WHITE PAPER

York EMC Services

Tackling the Issue of Non-Compliant Products with a New EMC Directive

By Nick Wainwright
Chief Executive
Eurofins York Ltd
www.yorkemc.com

eurofins

***Abstract*—Both anecdotal evidence and the results of European market surveillance campaigns have highlighted unacceptably low levels of conformity with the EMC Directive. In 2014 the third edition of the EMC Directive was amongst a raft of updated Union Acts published and included provisions aimed at increasing conformity rates by embedding regulatory responsibilities throughout the whole supply chain. With the Directive now in force, how likely is it to meet its stated aim?**

Keywords—EMC Directive, 2004/108/EC, 2014/30/EU, conformity, compliance, market surveillance, non-compliance, Technical Documentation, Declaration of Conformity

I. Introduction

European legislation covering Electromagnetic Compatibility (EMC) has been in existence for 20 years. It was 1996 when the original EMC Directive, 89/336/EEC, [1] came into force requiring manufacturers for the first time to meet a series of regulatory requirements aimed at ensuring products intended to work together could do so without unacceptable levels of interference and that intentional communications could operate as intended.

So EMC legislation is not new; the regulatory process is neither new nor has it changed significantly for most manufacturers over that time and as regards to the EMC standards and tests it has very much been evolution rather than revolution. Perhaps then, 20 years on, it could reasonably be expected that knowledge of the regulatory process would be widespread and that manufacturers would routinely embed EMC design and testing into a product development cycle.

There is widespread anecdotal evidence as well as much more quantifiable statistics from market surveillance campaigns, that supports the assertion that that this is not the case. Indeed, in some respects, conformity levels are shown to be falling.

II. European Market Surveillance

Products subject to EU harmonised legislation can circulate freely within the European Single Market providing that they are in conformity with the applicable Directives. EU Member States are responsible for market surveillance at national level and cooperation between Market Surveillance Authorities (MSAs) is a key element for the functioning of the Internal Market.

European cooperation on market surveillance takes place through informal groups of MSAs, called Administrative Co-operation Groups (ADCOs). The members of these groups are appointed by Member States and represent national authorities competent for market surveillance in a given sector. They meet several times a year to discuss market surveillance issues in their area of competence and to ensure efficient, comprehensive and consistent market surveillance.

Cross-border market surveillance is based upon the selection of often between 50 and 150 products which are assessed for their technical compliance against the relevant harmonised European standards and for their administrative compliance against the requirements set out in the EMC Directive itself. The sectors subject to market surveillance usually consist of mass market products where there is already evidence of non-conformity issues.

The evidence is gathered by the EMC ADCO and published in its subsequent reports [4]-[9]. To date six joint cross-border EMC market surveillance campaigns have been undertaken over the last 10 years, with a seventh currently underway.

The market surveillance campaigns carried out from 2004 to date are shown in Table I.

Industry Sector	Year
Energy Saving Lamps	2004-5
Domestic Power Tools	2007-8
Consumer Entertainment Electronics Products	2009-10
LED Lights	2011
Information Technology Equipment Switching	2012-13
Solar Panel Inverters	2014

Table 1: EMC Market Surveillance Campaigns

A. Solar Panel Inverters Market Surveillance

Solar photovoltaic (PV) modules generate electricity from sunlight and using an inverter, this electricity can be fed into the mains electrical supply of a building, or directly into the public electricity grid.

Grid-connected solar panel systems are already widely used throughout Europe and the market is growing continuously. The associated inverters have been observed to be a source of interference to radio communications and consequently were chosen to be the subject of the 6th ADCO market surveillance campaign to assess the conformity of samples taken from the market with the requirements of the EMC Directive, 2004/108/EC.

Fourteen European countries participated in the market surveillance which represents only half of the eligible Member States. The campaign ran from January to June 2014 and involved the sampling of 55 solar panel inverters. It should be noted that the sample size was considerably smaller than for some previous campaigns, eg LED lighting, it was considered to adequately reflect the number of manufacturers in the sector.

