

# UNECE WP on Regulatory Cooperation and Standardisation Policies

MARS group

## **Update to the Market Surveillance Model**

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# Introduction

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## **General MS Model draft 3**

(developed within UNECE WP6 MARS)

Available at

[http://www.unece.org/fileadmin/DAM/trade/wp6/SectoralInitiatives/MARS/Slovakia\\_Oct09/GMSP3.pdf](http://www.unece.org/fileadmin/DAM/trade/wp6/SectoralInitiatives/MARS/Slovakia_Oct09/GMSP3.pdf)

# Introduction

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- ✓ MS Model developed since 2007 within the UNECE WP6 MARS group;
- ✓ Based on recommendations N and L
- ✓ The Model has been inspiring MS entities including industry initiatives worldwide and its contents are still prominent;
- ✓ Effectiveness of MS actions has always been the leading target of the Model.

# Introduction

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## Scope

- ✓ Non-food area
- ✓ Basically, developed with the background of sectoral technical legislation
- ✓ Electrical equipment has been taken as an example

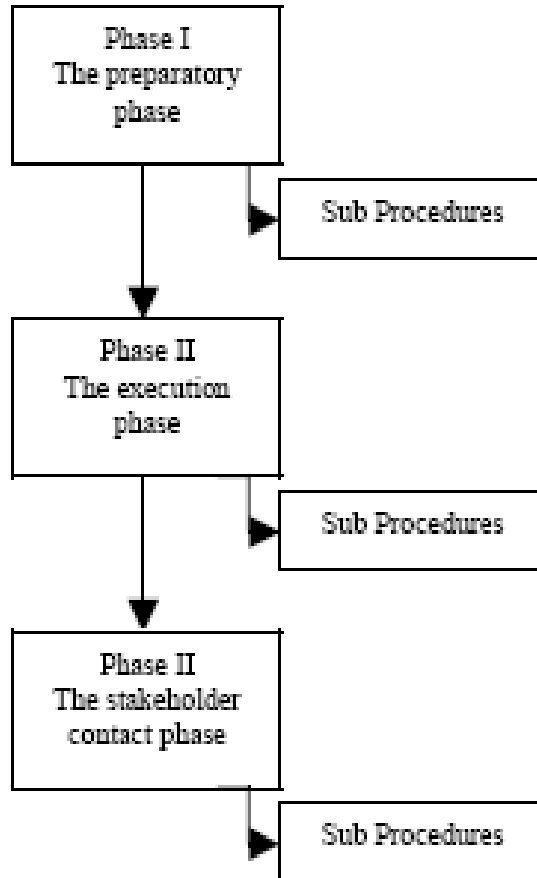
The idea is that it can be used by other sectors (this was tested successfully)

