EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Regulatory policy
Regulatory approach for the free circulation of goods and market surveillance

NOTE TO THE SENIOR OFFICIALS GROUP ON STANDARDISATION AND CONFORMITY ASSESSMENT POLICY – MARKET SURVEILLANCE GROUP (SOGS-MSG)

Title:	**CERTIF 2011-02 - Draft ROADMAP – Enhancing the Market Surveillance enforcement for goods – A multi-annual plan**		
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Abstract:

The European Commission has identified market surveillance as an area where further developments are essential to ensure proper implementation of Regulation 765/2008 and the GPSD in particular. Among the 50 actions listed in the "Single Market Act", the development of a multi-annual market surveillance plan is foreseen.

The political objectives of this plan are included in the attached roadmap. In its Annex are identified, for the eight range of activities specified in the roadmap, the market surveillance activities that should be further developed.

The market surveillance plan applies to products covered by the Regulation 765/2008/EC and Directive 2001/95/EC (GPSD). The activities should be intended to protect the public interests such as health, safety, protection of consumers, environment and energy efficiency.

This paper has the following objectives:

1. to report on the political objectives as set out in the roadmap. It reports in particular on the general orientations and background as well as on the specific areas where market surveillance initiatives should be developed and/or enhanced;

2. to provide a draft of the future activities to develop in relation to the specific areas reported in the roadmap.

The majority of the activities are sector-oriented and should be developed taking account of the specificities of the harmonised and non-harmonised products.

Keywords:	Market surveillance, national market surveillance programmes, exchanges of information systems, cooperation, trainings, restrictive measures, statistics , …
References:	Regulation 765/2008; Decision 768/2008/EC Directive 2001/95 (GPSD); RAPEX system;

ROADMAP			
TITLE OF THE INITIATIVE	**Enhancing the Market Surveillance enforcement for goods – A multi-annual plan**		
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A. Context, problem definition

(i) What is the political context of the initiative?

(ii) How does it relate to past and possible future initiatives, and to other EU policies?

(iii) What ex-post analysis of the existing policy has been carried out and what results are relevant for this initiative?

The European Commission has identified the re-launch of the single market as one of the strategic initiatives in its working programme for 2010. President Barroso in his Political Guidelines of 2009 asked for an in-depth analysis of the "missing links" for a proper implementation of the internal market, and for a plan to bring forward measures for its achievement in time for the 20th anniversary of the 1992 Internal Market achievement.

Further to the request of President Barroso, Prof. Monti presented in May 2010 a report on a new strategy for the single market where he pleads for a dynamic and expanding single market for goods. The report considers that the new regulatory framework (more often called "New Legislative Framework" – NLF) adopted in 2008 fully implements in particular the market surveillance framework.

The Commission reiterated the same request in its Communication to the EP and Council on "An integrated industrial policy for the globalisation era" of October 2010. The project is also fully integrated in the EU2020 strategy and the better regulation principles.

The NLF has the objective to strengthen the effectiveness of the Union's legislation on product safety. Its effective implementation brings a modernised and simplified legal environment for businesses, strengthens the safety of products available on the market, and ensures a better internal market functioning through, inter alia, equal treatment of economic operators. It consists of two complementary instruments, Regulation 765/2008/EC on accreditation and market surveillance (and repealing Regulation 339/1993 on customs controls) and Decision 768/2008/EC establishing a common framework for the marketing of products. The Regulation came into force on January 1st 2010, while the Decision provisions have to be included in the existing legislation when reviewed.

In the EU, market surveillance organisation is covered by the NLF for the products covered by Community harmonisation legislation, the GPSD (General Product Safety Directive 2001/95/EC) and by sector specific legislation, thus:

- The Decision harmonises mainly the obligations of the economic operators such as manufacturer, importer, distributors, as well as the procedures for the withdrawal or recall of dangerous or non-compliant products and safeguard clauses. Clear obligations for economic operators in the supply chain are essential for the proper functioning of the single market in the harmonised area.

- The Regulation strengthens the foundations of an effective policy in the EU for the surveillance of products placed on the market and controls of products coming from third countries.

- The GPSD ensures a high level of consumer protection with general obligations for producers and distributors, on market surveillance for products already placed on the EU market under its scope and on a rapid exchange of information and action, RAPEX.

The Commission is very active in ensuring the enforcement of GPSD provisions (see Decision 1926/2006/CE). In addition, since the adoption of the NLF, the Commission started initiatives for its implementation. They were

joined by other initiatives coming from the EP, the European Council, the Member States and also stakeholders. Their common objective is to strengthen the implementation of the EU market surveillance framework.

In fact:

- In 2009 the Council, under the Swedish Presidency, all interested parties met in Stockholm and made recommendations for the future based on a survey of the needs and possible ways forward.

- The EP has seen market surveillance as an instrument, in a globalised market, in fighting against the negative effects of the crisis and of unscrupulous operators. Reports from Mrs Hedh and Mr Grech and studies ordered by the IMCO Committee in 2009 and 2010 - which form the basis of the still to be adopted report of Mrs Schaldemose on the review of the GPSD and market surveillance - are the most important.

