

Proposal for the development of a Market Surveillance procedure

UNECE MARS meeting

Bratislava 10-12 October 2007

Ivan Hendriks

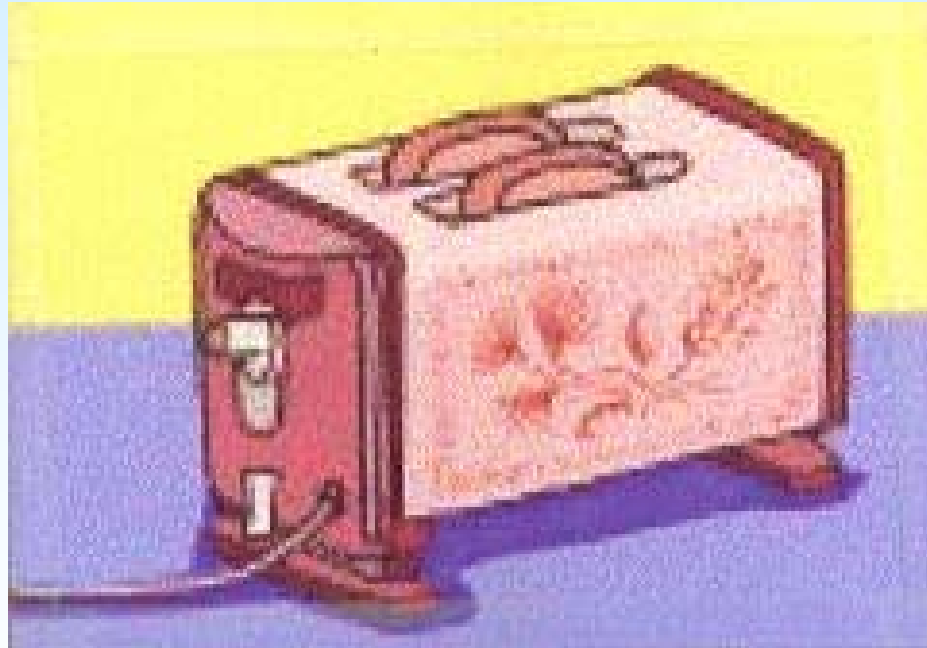
Market Surveillance expert

Contents of this presentation

1. Case of unsafe toaster in EU legislation
2. Market surveillance trends in EU today
3. The general market surveillance procedure
4. Costs of MS actions
5. Preliminary conclusions
6. Reference documents

2. Case of unsafe toaster in EU

(Refer to EC website – LVD for information)



2. Case of unsafe toaster in EU

COMMISSION OPINION

- within the framework of Council Directive 73/23/EEC (now 2006/95/EC) relating to electrical equipment designed for use within certain voltage limits, safety of toasters (decision 2002/C 300/04)
- refers to the application of Article 5 (use of harmonized standards that provided for presumption of compliance with LVD) of that Directive.
- Harmonised standards EN 60335-1 and EN 60335-2-9 were published in the *Official Journal of the European Communities*.
- **Safeguard clause procedure Article 9 with regard to EN 60335-2-9 had to be applied**

2. Case of unsafe toaster in EU

- This standard, in its current version, does not adequately address functional safety in terms of protection against electromagnetic disturbances and normally occurring voltage transients from the main electricity supply. Electrical appliances which are electronically controlled (e.g. with an electronic timer) and in compliance with the requirements of the above mentioned standard might not comply with the requirements of the LVD with regard to foreseeable external influences on electrical equipment. This may require a risk analysis and assessments.

2. Case of unsafe toaster in EU

Conclusions of the previous slides

- This unsafe toaster may still be on the market and is not detected,
- There may be a need to simulate the default using a test set-up to make some authorities aware of the danger,

3. Market surveillance trends in EU

Scope of Market Surveillance (currently)

1. Free trade of products on single market in EU
2. EU member states are responsible (subsidiarity principle, see art. 95 of the Treaty) for market surveillance actions

3. Market surveillance trends in EU

Aims of Market Surveillance in EU

Refer to [1]

Checking and ensuring

1. That the products are in conformity with the essential requirements and are safe
2. That CE marking and EC conformity declarations are correct
3. That the conformity assessment procedures have been correctly applied and if necessary to bring the equipment in line with the ERs.

