Joint Action 2013 GPSD

Joint Market Surveillance Action co-funded by the European Union
Agreement No: 2013 82 01

Final Technical Report
CHEMICALS IN CLOTHING

Covering the period: 1 January 2014 - 30 December 2015

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PROSAFE
Joint Actions
Best Practice

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Disclaimer

This report arises from the Joint Market Surveillance Action on GPSD Products – JA2013, which received funding from the European Union in the framework of the 'Programme of Community Action in the field of Consumer Policy (2007-2013)'.

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

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Executive Summary

This report details the activities undertaken and the results achieved in the product activity on CHEMICALS IN CLOTHING, which formed part of the "Joint Market Surveillance Action on GPSD Products – JA 2013", which was supported financially by the European Union under Grant Agreement No. 2013 82 01 and coordinated by PROSAFE.

25 market surveillance authorities from 21 different countries within the European Economic Area took part in the overall joint market surveillance action - JA2013. They included: Austria, Belgium, 2 authorities from Bulgaria, Cyprus, Czech Republic, Denmark, 2 authorities from Germany, 2 authorities from Greece, Iceland, Latvia, Lithuania, Malta, The Netherlands, 2 authorities from Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden and the United Kingdom.

With regard to the product specific activity on Chemicals in Clothing within JA2013, 6 countries took part in this market surveillance action: Latvia, Malta, Portugal, Slovakia, Spain and The Netherlands.

External stakeholders were invited to attend the first two project meetings. The contributions from ANEC, BEUC, CEN and EURATEX were particularly useful. Cooperation existed between the market surveillance authorities and these stakeholders throughout the project. It was found that the cross sharing of experience and expertise between the market surveillance authorities involved in the project and the other stakeholders was particularly useful.

The project focused on the following types of clothing:

- Products used by children and which are in regular contact with the skin, viz.: Nightwear; Plastic shoes, Swimwear, Underwear;
- Sportswear sold by specialist sports shops;
- Trousers used by pregnant women;
- Unlined leather gloves.

A total of 302 products were collected from the market by the 6 market surveillance authorities, with approximately 50 samples being sampled by each authority. The samples were collected in two market surveillance exercises, one during the summer 2014, the other during the winter 2014/15. This enabled those products that are particularly seasonal to be collected during the summer 2014 and items made from heavier material to be collected during the winter 2014/15 sweep. It was thought that by sampling products at different periods during the year, the fabrics in products that were on sale during the summer may contain a different range of potentially hazardous substances from the products that are on sale during the winter. The products were almost exclusively collected either from economic operators who had imported the items of clothing into the EU and were acting as a distributor of these items, or from shops that were stand alone businesses, or part of a chain.

The Project Group conducted a very thorough review concerning the hazardous substances that are likely to be found in the various types of clothing listed above. They also reviewed the legislation relating to hazardous substances in clothing and the various safety standards used to determine the presence of these substances. Following this review it was decided to test the different types of clothing for the following potentially hazardous substances:

CHILDREN'S PRODUCTS –

Nightwear -	Azo dyes; Formaldehyde; Organotins; Phthalates
Plastic shoes –	Azo dyes; Cadmium; Lead; Phthalates
Swimwear -	Azo dyes; Cadmium; Formaldehyde; Lead
Underwear -	Azo dyes; Formaldehyde; Organotins; Phthalates

TROUSERS USED BY PREGNANT WOMEN - Azo dyes; Formaldehyde; Organotins

SPORTSWEAR - Azo dyes; Cadmium; Lead; Organotins; Phthalates

UNLINED LEATHER GLOVES - Chromium (III) and (VI)

Following an invitation to tender to a wide range of test laboratories, AIJU, who are based in Ibi, Alicante, Spain was appointed to undertake the testing of the samples collected from the market.

A total of 30 products were found to be non-compliant. A risk assessment was undertaken on these products by the market surveillance authority. As a result of the risk assessment it was found that the bulk of the products did not present a serious risk to consumers, or that stocks had been 'sold out' by the economic operator concerned. In many cases the products were seasonal items that had a relatively short lifespan because they were made for young, growing, children. There were, however, 4 products which presented a serious risk to consumers and which were placed on the market in more than one EU Member State. These products were the subject of an 'Article 12' RAPEX notification.

Four of the non-conforming products were subsequently subject to further investigation. A chemical risk assessment was undertaken by AIJU on these items. The methodology adopted for this analysis is that prescribed in CEN/TR 13387: 2004 – Child Care Articles – Safety Guidelines. The method was used to establish the 'daily intake of a potentially hazardous substance' by a consumer, in this case from a non-compliant item of clothing. This result is then compared with the Tolerable Daily Intake (TDI) for the user of the product, bearing in mind his/her age and weight. A risk assessment was then undertaken on each item using the methodology outlined in the Risk Assessment Guidelines for Consumer Products, part IV, Chapter 5 in Decision 2010/15/EU - 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). It was concluded that the method for 'risk assessment', as outlined in Decision 2010/15/EU, can be applied successfully to chemical hazards and not just to physical, mechanical and electrical hazards.

Although the project found that the hazardous substances in very few samples presented a serious risk to consumers, the activity has made a significant contribution to market surveillance in a product sector that has hitherto been the subject of very little regulatory activity. It has also demonstrated a willingness to cooperate by the economic operators with the regulatory authorities in this product sector, whilst recognizing that the testing for hazardous substances in textile items is a demanding activity.

Caution!

The test results, which are included in this Report, are based on products that were sampled from the markets in the participating countries by experienced market surveillance inspectors that were looking for potentially non-compliant and 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. In this Action the term 'targeted' refers to the fact that specific types of clothing were selected for inclusion in the market surveillance exercises, rather than clothing in general as we believed that these types of clothing were likely to contain chemicals that could prove to be a hazard to the user.

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

Introduction

This is the Final Technical Report relating to the market surveillance activity on CHEMICALS IN CLOTHING, and was part of the Joint Market Surveillance Action on GPSD Products – JA2013. The Joint Action received funding from the European Union in the framework of the 'Programme of Community action in the field of Consumer policy (2007-2013)'.

Section 1 of the report introduces the project and provides some background information relating to the activity. Section 2 discusses the work that was undertaken during the first, preparatory, stage of the project. Section 3 provides a summary of the number and types of products that were collected during the two market surveillance activities.

The results from the tests on the samples that were collected by the participating Member States are summarised at Sections 4 and 5. A short summary about the methodology used is given at the beginning of each of these two sections. Section 4 discusses the key area of risk assessment and identifies a number of dangerous products. It also includes information on the measures taken by the market surveillance authorities with regard to these products. Section 5 reviews the further work that was undertaken on 4 products for which a 'chemical risk assessment' was undertaken.

Section 6 discusses the links that the Project Group established with a range of external stakeholders. These included the European Commission and the Expert Group on Textile Names. Finally, Section 7 summarises the lessons learnt from the conduct of this project.

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

As in any market surveillance activity, the results represent the targeted efforts that authorities undertake to identify unsafe products. In this connection products were sampled from the market that were likely to contain hazardous substances. The market surveillance officers recognised that in this particular project it was not possible to identify products at the premises of the economic operator that were likely to be non-compliant without recourse to laboratory testing on the items concerned. The results do not give a statistically valid picture of the market situation. Having said that, it is hoped that both market surveillance authorities and the external stakeholders find this report useful and informative.

1 Background Information

This chapter presents a short introduction to the Chemicals in Clothing project. A more extensive description of this product specific Joint Action 2013 can be found in the Grant Agreement between the Executive Agency for Health and Consumers and PROSAFE[1].

1.1 Title of the Activity

The activity focussed on the dangers to consumers that are presented by a range of hazardous chemicals or substances that are likely to be present in items of clothing. As has been mentioned previously, the activity was part of Joint Market Surveillance Action on GPSD[2] Products – JA2013.

The European Commission supported the Joint Action financially under Grant Agreement No. 2013 82 01.

1.2 Participating Member States

The activity was undertaken by PROSAFE and 6 market surveillance authorities from 6 Member States took part in this activity, viz.: Latvia, Malta, Portugal, Slovakia, Spain and The Netherlands.

1.3 Overview of key staff in the Activity

The Activity Leader was Linda Rinkule from the Consumer Rights Protection Centre, Latvia.

The Activity Leader was supported by PROSAFE consultant, Robert Chantry-Price.

A Project Group was established by PROSAFE to oversee the conduct of the activity. The membership of the Group included the following representatives from the participating Member States:

Latvia -	Agrita Birzule, Latvian Consumer Rights Centre
Malta –	Charles Tanti, Malta Competition and Consumer Affairs Authority
Portugal –	Goncalo Baptista, Food and Economic Safety Authority
Slovak Republic –	Andrea Valkova, who was replaced during the course of the project by Timea Mogyorosiová
Spain –	Ana Horta, National Institute for Consumer Protection
The Netherlands -	Durk Schakel, The Netherlands Food and Consumer Product Safety Authority

1.4 Main Objectives

The primary objective of this activity was to detect dangerous products on the market.

The product specific activities allowed the development of:

- Sharing of best practices and
- The exchange of experiences in relation to this market surveillance activity on CHEMICALS IN CLOTHING.

During the preparatory phase the Project Group focused on:

- Determining the activities to be undertaken during the course of the project;
- Establishing the project plan;
- Establishing which types of clothing presented the highest risk to consumers;
- Establishing which substances are likely to be present in items of clothing and determining how the garments might be tested for the presence of these substances.
- Issuing the invitation to test laboratories to tender for the testing of samples.

[1] Grant Agreement for an action with multiple beneficiaries. Agreement No 2013 82 01. European Commission – Executive Agency for Health and Consumers

[2] Directive 2001/95/EC – on General Product Safety

In the intermediate phase the Project Group focused on:

- The collection of samples from the market;
- The testing of the samples collected from the market;
- Conducting an initial risk assessment as to whether non-compliant products presented a serious risk to consumers.

