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European cooperation in legal metrology

Market Surveillance Guide (NAWI and MID)



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WELMEC

European cooperation in legal metrology

WELMEC is a co-operation between the legal metrology services of the Member States of the European Union and EFTA. This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to notified bodies responsible for conformity assessment of their products. The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EC Directives. Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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Market Surveillance Guide

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1. Introduction

- 1.1. The legislation applicable to measuring instruments is covered by two new approach directives: 90/384/EEC (amended by 93/68) relating to non-automatic weighing instruments (The NAWI directive) and 2004/22/EC relating to measuring instruments (The MID). These directives are specific in respect of requirements for electromagnetic immunity in that Article 2(2) of the Directive 89/336/EEC continues to apply with regard to emission requirements.
- 1.2. The NAWI directive covers all non-automatic weighing instruments.
- 1.3. The MID covers water meters, gas meters and volume conversion devices, active electrical energy meters, heat meters and their sub-assemblies, measuring systems for continuous and dynamic measurement of quantities of liquids other than water, automatic weighing instruments, taximeters, material measures, dimensional measuring instruments, and exhaust gas analysers.
- 1.4. The aim of this document is to produce a guide that will be of use to personnel engaging in market surveillance under both the NAWI directive and the MID.
- 1.5. The NAWI directive and the MID share many common themes with regard to market surveillance. This guide will attempt to focus on the common strands between the two.
- 1.6. The focus on common themes will mean the guide can be used as a useful tool for engaging in market surveillance for all the instruments covered by both the NAWI Directive and MID.
- 1.7. Where there are significant differences between the two directives, these will be treated separately.
- 1.8. This means an officer will have available both the general principles and the specific requirements necessary to complete market surveillance.

2. General principles of Market Surveillance

2.1. Market Surveillance is an essential tool in the implementation of the New Approach Directives. The principles are outlined in the “Guide to the implementation of Directives based on the New Approach and the Global Approach”. This guide is referred to colloquially as the “Blue Guide” as a result of the colour of the cover. A revision of the new approach by the Commission is in process at the time of publication and it might result in further obligations for the member state in the field of market surveillance. This guide will be revised in the future according to the decisions taken.

2.2. Chapter 8 of the Blue Guide and some of the articles of the above mentioned directives are the starting points of this WELMEC Guide. Chapter 8 address the principles of market surveillance for all new approach directives. This chapter sets out:

- Principles of market surveillance
- Market surveillance activities
- Corrective actions
- Complementary activities
- Safeguard clause procedures
- Protection of CE marking
- Information exchange systems
- Administrative cooperation
- Products imported from third countries

2.3. Chapter 8 further goes on to state “The purpose of market surveillance is to ensure that the provisions of applicable directives are complied with across the Community.¹” This cannot be achieved without close cooperation between Member State Authorities. Citizens are entitled to an equivalent level of protection throughout the single market, regardless of the origin of the product. Further, market surveillance is important for the interest of economic operators, because it helps to eliminate unfair competition. Member States must nominate or establish authorities to be responsible for market surveillance. These authorities need to have the necessary resources and powers for their surveillance activities, ensure technical competence and professional integrity of their personnel, and act in an independent and non-discriminatory way respecting the principle of proportionality

2.4. This definition indicates that “market surveillance cannot take place during the design and production stages that is before the manufacturer has taken formal responsibility for the conformity of the products. However, this does not exclude collaboration between the

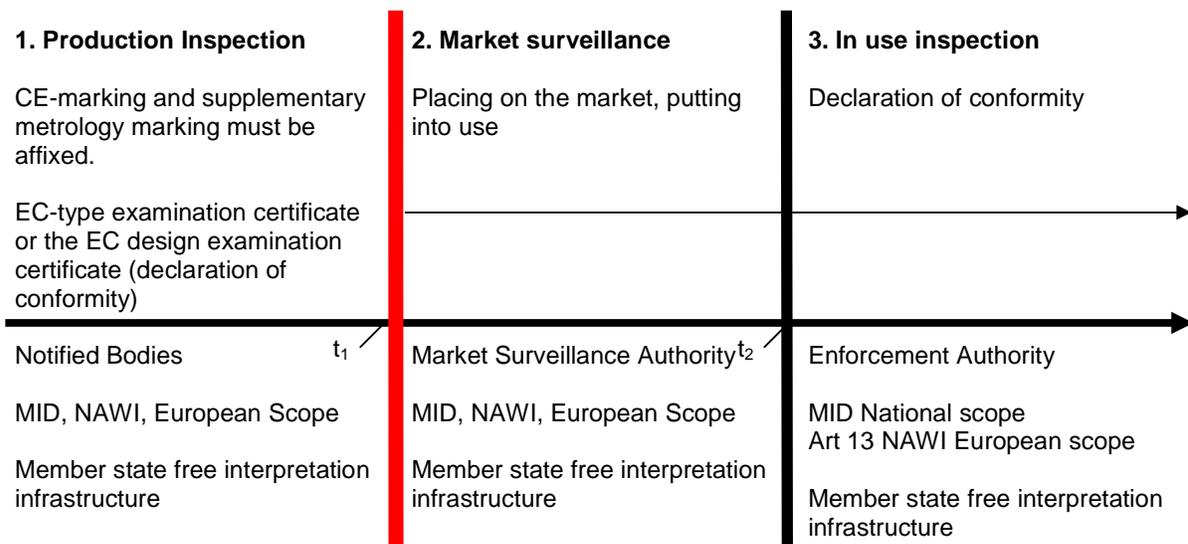
¹ The objective of market surveillance is to take appropriate measures to guarantee that the provisions of the Directive in force are respected in the EU and, in particular, to prevent the placing on the market, and subsequent use, of non-compliant products

market surveillance authority and the manufacturers and suppliers.”² Although the market surveillance authority may make a check on the production premises after non-compliance has been discovered to verify whether or not a systematic error can be established.

2.5. The other important definitions that must be considered are:

- 2.5.1. Placing on the market is defined in the directive 2004/22/EC as making available for the first time in the Community an instrument intended for an end user, whether for reward or free of charge.
- 2.5.2. Putting into use is defined in the directive 2004/22/EC as the first use of an instrument intended for the end user for the purpose for which it is intended.
- 2.5.3. Putting into service is defined in the directive 90/384/EEC as the moment of first use within the Community by the end user.
- 2.5.4. For the purpose of market surveillance the definitions in 2.5.2 and 2.5.3 are essentially the same and relate to instruments which
 - Which can only be used after an assembly, an installation or other manipulation has been carried out;
 - Whose compliance can be influenced by the distribution conditions (for example, storage or transport);
 - Which are not placed on the market prior to putting into service (for example product manufactured for own use).
- 2.5.5. As the definitions in 2.5.2 and 2.5.3 are essentially the same, this guide uses the phrase putting into use to cover both definitions.

