

# Final Implementation Report

Covering the period 1 November 2008 to 31 December 2011

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## Introduction

This is the Final Technical Implementation Report for the Joint Action Follow-Up Market Surveillance Action MARS II - “Enhancing market surveillance through best practice - EMARS II. In accordance with the Grant Agreement the report is due 31<sup>st</sup> of March 2012 and it shall provide a concise overview of the implementation of the Joint Action from its 1<sup>st</sup> of November 2008 to 31<sup>st</sup> of December 2011.

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 activities undertaken throughout the Joint Action in chapter 2.
- Deviations from the initial work programme are identified and explained in chapter 2.5.
- The results obtained during the implementation are presented in chapter 4.
- Differences between the foreseen results of the Joint Action and those actually achieved are explained in chapter 0.

Copies of deliverables and other material produced by the Action are annexed in Annex 2 and 3.

Information on the participants in the Joint Action can be found in chapter 3. The information presented there includes an overview of all organisations and persons who participated in the execution of the Joint Action. Any differences between the foreseen participation in the Joint Action and that actually realised is highlighted and explained.

The final report also includes a financial analysis of the expenditures in the Joint Action. The analysis compares the expenditure incurred during the period 1<sup>st</sup> of November 2008 to 31<sup>st</sup> of December 2011 with the foreseen budget as laid down in the Grant Agreement. A breakdown of the expenditure per participant is also provided.

The Joint Action is executed under the 2008 call for tender. Thus, the reporting requirements may differ from Actions granted under the call for tenders outlined in other years.

# 1 Background Information

## Summary of Project Description

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

### *1.1.1 Title of the Joint Action*

Joint Action Enhancing market surveillance through best practice - EMARS II

The European Commission has supported the Joint Action financially under Grant Agreement 17.020200 / 08 / 507572.

### *1.1.2 Participating Member States*

The application for the Joint Action was signed by PROSAFE and 21 Member States Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Iceland, Ireland, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Slovenia, Sweden and the UK.

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

The project leader at the beginning of the project was Dirk Meijer of the VWA from the Netherlands. Gunnar Wold from DSB in Norway took over approximately halfway through the project.

There were a number of project consultants all of whom are independent consultants subcontracted by PROSAFE.

### *1.1.3 Budget*

The total budget cost for the Joint Action was 2.493.618,77 € out of which the Commission funds 69 %, equivalent to 1.721.477,86 €.

### *1.1.4 Primary Objective*

The overall objective of the project was to further enhance the market surveillance of non-food consumer products in Europe. This was to be achieved through the practical application of the best practice developed under the first EMARS project and the development of additional best practices.

### *1.1.5 Secondary Objective*

The project also sought to further capitalise on the improved climate for collaboration amongst national market surveillance authorities that the current EMARS project has

contributed to. It was envisaged that EMARS II would provide a framework for closer collaboration within which future Joint Actions and coordinated activities on specific products and other market surveillance related issues could be identified.

### ***1.1.6 Specific Goals of the Joint Action***

The specific goals of the project included

- Developing a more rigorous and systematic approach to the identification and execution of Joint Actions
- Promoting a more consistent approach to market surveillance through the development of best practice and a training programme for market surveillance officials in the field of consumer product safety
- Ensuring adequate liaison between market surveillance authorities and standards development
- Improving collaboration with Customs officials through networking opportunities and the identification of best practice
- Improving operational level collaboration with relevant enforcement authorities outside the EEA

### **1.1.7 Deliverables of the Joint Action**

The following deliverables were identified in the contract

#### **Core Coordination Tasks**

- The continued operation and further development of the RAF
- The continued operation and further development of the Knowledge Base
- Annual compilation of market surveillance plans and the identification of Joint Actions and coordinated activities amongst the member states
- Six coordination meetings
- Two workshops and a final conference
- Dissemination of the results of the project
- Strategy for the further enhancement of market surveillance after the completion of the project

#### **Best Practice**

- Practical guidance to apply the EMARS Best Practice Book to different product sectors
- Guidelines, checklists and other material related to other issues where best practice can be identified

#### **Management and Planning of Future Joint Actions and Coordinated Market Surveillance Activities**

- Development of best practice handbook for the planning and implementation of Joint Actions
- Annual inventory of national market surveillance plans
- Annual programmes of Joint Actions and coordinated market surveillance activities

#### **Risk Assessment**

- Establishment of RAF type risk assessment group
- Manual of contentious risk assessment sand how they were resolved
- System for collecting and publishing data on probability factors.
- Risk Assessment training materials

#### **Market surveillance guidance material for external stakeholders**

- Analysis of stakeholder needs
- Revision of existing corrective action guide if the need is identified
- Production of other deliverables depending on needs identified

#### **Training**

- Development of Training programme based on EMARS Training Strategy
- Development of appropriate materials
- Delivery of pilot European train the trainer events and specialised European training events
- Help delivery of pilot national training events

#### **Continuous improvement of national market surveillance programmes**

- Development of criteria for peer review

#### **Standards related activities**

- Inventory of standards projects of interest to market surveillance authorities
- Procedure for ensuring results of market surveillance actions are fed into standards committees

- Development of protocol for participation of national authorities in European standardisation - where should this take place - relations with consultants and other NGOs,
- European level coordination of activities by national market surveillance authorities through establishment of European Network

#### **Liaison with Notified Bodies**

- Survey national market surveillance authorities on issues arising out of relations with notified bodies
- Identify best practice in respect of these issues
- Establish links with groups of notified bodies
- Report on the feasibility and options for reference laboratories for non-food consumer products

### ***1.1.8 The Activities of the Joint Action***

A modular approach to the activities was foreseen whereby all Member States participating in the project would commit to a core set of tasks aimed at further promoting coordination and cooperation in relation to market surveillance activities. This would primarily be through the exchange of information at regular coordination meetings, participation in the information systems established under EMARS such as the Knowledge Base and the Rapid Advice Forum. Participating Member States would also commit to supply information on their market surveillance activities on at least a yearly basis.

Further tasks were grouped around other specific themes that were identified to have the potential to improve coordination and cooperation on market surveillance activities. Member States choose themselves how many of these initiatives they will play an active role in. At the same time all Member States in the project have had access to the results of the work carried out under these themes through the information systems operated as part of the core coordination tasks. The following Tasks were identified

- A. Best Practice
- B. Management and Planning of Future Joint Actions and Coordinated Market Surveillance Activities
- C. Risk Assessment
- D. Market surveillance guidance material for external stakeholders
- E. Training
- F. Continuous improvement of national market surveillance programmes
- G. Standards related activities
- H. Liaison with Notified Bodies

## 2 Activities Undertaken in the Joint Action

This chapter presents the activities undertaken during the Joint Action, which ran from the 1<sup>st</sup> of November 2008 to the 31<sup>st</sup> of December 2011.

### Meetings

We can differentiate between meetings organised specifically within the framework of the Joint Action and external meetings attended by participants in pursuit of the objectives of the Joint Action.

#### *2.1.1 Other Meetings Attended within the Framework of the Joint Action*

A broad range of external meetings were attended by representatives of the project as means to further the realisation of the aims and objectives of the project and to disseminate the results and raise awareness of the project. The meetings included regulatory committees of different Directorate-Generals of the European Commission, meetings of the European Parliament, international conferences and meetings held by standards development organisations and other interested parties.

A list of external meetings attended is given in an annex to this report.

#### *2.1.2 Project meetings*

A considerable number of meetings were organised within the framework of the Joint Actions to assist in the implementation of the project. These included

- Coordination meetings
- Conferences, workshops, risk assessment seminars
- Task meetings
- Core group meetings
- Management team teleconferences
- Progress meetings with the European Commission

A full list of all the meetings is given in an annex to this report.

##### **2.1.2.1 Coordination meetings**

Coordination meetings with the Member States participating in the Joint Action were held every six months. The aim of the meetings was to keep Member States abreast of developments in the implementation of the Joint Action and to plan for the forthcoming period. These meetings were particularly useful in ensuring that Member States were aware of developments in all of the Tasks even those in which they did not participate actively themselves. This was important to ensure that the work of the individual Tasks represented a broader consensus and the result so that all Member States would accept the work. This also helped leverage the very broad participation in the Joint Action as a whole.

##### **2.1.2.2 Conferences, workshops, risk assessment seminars**

A number of conferences, workshops and risk assessment seminars were held within the framework of the Joint Action. The primary goal of these events initially was to provide a platform for the broader discussion of the best practice being developed in specific tasks. As the project progressed these events provide an excellent opportunity to disseminate the results of the project. The vast majority of these events were open to interested parties.



### **2.1.2.3 Task meetings**

Every Task held a number of meetings throughout the lifetime of the project. On a number of occasions Task meetings were held together. This served to save on travel expenses and exposed the work of the Tasks involved to a broader group of Member States. Use was also made where appropriate of teleconferencing to control costs.

### **2.1.2.4 Core group meetings**

To assist with the coordination and management of the project a core group was established composed of the project leader, Task leaders and consultants. This group served as a focus for project management issues and was especially useful in the launch and earlier on in the project to ensure a consistent approach across the different Tasks and to ensure that there was no unnecessary duplication of work. The group met approximately every six months initially. As the project matured the core group met less regularly and it was possible to meet with a less formal agenda in the margins of other events.

### **2.1.2.5 Management Team Teleconferences**

To help deal with day-to-day issues that arose with the implementation of the project a small management team was established - the PROSAFE Project Management Team (PPMT). This was comprised of the project leader, Executive Director and two senior consultants. This group met approximately bi-weekly by teleconference. The PPMT provided a first point of reference for any project management issues and was able to prepare many different aspects of the forthcoming work associated with the implementation of the project.

### **2.1.2.6 Progress meetings with the European Commission**

Regular meetings were held with DG-SANCO to discuss the formal interim implementation reports and other progress reports.

## **Activities Undertaken at the European Level and by the coordinating body**

The vast majority of the work was undertaken at the European level. The principal working method employed within the project was to bring together groups of Member States at the European level and have them work on developing best practice in respect of different aspects of market surveillance. The structure of the project being broken down into a number of different Task groups allowed for a more efficient allocation of resources by the Member States who were free to choose to participate on those activities in which they were most interested. However the work of the Task groups was also brought back regularly through workshops and consultations to the larger group of Member States participating in the action. This helped ensure the dissemination of the results of the work of the project. The following chapter presents in greater detail the activities undertaken at the European level in respect of the core coordination tasks and the individual tasks.

### ***2.1.3 Core coordination Tasks***

#### **Future Joint Actions**

Much of the preparatory work directed at the identification of future Joint Actions was delegated to Task B. Please also refer therefore to the reports of Task B's activities. The main activity undertaken at the project management level was to ensure that discussion of future Joint Actions featured on the agendas of the coordination meetings and workshops so as to ensure that all Member States were involved. This effort was designed to help maintain a high

level of participation in the new Joint Actions.

## **Knowledge Base**

The interface for the Knowledge-Base (KB) was improved by developing a special PDF-portfolio which can be accessed and downloaded very easily via the PROSAFE website.

Presentations on the KB were given during various meetings in order to make market surveillance authorities more aware of this KB.

Finally, a short questionnaire was distributed near the end of the programme to find out whether the awareness on the KB has improved.

The main thrust of the work done at European level was the presentations given during the Joint Task A, E and F meetings, the Annual EMARS II Workshops and the Training Workshops, regarding the new interface of the KB in order to make market surveillance authorities more aware of the information found on the KB.

A review of the awareness and usefulness of the KB was developed at the end of the EMARS-II programme in order to determine the extent of awareness and usage of this KB.

## **Rapid Advice Forum (RAF)**

Only the management of the activity was undertaken at European level (by the PROSAFE secretariat supported by a consultant). This included the following activities:

- Start-up of task

A work programme was developed and finalised in August 2009.

