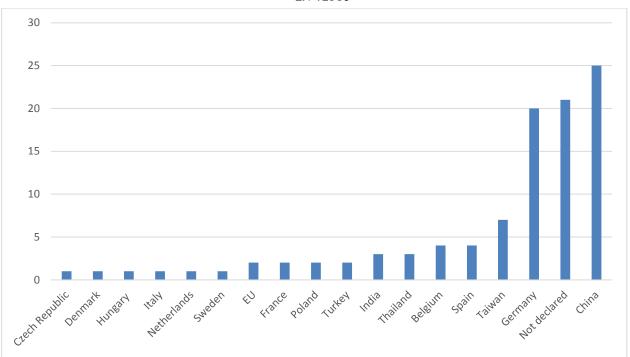
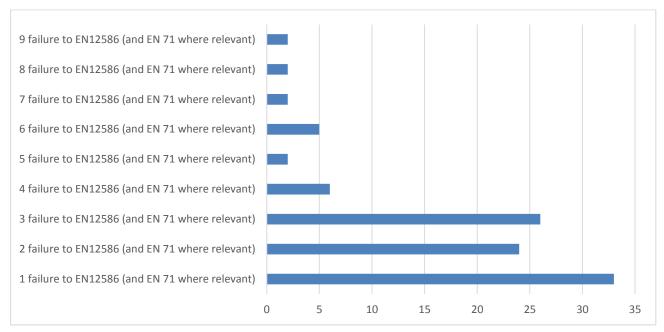


Figure 10 Country of origin for those 95 soother holders that were non-compliant to EN 12586

Figure 11 Number of soother holders that demonstrated multiple non-compliances according to the physical laboratory testing (i.e. excluding non-compliances to clauses 7 & 8)



As can be seen above, the majority of non-compliant soother holders exhibited one, two or three physical failures to the standard. A small number of samples showed a large quantity of non-compliances, with six samples failing a total of 7, 8 or 9 clauses.

Finally, the participants undertook some analysis on those soother holders that contained a toy or play element. A total of 45 samples were also subject to the Toy Safety Directive and therefore the relevant tests contained within EN 71-1:2014 part 5 as follows:

- 5.1 Toys intended for children under 36 months General requirements
- 5.2 Soft-filled toys and soft filled parts of a toy
- 5.8 Shape and size of certain toys
- 5.10 Small balls

As can be seen in Table 6 above, high numbers of non-compliances were seen for clause 5.1, with 11 failures (or 24%) and clause 5.8, with 30 failures (or 68%).

Under clause 5.1 the soother holders were subject to a number of abuse tests (torque test, tension test, drop test, impact test, compression test), the idea being to replicate the hard life of a toy in the hands of a young child. After the tests, the soother holders were checked for any resulting sharp edges/points or small parts that had become detached (which would then fit into the small parts cylinder as explained above). Pictures 22 and 23 below show some examples of failures to this clause.



Picture 22: Failure for 5.1 General



Picture 23: Failure for 5.1 General

The tests under 5.8 are designed to reduce injury hazards by examining the dimensions and certain other properties associated with spherical or circular elements of soother holders (in this case). The majority of issues seen under this clause related to the garment clips of the soother holders as can be seen in Pictures 24 and 25.



Picture 24: Failure for 5.8 Shape and size



Picture 25: Failure for 5.8 Shape and size

Overall, for the 45 soother holders subject to the toy standard, only 9 were regarded by the MSAs as being fully compliant to the relevant standards.

#### 3.3 Conclusions of testing (all 73 soothers and 122 soother holders)

Overall, 51 of the 73 products examined were fully compliant according to the MSA participants.

The results for soother holders were more disappointing, with 95 of 122 failing the current standard(s). A non-conformity rate of 78% for soother holders is concerning, but also demonstrates that the sampling process was very effective i.e. the MSAs successfully identified potentially non-compliant products when sampling.

The same trend can be seen (i.e. a large number of non-compliances) when we examine the information provided on or with all of the products. The share of non-compliant products is high, with 17 of the 60 soothers that were checked and 52 of 109 soother holders similarly examined demonstrating non-compliances to the clauses relating to information on/supplied with the products. Errors with marking, instructions or other product information was one of the indicators used by the inspectors when selecting and sampling potentially non-compliant products.

