Subject: Guide to the The General Market Surveillance Procedure – draft 2

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Version N°	Date	Changes
Draft 1	2009-05-05	First draft
Draft 2	2009-05-27	Changes made to draft 1 after meeting with Slovak authorities on 11 & 12 May 209

Changes to the former version are indicated with a "|" before the text.

1. Contents

1. Objective

The objective of this document is to provide guidance to the General Market Surveillance Procedure[1]. 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 General Market Surveillance Procedure 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 1st 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.

[1] Terms of Reference of the Market Surveillance Model Initiative as described in ECE/TRADE/C/WP.6/2008/13 and endorsed at the 18 session meeting held in Geneva on 3-4 November 2008.

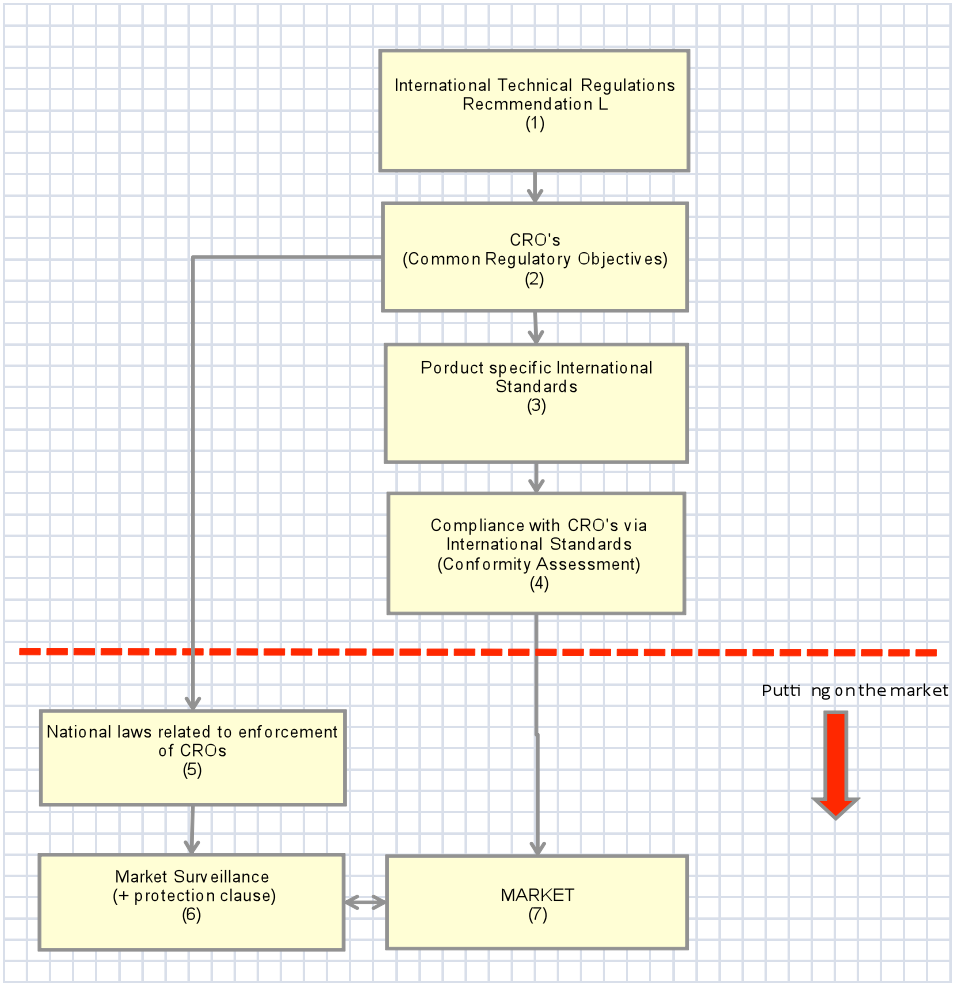


Figure 1: relation between Recommendation L[2] of UNECE and market surveillance

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:

[2] An international model for Technical Harmonisation base don 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

> '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 Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection.

Related to the discussion above about the use of the Recommendation L, Community harmonisation legislation may be replaced by the CROs.

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 designed 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 notificiations and with 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.
[more written comments needed here]

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 to be used 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 (like household equipment), but other areas may be developed.

This procedure can also be used by the Coordination Body for Market Surveillance (CB) as a guidance document and the CB 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:

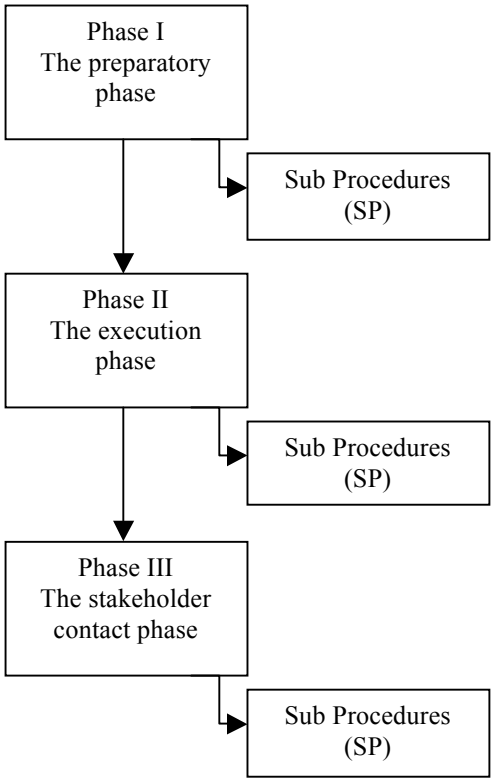


Figure 2: the structure of the GMSP

The GMSP is provided on page 9 as a flow chart.
On pages 10, 11 and 12 sub-parts of the GMSP are provided.
Different 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.