2.6. Market surveillance must take place between t_1 (placing on the market) and t_2 (putting into use). The following diagram clearly illustrates this process. This diagram presents the general pragmatic principle:



2: Blue Guide to the implementation of directives based on the New Approach and the Global Approach 2000, p48

- 2.7. However, for practical reasons it could be appropriate to extend the period in time. Even if problems are detected during in service inspection, if it is established that they are clearly related to conformity to the directive the action taken belongs to market surveillance.
- 2.8. This means that instruments can be checked at the moment when CE-marking and supplementary metrology marking are affixed and the products are placed on the market before they are put into use.
- 2.9. Market surveillance projects may reveal other information which does not fall within the strict parameters of market surveillance. This information can fall within two categories: Before instruments are placed on the market (before t_1 on the diagram) and after the instruments are in service, (after t_2 on the diagram)
- 2.10. Information gathered during a market surveillance operation may regard the conformity assessment procedures and the operation of a notified body before the instruments are placed on the market (before t_1 on the diagram). This is not market surveillance and the market surveillance authority should not duplicate the operation of the notified body. If a market surveillance authority is concerned about compliance with conformity assessment procedures or operation of a notified body, the information gathered should be passed on to the member state in which the notified body was designated.
- 2.11. Information gathered after the instrument has been put into service (after t_2 on the diagram) is market surveillance when it is clearly related to conformity with the directives. Information gathered during in service inspection could be used for market surveillance purposes if it is established that the problem with the instrument was present before the instrument was placed on the market.
- 2.12. Placing on the market is considered not to take place where a product is:³
- Transferred from the manufacturer in a third country to an authorised representative in the Community whom the manufacturer has engaged to ensure that the product complies with the directive to the extent allowed by the directive;
 - Transferred to a manufacturer for further measure (for example assembling, packaging, processing, or labelling);
 - Not (yet) granted release for free circulation by customs, or has been placed under another customs procedure (for example transit, warehousing or temporary importation), or is in a free zone;
 - Manufactured in a member state with a view to exporting it to a third country;
 - Displayed at trade fairs, exhibitions or demonstrations; or

³ Blue Guide paragraph 2.3.1

- In the stocks of the manufacturer, or authorised representative established in the Community, where the product is not yet made available, unless otherwise provided for in the applicable directives.

None of the above excludes member states from their obligations regarding unduly fixed CE-markings and metrology markings.

2.13. If a market surveillance authority discovers that there is:

- A non-systematic failure, the authority takes care that the instrument is brought into conformity with the directive and when felt necessary informs the other market surveillance authorities.
- A systematic failure of an instrument to comply with the provisions of the directive and / or the systematic failure presents a risk the procedure described below should be followed.

2.14. The evaluation of the non-compliances shall, whenever possible, be carried out with the relevant stakeholders, e.g. the manufacturer, importer, distributor or other parties concerned.

2.15. The market surveillance authority contacts the manufacturer, or his authorised representative, or when these contacts cannot be established, any other persons having made the instrument available in the EU. To ensure efficient market surveillance at a European level the authority should also contact the responsible market surveillance authority in the country of manufacture.

2.16. The market surveillance authority will then require the manufacturer, or importer to take corrective action to bring the instrument/s into compliance or withdraw it/them from supply throughout the EU.

2.17. If the manufacturer, importer, distributor agrees to the measures in 2.15 the market surveillance authority inform the Commission and other member states in order to enable them to verify that the corrective measures are effectively implemented throughout the EU.

2.18. If the manufacturer, importer, distributor does not agree to the corrective action, or refuses to withdraw the instrument; the market surveillance authority shall ensure the instrument is withdrawn from its own national market. The national market surveillance authority shall trigger the community procedure and notify the Commission and other member states, explaining the reasons for its decision and ask other member states to do the same and if not to provide an explanation.

2.19. It should be noted that it is considered appropriate for individual member states to question the conformity of instruments. If no other member state disagree with the decision it is assumed the measure will be justified, even if the manufacturer disagrees with the decision. If the Commission considers the decision is contrary to EU legislation it should discuss the matter with the member state. If there is still no

agreement, there should be recourse to the infringement process (Article 206 of the Treaty)

- 2.20. The manufacturer's declaration of conformity and the associated technical documentation (specified in article 10 and annex 1 9.3 of the MID) as well as the CE marking on the instrument, and access to the certificates and /or reports of notified bodies will provide the surveillance authority with the necessary information about the instrument. "Efficient enforcement usually requires that surveillance authorities act in collaboration with manufacturers and suppliers in order to prevent the placing on the market of non-compliant products."⁴
- 2.21. A national authority, if it is required for the correct use of the instrument, may require the information outlined in the annex 1 and the relevant instrument specific annexes in 2004/22/EEC to be provided in the official language(s) of the member state in which the instrument is placed on the market.
- 2.22. Although the appropriate harmonised standard or normative document provides a presumption of conformity with the essential requirements, it must be remembered that the market surveillance authority must check for compliance with the essential requirements, not the harmonised standard or normative document.
- 2.23. Market surveillance may include inspections on the market and in the field, inspection of documents, and special surveillance campaigns.
- 2.24. Market surveillance should be carried out by officers who have a competent understanding of the instruments and processes they are surveying. Such people will also have the authority to enter the premises of people placing on the market, or putting instruments into service and to take enforcement action if necessary. The authority / officers may sub-contract re-assessment / testing or parts of it to expert organisations but the decisions on non-compliances and possible enforcement actions shall be made by the authority. Notified bodies must be excluded from the responsibility of market surveillance activities. In order to avoid conflict of interest it is necessary to make a clear distinction between conformity assessment and market surveillance.
- 2.25. The exchange of information between all stakeholders involved is a fundamental part of the process of market surveillance.
- 2.26. In some member states, different expressions may be used to cover or describe the various enforcement activities that are carried out. In some cases, data gathered at periodic re-verification or on inspection may be useful in contributing to market surveillance work.

⁴ Blue Guide, p48 paragraph 8.2

- 2.27. Market surveillance should take into account results coming from application of other directives (for example LVD, EMC, Machinery) if relevant.
- 2.28. Complaints about the product from competitors, consumers or other end users can also provide information for market surveillance purposes.

3. Specific requirements of the NAWI directive

- 3.1. Article 2 and Article 7 of the NAWI directive create the obligation on member states to carry out market surveillance.
- 3.2. Member States shall take all steps to ensure that instruments may not be placed on the market unless they meet all the requirements of this directive which apply to them (Article 2(1)).
- 3.3. Member States shall also take all steps to ensure that instruments that may not be put into service for the uses referred to in Article 1(2) (a) of the NAWI directive unless they meet the relevant requirements of this NAWI directive which apply to them. Those instruments mentioned in Article 1 (2) (a) of the NAWI directive are:
- Determination of mass for commercial transactions;
 - Determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment;
 - Determination of mass for the application of laws or regulations; expert opinion given in court proceedings;
 - Determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment;
 - Determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories;
 - Determination of price on the basis of mass for the purposes of direct sales to the public and the making-up of pre-packages;
- 3.4. “Where a Member State considers that instruments bearing the EC mark of conformity referred to in Annex 2, sections 2, 3 and 4, do not meet the requirements of this Directive when properly installed and used for the purpose for which they are intended, it shall take all appropriate measures to withdraw those instruments from the market or to prohibit or restrict their being put into service and/or placed on the market.”⁵
- 3.5. It is important to note, that the ranges of applications for instruments mentioned in the NAWI directive is different and more specific than those in the MID.