During the final phase the Project Group

- Undertook a final risk assessment on the non-compliant products to ascertain whether they presented a serious risk to consumers;
- Disseminated the results on the testing of products;
- Formulated a number of best practices in relation to the 'chemical risk assessment' of non-compliant products;
- Collected information on the measures taken by market surveillance authorities in relation to non-compliant products.

1.5 Number of samples tested

A total of 302 separate products were sent for testing. As each of the samples were usually subjected to a number of tests for a range of potentially hazardous substances a total of 1454 separate tests were performed on these samples.

1.6 The main activities

The project included the following activities:

- *Decide on the hazardous substances for which each sample should be tested*
  In this connection it was necessary to identify the appropriate legislation and safety standards that are appropriate in order to conduct tests on each sample.
- *Decide on sampling criteria*
  To decide on how the Member States should carry out sampling, i.e. how many samples should be taken by each authority, when the sampling should take place, what criteria should be applied when selecting the specific samples, and how many items should be taken of each product.
- *Sample products*
  The Member States agreed to acquire products according to the sampling criteria and to visit manufacturers, importers and retailers, as appropriate, to collect products.
- *Test products at an accredited laboratory*
  The Activity issued a call for tender and selected an appropriately accredited laboratory. The Member States were instructed how to send their products to the test laboratory for testing.
- *Undertake a Risk Assessment on non-compliant products*
  The participants developed a common approach to risk assessment so as to ensure that the resulting assessments were harmonised as far as possible. The Member States then assessed the risk to consumers for the non-compliant products by applying the agreed approach, together with any relevant national conditions.
- *Follow-up on non-compliant products and exchange information on the follow-up activities.*
  After conducting a risk assessment on non-compliant products the Member State authorities followed up with the economic operators in their country on the results from the risk assessment, agreed on appropriate measures and ensured that these measures were implemented. The resulting measures were reported to the Joint Action and shared with all participants.

1.7 Timeline of the Activity

The phasing of the activity was:

Phase 1 – Month 3- Month 8 - The preparatory phase.

During this phase the 'kick off', or first Project Group meeting, was held. It consisted of an 'open meeting' to which representatives of the participating Member States and the stakeholders were invited and a 'closed' meeting for the participating Member States. The 'open' meeting was held at PROSAFE's offices in Brussels on 25th March 2014. The 'closed' meeting was held in the same location on 25th and 26th March 2014.

The external stakeholders that attended the 'open' meeting included representatives from: DG SANCO/JUST and DG Enterprise as well as from ANEC, BEUC, CEN - Technical Committee TC 248 – Textiles and textile products and the European Textiles Association (EURATEX).

The second Project Group meeting was also held during this phase. It consisted of an 'open meeting' to which representatives of the participating Member States and the stakeholders were invited and a 'closed' meeting for the participating Member States. Both meetings were held at PROSAFE's offices in Brussels on 3rd June 2014.

Phase 2 – Month 9 – Month 16 – The second phase

The third Project Group meeting was also held during this phase. It consisted of a 'closed' meeting for the participating Member States and was held at PROSAFE's offices in Brussels on 16th September 2014.

The fourth Project Group meeting was a 'closed' meeting for the participating Member States. It was held at AIJU's premises, Ibi, Alicante, Spain on 3rd December 2014. The meeting reviewed the results of the tests on the products collected during the Summer 2014 market surveillance exercise. The opportunity was also taken to visit the AIJU's labs, to meet the staff who had been involved in testing our samples and to see the equipment used during the testing process.

The fifth and final Project Group meeting was also held during this phase. It consisted of a 'closed' meeting for the participating Member States and was held at PROSAFE's offices in Brussels on 21st April 2015. Inter alia, the meeting reviewed the results of the tests on the products collected during the Winter 2014/15 market surveillance exercise.

Phase 3 – Month 17 – Month 26 - The final phase

No Project Group meetings were held during this phase as it was principally devoted to conducting a final risk assessment on non-compliant products and to the regulatory authorities taking measures concerning non-compliant products.

The Final Technical Report was prepared during this phase.

The Activity Leader and the Activity Coordinator attended the Final Workshop on JA 2016 in January 2016 and presented an oral report on the conduct of the Joint Action on Chemicals in Clothing.

2 Setting up the Product Activity

2.1 The preparatory phase

This was the first occasion on which PROSAFE, or we believe that any other organization with an interest in product safety, has conducted a multi-national market surveillance exercise into the compliance of clothing items with the relevant legislation and safety requirements. Previous studies have looked at a restricted range of potentially hazardous substances in a limited range of types of clothing. The aim of this project was to collect from the market a wide range of items of clothing and to examine them for as extensive a range of potentially hazardous substances as the time restrains and the budget would permit.

At the start of the project the Project Group reviewed the terms of reference of the Joint Action and concluded that it needed to determine, as soon as possible:

Which types of clothing should be included in the market surveillance exercise;

When the market surveillance exercise(s) should be conducted;

The number of samples that should be collected from the premises of economic operators during the course of the market surveillance exercise(s);

The legislation that is applicable to hazardous chemicals in clothing;

The potentially hazardous substances that are likely to be found in each type of clothing;

How to proceed with regard to the call for tender for the testing of items collected from the marketplace and how to select the test laboratory that would undertake the testing of the samples;

How to establish which safety standards are applicable when determining the quantity of a particular hazardous chemical in an item of clothing.

Members also noted that during the course of the project new legislation concerning the requirements for Chromium (VI) would come into force and this would need to be taken into account when deciding on the testing regime.

2.2 Types of clothing and timescale

All 21 Member States that are participants in JA 2013 were surveyed to ascertain which items of clothing should be included in the market surveillance exercise. This information, together with the views of the Member States that participated in the project and the stakeholders, were used to establish a definitive list of the types of clothing that would be collected during the course of the market surveillance exercise.

It was noted that the range of clothing on the market is significantly different in the summer to that available during the winter and that the items on sale during the summer are likely to contain a different range of potentially hazardous substances to those being placed on the market during the winter. It was agreed therefore that two market surveillance exercises be conducted, one during the Summer 2014; the other during the Winter 2015/15.

After discussion it was agreed that the following types of clothing should be collected from the market:

(a) Products used by children and which are in close contact with the skin, viz.:

Nightwear - to be collected during the Summer 2014 and Winter 2014/15;

Plastic shoes made from coloured plastic – flip flops, sandals and rain boots - i.e. not made from transparent plastic – to be collected during the Summer 2014;

Swimwear – to be collected during the Summer 2014;

Underwear - made from both man made & from natural fibres - to be collected during the Summer 2014 and Winter 2014/15.
(Items selected should include those made of a dark material &/or those with plastic parts or, decals, &/or those with a large area of rubberized fabric or fabric with a significant amount of printing in ink).

(b) Products used by pregnant, viz.: trousers - with an elasticated belt – to be collected during the Winter 2014/15;

(c) Sportswear - sold by economic operators specializing in sportswear, NOT sold by traders who sell a wide range of items of apparel. The items selected should include: printed polyester T-shirts &/or cycling shorts, including those made with elasticated fabric(s) - to be collected during the Summer 2014 and Winter 2014/15.

(d) Unlined leather gloves – for general use, as PPE or as sportswear - to be collected during the Winter 2014/15.

Members considered that it would be appropriate to focus on products that are in close contact with the skin, particularly those used by children and those used by pregnant women as it is during this period in their life that the skin is most sensitive and therefore more likely to absorb any harmful substances.

2.3 Applicable legislation and likely potentially hazardous substances

This proved to be a particularly demanding issue, as no complete and up to date list exists of the potentially hazardous substances that are likely to be found in clothing. Furthermore, we were unable to find a list of the legislation that is applicable to this group of consumer products in the EU and its constituent Member States.

The most extensive list of hazardous substances likely to be found in clothing is that given in the Oeko-tex 100 standard. The standard, is a private independent testing and certification system for textile raw materials, intermediate and end products at all stages of production. The testing for harmful substances includes: illegal substances; legally regulated substances; known harmful (but not legally regulated) chemicals, as well as parameters for health care. In its entirety the requirements clearly exceeds the range of current European and national legislation in the EEA for textile items. The standard covers over 200 substances and includes:

24 x	Arylamines having carcinogenic properties;
10 x	Chlorinated benzenes and toluenes;
3 x	Chlorinated phenols;
34 x	Dyestuffs and pigments classified as allergenic, carcinogenic, or banned for other reasons;
9 x	For the emission of volatiles;
12 x	Extractable heavy metals;
18 x	Forbidden flame retardant substances;
1 x	Formaldehyde;
4 x	Organic tin compounds;
4 x	Other chemical residues;
60 x	Pesticides;
6 x	PFC's, Perfluorinated Compounds;
14 x	Phthalates;
23 x	Polycyclic aromatic hydrocarbons (PAH);
4 x	Solvent residues;
6 x	Surfactant, wetting agent residues.

There are four product classes, viz.:

Product Class I: Textile items for babies and toddlers up to 3 years (clothing, toys, bed linen, terry cloth items etc.);
Product Class II: Textiles used close to the skin (underwear, bed linen, T-shirts etc.);
Product Class III: Textiles used away from the skin (jackets, coats etc.);
Product Class IV: Furnishing materials.

The requirements for Class I are the most onerous, with the requirements for Classes II, III and IV each becoming less onerous.

The Oeko-tex 100 standard has been compiled from the statutory requirements that pertain in the EEA, in North America and elsewhere, e.g. Japan. It also includes some additional requirements imposed by Oeko-tex. It provides a useful baseline from which to start reviewing the range of harmful substances that might be included in the testing regime for the Joint Action.

The legislative framework for those chemicals that are likely to be found in clothing is scatteredin several pieces of legislation. It is principally embedded in REACH (Registration, Evaluation, Authorisation & Restriction of Chemicals) Regulation (EC) No 1907/2006 – Annex XVII, as well as other items of legislation.

The Project Group noted that during the course of the activity the REACH restriction on Chromium (VI) in leather articles. Details of the requirements are contained in Regulation (EU) No 301/2014 as regards Chromium (VI). The Regulations became applicable on 1 May 2015, some months after the period during which the second market surveillance exercise was completed. They require that leather articles, or parts thereof, coming into contact with the skin shall not be placed on the market where they contain Chromium (VI) in concentrations equal to, or greater than, 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather.