- Operation of the Rapid Advice Forum

The PROSAFE secretariat monitored the Rapid Advice Forum. This included forwarding questions to the national experts, recording the replies, issuing reminders if questions were not answered within the given deadline and drafting statistics twice a year.

- Promotion of Rapid Advice Forum

The RAF was mentioned in all presentations of the EMARS project and the idea was introduced in all PROSAFE Joint Actions to make the participants aware of the tool.

- Continuous Improvement of the RAF

This activity was partly taken over by Task C as the bulk part of the questions in 2011 dealt with risk assessment and was handled by the Rapid Advice Forum for risk assessment. The activity comprised 2 evaluations of the operation of the RAF: Early 2010 to evaluate the operations of the forum in 2009 and spring 2011 to evaluate the operations in 2010. The major result from the evaluations was the introduction of an objective for the activity: All questions must have at least 2 replies within 2 weeks. Otherwise the secretariat will issue a reminder to the experts.

- Publishing of questions and answers from the RAF

The evaluation of the operation of the RAF in the EMARS project suggested that a list of questions and answers be developed. This idea was taken up as an activity in EMARS II. There is however a consideration about confidentiality of the information: The replies are given by national experts with the intention to inspire other market surveillance officials. They are not considered to be generally available for anybody. Therefore it was decided

to publish the questions and answers on WebEx as only PROSAFE members would then have access to the information.

## Strategy

The experience with the first EMARS project demonstrated the value of an early start on the development of the strategy. Moreover the development of the strategy under EMARS II has taken place against the backdrop of the revision of the General Product Safety Directive and the implementation of the new Legislative Framework. The European Parliament has also focussed very much on market surveillance issues during the lifetime of the project. As a result reflections of the future direction of market surveillance in Europe have been very much to the fore both within the project and at the political level in Brussels. PROSAFE has tried to develop a vision for its own future and that of market surveillance in Europe to feed into the political discussions and this has provided valuable input into the process of developing the strategy deliverable under EMARS II. More specifically a background report was prepared to survey the progress with the implementation of the first EMARS strategy and to reflect on the discussions at the political level. This served as the basis of for presentations and discussions during the EMARS II Coordination meetings and the Workshop held in December 2010. The outcome of these discussions facilitated the preparations for a dedicated Strategy Workshop held on the 15th of June 2011. The presentations included background material on the progress that had been made with the Joint Actions and strategic challenges for market surveillance. The material prepared for the Workshop was well received by PROSAFE's members and the other interested parties present. A draft strategy was prepared reflecting the outcome of the Workshop and circulated widely for comment. The final strategy was adopted later in the autumn and presented during the Final Conference.

## Activities undertaken with respect to horizontal issues

One of the objectives of the project was to ensure a more consistent approach to some horizontal issues that affect a number of the issues being addressed in the individual Tasks. In the reports below on the work of the Tasks we can read about some very specific activities targeting these issues. However there were also a number of initiatives taken at the project management level to help encourage appropriate treatment of these issues by the individual Tasks. These include a reporting obligation being placed on the Tasks to ensure greater transparency of their efforts to address the horizontal issues in their activities. This information has then been fed into the interim and progress reports. A particular effort was also made to showcase the horizontal issues during the Workshops and in the second interim implementation report.

### 2.1.4 Task A

The bulk part of the activities in Task A has been undertaken a European level rather than in the individual Member States. These activities include:

- Organisation of 9 meetings (including 1 half-day preparatory meeting and 3 meetings jointly with Tasks E and F).
- Further development of "The Book"

The work plan for Task A foresaw annual updates of "The Book". Task A consulted with individual Member States and groups of stakeholders such as ADCO groups to identify needs for updates. The only major proposal that came up was the need for updating the risk assessment chapters to accommodate the final version of the method as presented in the RAPEX guidelines.

The revised text was prepared by Task C and introduced in the electronic version of “The Book” in December 2012.

- Development of generic version of “The Book”

The work plan envisaged the development of a generic version based on the relevant chapters of “The Book” to serve as a base for sector-specific versions of “The Book”, i.e. guideline documents addressing particular issues relevant for market surveillance of e.g. electrical consumer products.

A draft generic version (a “guideline for guidelines”) was prepared and discussed in the joint meeting between Tasks A, E and F 19<sup>th</sup> October 2009. This draft was discussed at the following EMARS conferences and PROSAFE meetings to obtain comments from other Tasks and PROSAFE members.

The document underwent a major revision and a more final version was prepared and discussed at the meeting in November 2010. The document was finalised in May 2011 and named “PROSAFE Recommendations for Market Surveillance Guidelines”.

- Development of sector-specific versions of “The Book”

The work plan also foresaw the development of a number of “sector-specific guidelines”, i.e. guidelines adapted specifically to the particular requirements for a particular directive, e.g. the Low Voltage Directive.

Task A started by clarifying the needs in consultations with the ADCO groups and the GPSD committee. This process resulted in the discovery of a number of existing procedures, checklists and guidelines. Task A prepared an overview of these to identify what was missing. This overview turned out to be very useful so Task A decided to continue the compilation of guidelines from the Member States and continue the development of the overview document. At the end of the project some 70 guideline documents had been collected.

Next to this Task A developed 3 sector-specific books (for LVD, PPE and Toys). No guideline was developed specifically for the GPSD as it was noted that it would be similar to the generic guideline.

The 3 sector-specific guidelines were discussed at the meeting in May and it was agreed to end the development even though they had not been completely finished. The participants in Task A however realised that such guidelines would add little value to the guidelines collected from the Member States or to the generic guideline.

- Development of an electronic version of “The Book”

The activities undertaken to deal with this were the following:

The final version of “The Book” was made available on PROSAFE's website in April 2009 by uploading the final PDF file. (Originally it was posted on [www.emars.eu](http://www.emars.eu). It was transferred to [www.prosafe.org](http://www.prosafe.org) when this site took over the contents and [www.emars.eu](http://www.emars.eu) was discontinued.)

Task A then discussed the need for restructuring the text in the Book for web use. The participants decided to go for a limited restructuring that would fit the budget of the activity and respect the nature of the document as a “reference document” rather than a web publication. The result was that the Book was split into its individual chapters and uploaded to [www.prosafe.org](http://www.prosafe.org) next to the full PDF version.

### 2.1.5 Task B

All activities in Task B have been undertaken a European. These activities include:

- Organisation of 8 meetings (including 2 planning meetings between the task leader and the consultant) plus one teleconference between the task leader and the consultant.
- Production of guidance material for Joint Actions (Model and procedures)

The intention was to develop guidance material on how to plan and carry out joint market surveillance actions involving several Member States with or without financial support from outside organisations (e.g. the European Commission). Part of such material was a "model Joint Action", i.e. a workflow showing the steps in a typical Joint Action at the European level.

This first activity was to establish an overview of the activities and "tips and tricks" that should be included in such a guideline. This was done in a brainstorming meeting that took place in April 2009, i.e. very early in the project.

The ideas and statements that were brought forward at this meeting were compiled into a first draft handbook for management of Joint Actions that was ready in September 2009. This draft handbook also included the first draft model Joint Action that was even used to structure the contents of the guideline.

A second draft guideline was discussed at a meeting in April 2010. Several comments were given that significantly improved the book but also meant that part of the contents had to be reworked.

The final draft was discussed in May 2011 and finalised over the summer 2011.

This work however quickly uncovered the need also to develop a book with PROSAFE policies and procedures. One of the purposes was to capture a number of statements from the first meetings that addressed relevant issues with a broader scope than simply Joint Actions. Another purpose was to create a compilation of procedures and approaches that would be advantageous for PROSAFE to have in written form to be able to document e.g. policies. Such ideas had popped up at many different occasions and the main problem had been to have a proper facility to capture the ideas.

This document was developed in parallel to the development of the guidance material for Joint Actions. It was influenced by the development of PROSAFE's charter in 2010, which in turn meant that the development of the guidance material was also influenced.

Both documents were finalised after summer 2011.

The guidelines and the policies have however been implemented in all of PROSAFE's Joint Actions as soon as they were developed. This was done by establishing a "mentoring" function for all PROSAFE consultants where the Task B consultant became responsible for following the work in PROSAFE's Joint Actions and ensuring that the best practiced developed by PROSAFE was actually applied. This consultant also attended the first briefing meeting in Joint Actions 2009 and Joint Action 2010 to show how typical Joint Actions would run and to explain how the best practices were applied. Moreover he would attend the first meetings in several of the Joint Actions, again to familiarise the participants with the practical procedures.

- Develop procedures and tools for management of Joint Actions

This activity was envisaged to run separately from the above one. It turned out however that it was more practical to combine it with the development of the guidance material as the ideas that were stated at the brain-storming session also included ideas for management of Joint Actions so at the end the activity formed an integral part of the drafting of the guideline.

- Develop procedures and tools for identification and planning of Joint Actions

As was the case with the above activity, it also turned out to be more practical to integrate this activity in the drafting of the guideline.

- Collect inventories of market surveillance plans and identify potential Joint Actions and collaborative studies - identify potential Joint Actions

Task B conducted an annual process whereby ideas for future Joint Actions were collected from the PROSAFE members and developed into Joint Actions. The annual process went through the following steps:

- PROSAFE members were asked for ideas for future Joint Actions.
- A list of the most promising ideas was compiled and shared with the participants in the EMARS project.
- Short project descriptions were prepared and circulated to the participants to gather the first indications of interest.
- Potential Joint Actions were identified based on the responses from the participants. Short technical descriptions or pre-proposals were drafted for these and sent to the Commission.
- The PROSAFE members were asked to express their interest in joining the actions.
- Applications for Joint Actions were prepared and submitted to the Commission including an indication of the interested Member States.
- Negotiations with the Commission were undertaken and grant agreements were signed towards the end of the year.

The process was adapted from year to year to accommodate changes in the Commission's administrative procedures and to incorporate the experiences gained from previous year's negotiations. The most notable modification being the single-programme-approach where all activities (directed against several products) are combined into one big Joint Action. The advantage is that the administrative burden per product activity decreases, the flexibility increases (because PROSAFE can shift resources between activities), it is possible to commit a larger number of countries to follow up on the results and it is possible to introduce a lead-participants-principle where only few countries undertake the preparatory work while many countries are involved in the follow up of the results.

In 2011 this procedure proved to work for other types of action, as PROSAFE was encouraged to prepare a proposal for a Joint Action for cooperation with the Chinese export control authorities AQSIQ. This was done using the above procedure.

Activities to prepare proposals for the expected 2012 call for proposals have already started and a first shortlist of ideas for project were prepared during the autumn PROSAFE and EMARS meetings.

- Collect inventories of market surveillance plans and identify potential Joint Actions and collaborative studies - collect market surveillance plans

Another important activity under this activity is the annual collection of market surveillance plans from the Member States. The intention is to gather more input for the selection of ideas for future Joint Actions.

This activity started as a manual activity where Member States were asked to submit market surveillance plans in a list in Excel format. The list identified each project and described it using parameters such as product, product group, number of tests, number of inspections, start and end date, primary objective, plans for international cooperation and contact person.

This approach however meant that it was difficult to search in the lists of plans and data quality was poor (because of errors in spelling, differences in naming of the same properties, different formats and other things). Therefore Task B developed a database that would make it easier for Member States to deliver the information in the correct format. The first year 8 members entered their market surveillance plans in the database.

The database was finalised at the same time as the Commission's SOGS-MSG group developed began to ask Member States to submit their market surveillance plans to DG Entr to fulfil their obligations under the New Legislative Framework. PROSAFE gave input to the development of the criteria that Member State should report to the Commission to ensure that the database was brought in line with the SOGS-MSG requirements with the purpose that Member States could use the database to support and guide their reporting of markets surveillance plans. It was emphasised, though, that a Member State cannot fulfil its legal obligations only by entering its plans in the PROSAFE database. It must send its reports to the Commission.

