Review of the recast of the NAWI Directive and the MID

The following comments are to assist in the analysis of the documents and the affect they may have on economic operators. The comments are made in the context of the Directive 2009/23/EC (NAWID), but are equally applicable to the Directive 2004/22/EC (MID)

Article 1: This is the same as the existing directive and appears to have no implications.

Article 2: This has some important new definitions. Many of these are not present in the NAWID and some are already in the MID but with slightly different wording. It is hoped that these definitions will help clarify the present situation. The important new definitions would be.

'Making available on the market' means, "any supply of an instrument for distribution, or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge". This replaces the phrase "placed on the market" which is in the existing NAWID and the MID.

It is felt to be unlikely that this change will have any material effect on economic operators.

'Placing on the market' means the first making available of an instrument on the Union market**;**

There is an important contrast with the present definition used in the NAWID and the MID[1]. The present definition is limited to an instrument intended for the end user. In contrast, the new definition is not limited to instruments intended for the end user. The effect of this is to make the new definition in both recast directives is much wider.

The new definition is applied in chapter 2 of the directive, which creates new obligations for all economic operators. The important effect is that an economic operator placing all instruments on the market, not merely those intended for an end user, will need to meet the obligations in chapter 2. The practical implications of this are presently unclear.

"Putting into service/putting into use" - It is odd to note that the recast NAWID use the term "putting into service" (Article 3(2)) which is not defined. The recast MID use the phrase "putting into use" (Article 7) which is defined and has the same meaning as the existing MID.

It is assumed that the term "putting into service" will have a similar meaning to that used in the recast and the current MID, which means the first use of an instrument intended for the end user for the purpose for which it was intended. It is felt that the absence of this definition will have little practical effect on the operation of the directive.

'Manufacturer' means any natural or legal person who manufactures an instrument or has an instrument designed or manufactured, and markets that instrument under his name or trademark.

This is an important definition, as it appears to clarify the fact that the manufacturer does not need to be the assembler of the instrument. It allows within this definition an economic operator that sub-contracts the entire design or manufacturing process.

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1 The phrase is not defined in the existing NAWID , but it is assumed that the definition in the MID would be suitable.

'Authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks.

This definition is the same as existing definition in the MID (It is not defined in the existing NAWID). It is assumed that any business that has an economic base within the union will meet this requirement.

'Importer' means any natural or legal person established within the Union who places an instrument from a third country on the Union market;

This definition does not appear in either the NAWID or the MID. It is useful to have this definition.

'Distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an instrument available on the market.

This is an important definition that does not appear in previous legal metrology directives. It creates a new set of obligations that are outlined in chapter 2, which any business falling within the definition of distributor must comply with.

'Economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

This is an important new definition that appears in all directives that are aligned to the New Legislative Framework.

There are a number of other new definitions, but it is felt that these are the most relevant ones to the membership of CECIP.

Article 3(1): This is similar to the article 3(1) of the existing NAWI Directive but changes the obligation from instruments being placed on the market to instruments being available on the market. It is thought to be unlikely that this will have a major effect on economic operators.

Article 3(2) This is similar to the article 3(2) of the existing NAWI Directive. It is odd that the phrase "bought into service" is not defined in this review of the directive. It is assumed that it will continue to have the already existing meanings. This point has been considered above.

Article 3(3): This is similar to the article 14 of the existing Directive. This clause is always felt to be anomalous, as it appears to impose an obligation on member states with regard to instruments after they have been made available on the market or bought into service. There does not appear to be a similar obligation in the recast MID.

Article 4: This appears to confirm that the essential requirements remain unchanged.

Article 5; This changes the term "placing on the market" to "making available on the market".

CHAPTER 2: ***Obligations of Economic Operators***

This is a completely new set of obligations and reflects the requirements of the article 6 of Decision 765/2008.

All of the requirements of chapter 2 relate to the new definition of “placing on the market”, which is not limited to instruments intended for the end user. This contrasts with the definition in the existing directives that limited the obligation to instruments intended for the end user. It is not clear at the moment what effect this change may have.

Article 6: This relates to the obligations of manufacturers. The article is useful in explicitly stating the obligations that it would be hoped many manufacturers already meet. The one clause that may pose concern is 6(7) which states that the instrument is accompanied by instructions that can be easily understood by consumers and end users. This appears to require a handbook in up to 27 (shortly 28) languages that would cover all aspects of the instrument and must accompany it.

Article 7: This relates to authorised representatives. This article is useful in explicitly stating the minimum requirements that such an economic operator should have. It is felt that this does not greatly extend the obligations that they should be operating to at present.

Article 8: This relates to the obligations of importers. It must be remembered that the authorised representative and the importer can be the same economic operator.

This article creates a positive obligation on the importer to ensure that the manufacturer has complied with the requirements of the directive and the instrument meets the obligations of the essential requirements.

