

## **EMARS Strategy Document**

### **Further Enhancement of Market Surveillance in Europe**

#### **1. Introduction**

##### **The legal base for market surveillance**

Market surveillance forms one of the most important cornerstones of Community law regarding the safety of products. The General Product Safety Directive lays down the obligation for the Member States to establish or nominate authorities competent to monitor the compliance of products with the general safety requirements. Member States are furthermore required to arrange for such authorities to have and use the necessary powers to take the appropriate measures incumbent upon them under this Directive and to define the tasks, powers, organisation and cooperation arrangements of these competent authorities. The GPSD also requires that the competent authorities have the legal powers to organise checks and take specific measures for products failing to comply with the safety requirements. Finally the GPSD requires cooperation and information exchange between the market surveillance authorities within the Member States and between the authorities of the Member States.

The provisions of the GPSD provide a framework for the enforcement of the Directive through market surveillance. The GPSD encompasses all non-food consumer products; insofar as sector-specific directives do not regulate them. Most of the product-specific directives do not specify the way market surveillance should be performed. As a result the market surveillance provisions of the GPSD fully apply.

For consumer products, the provisions contained in the GPSD provide the market surveillance authorities with the minimum requirements necessary to meet their obligations. There are also provisions on market surveillance within the so-called New Approach to technical harmonisation. Many of the product-specific European legislation has been promulgated under the New Approach. The New Approach has been revised in 2008 as a result of the adoption of the Internal Market Goods Package. The provisions on market surveillance under the New Approach now place requirements on Member States to produce, publicise and implement market surveillance programmes. There are also stronger requirements for checks on products entering the EU that supersede the current legal framework for checks on products imposed from third countries, Council Regulation (EEC) 339/93 on checks for conformity with the rules on product safety in the case of products imported from third countries OJ L 40, 17 February 1993. These provisions come into force on 1st January 2010. Though not completely identical, the new provisions bring the requirements for market surveillance under the New Approach broadly in line with those in the GPSD.

## **The development of market surveillance in the Internal Market**

Market surveillance has been discussed and promoted at the European level in particular since the adoption of the General Product Safety Directive but also within the context of the New Approach to technical harmonisation that also addresses some consumer product sectors. A series of initiatives have been launched over the years to improve market surveillance across Europe. These include the Mutual Joint Visit Programme, the Cross-Border European Market Surveillance Actions Programme and more recently joint actions and the exchange of officials supported within the framework of the current Consumer Policy Strategy. Three major conferences one in Paris in 1999, one in Berlin in 2002 and one in Brussels in 2005 have examined ways to improve market surveillance and all of them supported greater European level coordination and co-operation. The importance of closer co-operation with Customs has been highlighted at the recent Saalfelden conference on preventing imports of dangerous products. The European product safety framework itself has been the subject of scrutiny as the Commission has reflected on the lessons to be learnt from the recalls of the summer of 2007. The Commission concluded that the current EU legislative Framework is considered to be fit for propose – when it is properly applied. The main issue the Commission identified is enforcement with all actors involved needing to raise their game. Industry must take its full responsibilities and whilst national authorities are doing more but the Commission have made it clear that the enforcement of product safety rules needs to receive constant attention and sufficient resources need to be made available throughout the internal market.

### **2. Principles of market surveillance**

The EMARS Open Workshop held in October 2007 resulted in broad agreement emerging around a set of principles concerning market surveillance. The participants at the workshop were drawn from all relevant stakeholder groups. The headline objectives of market surveillance were clearly identified as being

- To protect consumers
- To support enterprise and fair competition
- To base ongoing activity on effective consultation with all stakeholders

In addition the important roles of industry, the European Commission and national governments were underlined. For example in the case of Industry to produce safe products and be prepared to demonstrate their conformity with the legal requirements and the integrity of the CE mark. The Commission/Member Governments can contribute to the overall objectives by making legislation clear, understandable and simple and ensuring the availability of effective and adequate sanctions

A number of principles were identified for market surveillance authorities themselves

- Taking a preventative approach by employing best market surveillance practice and effective communication strategies to inform and advise consumers and businesses
- Targeting serious and deliberately unfair and unsafe products, services and practices by using a co-ordinated risk based approach
- Dealing swiftly and proportionately with problems identified by ensuring offending products, services and practices cease to put consumers at risk

- Being efficient and effective by working in partnerships with other enforcement agencies and co-ordinating operational programmes and practices
- Ensuring market surveillance officials are appropriately trained by ensuring they are aware of the business context in which they operate, employ best practice and are supported by continuing professional development
- Supporting the training of business by sharing training materials
- Resolving problems at source and in a coordinated manner by adopting a lead authority approach as part of a coordinated approach with other enforcement agencies
- Ensuring that all policies and strategies which affect business are relevant, appropriate and clearly understood by a process of consultation
- Market surveillance officials to participate in standard making
- Ensuring a common approach to resourcing to achieve competent and uniform enforcement

These principles can help guide a vision for the future and the strategy necessary to implement this vision.