The participating Member States thought it would be useful to collect a number of leather articles from the market during the course of the project in order to ascertain the extent to which leather items of apparel contain more than 3 mg/kg of Chromium (VI).

The Project Group conducted a thorough review of the legislation that is relevant to chemicals in the various types of clothing listed at 2.2 above and the range of potentially hazardous chemicals specified in Oeko-tex 100. They concluded that, for the most part, only those hazardous substances for which there is a legislative safety requirement should be assessed. As a range of different hazardous substances are likely to be present in each type of clothing it was agreed that the test lab should be requested to test each sample for a specified range of potentially hazardous substances. The matrix that was finally agreed is given at Table 2.1.

PRODUCT	*HAZARDOUS SUBSTANCES LIKELY TO BE FOUND IN THESE PRODUCTS*
CHILDREN'S PRODUCTS –	
Nightwear -	Azo dyes; Formaldehyde; Organotins; Phthalates
Plastic shoes –	Azo dyes; Cadmium; Lead; Phthalates
Swimwear -	Azo dyes; Cadmium; Formaldehyde; Lead
Underwear -	Azo dyes; Formaldehyde; Organotins; Phthalates
TROUSERS USED BY PREGNANT WOMEN -	Azo dyes; Formaldehyde; Organotins
SPORTSWEAR -	Azo dyes; Cadmium; Lead; Organotins; Phthalates
UNLINED LEATHER GLOVES -	Azo dyes; Chromium III and VI

Table 2.1 – List of hazardous substances to which the various types of clothing selected for inclusion in the market surveillance exercise would be subjected.

The legislative requirements for each of the types of clothing are:

Azo colourants and Azo dyes – REACH Annex XVII: Entry 43 –
22 Aromatic amines are listed at Appendix 8 and require that:
(1) Azo dyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations, i.e. above 30 mg/kg (0,003 % by weight) in the articles or in the dyed parts thereof, according to the testing methods listed in Appendix

10, shall not be used, in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as: — clothing, … footwear, gloves ….
Furthermore, the textile and leather articles referred to in paragraph (1) shall not be placed on the market unless they conform to the requirements set out in that paragraph.

The following test methods are referenced in Appendix 10 –
EN ISO 17234: 2003 - Leather. Chemical tests for the determination of certain azo colorants in dyed leathers;
EN 14362-1:2003 - Textiles. Methods for determination of certain aromatic amines derived from azo colorants. Detection of the use of certain azo colorants accessible with and without extracting the fibres;
EN 14362-2:2003 - Textiles. Methods for determination of certain aromatic amines derived from azo colorants. Detection of the use of certain azo colorants, which may release 4-aminoazobenzene
(Note: The updated version of these standards are EN ISO 17234-1: 2010 and EN ISO 17234-2: 2011; EN 14362-1: 2012. EN 14362-2: 2003 has been superseded by EN 14362-1: 2013.

Cadmium – REACH Annex XVII: Entry 23 - Cadmium and its compounds...
1. Shall not be used in mixtures and articles produced from the following synthetic organic polymers (hereafter referred to as plastic material) – (then follows a list of substances) - Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01% by weight of the plastic material.
(Note: No test method is specified in REACH for the determination of the weight of Cadmium in a sample.)

Chromium (VI) –
Regulation (EU) 301/2014 amending Annex XVII to Regulation (EC) No 1907/2006 REACH as regards Chromium (VI) compounds –
5. Leather articles coming into contact with the skin shall not be placed on the market where they contain Chromium (VI) in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather.
6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains Chromium (VI) in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of that leather part.
7. Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015.'

Note: 1. The test method EN ISO 17075 – Leather – Chemical requirements – Determination of Chromium (VI) is specified in REACH for the determination of the concentration of Chromium (VI) in a sample;
2. It is understood that Chromium (III) degrades under certain conditions to Chromium (VI). EN 71-3 – Safety of toys – Heavy metals was used to test for the presence of Chromium (III).

Formaldehyde – There are no EU wide requirements for formaldehyde in clothing. However a number of Member States have national requirements, viz.:

Finland and Norway - limit levels in:
textiles for babies under 10 years old—30 ppm;
textiles in direct skin contact—100 ppm;
textiles not in direct skin contact—300 ppm.

France - limits levels in:
textiles in baby products intended to come in contact with skin—20 ppm;
textiles in direct skin contact—100 ppm;
textiles not in direct skin contact—400ppm.

Germany – states that:
textiles that normally come in direct contact with the skin and release more than 1500 ppm formaldehyde must bear a label that states: 'Contains formaldehyde. Washing this garment is recommended prior to first time use in order to avoid irritation of the skin.'

The Netherlands:
has the following limits on formaldehyde in textiles that come in direct contact with the skin: any textile containing more than 120 ppm formaldehyde must be labelled: 'Wash before first use'. After washing, these products must not contain more than 120 ppm.

Organostannic compounds – REACH Annex XVII – Entry 20 –
Tri-substituted organostannic compounds such as tributyltin (TBT) compounds and triphenyltin (TPT) compounds shall not be used after 1 July 2010 in articles where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin.
Dibutyltin (DBT) compounds shall not be used after 1 January 2012 in mixtures and articles for supply to the general public where the concentration in the mixture or the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin.
Dioctyltin (DOT) compounds shall not be used after 1 January 2012 in the following articles for supply to, or use by, the general public, where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin:
— textile articles intended to come into contact with the skin,
— gloves,
— footwear or part of footwear intended to come into contact with the skin.
(Note: No test method test is specified in REACH for the determination of the weight of tin in a sample.)

Phthalates – REACH Annex XVII – Entry 51 –
The following phthalates DEHP, DBP, BBP –
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.
2. Toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market.
3. The Commission shall re-evaluate, by 16 January 2010, the measures provided for in relation to this entry in the light of new scientific information on such substances and their substitutes, and if justified, these measures shall be modified accordingly.
4. For the purpose of this entry 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.

REACH Annex XVII – Entry 52 –
The following phthalates DINP, DIDP, DNOP -
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.
2. Such toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market.
3. The Commission shall re-evaluate, by 16 January 2010, the measures provided for in relation to this entry in the light of new scientific information on such substances and their substitutes, and if justified, these measures shall be modified accordingly.
4. For the purpose of this entry 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.
(Note: No test method test is specified in REACH for the determination of the percentage by weight of phthalate in the plasticized material in a sample.)

It was noted that the EU have published two statements clarifying the application of REACH Annex XVII – Entries 51 and 52 with regard to phthalates in textile items, viz.:

EU statement 'Phthalates in Consumer Products including toys and childcare articles' in 2010:
"… in view of the Commission services, children's shoes and textile products, such as T-shirts are neither toys or childcare articles and thus do not fall under the scope of entries 51 and 52 of Annex XVII of REACH, which only applies to toys and child care articles."

EU statement 'Conclusions of the review clause in toys & child care articles REACH restriction (DINP, DIDP, DNOP) entry 52' in 2014:
'For other consumer products (i.e. textile items) containing the phthalates DEHP, DBP, or BBP and possibly other phthalates above 0.1% could be notified as posing a serious risk under Article 12 of the General Product Safety Directive 2001/95/EC & Article 22 of Regulation (EC) 765/2008 provided that a state of the art risk assessment justifies it, and this will be assessed on a case by case basis.'

It was noted therefore that any risk assessment undertaken in relation to phthalates would need to be undertaken on an item of clothing under the provisions of the General Product Safety Directive, rather than under the provisions of REACH Annex XVII – Entries 51 & 52.

Heavy metals – Chromium (III) and Lead –
These metals are likely to be contained in plastic decals, metal threads etc. on clothing so a check was made for the presence of these substances even though they are not subject to legal a requirement. The migrations limits prescribed in the toy directive (2009/48/EC) were used as a guide for the maximum safety level of dry, brittle or pliable material of the metal concerned in the product, viz.: for Chromium (III) - 37.5 mg/kg and for Lead 13,5 mg/kg.

2.4 Appointment of test laboratory

At the second Project Group meeting it was agreed to invite a wide range of test labs to tender for the testing of the items of clothing collected during the course of the Joint Action. An invitation to tender was placed on the PROSAFE website. Subsequently, all the test labs that were listed on the NANDO website for the Toy Directive (2009/48/EC), together with four labs that specialized in the testing of items of clothing, were formally invited to tender. A total of 11 submissions were received by the closing date for applications. A further application was received after the deadline. This was disallowed.

A shortlist of 4 labs was prepared from which a preferred test lab, AIJU based at Ibi, Alicante, Spain was selected to act as the test lab for the project. The Task Leader and the Task Coordinator visited the lab to discuss the laboratory's submission with the staff; meet the staff that would be involved in testing our samples; inspect the facilities and to discuss the draft contract with the lab manager. AIJU is a very experienced lab and have an excellent reputation for testing toys, childcare articles and clothing. Following the visit to AIJU by the Project leader and the Project Coordinator a contract to undertake the testing of the Project's samples was signed by AIJU and by PROSAE.

As the legislation did not usually prescribe the methods that should be adopted for determining the quantity of each substance in an item of clothing the lab's advice was requested as to which test method to adopt.

The lab advised the following test methods:

For Azo colourants and azo dyes: - EN 14362-1 & -3: 2012 – Textiles. Method for the determination of certain aromatic amines derived from azo colourants.

For Chromium (VI): - EN ISO 17075: 2007 – Leather – Chemical tests. Determination of Cr (VI) content.

For Formaldehyde: - EN ISO 14184-1: 2011 Textiles. Determination of formaldehyde. Free & hydrolized formaldehyde (water extraction method).

