

Working Party on Regulatory Cooperation and  
Standardization Policies

Nineteenth session  
Geneva, 23 - 26 November 2009  
Item 8 (b) of the provisional agenda

## **MARKET SURVEILLANCE**

### **Update on the Market Surveillance Model Initiative**

#### **Draft guide to the use of the general market surveillance procedure**

##### *Summary*

This document is the third draft of the General Market Surveillance Procedure. It is intended to guide market surveillance authorities in organizing controls on the national markets to ensure that products are in compliance with the regulations. It describes the steps to follow in preparing and carrying out market surveillance plans, as well as how to keep all stakeholders informed during this process. It is not an official document and is for informative purposes only.

## 1. OBJECTIVE

The objective of this document is to provide guidance to the General Market Surveillance Procedure (GMSP)<sup>1</sup>. This guidance document explains in simple terms what market surveillance is and how it relates to the activities of the UNECE Working Party on Regulatory Cooperation and Standardization Policies. Further the guide should allow the use of the GMSP by the Market Surveillance Authorities, providing some case studies (practical implementations of the procedure).

## 2. INTRODUCTION

### 2.1 What is Market Surveillance?

Free market access of products worldwide is currently in development in nearly all product sectors over the globe either in the consumer field or even in the industrial field. The intentions of economic operators are clearly to ensure compliance to legal requirements and to limit cost of importing and other conformity assessment costs. Compliance with mandatory safety requirements is a requirement which is legitimate and in all cases evidence of (some) compliance must be provided by the Economic Operator.

Regardless of conformity assessment system used to show compliance to its regulation(s), a country has to maintain a market surveillance system due to 2 (two) reasons:

- Illegal and unsafe products should not be allowed to be put on and remain on the market.
- Fair market conditions should prevail. Suppliers which follow the rules and bear the administrative costs and delays due to regulations should not be disadvantaged compared to those who do not comply to the rules.

In the life time of a product, compliance to mandatory requirements may be requested at:

- The design/production stage (so called pre-market control)
- The post-market surveillance stage (or market surveillance)

However nowadays a clear shift is detectable from the 1<sup>st</sup> stage to the second (post-market) phase, introduced by:

- Cost considerations (e.g. pre-certifications costs are high for some products)
- The manufacturer is eager to bring the product on the market quickly and any (external) conformity assessment could hamper this,

Market surveillance is more and more recognized as an essential step in the process of putting a product on the market, i.e. compliance with essential requirements must be checked after the product was put on the market to ensure compliance with the technical regulations, refer to figure 1.

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<sup>1</sup> The Terms of Reference of the Market Surveillance Model Initiative are contained in ECE/TRADE/C/WP.6/2008/13, endorsed at the 18<sup>th</sup> session of the WP 6. (Geneva, 3-4 November 2008). The secretariat acknowledges with thanks the contribution of Mr. I.Hendrikx to this guide and to the GMSP Initiative

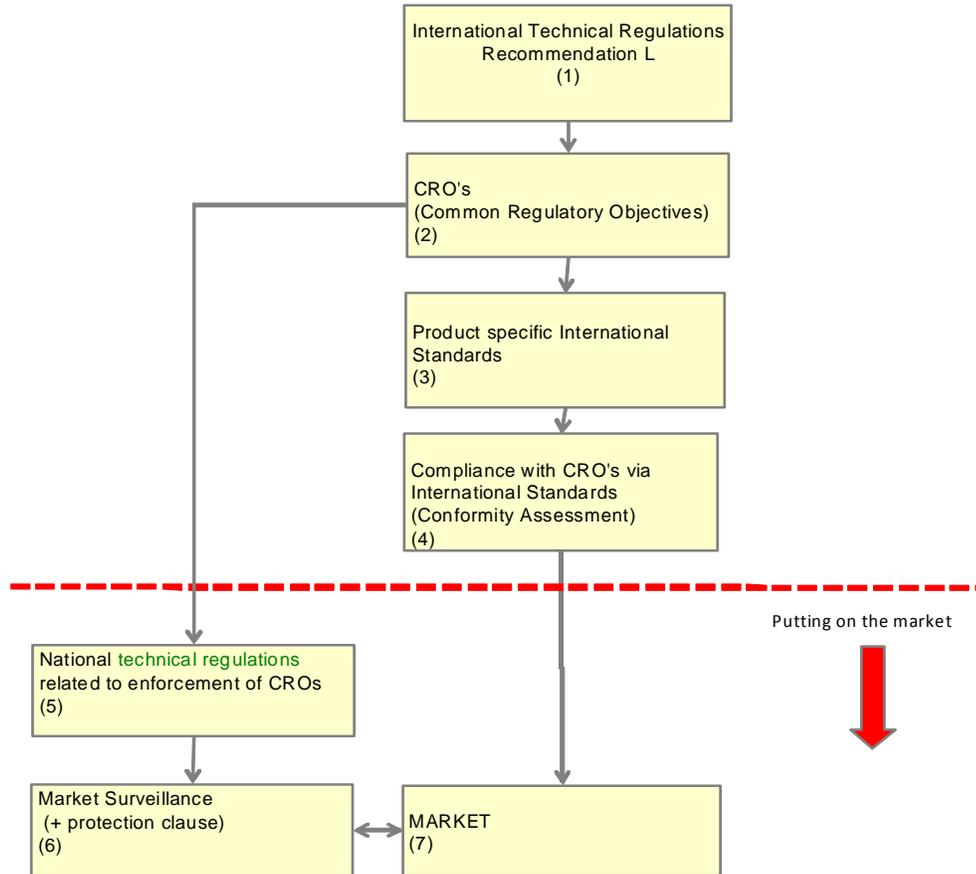


Figure 1: relation between Recommendation L<sup>2</sup> of UNECE and market surveillance

One of the main challenges confronting market surveillance are the increased consumer products that are being manufactured in developing economies, a pertinent example being toys. Most of the toys to be found on the developed countries markets are coming from developing economy countries. Also traceability of products becomes an important issue with a longer supply chain that reaches back to the manufacturing countries. The issue of traceability requires closer cooperation with customs and market surveillance authorities for jurisdiction applicable to the manufacturing countries. This would imply closer international cooperation.

#### Definition of Market Surveillance

There has some debate (and this debate is ongoing) on the definition of Market Surveillance. Related to the scope of this document, we accept to use this definition:

‘market surveillance’ shall mean the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant technical legislation and do not endanger health, safety or any other aspect of public interest protection.

<sup>2</sup> An international model for Technical Harmonization based on good regulatory practice for the preparation, adoption and application of technical regulations via the use of international standards, TRADE/WP.6/2002/7 14 June 2002

## 2.2 Why do countries need an effective Market Surveillance system?

The responsibility for market surveillance rests with the authorities. All countries and UNECE countries in particular, have, in most cases, a legal duty to enforce the legal framework for which they were designated as Market Surveillance Authority (MSA).

The national MSA's need to have adequate resources at their disposal to ensure that they can deal with the volume of imported products, the needed dangerous product notifications and the technical complexity of the regulations and the standards.

As in most countries on the globe, resources i.e. manpower and financial means of MSA's are limited, it is now generally believed that a strategy for market surveillance is required.

