



EU CE-MARKING ENFORCEMENT

By Yvonne Halpaus

Industry in Europe has brought to the attention of the European Commission that they support the self-certification of safe products with the CE-Mark, and their opinion that Third Party (Notified Body) Certification not become mandatory but be used on a voluntary basis.

Industry also agreed that unsafe products are being brought to the market by criminally acting manufacturers, who falsify Declarations of Conformity, which is undermining the credibility of the Declarations of Conformity. Industry recommends that future emphasis is to be placed on better market surveillance by the European Governments and penalties for 1) unsafe products and 2) misuse of the CE-mark, to serve as a source of funding for increased market surveillance.

Consumer organizations and government market surveillance authorities agree that significant numbers of dangerous products still circulate throughout Europe although considerable progress has been made.

Findings in earlier reports show that 37,600 items of equipment tested in Switzerland showed 1,100 cases of CE Conformity problems. Of 3,962 items that were subjected to rigorous measurements, a high proportion of the devices were found defective (976 altogether) and that none of these met the EMC specified requirements. In 23 cases a sales ban was imposed and legal proceedings were launched. Two other Member States also revealed problems when testing against the EMC & Machinery Directive: 33% failed the EMC tests, 47% did not meet the Machinery Directive formal rules and 89% had technical non-conformities.

These negative findings were not the result of regular surveillance mechanisms, 58% was based on examinations triggered by accidents, 33.3% following inspection of equipment installation, 8.5% based on complaints from competing manufacturers and 0.2% following visits to trade fairs.

Many EU States and other organizations involved in market surveillance explained their present strategies and experiences to discover non-compliance but in the end they all agreed that the priority should be given to:

- 1) intensified cross-border co-operation between market surveillance authorities;
- 2) a vital need for a relevant and well managed information system;
- 3) consistency for all aspects of administration both within and between different national systems;
- 4) the need for clear guidelines on market surveillance principles to be applied by applicant countries;
- 5) the need for special alertness and rapid action in relation to non-compliant products which particularly impact seasonally on consumers and to the growing problem of “grey imports” from third countries.

Country by Country Market Surveillance activity

Government officials from different European Countries have reported the following experience with monitoring for accurate CE-Marked goods:

United Kingdom

The UK Health and Safety Executive (HSE) is responsible for market surveillance for products used in the marketplace. Priorities are based on the basic risk and established accident and ill-health data. Internal specialists are used to target particular products and suppliers.

The HSE support the local authorities consisting of 202 offices called “Trading Standards Departments”. Their responsibilities include the Toys, Low Voltage, Electro-Magnetic Compatibility, Machinery, Simple Pressure vessel, Recreational Craft and Personal Protective Equipment Directives. Local Authorities communicate with each other through the TSLink, a closed Intranet System, that is frequently used to transmit information about non-compliant products to ensure rapid enforcement action. Principal sectors covered are: Machinery, Electrical Equipment, Lifts, Pressure Equipment and “ATEX” equipment, designed for use in the workplace.

The success of this surveillance regime results in lower British rates of fatalities and injury (1.3 compared to the 4.6 for the EU average) and is lower than in the USA.

France

Market Surveillance is considered an indispensable condition for effective application of the New Approach Directives (CE-Marking).

Market Surveillance is a job to be done by the public authorities. In the course of the market surveillance recourse to advice from appropriate authorities or testing by competent laboratories should be available. This is important in all countries because infringements against the directives may give rise to legal penalties and in several countries, including France, and they may be criminal offences.

The Directives give the enforcement authorities the tools to carry out market surveillance. These include: first and foremost the EC conformity declaration, certificates issued following EC-type examinations or approval of the manufacturer’s quality system and the manufacturers technical documentation. Checking this documentation is the easiest and least costly method of market surveillance. But the Authorities must also check that the conformity evaluating procedures are actually producing safe products. Also taken into account should be occupational, domestic and sports accident data. Trade Unions and consumer associations have a key role to play in this feedback.