Technical compliance was determined by testing the samples against the relevant harmonised emission standard. For each sample, the measured result was compared directly with the limit without taking into account the measurement uncertainty. The results shown in Figure 1 illustrate that 33% of the samples met the emission requirements. Given the nature of inverters, the emissions performance is likely to have been the most critical aspect of EMC.

It is important to note, particularly when reporting overall compliance levels, that no immunity tests were performed and therefore the immunity performance of the samples was unknown.

Administrative compliance was checked against a number of criteria contained in the EMC Directive. Each sample was assessed for the presence and format of CE Marking, as well as the availability and correctness of the Declaration of Conformity (DoC). The Technical Documentation was also checked, but on a voluntary basis; that is to say that the Market Surveillance Authorities only requested it for a subset of the samples.

Overall compliance with the administrative requirements was determined to be 38% as illustrated in Figure 1, however, there were significant variations in the compliance levels of the constituent parts. Figure 1 shows that 95% of the samples were compliant with the CE Marking requirements; a high level compared with some previous campaigns. It is interesting to note that in only one market surveillance campaign have all the samples assessed had the CE Marking correctly affixed and up to 25% of samples have been deficient in this respect in some campaigns.

In the case of the solar panel inverters, one of the samples did not have the CE Marking affixed at all and two samples did not fulfill the formatting requirements.

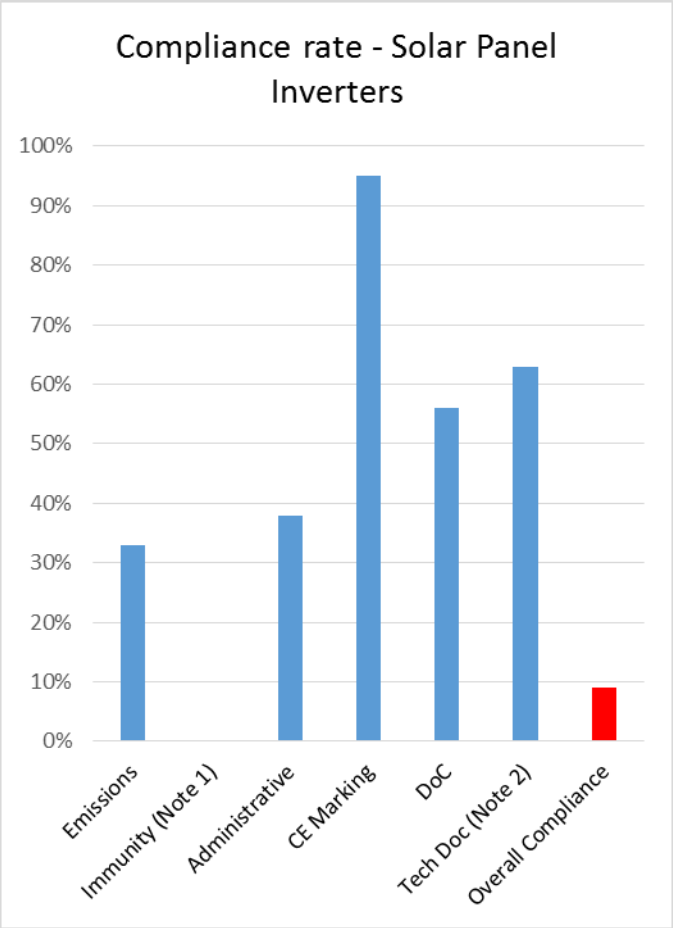

Fig 1: Market Surveillance Campaign Levels

Note 1: No assessment of the samples' immunity performance was carried out

Note 2: Only 19 out of 55 samples were assessed with regards to their Technical Documentation

Figure 1 shows that the overall compliance level of DoCs was 56%, however it is significant that DoCs were available for three-quarters (77%) of the samples and of those available 71% were correct.

Until recently, the market surveillance campaigns tended to focus on the CE Marking and DoC aspects of administrative compliance, however, the last two have also included an assessment of the availability and correctness of Technical Documentation, albeit on a voluntary basis and only including a subset of the samples. In this market surveillance campaign Technical Documentation was assessed for 19 out of a total of 55 samples.

Although no information is available on the process for selecting the 19 samples, Technical Documentation was available for 90% of the samples selected and 71% of those were deemed to meet the requirements set out in the EMC Directive.