### **3. Vision for the future**

The complexity of delivering of the above principles across the thirty Member States of the European Economic Area should not be under-estimated and will require considerable coordination, information sharing and cultural change. We believe that this effort needs to be supported by a central resource that is both a clearinghouse for information and a driver of best practice and active collaboration and coordination. To help frame a strategy a vision for the future should be outlined respecting the principles identified above.

Projecting forward a few years all Member States should be collaborating regularly on market surveillance activities. In addition to each Member State pursuing it's own published market surveillance plans there would also be a range of joint actions being carried out at the European or even international level. All of these market surveillance actions would be being carried out in close conjunction with customs and other relevant authorities at the national level, as much as possible.

The priorities for joint actions should be based on an analysis of relevant information such as accident data, consumer complaints, knowledge of the implementation of new and revised standards and intelligence garnered from around the globe on new and emerging hazards.

The results of market surveillance should be readily available and the follow-up of market surveillance actions should be carried out not only in Europe but also in the countries where manufacturing was based. Increasingly more initiatives involving international collaboration and outreach to business will be undertaken in the future by the European authorities to ensure that products are safe at the point of manufacture.

Reflecting the increasing importance of services in the consumer economy the scope of initiatives will reflect the need to address the safety of products and of services.

A central resource should provide a clearinghouse for the flow of information and would have developed expertise in the field of carrying out joint actions. Expertise with respect to

specific products, services and hazards will have been identified and developed in different Member States throughout the EU.

The transparent exchange of information promoted by the intensified cooperation and collaboration facilitated by this central resource and the activities it oversees in turn allows for better identification of priorities at the national level. This effort greatly improves how Member States can deploy the limited resources at their disposal. Market surveillance authorities will benefit from much greater operational efficiency as a result.

Greater consistency between Member States and greater understanding of different national standpoints would be promoted by ongoing European and national level training.

Industry would benefit from the provision of a level playing field and would be given practical help in respecting its legal obligations.

The consumer would benefit from a more consistent approach to enforcement resulting in a more coherent and ultimately safer European market.

#### **4. Main challenges confronting market surveillance**

The recent European Product Safety stocktaking exercise has not only placed the emphasis on enforcement but has also given a unique insight into the challenges facing us.

##### **Overseas manufacturing**

Increasingly consumer products are being manufactured overseas. For example 85% of all toys circulating on the European market are manufactured in China. Chinese manufactured products account for approximately 50% of all the products notified under Rapex reflecting the share of the broader consumer product market manufactured in China. Traceability of products becomes an important issue with a longer supply chain that reaches back outside Europe to the manufacturing nations. The issue of traceability requires closer cooperation with customs and with market surveillance authorities for jurisdictions outside Europe in particular those from the manufacturing countries. The European Commission has concluded that in a global open economy our ability to ensure the safety of products coming onto the European market is also dependant on the strength and effectiveness of international co-operation.

##### **Complexity of regulations and standards**

In particular with the increase in manufacturing overseas it will be necessary to ensure that business has access to up to date information concerning the appropriate regulations and standards to be applied. If necessary to ensure the safety of products reaching Europe's shores, assistance may need to be given in applying the correct requirements during the design and manufacturing process. Closer international collaboration on the inspection of products at the manufacturing plants would also reinforce the effort to ensure only safe products are placed onto the European market. Not only business operators may need help navigating themselves through the product safety framework. It is also felt that market surveillance authorities themselves may need better access to the relevant expertise to help them deal with technical files and test reports. This is to avoid depending exclusively on test reports from notified bodies that in many cases is not a formal legal requirement.

##### **Small Operators**

All businesses large or small have to respect their legal obligations and may need help to do so. Larger businesses are however in the best position to take the ideal holistic approach with safety being embedded throughout the entire product development and production process. Smaller economic operators present a particular challenge as they are generally far less well equipped to deal with safety issues.