- Member States are also conscious of the importance of uniform market surveillance in the EU. Already in 2008, they asked for more cooperation between MS and the Commission for a common enforcement. They are aware of the stagnation/lack of resources in this area, which has been denounced by the EP.

- The European stakeholders have also tested the EU market and reported (see ANEC-ORGALIME joint statement, BUSINESSEUROPE, CECE, etc. views) on the negative consequences that failures of the EU market surveillance system can cause to the functioning of the internal market such as, in particular, the distortion of the market, high costs and burdens for all parties, unsafe and non-compliant products on the market, unfair competition, etc.

Market surveillance is an activity which is primarily the responsibility of the Member States, especially in relation to its organisation and operation. The Commission recognises its high importance for the completion of the internal market and for the protection of the health and safety of the citizens, but also in relation to energy issues and the environment. Accordingly, it has been included in the 50 actions listed in the “Single Market Act” as well as in the Communication on industrial policy mentioned above.

Against this background and in response to the above-mentioned political priorities, in particular the re-launch of the single market, appropriate means and ways have to be explored to enhance the implementation and enforcement of the EU market surveillance framework. The purpose of the initiative is to assess to which extent this can be done on the basis of the EU market surveillance objectives and with a view to contributing to industrial sectors covered by the Regulation or GPSD to which the market surveillance framework applies.

What are the main problems which this initiative will address?

The initiative aims to address market surveillance organisation failures arising from non-compliant or dangerous products on the EU market e.g. lighters, eco-design, cosmetics, medical devices, machinery, electrical appliances, bicycles, child care articles, etc. to which the Regulation and/or GPSD apply.

For a long time market surveillance has been considered by Member States to be an activity that comes under the subsidiarity principle because, it was considered that there was no added value at EU level. Over the last decade views among Member State authorities have evolved, with increasing demands for greater coordination at EU level, partly as a result of Member States' own positive experiences in enforcement cooperation.

With the adoption in 2008 of the Regulation, the intention of the EU legislator was to have a stringent common framework for the organisation and performance of safety controls of products on the market or coming from third countries. Its proper implementation alongside the GPSD provisions is essential to achieve its objectives i.e. the protection of citizens and to ensure fair competition across the Single Market. However, the proper achievement of these objectives requires coordination on the basis of long/medium term forecasts to respond to the EP and Commission opinions.

The legal market surveillance system still in place leaves the responsibility to MS to organise and carry out market surveillance, which in particular requires national market surveillance authorities (including customs) to be entrusted with the powers, resources and knowledge necessary to properly perform appropriate checks on an adequate scale.

The range of products to control is very large thus national market surveillance system need to be very well organised to ensure that only safe and conforming products are on the market. Accordingly, national products infrastructure and programmes shall ensure that effective measures are taken in relation to any product category.

Moreover, the Regulation and GPSD establish the activities to be performed by MS to comply with the common framework for market surveillance e.g. follow-up complaints, monitor accidents, follow up scientific and technical knowledge, perform documentary, physical or laboratory tests on the basis of an appropriate risk assessment, inform the public, organise cooperation at regional, national and European levels, cooperate with stakeholders, verify the corrective measures taken, follow the restrictive measures, etc. The same measures have to be taken

in relation to products imported from third countries.

Although, MS have the experience and means to control products on their market:

- there are important changes in the market organisation due to globalisation. Accordingly the organisation of controls have to be adapted to the new environment since more products are imported and controls have to be performed at borders instead of on the EU market when the products are already distributed on EU territory; and

- the economic crisis has drastically reduced the national resources available for this purpose.

In addition, this situation creates unfair and fierce competition, in particular between operators concerned by imported products. Honest manufacturers suffer from the situation and ask for appropriate controls to reject products that are unsafe and/or non-compliant and restore a level playing field and save them from bankruptcy since these products are often sold at lower prices.

The large number of dangerous products notified in RAPEX also demonstrates how it is important to control the safety aspects of products on the market in order to avoid accidents that can be fatal. For more information visit: http://ec.europa.eu/consumers/safety/rapex/index_en.htms

The experience of a limited number of general and sector-specific joint actions has shown that market surveillance could be better organised and even performed at the EU level; thus the general knowledge is taken into account which profits to all in a shared environment.

However, the main objective will be the definition of a general approach that has the goal of increasing convergence of the different national systems. This shall be supported by a list of initiatives (see Annex) i.e. forums, communication and information IT tools, programmes fixing items/issues to be developed during a specified period of time and deadlines, etc. (e.g. until 2020). The initiative aims at providing appropriate answers to the challenges facing market surveillance in the EU by creating systems or by assessing means and approaches currently in use and find common solutions to the problems and needs under this initiative which are common to consumer and professional products i.e. products covered by Regulation 765/2008 and GPSD. The multi-annual plan will involve EU financial support to all of these activities, provided that the necessary budgets are made available.