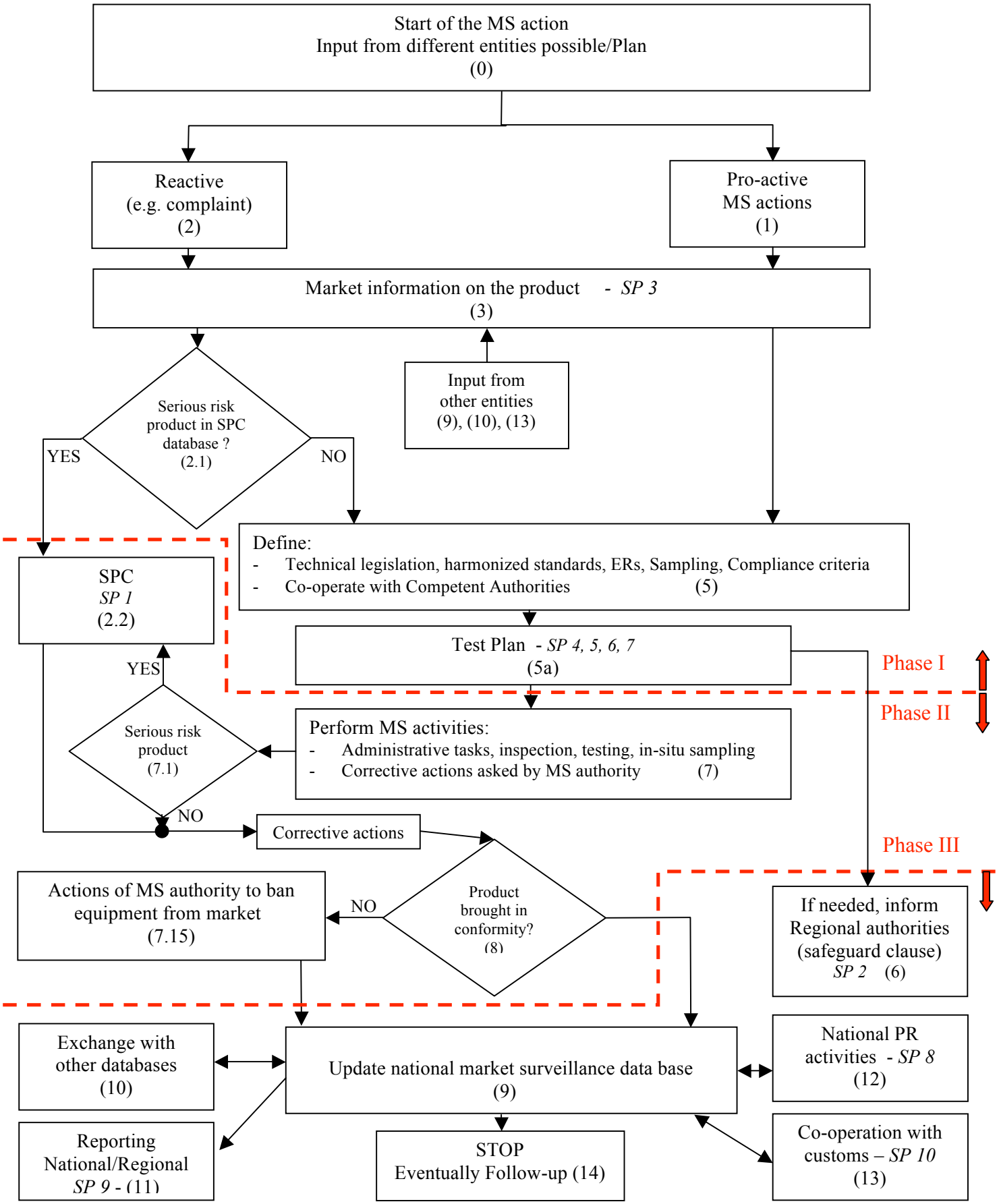
Reporting templates resulting from the GMSP and its sub procedures are in the annexes of this document or are in development. This is particularly the case for ‘difficult’ areas e.g. sampling were there exist no appropriate standards/requirements up to date.