# Introduction

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## Structure of the GMSP

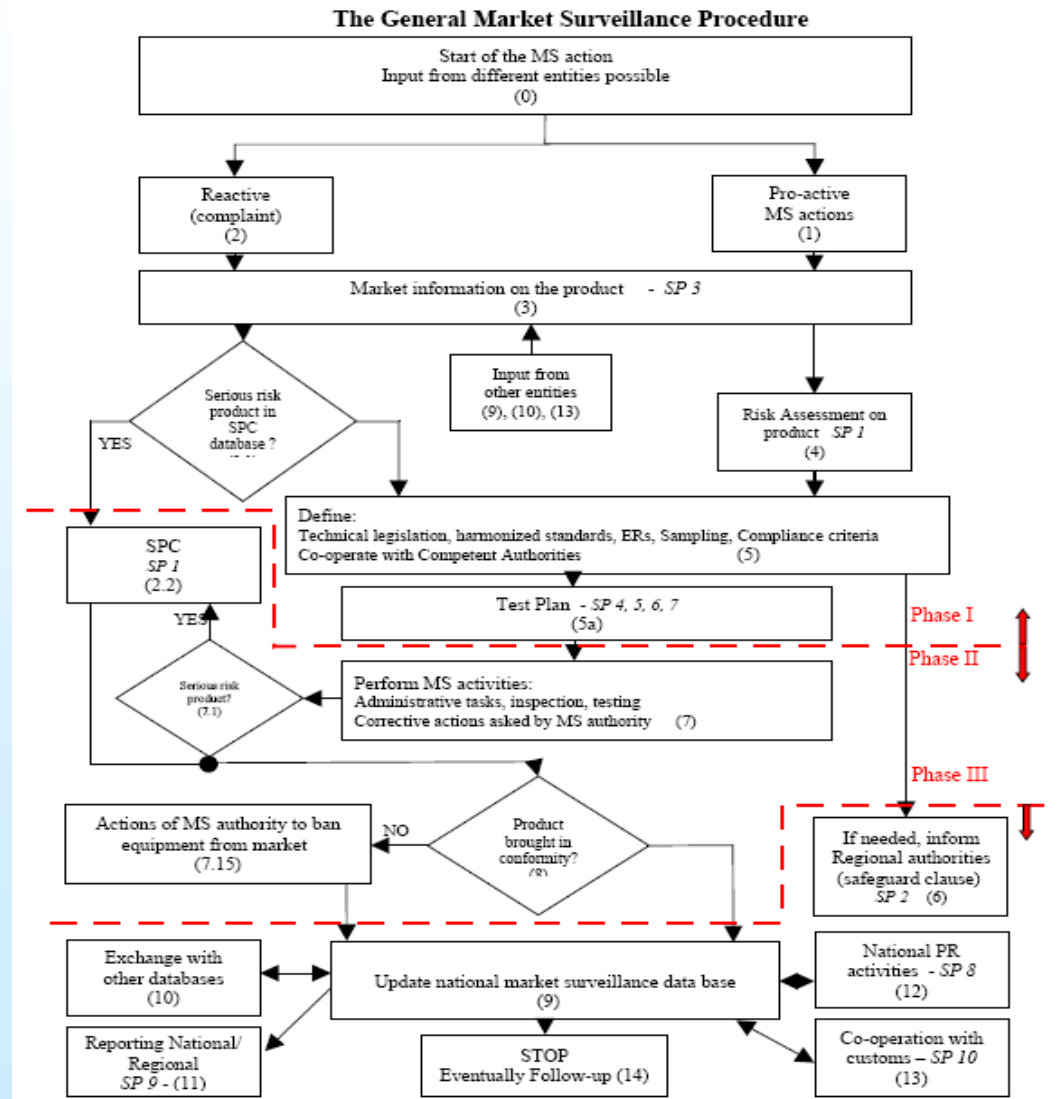
3 phases, each MS phase has sub-procedures



# Introduction

## Structure of the GMSP

The overall procedure (all 3 phases)



# Introduction

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## Structure of the GMSP

### Annex 1: List of sub-procedures

*About 10 Sub-procedures were identified and some work has been done:*

General MS test plan, Sampling procedure, Procurement procedure, Requirements for and follow-up of CABs, Communications, PR and visibility, Reporting of MSA to national/regional authorities, Market Surveillance and Customs, among others.

Some templates have been issued e.g. for the MS test plan



# Introduction

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New work done since 2009:

- ✓ Conformity rate (CR) put forward as objective (KPI) to get and keep effective MS system
- ✓ Sampling procedures
  - ✓ Homogenous sampling
  - ✓ Non-homogenous sampling
- ✓ Importance of in-house assessments (testing) for MSAs

# Why to update the Model?

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- ✓ Regulatory frameworks do not clearly define outcomes of MS actions, i.e. what is the need on human and financial resources to get an effective MS system
- ✓ We even do not know exactly what is “an effective MS system”
- ✓ This situation leaves freedom to MSAs to implement a performing or a less performing MS system
- ✓ Change in doing business (e-commerce)

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# Setting objectives for MS actions