⁵ NAWI directive Article 7 (1)

- 3.6. It should be noted that the NAWI directive also creates an obligation on member states to ensure that instruments bearing a CE mark attesting conformity with the requirements of the directive continue to conform to those requirements. This obligation is not present in the MID.
- 3.7. This process is not market surveillance, but inspection of in-use equipment. If it can be shown that any failure to comply with the essential requirements had occurred before any instrument was placed on the market, such information can be used in contributing to market surveillance activities.

4. Specific Requirements of the MID

- 4.1. Many of the requirements with regard to market surveillance under the MID are outlined in article 18 of the directive. This article considers the obligations of member states with regard to market surveillance. It is more explicit than the NAWI directive with regard to these obligations.
- 4.2. The following attempts to contrast with the NAWI directive the extra obligations of the MID.
- 4.3. The obligation to carry out market surveillance relates to both instruments being placed on the market and putting into use. The range of applications for those instruments subject to legal metrological control is much broader in the MID and can cover instruments used for public interest, public health, public safety, public order, protection of the environment, protection of the consumers, levying of taxes and duties and fair trading.
- 4.4. Member States may prescribe the range of applications of measuring instruments outlined on paragraph 4.3. This will lead to a variation between member states which will mean that for the same use, instruments in some member states will be required to have a CE-marking and supplement metrological markings whereas in some member states they will not.
- 4.5. The MID has many more conformity assessment procedures than the NAWI directive. The manufacturer or importer may use different conformity assessment procedures at the same time. The market surveillance authority will need to be aware of which conformity assessment procedure is allowed for each specific instrument. For an overview of this see annex 5.
- 4.6. The MID includes essential requirements not present in the NAWI directive: For example, mandatory information on non-simple instruments, software controls, and where relevant, local temperature requirements. The market surveillance authority must have sufficient competent staff to be aware of, and understand the extra requirements and to ensure that instruments are in conformity. It should be noted

that the MID contains a specific essential requirement that relates to EMC. This explicit requirement is not present in the NAWI Directive.

- 4.7. In the four annexes relating to utility meters (M001/2/3/4) there is a specific requirement placed upon the distributor or the person legally designated for installing the meter to ensure that the meter is appropriate for accurate measurement of consumption that is foreseen or foreseeable. Such an essential requirements is not present in the NAWI Directive. Early information of distributors and representatives of utilities would be essential to ensure as far as possible that appropriate meters are put into use.
- 4.8. The MID gives member states the opportunity to introduce provisions justified by local climatic conditions. If relevant, the market surveillance authority will have to be aware of any such criteria and refer to the operating conditions specified by the manufacturer.
- 4.9. The MID creates specific requirements for the information relating to an instrument to be easily understandable and relevant. A member state may require the information accompanying the instrument to be in the official language of the member state in which the instrument is placed on the market. It is the responsibility of the manufacturer, importer, or distributor to provide this information.
- 4.10. With regard to specific types of instrument, the MID creates requirements with regard to sub-assemblies. The provisions of the MID shall apply to sub-assemblies as they apply to complete instruments.
- 4.11. It should be noted that a member state has an obligation, as described in article 18, to ensure that instruments that are subject to legal metrological control, but do not comply with the applicable provision of the MID are neither placed on the market nor put in to use.
- 4.12. Article 19 of the MID makes it incumbent on member states to take all appropriate measures to withdraw instruments from the market, or prohibit or restrict them being used, if they establish that all or part of the measuring instrument of a particular model bearing a CE mark and supplementary markings does not comply with the essential requirements of the directive.

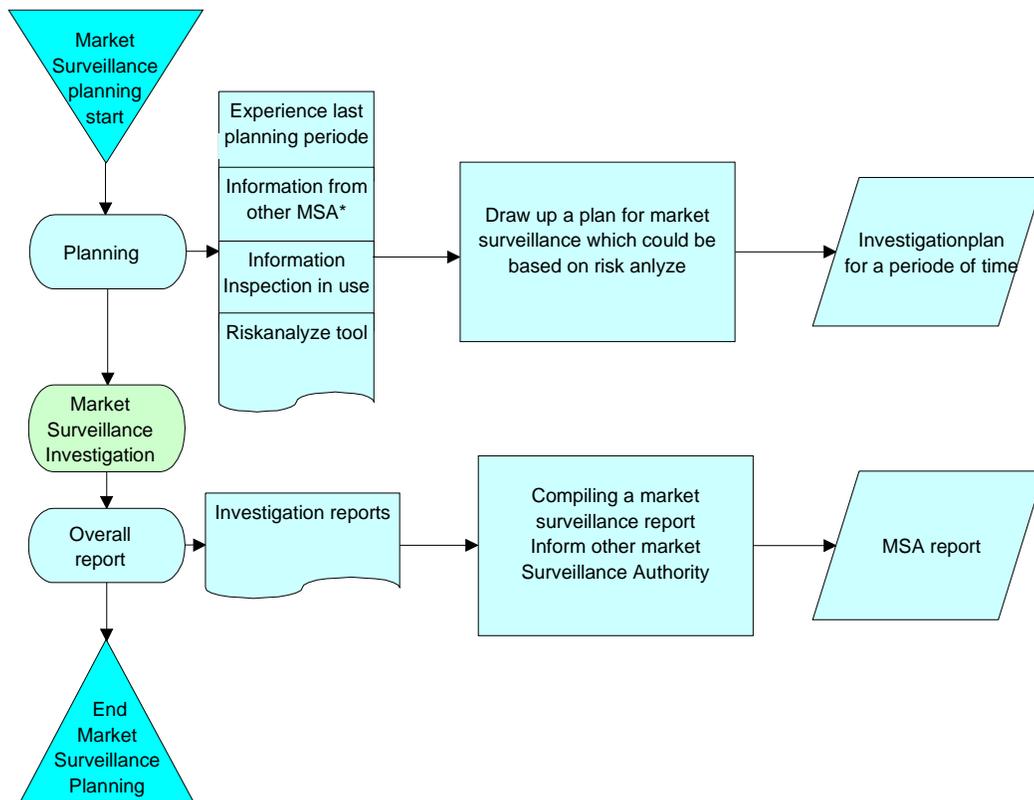
5. How to carry out Market Surveillance

5.1. This chapter gives an example of how market surveillance may be done. The process is visualised in paragraph 5.1 for planning, investigation and corrective action. The following processes can be used for all types of instruments, but for some categories it will be easier to complete all elements than for others. For an ease of understanding it may be beneficial to sub-divide the instruments into three categories.

- Technically uncomplicated instruments
- Standard mass produced instruments
- Customised technically complicated instruments and systems.

