Joint Action 2015 GPSD

Joint Market Surveillance Action co-funded by the European Union

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Final Technical Report

CHEMICAL RISKS IN PLASTICISED TOYS

Covering the period April 2016 - February 2018

Co-funded by
the European Union

PROSAFE Joint Actions Best Practice

March 2017

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Abbreviations & Chemical Acronyms

ADCOs	Administrative Cooperation Groups of market surveillance authorities
DG-GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG-JUST	Directorate-General for Justice and Consumers
DoC	Declaration of Conformity
ECHA	European Chemicals Agency
GPSD	General Product Safety Directive 2001/95/EC
JA2015	Joint Market Surveillance Action 2015, GA no. 705038, coordinated by PROSAFE with an implementation time-frame of April 2016 up to June 2018
MRA	Mutual Recognition Agreements
MS	Member States
MSA/s	Market surveillance authority(ies)
PROSAFE	Product Safety Forum of Europe
RAPEX	The EU Rapid Alert System for dangerous non-food products
RCR	Risk Characterisation Ratio
REACH	European Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals
Toys Directive	Directive 2009/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 June 2009 on the safety of toys
TIE	Toys Industries for Europe

List of acronyms for various chemicals:

BPA	bisphenol A
PAH	polycyclic aromatic hydrocarbon
SCCP	short chained chlorinated paraffins

Phthalate Acronyms	**Substance Name**
DEHP	bis(2-ethylhexyl) phthalate
DBP	dibutyl phthalate
BBP	benzyl butyl phthalate
DINP	diisononyl phthalate
DIDP	di-'isodecyl' phthalate
DNOP	di-n-octyl phthalate
DnHP	di-n-hexyl phthalate
DPP	dipentyl phthalate
DIBP	diisobutyl phthalate
DIHP	diisohexyl phthalate

Executive Summary

A joint market surveillance activity was organised across a number of European countries, mainly focusing on risks associated with chemicals in plasticised toys. This activity was part of a much larger project, the "Joint Market Surveillance Action on GPSD Products – JA2015" (JA2105). 35 market surveillance authorities from 27 Member States participated in JA2015, which was co-funded by the European Union and coordinated by PROSAFE.

Plasticised toys are toys made of soft plastic and various chemicals could be used in the manufacturing process for various reasons. Phthalates, SCCPs (short chained chlorinated paraffins), PAHs (Polycyclic aromatic hydrocarbons), BPA (Bisphenol A) and also certain elements such as lead, cadmium and organic tin can all be very dangerous to children if the concentrations and in some cases the migration of these chemicals, exceed the respective limits as required by legislation. For this reason, a number of toys were sent for testing to check whether such toys were in compliance with the respective legislation.

The activity was undertaken by seventeen market surveillance authorities under PROSAFE's coordination. The following countries from within the European Economic Area participated in the activity: Belgium, Czech Republic, Estonia, Germany, Greece, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Spain, Sweden and The Netherlands.

All types of economic operators were inspected including manufacturers, importers and all kinds of distributors. Special attention was given to low-cost toys and to toys which lacked proper markings and warnings since from previous experience these have been found to present the highest levels of risk.

In total, 255 toy samples were sent for testing. These were split up into four main categories. The largest sector was plastic dolls, which made up 48% of all samples tested, followed by bath/squeezable toys (27%), plastic books (13%) and inflatable toys (12%). It is worth noting that 130 samples (51%) were collected via traditional market surveillance activities, another 47 samples (18%) were collected with assistance from customs authorities and 78 samples (31%) were collected via online sales.

The testing criteria for each of the chemicals focused upon was finalised with support from the laboratory chosen for testing these samples. Various standards or analytical methods were utilised for this purpose.

The positive results from testing show that there were no detected non-compliances related to migration of lead, cadmium or organic tin in these plasticised toys. This is worth noting especially since lead was a major concern for market surveillance authorities some years back. Additionally, there were no non-compliances related to the chemical, polycyclic aromatic hydrocarbon (PAH).

On the other hand, the level of non-compliance with regards to phthalates, SCCP and BPA, still needs to be better controlled so as to ensure that economic operators only place safe toys on the Single Market. With regards to phthalates, DEHP and DINP were the two predominant phthalates which were found in concentrations higher than the respective limits stipulated in legislation.

Aware of the difficulties faced by national authorities with regards to adopting the best approach for risk assessment, a few months before the end of the activity the European Commission issued some guidance to help authorities to take a much simpler approach to risk assessment for future surveillance actions. It is worth noting that 48 out of the 49 toy samples that were non-compliant were determined to present a "serious risk". There was also one other sample which was non-compliant. However, this was considered to be a border-line product. This sample was assessed by the participating authorities to be a GPSD product rather than a toy. The respective authority still took the necessary action and formal measures were taken accordingly.

A sales-ban was issued in respect of 71% of the non-compliant toys and a recall was issued for an additional 25% of these toys. It is worth noting that out of the 48 samples with a serious risk, 43 Rapid Alert Notifications (88%) have been issued or are about to be issued in RAPEX, the European Commission's rapid alert system for dangerous non-food products. The information concerning each dangerous product notified within this rapid alert system is publicly available on the European Commission website which is being updated continuously in order to ensure that consumers are always aware of any particular dangerous products found within the Single Market.

This market surveillance activity provided added value in various ways. With so many Member States working together, the product activity was a truly pan-European exercise, which has provided a platform for sharing best practices, experiences and expertise amongst market surveillance authorities. The European Union's funding ensured that the number of samples tested exceeded the number that individual Member States could otherwise afford to test. Moreover, due to economies of scale, the unit costs of testing were driven down, helping to perform more tests with the available resources available. Member States also discussed their risk assessment methods, promoting a more consistent approach. Overall this market surveillance activity has made a significant contribution to achieving a higher level of consumer protection and a more level playing field for all economic operators throughout Europe.

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 accredited laboratories. The test focused on those safety requirements that have the largest impact on consumer safety.

1 Introduction

This chapter presents a short extract of the project description. The full description can be found in the respective Grant Agreement [1].

The report contains the following sections:

- Chapter 1 of this final technical report sets out the basic facts about this activity on chemical risks in toys. The main phases of the activity and the timeline are described in this section.
- Chapter 2 explains how a test laboratory was chosen for this activity and indicates how sampling was carried out by the market surveillance authorities (MSAs) participating in the activity.
- Chapter 3 summarises the test results and focuses on the non-compliances found within the tested samples. Additionally, some information is given on the checks performed by MSAs in relation to the respective declarations of conformities and markings of the samples tested.
- Chapter 4 presents the way the participating authorities assessed the risks associated with the non-conformities detected and describes the follow-up action and measures taken by the MSAs.
- Chapter 5 describes the number of liaisons maintained during this activity.
- Chapter 6 highlights the main lessons learnt at technical and administrative levels. It also includes a section on the way forward.

Failed Samples - It is important to note that a 'failed' sample in this Final Technical Report denotes a legislative 'non-compliance' in that particular sample according to the tests performed by the laboratory in line with section 3.1 of this report. This means that the limit value of one or more chemicals has exceeded the legislative limit after also subtracting the respective uncertainty value from the test result.

1.1 Participating Member States

The activity was undertaken by seventeen MSAs from as many countries from within the European Economic Area (EEA): Belgium, the Czech Republic, Estonia, Germany, Greece, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Spain, Sweden and The Netherlands.

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

1.2 Overview of Key Staff in the Activity

The Activity Leader was initially Kari Lokken from Norwegian Environment Agency (Norway). Later she was succeeded by Camilla Westlund from the Swedish Chemicals Agency (Sweden). The Activity Leader was supported by the PROSAFE Consultant, Noel Toledo, acting as Activity Coordinator.

1.3 Main Objectives

The general objectives of the activity were to continue to create conditions whereby Member States (MS) could cooperate successfully on market surveillance activities and to co-ordinate a number of product activities sharing the results of the activities with the largest number of MS 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.

1.4 The volume of the Activity

In line with the Grant Agreement, 255 samples of plasticised toys were tested for various types of chemicals.

The 255 samples have been categorised into four main sectors as can be seen in Figure 1 below. The largest sector was plastic dolls, which made up 48% of all samples tested, followed by bath toys/squeezable toys (27%), plastic books (13%) and inflatable toys (12%). The plastic dolls were, if possible, collected with the help of the customs authorities. Further detailed information is given about this in section 2.2.

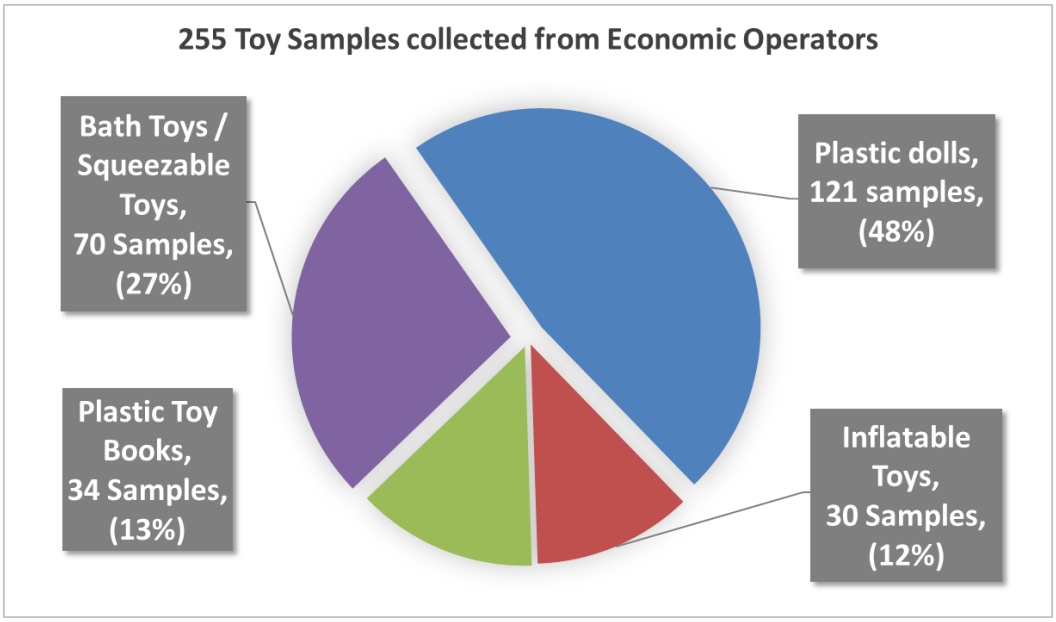


Figure 1 - The number of samples collected from each of the four main toy categories

1.5 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; what criteria would be applied when selecting the specific samples; and how many items should be taken of each product.

- Sample products

  The MS collected products according to the sampling criteria. This meant that the MSAs visited manufacturers, importers, wholesalers and retailers to collect these plasticised toys. Customs authorities were also involved by some MS. This was fully coordinated and information was collected about all the toy samples sent for testing.

- Test products at a laboratory

  The activity issued a call for tender that was published on the PROSAFE website. Based on a thorough evaluation, the MS selected an appropriate laboratory to which their samples were sent. In turn the laboratory submitted test reports after the testing had taken place. Each participant received the test reports for their respective toys tested at the laboratory.

- Risk assessment

  MSAs have several times raised the difficulties they have to carry out a risk assessment as required by Commission Decision 2010/15/EU to assess the level of risk when the hazard is the presence of a chemical. During the implementation phase of this activity, the Sub-Group Chemicals of the Toy Expert Group developed a spreadsheet on how to perform risk assessment of certain phthalates. The spreadsheet was tested and adapted with some simplified simulations developed through this activity. As national authorities found this approach complex to apply and very time-consuming, a few months before the end of the activity the European Commission gave an outline recommendation to all MSAs, including the participants of this activity, on how to establish the level of risk based on existing legislative limits on certain chemicals. This was taken into account for those Member State who had not yet performed a risk assessment on the non-compliant samples collected in this joint action.
- Follow-up on non-compliant products and exchange information on follow-up activities.

  The Member State authorities took the necessary action and measures in their countries, in liaison with the respective economic operators. Appropriate measures and follow-up action was taken to ensure that any unsafe toys were removed from the market. Additionally, action was taken by the MSAs whenever the declaration of conformity was missing or did not comply with the requirements. The resulting measures were reported to the Joint Action and shared with all participants. RAPEX Alerts were issued for those toys which were found to pose a serious risk.

1.6 Timeline for Activity

As can be seen from Table 1, PROSAFE organised six physical meetings throughout the lifetime of this project. The final meeting, which took place in February 2018, had as its main purpose to inform everyone about the results of this project and to further fine-tune this final technical report with the latest information. Stakeholders were invited and discussion time was available to better explain these results and also get any final input from MSAs and external stakeholders. The recommendations were included in this final version of the report.

Calendar Month	Phase	Main activities	Meeting	Deliverables / Milestones	
					Project
				ID	Month
April '16	Phase 1 - Starting Phase & preliminary work for the activity	Participation in JA2015 Launch Event by Task Leader (TL) & Task Coordinator (TC) & preliminary work related to the activity.			1
May '16					2
June '16		**Meeting No.1** - Kick-off meeting - Initial Discussions on activity plan for the project and identifying the best way forward.	Toys Meeting No.1 (Kick-off)	MS23	3
July '16		Work on Activity Plan, preliminary research, tools for market surveillance, toys priority list, lab testing			4
Aug '16					5
Sept '16		**DELIVERABLE** - Finalisation of Detailed Activity Plan		D9.1	6
Oct '16		**Meeting No.2** - Work on tools for market surveillance, toys priority list, lab testing	Toys Meeting No.2		7
Nov '16		**DELIVERABLE** - Finalisation of Tools for market surveillance - Exchange of Information guideline on toys, Sampling Scheme, Checklists. Participation by TL & TC within the autumn JA2015 market surveillance workshop.		D9.3	8

Dec '16		**Final Report on Toys Priority List**			9
Jan '17	PHASE 2 - Implementation Phase	**Meeting No.3** - Finalisation of work on Lab testing & sampling strategy. Milestone - Finalisation & confirmation of Planning of activities.	Toys Meeting No.3	MS24	10
Feb '17		Contract for testing of samples finalised with laboratory.			11
Mar '17		**DELIVERABLE - Organisation of Lab Testing**		D9.4	12
April '17		Collection of toy samples for testing carried out (April to May 2016) & start of collection of statistics on inspections, including initiation of testing by laboratory.			13
May '17		Participation of TL & TC in JA2015 Spring Workshop			14
June '17		**Meeting No.4** - On-site meeting at end of June at the Laboratory to inspect samples and discuss final test reports / risk assessment & measures to be taken. Milestone - Completion of sampling and testing.	Toys Meeting 4	MS25	15
July '17	PHASE 3 - Final Results & Follow-up	Additional market surveillance statistics collected regarding non-compliant samples. Follow-up action by MSAs initiated after risk assessment finalised.			16
Aug '17		Start of development of Final Technical Report, including aggregate statistics on non-compliances, risk and measures taken.			17
Sept '17					18
Oct '17		**Meeting No.5** - Further discussions on risk assessment & measures taken / to be taken - further ensuring a coordinated approach by all MSAs.	Toys Meeting 5		19
Nov '17		Further coordination work on follow-ups, RAPEX alerts, ensuring that measures have been taken as per agreed deadlines			20
Dec '17					21
Jan '18					22
Feb '18		**Meeting No.6 - Final Workshop** - Presentation of all final results and conclusions / recommendations to all participants & external stakeholders. Further fine-tuning of Final Technical Report.	Toys Meeting 6		23
Mar '18		**DELIVERABLE** - Delivery of minutes of all 6 project meetings to the Commission		D9.2	24
		DELIVERABLE - Market Surveillance Toys - Statistics & Follow-up Report		D9.5	
		DELIVERABLE - Final Technical Report on Toys (publicly available)		D9.6	
April '18		Participation of TL & TC in the Final Conference for JA2015			25
May '18		**Milestone** - Risk Assessment and follow-up action on Toys & closure of the project activity.		M26	26

LEGEND: 'MSXX' denotes the specific ID number of the respective milestone within the project. 'DX.X' denotes the specific ID number of the respective deliverable within the project.

Table 1 - Timeline for the project activity - chemical risks in plasticised toys

Workshops & Final Conference

In addition to the six main meetings, PROSAFE organised periodic workshops and seminars as part of the events surrounding all the activities within JA2015, including the JA2015 Final Conference. 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 JA2015.

TOY-ADCO Meetings

Strong liaison with the TOY-ADCO Members continued throughout the lifetime of the project. There is now 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.

1.7 Toys Priority List

It was agreed by the seventeen MS participating in TOYS-JA2015 that it was time to completely update the Toys Priority List that was updated in December 2015. A special spreadsheet in the form of a matrix was developed for this purpose. The scope, this time round, was not only to determine the type of toy groups which MSAs were interested in, but also to determine the type of risk factors that they were particularly interested in.

Twenty-four MSAs from twenty-three different MS participated in this exercise. In January 2017, an updated Toys Priority List was finalised after taking input from stakeholders as well.

2 Setting up the Product Activity

2.1 Tendering Process for Test Laboratories

The call for tenders was published on the PROSAFE website on 31st October 2016. Various laboratories were also directly informed, including the Secretariat of the Toys Notified Body Group. Specific criteria were included within the tender to ensure that the respective laboratories had the necessary accreditation, competence and experience in the type of tests that needed to be done as part of this activity. All participating authorities were also asked to inform any laboratories from their end too. Four (4) tenders were received before the 25th Nov 2016, the deadline for receiving these tenders.

In view of economies of scale, (a total of 255 samples needed to be tested from 17 MSAs), the price of testing in the respective tender offers was very competitive and this meant that more tests could be performed than if the MSAs had decided to do the same tests individually.

After an adjudication process, the proposed laboratory was visited by the task leader, the task coordinator and another member of the participating authorities who had considerable experience in the area of chemical testing. This final on-site visit ensured that the laboratory had the necessary competence as presented in the tender document and that the management understood perfectly what needed to be done according to the projected deadlines. Finally, an online Skype meeting was held during the third meeting of this activity between the laboratory manager and the respective experts as well as the participants from the MSAs. A contract was finalised between PROSAFE and this laboratory in order to perform the required tests.

In view of their experience, the laboratory experts also gave some final suggestions and advice as to how to best perform the type of tests needed in line with the proposed test criteria. They also gave advice to MSAs as to which parts of the toy sample possibly had a higher chance of containing particular chemical risks, as a result of which specific areas/materials within the toy sample were tested. This was also found to be useful and ensured that the respective budget was utilised as effectively as possible by the respective MSAs.