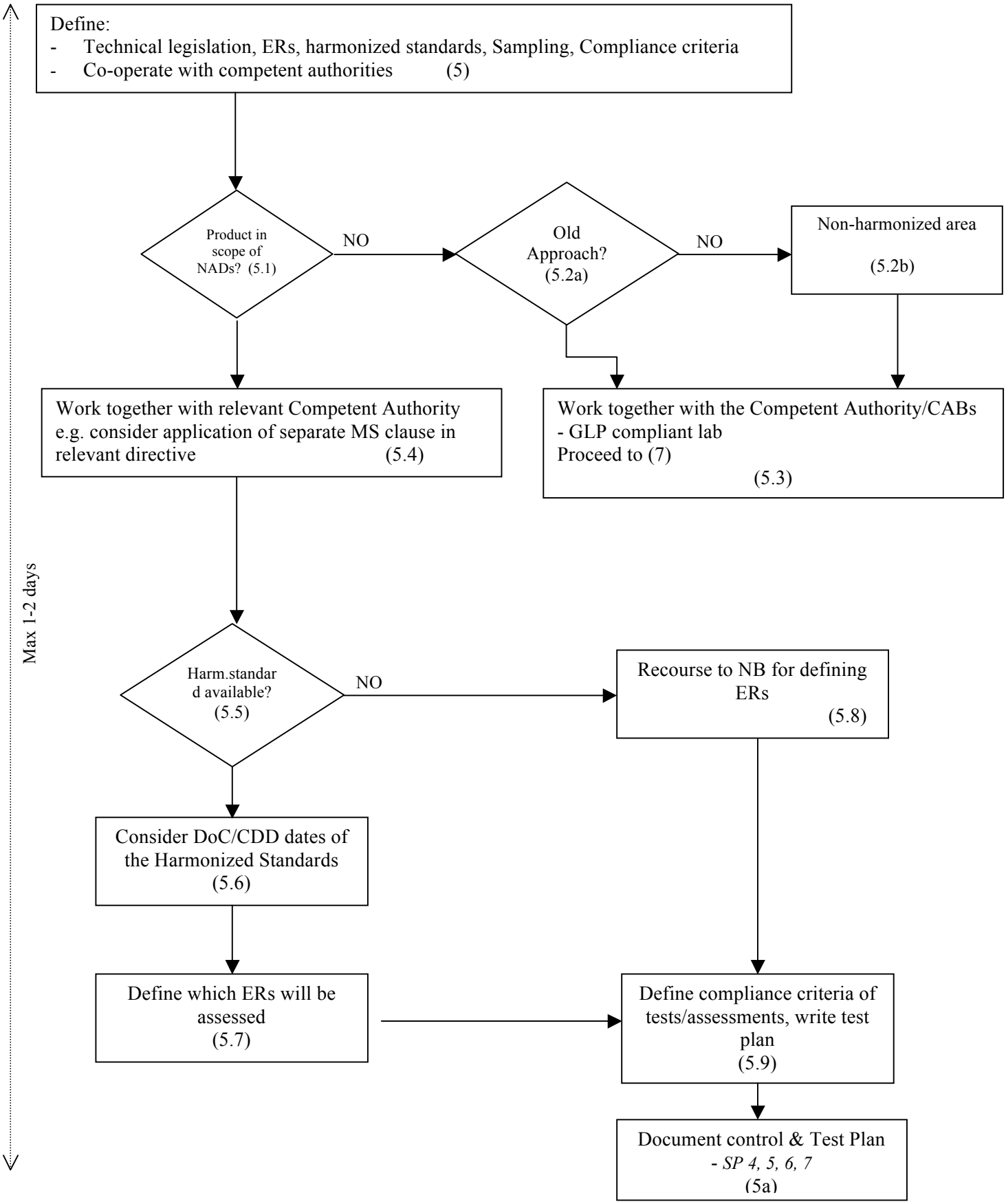
5. Abbreviations and Glossary

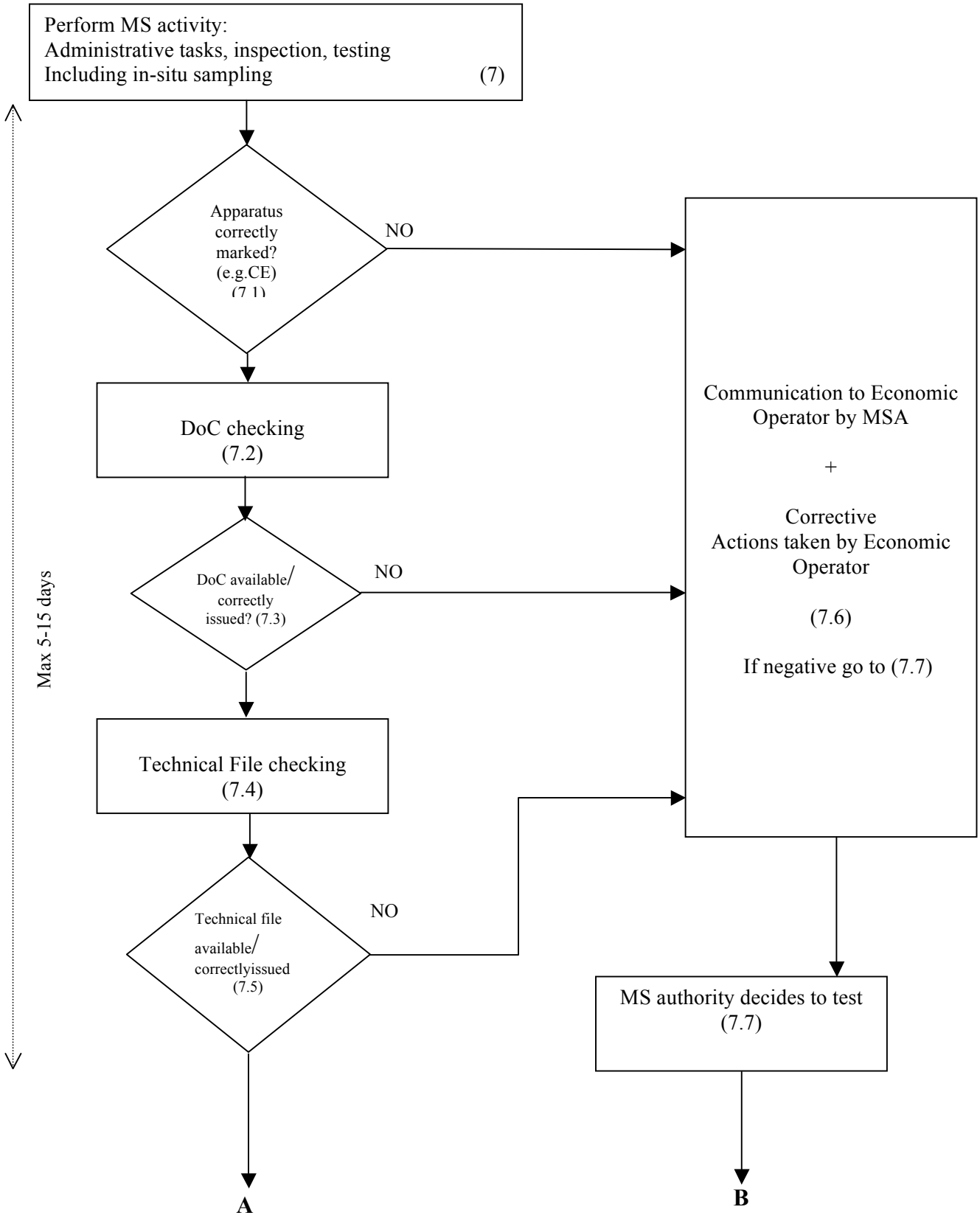
CA	Competent Authority (of a technical legislation)
CB	Co-ordination Body (national)
CAB	Conformity Assessment Body
CRO	Common Regulatory Objective
DoC	Declaration of Conformity
DoC/CDD	Date of Cessation/Commission Decision Dates
DoW	Date of Withdrawal
EC	European Commission
EO	Economic Operator
ERs	Essential Requirements
GPSD	General Product Safety Directive
MS	Market Surveillance
MSA	Market Surveillance Authority
NADs	New Approach Directives
NB	Notified Body
PR	Public Relations
SP	Sub Procedure
SPC	Single Point of Contact (related to GPSD and NAD safeguard clause)

