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PANEL SESSIONS

Panel session 1 – Market Surveillance Model Initiative*

Note by the secretariat

Addendum

The General Market Surveillance Procedure

Summary

At its thirteenth session, the Working Party established an Advisory Group on Market Surveillance (“MARS” Group) and mandated it to report on its activities.

This document is intended to guide market surveillance authorities in the organization of controls on the national markets to ensure product compliance.

The document is submitted to the Working Party for discussion with a view to future adoption as a recommendation.

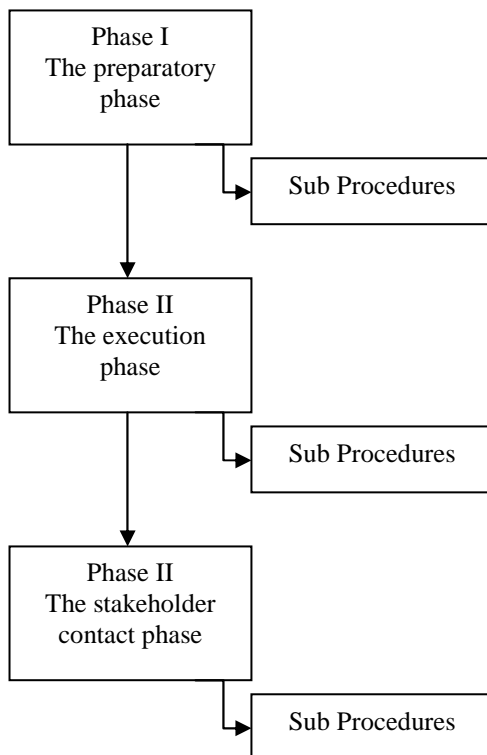
* This document was submitted late due to delayed inputs from other sources.

I. Scope of the document

1. This General Market Surveillance Procedure (GMSP) has been developed to be used by the national Market Surveillance Authorities (MSA) in the non-food area.
2. It is a proposal for a concept to be used in this globalized world where products can be imported from all over the globe. MS actions are usually monitored/steered by a regional entity. Currently there is no international entity for this important task.
3. It can also be used by the Coordination Body for Market Surveillance (CB) as a guidance document.
4. References to specific sub-procedures (SPs) have been added in this draft 2, refer to annex 1.
5. The focus in these sub procedures is on mass produced electrical equipment (like household equipment).
6. Reporting templates resulting from the GMSP and its sub procedures are in development.

II. Structure of the document

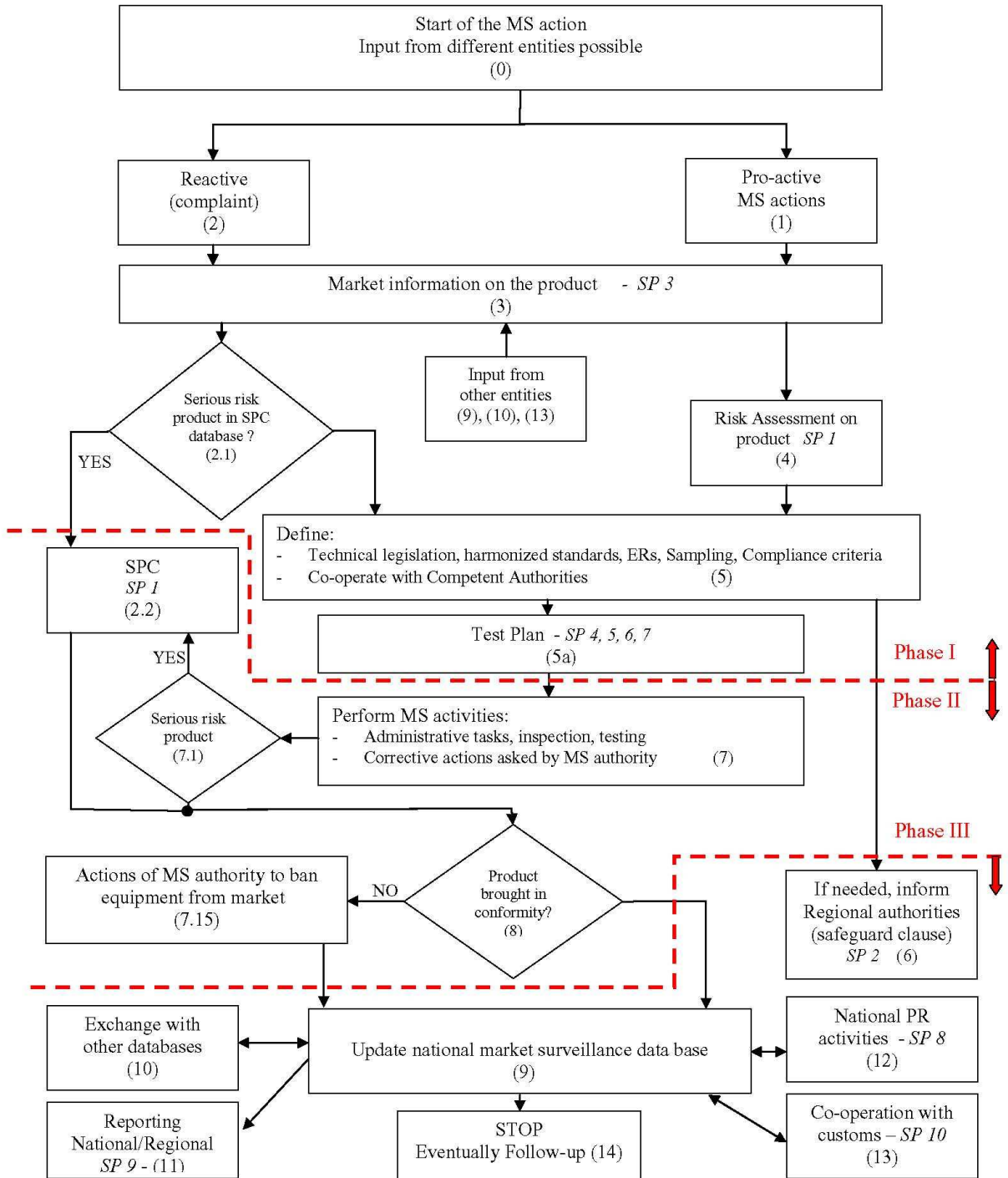
7. A MS action may be broken down into three phases:

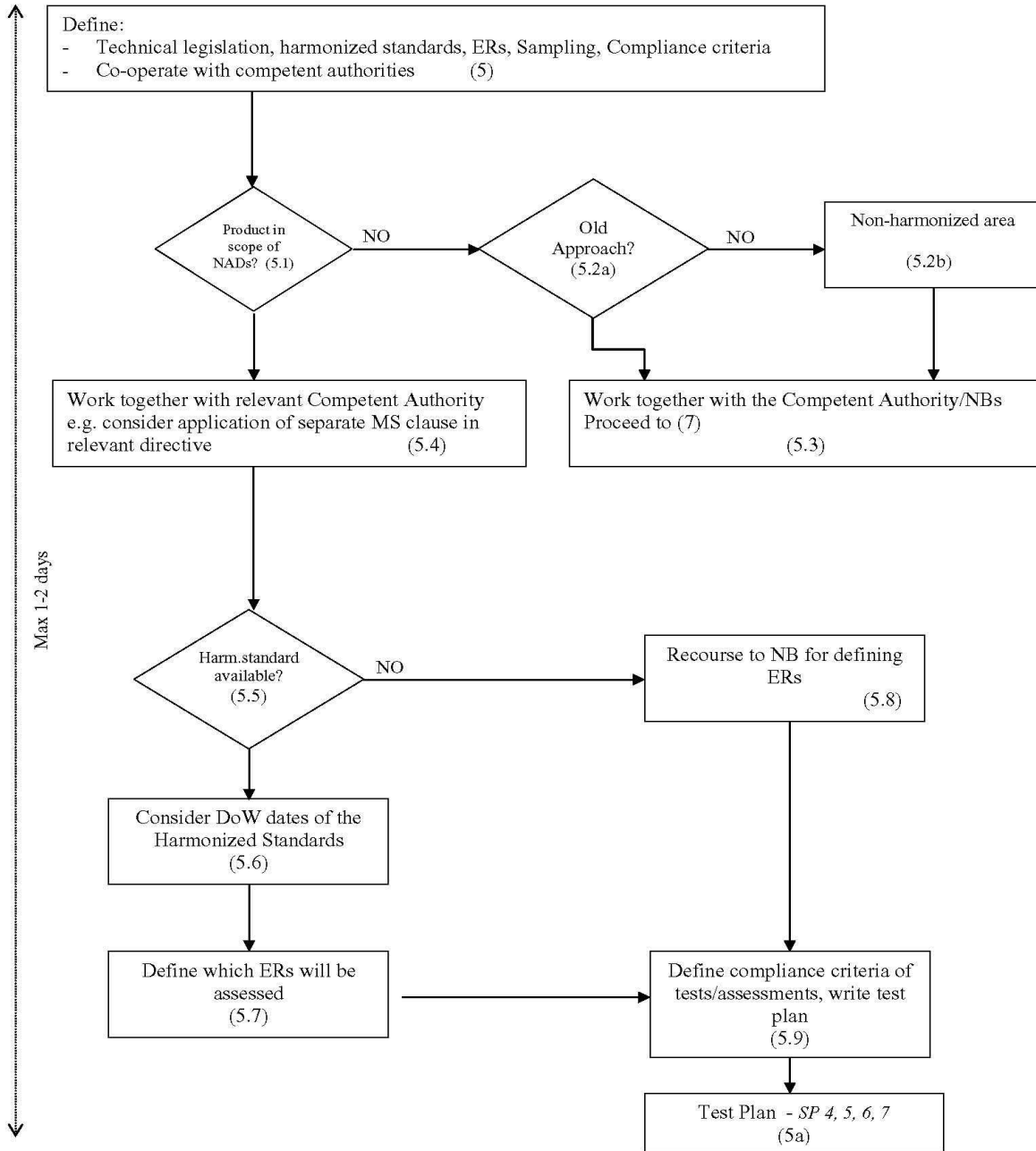


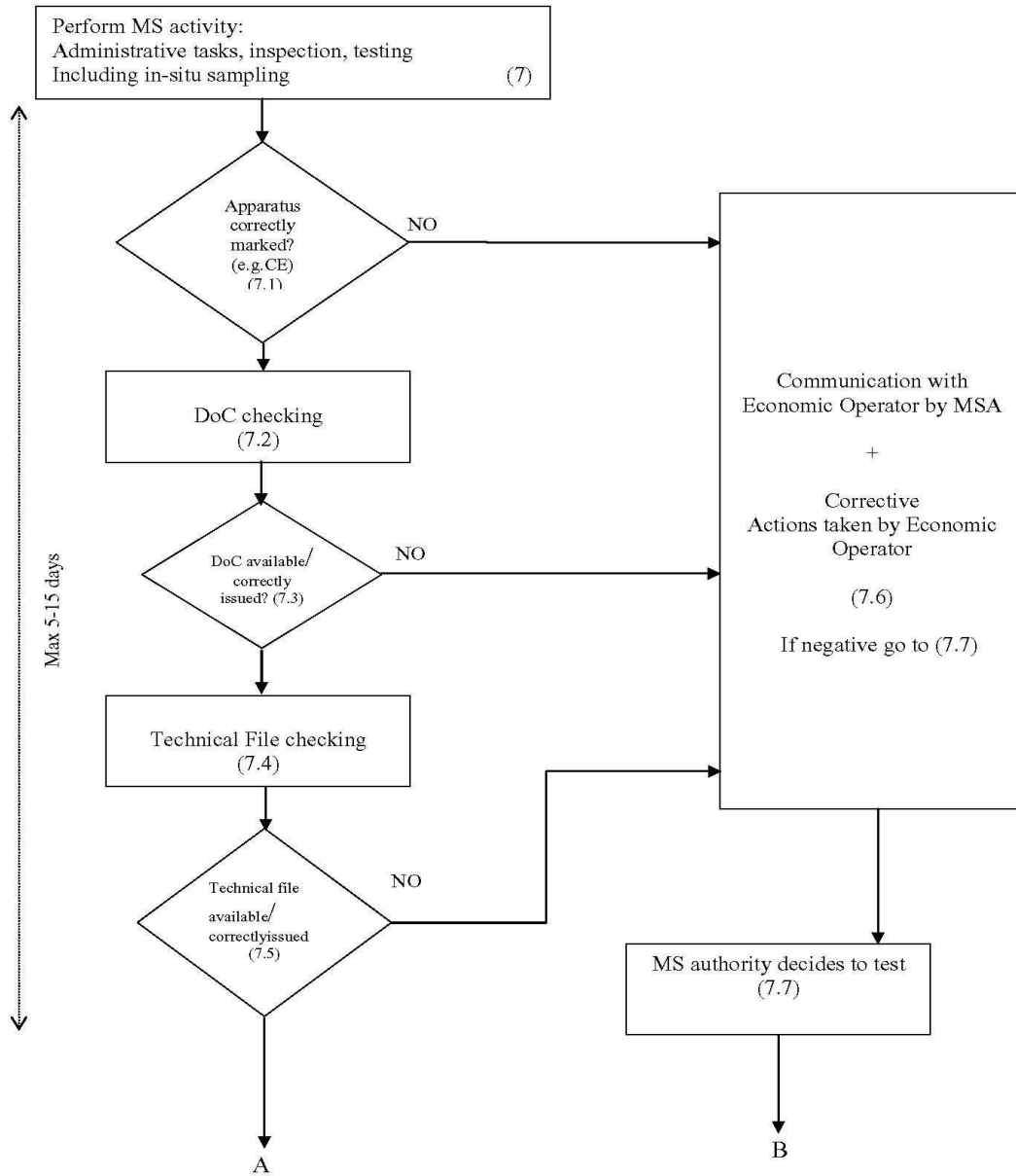
III. Abbreviations

CA	Competent Authority (of a technical legislation)
CB	Co-ordination Body (national)
DoC	Declaration of Conformity
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

IV. The General Market Surveillance Procedure







V. Explanations

A. Start of the MS action (0)

8. The initiation of a MS action may come from different entities:

- (a) The MSA own unit
- (b) The SPC point
- (c) The CB (national Coordination Body)
- (d) Other MS entities
- (e) Customs¹

9. In market surveillance, there are basically two kinds of actions:

- (a) Reactive actions 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)
- (b) Pro-active MS 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.

B. Pro-active MS actions (1)

10. 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.

C. Reactive MS actions (2)

11. (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.

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

¹ EEC 339/93 procedure, see also (13) cooperation with Customs

D. Market information on the product (3)

13. The criteria/information sources which can be used to plan a pro-active MS action are:
- (a) Market information of the products on the national market (national statistical office, Customs data)
 - (b) Monitoring of accidents
