An Introduction to the Directive 2014/31/EU
The new NAWI Directive

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Introduction

- The Directive is a recast of 2009/23/EU
- Reflects the concepts of the New Legislative Framework (The NLF)
- These can be found in Decision 768/2008/EC
- Also relevant is the Regulation 765/2008/EC on Market Surveillance for the purpose of understanding Chapter 5 on Market Surveillance

Introduction

- The Directive must be implemented in member states by April 20 2016
- It has six chapters which have different affects on economic operators
- It has 6 Annexes
- The essential requirements are the same
- Must be seen against the background of the new EN45501

The Parts

- The Recitals
- Chapter 1- General provisions
- Chapter 2- Obligations of economic operators
- Chapter 3-Conformity of instruments
- Chapter 4-Notification of conformity assessment bodies
- Chapter 5-Union Market Surveillance, Control of instruments entering the union market, and safeguard procedure.
- Chapter 6- Committee, Transitional and Final Provisions
- The Annexes

The Recitals

- Recitals explain the background and the aims and objectives of the legislation.
- They are important to an understanding of the legislation which follows.
- They are not part of the Directive
- Must read them and understand the context

The Recitals

- *(6) This Directive should apply to all forms of supply, including distance selling*.
- This clearly directs us towards the principles of the distance selling directive 97/7/EC
- Will not apply directly because they will not be consumer goods

The Recitals

- *(7) Economic operators should be responsible for the compliance of non-automatic weighing instruments with this Directive in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests covered by this Directive, and to guarantee fair competition on the Union market*
- Outlines the responsibility for ensuring a **high** level of protection
- Guarantee fair competition.
- This is important as it makes fair competition a criteria for governments

The Recitals

- *(8)All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market non-automatic weighing instruments which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain*.
- The responsibilities must be clear and proportionate
- Must correspond to the role of the economic operator in the supply chain
- This is the first explicit statement of these responsibilities

The Recitals

- *(9) In order to facilitate communication between economic operators, market surveillance authorities and end-users, Member States should encourage economic operators to include a website address in addition to the postal address*.
- This is a positive intention as it is beginning to realise the importance of websites
- Can for see problems with too much information need to go on labels
- Article 6(6) – Must have name AND registered postal address at which they can be contacted
- Contact details must be in a language that can be easily understood- may need to be in more than one language
- Article 8(3)-Same obligation for importers if they are not the manufacturer
- May be difficultly in marking with a web address

The Recitals

- *(10) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer*

- *(11) It is necessary to ensure that non-automatic weighing instruments from third countries entering the Union market comply with this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to those non-automatic weighing instruments. Provision should therefore be made for importers to make sure that the non-automatic weighing instruments they place on the market comply with the requirements of this Directive and that they do not place on the market non-automatic weighing instruments which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that marking of non-automatic weighing instruments and documentation drawn up by manufacturers are available for inspection by the competent national authorities.*

The Recitals

- Recital 10- Focuses on the fact that the manufacturer is the economic actor that has the obligation for the compliance of the instrument
- This is important in future discussions with market surveillance authorities and notified bodies
- Recital 11- Important as it clarifies the principles relating to the obligations of importers
- Must make sure that the correct conformity assessment procedures have taken place
- Must make sure that access to the documentation as drawn up by the original manufacturer is available

The Recitals

- *(12)When placing a non-automatic weighing instrument on the market, every importer should indicate on the non-automatic weighing instrument his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided, including for cases where the importer should have to open the packaging only for the purpose of putting his name and address on the instrument*.
- This is a new obligation- must be the name and postal address
- An exception if the only reason that the package is opened is to place the name and address on the instrument.
- This would appear to lack clarity
- Would open one or two in a consignment to check- presumably would need to put the label on these
- Not sure how this will work for product that is shipped straight to the end user

The Recitals

- *(14) Any economic operator that either places a non- automatic weighing instrument on the market under his own name or trade mark or modifies a non- automatic weighing instrument in such a way that compliance with this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.*
- This is a significant statement is giving us clarity that the manufacturer is the person that places the instrument on the market under his own name
- Does not need to be the type approval holder
- In line with the advice of the Blue Guide

The Recitals

- *(15) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the non-automatic weighing instrument concerned*
- This is important in clarifying that distributors and importers must be actively involved in the market surveillance tasks
- Should also be seen as an obligation on market surveillance authorities not to exclude them from the process

The Recitals

- *(16)Ensuring traceability of a non-automatic weighing instrument throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' tasks of tracing economic operators who made non-compliant non-automatic weighing instruments available on the market.. When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a non-automatic weighing instrument or to whom they have supplied a non-automatic weighing instrument.*

- This appears to be stating that economic operators do not need to maintain up to date information on who has supplied them with instruments or to whom the instruments have been supplied to.