This means that there is a certain overlapping between PROSAFE's activities to collect plans and the Commission's activities so PROSAFE has spent some efforts in 2011 to explore the opportunities for utilising the plans collected by SOGS-MS directly rather than asking Member States to duplicate their reporting.

### 2.1.6 Task C

The bulk part of the activities in Task C has been undertaken a European level rather than in the individual Member States. These activities include:

- Organisation of 8 meetings (including 2 half-day preparatory meetings).
- Joint risk assessments of cases

Task C has analysed 21 risk assessment cases at its meetings:

- Fire extinguisher
- Sky lantern
- Wooden toy dog
- Residual current circuit breaker (RCCB)
- Children's trousers with a long drawstring around the waist.
- Toy motorcycle driven by compressed air.
- Conveyor belt.
- Cable reel.
- Multifunctional digital instrument.
- Cigarette lighters.
- Bag shaped like a plush cat.
- Antenna amplifier
- Wheel chair swing.
- Winter coat with cords in the hood.
- Chocolate soap (food imitating product).
- Charcoal grill.
- Pushchair.
- Wooden rattle.
- Halogen lamp ("uplight").
- Tricycle.
- Clothes for football fans.

The results have been reported in the minutes from the meetings and particularly interesting cases have been included in the databases with model risk assessments. Furthermore interesting probability factors have been extracted and entered in the database with probability factors.

- Continuous development of risk assessment chapters in “The Book”

The final version of the RAPEX risk assessment guidelines showed a method for risk assessment with subtle differences compared to the one used as basis for the risk assessment chapter in the best practice book from the EMARS project. Therefore it was pertinent to revise the chapter once the RAPEX guidelines were finalised and published. Moreover, the practical work with the method gave rise to further comments and observations to be included.

This was tackled in a two-stage approach.

Firstly the best practice book was transferred to a fully digital version where the individual chapters were accessible on PROSAFE's website.

Secondly, Task C prepared an updated chapter on risk assessment as well as updated annexes on risk assessment terminology (Annex B in the book) and risk assessment case (Annex C in the book). The chapter now shows how risk assessment is carried out using the method exactly as shown in the RAPEX guidelines. Moreover, it has been possible to show how the Commission's web tool is applied to risk assessment cases, thus promoting a uniform European approach.

- Development of network of risk assessment experts, establishment of a Rapid Advice Forum for risk assessment

One of the notable successes of the first EMARS project was the establishing of a Rapid Advice Forum, where market surveillance officials from Europe could ask their colleagues for advice on market surveillance issues.

This idea was taken further in EMARS II by establishing a Rapid Advice Forum dedicated to risk assessment. The backbone of the Forum was the participants in Task C.

The Rapid Advice Forum on risk assessment seems to fulfil a big demand from the Member States as approximately one third of all questions concern risk assessment.

- Development of a manual of contentious risk assessment cases

Task C developed a database with "model risk assessments", i.e. risk assessments that are fairly generic in their nature so that market surveillance officials with access to WebEx can look for inspiration when they are faced with difficult cases. This is expected to further harmonise the risk assessments in Europe.

- System for collection and publishing of data on probability factors

Task C discussed how to capture and publish probability factors and ended up developing a database for this purpose. The members found it particularly challenging to extract probability factors from specific cases and generalise them. It was also seen as a major challenge to ensure that the factors in the database are perceived as inspiration only that must be adapted to each particular case.

- Organisation of risk assessment seminars in 2009, 2010 and 2011

Task C has organised annual risk assessment seminars in the 3 years of the EMARS project. All seminars have been well attended by stakeholders as well as market surveillance officials from



PROSAFE members and from organisations outside PROSAFE and the EMARS projects.

The seminars have developed the concept of a "risk assessment market" where Task C members present different cases at "booths" so that the participants in the seminar can circulate and have face-to-face in-depth discussions of the particular details they find interesting for their work. Such "marketplaces" have featured in the two most recent seminars and seem to be highly valued by the participants.

- Development of risk assessment training material

Task C developed risk assessment training material for future training sessions. The development was based on a list training needs that were uncovered via a questionnaire to all EMARS II participants.

The questionnaire was distributed in November 2009. In total 52 replies were received from 22 countries: 20 EEA Member States plus Turkey and Bosnia. The replies showed that Task C's ideas and intentions were reasonably well in line with the market surveillance organisations' expectations. Moreover they gave a good overview of the different levels that the risk assessors are at and how risk assessment work is organised in the authorities.

Task C then developed training material for two pilot courses, one for the Irish National Consumer Agency (May 2010) and one for the Maltese Standards Authority (September 2010). The outcome of the two courses was evaluated and the training material was adapted accordingly.

The material will be the basis for the development of an e-learning module on risk assessment that is envisaged in Joint Action 2011.

- Customs and risk assessment

Several members of Task C contacted their national customs authorities to discuss their need for training on risk assessment.

It turned out that customs demand very basic information (like which product group, exporting countries and importer to look out for) that could be inputted into their risk profiles. The discussions revealed that there was little need for information on risk assessment methods as customs would always contact the market surveillance authorities once a consignment that fitted the risk profile was discovered. Customs would at the most need check lists with basic checks that could be done in a visual inspection on-site to "test" whether the product potentially was unsafe or not.

### **2.1.7 Task D**

One of the primary, even the most important, part of the execution of the activity of Task D was the need to duly involve a good representation of the stakeholders interested in the performance of the Task. In fact as its definition says, the Task D was meant to develop "Guidance material for external stakeholders".

Several meetings of the Task D and all the different versions of the documents drafted in the frame of the Task D activity were circulated to and commented by the following stakeholders: DG SANCO, DG ENTR, ANEC, BUSINESSEUROPE, Eurocommerce, Orgalime, IFIA that were duly involved in the activity.

### 2.1.8 Task E

The main activity revolved around the development and subsequent training of a number of market surveillance officers via e-learning and training workshops. Additionally, another activity was related to the assistance given by PROSAFE to assist market surveillance authorities to participate more in 'exchange of officials' by trying to act as a 'match-maker' between various market surveillance authorities. PROSAFE also assisted various national training activities by focusing the two European-level training workshops to 'train the trainers'. This ensured a positive spill-over effect when these trainers returned back to their market surveillance authorities since they were able to further train other officers in what they had learnt.

The bulk part of the activities in Task E has been undertaken at European level: These activities include:

- Organisation of 5 meetings (including 2 meetings jointly with Tasks A and F and 2 training workshops).
- Interaction with market surveillance authorities from across the EEA to identify who is interested in attending the exchange of officials programme. A spreadsheet was developed to identify which authorities needed to send market surveillance officers for exchange programmes and to where so that a match could be found across all market surveillance authorities.
- Development, implementation and use of e-learning system made up of 4 modules related mainly to the General Product Safety Directive.
- Development of two training workshops at VWA in The Netherlands to compliment the training given via e-learning. The overall blended approach to learning, that is, the introduction of both e-learning as well as physical training workshops was much welcome by market surveillance officers.
- Questionnaires on both e-learning and the training workshops were distributed to the officers who participated in these activities.

### 2.1.9 Task F

The main activity revolved around the development of a review system amongst market surveillance authorities which has been called CIMS (Continuous Improvement in Market Surveillance), including the development of a guidance document on CIMS which acts as a basic framework for such activities.

Additionally, support was given to the Commission's working group on the Consumer Market Scoreboard. This took the form of direct participation by TASK F participants in that working group as well as giving input from TASK F to the Commission via the GPSD Committee Meeting.

The activities at European level were mainly related to preliminary discussions on how to best undergo a review by peer market surveillance authorities. Additionally, after the two CIMS pilot reviews, further discussions were organised via joint meetings on how to best improve and go about further CIMS reviews in the future. The following activities are being highlighted:

Organisation of 4 meetings (including 3 meetings jointly with Tasks A and Task E).

Development of a Guidance Document on CIMS

Feedback given to the Commission's Working Group on the Consumer Market Scoreboard as well as additional feedback given directly to the Commission and to the GPSD Committee.

### 2.1.10 Task G

The majority of Task G's activities were also undertaken at the European level. These included background research analysing the results of a questionnaire circulated to the Member States authorities. Work was then undertaken on identifying the scope of coordination activities that could be encouraged. A protocol was developed to help ensure adequate liaison between market surveillance activities and standards development. Lastly an inventory was drawn up of standards and standards projects of interest to market surveillance officials.

### 2.1.11 Task H

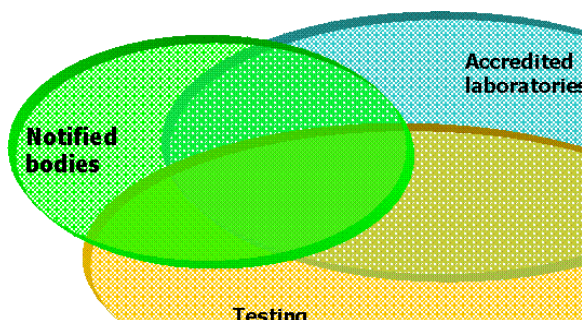
Through the requirements of the NLF, in particular of Regulation 765/2008 and the higher integration between the different Market Surveillance activities, the European Union is moving towards more explicit requirements and obligation being placed on Market Surveillance authorities as far as the reference to expert and accredited laboratories is concerned.

Testing laboratories and Notified Bodies hold a key role in the process of the Market Surveillance; their activity shall be independent and transparent, and their results shall be objective and reliable. Good contacts and working relationships with laboratories on a regular basis will surely have a positive effect by increasing the efficiency of the Market Surveillance activities and reducing the occurrence of dangerous products in Europe

Market surveillance authorities should have very good working relationships with the testing laboratories and Notified Bodies in their Member State and also at cross-border level. When deciding which laboratories should be involved in a Market Surveillance project, a number of considerations must be made and tests should be reliable, substantiated by the use of accredited laboratories wherever possible.

It is important to take into account that several types of laboratories exist based on their status as Notified Bodies and/or Accredited Laboratories, or testing laboratories. It has to be considered that some testing laboratories operating in the European market are neither accredited laboratories nor notified bodies.

The following schema may help in better understanding the situation.



The most important activities that were performed in the frame of Task H at European level were:

- Contacts with EU Commission involved DGs on the best approach to be taken towards Notified Bodies;
- Contacts with European Accreditation with the view to strengthen the contacts with PROSAFE and to have the possibility to contribute to development of the Guidance documents developed by European Accreditation and that are of interest for Task H

Particular attention was given on the need to clearly define the frame of the activities developed by the Task H to avoid they overlap and create undue repetition

of the activities with those performed by the European Accreditation system or under the responsibility of Notifying Authorities.

## Activities Undertaken at the National Level

### *2.1.12 Core Coordination Tasks*

#### **Future Joint Actions**

The main activity that was undertaken at the national level was for market surveillance authorities to identify priorities for participation in Joint Actions at the European level. In those Member States where there are a number of different authorities involved in market surveillance one task for the participants in the EMARS II project was to consult with their colleagues at the national level.

#### **Knowledge Base**

The Member States have consulted the Knowledge Base periodically for their own use at national level.

#### **Rapid Advice Forum (RAF)**

The bulk part of the work with the Rapid Advice Forum has been undertaken at the national level by the experts that have answered the questions.

#### **Strategy**

Obviously the main thrust of the activities in respect of the development of the strategy was at the European level. Participants whoever were encouraged to consult at the national level and with the active discussion at the political level there is no doubt that there have been more discussions at the national level in respect of the future of market surveillance in Europe.