We note once again that these results do not represent the actual safety level of the European market.



## 4 Risk Assessment & Action Taken

#### 4.1 The Risk Assessment Method

The representatives from the participating authorities, DG JUST and PROSAFE met together with the expert staff from the test laboratory to review and evaluate the test results received. The participating MSAs then developed risk assessment templates for many of the scenarios presented (using the on-line risk assessment application <a href="http://ec.europa.eu/consumers/consumer-safety/rag/public">http://ec.europa.eu/consumers/consumer-safety/rag/public</a>). These included:

- EN 1400 8.3: Shield
- EN 1400 8.4: Shield ventilation
- EN 1400 9.12: Impact
- EN 1400 11: Teat protectors
- EN 12586 5.1.4.2: Ventilation (of a garment fastener)
- EN 12586 5.1.6: Length (for a soother holder measuring 225mm, so 5mm longer than allowed)
- EN 12586 5.1.6: Length (for a soother holder measuring 260mm, so 35mm longer than allowed)
- EN 71-1 5.1: General requirements (with small parts resulting)

Moreover, this work was later completed by the participants for each of the non-compliant samples that they supplied.

#### 4.2 The Risk Assessment Results

The participating MSAs assessed the risk presented by all the identified non-compliances using the methodology outlined above. The conclusion for soothers was that 6 products carried a medium to serious risk. The results can be seen in table 7.

Table 7 The risk level associated with the identified non-compliances for soothers (all 73 samples)

Risk level	Number of samples	Percentage
Compliant/Remedial non-compliance	50	68%
Minor non-compliance - or low risk	15	21%
Major non-compliance - or medium risk	3	4%
Serious non-compliance - or serious risk	3	4%

The risk level associated with the non-compliant soother holders was similarly assessed. A far higher level of risk was defined, with 61 of the 122 samples (or 50%) regarded as presenting a medium to serious risk to consumers.



Table 8 The risk level associated with the identified non-compliances for traditional soother holders (77 samples)

Risk level	Number of samples	Percentage
Compliant/Remedial non-compliance	16	21%
Minor non-compliance - or low risk	21	27%
Major non-compliance - or medium risk	27	35%
Serious non-compliance - or serious risk	13	17%

Table 9 The risk level associated with the identified non-compliances for soother holders with a toy or play element so also subject to EN-71 (45 samples)

Risk level	Number of samples	Percentage
Compliant/Remedial non-compliance	9	20%
Minor non-compliance - or low risk	16	36%
Major non-compliance - or medium risk	7	16%
Serious non-compliance - or serious risk	13	29%

#### 4.3 Action and Measures taken

As a result, the participating MSAs took enforcement actions on 25 of the 73 soothers and 94 of the 122 soother holders charted above. In some cases, the actions and measures taken were straightforward (for example - an Economic Operator given a notice to adapt the instructions) but in other cases the follow up actions required were both complicated and numerous (for example - some products were banned from sale, withdrawn, recalled and placed on RAPEX under Article 12). In tables 10, 11 and 12 below only the most severe action undertaken has been recorded (so each product is listed once only).

Table 10 Overview of measures taken against the non-compliant soothers (all 73 samples)

Actions taken	Number of samples
Still under evaluation	1
No action	46
Later accepted as compliant by the MSAs (following counter expertise)	1
Minor measures or notification to economic operator	19
Sales ban	0
Withdrawal from the market	1
Recall from consumers	2
RAPEX A11 notifications made	1
RAPEX A12 notifications made	2

Table 11 Overview of measures taken against the non-compliant soother holders (all 122 samples)

Actions taken	Number of samples
No action	25
Minor measures or notification to economic operator	26
Later accepted as compliant by the MSAs (following counter expertise)	1
Voluntary action	1
Action pending	2
Pecuniary sanction (fine to seller)	3
Sales ban	11
Withdrawal from the market	12
Recall from consumers	13
RAPEX A11 notifications made	9
RAPEX A12 notifications made	19

Table 12 Overview of all measures taken against the non-compliant products as a result of this JA (all 195 samples)

