

Five Consumer Products

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Executive Agency for Health and Consumers (EAHC)

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Final Implementation Report

Covering the period 1 January 2011 - 30 April 2013



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Management Summary

This is the final technical implementation report prepared for the Joint Market Surveillance Action on 5 Consumer Products. The European Commission supported the Action financially. It was carried out by PROSAFE and representatives from Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Germany (Hessen), Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, the Slovak Republic, Slovenia and Spain. The Action ran from 1st January 2011 to 30th of April 2013. The total budget of the Action was € 2.032.530,51 with Commission funding not to exceed € 1.422.697,29.

Objectives

The primary objective of the action was to co-ordinate a number of product-specific market surveillance activities and to expose the results of the activities to the greatest number of Member States national authorities possible. The overall action also sought to co-ordinate the product-specific market surveillance activities in the most efficient manner and provides an opportunity for evaluating the best practice developed under EMARS II. This included improving co-operation with customs, outreach to China and international collaboration.

Main achievements

The Joint Action represented a shift in thinking from PROSAFE. Previously Joint Actions had focussed on a single product. With JA2010 five different products were combined into a single Joint Action. This greatly increased the number of Member States participating to twenty-one as compared to an average of twelve for previous Joint Actions. All of the Member States undertook to follow up the results of the Joint Action so this ensured much greater geographical coverage of the project. The Member States have taken appropriate enforcement action and the recent media event announcing the publication of the RAPEX Report for 2012 featured many of the dangerous products detected during JA2010. The RAPEX notifications that resulted from JA2010 have made a significant impact with, for example, the vast majority of RAPEX notifications for laser pointers being made as a result of the testing carried out under the Joint Action.

All the product activities have produced significant results in terms of the numbers of products tested and the corrective action undertaken. However the product activities have also had other impacts that may be at least as significant as the results of the market surveillance activities as they have the potential to bring about real lasting change to the product sectors concerned. Examples are given below of how the Joint Action has, for example, contributed to a better understanding of the risk assessment of certain products and inform future revisions of existing standards and regulations in respect of others.

The success of the approach taken under JA2010 has helped change the landscape of market surveillance in Europe. The focus of market surveillance activities has changed from individual Joint Actions to large projects covering a range of products with over 20 Member States involved. The product and method development activities are giving market surveillance authorities the tools that they need to implement market surveillance more efficiently, sharing experience and best practice. The costs for product testing are also being shared and reduced. For many of the Member States involved the activities coordinated by PROSAFE constitute a major part of their national market surveillance programmes. PROSAFE's activities now constitute a de facto multi-annual European level market surveillance programme. Lastly, the success of the approach is demonstrated by the enthusiastic participation of the Member States, continued political support and increased levels of financial support.

Horizontal issues

An important feature of the Joint Action was the adoption of a coordinated approach to certain key horizontal issues. These were cooperation with customs, feedback to standards and international outreach. This improved the efficiency of the project, the quality of its implementation and ensured the spread of best practice. The overall approach also helped reduce the administrative burden and costs and improved the administrative cooperation between the Member States. The horizontal issues were where appropriate to be addressed within the individual product activities as they implemented their own work. The innovative approach adopted under JA2010 provided some focus on these issues at a higher level to ensure that that best practices were identified and applied consistently throughout the entire Joint Action.

Methodology

Each of the product activities followed some specific steps. First the Member States decided on a sampling plan. This identified exactly what products would be sampled and how many by each authority. Once the samples

had been obtained the Member States would then decide which samples needed to be tested at a laboratory. The laboratories were chosen following an open call for tender. The results of the tests were shared with all participants. The participants then discussed a common set of principles for risk assessment. This helped ensure the consistency of the results of the market surveillance activities. The Member State authorities followed up with the economic operators in their countries, i.e. they consulted the economic operators on the results from the risk assessment, agreed on appropriate measures and followed-up that these were followed through. The resulting measures were reported to the Joint Action and shared with all participants (not only the ones who take part in that particular product-specific activity).

Food Imitation products

The presence of food imitation child-appealing products may give rise to serious risks for children that confuse them with food. Two main risks are associated with such products, small parts and ingestion of substances such as shampoos that are mistaken for food products. The primary objective of the action was to remove from the EU market dangerous food imitation products in respect of which a high or serious risk has been demonstrated by a specific risk assessment. A secondary objective was to raise the awareness within the Member States for the need for increased harmonisation in the evaluation of food imitation products. 379 products were inspected, 60 cosmetics, 254 decorative items, 43 toys and 22 other products. 113 of the products inspected were sent to a lab for tests. After the tests 29 passed and 84 failed. The result of the risk assessment on the products failing tests and on others done by members in the activity resulted in 105 products presenting a low risk, 5 a medium risk, 8 a high risk and 3 a serious risk. Based on the results of Risk Assessment and the overall evaluation that food imitation products rarely represent serious or high risks, limited enforcement actions have been taken. 9 products were recalled, 19 were removed, 6 of them under RAPEX for info, 16 products were removed and destroyed and in 12 cases economic operators were invited to take actions. All the participants found the in-depth discussion of the risk assessment of the indispensable. It is considered that this has contributed to a better understanding of the risks presented by these products and this is seen in the decline in RAPEX notifications made following the implementation of the Action. In some instances better enforcement does not result in more notifications but rather in notifications being made on a more objective basis.

Ladders

Ladders are estimated to cause more than half a million hospital treatments and more than 100 fatalities each year in the 27 EU Member States. Two thirds of the accidents concern consumer's use of ladders. This places portable ladders and stepladders among the most risky consumer products on the market. The primary objective of the action is to build knowledge about the market for ladders, the standards applied and to what degree the ladders on the market comply with the standards. Secondary objectives were to generate information on e.g. safety requirements to go into the standardisation work on ladders presently undertaken by CEN and to raise awareness amongst the Member States for the need for increased safety and harmonisation in this area. 17 stepladders were sampled and 21 multi-purpose or leaning ladders. 20 of the samples tested presented a serious risk, the majority due to inadequate strength, and 4 presented a medium risk. Of the 38 models tested, the respective market surveillance authorities took action in respect of 32 of them. It needs to be understood however that the actions taken at Member state level were not necessarily consistent. This is because the status of the current EN131 standard varies between member states. Some Member States recognise EN131 and apply it others have their own national standard. EN131 is considered deficient and the results of the testing were fed into the European Commission's Ladders Expert group as well as the CEN Technical Committee with a view to helping to provide input to the revision of the standard.

Laser Pointers

Non-compliant and dangerous laser pointers (and other laser products) can cause safety problems such as serious and permanent eye damages, temporary blinding and skin burns during skin care treatments. The primary objective of the activity was to ensure that laser products available on the EU market for consumers are safe, classified correct and carry the appropriate warnings and instructions. 88 samples were taken. 74% were class 3 which are not to be sold to consumers and of these 95% were not correctly labelled. As a result of the results there were in total 29 formal RAPEX notifications, 13 RAPEX notifications for information, 5 blocked at customs, 3 sales bans and withdrawal and ICSMS notification, 16 warnings/fines with withdrawal from market and 24 reporting test result and eventual small non-compliances. The impact the activity had can be seen in the fact that 80% of the RAPEX notifications of laser pointers made during 2012 were as a result of the testing carried out by the Joint Action combined with the application of the Risk Assessment tool on test-identified samples.

Children's Fancy Dress

Two main risks for children's fancy dresses were addressed in this part of the Joint Action, flammability and chemical risk. Neither of these risks can be assessed by the consumers themselves. The RAPEX statistics shows that the Member States since 2005 have submitted 26 RAPEX notifications on products because of contents of azo-colourants. The primary objective of the action is to ensure that all toy disguise costumes for children on the EU market are safe. 237 products were sampled. 64 non-compliances were found, mostly due to a lack of warnings when rate of flaming of fabric was in 10-30mm/s range. A number of RAPEX notifications were made as a result of these findings. One of the conclusions of this activity was that many economic operators could avoid their products presenting a minor non-compliance if they correctly labelled their products with - 'Warning - Keep away from fire'.

Visibility Clothing and Accessories

Visibility clothing and accessories (like visibility tabs) can be vital for the safety of consumers who walk or bicycle on dark roads. Several Member States have carried out market surveillance actions on these products and come across equipment that provides the user with inadequate protection. The primary objective of the work undertaken was to ensure that visibility clothing and accessories (e.g. visibility tabs) on the EU market comply with the requirements in the European legislation. 135 products were inspected. 39 samples were tested, 19 pieces of clothing and 20 accessories. 7 pieces of clothing failed retro-reflective performance test, 2 accessories failed photometric test. Five products were removed from the market as a result of these findings. In general it was noted that there is some confusion in the manufacturing sector with respect to EN471 [High visibility warning clothing for professional use] and EN1150 [Visibility clothing for non-professional use]. There were very few products on the market manufactured to EN1150 with most products on offer to the consumer being made to EN471.

Timeline of Activities in JA2010

1st January 2011	Formal launch of JA2010
9 th March 2011	Launch Event in Brussels
Spring 2011	Kick off events of Food Imitation Products, Ladders and Laser Pointers
Autumn 2011	Kick off events of Fancy Dress and Visibility Clothing
Winter 2011 and spring 2012	Product testing
25th and 26th April 2012	First Workshop in Bonn with presentation of preliminary results
Summer through winter 2012	Further testing and market surveillance follow-up
21st February 2013	Final Workshop in Brussels
30th April 2013	Formal close of Joint Action

Introduction

This is the final technical implementation report prepared for the Joint Market Surveillance Action on 5 Consumer Products. In accordance with the Grant Agreement the report is due 30th of June 2013 and it shall provide a concise overview of the progress of the Joint Action in the period 1st of January 2011 to 30th of April 2013.

In accordance with Annex III in the Grant Agreement the report in particular includes the following information on the work carried out and the results achieved:

- A description of the work carried out in the Joint Action.
- Deviations from the initial work programme.
- The results obtained in the Joint Action.
- Differences between the foreseen results of the Joint Action and those actually achieved.

This is the first final implementation report of a project that has addressed a number of different product groups. This presents a challenge in how to best structure the report so as to allow the reader to access the information contained therein as easily as possible. In order to present the information as logically as possible the first part of the report deals with the Joint Action in general and in particular the horizontal and project management activities and contains the relevant information identified above. The second part presents the information identified above in respect of the individual product activities one by one. The reader is therefore presented with an overview of the Joint Action in the first part and detailed information on the product activities in the second part.

The participation in the Joint Action is compared to the planned commitment in chapter 5 and Annex II. A financial analysis of the expenditures in the Joint Action is included in Annex III. The analysis compares the expenditure incurred during the Joint Action with the foreseen budget as laid down in the Grant Agreement. Copies of deliverables and other material produced by the Action are annexed in Annex I.

The Joint Action is executed under the 2010 call for tender. Thus, the reporting requirements may differ from Actions granted under the call for tenders outlined in other years.

1 Background Information

1.1 Summary of the Project Description

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

1.1.1 Title of the Joint Action

Joint Market Surveillance Action on 5 Consumer Products. The Joint Action is supported by European Union Funding in the framework of the “Programme of Community action in the field of Consumer policy (2007-2013)” Agreement No: 2010 81 01.

1.1.2 Structure of the joint Action

JA2010 represented a shift in thinking from PROSAFE. Previously Joint Actions had focussed on a single product. With JA2010 five different products were combined into a single Joint Action.

Member States were not obliged to participate actively in all five of the product activities but could choose those of greatest interest to them respecting their own limited resources. At the same time the Member States committed to follow-up the results of all the five product activities.

1.1.3 Participating Member States

The application for the Joint Action was signed by PROSAFE and 21 Member States (Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Germany (Hessen), Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, the Slovak Republic, Slovenia and Spain.

Furthermore, France, Italy, Bosnia and Herzegovina, Switzerland, Sweden, Turkey and the German authorities in Sachsen have expressed interest in participating in the Joint Action as collaborating partners outside the financial scheme. The applicant body that also took overall responsibility for the Joint Action was PROSAFE.

The project leader was Michael Cassar from MCCA in Malta. Two consultants, Bruce Farquhar and Torben Rahbek, supported the project leader. The activity leaders and their consultants are noted below.

Product	Activity	Leader	Consultant
	Horizontal Activities	Michael Cassar, Malta	Bruce Farquhar Torben Rahbek
A	Food imitation child appealing products	Durk Schakel, The Netherlands	Fabio Gargantini
B	Ladders	Maksmiljan Bornšek, Slovenia	Chris Evans
C	Laser Pointers	Marina Dias, Portugal	Berend Kamerling
D	Children’s Fancy Dress	Agrita Birzule, Latvia	Robert Chantry-Price
E	Visibility Clothing and Accessories	Aleksejs Niščaks, Latvia	Emmanuel Scerri

1.1.4 Budget

The total budget for the Joint Action was 2,032,530.51 €. The Executive Agency shall contribute a maximum of 1,422,697.29 € equivalent to 70% of the estimated total eligible costs.

1.1.5 Primary Objective

The primary objective of the action was to co-ordinate a number of product-specific market surveillance activities and to expose the results of the activities to the greatest number of Member States national authorities possible.

The objectives of the product-specific activities were:

Food imitation products

The primary objective of the action is to remove from the EU market dangerous food imitation products for which a high or serious risk has been demonstrated by a specific risk assessment.

Ladders

The primary objective of the action was to build knowledge about the market for ladders, the standards applied and to what degree the ladders on the market comply with the standards.

The secondary objective was to generate information on e.g. safety requirements to go into the standardisation work on ladders presently undertaken by CEN.

The tertiary objective was to raise the awareness within the Member States for the need for increased safety and harmonisation in the area.

Laser Pointers

The primary objective of the action was to ensure that laser products available on the EU market for consumers are safe, classified correct and carry the appropriate warnings and instructions.

Children's Fancy Dresses (chemicals in textiles and flammability of these products)

The primary objective of the action was to ensure that all toy disguise costumes for children on the EU market are safe.

Visibility clothing & accessories

The primary objective of the action was to ensure that visibility clothing and accessories (e.g. visibility tabs) on the EU market comply with the requirements in the European legislation.

1.1.6 Secondary Objective

The overall action sought to co-ordinate the product-specific market surveillance activities in the most efficient manner and provides an opportunity for evaluating the best practice developed under EMARS II. This included improving co-operation with customs, outreach to China and international collaboration.

1.1.7 The Activities of the Joint Action

The Joint Action contained three types of activities

- Project management activities
- Horizontal activities
- Product Activities

The project management activities were necessary for the efficient implementation of the project and dealt inter alia with the planning, administration, monitoring and reporting of the project.

The horizontal activities focused attention on a number of important issues including

- **Co-operation with Customs**
Existing best practices developed under the EMARS projects and lighters projects were further developed. This was done in cooperation with DG TAXUD through PROSAFE's participation in their expert working group who for example developed the guidelines for drawing up checklists. The best practice was put at the disposal of the individual product activities that could use this as appropriate.
- **Outreach to China**
As reported on more fully below PROSAFE has developed a harmonised approach to outreach to China through the two China Joint Actions that have been launched in recent years. This provides a framework within which individual product activities can communicate their results to the Chinese authorities and will develop other best practices that can be applied by individual product activities.
- **International Co-operation**
PROSAFE ensured lines of communication were open to jurisdictions outside Europe so individual product activities could solicit information as appropriate. As reported elsewhere some countries

outside the EEA were also able to participate within certain limits in the work of the product activities as well as attend the launch event and workshops.

- **Coordination of dissemination and use of results by all Member States**
One of the features of the Joint Action was the commitment by all Member States to follow up on the results of all five product activities regardless of whether they participated directly in them or not. PROSAFE facilitated this through the presentation of results to all Member States during the workshops and by providing a harmonised means to disseminate the results to all the Member States. The more flexible structure of the Joint action also allowed Member States who were not participating directly in specific product activities to contribute in other ways for example through the provision of samples or providing feedback to the presentations made during workshops or responding to other information that was circulated.
- **Stakeholder outreach and other communications activities**
PROSAFE helped ensure the application of best practice by all the product activities. In particular PROSAFE was able to help identify suitable stakeholders for the individual product activities and provided another channel of communication to stakeholders through the workshops, press releases and newsletters that were distributed.
- **Follow-up with standards organisations**
PROSAFE has again developed best practice in engaging with the standard development bodies and feeding the results of the Joint Actions into the appropriate arenas. The individual product activities have been able to follow this best practice with their individual dealings with the standards bodies and the platforms provided by the workshops especially the final one have also provided another means to follow-up the results of the joint action with the standards bodies.
- **Coordination with EMARS II and other on-going and future Joint Actions**
PROSAFE has sought to develop a harmonised and consistent approach to the implementation of all its joint actions. In particular considerable emphasis has been placed on the development and further refinement of best practice across all its activities. The workshops held within the framework of JA2010 and other Joint actions have provided an excellent opportunity for the Member States to contribute to discussions concerning the implementation of the joint Actions and to discuss the direction of future Joint actions.

The goal of all the horizontal activities was to complement the product activities and to facilitate the implementation of the individual product activities in a consistent and coherent way. The best practice they have nurtured can of course also be applied and is being applied at the national level outside the scope of the joint Actions. Lastly, all of the horizontal issues were featured during the launch events and workshops allowing the Member States to participate in the discussion of these issues and to be exposed to the best practise being developed.

The product activities undertook the market surveillance following these phases:

- **Deciding on sampling criteria**
The Joint Action decided on how the Member States shall carry out sampling, i.e. how many samples will be taken by each authority, when will the sampling take place, should sampling take place in one or more rounds, what were the criteria to be applied to decide on the specific products to sample, and how many specimens should be taken of each product.
- **Sample products**
The Member States acquired products according to the criteria defined in the previous phase. This meant that the market surveillance authorities visited manufacturers, importers, wholesalers and retailers to collect products. This was coordinated and reported back to the Joint Action.
- **Test products at a laboratory**
The Joint Action decided which of the products sampled that will have to undergo a test at an accredited laboratory. A call for tender was issued and an appropriate laboratory selected and the Member States were instructed as to how to send their products for testing. The products were

shipped and the laboratory submitted test reports after the testing took place. The Joint Action shared all the test reports with all the participants.

- **Risk assessment**
The participants discussed a common set of principles for risk assessment to assure that the results are harmonised to the extent possible. The Member States then carried out the risk assessment for the products based on these principles and their local conditions.
- **Follow-up on non-compliant products and exchange information on follow-up activities**
The Member State authorities followed up with the economic operators in their countries, i.e. they consulted the economic operators on the results from the risk assessment, agreed on appropriate measures and followed-up that these were followed through. The resulting measures were reported to the Joint Action and shared with all participants (not only the ones who take part in that particular product-specific activity).

1.2 Other background information

1.2.1 Risks and accidents associated with the products

These are presented in the chapters on the product activities in Part 2 of this report.

1.2.2 Regulation and standards in force

The Joint Action was implemented to support the enforcement of the provisions of the General Product Safety Directive (2001/95/EC). Where appropriate, additional information concerning the specific regulations and standards in force for each of the products is given in chapter 3 in the discussion of the tests that the products were subjected to.

1.2.3 Deliverables of the Joint Action

Copies of all the deliverables are contained in annex I to this report. The deliverables for the project management and horizontal activities are identified in chapter 2. Following consultation prior to and discussion during the launch event the product specific activities were to be identified as follows:

Product A - Food imitation products

Product B - Ladders

Product C - Laser Pointers

Product D - Children's Fancy Dress (chemicals in textiles and flammability of these products)

Product E - Visibility Clothing and Accessories

1.2.4 Relating the deliverables to the market surveillance activities undertaken

The product deliverables are identified generically below where X stands in for the appropriate identifying letter as explained above.

Project management

Planning of Activities D5.1X

Minutes from Kick-off and planning Meeting D5.1X

Minutes from second project meeting D6.1X

Minutes from third project meeting D6.2X

Minutes from fourth project meeting D6.3X

Minutes from fifth project meeting D6.4X

Minutes from sixth project meeting D6.5X

Sampling

Guideline to Member States on how to exchange information D7X

Memo to Member States on which products to sample D8X

Testing

List of test criteria D9.1X

Letter to laboratories requesting them to make a quotation D9.2X

Overview of responses to call for tender D9.3X

Contract with laboratory D9.4X

Market surveillance and follow-up activities

Statistics on Activities D10X

Memo with description of follow-up activities D11X

2 Project Management and Horizontal Activities and the Results obtained

This chapter presents the project management activities and horizontal activities undertaken during the Joint Action and the results obtained.

2.1 Project Management Activities

A number of project management activities were essential to the successful implementation of the project.

Selection of consultants

The first activity in the Joint Action was to select consultants to manage and coordinate the different activities to be undertaken within the Joint Action. Stichting PROSAFE appointed the consultants following an open call for expressions of interest.

Project planning, Launch event

A kick off meeting of the project management was held prior to the launch meeting. Preparations for the launch event itself included the drafting of extensive briefing material. The material reflected the multi-faceted nature of the project and separate documents were developed for the Member States and for stakeholders and also for individual product activities as well as the Joint Action overall. The first deliverables of the project included the work programme and the communications and outreach plan. Further information can be obtained from the appropriate deliverables contained in the Annex I to this report. These are D1.1 Work Plan, D1.2 Memo from the launch event, and D3.1 and D4.1 containing the plans for outreach to China and to stakeholders.

Project core meetings

The project core group had 3 meetings including the kick-off meeting. The participants finalised a project plan and a communication plan during the kick-off meeting.

Management of the Joint Action

Tools and documents were developed by the consultants to facilitate the follow up of the operational stages in the Joint Action. The tools and documents were discussed at the meetings in the project core group and latterly during the consultants meetings that have superseded core meetings of the individual Joint Actions and the bi-weekly teleconferences of the PROSAFE Projects Management Team.

Selection of test laboratories

The selection of test laboratories to support the Joint Action has followed the standard call for tender procedure previously established by PROSAFE. Further information specific to individual product activities is presented in chapter 3 of the report.

Reporting

Two progress reports were produced, one after six months of the Action and one describing the activities from February 2012 to the end of August 2012. A first interim implementation report was in March 2012 covering the period 1st January 2011 to 31st January 2012. Further information can be obtained from the appropriate deliverables contained in the Annex I to this report. These are D12.1 First progress Report, D12.2 First Interim Implementation report, and D12.3 Second Progress Report. Regular reports were also made to the GPSD Committee and the Consumer Safety Network.

Ensuring the quality of the tasks and deliverables

The project management activities described above formed an important component of the overall system that was put in place to ensure the quality of the tasks and deliverables. One of the other major components of the system was the introduction of a consistent approach to certain horizontal issues. This is described in greater detail below. Briefly the focus on the horizontal issues was to ensure that the individual product activities adopted consistent approaches to these horizontal issues. Policies and procedures to be applied in respect of

these issues were developed or further refined from best practices already identified under the EMARS project or previous Joint actions most notably the Joint Action on lighters. The product activities then took these policies and procedures and applied them to the specific circumstances of their activities. The groups convened under the project management activities such as the PPMT or the Core group then provided a platform for the discussion of any issues that were encountered in the practical implementation of the best practice in respect of the horizontal issues and other issues such as the selection of laboratories or reporting.

PROSAFE always has had to strive to strike a balance between allowing the product activities too much freedom in the way they implemented their work thereby risking too much inconsistency in the results obtained and undermining some of the objectives of the Joint Action and over prescriptive supervision of the activities that would duplicate efforts and greatly increase the resources needed to implement the Joint Action.

Towards the end of the Joint Action it has become clear that some greater control is necessary. A first effort has been made with this final report. The deliverables and the contributions to the final report from the individual product activities have been compared and edited to ensure a more consistent presentation of the results of the Joint Action. Part of this editing process included the drafting of more detailed guidance for the product activities not only as to the formatting of the documents but also as to their presentation and technical content. PROSAFE will build on these efforts in future Joint Actions.

2.2 Horizontal Activities

The approach adopted under JA2010 of focussing attention on a number of horizontal issues at a higher level has been continued in subsequent Joint Actions.

The activities reported on below therefore reflect the more strategic approach that PROSAFE has taken to these issues whereby the activities that have been undertaken have been coordinated so as to benefit all the Joint Actions being implemented by PROSAFE. Where product activities have engaged in their own specific activities in respect of these horizontal issues these are reported in chapter 3 of this report.

2.2.1 Co-operation with Customs

Customs officials have been invited to participate in the Launch event and workshops held within the framework of JA2010. Where appropriate there has also been direct contact between product activities and customs as reported under chapter 3. The laser pointers activity in particular was active with Customs authorities. The cooperation with Customs has also benefited from the launch of the initiative led by DG TAXUD. PROSAFE has participated in the expert working group and contributed its experience from the Joint Actions, including JA2010, to the drafting of the guidelines and checklists that have been developed by the Expert group. These guidelines have been adopted by PROSAFE as best practice and are implemented within the Joint Actions.

2.2.2 Outreach to China

A range of activities have been undertaken to promote outreach to China. All RAPEX notifications that concern products manufactured in China are reported to the Chinese authorities under the China RAPEX scheme. The intention behind outreach from the Joint Actions to China is however not only to deal with specific RAPEX notifications but to raise awareness of the market surveillance activities being undertaken in Europe. This should highlight specific product sectors and the problems they pose so that a more consistent message can be communicated to the Chinese manufacturers who are also subject to export controls carried out by the Chinese authorities. The success of the initiative therefore depends on the quality of the relationship with the Chinese authorities. It has been clear then that PROSAFE has had to engage in a period of relationship building with the Chinese authorities and that this would benefit from a common approach being taken on behalf of all the Joint Actions and PROSAFE's future activities.