### *2.1.13 Task A*

The main activity undertaken at national level linked to Task A was the Member States' implementation of best practices in their own procedures. PROSAFE has little evidence of the extent to which this has taken place, but during the Joint A-E-F-meeting in May 2010, the group made a "tour de table" to discuss their use of the best practices handbook:

- The PROSAFE secretariat had sent copies to all EU Member States plus a couple of other countries, e.g. Turkey. All 3.000 copies had been handed out in autumn 2011.
- Some authorities indicated that the handbook was used to give guidance to businesses.
- Several authorities indicated that they used the book as a reference document and had implemented it in their national guidelines. Some authorities had even translated the book into their national language to allow an even wider distribution nationally, for instance to inspectors with poor English skills.

It was noted that the Book seems to have been applied in many Member States but language is a big obstacle.

### **2.1.14 Task B**

Only a very small share of Task B's activities was undertaken at national level. The Member States replied to the call for market surveillance plans and did some efforts to reply to PROSAFE's call for information for the applications for Joint Actions.

The rest of the activities were undertaken at European level.

### **2.1.15 Task C**

As already stated in chapter 2.3, almost all Task C activities were undertaken at European level. Member States however carried out some activities to support the work in the Task:

- Reply to questionnaires on training needs and safety of services.
- Several Member States carried out training in risk assessment for colleagues in other units of the authority or for other authorities. This activity includes training sessions in Germany, Cyprus, Sweden, the Czech Republic, Norway, Malta, Ireland and Austria.
- The outreach to customs has been undertaken at national level.

Finally it is worth noting that many of the authorities that participated in Task C carry out risk assessments in their own organisations and go back to Task C to share findings and discuss lessons learned and interesting challenges faced. This work is also seen as a spin-off from the Task C activities.

### **2.1.16 Task D**

In addition to the three Countries: NL, CZ and UK that were directly members of the Task D, all the PROSAFE members were involved by receiving information on the development of the activity in the Task, by answering to a questionnaire that was circulated to ask their views and proposals on the revision of the CAG, to investigate the need for further documentation to help and improve cooperation between market surveillance authorities and stakeholders.

All the PROSAFE members were also required to analyse and to deliver their comments on the draft of the CAG prepared in the frame of the project. It was mentioned by some of the members of the Task D that this was done, in most cases, by duly involving the members of the national Authority.

### **2.1.17 Task E**

The main activity undertaken at national level was the training given within their own authority by those officers (trainers) who were actually trained via the blended learning approach (that is, via e-learning + training workshops). Although most of this internal training at national level was not recorded directly by PROSAFE since it was outside the scope of the grant agreement, in the case of market surveillance authorities from Czech Republic, Lithuania and Malta, in view that they had actually included a number of day of contributions within the Grant Agreement, these were recorded as part of their work that needed to be done. Indeed, the overall feedback has been very positive and practically a large number of inspectors at national level were involved in this training.

### **2.1.18 Task F**

The main activities were the actual CIMS Reviews undergone in Malta and in Slovenia with assistance from peer market surveillance authorities.

- Organisation of two CIMS Reviews
  - CIMS Review in Malta (including participation from Slovenia, UK, Netherlands as reviewers)
  - CIMS Review in Slovenia (including participation from Malta, UK, Netherlands as well as the Project Leader (EMARS-II) as reviewers)

### **2.1.19 Task G**

The main activity undertaken at the national level related to responding to the questionnaire on standards. The pilot informal networks that were also established would also directly involve Member States representatives.

The rest of the activities were undertaken at the European level.

### **2.1.20 Task H**

In addition to the two Countries: NL and NO that were directly members of the Task H, all the PROSAFE members were involved by receiving information on the development of the activity in the Task, by answering to a questionnaire that was circulated to ask their views and proposals on the best ways for cooperation with Notified Bodies and expert testing laboratories, to investigate the need for further documentation to help and improve cooperation between market surveillance authorities and such Bodies.

It was mentioned by some of the members of the Task H that this was done, in most cases, by duly involving the members of the national Authority.

### **2.1.21 Synergies with other PROSAFE Activities**

EMARS II has provided a framework for PROSAFE to further develop its activities on specific products through the launch of other Joint Actions. EMARS II has provided not only a means to identify subjects for new Joint Actions but has also provided a means to develop best practice to be applied in these Joint Actions. The Joint Actions for their part have provided EMARS II with a test bed within which the best practice could be validated and further refined and developed. It is particularly noteworthy that much of the best practice developed within EMARS II has been applied in the new product specific Joint Actions before the deliverables were formally finalised.

In this regard we can in particular point to the work undertaken within EMARS II on the cooperation with customs, risk assessment and liaison with standards development. The concept of a single large Joint Action encompassing a number of different activities as also been adopted in the Joint Actions funded under the 2010 and 2011 calls for proposals.

## **Communications Activities**



## 2.1.22 Communications Strategy

The Communications activities under EMARS II built on the strategy adopted under the first EMARS project. The following activities were foreseen.

- (i) the utilisation of newsletters
- (ii) Further diffusion of information via the websites, WebEx, PROSAFE Meetings & Press Releases
- (iii) Outreach activities to ADCOs
- (iv) Outreach activities to other regulatory authorities
- (v) Outreach beyond Europe
- (vi) Establishment of a Stakeholder Liaison Group

A work programme for communication activities was drawn up. Communications activities for the individual tasks were also identified. Progress on these activities was regularly reviewed and reported on in the progress and interim implementation reports.

## 2.1.23 Awareness-Raising Activities

The Joint Action undertook numerous activities to increase the awareness of the Action:

- Member States and other countries outside the Joint Action

The Joint Action has become a focal point for European market surveillance activities

- The European Commission

DG SANCO of the European Commission is the most important stakeholder for the Joint Action and representatives attended all the coordination meetings and main events and even some Task meetings. Regular progress meetings were also held with DG-SANCO approximately every six months. 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). DG TAXUD of the European Commission was also a key stakeholder, in particular in light of their own project to develop guidelines for the cooperation between customs authorities and their market surveillance colleagues. Representatives from DG TAXUD were invited to key events and participated very actively. DG ENTR with the implementation of the New Legislative Framework was another key stakeholder who was invited to and participated very actively in coordination meetings and key events.

- The EFTA Secretariat

The EFTA Secretariat were also invited to coordination meetings and key events and participated very actively.

- Stakeholders

The Action attracted a high level of interest from a wide range of business and consumer interests. All the main events were open to stakeholder participation and stakeholders were directly consulted on some of the work of the individual Tasks, most notably as reported elsewhere in this report on the revised corrective action guide developed by Task D.

- Outreach to China

Outreach to China was identified as one of the horizontal issues that should be addressed to the greatest extent possible across all the Tasks.

## **2.1.24 Dissemination Activities**

The web-site, newsletters, workshops and Final Conference provided the principal means for the dissemination of the results of the project. Details of the workshops and the final conference are given elsewhere in this report. Six newsletters were produced during the project. The emphasis however shifted to the regular updating of the PROSAFE web site with news stories. All of PROSAFE's activities were consolidated in a revamped PROSAFE web site and the original EMARS web site was mothballed. As a result the web site received greatly increased traffic up from less than one thousand hits a month to almost nine thousand at one stage.

## **Differences between Work Programme and Activities Actually Undertaken**

### **Core Coordination Tasks**

### **Future Joint Actions**

The only difference to the work programme related to the collection of national market surveillance plans. A requirement for the Member States to submit national plans to the European Commission was introduced under the NLF. This essentially pre-empted the activity proposed by PROSAFE in the original work programme. The impact of this on the planned activities is explained in greater detail below under the report from Task B who led this work.

### **Knowledge Base**

There was no difference between the activities undertaken and the initial work programme. However, it is envisaged that more attention should now be given on developing an effective system which could periodically further review and update the information within the knowledge-base itself.

### **Rapid Advice Forum (RAF)**

The work with the Rapid Advice Forum followed the work programme with one exception: The work programme foresaw a kick-off meeting to launch the activity. It was decided to cancel this as the entire activity by and large is a continuation of the similar activity from the first EMARS project with the same participants so there was no apparent need for the meeting.

### **Strategy**

The activity was carried out as foreseen in the original work programme.

### **Task A**

The main differences in the activities undertaken compared to the work programme are:

- Organisation of 9 meetings instead of 6 as budgeted.
- Three of these meetings were organised jointly with Tasks E and F. No joint meetings were foreseen.
- The work plan for Task A foresaw annual updates of "The Book". Consultations however showed no emerging need for updates (besides the one necessitated by the modifications of the risk assessment method as presented in the RAPEX guidelines). Member States rather seemed to focus on their implementation of the guideline in their national systems. Therefore there was only one revision of the text; the revised text for the risk assessment chapters.



- A number of guidelines on market surveillance were compiled. This activity was not foreseen in the work programme but it became evident during the development of the generic version of “The Book” that Member States had developed a lot of guidance material that it would be relevant to share. At the end of the project some 70 guideline documents had been collected.

Sector-specific versions of “The Book” were drafted but not finalised as the practical work showed that such documents added little value to the guidance material already compiled.

## Task B

The work in Task B turned out to be rather heavily influenced from a number of outside sources, which meant that there were a number of changes to the work programme:

- Production of guidance material for Joint Actions (Model and procedures)

This activity was changed in several ways:

Firstly, it turned out to be beneficial also to develop a compilation of PROSAFE policies and procedures. The development of the guidance material uncovered a lot of material having a policy nature. Moreover it was realised that PROSAFE's activities had grown to a volume where it seemed appropriate to establish formal policies to ensure a suitable level of consistency. This activity was included in the work of Task B.

Several changes to the organisation of PROSAFE happened while the policy document was drawn up. This influenced the progress as the policy paper had to await the outcome of the changes. This delay in turn delayed the guidance material for Joint Actions as the two documents were drafted together.

Secondly, the importance of applying the procedures and best practices as early as possible to all of PROSAFE's Joint Actions was acknowledged by PROSAFE's project management team. It was decided to establish a "mentoring" function for all PROSAFE consultants to facilitate this purpose. In practice the Task B consultant became responsible for following the work in all PROSAFE's Joint Actions and ensuring that the best practices were actually applied. During 2010 and 2011, this consultant became the contact point for all enquiries on procedures and practices. Moreover the consultant participated in the consultant's briefing meetings and often also in the kick-off meetings in the product activities.

- Develop procedures and tools for management of Joint Actions

This activity was merged with the drafting of the guidance material for practical reasons.

- Develop procedures and tools for identification and planning of Joint Actions

This activity was merged with the drafting of the guidance material for practical reasons.

- Collect inventories of market surveillance plans and identify potential Joint Actions and collaborative studies - identify potential Joint Actions

This activity by and large followed the envisaged plans except that PROSAFE decided to prepare an application for a Joint Action in cooperation with the Chinese export control authorities, AQSIQ in 2011 in response to the Commission's call for proposal in August.

- Collect inventories of market surveillance plans and identify potential Joint Actions and collaborative studies - collect market surveillance plans

The annual collecting of market surveillance plans from the Member States was changes in two ways:

Firstly, Task B decided to develop a database for the Member States to enter their plans in. The reason for this change was that there were several practical problems with

the original setup where the plans were collected in a list in an Excel file. It was difficult search the list due to poor data quality (e.g. lack of uniformity in spelling, naming and format).

Secondly, the European Commission's SOGS-MSG group launched its efforts to ask Member States to submit their market surveillance plans to DG Enterprise to fulfil their obligations under the New Legislative Framework. PROSAFE aligned the database with the SOGS-MSG reporting requirements to allow Member States to use the database to support their reporting. This option however was not used as a Member State can not fulfil its legal obligations only by entering its plans in the PROSAFE database. The reports must be sent to the Commission.

This overlapping between PROSAFE's activities to collect plans and the SOGS-MSG activities to do the same meant that very few Member States reported their plans to PROSAFE in 2010. In 2011 PROSAFE focussed its activities on exploring the opportunities for utilising the plans collected by SOGS-MSG directly rather than asking Member States to duplicate their reporting.