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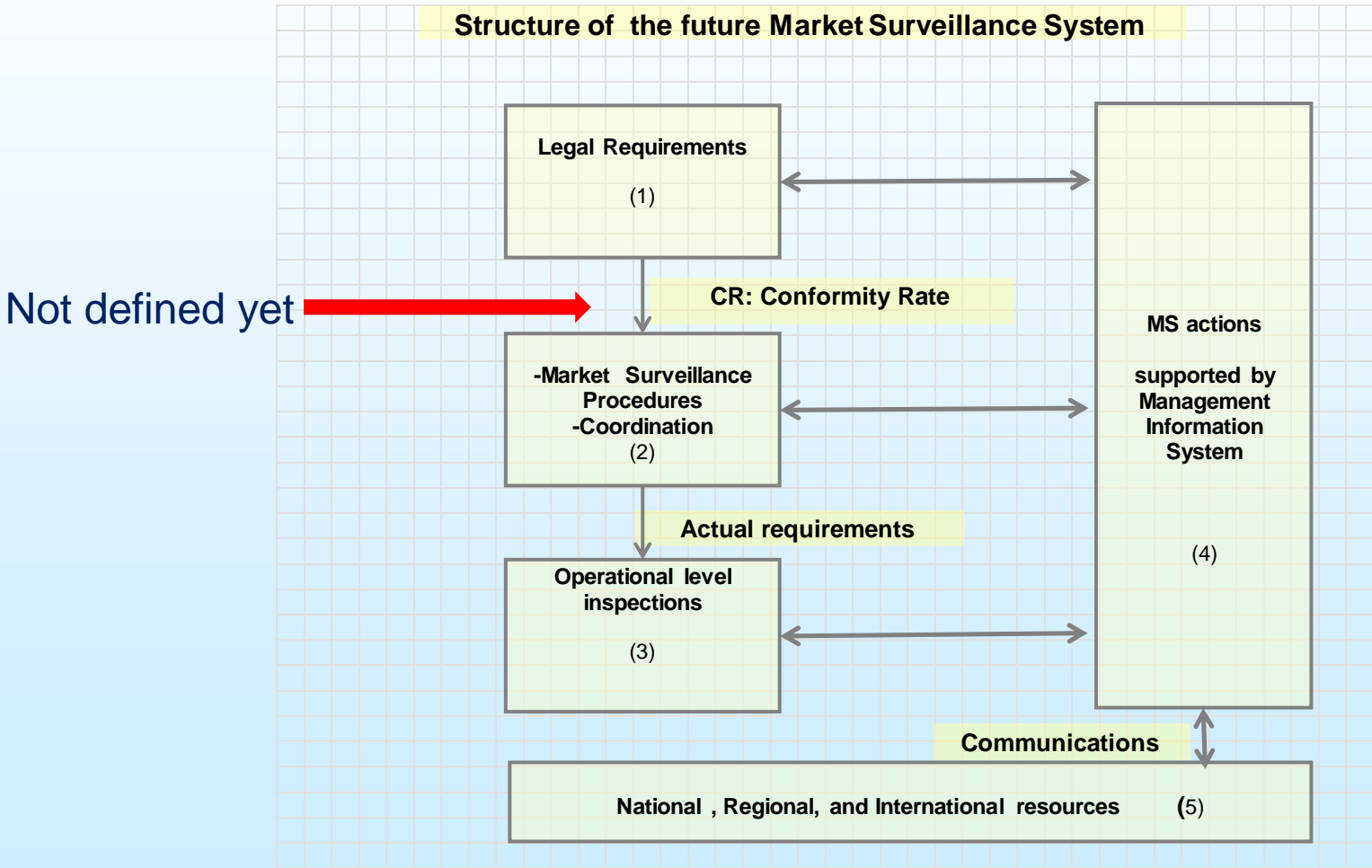
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## Introduction

- ✓ An essential requirement of a performing MS system is that it protects the legislative system applicable upon products placed on the market (sustainability, confidence)

# Setting objectives for MS actions

## Current status of the MS model



# Setting objectives for MS actions

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## ✓ Adequate scale: what does it mean?

- First requirement of Recommendation N (page 1: “..to ensure that products meet legal requirements... ”);
- Currently not clear what it means practically.

Recognizing the need to ensure that products placed on the market or imported meet legal requirements on safety, health, environment, fair competition between economic operators, and any other aspects of public interest (hereinafter “legal requirements”).