1. Organisation of market surveillance in general

The provisions on market surveillance require efforts from all concerned parties - i.e. the various national authorities including customs and the Commission - because they are more stringent than in the past and contain new obligations. MS are obliged to act in the presence of non-compliant and/or dangerous products.

It is widely known that the control of the compliance of goods with the relevant Community or national legislation is an activity which is primarily the responsibility of the Member States, especially in relation to its organisation and proper operation. Health and safety protection, but also protection of workers or environment or energy efficiency is certainly a public activity.

For long time Community legislation has provided for a general obligation on MS to make sure that only compliant and safe products which do not endanger the users are placed on their market. It is now also recognised that market surveillance organisation and implementation is a shared responsibility and not the responsibility of an individual MS since, in a globalised market, a product placed in one MS can easily be found and sold in another MS. A shared responsibility will help to increase trust in the system, but also create benefits of scale (e.g. better use of resources, shared best practices, tests not repeated etc.) and benefits to the citizens (e.g. more controlled products on the market and fewer accidents).

All concerned parties, in particular the EP and some European organisations, are of the opinion that a lack of intervention at the EU level will create unreachable gaps between MS, considering the different levels of available resources. These enormous gaps are now more significant than in the past when the majority of goods were manufactured in the EU.

EU sectoral legislation focuses on the manufacturing process and there are few provisions as regards the responsibility of MS to organise and carry out the controls of in-house or imported products, or the responsibility of the economic operators when placing on the EU market products coming from third countries. The economic crisis, in addition, has not helped MS to fight alone against unscrupulous economic operators, as in principle the EU legislation requires.

Effective and consistent general market surveillance organisation will entail activities and actions which will contribute to an overall accepted system in which all actors can have confidence e.g. horizontal skills, training and exchange of officials and experience, common approach for checks, follow security-standards developments, etc.

2. Specific needs for controls at borders (custom controls)

Regulation 765/2008, for the first time, introduces a clear obligation for authorities responsible for controls of products entering the EU market to perform checks on the safety of imported products, both consumer and professional goods before the goods can be released for free circulation by customs. It also provides for the possibility to destroy dangerous goods, since experience has shown that products often subsequently re-enter the Community market at other points of entry, thus annihilating the efforts of all the authorities involved in the control process.

The Community has organised common rules for the processing of compliance control on imported goods since 1993 by the Regulation 339/93. Its main objectives were confirmed by the Regulation in 2008 and also enlarged. The main elements are:

- Performance of checks of a very large range of goods prior to import on an adequate scale n;
- Suspension of importation by customs in case of suspicion;
- Feedback from the market surveillance authorities within 3 working days.
- Close cooperation between Customs and MSA to ensure efficient enforcement and implementation of the product safety controls at borders.

However, experience shows how difficult the organisation of border controls on the compliance of goods can be. What is maybe feasible for the protection of public health, is not so for manufactured goods for several reasons:

- The diversity and the quantity of imported goods governed by EU requirements;
- The diversity of the expertise needed to check compliance of the diversity of products (compared with the counterfeiting checks);
- The diverging administrative structures in the Member States: customs administration empowered to process technical controls in France or in the UK; cooperation between customs and technical administration in Italy, Belgium, Netherlands; decentralised technical controls at Länder levels in Germany, etc.;
- The need to avoid the setting up of technical barriers to trade that are not justified following the TBT Agreement of the WTO.

To ensure that cooperation and exchange of information between Customs and Market surveillance authorities during the control process is carried out in a proper way, a “Project Group” which will produce Guidelines for customs controls in the area of product safety has been established in 2010. The Guidelines should be finalised in first half of 2011.

3. Market surveillance implementing mechanisms and tools

To ensure effective and efficient market surveillance MS and the Commission should have the means to ensure appropriate organisation and development of specific market surveillance tools and ensure their wider access to all interested parties in particular the consumers. These tools are:

- National Market Surveillance Authorities (NMSAs)
- National Market Surveillance Programmes (NMSPs)
- Follow-up and organisation of complaints, accidents and injuries
- Ensure the implementation of corrective measures taken by the economic operators to comply with the EU legislation
- Perform appropriate checks on the characteristics of the products on an adequate scale on the basis of an appropriate risk assessment methodology
- Destroy dangerous products as a last resort
- Inform and alert the public properly.

In addition, there is a need for wide dissemination of information on the role and benefits of EU conformity markings and on the labelling requirements. The preliminary controls of the safety of a product, especially when it is covered by EU legislation, are done by simple control of the documentation which accompanies the product, and by checking the conformity marking(s) required. The best known is the CE marking. However, on this mark there are misunderstandings and lack of credibility. For that reason an information campaign is currently under development. However, this is a starting point since for consumers, but also for national authorities and

professionals its meaning and role is not always clear and gives raise to different interpretations. In addition there are other conformity markings provided for in EU legislation, and often products also bear other legal or voluntary marks or are accompanied by legal labelling provisions.