### **Task C**

The work in Task C by and large followed the work programme with minor shifts of deadlines backwards or forwards in time.

One major difference occurred:

- Continuous development of risk assessment chapters in “The Book”

The work programme foresaw a very strict procedure that would result in annual releases of updated chapters. Task C decided to deviate from this procedure so that the result was one major update released in 2011.

The reason for doing this was that the first trigger that necessitated an update was the publishing of the revised RAPEX guidelines. They were not published until early 2010, thus the 2009 update became superfluous. The 2010 and 2011 updates were combined as this turned out to be necessary to align the finalisation of the document with the meetings in Task C.

### **Task D**

There were no significant differences between the planned work program and the activities undertaken in the frame of the project.

During the discussion had in the several stages of the development of the activity in Task D it was evaluated if any other information material should be made available to stakeholders in addition to the CAG. The opinion of the members of Task D and of all the stakeholders involved in the discussion was that there was no need for further material to be developed at the present stage taking in consideration that the GPSD is currently under revision.

It was considered that making available a revised version of the CAG would, at this stage, perfectly meet the needs of the Market Surveillance Authorities and of the stakeholders.

A summary of the activities performed in the frame of Task D is listed at the end of this document.

### **Task E**

There were no major differences between the work programmes and activities actually undertaken.

### **Task F**

There were no major differences between the work programmes and activities actually undertaken.

Although the deliverable for Task F stated that criteria had to be developed for a Peer Review Scheme, after extensive discussions in various meetings, a decision was taken NOT to go for a direct peer review scheme but rather utilise a more informal approach called CIMS whereby market surveillance authorities were not rated but rather they were still reviewed by peers in an informal manner. At the same time, the guidance document developed on CIMS should help ensure a structured framework of activities when implementing such CIMS Reviews. This was mainly done in order to try to ensure higher participation in such reviews.

### **Task G**

The main difference in the implementation of the work programme was a shift in emphasis away from coordinating direct participation by Member States in standards development work to ensuring adequate liaison between the Joint Market Surveillance activities and standards. This change in direction resulted from a number of factors. Firstly the results of the questionnaire revealed that the level of participation by Member States is low. This obviously restricted the practical amount of coordination that could be envisaged. Secondly the standards-related activities of the GPSD Committee and the Consumer Safety Network grew considerably during the lifetime of the project filling some of the perceived void in the coordination of Member States activities.

### **Task H**

The Project encountered some problems due to the strong engagement European Accreditation had in implementing the requirements of the New Legislative Framework that dramatically impact on their activity and organisation. This was demanding strong concentration from the side of European Accreditation and was considered to be for them the top priority.

In addition, the new managerial duties that the Project Leader had to face in his Organisation caused a sensible fall out on the activity and delays in meeting the foreseen objectives. This caused a slowing down of the foreseen activities; in particular as far as the contacts with EA and other external bodies are concerned and on the planning of the activities to be performed as, in the distribution of activities amongst members of the Task, such strategic activities were taken on board by the Project Leader.

## 3 Results of the Joint Action

### Introduction

The overall objective of the project was to further enhance the market surveillance of non-food consumer products in Europe. This was to be achieved through the practical application of the best practice developed under the first EMARS project and the development of additional best practices.

The project also sought to further capitalise on the improved climate for collaboration amongst national market surveillance authorities that the current EMARS project has contributed to. It was envisaged that EMARS II would provide a framework for closer collaboration within which future Joint Actions and coordinated activities on specific products and other market surveillance related issues could be identified.

There can be no doubt that the project achieved its objectives and was indeed a success. There has been a substantial increase in the number of Joint Actions with the emergence of de facto European level market surveillance programme coordinated by PROSAFE. This implementation of this programme is underpinned by the best practice developed within the two EMARS projects. The best practice has also been implemented in many Member States and even outside Europe. The independent evaluation report presented in chapter 4.6 reflects the success of the project. The success of the project is also underlined by the consensus forming at the political level over the future of market surveillance in Europe that is discussed later when considering the broader impact of the Joint Action. The more specific results from the individual activities and tasks is reported on in greater detail immediately below.

The first EMARS project was considered to have led to a step change in the climate for cooperation amongst member States. It seems only fair to say that EMARS II has been able to capitalise on this and represents a further step change with the launch of so many new product activities and the emergence of an annual programme of market surveillance activities coordinated at the European level by PROSAFE. In going on to examine the broader impact of the project in chapter 4.5 below we will also see that the project has perhaps also contributed to a step change in the thinking about the future of market surveillance in Europe. There is no longer a debate about whether cooperation at the European level is needed or not. Rather the discussion has shifted to how it should be structured and resourced. We will go on to see that there is even consensus emerging about the future direction that reflects the experience gained with PROSAFE's activities. This obviously also reflects well on the outcome of the EMARS II project.

## Results from the core coordination activities

### 3.1.1 Future Joint Actions

Task B led much of this work, so reference should also be made to the chapters of the report dealing with the work of task B. There is no doubt that there has been an explosive growth in Joint Actions during the lifetime of the EMARS II project. In the past four years fourteen separate product activities have been launched with funding in excess of four million Euros. These activities coordinate almost 100 national market surveillance activities. All of the EU and EFTA Member States have been involved in at least one activity with on average each member State participating in five different activities. We have also seen growing participation from stakeholders, customs and the involvement of third countries and outreach to producer nations. The Joint Actions themselves have encompassed a wide range of activities verifying compliance with regulations and standards but also allowing a better understanding of the distribution chain for different products and providing an opportunity further develop and refine best practise for specific products, cooperation with customs and the use of screening tools. PROSAFE has also been able to adopt a programme approach with single Joint Actions awarded in 2010 and 2011 addressing a wide range of different activities. In 2010 these were mostly directed at specific products but in 2011 the new Joint Action addresses a number of products but also seeks to further develop and refine the best practices established under the two EMARS projects. Many benefits are derived from the approach adopted by PROSAFE. There are efficiencies of scale, better cost sharing and the administrative burden is reduced. The single Actions also provide a better platform for cooperation with customs, feedback to standards development, outreach to stakeholders and producer nations, addressing horizontal issues, international cooperation and the implementation of best practice generally.

### 3.1.2 Knowledge Base

The most important deliverable from this particular task is the development of a PDF-portfolio for the KB which served as an easy user-friendly measure so that market surveillance authorities were able to easily access all documents found within WebEx.

An additional improvement made from the last KB developed within the first EMARS Joint Action is a special section within the KB which hyper-links all the important documents and reports from each Joint Action being coordinated by PROSAFE. This has made it much easier to access information on various particular topics from each Joint Action.

From the final review held in November 2011, it was evident that the awareness and usage of this KB has improved.

### 3.1.3 RAF

The most important deliverable from this task are the following:

- Operation of the Rapid Advice Forum

The PROSAFE secretariat monitored the Rapid Advice Forum. This included forwarding questions to the national experts, recording the replies, issuing reminders if questions were not answered within the given deadline and drafting statistics twice a year.

The forum continues to function well and 53 questions have been handled during the EMARS II project. This is somewhat lower than in the first EMARS project where 59 questions were handled in two years (compared to 53 questions in 3 years in EMARS II). One major explanation is that the Lighters Advice Forum handled 26 of the 59 questions in 2007 and

2008. Almost all of these questions concerned the categorisation of lighters (novelty lighter or not). The conclusions were captured in an inventory, which the Member State representatives could consult. Moreover the questions and replies meant that the Member States quickly built up expertise in categorising such lighters. Therefore the number of such questions decreased over time and today there are hardly any questions on novelty lighters.

If the "lighter questions" are subtracted from the numbers, one will find that the level of activity measured by the number of questions has remained quite stable. The first EMARS project saw a level of 16,5 questions per year. EMARS II saw a level of 17,7 questions per year.

The quality of the service has increased steeply from the first EMARS project to EMARS II. In the original EMARS project, eleven of the questions had not been answered one year after they were posted. Under EMARS II only 3 questions remained unanswered. ((Two of the three questions were posted in the first few months of the project.) This means that 94% of all questions had at least one reaction.

The average number of replies to each question was 3,7. Ten of the questions received 6 or more replies. The highest number was 10 replies (to a question on the categorisation of a lighter with scent).

The average response time has increased. During the first EMARS project it was 7,4 days. During EMARS II it was 9,7 days. The statistics however shows that all but 4 questions received the first reaction within the indicative deadline of 10 working days. The remaining 4 questions received their first reaction between 19 and 114 calendar days after the question was posted. The secretariat issues reminders to the experts following a principle of "at least 2 replies in maximum 2 weeks".

The longest time for a reply to arrive was 133 days. This happened for a question where the first reply came in 114 days. The case shows an interesting trend; experts seem to react to each others comments and it is often seen that the first answer promptly attracts a number of supporting or disagreeing reactions.

- Continuous Improvement of the RAF

Two evaluations were carried out: Early 2010 to evaluate the operations of the forum in 2009 and spring 2011 to evaluate the operations in 2010.

The major result from the evaluations was the introduction of the 2-replies-in-2-weeks objective: All questions must have at least 2 replies within 2 weeks or the secretariat will issue a reminder.

- Publishing of questions and answers from the RAF

Almost 100 questions with replies have been uploaded to folders on WebEx.

### **3.1.4 Strategy**

The most important deliverable from this task was the future strategy for the further enhancement of market surveillance in Europe. This was to be the successor to the strategy developed at end of first EMARS project and to present a vision of what the future might look like- a roadmap for a pan European market surveillance programme.

The strategy also provided the orientation for JA2011. The vision for the future is built on three pillars; the establishment of single framework for market surveillance in Europe encompassing both harmonised and non-harmonised products, essentially an amalgamation of the regimes established under the GPSD and the NLF; the establishment of a multi-annual European market surveillance programme and finally the creation of a single coordination body at the European level.

The strategy went on to identify some other issues that needed to be addressed in the short to medium term. These included the further development and refinement of

the systems established under the two EMARS projects, more rigorous priority-setting for future Joint Actions and assessing the viability of developing a home or lead authority principle in Europe whereby Member States would take more responsibility for dealing with economic operators located within their borders. In addition to the new strategy being implemented through JA2011 we also note elsewhere in this report that there are a number of developments at the political level that are seeking to establish a new European market surveillance framework reflecting the vision contained in the new strategy.

### **3.1.5 Outreach to China**

The emphasis that was placed on outreach to China as a horizontal issue delivered a number of concrete results. From 2010 onwards all Joint Actions coordinated by PROSAFE have included where appropriate a component addressing outreach to China. PROSAFE has been working with the European Commission and the Chinese authorities to identify how best to structure the associated activities. The increased attention on China has also led to the launch of a specific Joint Action on cooperation with the Chinese authorities. This Joint Action, launched in the spring of 2012 will provide a framework for the coordination of all PROSAFE's outreach activities helping to ensure a consistent approach and ensure maximum leverage of all the different activities towards the achievement of the common objectives.

## **Results from the individual Tasks**

### **Task A**

The most important deliverables from Task A are the following:

- A generic version of "The Book" (a "guideline for guidelines").
- Draft sector-specific versions of "The Book" for LVD, PPE and Toys.
- A compilation of 70 guidance documents on market surveillance and a document with an overview of the documents.
- An electronic version of "The Book" on the PROSAFE web site - as one large PDF file and chapter-wise.