2.2 Selecting Products & chemicals to be focused upon

This generic risk and toy product group, 'chemical risks in plasticised toys', was identified through a priority-setting exercise coordinated by PROSAFE that was held by a previous working group of MSAs and finalised by the end of 2015. During the first two meetings of this activity, (held in 2016), discussions were held between the participating authorities, to identify which particular toy product categories and chemical risks could be focused upon.

An internal guidance document and checklists for inspectors were also developed to help the participating authorities collect the same type of samples and also extract the information needed from each of the samples sent for testing.

2.2.1 Toy Categories focused upon

Plasticised toys are toys made of soft plastic. Therefore, inspectors tried to choose those plastic toys that ideally had a soft body or at least had parts of the toy that were rather soft to the touch. Additionally, an analysis took place on all the rapid alert notifications (RAPEX notifications) related to toys that over the last years were considered as posing a serious risk due to some form of chemical risk. Plastic dolls, inflatable toys, plastic toy books and bath toy/squeezable toys were all identified as having the highest number of notifications. Additionally, some of the MSAs also confirmed that they had performed similar surveillance activities at a national level in previous years and they also found non-compliances related to chemical risks in such toy categories.

In the case of plastic dolls, in order to better involve customs authorities, it was agreed that plastic dolls depicting human figures was to be the primary target, with or without accessories. This category of toys was chosen since there was a specific customs TARIC code - 9503002190 and thus

ensured that customs authorities were able to better assist MSAs in taking some samples at the respective borders.

The four main toy sectors that were ultimately focused upon within this activity, were:

- **Plastic dolls depicting human figures**
- **Inflatable Toys**
- **Plastic Toy Books**
- **Bath Toys/Squeezable Toys**

2.2.2 Chemicals Risks focused upon

The next important step was to determine the chemical risks associated with these types of plasticised toys. As explained earlier on, plasticised toys are toys made of soft plastic. Manufacturers use particular plasticizers to make these plastic toys soft. Phthalates and SCCPs (short chained chlorinated paraffins) are two such examples.

Phthalates have been linked to damage to the reproductive system, and an increased risk of asthma and cancer. Phthalate non-compliances are by far the most common chemical risk in toys that have been alerted by MSAs in rapid alert notifications (RAPEX). **SCCPs** are highly toxic to the aquatic environment and are classified as a category 2 carcinogen. Although there are only a few rapid alert notifications associated with SCCP non-compliances, the Swedish Chemicals Agency, which participated in this activity, also explained that besides phthalates in toys (which had been the most common finding in the Swedish market) non-compliances associated with SCCPs was the third most common finding. For the reasons mentioned above, it was agreed that this activity would perform tests associated with concentrations of these two chemicals.

PAHs (polycyclic aromatic hydrocarbons) are organic molecules that consist of two or more adjacent aromatic rings. Although they only contain the elements carbon and hydrogen, these atoms can exist in many different structural arrangements, so a large number of PAHs exist. These compounds exist as a contamination in rubber and plastic, and the limit value is set low because of their carcinogenic abilities since they can easily be absorbed through the skin. Eight PAH became limited in toys under REACH on 27 December 2015 and that was the reason to include tests on PAHs within this activity in order to ascertain whether there were any particular non-compliances associated within this rather new restriction on PAHs.

BPA (Bisphenol A) is an organic synthetic compound that is usually used as a monomer in the manufacture of polycarbonate plastic. Polycarbonate plastic products include a variety of common consumer goods, such as re-usable plastic tableware and bottles for drinks, sports equipment, CDs, and DVDs. It may also be found in certain plastic toys. Bisphenol A is classified in the EU as a substance that has toxic effects on human ability to reproduce. A Norwegian national market surveillance activity had recently identified some non-compliances related to BPAs in plastic toys. In view of the fact that the migration limit of BPA was applicable as from 21 December 2015 (as set in the Toy Safety Directive), for toys intended for use by children under 36 months or in other toys intended to be placed in the mouth, it was decided to also include tests of migration of BPA within this joint activity.

It was also agreed to include tests related to the **migration of lead, cadmium and organic tin (organotin)** for the following reasons:

- Lead is a heavy metal which can also be used by manufacturers as a stabiliser in PVC and therefore may be found in plastic toys. Like most heavy metals, lead is poisonous. The symptoms of acute lead poisoning include vomiting, intestinal colic and constipation and even kidney failure in some cases.
- Cadmium, a heavy metal sometimes used as a cheap alternative to lead, can be found in some toys. Although cadmium shows up frequently in children's products particularly in children's jewellery, toys with batteries and paint coatings, there is also the possibility of having cadmium in plastic toys. Cadmium is primarily toxic to the kidney and can cause renal failure. Cadmium is classified as a human carcinogen (Group 1) on the basis of occupational studies. Newer data on

human exposure to cadmium have indicated an increased risk of cancer such as in the lung, endometrium, bladder, and breast.

- Organotin is commercially applied as stabilizers in polyvinyl chloride and therefore could be found in soft plastic toys. Organotin have endocrine disruptive effects on aquatic organisms and can pose a risk to human health through immunotoxicity (suppression of the immune system) and can even be toxic to reproduction.

Further information regarding the type of tests carried out and the test method used for each of the chemicals mentioned in this section is given in chapter 3 (testing).

2.2.3 Economic operators inspected

All types of economic operators were focused upon, that is, manufacturers, importers and all kinds of distributors. It was up to the MSA to decide exactly which and how many economic operators were focused upon within this project. Special attention was given to low-cost toys and to toys which lacked proper markings and warnings since from experience these were found to present the highest levels of risk.

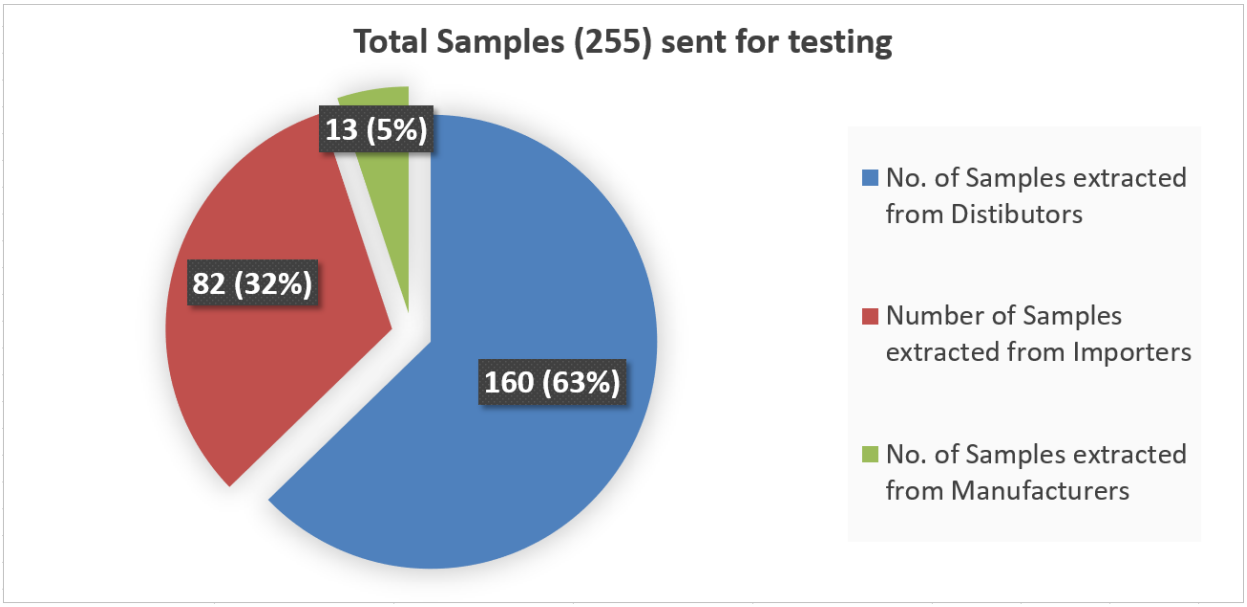


Figure 2 - Total number of samples sent for testing, categorised according to the number of samples extracted from economic operators

As can be seen in Figure 2 above, the inspectors collected 13 samples directly from local manufacturers, 82 samples from importers and 160 samples from distributors. One needs to remember that this does not mean that only 13 samples were manufactured in the European Economic Area. Indeed, out of the 160 samples within the distributors' category, 65 of these samples were either directly manufactured in another EU Member State or the economic operator within the EU took the responsibility to place his/her own name or trademark (thus also being considered as a manufacturer according to the Toy Safety Directive).

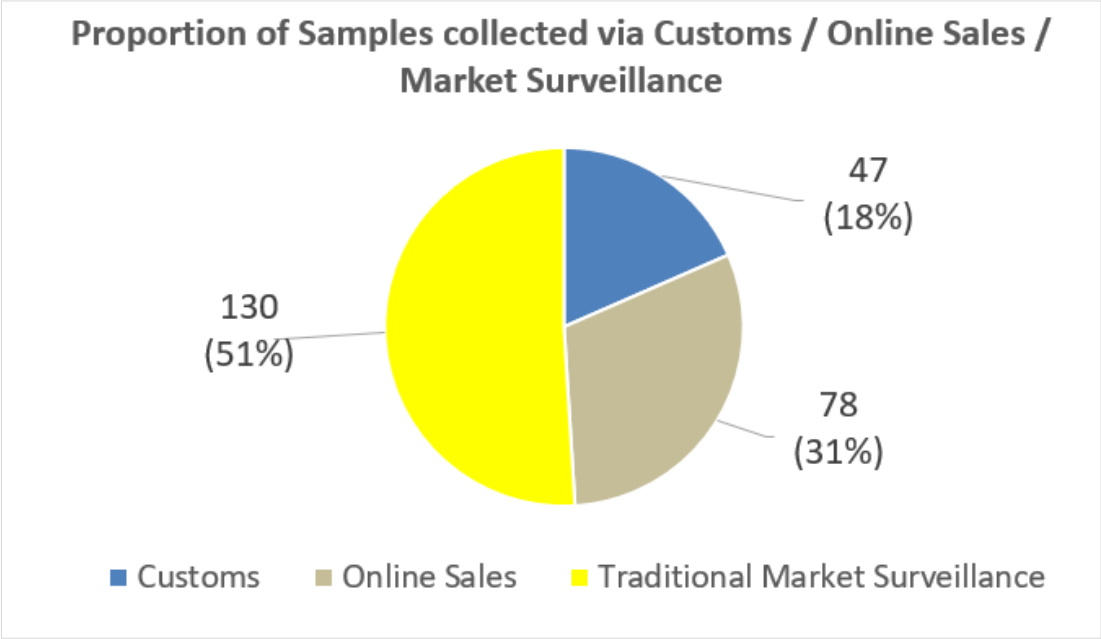


Figure 3 – Proportion of Samples collected

Figure 3 shows that 130 samples (51%) were collected via traditional market surveillance activities, another 47 samples (18%) were collected with assistance from the customs authorities and 78 samples (31%) were collected via online sales.

Table 2 gives further breakdown of information in relation to customs and online sales. With regards to assistance provided by customs authorities, 10 of the samples were collected directly from customs borders. An additional 37 samples were collected directly by MSAs after utilising information or intelligence provided by customs authorities.

In the case of online sales, 27 samples were directly bought via online sales. On the other hand, an additional 51 samples were collected from the economic operators after the MSAs selected the samples to be collected on the websites of the economic operators.

	Customs	Online Sales	Traditional Market Surveillance
Directly	10	27	130
Indirectly	37	51	0
Total	47	78	130

Table 2 – Basic breakdown of samples collected

Table 3 shows a further breakdown of information in relation to the actual samples collected by each participating Member State. The majority of MSAs each collected around 15 toy samples. The part highlighted in yellow in Table 3 is a detailed breakdown of each Member State in relation to the samples collected with assistance from Customs authorities and also via online sales.

	Plastic dolls	Inflatable Toys	Plastic Toy Books	Bath / Sqeezable Toys	TOTAL	Customs - Directly	Customs - Indirectly	Online - Directly	Online - Indirectly	Market Surveillance
Belgium	7	2	2	4	15	3			5	7
Czech Rep.	7	2	2	4	15		1		4	10
Estonia	7	2	2	4	15			4	1	10
Germany	7	2	2	4	15		5		5	5
Greece	9	4		2	15	2			4	9
Latvia	8	2	2	3	15		1	3	4	7
Lithuania	7	2	2	4	15		5		5	5
Luxembourg	7	1	2	4	14		5	3		6
Malta	7	2	2	4	15		5		5	5
Norway	8	2	2	3	15		7	5		3
Poland	8	2	1	4	15				2	13
Portugal	6	2	3	5	16		4		7	5
Romania	9	0	1	4	14				5	9
Slovakia	6	1	4	5	16			2	1	13
Spain	7	1	3	4	15	5		5		5
Sweden	4	1	2	8	15		4	1	3	7
The Netherlands	7	2	2	4	15			4		11
TOTAL	121	30	34	70	255	10	37	27	51	130
						4%	15%	11%	20%	51%

Table 3 - Detailed breakdown of proportion of samples collected

Using the Belgian samples as an example, Table 3 shows that the MSA from Belgium collected 7 plastic dolls, 2 inflatable toys, 2 plastic books and 4 bath / squeezable toys. These 15 samples have been taken from the market as follows; 3 of the sample were collected directly at the Customs border and 5 samples were collected from the economic operators after the MSAs selected the samples to be collected via the respective websites of the economic operators. Additionally, 7 samples were collected using traditional market surveillance activities.

3 Testing

As noted earlier, 255 samples were sent for testing from 17 different European countries. This chapter gives a detailed overview of all the type of tests carried out, including the test results achieved.

3.1 The Test Program

As indicated in the previous chapter, various chemicals have been given particular attention in this joint market surveillance activity. This section tries to give more information on the specific limits found within the respective legislation and the type of test methods carried out for each of the respective chemical analysed.

PHTHALATES. The type of phthalates focused upon in this activity are shown in Table 4.

	Name	Cas No	Legislation	Limit (% weight of plasticsed material)	Comments
DEHP	Bis(2-ethylhexyl) phthalate	117-81-7	Entry 51 of Annex XVII, Reach	0.1%	Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles
DBP	Dibutyl phthalate	84-74-2		0.1%	
BBP	Benzyl butyl phthalate	85-68-7		0.1%	
DINP	Diisononyl phthalate	28553-12-2 68515-48-0	Entry 52 of Annex XVII, Reach	0.1%	Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles which can be placed in the mouth by children
DIDP	Di-'isodecyl' phthalate 1,2-Benzenedicarboxylic acid di-C9-11-branched alkyl esters C10-rich	26761-40-0 68515-49-1		0.1%	
DNOP	di-n-octyl phthalate	117-84-0		0.1%	
DnHP	di-n-hexyl phthalate	84-75-3	Appendix III, point 3 of Annex II to TSD (the Toy Safety Directive 2009/48/EC)	0.3%	Phthalates classified as CMR within the CLP (Regulation (EC) No 1272/2008) n & only classified as toxic for reproduction
DPP	dipentyl phthalate	131-18-0		0.3%	
DHNUP	1,2-Benzenedicarboxylic acid, di-C7-11 -branched and linear alkyl esters	68515-42-4		0.3%	
DIHP	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6		0.3%	
DIBP	Diisobutyl Phthalate	84-69-5		5 %	Specific concentration limit for DIBP was deleted March 1st 2018 (CLP regulation).

Table 4 – Information related to phthalates analysed in this activity

As can be seen from the table above, it is worth noting that restrictions of the following phthalates are set out in entries 51 and 52 of Annex XVII to REACH:

- REACH, Annex XVII, Point 51: Bis (2-ethylhexyl) phthalate (DEHP), Dibutyl phthalate (DBP) and Benzyl butyl phthalate (BBP) shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles.
- REACH, Annex XVII, Point 52: Di-"isononyl" phthalate (DINP), Di-"isodecyl" phthalate (DIDP) and Di-n-octyl phthalate (DNOP) shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles which can be placed in the mouth by children.
- Restriction also applies to the combination of each group. A toy is not in compliance with REACH if the concentration of DEHP + DBP + BBP is greater than 0.1 %, or DINP + DIDP + DNOP is greater than 0.1%.

In light of the fact that some of the restrictions are related to whether a toy or part of a toy can be placed in the mouth, the MSAs referred to the ECHA Guideline on the interpretation of the concept "which can be placed in the mouth" as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006[1].

Phthalates classified as CMR (carcinogenic, mutagenic or toxic for reproduction), as specified in CLP (Regulation (EC) No 1272/2008), are also restricted by EU Toy Safety Directive 2009/48/EC. The limits of these type of phthalates (as shown in Table 4) are grouped as follows:

- DIHP, DHNUP, DPP, DnHP: A limit of 0,3% by weight of the plasticised material applies. These are classified as CMR within the CLP Regulation & only classified as toxic for reproduction.
- DiBP: A limit of 5% by weight of the plasticised material applies. A specific concentration limit for DIBP is specified in the CLP: Mixtures with 5 to <25% DIBP are reprotoxic category 2, with 25% DIBP or more they are reprotoxic category 1B. It is worth noting that it is a new classification for DIBP under the CLP Regulation from 1st March 2018.

The test method (sample preparation, extraction and analysis) for phthalate content in these toy samples was as laid down in ISO 8124-6:2014 - CPSC-CH-C1001-09.3. The laboratory was able to perform a chemical mix of up to three components together from the same toy sample. This meant that each sample could have a maximum of three different areas tested within the toy. However, in order to ensure better traceability of the test results achieved, the laboratory was asked to perform such mixes from the same material within the toy. This meant that, if a toy had soft plastic hands and feet made of the same colour and material, the laboratory was asked to extract materials from, for example, one left hand, one right hand and one left foot. However, different colours or materials were not mixed together since it would then be difficult for the authorities to ascertain exactly which material was non-compliant within the toy sample itself.

SCCP (Short Chain Chlorinated Paraffins) are classified as persistent chemicals. The Toy Safety Directive (TSD) originally restricted the use of SCCP since 20th July 2013 to 1 % based on the harmonised classification as a category 2 carcinogenic, mutagenic or reprotoxic (CMR) substance. SCCP were also restricted for use in certain applications under Entry 42 of REACH Annex XVII until this entry was deleted as a result of the current restriction in the Persistent Organic Pollutants (POPS) Regulation (EU) 519/2012 coming into force. The POPS Regulation first banned the use of SCCP in articles from January 2013. A further Regulation (EU) 2015/2030 entered into force on 4th December 2015 that amended the total concentration limit in articles to 0.15% - as can be seen in Table 5. This limit applies to all articles placed on the market and is not limited to toys.