## 2.3 What are the ingredients of a future, effective Market Surveillance system?

The new strategy should focus on 3 (three) important areas:

1. Developing a general procedure for market surveillance.
2. Increasing cooperation with stakeholders and sharing the work of Market Surveillance internationally.
3. Increasing the visibility of market surveillance to the outside world.

### A general market surveillance procedure.

This procedure is essential to streamline all actions of MSA's, to reduce tasks to the essential, to bring uniformity for a range of products. It is now believed that due to the long standing efforts put in product standardization, it is clear that parts of it e.g. test methods, limit values, classification of products, etc. are favoured sources in establishing MS procedures.

In the long end, the idea of adding specific market surveillance guidance into product standards has to be reviewed again. Due to the limited participation of MSA staff to the standardization working groups, this is believed to be a challenge for the future (refer also to MSA's cooperation with stakeholders, below).

### MSA's cooperation with stakeholders.

We can identify following stakeholders for a MSA:

- The economic operators
- The customs
- The line authorities adopting/implementing the technical regulations
- The Conformity Assessment Bodies (CABs)
- The other national MSA's responsible for other products
- The other international MSA's (international cooperation)
- The national accreditation body (follow-up of CAB's competence)
- The national/regional/international standardization bodies (for providing the essential input to standardization work)
- The judicial authorities
- The consumer associations
- The media (in case of e.g. recall actions)

### Visibility of Market Surveillance to outside world.

In a world dominated by media, visibility of market surveillance will amplify considerably the efforts provided by the MSA's.

### 3. SCOPE OF THE DOCUMENT

This General Market Surveillance Procedure (GMSP) has been developed to be used by the national Market Surveillance Authorities (MSA) in the non-food area.

This GMSP is a proposal for a concept MS procedure to be used by MSAs.

The focus in this GMSP is preliminary put on mass produced electrical equipment (electrical & electronics equipment, electrical household appliances and consumer electronics), but other areas may be developed.

This procedure can also be used by the Coordination Entity for Market Surveillance (CoE) as a guidance document and the CoE may ask other national MSAs under their co-operation mechanisms, to comply with it.

### 4. STRUCTURE OF THE DOCUMENT

A MS action may be broken down into 3 phases:

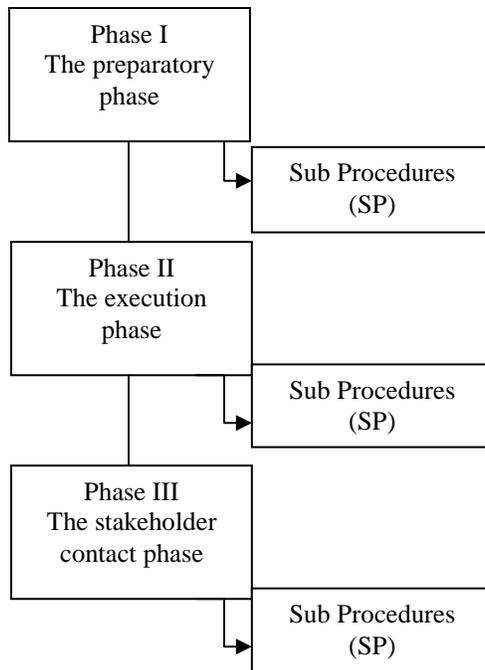


Figure 2: the structure of the GMSP

The GMSP is provided on page 9 as a flow chart.

On pages 10, 11 and 12 sub-parts of the GMSP are provided.

Other parts of the GMSP are further discussed on pages 13-18.

References to specific sub-procedures (SPs, see above) have been added in annex 1.

Reporting templates resulting from the GMSP and its sub procedures are in development. This is particularly the case for challenging areas e.g. sampling where there exist no appropriate standards/requirements up to date.

