

**PED ADCO 2013.01**

Market Surveillance ADCO Working Group  
on  
Model for  
Market Surveillance Intervention

Version 1.0, approved ADCO meeting of 23/10/2013

**Disclaimer**

This document is a "Model for Market Surveillance Intervention". It is therefore not legally binding to the national administration.

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## Introduction

Enforcement of Community legislation is an obligation of every Member State (MS).

Market surveillance is one important way to fulfill this obligation. It is therefore the responsibility of public authorities.

The objective of market surveillance is on one hand to ensure the availability of safe products in compliance with EU legislation and the other hand to create a level playing field for enterprises.

Each MS can decide upon the infrastructure of its market surveillance but the authorities need to have the necessary power, resources and competence. They must be able to act in an independent way respecting the principle of proportionality.

The working group of the MS and the Commission for **Administrative Co-operation** in the field of pressure equipment - the PED ADCO Group - set up a temporary working party consisting of representatives from France, United Kingdom, Norway and Germany in order to develop a good practice guide to harmonise market surveillance in the area of the Pressure Equipment Directive (PED)<sup>1</sup> and the Simple Pressure Vessel Directive (SPVD)<sup>2</sup>.

This group has drawn up this document on the basis of a pattern of the Machinery ADCO Group with the same intention. The group recommends this guidance is reviewed periodically to update it with all relevant developments (EU legislation, experience, etc.).

## 1 General Principles

Market surveillance should be seen in the context of solving issues at a European level. The main principle is to enhance cooperation between market surveillance authorities, between and within MS. To promote this, MS should participate in ADCO groups and seek to use specific tools to exchange relevant information (e.g. via RAPEX, ICSMS, CIRCA, etc.). In an environment of a globalised market it is very important to work together, also in the field of market surveillance (such as on the basis of an adequate exchange of experiences and cross border projects supported by the Commission). Market surveillance is normally based on surveillance programmes drawn up by member states and reactive market surveillance cases.

### 1.1 Market surveillance authority – initiating authority approach

The market surveillance authority who has found the non-compliant product on their market (‘Initiating authority’ hereinafter referred to as ‘**MSA1**’) should normally handle the case and try to solve it at a European level in cooperation with other members states. .

The principle is that<sup>3</sup>:

- a) Successful market surveillance depends on cooperation between the various market surveillance authorities (MSA).
- b) MSA1 is required to take action to remedy the situation for their jurisdiction.
- c) MSA1 should strive to completely resolve the problem.
- d) For reference, information sharing and awareness raising, the ADCO group and also other ways (e.g. ICSMS, RAPEX, CIRCA, etc.) should be used.
- e) MSA1 should make early contact with the market surveillance authority responsible for the relevant economic operator (hereinafter referred to as ‘**MSA2**’) to alert them of the issue and set up contact points for the further exchange of information.
- f) MSA2 should assist MSA1 in the collection of information if it is required.
- g) If after pursuing the case MSA1 having followed the approach in a) – e) above is still not satisfied that the European supply aspect has been adequately addressed by the relevant economic op-

<sup>1</sup> Directive 97/23/EC of 29 May 1997 concerning pressure equipment

<sup>2</sup> Directive 2009/105/EC of 16 September 2009 relating to simple pressure vessels

<sup>3</sup> See also Annex 1 and 2

erator, it should raise the matter with MSA2 and inform the other MSAs, for instance by using ICSMS and ADCO

- h) The safeguard action route will need to be taken by MSA1 if it is not solved voluntarily.
- i) MSA2 should then resolve the matter with its manufacturer/importer in respect of a supply other than in MSA1.

## 1.2 Voluntary phase

Regulation No 765/2008/EC and Decision No 768/2008/EC specify that the MSA should request the relevant economic operator to solve the problem voluntarily.

→ *Since it is only the manufacturer that is responsible for full compliance with the PED / SPVD, he should be requested to solve the problem within a reasonable time limit.*

The MSA should be in dialogue with the relevant economic operator in the 'voluntary phase'. The economic operator should, if necessary, be requested to solve the problem on a European level, and not only in the MS where the violation was discovered.

In the voluntary phase the MSA makes a formal inquiry to the relevant economic operator (in general, the manufacturer).

The MSA explains which shortcomings they have found. It asks for the relevant part of the technical file, and asks for comments.

The MSA should also indicate which measures it expects the economic operator to take (corrections, sales stop, withdrawal, recall). MSA may ask the relevant economic operator to modify the pressure equipment / simple pressure vessel in order to bring it into compliance with the PED / SPVD, but the MSA should never request a specific method for doing so. If possible, the economic operator should be given the opportunity to decide whether he wants to modify the pressure equipment / simple pressure vessel or to stop the sale and withdraw or recall it if there is a safety risk. **It is noted that currently the PED / SPVD does not give power of recall.** This is a requirement of Regulation No 765/2008/EC For consumer products the General Product Safety Directive, implemented in national legislation, also gives some powers of recall that can be used.

When the facts of the first evaluation are available, or the reply dead line has expired, the MSA makes a 'Conclusion on the inquiry', stating the shortcomings, and requesting the relevant economic operator to solve the problem voluntarily within a given time limit. A Copy of the correspondence and the conclusion on the inquiry should be sent to the MSA in the MS of the economic operator (MSA2) for information. Depending on the case, MSA2 may contact the manufacturer (and follow up in writing) to make sure that he takes the necessary measures. A Copy of the conclusion on the inquiry should also be sent to the importer, distributor and Notified Body, in order to make them aware of the MSA's opinion.