### **Task B**

The most important deliverables from Task B are the following:

- Guidance material for executing Joint Actions and collaborative market surveillance activities including a "model Joint Action" (a work flow showing the steps in a general Joint Action), procedures and tools for management of Joint Actions and procedures and tools for identification and planning of Joint Actions.
- A book with PROSAFE policies and procedures.
- A method for efficiently sharing PROSAFE best practices among all PROSAFE's Joint Actions and ensuring that they are consistently applied.
- Joint actions 2009. PROSAFE submitted 8 short technical descriptions to the EAHC. This resulted in proposals for 5 Joint Actions targeting baby walkers, helmets, child-appealing appliances, lighters and sunbeds.
- Joint actions 2010. PROSAFE submitted 9 pre-proposals covering 8 product groups to the EAHC. Following discussions with the Commission, PROSAFE combined these into two larger actions targeting in total 7 product groups. After negotiations PROSAFE signed a contract with the Commission for one Joint Action targeting 5 products (ladders, laser pointers, children's fancy dresses, visibility clothing and food-imitation products).

- Joint actions 2011. PROSAFE submitted one pre-proposal covering 4 products plus continued development of a number of PROSAFE core activities such as risk assessment, priority-setting, e-learning among others. A contract was signed with the Commission for this action at the end of the year.
- PROSAFE also prepared and submitted a proposal for a Joint Action in cooperation with the Chinese export control authorities, AQSIQ. A contract was signed on this action also in 2011.
- A database for collecting market surveillance plans from the Member States.
- An inventory of plans for some 150 market surveillance activities in 2010 from 8 countries.
- An inventory of plans for market surveillance activities in 2011 from 2 countries.

## Task C

The most important deliverables from Task C are the following:

- Continuous development of risk assessment chapters in “The Book”

The best practice book has been transferred to a fully digital version on PROSAFE's website where the chapters can be updated individually.

The chapter on risk assessment, the annex on risk assessment terminology (Annex B in the book) and the chapter with risk assessment case (Annex C in the book) were updated to accommodate the newest version of the RAPEX guidelines as well as the Commission's web tool.

- Development of network of risk assessment experts, establishment of a Rapid Advice Forum for risk assessment

A Rapid Advice Forum dedicated to risk assessment was established comprising the participants in Task C.

The Rapid Advice Forum on risk assessment seems to fulfil a big demand from the Member States as approximately one third of all questions concern risk assessment.

- Development of a manual of contentious risk assessment cases

Task C developed a database with "model risk assessments", i.e. risk assessments that are fairly generic in their nature so that market surveillance officials with access to WebEx can look for inspiration when they are faced with difficult cases. This is expected to further harmonise the risk assessments in Europe.

Each case is described using the following parameters:

- Product: An identification of the product in the case.
- Hazard: A description of the most important hazard that is analysed.
- Issue: A description of the main issue that is explored in the case. It can be the probability for a single step in the injury scenario.
- Conclusion: The findings and the conclusion on the issue raised in the case.
- Keywords: A number of keywords that can be used for finding the case later on.
- Scenarios: An attached description of the scenarios that have been analysed, e.g. the summary report.
- Further information: Attachments with supplementary information, e.g. the summary Excel sheet, scientific reports, or the like.
- Data file (for RAG tool): An attached data file that can be loaded into the Commission's web tool.
- Remark: Further information can be added as appropriate.

In total 22 cases have been stored in the database.

- Analysis of cases

Task C analysed 21 risk assessment cases at its meetings:

- Fire extinguisher
- Sky lantern
- Wooden toy dog



- Residual current circuit breaker (RCCB)
- Children's trousers with a long drawstring around the waist.
- Toy motorcycle driven by compressed air.
- Conveyor belt.
- Cable reel.
- Multifunctional digital instrument.
- Cigarette lighters.
- Bag shaped like a plush cat.
- Antenna amplifier
- Wheel chair swing.
- Winter coat with cords in the hood.
- Chocolate soap (food imitating product).
- Charcoal grill.
- Pushchair.
- Wooden rattle.
- Halogen lamp ("uplight").
- Tricycle.
- Clothes for football fans.

The results were reported in the minutes from the meetings and particularly interesting cases have been included in the databases with model risk assessments. Furthermore interesting probability factors were extracted and entered in the database with probability factors.

- System for collection and publishing of data on probability factors

Task C developed a database with probability factors. Each factor is described using the following parameters:

- Factor: A short description of the factor and any conditions that must be fulfilled for the factor to be valid.
- Use: A short description of the context where this factor typically would be used, e.g. an event in an injury scenario.
- Type: An indication of the nature of the factor (anthropometric, geometrical, injury occurrence or product use).
- Value: The estimated probability that the given event happens under the stated conditions.
- Rationale: Describes the rationale behind the value.
- Lower limit: The lowest value that the probability can reasonably take.
- Upper limit: The highest value that the probability can reasonably take.
- Influences: A description of what increases the probability and what decreases the probability.
- Data quality: A figure that describes how reliable the data are on a 4-value scale (1 - estimate by experts, no relevant data backs up the estimate; 2 - single data with personal judgement; 3 - satisfactory default value and 4 - good quality, reliable).
- Proposed by: An identification of the source of information (often a risk assessment case from the EMARS projects).
- Date proposed: The date when the factor was introduced in the database.
- RA Case: A reference to the corresponding case in the database of risk assessment cases.
- Date last revised: The date when the factor was most recently revised.
- Reason for change: The rationale for the revision of the probability.
- Contact person.

Eleven probability factors have been entered in the database.

- Organisation of risk assessment seminars

Risk Assessment Seminars were organised in 2009, 2010 and 2011. More information is presented in chapter 2.2.

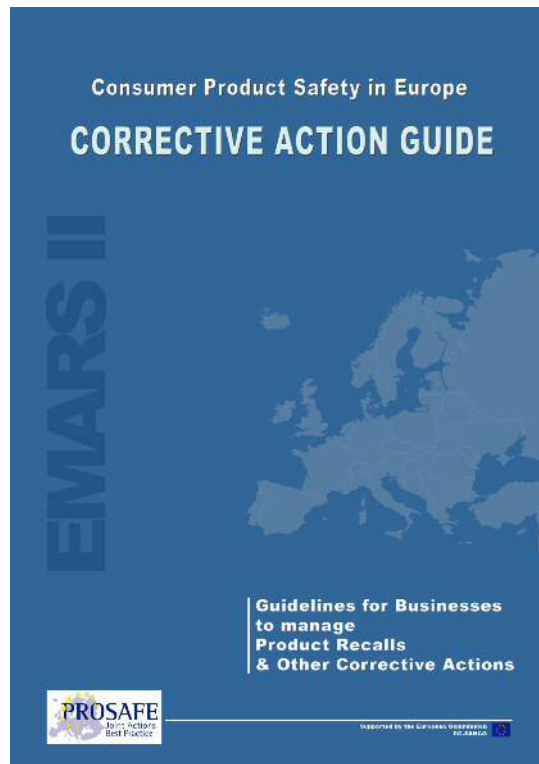
- Development of risk assessment training material

Training material was developed for pilot courses for the Irish National Consumer Agency (May 2010) and the Maltese Standards Authority (September 2010).

An evaluation done during the meeting in September 2010 revealed no needs for further updates.

#### Task D

The specific result of the activity in Task D has been the publication of a revised version of the Corrective Action Guide (CAG).



The main contents of the revised CAG are:

- Obligations of producers and distributors
- Who is responsible for Corrective Action?
- Corrective Action Procedure Checklist
- Assessing the Risk
- Managing the Corrective Action
- Example of a good Corrective Action announcement
- European Information Sources
- Reference to National Market Surveillance Authorities

The printed version of the revised CAG has been made available and distributed at the final Workshop of EMARS II that was held on December 8<sup>th</sup> 2011 and is available in PDF format on the PROSAFE web site.

#### Task E

The most important deliverables from Task E are the following:

- A match-making exercise done by PROSAFE for market surveillance authorities in order to further promote 'exchange of officials'
- A completely new e-learning system in the form of a pilot project.



- Two training workshops that complimented the training done by the e-learning content.
- National training performed by those who have been trained during the e-learning/training workshop sessions, in particular those related to Malta, Lithuania and Czech Republic.

## Task F

The most important deliverables from Task F are the following:

- Two CIMS Reviews organised by Task F Group.
- Development of a Guidance Document on CIMS.
- Feedback from Task F to the Commission and to the GPSD Committee on the Consumer Market Scoreboard.

## Task G

The most important deliverables from Task G are

- Protocol for ensuring liaison between market surveillance activities and standards development
- Inventory of standards of interest to market surveillance officials
- Pilot informal networks

The main elements of the protocol have been taken up in the best practice material produced within the framework of Task B. The inventory obviously presents snapshot of standards of interest to market surveillance of officials now but also identifies sources of information so that the up to date information can be easily be obtained in the future. The success and further development of the pilot informal networks will be very much dependant on the resources Member States make available for market surveillance officials to participate actively in standards development work.

## Task H

The specific result of the activity in Task H have been:

- Setting up and strengthening of contacts with European Accreditation;
- Drawing of specific detailed comments on the basic reference documents developed by European Accreditation and that are of interest for the Market Surveillance Authorities:
  - document EA 2/17 “European Accreditation Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes”,
  - “Best Practices on Communications with National Regulators”;
  - Document EA 1/15 “EA Policy for Relations with Stakeholders”
- Forwarding to European Accreditation of views on criteria applied by members of Task H for:
  - Institutions designated by the notifying Authority and that are authorised to perform certain inspection or certification duties (‘designated institutions’)
  - Institutions designated by the notifying Authority or the certificates of which have been found equivalent by the Authority to those issued by the designated institutions
- Increasing of awareness in the members of the Market Surveillance Authorities on the need of paying careful attention on the characteristics, competences and recognitions of expert laboratories that are not part of their organisation and that may be involved for specific testing and verification activities
- Analysis of the contents of Nando and highlighting of some areas of improvement, e.g.:
  - The information concerning the type of recognition of a given Body is not precise (e.g. a given Body was mentioned as Notified for testing but a

- check on the info submitted by that Body showed they are only accredited for Certification);
- One laboratory was listed to be in EU country whilst it was found that even if the reference was in the UK the tests would be carried out by a laboratory in China;
- no info is given in Nando, if a given Body is also accredited and if yes by which Accreditation Body it is accredited and for which activities/standards;
- The information on the laboratories mentioned seem not to be updated;
- A more detailed Nando system can be more useful and reliable.

## The broader impact of the project

The original EMARS strategy provided a blueprint for the EMARS II project and the activities undertaken within EMARS II have served to implement many aspects of the strategy developed under the first EMARS project. The strategy however also envisaged a European level programme of market surveillance activities to complement national programmes and a central resource to better coordinate the European level activities. The consensus that is now emerging at the political level over the future of market surveillance in Europe now reflects this vision.

The implementation of a multi-annual European level programme for market surveillance is identified by the European Commission itself as one of the 50 actions listed in the recent “Single Market Act”. The Commission have re-iterated their commitment in the recent communication on 12 levers to boost growth and strengthen confidence. The European Parliament also supports this initiative. As we have seen PROSAFE has sought to implement the programme concept through the JA2010 and JA2011 Joint Actions, bringing together a number of different product activities and related horizontal and coordination activities in single Joint Actions.

The European Parliament has lent its support to the establishment of a single coordination body. In an own-initiative report the European Parliament recognized the important contribution made today by PROSAFE as regards the coordination of joint market surveillance actions and the exchange of tried and tested practices in the framework of the GPSD. The Parliament went on to call on the Commission to consider under what conditions PROSAFE could serve as platform for an extended coordination between Member States for harmonised and non-harmonised products.

Interest from other product sectors has also been manifested during the implementation of EMARS II and there is now support for a single market surveillance framework bringing together the existing regimes under the NLF and GPSD and establishing a European market surveillance programme and a single coordination body at the European level.

It would only be fair to say that PROSAFE’s activities in recent years have demonstrated the viability of the approach now being advocated at the political level.

### *3.1.6 Broader impact of the individual Tasks*

#### **Task A**

The work in Task A had two major impacts.