- This would appear to be in contradiction to the whole ethos of the obligations of the NLF of clarifying the requirements of different economic operators

The Recitals

- *(17) This Directive should be limited to the expression of the essential requirements as regards metrology and performance in relation to non-automatic weighing instruments. In order to facilitate conformity assessment with those essential requirements as regards metrology and performance, it is necessary to provide for a presumption of conformity for non-automatic weighing instruments which are in conformity with Harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation (1) for the purpose of expressing detailed technical specifications of those requirements, in particular as to the metrological, design and construction characteristics*

- Regulation 1025/2012 relates to the production of harmonised standards.
- This will be EN45501 – shortly to be republished
- See the UKWF Presentation on this
- Recital 18 allows for objections to the standard

The Recitals

•*(20)In order to enable economic operators to demonstrate and the and the competent authorities to ensure that non- automatic weighing instruments made available on the market conform to the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules*

•All of the modules are defined in Decision 768/2008.

•For this Directive the choices are B+D, B+F, D1, F1 or G

•Less of a range than the 2014/32

The Recitals

- *(21)Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of a non-automatic weighing instrument with the requirements of this Directive and of other relevant Union harmonisation legislation*
- *(22)To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.*

- This outlines the focus to produce 1 Declaration of Conformity that shows compliance with all relevant Directives
- The Declaration may be a dossier made up of individual declarations
- Should be seen in the context of Article 14(3)
- The production of the dossier will be significant for the production of weighing instruments

The Recitals

(34)*Member States should take all appropriate measures to ensure that non-automatic weighing instruments may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Non- automatic weighing instruments should be considered as non-compliant with the essential requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behavior.*

•Very important recital as market surveillance authorities must only take actions when the instruments are used for their intended purpose OR conditions which can be reasonably foreseen

•If the use of the instrument could not be reasonably foreseen the market surveillance authority has no responsibility with regard to that instrument

•This is particularly important with regard to the pressure to increase EMC limits. If the instrument is in an EMC environment which could not have been readily predicted. –market surveillance authorities will have no responsibility

Article 2

- There are a number of new definitions in the Directive
- Non- automatic weighing instrument
- This is the same as the existing directive- but different from the new EN45501
- EN45501 requires intervention of an operator during the weighing process to decide the weighing result is acceptable
- The “ decision” element is not in the definition in the directive

Article 2- New Definitions

- making available on the market
- placing on the market
- Manufacturer-important must be seen in the context of the Blue Guide
- authorised representative
- Importer- this is the importer into the EU
- Distributor-if importing from another member state will be a distributor
- economic operator- general term for all parts of the supply chain
- technical specification

Article 2- New Definitions

- Harmonised standard
- accreditation
- national accreditation body
- conformity assessment
- conformity assessment body
- recall
- Withdrawal
- ‘Union harmonisation legislation
- ‘CE marking – remember this will apply to all applicable directives

Article 3

- Outlines the obligations of the of member states with regard to non-automatic weighing instruments
- Member states shall take ***all steps*** to ensure that compliant instruments are made available on the market or put into service.
- Article 3 (3)
- Member states shall take ***all steps*** to ensure that instruments continue to conform with the requirements of the Directive
- This is a new obligation and creates an EU obligation after the instruments have been made available or put into service
- Could be far reaching implications

Article 4

- All instruments used for an article 1(2)(a) application shall meet the essential requirements.
- If connected to devices not used for a 1(2)(a) application do not need to meet the requirements
- Would need to have a red M
- Includes a requirement for instruments intended to be used
- This is a new obligation

Chapter 2- New obligations

- These outline new and clearer obligations for
- Manufacturers
- Importer
- Authorised representatives
- Distributors
- New challenges for the industry