### **Effectiveness of corrective action**

There is concern over the effectiveness of recall action. This concern results from recall return rates and the sometimes-different approaches taken by national market surveillance authorities to cross-border recall actions.

### **Adequate Resources for market surveillance authorities**

The responsibility for market surveillance in Europe rests with the Member States. The Member States however have a legal duty to enforce legal framework and the European Commission have a responsibility to ensure that the legal framework is respected by the Member States. The national authorities need to have adequate resources at their disposal to ensure that they can deal with the volume of imported products and Rapex notifications and with the technical complexity of the regulations and standards.

## **5. Specific objectives of the strategy**

The strategy presented below seeks to achieve the vision set out above respecting the principles identified during the EMARS Workshop and addressing the main challenges outlined above.

The main objectives are:

- Developing a more rigorous and systematic approach to the identification and execution of joint actions
- Promoting a more consistent approach to market surveillance
- Improving collaboration with Customs officials
- Ensuring adequate liaison between market surveillance authorities and standards development
- Improving operational level collaboration with relevant enforcement authorities outside Europe
- Providing greater transparency about what the national market surveillance authorities are doing
- Helping economic operators better meet their obligations

## **6. Themes running through the strategy**

We can identify three over-arching themes that run throughout the strategy:

- Exchange of information and coordination between national authorities
- Cooperation with customs
- International Collaboration

### **Exchange of information and Coordination between national authorities**

The value and importance of European level co-operation has been stated time and time

again. A very useful suite of tools has been developed within the framework of the EMARS that has already contributed to a general improvement in the climate for cooperation at the European level. These tools as well as the existing tools such as ICSMS and RAPEX that promote the exchange of information should be continued and be further developed to strengthen and augment the existing level of cooperation. These basic tools also provide a basis for the information exchange that is necessary in respect of some of the more specific issues that need to be addressed. This would also have the advantage of ensuring that all Member States would be aware of and would benefit from the results of other initiatives. Liaison also needs to be maintained with other regulatory committees and ADCOs, customs authorities, other ongoing market surveillance initiatives, with market surveillance authorities from jurisdictions outside Europe and with external stakeholders. Regard also has to be had to other information systems such as the database of consumer complaints and the European Injury database that being developed elsewhere and that could provide information useful to market surveillance authorities.

### **Co-operation with Customs**

The increasing globalisation of the supply chain has had a profound impact on the regulation and enforcement of product safety. Products are increasingly sourced abroad and imported products make up by far the majority of Rapex notifications. This calls for greater co-operation with Customs to ensure that unsafe products do not gain entry to the European market in the first place. To implement this in practice the cooperative network between market surveillance authorities and customs needs to be enhanced. Improved information flow should be directed towards providing Customs with the necessary information to allow them to use risk management to prioritise their activities. Check lists and a Community risk profile are two initiatives that could be useful in this regard. Action on these issues in Europe could also provide a basis for broader international co-operation.

### **International Cooperation**

Improved liaisons with jurisdictions outside Europe are also needed to promote the safety of products circulating on the European market. Liaisons have been forged with many jurisdictions and the value of initiatives such as China-Rapex and coordinated approaches to the producer nations has been demonstrated. The International Consumer Product Safety Caucus (ICPSC) and the International Consumer Product Health and Safety Organisation (ICPHSO) provide two useful arenas within which to discuss further deepening of international collaboration. The OECD will also provide some sort of focus for discussion during their forthcoming project. Further efforts should be made to improve coordination and liaison with other jurisdictions to promote the spread of best practice, identify opportunities for the convergence of regulatory requirements and to deal effectively with emerging hazards. These efforts will further improve the efficiency of market surveillance in Europe and in particular help deal with the issues raised by the globalisation of the supply chain.

## **7. Specific Issues to address**

These three themes also run through a number of specific issues that need to be addressed. These are:

1. Best Practice
2. Management and Planning of Future Joint Actions and Coordinated Market Surveillance Activities

3. Risk Assessment
4. Market surveillance guidance material for external stakeholders
5. Training of Market Surveillance Officers
6. Continuous improvement of national market surveillance programmes
7. Standards related activities
8. Liaison with Notified Bodies

## **7.1 Best Practices**

Under the current EMARS project an effort has been made to identify best practice related to market surveillance techniques and these have been set down in a Book to be published at the end of the project. This marks an excellent first step towards encouraging a more constant approach to market surveillance throughout the EU. At the same time there is a need to evaluate the use of the book over a longer period of time, to examine the need to develop best practice in new areas and to develop guidance material to help implement the best practice contained in the Book for specific product groups. Future activities then should be directed towards assessing the practical application of the EMARS Book and then also using the Book as the basis for more detailed guidance in respect of specific products, sectors or directives and regulations. Best practices could be made available for stakeholders in order to improve transparency.