**To consider that sampling costs are “the” limiting factor in MS actions**

# Setting objectives for MS actions

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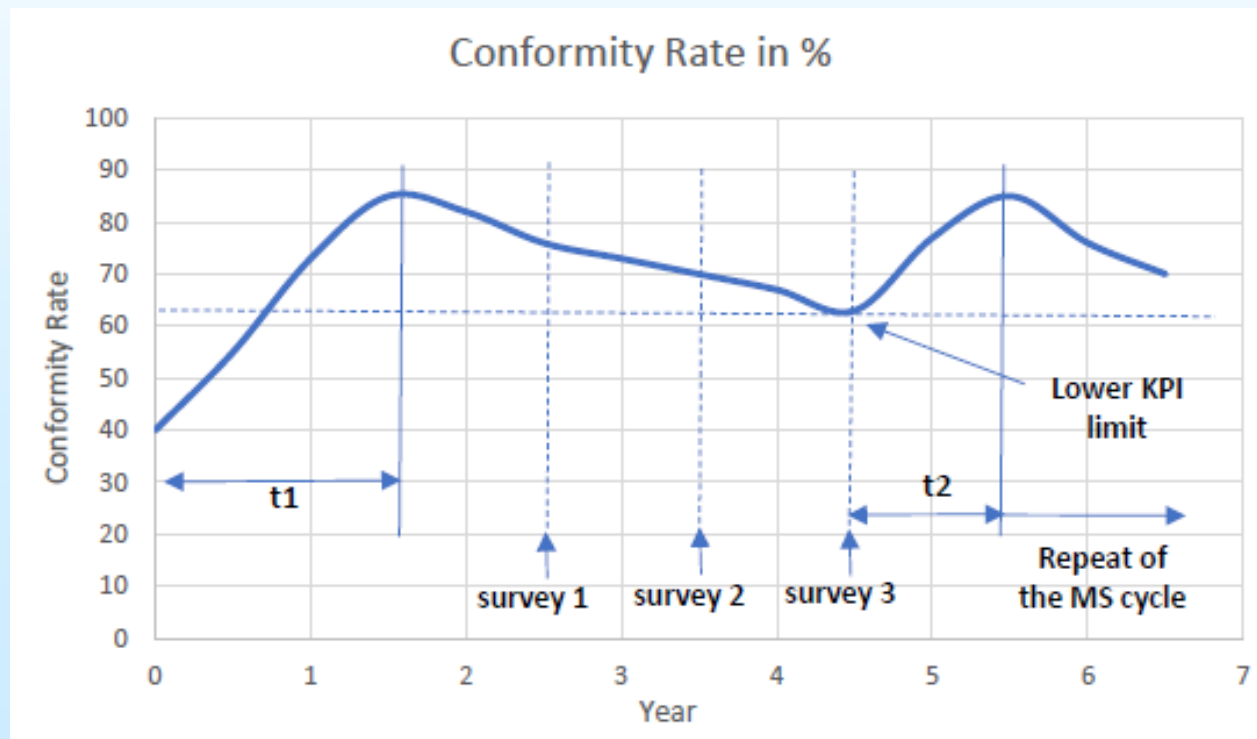
## Setting objectives on “adequate scale”

- ✓ Axiom on sustainability of the system :
  - ✓ Conformity Rate  $\geq 85\%$
- ✓ Target market is highly non-homogenous

# Setting objectives for MS actions

## Dynamics of the outcome indicators

The figure shows the dynamics of MS actions, i.e., the purpose is to control the market, in other words to control the conformity rates of consumer products, consumer services and consumer issues.





# Setting objectives for MS actions

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## Dynamics of the outcome indicators

Proposed KPIs (CRs) for product safety

<b>Risk category of the products (<i>Note 1</i>)</b>	<b>Conformity rate (KPI) (<i>Note 2</i>)</b>	<b>Comments</b>
Serious risk <sup>1</sup> products	99%	
High risk products	95%	
Medium risk products	85%	
Low risk products	80%	Most of products on the market are in this risk category
Average value for all risk categories mentioned above	85%	

# Setting objectives for MS actions

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## Setting objectives on “adequate scale”

Define cost function of market sampling

(used to develop the system level sampling procedure, see further)

$$C = C1.nLR + C2.nMR + C3.nHR + C4.nSR$$

Where:

C = total cost of sampling and should be minimal.