Actions taken	Number of samples
Still under evaluation	1
No action	71
Later accepted as compliant by the MSAs (following counter expertise)	2
Minor measures or notification to economic operator	45
Voluntary action	1
Action pending	2
Pecuniary sanction	3
Sales ban	11
Withdrawal from the market	13
Recall from consumers	15
RAPEX A11 notifications made	10
RAPEX A12 notifications made	21

The actions mentioned in the tables above have the following meaning:

- **Still under evaluation.** The results of our tests were queried by the Economic Operator and the product has been sent for counter analysis, the results of which are still awaited.
- No action. No action was necessary because no safety issues were identified with the product, or the risk is so low that no action is required.
- Later accepted as compliant by the MSAs. The results of our tests were queried by the Economic Operator who went on to prove that their product was in fact compliant to the relevant standard/s.
- Minor measures. To prevent future occurrences of the same problems with their product the
  economic operator takes measures following directions from the market surveillance authority.
  The measures could be minor design changes, minor changes in production or quality control,
  minor update of marking or instructions, etc.
- **Voluntary action.** The Economic Operator undertook relevant measures upon learning of the non-compliant product of their own accord.
- **Pecuniary sanction.** The MSA levied a financial sanction against the seller of the non-compliant product.
- Sales ban. The product is prohibited from sale permanently or until certain conditions are met.



- Withdrawal from the market. This measure is defined in the General Product Safety Directive (GPSD) (Directive 2001/95/EC<sup>6</sup>). The distribution, display and the offer of a product which is dangerous to consumers are stopped.
- **Recall from consumers.** This measure is defined in the GPSD (Directive 2001/95/EC)<sup>7</sup>. Any means aimed at achieving a return of a product that has already been supplied or made available to consumers.
- RAPEX A11 notifications made. The product has been placed on the EU's Rapid Alert System for dangerous non-food products under Article 11<sup>8</sup> of the GPSD, for those products posing a risk classified as less than serious.
- RAPEX A12 notifications made. The product has been placed on the EU's Rapid Alert System for non-food dangerous products under Article 12<sup>9</sup> of the GPSD as the products represent a serious risk to consumers.

#### 4.4 RAPEX

As can be seen in Table 12 above, up to the time of writing this report, the participating MSAs have made eleven A11 RAPEX notifications and twenty-one A12 RAPEX notifications as a result of this Joint Action. Not all those soothers and soother holders that were found to be of serious risk were notified within RAPEX, for a number of logical reasons that include:

- Economic operators communicating with all previous purchasers in certain cases the products were exclusively sold online and the Economic Operator could guarantee that they had communicated with all customers of the products
- Some 'borderline' products being notified under Article 11 for information (and not Article 12)
- On-going discussions with Economic Operators regarding the results of testing, therefore some Article 11 RAPEX alerts are still pending

#### 4.5 Conclusions of the Joint Action and associated impacts made

The overall results of this Activity showed that 52 out of the 73 soothers and 25 out of 122 soother holders passed all of the tests according to the laboratory and MSAs' examinations under the various clauses of the relevant standards. These results, combined with the risk analysis undertaken demonstrate the following points:

- the participating MSAs have improved their knowledge of the market for soothers and soother holders
- the participants now better understand the technical requirements and testing of such items
- the sampling process was very effective, the inspectors were able to identify potentially noncompliant products in their sampling process
- there appears to be a number of unsafe soothers and a significant number of unsafe soother holders available on the EU market, which is a cause for significant concern

<sup>&</sup>lt;sup>6</sup> General Product Safety Directive (GPSD) (Directive 2001/95/EC)

<sup>&#</sup>x27; Ibidem

<sup>&</sup>lt;sup>8</sup> Commission Decision 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) (notified under document C (2009) 9843)

<sup>9</sup> Idem.