 - (c) Follow-up of complaints
 - (d) The RAPEX, SPC, ICSMS and other information sources (10)
 - (e) Relevant information from stakeholders (e.g. consumer organizations)

E. Risk assessment on the product (4)

14. 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 14121-1² standard is used.

15. 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/EC³, provides a method for risk assessment, see also appendix C in annex 1 of this document.

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

F. Classification of equipment according to directive, harmonized standards and Essential Requirements (5)

17. (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.

18. So the first task is to define the technical regulations which are applicable to the product, refer to document COM(2007)37⁴, which defines the scope of the new EC MS regulation. COM(2007)37 refers to the harmonized area only. This procedure – the flow chart- includes the non-harmonized area.

² EN ISO 14121-1:2007 'Safety of machinery. Risk assessment. Principles'

³ Refer to www.newapproach.org

⁴ Refer to http://ec.europa.eu/enterprise/regulation/internal_market_package/index_en.htm, meanwhile this Regulation has been published in the OJ.

19. 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).
20. In the flowchart, a separate page has been reserved for the definition of the Harmonized Standards (5.5) including the DoW⁵ date, the ERs and the compliance criteria when performing tests or assessments.
21. For defining of 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-4/16⁶: EA guidelines on the expression of uncertainty in quantitative testing and to the requirements of the requirements of the ISO/IEC 17025⁷ 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. This does not mean that the MSA can perform preliminary testing using basic test equipment or highly automated test equipment which allows for straight forward operation.
22. (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 it as basis for transposing new sector technical legislation).
23. If for some reasons the harmonised standards are challenged (e.g. some LVD-harmonized standards did present some problems in practice) the opinion⁸ of the EC should also be sought.
24. (5.9) a test plan is written, which is to be used for requiring formal quotes of the CABs (mostly the labs). Refer also to the "Procurement procedure".

G. Speed of action within part (5)

25. 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.

H. Safeguard clause (6)

26. In certain cases when a defect to a harmonised standard is detected, the authority has to inform the services of the EC.
27. Also, the national SPC point will be informed.