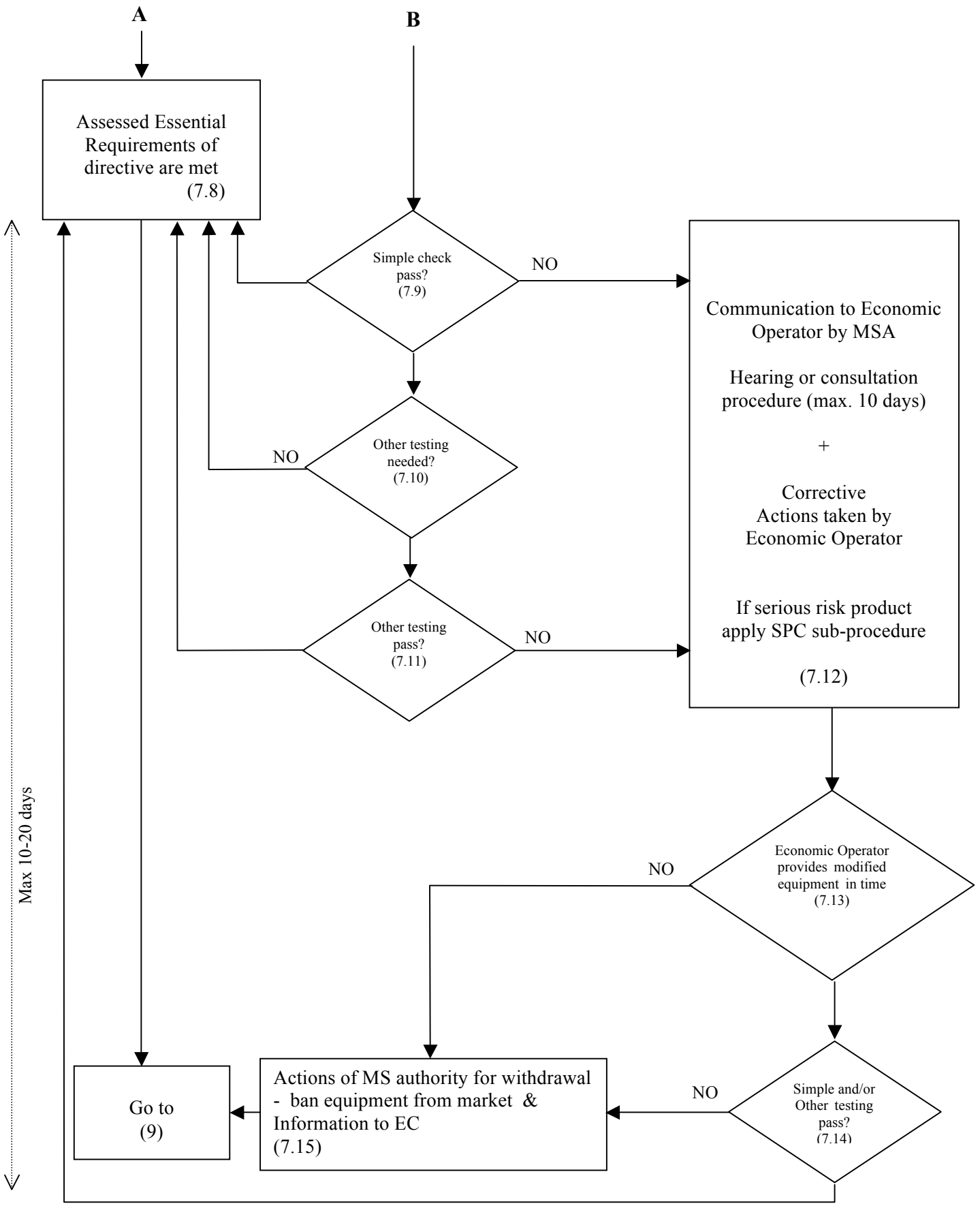
[Glossary needs to be developed]