Overall, as shown in Figure 1, the compliance level for Technical Documentation was 63%.

Comparison of the compliance levels for DoCs against Technical Documentation yields a surprising result; the compliance level for DoCs is actually lower. This is surprising in the sense that the DoC is actually a much simpler document to produce and much more guidance is freely available; indeed there is essentially a template in the EMC Directive itself. Technical Documentation can be a lot more complex and requires much higher levels of input from the manufacturer. Whilst this is the general conclusion, there is no information on how the samples were selected for Technical Documentation and whether this process was entirely random.

So the key points from the 6th joint cross-border market surveillance campaign can be summarised as:

- The majority of products - 32 (58%) were of EU / EFTA origin.
- Approximately a third (33%) of the products met the emissions compliance tests.
- Approximately a third (38%) of the products met the administrative requirements (as assessed).
- All but one assessed product (54) were CE Marked however in two cases the CE Marking was incorrectly formatted.
- A quarter (25%) of DoCs were not available however 75% of those were correct.
- Nearly all (91%) of the products were assessed as overall non-compliant as shown in Figure 1.
- Unlike most previous campaigns, administrative compliance levels were higher than those for technical compliance; albeit that the margin was small.

Whilst the headline figure is that 9% of the samples were compliant, this is unlikely to actually be the case. It must be remembered that no samples were assessed for their immunity performance and therefore the figure of 9% assumes that all samples passed all immunity tests; a questionable assumption.

Additionally only 19 of the 55 samples had their Technical Documentation assessed for availability and correctness and once again the 9% compliance rate assumes that Technical Documentation was available and correct for all the remaining 36 samples; again a questionable assumption.

So taking these two questionable assumptions into account, the reality is that the real compliance figure will be lower than 9% but it is impossible to gauge what that figure is actually likely to be. It is not beyond the bounds of possibility that no samples were compliant.

What is known is that the vast majority of the solar panel inverters assessed did not meet the requirements of the EMC Directive.

B. Campaign Comparisons

So how do the results of the 6th market surveillance campaign compare with those undertaken previously and does this indicate a trend towards increasing or decreasing compliance?

Comparison of results between campaigns has to be treated with caution as not all campaigns had the same scope. For example as far as technical compliance is concerned, some campaigns focused only on emissions, others on both emissions and immunity and in some cases not all samples were subjected to all the tests.

What can be concluded, is that the compliance levels reported are always optimistic since no campaign has addressed all of the technical requirements and all of the administrative requirements for all samples. Wherever an aspect is not assessed or only partially assessed, there is an assumption that all of those samples were compliant which is unlikely to be the case.

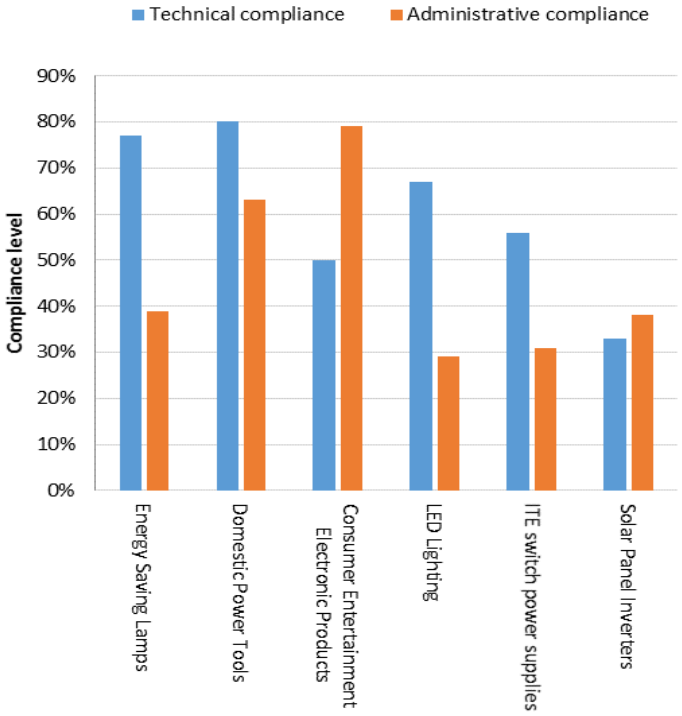

Fig 2: Market Surveillance Campaign Compliance Levels

III. Non-Compliance Equals Unfair Competition

Away from the headline statistic that 91% of the samples were non-compliant, the fact remains that the manufacturers of 9% of the samples took their CE Marking responsibilities seriously and placed compliant products onto the market.