[1] This can be downloaded from this link:
https://echa.europa.eu/documents/10162/13645/guideline_interpretation_concept_mouth_en.pdf

	Name	Cas No	Legislation	Limit (% weight of plasticsed material)	Comments
SCCP	Alkanes, C10-13, chloro	85535-84-8	Annex I of POP Regulation EC 850/2004	0.15%	SCCP are classified as persistent chemicals and are restricted under European POP Regulation EC 850/2004. Annex I to this regulation has been amended in accordance with the Annex to Regulation (EU) 2015/2030 which came into force as from 4th December 2015 whereby it set the limit for SCCP at 0.15% by weight (1500 mg/kg) in articles

Table 5 – Information related to SCCP analysed in this activity

The test method used by the laboratory was as laid down in ISO 18219:2015. This specifies a chromatographic method to determine the amount of short-chain chlorinated paraffins (SCCP). The laboratory was able to perform a chemical mix of up to two components together from the same toy sample.

PAH (Polycyclic Aromatic Hydrocarbons) have a limit value which is set low due to their carcinogenic abilities. Table 6 shows the various substance names and CAS numbers of PAH analysed by the laboratory, including the legislative limit.

	Name	Cas No	Legislation	Limit	Comments
PAH	Benzo(a)pyrene	50-32-8	Reach, Annex XVII, Entry 50	0.00005% by weight or 0.5mg/Kg	Toys, shall not be placed on the market, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 0,5 mg/kg (0,00005 % by weight of this component) of any of the listed PAHs.
	Benzo(e)pyrene	192-97-2			
	Benzo(a)anthracene	56-55-3			
	Chrysene	218-01-9			
	Benzo(b)fluoranthene	205-99-2			
	Benzo(j)fluoranthene	205-82-3			
	Benzo(k)fluoranthene	207-08-9			
	Dibenzo(a,h)anthracene	53-70-3			

Table 6 – Information on PAH analysed in this activity

An amendment of REACH, Annex XVII No.50 introduced specific requirements for PAHs in articles for supply to the general public, including toys, activity toys and childcare articles.

Commission Regulation 1272/2013 give a particular limit to eight polycyclic aromatic hydrocarbons (PAHs) in toys placed on the market after 27th December 2015 - in line with REACH, Annex XVII, Entry 50. The limit is well explained in Table 6 under the 'comments' section.

The test method used by the laboratory for the determination of PAH concentration in the toy samples was as laid down in AfPS GS 2014:01 PAK. The laboratory was able to perform a chemical mix of up to two components together from the same toy sample.

BPA (Bisphenol A). It is worth noting that both the content ((percentage weight of material) as well as the migration of BPA is restricted in toys.

The content of BPA is restricted in all toys distributed in the EU markets due to its classification as toxic for human reproduction in the CLP regulation. The content limit of BPA in toys until 1st March 2018 is 3% (based on the reproductive toxicity (Category 2B)). On the other hand, the European Commission has adopted Directive 2014/81/EU, which sets a migration limit on BPA of 0.1 mg/l in all toys intended for children up to the age of 3 years, and in any toys intended to be placed in the mouth, regardless of intended age. The migration limit of 0.1 mg/l is set in this Directive and has become applicable as from 21st December 2015.

In view of budget restrictions, it was decided by the participating authorities to only test for the migration of BPA rather than the content limit since the content limit was far higher than the migration limit and therefore there was less chance of finding non-compliances related to BPA content. The information related to BPA migration is shown in tabular format in Table 7 below.

	Name	Cas No	Legislation	Migration Limit	Comments
BPA	Bisphenol A	80-05-7	Appendix C of Annex II the Toy Safety Directive	0.1 mg/l	The limit is for toys intended for children up to the age of 3 years, and in any toys intended to be placed in the mouth, regardless of intended age.

Table 7 – Information on BPA analysed in this activity

Revised BPA limits in the near future – It is worth noting that after 1st March 2018, the new content limit of BPA in toys will be reduced from 3 % to 0.3 %, based on the reproductive toxicity (Category 1B). Additionally, the new limit for migration of BPA as from 26 November 2018 will be further reduced to 0.04 mg/l.

The test method used by the laboratory for the determination of migration of BPA in the toy samples was as laid down in EN 71-10:2005 + EN 71-11:2005. The laboratory was able to perform a chemical mix of up to three components together from the same toy sample.

Migration of lead, cadmium and organotin. The Toy Safety Directive (2009/48/EC) specifies maximum migration limits for three categories of toy materials. In this case, the particular focus was on 'scraped off material' due to the type of plastic toys tested. The specific limits for the migration of the respective elements are specified in Table 8.

Name	Cas No	Legislation	Migration Limit (for scraped off material)	Comments
Cadmium	7440-43-9	The limits for cadmium were amended by Commission Directive 2012/7/EU	17 mg/Kg	The Toy Safety Directive (2009/48/EC) specifies maximum migration limits for three categories of toy materials. The limits for the migration of certain elements are expressed in milligram per kilogram toy material and are detailed in Table 2 of EN 71-3:2013+A1:2014
Lead	7439-92-1		160 mg/Kg	
Organic Tin	Various CAS numbers		12 mg/Kg	

Table 8 – Information on Migration of Lead, Cadmium and Organotin, analysed in this activity

The test method used for testing of lead, cadmium and organotin was as laid down in Category III, of EN 71-3:2013+A1:2014, scraped-off materials.

Total tests carried out. Table 9 shows the number of samples tested for each type of chemical focused upon in this joint market surveillance activity. The samples are broken down according to the country from where these samples were extracted by MSAs.

	SCCP	Pb, Cd, & Organic SN	Phthalates	PAH	BPA
Country	Samples tested	Samples tested	Samples tested	Samples tested	Samples tested
Belgium	15	15	15	6	2
Czech Republic	15	15	15	5	1
Estonia	15	15	15	6	2
Germany	15	15	15	5	1
Greece	15	15	15	6	1
Latvia	15	15	15	6	3
Lithuania	15	15	15	6	3
Luxembourg	14	14	14	5	2
Malta	15	15	15	6	1
Netherlands	15	15	15	6	1
Norway	15	15	15	6	1
Poland	15	15	15	5	1
Portugal	16	16	16	7	2
Romania	14	14	14	3	3
Slovakia	16	16	16	7	2
Spain	15	15	15	6	2
Sweden	15	15	15	5	2
TOTAL	255	255	255	96	30

Table 9 - Number of samples tested for each type of chemical focused upon

It is worth noting that all the 255 samples were tested for phthalates, SCCP, lead, cadmium and organic tin. However, a smaller number of toys were tested for PAH and BPA; 96 samples in all were tested for PAH and 30 samples were tested for BPA. The main reason for this was to reduce costs and ensure that the activity did not exceed the estimated budget for testing.

One needs to also remember that these 255 toy samples were only tested for certain chemicals and it could be that the same toys may have other non-compliances in, for example, other physical properties. However, these other hazards were not the objective of this particular project.

3.2 Results

3.2.1 Results by economic operator

Failed Samples – As explained in Chapter 1, it is important to note that a 'failed' sample in this Final Technical Report denotes a legislative 'non-compliance' in that particular sample according to the tests performed by the laboratory in line with section 3.1 of this report. This means that the limit value of one or more chemicals has exceeded the legislative limit after also subtracting the respective uncertainty value from the test result.

Figure 4 below shows that the overall total percentage failure rate has been of **19.6%** out of all the 255 samples tested.
When analysing the distribution of failed samples according to the samples extracted from different economic operators (manufacturers, importers or distributors), it results that:

(i) The percentage failure rate of samples collected from distributors was 18.1% (29 out of 160 samples).

(ii) The percentage failure rate of samples collected from importers was 25.6% (21 out of 82 samples).

(iii) There were no failures from the 13 samples collected directly from local manufacturers.

	TOTAL	Failed Samples	Passed Samples	Percentage Failure
Distibutors	**160**	29	131	18.1%
Importers	**82**	21	61	25.6%
Manufacturers	**13**	0	13	0.0%
TOTAL	**255**	**50**	**205**	19.6%

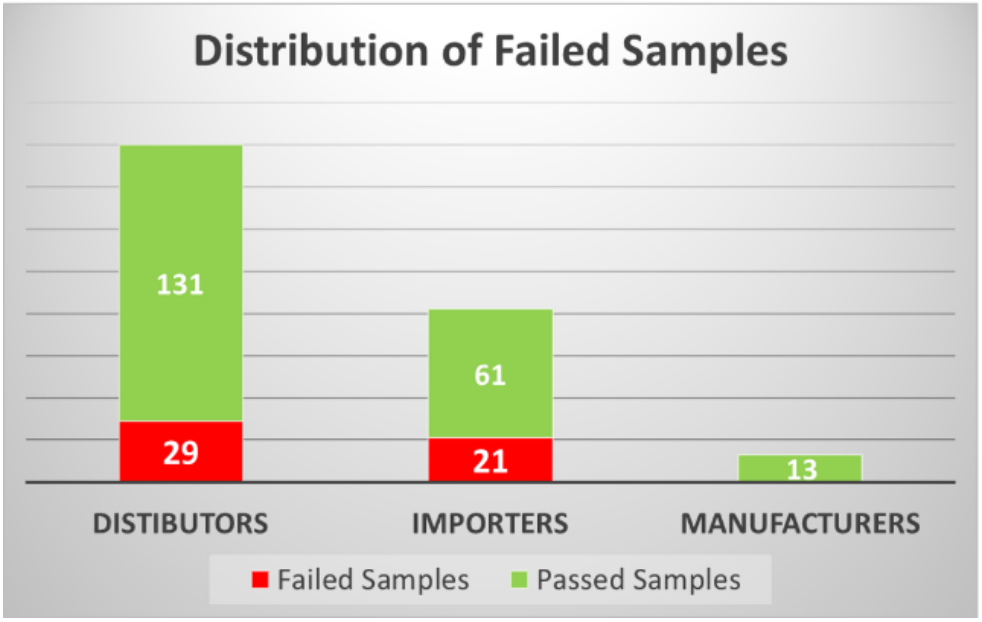


Figure 4 - Failure Rate according to type of economic operators inspected

(Failed Sample means a sample which had a non-compliance in any of the chemicals tested)

It is worth noting that in the case of the 160 samples collected from distributors, there were 65 samples that were either directly manufactured in another EU Member State or the economic operator within the EU took the responsibility to place his/her own name or trademark (also being considered as a manufacturer according to the Toy Safety Directive). It is interesting to note that only 5 samples failed out of these particular 65 samples. Thus, it seems that the economic operators that are acting as 'manufacturers' according to the Toy Safety Directive seem to be reasonably well aware of chemical risks and by far the majority have taken care not to have any unsafe chemicals in their toys.

On the other hand, the remaining samples collected from distributors, 95 samples (160-65=95) had a total of 24 samples (29-5=24)) that failed. These samples have been imported from outside the EEA and therefore have a failure rate of 24/95=**25.3%** which corresponds very closely to the failure rate (25.6%) found from those 82 samples (refer to Figure 4) which were directly collected from importers. Therefore, it seems that more awareness about chemical risks is needed amongst European importers in relation to the chemicals risks associated with these types of toys.

3.2.2 Results by type of chemical and by toy category

Table 10 below shows the results for each of the five main types of chemicals focused upon during this project. The number of samples tested from each country is also shown, together with the number of failed samples. None of the 255 tested samples showed any failures with regards to migration of lead, cadmium and organic tin. In addition, out of the 96 samples tested for PAH, there were also no failures detected.

	SCCP		Pb, Cd, & Organic SN		Phthalates		PAH		BPA	
Country	Samples tested	Samples Failed	Samples tested	Samples Failed	Samples tested	Samples Failed	Samples tested	Samples Failed	Samples tested	Samples Failed
Belgium	15	0	15	0	15	1	6	0	2	0
Czech Republic	15	0	15	0	15	3	5	0	1	0
Estonia	15	1	15	0	15	1	6	0	2	0
Germany	15	0	15	0	15	0	5	0	1	0
Greece	15	2	15	0	15	1	6	0	1	1
Latvia	15	2	15	0	15	3	6	0	3	0
Lithuania	15	1	15	0	15	7	6	0	3	0
Luxembourg	14	0	14	0	14	0	5	0	2	1
Malta	15	1	15	0	15	4	6	0	1	0
Netherlands	15	1	15	0	15	1	6	0	1	0
Norway	15	0	15	0	15	2	6	0	1	0
Poland	15	1	15	0	15	4	5	0	1	1
Portugal	16	1	16	0	16	7	7	0	2	0
Romania	14	0	14	0	14	3	3	0	3	0
Slovakia	16	0	16	0	16	5	7	0	2	0
Spain	15	0	15	0	15	2	6	0	2	0
Sweden	15	0	15	0	15	2	5	0	2	0
TOTAL	**255**	**10**	**255**	**0**	**255**	**46**	**96**	**0**	**30**	**3**
Percentage Failure from samples tested		**3.9%**		**0.0%**		**18.0%**		**0.0%**		**10.0%**

Table 10 - Generic number of tests carried out within this project

In the case of tests related to phthalates, 46 samples (18%) out of the 255 samples failed. On the other hand, there were only 10 samples (3.9%) that failed out of the total 255 samples when tested for SCCP. It was also interesting to note that out of the 30 samples tested for BPA content, 3 samples (10%) failed.

Figure 5 shows the 255 samples broken down into the 4 main toy categories.

- In the case of **plastic dolls**, 33 samples (27.3% out of a total of 121 samples in this category) failed one or more of the tests.
- With regards to **inflatable toys**, 7 samples failed one or more of the tests (23.3% out of a total of 30 samples in this category).
- There were no failures detected in the case of **plastic toy books**.
- 10 **bath toys and/or squeezable bath toys** failed these tests. This equates to 14.3% out of the total amount of 70 samples within this category.

	Plastic dolls	Inflatable Toys	Plastic Toy Books	Bath / Squeezable Toys
Passed	88	23	34	60
Failed	33	7	0	10
TOTAL	121	30	34	70

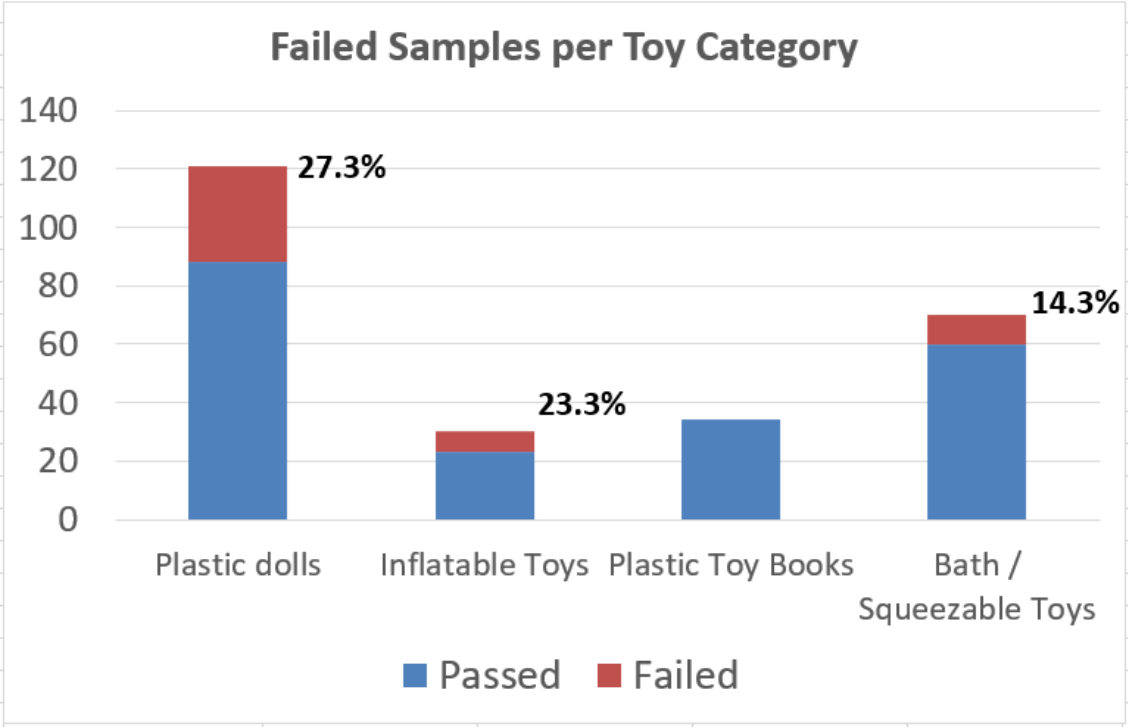


Figure 5 – Percentage failures according to the 4 main toy categories

PHTHALATE Testing

Figure 6, on the next page, shows a better graphical representation of the failed samples from each participating Member State in relation to phthalate content. As explained previously, a failed sample means a non-compliant sample whereby the respective legislative limit has been exceeded. One needs to be careful as to how to interpret such bar charts. This is because it is difficult to assess whether the rather high number of failed samples in some of the MS meant that the inspectors managed to zoom in and pick up samples which were found to be non-compliant or whether the market might have a higher number of non-compliances in this area.

It is worth noting that a total of 46 samples had failures associated with phthalate testing. Looking back at Figure 4, one can see that the total amount of samples that failed was 50. This means that 46 out of those 50 samples failed in phthalates, meaning that this chemical is still the most predominant chemical which needs to be better controlled in such toys.

Additionally, looking again at the conclusions from Figure 4, it transpires that the main problem is not associated with EU toy manufacturers but rather European toy importers who may need to be more aware about the risks associated with phthalates.