For Organostannic compounds: - As no satisfactory method has been prescribed by the standardization organisations an internal test method used by AIJU was adopted. The lab uses the Gas-Chromatography with Mass-Spectrometry detection method (Shimadzu) to detect the following organotin compounds:- Methyltin; Butyltin; Tributyltin (TBT); Monoctyltin; Dioctyltin; Dioctyltin (DOT); Dibutyltin (DBT); Dipropyltin; Tetrabutyltin; Diphenyltin; Triphenyltin (TPT).
(Note: Only the following organotins are specified in REACH – Annex – Entry 20 - Tri-substituted organostannic compounds - Tributyltin (TBT) and Triphenyltin (TPT); Dibutyltin (DBT) and Dioctyltin (DOT).)

For Phthalates:- CPSC-CH-C1001.09.3 - Standard operating procedure for determination of phthalates.
Note – This method was adopted instead of any of the following methods:

EN 15777: 2009. Textiles. Test methods for phthalates – which was withdrawn in June 2014 and replaced by:
EN ISO 14389: 2014 - Textiles. Determination of the phthalate content. Tetrahydrofuran method.
DD CEN ISO/TS 16181: 2011 - Footwear. Critical substances potentially present in footwear and footwear components. Determination of phthalates in footwear materials.
(Note:~ AIJU advised that the CPSC method gave virtually identical results to that provided by EN 15777 and that the method was considerably quicker and cheaper to undertake.)

For Heavy metals: – For Chromium (III) & (IV) and Lead – the method prescribed in EN 71-3: 2013+A1: 2014 - Safety of toys. Migration of certain elements.
On occasion XRF Screening was used to test for the elements prescribed in EN 71-3:2013.

3 Results obtained from testing

3.1 Overview of the market surveillance exercise

All six participating Member States took part in the two market surveillance exercises. During the course of each market surveillance exercise the inspectors from the participating Member States were asked to collect samples which were likely to contain the potentially hazardous substances listed at Table 2.1 in Section 2.3. They were asked to collect about 5 samples from each of the types of clothing during each exercise. It was recognized that this may not be practicable and that the inspectors who were undertaking this work should have a free hand to collect the most appropriate samples. In the event this approach worked well and a wide selection of the different types of clothing within each category was obtained for testing.

The first market surveillance exercise was conducted during the Summer 2014 when 153 products were collected from the market. During the second market surveillance exercise in the Winter 2014/15 a further 149 products were collected. This meant that a total of 302 samples were collected during the course of the two market surveillance exercises.

Generally only a single sample was collected from the premises of the economic operator, but for those samples where the amount of material was limited, 2 or even 3 samples were collected. This was in order to provide the test laboratory with sufficient material to undertake the testing.

A more detailed breakdown of the number of samples collected by each participating Member State is given at Tables 3.1, 3.2 and 3.3. During the course of the two market surveillance sweeps each participating collected about 50 samples from the market.

Summer 2014	PARTICIPATING MEMBER STATE						TOTALS
	LATVIA	MALTA	PORTUGAL	SLOVAK REPUBLIC	SPAIN	THE NETHERLANDS	
Children's products							
Nightwear	2	5	5	5	6	5	28
Plastic shoes	5	7	5	5	5	6	33
Swimwear	5	5	5	5	0	5	25
Underwear	7	5	5	5	6	6	34
Sportswear	6	5	4	5	7	6	33
Trousers for pregnant women	0	0	0	0	0	0	0
Unlined leather gloves	0	0	0	0	0	0	0
TOTALS	25	27	24	25	24	28	**153**

Table 3.1 – No of samples collected by each participating Member State during the Summer 2014 market surveillance exercise.

Winter 2014/15	PARTICIPATING MEMBER STATE						TOTALS
	LATVIA	MALTA	PORTUGAL	SLOVAK REPUBLIC	SPAIN	THE NETHERLANDS	
Children's products							
Nightwear	7	5	6	5	5	0	28
Plastic shoes	4	5	5	5	5	5	29
Swimwear	0	0	0	0	0	0	0
Underwear	4	6	3	5	5	4	27
Sportswear	0	0	0	0	0	0	0
Trousers for pregnant women	5	4	5	5	5	5	29
Unlined leather gloves	5	5	5	5	5	11	36
TOTALS	25	25	24	25	25	25	**149**

Table 3.2 – No of samples collected by each participating Member State during the Winter 2014/15 market surveillance exercise.

Summer 2014 and Winter 2014/15	PARTICIPATING MEMBER STATE						TOTALS
	LATVIA	MALTA	PORTUGAL	SLOVAK REPUBLIC	SPAIN	THE NETHERLANDS	
Children's products							
Nightwear	9	10	11	10		5	56
Plastic shoes	9	12	10	10	10	11	62
Swimwear	5	5	5	5	0	5	25
Underwear	11	11	8	10	11	10	61
Sportswear	6	5	4	5	7	6	33
Trousers for pregnant women	5	4	5	5	5	5	29
Unlined leather gloves	5	5	5	5	5	11	36
TOTALS	50	52	48	50	49	53	**302**

Table 3.3 – Total no of samples collected by each participating Member State during the Summer 2014 and the Winter 2014/15 market surveillance exercises.

The type of economic operator from which the samples were collected is given at Tables 3.4, 3.5 and 3.6. For the most part samples were collected from shops that had acted as the importer/distributor of the goods into the Member State concerned, or they were taken from a shop that was an independent business or part of a chain of shops.

Summer 2014	PARTICIPATING MEMBER STATE						TOTALS
	LATVIA	MALTA	PORTUGAL	SLOVAK REPUBLIC	SPAIN	THE NETHERLANDS	
Manufacturer	0	0	0	0	0	0	0
Ditributor/Importer	3	10	3	1	5	0	22
Distributor/Importer/Shop	22	10	15	9	0	0	56
Shop	0	7	6	15	19	28	75
TOTALS	25	27	24	25	24	28	**153**

Table 3.4 – Type of economic operator from which samples were collected during the Summer 2014 market surveillance exercise.

Winter 2014/15	PARTICIPATING MEMBER STATE						TOTALS
	LATVIA	MALTA	PORTUGAL	SLOVAK REPUBLIC	SPAIN	THE NETHERLANDS	
Manufacturer	0	0	0	1	0	0	1
Ditributor/Importer	0	6	0	3	1	0	10
Distributor/Importer/Shop	25	0	7	5	0	0	37
Shop	0	19	17	16	24	25	101
TOTALS	25	25	24	25	25	25	**149**

Table 3.5 – Type of economic operator from which samples were collected during the Winter 2014/15 market surveillance exercise.

Summer 2014 & Winter 2014/15	PARTICIPATING MEMBER STATE						TOTALS
	LATVIA	MALTA	PORTUGAL	SLOVAK REPUBLIC	SPAIN	THE NETHERLANDS	
Manufacturer	0	0	0	1	0	0	1
Ditributor/Importer	3	16	3	4	6	0	32
Distributor/Importer/Shop	47	10	22	14	0	0	93
Shop	0	26	23	31	43	53	176
TOTALS	50	53	48	50	49	53	**302**

Table 3.6 – Type of economic operator from which samples were collected during the Summer 2014 and the Winter 2014/15 market surveillance exercises.

The distribution of locations from which the samples were collected was at follows:

Latvia - mainly from the Riga area;
Malta - throughout the island of Malta, but not from Gozo;
Portugal and Slovakia - at locations throughout the country;
Spain - throughout mainland Spain, and in Tenerife and in the city of Ceuta; The Netherlands – mainly from the northern and north eastern provinces.

3.2 Test results

All the samples were sent by the market surveillance authorities to the test laboratory, AIJU at Ibi, Alicante, Spain. The number of tests performed by the laboratory for the various potentially hazardous substances is shown at Tables 2.7, 2.8 and 2.9.

A total of 771 tests were performed on the 153 samples collected during the Summer 2014 market surveillance exercise and a total of 683 tests were performed on the 149 samples collected during the Winter 2014/15 market surveillance exercise, i.e. a grand total of 1,454 tests on the samples collected during the course of both market surveillance exercises. This compares with the requirement for 150 tests to be undertaken on an unspecified number of samples at Clause 5.3 of the Grant Agreement.

No of tests undertaken on products during the Summer 2014 market surveillance exercise

	Total no of test reports	Azo dyes	Chromium (VI)	Formaldehyde	Total Cd/PB	Organotin Compounds	Phthalates	XRF Screening - EN 71-3	Metal content EN ISO 17072-2
COUNTRY									
Latvia	**25**	21	0	21	26	28	20	8	0
Malta	**28**	32	0	30	23	38	29	10	0
Portugal	**24**	24	0	22	19	17	19	8	0
Slovak Republic	**25**	21	0	21	30	6	17	8	0
Spain	**24**	32	0	17	21	41	25	19	0
The Netherlands	**27**	26	0	26	14	32	14	6	0
TOTAL	***153***	***156***	***0***	***137***	***133***	***162***	***124***	***59***	***0***

Total no of tests conduted during the summer 2014 = 771

Table 3.7 – No of tests undertaken by AIJU on the samples collected during the Summer 2014 market surveillance exercise.

	Total no of test reports	Azo dyes	Chromium (VI)	Formaldehyde	Total Cd/PB	Organotin Compounds	Phthalates	XRF Screening - EN 71-3	Metal content EN ISO 17072-2
COUNTRY									
Latvia	**25**	19	10	19	9	19	14	18	0
Malta	**25**	26	6	21	5	21	18	8	6
Portugal	**24**	28	5	19	0	22	16	23	1
Slovak Republic	**25**	32	6	21	7	10	16	6	6
Spain	**25**	41	5	36	5	36	17	5	5
The Netherlands	**25**	23	11	15	7	21	4	0	15
TOTAL	***149***	***169***	***43***	***131***	***33***	***129***	***85***	***60***	***33***

Total no of tests conduted during the winter 2014/15 = 683

Table 3.8 – No of tests undertaken by AIJU on the samples collected during the Winter 2014/15 market surveillance exercise.