6. The General Market Surveillance Procedure




Define:
- Technical legislation, ERs, harmonized standards, Sampling, Compliance criteria
- Co-operate with competent authorities (5)
Product in scope of NADs? (5.1)
NO
Old Approach? (5.2a)
NO
Non-harmonized area (5.2b)
Work together with relevant Competent Authority e.g. consider application of separate MS clause in relevant directive (5.4)
Work together with the Competent Authority/CABs - GLP compliant lab
Proceed to (7)
(5.3)
Max 1-2 days
Harm.standard available? (5.5)
NO
Recourse to NB for defining ERs (5.8)
Consider DoC/CDD dates of the Harmonized Standards (5.6)
Define which ERs will be assessed (5.7)
Define compliance criteria of tests/assessments, write test plan (5.9)
Document control & Test Plan
- SP 4, 5, 6, 7
(5a)


Perform MS activity:
Administrative tasks, inspection, testing
Including in-situ sampling (7)
Apparatus correctly marked? (e.g.CE) (7.1)
NO
DoC checking (7.2)
DoC available/ correctly issued? (7.3)
NO
Technical File checking (7.4)
Technical file available/ correctlyissued (7.5)
NO
Communication to Economic Operator by MSA
+
Corrective Actions taken by Economic Operator
(7.6)
If negative go to (7.7)
MS authority decides to test (7.7)
Max 5-15 days
A
B


A
B
Assessed Essential Requirements of directive are met (7.8)
Simple check pass? (7.9)
NO
Communication to Economic Operator by MSA
Hearing or consultation procedure (max. 10 days)
+
Corrective Actions taken by Economic Operator
If serious risk product apply SPC sub-procedure
(7.12)
Other testing needed? (7.10)
NO
Other testing pass? (7.11)
NO
Economic Operator provides modified equipment in time (7.13)
NO
Simple and/or Other testing pass? (7.14)
NO
Actions of MS authority for withdrawal - ban equipment from market & Information to EC (7.15)
Go to (9)
Max 10-20 days

7. The different parts of the GMSP explained.

(0) Start of the MS action

The initiation of a MS action may come form different entities:
- The MSA own unit
- The SPC point
- The CB (national Coordination Body)
- Other MS entities
- The Customs[3]

In market surveillance, there are basically 2 kinds of actions:
- Reactive actions
  These are actions which ask for immediate attention and follow-up; usually they are complaint driven (e.g. there is an acute safety problem with the products, in that case the input is coming from the national SPC point (RAPEX) or there is a complaint regarding unfair competition)
- Pro-active MS actions
  Pro-active actions relate to the planning of MS actions for the coming months or years and are performed taking in consideration criteria/information sources coming from (1), (2), (3), (4) and (9), (10) and (13). These actions normally originate from the own organization or the Coordination Body or other MSAs in the country. An example could be the planning of actions if a national legislation has been changed.

(1) 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 harmonised standards), and the limited resources of the national MS authorities, it is now generally believed that a pro-active approach is needed.

Risk assessment on the product

It is necessary to get an objective number for the potential risk(s) when using or installing a technical product. For certain industrial products within the context of the Machinery Directive, the EN ISO 14121-1[4] standard is used.
Regarding consumer products, annex II of the guideline for the notification of dangerous consumer products, related to art 5(3) of the GPSD 2001/95/EC[5], provides a method for risk assessment, see also appendix C in annex 1 of this document.
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)

[3] EEC 339/93 procedure, see also (13) cooperation with Customs
[4] EN ISO 14121-1:2007 'Safety of machinery. Risk assessment. Principles'
[5] Refer to www.newapproach.org

(2) Reactive MS actions

(2.1) Check if the product has been advised by SPC point as a serious risk product to the health and safety or other justified public interest. If yes perform the SPC procedure (2.2), use template 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.

(3) Market information on the product

The criteria/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,
- The RAPEX, SPC, ICSMS and other information sources (10),
- Relevant information from stakeholders (e.g. consumer protection organizations,..),

(4)

(5) Technical legislation, harmonized standards, Essential Requirements, sampling and compliance criteria.

(5.1) Historically in the EU, essential requirements related to safety, EMC, Spectrum use, of technical products were provided within New Approach directives like LVD, EMCD and R&TTED, including complimentary requirements of the GPSD if applicable.

So the first task is to define the technical regulations which are applicable to the product, refer to document. This procedure – the flow chart- includes the non-harmonized area also.

The definition of ERs is a very important task for the MS authorities, because in EU legislation compliance with harmonised standards (which enclose the ERs) provides for assumption of conformity with the directive (the ERs).
In the flowchart, a separate page has been reserved for the definition of the Harmonized Standards (5.5) including the DoW[6] date, the ERs and the compliance criteria when performing tests or assessments.
For defining the compliance criteria, the limits from the harmonised standard(s) or the limits defined by the NB are used, but also due consideration has to be given to the EA guidance document EA-4/16[7]: EA guidelines on the expression of uncertainty

[6] DoW: Date of Withdrawal , this term is explained in the list of harmonized standards published in the OJ, refer to www.newapproach.org
[7] refer to www.european.accreditation.org

in quantative testing and to the requirements of the requirements of the ISO/IEC 17025[8] standard in general. Due to the complexity of this standard 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 Competent Authority of a directive to define special MS requirements specified in this directive. The General Product Safety Directive provides extensive requirements for product safety and also provides for special MS clauses (some authorities used this legislation as basis for transposing new sector technical legislation).