Country	Samples	FAIL	% FAIL
Belgium	15	1	6.7%
Czech Republic	15	3	20.0%
Estonia	15	1	6.7%
Germany	15	0	--
Greece	15	1	6.7%
Latvia	15	3	20.0%
Lithuania	15	7	46.7%
Luxembourg	14	0	--
Malta	15	4	26.7%
Netherlands	15	1	6.7%
Norway	15	2	13.3%
Poland	15	4	26.7%
Portugal	16	7	43.8%
Romania	14	3	21.4%
Slovakia	16	5	31.3%
Spain	15	2	13.3%
Sweden	15	2	13.3%
TOTAL	255	46	18.0%

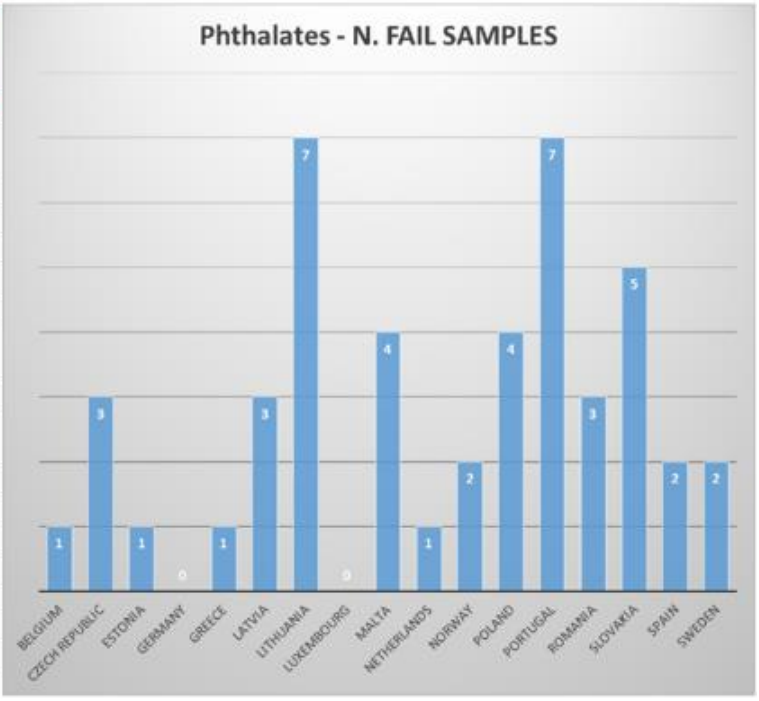


Figure 6 – Percentage Failure of samples associated with phthalate testing only, according to the country from where they have been extracted

On the other hand, Table 11 below gives a breakdown of the failures in phthalates associated with the categories – Plastic dolls, Inflatable Toys and Bath/Squeeze Toys. Out of a total of 46 samples, 32 samples were plastic dolls, showing that this is possibly the highest area of concern. It is also worth noting that 9 bath toys/squeezable toys failed, whereas there were just 5 inflatable toys that failed.

SAMPLES WITH PHTHALATE FAILURES IN DIFFERENT TOY CATEGORIES				
COUNTRY	**Plastic Dolls (P01)**	**Inflatable Toys (P02)**	**Bath Toys / Squeeze Toys (P04)**	**TOTAL**
Belgium	1			1
Czech Republic	1	1	1	3
Estonia	1			1
Spain	1	1		2
Greece	1			1
Lithuania	6	1		7
Latvia	3			3
Malta	3		1	4
Norway	1	1		2
Poland	4			4
Portugal	1	1	5	7
Romania	2		1	3
Slovakia	5			5
Sweden	2			2
The Netherlands			1	1
TOTAL	**32**	**5**	**9**	**46**

Table 11 – Further Breakdown by Toy Category on Phthalate Failures

Table 12 gives a final breakdown of the actual failure rate in each toy category, associated with phthalate test results only. It is clear that the main problem lies with plastic dolls, where there was a failure rate of 26.4% out of a total of 121 dolls tested for phthalates. In other words, 32 samples out of the 121 plastic dolls tested exceeded the respective legislative limits associated with certain phthalates.

PHTHALATE TEST RESULTS	Plastic dolls	Inflatable Toys	Plastic Toy Books	Bath Toys / Squeezable Toys	TOTAL
Total Samples Collected	121	30	34	70	**255**
Failed Samples	32	5	0	9	**46**
% Failure Rate	**26.4%**	**16.7%**	**0.0%**	**12.9%**	**18.0%**

Table 12 - Phthalates test results, showing the failure rate in each toy category

The next highest failure rate is related to inflatable toys, whereby 16.7% failed the phthalate tests. In the case of bath toys/squeezable toys, the failure rate was 12.9%. None of the 34 plastic toy books tested had any non-compliances associated with phthalate testing. More information about the actual type of phthalates that failed the test results is given further below.

Phthalates found in failed samples	NUMBER OF SAMPLES THAT FAILED PHTHALATE TESTS					
	PLASTIC DOLLS		INFLATABLE TOYS		BATH TOYS / SQUEEZE TOYS	
	Number of Failed Samples	% out of total 32 samples	Number of Failed Samples	% out of total 5 samples	Number of Failed Samples	% out of total 9 samples
DEHP	31	97%	4	80%	9	100%
DINP	18	56%	5	100%	3	33%
DBP	11	34%	1	20%	4	44%
DIBP	3	9%	1	20%	0	0%
DIDP	3	9%	0	0%	0	0%
TOTAL SAMPLES THAT FAILED THE PHTHALATE TESTS	**32**		**5**		**9**	

Table 13 - Number of samples that failed phthalate testing

Table 13 shows a breakdown of the type of phthalates that exceeded the legislative limits in the respective 46 samples. It is also important to note that the limit for each chemical also takes into

consideration uncertainty values and therefore any tests which were considered as border-line values have not been considered as a non-compliance.

It is evident that the highest number of failures are attributed to DEHP, followed by DINP, DBP and DIBP. Additionally, DNOP was found in one sample. However, the respective legislative limit was not exceeded and therefore was not considered to be non-compliant.

The following phthalates were not found at all in any of the toy samples tested within this project: BBP (benzyl butyl phthalate), DnHP (Di-n-hexyl phthalate) and DPP (dipentyl phthalate).

It is interesting to note that in the case of plastic dolls and bath toys/squeeze toys, DEHP was the most common chemical that failed the respective tests. On the other hand, in the case of inflatable toys, DINP was the most common chemical that failed the respective test.

SCCP Testing

In the case of SCCP, only a few of the samples failed this test. A total of 10 samples failed as can be seen in Figure 7. One needs to also note that there were three other additional samples with cases of SCCP. However, these were border line cases – that is, when the uncertainty value was taken into account, those three samples were found to be compliant. Therefore, they are not included in the statistics shown below.

Country	Samples	FAIl	% FAIL
Belgium	15		--
Czech Republic	15		--
Estonia	15	1	6.7%
Germany	15		--
Greece	15	2	13.3%
Latvia	15	2	13.3%
Lithuania	15	1	6.7%
Luxembourg	14		--
Malta	15	1	6.7%
Netherlands	15	1	6.7%
Norway	15		--
Poland	15	1	6.7%
Portugal	16	1	6.3%
Romania	14		--
Slovakia	16		--
Spain	15		--
Sweden	15		--
	255	10	3.9%

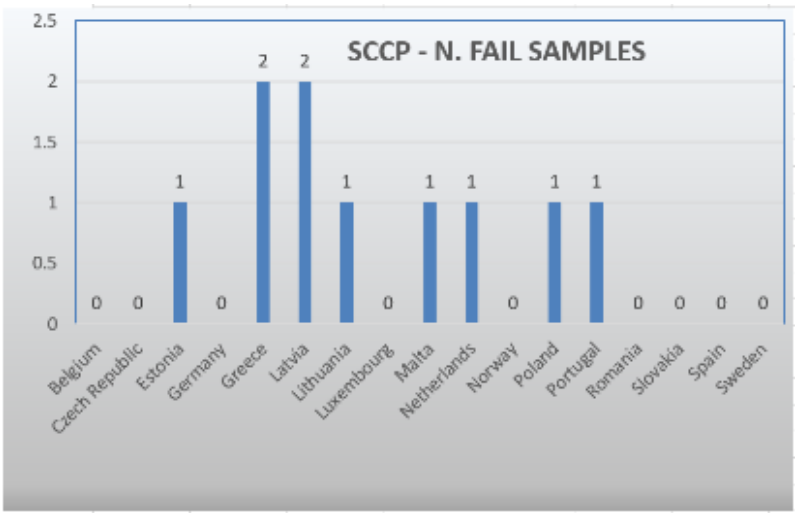


Figure 7 – Percentage Failure of samples associated with SCCP testing only, according to the country from where they have been extracted

As can be seen from Table 14, the highest percentage failure rate (10%) is associated with inflatable toys, followed by bath toys/squeezable toys and last in plastic dolls. It is worth noting that although, in the case of inflatable toys, only 3 samples failed, there were only 30 inflatable toys which were collected and sent for testing, thus the reason why the percentage failure is 10%. None of the 34 plastic toy books tested had any non-compliances associated with SCCP testing.

SCCP	NUMBER OF SAMPLES THAT FAILED SCCP TESTING			
	Plastic Dolls	Inflatable Toys	Plastic Toy Books	Bath Toys / Squeezable toys
Total Samples Collected	121	30	34	70
Samples with SCCP Limit exceeded	4	3	0	3
% Failure Rate	3.3%	10.0%	0.0%	4.3%

Table 14 – SCCP test results, showing the failure rate in each toy category

PAH Testing

Out of the 96 samples tested for PAHs, there were none which exceeded the legislative limit and therefore did not have any non-compliances associated with this chemical.

BPA Testing

With regards to migration of BPA, as can be seen in Figure 8, only 3 samples failed out of a total of 30 samples tested. It is important to note that only 30 out of the 255 samples were tested for migration of BPA. The reason for this was to minimise costs. Whenever the MSA did not specify which of the particular toys had to be tested for BPA, the laboratory, in view of their experience and expertise in the subject matter, was asked to give suggestions as to which toy and/or which parts of the toy most likely had possible concentrations of BPA. Tests were carried out accordingly. Out of the 30 samples tested, 3 samples (10%) failed.

Country	Samples	FAIL	% FAIL
Belgium	2	0	--
Czech Republic	1	0	--
Estonia	2	0	--
Germany	1	0	--
Greece	1	1	100.0%
Latvia	3	0	--
Lithuania	3	0	--
Luxembourg	2	1	50.0%
Malta	1	0	--
Netherlands	1	0	--
Norway	1	0	--
Poland	1	1	100.0%
Portugal	2	0	--
Romania	3	0	--
Slovakia	2	0	--
Spain	2	0	--
Sweden	2	0	--
TOTAL	30	3	10.0%

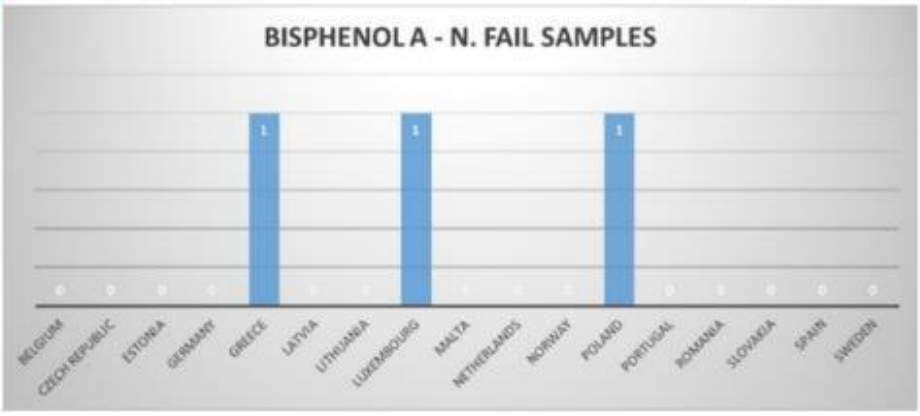
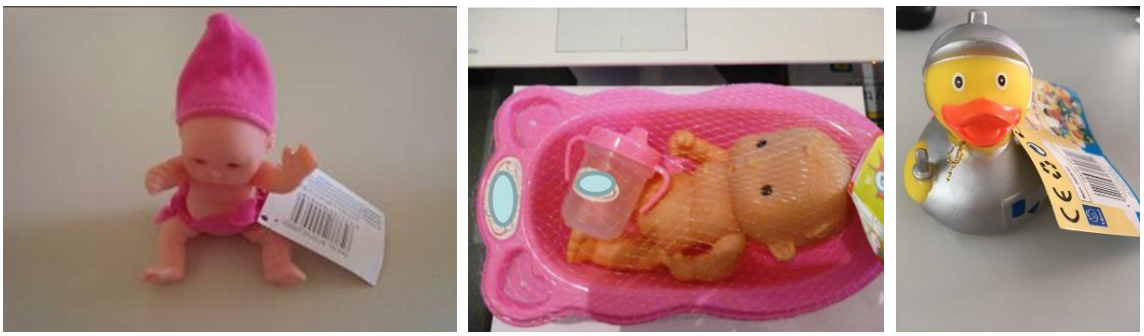


Figure 8 – Percentage Failure of samples associated with migration of BPA testing only, according to the country from where they have been extracted

It may be worth noting that, as can be seen in Figure 9, the 3 samples that failed were actually failures related to soft plastic. In the case of Sample A, the plastic left arm had a BPA migration rate of 78% over the limit. In the case of Sample B, the plastic left leg had a BPA migration rate of 57% whereas in the case of Sample C, the yellow plastic duck body had a BPA migration rate of 83% over the limit.

MSAs may be interested to know about these results regarding migration of BPA since this chemical is primarily used to harden plastics and normally checked in products such as water bottles, the mouthpieces of inflatable articles and other type of products that have harder plastic. These 3 particular toy samples had non-compliances related to migration of BPA found within coloured soft

plastic which was rather a surprise to a number of participating authorities. The tests results show quite a high degree of migration from the respective legislative limit. More tests on similar products may be needed in the future to better assess whether these results were just rare occasions or not.



Sample A **Sample B** **Sample C**

Figure 9 – Samples that failed the 'migration of BPA' test

Migration of Lead, Cadmium and Organotin Testing

All the 255 samples were tested for the migration of these two heavy metals (lead and cadmium) and organotin. Out of the 255 samples tested, there were none which exceeded the legislative limit and therefore these toy samples did not have any non-compliances associated with these heavy metals.

3.3 Additional Analysis by the MS

Similar to what happened in the previous joint action on toys (JA2014), it was agreed from the beginning of the project that the MSAs would also perform checks on labelling/markings and warnings and also check the **declaration of conformity (DoC)**.

The manufacturer or the authorised representative established within the Union must draw up and sign an EU declaration of conformity as part of the conformity assessment procedure provided for in the Union harmonisation legislation. The EU declaration of conformity must contain all relevant information to identify the Union harmonisation legislation according to which it is issued, as well as the manufacturer, the authorised representative, the notified body if applicable, the product, and where appropriate a reference to harmonised standards or other technical specifications.

Declaration of Conformity

Each MSA was asked to collect the respective declaration of conformity (DoC) for each of the samples tested. The scope of this exercise was ultimately to make the economic operators aware of the importance of having DoCs available to MSAs. The analysis in Figure 10 is based on those MSAs that asked for a DoC from the respective economic operators, whereby the MSAs managed to collect 78% of the DoCs asked for. It may be worth noting that during the previous joint action, 63% were collected from all the samples sent for testing.

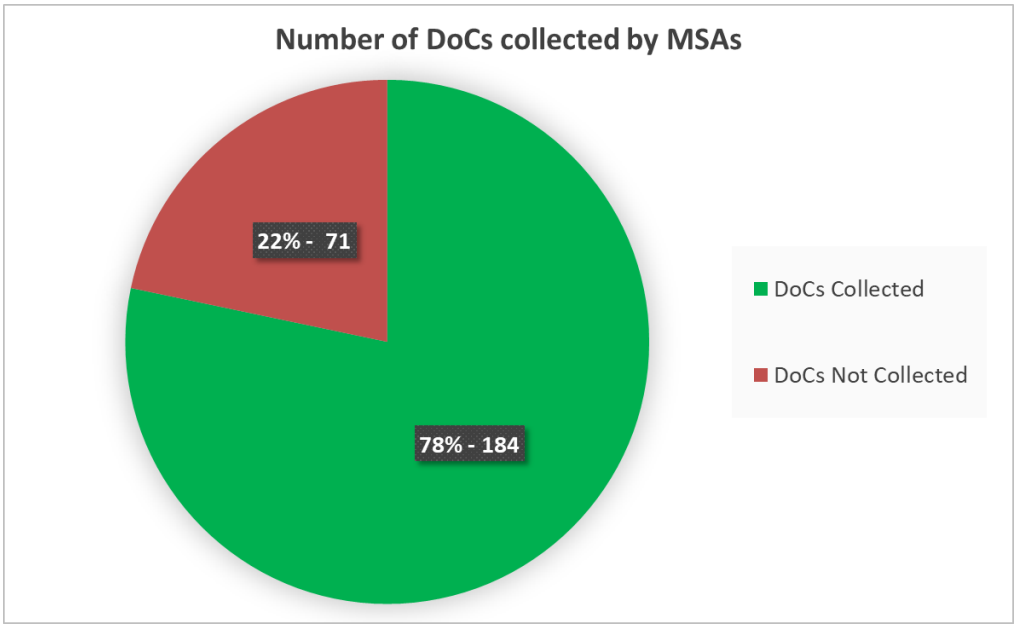


Figure 10 – Number of Declarations of Conformity (DoCs) made available to the MSAs

It is also worth mentioning that there is still a wide discrepancy in the percentage of DoCs made available to individual MSAs. Two of the MSAs managed to receive 100% of the DoCs asked for. In other cases, it was around 60%. Most of the MSAs had percentages in between these two extremes. It might be very interesting to further analyse such details in future joint actions and to see whether the level of availability from the respective economic operators can further be improved by getting them to be more aware of the importance of having DoCs available to MSAs.

	DECLARATION OF CONFORMITY (DoC)									
	Does the DoC contain a unique identification of the toy(s)? **YES/NO**	Does the DoC include the "name & address of the MFG or his authorized representative? **YES/NO**	Is the relevant Community harmonization legislation mentioned in the DoC? **YES/NO**	Is there reference to Directive 2009/48/EC (TSD) **YES/NO**	Is the DoC signed? **YES/NO**	Is there the name of the signatory and his/her function (designation) ?. **YES/NO**	Is there a place and date of issue? **YES/NO**	Does it include an image of the respectiv e toy? **YES/NO**	Is the image clear? **YES/NO**	Is the image in colour? **YES/NO**
YES	93%	95%	89%	94%	92%	82%	79%	95%	88%	76%
NO	7%	5%	11%	6%	8%	18%	21%	5%	12%	24%

Table 15 – Type of compulsory information found within the DoCs that were collected

Of particular interest is Table 15, showing the quality of the information found within the DoCs that were collected. Similar to the previous joint action, the overall response is reasonably good, with the worst responses being related to the place and date of issue of the declaration of conformity (79%). Additionally, although an image was present in 95% of all DoCs collected, the image was in colour in 76% of the time. These may be areas which need to be improved, besides of course concentrating mostly on ensuring that declaration of conformities for toys are more available.