Attention also needs to be given to identifying Best Practice with respect to cooperation with Customs. The ongoing Baltic Sea co-operation, the initiatives undertaken in the framework of the lighters joint action and the conclusions of the Saalfelden conference on Preventing Imports of Dangerous Products provide a basis for developing this very necessary co-operation. The recommendations of the conference call for example for the development of appropriate best practice guidelines.

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

Discernable improvements in the planning and implementation of cross-border market surveillance actions can already be detected in the operation of the European Commission's Action 8 under the community consumer policy action plan. More joint actions have recently been launched. These new actions and the ongoing lighters project have seen the adoption of a novel approach with Stichting PROSAFE as the contracting party with the Commission. The emergence of a European partner has allowed many more Member States to commit to participate in the joint actions. There is tremendous scope then in increasing the number of joint actions within the meaning of Action 8 and also in promoting coordinated actions that do not require substantial Community funding. At the same time all this needs to be done in a more rigorous and objective manner. The implementation of joint actions would also benefit from the development and application of appropriate of best practices.

There is a need to identify the best practice emerging from the joint actions undertaken in the past few years. In particular, regard has to be had to the experience being gained with the large number of Member States participating in the cigarette lighters project, the collaboration with customs being undertaken in this and other projects and to identifying different levels of engagement that Member States can have in joint actions so as to encourage as many Member States as possible to participate in joint actions in the future. The best practice so identified should be used to develop guidelines and procedures for the more

efficient execution of cross-border joint actions that serve as a very useful complement to national market surveillance plans.

### **7.3 Risk Assessment**

Risk assessment cuts across a number of the activities of market surveillance authorities. Best practice has been identified within the EMARS project and the revised risk assessment guidelines developed within the IRAG working group. The best practice developed under EMARS will require further evaluation and development. However in addition and in response to a need identified during the development of IRAG training materials and a training module for risk assessment should also be developed. Risk assessment can also be integrated into the EMARS Rapid Advice Forum thereby establishing an informal standing group of risk assessment experts to advise on risk assessment cases. This group would also be able to provide advice to work on standards. Other useful initiatives could include the development of a “chemrisk toolbox” – i.e. a toolbox with factors, studies, numbers, methods, etc. relevant for risk assessment and the establishment of a collection of “contentious” risk assessment cases and how they were resolved to be used as a sort of manual for market surveillance authorities (see for example:

[http://ec.europa.eu/enterprise/cosmetics/doc/manual\\_borderlines\\_version40.pdf](http://ec.europa.eu/enterprise/cosmetics/doc/manual_borderlines_version40.pdf)). The feasibility and the best way of setting up a system for collecting and publishing data on probability factors could also be investigated to complement the new approach under the RAPEX guidelines. An annual risk assessment forum in the field of non-food consumer safety could be held in conjunction with a training event and help promote the development and implementation of best practice in risk assessment for non-food consumer products. Consideration could also be given to promoting closer collaboration with Customs through better consideration of consumer safety in the risk assessments carried out by Customs as part of their inspection activities.

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

The majority of business seeks to carry on its activities in a responsible manner and desires to comply with the appropriate legislation. In order to help business fulfil its obligations guidance material has been developed e.g. Corrective Action Guide. The pace of regulatory developments in Europe however requires that such guidance be revised periodically to keep it up to date. It may also be useful to develop other guidance material directed at specific sectors or products. International initiatives aimed at promoting good practice amongst the business community are also to be welcomed and supported.

The current Corrective Action Guide could be revised with particular regard to the finding of the Commission’s stocktaking report that return rates of recalled products especially of lesser value products are very low. Best practice in improving rates of returns from recalls could be examined and where appropriate incorporated into the corrective action guide.

### **7.5 Training of Market Surveillance Officers.**

Training is being successfully applied to the food safety sector. The non-food sector could also benefit through spread of best practice, the exchange of ideas and experience between officials from different countries helping to increase understanding.