Firstly, many Member States indicated that they were working to implement the best practices described in the best practice handbook. This book was seen to begin to play a major role as reference handbook in market surveillance in Europe and even abroad as it was referenced in many international training and twinning projects.

Secondly, the overview of guidance material worked in the way that Member States began to consult PROSAFE to acquire information on how to carry out market

surveillance on this or that activity rather than start developing their own guidelines from scratch every time.

Both these are seen to increase the uniformity of the ways Member States carry out market surveillance in their respective territories.

Moreover, the guidance material and the best practice handbook have given the Member States a common framework for their discussions on market surveillance procedures. This is seen to increase the common understanding of the different elements in the market surveillance process which in itself will also lead to an increased harmonisation of the approaches across Europe.

### **Task B**

Task B had a very long-ranging impact on market surveillance in Europe as it was the vehicle that was used to produce and conclude applications for Joint Actions. These Joint Actions have over the course of the EMARS II project developed into a very important means that brings together market surveillance authorities from all European countries. This has made a major step change in the European market surveillance environment from occasional cooperation to regular involvement of almost all Member States in large actions targeting several products. This development can be seen as the first steps in the direction of a European multi-annual market surveillance plan.

### **Task C**

The most immediate impact of the work in Task C is that it served as a platform for gaining and sharing practical experience with the new risk assessment method that was developed and published in the revised RAPEX guidelines in January 2010. The first EMARS project featured a working group (WP4) that supported the Commission's working group IRAG with testing of the risk assessment method on a number of practical cases. The procedure was finalised when EMARS II started so Task C could immediately begin to work with the method and get practical experience on strengths, weaknesses, pitfalls and countermeasures. Later on, this experience was shared in training sessions that spread the knowledge to market surveillance officials outside Task C. A study carried out by Task C shows that 25 - 30% of today's RAPEX notifications include a risk assessment based on the new method.

Members of Task C have organised several training sessions across Europe (in Germany, Cyprus, Sweden, the Czech Republic, Norway, Malta, Ireland, Austria among others). Furthermore presentations have been given for other PROSAFE led Joint Actions (e.g. lighters, food-imitation products and visibility clothing) to support the project groups developing generic risk assessments ("model risk assessments") that all Member States can use to do their own risk assessment of particular products.

### **Task D**

The result of the activity of Task D: the revised Corrective Action Guide, will allow to all economic operators active at European and at worldwide level to make use of an up to date document giving clear and easily understandable reference on the best way to approach products recalls and other corrective actions as foreseen by European applicable legislation.

Through the application of the revised CAG the exchange of information between Market Surveillance Authorities and economic operators will be made easier and more fluent, giving the chance of an overall improvement on the approach to evaluation of risk of products put on the EU market and on their correct management in case they have been found unsafe.

## **Task E**

The work done by Task E has shown the importance of training amongst market surveillance authorities across Europe. Indeed, it was quite evident that there is considerable interest in e-learning from amongst various market surveillance authorities since this will not only ensure a more uniform and coordinated approach to market surveillance across Europe but it will also help to minimise costs by being able to learn a number of subject matter on market surveillance/product safety without actually leaving your own country.

The future impact on other stakeholders is also evident. Indeed, such an e-learning system may be used to train Customs Officials, to make other surveillance authorities aware of EEA Regulations and it may also be used to update businesses on European legislation related to product safety issues of various products.

## **Task F**

The work done by Task F has shown the importance of reviewing amongst market surveillance authorities across Europe in order to share best practices and further improve upon market surveillance systems.

## **Task G**

The philosophy promoted by Task G of adequately addressing standards-related issues throughout the Joint Actions was reflected in many practical ways during the lifetime of the project. A number of new Joint Actions were launched where the choice of products was influenced by the existence of new or amended standards and their implementation. Many product-specific Joint Actions carried out during EMARS II also developed very close working relationships with the appropriate standards development community.

## **Task H**

The result of the activity of Task H will give to all Prosafe members and to European Accreditation members the possibility of a mutual exchange of information and proposals on the best approach to be taken on both sides: for the accreditation and designation of Notified Bodies and experts laboratories and for their involvement in the activities of the Market Surveillance Authorities.

The exchange of information will be made easier and more fluent, giving the chance of an overall improvement on the approach to evaluation of risk of products put on the EU market and on their correct management in case they have been found unsafe.

## Analysis of results - lessons learned

### Project generally

As part of the preparations for the Final Conference some consideration was given to the implementation of the project with a view to learning lessons that could help for the future. Individual tasks were asked to identify from their perspective what went well and what went less well. Information from the individual tasks is presented below.

Some of the things that went well included

- Creating real interest and active participation on behalf of the Member States
- Opportunities for Multi-stakeholder discussion
- Concrete results gained during the project
- Developing the horizontal issues approach
- Establishing EMARS/PROSAFE as the focal point for market surveillance in Europe
- Novel approaches to ensure broader participation by Member States in different activities

Things that went less well and that provide learning points included

- Some activities dragging on or losing focus
- Managing expectations amongst project members
- Best practices versus good enough practices
- Using the results
- Linking to national programmes

It was possible to go on to identify learning points relating to a number of different aspects. These were

- Design of Joint Actions
- Execution of a Joint Action
- Dissemination of information
- PROSAFE

### Design of Joint Actions

A number of points can be highlighted. These include the success of the "horizontal issues" approach. A number of novel approaches have been adopted to ensure broader participation by Member States in activities. This includes the single programme approach whereby a number of different activities are grouped together in one action. Also providing for the possibility of different levels of participation in specific activities has also helped promote broader participation. The greater involvement of stakeholders in inputting to priority setting, planning, etc has also been acknowledged as a good direction to pursue.

### Execution of a Joint Action

Issues identified with the implementation of Joint Actions include where appropriate the compression of activities, maintaining the focus on consumer safety. It is also felt important to engage in thorough activity planning to help manage expectations (of the participants themselves as well the stakeholders). There has also been a discussion around the concept of "Best practices" versus "Good enough practices" and an acknowledgement that we sometimes have to settle for a result and cannot always pursue perfection in what we do. It was also noted that some tools are not generally applicable due to differences in national legislation.

### Dissemination of information

There is a need for a further increase in the accessibility of tools and results. The question has been raised as to whether PROSAFE wants to promote itself (to authorities in other jurisdictions, consumers, businesses)?

## PROSAFE

With respect to PROSAFE there is a certain tension around "Development" vs. "Operations"

### Knowledge Base

In order to continue with the success of the KB, it has become evident that one needs to have:

- - continually updated documents & inclusion of new documents on a periodic basis AND
- - a user-friendly interface which can be easily used by as many users as possible.

### RAF

At present all questions and replies are filed in the WebEx document depository so that all PROSAFE members can access them. This is however seldom seen to happen probably because people are unaware of the existence of the information. The questions are however believed to contain a wealth of knowledge so it seems reasonable to increase their accessibility in e.g. an FAQ (Frequently Asked Questions). This however calls for a decision on what information can be public and what information must be restricted to Member State authorities.

### From the individual tasks

#### Task A

The most important lessons learned from the work in Task A is that the work needs to continue to keep the information up to date:

- The best practices handbook will most probably need regular updates as methods and other parts of the contents become out-dated or newer knowledge emerges.
- New guidance material will emerge (from other PROSAFE Joint Actions or from Member States) and existing material will become outdated. This necessitates maintenance of the overview and the compilation of guidelines.
- Member States will need support to their implementation of the best practices.

It was also recognised that it seems to be a problem for the participants to find enough time to do the work for Task A between the meetings. Instead Task A tried with some success to apply a working method where the meetings were longer (e.g. 2-day meetings) allowing the participants to work during the meetings.

Finally it is seen to be a challenge to make all other PROSAFE members aware of the guidance material and where to find it. The existing IT infrastructure doesn't provide enough support to this. An interface has been developed to the knowledge base that seems to be a useful tool until the new IT system being implemented by PROSAFE is in place.

#### Task B

The participants discussed lessons learned during the last meeting in Task B:

- At the end of the first EMARS project, PROSAFE had begun to collect market surveillance plans and develop best practices so the recommendation was to continue and enhance this work to improve the Joint Actions and to improve the cooperation between the Member States. It was a success. All 27 EU Member States and 3 EFTA Member States have been involved in joint market surveillance actions. This was seen to mark a major step forward in the cooperation in European market surveillance.
- Joint Actions are considered useful as unsafe products are targeted at the same time in many Member States, so it is more difficult to "dump" unsafe products elsewhere in Europe. To make this even more efficient, PROSAFE should encourage more Member States to take part and tell more about the benefits.



- PROSAFE does make an impact. Several participants notice this, when they work in other areas where PROSAFE doesn't operate.
- The guidance material was found to be useful in the practical market surveillance work and in discussions with business operators because they show that there are EU-wide procedures for market surveillance.
- Member States should be motivated to increase their use of the WebEx database.
- When planning future activities it was seen to be beneficial to consider how to "compress" the activities to maintain energy and focus when producing the results.
- It was seen to be important to put in place procedures to keep the documents "alive".
- It might be useful to include a session on how to run Joint Actions in a future PROSAFE meeting.

It was suggested to prepare an explanation of the financing model behind the Joint Actions that the Secretariat could send to potential participants.

### Task C

The participants in Task C shared their observations and lessons learned during the last meeting in Task C:

- The work had been a learning experience for all members of Task C and had become very practical during the lifetime of the group. The number of participants as well as the quality of work had increased significantly since the first EMARS project and the members of Task C have become national experts in the RAPEX guideline. The RAPEX procedure was brand new when EMARS II started so it had been helpful to use Task C to gain some practical experience with the method.
- The members of Task C had found that the decision-making in the group was very slow. It takes long time to do a risk assessment and it may be difficult to get the group to make decisions (on probability factors, scenarios, etc.). It seems important to find out how to be efficient in such work in the future so the group could become more conclusive.
- It seems to be a problem to find time to do the Task C work between the meetings, so the biggest progress appears to be made at the meetings. It might be an idea to take this into account when the work in future activities is organised.
- The joint assessment of cases during the meetings and in the Rapid Advice Forum was a very efficient means for aligning approaches to different cases as well as training the participants.
- One of the challenges faced by Task C has been to disseminate its knowledge to relevant outside parties. As a minimum the Task C members should consider how to transfer their knowledge to the colleagues in their countries.
- The participants found that the work needs to continue for a number of reasons:
  - There is a need for future updates of the risk assessment case database and the probability factor database.
  - There is a need for constantly monitoring the functioning of the RAPEX guideline "in real life" and to help the Commission further develop this tool and the web tool.
  - There is a need for further development of the method to answer a couple of principle questions like where to start and where to end a risk assessment.
  - New products will show on the market so the authorities need a group to align their assessments of such products.

## Task D

The main lesson that was learned from the Task D activity is that the continuous exchange of information amongst all interested parties that play a role on the making available of safe products on the EU market can only be beneficial and has to be strengthened.

The discussion of common problems and the search of commonly agreed solutions and approaches, having a clear understanding of the different roles and responsibilities of the involved parties, has proved to be very positive for the increase of the awareness of the common problems and of the different points of view.

Finally it is envisaged that, with the application of the CAG, the presence of safe products on the EU market can be widened.

## Task E

Developing an e-learning platform requires substantial investment. The pilot project within Task E wanted to experiment and identify whether there is enough interest in e-learning from amongst market surveillance authorities. Indeed, the result was very positive.

Additionally, the importance of a blended approach to learning was also recognised, that is, the combination of both e-learning coupled with traditional training workshops. This seems to create the right atmosphere for effective learning.

## Task F

The feedback received from various market surveillance authorities showed that they were not ready as yet to develop a full peer review system. On the other hand, the next best alternative was found to be CIMS reviews. This has tried to integrate a lot of concepts from peer reviewing but in a more flexible and informal manner, whilst keeping a rather structured approach in all activities held in such reviews.