Other labelling checks

The MSAs also performed some additional labelling checks. Table 16 gives some information on the basic requirements that are needed on samples. As can be seen from this table there are still non-compliances related to each and every aspect, even though the majority (over 80%) have been found to be correct.

	BASIC REQUIREMENTS					
	Are labels and warnings visible, legible, permanent and in a language or languages as determined by the national authority?	Does the sample have a CE mark?	Out of the samples which had a CE mark, is the CE mark correctly marked?	**Manufacturer Details** - Is all the related information available?	**Importer Details** – Is all the related information available, where relevant?	Manufacturers must ensure that their toys bear a type, batch, serial or model number or other element allowing their identification. Is this present?
% YES	80%	96%	97%	80%	85%	95%
% NO	20%	4%	3%	20%	15%	5%

Table 16 - Basic labelling requirements

There were some additional checks on markings, but it goes beyond the scope of this report to include all the details. By far the most interesting and worth noting is the information shown above.

3.4 Conclusions

The overall testing shows that there were no non-compliances detected related to migration of lead, cadmium or organic tin. This is worth noting especially since lead was a major concern for MSAs some years back. Additionally, there were no non-compliances found in relation to Polycyclic Aromatic Hydrocarbon (PAH) content.

The level of non-compliance with regards to phthalates, SCCP and BPA, still needs to be better controlled so as to ensure that economic operators only place safe toys in the Single Market. The economic operators (as well as the MSAs) need to be aware that toys are regulated in several directives, in particular in the area of chemicals where various other related legislations come into play.

The information gathered in relation to the declaration of conformities was also quite interesting. Although the overall percentage of DoCs made available by economic operators seems to be higher than that in the previous joint action, there are still considerable differences between the level of availability of the DoCs amongst various countries, meaning that more work is needed in this area to ensure a more uniform availability across all MS.

Refer also to results of other labelling checks whereby one out of five samples had the respective contact information of the manufacturer or the importer missing. It is also worth noting that one out of five samples were labelled in a language that was not in compliance with the Member State legislation.

4 Risk Assessment & Action Taken

4.1 Introduction

Risk assessment of chemicals in consumer products has always been a challenge to MSAs and several times they have encountered difficulties to carry out a risk assessment as required by Commission Decision 2010/15/EU, to assess the level of risk when the hazard is related to the presence of a chemical

During the implementation phase of this activity, the Sub-Group Chemicals of the Toy Expert Group developed a spreadsheet on how to perform risk assessment of certain phthalates. The spreadsheet was tested and adapted with some simplified simulations and flowcharts developed through this activity.

However, many participating national authorities were sceptical about the practical application of the proposed spreadsheet and found if too difficult and time-consuming to fill in. Aware of such difficulties, the European Commission gave in October 2017 an outline recommendation to all MSAs, including the participants of this activity, on how to determine the level of risk related to the presence of certain chemicals for which legislative limits are established. This was taken into account for those Member States who had not yet performed a risk assessment on the non-compliant samples collected in this joint action.

4.2 Risk Assessment Methodology

As explained in the introduction of this chapter, the Sub-Group Chemicals of the Toy Expert Group had developed a detailed spreadsheet, based on scientific information available to them at that time, in order to try to better assess the risks posed by certain phthalates. In view that the spreadsheet itself was found by the 17 participating authorities to be rather a challenge to calculate the respective risk assessment, simpler versions of this spreadsheet in the form of simulations and flowcharts were developed by the task coordinator. A detailed report on the methodology used can be found in **Annex 1** to this Final Technical Report.

Having said that, a number of MSAs had some reservations on this approach as developed by the Sub Group Chemicals of the Toy Expert Group. However, for the sake of consistency and proper coordination, it was agreed by all the 17 participating authorities that they had to try to:

(i) Utilise these flowcharts and simulations as developed by the task coordinator, in order to perform risk assessment of the respective non-compliant toy samples.
(ii) Give feedback to this Sub-Group Chemicals on the results achieved using this methodology

Responding to the concerns of a number of Member States on the best approach risk assessment for chemical risks, an in view of the difficulties faced by national authorities when applying the approach developed by the Toy expert Group, the European Commission provide during the 5th meeting of this working group a series of recommendations on how to help MS enforcement authorities carry out risk assessment of chemical risks in products, including toys. This decision was welcome and those authorities that had not as yet performed their respective risk assessment were guided accordingly by these recommendations.

This implied that in the particular case of this project, the non-compliant toy samples that had exceeded the respective legislative limits in respect of phthalates, SCCP and the migration of BPA, could be considered by the MSAs as having a 'serious risk'. It was however up to the respective MSA to take the final decision on a case-by-case basis, taking into account any particular characteristics of the toy in question. **Annex 2** gives an overview of the outline recommendations presented by the European Commission.

It is worth noting that for this particular project the risks assessment methodologies described in Annex 1 and 2 were more or less the same.

4.3 Risk Assessment results

The 17 MSAs mainly utilised the methodology shown in Annex 1 since most of them had already taken a risk assessment decision before October 2017. The result was that 48 out of the 49 toy samples that were non-compliant, were determined to have a "serious risk" according to the preferences made for phthalates.

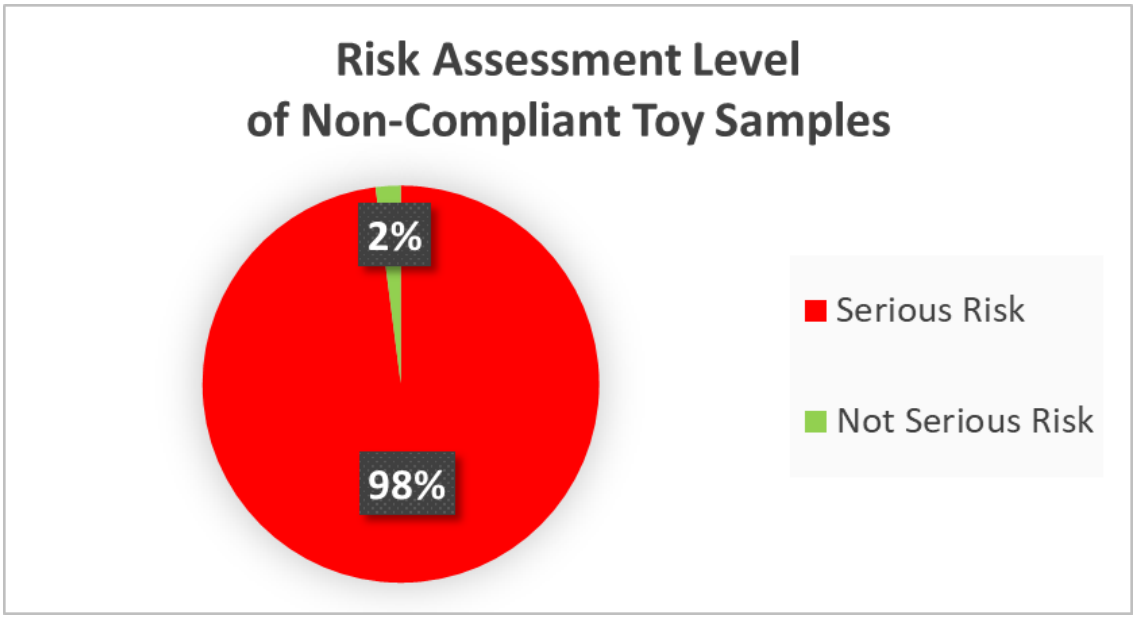


Figure 11 – Risk Assessment Level found within Non-Compliant Toy Samples

Figure 11 shows a representation of this percentage in graphical format. Although the results show an extremely high percentage of "serious risks", it is worth noting that this is very much similar to the outcome that would have been achieved if the participating authorities had utilised from the start the direction given by the European Commission as from October 2017 (as described in Annex 2). Therefore, for this particular project, the final risk assessment outcomes from both methodologies described in Annex 1 and Annex 2, were more or less the same.

In addition to the 49 samples described above, there was also one other sample which was non-compliant, and which was considered to be a border-line product. After further discussion during the on-site group meeting held at the laboratory, it was agreed by all the participating authorities that this borderline product was not a toy but rather a GPSD product. The respective authority still took the necessary action and a formal measure was taken by them and the company who imported this article was forbidden to sell this product, based on the content of SCCP's in line with Regulation (EC) No 850/2004.

4.4 Action & Measures taken

The main measures taken by the respective MSAs on the 49 non-complaint toy samples are shown below in Figure 12. The majority of the measures taken were sale bans and/or withdrawals from the market. This accounted for 71% of all 49 non-compliant samples. Additionally, the MSAs decided to perform a recall on 12 of the samples (25% of all non-compliant samples). There were just two samples where the respective authorities were still working on them at the time of publishing this report.

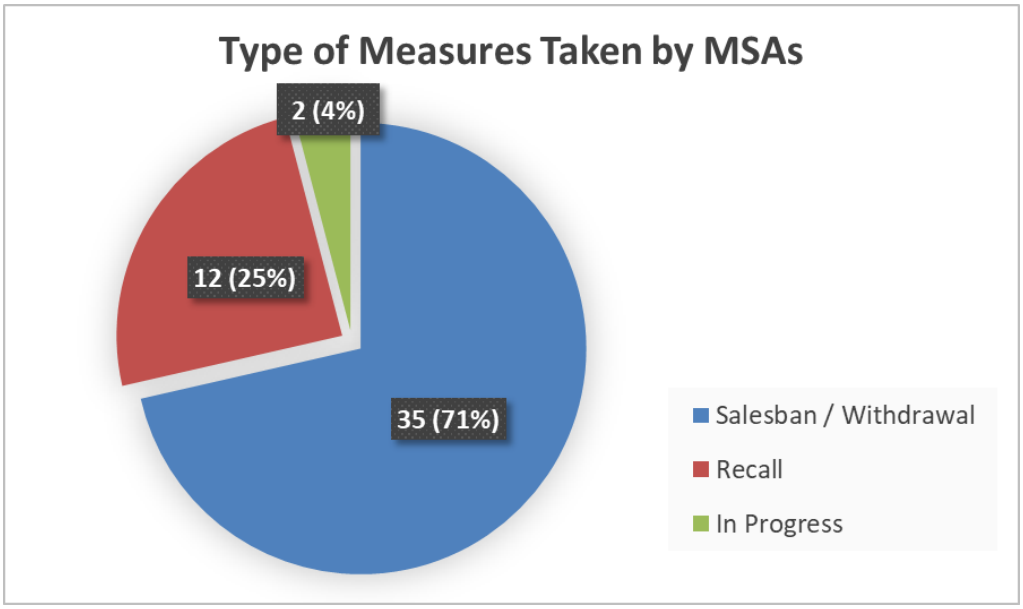


Figure 12 – Measures taken by MSAs

This meant that the MSAs were able to take the necessary action from their end after assessing the test results given by the laboratory and after taking a risk assessment decision mainly based on Annex 1 of this report.

4.5 Notifications Issued by MSAs in the Rapid Alert System (RAPEX).

Member States' obligations to notify via RAPEX, which is established under Article 12 of the GPSD, apply to measures which prevent, restrict or impose specific conditions on the marketing and use of consumer products posing a serious risk to the health and safety of consumers.

Out of the 48 samples that were assessed to have a serious risk, 43 Rapid Alert Notifications (88%) have been issued over these last eight months by the MSAs. This is represented in a graphical manner in Figure 13. Out of the six remaining non-compliant samples that had a serious risk, 4 of them are related to just one authority where internal administrative proceedings are underway to eventually recall these 4 samples from the market. This means that the number of Rapid Alert Notifications may also increase in the near future. The other two remaining samples did not pose any serious risk management issues according to the respective MSAs and therefore no rapid alert notifications were issued.

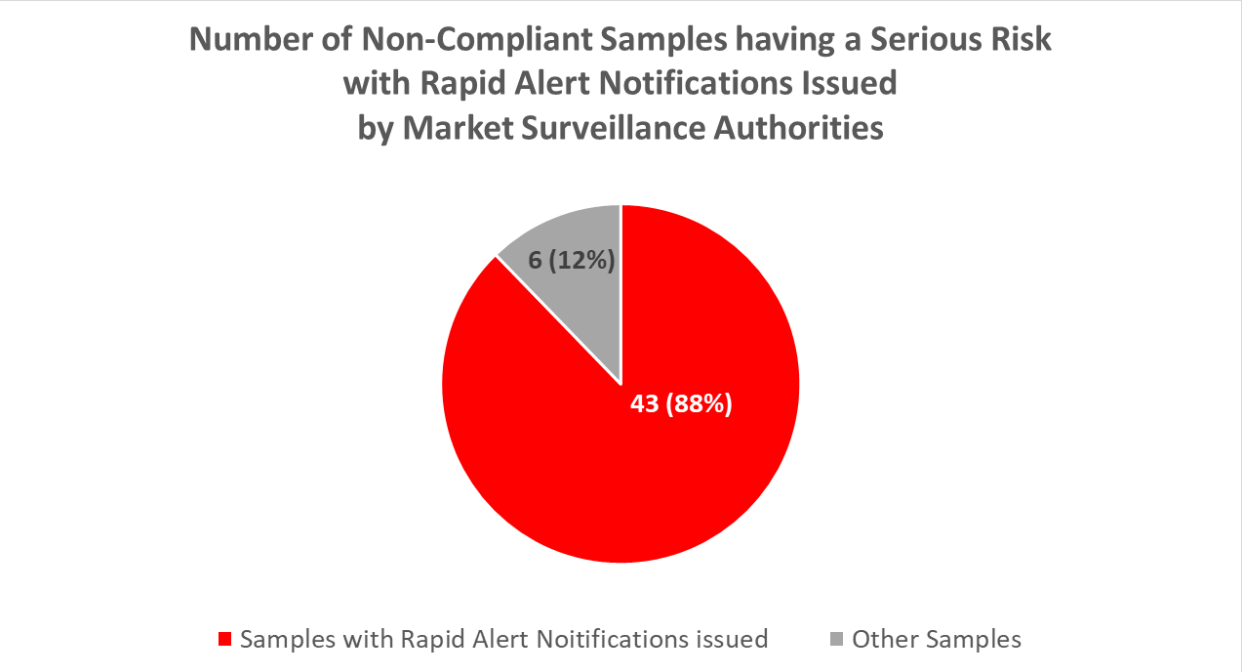


Figure 13 - Rapid Alerts Issued by MSAs

These rapid alert notifications will eventually all be shown in the European Commission's rapid alert system for dangerous non-food products[2], which is continuously updated in order to ensure that consumers are always aware of any particular dangerous products found within the Single Market.

4.6 Additional Action

Declaration of Conformity

As indicated earlier on in this report, the authorities also tried to collect information about the declaration of conformities 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. Enforcement action was taken accordingly.

It was emphasized and agreed by all the MSAs that the checking of the declaration of conformity was meant to continue to raise a certain level of awareness amongst economic operators about the importance of being able to produce these documents to the respective MSAs.

[2] https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.search

5 Liaisons

5.1 Involvement of Customs

The participating authorities tried to involve Customs authorities in this project. Some managed to directly involve them by asking them to extract a number of samples for testing. In other cases, the Customs authorities were utilised by asking them to send to the market surveillance authorities information on the type of importers who mainly imported certain type of plasticised toys as well as any other related useful information. In turn, the market surveillance authorities then were able to contact these respective importers in order to extract samples for testing. In both cases, they mainly focused on those importers that imported plastic dolls (irrespective whether intended for children under or over 3 years of age) with the Customs Taric Code 9503 00 21 90.

In total, 47 samples have been taken with assistance from Customs. This represents 18.4% of all samples sent for testing. Statistics has been given in section 2.2 of this report. Figures 3, Table 2 and Table 3 give some useful information as to how many samples were gathered with assistance from Customs.

5.2 External 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.

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).

- ☐ **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**

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 MS, 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.

5.3 Other Liaisons

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

This activity was mainly carried out through the direct participation of seventeen countries from the European Economic Area. Similar to previous joint actions, this working group continued to closely liaise with all the TOY-ADCO members so that the information is cross-shared with a much wider network of MSAs. For this reason, updates and presentations were given during each TOY-ADCO meeting of the various projects on toys coordinated by PROSAFE.

The working group is grateful for the collaboration with the Sub-Group Chemicals of the Toy Expert Group and the toy safety contact point within DG-GROW. Similarly, the PROSAFE Risk Assessment Working Group was utilised from the beginning and close cooperation existed from the start. All this helped the participating authorities to have the best possible knowledge on how to best assess risks of the non-compliant toy samples, given the circumstances.

In addition to all the above, similar to other market surveillance projects on toys coordinated by PROSAFE, 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 – JA2015. One needs to remember that although this activity involved the direct participation of 17 EEA Countries, the whole joint action involved 35 MSAs 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

6 Evaluation, Lessons Learned

6.1 Lessons learnt

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. MSAs, in order to be more efficient, will continue to focus on those products which are possibly non-compliant. Therefore, any statistics need to be evaluated with certain caution. It is true that this time round, it was difficult for inspectors to zoom in on any non-compliances related to chemicals prior to the actual testing itself. However, it was agreed from the start that special attention would be given to low-cost toys and to toys which lacked proper markings and warnings since from experience these have been found to have the highest levels of risk. Thus, the sampling was not random and cannot be used to show the level of non-compliance in the market.

- ✓ Risk assessment of chemicals in consumer products has always been a challenge to MSAs and several times they have encountered difficulties to carry out a risk assessment as required by Commission Decision 2010/15/EU, to assess the level of risk when the hazard is related to the presence of a chemical. The internal proposal for risk assessment as described in Annex 1, gives some insight on the methodology used behind the risk assessment that was performed by the majority of the participating authorities, in order to ensure a coordinated approach amongst all the authorities. As said earlier on, this was based on the original spreadsheet developed by the Sub-Group Chemicals of the Toy Expert Group and therefore credit on the scientific methodology should go to them. Having said that, there were still some participating authorities who were sceptical about the original spreadsheet itself.

- ✓ Responding to the concern of a number of Member States on the best approach for risk assessment for chemical risks, and in view of the difficulties faced by participating national authorities when applying the proposed approach, some months before the end of the activity the European Commission developed and provided an outline recommendation to all MSAs, including the participants of this activity, on how to establish the level of risk based on existing legislative limits of certain chemicals. This was very much welcomed by the MSAs and was taken into account for those participating authorities who had not yet performed a risk assessment on the respective non-compliant samples. Both methodologiues applied lead to very similar results.