Information to the parties concerned on the real role and benefits of all marks in particular the conformity markings provided for in EU legislation will contribute: (a) to make sure that the consumer makes a good choice by buying only products that have been tested and approved by an independent third party or authority and (b) to evaluate the negative impacts on the safety of users by the relevant economic operators in the distribution chain.

The above-mentioned technical means are key players in the organisation of market surveillance. The proper functioning of all these parameters will ensure the success of the EU market surveillance system. In view of the role and relevance of the market surveillance objectives (protection of health, safety, etc.) these objectives should be held accountable in cases where a non-compliant or dangerous product is found to be on the EU market due to shortcomings in the market surveillance controls. Differing levels in controls will hamper the proper implementation not only of the EU market surveillance framework itself, but also of the sectoral EU or national legislation to which it applies (see above).

4. Communication and exchange of information IT tools

For the communication and exchange of information IT tools are essential. The EU legislation currently provides for two main IT tools: the REIS platform hosting the RAPEX system for the rapid information by national authorities of dangerous products, and a general database for the archiving and exchange of information aiming to make use of available best practices, tests laboratory results, general market surveillance information on risks, restrictive measures, etc. foreseen under Art. 23 of Regulation 765/2008.

These IT tools are currently differently developed. REIS/RAPEX has been working since 2001 under the GPSD regime, and MS use this system to notify products presenting a serious risk. This system is working quite well. Its efficiency will be enhanced shortly when the new IT platform GRAS-RAPEX will come into operation. The situation is not the same as regards the development of the ICSMS database which needs to be enlarged and adapted consistently to reply to the needs of the EU legislation since its objectives are wider.

However an efficient market surveillance organisation requires the development and management of other specific IT tools e.g. for complaints of accidents and injuries, for the collection and organisation of data on market surveillance measures taken by MS, etc.

Taking account of the constant changes either for the IT facilities or to adapt and reach all relevant parties including the public, the above-mentioned IT tools need support so that the objectives of the EU legislator are not disregarded.

5. Sharing of resources

The control of the safety of products is not new. National authorities have always put in place the means/systems to better perform controls and ensure the protection of their citizens. The sharing of existing knowledge is essential to make correct use of resources, both financial and human. The EU legislator has in the current EU legislation listed fields where the sharing of resources should be ensured e.g. training programmes and exchange of national officials and experts including customs authorities, joint visit programmes, joint actions, best practices, information campaigns, common projects, exchange of experience, testing procedures, etc. It is widely recognised that joint actions are the most appropriate way to share appropriately resources and develop best practices by MS themselves.

The Commission should establish and coordinate ad hoc market surveillance projects, in particular sector oriented, for which expertise and cooperation between two or more Member States are required in order to share resources and expertise. The participation of all Member States is essential for the success of the projects.

The development and management of the above-mentioned activities constitute a very important connecting link between the obligation for national authorities to ensure that only safe and compliant products are placed on their market and the coherence required of the implementing measures i.e. ensure the same level of protection with the same means. It is therefore of the outmost importance that mainly national authorities use the same parameters to control products, and be informed and trained on the same basis to do so. Lack of EU intervention in this area will help to prevent the development of diverging control methodologies and of new barriers to the proper functioning of the internal market.

6. Coordination and cooperation in the EU

As regards cooperation, MS are, inter alia, obliged to coordinate their actions, both in-house and at EU level,

with national authorities of other MS including customs authorities. Cooperation should also be ensured with the economic operators concerned. The cooperation contributes to a better enforcement of the EU and national legislation by ensuring coherent and uniform application of the rules and decision making. Therefore the existing weaknesses in cooperation should be avoided at all levels i.e. in the EU and internationally (see point 7).

Co-operation between the MS and the Commission should mainly ensure: (a) the meeting of the relevant actors (enforcement authorities including customs and where appropriate concerned stakeholders) in the ADCO (Administrative Cooperation) Groups which aim to deal only with enforcement issues in order to ensure communication and coordination; (b) to consistently reduce duplication; (c) to share resources and the development of joint projects and guides, but above all to ensure transparency, confidentiality and professional secrecy given the diversity of the market surveillance organisation in the different Member States.

The proper organisation of ADCO Groups, for sectors covered by EU legislation, whenever necessary, is a priority as well as for non-harmonised products where the coordination of surveillance actions takes place through the committee and network structures of the GPSD. Efficient cooperation and coordination needs moreover an overall organisation including a horizontal infrastructure since a certain number of issues in this area are common to sectoral ADCO groups. Currently, the information exchange between the members of the ADCO Groups is ensured via CIRCA. Often the information is confidential. Can this tool, however, ensure that this objective is met in an efficient way in the immediate future? Alternatives should be envisaged and developed since gaps or cuts in the main information exchange tool could cause serious problems to the health and safety of citizens.

Efficient co-operation should also be organised at Member States level between national competent authorities. Such cooperation should include: the establishment, implementation and periodic updating of sectoral market surveillance programmes by product categories or risk categories, including monitoring of surveillance activities and results, exchange of views, expertise and best practices as well as approaches on the implementation of the related sectoral legislation, the periodic review and assessment of the functioning of the control activities and their effectiveness and, if necessary, the revision of the surveillance approach and organisation put in place, etc.