When the MSA is making an evaluation of compliance against the applicable directives, initial information about the case should be sent to the other MSA (e.g. by CIRCA, ICSMS, etc.), and afterwards the information must be updated as the case progresses. **This is important as it can prevent another MS wasting resources.** Further, a RAPEX<sup>4</sup> notification must be made where a serious risk has been identified and confirmed.

## 1.3 Enforcement Phase<sup>5</sup>

If the relevant economic operator doesn't solve the problem within the given time limit, the MSA (MSA1) must inform him of its decision, citing the breach of law in the MSA's country, but asking in the accompanying letter that the breach of the PED / SPVD is addressed in all EU/EFTA MS.

<sup>4</sup> Community Rapid Information System (RAPEX).

<sup>5</sup> Enforcement phase covers everything from warning letters (explaining the decision of the MSA that is required to be addressed by the Manufacturer) to sanctions notices and the resulting "safeguard action procedure".

. If the pressure equipment has been manufactured or sold in another MS, the safeguard action must be notified to the COM and the other MS by using the form in annex 3.

The MSA (MSA1) can only take legal action in its own country (e.g prosecute) against an economic operator located in another MS, for an offence committed in its country. Less formal enforcement such as letters and other 'notices' can be used to explain the legal remedies (e.g safeguard action) that will be taken if the relevant economic operator does not stop the breach. If the economic operator continues to supply to other MS, the MSA (MSA2) situated in that Member State must take action to stop this continued breach after the COM has given their opinion of the safeguard case.

#### *Enforcement actions*

Enforcement action concerning a non-compliant product can take a number of forms, and this will also depend on the Member State's legal system. Provided the supply was into the Member State concerned then legal enforcement, by the MSA, is possible. Importantly, no other Member State can take this enforcement action as the offence is not in their legal jurisdiction

Legal action by the MSA will instigate a Safeguard Action. If the Commission find the enforcement by the MSA was correct, it will result in a Commission Decision. This Decision will require all Member States to take action in their Member State concerning the non-conformant product. This consequence due to the Safeguard Action should be explained to the legal entity by the MSA concerned so the legal entity fully understands the legal implications. This may help and make more likely better cooperation and voluntary action across the whole EU/EEA.

### **1.4 The manufacturer or his authorised representative**

It is solely the manufacturer<sup>6</sup> or his authorised representative<sup>7</sup> who can be held responsible for compliance of pressure equipment / assembly / simple pressure vessel with the essential safety requirements of the applicable directive and has to apply the relevant conformity assessment procedure(s).

Therefore, a decision that a pressure equipment / assembly / simple pressure vessel is not in compliance with the PED / SPVD should normally not be taken before the manufacturer or his authorised representative has had the opportunity to present his technical file and give their comments.

If rapid intervention is required to avoid serious risk, the manufacturer or his authorised representative should be heard afterwards, and, if necessary, the decision has to be re-evaluated.

### **1.5 Importers and distributors**

The PED or SPVD do not contain obligations for importers and distributors. Requirements towards these economic operators are laid down in Decision No 768/2008/EC, except obligations concerning translation of declarations and instructions (the person importing pressure equipment into a language area must translate the relevant documents into the official language). PED guideline 9/21 must also be taken into account when translations of instructions and markings are provided.

Once the appropriate directives are brought into line with the Decision No 768/2008/EC, then there will be other duties imposed on importers and distributors, until that time national legislation determines what an importer and a distributor can be required to do. MSA's interventions should be proportionate and target the relevant economic operators in relation to the obligations they have in a given case.

### **1.6 Notified Bodies**

If a Notified Body (NB) has been involved in the conformity assessment process of the pressure equipment / simple pressure vessel, it should be heard before making a conclusion on the inquiry or a decision (certificates from NBs do not give a presumption of conformity). A copy of the conclusion letter and/or a decision against the economic operator should also be sent to the NB, with a request to withdraw its approval (and any relevant certificate), and a copy should be sent to the notifying authority.

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<sup>6</sup> see Article 2 (3) of Regulation No 765/2008/EC

<sup>7</sup> see Article 2 (4) of Regulation No 765/2008/EC

## 2. Evaluation of compliance

The MSA evaluates the compliance with the relevant requirements of PED / SPVD (considering the non-compliance and any other apparent defects). This can be performed / treated in collaboration with the economic operator. The MSA shall try to obtain all necessary documents, relating to the conformity assessment of the product and its distribution.. Depending on circumstances the MSA may seek information from the relevant notified body about its assessment of the product or production process conformity.

The MSA, when seeking to rely on tests performed by the economic operator for regulatory purposes, should determine the tests to be performed and the choice of the laboratory to be used (it is advisable that the testing facility be accredited according to EN ISO/IEC 17025).

## 3. Risk Assessment

Pursuant to Art. 20 of Regulation No 765/2008/EC the decision whether or not a product represents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard (caused by the existing non-conformity of the product) and the likelihood of its occurrence. Further, no risk assessment is required for formal non-compliances (see annex 4 point 1).

Regulation (EC) No 765/2008 does not require that a specific methodology be used. However, RAPEX guidelines have been established (Decision of the Commission 2010/15/EU) to harmonise practices for consumers products. For industrial products, the risk assessment must also take into account all relevant factors.