- the current standards for soothers and soother holders are not as clear as they could be in some areas (as detailed below)
- an increasingly uniform approach was used to evaluate and follow up on test results
- numerous risk assessments templates were developed for future use by all EU states
- in a few cases the samples failed the laboratory testing according to the relevant standards, but the products were not regarded as being dangerous according to the MSAs risk assessments, just as being of poor quality

As an overall consequence of the activity, the participants have undertaken the following actions on the 195 products sampled in total:

- 31 RAPEX (A11 and A12) notifications made
- 39 models of soothers and soother holders were recalled, withdrawn or sales bans put in place
- 45 products required a notice, or some guidance to be given to the Economic Operator
- Regular liaison maintained with the GPSD Committee via the European Commission Directorate-General for Justice and Consumers (DG JUST) representatives who attended all 6 meetings for this Joint Action
- Regular cooperation with stakeholders, in particular CEN (European Committee for Standardisation), ANEC (European Consumer Voice in Standardisation) and ENPC (European Nursery Products Confederation)
- Formally communicated the findings of this project to the above parties
- Developed checklists for Market Surveillance Inspectors and Customs Authorities, to be used as guidelines when undertaking product evaluations
- Secured press coverage on dangerous products (see Chapter 7 below for examples)
- The MSAs from BE, BG, IS and LT published their findings on their own websites
- DK will publish the results as soon as this report is uploaded to the PROSAFE website, allowing them to link their communications to it
- Notified many products within ICSMS
- A representative of the working group, namely the Belgian Activity Leader attended the CEN/TC 252/WG 5 meeting (on 12 and 13 April 2018) in order to present the results of this project. The MSAs were in a unique position to provide feedback, as never before have 195 soothers and soother holders been examined together. This enabled the JA to provide detailed feedback on the current versions of EN 1400 and EN 12586 (as detailed below):

#### EN 1400 for soothers:

- ✓ an amendment to the wording regarding the need to remove any trapped water before testing
  - further clauses need to be worded more clearly
- ✓ further tests or warnings for soothers with aged latex teats. The addition of an expiration date was advised
- ✓ a warning is added to the products reminding parents/carers not to hand teat protectors to children perhaps via a pictogram?

#### EN 12586 for soother holders:

✓ some queries arose regarding the ventilation holes - some inconsistencies were experienced between the measurement advice contained within EN 12586 and CEN TR 16411:2014. Also, some discrepancies between the wording in the test clause (EN 12586 clause 5.1.4.2) and the annex (B10)



- ✓ a clarification of the length test is needed, which clearly states that the clip should be in the open position during the test. The MSAs also recommend that a measurement of time is also included within the test method
- ✓ the test for exposed cord length needs additional explanation regarding the exclusion of the
  attachment loop, as accredited laboratories are undertaking this test incorrectly
- ✓ small parts resulting from any test are not currently placed into the small parts cylinder (a common piece of test equipment throughout child care articles standards that assesses the risk associated with the broken part in question i.e. whether it is a choking hazard)
- ✓ when undertaking the tensile test, the method of clamping and the type of clamp used by
  the test laboratory can have an effect on the results. Naming the test clamp is advised
  under this clause
- ✓ the current EN makes reference to EN 71-3:1994 which is obsolete
- ✓ the normative warnings are not given in the Lithuanian language

EN 12586 for soother holders when being used in combination with EN 71 for those with a toy or play element:

- √ inconsistencies exist regarding the drop test, EN 12586 states a test method with 5 drops, EN 71 askes for only 1 drop
- ✓ concerning the ventilation of permanent fasteners a definition regarding the fastener being a rigid element/or not is required a variation exists between EN 71 and EN 12586
- ✓ the MSAs experienced some garment clips that meet the requirements of EN 12586 but not EN 71
- √ when examining the supplementary components of soother holders, an
  undamaged/unreleased part of a soother holder may meet the requirements of EN 12586,
  but at the same time fail to meet the requirements of EN 71
- ✓ a contradiction exists between clause 6.1.9 of EN 12586 and clause 5.8 of EN 71-1. Both standards use the same templates 1(A) and 2(B) but the test methods are different
- ✓ a second contradiction exists regarding clause 5.8 of EN 71-1. The test is not applied to rigid elements having a major dimension equal to 30 mm or less, and according to Annex A.31 the test should be carried out in the delivered condition. However, according to clause 6.1.2 of EN 12586 (for permanent fasteners), this test will be carried out after the tensile strength test
- ✓ the final contradiction relates to the tensile tests under EN 12586 and EN 71-1. Clause 5.2.3 of EN 12586 states that following the tests for impact resistance and the durability of the garment fastener, the integrity of the soother holder should be checked according to clause 6.1.7 no part should break, tear or loosen. Clause 5.1 of EN 71-1 states that the tensile requirements do not apply to certain materials. If the soother holder is not a toy but during the test loose parts occur, which requirements should be followed? EN 12586 states that no part should break, tear or loosen but the requirements for EN 71-1 depend on the material used to determine whether the tensile test should be performed or not
- ✓ EN 12586 states that 'a soother holder should not be used as a toy or a teether' but some are designed to be toys as well (as covered above in this report)
- ✓ lastly some inconsistencies exist regarding soother holders with a toy/play element which become a toy according to the introduction of EN 12586, but should not be used as such according to the warnings clause of the same standard