Apart from posing potential risks to users and impaired functionality of products, non-compliance has important economic consequences; it is a form of unfair competition. Manufacturers placing non-compliant products on the market can make significant savings on the costs of compliance by avoiding potentially costly conformity assessment procedures. This enables

them to offer their products at lower prices than their competitors who respect the law and produce compliant products.

In sectors where there is tough competition from low-price, potentially non-compliant, products those manufacturers abiding by the rules are disadvantaged. The situation "punishes" the law-abiding manufacturer, as compliance becomes a "competitive disadvantage".

In the case of the overwhelming level of non-compliant products in the solar panel inverter market, manufacturers producing compliant products may be left with a stark choice; withdraw from the market or reduce their compliance efforts and therefore costs in order to compete on more even terms.

The reality is that this is not a choice that a manufacturer should be forced to make and potentially risks the whole basis of the free movement of goods throughout the Single European Market if Member States lose faith in the CE Marking regime.

The results of the EU's public consultation [10] showed that 87% of Economic Operators who responded considered that they had suffered from regulatory unfair competition.

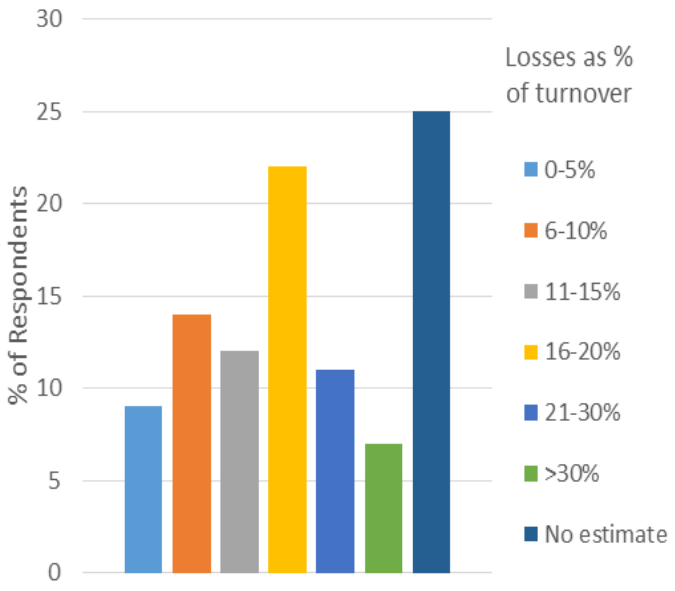

Fig 3: Perceived Losses in Percentage of Annual Turnover.

Figure 3 gives an estimate of the size of losses in terms of their annual turnover. Perhaps most strikingly, the largest single category of respondents (25%), were not able to assess the impact of non-compliant products on their business. This not only illustrates the challenge facing manufacturers but is also an indication that the true financial impact may be significantly higher.

IV. The New Legislative Framework

The European Commission regularly carries out Impact Assessments of its Directives to determine whether they are fulfilling their intended purpose and to assess the likely impact of any proposed changes on stakeholders.

Recurring themes highlighted have included:

- The number of non-compliant products on the market and the unfair competition that this introduces
- The difficulties in tracing the route of some products through the supply chain, particularly where rebranding has occurred
- The inconsistent participation in market surveillance activities across Member States.

These issues are not confined to the application of the EMC Directive; the same applies across most of the New Approach Directives.

In view to these common issues, the Commission decided to take a horizontal approach and develop a piece of separate legislation that would be used as the catalyst to recast all of the Directives in the same way; this became known as the New Legislative Framework (NLF).

The NLF is a flexible regulatory framework for the marketing of products and that sets the essential requirements to be fulfilled. The conformity assessment procedure is facilitated through the use of harmonised standards that provide a

presumption of conformity. Thus compliance is declared through the affixing of the CE Marking on the product or its packaging.