Beside the above mentioned decision a short guidance can be found in annex 4. An online tool for RAPEX is provided by the Commission under: <http://europa.eu/sanco/rag/> . Examples are provided in annex 5.

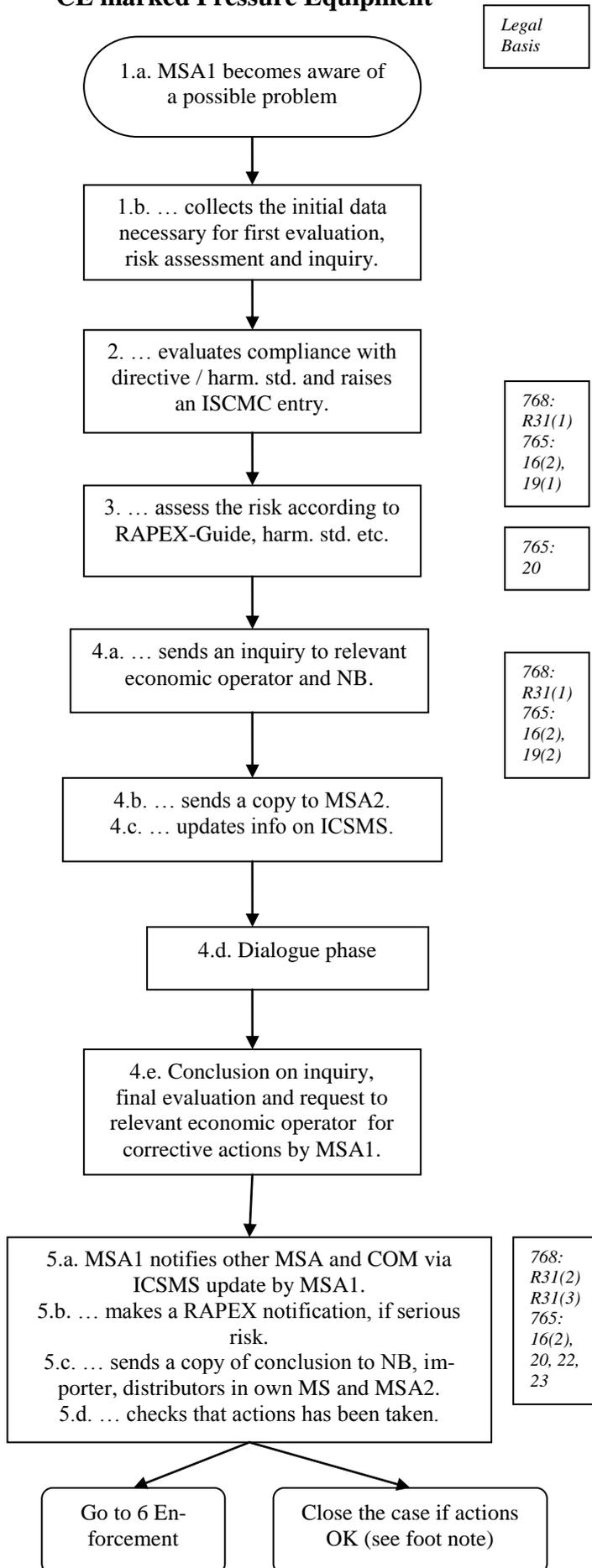
## 4. Measures

The MSA shall take appropriate actions in accordance with the level of risk (principle of proportionality) and in accordance with National and European legislation. Indicative measures that can be taken are mentioned in the following table.

| Indicative Measures      |   |
|--------------------------|---|
| Restrictive measure      | Depending on the level of risk, and if the national regulation allow, the MSA decides to require a ban / withdrawal / recall of the equipment from the market by the economic operator.<br>Withdrawal has to be considered when the equipment does not comply with ESRs mentioned in annex 4.   |
| Corrective measure       | The economic operator can be required to take corrective actions to bring the equipment into compliance (e.g. modification of the minimum allowable temperature, etc.). These measures shall be submitted to the MSA. In such cases, modifications of the equipment can be assessed by the notified body involved in the conformity assessment. MSA should then review the analysis of the notified body and the updated certificates as proof of compliance. |
| Information to the users | The user of the equipment must be informed of the risk of injury or other damage by the economic operator and actions , agreed by the economic operator and the MSA, to be taken to avoid them.   |