4. The general market surveillance procedure

Overview of phases

Phase I
Preparation

Phase II
Actions

Phase III
contact with stakeholders

Supported by:

- * management
- * Quality ISO/IEC 17020
- * PR, communications and visibility actions

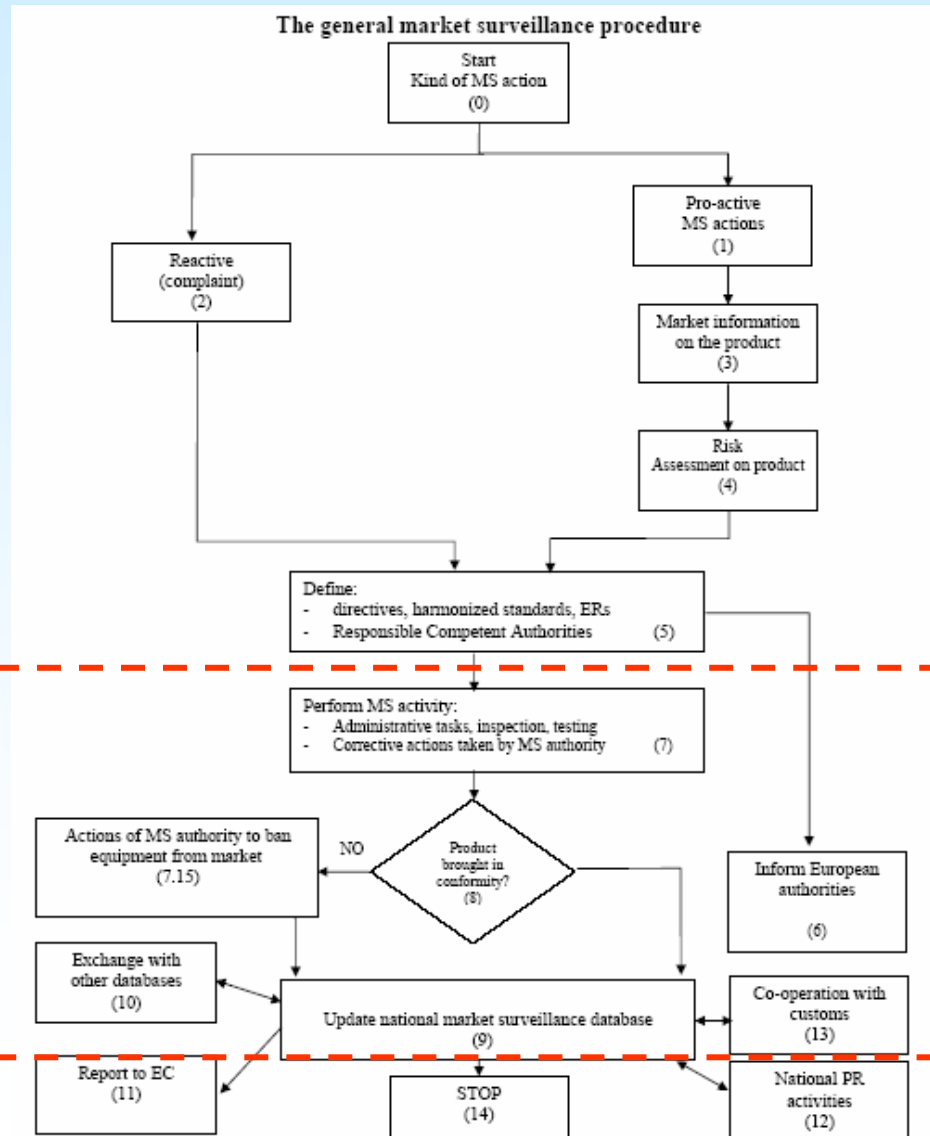
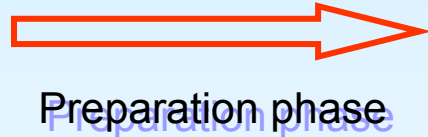
4. The general market surveillance procedure

An overall flowchart, to be used for products, is provided but to be further developed for different kind of equipment

Integrates:

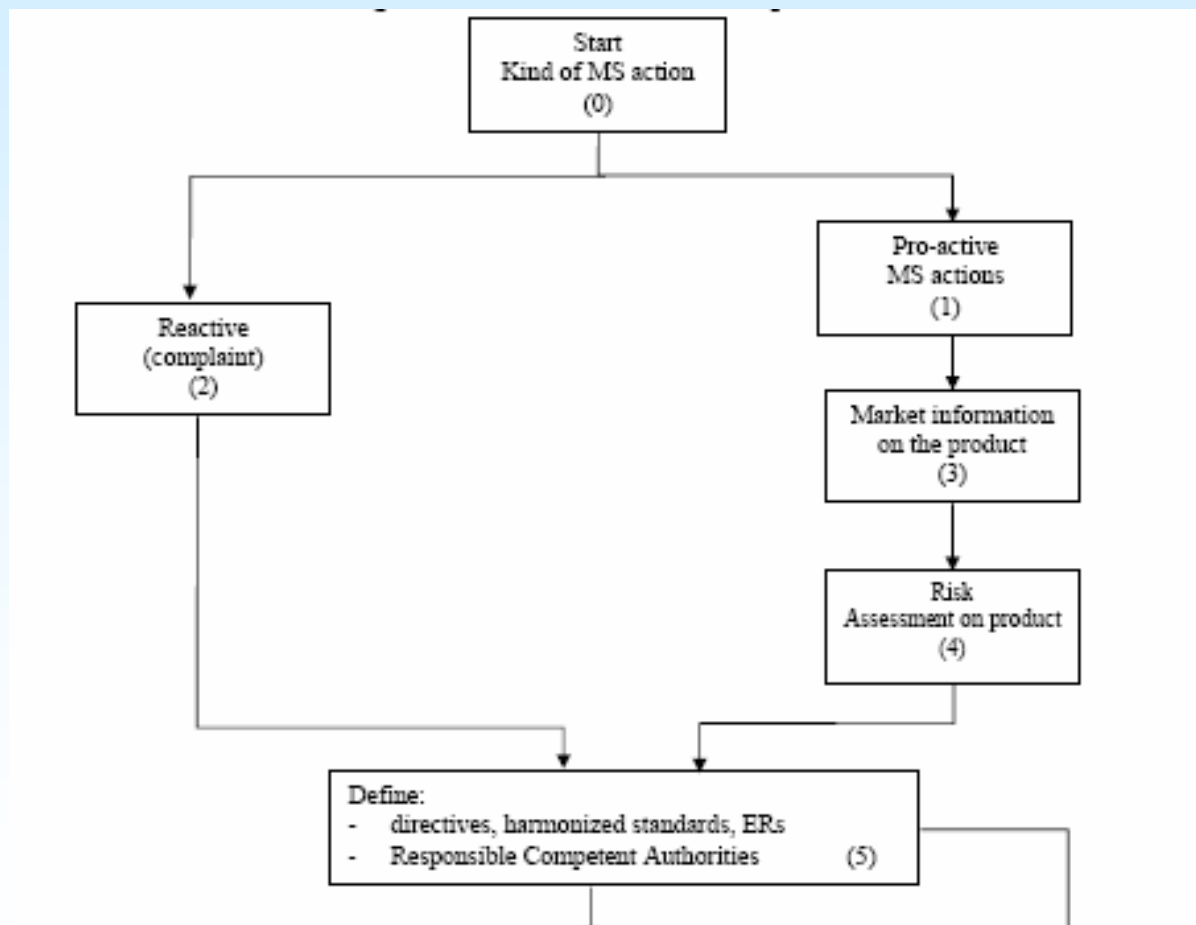
- The MS actions either national or European (incl. border controls)
- Conformity assessment methods
- Coordination at EU level

4. The general market surveillance procedure



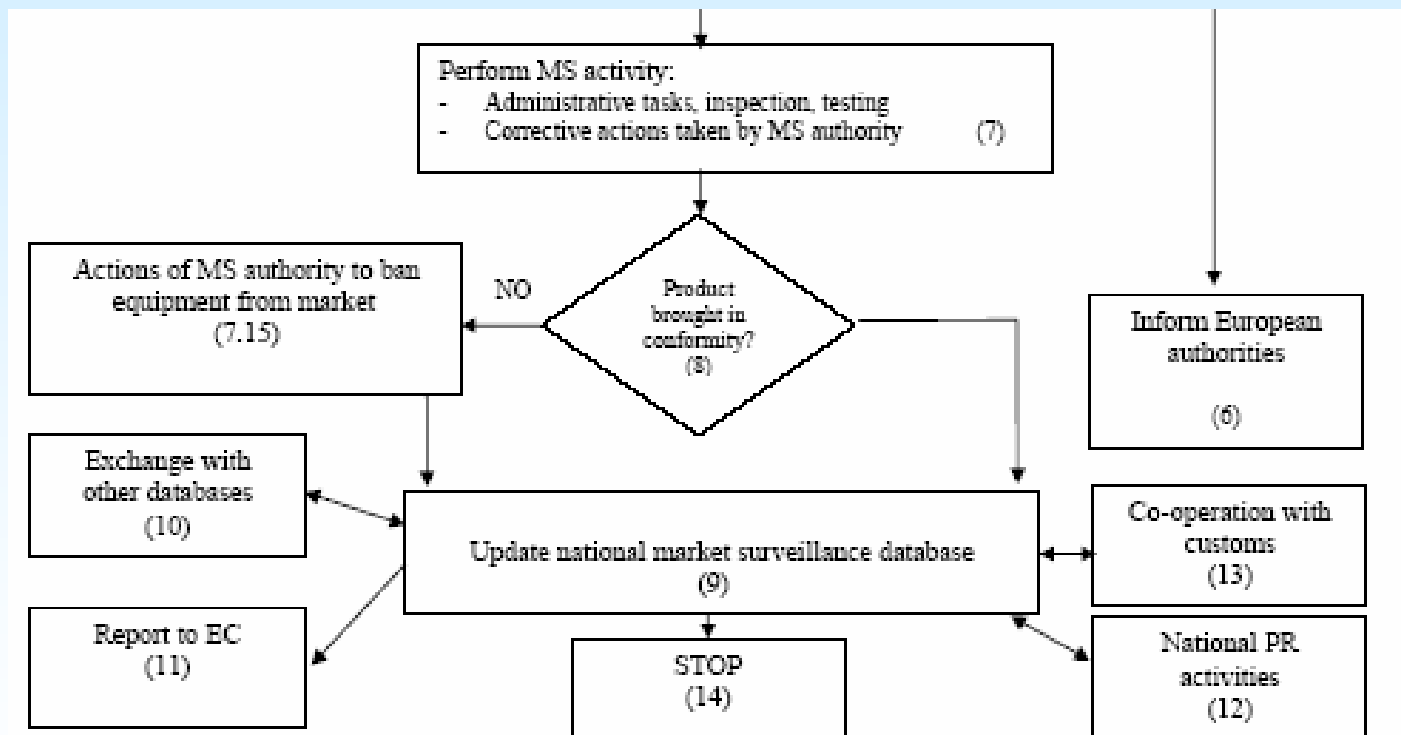
4. The general market surveillance procedure