PROSAFE'S activities towards China started even before the launch of JA2010. A first mission was therefore coordinated with the joint Commission-China activities and with similar outreach activities in other PROSAFE Joint Actions (on helmets and baby walkers). This was discussed with the European Commission in September 2010 and the result was that PROSAFE's chairman, Jan Deconinck, presented PROSAFE and its activities during the Shanghai summit in October 2010.

It was decided to expand these activities with a more sharp focus on lighters, helmets and baby walkers; so PROSAFE continued the discussions with the European Commission aiming at another visit in 2010.

Unfortunately this was so late that the Chinese authorities replied back that it was impossible for them to organise anything before the end of the year.

New discussions were started in 2011 together with the European Lighter Importers' Association, but this initiative soon turned out to stumble over the upcoming Joint Action on China that was beginning to materialise. Still, one result of the activity was that the consultant supporting the Lighters Joint Action participated in a trilateral round table in Beijing in November 2011 in an effort to find ways to share information on dangerous products with Chinese manufacturers. The roundtable was also attended by several representatives from the Chinese lighter industry and the European lighter importers as well as other product sectors.

One of the key lessons learnt has been that all such activities have to be closely coordinated to avoid that they present a scattered picture to the counterparts and to ensure that the European side maximises the benefits from the activities. PROSAFE has therefore nominated a person to be responsible for all outreach to China and all contacts from PROSAFE actions will be coordinated via the Joint Action on China. Reflecting at this experience the European Commission has also funded Joint Actions specifically aimed at increasing collaboration with the Chinese authorities.

The activities towards China are now being coordinated through two specific Joint Actions being undertaken by PROSAFE and a number of Member States together with the Chinese Authorities. The first of these Joint Actions was launched in 2012.

The Action seeks in particular to build on a number of successful bi-lateral initiatives being undertaken by a number of Member States and the Chinese authorities. The main activities of the first Joint Action thus far have been a study visit to China followed by a visit from the Chinese Authorities to the port of Rotterdam. A final evaluation visit to China will take place in the autumn of 2013. The results and experience from JA2010 and the other Joint Actions have been fed into these visits.

The second Joint action will be launched in July 2013 and will seek to further develop and implement practical the best practice that has been identified. PROSAFE will continue to use the opportunities presented by the second Joint action to communicate the experience and results of its Joint Actions to the Chinese authorities.

Further information can be obtained from the appropriate deliverables contained in the Annex I to this report. These are D3.1 plan for outreach to China and to stakeholders and D3.2 memo with conclusions from the activity.

2.2.3 International Co-operation

Again PROSAFE has sought to take a consistent approach to international outreach across all of its activities. Invitations have been extended to international colleagues to the events held within the framework of the Joint Actions. This effort has proven successful where the PROSAFE events are held in conjunction with the International Product Safety Weeks that have been held biennially in Brussels. The experience and results of JA2010 has featured on the programmes of these PROSAFE events.

As a result of this outreach interest has been shown in some specific products most notably ladders. PROSAFE is currently exploring how to encourage more partial collaboration with international colleagues. The ICPSC is promoting a series of virtual symposia, which are held by teleconference and encourage contact between the relevant experts from different jurisdictions around the world. PROSAFE will host during the summer of 2013 a symposium on the Joint Actions. Interest has already been shown in a follow-up symposium dealing with ladders and possibly other specific products.

Information on PROSAFE's activities has been shared regularly with the informal international regulators forum, the ICPSC, the OECD Working party on consumer safety and with the global multi-stakeholder forum, ICPHSO. Information has been provided through presentations and contributions to the newsletters of these groups.

2.2.4 Coordination of dissemination and use of results by all Member States

The use of the results of the five product activities by all the Member States participating in the Joint Action was one of the most important novel features of JA2010. In order to facilitate information flow throughout the Joint Action core coordination tasks contact point was identified in each Member State. This was especially important when a Member State is not participating on a particular product activity.

The progress with the product activities was presented during the first workshop in Bonn in the spring of 2012. During the final workshop in February 2013 the final results of the product activities were presented and Member States were reminded of their obligation to follow up on the results of all the product activities. Of course all Member States, even those out with JA2010, are already obligated to follow up on any RAPEX notifications that resulted from the Joint Action.

The further added value of the initiative under JA2010 was to ensure that Member States were able to follow up on unsafe products, which, although they did not give rise to a RAPEX notification, may still be the subject of corrective action whether required by the authorities or undertaken voluntarily by the economic operators.

In order to facilitate the Member States to follow-up on the results, a letter was sent to them before the end of the Joint Action. The letter was accompanied by the detailed results of the product activities. The results were presented in a format that allowed the easy identification of the products concerned, the non-companies and any corrective action that was undertaken.

2.2.5 Stakeholder outreach and other communications activities

A range of outreach and communications activities were undertaken within the framework of the Joint Action. Activities related to international outreach, outreach to China, Customs and standards bodies are addressed elsewhere in this chapter. Alongside those activities the following outreach and communication activities were also undertaken. Further information can be obtained from the appropriate deliverables contained in the Annex I to this report. These are D3.1 and D4.1 containing the plans for outreach to China and to stakeholders and D3.2 and D4.2 memos on the conclusions from these activities. The individual product activities also engaged directly with stakeholders relevant to their work. Further information specific to the individual product activities is also presented in chapter 3 of the present report.

Publication of joint News Releases

Three deliverables have been produced as foreseen under the Grant Agreement. The first press release was published in the spring of 2011 after the launch event and the second one after the first workshop in the spring of 2012. The third deliverable was published as a newsletter in the summer of 2013 following on from the Final Workshop and the finalisation of the project. The decision to publish the deliverable as a newsletter and not as a press release reflects discussions PROSAFE has had with the European commission and the EAHC and is the policy now applied to all Joint Actions. Further information can be obtained from the appropriate deliverables contained in the Annex I to this report. These are D2.2 First Press Release, D2.4 second press release and D2.6 final newsletter.

Organisation of common workshops

Three events were organised during the Joint Action. The first was the Launch Event held in Brussels on the 9th March 2011, in Brussels. The second event was a workshop held in Bonn in the spring of 2012 to review progress with the Joint Action. The third and last event was the final workshop held in February 2013 during which the results of the Joint Action were presented. Further information can be obtained from the appropriate deliverables contained in the Annex I to this report. These are D1.2 Memo from the launch event, D2.3 memo from the first workshop and D2.6 memo from the final workshop.

Publication of articles and news in the PROSAFE newsletter

Progress reports have been published in the PROSAFE newsletter. In recent years the original PROSAFE newsletter published under EMARS II has been superseded by information regularly posted to the PROSAFE web site and updated. At the same time as noted directly above there has been a move away from press releases and individual Joint Actions now publish their own newsletters in their stead.

Publication of articles in other media

PROSAFE has regularly provided information about JA2010 and the other Joint Actions to relevant organisations such as the ICPSC, ICPHSO and the OECD. Other organisations such as ANEC have also picked up on information published by PROSAFE and included that in their own publications.

Presentations at international conferences

The work of the Joint Action has been presented at a number of international conferences and meetings. These include meetings of the ICPSC and ICPHSO and during the International Product Safety Week in Brussels in 2012. Further details are included in the sections in this report dealing with international collaboration, outreach to China and in chapter 3 dealing with the product activities.

2.2.6 Follow-up with standards organizations

Representatives of the standards bodies were invited to participate in the launch event and the workshops of the Joint action. In addition the standards bodies were also invited to attend the kick off meetings of the product activities this often led to a closer liaison being established between the product activity and the technical body responsible for the development of the standard for that product. In some instances participants in the product activities from the Member States were also involved in standards development work, thereby also promoting closer collaboration. Where appropriate individual product activities have provided feedback directly to the relevant technical bodies of the standards organisations. The feedback to standards was particularly relevant in the case of the Ladders activity for example. These activities are reported on in greater detail in chapter 3.

2.2.7 Coordination with EMARS II and other on-going and future Joint Actions

EMARS II was finalised one year after the launch of JA2010. The best practices from EMARS II have been implemented and further developed within JA2010 and the other Joint Actions undertaken by PROSAFE. PROSAFE has developed mechanisms to ensure that the best practices are applied in practice and that we learn from our on-going experiences in a climate of continuous improvement. A consultant has been appointed with responsibility for the further development and implementation of best practice across all Joint Actions. Regular consultants' meetings are now held which provide a forum for the exchange of experiences and the discussion of the implementation of best practices. The regular bi-weekly teleconferences of the PROSAFE Projects Management Team also provide a forum for dealing with emerging issues and coordinating appropriate responses across all of PROSAFE's activities.

2.3 Achievement of the Objectives and Lessons Learnt

Achievement of the primary objectives

The primary objective of the Joint action was to undertake market surveillance work in respect of the five products. The summaries of the results of the product activities presented in chapter three reflect the success of the Joint Action. All the product activities have produced significant results in terms of the numbers of products tested and the corrective action undertaken. The laser pointers activity, for example, accounted for 70% of the RAPEX notifications of such products made during 2012. The effect of these has been leveraged due to the increased geographical reach as a result of all Member States committing to follow up the results.

However the product activities have also had other impacts that may be at least as significant as the results of the market surveillance activities as they have the potential to bring about real lasting change to the product sectors concerned. For example, the results of the ladders activity reinforced the widely held concerns that inadequacies in EN131 were contributing to the higher than necessary level of ladder related accidents in Europe. The food imitation products activity has led to a much better understanding of the real risk these products pose. The laser pointers activity featured active cooperation with Customs officials. Each of the product activities has made its own unique impression on the marketplace.

Improvement of administrative cooperation

We also have to recognise that the cooperation between the Member States within the Joint Actions is intensifying. The Joint Actions are no longer simply about sampling and testing products at the same time. The approach to risk assessment is also discussed and best practices emerging in the practical application to different product sectors. The Member States are also discussing and drawing up intervention schemes to help guide the Member States assess what corrective action is appropriate for different levels of non-compliance. These initiatives greatly improve the consistency of market surveillance aims throughout the EU raising levels of consumer protection and providing a level playing field for economic operators. This outcome-focussed approach is also reflected in the testing programmes themselves. The programmes increasingly target tests that will result in serious non-compliances. This selective testing helps reduce the cost of the overall programme and allows better use of the scarce resources market surveillance authorities have at their disposal.

Other benefits resulting from JA2010

Previously Joint Actions had focussed on a single product. With JA2010 five different products were combined into a single Joint Action. This greatly increased the number of Member States participating twenty-one as compared to an average of twelve for previous Joint Actions. Member States were not obliged to participate actively in all five product activities but could choose those of greatest interest to them whilst respecting their own limited resources. This meant in practice that project groups that contained less than 10 Member States implemented some activities. This would have been impossible as a stand-alone Joint Action under the current Commission financial rules. At the same time the Member States committed to follow-up the results of all the five product activities thereby greatly increasing the geographic reach of the project.

A very significant benefit was derived from the multiplier effect of combining so many activities in one Joint Action. These included the joint testing, follow up of test results by all Member States and increased value for money from combined Joint Actions.

The value of best practices was demonstrated through the use of the Model Joint Action and Best Practice Manual and Standard operating procedures for tendering and other activities. Another feature of the Joint Action was the adoption of a coordinated approach to certain key horizontal issues. These were cooperation with customs, feedback to standards and international outreach. This has resulted in many concrete accomplishments within the framework of the Joint Action. Good feedback has been provided to standards. Customs checklists have been drafted and activities carried out in conjunction with Customs officials.

The results of the Joint Action have been fed into the Chinese authorities as appropriate and have gained international exposure. Some guidance for business has also been prepared. Other examples from the product activities can be found in Chapter 3. We can also reflect however that the approach adopted by PROSAFE has ensured the transfer of these benefits to all of its activities. This can be seen in the best practices applied throughout all the Joint Actions, the practical cooperation PROSAFE has had with DG TAXUD, the launch of the Joint Action on China and the enduring enthusiastic participation of a range of stakeholders and interest parties in PROSAFE's activities.

PROSAFE's approach focuses on continuous improvement, in all aspects of the Joint Actions; technical implementation and management. This has improved the efficiency of the project and ensured the spread of best practice. The overall approach has also helped reduce the administrative burden and costs.

The Broader Impact of the Joint Action - JA2010's Legacy

The success of the approach taken under JA2010 has helped change market surveillance in Europe. The market surveillance scenery has changed from individual Joint Actions to big projects with over 20 Member States involved. At the same time continues to build on the experience gained during the two EMARS projects. The product and method development activities are giving market surveillance authorities the tools that they need to implement market surveillance more efficiently, sharing experience and best practice. A diverse range of products is being addressed through the Joint Actions. The costs for product testing are also being shared and reduced. For many of the Member States involved the activities coordinated by PROSAFE constitute a major part of their national market surveillance programmes. PROSAFE's activities now constitute a de facto multi-annual European level market surveillance programme. Lastly, the success of the approach is demonstrated by the enthusiastic participation of the Member States, continued political support and increased levels of financial support.

Lessons Learnt

There were a number of valuable lessons learnt as result of the implementation of the Joint Action. Each of the product activities of course told us something about the state of the market in each of the product sectors.

However, although all the activities followed the same model, the relative importance of the different components varied considerably. Standards, for example, were very important to the ladders activity, as there was concern over the efficacy of the standard. Cooperation with customs was important for laser pointers, as these were generally low cost imported products. Developing a better understanding of risk assessment was a secondary objective of the food imitation products activity and so on. The way these issues were tackled was very important to the achievement of the broader objectives of the project and provided valuable lessons. Recommendations have also been made in respect of RAPEX notifications, the best test methods to use for specific products and improvements that could be made to the requirements contained in legislation or standards. Further details of the product activities are presented in Chapter 3.

There were then also a number of lessons learnt at a more general level. The value of best practices was demonstrated through the use of the Model Joint Action and Best Practice Manual and Standard operating procedures - tendering etc. It was also noted that testing can be nuanced with a focus on testing to drop-dead clauses that indicate serious non-compliances. This rationalises the testing programme and reduces costs. The common approach to specific issues such as intervention limits also brought benefits and could be extended to other aspects of the implementation of the market surveillance activities promoting even greater consistency and coherence of the activities undertaken by national authorities.

We can also acknowledge the value of the multi-dimensional approach that was taken. There was a common approach to many horizontal aspects, cooperation with Customs, outreach to China, feedback to standards and outreach to stakeholders. This has resulted in many positive examples of best practices that can be applied in the future.

The adoption by PROSAFE of a coordinated approach across all its activities to these horizontal issues, and indeed to best practice itself, helps ensure that best practice once developed is applied in practice and further refined and developed. This again helps drives greater efficiency of market surveillance activities and ensures more consistent and coherent results. Our experience with JA2010 has if anything clearly identified the need to intensify our efforts in this regard providing more detailed guidance to product activities on the production of their deliverables and the completion of their tasks at the same time as putting in place better procedures to monitor the quality of their work.

The value of a central coordination body therefore cannot be under-estimated. An important part of PROSAFE's added value to the Joint Actions is in the contribution it makes to the administration and the management of the projects. In fulfilling the role of central coordination body in the manner it has PROSAFE has allowed the market surveillance officials to concentrate on what they do best.

The novel approach of combining five products into one Joint Action was obviously a success driving up participation, increasing the geographic reach of the follow up of the results of the Action and has served as a model for subsequent Joint Actions.

The impact of more Member States has however also felt in other perhaps less obvious ways. Where product activities had difficulty sourcing samples from amongst the participants in the specific activity they were able to reach out to other Member States to obtain samples.

Member States have also been encouraged to contribute experience or expertise to the different product activities without having to commit to participate fully. This has been especially valuable in subsequent Joint Actions where for example Member States who have recently completed their own national market surveillance activities have made useful contributions to the planning of new Joint activities in respect of the same product. The more flexible structure of the new model and the emphasis PROSAFE has placed on its activities being a coherent multi-annual programme of work at the European level has created a much improved climate for collaboration between the Member States.

All in all the success of the Joint Action has been a vindication of the novel approach adopted under JA2010 and as already noted this is borne out in the developments since JA2010. Member States have enthusiastically embraced the approach and supported the Joint Actions launched by PROSAFE. 24 Member States are participating in JA2012 and every EU Member States has participated in at least one of JA2010, JA2011 and JA2012. Many of the issues addressed by PROSAFE are also being addressed in the New Product Safety and Market Surveillance Package and we can see that many of the lessons learnt from JA2010 and previous Joint Actions are reflected in the approach being taken and the provisions contained in the package.

2.4 Differences between the work programme and the activities actually undertaken

In general there were no substantive differences between the work programme and the activities actually undertaken. The differences, such as they were, are presented in the table below.

Planning	The project planning was adjusted to permit the launch of three product specific activities immediately and two later. The original Gantt chart foresaw two products being launched immediately and three later. A revised Gantt chart was prepared reflecting these changes.
China	The focus of the China Outreach activities became the Joint Action that was launched to promote cooperation with China. Information from JA2010 was fed into the Joint Action on China. This resulted in some costs savings of the Joint Actions care was taken to properly assign the expenses incurred.
Ladders	<p>The only difference between the work programme and the activities undertaken was the addition of some pilot testing on telescopic ladders. Concerns were raised at the kick-off meeting of the activity about the safety of some telescopic ladders.</p> <p>However, the market studies in the participating member states revealed that though this type of ladder may be in a growing market sector, its overall market presence is still quite small when compared to step and conventional leaning ladders. For this reason, and given the limitations of testing budget, it was decided at that time not to develop a special programme of tests for telescopic ladders.</p> <p>At the time of locating a laboratory to conduct tests for the programme on ladders, an offer to conduct some special investigative (or pilot) tests on telescopic ladders at no cost was made by the DGUV laboratory. A small number of telescopic ladder samples were obtained from CZ and ES and sent to DGUV for testing. The results of this testing were intended to inform a full test on telescopic ladders expected to be undertaken as an activity under JA2012.</p>
Laser Pointers	An additional meeting of the activity was held in order to present the results to the broad audience that were specifically interested in this activity.
Children's Fancy Dress	<p>There were only minor differences between the work programme and the activities actually undertaken and these did not affect the achievement of the objectives.</p> <p>At the second Project Meeting held on 8 & 9 November 2011 members reviewed the scope of the project. A number of participating Member States reported that 'children's nightwear with a dress theme ("playamases") and that t-shirts and nightwear with plastic decorations' are not available on their national market. As a consequence it was not possible to collect these products from their marketplaces. This deviation from the programme's objectives was recorded in the Interim Technical Implementation Report on this Joint Action. In any event, members took the view that children's nightwear were not 'fancy dresses', but ordinary nightwear with plastic, rather than fabric decoration and therefore were outside the scope of the project.</p> <p>The other difference between the 'work programme' and the 'activities actually undertaken' was in relation to the number of samples tested. A total of 1209 tests were conducted on children's fancy dress, compared with the 180 referred to in the Grant Agreement. The large number of tests conducted on a wide variety of different types of children's fancy dress has enabled a much better picture of the chemical and flammability hazards associated with these products to be obtained and analysed than was envisaged when the Grant Agreement was drafted.</p>

	<p>The activity also produced two additional deliverables not foreseen under the Grant Agreement. The participants were aware that economic operators are likely to have some difficulties in establishing which items of legislation and which safety standards are relevant when undertaking the testing of their products. A 'Guidance document for economic operators concerning the safety requirements and marking for Children's Fancy Dresses has been prepared by the activity.</p> <p>The activity has compiled a short paper listing the 'good practices' that it has adopted during the course of the Joint Action. These relate to topics that are not covered in PROSAFE's book 'Best Practice Techniques in Market Surveillance'. The paper on this topic is being forwarded to the EMARS Project Group for information.</p>
<p>Visibility Clothing</p>	<p>There were only minor differences between the work programme and the activities actually undertaken and these did not affect the achievement of the objectives. It proved possible to implement the Action with only five project meetings instead of the six originally foreseen. Secondly despite considerable efforts it was only possible to identify 39 samples for testing and not the 40 originally estimated in the proposal.</p>

2.5 Differences between foreseen results and those achieved

There were no substantive differences in the results foreseen and those achieved in practice.

3 The Product Activities and their Results

The following chapter presents the work undertaken within the product activities. All of these activities followed the same model outlined earlier: sampling, testing, risk assessment and follow-up activities. The information presented follows this structure for each of the products in turn and also reflects on the achievement of the objectives, the lessons learnt and any deviation from the work programme and the expected results. Whilst more detailed information is always available from the deliverable as identified under 1.2.4 above an effort has been made in the following chapter to try to capture something of the unique characteristics of each activity.

Although all the activities followed the same model the relative importance of the different components varied considerably. Standards, for example, were very important to the ladders activity, as there was concern over the efficacy of the standard. Cooperation with customs was important for laser pointers, as these were generally low cost imported products. Developing a better understanding of risk assessment was a secondary objective of the food imitation products activity and so on. The way these issues were tackled was very important to the achievement of the broader objectives of the project so they have been highlighted in the following chapter and additional information provided where appropriate.

Interpreting the results of the product activities

We do have to sound a note of caution however when interpreting the results of the testing carried out under the Joint Action. The results obtained are based on samples of the products from the markets in the participating countries. 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 proper picture of the market situation. The products sampled were tested at accredited laboratories. The test focused on those safety requirements that have the largest impact on consumer safety.

We also have to acknowledge that that measuring the impact of the activities of the Joint Action is difficult, if it is even at all possible. The real impact of market surveillance activities is a decrease in the number of injuries, something that cannot be measured due to the limitations of the data collection systems currently in place in Europe

Alternatively, the number of unsafe products on the market would be a measure of the impact of the activities. It is possible to measure this number, but it requires two extra market surveillance actions. First, the authority needs to sample a high number of products from the market at random to find the share of products that are unsafe before the activity starts. Next, the authority will run the real market surveillance action where the inspectors sample dangerous products, test them and take action. And last the authority will have to repeat the first random sample of products to see if the share of unsafe products has indeed come down. In practice the costs for sampling and checking a product will be the same no matter if the purpose is to take action against an unsafe product or to check whether it is unsafe. Therefore, random sampling twice would mean that the authorities would waste a lot of resources (and public money) checking safe products - money that would be better spent on checking unsafe products to remove them from the market.

As a consequence the impact should be measured via more indirect indicators like the number of unsafe products taken from the market, the number of RAPEX notifications, etc. These are among the indicators identified in the following chapter.

3.1 Food Imitation Products

3.1.1 Background information

Objectives

The primary objective of the action is to remove from the EU market dangerous food imitation products in respect of which a high or serious risk has been demonstrated by a specific risk assessment.

The secondary objective was to raise the awareness within the Member States for the need for increased harmonisation in the evaluation of food imitation products

Risks presented by Food Imitation products

The presence of food imitation child-appealing products may give rise to serious risks for children that confuse them with food.

In addition food imitation products may be accessed by other vulnerable persons (e.g. elderly) that may confuse them with real food: This may be the case of shampoos or bath gels.

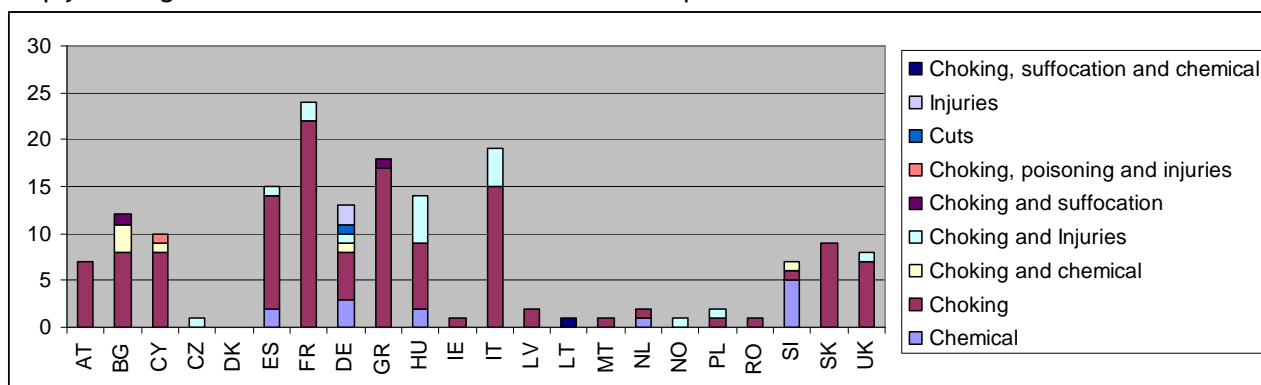
Two main risks are associated with such products:

- Small parts can detach when a child chews or sucks such a product (e.g. a candle or a piece of soap). The child may swallow the parts that may in turn block the airways of the child leading to choking or suffocation.
- Shampoos that can be confused with yoghurt or other milk products often contain dangerous substances that may cause poisoning or chemical pneumonia if swallowed.

The RAPEX statistics shows that the Member States issued 40 RAPEX notifications in 2009 on such products plus another 51 products that were notified 'For information only'.

During the setting up of the activities of the Joint Action, based on the data shown in the Figure 1 and of the discussion held with some EU Commission representatives, that most of the cases of Food imitation products that were posted on RAPEX in the considered years were probably over-evaluated as the products, although being food imitation products, didn't cause serious problem to the consumer.

Based on the comments from the participating Member States, it was considered that the Joint Action should deeply investigate on the risk assessment of food imitation products.