## Annex 1 - Flow chart for market surveillance intervention

### The voluntary phase CE marked Pressure Equipment



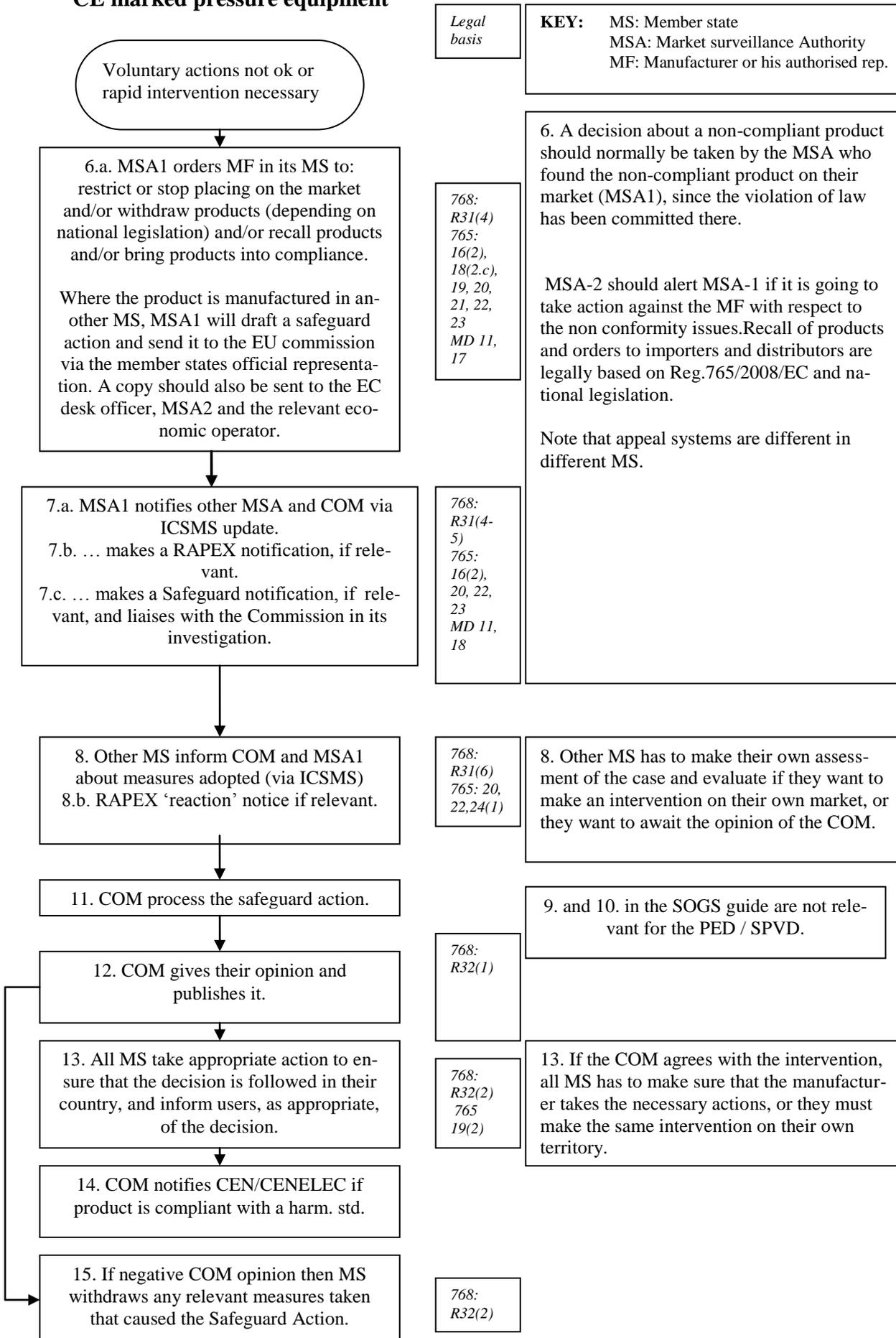
### Remarks

|  |
|--|
| <p><b>KEY:</b> MS: Member state<br/>MSA: Market surveillance Authority<br/>MF: Manufacturer or his authorised rep.</p>   |
| <p>1.a. Based on reactive or proactive market surveillance.</p>  |
| <p>1.b. MSA1 should inform MSA2 of its proposed action (footnote : ADCO contact points up to date)</p>   |
| <p>2. If product is compliant: Stop. Info should be exchanged with other MS (ICSMS, ...)</p>   |
| <p>3. Risk assessment to be carried out according to RAPEX guidelines, std.'s etc.<br/>If risk is low, case may be closed, depending on priorities.<br/>If risk is serious, normally step 4 and 5 should be followed, but it is possible to jump to step 6 if necessary.</p>   |
| <p>4.a. The relevant economic operator is heard about the nonconformities. He is asked to send appropriate parts of technical file and his comments. He is asked to take necessary measures if he agrees. Measures to be indicated in the inquiry letter in which a timeframe for reply is given.<br/>Importers and distributors can be heard depending on situation and national law.</p> |
| <p>4.b. Copy to MSA2 of inquiry letter is for information only. However MSA2 in MF MS should contact MF to make sure that he cooperates with MSA1's investigation, to give guidance and to assess the wider EU safety implications.<br/>It will often be necessary for MSA-2 to assist with the case, or it may exceptionally be agreed that the case is passed on.</p>                    |
| <p>4.d. Dialog may be by correspondence, phone and/or visits.</p>  |
| <p>4.e. If MSA1 still considers that there is a non-compliance, this is communicated to the relevant economic operator, and he is requested to take the voluntary corrective actions specified. The economic operator should be requested to take action in all EU MS. Time limit is given for feedback and action.</p>  |
| <p>5. Other MSA and COM are informed via update on ICSMS, which allows them to monitor actions taken in their MS.<br/>It is only possible for initiating MSA to intervene against violations in their territory.<br/>However, initiating MSA should inform other MS if they become aware that voluntary actions are not being taken in other MS.</p>                                       |

## Annex 1 - Flow chart for market surveillance intervention

### Enforcement phase CE marked pressure equipment

### Remarks



## Annex 1 - Flow chart for market surveillance intervention

### Notes to the flow chart:

Checklists should be drafted to address relevant points, e.g. listing typical data to be collected in relation to point 2.

In annex 2, guidance is given for the content of following letters:

- Inquiry to the relevant economic operator (flowchart pt. 4.a) incl. annex I to the inquiry, listing the shortcomings in a table
- Inquiry to NB (flowchart pt. 4.a)
- Conclusion on inquiry (flowchart pt. 4.e.)
- Information of MSA2 (flowchart pt. 4.b.)
- Decision against the MF (flowchart pt. 6).