#### In general:

- ✓ a number of clauses could be worded a little differently to help with the interpretation of the test methods by laboratories
- ✓ some concerns remain as to why accredited labs are undertaking some of the test clauses incorrectly



## 5 Liaisons

As per previous activities on Child Care Articles, the participating authorities wanted to involve as many stakeholders as possible. Open sessions for external stakeholders were organised during the first meeting, to discuss the goals of the activity and any known issues with soothers and soother holders, and also, during the final meeting, to present our findings from this project.

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 Standardisation Bodies make up the CEN membership and they represent CEN in their country, besides various other affiliates. In particular, the specific CEN Working Group Technical Committee who are responsible for the provision of EN standards (TC 252/WG5 for soothers and soother holders, as reported above).

#### • ENPC - European Nursery Products Confederation

ENPC is the trade association for the European child care industry, representing the industry in Europe with the objective of creating a united voice to European Institutions and National administration as well as participating actively in relevant European policy for the sector. ENPC is composed of eight national associations, each representing small-medium enterprises and large industry leaders in the sector.

#### 5.1 Involvement of Customs

The liaison between Customs Authorities and the Activity was well intentioned, but almost impossible to deliver as no specific TARIC code exists for either soothers or soother holders, so they are incredibly difficult for Customs to detect at the border.

Consequently, the Activity group drafted checklists for Customs Authorities' use, one for soothers (subject to EN 1400) and one for soother holders (subject to EN 12586). They were of simple design, making them easy to complete and therefore provide straightforward indicators regarding the products' compliance and safety.

#### 5.2 Other Liaisons

The Child Care Articles Activity again maintained close links with DG JUST, who participated in all activity Meetings. This ensured that the EC were fully involved and up-to-date with the activity at all times, whilst ensuring that information was able to be shared quickly amongst the MSAs and DG JUST as and when necessary.



In addition to the 6 meetings associated with this specific JA, the 13 participating MSAs also had the opportunity to attend two market surveillance workshops allowing them to discuss any experiences/challenges, share good practices, etc. with all the other Member States involved in JA2015.

The CCA5 participants also liaised with the JA2015 Risk Assessment Group regarding the best way to perform risk assessment on relevant products.

### 6 Evaluation, Lessons Learned

Looking back over the project, it can be concluded that the objectives were met (where possible). Significantly, work regarding 'to ensure that soothers and soother holders are safe in use' has resulted in some detailed feedback to the relevant standards committee (as detailed in 4.5 above).

Beyond the work with CEN on EN 1400 and EN 12586 we can conclude that:

- Lessons learned on previous CCA JAs were applied saving time during the planning, sampling and tendering processes
- Joint testing of products enabled the MSAs involved to examine a large quantity of soothers and soother holders and take measures on many products across the EU
- Selecting a product with a specific TARIC code may enable a joint project with some Customs Authorities
- Economic Operators need to have increased focus upon the warnings, markings and instructions of these products
- The participants again suggest that some focus on lab testing within CCA is perhaps needed with accredited labs undertaking testing using incorrect methods
- Input from stakeholders is extremely valuable, maintaining a healthy dialogue between all stakeholders helps to identify and prevent possible future safety issues and at the same time identify practical solutions