A training strategy has been developed within the EMARS project. The strategy foresees a

programme based around six pillars. These are:

1. Web based learning on basic principles and regulation
2. Participation in national market surveillance projects
3. Courses and workshops nationally and EU-based
4. Exchange of officers within EU
5. Joint cross-border projects within EU
6. Train the trainer for the use in training field officers nationally

A training programme could be developed based on these pillars and a number of pilot schemes carried out that would point the way to the future implementation of the training strategy. The training programme could include European train the trainers events, European level training events on specific topics, examination of web-based training based on the EMARS Best Practice Book, coordinating the exchange of officials and using joint actions as the basis for training. The training programme could also provide training concerning the tools that have been developed within the first EMARS project and that are being further enhanced under EMARS II e.g. Rapid Advice Forum and the Knowledge Base. This would also serve to help promote the more widespread use of these tools at the national level. Consideration could also be given to the feasibility of joint training with customs officials and to offer participation to business in order to develop market surveillance as a tool for business itself.

## **7.6 Continuous Improvement of National Market Surveillance Programs**

With the GPSD, the ongoing revision of the New Approach and the development of the scoreboard for better consumer markets the European Union is moving towards more explicit requirements and obligation being placed on market surveillance authorities. One way to help national authorities continually improve their own programmes would be through mutual inspection visits and objective independent assessment of their activities. This activity will build on the exchanges of officials currently being undertaken and identified as an important part of the training strategy and also seek to examine the feasibility of developing criteria for independent audits of national market surveillance programmes. Regard should be had to the previous experience from the Mutual Joint Visit Programme, the activities in the food safety sector and other relevant initiative undertaken for example by the OECD.

## **7.7 Standards related activities**

European Standards form the primary reference sources for very many market surveillance activities. It is imperative for their consistent application by market surveillance authorities that the market surveillance authorities have confidence in the content of the standards and can apply them correctly. This implies that market surveillance authorities participate in the development of standards and that there is feedback from the particular experience of the adequacy of the European standards that is to be gained through market surveillance activities. An active participation of the national authorities has been encouraged at a political level throughout the development and implementation of the New Approach. However whilst other stakeholders such as consumers, trade unions, SMEs and environmental groups have developed networks to coordinate their participation and thereby ensure the efficient use of their resources, national administrations have not to date coordinated their activities to the same degree.

A primary concern should be to coordinate the input of national market surveillance authorities into the standards development process. This is not to be done by replacing or even supplementing participation at the national level with direct representation at the European level but rather through improving the transparency and efficiency of participation at the national level. This could be achieved through maintaining an inventory of national activities and through coordinating the direct participation of market surveillance authorities in their national standards bodies. At the same time effective feedback mechanisms could be developed on the back of existing information systems especially in the case of joint actions and national market surveillance activities. Through the coordination activities market surveillance authorities may also be in a position to offer support and advice of the Commission on mandates and the process of publishing references in the Official Journal under the GPSD.

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

Following the revision of the New Approach the activities of the notified bodies are to be much more closely monitored. Much of this work is to be undertaken by European Accreditation (EA). At the same time it will also be useful for there to be greater coordination between the notified bodies and national market surveillance authorities with respect to the interpretations they apply with respect to the European Standards and in the absence of such standards the test protocols they apply. Some effort could then be made to improve the liaison between the groups of notified bodies that already meet and the national market surveillance authorities. Research could also be carried out into the feasibility and options for reference laboratories for non-food consumer products.

## **8. Implementation of the strategy**

There are a number of measures already proposed that would serve to help implement this strategy. These are being proposed within the framework of existing consumer policy strategy, the follow-up of the stocktaking exercise, a number of joint actions such as EMARS II, the Baltic Sea Co-operation and the implementation of the internal market goods package. A compendium of these measures is given in an annex to this document. In addition the one major development that could serve to underpin the implementation of this strategy and the long term sustainability of the action envisaged would be the establishment of a more permanent arrangement for collaboration between national market surveillance authorities at the European level.

### **Professionalization of support for closer cooperation amongst market surveillance authorities**

It is clear from the experience that has been gained over the past few years that the existence of a central resource at the European level is essential to the continued improvement of market surveillance in Europe. This should be a medium to long-term objective but a means should be found to ensure that there is a core competency at the European level that is given sustainable funding. The Commission has acknowledged in the analysis of the stocktaking that product safety is an issue that needs constant attention and the allocation of adequate resources. This is equally true at the national and European levels. The emergence of Stichting PROSAFE as a contracting party with the European Commission on behalf of the Member States is a development that is worth pursuing and may form a good basis for the professionalization of the support for European level activities in the future.