The main concern has been to instigate market surveillance authorities to perform these CIMS reviews since currently most authorities are under tight budgets and have possible lack of human resources, which means that any extra activities such as CIMS reviews, although useful, may not be considered a priority at this point in time.

## Task G

The work of Task G took on a slightly different direction once it became apparent that the direct involvement of market surveillance authorities in standards development was not as great as originally imagined. It was also clear that one of the challenges that Member States face in making resources available for standards development work is that it is not always seen as part of the core business for the authorities. The importance of standards for market surveillance cannot be overstated however at the same time there is a balance to be achieved between the allocation of resources directly on market surveillance activities and on other related activities that complement that principal activity. There is then a need to manage expectations when undertaking such activities in the future and also to always bear in mind the principal aims and objectives of market surveillance authorities and how best to realise these with limited resources.

## Task H

The main lesson that was learned from the Task H activity is that the continuous exchange of information amongst all interested parties that play a role on the making available of safe products on the EU market can only be beneficial and has to be strengthened.

The discussion of common problems and the search of commonly agreed solutions and approaches, having a clear understanding of the different roles and responsibilities of the

involved parties, has proved to be very positive for the increase of the awareness of the common problems and of the different points of view.

## Evaluation Report

An independent evaluation was undertaken as was the case for the first EMARS project. A number of initial findings help place the findings of the evaluation report in context.

Many actors are not aware that EMARS II and PROSAFE are different entities and so intermix them. They did not recognise that one is a programme of activities (EMARS II), and the other is the organisation (PROSAFE) that manages the programme. This evaluation was primarily focused on the EMARS II project, which was just coming to a finish. The evaluation was also required to review the impact of the recommendations from the evaluation report from the first EMARS project. For this reason and the explanation given in the previous slide, some comments related to PROSAFE were in the evaluation.

### Overall findings

EMARS II was an ambitious project that was to continue the development and consolidation of the innovative work done in the first EMARS project. Some of those who sanctioned it did not expect that it would achieve all of its goals. Overall, the evaluation revealed a positive picture of EMARS II. Substantial progress has been made in coordinating product safety market surveillance across the EU. Outputs from EMARS II facilitated a huge increase in the number of Joint Actions, which are currently the best tool for establishing coordination and harmonisation of market surveillance across the EU.

### Driving the adoption of best practice

The core activities, including training and coordination, of EMARS II need to continue if best practice in market surveillance is to be uniformly adopted across the EU. The pilot for CIMS (Continuous Improvement in Market Surveillance) system, which was intended to deliver improvement through peer reviews, was very successful. Ways will need to be found to overcome the reluctance of the Member States to become involved in CIMS activities.

### Involvement of the Member States

There are limits to what EMARS II/PROSAFE could achieve on its own. All Member States have been involved in some way, though southern European countries have been less active. The Member States have responsibility for alerting market surveillance staff in their country to the materials developed in EMARS II. It is for them to drive the adoption of best practice in their country. The example of the Czech Republic was cited which had translated the Best Practice Book from the first EMARS project into Czech and had issued it to all of its inspectors.

### Access to information

There is a substantial amount of material available through the PROSAFE website, much of which will require continual maintenance or some other form of knowledge management in order to prevent it from going out of date.

Potential users of outputs from EMARS II (such as the improved Knowledge Base, Best Practice Guidelines, etc.) will not be able to easily locate and access these materials unless improvements are made to enable better web access.

### Role of PROSAFE



There is strong political recognition that coordination for market surveillance across the EU is necessary. PROSAFE has been widely seen as succeeding in this task as it has been unique in demonstrating, during the EMARS II programme, that it can effectively coordinate market surveillance across multiple numbers of Member States.

### **Challenges for PROSAFE**

PROSAFE has successfully overcome many of the challenges previously identified in the evaluation of the first EMARS project. There remains a need for PROSAFE activities to be based on a more continuous budget basis and not to be totally dependent on project funding. This is a weak business model that impedes investment in staff development and other cost efficient measures. PROSAFE, or an equivalent organisation, would need to be structured differently if this were to be achieved.

### **Differences between Foreseen Results and Those Actually Achieved**

The project overall achieved the results originally foreseen. We have seen from the Evaluation report that indeed the project was perceived to be an ambitious one and it is a testament to the success of the project that it has achieved the projected results without any substantial differences.

#### **Core coordination activities**

The results foreseen for the core coordination tasks were generally achieved. Some remarks below relate to specific activities where there were some differences in the results actually achieved.

#### **Communication activities**

The one difference between the foreseen results and those actually achieved relates to the original proposal for the formation of a stakeholder liaison group. The idea of establishing a stakeholder liaison group was raised with a number of the interested stakeholders. There was some resistance to the establishment of a permanent group as such. This in no way reflected any lack of interest in PROSAFE's activities on the part of the stakeholders. Many stakeholders who have engaged actively in the first EMARS project participated in EMARS II and in the other Joint Actions. The issue was not to find stakeholders to engage with but to manage the expectations of those who are only too willing to participate. Rather there appeared to be a desire on the part of the stakeholders to prioritize their own activities and they have expressed a preference to collaboration with PROSAFE on specific issues and projects. We therefore made an effort to more systematically inform stakeholders of relevant developments and also to ensure stakeholders are involved in issues that are likely to interest them. There were specific contacts with stakeholders in the framework of drafting the EMARS II Strategy and in Task D, especially related to the revision of the Corrective Action Guide (see the report on Task D's activities for further details). It was also proposed to have new Joint Actions draw up specific communications plans and stakeholder outreach plans.

#### **Knowledge Base**

The Knowledge Base has operated as planned. However, it is envisaged that more attention should now be given on developing an effective system, which could periodically further review and update the information within the Knowledge Base.

#### **Rapid Advice Forum**

The Rapid Advice Forum has been operated as envisaged. The number of questions has gradually decreased since the establishing of the RAF but this is not seen as a problem in itself as long as people are aware of the RAF. This seems to be the case as questions keep on coming at irregular intervals.

### **Task A**

Task A has by and large delivered the results foreseen in the work programme with the following major differences:

- The sector-specific versions of “The Book” only exist as draft versions and not as final versions. The participants agreed that such guidelines would add too little value to justify the effort to finalise them.

A compilation of guidance material from the Member States was prepared together with an overview document. At the end of the project some 70 guideline documents had been collected.

### **Task B**

Task B has delivered the results foreseen in the work programme with four important differences:

- The drafting of a book with PROSAFE policies and procedures that was not foreseen in the work programme.
- The implementation of a practice for training and "mentoring" all PROSAFE consultants to ensure that all the best practices that are collected are applied in all of PROSAFE's Joint Actions.
- The drafting of an additional Joint Action for cooperation with the Chinese export control authorities AQSIQ. This was done using the above procedure.

Only few market surveillance plans for 2011 and none for 2012 were collected as the activity was seen to duplicate the Commission's activities in the SOGS-MSG group.

### **Task C**

Task C has by and large delivered the results foreseen in the work programme with one difference:

- Development of a manual of contentious risk assessment cases

The work programme envisaged a manual of "contentious" risk assessment cases but Task C delivered a database of "interesting" cases.

The reasons were that a database was found to be more practical to maintain and use than a manual (understood as a long document) and that Task C found it useful also to provide information on cases where everybody agreed on the assessment and the outcome. These cases were selected from all the cases that the members of Task C analysed including the "contentious" cases where two Member States disagreed on the risk assessment in the RAPEX notification.

### **Task D**

It is considered that Task D met the foreseen planning and the publication of the revised Corrective Action Guide fully fits in the framework of the project.

### **Task E**

Task E has by and large delivered the results foreseen in the work programme.

#### **Task F**

Task F has by and large delivered the results foreseen in the work programme with the minor exception as stated in section 2.7.

#### **Task G**

The main difference has been the shift away from the coordination of participation by market surveillance officials in standards development to ensuring adequate liaison between market surveillance activities and standards development.

#### **Task H**

Taking into consideration the limited time available and the problems commented under item 2.7, some other items need to be further developed in the frame of the activity of Task H:

- Drafting of Best Practices between Member State Authorities/European Accreditation/Notified Bodies and expert laboratories with a list of actions to eventually adapt the contents of the accreditation to the specific needs of Market Surveillance authorities, avoiding unnecessary duplication of activities;
  - A register of all the available competent laboratories may also be developed in the frame of the activity of European Accreditation and updating the current repository managed by European Accreditation on the Accredited laboratories;
  - Definition of basic references on the selection of expert laboratories and what selection conditions apply;
- 4 Criteria for recognition of sub-contracted bodies.

## Annex I. Deliverables Produced by the Action

The following deliverables from the Grant Agreement have been produced.

### Core Coordination tasks

#### RAF

Statistics from the operation of the RAF  
Evaluation of Burden  
Proposals for future operation and development of RAF

#### Knowledge Base

Re-designed interface  
Proposals for future operation and development of KB

#### Six coordination meetings

Reports of meetings

#### Two Workshops and final conference

Reports of meetings

#### Dissemination of the results of the project

Communications Strategy  
Web-site Statistics  
Newsletters

#### Strategy for the further enhancement of market surveillance after the completion of the project

Strategy Document  
Report of Strategy Workshop

#### Notes from Meetings

Core-coordination Meetings  
Workshops and Conferences

### Task A Best Practice

Practical guidance to apply the EMARS Best Practice Book to different product sectors  
Guidelines, checklists and other material related to other issues where best practice can be identified  
Results of questionnaire on market surveillance in relation to the safety of services  
List of documents compiled (check lists etc?)  
Notes from the meetings

### Task B Management and Planning of Future Joint Actions and Coordinated Market Surveillance Activities

Best Practice Handbook for management of Joint Actions  
PROSAFE policies and management system  
Annual inventories of national market surveillance plans - results from annual surveys (DG ENTR started collecting national market surveillance plans half-way through the EMARS II project)  
Proposals for Joint Actions in 2009, JA2010, JA2011 and JA China in 2011  
Application forms for Joint Actions in 2009, JA2010, JA2011 and JA China in 2011  
Signed Grant Agreement JA2010  
Notes from the meetings  
Memo from EMARS II workshops  
List of potential topics for JA2011

## **Task C Risk Assessment**

Statistics from Risk Assessment RAF  
Analysis of Risk Assessment Cases  
Proposals for future operation and development of RA-RAF  
Database of risk assessment cases  
System for collecting and publishing data on probability factors  
Risk Assessment training materials  
Memo on risk assessment of services  
Notes from the meetings  
Revision of the Book Best Practice in Market Surveillance, revision of the risk Assessment Chapters  
Risk Assessment Seminars

## **Task D Market surveillance guidance material for external stakeholders**

Results of analysis of stakeholder needs  
Revised Corrective Action Guide  
Notes from the meetings

## **Task E Training**

Training Programme  
Training Materials  
Reports from pilot European train the trainer events  
Reports from pilot national training events  
Proposals for future operation and development of training activities  
Notes from the meetings

## **Task F Continuous improvement of national market surveillance programmes**

Criteria for peer review  
Reports of CIMS reviews undertaken  
Notes from the meetings

## **Task G Standards Related Activities**

Inventory of standards projects of interest to market surveillance authorities  
Protocol for ensuring liaison between market surveillance activities and standards development  
Procedure for ensuring results of market surveillance actions are fed into standards committees (contained in Task B deliverable)  
Results of questionnaire on standards activities  
Notes from the meetings

## **Task H Liaison with expert laboratories and test houses**

Results of survey of national authorities  
Best practice identified through questionnaire  
Notes of meetings with EA  
Guidelines on co-operation between Market Surveillance Bodies and NBs/laboratories  
Notes from the meetings