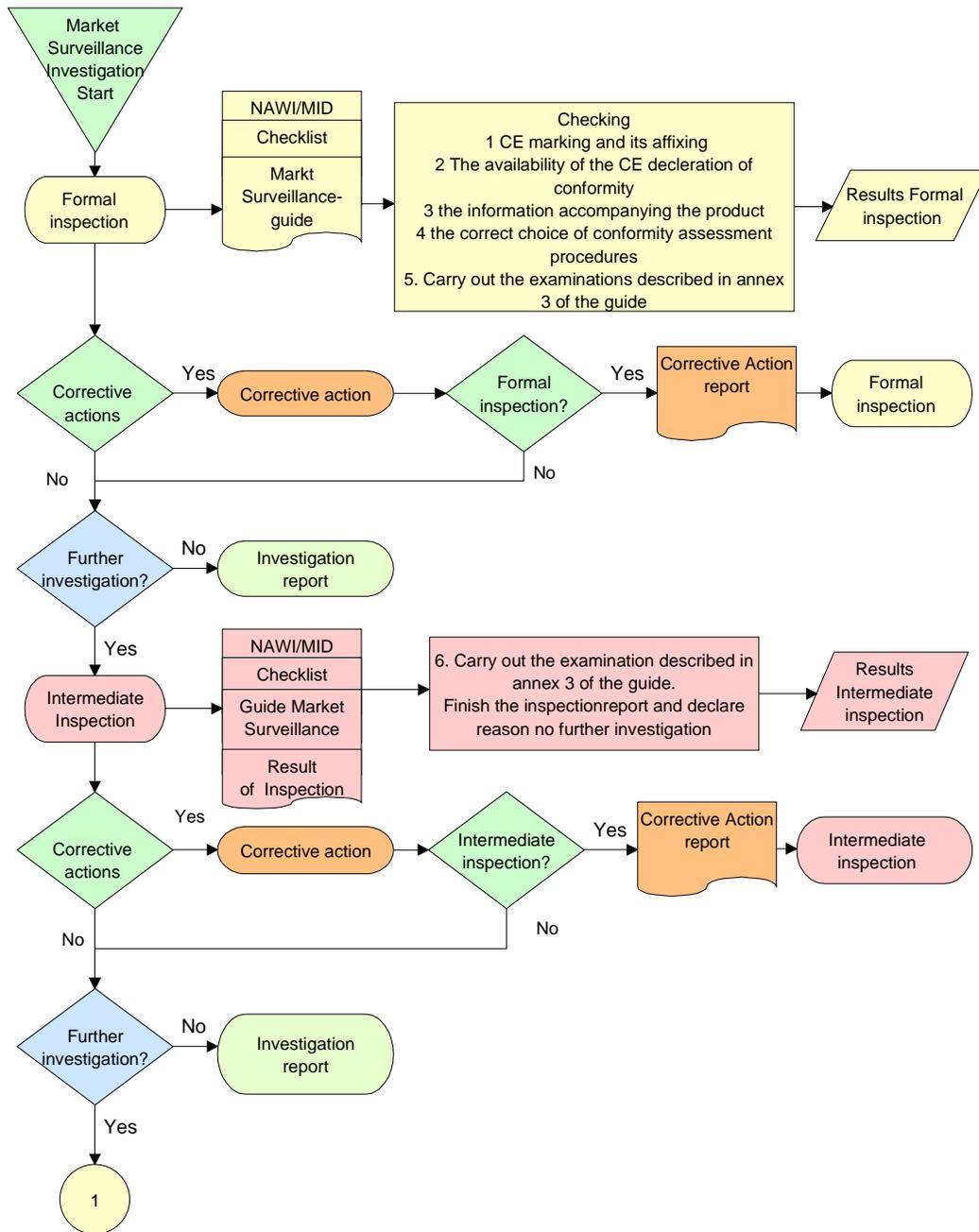
5.1.1. General Planning

The general planning process is not static. The experience of the Market surveillance authority will bring new opinions on how to fulfil the planning process



* MSA = Market Surveillance Authority

5.1.1 Investigation

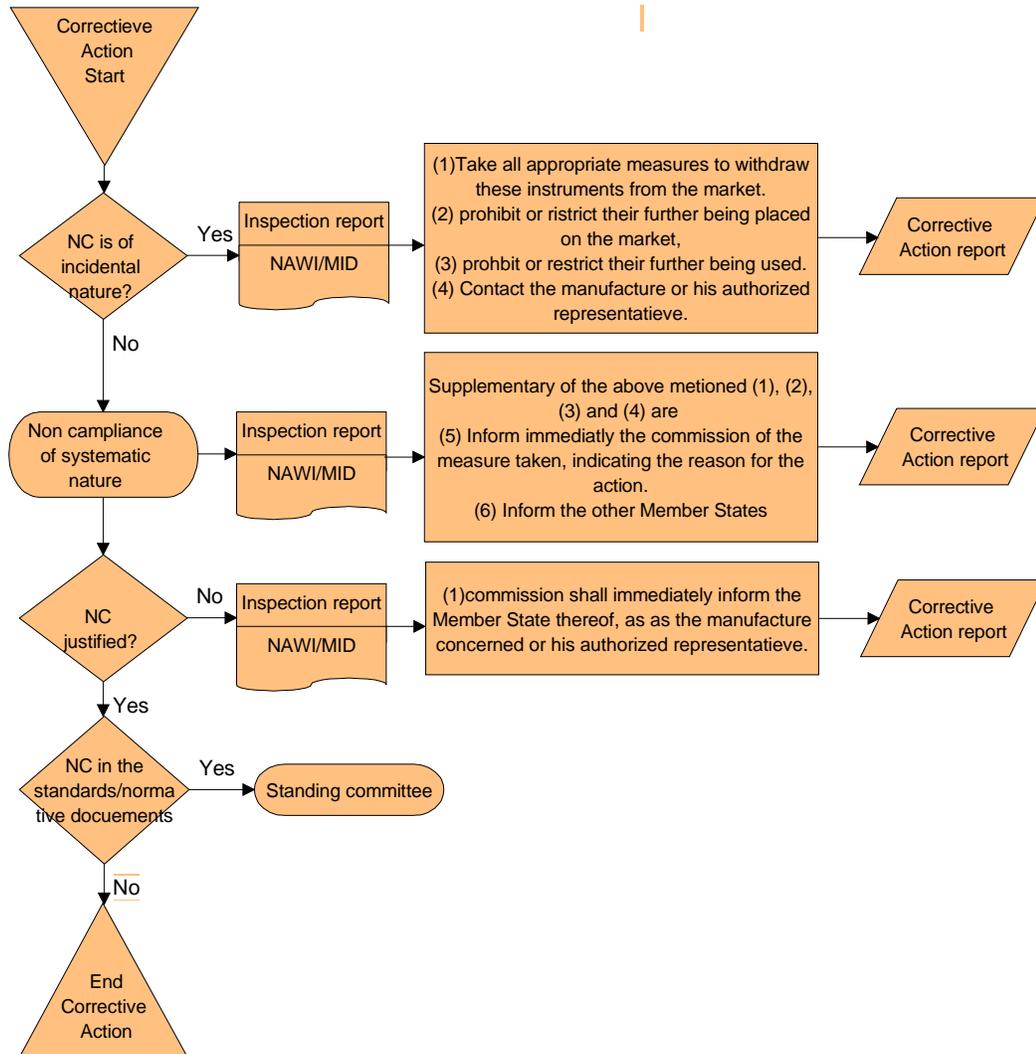


5.1.2 Investigation, continued



5.1.3 Corrective Action

This flow diagram is a sub-section of the diagram in 5.12 (Investigation)
 At the end of the corrective action flow chart you return to the investigation flowchart at the relevant point.