- ✓ It is worth noting that all the 255 samples tested were compliant with respective legislative limits for PAHs and the migration of lead, cadmium and organotin. All the plastic toy books tested were also compliant with all the respective legislative limits that were tested by the laboratory. Non-compliances were only found in the following chemicals: phthalates, SCCPs and BPA.

- ✓ The majority of non-compliances that were determined with the help of the laboratory were associated to phthalates. It is worth noting that 46 out of a total of 50 non-complaint samples, had the respective legislative limit in phthalates exceeded. It is also worth noting that the majority of the particular samples had non-compliances associated with DEHP, DINP, DBP, DIBP and DIDP. Special attention needs to be given to toy importers of these type of toys since the majority of non-compliances were associated with toys that were placed on the Single Market by importers. Out of the 4 main toy categories focused upon, the highest level of non-compliances was found in plastic dolls.

- ✓ 10 out of a total of 255 samples tested (3.9 %), had legislative limits exceeded in the case of SCCP. The highest percentage failure rate is associated with inflatable toys, followed by bath toys / squeezable toys and last in plastic dolls.

- ✓ 3 out of a total of 30 samples tested (10%), had legislative limits exceeded in the case of migration of BPA. This chemical is primarily used to harden plastics and normally this type of chemical is found in products such as water bottles, the mouthpieces of inflatable articles and other type of products that have harder plastic. BPA was found in coloured soft plastic in these 3 particular toy samples. It is difficult to assess whether this chemical in these particular three samples could have been a result of some kind of contamination during the manufacturing stage. However, the tests results show quite a high degree of migration from the respective legislative limit. More tests on similar products may be needed in the future to better assess whether these results were just rare occasions or not.

- ✓ It is worth noting that after 1st March 2018, the new content limit of BPA in toys is going to be reduced from 3 % to 0.3 %, based on the reproductive toxicity (Category 1B). Additionally, the new limit for migration of BPA as from 26 November 2018 will be further reduced to 0.04 mg/l.

- ✓ More coordination may still be needed with Customs in order to involve them as much as possible in such joint market surveillance activities. It was found that utilising the customs taric code helped to a certain degree to better involve them in this project since they are used to following this type of product classification. It is worth noting that during the implementation of this project, there was also another separate project with Customs Authorities by the Visegrad Group Countries (Czech Republic, Slovakia, Hungary and Poland) regarding phthalates in toys. The results and best practices from both projects were discussed and shared during the final meeting of this project[3].

- ✓ More awareness is needed to ensure the proper availability of declaration of conformities to MSAs. Although in some MS this is already quite high, in others more effort may be needed in this area. Additionally, it may be interesting to further analyse how the MS act when a toy lacks a DoC in order to ensure a consistent and coordinated approach by the MSAs themselves. This could be something worth discussing in future joint actions too.

- ✓ As in previous joint actions, 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 a more focused and effective approach.

- ✓ The impact of enforcement is stronger when the market surveillance authorities work together at European level, sharing experiences and ensuring an effective coordinated approach to remove unsafe products from the Single Market.

At an administrative level;

- ✓ Joint testing of samples continued to prove itself advantageous for MSAs, since larger amounts of samples tested meant better test prices for surveillance authorities. This reduction in price due to economies of scale meant that the participating authorities could perform higher numbers of tests and focus on a much larger number of samples.

- ✓ Some participating authorities have been utilising these joint actions to further boost their experience and expertise in the subject being focused upon. Additionally, in particular in smaller Member State with possible lack of adequate administrative resources, these joint actions helped them to check their own market by testing a number of products from within their own Member State.

[3] More information about this other project can be eventually retrieved by sending an email to the PROSAFE Office on info@prosafe.org.

- ✓ The involvement of the TOY-ADCO group, in particular, who were updated 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. The close cooperation with the Sub-Group Chemicals also helped the participating authorities to better understand the complexities behind the proposed spreadsheet that the Sub-Group had developed, even if not all the MSAs agreed on it.

7 References and related legal texts

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 705038". Grant Agreement no 705038 – JA2015 - GPSD.
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 Internal proposal to help determine “Serious Risk” in plasticized toys regarding the levels of phthalates

IMPORTANT NOTE (Dated Feb 2018)

It is worth noting that the scope of this document was NOT to give particular guidance to all MSAs in the area of risk assessment. It is a document that was developed to just help the specific participating authorities within TOYS-JA2015 to have a more coordinated approach to risk assessment during June – Aug 2017. Although at that time there was no complete consensus by all authorities as to the best way forward on risk assessment, it was agreed that this document (based on the spreadsheet developed by the Chemicals Group of the Toy Expert Group) was to be used by this by the participating authorities as a way to ensure a coordinated approach to risk assessment.

Ultimately, and seeing the difficulties encountered by participating authorities when applying the proposed approach, the European Commission developed a pragmatic approach for risk assessment for chemical risks, which was presented in the 5th meeting of the toys activity. It outlined recommendations to MSAs which should be used by MSAs performing future similar risk assessment of chemical risks in toys. Annex II gives a summary of these recommendations.

At the same time, this document may be of interest, in particular, to the Chemicals Group of the Toy Expert Group who ultimately developed the original spreadsheet as explained in the Final Technical Report (Feb 2018). Indeed, a copy has been given to them together with the risk assessment results achieved on the respective non-compliant toys found within this project. It is hoped that this document may be of use to this particular working group and to other interested MSAs in order to further assess and develop particular future risk assessment strategies in this specific area.

Joint Action 2015 GPSD

Joint Market Surveillance Action co-funded by the European Union
Agreement No: 705038 – GPSD

Internal Proposal for the Participating Authorities within TOYS-JA2015 to help determine "Serious Risk" in relation to unacceptable levels of phthalates in plasticized toys

Co-funded by
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PROSAFE
Joint Actions
Best Practice

July 2017

Disclaimer

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Table of Contents

1.0 Summary

PROSAFE is coordinating a joint action of 17 MSAs (MSAs) from across Europe who are performing market surveillance of chemical risks in plasticised toys. 255 toy samples have been sent for testing and an on-site meeting has been held at the end of June 2017 at the respective laboratory to discuss the non-compliances found and how to possibly identify which of the non-compliant toys can be considered to have a "serious risk", thus helping in ultimately also having a more proportionate risk management strategy.

This document is just an internal proposal to help the 17 MSAs participating in this joint market surveillance action on chemical risks in plasticized toys, to be able to better assess whether a non-compliant toy has a "serious risk" or not. This joint action 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)'.

1.1 Current Situation

The Sub-Group on Chemicals of the Toy Expert Group has developed a '***detailed spreadsheet' in relation to the phthalates (DBP, DEHP, DINP, BBP and DIBP)*** - together with guidance for this spreadsheet - to show a possible alternative how to arrive at the risk level associated with such chemicals by estimating the respective **Risk Characterisation Ratio (RCR)**. It seems that within this Sub-Group on Chemicals there are two different schools of thought – one takes '**RCR=1'** as the limit value above which it is considered as a serious risk. The others think that '**RCR=0.1'** should be the limit, above which it is a serious risk. It is not the scope to stay going into the reasons behind these two opinions. However, it is clear that at this moment in time there is no consensus about which of these two should be adopted.

Indeed, during the last meeting held in June at the laboratory premises, there is still no consensus on the best way forward. Most of the MSAs still have serious doubt about the ***detailed spreadsheet*** itself. For this particular joint action only, the majority of the MSAs agreed to utilise "RCR= 0.1" as the limit. However, it is important to note that they still have reservations on this spreadsheet and the majority agree on this since the outcome was very similar to what the MSA use to decide in such circumstances.

More detailed explanations and discussions is needed to ensure that everyone understands the details of these spreadsheets. At the same time, simpler ways of arriving at a decision by MSAs is needed. The "**simulations, including the summary sheets in Annex 2 of this document**" and "**flowcharts**" used by this joint action have been found to be very useful to simplify the process and help MSA take a quick decision.

1.2 Primary Objective of this document

The objective of this document is to try to assist the 17 MSAs participating in this joint action to identify "serious risk" in a simple way. The **flowcharts** are all based and derived from "**simulations**" developed by the task coordinator to help the MSAs arrive at a quick decision where possible. These "**simulations**", in turn, have been completely developed using the detailed spreadsheets developed by the Sub-Group on Chemicals of the Toy Expert Group.

If, through the flowcharts or simulations, one is unable to determine whether there is a "serious risk", it is then suggested to go directly to the detailed spreadsheet of the Sub-Group Chemicals (Toy Expert Group) to determine the total RCR level of that particular sample.

2.0 Points worth noting

2.1 Understanding the spreadsheet through further simulations

Besides the ***original spreadsheet*** developed by the Toy Expert Group (Chemicals), a special additional spreadsheet called "**RA_Simulations.xlsx**" has been developed by the task coordinator of this group to assist the 17 MSAs in taking a risk assessment decision. The scope of this additional spreadsheet is to try to better understand the outcomes and simulations possible out of the ***original spreadsheet***. Annex 2 shows the summary sheets of these simulations for each phthalate.

The spreadsheet "**RA_Simulations.xlsx**" tries to highlight:

- The possible RCR outcomes available **
- Each sheet represents one of the 5 phthalates and they have been developed to fit into one page so that it can easily be printed
- Calculations are all based on the original spreadsheet developed by the Toys Expert Group (Chemicals) and the respective data for DNEL and migration rates have been taken into account
- The "constants" within the calculations
- The "variables" within the calculations
- Each Spreadsheet shows the calculations made for:
    - Dermal Exposure
    - Oral Exposure (direct intake)
    - Oral Exposure (mouthing)

***The spreadsheet only uses the default values as indicated in the original spreadsheet developed by the Toy Expert Group (Chemicals). Other possible outcomes are possible if more accurate data is used. However, the scope here is to give a generic overview.*

NB: LIMITATION of the RA Simulations - The "total exposure", that is, the exposure levels from dermal, oral (direct intake) and oral (mouthing) **CANNOT** be added together. Ultimately, one needs to use the detailed spreadsheets for this purpose. However, it was found that the risk could easily be determined for most of the non-compliant samples just by using these "simulations" and/or "flowcharts".

2.2 Assessing Risk Outcome

The scope of these simulations was to try to possibly give a logical outcome of the calculations that can be derived from using the ***original spreadsheet*** developed by the Toy Expert Group (Chemicals).

The final risk within the original spreadsheet of the Toys Expert Group (Chemicals) is categorised as:

Serious risk - if the target (or critical) RCR value is exceeded
High Risk if - if it is the same as the target (or critical) RCR value
Low to High Risk - if it is below the target (or critical) RCR Value

The possibility of having the final value exactly equal to the RCR value is rather minimal and it was agreed during this last joint action meeting that it would be better if just two final risk assessment outcomes are given:

- **SERIOUS RISK** (For anything over the RCR limit)
- **Less-than-Serious Risk** (For anything equal to OR less than the RCR limit)

From a risk management point of view, having two risk assessment outcomes would probably be enough since the market surveillance authority (MSA) would probably need to determine:

- The highest level of action taken in the case of "serious risk"
- 'Normal' Enforcement Action taken in the case of "less-than-serious risk"

2.3. Main Variables within the calculations

If one were to look at the spreadsheet "**RA_Simulations.xlsx**", each of the 5 main work sheets pertaining to each of the 5 phthalates, show a number of constants and variables in the respective calculations. The main variables for each type of exposure are shown below:

Oral Exposure (Mouthing)

In the case of **Oral Exposure (Mouthing)**, the main variable is whether the toy is intended for children under 3 years of age or not. It is assumed that:

Toys intended for children over 3 years of age	Mouthing time - 1 h/day = default value for children > 3 years Weight - 15 kg for children > 3 years (according to RIVM report 2008)
Toys intended for children under 3 years of age	Mouthing time - 4 h/day = default value for children < 3 years Weight - 7,5 kg for children < 3 years (according to RIVM report 2008)

Dermal Exposure
In the case of **Dermal Exposure**, the following variables are found within the spreadsheet:

Surface Area, dermal exposure	Surface area in contact with the skin This depends on the surface area of the toy and the surface area of the part of skin which is in contact with the toy.
Playing Time	4 h/day = default value for children < 3 years 1 h/day = default value for children > 3 years Playing time can be different from mouthing time especially for children > 3 years
Body weight of children	7,5 kg for children < 3 years (according to RIVM report 2008) 15 kg for children > 3 years (according to RIVM report 2008)

IMPORTANT NOTE: It is worth noting that the original spreadsheet does not show any correlation with the actual concentration of content of phthalate found within the toy with regards to oral exposure(mouthing) and dermal exposure. This is also respected by this proposal and therefore the actual amount of content over and above the limit as per legislation is not shown to be a determinant factor within the recommended flowcharts.

2.4 Oral Exposure (direct intake)

Oral exposure (direct intake) has NOT been taken into account simply because the type of non-complaint toys (plastic dolls, inflatable toys and bath/squeezable toys) are not the type of toys which are specifically intended for being placed in the mouth (such as teethes). Therefore, this type of exposue was not taken into account for all the non-compliant samples.

2.5 RCR Level

As indicated in section 1, there is no consensus as yet on whether to estimate the risk based on RCR = 1 or RCR = 0.1.
However, 14 out of 17 MSAs within this project agreed to use “RCR = 0.1” as the limit. The basic reason for this was that:
(i) the outcomes of the risk assessment using RCR = 0.1 is very close to the decisions that are already been taken by MSAs over these last years
(ii) taking the most honorous assumption in favour of consumers (RCR = 0.1) in line with the latest information available to this group
However, three others were not convinced and were not sure about this. Indeed, the “**RA_Simulations.xlsx**” also shows the respective outcomes for RCR = 1 as well for this purpose.
It is also worth noting that almost all the MSAs still have certain reservations as to whether the “detailed spreadsheet” is the best way how to calculate risk assessment and whether the RCR limits have been identified and based on adequate scientific information. More discussions may be needed about this at the TOY-ADCO and Toy Expert Group level.

3.0 The Recommended Flow Charts

This section tries to give a simplistic and qualitative approach to determining whether a non-complaint toy with a phthalate that has higher content values than those stipulated by legislation, has serious risk or not.

These flowcharts are mainly related to just five phthalates: DBP, DIBP, DEHP, DINP and BBP.

3.1 Basic Assumptions

Playing / Mouthing Time - Children under there years of age tend to have a higher playing time and/or mouthing time than those over three years of age. In the spreadsheets, this is distinguished by giving two main values: 1hr per day or 4 hrs or more per day. In the case of these flowcharts, it is assumed that any child under 3 years of age will usually have higher playing time /mouthing time since the toy is most likely very close to the child for longer periods of time.

Body Weight – It is assumed that the average body weight of children under three years of age will be much less (around 7.5Kg) than those of higher ages (15Kg).

These figures are all derived from the ***detailed spreadsheet***.

3.2 Reference Numbers shown within the flowcharts

(1) Placing in the mouth is defined very clearly within the ECHA Guidance Document - https://echa.europa.eu/documents/10162/13645/guideline_interpretation_concept_mouth_en.pdf

(2) Age Grading – Toys intended for children under 3 years of age – Reference is to be made to the Toy Expert Group Guidance Document No.11 – "Guidance document on the classification of toys intended for children under 3 years of age"

(3) Non-compliant Surface Area – this relates to the surface area in contact with the skin of that part of the toy where a chemical has been found to be over the required limit as per respective legislation. Therefore, one needs to take note of the appropriate accessibility to that part of the toy.