Article 6
Obligations of manufacturers

- 6(2) The manufacturer must draw up the technical information, the Declaration of Conformity and affix the CE mark and the supplementary metrology markings

- 6(3) Technical information and Declaration of Conformity shall be kept for 10 years

Article 6(4) Obligations of manufacturers

- 6(4) Manufacturers must have procedures in place to ensure continued conformity with the Directive
- Unclear whether these must be written procedures
- ***When deemed appropriate*** with ***regard to the risks presented by the instruments***
- Shall carry out sample testing of instruments made available on the market
- Investigate ***and if necessary*** keep a register of
- Complaints
- Non-conforming instruments
- Instrument Recalls
- ***Shall keep distributors informed of any such monitoring***

Article 6(4) Obligations of manufacturers

- ***When deemed appropriate –*** It is assumed that this is the decision of the manufacturer
- ***regard to the risks presented by the instruments-*** These would be the protection of public interests such as
- Health and safety in general, health and safety at the workplace,
- Protection of consumers,
- protection of the environment and security,
- While ensuring that the free movement of products is not restricted to any extent greater than that which is allowed (Recital 1 of 765)
- ***Shall keep distributors informed of any such monitoring***
- Bizarre that this does not apply to other economic operators in the chain

Article 6(5)
Obligations of manufacturers-Markings

- Must bear a
- Type, batch or serial number – likely to be a serial number and markings as in annex III-Inscriptions
- If used for a controlled application must bear all of the markings
- If not used for a controlled application
- Name and maximum capacity

Article 6(6)
Obligations of manufacturers- Markings

- Must bear a
- Name and Postal Address
- Must be a single point
- ***Must be easily understood by end users and market surveillance authorities***
- This may pose a number of problems
- 24 Official languages
- ***The postal address is a new obligation***
- Compared with 7(3) where the same obligations apply to importers

Article 6(7)
Obligations of manufacturers- Instructions and information

- Instructions and information must accompany the instrument
- Must be in a language easily understood by the end user
- This is determined by the member state
- Shall be clear, understandable, and intelligible.
- Not clear what “accompany” means
- Can this be on a website ?

Article 6(8)

- If the manufacturer believes that the instrument is not in conformity.
- **Must *immediately* take the corrective measures to bring the instrument back into conformity (or withdraw or recall it)**
- **If the instrument presents a risk *must* inform the competent authorities**

Article 6(8)

- If the action must be immediate
- How can this be rectified in terms of alteration to the type approval
- Particular problem with software patches and bug fixes
- Identifying the need for a patch implicitly shows that there may be weakness
- Increasing problem if the software is secured by checksums

Article 6(8)

- If the non-compliance presents a risk
- ***Must inform the authorities***
- Looked at what may constitute a risk under article 6(4)
- Not clear when a non-conformity would or would not constitute a risk and the authorities must be informed

Article 6(9)

- *Reasoned request from a competent national authority*
- *All information and documentation necessary to demonstrate conformity*
- *In a language which can be easily understood*
- Must be a ***reasoned request*** ; If the request is not reasoned it is not necessary to comply.
- Authorities cannot ask for information that is not necessary to demonstrate compliance
- Language need to be understood by the authority
- This is not the end user and is not determined by the member state
- Still likely that you will need the technical file in several languages

Article 7
Authorised representatives

- Shall perform the tasks issued in the mandate by the manufacturer
- Must include
- Declaration of Conformity and technical documentation maintained for 10 years.
- Reasoned request from a competent authority must provide all the relevant information
- Cooperate with competent national authorities at their request.
- This request does not need to be reasoned?

Article 8(2)
Obligations of Importers

- Shall ensure that the *appropriate* conformity assessment procedures have been carried out
- Shall ensure that the technical file, the CE mark and other marks have been applied
- The manufacturer has complied with other marking requirements
- *These are new obligations*

Article 8(3)
Name and Address

- Importers name and postal address must be applied
- If this requires the packaging to be opened for this purpose- can be give on the packaging *and* in accompanying documents
- Must be in a language easily understood by the end user and market surveillance authorities
- *This is a new obligation*

Article 8(4) and 8(5)

- Must ensure that the instrument is accompanied by instructions and information *in a language easily understood*
- Must ensure that storage and transport conditions do not jeopardise conformity
- *These are new obligations and businesses must have a positive process*