No of tests undertaken on products during the Summer 2014 and Winter 2014/15 market surveillance exercise

	Total no of test reports	Azo dyes	Chromium (VI)	Formaldehyde	Total Cd/PB	Organotin Compounds	Phthalates	XRF Screening - EN 71-3	Metal content EN ISO 17072-2
COUNTRY									
Latvia	**50**	40	10	40	35	47	34	26	0
Malta	**53**	58	6	51	28	59	47	18	6
Portugal	**48**	52	5	41	19	39	35	31	1
Slovak Republic	**50**	53	6	42	37	16	33	14	6
Spain	**49**	73	5	53	26	77	42	24	5
The Netherlands	**52**	49	11	41	21	53	18	6	15
TOTAL	***302***	***325***	***43***	***268***	***166***	***291***	***209***	***119***	***33***

Total no of tests conduted during the summer 2014 and the winter 2014/15 = 1454

Table 3.9 – Total no of tests undertaken by AIJU on the samples collected during the Summer 2014 and the Winter 2014/15 market surveillance exercises.

4 Follow-up with economic operators

4.1 Follow-up, non-compliant products collected during Summer 2014

The test laboratory reported on the 153 products collected during this market surveillance exercise. The Member States were informed that 19 products contained one or more substances that were in excess of the requirements specified in the relevant legislation or safety standard. The results of the tests on these samples are given below. In each case the action subsequently taken by the regulatory authority is recorded.

LATVIA

LV-P 35 - Underwear - yellow plastic – Phthalate - DINP in the print at 5.0%
LV-P 38 – Sportswear – blue fabric top – Azo dye - 93 mg/kg 3,3'-Dimethoxybenzidine

Figure 4.1 - Latvian sample LV-P 38

In the case of product LV-P 38 (see Figure 4.1) the product was recalled from the market. As the product had been placed on the market in more than one Member State it was the subject of a RAPEX notification, viz. No A12/0161/15. The economic operator chose as a voluntary measure to withdraw the product from the market, recall it from consumers and destroy the remaining stock.

LV-P 41 – Plastic shoes – blue plastic – Phthalate - DEHP on the blue strap at 0.89%

In the case of sample LV-P 35 distributor was informed about the test results, but as phthalates were detected on the print, which does not have direct contact to skin, no corrective actions were taken. For the sample LV-P 41, a risk assessment was carried out resulting in 'low' risk. The distributor was informed about the test results and the risk level; a voluntary action on sales ban was taken.

MALTA

MT 05 – Nightwear – black print on top of product – Phthalate DINP 0.8%

MT 07 - Plastic shoes – red – Phthalate in the plastic figure - DEHP 28%

MT 08 – White/coloured plastic shoes – Phthalates in shoe - DEHP 0.07%; and on black straps - DEHP 18%; DINP 1%; DIDP 0.22%

MT 18 – Underwear – red – Phthalate in the print - DEHP 2.3%

MT 19 – Underwear blue – Phthalate in the print - DEHP 0.3%

In each case the distributor was informed that the product presented a risk to consumers. The phthalates present in samples MT 05, MT 07, MT 18 and MT 19 are not in direct contact with the skin and therefore any risk would be minimal. A risk assessment by the test lab AIJU was undertaken on product MT08, which had a high percentage of DEHP. Although the material in which the phthalate is present is in direct contact with the skin, the risk assessment concluded that the item presented only a low risk to the consumer taking into consideration the contact area and the time of exposure to the material.

PORTUGAL

PT 01 – Nightwear – blue pants and sleeves - Azo dye - 56 mg/kg 3,3'-Dimethoxybenzidine

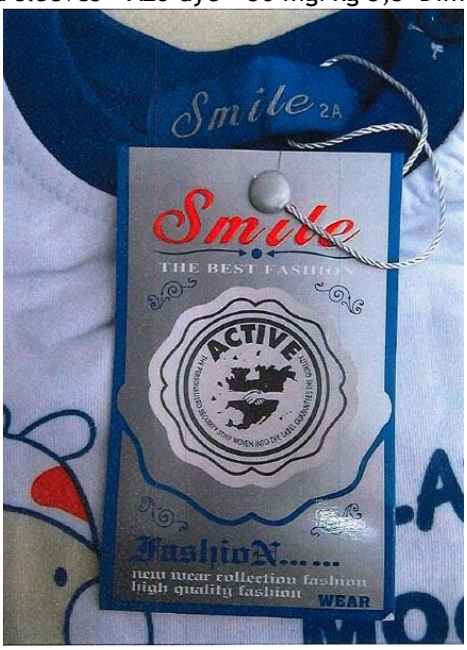


Figure 4.2 Portuguese sample PT 01

Sample PT01 (see Figure 4.2) was the subject of RAPEX notification No A12/0870/15 as the product had

also been placed on the Spanish market. The voluntary measure undertaken by the economic operator was to withdraw the product from the market. The economic operator has been prosecuted for placing on the market a substance contained in an article without fulfilling the requirements of REACH, Annex XVII,

PT 05 – Nightwear – blue – Phthalate in print - DEHP 0.82%

PT 08 – Flip flops – Pink – Phthalate in plastic figure - DEHP 4.2%

PT 10 – Flip flops – Orange - Phthalate in orange band - DBP 23.09%; Phthalate in blue insole - DBP 0.029%

In the case of the other samples, PT 05, PT 08 and PT 10, the economic operator was informed that the product posed a low risk to consumers.

SLOVAKIA

SVK 05 – Underwear – blue/green – Phthalate in plastic print - DEHP 0.33%

SVK 19 – Plastic shoes – Phthalate in transparent blue plastic - DBP 32% in yellow plastic - DBP 2.28%; In plastic blue antennae - Cd 396 mg/kg
(Note - The level of Cd in the product is only in excess of requirement for toys, not that for clothing items)

The economic operators were informed of the risks posed by their products, but was not subjected to any legal action.

SPAIN

SP 17 – Underwear multi-coloured. – Phthalate in the print - DEHP 0.2%

SP 19 – Plastic shoes blue – Phthalates - DEHP 11.5%; DBP 12.35%

The economic operator was informed of the high concentration of phthalate in samples SP 17 and SP 19.

Figure 4.3 - Sample SP19 – Plastic shoes for 2-3 year old

In the case of sample SP 19 (see Figure 4.3), the test lab was asked to conduct a risk assessment on the product. Although the laboratory rated the risk as being high for DBP, the regulatory authority decided not to take any further action against the economic operator, as this item was no longer available to the consumer.

THE NETHERLANDS

NL 77 314 598 – Plastic shoes – blue – Phthalate - DEHP 38%

NL 77 315 698 – Plastic shoes pink – Phthalate - DEHP 0.169%

NL 77 316 795 – Sportswear – turquoise – Phthalate in print – DINP 1.25%

Sample NL 77 314 598 was subjected to a risk assessment by the NVWA. As it presented only a low risk to consumers no further legal action was taken against the economic operator. In the case of the other two samples, the market surveillance authority took no further action.

4.2 Follow-up, non -compliant products collected during Winter 2014/15

The test laboratory reported on the 149 products collected during this market surveillance exercise. The Member States were informed that 12 products contained one or more substances that were in excess of the requirements specified in the relevant legislation or safety standard. In each case the action subsequently taken by the regulatory authority is recorded.

LATVIA

LV-P 11 – Leather gloves for working – 1855 mg/kg Cr, of which Cr (VI) < 3mg/kg
(Note – The level of Chromium in the product is only in excess of requirement for toys, not that for clothing items). The product complies with the new requirements for Cr (VI), which means that the migration of Cr (III) was detected at a level of circa 1852 mg/kg. See also Section 5.4 for a report on the risk assessment relating to the level of Chromium (III) and (IV) in this sample.

LV-P 12 – Lined plastic boots - Phthalate - DEHP 36%

In the case of sample LVP-12 it was noted that the phthalates were in the material of the boots, rather than the lining. As a consequence the wearer's skin was not in direct contract with the phthalate bearing material and no further action was taken against the economic operator.

MALTA

MT 32 – Girl's underwear – print – Phthalates - 1.5% DEHP; 0.002% DIDP; 0.05% DINP
MT 44 – Lined plastic boots – dark blue material – Phthalates - 6.7% DEHP; 4.8% DINP; 2.2% DIDP

No further action was taken by the authority in relation to products MT 32 and MT 44 as it was thought that the level of phthalate present in the product did not present a serious risk to consumers as the phthalate bearing material was not in direct contact with the skin/

MT 45 – Fabric lined plastic shoes – pink – Phthalate - 10.9% DEHP on print.

As the lining in the shoes may be removed it was agreed by the market surveillance authority that the plastic used for the boots itself did not present any risk since the phthalate was present in the external decoration of the shoes. No further action was taken by the authority in relation to this product.

PORTUGAL

PT 27 – Lined plastic boots – Phthalates - 0.65% DBP; 9.3% DEHP; 2.6% DINP
PT 48 – Pyjamas for boys – Phthalates - 0.55% DEHP; 0.13% DINP

No regulatory action was taken in relation to these products as, following a risk assessment, it was agreed that they did not present a serious risk to consumers.

SLOVAK REPUBLIC

SVK 027 – Girl's underwear – Phthalate - DEHP 0.85%

No regulatory action was taken in regard to sample SVK 027 as the phthalate was not in the part of the product that was in direct contact with the skin.

SVK 046 – Unlined dark green leather gloves – Azo dye – 4 aminobenzidine & p-cresidine 102 mg/kg

Figure 4.4 - Slovak sample SVK 046

Sample SVK 046 (see Figure 4.4) was sold in more than one Member State and, following a risk assessment, was considered to present a serious risk to consumers. It was therefore the subject of a RAPEX notification, viz. No A12/1046/15.

The compulsory measures undertaken by the regulatory authority included:

- a ban on the marketing of the product;
- a warning to consumers of the risks posed by this item of clothing and
- a recall of the product from the end users.

SPAIN

SP 36 – Leather gloves for working – 4.6 mg/kg Cr VI

Sample SP 36 (see Figure 4.5) was sold in more than one Member State and, following a risk assessment, was considered to present a serious risk to consumers. It was therefore the subject of a RAPEX notification, viz. No A12/1066/15.