Guidance concerning closure of a case:

- Normally a written letter from the economic operator, declaring which corrective actions he has taken, is considered to be adequate to close the case. Depending on circumstances it may be necessary to confirm that the corrective actions has been carried out.
- If the economic operator informs the MSA that he will change the product before future deliveries, the case can be closed (in this respect). Note, the MSA should take care not to imply any approval of the new design. If the modified product is non-compliant, this is a new case.
- It should be investigated if there are similar products from other MF's on the market, where market intervention is also necessary.

Note to point 12, COM opinion: (check with the commission)

- The COM does not need to give their opinion if the manufacturer follows the order and brings the product into compliance in all MS before the opinion is published.

## Annex 2 - Content of letters.

### **Key items relating to an inquiry letter to the relevant economic operator (flow diagram pt. 4.a.).**

- Identification of the authority and their competence according to the applicable directive
- Identification of the economic operator and the product concerned (Details should be listed in an annex).
- Description of legislation and breaches observed (Details should be listed in an annex).
- Information about the obligations of the economic operator according to the applicable directive
- Requested measures to be taken voluntarily, if the economic operator agrees that he is responsible for the non-conformities
- Requested response from the economic operator containing:
  - comments on the observations made by the authority
  - comments on the alleged breach of legislation, explained in the above, information about the measures the economic operator intends to initiate to meet his obligations under the PED / SPVD, including a time frame for implementation
  - relevant technical documentation etc. on conformity assessment, and other information relevant for the case [specify if possible]
  - list of the distributors to whom the economic operator has supplied products of the same type.
- A specified date for response
- Information about further steps and possible consequences
- A copy of the letter should be sent to
  - the NB, if such a body has assisted
  - the foreign MSA, if the MF is domiciled in another MS
  - importer and distributor depending on the case

### **Key items relating to the letter with inquiry to NB (flow diagram pt. 4.a.).**

- Identification of the authority and their competence in according to the applicable directive
- Identification of the MF and the product concerned (Details should be specified in an annex, e.g. by enclosing a copy of the inquiry letter to the manufacturer).
- Description of legislation and breaches observed (Details should be listed in an annex).
- Information about observations concerning the role of the NB
- Requested response from the NB containing:
  - copy of the EC Type examination certificate, the test report made by the NB and if necessary relevant technical documentation in possession of the NB
  - comments on the observations made by the authority
  - comments on the alleged breach of legislation
- A specified date for response

### **Key items relating the information letter to the MSA in MF's country 'MSA2' (flow diagram pt. 4.b.).**

- Identification of the authority
- Identification of the MF and the product concerned. (Details to be specified in an annex by enclosing a copy of the inquiry letter to the MF)
- Description of legislation and breaches observed. (Details to be specified in an annex by enclosing a copy of the inquiry letter to the MF)
- Information about future steps planned to be taken

### **Key items relating to the letter to the economic operator with conclusion on the inquiry (flow diagram pt. 4.e.).**

- Identification of the economic operator and the product concerned
- Reference to the inquiry letter with case details (could be attached as an annex)
- Information about new details not covered by the inquiry letter, e.g. dialog, visits etc.
- Reference to economic operator's response to the inquiry

## Annex 2 - Content of letters.

- Final assessment and evaluation by the authority
- Requested measures to be taken voluntarily by the economic operator
- A specified date for implementation of requested measures and confirmation response
- Information about further steps and possible consequences (if required)
- A copy of the letter should be sent to
  - the NB, if such a body has assisted
  - the foreign MSA, if the MF is domiciled in another MS importer and distributors in the MSA's own country.

NOTE: examples of letters can be found in the Good Practice Guide on Market Surveillance Intervention - Machinery. MD ADCO.2012.38.rev1

### Annex 3 – Safeguard Clause Form

**Form for information to be forwarded to the Commission and the other Member States on the application of Article 8 of the European Parliament and Council Directive 97/23/CE of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment. (check with the commission)**

Note : This form should be sent where a Member State establishes that the CE marking has been affixed to products not complying the essential requirements of the Directive and takes all appropriate measures or prohibit the placing on the market of the product.

1. Name of the authority for market surveillance
  - a) Member State :
  - b) Full name and address, telephone and e-mail address of the department and the competent official supplying the information :
  - c) Date :
  
2. Identification of the product
  - a) Product category (vessel, piping, ...):
  - b) Product name :
  - c) Model designation :
  - d) Name and address of manufacturer or person responsible for placing on the market:
  - e) Countries of destination:
  - f) Other specific data :
  
3. Marking and declaration of conformity
  - a) CE marking with, where appropriate, the identification number of the notified body :
  - b) Where necessary, EC Declaration of conformity ( a copy should be annexed) :
  
4. Details of measures taken.
  - a) Type of measure - restriction of the placing on the market  
- prohibition of the placing on the market  
- withdrawal from the market :
  - b) Date of the measure :
  
5. Reasons for measures taken
  - a) Non-conformity with the ESRs of the Annex I of the Directive 97/23/CE :
  - b) Brief description of faults and nature of hazard/risk identified :
  
6. Additional information

## Annex 4 - Classification of non-conformities

### 1 General Classification of non-conformities

The Blue Guide distinguishes between non-substantial and substantial non-compliance, while Decision No 768/2008/EC introduces formal non-compliances. The following table summarises the different cases (a case by case analysis is however always necessary).