The preparation phase



4. The general market surveillance procedure

The MS actions and contact with stakeholders phase



5. Cost of MS actions

- Analysis of costs to be provided per sector directive
- Example of cost of MS actions for a toaster (next slide)
- For some cost factors the data of MSAs of other EU countries were used

5. Cost of MS actions

Market Surveillance Action costs					
(example)					
	Kind of equipment:	household		Directive:	LVD
N°	Item	Value	Units	reference doc	Remarks
1	Estimated number of products on national market				
	# of household products, safety critical	150000	pcs		Estimated: 1/3 on local market, 2/3 exported
	Number of toasters	15000	pcs		Estimated
	Sample size	315	pcs	ISO 2859-1:1989	Normal inspection
	# lot 1	pcs		Model x, manufacturer y, SN z
	# lot 2	pcs		Model x, manufacturer y, SN z
	# lot 3	pcs		Model x, manufacturer y, SN z
				
	# lot n	pcs		Model x, manufacturer y, SN z
2	Test plan				
	Product standard	EN 60335-1 (general), EN 60335-2-9 (product safety standard)			
	Administrative checking A1	1			CE-marking, labelling
	Administrative checking A2	1			EC DoC
	Administrative checking A3				TF (Technical File)
	Testing ER1	60	°K		Heating in power cable (delta T)
	Testing ER2	1000	V		Abnormal operation
		equipment must be safe			
3	Costs				
	A1	10	€		Estimated cost
	A2	20	€		Estimated cost
	A3		€		
	T-ER1	200	€		Estimated cost
	T-ER2	200	€		Estimated cost
	Global cost tests/assessments (samples X costs A1 to T-ER2)	22050	€		# of tests = 1/10 of sample size
	cost of samples + transport to MSA/CABs	31500			Estimated
	Income	5513	€		Estimated: 25 % of Global tests/assessments costs
	MSA costs: staff fee, overhead, indirect costs	4410	€		Estimated: 20 % of Global tests/assessments costs data of other EU countries
	Overall costs of this MS action	52448	€		

5. Cost of MS actions

- Due to large number of household equipment on the national market, costs of MS actions can be high..
- MSA needs to make choices!
- Co-operation with peer authorities in EU countries is a necessity

6. Preliminary conclusions

- Establish priorities (New Approach directives) because cost of MSTQ infrastructure are enormous,
- Focus on high volumes products and those of greatest concern on safety!
- Proposal: to develop MS procedures first for products of which legislation is harmonized (NAD's),
- Develop in parallel outputs for standardization (harmonized standards, wgs), accreditation (ISO/IEC 17025) and laboratories (their scope to be in line with scope of chosen NAD's)

7. Reference documents

Relevant web sites

- **The 'Blue Guide'**
<http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm>
- **"The revision of the New Approach" EC DG Enterprise**
http://ec.europa.eu/enterprise/newapproach/review_en.thm
 - **CERTIF 2006-4 29/6/2006**
 - **[2] COM(2007)37 final**