The NLF was published in 2008 on the basis of the long standing experience of the New Approach to technical harmonisation that started in 1973. It consists of a Regulation (765/2008/EC) setting out the requirements for accreditation and market surveillance relating to the marketing of products and a Decision (768/2008/EC) which is used as a cast for all future product harmonisation legislation. This set of rules builds on the innovative 'New Approach'.

Crucially the NLF facilitates the work of MSAs as both defines and establishes obligations for all Economic Operators in the supply chain and sets strict traceability requirements for products.

V. The New EMC Directive, 2014/30/EU

The twentieth anniversary of the implementation of the first edition of the EMC Directive sees the third edition come into force. On 20th April 2016 Directive 2004/108/EC [2] is replaced by 2014/30/EU [3], which includes the provisions of the NLF.

As is often the case when Directives are re-issued, the changes are a combination of new requirements and the clarification of existing requirements; often making those that were implicit in the previous edition, explicit.

Directive 2014/30/EU makes no change to the technical requirements. The same harmonised European standards continue to apply and essentially a product that was compliant with the technical requirements of 2004/108/EC will continue to be compliant with 2014/30/EU.

Since there are no technical changes, there is no corresponding transition period; a product placed on the market on 19th April 2016 should be declared against 2004/108/EC and the same product placed on the market a day later should be declared against 2014/30/EU.

The scope of the Directive is changed very slightly in that Broadcast Receivers move out of the scope of the EMC Directive into the new Radio Equipment Directive (RED), 2014/53/EU [11]. Coming the other way from the current Radio and Telecommunications Terminal Equipment (RTTE) Directive into the EMC Directive is wired telecommunications equipment.

A. Manufacturers' Obligations

2014/30/EU changes little as far as the manufacturer is concerned; the essential requirements are unchanged, as are the technical requirements and there are only relatively minor changes to the administrative requirements, mainly in relation to the Instructions for Use and the languages that this should be available in.

The manufacturer must still go through a series of checks to assess and ensure that his products conform to the essential requirements of the EMC Directive. By affixing the CE Marking, drafting the Technical Documentation and signing the DoC, the manufacturer declares, on his sole responsibility, that the conformity of the product to the legislative requirements and confirms that the necessary assessments have been completed.

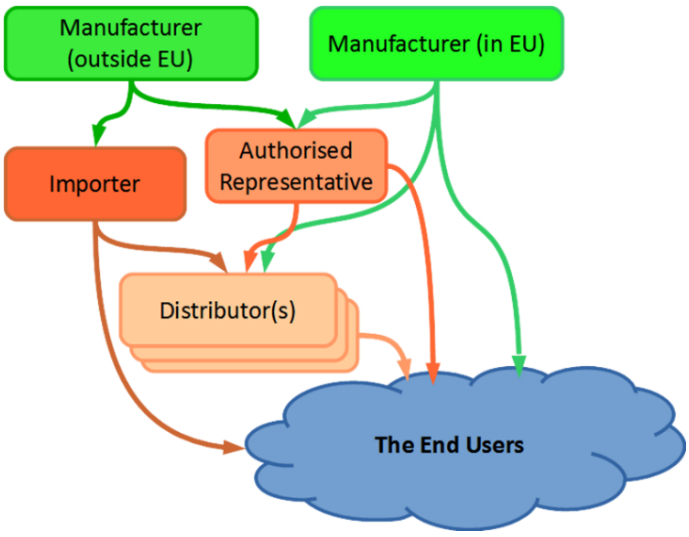

Fig 4: Routes to Market

2014/30/EU makes it clear that the obligations continue to apply irrespective of whether the manufacturer is based within the EEA or not, quashing the perception that the further a manufacturer is geographically from the EU market, the less the requirements apply.

Whether a manufacturer is based in the EEA or elsewhere, he can still choose to appoint an Authorised Representative based in the EEA to carry out certain administrative tasks on his behalf, including affixing the CE Marking. Under 2014/30/EU, however, the checks and tests required to ensure the conformity of the product can only be carried out by the manufacturer. In order to ensure clarity, the manufacturer must clearly state in writing the tasks being delegated to the Authorised Representative.