LR: Low-acceptable Risk product

MR: Medium Risk

HR: High Risk

SR: Serious Risk

(risk categories from EC Risk Assessment Decision).

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# System level sampling

# System level sampling

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## 1. Introduction

### Why sampling at system level sampling is important?

- Large number of products on the market
- Cost/time are limiting factors in MS actions
- Numeric classification of hazard/risk is getting of more importance (classification of essential requirements), e.g. See IEC Guide 116:2018 - Guidelines for safety related risk assessment and risk reduction for low voltage equipment. Now used for development of product safety standards.

# System level sampling

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## Objectives sampling at system level

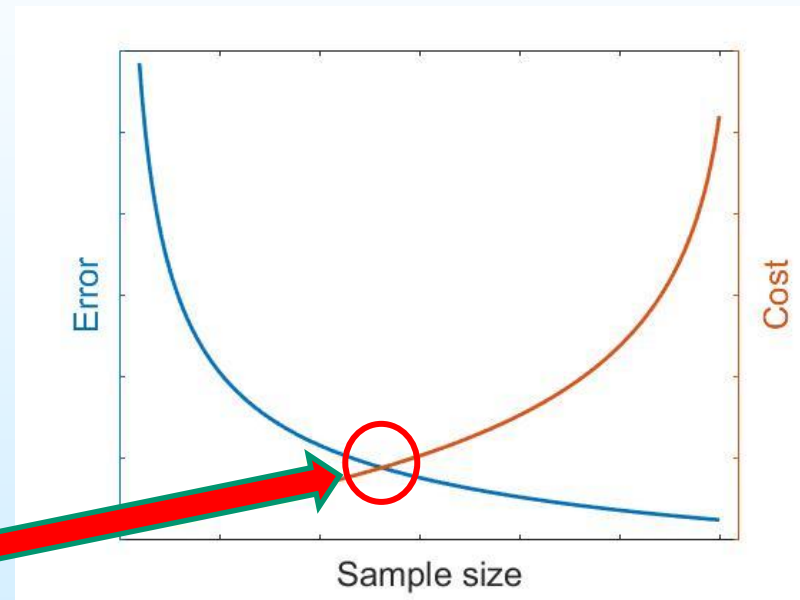
- ✓ Large quantities of products may be analysed
- ✓ Optimisation of costs/time
- ✓ Based on Bayesian statistics  
(i.e. using previous information to allow predictions for future MS actions).

# System level sampling

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Considering the cost function, sampling (sample size) is compromise between:

costs and precision



**Optimal choice  
is possible**

# System level sampling

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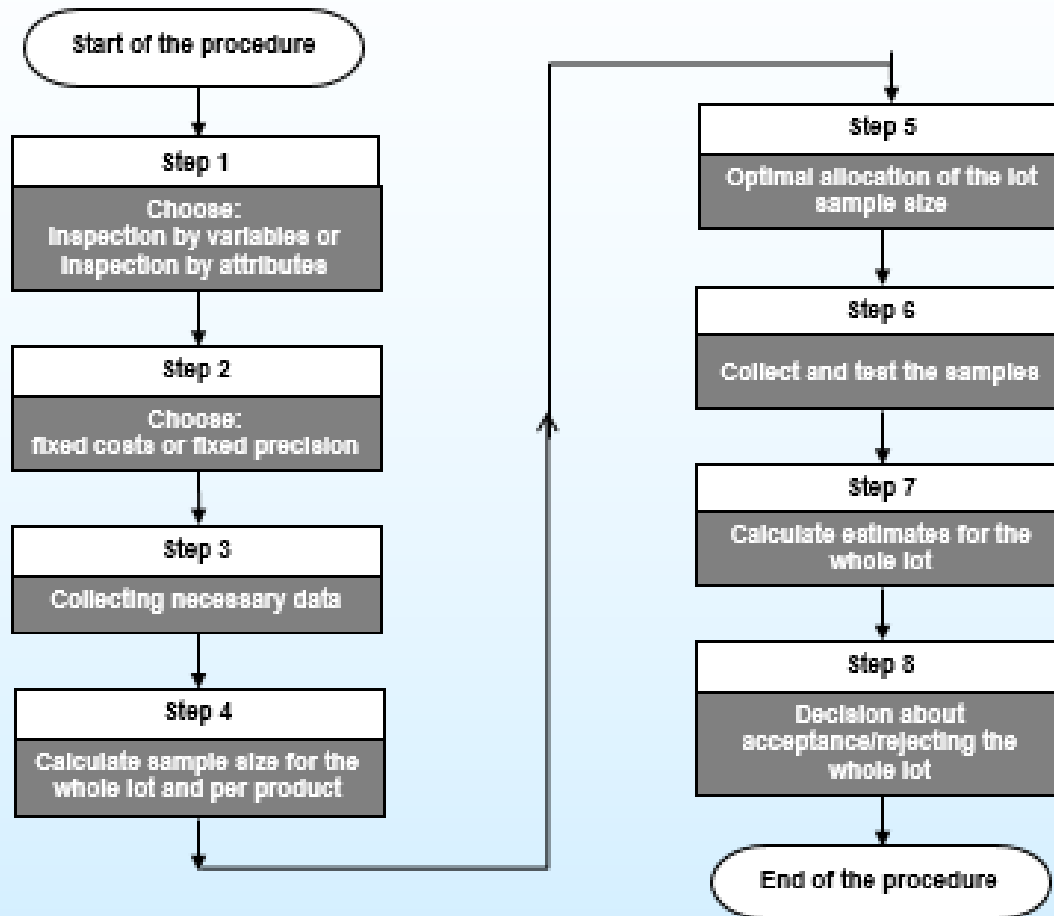
## Classification of risk category of products