RAPEX Notifications in the years 2006-2011

The European Commission have clarified that for mentioning in RAPEX something more than the indication that a product is food imitating, they need demonstration (in particular for cosmetic products like bath gels) that the product is causing serious risks and for chemical risks a chemical analysis report is needed

3.1.2 Project management activities

Project Meetings

Six project meetings have been organised by the Joint Action as foreseen in the original project plan:

- Kick-off Meeting 27 April 2011 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D5.2A
- Meeting 12-13 July 2011 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D6.1A
- Meeting 27 September 2011 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D6.2A
- Meeting 10 January 2012 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D6.3A
- Meeting 27-28 March 2012 in Groningen NL

- The minutes from the meeting are annexed in Annex I, deliverable D6.4A
- Meeting 10-11 July 2012 in Brussels
 - The minutes from the meeting are annexed in Annex I, deliverable D6.5A

In addition a meeting of a small group including the Task Leader, the Task Coordinator and two experts from participating Members was held on 16 October 2012 in Brussels to discuss the harmonisation on the Risk Assessment approach.

Selection of Laboratories

The selection of the laboratory in charge of the tests was done applying the following process:

1. A call for tenders was sent to 42 prospected laboratories;
2. The 3 answers received were analysed by the Task Coordinator who considered only those meeting all the requirements in the call for tenders;
3. The remaining laboratories were listed in a matrix showing in essence the characteristics of the laboratories and the contents of the tenders received

During the process for the selection of the laboratory it was noted that one of the laboratories that answered to the call for tenders and that was shortlisted amongst the laboratories that could be selected, was in the same Organisation of the Project Leader.

Considering the peculiar situation, the activity coordinator proposed that, for reasons of transparency and impartiality in judgment, the activity leader would need to leave the meeting when the discussion on the selection of the laboratory and the relevant decision will be made. The proposal was agreed by the members of the activity attending the meeting and by the project leader, who left the meeting when the following discussion was held.

The members of the activity went through the detailed answers received and commented the main contents of the tenders, concentrating on the capability of the laboratory to deal with the specific contents of the call for tenders and the requirements of the products covered by the activity.

In particular it was considered that the selected laboratory should have the sufficient competence to analyse the risks deriving from ingestion of shampoos or bath gels looking like Food Imitation Products and the risk cause by chemical components in such products, if ingested.

A detailed sheet summing-up the answers received and showing their contents, as far the competences of the laboratories and the information they delivered on the testing activity to be carried out by the laboratory, was prepared by the activity coordinator and was discussed under his guidance.

Based on the discussion held and the analysis made by the expert group, the laboratory from the Netherlands Food and Consumer Product Safety Authority (NVWA) was selected.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the list of test criteria D9.1A, the letter to laboratories requesting them to make a quotation D9.2A, the overview of responses to call for tender D9.3A and the contract with laboratory D9.4A.

Awareness-Raising and Outreach Activities

The Joint Action has become a focal point for the European activities on food imitation products, and several countries outside the Action contact the activity leader or the activity coordinator when they have issues with such products.

Examples include:

- Outside Member States outside the activity benefitted from information obtained in the frame of the Joint Action, in particular as far as the approach to risks categorisation and evaluation is concerned.
- Several countries benefitted from the knowledge gained by the Joint Action.
- Member States direct members of the Joint Action received copies of some of the information produced by the Joint Action.

DG SANCO of the European Commission is the most important stakeholder for the Joint Action and representatives were invited to participate in all activity meetings. In addition, updates were produced when requested by the Commission (e.g. for reporting to meetings in the Consumer Safety Network or the GPSD committee).

Other Meetings Attended within the Framework of the Joint Action

- The activity coordinator of the activity attended the Risk Assessment workshop held in Brussels on 6 December 2011. He delivered a presentation on the status of the activity, underlining the main activities performed up to date and describing in detail the approach to the Risk Assessment.

The presentation was welcomed by those attending that were specifically interested in the way the Risk Assessments were performed and in the relevant outcome.

- The activity leader of the activity attended a workshop on Risk Assessment during the International Product Safety week organised by PROSAFE held in Brussels on 15 October 2012. He delivered a presentation on the use of the Commission's web tool for risk assessment for the food imitation products. He outlined the uncertainty in the final assessment using an example of a food imitation product with a potential danger. The debate about the number of steps in a scenario and the probabilities was recognized by the participants.

3.1.3 Sampling

Establishing a market picture

Due to the extreme fragmentation of the market and the difficulty of finding manufacturers or retailers associations that deal specifically with the products covered by the Joint Action, it was difficult to obtain objective data on the market trends.

The representatives of ANEC and Eurocommerce that participated in the activity of the Joint Action by attending dedicated meetings and were informed on the scope and on the program of the JA, were also asked to check with their members on any eventual proposal to help in the better targeting of the inspections as far the type of products to be selected and the type of shops to be visited to have the best outcome from the Joint Action.

Some basic information collected on the market situation showed that a significant share of the food imitation products on the markets in the participating Member States is imported. It is estimated that approximately 35% of all food imitation products on the European market, as a whole, are imported from outside the European Union. The main exporter is China. The remaining products come essentially from European Countries.

To duly address the Join Action, the participating Member States were also invited to share their impressions of the situation on their markets.

Considering the characteristics of food imitation products that are sold under anonymous brand names the traceability is quite difficult (if at all possible) for the market surveillance authority.

This enabled a market picture overview to be established from the inputs provided by each participant.

Selecting and obtaining samples for testing

The market surveillance authorities have been actively carrying out inspections in the market, which covered different types of products, as shown in the table below

Type of product	Inspected products
Cosmetic	60
Decorative	254
Toy	43
Other	22
TOTAL	379

Type of products inspected

In the period October 2011- April 2012 the members of the Joint Action surveillance authorities assessed a total of 379 products.

In total 379 food imitation products were inspected, some of them were sent to the laboratory for the laboratory tests, those that were non-compliant to the laboratory tests, plus other products that were directly

analysed by the members as far as the mechanical properties in particular possible ingestion of small parts, are concerned, were directly analysed by the specific member who did also the following risk assessment along the common lines agreed in the frame of the Joint Action.

The different type of shops that were visited is shown in the table below that indicates the number of products with reference to the type of shop:

Type of product	HY	IN	PH	SC	SD	SM	SU	Others	Total
Cosmetic		2		28	14		15	1	60
Decorative	11	5			215	3	13	7	254
Others			1	1	14		5	1	22
Toys	1				11		18	13	43
Total	12	7	1	29	254	3	51	22	379

Number of products per type of products inspected

Legend on type of shop: HY= Hypermarket, IN= Internet, PH= Pharmacy, SC= Small shop cosmetics, SD= Small shop decorative goods, SM= Street Market, SU= Supermarket

The focus of the inspections has been on small decorative shops (254 inspections, 67% of all inspections).

The main purpose of visiting an economic operator in the context of this Joint Action was to carry out visual inspections of one or more food imitation products. Such inspections had one of the following three purposes:

1. To identify obvious non-conformities, e.g. the possibility to easily remove small parts that can be ingested.
2. To decide whether a product should be taken for further investigations for laboratory tests or checking with small parts test tool.
3. To select products for which there were doubts and that were analysed by all the members in the Joint Action by means of a desktop evaluation in the Group of experts.

The Joint Action has recorded the number of food imitation products that were inspected or taken for further investigation during such visits.

The structure of the market where thousands of products are sold all different each other and with different brand/models/denominations, the organisation of the market surveillance activities and the level of reporting do not allow filtering out cases where several authorities inspected the same model of food imitation products in different markets: from analysis made by the Task Coordinator, in the desktop evaluation and by use of the spread sheet developed for purpose it was proven that no overlapping samples were inspected.

Further information can be obtained from the appropriate deliverables in the Annex I. These are *the* guideline to Member States on how to exchange information D7A and the Memo to Member States on which products to sample D8A.

3.1.4 Testing

Tests focused on the requirements that are most important for the detection of possible dangers caused by the products.

The main part of the tests was taken by the verification of the possibility of ingesting or biting parts of the food imitation products. Additionally the consequence of the ingestion of chemical substances was verified.

The mechanical tests were carried out according to:

1. EN 71-1:2011, Clauses 8.2 (small parts cylinder) and 8.4 (pull test)
2. EN 716-2:2008, Clause 5.5 (bite test)

As follows the detail of tests that were carried out, depending on the type of food imitation product and relevant risk:

Test requirement	Standard
Bite test according to	NPR CEN TR13387:2004 Cl. 3.6.3.3 and 3.6.3.4
Small Parts test	EN 71-1 Cl. 8.2
Drop test	EN 71-1 Cl. 8.5
Tension test	EN 71-1 Cl. 8.4.2.1
Research and analysis of Surface tension	Tensiometer analysis
Research and analysis of Viscosity	NEN-EN-ISO3219:1993
Research and analysis of Detergents	Screening by titration
Research and analysis of Solvents	CG-MS analysis

As far the bite test is concerned, the participants decided to apply the Standard EN 716-2 that seemed to be the more suitable to cover the typical biting situation that may be encountered in case of food imitation products accessed by children that may be tempted to bite part of the FIP.

Also standards EN 1400-2 “*Babies Soothers*” (with a different test tool as the one in EN 716) and EN 12227 “*Playpens for Domestic Use*” (with the same test tool as in EN 716-2 but different force), that may be considered as suitable, were analysed and it was considered that they did not cover appropriately the biting conditions that are reasonably expected in case of food imitation products.

The chemical tests covered the verification of the following chemicals that may be present in food imitation products:

- Household chemicals Disinfectants, Sodium hypochlorite, Hydrogen peroxide;
- Cosmetics and toiletries, Aftershave lotions, cologne, perfume, shampoo, soap bar, hair remover;
- Detergents: Washing-up liquid, Fabric conditioner, Automatic washing/dishwashing liquids

The chemical analysis was made to detect if the above-mentioned materials that were present in the analysed food imitation products were in accordance with common recognised practices for chemical analysis.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the list of test criteria D9.1A and the contract with laboratory D9.4A.

3.1.5 Risk assessment

The RAPEX risk assessment tool was found to be ideal for application to the analysis of risks caused by food imitation products.

When evaluating the risks posed by food imitation products all members applied the tool developed in the frame of the RAPEX Guidelines and made available for purpose by DG SANCO.

To cope with this, the Joint Action developed specific reference risk assessments, i.e. generic assessments for typical non-compliances illustrating what the scenario would look like, what the steps would be and what the probabilities would be.

The model risk assessments were developed together with the Task Coordinator of EMARS Task C, the working group that was responsible for risk assessment in the EMARS project.

Intervention Scheme

When a model of food imitation product is tested at the laboratory in the Joint Action, the results are captured in a test report. If the food imitation product did not comply with the requirements, it may be dangerous and measures may be necessary. Such measures should be uniform across Europe (or the authorities should at least

be able to justify differences) as many manufacturers and importers operate in many Member States and would immediately recognise differences.

In practice the Member State authorities need tools to achieve the required uniformity in judging if a FIP causes a significant risk to the users.

It was decided to develop intervention schemes and intervention limit values to guide the decision-making from the members of the Joint Action.

The intervention scheme was based on the Risk Assessment that was performed on all , either failing the tests in the laboratory, or verified by the members concerned as far the mechanical risks, in particular ingestion of small parts, are concerned.

The project group was basing the intervention scheme to the results of the Risk Assessments performed and considered that actions should be taken for products for which Serious or high risks have been obtained as result of the Risk Assessment.

This enabled an assessment of the results from the Joint Action.

The results of these Risk Assessments were strongly influenced by the research on the foreign body aspiration and-ingestion in childhood and adolescence.

In addition to the intervention schemes, the memo also lists the main injuries that may be caused by food imitation products that do not conform to the tested safety requirements. The participating Member States have indicated that this is useful for their communication with economic operators as they have to justify legal measures by referring to the risks that are posed to consumers.

The opinion of SCCS Scientific Committee on Consumer Safety on the potential health risks posed by chemical consumer products resembling food and/or having child-appealing properties

SSCS opinion on the potential health risks posed by chemical consumer products resembling food and/or having child-appealing properties was published in March 2011 and was discussed by the activity as it was considered to be an important contribution for the discussion on the chemical risks posed by food imitation products.

Based on the data actually available as reported under the answer to question 4 in the SCCS report: *“....For children, no fatalities are reported for CPRF (Consumer products resembling food) and CAP (Child Appealing Products) ingestions. In addition, only rare, adverse severe health effects as a result of CPRF and CAP ingestions are reported. These effects are the exacerbation of the symptoms listed above, or consequences of the treatment used. For the elderly, there are a few case histories reported as either serious adverse health effects or fatalities....”* there is no evidence that chemical substances contained in FIP cosmetics can cause serious risks.

In the discussion that was held in the third meeting of the Joint Action, where the SCCS report was discussed, and that involved the Chairman of the SCCS it was considered that, even if based on the cases analysed by the SCCS (that, as stated in the SCCS opinion, were limited in number and not detailed in the root cause), it may appear that there are no serious injuries, it was worthwhile for the activity to select and test samples of food imitation products that may cause problems due to chemicals.

This will add info to the source of data based on which the SCCS opinion was delivered and may be further considered by the SCCS in the view of the opinion they expressed.

It was also mentioned that, as the scope of the Joint Action is to verify if dangerous food imitation products are available on the market, the relevant verification shall be made by the application of the requirements in Directive 87/357/EEC and of the Risk Assessment methodology as detailed in “Commission Decision of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System

'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive)".

When the report from SCCS was considered it was agreed that it would be advisable to have a specific Risk Assessment - carried out applying the above mentioned guidelines and with the support of an expert on Risk Assessment - of a FIP with liquid (e.g. a shampoo) that can be ingested and can cause vomiting or chemical pneumonia.

Risk Assessment for food imitation products

As already detailed in the previous parts of this Report it was considered that the Risk Assessment takes a fundamental role in the evaluation of the dangers posed by the food imitation products and ands the level/proportionality of action taken in case of food imitation products for which significant risks are detected.

When assessing the risk for an unsafe FIP, the risk assessor has to make a number of decisions on the appropriate scenario, the steps in the scenario and the probabilities. All of this involves a certain amount of estimation which will inevitably give rise to uncertainties in the final assessment. This may cause differences if two people carry out a risk assessment for the same product.

To cope with this, the Joint Action developed specific reference risk assessments, i.e. generic assessments for typical non-compliances illustrating what the scenario would look like, what the steps would be and what the probabilities would be.

The model risk assessments were developed together with the Task Coordinator of EMARS Task C, the working group that was responsible for risk assessment in the EMARS project.

The risk assessments that were made for food imitation products cover the following products that were collected by some of the members:

- Decorative cherries;
- Candle resembling water melon;
- Shampoo resembling orange energy drink;

The main risks that may be expected from food imitation products are:

- Suffocation due to small parts
- Poisoning due to solvents, poisonous components
- Perforation due to sharp parts
- Chemical pneumonia due to detergents or thin viscous oils

Research on the foreign body aspiration and-ingestion in childhood and adolescence

A research on the foreign body aspiration and ingestion in childhood and adolescence was made available by the member of Austria. The report covered an analysis of cases concerning all children younger than 16 years, who were presented between January 2005 and December 2011 at the Department of Paediatric and Adolescent Surgery in Graz with a history of foreign body ingestion or aspiration. Members considered this research very interesting.

As stated under item 5 of the research, that was taking into account all types of ingestion (from food, coins, toys and other objects) involving children *"aspiration or ingestion of foreign bodies is extremely rare and accounts for only 0.4% of all trauma presentations among this age group..."*. In particular it was noted that, seemingly, amongst those analysed in the research, no cases were traced due to ingestion of food imitation products or part of them.

In addition the following statement was commented: *"Safe Kids Austria" recorded only 2 fatal cases of accidents with foreign bodies in the airways in Austria. One of these children was a 7 years old boy, who had a small rubber ball in his mouth that got stuck in the upper airways while sitting on the back seat of a car."*

This was considered important also for food imitation products, as it confirms an assumption already made by the Group when discussing the risk assessment for food imitation products: one of the major risks is that a FIP having a spherical shape of a given diameter gets stuck in the esophagus, thus blocking completely the airways.

The conclusion of the report that states “*Accidents with foreign bodies in the airways or the gastrointestinal tract requiring medical attention are extremely rare among children and adolescents and account for only 0.4% of all accidents. The medical course is typically uneventful, late complications will not occur in most cases. Prevention strategies should focus on aspiration of nuts and swallowing of coins*” was also commented and members considered this is an important statement to be taken into account for risk assessment on the products selected and verified/tested.

Procedure for the evaluation and decision tree for food imitation products

Food imitation products are a diminishing safety issue on the European market, but Member States still face situations where they have to decide whether a given product may cause significant risks.

A list of basic items to be verified by the inspector during the inspection to verify if a product is to be considered FIP was developed and it was included in the instructions for inspection and in the checklist.

The main parts of the document covers the questions on items to be considered to decide if a product is a FIP and may cause potential dangers:

To evaluate if a product is food imitation product

- Are the dimensions like the food it resembles?
- Does it resemble food, e.g. sweets in form of a food?
- Does it smell like food?
- Or does it smell very appealing?
- Is the weight like the food it resembles?
- Does the real foodstuff need to be peeled (or treated otherwise) before eating?
- Does it feel like a foodstuff when it is touched (for people who can't see)?
- Is it as similar to be really confused?
- Is it round or flat or otherwise?
- What are the colours like?
- Which material is it?
- Is the product sold or made available to consumers?
- Does the package or the product looks like the package of food?
- Is the packaging like to be considered as for foodstuff?
- Is the content visible or not?
- Is the labelling like to be considered as for foodstuff?

For the Risk Assessment it might be important to evaluate if the product is also “child appealing“

- With age of children is it intended for - below 36 months or also elder?
- Are small children attracted because it looks like foodstuff?
- Is it appealing because of the attractive colours, smell, other...?
- Does a child below 36 months know this kind of food (e.g. candied sugar)? (aren't children under 36 months attracted by nearly everything?)
- Is it a toy for elder children (board game or fruit /vegetable shop)

To evaluate the possible dangers

Suffocation

- possibility that the product can be swallowed - because of smallness (test-cylinder)
- possibility to bite off, removable small parts (evaluate the effort it takes to bite or remove the small part),

Possibility of hurting digestive organs

- it is/becomes too sharp
- it sticks together or swells
- it is/becomes too big to get out (sticks together, swells)
- it corrodes the gullet, stomach
- it poses a chemical/toxic risk (e.g. chemical pneumonia)
- it contains hazardous chemicals that can cause poisoning/contamination

To evaluate the categories of users to be protected

- Children - which age?
- Handicapped persons (body or mind)
- Elderly people

„normal“ consumers

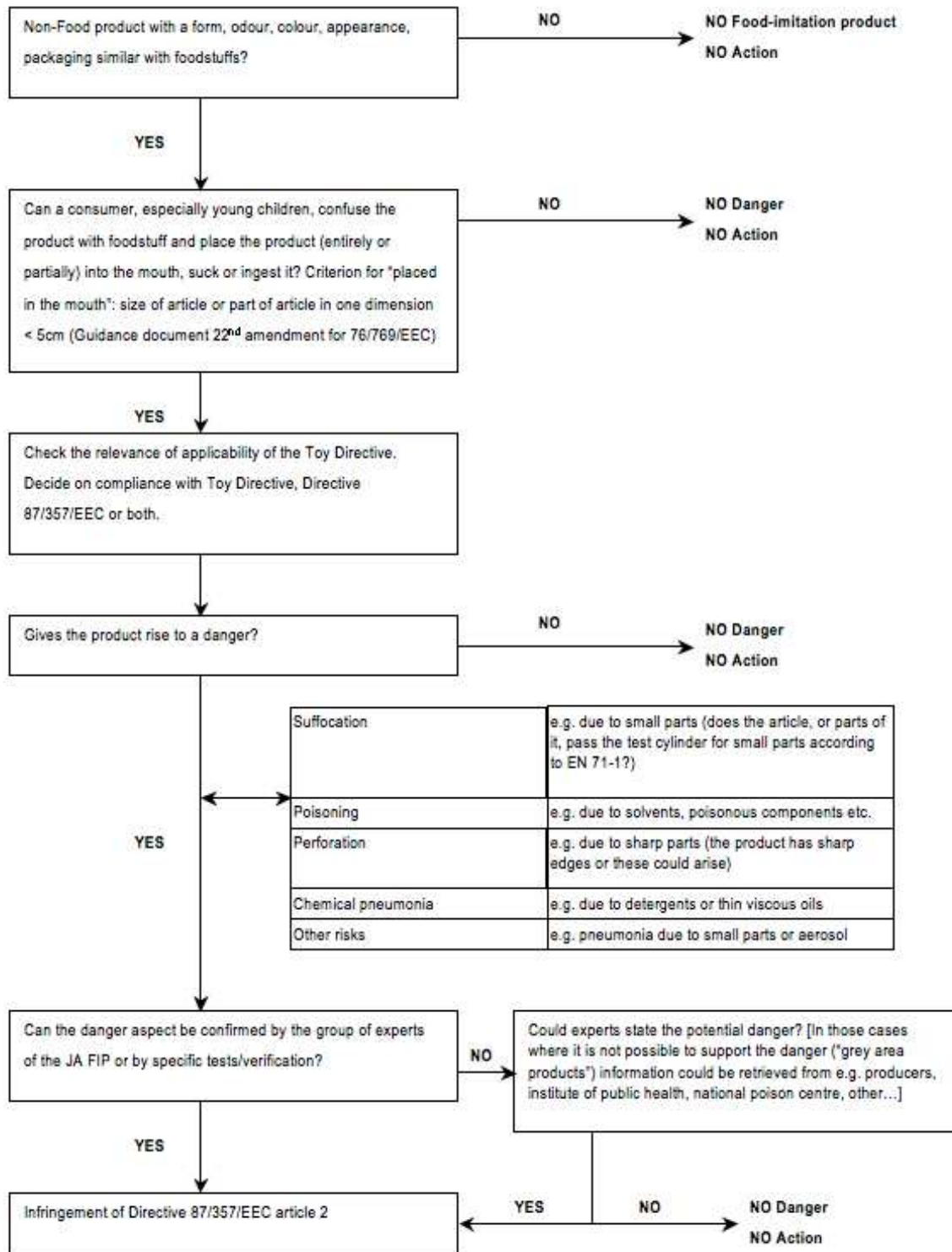
To describe the type of product

- Decoration
- Cosmetic
- Toy
- Others that look incidentally like foodstuff (orbs against carpet moths or jelly-like decoration)

The decision-making process in itself was found to be complicated as the market surveillance authority must check several properties in a proper sequence to make the decision. It was therefore decided to develop a decision tree to support the decision-making process. The decision tree is based on the approach taken by one of the members and its purpose is to take the market surveillance official through the necessary decisions one by one in the correct sequence. The participating Member States have indicated that they find this useful for the work in the field. Based on the discussion amongst the participants a document *“Procedure for the inspection and selection of food imitation products”* was developed and was made available to all members of the Joint Action.

The decision tree is shown below.

ANNEX 1 - DECISION TREE



The desktop approach

To make the common understanding of the problems to be faced in the performance of the Joint Action and to agree on common harmonised approaches on the evaluation of the risks posed by the FIP, it was agreed that the desktop analysis of the products selected by members would take a primary role in the Joint Action.

The desktop consisted in the fact that samples representative of each category, that were brought to the meetings by the members of the activity, were examined and discussed, in particular to clarify the approach

and to define which of the checks/tests that were defined during the discussion and that will need to be done, shall be done by the laboratory or by the Member.

The discussion was based on a document that was prepared by the Project Leader who collated together the most representative samples taken by the members and divided them into different sub-categories, in addition to the categories (Decorative, Toy, Cosmetic, Others) that were previously defined by the WG and that are mentioned in the check list. This further detailed subdivision will help in better defining which verification/test is needed.

The defined sub-categories were:

- Decoration fruit/vegetable/sponges looking like cakes (plastic), attached to branch or standing alone
- Decorative (stone)
- Toys
- Lip gloss, balm
- Shampoo, detergent
- Soap
- Candles
- Gels
- Others: Car freshener, Potpourri, Biocide peppermint flavour, Magnets (chocolate, cake), Medicine (painkiller), Butterfly water (46% alcohol)

Representative samples of each category were examined and discussed in the Task group, in particular to clarify the approach and to define the next steps in the process of testing and risk analysis.