| General classification |  |   |
|------------------------|--|---|
| Substantial            | Non compliance with marking or documentation | This could be an indication that the product does not comply with the ESRs or the conformity assessment procedure has not been applied and consequently, the product may, for instance, endanger health and safety of persons. Such non-compliance is important particularly since it may suggest other areas of non-compliance.  |
|                        | Non-compliance with ESRs                     | The product could present a potential or actual risk to the safety of people. In practice, some ESRs in the PED/SPVD are not linked to safety and can be considered as administrative breaches (marking).   |
|                        | Non-compliance with Modules                  | It has to be assumed an insufficient application of the directive (e.g. choice of the wrong module, evaluation by a body not notified to the commission, ...)   |
| Non-Substantial        | Minor non-compliance                         | The product has been properly assessed but minor non-compliance remain ( Decision No 768/2008/EC) for example :<br>a) the conformity marking has been affixed in violation of xxxx<br>b) the conformity marking has not been affixed<br>c) the EC declaration of conformity has not been drawn up<br>d) the EC declaration of conformity has not been drawn up correctly<br>e) technical documentation is either not available or not complete. |

### 2 Specific Classification of non-conformities regarding the PED/SPVD

Examples of ESRs where non-conformity would lead to the equipment being dangerous:

#### 2.1 Design (PED / SPVD)

|                     |  |
|---------------------|--|
| Description         | The pressure equipment / simple pressure vessel is not designed for loadings appropriate to its intended use and other reasonably foreseeable operating conditions.  |
| Annex I of the PED  | <ul style="list-style-type: none"> <li>- 2.2.1 "design for adequate strength"</li> <li>- 5 "fired or otherwise heated pressure equipment with a risk of overheating"</li> <li>- 6 "piping"</li> <li>- 7 "specific quantitative requirements" (allowable stress, joint coefficient)</li> </ul>  |
| Annex I of the SPVD | <ul style="list-style-type: none"> <li>- 2 "vessel design"</li> <li>- 2.1 "wall thickness"</li> </ul>  |
| Examples            | <ul style="list-style-type: none"> <li>- wall thickness too small</li> <li>- inadequate corrosion allowance</li> <li>- inadequate ambient or operational temperatures</li> <li>- lack of a fatigue analysis</li> <li>- no or inappropriate closures and openings</li> <li>- loadings due to traffic, wind or earthquake not appropriately considered</li> <li>- load cycles, cyclic design life</li> <li>- etc.</li> </ul> |

## Annex 4 - Classification of non-conformities

### 2.2 Safety accessories (only for PED)

|                    |  |
|--------------------|--|
| Description        | The pressure equipment or assembly is not designed with appropriate safety accessories to its intended use and other reasonably foreseeable operating conditions.  |
| Annex I of the PED | <ul style="list-style-type: none"> <li>- 2.11 “safety accessories”</li> <li>- 3.2.3 “functional testing of safety equipment”</li> <li>- 7.3 “specific quantitative requirements” (pressure limiting devices)</li> </ul>  |
| Examples           | <ul style="list-style-type: none"> <li>- inadequate sizing (coefficient of discharge, pressure relief opening cross section, etc.)</li> <li>- dangerous discharge of pressure relief blow-off</li> <li>- etc.</li> </ul> |

### 2.3 Safety measures to prevent the opening of doors under pressure (quick-opening doors) (only for PED)

|                    |  |
|--------------------|--|
| Description        | The pressure equipment or assembly are not designed with appropriate interlocks to prevent opening the door whenever the pressure or temperature of the fluid presents a hazard. . |
| Annex I of the PED | <ul style="list-style-type: none"> <li>- 2.3 “Provisions to ensure safe handling and operation”</li> </ul>   |
| Examples           | <ul style="list-style-type: none"> <li>- Missing interlocks.</li> <li>- Missing relief hole.</li> <li>- etc.</li> </ul>  |