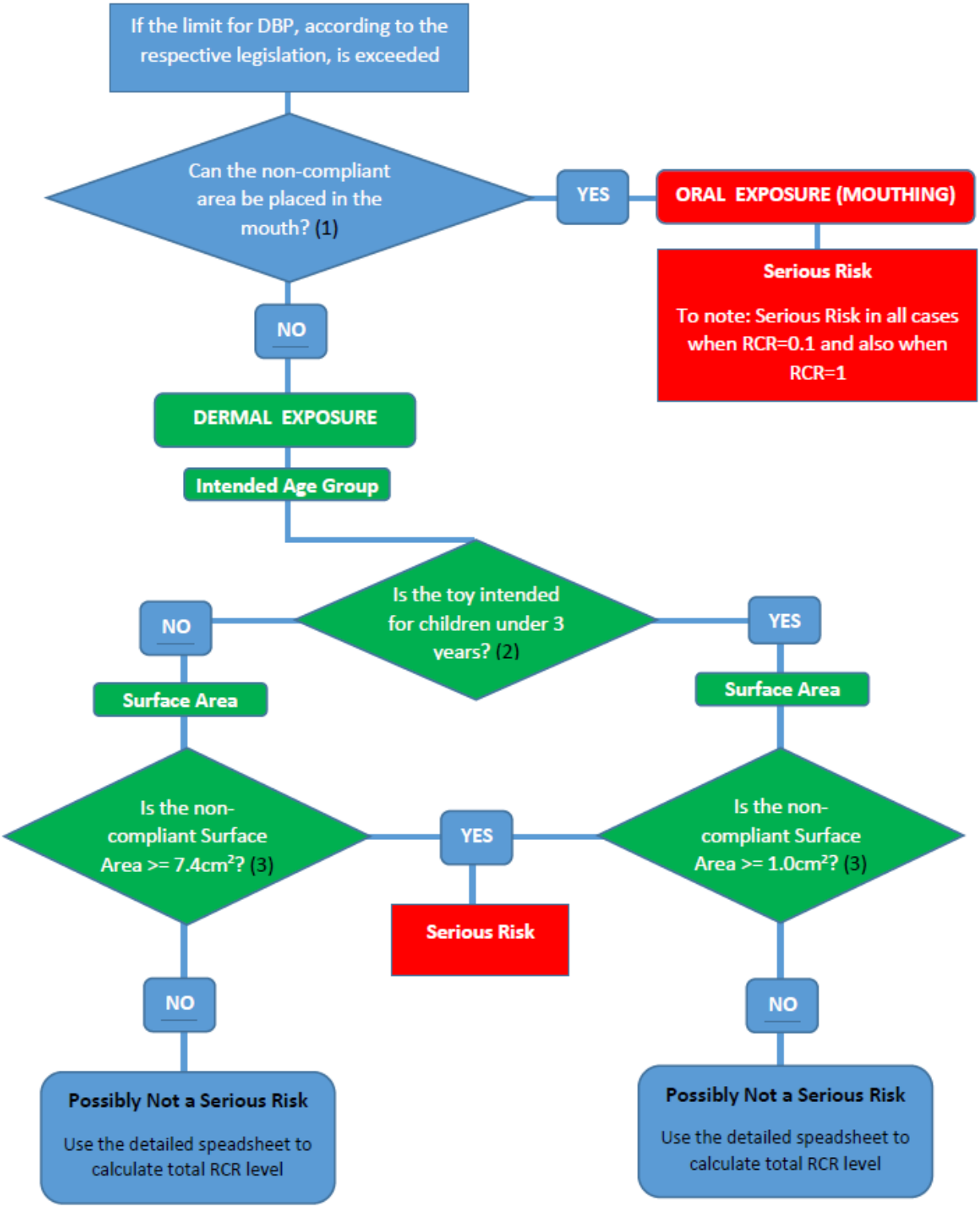
FLOWCHARTS

USING RCR = 0.1

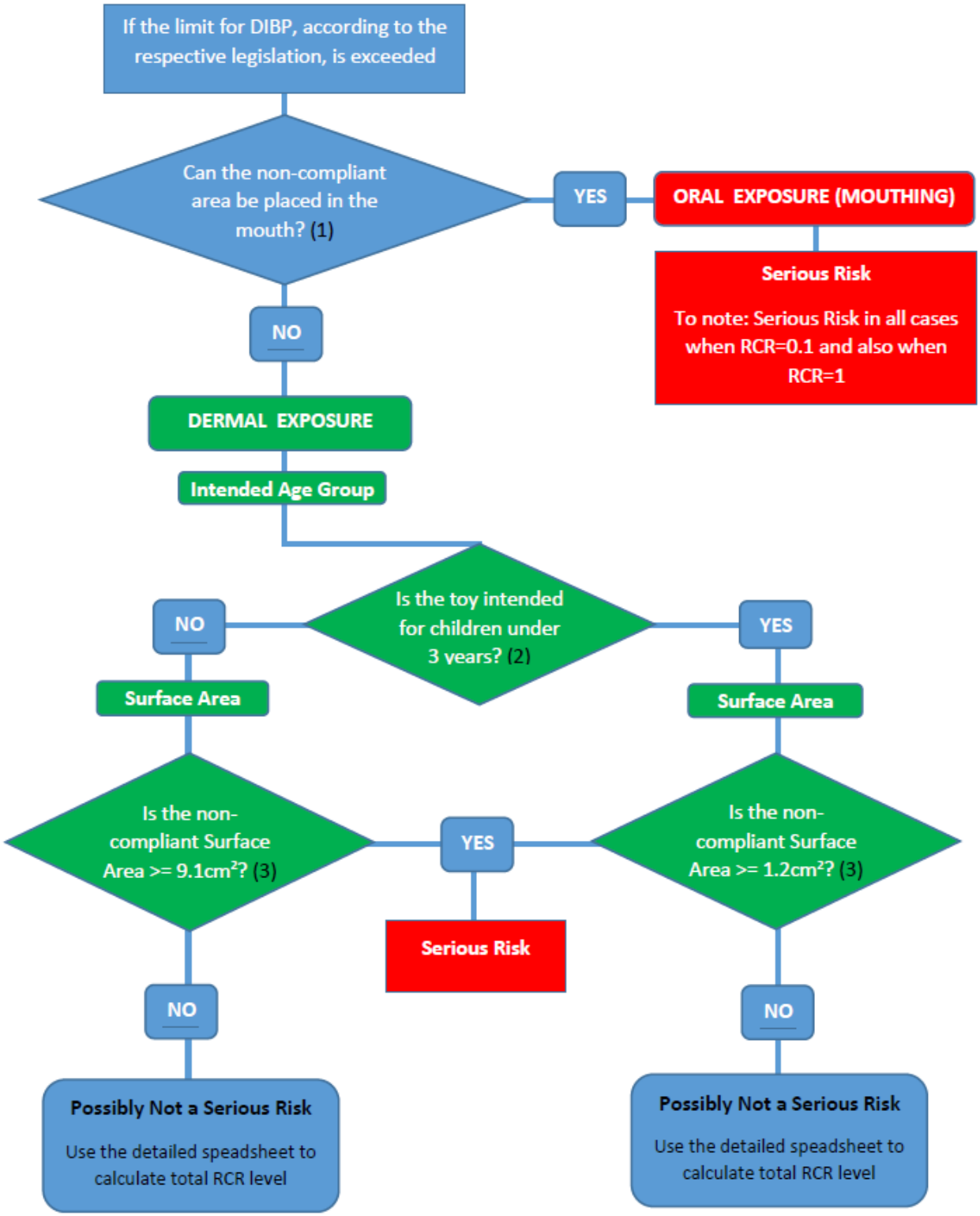
as the CRITICAL LIMIT VALUE

These are based on "summary sheets" shown in Annex 2 which in turn are completely based on the "detailed spreadsheet" developed by the Sub-Group Chemicals of the Toy Expert Group.

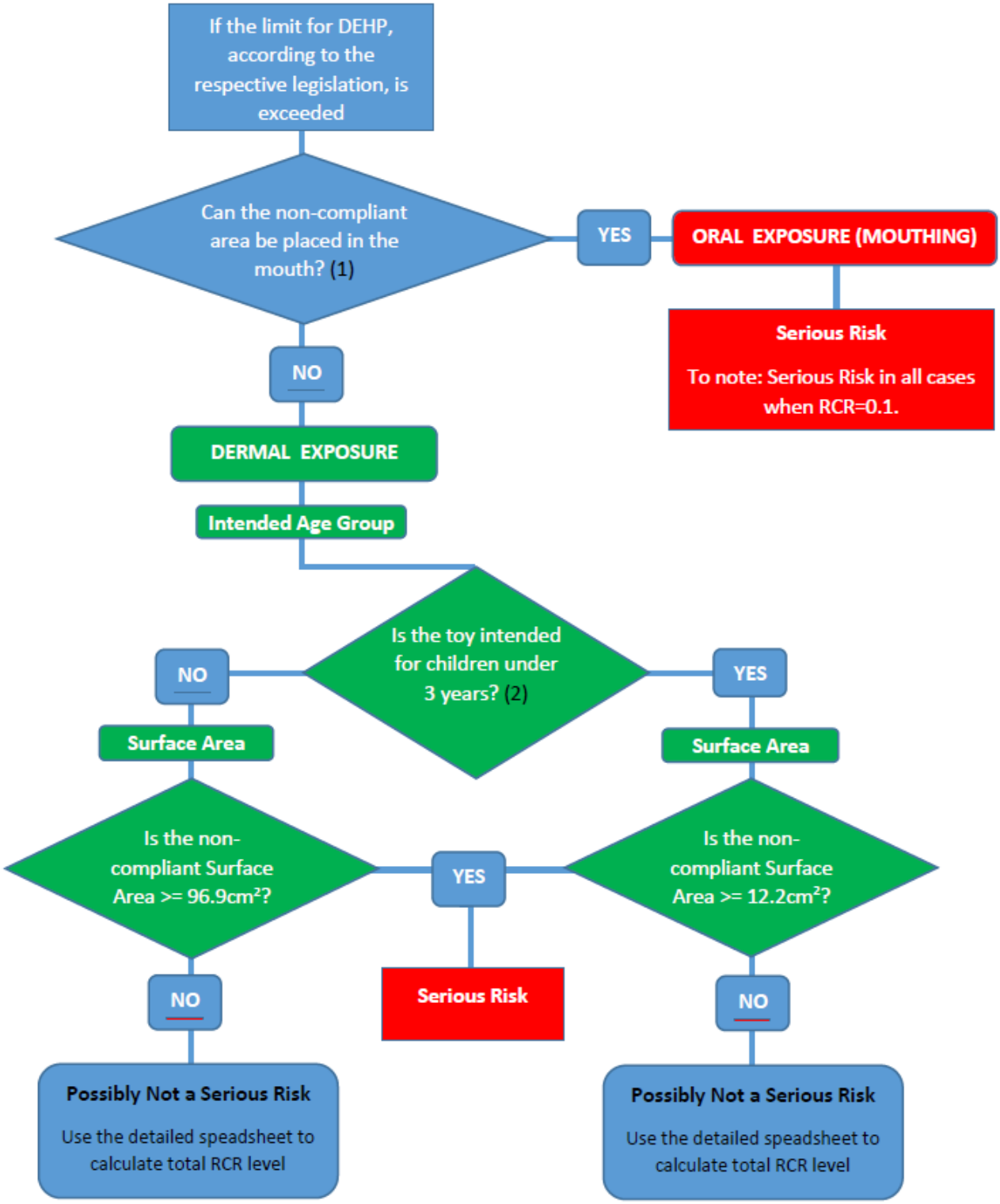
FLOWCHART 1 - Phthalate – DBP (Internal DNEL Value [µg/kgbw/day] = 6.7)



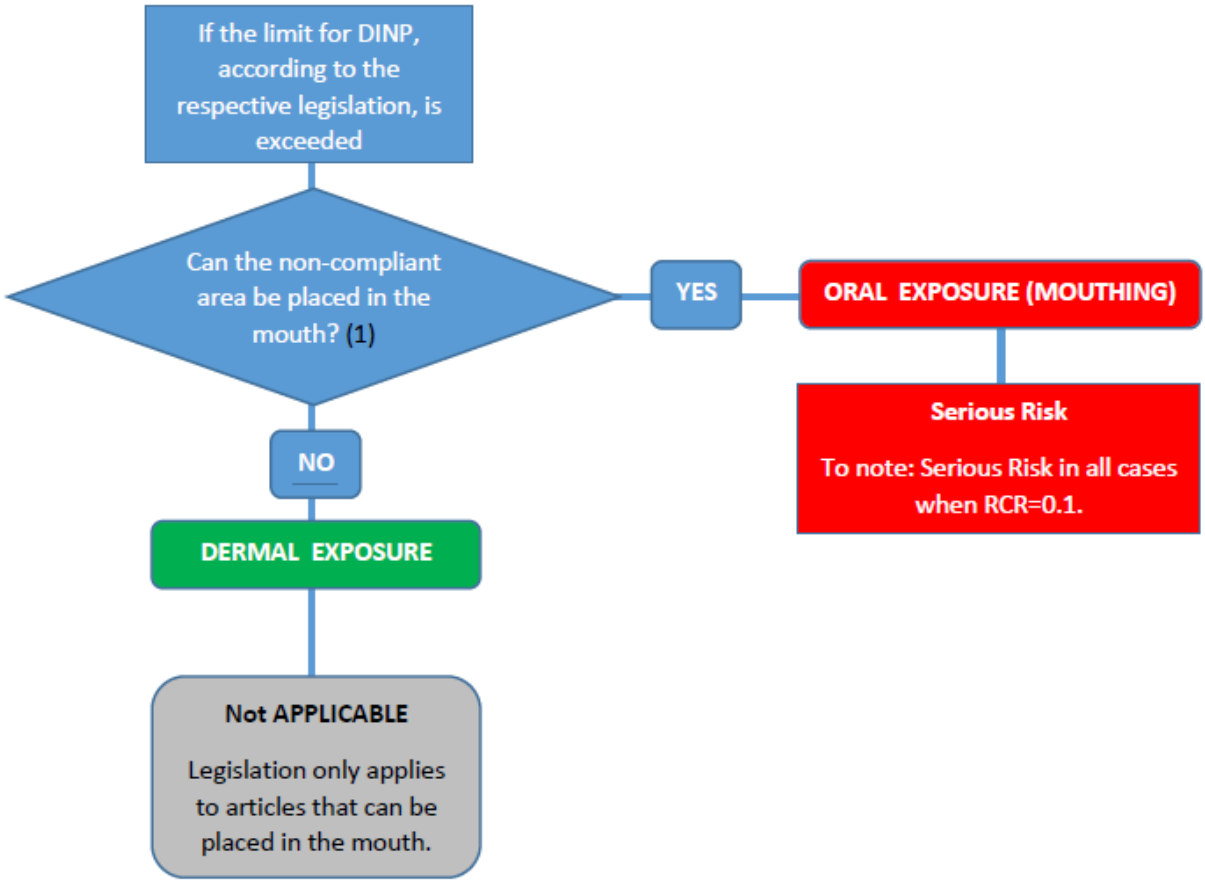
FLOWCHART 2 - Phthalate –DIBP (Internal DNEL Value [µg/kgbw/day] = 8.3)



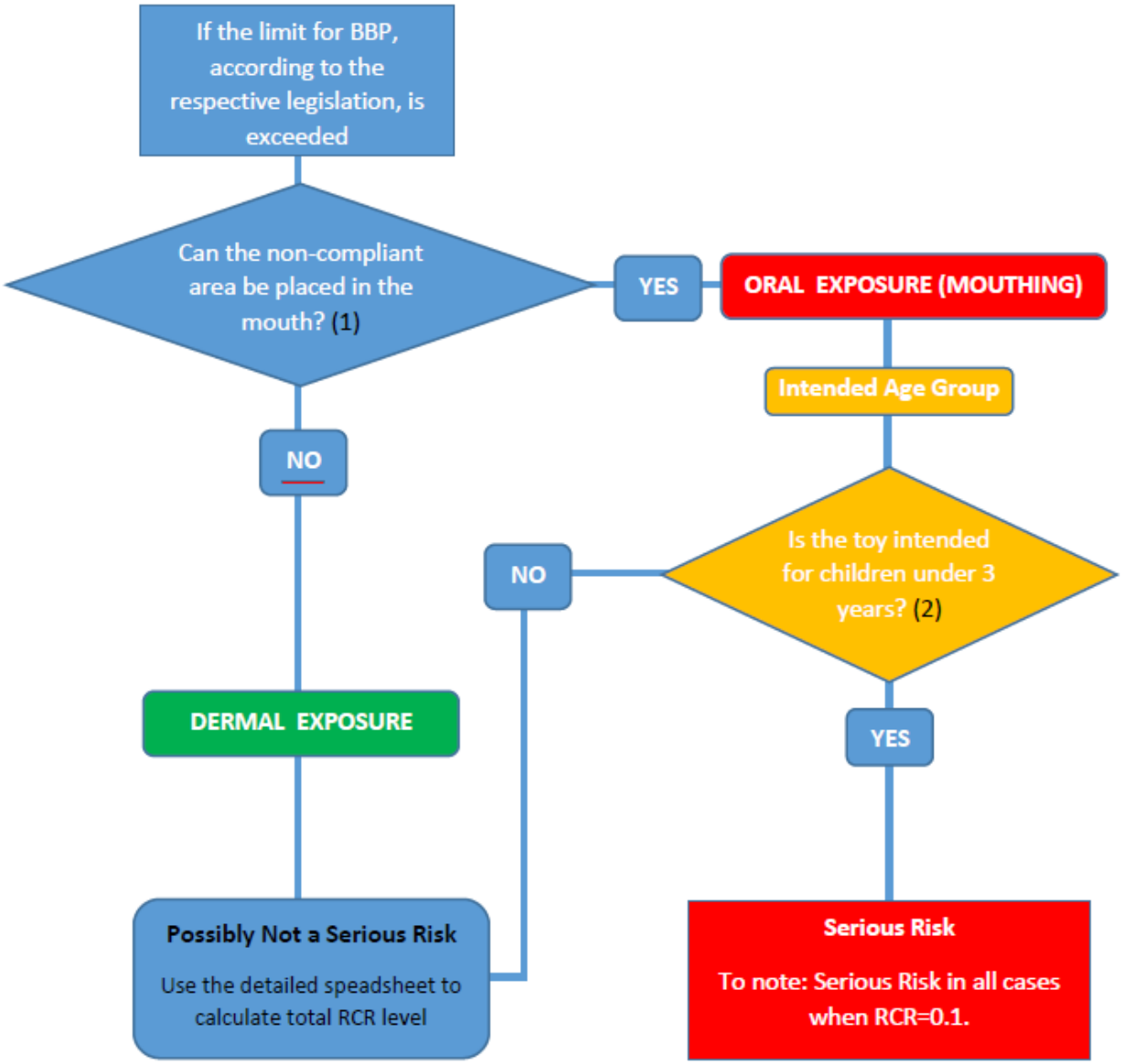
FLOWCHART 3 - Phthalate – DEHP (Internal DNEL Value [µg/kgbw/day] = 34)



FLOWCHART 4 - Phthalate – DINP (Internal DNEL Value [µg/kgbw/day] = 75)



FLOWCHART 5 - Phthalate – BBP (Internal DNEL Value [µg/kgbw/day] = 500)



4.0 What about other chemicals?

In the case of this joint action, the plasticised toys were also tested for other phthalates and chemicals such as Bisphenol A (BPA), Short Chain Chlorinated Paraffin (SCCP) and Polycyclic Aromatic Hydrocarbons (PAH), besides testing for migration of heavy metals, particularly, lead, cadmium and organic tin.

It was found that there were only non-compliances with respect to BPA and SCCP (besides phthalates).

In the case of BPA, 1 out of the 3 non-compliant samples already had a failure in one of the phthalates. Similarly, in the case of SCCP, 8 out of 10 non-compliant samples also had failures in phthalates. This meant that the group had to decide on only four samples:

- 2 samples with solely non-compliances in BPA and
- 2 samples with solely non-compliance in SCCP.

From the experience gathered from the "RA_Simulations.xlsx" and "flowcharts", it is clear that the following three elements are of particular critical importance:

(i) Whether the respective non-compliant part can be placed in the mouth or not
(ii) Whether the non-compliant sample is intended for children under 3 years of age or not
(iii) In the case of dermal exposure, how large is the non-compliant accessible surface area

In all these four samples, the non-compliant area could be placed in the mouth and all were intended for children under 3 years of age. For this reason and in view of the lack of additional scientific knowledge to this group in the area of risk assessment for these chemicals, it was agreed that the final risk assessment outcome should therefore be "serious risk".

More scientific knowledge is needed to develop flow charts for other chemicals. Although the DNEL values could be an indication of the type of flowchart that one uses, it is not the only factor and one needs to be careful not to over-simplify any particular strategy on risk assessment.

5.0 Points raised by MSAs during the meeting held in June 2017

Although all the MSAs appreciated the work done by the Sub-Group Chemicals of the Toy Expert Group, a number of points were raised during the meeting which was decided to include in this document as constructive criticism to the actual "detailed spreadsheets".

1. All MSAs found the "detailed spreadsheets" rather difficult and time consuming to fill in. During the meeting itself, with all the 17 MSAs, difficulties were encountered in establishing the total RCR for each sample and indeed this could not be done for all the cases since it was taking too long, even with the samples next to the group.