It was agreed that, as outcome of the discussion, the following actions shall be performed, by members, on the check lists that concerned the products they selected and for which it was indicated that further investigation is needed:

- For check lists where it was stated that items need to be discussed, to modify the answer considering the discussion at the meeting and to mention if a laboratory test should be done.
- For check lists for which the small parts tests shall be done, to do the test and modify accordingly the relevant answers in the check list, by adding specific comments on the evaluation of the results

An indication of the different products that were considered in the desktop evaluation is given below

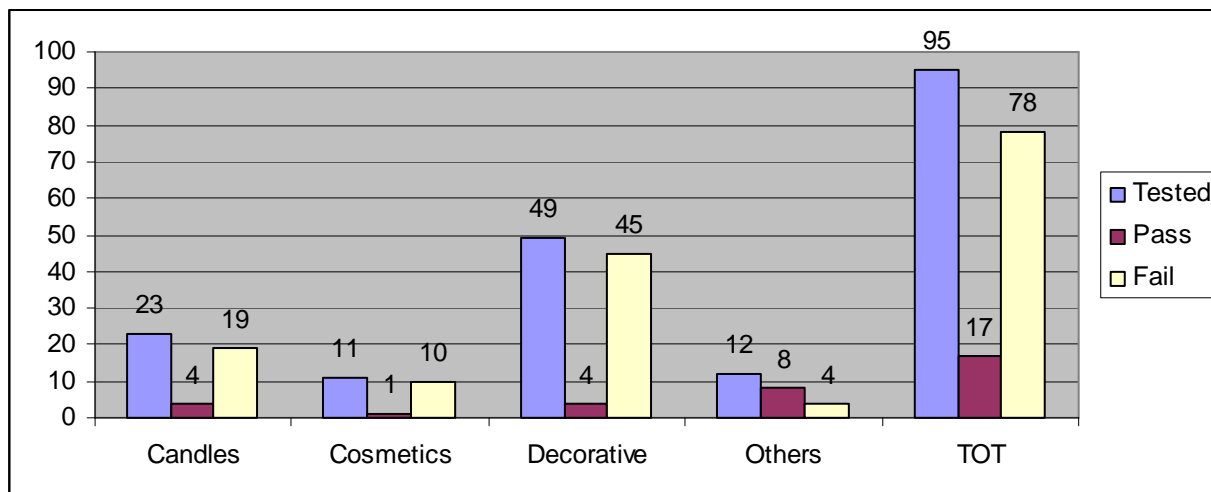


Examples of different products

3.1.6 Results of the lab tests and risk assessment

A total of 95 food imitation products models have been sampled and sent for laboratory testing. The test reports were uploaded to WebEx so that all participating Member States could follow up on the results.

The results of the laboratory tests, that are shown in Figure 5 and in Table 7 were discussed by the members of the Joint Action in the view of developing a suitable Risk Assessment approach to consider the risks that may be originated by the products, to develop Risk Assessment reference examples to be used for all other product that the members considered suitable to pose risk, in particular due to ingestion of small parts.



Results of laboratory tests

Samples tested	Candles	Cosmetics	Decorative	Miscellaneous
95	23	11	49	12
17 pass / 78 fail	4 pass / 19 fail	1 pass / 10 fail	4 pass / 45 fail	8 pass / 4 fail

Results of laboratory tests

Following application of the RAPEX risk analysis tool to the results of inspections and testing it was verified that the risks for consumers are low.

Out of 379 food imitation products verified within the project 106 are posing low risks, 7 Medium risk, 4 High risk and 12 Serious risks, the other 250 were considered not dangerous or not food imitation products. Less than 5% are posing high or serious risks, the overall risks are not significant.

This result is mainly due to the fact that, based also on the results of the “Research on the foreign body aspiration and-ingestion in childhood and adolescence” mentioned in a specific chapter under this heading, the ingestion of foreign bodies, like small parts that can be bitten from food imitation products will never cause a significant block in the oesophagus. As far the ingestion of liquids in shampoos and bath foams, it was considered, confirming the results of the SCCS, that in principle they are not ingested as their flavour is quite bitter and they are more viscous than the liquid in the real food. In addition, even if ingested they will not cause any harm and are eventually ejected by vomit.

Also the risks from vomit were considered non-significant.

Each risk assessment, that was performed describes the injury scenario, type of injuries, severity of injuries, probability factors, calculated probability and total risk.

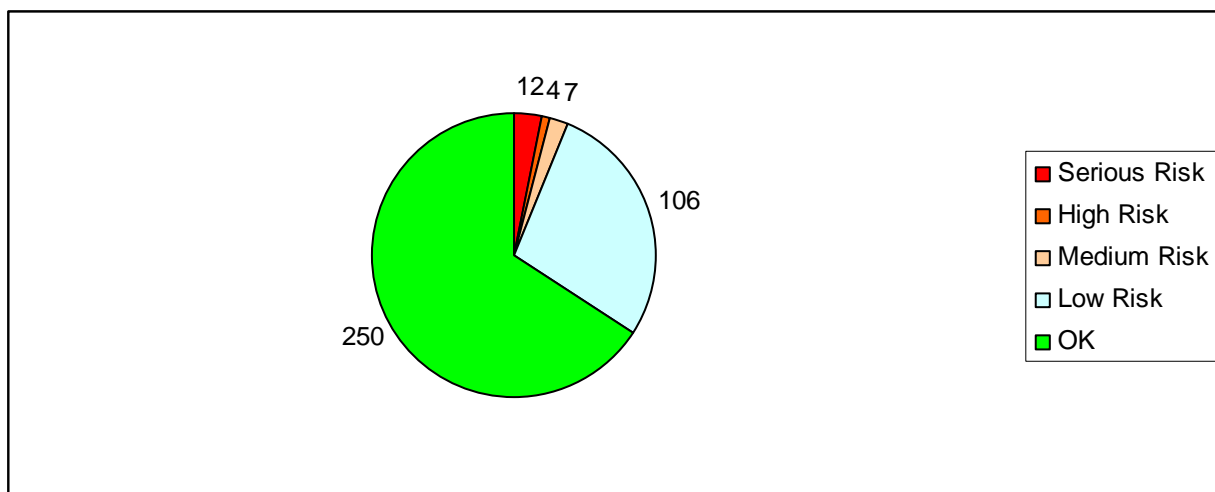
Probabilities factors were considered to be the more disputable part of the assessment made due to low number of injury databases available.

The results are shown below. The table shows that the risk varied between low risk and serious risk even if the injuries were quite severe (injury class 3 or 4). The reason is that the resulting probabilities are low, in one case even extremely low. The probabilities however seems to compare well with the participants' immediate feeling: Severe accidents with food imitation products seem to be rare even though such products are extremely common with billions items sold annually in Europe.

Non-compliance	Injury scenario	Type of injuries	Calculated probability	Risk
The "ice cream" ball is so big that it gets in the larynx and block the airways.	A child gets hold of the candle and believes it is chocolate. It tears of one of the "ice cream" balls and puts it in the mouth.	The child suffocates.	> 1/10.000	Serious risk
The cherry gets in the larynx and blocks the airways.	A child gets hold of the cherry and puts it in the mouth. The child pulls off the stem and swallows the cherry.	The child suffocates.	< 1/1.000.000	Low risk
The child swallows the small parts. The small parts get in the airways.	A candle shaped like a piece of water melon. A child can bite off small parts.	Internal organ injury (Refer also to internal airway obstruction in case the ingested object gets stuck high in the oesophagus.)	< 1/1,000,000	Low risk
An adult confuses the shampoo for juice and drinks some of the liquid. The adult realises that it is shampoo and vomits. Some of the substance gets in the lungs.	A bottle with shampoo resembling orange juice. The bottle has a drinking cap like a bottle with "sports drink". It smells like orange juice. The liquid is orange. The liquid is high viscosity liquid (the liquid is "thick").	Lungs, respiratory insufficiency, chemical pneumonia	< 1/1,000,000	Low risk

Model risk assessments for four typical non-compliances with food imitation products.

Based on the above evaluations, the overall results of the risk assessment showed what indicated in the following figure:



Results of the risk assessment on food imitation products

It has to be noted that according to the legislation on FIP's, it is forbidden to sell these products because the products may cause harm to e.g. children. In fact, as outlined in previous parts of this report the legislation for food imitation products does not foresee the Risk Assessment approach to define if a FIP is dangerous.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the Statistics on Activities D10A and the Memo with description of follow-up activities D11A.

3.1.7 Follow-up

Results from Member States market surveillance activities

The Member States have been asked to report the results of their market surveillance activities following on from the tests that were conducted on their behalf in this activity.

Based on the results of Risk Assessment and the overall evaluation that food imitation products rarely represent serious or high risks, limited enforcement actions have been taken. 9 products were recalled, 19 were removed, 6 of them under RAPEX for info, 16 products were removed and destroyed and in 12 cases economic operators were invited to take actions.

It is also worth noting that some of the above actions were already taken during the interim steps of the project, before the full approach to risk assessment was considered and finalised with specific guidance.

Further information is can be obtained from the appropriate deliverable in the Annex I. This is the Memo with description of follow-up activities D11A.

Cooperation with customs

The Check List developed in the framework of the activity will be shared with the Customs together with the “Procedure for the selection of food imitating products (food imitation products)”. The procedure contains also some hints for the approach to the evaluation of the possible dangers caused by food imitation products. Considering that a good part of products are produced in China, the Check List & the Procedure for the selection of food imitation products will be shared with the Chinese market surveillance Authorities.

Outreach to Standards Development Bodies

No specific items were emerging from the joint action that needed the involvement of Standards Development Bodies or the request for evaluation of possible modifications or improvements.

As far mechanical risks are concerned it was found that the applied standards duly cover the matter, as far chemical risks it was considered to apply the good laboratory practice on the analysis of the relevant chemical components and this did not cause any problem.

3.1.8 Achievement of objectives and lessons learnt

Impressions of the European Market in General

It may be considered that the results of the Joint Action were significant although, after the discussion and the approach taken on the risk assessment, it was verified that the risks for consumers are low, in fact less than 5% of food imitation products inspected are posing high or serious risks.

In spite of any evaluation on the low number of food imitation products posing high or serious risks, the Joint Actions served its purpose to clarify that the Risk Assessment is an indispensable tool for the evaluation of the compliance of food imitation products to the requirements of Directive 87/357/EEC.

All the members found the deep discussion held on the approach to Risk Assessment, the tools that were developed for this purpose and the specific Risk Assessment that were made on representative products, very useful for their future activity on food imitation products and for an overall understanding of the approach to Risk Assessment.

It is interesting to note that the trend of the RAPEX notifications for food imitation products was:

2010: 53

2011: 29

2012: 23

and that in 2012 only one RAPEX notification was sent from a Member State participating in the food imitation products activity and this was in respect of a product not amongst those selected in the Joint Action.

It is the feeling of the members of the participants that this can be considered as an outcome of the Joint Action on food imitation products and a confirmation of the good success of the Joint Action.

Lessons learnt

Risk Assessment

Most of the cases of food imitation products that were posted on RAPEX in the considered years were probably over-evaluated as the products, although being food imitation products, didn't cause serious problem to the consumer.

The primary recommendation that can be drawn from the Joint Action is that the Risk Assessment of food imitation products takes a fundamental role in deciding if a given product can cause significant risks to the potential users.

Standard to be used for the tests concerning the possibility to bite pieces out of the product

The tests were carried out according to EN 716-2:2008, Clause 5. The activity, based on detailed info delivered by the Task Coordinator, decided to apply the Standard EN 716-2 that seemed to be the more suitable to cover the typical biting situation that may be encountered in case of food imitation products accessed by children that may be tempted to bite part of the product.

In fact the testing tool that is foreseen for this purpose in EN 716-2 (see Figure 7) is simulating the structure of a mouth with some teeth and the force applied for the bite is close to the one applied in reality by a children.



Testing tool for bite test

Also standards EN 1400-2 "*Babies Soothers*" (with a different test tool as the one in EN 716) and EN 12227 "*Playpens for Domestic Use*" (with the same test tool as in EN 716-2 but different force), that may be considered as suitable were analysed and it was considered that they did not cover appropriately the biting conditions that are reasonably expected in case of food imitation products.

In fact the tool foreseen by EN 1400-2 simulates the situation were a small child is teething that is quite different from the situation of biting, whilst the force applied by 12227 is considered not suitable although the tool is the same as the one of EN 716-2.

It is advised to use for the bite tests of food imitation products the requirements of EN 716-2

Scientific Committee on Consumer Safety report on the potential health risks posed by chemical consumer products resembling food and/or having child-appealing properties

The results of the Joint Action confirmed the conclusion of the SCCS report: from the cases that were analysed in the activity there is very low evidence that chemical substances contained in cosmetic food imitation products can cause significant risks.

Modification to the Directive

One important matter that was considered during the Joint Action, is that following the requirement in Directive 87/357/EEC Art. 2: *“Member States shall take all measures necessary to prohibit the marketing, import and either manufacture or export of products referred in the Directive”* it may be possible to take actions on products for which no specific Risk Evaluation has been made and for which no Serious or High risks have been proved.

The discussion showed that there is a need to better detail the requirements of the Directive and make a clearer and stronger link to the evaluation of the risks posed by food imitation products.

The problem seems to be duly addressed in the “Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC” that was circulated on 13th February 2013.

3.2 Ladders

3.2.1 Background Information

Objectives

The primary objective of the action was to build knowledge about the market for ladders, the standards applied and to what degree the ladders on the market comply with those current standards.

The secondary objective was to generate information on improved safety requirements to go into the standardisation development work on ladders currently being undertaken by CEN.

The tertiary objective was to raise the awareness within the Member States for the need for increased safety and harmonisation in this product area.

Risks presented by ladders

Ladders are estimated to cause more than half a million hospital treatments and more than 100 fatalities each year in the 27 EU Member States. (A search on the European Injury Database suggests that the number of accidents in each of the countries Austria, Denmark and Sweden is a couple of thousand per annum whereas the figures suggest that the number of accidents for a big country, i.e. France is around 25 - 40.000 accidents annually.) Each participating market surveillance authority was asked to obtain accident data from their own country. However, none of the participating countries collects accident data in a consistent way and the only data reported was of an anecdotal nature.

Two thirds of the accidents concern consumer's use of ladders. This places portable ladders and stepladders among the most risky consumer products on the EU market.

This is partly due to the fact that the intended use, climbing to a certain height, always implies an increased risk for the user. Still, accident data suggests that a large number of the accidents could have been prevented if the product had been safer.

3.2.2 Project management activities

Project Meetings

Six project meetings have been organised by the activity as foreseen in the original project plan:

- Kick-off Meeting: 20 May 2011 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D5.2B.
- Meeting 2: 22/23 June 2011 in Zwijndrecht
The minutes from the meeting are annexed in Annex I, deliverable D6.1B.
- Meeting 3: 13/14 October 2011 in Prague
The minutes from the meeting are annexed in Annex I, deliverable D6.2B.
- Meeting 4: 10/11 May 2012 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D6.3B.
- Meeting 5: 5 July 2012 in Valetta
The minutes from the meeting are annexed in Annex I, deliverable D6.4B.
- Meeting 6: 29/30 November 2012 in Ljubljana
The minutes from the meeting are annexed in Annex I, deliverable D6.5B.

Selection of Laboratories

The selection of test laboratories to support the activity began by asking participants if they knew of any laboratories that were expert in conducting tests on ladders. Through this and other enquires, 13 European laboratories were identified that had the potential to conduct tests on ladders for the activity. The laboratories were based in Belgium (1), Bulgaria (1), the Czech Republic (2), Germany (3), Italy (1), the Netherlands (1), Slovenia (1), and the UK (3).

The laboratories were contacted via an *Expression of Interest* letter that described the planned testing programme and requested for them to respond, should they be interested in undertaking the tests.

The responding laboratories received a *Call for Tender* to conduct testing, including the test criteria/work programme which outlined the type of tests that were required in the scope of the activity, e.g. EN131-2 tests and additional tests. The laboratories were informed that accreditation to EN17025 for ladder testing was required in order to be eligible to perform the tests for the activity. The laboratories were asked to provide cost estimates for the various types of tests that needed to be performed.

The evaluations of the responses received from the 4 eligible laboratories were initially undertaken by the activity coordinator and the activity leader. (3 laboratories were ruled out at that stage as they did not have accreditation, nor were willing to obtain it, or were unable to perform some of the required tests.) The results of the evaluations of the offers from the remaining 4 laboratories were made available to all participants who collectively agreed upon which testing laboratory to select.

The laboratory selected to conduct the testing was nVWA at Zwijndrecht. This institution offered the best costs as well as having substantial experience in the testing of ladders.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the list of test criteria D9.1B, the letter to laboratories requesting them to make a quotation D9.2B, the overview of responses to call for tender D9.3B and the contract with laboratory D9.4B.

Outreach and Communication Activities

Outreach activities were focussed on the European Commission, particularly DG SANCO, and on other stakeholders. DG SANCO's interest was very high, as they had been attempting to improve the safety of ladders through encouraging an improvement in EN 131 for many years. Presentations of progress were made to the GPSD committee and the GPSD Ladders Group was re-convened by DG SANCO in order to take action fuelled by the results of this activity.

Efforts to reach out to manufacturers were also made. These were difficult to begin with, as no EU trade federation existed but one was formed (in part, it is believed because of the high profile of activities being undertaken by this activity) during the time period of the activity. The President and Secretary of the new trade body, the European Ladder Federation (ELF), joined a special stakeholder meeting with representatives of the activity the day after the ELF was incorporated.

A meeting was held between stakeholders and the activity leader, activity coordinator and the participant from NL. It took place on 12 Oct 2012 in Brussels. Stakeholders attending the meeting included representatives of consumers (ANEC), standard developers (from CEN TC93) and the President and Secretary of the EU trade association for ladder manufacturers (European Ladder Federation - ELF) that had been inaugurated on the previous day.

The reason for providing the special meeting for stakeholders was to give them a briefing on the results obtained, and actions subsequently taken, by the participants in the activity. This gave the stakeholders a better sense of involvement and prevented them from having to wait until the Final Conference to learn of what had been accomplished by the activity. It also ensured that the manufacturers could become involved in the activity at the earliest opportunity - the absence of any federation representing manufacturers at the European level having been a matter of concern up until that time.

Maintaining liaison with stakeholders was regarded as an important task throughout the whole life of the activity. Additional communications with them had taken place prior to their special meeting and an updating briefing note was sent to them in Feb 2012.

In addition to the conventional dissemination routes of the Joint Action's Workshop and Final Conference, much dissemination activity was concentrated on informing and supporting the development of improved safety standards by CEN TC93. Plenary meetings of the main technical committee and intensive working meetings of the working group (WG10) responsible for developing the specific tests requirements for the ladders being tested by the activity were attended by representatives of the activity.

Other Meetings Attended within the Framework of the Joint Action

Representatives of the activity attended the following meetings and events:

- Meeting with DG SANCO's GPSD ladders expert group;
- Meeting with GPSD Committee
- Attendance at a plenary meeting of CEN TC 93, the CEN technical committee responsible for developing the safety test standards for ladders, EN131. This meeting took place on 5 Oct 2012 in Stockholm.
- Attendance at CEN TC 93 Working Group 10, the WG responsible for developing new tests for inclusion in EN131. The detailed results and explanations of the test methodologies developed were shared with members of WG10 at this meeting.

3.2.3 Sampling

Establishing a market picture

At the outset of the activity, there was a lack of authoritative knowledge amongst the participants as to what types of ladders featured most prominently in their markets. Each of the 5 member states surveyed the ladder market within their countries to determine the range and type of ladders present in their economies. Each participating country was asked to provide details (e.g. ladder type, model, price, photos, etc.) of each ladder type for a minimum of 20 ladder samples.

To assist this process, the activity coordinator produced guidelines for the participants. The purpose of this document was to provide a common basis for nomenclature and ensure that each participant recorded information in a consistent manner.

The results obtained by each Member State were collated together in a spread sheet that enabled a market picture overview to be identified across these Member States and enabled each Member State to compare its findings with those of the other Member States.

The collated market picture showed that the market for ladders (excluding step stools) was dominated by step, multipurpose and leaning ladders and that this pattern was consistent across all the Member States.

Further information can be obtained from the appropriate deliverable in the Annex I. This is a further description of the preparations made to assist the participating MS to obtain a market picture in a consistent way, D7.1B, which was supplied to each MS complete with a blank questionnaire and a pictorial guide to ladder types - copies of these being annexed to D7.1B.

Selecting and obtaining samples for testing

An important part of the national activities was sampling of a number of ladder models for joint testing. It was decided to focus the selection of samples on those types of ladders that were the most common types in each of the national markets. In every case, the most common types of ladders were stepladders, multi-purpose stepladders and leaning ladders.

The sampling process began with each participant undertaking a market survey in their Member State. The activity coordinator provided each with a pictorial guide to ensure that everybody conducting the surveys used consistent descriptions. The results of the surveys clearly identified that each market was still dominated by the conventional step, multi-purpose step and leaning ladders.

Thereafter, each participant was provided with a target number of samples to obtain from their market; this target number being based on the available budget for testing being shared equally between the participating Member states. In the event, not all the testing budget was required for the samples sent by the participants and so additional samples were obtained from two other Member States who were not formally participating in the activity.

Discussions were held at the meetings to determine which samples to test and a memo was sent to all the member states advising on which ladders to sample.

The number of samples that could be tested at the selected laboratory was calculated (by dividing the budget with the unit cost for tests) and split over the economic operators (minus a little reserve).

In the event, the participating Members States did not supply enough samples to use up the entire available budget for testing. PROSAFE contacted the non-participating member states to inform them of the opportunity to submit samples for testing. This opportunity was accepted by Belgium and Malta.

A total of 38 ladder models were sampled and sent for laboratory testing. The test reports were uploaded to WebEx so that all participating Member States could follow up on the results.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the guideline to Member States on how to exchange information D7B and the Memo to Member States on which products to sample D8B.

3.2.4 Testing

One of the main objectives for this activity was to support the development of the test standard for ladders, EN131-2. The standard was known to be lacking test requirements for some specific risks associated with using ladders, such as side slip and base slip. Work was being done in CEN TC93 to correct these deficiencies but this had not reached a final stage of development at the time of needing to develop a test programme for the activity.

Guided by the participant from NL, who was already an established ladder expert and also a member of CEN TC93, the participants undertook the task of developing their own test program.

They began by reviewing the current list of tests in the published standard, EN 131-2, and identified those that were important for the safety of ladders and which were sufficiently stringent such as the strength of styles (Cl 5.2) and bending of styles (Cl 5.3), security of the style/rung joint (Cl 5.7) and the feet-pull test (Cl 5.11). This latter test being regarded as vitally important as the rubber/plastic feet are all that provides the frictional grip between the foot of the ladder and the surface upon which it is rested. Since so many accidents are caused by the feet slipping, it can be seen that security of grip will play a significant role in reducing accidents.

Comparing the contents of EN131-2 with known causes of accidents such as side and base slip enabled the participants to identify where EN131-2 currently contained no requirements e.g. side slip and sideways stability, and where the requirements were insufficiently stringent e.g. base slip. In each of these cases they added further test requirements.

A number of these additional tests were based on work currently being undertaken in CEN TC93 WG10, who are currently developing further testing requirements for EN131-2; some were based on tests in safety standards published elsewhere in the world and some were based on replicating how ladders are used in practice.

Due to limitations of budget available for testing, it was decided to test one sample to the requirements based on EN131-2 and a second sample to the requirements of the additional tests. This represented a small risk to the activity as the laboratory had experienced that reproducibility of all EN131 tests is limited. This means that if a sample just passes a test, there is a good chance another sample of the same product will fail.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the list of test criteria D9.1B and the contract with laboratory D9.4B.

3.2.5 Risk assessment

As ladders were a class of product covered by the GPSD, it was decided to first investigate whether the published RAPEX risk assessment tool was appropriate to be applied to the results of ladder testing.

The RAPEX risk assessment tool is a public document available for (easy) use on-line that requires a number of inputs in order for it to then automatically derive an overall risk assessment - the most severe being "Serious Risk".

The inputs require the hazard group and hazard type to be identified by the user. The type of consumer user has to be identified too. Information detailing how the hazard causes an injury to the user and the severity of the resultant injury needs to be inputted. The final input required is an assessment of the probability of the various steps that would be followed until an injury resulted. Once this is done, the software computes the risk of the scenario described through the inputted data.

Though this may seem complicated, the guidance provided and the step by step nature of the programme makes for a simple to operate process which was judged to be entirely appropriate by the participating MS.

However, before they could use the tool they needed to understand the relationship between the hazards and risk covered by the various requirements in the test programme. Some examples of these are provided below:

Handrail/knee rail on stepladders

The absence of a rail or a low rail brings an increased risk for the user of losing balance and falling. This risk is much higher if the stepladder is higher: the fall is from larger height and you have much less opportunity to correct by stepping on the ground. The absence of sufficient body support on a stepladder could be a high risk factor.

Step distance from floor to bottom rung

It has been suggested that that about 8 to 10% of injury treatment with ladder accidents are caused by losing balance because of an uneven step distance when stepping off the ladder. It is likely that they are not the most severe injuries, but still they require professional treatment. This could be a medium risk factor

Knowledge of the user

Manufacturers have been known to claim that most ladder accidents are the result of misuse, while there is nothing wrong with their product. It is known that user instructions usually get very little attention from the user, so it is important that the most essential information/warnings are very clearly presented. The absence of essential information or their poor presentation brings risks varying from low to serious. The absence of an angle indication or an angle indication that advises unsafe angles is thought to be a serious risk for leaning ladders (roughly 50% of leaning ladder accidents are caused by base slip, and leaning at too shallow an angle is

a major cause of base slip). A warning against leaning outside of the styles is also important, certainly for stepladders. Also important for stepladders is a warning about avoiding use on uneven or soft underground. Presenting the information for use in an unattractive way (too small pictograms, an excess of similar information etc) can mean that there is more chance that it won't be read. These factors can amount to a high risk.

Durability

Since accidents are known to occur on stepladders due of fatigue of connections (and the resultant collapsing can occur without any warning) this can cause a fall and a resultant injury. So samples that fail the durability test, particularly after a relatively short period of testing, can pose a serious risk.

Base slip

This, according to several sources, is the No.1 cause of accidents with leaning ladders. The “correct” angle of lean is 70° but many users instinctively lean ladders at a shallower angle. So ladders should exhibit good resistance to base slip at 65°. Those that do not could be considered to present a serious risk.

Side slip

Accidents caused by side slip are thought to be responsible for some 20% of leaning ladder accidents and the more severe injuries/fatalities too - so poor results to this test could result in a serious risk.