7. Cooperation at international level

International cooperation also has an important role to play in the safety and compliance of products. In a globalised world it is very easy for economic operators from third countries to place their products in the EU. In addition cooperation and exchange of information based on reciprocity on specific dangerous products, suspect manufacturers or more general issues such as emerging risks, could contribute to action.

As a result the Commission already has a programme of international cooperation that involves participation in multilateral fora such as the OECD and the International Consumer Product Safety Caucus and UNECE. It also has intensive bilateral cooperation with the US and China in particular, including a trilateral EU-US-China work-stream. Nonetheless more could be done to develop this international cooperation including providing more funding to multilateral work and the expansion of bilateral relations to other important partners.

Ultimately international cooperation that involved early information sharing on specific dangerous products before they found their way onto the EU market, would be hugely beneficial since the control and withdrawal of products already circulating on the market is difficult and requires additional resources and costs often without better results.

The huge amount of non-EU products traded on the EU market also demands an examination of the efficiency of the import and distribution channels by e.g. appropriate cross border dialogues, technical assistance and projects.

8. Penalties

Infringements of EU legal provisions should call for effective, proportionate and dissuasive penalties by MS in order to ensure transparency and incentives for stakeholders (see EP report, point 32). The penalties could be increased if the infringement is recurrent. MS must also ensure that the penalties are properly implemented. They are free to organise the system and to fix the financial amount to pay and the levels of the risk/infringement.

In this context, there is a need to evaluate and compare the penalties, rules and systems in use in Member States. This will allow making recommendations towards a common approach for sanctions in the EU that will be applied in a similar context, avoiding discrepancies and ensuring equal treatment to economic operators. The sanctions should take account of SMEs and the level of the risk.

Who will be affected by it?

Any failure in the safety controls of harmonised and non-harmonised products arising from a failure of or poor implementation of the market surveillance EU framework entails the risk of endangering the public interests as required by the Lisbon Treaty. As a result, consumers, but also workers and the society as a whole, will be affected.

The presence of unsafe or non-compliant products on the EU market will in addition result in an unlevel playing field in favour of unscrupulous economic operators which will benefit from the gaps and will create unfair competition as well as burdens for the enforcement authorities to take remedial actions.

(i) Is EU action justified on grounds of subsidiarity?

(ii) Why can Member States not achieve the objectives of the proposed action sufficiently by themselves?

(Necessity Test)

(iii) Can the EU achieve the objectives better? (Test of EU Value Added)

The multi-annual market surveillance plan aims to implement the provisions of Regulation 765/2008 on accreditation and market surveillance and of Directive 2001/95 on general product safety (GPSD). These two legal instruments are based on (ex) Article 95 of the Treaty which contributes to the implementation of the internal market for goods.

The Commission, in its Communications of 2010, "Towards for a Single Market Act" and "An integrated industrial policy for the globalisation era", states that a multi-annual plan should be developed to ensure proper market surveillance implementation and enforcement. The initiative under discussion envisages replying to the Commission invitation by aiming to render the implementation and enforcement of the EU market surveillance system more effective and uniform.

Although Member States are responsible for the implementation of the Community market surveillance framework as in Regulation 765/2008 and GPSD in their territory, a harmonised and co-ordinated approach based on commonly applicable means and criteria such as those in section A, points 1 to 8, above, which will be uniformly applied by MS, is crucial for ensuring a level playing field for product safety between MS.

MS are conscious of the benefits (e.g. common risk assessment method, best practices, common criteria/rules, training, etc.) deriving from common rules/means and have already asked the Commission to intervene in subsidiarity areas (e.g. elaboration of common rules for the development of National Market Surveillance Programmes required by Article 18(5) of the Regulation).

If all of the enforcement initiatives had to be taken individually by MS at national level to ensure proper organisation of market surveillance, this could entail the risk of creating different approaches and consequently problems to protect public interests, and would create new barriers to the free movement of goods. Hence it is more appropriate to take action at EU level.

B. Objectives of the initiative

What are the main policy objectives?

The main overall objective is to ensure the protection of health and safety, the protection of consumers and workers - but also of energy efficiency and the environment - in the EU single internal market by ensuring that all necessary mechanisms are in place for an effective and uniform implementation and enforcement of the EU market surveillance framework.

It aims at developing the relevant infrastructure, mechanisms, rules and criteria necessary to fulfil the applicable general and sectoral requirements and to ensure proper implementation of the market surveillance framework with a view to achieving the high level of safety required by the sectoral legislation, and maintaining a level playing field between the national authorities and the economic operators concerned.

Main specific objectives:

• Reduce the number of unsafe and non-compliant products on the market for the protection of citizens and maintain the high level of safety required by the sectoral legislation ;

• Ensure a coherent and uniform organisation of controls of products already placed on the EU and at external borders for those coming from third countries ;

• Develop mechanisms that will allow a consistent and uniform implementation of the Community market

surveillance framework against unsafe and non-compliant products across the EU and equal treatment of the economic operators

• Ensure proper cooperation at EU and international levels.