(5.7) If for some reasons the harmonised standards are challenged (e.g. some LVD harmonized standards did present some problems in practice) the opinion[9] of the EC should also be seeked.
Grey areas: for some specific cases it will be difficult to define the ERs, e.g. to assess sharp edges on equipment. The reader is referred to guidance on the GPSD and other NAD guidance documents.

(5.8) The NB may be consulted for selecting the tests to be executed. This NB 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 harmonised product standards include sampling schemes when e.g. regulatory compliance has to be assessed, but these standards are merely exceptions. However for some directives like e.g. the Cosmetics directive 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 approach for MS sampling.

[8] refer to www.cenorm.org
[9] refer to http://europa.eu.int/comm/enterprise/electr_equipment/lv/opinions.htm

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) Safeguard clause

In certain cases when during the execution of a MS action a non-compliant result is obtained due to e.g. a defect in a harmonised standard, the authority has to inform the services of the EC. The MSA takes further on the necessary steps so that the equipment will be brought in compliance with regulations.

Also the national SPC point will be informed.

(7) Perform the MS activity: administrative tasks, inspection, testing

This is the core activity of the MSA.

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 the CE marking directive is applicable.

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

1. To check if CE marking and other labelling is on the equipment
2. To verify the availability/correctness of the DoC (EC Declaration of Conformity)
   Verify if there are reasonably suspicions of compliance with essential requirements
3. To verify the availability/correctness of the Technical File

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 MS 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 methodological 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 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 form 3rd 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 derived basically from the "blue guide" with some additional requirements (refer to the sub-procedure "Requirements and follow-up of CABs").

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 Member State 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 Community harmonisation 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-compliance product dissemination on the market during consultation with the EO must be avoided.

If serious risk is involved the sub-procedure SPC 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.

(9) Updating of the national MS database

Refer to the MS sub-procedure "Information systems".

(10) Exchange with other databases

These are data bases as RAPEX, ICSMS, SPC, CIRCA, ADCO. At national level, the SPC database would be a subset of the national MS database.

Refer to the MS sub-procedure "Information systems".

(11) Report to EC

For some NADs, there is an obligation for Member countries to inform the EC of their activities.

(12) Public Relation activities

Refer to the MS sub-procedure "Communications, PR and visibility".

(13) Co-operation with customs

Customs play an important role to detect any non-compliant 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 provided for under Community and national rules, in cases relating to products from third countries.

Refer to the MS sub-procedure "Market surveillance and customs".

(14) STOP – Ending of the MS action

After the national MS database has been updated and stakeholders were informed, it is considered that the specific MS action has ended.
It is advised, however, to check the correct implementation of the changes performed by the Economic Operator after some time e.g 1 year (called follow-up MS action).

8. Limitations of the GMSP/future work

This GMSP has been developed having harmonized new approach technical legislation in mind. In particular it is strongly linked to the needs of electrical household equipment.
This procedure has not been assessed for:

- Other kind of NA technical products
- So called old approach technical legislation
- 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.

At the latest working party on Regulatory Cooperation and Standardization Policies meeting of 3-4 November 2008 in Geneva, the need for relating statistical aspects (sampling) and technical requirements (technical legislation, standards) 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 see figure 3 would serve as a tool to MSA's to assess the effectiveness of their MS actions.