Strength test of styles

Interpretation of the test results should take a reasonable factor for dynamic effects (perhaps 1,7) and a reasonable safety factor of (perhaps 1,1) in order to assess a minimum load resistance requirement. This equates to about 280kg, which is far more than that represented by the EN131-2 test. For ladders that fail at loads significantly below this figure, the risk can be estimated as serious.

Based on the failure scenarios described above, it became a simple task to reach a consensus amongst the participating MS (including delegates from Malta) for how to describe the scenarios and inputs required by the RAPEX risk evaluation tool.

The tool was subsequently used by all the participants working together to evaluate the risk posed by all the ladders that were tested

One such evaluation, using an application of the RAPEX tool, is described in more detail below:

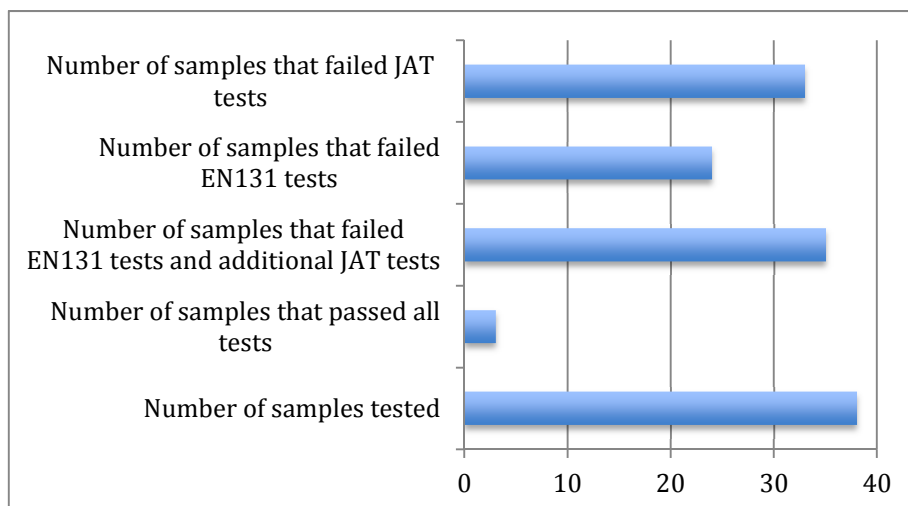
Scenario
Person at high position on the product loses balance, has no support to hold on to and falls from height
Product hazard
Hazard Group: Potential energy Hazard type: High position of user
Consumer
Consumer type: Other consumers - Consumers other than vulnerable or very vulnerable consumers
How the hazard causes an injury to the consumer
Injury scenario: Person at high position on the product loses balance, has no support to hold on to and falls from height
Severity of Injury

Scenario
Injury: Fracture
Level: 3
Ankle
Leg (femur and lower leg)
Hip
Thigh
Skull
Spine (minor compression fracture)
Jaw (severe)
Larynx
Multiple rib fractures
Blood or air in chest
Probability of the steps to injury
Step 1: rung or style failed > 1/300
Step 2: person falls > 90 %
Step 3: person injured > 50 %
Calculated probability: 0.0015
Overall probability: > 1/1,000
Risk of this scenario: Serious risk

3.2.6 Results of the lab tests and risk assessment

A total of 38 ladders were to be tested in the main program in a laboratory during the Action. Individual test reports were uploaded to WebEx so that all participating Member States could most effectively follow up on the results. The test-by-test results were also combined into a single spread sheet that enabled direct comparisons of results. For convenience, each result cell was colour coded (green for pass, amber for fail) so that an overview of results could be gathered at a glance. This colour coding also made easy the task of evaluating how different types of failure were grouped together or whether there were any patterns in the failures that may have indicated generic design failures. More than half of the samples were found to present an unacceptable level of risk. Although most failures were related to inadequate strength of the products, it could be readily seen from the spread sheet that many samples failed multiple tests.

A summary of the results of the testing is presented in the Table below



An excerpt for the overview table of test results is presented in the Table below

Country of supply	Fail	Pass	par. 4.10.1 Rung-step hooks-locking devices	par. 5.3 Bending test of stiles	par. 5.2 Strength test of stiles	par. 5.11.1 Feet pull test for ladder feet made of one part
NL		X	pass	pass	pass	pass
NL	X		NA	pass	pass	Fail
CZ		X	NA	pass	pass	pass
NL	X		pass	Fail	pass	pass

The RAPEX risk analysis tool was applied to the results of testing for each of the ladder samples. This was done twice, once just to the EN131-2 derived tests and, separately, to the additional tests developed within this activity. This was necessary as some MS, such as CZ, recognise EN131 and so are only able to enforce actions based on the perform of ladders to that standard.

A simple analysis of the derived risk assessment showed that 20 of the 38 were rated Serious Risk in either for EN131-2 test results or the results obtained in the JA additional tests (or, in some cases, both). A further 4 ladders were rated High Risk.

Further review of the risk ratings and the results that were used to derive them show some disturbing patterns. For example, only 2 of the 17 stepladders passed all the EN131-2 tests that were applied and 10 of the 17 models had such serious failures that they were rated high or serious risk. 9 of the 10 models of stepladders rated high or serious risk failed more than one of the EN131-2 tests that were applied.

Overall, the most common failures that led to the highest available risk rating provided for in the RAPEX tool (“Serious risk”) were failures in the load tests. These tests are designed to ensure the construction and materials of the ladder are strong enough to withstand the forces that can occur in use. Clearly, a failure of a stile or rung or platform can result in the ladder buckling away from underneath the user causing them to fall. The weaker the product (and this can be derived from the test results themselves) the higher the probability of an injury occurring - and this is the key data that is input to the RAPEX tool in order to derive the risk rating.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the Statistics on Activities D10B and the Memo with description of follow-up activities D11B.

3.2.7 Follow-up

Results from Member States market surveillance activities

The Member States were asked to report the results of their market surveillance activities following on from the tests that were conducted on their behalf in this activity.

It needs to be understood that actions taken at Member state level were not necessarily consistent. This is because the status of the current EN131 standard varies between member states. Some, like Belgium, recognise it and require ladders to be compliant with it. Others, notably the Netherlands, do not recognise EN131 and continue to apply their own (generally more demanding) national standard. Thus a ladder found to be compliant by the authorities in Belgium may not necessarily be compliant in the Netherlands and vice versa. Similarly, some participants were able to take into consideration the results of the additional non-EN131 tests that had been developed by the activity, whilst others, such as Czech Republic and Slovenia, could not.

This inconsistency of actions taken was a disappointment, but not a surprise. It was the underlying reason why the activity had the objective to support the development of an improved EN131.

The actions taken to follow up these results, although significant, were therefore not consistent. Of the 38 models tested, the respective market surveillance authorities took action for 32 of them. In many cases, the action taken - the minimum - was to inform the supplier of the faults exposed by the testing. This can lead to the supplier taking actions to improve the products they will bring to market in future. At the other extreme,

five RAPEX notifications were made with these, and a number of other ladders, targeted for removal from their markets.

Further information can be obtained from the appropriate deliverable in the Annex I. This is the Memo with description of follow-up activities D11B.

Cooperation with customs

No coordinated cooperation with customs was made. This was because it was not possible to develop a checklist or other simple guidance tool that enabled the identification of an inadequately strong ladder through no more than a visual inspection. The only way that inadequately strong ladders can be identified is through conducting strength tests under laboratory conditions.

Outreach to Standards Development Bodies

Significant efforts were made to work closely with CEN. Most of these activities were described earlier. However, there was one additional and substantial outreach to CEN not reported. This was the provision of the full results (minus the model and brand identification of the products tested) of the testing conducted by the activity. The results were intended to support the development of the much needed improved safety test standard and were particularly valuable to CEN TC 93 WG10 as they described additional methods of test, complete with results, for base slip, side slip etc. which were exactly the types of test that WG10 was attempting to develop. The results were not simply and passively handed over but were provided with a complete briefing by the NL participant who was an expert in ladder testing and also an active member of WG10.

3.2.8 Achievement of objectives and lessons learnt

Impressions of the European Ladder Market in General

It would appear that the European ladder market provides products in a variety of grades of strengths. For example, the long established and still current British Standard 2037, provides for three classifications of duty rating: *domestic*, *light trades*, and *industrial*. The implication of this being that some ladders need to be stronger than others. EN131 does not include this concept but the impressions gained by the participants from their results is that many ladder products on their market are simply not strong enough for the roles that they have to fulfil.

The samples were selected from the individual markets for consumer products based on a visual examination only. The inspectors who selected the samples cannot have known how strong the chosen ladders were. They cannot have known they were picking just the weakest ones, yet the majority of those tested were not strong enough. So, the overall impression provided by the test results from the activity is that the poor strength of ladders on the EU market is a significant contributing factor to the level of accidents involving ladders within the EU.

Another very important impression is that the current standard EN131 is woefully inadequate. It is missing vital test requirements and some of its strength requirements are very low.

Something that is not an impression but a fact exposed by this activity is that market surveillance authorities are being highly inconsistent when it comes to taking actions on ladders. These inconsistencies seem likely to continue until such time as a much-improved EN131 is published or an alternative guidance document is made available by the European Commission for adoption by all member states.

Lessons learnt

The main lesson learnt was that conducting an activity involving testing of products can be technically challenging. Knowing just what test methodology is deficient and deciding which test methodology to apply requires expertise that specialist test laboratories may have but which most market surveillance authorities will not have. This was not a problem for this activity as one participant had had a professional involvement with ladder design and testing before becoming a market surveillance official. If his guidance had not been available, then it is possible that the results obtained in this activity would not have been as revealing as they were.

Extensive use was made of the RAPEX risk assessment tool, which was found to be very easy to use.

Access to test standards is essential as they are almost invariably the only source of the accepted safety test methodologies. Yet these documents are only available at a high cost and copies cannot be readily shared between authorities due to copyright restrictions. Ideally, a means should exist to enable market surveillance authorities to be able to check the contents of a test standard for their relevance without incurring the cost of some €100+ per standard.

3.3 Laser Pointers

3.3.1 Background information

Objective

The primary objective of the action is to ensure that laser products available on the EU market for consumers are safe, classified correct and carry the appropriate warnings and instructions.

Risks presented by laser pointers

Non-compliant and dangerous laser pointers (and other laser products) can cause safety problems such as serious and permanent eye damages, temporary blinding and skin burns during skin care treatments. Several cases have been reported where high-power laser pointers have been used to (temporarily) blind airline pilots, engine drivers and car drivers, thus putting many more people at risk. The Danish Civil Aviation Administration reported 19 attempts in July and August 2010 to blind airline pilots. This activity makes use of high-power green long-ranging laser pointers. The light does not have to hit the eye of the pilot to disturb him seriously; the light scatters in the cockpit window. At night time this causes the pilot to lose his night sight temporarily. This can have fatal consequences if it occurs at low altitudes during landing.

Low-cost lasers are red and do not have sufficient power to blind pilots as the distances are too large. Several Member States have carried out campaigns focussing on such laser pointers and found that they can also be very powerful, exceeding the permitted output level by a factor 10 or more. (A Danish investigation from 2008 showed that none of the tested laser pointers complied with the safety requirements and several lasers with outputs exceeding 10 times the permitted were found.) This is dangerous as the price and nature of the products suggest that they are purchased by children that use them for play pointing into each other's eyes.

3.3.2 Project management activities

Project Meetings

Six project meetings have been organised by the Joint Action as foreseen in the original project plan and one final workshop extra to share and discuss results of the follow-up activities.

- Kick-off meeting 28 April 2011 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D5.2C.
- 2nd project meeting 29 June 2011 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D6.1C.
- 3rd project meeting 30 September 2011 in Lisbon
The minutes from the meeting are annexed in Annex I, deliverable D6.2C.
- 4th project meeting 25 November 2011 in Vienna
The minutes from the meeting are annexed in Annex I, deliverable D6.3C.
- 5th project meeting 1 March 2012 in Vienna
The minutes from the meeting are annexed in Annex I, deliverable D6.4C.
- 6th project meeting 31 May 2012 in Lisbon
The minutes from the meeting are annexed in Annex I, deliverable D6.5C.
- Final workshop 27 September 2012 in Malta
The minutes from the workshop are annexed in Annex I, deliverable D6.6C.

Selection of Laboratories

As preparation for the set-up of a call for tender and the forthcoming assessment and equipment of test laboratories, the coordinator has visited the British Health Protection Agency in Didcot (UK). Head of Laboratory is the convenor of TC 76, the workgroup who elaborated the Standard EN 60825-1.

The selection of a test laboratory started with a draft-call for tender, discussed in the third and fourth meeting. A letter to eight laboratories in Europe was sent out requesting them to make a quotation (Annex I deliverable 9.2C); eight relevant selection criteria were mentioned in the letter. One laboratory asked for further explanations necessary for considering a response. The coordinator could provide that information. Finally seven responses were received. An overview of the responses to the call for tender was set up (Annex I deliverable D9.3C) to facilitate participants choice. By giving the selection criteria priority values a relative total score to the laboratories was generated. Highest priority has been given to the criteria 'valid accreditation of the laboratory in the specific field of laser light'. Outcome of the selection process has been: 'Seibersdorf Labor GmbH', Seibersdorf, Austria.

After the selection of the laboratory the coordinator visited the laboratory to discuss important items regarding the set-up of a contract. The laboratory, the laser pointer measurement equipment and knowledge level of the operating employees was assessed.

Negotiations took place on price per tested sample with report-certificate and a strongly reduced price for eventual 'more samples of the same kind' submitted in a parcel or box. More of the same kind samples could give an impression upon the variability in performance of beam power levels under a uniform labelling and was needed also to make a worst case choice out of them for the extended test. The contract included an explanatory presentation during a meeting planned in Vienna by dr.K. Schulmeister, head of the test laboratory. Due to the short distance between Seibersdorf and Vienna also sample testing could be demonstrated at the meeting by transporting carefully some measurement equipment taken from the laboratory nearby.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the list of test criteria D9.1A, the letter to laboratories requesting them to make a quotation D9.2A, the overview of responses to call for tender D9.3A and the contract with laboratory D9.4A.

Outreach and Communications Activities

At the kick-off stage Orgalime and ANEC were informed upon the activity work. At certain moments contacts with ANEC (IT, GR) have been established. Representatives of DG SANCO of the European Commission, the most important stakeholder for the Joint Action, were invited to participate in all activity meetings and attended the Kick-off meeting. The Standardiser's spokesman (member of IEC EN 60825/TC 76WG8) informed regarding test results from the Health Protection Agency (HPA) in the UK and the fruitful collaboration with customs through laboratory tests on consignments laser pointers with EU destination.

On request of National Authorities the non-participating countries Sweden, Swiss, Cyprus are informed continuously. A representative of the Swedish Radiation Safety Authority even attended all meetings.

The laser pointers market surveillance activity was mentioned in Commission's (DG Sanco) presentation 'Laser pointers intended for consumers' on the two days Seminar 'Laser interference in aviation' organised by Euro-control , Oct 2011 in Brussels. Very effective has been the fact that the head of laboratory responsible for reporting and personal involved in carrying out tests and assessments, is one of the writers of the relevant standard EN 60825 which soon comes into revision.

At the final workshop of the activity in Malta d.d. 27-09-2012, a delegation from Montenegro, visiting MCCA those days, received a short explanation regarding Prosafe and the current laser pointer activity. Finally, results of test and assessments have, conventionally, been presented at the Final Conference of the Joint Action.

Other Meetings Attended within the Framework of the Joint Action

Representatives of the activity attended the following meetings and events:

- Several meetings with GPSD Committee, where laser pointers for consumers have been on the agenda (draft versions Commission Decisions).
- Participation with a laser pointer case in a risk assessment expert meeting. This meeting took place on Oct 2011 in Tønsberg Norway.
- Participation with a laser pointer case in a risk assessment workshop. This seminar took place on Dec 2011 in Brussels.
- The task coordinator attended the two days seminar 'Laser interference in aviation' organised by Euro control in Brussels, Oct 2011.

3.3.3 Sampling

Establishing a market picture

Much information upon the laser pointers market has been established by earlier market surveillance projects in Denmark and Luxembourg.

The information has been distributed among participants. The Danish showed overviews of product pictures, test results and trading data produced in the year 1998 and repeated in 2008 . The Luxembourg participant distributed RAPEX cases including Risk Assessments, pictures and test reports from the past year 2010. Much relevant information has been delivered by the Swiss participant who distributed a METAS (Federal Office of Metrology) report analysing the market and test results of an internet purchase financed by the METAS laboratory itself.

The activity coordinator has found on internet a laser pointers market survey by the Japanese Government also through purchasing the products. This happened after an accident had taken place with a schoolboy (pointing pen). Further information can be found in the minutes of the Kick-off meeting.

Selecting and obtaining samples for testing

The market surveillance authorities have been actively sampling laser pointers in the market, mainly at retailers. All Member States sampled between 7 and 13 *first* samples. The 10 participating Member States together sampled 88 different LP's for testing and assessment by an accredited lab in Austria.

In addition, 8 Member States submitted from 29 of the 88 different LP's, 139 *more of the same kind* samples. These more-of-a-kind samples were obtained by taking additional samples from the same box confiscating two, three or a box of twelve laser pointers or key-ring laser-gadgets. 139 more of the same kind samples from 29 originals out of the 88 originals were collected to be prepared for testing on varying properties in the box of the same (equal labelled) products. Relevant information regarding product identification (including a picture) and economic operators was registered on a sample list provided with information for use of the list. Each sample received a specific sample code to facilitate communication and exchange of information.

No specific selection in sampling products in the consumer market has been made due to the large variety of possibilities to incorporate laser pointers into consumer products and the variety of brands and fantasy names given to the products whether or not equally looking.

Defining the product seemed to be sufficient and sounds as follows: Laser pointers are battery operated handhold consumer products, which as single- or as 'build in' product can produce an outside pointing or targeting laser beam.

Examples of such laser pointers are: laser pointers as such, laser-gadgets, hobby laser-levelling devices, laser-key rings, key rings with LED's and laser, laser-air guns, torches with laser, etc.

The Joint Action planned not to sample toys with laser; this laser product is regulated under the Toy directive and restricted as class 1.

Further information can be obtained from the appropriate deliverable annex I. These are *the* guideline to Member States on how to exchange information (D7C) and the Memo to Member States on which products to sample (D8C).

3.3.4 Testing

The safety of laser pointers has been on the EU agenda during this Joint Action period. Several Commission decision drafts have been discussed in the GPSD Committee with the aim to come to a workable document to protect (vulnerable) consumers. Much of the laser pointer gadgets have 'child appeal' properties. The existing standard EN IEC 60825-1 (2007) 'Safety of laser products, Part 1: Equipment classification and requirements', gives useful information concerning classification, warning - and explanatory labels, users instruction, specifications upon engineering requirements for the higher powered (industrial) laser products with an impressive couple of annexes and tables with physical data and bio medical investigations.

The standard gives no restrictions on class for whatever specific laser-product. The current standard doesn't define specific safety thresholds for consumer laser-products. Never the less the laser-samples taken must comply with the general classification rules and the general requirements from the standard as set out above which is echoing in the primary objective of the activity.

The test programme included testing and assessment of all the relevant clauses in the standard. The programme was characterized by a continuous testing and assessment period just after the gathering and sent off to the laboratory of all samples. All exchange of information with the laboratory has been exclusive guided by the activity coordinator. Support forms were developed to streamline the transport process from sample to test report.

At the 5th meeting in Vienna, head of laboratory has given a demonstration to participants of testing and assessing some samples.

Laser classification

One of the most important test items has been the beam power measurement through an integrating-sphere measure device which means that power amounts from all emitted wavelengths are integrated to one output value. Laser classification in EN IEC 60825-1 (2007) distinguish classes by defined ranges in Accessible (beam) Emission (AE) with their Accessible Emission Limits (AEL 's) as follows:

Laser classes:	EN IEC 60825-1 (2007)
Classes 1 and 1M	$AE < 0,39mW$ (AEL class1)
Classes 2 and 2M	$AE < 1mW$ (AEL class2)
Class 3R	$1 < AE < 5mW$ (AEL class 3R)
Class 3B	$5 < AE < 500mW$ (AEL class 3B)
Class 4	$> 500mW$ (professional use)

Only class 1 and 2 lasers (as had to appear from tests) are acceptable for consumers.

Further information can be obtained from the appropriate deliverables in the Annex. These are the memo test criteria (D9.1C) and the contract with laboratory (D9.4C) where the formal test programme is written down.

3.3.5 Risk assessment

As a result of the failure of the standards to specify safety thresholds for consumers market surveillance authorities in member states use nowadays their power to take measures under the provisions of national law transposing the GPSD. On average one can state, and participants agreed this point of view in the Joint Action, that laser pointers exceeding class 2 are considered as harmful for consumers. Enforcement activities (including RAPEX notifications) have to be supported by test reports and Risk Assessments of laser products to justify their presence on the consumer market as a safe product.

When assessing the risk for a specific laser pointer, the risk assessor has to make a number of decisions on the appropriate scenario, the steps in the scenario and the probabilities. All of this involves a certain amount of estimation, which will inevitably give rise to uncertainties in the final assessment. This may cause differences if two people carry out a risk assessment for the same product.

To cope with this, firstly the revised risk assessment chapters from the EMARS II Best Practice (version 13 December 2011), based on the RAPEX Guidelines, provided system support and secondly, participants from several member states gathered laser pointer risk assessment cases which have been discussed at the meetings. One of the participants took the lead to discuss these gathered cases also with the EMARS II Task C group Risk Assessment experts during an expert meeting in Tønsberg, Norway in October 2011 and during the Risk Assessment Workshop in Brussels in December 2011. These occasions provided the Joint Action finally with an approved model scenario risk assessment laser pointers in an applicable 'worst case' scenario for children (vulnerable consumers). See table 1 below. There is a remarkable similarity noticed between the model risk scenario's and the reality cases of some hospitalised children, victim to described scenario's or look like's.

Product:	Class 3R or 3B Laser (laser products with child appeal)					
Assessor:	Participants laser pointers (advised by EMARS II TASK C group)					
Scenario						
Hazard Group	<i>Radiation</i>					
Hazard	<i>Laser</i>					
Typical injury	<i>Eye injury</i>					
Injury scenario	<i>Two children play with the laser. They point directly to the eyes several times. It is the purpose to hit the eyes. One of the children is hit directly into one of the pupils for more than 1 second and gets temporary eye damage</i>					
Severity of injury						
Injury:	<i>Temporary loss of sight (class 3R) Damage to sight, burn of cornea (class 3B)</i>					
Severity of injury:	2 (class 3R)		3 (class 3B)			
Probability of injury					Sub-probability	
Step in scenario:	1. Two children play with the laser				1,000000	
	2. They sign directly to the eyes several times. It is the purpose to hit the eyes				1,000000	
	3. One child is hit directly into one of the pupils				0,125000	
	4. The exposure time is more than 1 second and the child gets temporary eye damage				0,100000	
Overall probability (product of sub-probabilities)	0,0125				(1/80)	
Risk Level (combination of the severity of injury and probability)					Serious risk	
					High risk	
					Medium risk	
					Low risk	
Combination of severity and probability to risk level						
Probability of damage during the foreseeable lifetime of the product		Severity of injury				
		1	2	3	4	
High ▼	> 50 %	High risk	Serious risk	Serious risk	Serious risk	###
	> 1/10	Medium risk	Serious risk	Serious risk	Serious risk	###
	> 1/100	Medium risk	Serious risk	Serious risk	Serious risk	###
	> 1/1.000	Low risk	High risk	Serious risk	Serious risk	###
	> 1/10.000	Low risk	Medium risk	High risk	Serious risk	###
	> 1/100.000	Low risk	Low risk	Medium risk	High risk	###
	> 1/1.000.000	Low risk	Low risk	Low risk	Medium risk	###
Low	< 1/1.000.000	Low risk	Low risk	Low risk	Low risk	###

Risk assessment form - injury scenario analysis

As said, the scenario contained in the table above is to be seen as worst case because it regards children playing with powerful laser products that are to be considered as child appealing (caused by the presence of a laser), easily can come into the hands of children while the children's play also come within the reach of the beam (within the so called Nominal Ocular Hazard Distance). Some of the laser product varieties with child appeal found on the consumer market are: (ball) pen like laser pointers, laser key-ring gadgets, laser guns, laser pistols, bow and arrow with laser sight, LED with laser, Laser surrounded by a couple of LED's in a torch, cat toy with laser etc. All these products are light in weight 'handy hand hold' and battery supplied (cell or penlight).

The worst-case scenario above is derived from a couple of scenarios as shown in the table below. Scenarios relating to adults will show lower risks like medium and even low, the same for scenarios with class 2 lasers. Class 1 is considered to be safe even for longer exposure duration (staring into the beam).

Scenario	Calculated Probability	Injury	Severity of injury	Risk
1. Two children play with the laser. 2. They point directly to the eyes several times. It is the purpose to hit the eyes 3. One child is hit directly into one of the pupils 4. The exposure time is more than one second and the child gets temporary eye damage	$1/8 = 0,125$	eye injury	2	serious risk
1. Two children play with the laser. 2. They point directly to the face several times to simulate a head shot. It is not the purpose to hit the eyes 3. One child is hit directly into one of the pupils 4. The exposure time is more than one second and the child gets temporary eye damage	$1/340 = 0.0003$	eye injury	2	medium risk
1. Two children play with the laser. 2. They point at the upper part of the body to simulate a heart shot. It is not the purpose to hit the eyes 3. One child is hit directly into one of the pupils 4. The exposure time is more than one second and the child gets temporary eye damage	$1/(680+340) = 0,0001$	eye injury	2	low risk
1. A child has just got a laser. 2. The child is curious and looks directly into the beam to study it. 3. The child hits the pupil directly. 4. The exposure time is more than one second and the child gets temporary eye damage	$1/10 = 0,1$	eye injury	2	serious risk

Risk assessments for 4 realistic 'child' scenarios.

