



# Legal Updates

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UK Weighing Federation

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# Review

- European Changes
- National Changes
- UKWF matters
- Other issues



# EN45501

- The standard has now passed
- There are some minor changes that must be made
- Waiting for publication
- Proposed transition dates are 36 months
- Have heard nothing to the contrary



# Product Safety and Market Surveillance Package

- The first draft of the Regulations have been published
- Based around the market surveillance of issue that relate to the protection of health and safety
- Must be aware of the safe guard procedures that some market surveillance authorities seem keen to use
- Has ground to a halt on the requirement for “made in”
- Will come to fruition in due course



# The New Legislative Framework

- The new NAWI Directive and MID have now been published
- Changes to the way we operate
- Must begin to react to this now



# 4 Types of Economic Operator

- Manufacturer
- Importer
- Authorised representative
- Distributor
- Creates new obligations



# Manufacturer Testing Obligations

- 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***



# Manufacturer-Markings and Instructions

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 importer
- Must ensure the instrument is accompanied by instructions and information
- **In a language which is easily understood by the end user**



# Manufacturer-Non Compliant Equipment

- 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**
- Significant clause in the context of software



# Manufacturer-Non Compliant Equipment

Must be able to provide:

- All information necessary to demonstrate compliance with the Directive
- Language that can be understood by the requesting authority
- May well need to have the technical files in different languages



# 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



# Importers-Markings and Instructions

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***
- Must ensure the instrument is accompanied by instructions and information
- **In a language which is easily understood by the end user**



# Importers-Other Obligations

- Same obligations as to manufacturers with regard to testing
- Must take immediate action to rectify if not in compliance
- Must inform the authorities if the instrument presents a risk
- Must have positive obligations to demonstrate this compliance



# Distributors

- 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**



# All Economic Operators

An economic operator must be able to identify:

- Who has supplied them with an instrument
- To whom they have supplied an instrument

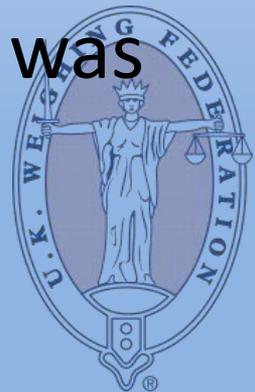
For 10 years:

- 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



# Markings

- 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



# 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)



# Declaration of Conformity

- 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 obligation



# Declaration of Conformity

- 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 of individual Declarations
- Not quite clear how this will work



# Food Information for Consumers (FIC)

These are new regulations for food labelling:

- the requirement for all sellers of food to provide information on any allergens (there are currently 14 recognised ones) in their products. This was previously limited to prepacked foods-for prepacked foods, each allergen must be highlighted in the ingredients list
- a minimum font size for compulsory information such as the name, ingredients, etc.prepacked
- foods must be labelled with nutritional information (calories, fat, sugar, salt etc.) from December 2016.
- this is currently only required if claims such as “low fat”, “reduced sugar” etc. are made on a label
- food on sale after it’s “use by” date (not to be confused with “best before” date) will automatically be deemed to be unsafe
- other special provisions relating to oils and fats, frozen meat and fish and country of origin labelling for meat



# Weight Marking Aspects of the FIC

- Contradiction between the FIC and the PGR
- FIC weight marking shall be in the same field of vision
- PGR visible in normal conditions of use
- Should be aware when advising customers



# Weight Marking Aspects of the FIC

- If packing a drained weight- will need to have net weight and net drained weight.
- The list of products that will now be covered by the Packaged Goods Regulations between 5g and 25kg has been increased.
- This means that these products must have verified NAWI's when they are being packed



# Other Matters- Medical Weighing

- There has been no further progress with the medical weighing project
- Supportive but little action
- Clarification on the Medical Devices Directive
- If your weighing instrument only has a weighing function it is not covered by the medical devices directive
- Will not need to be noted on the Declaration of Conformity
- If it has more than a weighing function- BMI calculation- will be a medical device
- Must be registered under the medical devices directive



# Other Matters-Software

- The CECIP software project has been presented to the European authorities
- Has been accepted as a project for suitable further consideration
- This is a positive move and begins a development process



# Other Matters

- The possibility of a period between a repair and the verification of a changed load cell
- Must now produce a detailed procedure for this to happen
- Confirmed – four wire load cells must not be cut
- Confirmed-a type approval can use other manufacturers indicators
- Confirmed – an EPOS system must print a ticket at the end of the process



**Thank you**