B. Importers and Distributors' Obligations

It has always been the case that products from third countries that fall within the scope of the EMC Directive and which will be sold within the EEA must also bear the CE Marking.

While manufacturers retain responsibility for ensuring product compliance and affixing the CE Marking, under 2014/30/EU importers and distributors play an additional and important role in making sure that only products which comply with the legislation and bear the CE Marking are placed on the market. Not only does this help to reinforce the EU's health, safety and environmental protection requirements, it also supports fair competition with all players being held accountable to the same rules.

When goods are produced in third countries and the manufacturer is not represented in the EEA, importers must make sure that the products they place on the market comply with the applicable requirements and do not present a risk to the European public.

The new requirements mean that the importer will be obligated to verify that the manufacturer outside the EU has applied the correct conformity assessment process and that the documentation is available upon request. Thus, they must have a thorough understanding of the EMC Directive or have access to specialist advice to ensure that they can fulfil their regulatory obligations. Furthermore they are obliged to support national authorities in any market surveillance or investigation work.

Importers should have a written assurance from the manufacturer that they will have access to the necessary documentation, such as the DoC and the Technical Documentation and be able to provide it to national authorities, if requested. Importers are also required to ensure that contact with the manufacturer can always be established.

At this point, the Commission's approach starts to become clearer. Any manufacturer that is deficient in meeting the requirements of the EMC Directive now comes under pressure from importers. For example if the importer does not receive sufficient assurance that the correct conformity assessment procedure has been followed or that the Technical Documentation can be made available or likewise the DoC, they may decline to represent the manufacturer as an importer.

In theory a manufacturer producing non-compliant products should find access to the supply chain more difficult.

Distributors now also have an important role to play in ensuring that only compliant products reach the end user. They must act with due care to ensure that the storage and transportation of the product whilst in their possession does not adversely affect its compliance. The distributor must also have a basic knowledge of the legal

requirements including which products must bear the CE Marking and the accompanying documentation and should be able to identify products that are clearly not in compliance.

Another obligation is that distributors must be able to demonstrate to national authorities that they have acted with due care and also have affirmation from the manufacturer or the importer that the necessary measures have been taken. Furthermore, a distributor must be able to assist the national authority in its efforts to receive the required documentation.

C. Improving Traceability

A recurring issue facing MSAs has often been the difficulty in identifying the manufacturer, who placed the product on the market in the EEA and its subsequent route through the supply chain to the end user.

The new EMC Directive aims to improve this situation and now requires Economic Operators to keep records that identify who has supplied them with products and in turn who they have supplied; including product names and model and serial numbers. This is for a ten year period.

2014/30/EU introduces a significant change for organisations that re-brand products and/or modify them such that the original conformity assessment is affected. In either case the re-brander is now considered to be the manufacturer and therefore is subject to all of the regulatory obligations of the manufacturer.

By improving traceability, the intention is to make it easier for MSAs to trace where product has originated from and its path through the supply chain. The reality is that if a non-compliant product reaches the end user, then a number of parties within the supply chain will have committed an offence and improved traceability will enable easier identification of these parties.

D. Member State Obligations

The market surveillance framework introduced by the NLF includes a commitment to a consistent and equivalent enforcement of the EU legislation; that is providing a level playing field for Economic Operators.

The Commission, in co-operation with Member States, is responsible for the enforcement of the framework and in particular, this includes:

- Coordination of the national programmes.
- Organisation of market surveillance.
- Coordination of the application of restrictive measures including the cooperation and exchange of information with other national authorities.
- The sharing of resources.

So whilst this is clearly a step forwards in so far as a framework is established, the actual implementation would appear to still be the responsibility of individual Member States. It will be interesting to see how this works in practice. Historically the enforcement of European Directives has resulted in anything but a level playing field, with the resulting consequences on their effectiveness.

VI. Conclusions

The market surveillance carried out over the last ten years has consistently highlighted the high levels of non-compliance in the industry sectors assessed. Anecdotal evidence is rife that this is just the tip of the iceberg.