Based on an HPA advice a practical split up in classification will be introduced here, of 'safe classes' for consumers (class 1 and 2) and 'hazardous classes' (class 3R, 3B and 4) laser products, to facilitate market surveillance officers during their interventions. From the Risk Assessment table 3 both the class 3R and class 3B classified laser products can be seen as 'dangerous class' laser products because they have led, along the same scenario, to a serious risk.

Intervention scheme and Accessible Emission Limit values

With the knowledge of the sample test results it has been decided in the 5th meeting by the participants to set up a common intervention scheme to facilitate officers in the market surveillance intervention activities. Due to the huge share of 'hazardous classes' laser products combined with the expected low grade of reliability of label information or even missing labelling, dominance is given to the frequent application of the formal 'art12 GPSD RAPEX notification' or the informal 'RAPEX notification for information' in case of poor product identification data. This means a frequent application of the developed model Risk Assessment. Table 5 shows the by participants agreed proposal.

(1)	Proposed intervention	(4) Safe classes		(5) Hazardous classes	
(2)		(6) Class 1	(7) Class 2	(8) Class 3R	(9) Class 3B (+ Class 4)
(10)	RAPEX for information	(11) --	(12) --	(13) (optional for other)	(14) --
(15)	RAPEX notification	(16) --	(17) toys (18)	(19) toys and gadgets (20) (optional for other)	(21) all laser products
(22)	Recall from shops	(23) --	(24) toys (25)	(26) toys and gadgets (27) (optional for other)	(28) all laser products
(29)	Recall from consumers	(31) --	(32) toys (33)	(34) toys and gadgets (35)	(36) all laser products (37) (optional for other if (38) > 10mW)
(39)	Table note: 1) 'gadgets' is used to denote 'child appealing products'				
(40)	2) 'for other' means: for other laser products than toys and gadgets				
(41)					

Intervention scheme proposed by participants

Some remarks to the intervention scheme must be made.

- Toys are regulated by the Toys directive and for that reason outside the scope of the GPSD and this Joint Action. Nevertheless an intervention would be considered whether a toy is found on the consumer market exceeding class 1. This has happened for one toy (sample (1MT)).
- A recall from consumers is considered to be a too severe intervention for some laser hobby tools (e.g. laser leveller, laser length measure device) that often were measured in the lower end of the class 3B power range.

3.3.6 Results of the lab tests and risk assessment

Out of the 92 samples the laboratory received, 10 samples did not operate. In 6 cases the sample could be replaced by a 'same kind one' out of a multi package. Remaining 88 operating samples appeared appropriate for full testing and assessment. The related Member State Authority received for each tested sample a certified report based on EN IEC 60825-1(2007) compliance investigation (contract price €275).

Moreover, for 29 different product types out of the 88 operating samples 139 more of 'the same kind' have been tested on beam power only, to get an impression concerning variabilities in beam power. A sole overview of beam outputs and beam ratio's to the highest powered one among the 'same kind's' has been submitted to all participants (contract price €12).

Also submitted to all participating Member has been a 'one page' overview of all tested samples with short summary.

Only class 1 and 2 lasers (as had to appear from tests) are acceptable for consumers. 15 % of the lasers tested were violet or green lasers class 3B. 59 % were red lasers in the classes 3B and 3R and 26 % were red lasers in the classes 1 and 2. These Class 1 and 2 red lasers were the only ones that should have been on the consumer market.

Furthermore most of the laser products (95%) from both the classes (3R, 3B) together, appeared not or not correct classified (*and not or not correct labelled*). However, most of the laser products (92%) from the two classes (1, 2) together, were correct classified.

With respect to the *most common* red lasers, 70 % out of them should not be placed on the market for consumers (class 3R, 3B identified). None of the *rather rare* violet and green lasers should be placed on the market for consumers (class 3R, 3B identified).

There was a huge variability in measured laser power output within the same box demonstrated by the “more of the same kind” samples. Therefore ‘per box’ uniform maximum power labelling was problematic and ‘per box’ uniform class labelling was not always correct. IEC EN 60825 lays down a variety of requirements for labelling of radiation output data, classification, warning and explanatory labelling or wording as appropriate.

Radiation output data was missing altogether from 35% of the 37 class 3B samples that required such labelling. All of the products that were labelled were in fact incorrectly labelled. With respect to the remaining samples the values were neither correct, nor precise enough (not the max. accessible emission to use in determining the class). Further, often wavelength values were missing. In fact, none of the products met this requirement.

The 37 class 3B samples should also have had the EN class indicated but in fact none of them did so. 32% had no class mentioned at all and 65% bore a class according to the US Code of Federal Regulations. With respect to the 27 class 3R lasers 48% had no class indicated on the labelling, 11% were incorrectly labelled and 41% bore the US class. So again no sample was correctly labelled. 92% of the Class 1 and 2 lasers were however correctly labelled.

Explanatory wording required for Class 3B lasers was missing in 32% of the samples. 3% were bore the wrong labelling as the remainder bore the labelling mandated in the US but also considered to comply with European requirements.

Explanatory wording is also required on class 3R lasers but was absent from 52% of the samples. 19% bore the wrong wording. The remainder were correctly marked.

All laser products (except class 1) are required to have affixed on to them the yellow-black warning label. Again these were missing from a number of products.

EN IEC 60825 also requires information for use. However, for most samples it was omitted and if present it duplicated the meaning of the explanatory wording, or was supposed to act as a substitute for it, so there was no added value in its inclusion.

Lastly engineering features are required for class 3B. Only found in one class 3B sample out of the 37 had the required feature.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the Statistics on Activities D10C and the Memo with description of follow-up activities D11C.

3.3.7 Follow-up

Results from Member States market surveillance activities

The results from the development of an harmonised laser pointer-specific tool for Risk Assessment prompted in a substantial amount of enforcement action. There were in total 29 formal RAPEX notifications, 13 RAPEX notifications for information, 5 blocked at customs, 3 sales bans and withdrawal and ICSMS notification, 16 warnings/fines with withdrawal from market and 24 reporting test result and eventual small non-compliances. The impact the activity had can be seen in the fact that 80% of the RAPEX notifications of laser pointers made during 2012 were as a result of the testing carried out by the Joint Action combined with the application of the Risk Assessment tool on test- identified samples.

Further information can be obtained from the appropriate deliverable in the Annex I. This is the Memo with description of follow-up activities D11C.

Cooperation with Customs

In two project meetings, Lisbon (31 May 2012) and Malta (27 September 2012), customs officials were invited. In both occasions presentations of the officials illustrated their collaboration with the National Market Surveillance Authority. The Portuguese official could, as a member of the DG TAXUD working group on product safety, also inform participants concerning the ongoing work by this group. Several Participants reported that

during the Joint Action market surveillance expertise was called in by customs to judge the hazards of laser pointer consignments imported from outside the EU.

The Dutch nVWA import control group carried out in 2012 a broad national project on product safety in collaboration with customs at the central clerical address of the courier services in the Netherlands, where internet ordered products enter the Netherlands. On request of our Dutch nVWA participant in the Joint Action, Laser pointers were comprised in the two 2012 action weeks (week 25 and 46). The interesting results (32 consignments with in total 1265 hazardous class 3 laser pointers found, blocked and destroyed) have been reported the Final workshop.

Outreach to Standards Development Bodies

Head of Seibersdorf laboratory who was personally involved in the whole Laser pointer test and assessment program of the Joint Action laser pointers, has given an expert presentation and demonstration of the results at the Vienna meeting. He is one of the writers of EN IEC standard 60825-1 (2007) and will without doubts apply his experience from the Joint Action in the on-going revision of the standard. A new mandate to CEN related to consumer safety could be a useful next follow-up.

In the 2nd meeting the convenor of TC 76 the workgroup working on the standard revision has given a presentation as introduction on theory and test practices. The convener is Head of the Laser Laboratory of Health Protection Agency (HPA) in UK, a governmental organization. His point of view of laser pointers for the consumer market has been shared by participants (and laid down in a distributed readable summary. HPA is responsible for providing advice and is carrying out laboratory measurements on laser products for Governmental and local Authorities e.g. customs.

3.3.8 Achievement of objectives and lessons learnt

Impressions of the European Laser pointer Market in General

The impact the activity had can be seen in the fact that 71% of the RAPEX notifications of laser pointers made during 2012 were as a result of the testing carried out by the Joint Action.

The dominant phenomena in the market is the large number of retailers (or even private individuals), spread over the Member States, purchasing more or less frequently small numbers from the Internet. This is the same experience that the Dutch nVWA import team had in collaboration with customs had during a broad national project on product safety at the central clerical address of the courier services, where internet ordered products enter the Netherlands. Within two spread action weeks (week 25 and 46 in 2012) 32 consignments with in total 1265 hazardous class 3 laser pointers were found, blocked and destroyed. The low price (5-10 euro) of laser pointers and laser pointing gadgets combined with small postal measurements and weights facilitate these developments on the consumer market. The Swiss Federal Office of Metrology (METAS) reported in June 2011 that the high power laser pointers confiscated by the Swiss Federal Customs Administration were most probably bought directly through the Internet from sellers outside Europe. And finally, the impression arises that the low quality part of laser products in the lower end of the market, with appointed beam power variability, are put on the market by manufactures and too easily are accepted by importers and consumers.

Lessons learned

With respect to the standards there are problematic differences between CFR and IEC regulation illustrated to IEC standardisers. There is also more awareness now that the present harmonized standard is missing a specific focus on consumers.

In respect of laser pointers it was noted that high quality enforcement starts with careful information gathering from the early sampling stage. Seeking for more cross-border contacts in the enforcement process must be encouraged.

3.4 Children's Fancy Dress

3.4.1 Background information

Objective

The primary objective of the activity was to conduct a market surveillance exercise relating to the Children's Fancy Dress (toy disguise costumes for children) that are currently on the market in the participating member states with a view to assessing the extent to which these products conform to the various flammability and chemical safety requirements prescribed by the EU and CEN.

Risks presented by Children's Fancy Dresses

Two main risks for children's fancy dresses were addressed in this part of the Joint Action, flammability and chemical risk.

Toy disguise costumes often don't meet the flammability requirements because the fabrics are thin and decorations are attached to the clothes. Furthermore, the probability that such costumes accidentally get in contact with flames is significantly higher than for ordinary children's clothes as they are likely to be used under circumstances where flames (from candles) are present. Children often wear these products in the presence of a naked flame, e.g. when playing near a barbecue, a bonfire, at a Halloween party, or near an open fire in their home. A spark from any of these sources is likely to fall on a children's fancy dress and to cause the material to ignite and so burn the child. Although the risk of this happening is probably quite low, the severity of the injury, when it occurs, can be very high.

The risks presented by chemical hazards in children's fancy dress are more insidious. The child or their carer is likely to be unaware that their costume contains a hazardous substance which may, inter alia, be carcinogenic, toxic or dangerous to reproduction. Children often wear these products next to their skin for a prolonged period of time, particularly during the hot weather in the summer holidays.

The chemical risks include those associated with azo-colorants, formaldehyde and phthalates. Azo-colorants may form aromatic amines that are known to be carcinogens and can be absorbed through the skin. Formaldehyde may cause irritation (watery eyes, irritation in nose, and throat, coughing and skin irritation among others) and is classified as a carcinogen. Phthalates are suspected to have adverse effects on the health of children. When these substances are present in clothes that are in direct contact with the skin of the user, the exposure and the probability for experiencing the adverse effects increase. This is particularly worrying in the case of children's clothes as children are in general supposed to be more sensitive to exposure from these chemicals.

No statistics were available concerning the number accidents in the EU to children whilst wearing fancy dress. RAPEX notifications relating to chemical and flammability hazards in children's fancy dress are comparatively rare. The total number of RAPEX notifications relating to such products during the period 1 January 2005 - 31 December 2012 were 60.

3.4.2 Project management activities

Project Meetings

Six project meetings have been organised by the activity as foreseen in the original project plan:

- Kick-off Meeting: 28 September 2011 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D5.2D.
- Meeting 2: 8/9 November 2011 in Groningen
The minutes from the meeting are annexed in Annex I, deliverable D6.1D.
- Meeting 3: 19 April 2012 in Lisbon
The minutes from the meeting are annexed in Annex I, deliverable D6.2D.
- Meeting 4: 3 July 2012 in Cabiato in Italy
The minutes from the meeting are annexed in Annex I, deliverable D6.3D.
- Meeting 5: 4 December 2012 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D6.4D.
- Meeting 6: 5 February 2013 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D6.5D.

Selection of Laboratories

Thirteen test laboratories were invited to tender, eleven submitted a tender. Four laboratories were included on the final 'short list' for more detailed examination.

After a careful review of the submissions, the Istituto Italiano Sicurezza dei Giocattoli SRL (IISG), Cabiato (CO), Italy was appointed to undertake the testing of the samples collected during the market surveillance exercise.

By inviting a large number of test laboratories to quote for this work and by structuring the tender so that the unit cost of testing for each particular hazard decreased as the number of tests for that hazard increased, some very competitive quotes were received. This approach enabled a much larger number of tests to be conducted on each product than is envisaged in the Grant Agreement.

Prior to testing each sample was inspected very carefully by the member of the Project Group in the relevant Member State to determine which chemical tests should be conducted on each sample. This avoided money being spent on testing for chemicals that were unlikely to be present in the garment concerned.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the list of test criteria D9.1D, the letter to laboratories requesting them to make a quotation D9.2D, the overview of responses to call for tender D9.3D and the contract with laboratory D9.4D.

Outreach and communications Activities

During the course of the Joint Action the principal means of raising awareness of the project and its work was through contact with the stakeholders.

Towards the close of the Joint Action the Project Coordinator will be contacting the following stakeholders: DG Enterprise & Industry - the Project Group has concerns relating to the text of Guidance Document No 17 - On the application of the Directive on the safety of toys - Carnival Costumes (Disguise Costumes, Fancy Dress) - Minute 10.1 of the 6th Project Meeting relates to this issue.

The trade association - Toy Industries of Europe are being asked if they would kindly disseminate the Project Group's 'Guidelines for economic operators on the safety requirements relating to children's fancy dress to their member organisations - Minute 8 of the 6th Project Meeting refers. This document is also being published on the PROSAFE website.

CEN - The Project Coordinator will be raising concerns regarding the current wording of EN 71-2 - clause 4.3 with CEN TC 52 - Safety of toys. The Project Group consider that a rate of burning of the flammable material in Children's Fancy Dresses in excess of 30mm/s presents a serious hazard to children and that EN 71-2 should reflect this.

The Project Coordinator has also been asked to contact the Project Leader for the PROSAFE EMARS project concerning issues relating to best practice that have been identified during the course of the project - Minute 10.2 of the 6th Project Meeting refers to this issue.

The Kick Off meeting served to inform a wide range of stakeholders about the aims, scope and objectives of the children's fancy dress activity. Stakeholders were provided with an update on the progress of the project during the autumn 2012. It was intended to provide stakeholders with a further update on the project's progress in the spring 2013.

Other Meetings Attended within the Framework of the Joint Action

The following meetings and events were attended by representatives from the Joint Action:

- 6 September 2011 - The Project Coordinator met with Oeko-Tex, Shirley Technologies Ltd, Trafford Park, Manchester, UK to gain an understanding of the standard Oeko-tex 100 and to discuss whether the fabrics in the CFDs collected during the market surveillance exercise should be tested to Oeko-Tex 100.
- 25 January 2012 - The Project Coordinator visited the Toy Fair, Olympia, London, UK - to meet with exhibitors supplying children's fancy dress into the domestic and EU markets.
- 7 February 2012 - The Project Coordinator visited the 'Spring Fair', National Exhibition Centre, Birmingham, UK - to meet with exhibitors supplying children's fancy dress into the domestic and EU markets.

3.4.3 Sampling

Establishing a market picture

Children's Fancy Dresses are widely available on the European market. They come in a wide variety of styles and for the age range circa 6 months to 14 years. They are widely available and are sold in shops, some of which specialise in the sale of costumes for sale or hire, by mail order and, increasingly, on the Internet. As they are relatively light they can easily be posted to the consumer. As a consequence, the sale of these products from economic operators in one Member State to consumers in another Member State has grown recently and is likely to continue to grow in the foreseeable future.

For the most part the same types of product are widely available across the EU marketplace e.g. themed or character costumes enabling children to dress up as: fairies; wizards; book, TV and film characters; animals; etc. More specialist costumes are also available for Halloween and Xmas and for occupations, such as - firemen, police, nurses etc.

An examination of the websites of a number of retailers of children's fancy dresses revealed that there is no easy way to classify these products. The market surveillance staff were, therefore, given a free hand to select products from the market in each of the participating Member States. A total of 100 differently themed children's fancy dress were collected during the course of the Joint Action.

Closer examination of the products on the market reveals that many costumes contain as many as seven different fabrics, each of which could present different flammability characteristics and chemical hazards. In some cases the quantity of some of these fabrics used in the outfit is very small, for example, when used for decorative purposes, or for a belt or a shoe. In other cases, such as in fairy costumes, garments usually contain quite a large amount of 4 or 5 different materials. This meant that, in some cases, as many as five flammability tests and a similar number of tests for potentially hazardous substances were conducted on the same article. Over 90% of the samples were made from 100% polyester. The remaining samples were made from: cotton; cotton/acrylic; polyamide/nylon; polyester/nylon; $\geq 90\%$ polyester and $\leq 10\%$ other fibres.

Market surveillance staff were asked to collect samples of the largest size available in the store or warehouse they visited as this maximised the amount of fabric available to test the product for hazardous chemicals and/or for its flammability.

Selecting and obtaining samples for testing

A total of 237 products were collected during the market surveillances exercise, 179 of these were collected during the spring 2012. The remaining 58 were collected during the autumn 2012. The products collected during the spring 2012 included a wide variety of fancy dress 'characters' for use by boys, for use by girls as well as products that could be worn by either sex. Those collected during the autumn 2012 included a number of Halloween outfits and some Xmas fancy dress.

Spring is the period when the greatest quantity of children's fancy dress are placed on the market in EU Member States as 'carnivals' take place during this season in many countries, Market surveillance staff were asked when collecting products from the market during the spring 2012 to sample products containing dark fabrics as these products were more likely to contain fabrics that included azo dyes. In the event, a wide range of samples were collected, some containing dark fabrics, others that included a number of different types of tulle or net.

In the majority of cases only one samples of each product could be collected at the premises of the economic operator.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the guideline to Member States on how to exchange information D7D and the Memo to Member States on which products to sample D8D.

3.4.4 Testing

Testing was undertaken in accordance with a range of legislative requirements and safety standards. The most important pieces of legislation were Directive 93/11/EC - concerning the release of N-nitrosamines & N-nitrosatable substances; Regulation (EC) 1907/2006 - REACH - Annex XVII and Directive 2009/48/EC - on the safety of toys. Reference was also had to the ECHA Candidate List of Substances of Very High Concern. The substances that were included in the 'short list' of hazardous substances likely to be found in children's fancy dress are listed in the contract with the test laboratory.

Children's fancy dress for the age range 1-14 come within the scope of the Toy Directive (2009/48/EC) in that they are: 'products designed or intended, whether or not exclusively, for use in play by children under 14 years of age (hereinafter referred to as toys)' (Article 2.1).

The 'new' toy Directive 2009/48/EC was published on 18 June 2009 and came into force the following month. EU Member States were given until 20 January 2011 to bring into force the laws, regulations and administrative procedures to comply with the Directive. The new Directive became effective from 20 July 2011, except for the provisions relating to those properties listed at Part III of Annex II, i.e. the 'chemical properties' of toys. For these properties the 'old' toy Directive - 88/378/EEC applies until 20 July 2013.

Part III of Annex II - Particular Safety Requirements - Chemical properties - details more onerous requirements for a range of chemicals than were prescribed in Directive 88/378/EEC. These include allergenic fragrances and a range of elements. The more exacting requirements relating to the extensive range of elements detailed at Annex II, Part III, Clause 13 are important as far as this project is concerned as they will apply to products placed on the market shortly after this Joint Action has come to a close.

It is important, therefore, to draw attention to the fact that the requirements that applied to the 'chemical properties' of children's fancy dress both before and during the Joint Action will be varied very shortly after the Joint Action comes to a close.

The threshold limits for some of the hazardous substances likely to be found in children's fancy dress are not included in the toy directive, but are to be found in other legislation and safety standards, some of which are not easily accessible by economic operators.

Further information can be obtained from the appropriate deliverable in the Annex I. This is the list of test criteria D9.1D and the contract with laboratory D9.4D.

3.4.5 Risk assessment

At the final project meeting examples of three different risk assessments concerning a particular risk scenario relating to children's fancy dress were presented for review. All three assessments related to the flammability of such a product using the method outlined at Table 4 of the Risk Assessment Guidelines detailed in Decision 2010/15/EU.

The assessments envisaged the scenario where a child is invited to a party. He/she is wearing a fancy dress which makes contact with a lighted candle on a cake, or similar object. In this scenario the child is burned. When reviewing these risk assessments the Project Group agreed that the severity of the burn depends on a range of factors such as:

- a) The textile(s) that made up the product and the rate of spread of flame in each of the textiles that make up the product;
- b) The nature of the garment - i.e. whether it consisted of just 1 layer of fabric, or whether it consists of a number of layers of fabric, as in the case of the skirt on a fairy outfit, which could have 4 or 5 layers of material. An increase in the number of layers could afford greater protection for the child as the outermost layers, should they catch fire, could be some distance from the child's skin;
- c) The length of time that the clothing is in contact with the flame;
- d) The length of time that elapses between the child, or its carers, becoming aware that the clothing is on fire - a child is more likely to notice if the flame is in contact with its arm or legs, than if it burns a hat, mask or wig;
- e) The speed with which the flame is extinguished;
- f) The age of the child - children in the age range 0-5 are likely to be less aware that their clothing is alight than an older child.

Members were concerned about the variations in the number of steps involved in each of these risk assessments and the variations in the probability ascribed at each step. It was apparent from the methodology, that in some cases, increasing the number of 'steps' in the risk scenario will lower the probability that an injury will occur. It seemed, therefore, that when evaluating the risks associated with this type of accident they could, all too easily, vary significantly from one evaluator to another.

It was agreed that, as the risks to the child in the scenario discussed above varied considerably from one situation to another, the probabilities assigned in the risk assessment could, quite legitimately, be very different depending on the circumstances of the scenario.

It was concluded that, in the first instance, a children's fancy dress would need to be assessed for the presence of a potentially hazardous chemical and its mechanical and physical hazards. Following these assessments, which will use the relevant legislation, the product can be declared 'compliant' or 'non-compliant'. A 'risk assessment' is needed to conclude the type of intervention that is required. The methodology outlined in the RAPEX Guideline can be interpreted differently. As a consequence this can lead to differences in intervention policies between Member States. Further guidance is necessary in order to achieve harmonization of approach on this issue.

3.4.6 Results of the lab tests and risk assessment

Capturing Results from the Member States

The results were distributed to the participating Member States by copying each report from IISG to the representative of the country concerned, the Project Leader and the Project Coordinator.

Each report consisted of an overview of the results relating to the product concerned and, where appropriate, separate reports on the flammability testing; the chemical testing and/or the fabric composition of the product.

The other members of the Project Group had the opportunity to receive the reports from products collected in the countries that participated in the project should they wish to do so.

Following the testing of the products collected during the spring 2012 and during the autumn 2012 for flammability and for hazardous substances a summary sheet outlining all the results of the products collected by each Member State, other than those relating to fibre content and fibre composition was prepared.

Results

68 out of the 237 products sampled were non-compliant (29%). Of these with to flammability minor - Surface flash was observed in 11 samples (Rate of flame spread 10-30 mm/s - 47). Major surface flash was observed in 16 samples (Rate of flame spread > 30mm/s). With respect to *Hazardous substances* nickel was found in 2 samples, Azo dyes in 2, Phthalates in 8 and there was Migration of elements in one sample. In total there were 87 non-conformities (Note: Some products had more than 1 non-compliance).

Flame retardants - A limited quantity of samples were investigated for the presence of the flame retardants:

Tris (2,3 dichloropropyl) phosphate;
HBCDD, and/or
Tris (2-chloroethyl) phosphate.

IISG were consulted as to which samples, from amongst those collected during the spring 2012, would be most appropriate to test for the presence of these substances. They included products containing tulle and those with other fabrics. Twelve samples were selected for testing, 3 from Greece, 3 from Latvia and 2 from each of the other participating EU Member States.

In previous tests all these samples were found to have rate of burning below 10mm/s. The test results showed that none of the samples had been treated with any of these three fire retardants. Although none of these three flame retardants mentioned was detected in the twelve samples, this does not prove that other flame retardants were not used in these samples as currently a large number of other flame retardants are on the market

Fibre composition - At the sixth Project Meeting it was agreed that a number of samples of tulle should be subjected to analysis to determine whether those with a high rate of flaming (>30 mm/s) are of a different fibre composition to those with a low rate of burning (<10 mm/s). Seventeen samples were selected for analysis, 10 with a high rate of spread of flame and 7 with a low rate of flame spread.