## 5. ABBREVIATIONS AND GLOSSARY

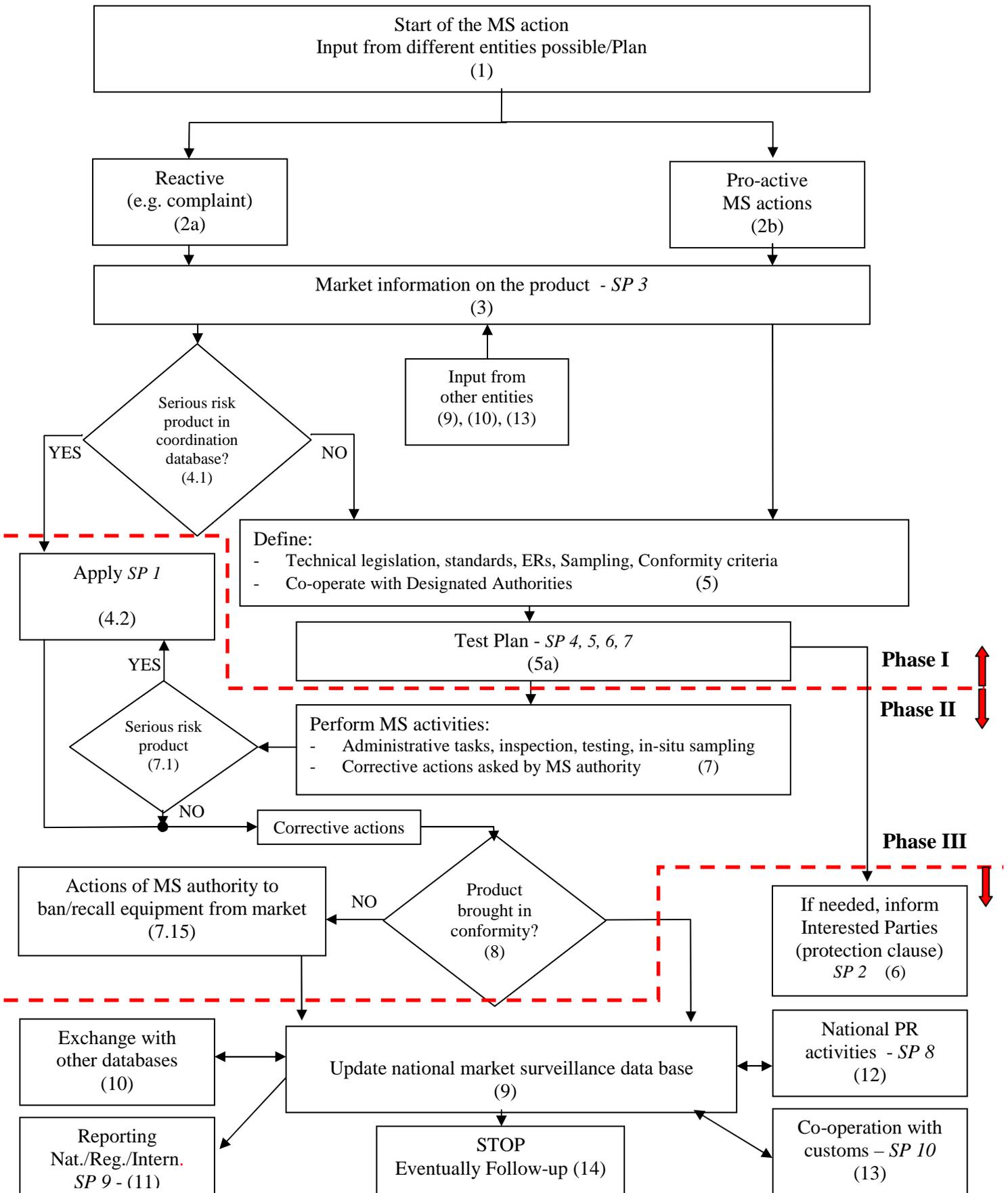
### Abbreviations

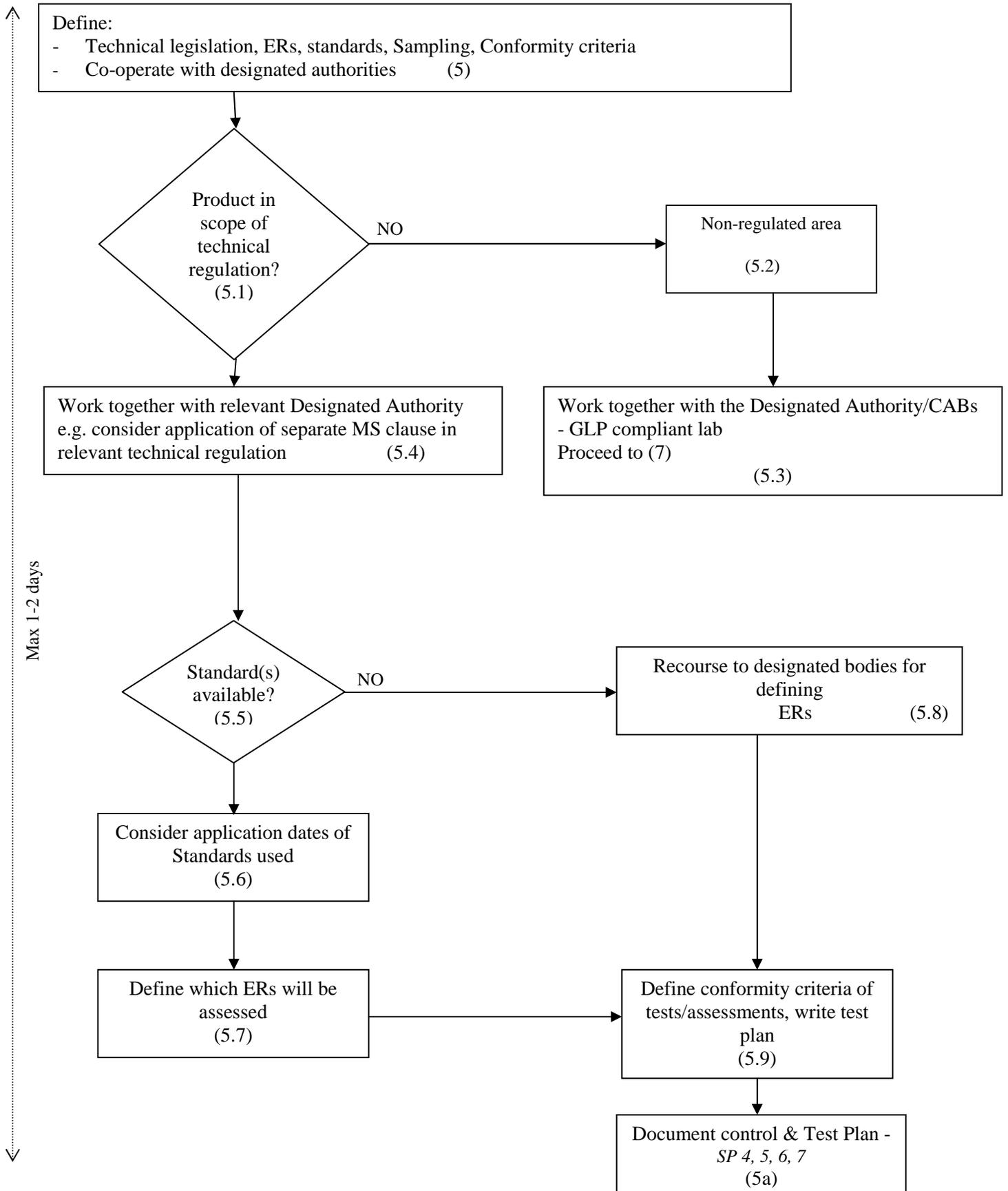
CA	Competent Authority (of a technical legislation)
CoE	Co-ordination Entity (national)
CAB	Conformity Assessment Body
CRO	Common Regulatory Objective
DoC	Declaration of Conformity
EO	Economic Operator
ERs	Essential Requirements
MS	Market Surveillance
MSA	Market Surveillance Authority
PR	Public Relations
SP	Sub Procedure