The following definitions are also useful in understanding the flow charts above:

Formal Inspection: To a certain extent formal checks are sufficient, for example the affixing of the CE marking, the availability of the EC Declaration of Conformity, the information accompanying the product and the correct choice of conformity assessment procedures.

Intermediate inspection: Technical documentation and the correct application of the conformity assessment procedure. Technical documentation is required by some modules dependent upon the compliance route chosen. Any manufacturer that utilises modules A1, B, D1, E1, F1, G or H1 to ensure compliance with the essential requirements will require a technical file. The contents of the file are outlined in article 10 of 2004/22/EEC.

Detailed Inspection: The market surveillance authority could check the correct application of the conformity assessment procedure, compliance with the essential requirements and the contents of the EC declaration of conformity.

The market surveillance authority can focus on certain aspects of the requirements.⁶

If any concerns are raised by the surveillance authority, they may subcontract technical tasks (such as testing or inspection) to another body; provided that it retains the responsibility for its decisions and that there is no conflict of interest between the other body's conformity and its surveillance task.

The outcome of the process should result in any relevant alteration to the instrument; or the manufacturer or supplier withdrawing the instrument from the market. Where relevant, they may communicate any findings to other member states.

If the member state should find any instruments placed on the market or put into use that do not comply with the essential requirements of the directive, it shall take all appropriate measures to withdraw the instruments from the market. The process is considered in more detail in 2.10 onwards.

The level of information obtained from any market surveillance process will be dependent upon whether the process was programmed i.e. planned in conjunction with the manufacturer or importer, or re-active, using instruments found during the normal day to day operation of the market surveillance authority. It is likely that the planned programmed market surveillance will produce more detailed information. The information found during re-active market surveillance should not be disregarded as this will better reflect the reality of the markets of measuring instruments.

⁶ Blue Guide 8.2 page 49

5.2 Technically uncomplicated instruments

5.2.1 An example of a technically uncomplicated instrument is a material measure of length or a capacity serving measure.

5.2.2 The market surveillance for technically uncomplicated instruments should consist of formal or intermediate inspection as mentioned above.

5.3 Standard mass produced instruments

5.3.1 An example of mass produced instruments may be those mentioned in annex 001/3/7/9/and 10 of the MID or a simple NAWI.

5.3.2 The market surveillance process for standard mass produced instruments should follow broadly similar principles as mentioned above.

5.3.3 The market surveillance authority will be able to check markings and basic physical characteristics of the instrument, either in situ or at commercial, industrial, and storage premises, work places and other premises where the instruments are put into use.

5.3.4 It is more likely that the market surveillance of these instruments will take place at the premises of the manufacturer or importer. This will give the surveillance authority greater opportunity to obtain relevant equipment necessary for testing the instrument and engage in a more detailed analysis of the instrument by comparing it with the technical file.

5.4 Customised technically complicated instruments and systems

5.4.1 An example of a technically complicated instrument would be those mentioned in annex 005/6.of the MID

5.4.2 The process for the surveillance of technically complicated custom made instruments will follow a similar framework to the process outlined in section 5.1 above.

5.4.3 The comparison of the instrument against the technical documentation will have a greater significance because of the more complicated nature of the instruments.

5.5 Risk Assessment

5.5.1 Another useful tool for market surveillance authorities is risk assessment. This is a process by which a planned project will be targeted e.g. specific instruments or routes of supply.

5.5.2 These targets will involve evidence based decisions based on specific criteria. For example: The risk to the consumer of the effect of a

contravention, the likelihood of contravention depending upon the source of the supply, or the financial disadvantages to compliant businesses from others seeking benefit by non-compliance.

5.5.3 All of the decisions for a targeted risk assessment must be evidence lead and must not be based upon uninformed speculation.

5.5.4 Risk Assessment can also be a helpful tool during the investigation process. If certain instruments are easier to tamper with, more expensive or more susceptible to a decline in stability during a short period of time they may be targeted above other instruments.

6 Procedure and arrangements for exchange of results of market surveillance.

- 6.1 The primary objective of cooperation is to ensure an equal level of safety and fair competition throughout the community.
- 6.2 Member states are obliged to inform the commission and other member states when any action is taken that restrict the free circulation of instruments as a result of non-compliance with the directives.
- 6.3 Exchange of information shall be ensured for notifications of serious non-compliances requiring rapid intervention by the use of an exchange system⁷
- 6.4 Wider information concerning the overall cooperation activities will be stored in a single database.⁸
- 6.5 Coordination and exchange of information between national market surveillance authorities could be done by the WELMEC WG 5 web site and notify other contact by e-mail. This website area is confidential to WELMEC Working Group 5 members.
- 6.6 Any comment on the results by any other market surveillance authority could be given within two months.
- 6.7 The results of the market surveillance authority that identify the manufacturer and / or the instruments by recognisable names or characteristics must be kept confidential so as to avoid adverse effects on the market place. The manufacturer may agree to release the results of market surveillance results, if he so wishes. In some Member States there may be overriding requirements relating to public access to information.
- 6.8 The need for confidentiality does not apply where the procedure in Article 7 of NAWI or Article 19 of the MID has been followed, when and only when the Commission has confirmed that the action taken by the Member State was justified.
- 6.9 The market surveillance authority could adhere to the following cycle:
 - 1 Propose and plan what market surveillance is appropriate (this may differ from Member State to Member State), having regard to the views of interested parties such as instrument manufacturers federations and associations (e.g. CECIP CECOD, CITEF, AQUA and Notified Bodies); and national representative bodies
 - 2 Note what each participating Member State is planning to do;
 - 3 Member States carry out market surveillance activities;

⁷ Short term: website area only intended for the members of WELMEC Working Group 5

⁸ A website only intended for members of the WELMEC working group 5

- 4 Collect the results on the website and share this with other market surveillance authorities;
- 5 Review those results with all interested parties including manufacturers federations, other manufacturers who are not members of manufacturers federations, and representatives of the Notified Bodies;
- 6 Publish a summary and analysis, which is circulated widely and on publicly accessible websites, including to the Commission, to show that the Member States are carrying out their responsibilities, so that buyers and users of measuring instruments may have confidence in them, and manufacturers and Notified Bodies are being treated on an equal basis; (If notified bodies are involved, the member state who notified the body should always be informed)
- 7 Review and repeat the cycle.