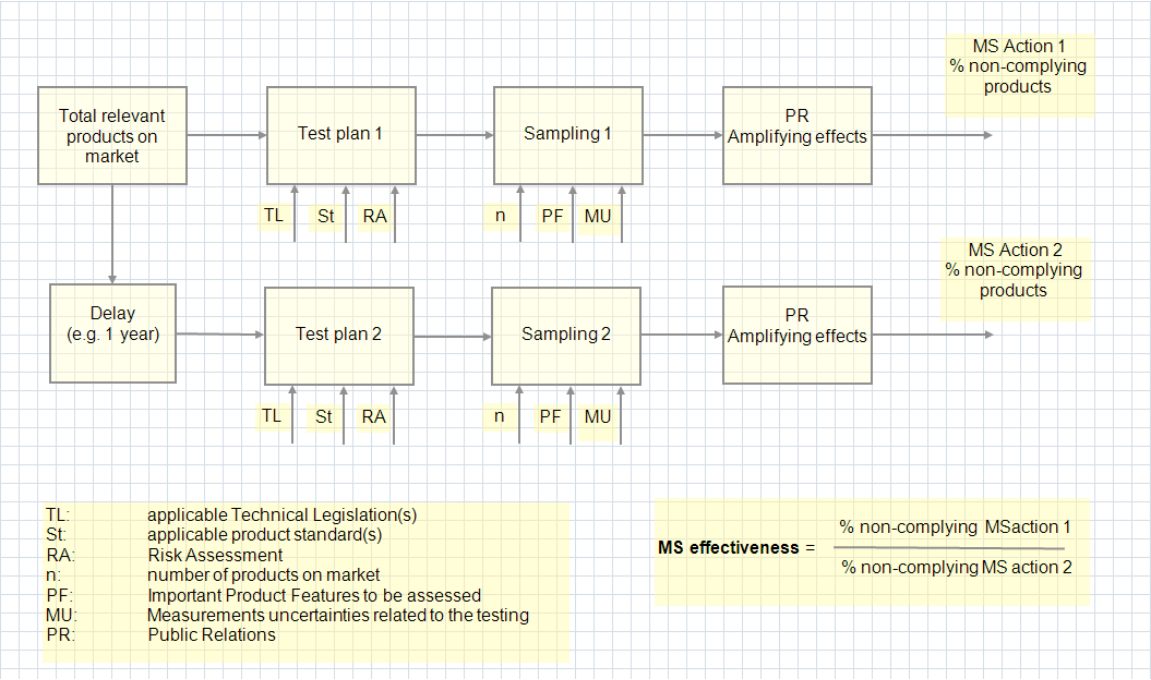


Figure 3: the MS effectiveness model

Annex 1: List of sub-procedures and related reporting templates

SP	Sub-procedure title	Template reference	Template/information availability
1	SPC sub-procedure Methodological guide for notifications regarding dangerous products	Appendix A: Contact information for respective government inspectorates (MSAs) Appendix B: Safety notification form (to be performed by Economic Operators) Appendix C: Risk Assessment Appendix D: checklist corrective actions, for Economic Operators Appendix E: notification form for dangerous products to be used by other MSAs and to be sent to the SPC Appendix F: standard list of product types Appendix G: Standard list of risks (GPSD)	**ec**.europa.eu/consumers/cons_safe/prod_safe/gpsd
2	Notification procedure according to Art. 9 of LVD (safeguard clause)	Version 1.2 Oct. 1998	Only available to EU member states administrations
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

Introduction

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

Directives

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 directive(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 Cessation (DoC[10]). This may involve the analysis of different versions of the same product standard including its amendments. An example of this analysis is provided in the list of Harmonized standards published in the OJ for each directive but also in the example in appendix 1.

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 (CE-marking, labelling such as name of manufacturer/importer, model N°, serial N°…),
- EC DoC (see for an example page 42 of the EC guide to the new EMCD 2004/108/EC)
- TF (technical file)
  The technical file is sometimes extensive (for complex products like some R&TTE products like receivers). The assessment of the TF is usually performed by the CAB.

Essential requirements

[10] In some countries IEC may still be used although due to the DoC mechanisms these may not be in use EU countries

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

The requirements of a directive for a technical product are met if the product complies to the harmonized product standards as referred to in the OJ. The essential requirements are thus included in the harmonized 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 (CABs) is usually given per tested phenomenon (e.g. mains conducted emission of the EN 55022 product standard).

Compliance criteria

Refer to (5.9) in the GMSP

A general table can be defined as follows:

Directive	**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.

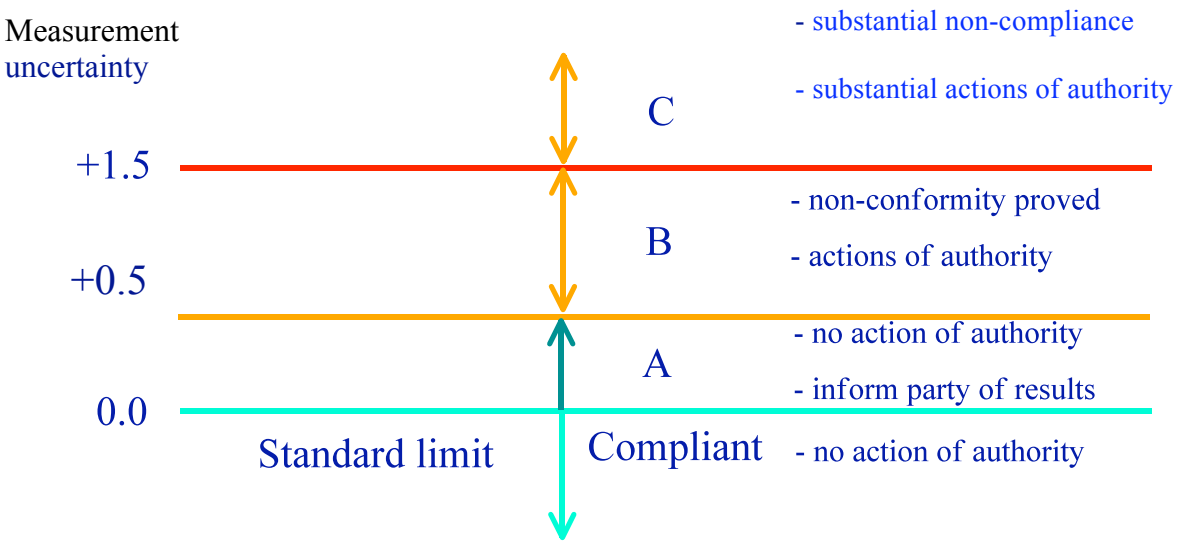


Figure: visualising compliance criteria for a specific test on a product (conducted emission)

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 information system like ICSMS. As working with this information source may not operational yet, the table used for the conformity criteria could be used. 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 the EMC Directive (2004/108/EC)

Introduction

The focus of market surveillance in the field of EMC, as product safety is not included in the scope of the directive 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 in Europe 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.

Directives

The applicable directive is the EMCD 2004/108/EC

Harmonized standards

The applicable harmonized EMC product standards are published in the OJ, refer to www.newapproach.org or the national standardization site.

The relevant EMC product standards for this product are:

- EN 55022:1994 for the HF emission part (including amendments)
- EN 61000-3-2:2000 for the harmonics part (including amendments)
- EN 61000-3-3:1995 for the flicker part (including amendments)
- EN 55024:1998 for the immunity part (including amendments)

These product standards refer to basic standards and the latest version of these should be used.

The relevant DoW date can be found in the utmost right column of the list of harmonised standards (refer to appendix 4).

Please remark that the text of the standard is in the IEC document and eventual modifications to it are in the EN version.