Assignment of 4 classes of risks to 4 levels of confidence:

Curve	Classification of risk	Level of confidence (LC)
1	Serious	0,9986
2	High	0,95
3	Medium	0,9
4	Low or acceptable risk	0,8

# System level sampling

Flow chart may also be applied to develop annual MS plans



(Excel template available)



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# Organisation of MSA and QMS

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## Requirements for establishing a modern MSA

- Recommendation N used as basis
- Quality Management System based on ISO/IEC 17020

# Organisation of MSA and QMS

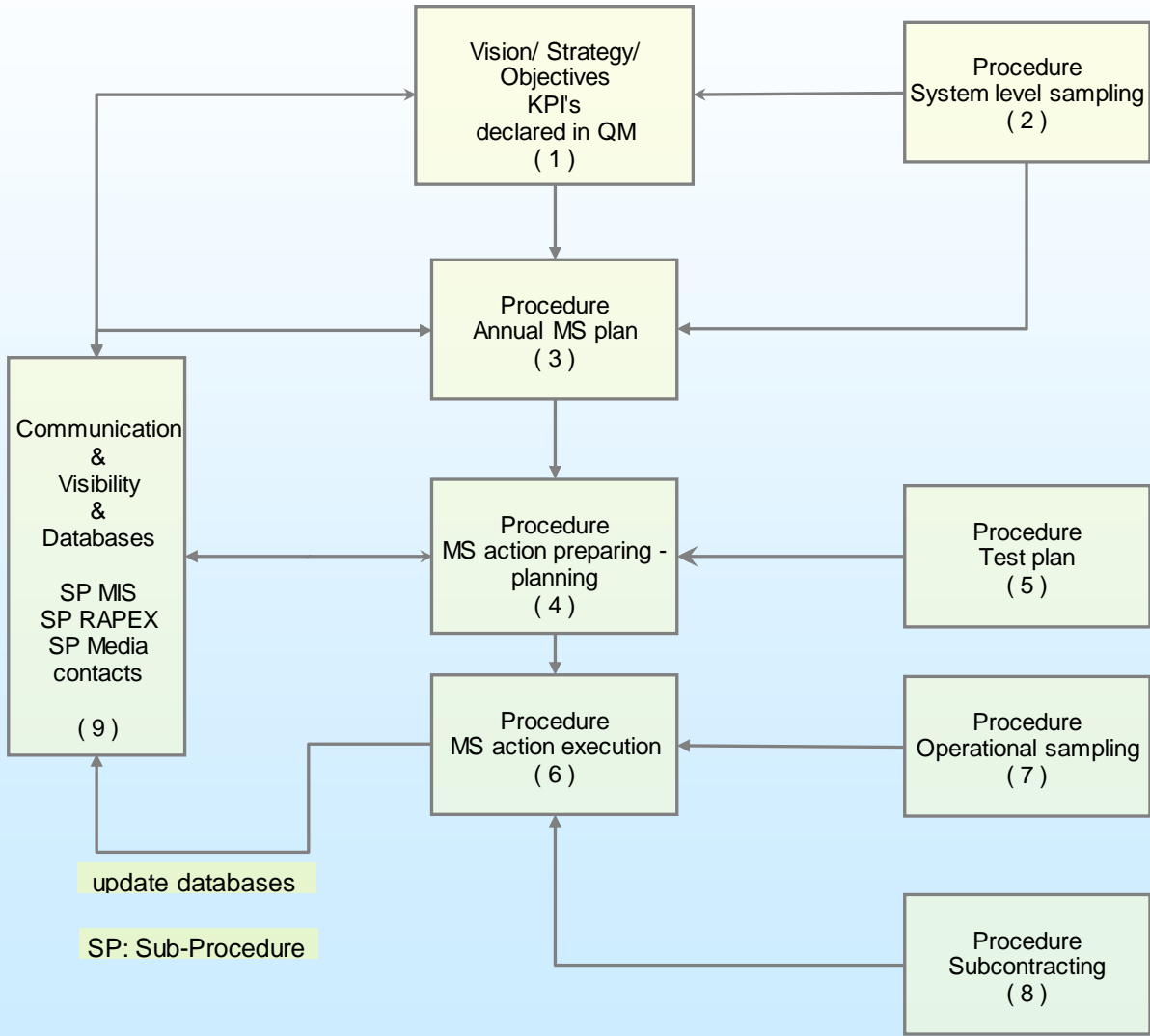
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## Structure of the QMS for a modern MSA