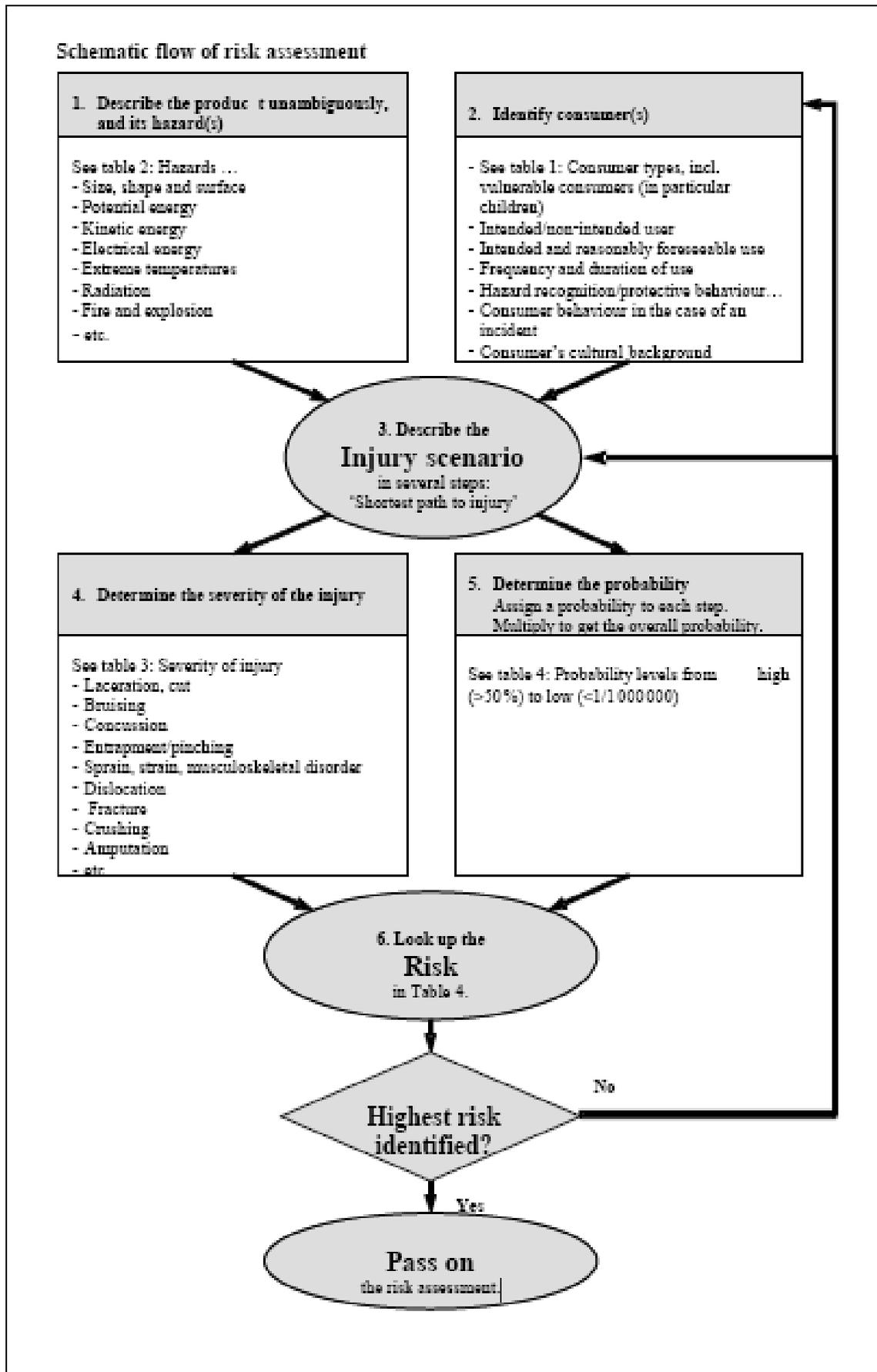
### 2.4 Manufacturing and testing (PED/SPVD)

|                     |   |
|---------------------|---|
| Description         | The pressure equipment is not properly manufactured and tested.   |
| Annex I of the PED  | <ul style="list-style-type: none"> <li>- 3.1.1 “preparation of the component parts”</li> <li>- 3.1.2, “permanent joining”</li> <li>- 3.1.3, “non-destructive tests”</li> <li>- 3.2.2, “proof test”</li> <li>- 7 “specific quantitative requirements” (hydrostatic test pressure)</li> </ul>                                   |
| Annex I of the SPVD | <ul style="list-style-type: none"> <li>- 3.1 “preparation of the component parts”</li> <li>- 3.2 “welds on pressurized parts”</li> </ul>  |
| Examples            | <ul style="list-style-type: none"> <li>- weld defects (e.g. unacceptable lack of fusion or penetration, porosity, cracks – see EN ISO 5817)</li> <li>- heat treatment defects (e.g. inappropriate metallurgy, ...)</li> <li>- no (eg. Hydrostatic, pneumatic) pressure test or wrong pressure test</li> <li>- etc.</li> </ul> |

### 2.5 Materials (PED/SPVD)

|                     |   |
|---------------------|---|
| Description         | Materials used for the manufacture of pressure equipment / simple pressure vessel are not suitable for the foreseeable use during the scheduled lifetime.   |
| Annex I of the PED  | <ul style="list-style-type: none"> <li>- 4 “materials”</li> <li>- 7 “specific quantitative requirements” (materials)</li> </ul>   |
| Annex I of the SPVD | <ul style="list-style-type: none"> <li>- 1.1 “materials for pressurized parts”</li> <li>- 1.2 “welding materials”</li> <li>- 1.3 “Accessories contributing to the strength of the vessel”</li> </ul>  |
| Examples            | <ul style="list-style-type: none"> <li>- inadequate properties (impact strength, tensile strength,..)</li> <li>- internal defects (shrink hole, laminar imperfection, ...)</li> <li>- etc.</li> </ul> |

Extract from RAPEX guidelines – risk assessment part (section 5)



Example n°1: Sandblaster (V = xx l; PS = 8 bar) with shortcomings in the longitudinal weld

| <b>Scenario 1 : Other consumers - Flying objects</b>              |   |
|---|---|
| <b>Product hazard</b>   |   |
| Hazard Group:   | Kinetic energy  |
| Hazard Type:  | Flying objects  |
| <b>Consumer</b>   |   |
| Consumer Type:  | Other consumers - Consumers other than vulnerable or very vulnerable consumers                  |
| <b>How the hazard causes an injury to the consumer</b>            |   |
| Injury scenario:  | Person is hit by the flying objects or blast wave and depending on the energy sustains injuries |
| <b>Severity of Injury</b>   |   |
| Injury:   | Fracture  |
| Level:  | 4 Neck<br>Spinal column   |
| <b>Probability of the steps to injury</b>                         |   |
| Step(s) to Injury   | Probability   |
| Step 1: Pressure vessel bursts due to imperfect weld seams.       | > 70 %  |
| Step 2: Parts of the vessel tear off and accelerate.              | > 90 %  |
| Step 3: A person is is in close proximity to the vessel.          | > 70 %  |
| Step 4: The person is hit by parts or knocked over by burst wave. | > 70 %  |
| Step 5: Person sustains injuries.                                 | 100 %   |
| <b>Calculated probability: 0.31</b>                               |   |
| <b>Overall probability:</b>                                       | > 1/10  |
| <b>Risk of this scenario:</b>                                     | Serious risk  |