Do the objectives imply developing EU policy in new areas?

The initiative does not introduce a new policy although the organisation of a mandatory market surveillance framework at EU level is quite recent.

It aims at enhancing the operation of the existing legislation setting out the provisions to be observed for the purpose of protecting public interests such as health, safety and protection of consumers and workers, and energy and the environment, on the basis of consistent and uniform means and criteria.

C. Options

(i) What are the policy options being considered?

(ii) What legislative or 'soft law' instruments could be considered?

(iii) How do the options respect the proportionality principle?

For the eight main groups of the identified areas to be enhanced and developed to ensure effective and consistent market surveillance in the EU (see section A), an impact assessment could be elaborated, in particular to present information on the financial pros and cons that would ensue from the development of the actions and activities required, which are detailed in the Annex.

As an example the following options could be considered:

1. Organisation of market surveillance in general

- Option A1: baseline scenario/do nothing option: not introduce any changes to the existing situation
- Option A2: Better implementation and enforcement: …..
- Option A3: self-regulatory initiatives/ …..

2. Specific needs for controls at borders (custom controls)…….

Draft (rev.2)

ANNEX

Multi-annual Market Surveillance Plan

ACTIVITIES

INTRODUCTION

The European Commission has identified market surveillance as an area where further developments are essential to ensure the proper implementation of Regulation 765/2008 and GPSD in particular. Among the 50 actions listed in the "Single Market Act", the development of a multi-annual market surveillance plan is foreseen. The political objectives of this plan are included in the roadmap on this subject.

In this Annex are identified, for the eight range of activities specified in the roadmap, the market surveillance activities that should be further developed.

The market surveillance plan applies to products covered by Regulation 765/2008/EC and Directive 2001/95/EC (GPSD). The activities should be intended to protect the public interests such as health, safety, protection of consumers, environment and energy efficiency.

The majority of the activities are sector-oriented and should be developed taking account of the specificities of the harmonised and non-harmonised products. It could be envisaged to develop for some sectors specific market surveillance programmes on the basis of the activities foreseen in this multi-annual market surveillance plan.

The market surveillance activities of the market surveillance multi-annual plan are:

1. ORGANISATION OF MARKET SURVEILLANCE IN GENERAL

For the purpose of ensuring consistency in the enforcement of product safety controls required by the EU legislation (Regulation 765/2008, GPSD, sectoral legislation and Decision 768/2008) there is a need for a proper coordination of relevant general and horizontal surveillance activities between the Member States.

This will entail:

(1) monitoring of national legislation, surveys, studies, public consultations, examination of RAPEX notifications and notifications of Notified Bodies without accreditation, and other conformity assessment bodies accredited;

(2) organisation of workshops, seminars, conferences in EU and EEA, both sectoral and horizontal;

(3) Put in place of an EU infrastructure/system/measures allowing:

- the coordination and support in particular the technical and administrative assistance to Member States such as: improve horizontal skills, assist Member States in case of new/occasional events, enlarge or update the sphere of activities, etc. Improvements

should include training, general and sectoral surveys of the national market surveillance system(s), etc.;

- a proactive intervention of the relevant national authorities when an unsafe or non-compliant product has caused an accident/injury. The system will include a harmonised approach for gathering information on the accident/injury and on the product and operator(s) concerned;

- to MSA (Market Surveillance Authorities) to be informed and to react to the relevant standard under development by ESO (European Standardisation Organisations) or already in use;

- to MSA to fully participate in the market surveillance activities in particular to those concerning the sharing of resources at point 5 below.

(4) elaboration of overall guidance documents in particular as regards:

(a) the evaluation of a risk including general and sector oriented risk assessment methodologies, definition of risk assessment basic terms, testing programmes allowing readily available and easily accessible testing results on specific products, …

(b) determination of a common approach to deal with different types of checks (documentary, physical and laboratory),

(c) establishment of a general system determining in particular the frequency of the inspections/controls in relation to the intrinsic level of risk or to the great number of accidents and for seasonal products, or the type of trade (e.g. e-commerce). The evaluation of the supply chains organisation and the weaknesses.

2. SPECIFIC NEEDS FOR CONTROLS AT BORDERS (CUSTOM CONTROLS)

Regulation 765/2008, Section 3, clearly indicates that surveillance to be performed on products already placed on the EU market and that carried out on imported products at EU borders should be the same, i.e. that the activities under points 1 and 3 to 7 should be applied to imported products when the procedure for the release for free circulation in the EU is opened for them.

Controls at borders require in addition specific actions and the most effective way to ensure that unsafe or non-conforming imported products are not placed on the market is to carry out adequate checks already before those products are released for free circulation. This requires the involvement of Customs which have a complete overview over trade flows across the EU external border and the development of appropriate technical and IT means facilitating the management of complex administrative procedures and the respect of strict delays (3 working days).