At the time the product was placed on the market the amendment to REACH concerning the restrictions on Chromium (VI) was yet not in force. However, as the product is clearly 'work-wear' and therefore worn for personal protection the regulatory authority decided to take action under the provisions of the PPE Directive[3]. The compulsory measures undertaken by the market surveillance authority were: Withdrawal of the product from the market. The product was also withdrawn from the market in France, where it was also on sale.

[3] Directive 69/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment

Figure 4.5 - Spanish sample SP 36

SP 44 – Children's nightwear – plastic picture – Phthalates - 0.110% DEHP; 26% DINP
No regulatory action was taken in regard to sample SP 44, as the plastic print was not in contact with the user's skin.

SP 47 – Plastic shoes - Migration Sn 86 ± 15 mg/kg
(Note – The level of Sn in the product is only in excess of requirement for toys, not that for clothing items, so no further action was taken by the regulatory authorities.)

THE NETHERLANDS

NL 87 018 733 - Lined plastic shoes – Phthalate - DEHP 28%

NL 87 018 768 – Lined plastic shoes – Phthalate – DEHP 31%

Following a risk assessment on samples NL 87 018 733 and 87 018 768 the regulatory authorities decided not to take any further action as the products were considered not to present a serious risk to consumers.

4.3 Conclusions

A total of 31 products were found to be non-compliant from the 302 samples taken from the market, i.e. 10.3 % of the products. Whilst the sampling undertaken during the course of the activity cannot be considered as being representative of the hazardous chemicals present in clothing market, it nevertheless shows that the proportion of non-compliant products on the market is a matter of concern.

A risk assessment of the non-compliant products revealed that only 4 products, viz.:

LV-P 38 – Sports wear – Blue fabric top

PT 01 – Nightwear – Blue pants and sleeves

SVK 046 – Dark green unlined leather gloves

SP 36 – Leather gloves for working

presented a serious risk to consumers. These products were the subject of a RAPEX notification.

In addition, two products were of some concern to the regulatory authorities viz.:

LV-P 41 - Plastic shoes – blue plastic, presented a low risk to consumers and the economic operator withdrew the product from the market.

SP19 – Plastic shoes for 2-3 year old – which presented a high risk to consumers. In this case the regulatory authority decided, however, not to take any further action on this product as it was no longer on sale.

From the limited survey of the market the conclusion of the Joint Action is that, following a risk assessment on the non-compliant products, very few items of clothing would seem to present a serious risk to consumers as, in the case of the current market surveillance exercise, only 4 from the 302 products sampled (1.3%) presented a 'serious' risk.

5 Risk assessment of chemicals in clothing

5.1 Additional tests

The test laboratory was asked to perform some further tests on the following samples:

LV-P 11 – Unlined leather gloves for work, in which the migration of Chromium (III) + (VI) was 1855 ± 297 mg/kg and the concentration of Chromium (VI) [illegible]3 mg/kg;

MT 08 – Plastic shoes for a 7-8 year old, containing the phthalates DEHP at a concentration level of 18% ± 6%; DINP at a concentration level of 1% ±0.5%; and DIDP at a concentration level of 0.22% ± 0.01%;

SP 19 – Plastic shoes for a 2-3 year old, containing the phthalate DEHP at a concentration level of 11.5% ± 0.8% and DBP at a concentration level of 12.35% ± 0.02%;
(Note: In the case of sample SP 19, the phthalate substances were only present in the black straps on the sample. No phthalates were detected in the blue shoe.)

SP 44 – an item of children's nightwear, containing the phthalate DEHP at a concentration level of 0.11% ± 0.009% and DINP at a concentration level of 26% ± 2%.

Photographs of each of these samples are given at Figures 5.3, 5.4, 4.3 and 5.5 respectively.

The additional tests were conducted in order compare the tolerable daily intake (*TDI*) of the hazardous substance concerned with the daily intake (*I*) by the consumer of the hazardous substance obtained by testing the sample.

This was followed by the application of the risk analysis method outlined in Decision 2010/15/EU[4]. The methodology outlined in Decision 2010/15/EU has been extensive applied when a product presents a physical, mechanical or electrical hazard but, to date, has only been applied occasionally when a product presents a chemical hazard.

5.2 Method for establishing the daily intake of a hazardous substance

The methodology relating to the assessment of a hazardous substance in childcare product is detailed in CEN TR 13387: 2004 - Child Use & Care Articles – Safety Guidelines.

[4] 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)". Published in the Official Journal of the European Union L22/1. The Risk Assessment Guidelines for Consumer Products are specified at page 33 et seq. of the Decision.

The method requires that the Tolerable Daily Intake (*TDI*) for the substance concerned be established from the literature. This is the level of intake of a chemical that can be ingested daily over an entire lifetime without any appreciable risk to health.

In the case of a vulnerable consumer, such as a child, the limit of the Tolerable Daily Intake (*TDI*) is considered to be just 10% of the *TDI*. In the case of an adult it is 100% of the *TDI*.

This value is then compared with the Daily Intake (*I*) of the substance in each injury scenario.

For children:

I (mg/day) < 10% *TDI* (mg/kg bw/day),
where 'bw' is the body weight of the child.

Whereas for adults:

I (mg/day) < *TDI* (mg/kg bw/day),
where 'bw' is the body weight of the adult.

To calculate the Daily Intake *(I*) for each substance from a sample the following formula is used:

$$I = (C/S \times T) \times A \times M \times F,$$

Where:

I = The daily intake of the substance concerned by the user of the product (mg/day);
C = The analytical result obtained for the mass of the chemical extracted (mg);
S = The surface area of the sample analysed (cm2);
T = The extraction time (h);
A = The area of skin in contact with the material of the sample which contains the substance (cm2);
M = The duration of skin contact (h/day);
F = The fraction of the chemical absorbed through the skin.
(This is assumed to be 1 as there is no data to assume otherwise.)

5.3 Risk assessment of hazardous substances in consumer products

The method for establishing the risk to the consumer from a particular hazard in a consumer product is shown schematically at Figure 5.1[5] on page 50 of Decision 201/15/EU.

In summary, the method requires:

1. A description of the product and its hazards

In the case of the samples collected during the course of the Joint Action the hazard presented by a hazardous substance may not become apparent for some years. The methodology outlined at 5.2 above is appropriate as it enables the Daily Intake (*I*) for each substance to be calculated and for this to be compared with the Tolerable Daily Intake (*TDI*) for the user of the product. This assumes, of course that the Tolerable Daily Intake (*TDI*) for the substance concerned is available.

2. The identity of the consumer to be considered

For each of the products selected, other than unlined leather gloves, the user is in the 'very vulnerable' or the 'vulnerable' category as they were designed specifically for children in the 0-3 age range, or for children in the 3-14 age range.

3. The injury scenario

In most cases this will be by absorption of the hazardous substance through the skin, although it may be by ingestion when a child in the 0-3 age range sucks an item of clothing for a period of time.

4. The severity of the injury

For a number of the substances for which the products collected during the course of the Joint Action have been tested the severity of the injury could be in the 'serious' category as the substance could be carcinogenic, mutagenic or dangerous to reproduction. This is the case for azo dyes and for phthalates. In

[5] Figure 5.1 is a copy of the figure at page 50 of Decision 2010/15/EU – (see previous footnote.)

other cases the severity of the injury could be less serious, e.g. in the case of formaldehyde, which can produce an allergic reaction, or skin irritation.

5. Determination of the probability of injury

This is certainly the most difficult issue to assess as it is virtually impossible to make an accurate estimate of the probability that an unknown amount of a hazardous substance will cause a long-term injury to the consumer.

6. Look up the level of risk from the table at Figure 5.2

Figure 5.2[6] shows the two main factors that lead to a risk assessment: (i) the severity level of the injury and (ii) the probability of damage occurring during the foreseeable lifetime of the product.

When advising on the level of risk associated with each of the products listed at 5.1 above the test laboratory applied the information obtained at stages 1-5 above to the table at Figure 5.2. This helped to establish a common approach in relation to the severity and probability factors for the samples, which in turn ensured a more synergised approach to risk assessment and, ultimately, to the measures taken.

As each of the samples listed at Section 5.1 contained only one type of hazardous substance, i.e. phthalate or chromium, it was not necessary to undertake a 'Highest Risk Assessment'. However as samples MT08, SP 19 and SP 44 contained at least 2 different phthalates, it was necessary for a risk assessment to be undertaken for *each* of the phthalates present in the article of clothing.

[6] Figure 5.2 is a copy of the figure at page 64 of Decision 2010/15/EC – see footnote No 4