6.10 The exchange of results will inform the Member States of what has been found. The initial planning of a cycle of market surveillance activities can, as a consequence, take account of what has been done previously and the results that were found. In this way the new work can focus on where market surveillance is needed and avoid areas where it is not needed, thus leading to better use of resources. The exchange will also show whether or not an equivalent level of protection is being achieved.

6.11 Market Surveillance authorities should consider the possibility of joint action between member states; this could involve joint projects between states undertaking surveillance on common instruments or from similar sources. Other examples could be the sharing of laboratory services or expertise.

Annex 1 – Co-ordination of market surveillance weighing and measuring instruments in the member states

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Sweden	Hillevi Stein SWEDAC	+46 8 406 83 11 +46 8 791 89 29 hillevi.stein@swedac.se
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Annex 2 – Powers and responsibilities of those responsible for market surveillance

Country	Organisation responsible for market Surveillance	Powers and Responsibilities
<p>Austria:</p> <p>From: 22/01/2003</p>	<p>Authorised inspectors of BEV</p>	<p>They can enter all places where instruments under verification obligation are used, stored or produced. They do not have to announce their visits in advance. Proprietors of companies, their representatives and agents, are obliged to facilitate the official operations of the surveillance authority. Illegal, incorrect or otherwise not complying instruments may be put out of use. The further use of disputed objects can be prevented by their total or partial confiscation into official safekeeping or by the creation of a disabling device for a maximum period of six months (immediate enforcement action). This may be associated with advice to an administrative body, which can set a fine and take further measures. If non-compliant instruments are revealed, the following measures can be taken:</p> <ol style="list-style-type: none"> 1. a ban on further marketing, 2. requisition of lists of suppliers, 3. order to revert to the statutory condition, for which an appropriate period must be specified, 4. notification to the notified body or the type approval body involved, 5. implementation of suitable measures, in order to prevent unintentional use, 6. publication in the Official Journal for the Verification Service and in the appropriate media for the sales channels concerned
<p>Belgium</p>	<p>from: [date of regulation] Verification officers mandated by the Federal Government</p>	<p>The power and responsibilities are regulated by :</p> <ol style="list-style-type: none"> 1. - articles 12, 24, 26 and 27 from the Law on weights and measures of 16 June 1970; 2. - article 1 from the Royal Decree of 5 December 1978; 3. - article 7 from the Royal Decree of 4 August 1992. 4. They can enter all places where instruments under verification obligation are used, stored or produced. 5. There is no obligation to announce the inspections in advance. 6. Illegal, incorrect or non-compliant instruments shall be disapproved. 7. Legal proceedings (enforcements) are foreseen in collaboration with the court
<p>Bulgaria</p>	<p>State Agency for Metrological and Technical Surveillance /SAMTS/</p> <p>Legislation: Law on technical requirements to products since 1999, last amended in 2006; Ordinances for the implementation of the above law transposing the requirements of NAWI Directive and MID; Ordinance on the conditions and order for</p>	<p>Performs monitoring and checks on sites where MI are placed on the market, put into use, and used as intended. The inspectors have the power to:</p> <ol style="list-style-type: none"> 1. Prohibit the distribution and/or the use of MI that do not comply with the relevant essential requirements; 2. Require from the manufacturer, his authorised representative or any other person, who has placed the non-complying MI on market and/or put them into use to withdraw them from the market; 3. Stop the distribution and/or the use of MI until their conformity assessment and marking;

	carrying out Market Surveillance	Release announcements on established dangerous MI.
Cyprus		
Czech Republic	Inspectors of the Czech Trade Inspection	<p>1. Act No. 22/1997 Coll., on Technical Requirements for Products and on Amendments to Some Acts, as amended, that lay down technical requirements for products.</p> <p>2. Government Order No. 326/2002 Coll. that lays down technical requirements for non-automatic weighing instruments.</p> <p>3. Government Order No. 464/2005 Coll. that lays down technical requirements for measuring instruments.</p> <p>Inspectors have the power to enter premises to inspect NAWIs and MI and they do not have to announce their visit in advance. They may take appropriate enforcement actions (e.g. to check the associated documentation, ban of the sale, withdraw from the market, take out of use, take away for testing, impose a fine etc.), where the essential requirements are not satisfied and when the marking is not correct.</p>
Denmark	<p>Den Danske Akkrediterings- og Metrologifond or persons or Organisations authorised by Den Danske Akkrediterings- og Metrologifond according to Statutory Order no: 597 dated 29 June 19949</p> <p>Ref. Made to specific §§ in Statutory Order no: 597 dated 29. June 1994: §6, §10 Den Danske Akkrediterings- og Metrologifond may stop marketing and use of CE-marked non-automatic weighing instruments not fulfilling requirements of the Directive.</p> <p>§14 Authorised persons have the power to enter certain premises to inspect and test non-automatic weighing instruments. They may enter premises by force. They do not have to announce their visits in advance.</p>	<p>Ref. Made to specific §§ in Statutory Order no: 597 dated 29. June 1994:</p> <p>§6, §10 Den Danske Akkrediterings- og Metrologifond may stop marketing and use of CE-marked non-automatic weighing instruments not fulfilling requirements of the Directive.</p> <p>§14 Authorised persons have the power to enter certain premises to inspect and test non-automatic weighing instruments.</p>
Estonia	Officials of the Department on Legal Metrology of the Technical inspectorate of Estonia (Metrology Act of 2004; modified in 2005 and 2006)	<p>They can monitor compliance with legislation without hindrance and without giving prior notice; enter premises and territory where MI intended for placing on the market or putting into use are used or kept, inspect the said non-compliance with the established requirements, document offences, and issue precepts.</p> <p>Officials exercising state supervision may request additional proof, if doubt has arisen concerning the compliance of the MI with the requirements prescribed in Metrology Act and legislation established on the basis thereof; may prohibit the placing on the market, putting into use or use of a MI, if the MI does not comply with the established requirements. The Technical Inspectorate shall conduct the extra-judicial proceedings concerning the misdemeanours provided in Metrology Act.</p>