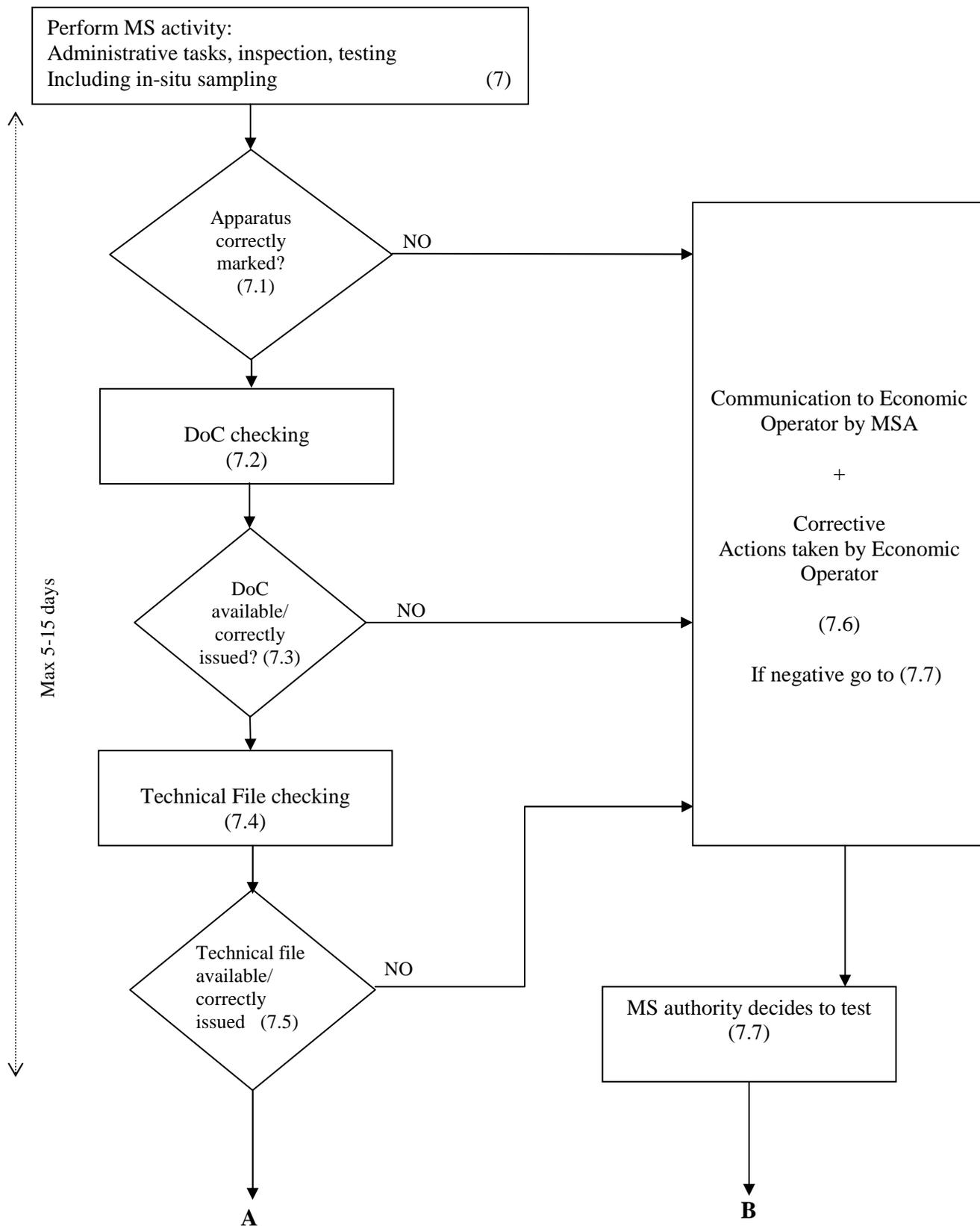
### Glossary

Refer to “Draft common definitions and terminology in Market Surveillance” available at ECE/TRADE/C/WP.6/2009/13. This document used mainly the definitions available in ISO/IEC 17000 and EU regulation 765/2008/EC.

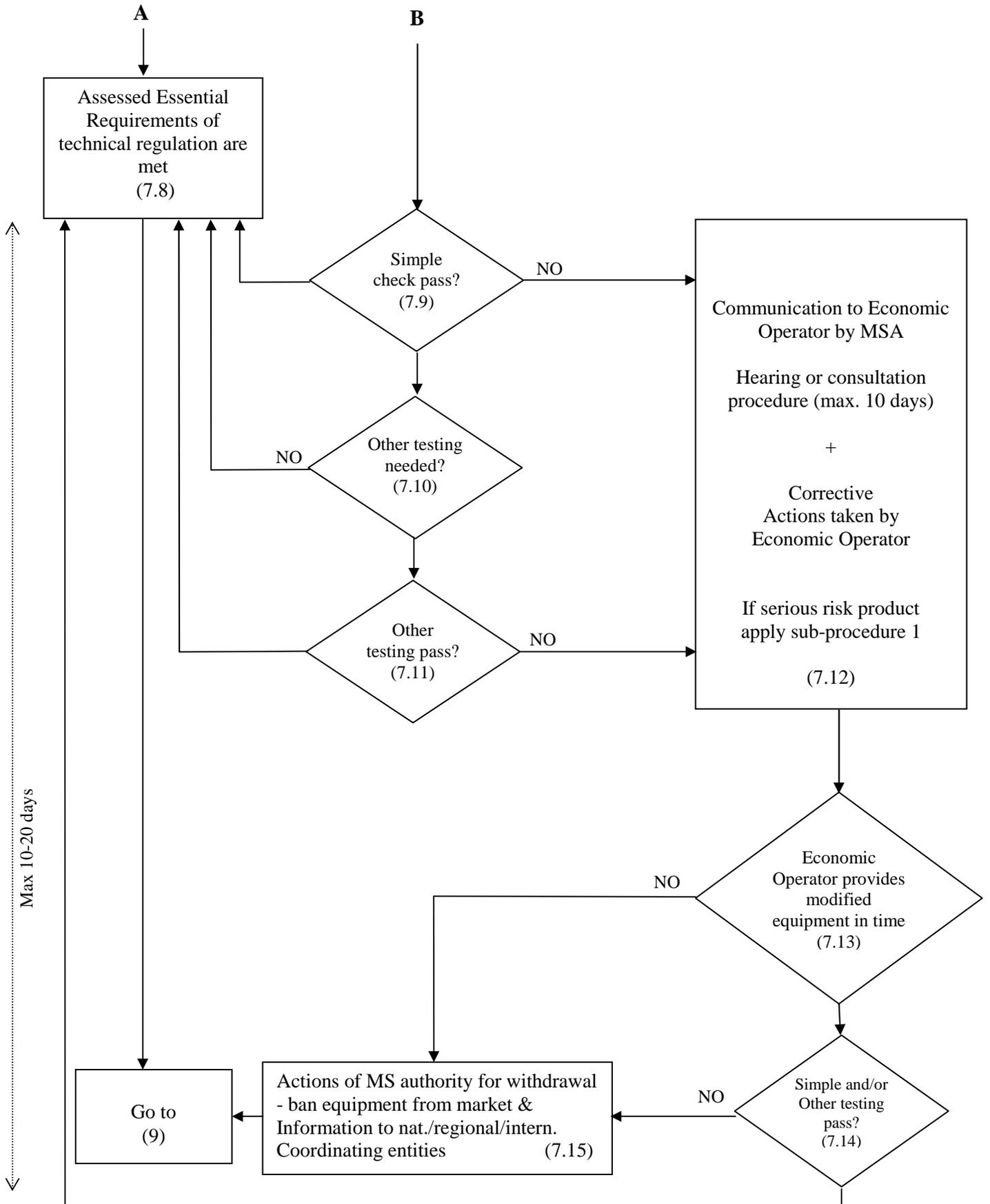
## 6. THE GENERAL MARKET SURVEILLANCE PROCEDURE



**Flow chart for phase I**

**Flow chart for phase II**

**Flow chart for phase II - continued**



## 7. THE DIFFERENT PARTS OF THE GMSP EXPLAINED.

### Phase I: the preparatory phase

Several actors can initiate [1] market surveillance actions, the following being the most common: Coordination Entity, market surveillance authorities, contact points and Customs authorities:

- The Coordination Entity  
Monitors surveillance activities across sectors of the food and non-food areas to build up intersectoral best practice. Given the necessary degree of specialization, the expertise remains at the level of sectoral authorities. Only certain elements of market surveillance are coordinated by this Entity.
- The Market surveillance authorities  
Responsible for planning, carrying out and following-up on surveillance activities undertaken in one sector.
- The contact points  
It is advisable to have contact points at the sector-, company- or even at the product-level to enable fast and effective communication between public authorities and private actors whenever concerns arise about a product.
- The Customs authorities

Market surveillance actions can be either pro-active or reactive. In the former case, it is planned based on a decision of the Coordination Entity or of market surveillance authorities, which identify priority sectors and products. In the latter case, they are complaint- or accident-driven. They can also be initiated after a substantial risk has been identified by authorities (during an inspection) or by the economic operator himself.

Market surveillance authorities should plan on different horizons. Long-term plans should address the overall strategy, based on the anticipated industrial, economic and political developments both nationally and internationally. Short-term plans should address more pressing issues such as the annual allocation of resources between planned activities, and their prioritisation.

To set up their plans, the authorities must analyse risks, taking into account available information concerning these products coming from other stakeholders, as well as information about previous accidents from domestic, regional and international databases. Detailed results of these risk analyses should remain confidential to avoid damage being caused to the reputation of any sector or economic operator.

#### Pro-active MS actions

For the achievement of an effective MS system, taking in consideration the large number of products on the national market, the high number of technical requirements (regulatory documents and underlying standards), and the limited resources of the national MS authorities, it is now generally believed that a pro-active approach is needed.