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 [dBµV/m]**
EMC	EN 55022:1994, Incl. A1 and A2	5.1	60 dBµV (1)	3.4	A: 62 (3) B: 66 C: >66
	EN 61000-3-2:2000		(2)		
	EN 61000-3-3:1995 Incl. A1		(2)		
	EN 55024:1998 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 EN 55022

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.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
Industrial (1)									
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	7		8	5	7				27
Power Supply)									
Non-industrial (2)									
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
White products using DC motor									
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	7		9	8		8	6	Harm., flicker, CE	38
(using electronic control)									
Electric tools									
Drilling equipment	7			7	8	8	7	CE, Harm., ESD, EFT	37
Saw equipment	7			6	8	8	7	CE, Harm., ESD, EFT	36

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
High speed grinding equipment	9			6	9	8	7	CE, Harm., ESD, EFT	39
Brown products									
TV			9	8	6	8	8	CE, RS, ESD, EFT	39
VCR			8	7	6	6	8	CE, RS, ESD, EFT	35
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
IT & Telecom									
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
Lighting									
TL lamp using electronic converter	2		8	6	8	8	6	CE, RE, Harm., flicker,	38
electronic ballast								RS, ESD, EFT	
Phase controlled device	2		9	9	8	8	8	CE, RE, Harm., flicker,	44
								RS, ESD, EFT	

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 MDD & the medical EMC standards !!

ESD : ElectroStatic Discharge
EFT : Electrical Fast Transient
CE : Conducted Emission
RE : Radiated Emission
Harm. : Harmonics on mains

Annex 4: Definition of the applicable Harmonized standard and DoC date

From the website of the EC – Official Journal
http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/emc.html
we have:

European Standardisation Organisation	Reference and title of the standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard Note 1
CENELEC	EN 55022:1994 Limits and methods of measurement of radio disturbance characteristics of information technology equipment (CISPR 22:1993)	EN 55022:1987 Note 2.1	Date expired (31.12.1998)
	Amendment A1:1995 to EN 55022:1994 (CISPR 22:1993/A1:1995)	Note 3	Date expired (31.12.1998)
	Amendment A2:1997 to EN 55022:1994 (CISPR 22:1993/A2:1996 (Modified))	Note 3	Date expired (31.12.1998)
CENELEC	EN 55022:1998 Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement (CISPR 22:1997 (Modified))	EN 55022:1994 and its amendments Note 2.1	01.08.2007
	Amendment A1:2000 to EN 55022:1998 (CISPR 22:1997/A1:2000)	Note 3	01.08.2005
	Amendment A2:2003 to EN 55022:1998 (CISPR 22:1997/A2:2002)	Note 3	01.12.2005

European Standardisation Organisation	Reference and title of the standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard Note 1
European Standardisation Organisation	Reference and title of the standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard Note 1
CENELEC	EN 61000-3-2:2000 Electromagnetic compatibility (EMC) -- Part 3-2: Limits - Limits for harmonic current emissions (equipment input current up to and including 16 A per phase) (IEC 61000-3-2:2000 (Modified))	EN 61000-3-2:1995 +A1:1998 +A2:1998 +A14:2000 Note 2.1	Date expired (01.01.2004)
CENELEC	EN 61000-3-3:1995 Electromagnetic compatibility (EMC) -- Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection (IEC 61000-3-3:1994)	EN 60555-3:1987 +A1:1991 Note 2.2	Date expired (01.01.2001)
	Amendment A1:2001 to EN 61000-3-3:1995 (IEC 61000-3-3:1994/A1:2001)	Note 3	Date expired (01.05.2004
CENELEC	EN 55024:1998 Information technology equipment - Immunity characteristics - Limits and methods of measurement (CISPR 24:1997 (Modified))	Relevant generic standard(s) Note 2.3	Date expired (01.07.2001)
	Amendment A1:2001 to EN 55024:1998	Note 3	Date expired

European Standardisation Organisation	Reference and title of the standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard Note 1
	(CISPR 24:1997/A1:2001) Amendment A2:2003 to EN 55024:1998 (CISPR 24:1997/A2:2002)	 Note 3	(01.10.2004) 01.12.2005

General remark: when there is a stroke in the column 4 (reference of the superseded standard), it means that the referenced standard may not be used without amendment or particular part for EMC purpose.

Note 1: Generally the date of cessation of presumption of conformity will be the date of withdrawal ("dow"), set by the European standards body, but attention of users of these standards is drawn to the fact that in certain exceptional cases this can be otherwise[11].

Note 2.1: The new (or amended) standard has the same scope as the superseded standard. On the date stated, the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

Note 2.2: The new standard has a broader scope than the superseded standard. On the date stated the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

Note 2.3: The new standard has a narrower scope than the superseded standard. On the date stated the (partially) superseded standard ceases to give presumption of conformity with the essential requirements of the directive for those products that fall within the scope of the new standard. Presumption of conformity with the essential requirements of the directive for products that still fall within the scope of the (partially) superseded standard, but that do not fall within the scope of the new standard, is unaffected.

Note 3: In case of amendments, the referenced standard is EN CCCCC:YY, its previous amendments, if any, and the new, quoted amendment. The superseded standard (column 4) therefore consists of EN CCCCC:YY and its previous amendments, if any, but without the new quoted amendment. On the date stated, the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

[11] For market surveillance actions the DoC is related to the directive and this date takes priority over the DoW date.

Annex 3: Practical guide for MS actions for LVD equipment (household)

Provided as external document