⁵ DoW: Date of Withdrawal , this term is explained in the list of harmonized standards published in the OJ, refer to www.newapproach.org

⁶ refer to www.european.accreditation.org

⁷ refer to www.cenorm.org

⁸ refer to http://europa.eu.int/comm/enterprise/electr_equipment/lv/opinions.htm

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

28. This is the core activity of the MSA.
29. Most market surveillance activities are administrative (inspection) tasks, as referred to in the flowchart (7.1-7.6).
30. This part of the chart applies to equipment for which the CE marking directive is applicable.
31. The successive administrative inspections are as follows, see (7.1) to (7.5):
- (a) To check if CE marking and other labelling is on the equipment
 - (b) To verify the availability/correctness of the DoC (EC Declaration of Conformity). Also, verify if there are reasonable suspicions of compliance with essential requirements.
 - (c) To verify the availability/correctness of the Technical File
32. It is only after the above-mentioned steps that the MS authority can decide to test (7.7).
33. The different corrective actions taken by the MS authority (7.6) may be:
- (a) Communications with the Economic Operator to solve the non-conformity within a defined period of time
 - (b) Refer also to the checklist corrective actions provided as appendix D of the methodological guide for dangerous products (see Annex 1 of this document)
34. Verification of Technical Files is usually performed in co-operation with CABs, as these entities have the competence to assess these files.

J. Speed of action within part (7.1) – (7.6):

35. 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 third countries).

K. The MS authority decides to test (7.7) – (7.15)

36. Essentially, two kinds of tests can be foreseen for MS purposes:
- (a) “Simple” tests
 - (b) “Other” tests

37. There is no clear definition for “simple” tests, 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, among others).

38. “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, among others.).

39. 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”).

L. Consultation (hearing) with the Economic Operator (7.12)

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

(a) 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.

(b) 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.

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

42. If serious risk is involved the sub-procedure SPC will be followed.

M. Sampling

43. 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.

44. There are proposals in some MS working groups to use the ISO 2859-1 standard called “Sampling procedures for inspection by attributes, part 1, Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection”.

45. However, ISO 2859-1, which is based mainly on Mil-Std documents, was developed for the purpose of acceptance of products (AQL levels, inspection levels).

46. This standard supports the contractual relation manufacturer (supplier) – client, so that ISO 2859-1 is used as a decision document and at the same time as a negotiation source. Apparently in MS actions, the Market Surveillance Authorities (MSAs) are free to take samples and no contract is signed for this purpose.

47. Also ISO 2859-1 assumes a homogeneous production lot onto which sampling/decisions will be executed; as far as MS is concerned, the basket of products is very heterogeneous and one cannot guarantee a normal distribution of product features.

48. Then may be the most critical issue: the number of samples. The number of samples ISO 2859-1 requires, especially for critical product features like safety requirements, is quite high (depending on the number of products assessed, this number may be more than 100). Assuming the cost of product assessments and the cost of the samples, it may not be feasible to use ISO 2859-1 directly.

49. Some harmonised product standards include sampling schemes when, for example, regulatory compliance has to be assessed, but these standards are merely exceptions.

50. There is currently no agreed approach for MS sampling.

N. Speed of action within part (7.7) – (7.15)

51. 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.

O. Updating of the national MS database (9)

52. Refer to the MS sub-procedure “Information systems”.

P. Exchange with other databases (10)

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

54. Refer to the MS sub-procedure “Information systems”.

Q. Report to EC (11)

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

R. Public Relation activities (12)

56. Refer to the MS sub-procedure “Communications, Public Relations and Visibility”.

S. Co-operation with customs (13)

57. The regulation (EEC)339/93⁹ on checks for conformity with the rules on product safety in the case of products imported from third countries requires the customs authorities to be closely involved in the market surveillance operations and information systems provided for under Community and national rules, in cases relating to products from third countries.

58. Reference is to be made to the MS sub-procedure “Market surveillance and customs”.

T. STOP – Ending of the MS action (14)

59. After the national MS database has been updated and stakeholders were informed, it is considered that the specific MS action has ended.

60. It is advised, however, to check the correct implementation of the changes performed by the Economic Operator after some time, e.g. one year (called follow-up MS action).

⁹ Refer to page 60 of the “blue guide”, meanwhile regulation (EEC) 339/93 has been repealed and replaced by the regulation setting out requirements for accreditation and market surveillance relating to the marketing of products.

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

N°	Sub-procedure	Template reference	Remarks – Template availability
1	SPC sub-procedure Methodological 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 SPC</p> <p>Appendix F: standard list of product types</p> <p>Appendix G: Standard list of risks (GPSD)</p>	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	
3	MS Information systems		
4	General MS test plan		
5	Sampling procedure		
6	Procurement procedure		
7	Requirements for and follow-up of CABs		
8	Communications, PR and visibility		
9	Reporting of MSA to national/Regional authorities		
10	Market Surveillance and Customs		