- Quality Manual
- Procedures
- Templates/Forms/Checklists etc.

# Organisation of MSA and QMS

## Quality Management System for a Market Surveillance Authority Core procedures



# Organisation of MSA and QMS

## Quality Management System for a Market Surveillance Authority Supporting procedures

### Human Resources

- Recruitment
  - Continuous Professional Development
- ( 10 )

### Continuous improvement

- Suggestions & proposals
  - Internal audits
- ( 11 )

### Cooperation with stakeholders

- Stakeholder management
- ( 12 )

### Reporting & Records

- Reporting
  - Records updating
  - Follow-up of TL/standards
- ( 13 )

### Facilities & equipment

- Inventories
  - Calibration/Validation of equipment
- ( 14 )

### Specific test procedures

- LVD
  - EMC
  - MD
- ( 15 )

Checklists  
Templates

( 16 )

# Organisation of MSA and QMS

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## Proposal: development of core procedures

Based on the requirements of recommendation N and the work of the UNECE-MARS working group since 2009, we propose to add following core procedures to GMSP:

- ✓ Introduce concept of NCR into GMSP (at top of flow chart: refer to core procedure 1 slide no 29)
- ✓ A system sampling procedure (refer to core procedure 2 slide no 29)
  - ✓ To be used to set objectives for MS actions (85 % CR)
  - ✓ To create annual/multi-annual MS plans

# Gaps in the GMSM

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## 1. Sub-procedures:

- ✓ Setting objectives in MS actions among different product categories using market surveys.
- ✓ A procedure to perform system level sampling in support of setting and keeping CRs.
- ✓ A Business Plan approach to MS actions: content and to include cost considerations.
- ✓ A structure of a QMS for an MSA.
- ✓ Content of an audit checklist for the assessment of the operation of MSAs.
- ✓ Requirements for a web crawler for data mining for market survey and market surveillance purposes.

## 2. Adjust the GMSP draft 3 to current state-of-the-art.

# Conclusions and way forward

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It is proposed, given the huge work load see previous slide, to work, within a small WG, on following items:

- ✓ Setting objectives in MS actions among different product categories using market surveys.
- ✓ A procedure to perform system level sampling in support of setting and keeping CRs.

Expected development duration would be 12 months if at least 6 experts engage in the development.