#### 6.1 Looking Ahead

Finally, the participating MSAs felt it was important that the good work undertaken on JA 2015 CCA5 was not simply forgotten once the Activity was finalised. As a consequence, those Authorities who took part plan to continue their work on soothers and soother holders as follows:

- Those cases that are still pending/on-going will be finalised
- Dialogue with CEN/TC 252/WG 5 will continue beyond the end of the Activity (if further support is required)
- MSAs will continue to monitor soothers and soother holders within their markets, and raise any ongoing concerns via the CSN
- DK are considering their own follow up market surveillance action on soother holders
- CY will be producing leaflets for Economic Operators and consumers, following up all RAPEX notifications made on soothers and soother holders in the past two years, sampling and testing of additional soother holders, carrying out inspections in relation to marking/purchase information and instructions for use, producing guidance/information documents for their inspectors
- LT will share the results of this JA with businesses as soon as this Final Report is published by holding seminars or some such similar communication strategy. The results will also be published in the national press. In addition, the MSA will continue to monitor soothers and soother holders within their market and have included them in their own annual inspection plans for future years
- BG are preparing detailed guidelines for their inspectors, allowing them to carry out inspections of additional soothers and soother holders



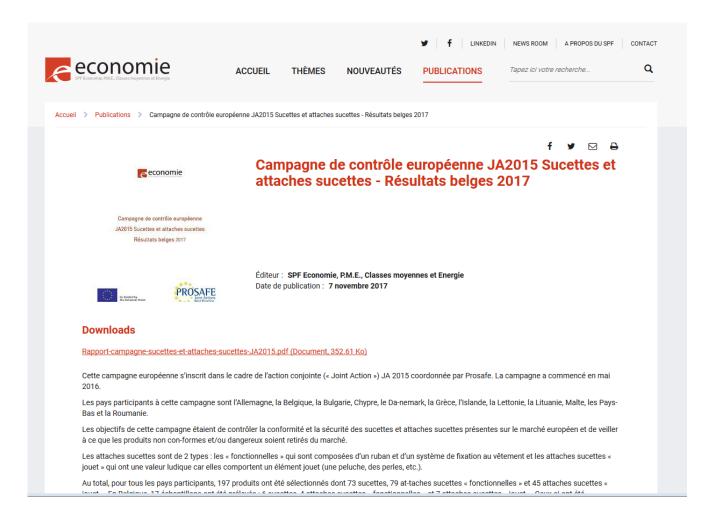
### 7 References

The full list of references in the text is given below:

- 1. Grant Agreement Number 705038 JA2015 GPSD
- 2. European Commission's Risk Assessment Guidelines tool: <a href="https://ec.europa.eu/consumers/consumer-safety/rag/">https://ec.europa.eu/consumers/consumer-safety/rag/</a>
- 3. EN 1400:2013 +A1:2014 European Standard for soothers
- 4. EN 12586:2007 + A1:2011 European Standard for soother holders
- 5. EN 71:2014 Safety of toys
- 6. General Product Safety Directive (GPSD) (Directive 2001/95/EC)
- 7. Commission Decision 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) (notified under document C(2009) 9843)

# Annex 1 - Examples of Press Releases or Media Releases

The following media update was made by Belgium regarding soothers and soother holders and communicated via the MSA's own website:



The following media updates were made by Iceland regarding soothers and communicated via the MSA's own website:

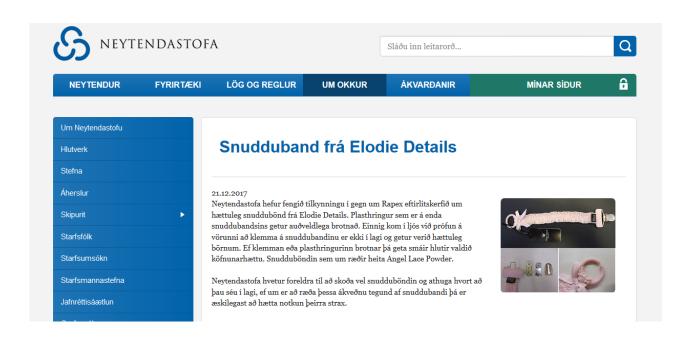






The following media updates were made by Iceland regarding soother holders and communicated via the MSas own website:

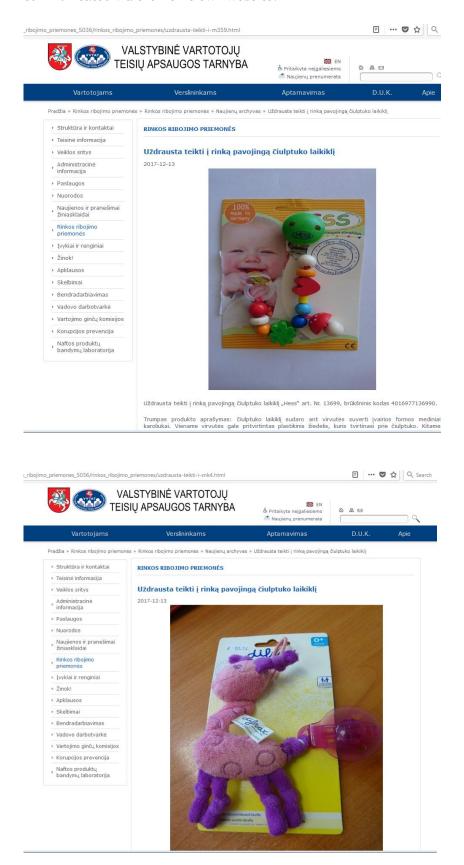








The following media updates were made by Lithuania regarding soothers and soother holders and communicated via the MSA's own website:







# **Annex 2 - Examples of Press Coverage Obtained**

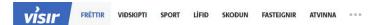
The following media coverage was obtained by Belgium regarding soothers and soother holders:



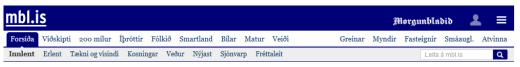




The following media coverage was obtained by Iceland regarding soothers:







Innient | mbl | 20.11.2017 | 11:18 | Uppfært 13:24

# Sólarljós hefur skaðleg áhrif á snuð



Snuð eru til af öllum gerðum, mbl.is/Golli

Skoðun Neytendastofu á snuðum fyrir börn hefur leitt í ljós að hérlendis hafa verið til sölu vörur sem hafa ekki verið í lagi og jafnvel hættulegar börnum. Skoðuð voru yfir 900 snuð af 74 tegundum. Kom í ljós að 27% af snuðunum voru ekki allar merkingar í lagi. Þetta kemur fram á vef Neytendastofu.

Könnunin leiddi í ljós að á markaðnum eru snuð sem eru "hókstarflega hættuleg fyrir bórn en þau hafa nú verið innkölluð og tekin af sölu. Um var að ræða silicon snuð frá framleiðendunum Camera og Cangaroo. Einnig hafa verið tekin af markaði snuð frá Lovi, BabyOno og frá NOVILAB snuð sem heita Marine. Allar þessar tegundir af snuðum eru það er Neytendastofa best veit ekki seldar á Íslandi." Þetta kemur jafnframt fram í tilkynningu.

Neytendastofa skoðaði í samstarfi við eftirlitsstjórnvöld á Evrópska efnahagssvæðinu snuð og snuðhönd

Bent er á að mikilvægt sé að kaupa snuð sem hæfir aldri barnsins því tútturnar eru misjafnar og verður m.a. að taka til greina bitkraft tannanna í börnum. Passa þarf að sjóða snuðið áður en það er notað í fyrsta skipti og þrýsta vel vatn-

inu úr túttunni ef það á við. Í hvert sinn sem á að nota snuð á að toga í túttuna til að vera viss um að hún sé í lagi og ef það eru komin bitför þá á að henda því strax.



The following media coverage was obtained by Iceland regarding soothers:



Innlent | mbl | 21.12.2017 | 10:50

## Hættuleg snuddubönd



hættuleg börnum.

Neytendastofa hefur fengið tilkynningu í gegnum Rapex-eftirlítskerfið um hættuleg snuddubönd frá Eiodie Details. Plasthringur sem er á enda snuddubandsins getur auðveldlega brotnað. Einnig kom í ljós við prófun á vörunni að klemma á snuddubandinu er ekkl í lagi og getur verið