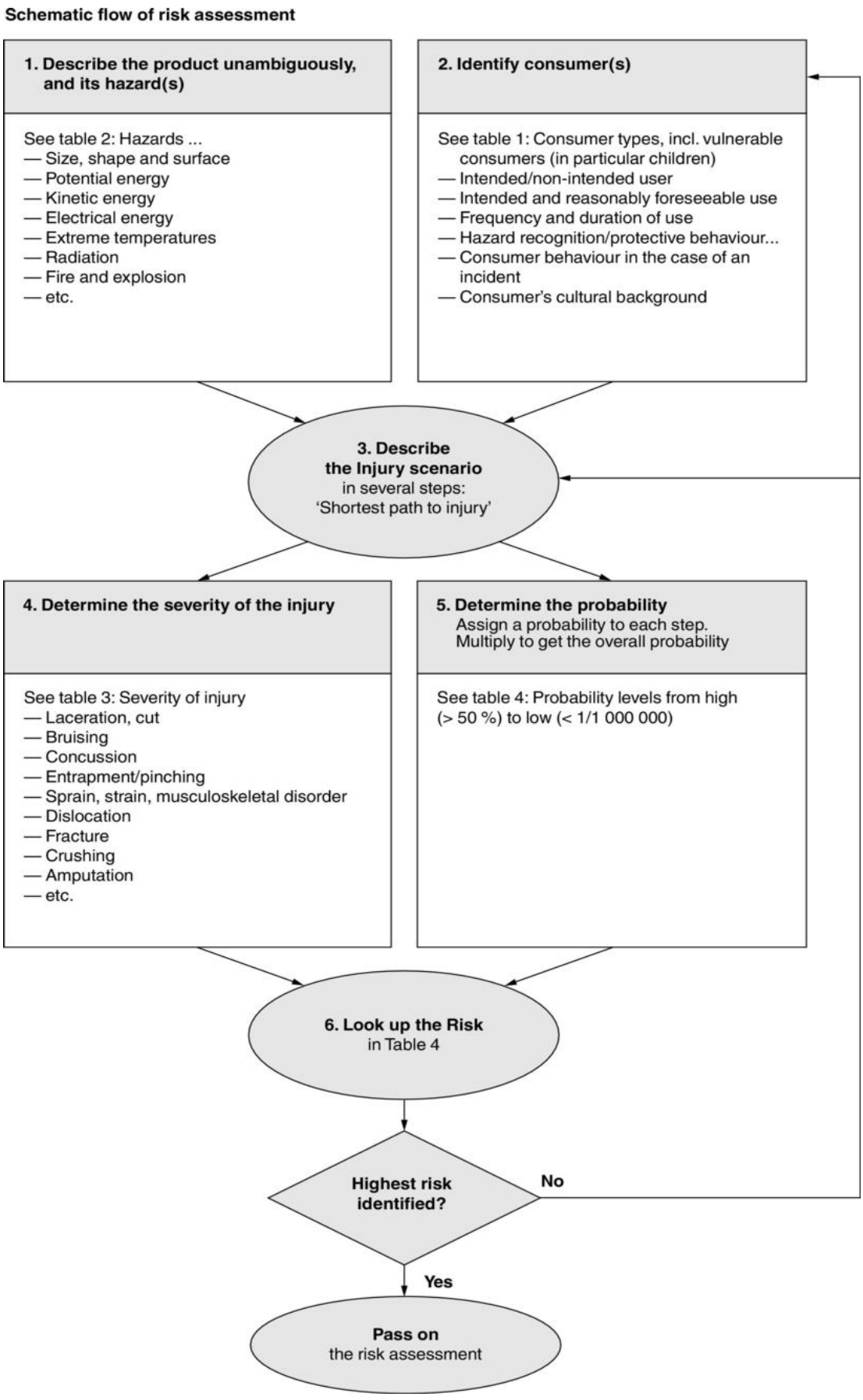
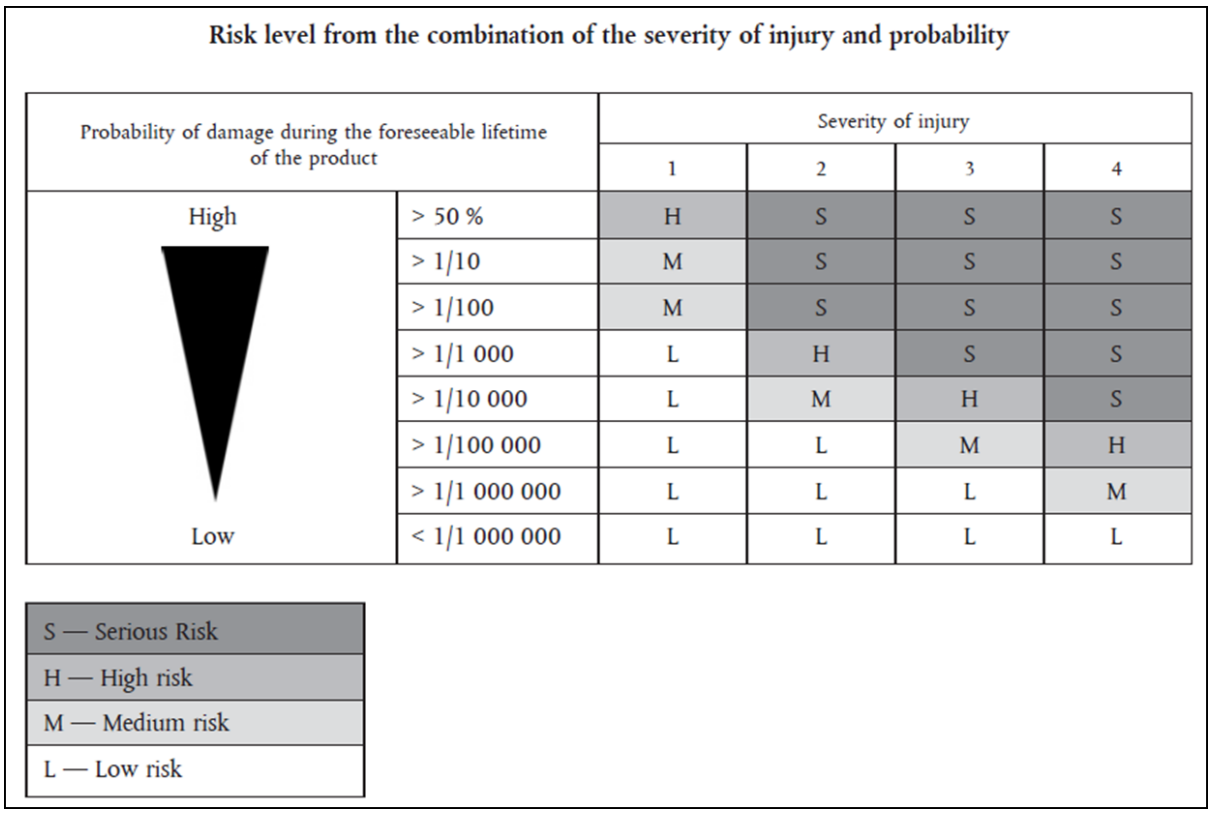


Figure 5.1 – Schematic flow chart for the risk assessment of consumer products



Risk level from the combination of the severity of injury and probability

Probability of damage during the foreseeable lifetime of the product		Severity of injury			
		1	2	3	4
High	> 50 %	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1 000	L	H	S	S
	> 1/10 000	L	M	H	S
	> 1/100 000	L	L	M	H
	> 1/1 000 000	L	L	L	M
Low	< 1/1 000 000	L	L	L	L

S — Serious Risk
H — High risk
M — Medium risk
L — Low risk

Figure 5.2 – Combination of Injury and Probability - from the Commission Guidelines

(Note: In Figure 5.2 – the 'Severity of Injury' is defined as follows:

1. Injury or consequence that after basic treatment (first aid, normally not by a doctor) does not substantially ham per functioning or cause excessive pain; usually the consequences are completely reversible.
2. Injury or consequence for which a visit to A&E may be necessary, but in general, hospitalisation is not required. Functioning may be affected for a limited period, not more than about 6 months, and recovery is more or less complete.
3. Injury or consequence that normally requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function.
4. Injury or consequence that is or could be fatal, including brain death; consequences that affect reproduction or offspring; severe loss of limbs and/or function, leading to more than approximately 10 % of disability.)

5.4 The application of the methodology to these 4 products

The test laboratory applied the methodology for establishing the daily intake of a hazardous substance and the assessment of the risks posed by a potentially hazardous substance to each of the samples listed at Section 5.1.

Phthalates & Sample SP 19

The results given below are those for sample SP 19 – a pair of plastic shoes for 2-3 year olds, which contained DBP at a concentration by weight of plasticized material of 12.35% +/- 0.02% and DEHP at a concentration by weight of plasticized material of 11.5% +/- 0.8%. A photograph of the sample is at Figure 4.3 on page 25. The phthalates are present only in the transparent blue plastic, i.e. the 'upper' part of the shoe.

DBP

The tolerable daily intake (*TDI*) for DBP for a child age 2-3 years is estimated at 10% of the *TDI* for each phthalate adapted to the user and to the sample, i.e. **0.143 mg/day** for the user of the plastic shoe. The child is assumed to weigh 14.3 kg.

In the formula *I = (C/S x T) x A x M x F*
The following values were applied for the straps in sample MT 08:

C = The mass of the chemical extracted (mg) = 0.051 mg
S = The surface area of the sample analysed (cm2) = 10.0 cm2
T = The extraction time (h) = 16 h
A = The area of skin in contact with the sample which contains the substance (cm2) =165.88 cm2
M = The duration of the skin contact (h/da) = 8 h/day
F = The fraction of the chemical absorbed through the skin = 1

This gives a value for *I* of **0.42 mg/day**, i.e. About 3 times that of the TDI.

Using the methodology illustrated at Figure 5.2, the provisional allocation of probability by the test lab to each stage of the injury scenario was:

Stage	Severity of injury	Probability
Consumer wears footwear		1/2
Consumer is exposed to/absorbs DBP	4	1/1
The lab suggested that quantity of DBP absorbed affects the health of consumer with a probability of		1/10,000

Risk = ½ x 1/10,000 = 1 /20,000
Severity of Injury = 4

Therefore the RISK from DBP = HIGH

DEHP
The tolerable daily intake (*TDI*) for DEHP for a child age 2-3 years is estimated at 10% of the *TDI* for each phthalate adapted to the user and to the sample, i.e. **0.0715 mg/day** for the user of the plastic shoe. The child is assumed to weigh 14.3 kg

The results for the concentration of DEHP in sample SP 19 gives the following results:

In the formula *I = (C/S x T) x A x M x F*
The following values were applied for the straps in sample MT 08:

C = The mass of the chemical extracted (mg) = 0.004725 mg
S = The surface area of the sample analysed (cm2) = 10.0 cm2
T = The extraction time (h) = 16 h
A = The area of skin in contact with the sample which contains the substance (cm2) =165.88 cm2
M = The duration of the skin contact (h/da) = 8 h/day
F = The fraction of the chemical absorbed through the skin = 1

This gives a value for *I* of **0.0392 mg/day**, i.e. Just over ½ that of the TDI.

Using the methodology illustrated at Figure 5.2, the provisional allocation of probability by the test lab to each stage of the injury scenario was:

Stage	Severity of injury	Probability
Consumer wears the footwear		1/2
Consumer is exposed to/absorbs DEHP	4	1/1

The lab suggested that quantity of DBP absorbed affects the health of consumer with a probability of 1/1,000,000

Risk = ½ x 1/1,000,000 = 1 /2,000,000

Severity of Injury = 1

Therefore the RISK from DEHP = LOW

The conclusion from the risk assessment is that the risk from DEHP is low, whereas that from DBP is HIGH. The regulatory authority decided, however, not to take any further action on this product as it was no longer on sale.