Article 8(6) and 8(7)

- If deemed appropriate with regard to risks must undertake testing and keep the records the same as the manufacturer
- Must take immediate action to rectify if not in compliance
- Must inform the authorities if the instrument presents a risk
- *New obligation. Must have positive steps*

Article 8(8) and 8(9)

- Must keep a copy of the Declaration of Conformity for 10 year
- Do not need to keep technical file for 10 years
- Reasoned request from a competent authority must provide all technical information to demonstrate conformity
- In a language which can be easily understood
- Probably rely on information provided by the manufacturer

Article 9
Obligations for distributors

- *These are new obligations*
- *Must act with due care*
- *Must verify that the instrument:*
- *Bears all of the markings*
- *Has the required documents in a language that can be easily understood by the end user*
- ***This will involve positive steps***

Article 9
Obligations for distributors

- If a distributor has reason to believe that the instrument is not in conformity with the essential requirements or the directive
- Shall not supply it
- If they believe it presents a risk they shall inform the manufacturer and importer as well as the authorities
- Shall ensure that storage or transport do not jeopardise its compliance
- Shall comply with a reasoned request from the authorities
- Note reasoned

Article 10

- If an economic operator places the instrument on the market under his own name he shall be considered the manufacturer

- This is important clarification for those companies that use other economic operators type approvals

Article 11

- *An economic operator must be able to identify*
- *Who has supplied the with an instrument*
- *To whom they have supplied an instrument*
- *For 10 years*

Chapter 3
Declaration of Conformity (Article 14)

- *The Declaration of Conformity shall have the structure as set out in the annex*
- It shall contain the elements of the relevant modules
- *It shall be continuously updated*
- *It shall be in a language required by the member state in which the instrument is made available in the market*
- *This is a new obligation and adds to all of the new language obligations*

Chapter 3
Declaration of Conformity (Article 14)

- *14(3)- Shall draw up one declaration for all relevant directives*
- *This poses problems for the supply of weighing machines as they are often placed on the market at a different point in time to the other relevant directives*
- *Recital 21 and 22 allows a dossier made up if individual Declarations*
- *Not quite clear how this will work*

Article 16
General principles of marking

- *The Green M has gone*
- *Shall be a capital M and the last two digits of the year in which the M was affixed*
- *All surrounded by a rectangle which must be at least 5mm high*
- *Same as the Measuring Instruments Directive*
- *Last two digits of the year in which the M was affixed?*
- *Surely should be the date it was placed on the market*

Article 17
Rules and conditions for markings

- *Shall be visible, legible and indelible*
- *The CE mark and the other marks shall be placed on before the instrument is placed on the market*
- *The supplementary marks shall immediately follow the CE mark*
- *These shall be followed by the identification number (notified body number)*

Chapter 4
Conformity Assessment of notified bodies

- Of limited concern to business
- All notified bodies must become re-approved
- Will hopefully see and improvement in quality and consistency
- Must ensure that any notified bodies that you use are reapproved
- Important if you are still using Trading Standards

Chapter 5
Market Surveillance

- If a market surveillance authority believes an instrument presents a risk- must carry out an evaluation
- Non-compliances shall be rectified without delay
- Market surveillance authorities must inform the notified body
- Shall inform the Commission and other member states if the non-compliance is not restricted to their national boundaries

Chapter 5
Market Surveillance

- Procedures to prevent the instrument being supplied if it is not bought back into compliance within the prescribed time period
- Safe guard procedure is an “appeal” over member states actions
- Procedure for standards to be changed if the instrument is complaint but still presents a risk

Chapter 6
Transitions

- Shall come into force by April 20th 2016

- Same as the requirements for the MID

Annex I and II – Essential Requirements

- Annex I- These are the same as the essential requirements as in the existing NAWI Directive
- *Must be read in the context of the new EN45501- when this is finally done*
- Annex II- These now mirror the requirement in the Decision 768 and the Measuring Instruments Directive
- No material change
- ***Will need to make administrative changes to documents***

Annex III-IV-V-VI Inscriptions

- Annex III- Inscriptions- similar to the existing Directive
- Annex IV-Declaration of Conformity- discussed earlier
- Annex V- Repeals
- Annex VI- Cross Reference Table