2. All the MSAs agreed that it was not acceptable to just decide at this point in time whether one should have an RCR limit of 0.1 or 1 when there are still a lot of concerns being raised by the MSAs about the whole detailed spreadsheet itself. However, for the sake of this project and in order to ensure a coordinated approach, the MSAs agreed to take a decision on a particular RCR limit.

3. There was a lot of discussions about which RCR limit should be taken into account (whether it should be 0.1 or 1). After a considerable amount of time,14 out of 17 MSAs chose the RCR limit to be "0.1". However, there is lack of clear scientific knowledge and information amongst this group of MSAs as to how the Sub-Group Chemicals arrived at these two particular RCR limits. More information and discussions are needed so that MSAs are fully aware of such information and how these limits were arrived at (in detail).

4. It is important to note that the majority of participating authorities taking part in the TOYS-JA2015 joint action are still of the opinion that if the limit value is exceeded it is enough for reporting it as a "serious risk" at this point in time.

5. One of the MSAs could not agree with how the calculations were made within the detailed spreadsheet and in view that their authority had their own experts in this field, they preferred to utilise their internal expertise to perform risk assessment.

6. Another authority preferred to use the limit RCR = 1 whereas yet another authority did not wish to come to a formal conclusion about such a limit at this point in time.

7. The "summary sheets" shown in Annex 2 and in particular the spreadsheet "RA-Simulations.xlsx" can be easily used to assess the outcomes when one uses different limit values for RCR (RCR = 0.1 or RCR = 1).

8. There were doubts why the phthalate content (derived from the test result) is only used in calculating oral exposure (direct intake) ONLY. To give an example - the main difference between a "**teether**" – used as an example within the detailed spreadsheet for oral exposure (direct intake) and a "**bath toy**" is possibly the amount of time that the toy is placed in the mouth – unless small parts can be swallowed into the stomach. However, the calculations are completely different from one another and indeed it is only in the case of oral exposure (direct intake) that the actual test result (in % weight) is taken into account. Although there is no doubt that there is a scientific explanation behind all this, it was not evident to the MSAs present. Lack of knowledge creates doubt and it is suggested that more time is needed for the experts within the Sub-Group Chemicals to really explain all this information in an informal scenario such as the TOY-ADCO group to all MSAs.

9. It could not be understood why the default values for both "mouthing time" and "playing time" are the same. It may be more appropriate to reduce default value of "mouthing" time by a percentage from the default playing time since it is assumed that children do not all the time place the toy in their mouth.

10. It is strongly suggested to the Sub-Group Chemicals that the "summary sheets" are analysed further to see if they can be used as a preliminary quick calculation of the risk. If it is already evident that there is a serious risk one can stop there. On the other hand, if it is not clear, a full RCR calculation is needed by using the "detailed spreadsheet".

6.0 Conclusion

The scope of this document has been to assist the group of 17 MSAs come up with some kind of simple and acceptable strategy for determining whether certain non-compliant toys pose a serious risk or not whenever there is non-compliance of a particular phthalate.

Credit here should be given to the work being done by the (Chemicals) Toy Expert Group who developed a spreadsheet for certain phthalates which was then used as a basis for developing this proposal. It is true that one may say that the flowcharts may over-simplify all the aspects shown in the original spreadsheet. One needs to remember that the detailed spreadsheet itself gives much more details and possibilities to determine a more precise Risk Characterisation Ratio (RCR). However, the scope here was to try to arrive at an agreed simplified proposal which could be accepted and used by all 17 MSAs. Ultimately, the scope here was to develop simple "simulations" and "flowcharts" for MSAs to come up with a quick decision. If the result is already a "serious risk" one could stop there. On the other hand, if the result is "possibly not a serious risk", the MSA should use the detailed spreadsheet to calculate the full RCR value.

It is clear from experience gathered by the MSAs of this joint action that using the detailed spreadsheets to determine the total RCR level is not practical and very time consuming. The summary sheets and flowcharts were used with ease and were found to be vey useful to help determine those non-compliant samples which clearly had a "serious risk".

One thing which was learnt from the detailed spreadsheet and which was integrated within the simulations and flowcharts is that MSAs should NOT determine the risk level based on how high the content is over and above the limit stipulated by legislation. Although this was found rather strange in the case of oral exposure (mouthing), it was not the scope of this project to challenge the scientific theory itself. This content level was therefore only important to just determine that there is non-compliance. Other factors seem to be far more important such as whether the non-compliant surface can be placed or not in the mouth, whether the toy is intended for children under 3 years of age or not and how accessible and large is the non-compliant surface area.

It is hoped that this document may serve as a basis for further discussion amongst all MSAs in order to come up with some form of acceptable basic guidance in this particular area. It should be made clear that it was never the scope of this project to develop some kind of consensus amongst all MSAs about this rather difficult subject. Eventually it is hoped that the respective test results and proposed strategy from this work group could also serve as a basis for further discussions to help the (Chemicals) Toy Expert Group, ECHA and the European Commission arrive at a pragmatic interim approach which could be acceptable by all MSAs. This will go a long way to create a positive impact amongst economic operators in Europe, since it will at least ensure a more consistent and proportionate approach when it comes to taking enforcement measures in this particular area of chemical risks in toys.

Annexure 1 What are DNELs and what are they used for?

Manufacturers and importers registering a substance under REACH in amounts of 10 tonnes or more per year are obliged to carry out a **chemical safety assessment**, which, as a minimum requirement, includes the hazard assessment of the substance.

As a result of the hazard assessment, **derived no-effect levels (DNELs)** are established. These are concentration levels below which a substance does not adversely affect human health. In line with the REACH Regulation, the registrants are required to address exposure via oral, dermal and inhalation exposure, taking into account identified local and systemic effects.

The DNELs can be used as reference values for establishing protective measures to control exposure in workplaces.

The registrants are expected to submit the DNELs as part of their technical dossier so that automated processing by authorities is possible, including dissemination through ECHA's website.

Together with the DNELs themselves some of the underlying assessment information is disseminated: the most sensitive endpoint, the route of exposure in the original study, the dose descriptor starting point (no observed adverse effect level), and the overall assessment factor and DNEL derivation method.

Registrants are also obliged to include the DNELs in the safety data sheets for their substances in order to make this information available to downstream users.

Annexure 2 Summary Sheets extracted from the Simulations Spreadsheet (RA_Simulations.xlsx)

Summary Sheet for Phthalate – DBP

Please refer to RA_Simulations.xlsx to better understand the default values used in this summary sheet

ORAL EXPOSURE (MOUTHING) (DBP)	**CONDITIONS needed to have RCR above limit**	
	For RCR limit >= 0.1	**For RCR limit >= 1**
For children over 3 years (mouthing time assumed to be 1hr/day and weight of the child to be 15Kg)	Serious Risk	Serious Risk
For children under 3 years (mouthing time assumed to be 4hrs/day and weight of the child to be 7.5Kg)	Serious Risk	Serious Risk
All outcomes are above RCR = 1 for children under or over 3 years of age **HOWEVER,** if the mouthing surface area is less than 10cm^2, one needs to re-calculate the outcomes with that particular value within the "DBP" worksheet		

DERMAL EXPOSURE (DBP)	**SURFACE AREA needed to have RCR above limit**	
	For RCR limit >= 0.1	**For RCR limit >= 1**
For children over 3 years (playing time assumed to be 1hr/day and weight of the child to be 15Kg)	7.4cm^2	77.0cm^2
For children under 3 years (playing time assumed to be 4hrs/day and weight of the child to be 7.5Kg)	1.0cm^2	9.7cm^2

ORAL EXPOSURE (DIRECT INTAKE) (DBP)	**CONCENTRATION (g/100g) needed to have RCR above limit**	
	For RCR limit >= 0.1	**For RCR limit >= 1**
For children over 3 years (weight of the child assumed to be 15Kg)	0.12	1.25
For children under 3 years (weight of the child assumed to be 7.5Kg)	0.06 (even less than the legislative limit)	0.63

Summary Sheet for Phthalate – DIBP

Please refer to RA_Simulations.xlsx to better understand the default values used in this summary sheet

ORAL EXPOSURE (MOUTHING) (DIBP)	CONDITIONS needed to have RCR above limit	
	For RCR limit >= 0.1	For RCR limit >= 1
For children over 3 years (mouthing time assumed to be 1hr/day and weight of the child to be 15Kg)	Serious Risk	Serious Risk
For children under 3 years (mouthing time assumed to be 4hrs/day and weight of the child to be 7.5Kg)	Serious Risk	Serious Risk
All outcomes are above RCR = 1 for children under or over 3 years of age **HOWEVER,** if the mouthing surface area is less than 10cm^2, one needs to re-calculate the outcomes with that particular value within the "DIBP" worksheet		

DERMAL EXPOSURE (DIBP)	SURFACE AREA needed to have RCR above limit	
	For RCR limit >= 0.1	For RCR limit >= 1
For children over 3 years (playing time assumed to be 1hr/day and weight of the child to be 15Kg)	9.1cm^2	95.3cm^2
For children under 3 years (playing time assumed to be 4hrs/day and weight of the child to be 7.5Kg)	1.2cm^2	12.0cm^2

ORAL EXPOSURE (DIRECT INTAKE) (DIBP)	CONCENTRATION (g/100g) needed to have RCR above limit	
	For RCR limit >= 0.1	For RCR limit >= 1
For children over 3 years (weight of the child assumed to be 15Kg)	0.15	1.55
For children under 3 years (weight of the child assumed to be 7.5Kg)	0.08 (even less than the legislative limit)	0.78

Summary Sheet for Phthalate – DEHP

Please refer to RA_Simulations.xlsx to better understand the default values used in this summary sheet

ORAL EXPOSURE (MOUTHING) (DEHP)	CONDITIONS needed to have RCR above limit	
	For RCR limit >= 0.1	For RCR limit >= 1
For children over 3 years (mouthing time assumed to be 1hr/day and weight of the child to be 15Kg)	Serious Risk	Not Serious Risk
For children under 3 years (mouthing time assumed to be 4hrs/day and weight of the child to be 7.5Kg)	Serious Risk	Serious Risk
TO NOTE - if the mouthing surface area is less than 10cm^2, one needs to re-calculate the outcomes with that particular value within the "DEHP" worksheet		

DERMAL EXPOSURE (DEHP)	SURFACE AREA needed to have RCR above limit	
	For RCR limit >= 0.1	For RCR limit >= 1
For children over 3 years (playing time assumed to be 1hr/day and weight of the child to be 15Kg)	96.9cm^2	Not Serious Risk (Area needed > 250cm^2)
For children under 3 years (playing time assumed to be 4hrs/day and weight of the child to be 7.5Kg)	12.2cm^2	Not Serious Risk (Area needed > 125cm^2)

TO NOTE:
The surface area needed to surpass the respective RCR limit of "1" is higher than 125cm^2 or 250cm^2. More information is provided in the "HELP" worksheet - section 3.1.

ORAL EXPOSURE (DIRECT INTAKE) (DEHP)	CONCENTRATION (g/100g) needed to have RCR above limit	
	For RCR limit >= 0.1	For RCR limit >= 1
For children over 3 years (weight of the child assumed to be 15Kg)	0.61	6.35
For children under 3 years (weight of the child assumed to be 7.5Kg)	0.40	3.18

Summary Sheet for Phthalate – DINP

Please refer to RA_Simulations.xlsx to better understand the default values used in this summary sheet

ORAL EXPOSURE (MOUTHING) (DINP)	CONDITIONS needed to have RCR above limit	
	For RCR limit >= 0.1	For RCR limit >= 1
For children over 3 years (mouthing time assumed to be 1hr/day and weight of the child to be 15Kg)	Serious Risk	Not Serious Risk
For children under 3 years (mouthing time assumed to be 4hrs/day and weight of the child to be 7.5Kg)	Serious Risk	Not Serious Risk
TO NOTE - if the mouthing surface area is less than 10cm^2, one needs to re-calculate the outcomes with that particular value within the "DINP" worksheet		

DERMAL EXPOSURE (DINP)	SURFACE AREA needed to have RCR above limit		**NOT APPLICABLE** since legislation specifies that the limit for DINP only applies for those articles which can be placed in the mouth.
	For RCR limit >= 0.1	For RCR limit >= 1	
For children over 3 years (playing time assumed to be 1hr/day and weight of the child to be 15Kg)	205.6cm^2	Not Serious Risk (Area needed > 250cm^2)	
For children under 3 years (playing time assumed to be 4hrs/day and weight of the child to be 7.5Kg)	25.7cm^2	Not Serious Risk (Area needed > 125cm^2)	

ORAL EXPOSURE (DIRECT INTAKE) (DINP)	CONCENTRATION (g/100g) needed to have RCR above limit	
	For RCR limit >= 0.1	For RCR limit >= 1
For children over 3 years (weight of the child assumed to be 15Kg)	1.34	14.00
For children under 3 years (weight of the child assumed to be 7.5Kg)	0.67	7.00

Summary Sheet for Phthalate – BBP

Please refer to RA_Simulations.xlsx to better understand the default values used in this summary sheet

ORAL EXPOSURE (MOUTHING) (BBP)	CONDITIONS needed to have RCR above limit	
	For RCR limit >= 0.1	For RCR limit >= 1
For children over 3 years (mouthing time assumed to be 1hr/day and weight of the child to be 15Kg)	Not Serious Risk	Not Serious Risk
For children under 3 years (mouthing time assumed to be 4hrs/day and weight of the child to be 7.5Kg)	Serious Risk	Not Serious Risk
TO NOTE - if the mouthing surface area is less than 10cm^2, one needs to re-calculate the outcomes with that particular value within the "BBP" worksheet		

DERMAL EXPOSURE (BBP)	SURFACE AREA needed to have RCR above limit		**TO NOTE:**
	For RCR limit >= 0.1	For RCR limit >= 1	The surface area needed to surpass the respective RCR level is higher than 125cm^2 or 250cm^2. More information is provided in the "HELP" worksheet - section 3.1.
For children over 3 years (playing time assumed to be 1hr/day and weight of the child to be 15Kg)	Not Serious Risk (Area needed > 250cm^2)	Not Serious Risk (Area needed > 250cm^2)	
For children under 3 years (playing time assumed to be 4hrs/day and weight of the child to be 7.5Kg)	Not Serious Risk (Area needed > 125cm^2)	Not Serious Risk (Area needed > 125cm^2)	

ORAL EXPOSURE (DIRECT INTAKE) (BBP)	CONCENTRATION (g/100g) needed to have RCR above limit	
	For RCR limit >= 0.1	For RCR limit >= 1
For children over 3 years (weight of the child assumed to be 15Kg)	8.91	93.29
For children under 3 years (weight of the child assumed to be 7.5Kg)	4.46	46.65

ANNEX 2 Commission Outline Recommendations on Risk Assessment of Chemicals in consumer products.

Risk assessments for RAPEX notifications: general principles

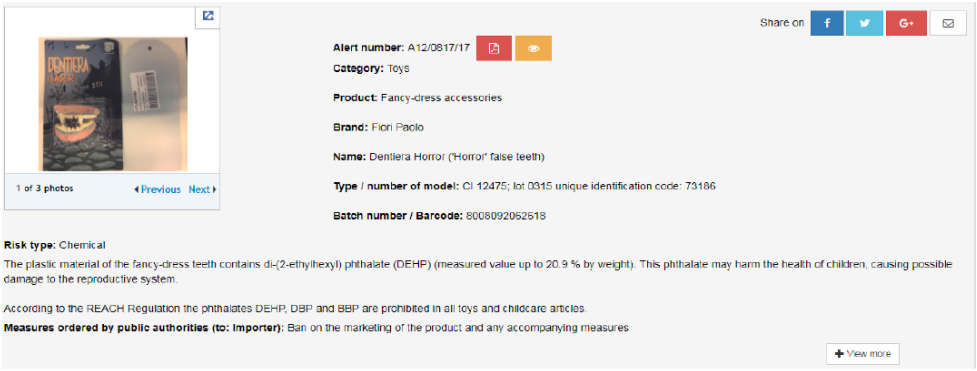
- Describe the **product** and its **hazard**
- Identify the type of **consumer** using the product
- "Let the accident happen": describe the **Injury Scenario**
- Determine the **severity of the injury**
- Determine the **probability** of the injury scenario happening
- Look up the **risk level**

Risk assesment for products containing Chemicals and RAPEX

Examples where individual risk assessment is not required for submission of alert (1)

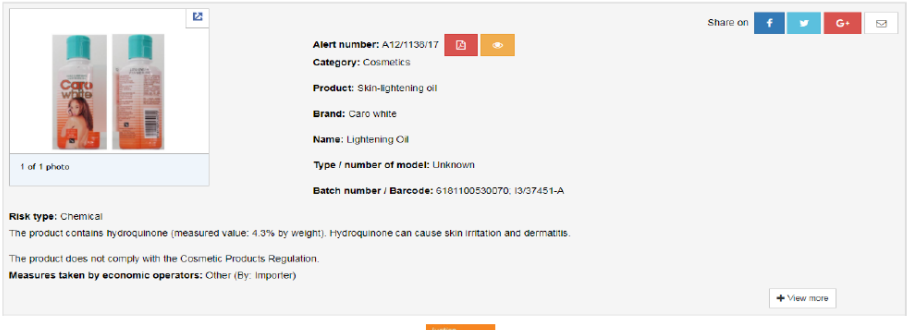
✓ REACH restrictions for the product/chemical

e.g. Cr VI in leather or certain phthalates in toys



Examples where individual risk assessment is not required for submission of alert (2)

✓ Restriction/ban in Cosmetics Regulation with SCCS opinion: ***e.g. hydroquinone***



Example where individual risk assessment required for submission of alert in RAPEX

X Restriction/ban in Cosmetics Regulation without clear SCCS opinion supporting the risk

e.g. isobutylparaben

SCCS noted that limited or no information was submitted by industry for the safety evaluation of isopropylparaben, isobutylparaben, phenylparaben, benzylparaben and pentylparaben.

- ***Assessment on a case-by-case basis***
- ***Take into consideration relevant factors, such as concentration, use, etc.***
- ***Without risk assessment an alert in RAPEX can only be included for information purposes***

Conclusions

- General rules of risk assessments also apply to chemical risks
- In general notifications should be accompanied by a risk assessment to avoid undermining the credibility of the system
- However, where scientific evidence shows that presence of the chemical in a product poses serious risk, subimssion of an individual risk assesment is not required when submitting a RAPEX alert.