#### The existence of appropriate technical regulations

Two situations may arise when planning market surveillance actions:

- ✓ If technical regulations specifying the tasks of market surveillance authorities already exist, the planning stage is simplified, as the authorities can use those criteria to carry out their activities.
- ✓ If such technical regulations do not exist, the authorities must first determine whether the product bears a serious risk(s) (in which case specific assessments have to be made) or not.

In both cases, the market surveillance authorities need to identify appropriate technical regulations so that they can assess the products and use the results of these assessments for their work. They must be able to:

- ✓ Perform risk assessment to determine the risk level of the product
- ✓ Cooperate with other stakeholders to define appropriate technical regulations.

Risk assessment on the product

The capacity to estimate the danger represented by a product and its probability of occurrence enables MSAs to quantify risks. To set priorities, the risks need to be quantified. Although there is no general risk assessment methodology, this area is currently being developed intensively. Some standards exist and can be used to develop specific risk assessment methodologies. Below are three examples of reference to standards relevant to risk-assessment:

- ✓ ISO/FDIS 31000: this standard also called “Risk management principles and guidelines” applies to all sectors and covers: Risk Identification, Risk Analysis, Risk Evaluation and Risk Treatment.
- ✓ Other standards are limited to certain sectors
  - Machinery (ISO 14121-2:2007, part 2)
  - Low voltage equipment (ACOS/542/INF)

Risk assessment is especially useful when there is no specific technical legislation for the product assessed, refer to (5.2b) in the flow chart.

For some applications the risk assessment exercise needs to be repeated by MSAs in some countries due to different environmental conditions (e.g. temperature in use for equipment)

Reactive MS actions (2a)

Reactive actions constitute an important part of market surveillance activities and can account for up to half of the resources, and as such are essential elements in the budget and planning strategy. They are usually driven by a complaint or an accident, which requires a risk assessment analysis. Complaints and accidents can be classified into two categories:

- Low-risk complaints, coming from consumers/users in relation to minor defects in a product, or from competitors concerning unfair competition.
- High-risk complaints or accidents. If an accident occurs or any stakeholder informs other actors that a product represents a serious risk to health and safety or to any other justified public interest, the authorities have to perform the relevant procedure and rapidly require corrective actions or take even more restrictive measures if necessary. Because such decisions can have adverse economic consequences, they should only be taken as measures of last resort;

Check if the product has been advised by a contact point as a serious risk product to the health and safety or other justified public interest. If yes perform the SP 1 procedure (2.2), use the Rapid Alert form, see annex 1 appendix E.

In principle the further treatment of this kind of actions is identical with a pro-active MS action.

Market information on the product (3)

The information sources which can be used to adjust the concrete MS plan are:

- Market information of the products on the national market (national statistical office, Customs data)
- Monitoring of accidents
- Follow-up of complaints
- National/regional/international MS databases (10)
- Relevant information from stakeholders (e.g. consumer protection organizations,..)

Technical legislation, standards, sampling and conformity criteria (4)

Identifying which technical requirements apply to what product is a major task of public authorities. What rules should be followed when selecting a sample of products to check? What tests should be conducted? What parameters and values should be observed? Market surveillance authorities are often not in a position to define such guidance on their own and need to collaborate with other stakeholders.

In most countries, requirements for products are specified in sectoral technical regulations which may be complemented by general technical regulation which requires the product to be safe.

So the first task is to define the technical regulations which are applicable to the product

The concept of essential requirements is a very important information for the MS authorities, because in some technical legislation there is reference made to essential requirements which on their turn refer to standards.

In the flowchart, a separate page has been reserved for the definition of the standards (5.5) including the application date, the ERs and the conformity criteria when performing tests or assessments.

For defining the conformity criteria, the limits from the standard(s) or the limits defined by a designated body are used, but also due consideration has to be given to international guidelines on the expression of uncertainty in quantitative testing ISO/IEC guide 98-3 and to the requirements of the ISO/IEC 17025<sup>3</sup> standard in general. Due to the complexity of these standards and the number of requirements it imposes to the body performing the test, in general, we can state that testing is not a task of the MS authority. Nevertheless, the MSA can perform preliminary testing using basic test equipment or highly automated test equipment which allows for straight forward operation.

(5.4) Co-operation with the Designated Authority of a technical regulation to define special MS requirements specified in this technical regulation.

(5.8) The Designated Body may be consulted for selecting the tests to be executed. This Designated Body may not be involved in the pre-market assessments of the product.

(5.9) a document control/test plan is written, which is to be used, among other administrative tasks, for requiring formal quotes of the CABs (mostly the labs). Refer also to the "Procurement procedure". A sample test plan is provided in annex 2 of this document.

### Sampling

Within phase 1, the preparation phase, an important subject is sampling. Indeed as the number of products put on the markets worldwide is important, an effective and intelligent system of sampling is needed. ISO 2859-1 is mentioned in more and more MS circles as a candidate for defining sampling in MS.

Some product standards include sampling schemes when e.g. regulatory conformity has to be assessed, but these standards are merely exceptions. However for some technical regulations, the numbers for the sampling are mentioned. In this regard it is important that an acceptable number of samples is requested by MSAs not to increase the burden on Economic Operators in appropriate way (i.e. high numbers of samples relates to high costs).

**There is currently no agreed general approach for MS sampling among the different product sectors.**

### Speed of action within part (5):

In our present global economy the average life time of a product is decreasing. For some equipment it is less than 3 years. The recommended throughput time for part (5) is 1-2 days.

### (6) Protection clause

In certain cases when during the execution of a MS action it is found that the product is in conformity with a CRO, but is found to endanger health and safety or other legitimate objectives, e.g. a defect in a standard, a country can take necessary steps to withdraw such a product from the market or restrict its free circulation by evoking the protection clause of a CRO. In that case the authority has to report such actions to the United Nations (UNECE) and indicate the reasons for this decision.

Also the national CoE or contact points will be informed.

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<sup>3</sup> refer to [www.iso.org](http://www.iso.org)

## **Phase II: the execution phase**

The second phase of the GMSP focuses on actions that market surveillance authorities have to perform to detect and deal with non-conform products. It is the core activity of the MSA.

The first step of the assessment consists in administrative tasks and visual inspections:

1. To check if regulatory marking and other labelling is on the equipment
2. To verify the availability/correctness of the supplier's DoC<sup>4</sup> (Declaration of Conformity)
3. To verify the availability/correctness of the Technical File
4. Verify if there are reasonable suspicions of compliance with essential requirements

Most market surveillance activities are administrative (inspection) tasks, refer to the flowchart (7.1-7.6).

This part of the chart applies to equipment for which there is an identified technical legislation.

The successive administrative inspections are as follows, see (7.1) to (7.5):

It is only after the above mentioned steps that the MS authority can decide to test (7.7).

Note: If during the visual inspection of 1 to 3 mentioned above, suspect information is found, the MSA may take more decisive action (e.g. to test as explained in (7.7)).

The different corrective actions initiated by the market surveillance authority (7.6) may be:

- Communications to the Economic Operator to solve the non-conformity within a defined period of time. Refer also to the checklist corrective actions provided as appendix D of the guide for dangerous products (see annex 1 of this document).

Verification of Technical Files is usually performed in co-operation with CABs as these entities have usually the means and competence to assess these files.