Article 8(2) Perhaps one of the most significant new obligations is the responsibility of the importer to ensure the instrument is bought back into compliance if he believes it outside those requirements. If the instrument presents “a risk" they must also notify the market surveillance authorities to that effect.

If this paragraph is to have any practical effect, there will need to be guidance issued on the phrase “where the instrument presents a risk” so that manufacturers will be aware when they have to notify the market surveillance authorities.

It is assumed that market surveillance authorities will need to develop the correct procedures and protocols to ensure that such information is acted upon, especially when such notifications may be international.

The same obligations appear to be echoed in article 8(7) and 8(8)

Article 8(3) This is an important new obligation. The importer must indicate their name, registered trade name or registered trade-mark and address at which they can be contacted. This can go on packaging or documents accompanying the instrument if they cannot go on the instrument.

This appears to mean that an instrument may need to have both the details of the importer and the manufacturer on the instrument. It is assumed that implementing regulations will make a requirement that each set of details must be clearly distinguished. This will have a great bearing on a range of small businesses that act as the importers for a broad range of different brands of scale.

It should also be noted that the trade name or trade-mark should be registered. If it is not registered, it is assumed it will not meet this obligation. It is not clear with who this registration should be.

Article 8(6) This appears to create an obligation for importers to carry out sample testing where it is "deemed appropriate with regard to the performance of an instrument". This obligation must be clarified if importers are not to become liable for subjecting instruments to very expensive testing. At the moment, it is not clear who shall deem it appropriate and that testing should be carried out and it is not clear what the phrase "performance of the instrument" may mean. If interpreted widely, this could make importers liable for EMC and LVD testing.

Article 9 This creates a new obligation on distributors: They will have a positive obligation to check that an instrument is in compliance with the requirements of the Directive. The distributor will have the same obligations as the importer if they have a reason to believe that an instrument is not in compliance with the Directive. The same obligation with regard to the need to notify the market surveillance authorities will exist if the instrument presents a risk. This responsibility does not stretch as far as the need to undertake sample testing as required in 8(6).

If these obligations are not to be too onerous on economic operators, clear guidance must be offered on the type of documentation that a distributor must have to make the requisite decisions and the nature of the risk that would precipitate notification to a market surveillance authority.

Article 10: This is an important clause, as it appears to give any of the economic operators the opportunity to become the manufacturer if they place the instrument on the market under their own name. This would appear to allow the rebranding of instruments which would enable different economic operators to be perceived as the manufacturer.

Article 11; This appears to create an obligation upon economic operators to provide information to the market surveillance authorities. It is assumed this will not contradict national judicial procedures that allow persons to withhold information, if it may incriminate themselves in any proceedings.

CHAPTER 3*: *Conformity of Instruments

This chapter represents a clarification of the existing procedures and brings it in to line with the obligations of the MID.

Article 14(2): This outlines the format of Declaration of Conformity that must be used. It is important to note that it must be in the language for the market in which it was placed or made available. This is important to note for all economic operators and although this represents an increased burden, it is an important clarification. It would be worth having a copy of the Declaration in the appropriate Guidance Notes.

Article 14(3): This important clarification outlines that the Declaration of Conformity should be one document that relates to all relevant directives. This may create difficulties where an economic operator uses more than one notified body, for example, in relation to medical devices.

CHAPTER 4: Notification of Conformity Assessment Bodies

This chapter is new and relates to the procedures for notifying conformity assessment bodies. It is felt that this will have little effect on the operation of economic operators.

CHAPTER 5: Union Market Surveillance, Control of Instruments Entering the Union Market and Safeguard Procedures

This is a significant new set of obligations that primarily relate to the responsibilities of market surveillance authorities. It is felt that these new obligations will also be of benefit to all economic operators, as it should ensure that market surveillance authorities are more diligent in executing their responsibilities.

Article 36(1): This article creates an obligation on market surveillance authorities to carry out an evaluation covering all requirements of the directive. Whilst this is a positive step in ensuring that the obligations of market surveillance authorities are clarified, such an evaluation only needs to be carried out if they have sufficient reason to believe that the instrument presents a risk to the aspects of public interest protection covered by this directive.

It is felt that it would be crucial to ensure clarification of the phrase "public interest protection". This would ensure that market surveillance does not have an opportunity to limit the scope and quantity of evaluations by claiming a contravention of the requirements of the directive does not constitute a risk to public interest protection.

It is comforting to see that any evaluation must apply to "all" of the requirements of the directive. The obligation outlined in the second paragraph of 36(1) indicates that the market surveillance authorities must take "all" appropriate corrective actions to bring the instrument into compliance. This is an onerous requirement that must be welcomed, but it is disappointing that such an obligation is only triggered by a risk to public interest protection.

Article 38: This relates to compliant instruments which present a risk. It would be good to have some examples of the nature of the risk that a presumably legal instrument would pose.

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