The results show that fibre composition does NOT seem to make any difference to the rate of burn of the fabric.

A total of 68 products were non-compliant products from the 237 products sampled, i.e. 29%.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the Statistics on Activities D10D and the Memo with description of follow-up activities D11D.

3.4.7 Follow-up

Results from Member States' Market Surveillance Activities

A number of RAPEX notifications were made concerning non-compliant products that were sampled during the course of the Joint Action. Major non-conformities resulted in the withdrawal of the product from the market. Minor non-conformities were generally taken up with the economic operator. Further information can be obtained from the appropriate deliverable in the Annex I. This is the Memo with description of follow-up activities D11D.

Outreach to Standards Development bodies

Subsequent to the discussion at the Final Workshop the Project Coordinator has been asked to contact with the Secretary to CEN TC 52 - Safety of Toys to raise the concerns about the requirements detailed at EN 71-2 - Safety of toys - Flammability - Clause 4.3.

Members were concerned about the requirement detailed at EN 71-2 - Safety of toys - Flammability clause 4.3 - Toy disguise costumes and toys intended to be worn by a child in play, paragraph 4. This relates to fabrics where the rate flaming is between 10 mm/s and 30 mm/s and requires that that the toy and its packaging should be labelled with the statement - "Warning - Keep away from fire".

Members were of the opinion that a rate of spread of flame between 10mm/s and 30 mm/s in children's fancy dress constitutes a serious hazard to children. The meeting has recommended that this issue should be reviewed by CEN TC 52 - Safety of Toys, with a view to making an amendment to the standard so as to indicate that this is a serious non-conformity and that products with this rate of spread of flame should be regarded as being non-compliant.

The Project Coordinator was also asked to review the flammability requirements relating to nightwear to ascertain the rate of spread of flame that is specified in these regulations. He was asked to consider if the rate of flame spread specified in the nightwear regulations is relevant to the rate to flaming for children's fancy dress. The Project Coordinator drew attention to the fact that the UK and The Netherlands are two of the few EU Member States with a safety requirement relating to the flammability of these articles.

The Project Coordinator has reviewed the UK's Nightwear (Safety) Regulations 1985 (as amended) (SI 1985 No 2043 and SI 1987 No 286) which call up BS 5722: 1984 - Flammability performance of fabrics and fabric assemblies used in sleepwear and dressing gowns.

This standard specifies at Clause 3.2 that 'none of the six specimens shall sever the 300 mm trip thread in less than 25 s' and that 'none of the six specimens shall sever the 600 mm trip thread in less than 50 s.', i.e. the standard provides for a maximum rate of burn for these garments of 12 mm/s.

A rate of spread of flame of circa 10-12 mm/s would, therefore, seem to be the upper limit that should be permitted for garments that are worn by children. Garments with a rate of spread of flame in excess of this rate should be regarded as being non-compliant as they are likely to present a serious hazard to children. Further information can be obtained from the appropriate deliverable in the Annex I. This is the Memo with description of follow-up activities D11D.

Cooperation with customs

No coordinated cooperation with customs was undertaken. This was because it was not possible to develop a checklist or other simple guidance tool that enabled the identification of non-compliant fancy dress no more than a visual inspection. The only way that non-compliant fancy dress can be identified is through laboratory testing.

3.4.8 Achievement of objectives and lessons learnt

Impression of the European Market in general

Bearing in mind that there are comparatively few RAPEX notifications concerning children's fancy dress, the participants had no preconceptions about the proportion of products that would be non-compliant. The fact that there were 74 flammability non-compliances was therefore not surprising bearing in mind that the 237 samples contained over 1,000 different fabrics.

The number of non-compliances with regard to chemical hazards was very low, particularly in relation to the use of azo dyes in these products. Those products that contained plasticised items often contained phthalates in excess of the legal requirements. This is a matter of concern as these requirements have been in force for a long period of time and the relevant legislation has been well publicised.

It is disappointing that, notwithstanding all the publicity following the Mattel scandal about lead in toys and the fact that about 10% of children become sensitised when nickel is present in toys etc that instances where this occurred were found.

The Joint Action has been a useful exercise in promoting a much better understanding amongst regulators of the safety requirements of children's fancy dress - a product that spans 2 major product sectors - textiles & toys.

Lessons learned

This project focused on 'dresses and costumes', i.e. complete dressing up outfits. Products worn only on the head, such as beards, wigs and hats were outside the scope of the Joint Action. These items are probably more dangerous as they are always worn in close contact with the most sensitive parts of the skin. Should they catch fire the user may not be aware that they are on fire. These products could therefore be included in future Joint Action - Children's Fancy Dress II.

One of the other conclusions of the Joint Action was that many economic operators could avoid their products presenting a minor non-compliance if they correctly labelled their products with - 'Warning - Keep away from fire'.

Methodology

The production of the 'long list' and the 'short list' of potentially hazardous substances that are likely to be found in children's fancy dress was a key aspect of the market surveillance exercise.

The availability of RAPEX notifications covering the 8 year period from 1 January 2005 until 31 December 2012 was very useful as it enabled the Project Coordinator to determine the hazardous substances that had been found in both textile items and toys during this period. This information was then screened to prepare a list of the hazardous substances that are likely to be found in children's fancy dress. During the course of this exercise some RAPEX notifications were neglected as the hazardous substances present in these products did not bear any similarity to those that are likely to be found in children's fancy dress. Examples of this are for textile items: DMF which is used as a desiccant for shoes, and for toys: acetophenone which is used to rubberise play mats and the specialist hazardous substances that are sometimes used in crayons and chemistry sets.

The Oeko-tex 100 standard is the 'gold standard' for textile items as it includes the wide range of hazardous chemicals that are likely to be found in these products. The standard is used by producers who are manufacturing the more expensive products and those where the specification does not vary over a period of time, e.g. underwear for young children. This contrasts with the children's fancy dress market where products are made to a short manufacturing runs with cheap fabrics and which can vary significantly from one season to another.

The production of the 'short list' that was used to specify the tender included a number of tests that, in the event were not required, e.g. measuring products for the presence of N-Nitosamines and N-Nitrosatable substances. The reason for this was that no products were collected that contained rubberised material. Similarly, no products were taken from the market that contained electrical apparatus that generated light and/or sound. As a consequence no tests were conducted to EN 62115 - Clause 9.

A number of areas of 'good practice' were recorded during the course of the Joint Exercise. This is the subject of a separate report to the Chairman of the EMARS Project Group. It is anticipated that some of these items will be incorporated into the next edition of the PROSAFE publication 'Best Practice Techniques in Market Surveillance'.

Recommendations for improvements to the RAPEX scheme

Following the review of the RAPEX notifications during the period 1 January 2005 to 31 December 2012 concerning children's fancy dresses, textile items and toys the Project Group would like to make the following recommendations to DG SANCO's RAPEX secretariat, viz:

1. Recommendation to DG SANCO that CAS No/EINECS Numbers be included for hazardous substances identified in RAPEX notifications

Some hazardous substances are known under a variety of different names. This is particularly true for aromatic amines. For example, the aromatic amine with the EC number 202-591-2 is known as o-aminoazotoluene, 4-amino-2',3-dimethylazobenzene and 4-o-tolylazo-o-toluidine. It is recommended that when a hazardous substance is referenced in a RAPEX notification that its CAS and/or EINECS number is included.

In some cases it seems the incorrect name of a chemical substance has been used in a RAPEX notification. An example is notification 698/11, which references 4-aminodiphenyl. This substance is not listed at REACH - Annex XVII - Appendix 8, but 4-aminobiphenyl is listed. As the names of chemical substances are complex and unfamiliar to many of those who use the RAPEX system, the inclusion of the CAS and/or EINECS number when referencing a hazardous substance in the RAPEX notifications would help minimise confusion when relatively minor mistakes are made in transposing the names of these substances.

2. Recommendation to DG SANCO that RAPEX notifications concerning chemical or flammability hazards in textile items include the type of fabric in the notification

It is recommended that when fabrics are referenced in a RAPEX notification that the name of the fabric used in the garment is included in the notification as per Regulation (EC) 1007/2011 on textile fabric names and related labelling and marking of the fibre composition of textile products and repealing Directive 73/44/EEC and Directives 96/73/EC and 2008/121/EC.

This is because (1) the same hazardous chemicals are likely to be used frequently used in a particular type of fabric and, (2) some fabrics are more flammable than others.

By including the name of the fabric that is used in the product in a RAPEX notification it should be possible, over time, to build up a picture as to which fabrics are more likely to contain a particular type of hazardous chemical, e.g. azocolourants, formaldehyde etc. and which fabrics are particularly flammable. This would be useful for the competent authorities when deciding which fabrics to sample during a Joint Action or during a market surveillance exercise that is organised locally by an individual country.

3.5 Visibility Clothing and Accessories

3.5.1 Background information

Objectives

The purpose and main objectives of the Joint Action was to ensure that Visibility Clothing and Accessories for non-professional use on the European Market comply with the requirements in the European Legislation.

Risks presented by Visibility Clothing

Visibility clothing and accessories (like visibility tabs) can be vital for the safety of consumers who walk or bicycle on dark roads. The products are seldom dangerous in themselves but using them makes the user change behaviour because he or she relies on the visibility of the clothes. If the clothes are less visible as they should be, then the users are put at risk when they walk or bicycle on a dark street.

Several Member States have carried out market surveillance actions on these products and come across equipment that provides the user with inadequate protection. Many such products come from countries outside the EU.

The use of such equipment is mandatory in some (northern) Member States during particular seasons of the year or circumstances. As an example, legislation requires a visibility vest be placed in all cars in several countries.

Furthermore the placing of products on the European Market which do not conform to Standards creates the risk of making obstacles to the open market economy across Europe.

3.5.2 Project management activities

Project meetings

Five project meetings have been organised by the activity. Six meetings were foreseen but there was no need to convene a sixth meeting.

- Kick-off Meeting: 29 September 2011 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D5.2E.
- Meeting 2: 20 January 2012 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D6.1E.
- Meeting 3: 4/5 June 2012 in Lisbon
The minutes from the meeting are annexed in Annex I, deliverable D6.2E.
- Meeting 4: 9 January 2013 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D6.3E.
- Meeting 5: 22 January 2012 in Brussels
The minutes from the meeting are annexed in Annex I, deliverable D6.4E.

Selection of Laboratories

The official call for tenders was issued and forwarded by e-mail to 48 Laboratories on the 3rd. April 2012 specifying a deadline date of the 23rd. April 2012.

Only three [3] laboratories submitted their tender within the deadline date and one other laboratory submitted the quotation after the closing date.

On consultation with the Participating Member States Representatives discussions started with the laboratory whose offer seemed the most advantageous, but this laboratory opted to withdraw its offer. This created a delay in the project since negotiations had to proceed with another test laboratory.

Option "B" was to start negotiations, which eventually led to the finalizing of the contract, with the other laboratory whose offer seemed to satisfy the requirements in the tender, namely SGS UK Ltd.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the list of test criteria D9.1E, the letter to laboratories requesting them to make a quotation D9.2E, the overview of responses to call for tender D9.3E and the contract with laboratory D9.4E.

Outreach and Communications Activities

The Joint action itself, by having six European Member States participating, is an awareness activity. During the market surveillance activities carried out by the Participants, direct awareness was created with economic operators selling visibility clothing and accessories.

During phase one of the project, about 31 manufacturers of PPE from Europe, USA, Hong Kong, India, and China were contacted aiming at making these manufacturers aware of the Joint Action and at the same time trying to obtain more information about their products and about the standards which are used in the manufacturing of their products.

Chambers of Commerce from Belgium, Hong Kong, UK, Maltese/Italian and from China were also contacted aiming to gather information about manufacturers of PPE in their countries.

Regret to say that responses from the manufacturers themselves and from the Chambers of Commerce was very minimal, but still, the communications with the above entities has been a means of making aware the purpose of this European Joint Action.

Constant perseverance in sending queries for information and eventual possibility for horizontal participation from stakeholders had the desired effect. Two organisations, one from Ireland and another from Holland made contact with the activity communicating their interest in Visibility clothing and Accessories. Correspondence also forwarded to the “European Safety Federation” and the “Federation of the European Sporting Goods” from whom, unfortunately, no feedback was received.

Attending the first project kick off meeting were Representatives of CEN, CEN TC 162, ANEC who also attended the second project meeting, DG SANCO and DG TAXUD.

Other meetings attended in the framework of the Joint Action

There were no external meetings attended within the framework of the Joint Action.

3.5.3 Sampling

Establishing a market picture

Visibility clothing and accessories products on the European market can be found for sale in various outlets such as outlets selling safety equipment, industrial supplies, sports goods, clothing, DIY stores, large department stores, print shops, petrol stations, automobiles spare parts, flea markets etc... These products can even be bought on line and from places where they are least expected to be found.

Normally visibility clothing and accessories for non-professional use are expected to be found at DIY stores, fashion shops, children’s clothing shops, sports shops, hobby shops and the like, but this is by no way the norm.

These clothing and accessories come in a wide variety of products such as jackets, trousers, raincoats, sleeveless vests, reflecting arm and leg bands, hanging reflectors, reflectors to be attached to clothing, bag covers, reflective belts, reflective bracelets backpacks etc...

Visibility clothing can be found on the market in various sizes suitable to be used also by school children.

One can also find on the European market visibility accessories which are used for the protection of animals such as leg bands for horses and back covers for dogs.

In some Northern European countries it is even compulsory to wear visibility clothing when walking in the streets during dark hours especially in winter time.

As has been stated elsewhere in this report, Visibility Clothing for non-professional use are not widely diffused on the European Market. Mainly visibility clothing is manufacture to EN471 [High visibility warning clothing for professional use]. Very few visibility clothing products encountered which are manufactured according to the appropriate standard for non-professional use, i.e. EN1150:1999 [Protective clothing-Visibility clothing for non-professional use - Test methods and requirement].

Many products are still manufactured and placed on the European Market as Visibility clothing and accessories but do not conform to any standards at all. The number of products found out of standards proved to be a huge obstacle to Market Surveillance Officials especially in determining if the specific product is to be considered as Visibility Clothing/Visibility accessory or not. This issue alone requires more focus on how to deal with this situation.

Selecting and obtaining samples for testing

A total of 39 products, were collected from the market by the participating Member States and sent for testing.

Note: Two visibility clothing products were collected by the Representative of the National Consumer Agency of Dublin which Country was not a participant in the Joint Action.

These were split as follows: 20 products of Visibility Accessories and 19 products of Visibility Clothing.

The collection and forwarding of products for testing, including in-house checking of these same products.

Check lists templates were provided for this aim.

Products were collected and sent for testing as follows:

Two visibility clothing products collected and sent for testing by the National consumer Agency of Dublin-Ireland [Not a Participating Country in this Joint Action]-Dublin was involved because required visibility clothing could not be found on the participants' market.

Further information can be obtained from the appropriate deliverables in the Annex I. These are the guideline to Member States on how to exchange information D7E and the Memo to Member States on which products to sample D8E.

3.5.4 Testing

Discussions held with the Participating Member States Representatives during the 2nd. Project Meeting, it was decided to test as follows:

- Visibility Accessories for non-professional use to EN13356 - Clause 5.2 - Photometric Testing
- Visibility Clothing for non-professional use to EN1150 - Clause 6.1-Retroreflective Performance [as received] and Clause 7.4.2-Retroreflection after exposure to flexing

Due to budget limitations test were limited to the above clauses which are among the main critical areas of Visibility Clothing and Accessories

Further information can be obtained from the appropriate deliverable in the Annex I. This is the list of test criteria D9.1E and the contract with laboratory D9.4E.

Apart from the testing scheduled to be carried out by the appointed testing laboratory, each Member State had also the responsibility to carry out in-house testing for each product collected to be sent for testing. For recording purposes of these in-house tests, separate checklists were prepared for each standard, namely for EN13356 and for EN1150. Some of these in-house tests consisted in checking of labelling for conformity to the standard and checking of areas of the retro-reflective materials.

In general, the purpose of the testing is to clarify/establish whether the investigated Visibility Clothing and Accessories are unsafe enough that the authorities will have to take prior action against them. This will lead to the expected results of the joint action, namely resulting in best practice for assessing and removing dangerous products from the market.

3.5.5 Risk assessment

During the 3rd. Project meeting which was held over a period of two days, almost a full day [05/06/2012] was dedicated to Risk Assessment.

This meeting on Risk assessment was split in two parts, The first part being a presentation by the Belgian Member State Representative on Risk assessment and the second part was a hands on practical session on how to proceed with carrying out an evaluation of risk.

The Belgian Member State Representative focused her presentation on the experience gained from the Belgian Market Surveillance campaign on high visibility vests during the period 2010 - 2011.

The Representative stated that in Belgium, standard procedure Market surveillance with Risk Assessment approach was adopted. The risk assessment being based on the risk assessment method from RAPEX Guidelines.

The Belgian Representative continued explaining how a risk assessment on a product is done. Several steps were indicated to arrive at carrying out the exercise in a transparent manner - namely:

- Identify the product. Identify whether the item is a high visibility clothing or accessory. This will pave the way for the next step.
- Identify the Consumer type. How will the product be made use of? Will the clothing be used by a particular consumer type? Will the geographical area influence consumer expectations. The same applies to a visibility accessory.

- Identify the hazard characteristics. One web tool for risk assessment is found at www.europa.eu/sanco/rag/public. On this website it is found a very simple tool for carrying out risk assessment - The hazard characteristics can be identified from the tabulation.

But all this, the Belgian Representative explained, is highly dependant on the hazard characteristics chosen for the particular scenario.

- Work out an injury scenario - namely on how the Consumer can be injured.
- Estimate the severity of the injury
- Attribute and calculate the probability of the (sub) scenarios). Several steps can lead to an injury, each step has a probability factor.
- Calculate risk. Risk = severity x probability.

A risk assessment can be carried out using different scenarios to achieve a risk category to apply to the product.

For the practical side of the risk assessment session, two products were analysed, one clothing product and one an accessory product.

Moreover, the Joint Action made use of the PROSAFE: “Best Practice Techniques in Market Surveillance” [The Blue Book] which has valuable information and guidelines on Risk Assessment.

3.5.6 Results of the lab tests and risk assessment

The official test reports for each product sent for testing was sent directly to the Participating Member State which had submitted the product for testing.

During the fifth Project Meeting held in Brussels, discussions were held by going through each and every test report and check list for each respective product and comments listed against each product.

Test results:

EN1150 Clothing:

Test requested: Clause 6.1 Retroreflective Performance [as received] - 8 products had at least one failure in test results

Test requested: Clause 7.4.2 Retroreflective Performance [after flexing] - All products [17] passed

EN13356 Accessories:

Test requested: Clause 5.2 Photometric tests/4.1 General requirements - All products passed

Test requested: Clause 5.2 Photometric test/4.2 Minimum coefficient - 2 products at least one failure in results

Further information can be obtained from the appropriate deliverables in the Annex I. These are the Statistics on Activities D10E and the Memo with description of follow-up activities D11E.

Results from Risk assessment

During phase one of the project, following the Market Surveillance Activity carried out by each respective Member State, a total of 135 visibility clothing and accessories products were inspected.

Of these products 61 in number did not show any standard on label - hence these are non compliant.

Following the availability of the test results from the testing laboratory, and up to the time that this information was requested from the Member States Representatives, and following the Market Surveillance carried out by the Participants, a total of 22 products were inspected, of these, a total of 5 products were banned from the market by the respective Participating Member State Representative - 2 products by the Czech Republic and 3 products by the Slovak Republic.

3.5.7 Follow-up

Results from Member States market surveillance activities

During the phase one of the project Market Surveillance activities, a total of 135 products were inspected with the following results:

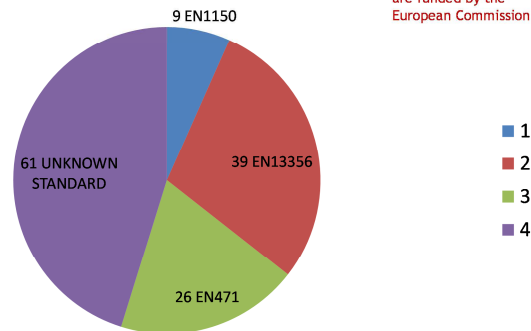
Total of 61 products do not show any standards on label

Total of 26 products were marked as manufactured according to EN 471 standard

Total of 39 products were marked as manufactured according to EN 13356 standard [Visibility accessories for non-professional use - Test methods and requirements]

Total of 9 products were marked as manufactured to EN1150 Standard [Protective clothing -Visibility clothing for non-professional use - Test methods and requirements]

The diagram below gives a good overview of findings:



FIRST FOUR MONTHS - SAMPLING OUTCOME - - TOTAL SAMPLED- 135
45% OF COLLECTED SAMPLES FALL UNDER UNKNOWN STANDARDS
6.7% OF COLLECTED SAMPLES FALL UNDER EN1150
29% OF COLLECTED SAMPLES FALL UNDER EN13356
19.3% OF COLLECTED SAMPLES FALL UNDER EN471

Following the testing of the Products, and following the availability of the test reports, five products were banned from the marketplace and 24 visits were made to economic operators. Further information can be obtained from the appropriate deliverable in the Annex I. This is the Memo with description of follow-up activities D11E.

Cooperation with Customs

For the Kick Off meeting of this Visibility Clothing and Accessory Joint Action, Representative for DG TAXUD was invited and attended. During this meeting, DG TAXUD Representative presented an informative Power Point presentation on “Import controls in the area of Product Safety and Compliance”.

DG TAXUD Representative ended his presentation by outlining the possibility of establishment of a permanent structure to enhance cooperation between Customs and Member States Authorities.

During this kick off meeting it came to be known that on the DG TAXUD website there exist standard products check lists for customs use.

When at a later stage these check lists were not found on the DG TAXUD website, assistance to obtain these check lists was asked from the Representative, who in turn informed the Coordinator that these documents are not for public use.

On commencement of the Joint Action, the Project Coordinator organised and attended a meeting in Malta with the local Customs Officials to discuss present Customs arrangements relative to the safety of imported products. During this meeting it was very clear that there was a very good working relation with the Maltese Market Surveillance Authority. It was also evident that the Customs were very much aware of EU legislation.

It was also evident that the local Customs Authority is always prepared to work hand in hand and to communicate more and exchange information with other EU Customs and Market Surveillance Authorities at European level.

Outreach to Standards development Bodies

For the kick off meeting of the Joint Action, Representative for CEN was invited and attended.

The CEN Representative gave a very interesting presentation on the standards relative to Visibility Clothing and Accessories, i.e. EN471 [clothing for professional Use], EN1150 [clothing for non-professional use], and EN13356 [accessories].

The CEN Representative defined the three classes of high visibility garments, namely class1, class 2 and class 3 and specified the relative properties of background material, retro reflective material and the combined performance material for each respective class.

On the topic of standardisation, the CEN Representative stated that the Standard EN471 is heading for a revision to ISO 20471.

An ANEC Representative was invited and attended for the second Project Meeting, which was held in Brussels.

Further information can be obtained from the appropriate deliverable in the Annex I. This is the Memo with description of follow-up activities D11E.

3.5.8 Achievement of objectives and lessons learnt

Impressions of the European Market in General

We have seen that the results of Market Surveillance Program show a high number of rogue products from samples inspected that were difficult to categories. There is some confusion in the manufacturing sector relative to EN471 [professional use] and EN1150 [non-professional use]. It also seems that there is not much awareness of the standard EN1150. The flexibility offered for manufacturing products to EN1150 is not taken advantage of by the fashion industry.

Following the market surveillance activities carried out by the Participating Member States, and through the experience gained through this Joint Action, it was practically established that:

- Visibility Clothing for non-professional use are not widely diffused on the European Market. Mainly visibility clothing is manufacture to EN471 [High visibility warning clothing for professional use]. Very few visibility clothing products encountered which are manufactured according to the appropriate standard for non-professional use, i.e. EN1150:1999 [Protective clothing-Visibility clothing for non-professional use - Test methods and requirement]
- Reflective materials normally used for visibility clothing is being used sporadically on clothing other than standardised visibility clothing
- There are a lot of rogue visibility products on the European market
- There is more focus on visibility clothing in the European Northern Countries
- Lack of Consumer information relative to visibility clothing
- Sports enthusiasts make use of visibility clothing
- Visibility accessories on the European market are more addressed to use for young children
- Main exporter to Europe of visibility clothing and accessories is China
- General lack of interest from laboratories to tender for testing of Visibility clothing and accessories
- Present European legislation on PPE is in the process of being updated. The sooner this is done the more the consumer will benefit

Lessons learned

There is some confusion in the manufacturing sector relative to EN471 [High visibility warning clothing for professional use] and EN1150 [Visibility clothing for non-professional use]. There is not much awareness of the standard EN1150. The flexibility offered for the manufacturing of products to EN1150 is not taken advantage of by the fashion industry.

Consumers can be exposed to more hazards through the use of unclassified high visibility apparel. Material use (that is normally indicated for PPE use) is being made use of without control. Extensive amount of non-conforming products are on the EU market. There is great unbalance between conforming products and non-conforming products on the EU market

Sometimes it is difficult to distinguish between conforming PPE products [visibility clothing and accessories] and other non-conforming products. Sometimes market surveillance officers have to take difficult decisions concerning the removal of certain products from the market.