### **Speed of action within part (7.1) – (7.6):**

The recommended throughput time for this administrative part is 5-15 days depending on the complexity of the product and on the distance in the supply chain tracing (imported products, especially from 3<sup>rd</sup> countries).

### **The MS authority decides to test (7.7) – (7.15)**

Essentially, 2 kinds of assessments can be foreseen for MS purposes:

- checking, and
- Other tests

There is no clear definition for “checking” but in general they can be performed by market surveillance inspectors taking into consideration certain quality items (e.g. measurement of dimensions, basic electrical quantities, etc.).

“Other” testing requires specific test equipment/infrastructure usually only available to accredited CABs or similar (e.g. EMC test equipment or radio-communication test equipment, etc.).

The designation of CABs that will perform MS assessments (tests and other conformity assessment tasks) is a task of the market surveillance authority or the CoE (refer to the sub-procedure “Requirements and follow-up of CABs”).

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<sup>4</sup> The supplier's declaration of conformity shall be based on ISO/IEC 17050

### Consultation (hearing) with the Economic Operator (7.12)

After evidence of non-compliance with selected essential requirements has been collected, the MSA will initiate corrective measures to be taken by the EO.

- Such measures as stated above shall be communicated without delay to the relevant EO, which shall at the same time be informed of the remedies available under the law of the country concerned and of the time limits to which such remedies are subject.
- Prior to the adoption of a measure referred to above, the Economic Operator concerned shall be given the opportunity to be heard within an appropriate period of not less than 10 days, unless such consultation is not possible because of the urgency of the measure to be taken, as justified by health or safety requirements or other grounds relating to the public interests covered by the relevant national technical legislation. If action has been taken without the Operator's being heard, the Operator shall be given the opportunity to be heard as soon as possible and the action taken shall be reviewed promptly thereafter.

Serious threats of non-conform product dissemination on the market during consultation with the EO must be avoided.

If serious risk is involved the sub-procedure 1 in annex 1, will be followed.

### Speed of action within part (7.7) – (7.15)

The recommended throughput time for this testing part is 10-20 days depending on the complexity of the product and the number of essential requirements assessed/tested.

### **Phase III: contacts with stakeholders**

The third phase is closely intertwined with the two first phases because consultation and rapid communication with stakeholders is necessary in order to prepare optimal market surveillance plans and minimize safety risks. Market surveillance authorities should remain informed and keep other actors informed through:

- Institutional channels of communication (e.g. contact points, other MSAs, Coordination Entity, Conformity Assessment Bodies, standardization organizations, regional organizations)
- Exchange of information between domestic, regional and international market surveillance authorities' databases [10], refer to the sub procedure "Information systems" in annex 1.
- The media (mostly in case of recall actions and awareness campaigns).

If corrective actions bring a product back into conformity with mandatory requirements, market surveillance authorities should update their database [9], exchange this information with other databases (10) and inform their domestic, regional<sup>5</sup> and international partners (11) as well as Customs. Customs play an important role to detect any non-conform products at the border. The custom authorities are expected to work closely with the MSA's. Both entities are to exchange critical product data, provided within information systems mentioned above. Refer to the MS sub-procedure "Market surveillance and customs" (13).

The market surveillance authorities also need to better use the leverage of media to raise public awareness of important issues (12). Until now, the various media have mainly been used to inform the public of acute risks and of recall actions (e.g. cars, toxic toys). However, the authorities could also work with the media to sensitise the public to the necessity to harmonize standards, improve the traceability of products, etc. Increasing the visibility of the work of market surveillance authorities might greatly help to ensure that more resources are devoted to this important task. A special sub procedure "Communications, PR and visibility" is referred to in annex 1.

Once all these steps have been taken, the surveillance authorities should follow up on non-conform products to check if economic operators have correctly implemented the required changes. The follow-up market surveillance action should be performed within a reasonable period of time (generally one year) (14).

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<sup>5</sup> For some regions there are requirements in the technical regulations to inform the member states of results of Market Surveillance actions.

### 8. DIRECTIONS FOR FUTURE WORK

This GMSP has been developed having harmonized technical legislation in mind. In particular it is strongly linked to the needs of Electrical and electronic equipment, electrical household equipment and consumer electronics.

This procedure has not been assessed for:

- Other kind of products within the non-food area
- For products for which no harmonized legislation or standards exists

In this globalized world where products can be imported from all over the globe, usually MS actions need to be monitored/steered by a regional entity. However, in light of the traceability of imported products, there is also a need for international monitoring/steering on market surveillance. There is currently no entity for this important task.

Apart from the sub procedures, see annex 1 of this GMSP, most of which still need to be developed, the WP put forward following elements for future collaboration:

- It is considered important that, to develop to its full extend this GMSP, the continued support and collaboration is needed of national, regional and international parties, in particular the standardization organizations, accreditation organizations, the conformity assessment bodies, the technical regulation authorities and last but not least the economic operators.
- Future work should also deal with fight against counterfeit products.
- The sectoral initiatives such as for telecom products, which apply the International Model (recommendation L), should collaborate more with the WP6 e.g. by applying the GMSP in their field.

At the latest working party on Regulatory Cooperation and Standardization Policies meeting of 3-4 November 2008 in Geneva, the need for relating technical requirements (technical legislation, standards), risk assessment, statistical aspects (sampling), along with conformity assessment aspects (measurement uncertainty), including non-tangible effects of public relation actions (visibility to the public/stakeholders), has been discussed. A more quantitative model figure 3 would serve as a tool to MSA's to assess the effectiveness of their MS actions.