This will entail:

(1) Efficient cooperation between MSA and authorities in charge of the control of products entering the Community market to ensure that checks are performed on adequate scale.

(2) Elaboration of overall guidance documents on: common criteria/procedures/approaches and means of proceedings. A "Project Group" is elaborating Guidelines for cooperation on customs controls. It should be available in 2011.

(3) Better definition of the overall IT systems to facilitate communication and exchange of information.

3. MARKET SURVEILLANCE IMPLEMENTING MECHANISMS AND TOOLS

The organisation of market surveillance activities implies appropriate communication and coordination mechanisms at national level (see in particular Article 18 of Regulation 765/2008). Although MS have an obligation to implement properly the foreseen market surveillance mechanisms, there is a need to share their organisation to ensure better and harmonised results.

This will entail:

(1) Establishment of a forum to facilitate and improve education on products safety and market surveillance organisation. It will also be the forum where to address or to be informed on issues relevant for market surveillance either for MS, citizens and businesses. Specific tasks could be:

For Member States and businesses: to collect, store and disseminate of the knowledge on e.g. unsafe/non-compliant products, procedures, standards, risk assessment practices and results (taking account of risks for vulnerable people, where necessary), training, etc. Its main objective will be to provide: easy access to the huge amount of market surveillance information and rapid processing/answer to questions/problems.

For citizens: to handle consumer complaints and inform and be informed on unsafe products. Citizens should also address questions/problems for a rapid processing/answer.

The Forum will also be in charge of activities concerning risk assessment, best practices and test results. In this context, it will: (a) collect useful and appropriate information, (b) organise events and meet experts to discuss and find solutions/results, (c) make sure that joint tests are developed and all concerned parties are informed and have easy access.

(2) Develop and manage a European consumer/professional/economic operator complaint system, including mechanisms to search for and find solutions, and develop simpler solutions/answers.

(3) Support the development and management by MS of a tool reporting on accident and injury to the attention of MS but also citizens and stakeholders.

(4) Develop elements to inform the public on product safety issues (e.g. NMSPs, list of national MSA) in particular on recalls or withdrawals and on defective products (Art. 9-GPSD and Art.17, 18-REG).

(5) Examine national market surveillance programmes (NMSPs) and identify EU wide priorities at sectoral and horizontal levels.

(6) Develop and ensure reliable and proportionate traceability general procedures/mechanisms and for specific products the possibility to trace unscrupulous operators and facilitate the application of appropriate corrective measures.

(7) The approach in paragraph (6) above has to be followed to inform on the real role and benefits of EU conformity marking in particular the CE marking and other marks as well as the labelling requirements.

4. COMMUNICATION AND EXCHANGE OF INFORMATION - IT TOOLS

Two types of IT tools should be developed. Those whose development, operation and maintenance are foreseen by the Regulation 765/2008 and by GPSD i.e. RAPEX and ICSMS, and those that could be essential for the proper implementation of market surveillance activities e.g. notifications of Notified Bodies, the IDB (Injury Database), etc. These IT tools should be opened to the public while ensuring the necessary confidentiality. The IT tools that should be developed or improved are:

(1) The RAPEX IT tool should be improved constantly to take account of the new IT technologies necessary to maintain its efficiency for the rapid exchange of information of products presenting a serious risk. Its operation should also be constantly updated. For the exchange of information with third countries specific IT RAPEX tools could also be developed taken account of the specific needs mentioned in the bilateral agreements (see point 7).

(2) The general archiving and exchange of information system for market surveillance should be developed by using the ICSMS database. ICSMS should be improved to be in line with REG-Article 23(1) and (2) provisions. ICSMS should be developed and organised in such a way that Member States may develop national interfaces that can ensure for them a single point of entry for communication and information on all market surveillance issues**.** The specific IT tools at paragraphs (3) to (6) below will be part of the ICSMS[1]. It will also include all relevant information covered by this plan.

In addition ICSMS should inform on products covered by the GPSD for which there is no a Community harmonisation legislation (archiving of e.g. assessment means in

[1] **NB**: The EP report on "The revision of the General Product Safety Directive and market surveillance (2010/2085(INI)) at point 8 proposes the establishment of a public "Consumer Product Safety Information Database", including a platform for complaints if possible based on already existing tools i.e. ICSMS and the IDB.

Article 3(3)-GPSD, appropriate measures taken by economic operators to comply with their obligations in Article 5(1), 1st paragraph-GPSD**).**

(3) Support the development and maintenance of IT tool(s) to ensure the operation of a EU complaint system as at point 3(2) and of ensuring exchange of information on accidents and injuries on the basis, if appropriate, of the existing IDB (Injury DataBase) database as at point 3(3).

(4) Development and maintenance of an IT tool for the needs of Article 24(3) ensuring the collection and organisation of data on market surveillance measures taken by MS enabling the Commission to fulfil its obligations. The tool will include information provided by economic operators to MSA when evaluating restrictive measures (Articles 21(3) and 24(4)-REG).