Finland	Authorised inspectors of TUKES and Provincial Authorities	<ol style="list-style-type: none"> 1. May limit or stop marketing and use of instruments not fulfilling requirements 2. May issue injunctions and prohibitions as required in any particular case in order to ensure compliance with the Act and the regulations. Such injunctions or prohibitions may be associated with fines. 3. Authorised persons have the power to enter certain premises to inspect and test instruments. They do not have to announce their visits in advance. 4. Proprietors of companies, their representatives and agents, are obliged to facilitate the official operations of the surveillance authority. 5. The right to get the information necessary for supervision from the owner, user or other body the regulations concern. 6. The police and customs may provide executive assistance if needed. <p>Verification Act from 1965 last modified 1999 Degree from 1992 last modified 1999 Degree on measurement units 1992 last modified 2001 Regulations V10-92, V1-93, V1-94 and V2-93</p>
France	Agents from SDM and DRIRE. They are mentioned in the Décret of 1991(modified in1993 and 1996) transposing the NAWI Directive by way of a reference to the Code de la consommation (Loi du 1er février 1995) A decree of 2006 transposed the MID requirements	<p>They can take the instrument and ask that they are put in conformity. It goes with a juridical procedure (papers and information of justice authorities and final decision by them).</p> <p>They can enter any place mentioned in the Décret of 1944 (places open to the public as well as shops, workshops, factories, cooperatives, stations, airports, hospitals, governmental premises...). If access is refused to them, then they have to request that a policeman or a representative of the city mayor or a judge accompany them and these required persons cannot refuse to accompany them. The amount of the penalties are fixed in the décret transposing the directive by reference to a general rule. Physical persons and companies (moral persons) can be punished.</p>
Germany	Verification officers mandated by the verification authorities of the federal states	They have the power to enter certain premises to inspect and test non-automatic weighing instruments subjected and all instruments to legal metrological control. They do not have to announce their visits in advance and may take appropriate enforcement actions, where the essential requirements are not satisfied or when the marking is not correct.
Greece		
Hungary		
Iceland	Neytendastofa	Neytendastofa has all the powers and responsibilities determined by directive 2001/95/EC <i>on general product safety</i> which has been implemented into national law by act no. 134/1995 on Product Safety and Official Market Control. According to the act no. 91/2006 <i>on measurement, measurement standards and official weighers</i> Neytendastofa is granted unhindered access to all premises and internal facilities needed to enforce the inspection and surveillance required by the act.

Ireland	Inspectors authorised under the NAWI Regulations 1992 and the Metrology Act, 1996	<p>Officers are authorised:</p> <ul style="list-style-type: none"> • to enter any premises for the purposes of inspecting measuring instruments • to examine and test instruments • to take away instruments from the premises for testing • to examine and take extracts of records <p>An offence is created by any person who places on the market any instrument which does not meet the requirements of the Regulations</p>
Italy		
Latvia		
Lithuania		
Luxembourg		
Malta		
Netherlands	Inspectors of Verispect bv mandated by the Central Government	<ol style="list-style-type: none"> 1. Inspectors of Verispect bv have the power to enter all premises to inspect and test all regulated instruments. In certain circumstances, they may enter premises by force. They do not have to announce their visits in advance. 2. Inspectors of Verispect bv may take immediate enforcement action, where for example the essential requirements are not met, with the effect that instruments must be withdrawn from the market. 3. Inspectors of Verispect bv may issue a compliance notice, where the CE marking is being affixed to instruments in contravention of a provision concerning CE marking.
Norway	Justervesenet	Reference is made to the Law on weights and measures and the following regulation. Justervesenet have the power to enter all premises (by force if necessary) where it is likely that measurements regulated by the law are done. Such visits shall generally not be announced in advance. If instruments are incorrect or illegal, they may be put out of use. If they are approved but do not fulfil the verification requirements, the inspector may give permission for use until they are repaired; not more than 1 month.
Poland	<p>Authorised inspectors of Trade Inspection.</p> <p>Officers of Office of Competition and Consumer Protection</p>	<p>The Council Directive of 20 June 1990 on the harmonization of the laws of the Member States relating to non-automatic weighing instruments (Directive 90/384) was transposed into the Polish legislation by:</p> <ol style="list-style-type: none"> 1. The Act of 30 August 2002 on Conformity Assessment (Journal of Laws of 2004, No 204, item 2087 with amendments), it contains procedural provisions; 2. The Regulation of 11 December 2003 of the Minister for Economic Affairs, Labour and Social Policy on essential requirements for non-automatic weighing instruments subject to conformity assessment (Journal of Laws of 2004 No 4, item 23); it was issued on the basis of Article 9 of the Act on Conformity Assessment. <p>Trade Inspection Both the Act on Conformity Assessment (Articles 40 – 42) and the Act on Trade Inspection confer certain powers</p>

		<p>upon the inspectors; the inspectors are authorized inter alia to:</p> <ol style="list-style-type: none"> 1. request any relevant information, documentation, evidence; 2. enter the premises where the products and documentation checked are being used or stored; 3. take sample of product and have it tested; <p>If, in the course of control procedure, it is discovered that the product may not be in compliance, the inspectors can, for a period not longer than 2 months, prohibit the further marketing of the product. If the administrative proceeding is launched the prohibition period can be prolonged till the proceeding is closed.</p> <p>If, in the course of administrative proceeding launched on the basis of the results of checks, it is stated that the product does not comply with the essential requirements the Trade Inspection can order to:</p> <ol style="list-style-type: none"> 1. withdraw the product from the market; 2. ban its further marketing; 3. restrict its further marketing; 4. destroy the product in question; <p>taking into account the level of non-compliance stated.</p> <p>Office of Competition and Consumer Protection In accordance with Article 44 of the Act on Conformity Assessment The President of OCCP informs the European Commission of every decision requesting the withdrawal of the product from the market, prohibition or restriction of its marketing (as foreseen by the Article 7.1 of the Directive).</p>
Portugal		
Romania		
Slovakia		
Slovenia	<p>Authorised Inspectors and Metrology supervisors of MIRS (Metrology Institute of the Republic of Slovenia)</p>	<p>The power and responsibilities are regulated by articles 18, 18a, 18b,19 and 23 from the Metrology Act of no. 26/ 2005; They can enter all places where instruments under verification obligation are used, stored or produced. They do not have to announce their visits in advance. May limit or stop marketing and use of instruments not fulfilling requirements 2. May issue injunctions and prohibitions as required in any particular case in order to ensure compliance with the Act and the regulations. Such injunctions or prohibitions may be associated with fines.</p>
Spain	<p>Regional Governments (Comunidades Autónomas)</p>	<p>The inspectors and agents of the Comunidades Autonomas have the power to enter certain premises to inspect and test NAWIs (e.g. shops, workshops, factories, public places). They do not have to announce their visit in advance. They are capable to take immediate enforcement action and put out of use the instrument when some irregularities or non-conformities are detected. Such actuation may be associated with penalties.</p>
Sweden	<p>Act (1992:1514) Concerning Quantity Units, Measurements</p>	<p>1. SWEDAC is granted access to areas and premises in which there are measuring devices or where goods are</p>

	and Measuring Devices and the Ordinance (1993:1066) Concerning Quantity Units, Measurements and Measuring Devices	packaged, stored or sold. The person on whose areas or premises inspection or surveillance is taking place is required to facilitate the work of the surveillance authority. In case refusal of access, SWEDAC is entitled to call upon the assistance of the executory authority in order to perform the work. 2. SWEDAC may issue injunctions and prohibitions as required in any particular case in order to ensure compliance with the Act and the regulations. Such injunctions or prohibitions may be associated with fines.
Switzerland	Authorised persons, inspector or some other person mandated by the weight and measures authority for surveillance and enforcement functions	Authorised persons have the power to enter certain premises, to inspect and test measuring instruments subjected to legal metrological control. They may take appropriate enforcement actions, where the essential requirements are not satisfied or when the marking is not correct.
United Kingdom	Authorised persons, an inspector or some other person so authorised. under the implementing regulations of 90/384/EEC or 2004/22 /EC	References in () are to the specific regulations that implement the Directives 90/384/EEC and 2004 /22/EC 1 Authorised persons have the power to enter certain premises to inspect and test any weighing or measuring instrument. In certain circumstances, they may enter premises by force. They do not have to announce their visits in advance. 2 They may suspend, for a period up to 28 days, a manufacturer's or authorised representative's authority to make EC declarations of type conformity, where the CE marking or stickers are being affixed to instruments contrary to the Directives 3 A person commits an offence that puts an instrument on the market which to his knowledge bears any CE marking, inscriptions, etc that is forgeries or counterfeits. 4 An authorised person may take immediate enforcement action, where for example the essential requirements are not met, with the effect that instruments must be withdrawn from the market. 5 An authorised person may issue a compliance notice, where the CE marking is being affixed to instruments in contravention of a provision concerning CE marking, but the matter is not so

Annex 3: Examinations and tests which can be carried out.