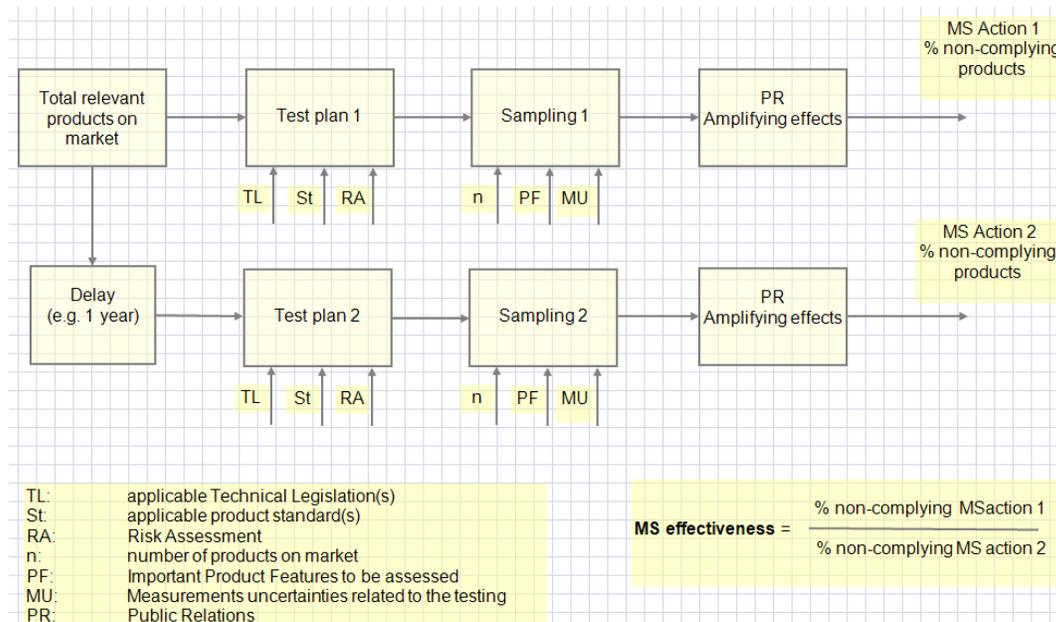


Figure 3: the MS effectiveness model

**ANNEX 1: LIST OF SUB-PROCEDURES AND RELATED REPORTING TEMPLATES**

<b>SP</b>	<b>Sub-procedure title</b>	<b>Template reference</b>	<b>Template/information availability</b>
1	guide for notifications regarding dangerous products	<p>Appendix A: Contact information for respective government inspectorates (MSAs)</p> <p>Appendix B: Safety notification form (to be performed by Economic Operators)</p> <p>Appendix C: Risk Assessment</p> <p>Appendix D: checklist corrective actions, for Economic Operators</p> <p>Appendix E: notification form for dangerous products to be used by other MSAs and to be sent to the CoE</p> <p>Appendix F: standard list of product types</p> <p>Appendix G: Standard list of risks related to dangerous products</p>	Need to be developed
2	Notification procedure according to a protection clause of a CRO		Needs to be developed
3	MS Information systems		Needs to be developed
4	General MS test plan		Refer to annex 2 of this guide
5	Sampling procedure		Needs to be developed
6	Procurement procedure		Needs to be developed
7	Requirements for and follow-up of CABs		Needs to be developed
8	Communications, PR and visibility		Needs to be developed
9	Reporting of MSA to national/Regional authorities		Needs to be developed
10	Market Surveillance and Customs		Needs to be developed

**ANNEX 2: GENERAL MS TEST PLAN****Contents**

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Administrative checklist

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Compliance criteria

Report

Annexes

Appendix 1: example of a test plan for a personal computer falling into the scope of the EMC technical regulation

Appendix 2: definition of the measurement uncertainty for conducted emission testing according to CISPR 22

Appendix 3: Classification of technical products according to its EMC features

Appendix 4: Definition of the applicable standard(s) and application dates

## **INTRODUCTION**

The purpose of this document is to define the test plan for assessing a technical product . It is implemented according (5) of the General Market Surveillance Procedure (GMSP).

## **TECHNICAL REGULATIONS**

Refer to (5), (5.1), (5.2) in GMSP

Analysis of the technical product features inherent to the product (Product safety, EMC, Spectrum control, Energy conservation, Environmental)

Definition of the national technical regulation(s) into which scope(s) the product falls.

## **HARMONIZED STANDARDS**

Refer to (5.5), (5.6) in GMSP

Look-up of the published nationally transposed harmonised product standards (<http://www.bsonline.bsi-global.com/server/index.jsp>). Generally the standards that will be used in an EU country are based on the EN standards (CEN, CENELEC, ETSI).

Definition of the date of application of the standard. This may involve the analysis of different versions of the same product standard including its amendments.

## **ADMINISTRATIVE CHECKLIST**

Refer to (7) in GMSP

3 main elements can be checked before any testing is performed:

- Marking of the product and user instructions (regulatory marking, labelling such as name of manufacturer/importer, model N°, serial N°...),
- Supplier's DoC
- TF (technical file)

The technical file is sometimes extensive (for complex products e.g. some R&TTE products like receivers). The assessment of the TF is usually performed by the CAB.

## **ESSENTIAL REQUIREMENTS**

Refer to (5.7), (5.8), of the GMSP

The requirements of a technical regulation for a product are met if the product complies to the relevant product standards. The essential requirements are thus included in the standards referred to above.

A market surveillance authority can:

- assess the product to all tests/assessments as defined in the product standard
- assess only some very important essential requirements

The decision factor is usually the cost of the assessments.

e.g. when product safety is the primary goal of the market surveillance authority (e.g. when assessing household products etc.) then testing to 2 to 3 essential requirements would normally be the case.

However if functional features are assessed (e.g. EMC) then the main goal of the authority would be to assess the product to prioritised product requirements (the harmonized EMC product standard) and the product is assessed (tested) to the full product standard to see if it complies to the requirements (level playing field).

The cost of assessments, if performed by CABs, is usually given per tested phenomenon (e.g. mains conducted emission of the CISPR 22 product standard).

**COMPLIANCE CRITERIA**

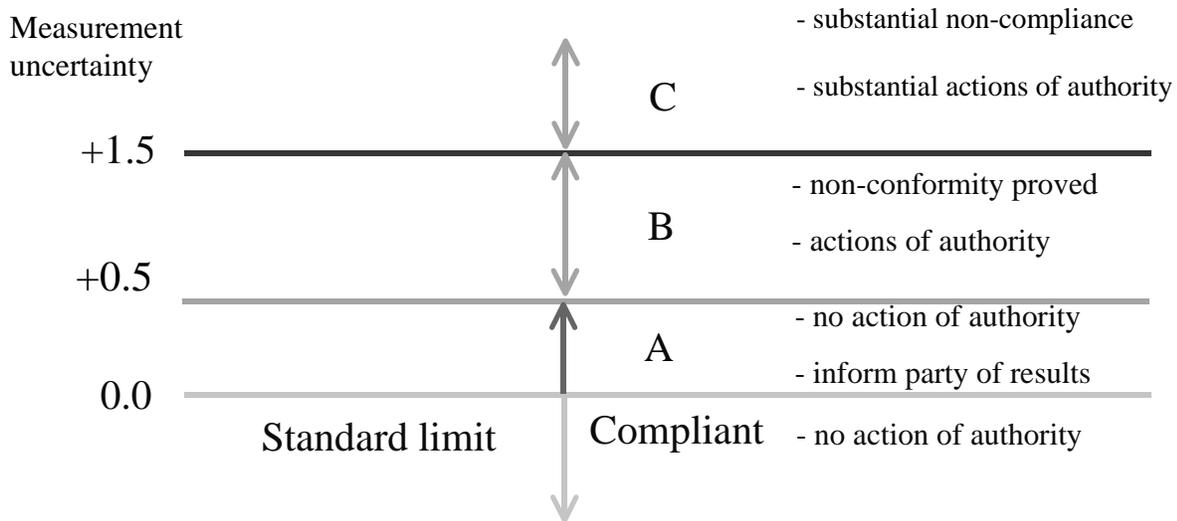
Refer to (5.9) in the GMSP

A general table can be defined as follows:

Technical regulation	Products standard	Paragraph(s) Of product standard	Limit value of product standard	Measurement uncertainty margin (1)	Levels of failure margin (2)

- (1) This the measurement uncertainty margin of the specific test reported by the CAB.
- (2) This provides for a classification of failures:
  - A. The results fall within the uncertainty margin and thus it is not possible to decide on non-conformity. The results can be provided to the party who’s product has been assessed,
  - B. The product does not comply with the requirements (test limit) within a certain margin. Actions of the authority to bring the product in conformity are needed.
  - C. The product non-compliance is substantial. Actions of the authority to bring the product in conformity are substantial.

Refer to the figure below to show the above definitions in a graphical format.



*Figure: visualising compliance criteria for a specific test on a product (conducted emission)*

**REPORT**

The format of reporting which the CABs provide is normally extensive as it will be used for pre-market purposes.