(5) Ensure synergies with existing IT tools such as IMI which already has the potential to complement the functionality with other existing IT systems and vice versa such as the Regulated Professions Database.[2]

5. SHARING OF RESOURCES

The sharing of resources is a necessity for economy of scale, but also to exchange information and experience at sectoral and horizontal levels.

This will entail, possibly through the appropriate coordination infrastructure:

(1) Gathering and exchange of information on risk assessment, dangerous products, test methods and results, scientific knowledge, expertise and best practices.

(2) Elaboration of studies, databases, statistics and data, comparative analysis, mutual joint visits, research activities.

(3) Develop and organise training programmes and activities and exchange of officials and experts.

(4) Develop organise and set up programmes for the exchange of experience, information and best practice; programmes and actions for common projects, information campaigns, joint visit programmes and surveillance. These actions shall also be developed to inform on CE marking and other EU conformity marks and labelling provisions.

(5) Development of sectoral coordinated inspection and control tools and benchmarks. Technical assistance for risk and impact assessments. Development and management of traceability systems. Development of new market surveillance techniques, pilot market surveillance schemes including withdrawn, bans and recalls, etc.

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[2] **NB**: Different IT systems could be made accessible with a single point of entry and a single login. Data entered into one system could be automatically updated in the other. This could save time and trouble for users.

(6) Inter-laboratory comparisons, Round Robins, proficiency testing, independent testing programmes and projects. External technical support to carry out such programmes to be able to take position on technical issues in cases of disagreements between Member States.

6. COORDINATION AND COOPERATION IN THE EU

For the proper coordination and cooperation on both conformity/safety and counterfeiting issues between relevant parties (national and regional authorities, customs and stakeholders) it is necessary to develop and manage ad hoc mechanisms i.e.:

(1) Support the organisation of the meetings and ensure the technical and administrative assistance to ad hoc enforcement working sectoral groups, the so called ADCO Groups, but also the Notified Bodies sectoral Groups (NBG). The exchange of information and communication should use the most innovative internet-based means. To ensure coordination of the sectoral ADCO activities a "Horizontal ADCO Group" will be put in place since a certain number of issues in this area are common to all sectoral groups.

(2) Support the organisation and management whenever considered appropriate of sectoral fora allowing all parties including stakeholders to be informed and to inform on their views3.

(3) Develop and maintain an interface for business and consumer organisations at EU and where necessary at national levels. The parties and in particular end users shall have the possibility to react/present comments on product safety.

(4) Cooperation with and possible contributions to the operation of specialized European associations and organizations (including professional organizations).

(5) Coordination and development of joint programmes, joint actions and projects, exchange of national experts and officials, exchange of best practices, development of EU best practices and common training programmes.

(6) Inventory of the National Market Surveillance Programmes (NMSPs) and relevant implementing measures and information.

(7) Organisation of events on market surveillance topics in particular on product safety and e-commerce e.g. week events, outreach activities, conferences, workshops, information campaigns and similar activities, etc. for the relevant parties in particular consumers.

(8) Development of information or training videos for all interested parties in particular for MSA, consumers and schools.

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[3] **NB**: Similar to the "Consultation Forum" established under the Eco-design Directive

7. COOPERATION AT INTERNATIONAL LEVEL

The cross-border cooperation on imported products and of the distribution channels is part of the market surveillance system. International cooperation and exchange of information will be based on EU bilateral agreements or MoU (Memorandum of Understanding).

This will entail:

(1) Elaboration of appropriate methods on which to base the cooperation and to share information. Emerging issues and risks will also be covered.

(2) Organisation of workshops, seminars, conferences, training sessions, technical projects, cooperation and coordination actions in specific areas such as traceability, export controls, etc., preventive missions and joint actions in/with third countries, study visits to manufacturers and laboratories in third countries. These activities could be developed with national authorities or stakeholders in third countries.

(3) Participation in regulatory dialogues with third countries aiming to inform on the EU regulatory and market surveillance organisation including the meaning of the CE marking and other EU conformity marks and labelling requirements and to promote and enhance the European conformity assessment organisation.

(4) Elaboration of technical assistance programmes for third countries. Development of specific technical assistance programmes for third countries in particular Med countries as well as for the New Neighbourhood countries.

(5) Preparation and signature of ACAAs and their follow-up if necessary.

(6) Include third countries and give them access to RAPEX and ICSMS under point 4 on the basis of clear pre-established criteria and conditions and in respect of the confidentiality principles (e.g. RAPEX-China system).

(7) Participation in all international fora relating to market surveillance (UN ECE, OECD, ICPHSO/ICPSC…)

8. PENALTIES

Infringements to the required provisions should call for effective, proportionate and dissuasive penalties by MS in order to ensure transparency and incentives for stakeholders.

The Commission should evaluate and compare the penalties rules and systems in use in Member States. This will allow making recommendations taking account of the industrial sector specificities/product towards a common minimum level approach for sanctions in the EU that should be applied in a similar context avoiding economical divergences ensuring equal treatment to economic operators. The sanctions should take account of SMEs and the level of the risk.