The following are suggested examinations that may be carried on measuring instruments that are being subject to market surveillance

1. Formal Inspection:

1.1. Check CE marking and other markings and inscriptions are present and correct

1.2. Check for the presence and accuracy of Declarations of Conformity

1.3. Check for the availability and accuracy of any other technical documentation with the instrument, e.g. type approval certificate or information under 9.3 of Annex 1 of the MID

1.4. The correct choice of the conformity assessment procedure and the surveillance reports of the notified body.

1.5. The following examinations and tests may be carried out

- Maximum permissible errors
- fraudulent use; user access to components
- Indications direct sales to the public, and any other requirements suspected to be relevant
- The identification and security of any software
- The presence and operation of approved functions

2. Intermediate Inspection

2.1. This would include all of the above and a more detailed examination of the type approval certificate and the associated technical documentation.

2.2. This may include checking the metrological characteristics of the instrument, including compliance with the maximum permissible errors.

3. Detailed Inspection

3.1. Detailed Inspection would include all of the above;

3.2. It would also include appropriate testing to ensure any instrument complied with all aspects of the Essential Requirements.

3.3. These tasks may subcontracted technical to another body; provided that it retains the responsibility for its decisions and that there is no conflict of interest between the other body's conformity

Annex 4 – Proposal form for sending results to other member states

NOTIFICATION UNDER ARTICLE xx OF THE NAWI / MID

Member State	
Organisation	
Officer Name	
Address	
Telephone	
Fax	
Email	

Identification of the instrument

Name	
Description	
Brand	
Type	
Brand Owner	
Address	
Manufacturer / Importer / Distributor name / address	
Other countries marketed / used	
Other specifications	

Proof of conformity

CE Marking	Yes <input type="checkbox"/> No <input type="checkbox"/>
Other directives covered by CE Marking?	
Other markings	

Written declaration of conformity requested	Yes <input type="checkbox"/> No <input type="checkbox"/>
Written declaration of conformity available	Yes <input type="checkbox"/> No <input type="checkbox"/>
Written declaration of conformity acceptable	Yes <input type="checkbox"/> No <input type="checkbox"/>
Technical documentation requested	Yes <input type="checkbox"/> No <input type="checkbox"/>
Technical documentation available	Yes <input type="checkbox"/> No <input type="checkbox"/>
Technical documentation acceptable	Yes <input type="checkbox"/> No <input type="checkbox"/>
Certificate and/or report drawn up by notified body requested	Yes <input type="checkbox"/> No <input type="checkbox"/>
Certificate and /or report drawn up by notified body available	Yes <input type="checkbox"/> No <input type="checkbox"/>
Certificate and or/ report drawn up by notified body acceptable	Yes <input type="checkbox"/> No <input type="checkbox"/>
Name of notified body	
Report reference number	

Details of the measures taken	manufacturer	importer into the EEA	retailer
Type of measure:			
removal from circulation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
prohibition of the placing of the instrument on the market or putting into use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
general measures making the placing of the instrument on the market or putting into use subject to specific conditions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Date:			
Reference:			

Method of notification:			
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Summary

Reasons for the measures taken

<input type="checkbox"/>	Non-conformity with NAWI / MID resulting from a shortcoming in the applicable standard(s) / Normative documents
	<i>Standard(s) reference:</i>
<input type="checkbox"/>	Non-conformity with NAWI / MID resulting from a faulty application of the applicable standard(s)
	<i>Standard(s) reference:</i>
<input type="checkbox"/>	Where no standard applies, non compliance with the rules of essential requirements of the documents as referred to in NAWI / MID
	<i>Standard(s) reference:</i>

Brief description of faults, nature of hazards and/or shortcomings in standards observed
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Additional information annexed	
<input type="checkbox"/> copy of test reports	<input type="checkbox"/> copy of declaration of conformity
<input type="checkbox"/> photographs	<input type="checkbox"/> distribution chain
<input type="checkbox"/> others	

Annex 5 – Conformity Assessment Procedures with MID and NAWI.

Overview of modules for the MID

Module	Technical documentation	Written declaration of conformity
A Declaration of conformity based on internal production process	X*	
A1 Declaration of conformity based on internal production control plus product testing by notified body	X	X
B EC Type examination	X	
C Declaration of conformity to type based on internal production control		X
D EC Declaration of type conformity (guarantee of production quality)		X
D1 Declaration of conformity based on quality assurance of the production process	X	X
E Declaration of conformity to type based on quality assurance of final product inspection and testing		X
E1 Declaration of conformity based on quality assurance of final product inspection and testing	X	X
F EC Verification		X
F1 Declaration of conformity based on product verification	X	X
G EC Unit Verification	X	X
H Declaration of conformity based on full quality assurance		X
H1 Declaration of conformity based on full quality assurance plus design examination		X
B+D, B+E, B+F	X	X

Overview of the Conformity Assessment Modules relating to Non-Automatic Weighing Instruments.

NAWI – annex II
1 EC Type examination (B)
2 EC Declaration of type conformity (guarantee of production quality) (D)
3 EC verification (F)
4 EC unit verification (G)

Overview of type of instruments under the MID related to the possible conformity assessment modules

- required

	A1	D1	E1	F1	B+F	B+D	B+E	H	H1	G
Water meters					•	•			•	
Gas meters and volume conversion devices					•	•			•	
Active electrical energy meters					•	•			•	
Heat meters					•	•			•	
Measuring systems for the continuous and dynamic measurement of quantities of liquids other than water					•	•			•	•
Automatic weighing instruments										
Mechanical systems		•		•	•	•	•		•	•
Electromechanical systems					•	•	•		•	•
Electronic systems / systems containing software					•	•			•	•
Taximeters					•	•			•	
Material Measures										
Length		•		•		•		•	•	
Capacity	•	•	•	•		•	•	•		
Dimensional measuring instruments										
Mechanical or electromechanical		•	•	•	•	•	•	•	•	•
Electronic instruments / instruments containing software					•	•			•	•
Exhaust Gas Analysers					•	•			•	

** A & C never required in the annex MI-xxx of the MID