The Commission, recognising the unfair competition introduced when manufacturers do not abide by the rules, has acted and the provisions of the NLF have now been enacted in the recasting of nine CE Marking Directives including the EMC Directive.

The new provisions seek to improve a number of

aspects of the existing legislation; reducing the amount of non-compliant products is the most compelling. The Commission has sought to do this by retaining the manufacturer's ultimate responsibility for product compliance whilst spreading obligations throughout the supply chain and improving the traceability of products through it.

It is not difficult to see what the Commission wishes to achieve and how it wishes to achieve it. Clearly the belief is that those Economic Operators that have new responsibilities within the supply chain will exert pressure on the manufacturer by virtue of the need to ensure that they meet their own obligations and do not commit an offence. Requests for information, assurances of product compliance and documentation are all intended to encourage manufacturers to ensure that the requirements of the EMC Directive are met. The unanswered question is whether this new approach will have the desired effect; the current EMC Directive is, after all, a plethora of rules and regulations designed to ensure that only compliant products are placed on the market and yet it results in a compliance rate that is optimistically 9%.

The stakes are high given that the same NLF provisions are being rolled out across all of the CE Marking Directives. In some market sectors non-compliant products make up such a significant proportion that, irrespective of the rights or wrongs of doing so, those manufacturers currently abiding by the rules but seeing their market and profits eroded by those who do not, may be tempted to relax their approach to compliance activities themselves. It would not take much more of a shift in this direction for the rules to be disregarded altogether.

In some respects the Commission has decided on a non-interventional approach by giving the supply chain the opportunity to regulate itself by ultimately turning the screws on non-compliant manufacturers.

In many aspects of life, experience shows that adherence to regulations is often most effectively achieved by active enforcement, where the penalties, whether they are in the form of a fine, remedial action or product recall, are known and sufficient to act as a true deterrent. Under 2014/30/EU, specific measures are incorporated to enhance market surveillance, however, enforcement remains the responsibility of individual Member States but working under a common framework designed to give a more consistent approach.

In the eyes of many observers, a robust enforcement of the EMC Directive would be a potent tool, however, the reality is that enforcement is its Achilles heel. Market surveillance activities continually highlight low compliance levels but the link between this as an information gathering exercise and enforcement action is unclear; certainly neither is well publicised; something that would provide its own deterrent.

The UK's enforcement of the EMC Directive has traditionally been complaint driven; that is it takes 'someone' to make a formal complaint to the MSA. It was originally envisaged that this would encourage self-regulation as manufacturers would keep an eye on their competitors' regulatory efforts. The reality was that complaints were not lodged; not because of the lack of non-compliant products but because manufacturers tended to 'keep their heads down' primarily due to a lack of confidence in their own efforts.

Despite the fact that 2014/30/EU is in force, it remains unclear as to how, or even whether, the

UK's complaint driven system will be adapted to meet the requirements of the NLF. Increased enforcement is likely to bring with it higher costs; not something easily achieved in the current financial conditions. Indeed, back as far as 2010, the Commission noted that almost half of the Member States had already announced that they did not envisage any increase in the resources and means for the implementation of market surveillance and controls of products from third countries.

So will 2014/30/EU achieve one of its central aims; that is to reduce the amount of non-compliant product on the market? Certainly there are provisions within it designed to improve the situation and the Commission, by spreading responsibilities throughout the supply chain whilst at the same time improving the traceability, has sent a clear message to the whole supply chain of its expectations.

However, there is a certain irony in the fact that many products start off as being compliant when first placed on the market but subsequently become non-compliant due to the manufacturer's failure to re-assess the technical compliance when changes are made to the product and to standards and their failure to reflect those changes in the required documentation such as the DoC.

The irony is that the implementation of a new Directive intended to reduce the number of non-compliant products is likely to actually increase that number, at least in the short term, as manufacturers fail to update their existing DoCs from 2004/108/EC to 2014/30/EU.

Nick Wainwright, Chief Executive at Eurofins York (formerly York EMC Services)

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For more information please contact us:

E-mail: enquiry@yorkemc.com

Tel: +44 (0) 330 430 3456

www.yorkemc.com

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