## Annex 5 - Risk assessment

**Example n°2:** Portable fire extinguisher (powder, 6 kg) with shortcomings in the circumferential weld

| <b>Scenario 1 : Other consumers - Flying objects</b>   |  |
|--|--|
| <b>Product hazard</b>  |  |
| Hazard Group:  | Kinetic energy   |
| Hazard Type:   | Flying objects   |
| <b>Consumer</b>  |  |
| Consumer Type:   | Other consumers - Consumers other than vulnerable or very vulnerable consumers |
| <b>How the hazard causes an injury to the consumer</b>   |  |
| Injury scenario:   | Rupture of the weld and tearing of the bottom                                  |
| <b>Severity of Injury</b>  |  |
| Injury:  | Bruising (abrasion/ contusion, swelling, oedema)                               |
| Level:   | 2 Major<br>>25 cm <sup>2</sup> on face<br>>50 cm <sup>2</sup> on body          |
| <b>Probability of the steps to injury</b>  |  |
| Step(s) to Injury  | Probability  |
| Step 1: The vessel will burst due to temperature related increase in pressure                        | 100 %  |
| Step 2: A dangerous increase in temperature and pressure will occur due to external sources of heat. | > 1/50   |
| Step 3: A person will be in close proximity of the busting extinguisher.                             | > 1/100  |
| Step 4: An injury will occur.  | > 70 %   |
| <b>Calculated probability:</b> 0.00014   |  |
| <b>Overall probability:</b> > 1/10,000   |  |
| <b>Risk of this scenario:</b> <u>Medium risk</u>   |  |

## Annex 5 - Risk assessment

Example n°3: Mobile air receiver (V = 50 l; PS = 8 bar)

### Scenario 1 : Other consumers - Flying objects

#### Product hazard

Hazard Group: Kinetic energy  
Hazard Type: Flying objects

#### Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

#### How the hazard causes an injury to the consumer

Injury scenario: Person is hit by the flying object and depending on the energy sustains injuries

#### Severity of Injury

Injury: Bruising (abrasion/ contusion, swelling, oedema)  
Level: 2 Major  
>25 cm<sup>2</sup> on face  
>50 cm<sup>2</sup> on body

#### Probability of the steps to injury

| Step(s) to Injury  | Probability |
|--|-------------|
| Step 1: vessel will burst due to the imperfect weld seam           | > 1/10      |
| Step 2: parts will tear off  | > 1/5       |
| Step 3: a person will be in close proximity of the bursting vessel | > 50 %      |
| Step 4: an injury will occur                                       | > 70 %      |

**Calculated probability:** 0.007

**Overall probability:** > 1/1.000

**Risk of this scenario:** High risk

## Market surveillance Framework<sup>8</sup>

### 1. New Legislative Framework (NLF) for the marketing of products

- a) **Regulation (EC) No 765/2008<sup>9</sup>** of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
- b) **Decision No. 768/2008/EC** of the Parliament and Council relating to a common framework for the marketing of products

### 2. Sectoral EU legislation

The Pressure Equipment Directive (97/23/EC)

<http://ec.europa.eu/enterprise/sectors/pressure-and-gas/documents/ped/>

The Simple Pressure Vessels Directive (2009/105/EC)

<http://ec.europa.eu/enterprise/sectors/pressure-and-gas/documents/spvd/>

### 3. Sectoral EU guidance

Guidelines to the Pressure Equipment Directive

[http://ec.europa.eu/enterprise/sectors/pressure-and-gas/documents/ped/guidelines/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/pressure-and-gas/documents/ped/guidelines/index_en.htm)

Guidelines to the Simple Pressure Vessels Directive

<http://ec.europa.eu/enterprise/sectors/pressure-and-gas/documents/spvd/>

### 4. SOGS ( Senior Officials Group) Guidance

- a) SOGS-MSG, CERTIF 2010-05 REV1 - Overview of market surveillance procedures (Including safeguard clause mechanism) in the area of harmonised products.
- b) CERTIF 2010/04 - Risk assessment for market surveillance
- c) SOGS-MSG N038 EN - Draft –Market Surveillance enforcement for goods – A multi-annual plan 2013-2015

### 5. Other relevant framework documents

- a) Directive 2001/95/EC of 3 December 2001 on general product safety (GPSD) (managed by Directorate-General Health and Consumers (DG SANCO), contains provisions on how to ensure safe consumer products. For instance, GPSD provides the legal basis for RAPEX
- b) Best practice techniques in market surveillance (PROSAFE guidance)
- c) Market Surveillance ADCO Working Group Good Practice Guide on Market Surveillance Intervention – Machinery
- d) UNECE documents on market surveillance

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<sup>8</sup> <http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/market-surveillance/>

<sup>9</sup> OJEU L 218/30 of 13.8.2008