In case of post market actions (market surveillance) a different format of reporting is to be provided which includes e.g. the data which will be put on a server of an market surveillance information system. The authority should make clear to the CAB he uses, which reporting is needed and this requirement could be put into the contract between the authority and the CAB.

## APPENDIXES

### APPENDIX 1: EXAMPLE OF A TEST PLAN FOR A PERSONAL COMPUTER FALLING INTO THE SCOPE OF EMC TECHNICAL REGULATIONS

#### INTRODUCTION

The focus of market surveillance in the field of EMC, as product safety is not included in the scope of the technical regulation but only functional features i.e. the product may not produce emissions so that other equipment in its environment may be influenced and it must have an intrinsic immunity to operate as expected in that environment, is more on the aspect of fair playing field (conformity with the directive). In this case, it is common use that all testing of the EMC product standard is performed. Some EM phenomena are however more important than others from a market surveillance point of view (e.g. number of products on the market, the time the products are functional and may cause interference, etc.) A proposal for classifying technical products based on their EMC features is provided in appendix 3.

Suppose that the product on the market to be assessed is a personal computer that is used stand-alone (not in a network or other equipment connected to it except the CRT, the keyboard and mouse).

The “EMC score” for this product is rather high (40) see appendix 3.

#### ESSENTIAL REQUIREMENTS

We decide to test to prioritised EM phenomena as defined in the list in appendix 3, i.e. the CE, RE, ESD, RS, EFT phenomena;

#### COMPLIANCE CRITERIA

Directive	Products standard	Paragraph(s) of product standard	Limit value of product standard	Measurement uncertainty margin [dB]	Levels of failure margin [dB $\mu$ V/m]
EMC	CISPR 22, Incl. A1 and A2	5.1	60 dB $\mu$ V (1)	3.4	A: 62 (3) B: 66 C: >66
	IEC 61000-3-2:2000		(2)		
	IEC 61000-3-3:1995 Incl. A1		(2)		
	CISPR 24 Incl. A1 (not A2) ESD RS EFT		(2) (2) (2)		

- (1) This is the standard emission level in the range of 5-30 MHz, the limits for 0.15-0.5 MHz and 0.5-5 MHz should also be calculated.
- (2) Similar calculations as in (1) above to be performed.
- (3) 3.4 dB rounded-off to 4 dB

## **APPENDIX 2: EVALUATION OF THE MEASUREMENT UNCERTAINTY FOR CONDUCTED EMISSION TESTING ACCORDING TO CISPR 22**

The MSA should be aware of the influence of measurement uncertainty on the decision of compliance with limits.

The reader is referred to the web sites below for obtaining more information to establish measurement uncertainty in the case of the conducted emission test.

### References:

UKAS LAB 34 guide 'The expression of uncertainty in EMC testing' -

<http://www.ukas.com/Library/downloads/publications/Lab34.pdf>

[http://www.schaffner.com/test\\_systems](http://www.schaffner.com/test_systems)

<http://www.emcia.org/Freeinformation/KeithArmstrong/010422.htm>

**APPENDIX 3: CLASSIFICATION OF TECHNICAL PRODUCTS ACCORDING TO ITS EMC FEATURES**

Type of apparatus	Safety critical	Environmental critical	High on time	High volume	High expected RF emissions	High mains harmonics & Flicker	High sensitivity (low immunity)	EMC tests (4)	Total Score
<b>Industrial (1)</b>									
PLC	8	5	7		5			CE, ESD, EFT	25
Frequency converter	8				9	10		CE, Harm., ESD, EFT	27
Dielectric welder 27Mc					10			CE, RE	10
Tool (3)	8		7		5		3	CE, ESD, EFT	23
UPS (Uninterruptable Power Supply)	7		8	5	7				27
<b>Non-industrial (2)</b>									
Medical equipm. (class I) (M)	2		2				3	CE	7
Medical equipm. (class II & III) (M)	5		4		1		2	CE	12
Access control equipment	6		9	7	7		8		37
Audio equipm. (professional)			6	7			8		21
Airco mobile equipment			8	6		10		Harm., flicker	24
<b>White products using DC motor</b>									
Mixer	7			9	8	6		CE	30
Vacuum cleaner (using electronic control)				8	8	8	6	CE, Harm., ESD, EFT	30
Dish washing machine			7	6	6	6	5	CE, Harm., ESD, EFT	30
Coffee grinder				8	9			CE	17
Washing machine			7	6	6	6	6	CE, Harm., ESD, EFT	31
Hairdryer (using diode in heating element)			9	9		9		Harm., flicker	27
Room heating equipment (using electronic control)	7		9	8		8	6	Harm., flicker, CE	38
<b>Electric tools</b>									
Drilling equipment	7			7	8	8	7	CE, Harm., ESD, EFT	37
Saw equipment	7			6	8	8	7	CE, Harm., ESD, EFT	36
High speed grinding equipment	9			6	9	8	7	CE, Harm., ESD, EFT	39
<b>Brown products</b>									
TV			9	8	6	8	8	CE, RS, ESD, EFT	39
VCR			8	7	6	6	8	CE, RS, ESD, EFT	35

Type of apparatus	Safety critical	Environmental critical	High on time	High volume	High expected RF emissions	High mains harmonics & Flicker	High sensitivity (low immunity)	EMC tests (4)	Total Score
CD			8	7	6	6	8	CE, RS, ESD, EFT	35
Amplifier			8	8	5	6	8	CE, RS, ESD, EFT	35
Tuner			8	8	5		9	CE, RS, ESD, EFT	30
Hi-fi audio system			8	8	6	8	9	CE, RS, ESD, EFT	39
<b>IT &amp; Telecom</b>									
Personal computer			8	8	8	8	8	CE, RE, RS, ESD, EFT	40
Modem			7	7	6		8	CE, RE, RS, ESD, EFT	28
Facsimile equipment			7	7	6	6	8	CE, RE, RS, ESD, EFT	34
Wireless telephone type CT2			8	7	7		8	CE, RS, ESD, EFT	30
Wireless babyphone			8	7	7		8	CE, RE, RS, ESD, EFT	30
<b>Lighting</b>									
TL lamp using electronic converter	2		8	6	8	8	6	CE, RE, Harm., flicker, RS, ESD, EFT	38
electronic ballast									
Phase controlled device	2		9	9	8	8	8	CE, RE, Harm., flicker, RS, ESD, EFT	44
Notes :									
(1) : equipment covered by industrial generic EMC standards or specific product standards									
(2) : equipment covered by light industry generic EMC standards or specific product standards									
(3) : tool means i.e. material cutting machine									
(4) : essential tests for market surveillance									
(M) : for electrical medical devices the EMC surveillance tests have to be done according the medical regulations & the medical EMC standards !!					ESD : ElectroStatic Discharge EFT : Electrical Fast Transient CE : Conducted Emission RE : Radiated Emission Harm. : Harmonics on mains				

**APPENDIX 4: DEFINITION OF THE APPLICABLE STANDARD(S) AND APPLICATION DATE(S)**

Needs to be analysed as international standards do not apply specific application dates

**ANNEX 3: PRACTICAL GUIDE FORMS ACTIONS FOR LVD EQUIPMENT (HOUSEHOLD)**

Provided as external document