Testing with the laboratory encountered some problems causing further delays in the project with the actual test reports themselves issued by SGS UK Ltd. These included late receipt of the hard copies of the test results by the Participants, misprints on the test reports, test reports not addressed correctly, one test report without photo, some test reports were without the respective Country identification number, discrepancy was also noted in one test report about the interpretation of "Pass"/"Fail".

It is to be noted here that some major Visibility Clothing and Accessories manufacturers do not even show their contact details on their websites.

4 Budget and Expenses

This Section contains the main financial information of this Joint Action.

To simplify the reading round figures in euros are used. For a better understanding of the budget lines, a short explanation is added.


	Budget (€)	Total expenditure	
		(€)	(%)
Direct costs			
1 Staff, non-officials	216.728	237.187	13,2%
2 Staff, Member State officials	609.833	576.747	32,2%
3 Travel and subsistence	334.524	234.977	13,1%
4 Equipment	0	0	0
5 Subcontracting	688.120	605.444	33,8%
6 Miscellaneous	50.356	18.658	1,0%
Total direct costs	1.899.561	1.673.012	
Indirect costs			
7 Flat rate 7%	132.969	117.111	
Total expenditure	2.032.531	1.790.123	100,0%
Revenue			
2 Staff, Member State officials	609.833	576.747	32,2%
8 Amount of EU support requested	1.422.697	1.213.376	67,8%
Total revenue	2.032.531	1.790.123	100,0%

Comparison of the budget and total expenses of JA 2010

Explanation of budget lines

- 1 Staff, non-officials: administrative and financial staff and PROSAFE management
- 2 Staff, public officials: time spent by the official staff of the participating Member States, expressed in €
- 3 Travel and Subsistence: costs of the public officials
- 4 Equipment: not applicable
- 5 Subcontracting: all costs of testing, consultants and communication
- 6 Miscellaneous: costs of external audits
- 7 Flat rate: for all costs indirectly connected with this Joint Action, a flat rate of 7% of total direct costs is granted
- 8 EU support requested: requested contribution from the European Commission

The next table gives an overview of the costs by activity expressed in % of the total expenditure

	<i>JA2010 total costs</i>		<i>JA Coordination</i>	<i>Food Imitation</i>	<i>Ladders</i>	<i>Fancy Dresses</i>	<i>Laser Pointers</i>	<i>Visibility Clothing</i>
<i>Direct costs</i>								
1 Staff, non-officials	13,2%	13,2%						
2 Staff, Member State officials	32,2%		3,8%	8,3%	4,7%	3,0%	10,1%	2,3%
3 Travel and Subsistence	13,1%	0,9%	2,8%	3,1%	1,7%	1,2%	2,5%	0,9%
5 Subcontracting	33,8%	1,5%	6,0%	3,1%	6,9%	5,4%	6,9%	3,9%
6 Miscellaneous	1,0%	0,9%			0,1%			
Total direct eligible costs	93,5%	16,6%	12,7%	14,5%	13,5%	9,6%	19,6%	7,1%
<i>Indirect costs</i>								
7 Flat rate 7%	6,5%	1,2%	0,9%	1,0%	0,9%	0,7%	1,4%	0,5%
Total Expenditure	100,0%	17,7%	13,5%	15,5%	14,4%	10,3%	20,9%	7,6%

Comparison of the costs by activity

5 Participation in the Joint Action

The table below shows the planned and actual involvement of each of the participating organisations in the Joint Action.

JA2010

MS	Acronym	BUDGET	Final Result	difference
		days	days	
BG	CCP	121	124,5	2,9
CZ	COI	251	260	3,6
DK	SIK	118	87,3	-26,0
DE	Hessen	118	109,5	-7,2
EL	GSCA	211	234,8	11,3
HU	HACP	45	50,2	11,6
IE	NCA	45	47,5	5,6
LV	CRPC	223	212,8	-4,6
LT	NFPI	168	117,4	-30,1
LU	ILNAS	184	149,5	-18,8
MT	MSA	194	198,5	2,3
NO	DSB	111	96,3	-13,2
PL	OCCP	111	107	-3,6
PT	DGC	127	141,8	11,7
SK	STL	168	189,6	12,9
SI	Health Insp	102	100,7	-1,3
ES	INC	194	240,8	24,1
PT	ASAE	216	193,2	-10,6
NL	VWA	317	189	-40,4
AT	LSACP	111	60,5	-45,5
CY	CCPS	111	113,5	2,3
SI	MARKET	121	124	2,5
BE	FPS Econ	95	94,6	-0,4
Total		3462	3243	-6,33

Days contributed by the individual Authorities to the Joint Action

Legend of the acronyms:

MIN LSACP	Federal Ministry of Labour, Social Affairs and Consumer Protection
FPS ECON	FPS Economy, SME's, Self-employed and Energy - Directorate General of Quality and Safety
CCP	Commission for Consumer Protection
CCPS	Competition and Consumer Protection Service under the Ministry of Commerce, Industry and Tourism
COI	Czech Trade Inspection under the Ministry of Industry and Trade
SIK	Danish Safety Technology Authority
Hessen	Regional Council Gießen - Department for Labour Protection and Interior Affairs
GSCA	General Secretariat for Consumer Affairs under the Ministry of Economy,

	Competitiveness and Shipping
CRPC	Consumer Rights Protection Centre
HACP	Hungarian Authority for Consumer Protection
NCA	National Consumer Agency
NFP-INSP	State Non-Food Products Inspectorate under the Ministry of Economy
ILNAS	Institute of Standardisation and Accreditation, of Security and Quality of Products and Services
MSA	Malta Standards Authority
VWA	Food and Consumer Product Safety Authority
DSB	Directorate for Civil Protection and Emergency Planning
OCCP	Office of Competition and Consumer Protection
DGC	Directorate General for Consumers
ASAE	Food and Economic Safety Authority
STL	Slovak Trade Inspection
MARKET	Market Inspectorate of the Republic of Slovenia
HIRS	Health Inspectorate of the Republic of Slovenia
INC	National Institute for Consumer Protection

The number of days in the budget is the result of a standardised estimate. In that stage of preparation of the Joint Action, it is impossible to take national or regional differences into account. The differences between Authorities originate from the number of activities they join.

During the implementation of the Joint Action, the differences become manifest and they can be caused by:

- The size of the market of a certain group of products;
- The experience or knowledge of the market of a certain group of products in the Market Surveillance Authority;

This can lead to unexpected differences in the number of days the Authorities need to fulfil the same tasks. Furthermore, one has to take into account:

- The priority given to the work for this Joint Action;
- The availability of staff, due to illness or other reasons.

All these factors influence the final number of days, which are registered based on the received time sheets. It is not possible to comment on national or specific deviations. Another reason for a lower numbers of days might be that not all time sheets were sent to the PROSAFE Secretariat.

Annex I Deliverables Produced by the Action

The following deliverables have been produced by the Joint Action.

The names and numbers of the deliverables are in accordance with the Grant Agreement.

ID	Title	Deliverable (Document)	Notes
D1.1	Planning of Joint Action	Work plan for the Joint Action including the sequence for the product-specific activities (i.e. what will be “Product A”, “B”, “C”, “D” and “E”).	
D1.2	Kick-off and planning workshop for Joint Action	Memo with conclusions from workshop	
D2.1	Planning of communication	Detailed communication plan	
D2.2	Joint press release on start of action	Press release	
D2.3	First workshop to disseminate results	Memo with conclusions from workshop	
D2.4	Joint press release, first workshop	Press release	
D2.5	Second workshop to disseminate results	Memo with conclusions from workshop	
D2.6	Joint press release, second workshop	Press release	
D3.1	Planning of outreach activities, China	Plan for outreach activity.	D3.1 and D4.1 have been merged and delivered together in one document
D3.2	Reporting results from outreach activities, China	Memo with conclusions from activity.	D3.2 and D4.2 have been merged and delivered together in one document
D4.1	Planning of stakeholder outreach activities	Plan for outreach activity.	D3.1 and D4.1 have been merged and delivered together in one document
D4.2	Reporting results from stakeholder outreach activities	Memo with conclusions from activity.	D3.2 and D4.2 have been merged and delivered together in one document
D5.1A	Planning of activities for product A	Detailed approach to market surveillance activities on product A	
D5.2A	Kick-off and planning meeting, product A	Memo from meeting	
D6.1A	2nd project meeting, product A	Minutes from meeting	
D6.2A	3rd project meeting, product A	Minutes from meeting	
D6.3A	4th project meeting, product A	Minutes from meeting	
D6.4A	5th project meeting, product A	Minutes from meeting	
D6.5A	6th project meeting, product A	Minutes from meeting	
D7A	Set up means for exchange of information on product A	Guideline to Member States on how to exchange information on product A	
D8A	Sampling schemes, product A	Memo to Member States on which products to sample	

ID	Title	Deliverable (Document)	Notes
D9.1A	Develop test criteria, product A	List of test criteria	
D9.2A	Joint testing, product A	Letter to laboratories requesting them to make a quotation	
D9.3A	Joint testing, product A	Overview of responses to call for tender	
D9.4A	Joint testing, product A	Contract with laboratory	
D10A	Market surveillance activities, product A	Statistics on activities (i.e. number of products inspected, assessed and banned, number of visits to economic operators.)	
D11A	Follow-up activities, product A	Memo with description of follow-up activities.	
D5.1B	Planning of activities for product B	Detailed approach to market surveillance activities on product B	
D5.2B	Kick-off and planning meeting, product B	Memo from meeting	
D6.1B	2nd project meeting, product B	Minutes from meeting	
D6.2B	3rd project meeting, product B	Minutes from meeting	
D6.3B	4th project meeting, product B	Minutes from meeting	
D6.4B	5th project meeting, product B	Minutes from meeting	
D6.5B	6th project meeting, product B	Minutes from meeting	
D7B	Set up means for exchange of information on product B	Guideline to Member States on how to exchange information on product B	
D8B	Sampling schemes, product B	Memo to Member States on which products to sample	
D9.1B	Develop test criteria, product B	List of test criteria	
D9.2B	Joint testing, product B	Letter to laboratories requesting them to make a quotation	
D9.3B	Joint testing, product B	Overview of responses to call for tender	
D9.4B	Joint testing, product B	Contract with laboratory	
D10B	Market surveillance activities, product B	Statistics on activities (i.e. number of products inspected, assessed and banned, number of visits to economic operators.)	
D11B	Follow-up activities, product B	Memo with description of follow-up activities.	
D5.1C	Planning of activities for product C	Detailed approach to market surveillance activities on product C	
D5.2C	Kick-off and planning meeting, product C	Memo from meeting	
D6.1C	2nd project meeting, product C	Minutes from meeting	
D6.2C	3rd project meeting, product C	Minutes from meeting	
D6.3C	4th project meeting, product C	Minutes from meeting	
D6.4C	5th project meeting, product C	Minutes from meeting	
D6.5C	6th project meeting, product C	Minutes from meeting	

ID	Title	Deliverable (Document)	Notes
D7C	Set up means for exchange of information on product C	Guideline to Member States on how to exchange information on product C	
D8C	Sampling schemes, product C	Memo to Member States on which products to sample	
D9.1C	Develop test criteria, product C	List of test criteria	
D9.2C	Joint testing, product C	Letter to laboratories requesting them to make a quotation	
D9.3C	Joint testing, product C	Overview of responses to call for tender	
D9.4C	Joint testing, product C	Contract with laboratory	
D10C	Market surveillance activities, product C	Statistics on activities (i.e. number of products inspected, assessed and banned, number of visits to economic operators.)	
D11C	Follow-up activities, product C	Memo with description of follow-up activities.	
D5.1D	Planning of activities for product D	Detailed approach to market surveillance activities on product D	
D5.2D	Kick-off and planning meeting, product D	Memo from meeting	
D6.1D	2nd project meeting, product D	Minutes from meeting	
D6.2D	3rd project meeting, product D	Minutes from meeting	
D6.3D	4th project meeting, product D	Minutes from meeting	
D6.4D	5th project meeting, product D	Minutes from meeting	
D6.5D	6th project meeting, product D	Minutes from meeting	
D7D	Set up means for exchange of information on product D	Guideline to Member States on how to exchange information on product D	
D8D	Sampling schemes, product D	Memo to Member States on which products to sample	
D9.1D	Develop test criteria, product D	List of test criteria	
D9.2D	Joint testing, product D	Letter to laboratories requesting them to make a quotation	
D9.3D	Joint testing, product D	Overview of responses to call for tender	
D9.4D	Joint testing, product D	Contract with laboratory	
D10D	Market surveillance activities, product D	Statistics on activities (i.e. number of products inspected, assessed and banned, number of visits to economic operators.)	
D11D	Follow-up activities, product D	Memo with description of follow-up activities.	
D5.1E	Planning of activities for product E	Detailed approach to market surveillance activities on product E	
D5.2E	Kick-off and planning meeting, product E	Memo from meeting	
D6.1E	2nd project meeting, product E	Minutes from meeting	
D6.2E	3rd project meeting, product E	Minutes from meeting	

ID	Title	Deliverable (Document)	Notes
D6.3E	4th project meeting, product E	Minutes from meeting	
D6.4E	5th project meeting, product E	Minutes from meeting	
D6.5E	6th project meeting, product E	Minutes from meeting	The meeting did not take place, hence no minutes were drafted. For more information please refer to the report point 3.5.2.
D7E	Set up means for exchange of information on product E	Guideline to Member States on how to exchange information on product E	
D8E	Sampling schemes, product E	Memo to Member States on which products to sample	
D9.1E	Develop test criteria, product E	List of test criteria	
D9.2E	Joint testing, product E	Letter to laboratories requesting them to make a quotation	
D9.3E	Joint testing, product E	Overview of responses to call for tender	
D9.4E	Joint testing, product E	Contract with laboratory	
D10E	Market surveillance activities, product E	Statistics on activities (i.e. number of products inspected, assessed and banned, number of visits to economic operators.)	
D11E	Follow-up activities, product E	Memo with description of follow-up activities.	
D12.1	First progress report		
D12.2	First interim implementation report		
D12.2.1		Audit report	
D12.3	Second progress report		
D12.3.1		Audit report	
D12.4	Final technical implementation report		
D12.4.1		Audit report	

Annex II Participation in the Joint Action

Planned and Actual Involvement of Participants

Table 1 below shows the planned and actual involvement of each of the participating organisations in the Joint Action.

Participation in JA2010					
Member State	Participating Authority's acronym	Participants' Name	Number of days worked	Total number of days per MS/Authority	
				Actual	Plan
Austria	MIN LSACP	Disa Medwed	36,1	60,5	111,0
Austria	MIN LSACP	Helmuth Perz	24,4		
Belgium	FPS ECON	Benoit Miclotte	4,5	94,7	95,0
Belgium	FPS ECON	Christof Plas	12,0		
Belgium	FPS ECON	Jan Deconinck	15,0		
Belgium	FPS ECON	Maries Merken	42,1		
Belgium	FPS ECON	Bart Evens	3,0		
Belgium	FPS ECON	Marina Vos	3,0		
Belgium	FPS ECON	Jacky Bloemen	7,0		
Belgium	FPS ECON	Veerle van den Broucke	6,0		
Belgium	FPS ECON	Carine Renard	2,1		
Bulgaria	CCP	Elena Georgieva	114,5		
Bulgaria	CCP	Veselina Bobocheva	10,0		
Cyprus	CCPS	Ioannis Makrides	113,5	113,5	111,0
Czech Republic	COI	Eva Suchankova	1,7	260,0	251,0
Czech Republic	COI	Frantisek Zemek	5,7		
Czech Republic	COI	Hana Vondraskova	12,9		
Czech Republic	COI	Jan Groulik	1,6		
Czech Republic	COI	Jana Grdinova	34,9		
Czech Republic	COI	Jiri Studlar	28,7		
Czech Republic	COI	Jirina Sramkova	12,3		
Czech Republic	COI	Josef Balvin	3,8		
Czech Republic	COI	Karel Grunes	8,0		
Czech Republic	COI	Libor Vaclavek	7,2		
Czech Republic	COI	Marcela Kvasnickova	10,7		
Czech Republic	COI	Marie Vilimova	42,5		
Czech Republic	COI	Michal Hrabovcin	7,2		
Czech Republic	COI	Michal Kysilka	7,1		
Czech Republic	COI	Michal Pavlica	3,9		
Czech Republic	COI	Milan Bousa	23,1		
Czech Republic	COI	Monica Ketternerova	1,0		
Czech Republic	COI	Monika Syslova	4,9		
Czech Republic	COI	Radoslav Prsala	14,1		
Czech Republic	COI	Pravoslav Kucera	10,2		
Czech Republic	COI	Petr Priborsky	8,8		
Czech Republic	COI	Vladimira Soukupova	9,8		

Participation in JA2010					
Member State	Participating Authority's acronym	Participants' Name	Number of days worked	Total number of days per MS/Authority	
				Actual	Plan
Denmark	SIK	Alex Jensen	48,3	87,3	118,0
Denmark	SIK	Bjarne Lehrmann	27,5		
Denmark	SIK	Signe Tapdrup	8,5		
Denmark	SIK	Anders Grønbech Jørgensen	3,0		
Germany	Hessen	Michael Axmann	96,8	109,5	118,0
Germany	Hessen	Wolfram Balles	12,7		
Greece	GSCA	Alexiou Petra Trantafillia	24,5	234,8	211,0
Greece	GSCA	Konstantinos Zisis	3,3		
Greece	GSCA	Stamatia Chroni	207,0		
Latvia	CRPC	Agrita Birzule	60,0	212,8	223,0
Latvia	CRPC	Aleksejs Niscaks	87,0		
Latvia	CRPC	Linda Rinkule	5,0		
Latvia	CRPC	Vita Visocka	60,8		
Hungary	HACP	Alexandra Zsitkovszky	15,0	50,2	45,0
Hungary	HACP	Marta Palne Toth	20,2		
Hungary	HACP	Magdolna Csonkane Kojnok	15,0		
Ireland	NCA	Denis Mc Guinness	29,5	47,5	45,0
Ireland	NCA	Thomas Bourke	5,0		
Ireland	NCA	Niamh Martin	5,0		
Ireland	NCA	Teresa White	8,0		
Lithuania	NFP-INSP	Ramunas Lebedys	3,6	117,4	168,0
Lithuania	NFP-INSP	Simona Bieliauskaite	32,0		
Lithuania	NFP-INSP	Valda Nemaniene	23,0		
Lithuania	NFP-INSP	Danute Banyte	14,0		
Lithuania	NFP-INSP	Rima Tugauskaite	14,0		
Lithuania	NFP-INSP	Ona Kuseliauskaite	12,8		
Lithuania	NFP-INSP	Elena Rinkevicienne	18,0		
Luxembourg	ILNAS	Jean-Marie Weiler	89,5		
Luxembourg	ILNAS	Romain Borrelbach	60,0		
Malta	MSA	Charles Borg	18,3	198,5	194,0
Malta	MSA	Charles Tanti	57,7		
Malta	MSA	James Spiteri	61,2		
Malta	MSA	Michael Cassar	58,8		
Malta	MSA	Nicholas Magro	2,5		
Netherlands	VWA	Durk Schakel	59,5		
Netherlands	VWA	Edwin Velsink	51,5		

Participation in JA2010					
Member State	Participating Authority's acronym	Participants' Name	Number of days worked	Total number of days per MS/Authority	
				Actual	Plan
Netherlands	VWA	Marijn Colijn	11,5	189,0	317,0
Netherlands	VWA	Hans Jacobs	17,8		
Netherlands	VWA	Michael (Misja) Oosterwijk	48,7		
Norway	DSB	Berit Jaritz	52,5	96,3	111,0
Norway	DSB	Gunnar Wold	14,4		
Norway	DSB	Sverre Limtun	29,4		
Poland	OCCP	Barbara Zysko	107,0	107,0	111,0
Portugal	DGC	Filomena Barreira	124,8	141,8	127,0
Portugal	DGC	Rui Fernandes	2,9		
Portugal	DGC	Sónia L. Passos	14,1		
Portugal	ASAE	Sarogini Carmen Monteiro	33,5	193,2	216,0
Portugal	ASAE	Marina Dias	159,7		
Slovakia	STL	Adriana Vajdova	8,0	189,6	168,0
Slovakia	STL	Andrea Valkova	105,5		
Slovakia	STL	Jaroslav Laca	5,5		
Slovakia	STL	Marcela Lehocka	11,0		
Slovakia	STL	Marta Krupova	38,5		
Slovakia	STL	Renata Karbulova	8,0		
Slovakia	STL	Renata Vlacilova	5,2		
Slovakia	STL	Stanislava Zorvanova	8,0		
Slovenia	MARKET	Tomaz Cernec	3,5	124,0	121,0
Slovenia	MARKET	Maksimiljan Bornsek	106,7		
Slovenia	MARKET	Primoz Perne	3,9		
Slovenia	MARKET	Joze Keber	9,9		
Slovenia	HIRS	Matej Gros	50,3	100,8	102,0
Slovenia	HIRS	Helena Hocevar	50,5		
Spain	INC	Miguel Ysa Valle	240,8	240,8	194,0
TOTAL				3243,1	3462,0

Table 1: Planned and actual involvement of the participants in the Action

Legend of the acronyms:

MIN LSACP	Federal Ministry of Labour, Social Affairs and Consumer Protection
FPS ECON	FPS Economy, SME's, Self-employed and Energy - Directorate General of Quality and Safety
CCP	Commission for Consumer Protection
CCPS	Competition and Consumer Protection Service under the Ministry of Commerce, Industry and Tourism
COI	Czech Trade Inspection under the Ministry of Industry and Trade
SIK	Danish Safety Technology Authority
Hessen	Regional Council Gießen - Department for Labour Protection and Interior Affairs
GSCA	General Secretariat for Consumer Affairs under the Ministry of Economy, Competitiveness and Shipping
CRPC	Consumer Rights Protection Centre
HACP	Hungarian Authority for Consumer Protection
NCA	National Consumer Agency
NFP-INSP	State Non-Food Products Inspectorate under the Ministry of Economy
ILNAS	Institute of Standardisation and Accreditation, of Security and Quality of Products and Services
MSA	Malta Standards Authority
VWA	Food and Consumer Product Safety Authority
DSB	Directorate for Civil Protection and Emergency Planning
OCCP	Office of Competition and Consumer Protection
DGC	Directorate General for Consumers
ASAE	Food and Economic Safety Authority
STL	Slovak Trade Inspection
MARKET	Market Inspectorate of the Republic of Slovenia
HIRS	Health Inspectorate of the Republic of Slovenia
INC	National Institute for Consumer Protection

Annex III Financial Analysis

3.1 Budget and Actual Expenses

The table below presents the original budget, the amended budget and the actual expenses for Joint Action.

	Budget original (€)	Budget amended (€)	Actual expenses (€)	Difference (budget -/- actual) (€)
Direct costs				
Staff, non-officials	134.400,00	216.728,00	237.187,29	20.459,29
Staff, officials	609.833,22	609.833,22	576.747,06	-33.086,16
Travel and subsistence	334.524,00	334.524,00	234.976,52	-99.547,48
Equipment	-	-	-	-
Subcontracting	728.952,00	688.120,00	605.443,51	-82.676,49
Miscellaneous	91.852,00	50.356,00	18.658,07	-31.697,93
Total direct costs	1.899.561,22	1.899.561,22	1.673.012,45	-226.548,77
Indirect costs				
7%	132.969,29	132.969,29	117.110,87	-15.858,42
Total expenditure	2.032.530,51	2.032.530,51	1.790.123,32	-242.407,19
Revenue				
Resources of the participant	609.833,22	609.833,22	576.747,06	-33.086,16
Amount of EU support requested	1.422.697,29	1.422.697,29	1.213.376,26	-209.321,03
Total revenue	2.032.530,51	2.032.530,51	1.790.123,32	-242.407,19

3.2 Differences between Amended Budget and Actual Expenses

- **Staff - non officials**

The amendment of the budget was necessary to increase the PROSAFE staff costs to a realistic level, and to transfer the accounting costs from Subcontracting to the PROSAFE Staff costs chapter. The final result now shows that the amendment was realistic.

Since 2010 all PROSAFE staff costs are proportionally divided over all ongoing Joint Actions. The key for the distribution of costs is the amount of EU support.

- **Staff - MS public officials**

The value of all time spent to the Joint action by the Marker surveillance officials is only 5,4 % lower than foreseen. This indicates that more and more activities from the Joint action are really performed in the Member States, and less at meetings.

- **Travel and subsistence**

The difference between the amended budget and the actual figures is approximately 30% and the figures show that the Joint Action has underspent on travel and subsistence costs. In the original budget travel and subsistence costs were foreseen for the participation of customs officials from Member States. In the amended budget most of these costs were transferred to the general budget for these costs.

The reasons for the under spending are mainly:

- Average participation in the meetings was below 100% of the participants, as usual;
 - PROSAFE has become increasingly better at combining PROSAFE meetings with other meetings thus creating cost savings.
- **Subcontracting**
The budget for subcontracting was decreased at the amendment of the budget. This reduction was mainly a transfer of the budget for accounting to staff costs, but the budget for laboratory tests was unchanged: € 148.200. Actual test costs were more than € 30.200 lower. Consultant's costs were € 25.000 lower, as well as their travel costs.
 - **Miscellaneous**
The amended budget foresaw cost under this budget heading for purchase and transport of test samples, but the actual costs were lower. The actual costs for the external audits were at the same level as in the budget.
The main saving was not using the reservation for outreach to China.
 - **Amount of EU support requested.**
This figure is calculated to balance the budget of the Joint Action at the same time respecting the demands of the Grant Agreement.