Chromium (VI) & Sample LVP-11
The results given below are those for sample LV-P 11 - Unlined leather gloves for work, A photograph of the sample is at Figure 5.3.

Figure 5.3 – Sample LVP-11 -Unlined leather gloves

Regulation (EC) 301/2014 – amending REACH regarding the Cr (VI) content of leather articles, requires that the content of Cr (VI) is < 3mg/kg dry weight of leather.

The results of the test on the gloves show that the concentration of these substances in the gloves is: Migration of Chromium 1855 +/- 297 mg/kg; of which Chromium (VI) < 3 mg/kg.

The content of Cr (VI) is less than 3 mg/kg. The product is compliant therefore as far as its content of Chromium (VI) is concerned.

The value for the migration of Chromium (III) is therefore circa 1852 +/- 297 mg/kg.

The tolerable daily intake (*TDI*) for Cr (III) for humans is estimated, when adapted to an adult user of the product and to the sample, is **0.3 mg/day.**

In the formula $I = (C/S \times T) \times A \times M \times F$

The following values were applied for the straps in sample LV-P 11:

C =	The mass of the chemical extracted (mg)	= 0.754 mg
S =	The surface area of the sample analysed (cm2)	= 12.0 cm2
T =	The extraction time (h)	= 2 h
A =	The area of skin in contact with the sample which contains the substance (cm2)	= 428.8 cm2
M =	The duration of skin contact (h/da	= 8 h/day

F = The fraction of the chemical absorbed through the skin = 0. 1

This gives a value for *I* of **10.78 mg/day**, i.e. over 30 times that of the TDI.
Using the methodology illustrated at Figure 5.2, the provisional allocation of probability by the test lab to each stage of the injury scenario was:

Stage	Severity of injury	Probability
Consumer wears the gloves		1/2
Consumer is exposed to/absorbs Cr (III)	2	1/1
The lab suggested that quantity of Cr (III) absorbed affects the health of consumer with a probability of		1/10,000

Risk = ½ x 1/10,000 = 1 /20,000

Severity of Injury = 2

Therefore the RISK from Chromium (III) = LOW

The regulatory authority decided not to take any further action on this product as a result of the risk assessment.

Phthalates & Sample MT 08
The chemical risk assessment reports on sample MT 08 – plastic shoes, where the concentration of phthalates DEHP, DINP and DIDP was confined to the straps. Following a risk assessment it was shown that in the case of each phthalate the risk level was **LOW**. A photograph of sample MT 08 is at Figure 5.4.

Figure 5.4 - Sample MT 08 – Plastic shoes

Phthalates and Sample SP 44
The chemical risk assessment reports on sample SP 44 – children's nightwear – a two piece set of green pajamas, where the concentration of phthalates DEHP was 0.11% and DINP was 26%. The phthalates were

confined to the illustration on the front of the upper garment. Following a risk assessment it was shown that in the case of each phthalate the risk level was **LOW**. A photograph of Sample SP 44 is at Figure %.5

Figure 5.5 – Sample SP 44 – Children's nightwear – 2-piece pajama set

6 Liaison with stakeholders

6.1 Cooperation with customs

Cooperation with customs is included as an area to be investigated in the Grant Agreement. The Project Group considered that, as very little information was available during the first phase of the project on the extent that hazardous chemicals were present in items of clothing, it would be very difficult to advise the custom authorities as to how to identify clothing that contained these hazards.

The Group noted that in other product areas, such as toys and fireworks, it is practicable to provide the customs authorities with a checklist of the features on the product, or on the packaging or markings on the product, that indicate that the item concerned is likely to be non-compliant.

In the case of hazardous chemicals in clothes it is not possible to identify, without recourse to a test lab, which items are likely to be non-compliant. For this reason the project did not seek to establish a liaison with DG TAXUD, or the customs authorities in the participating Member States.

6.2 Liaison with other stakeholders

At Commission level, both DG-SANCO/JUSTICE & CONSUMERS and DG-Enterprise/Growth were involved with the project from the start of the activity and during its subsequent progress. Representatives from both DGs were invited to each meeting, ensuring that related information was cross-shared between the market surveillance authorities and the Commission.

The European Apparel and Textile Confederation (EURATEX) were very supportive of the project and

provided a very useful input into the discussions on the hazardous substances that are likely to be present in the various types of clothing. The Project Coordinator attended a meeting of EURATEX's Technical Committee on 22nd May 2014 at which he outlined the progress on the project to date and the activities that would be undertaken during the remainder of the project.

The Project Coordinator also established a link with the Commission's Expert Group on Textile Names and Labelling. (This is the Group responsible for discussing and exchanging information on the application of Regulation (EU) No 1007/2011 - on textile fibre names and related labelling and marking of the fibre composition of textile products.) The Project Coordinator attended the meeting of Group held on 26th September 2014 and gave a report on the progress of the activity to date and the programme of work for the reminder of the project. The meeting of the Group also provided the opportunity for the Project Coordinator to meet with representatives of: The Confederation of National Associations of Tanners and Dressers (COTANCE); The Federation of the European Sporting Goods Industry (FESI) and International Wool Textile Organisation (IWTO).

Besides the above, the autumn and spring market surveillance workshops coordinated by PROSAFE, were used as a basis for further discussion with all the participants of the whole Joint Action – JA2013. Although this activity involved the direct participation of only 6 Member States, the whole Joint Action involved 25 market surveillance authorities from 21 different countries within the European Economic Area. This ensured that the good practices and experiences, including the challenges related to this activity, were discussed and shared with a much wider group across Europe.

It is envisaged that shortly after the close of this project the Final Technical Report will be published on the PROSAFE website. This will therefore serve to further create additional liaison and discussions in the area of product safety relating to the presence of hazardous chemicals in clothing.

7 Evaluation and lessons learned

On reviewing this activity there are a number of lessons at a technical level and at an administrative level that could be learned from the conduct of the project.

7.1 Difficult to determine which substances are present in clothing

Ascertaining which hazardous substances are likely to be present in items of clothing is a difficult matter as no list exists as to which hazardous substances are likely to be present in the various fibres used in the various types of garment.

Trade associations such as EURATEX are able to advise their members on this issue, but as small and medium sized enterprises are not likely to belong to the national constituent organisation of EURATEX, this presents problems for this type of economic operator. Similarly, the market surveillance authorities are likely to have difficulty when, having taken a product from the market, they need to decide on the hazardous substances for which the product should be tested.

7.2 Fragmented legislation

The legislation relating to the hazardous substances likely to be found in textile items is fragmented amongst European and national legislation. This is particularly the case for those substances that are regulated by national, rather than European legislation, as the threshold values sometimes vary from one jurisdiction to another. For example, in the case of the requirements for formaldehyde.

7.3 Uncertain which test methods to apply

The legislation often fails to specify which test method should be adopted when testing for the presence of a hazardous substance. In some cases, such as in the case of the test for organotins, a test method has not been published by CEN or ISO. This presents for considerably difficulty for both economic operators and the market surveillance authorities when testing for the presence of these substances.

7.4 Useful to acquire input from stakeholders

On a positive note, the technical input from the stakeholders involved in the project proved to be extremely useful as it contributed both experience and expertise to the deliberations of the Project Group.

7.5 Joint tendering for testing proved successful

The joint tendering for testing of samples continued to show that it is very advantageous for market surveillance authorities since the large number of samples tested lead to achieving better prices for the testing of products. In turn this meant that the Project Group could perform a higher numbers of tests than is specified in the Grant Agreement and thereby increasing the validity and reliability of the Group's conclusions concerning the proportion of non-compliant products on the market.

8 Conclusions

As expected the testing of samples resulted in finding a number of non-compliant products, 30 from the 302 products taken from the market. However, this resulted in only 4 cases of products being the subject of RAPEX notifications. Following a risk assessment on the non-compliant products it was noted that, overall, the number of products that presented a serious risk to consumers was very low.

In a handful of cases the regulatory authority discovered, when referring the non-compliance to the economic operator that the product had been 'sold out' and that it was no longer available on the market. It was noted that both children and pregnant women use a particular item for a relatively short period of time and that by the time the product could have been recalled most of the users of these garments would have finished using the product. In other cases, particularly those where phthalates were found in excess of 0.1% by weight of the rubberized material on T-shirts, it was thought, following a risk assessment, that the risk to the consumer was low as the rubberized material is not in contact with the skin.

Although the project found that the hazardous substances presented a 'serious' risk to consumers in very few samples, the activity has made a significant contribution to market surveillance in a product sector that has hitherto been the subject of very little regulatory activity. It has also demonstrated to the fraternity of economic operators in this product sector that, whilst the testing for hazardous substances in textile items is a demanding activity, the regulatory authorities are, nevertheless, able to undertaking market surveillance successfully in this product sector.

The principal outcomes of the project have been:

- The identification of those hazardous substances that are likely to be found in clothing and which are the subject of legislation concerning the quantity of the substance concerned that may be present in the article concerned;

- That joint working by a number of Member States has resulted in the regulatory staff in these countries gaining a much better understanding of the procedures and practices by which regulatory activity in this product sector can be undertaken. As a consequence valuable expertise and experience has been achieved by the Member States concerned;

- Establishing that there are a number of test labs in the EU that are able to undertake testing for a range of hazardous substances that are likely to be present in clothing. This has required the identification of the appropriate test methods to determine the quantity of the various substances present in the garment. In those cases where no test method has been published, these laboratories have been able to advise as to whether they have a valid, reliable and practicable 'In House Test Method' (IHTM) to measure the quantity of the substance present in the garment;

- Establishing that the method for 'risk assessment' outlined in Decision 2010/15/EU can be applied successfully to chemical hazards and not just to physical, mechanical and electrical hazards.