Product entering the market from third countries should be checked because of unfamiliarity with European regulations and imports from third countries where production costs are low tend to have quality consequences. It is easier and more effective to check at the point of entry before

they are dispersed through multiple distribution channels. In France, customs has been appointed as an enforcement authority in their own right.

The Netherlands

Emphasis is on the co-operation between Customs and Inspectorate for Health protection. The Inspectorate of Health covers three main areas: 1) Food; 2) Non-food, including following directives: Low Voltage, Toys, Machines (for consumers), Personal Protective Equipment, Gas appliances. 3) Veterinary affairs.

They consist of 1 General Inspectorate and 5 Regionals. All are responsible for enforcement activities, including sample testing in their laboratories and a toll-free number for members of the public. They hold the following powers: Inspection, Powers of entry into manufacturers and supplier premises, sampling and testing, investigation of producer activities, suspension of sale of unsafe goods, advising the Ministry of Public Health to publish warnings and on prosecutions to be handled by the Public Prosecutor.

On October 27, 1997 an “Agreement on product safety” between Customs and the Inspectorate for Health Protection in the Netherlands went into effect. Together they determine which categories of products should be given specific attention during a certain period.

These categories are red-profiled and all customs declarations fitting these categories are faxed to the Inspectorate who decides within 3 hours if checks are necessary, or to allow free movement, or to indicate that checks are necessary, which means that the products are suspended for 3 days at the importers premises. If everything checks out the products are brought into the free movements of goods, if there is any serious doubt, they can hold them longer. If products are found in non-compliance they can take legal measure including: written warning, seizure, public prosecution. Rotterdam and Amsterdam locations are staffed to handle these faxes 24 hours per day.

Producers, importers and traders are responsible for the safety, read “CE-marking” of these products and are expected to make sure that all products meet legal requirements. Containers are scanned at the rate of 1 every 15 minutes looking for undocumented and improperly documented imports.

Portugal

Responsibility for market surveillance and enforcement rests with the Ministry of Economy and Consumer Affairs called IGAE, and they have 5 regional directorates. IGAE expect to become the exclusive Competent Authority for enforcement in the future. The Directorate General of Industry, Portuguese Institute of Quality & Consumer, is responsible for implementing directives. Other agencies that play a role are: Rapex System and Ehllass, Safety Commission of products and services.

Labeling requirements are considered the most problematic; most often found are non-conforming logotypes and the use of English language only.

For example:

CE-marked decorative lamps, rocket shape, glass section filled with water and wax. They were breaking, exploding and leaking wax. Country of Origin was China and other unknown. When tested they did not meet electrical standard EN-60598 for impact and resistance. The same lamp found under a different name, certified by 2 Notified Bodies (1 for LVD and 1 for EMC). The technical file supplied by the distributor only contained a Declaration of Conformity and test reports with models and serial numbers that did not match. Total lack of efficient design, process and document control, and traceability. The distributor was held responsible.

Enforcement results to be released on monthly basis identifying dangerous and non-conforming products.

Iceland

A Central Authority, Loggildingarstofa leads the sectoral surveillance authorities and inspection bodies. All inspection bodies must be accredited to EN 45000 and follow the methods and procedures set out in an inspection manual published by the sectoral authorities.

General law on official market control passed in 1999 it emphasizes that duplication between regulatory authorities should be avoided.

Hungary (Not yet an EU member State)

The Hungarian legal system is inserting the practical implementation of the European New Approach Directives. The objective is free movement of products and services in Hungary. Free movement means having the obligation to introduce and operate a market surveillance system. This system was started December 1999.

ROLE OF NOTIFIED BODIES in Market Surveillance

The European Coordination of Notified Bodies for Machinery and Safety Components has raised the issue of how to ensure that Notified Bodies and the Authorities, responsible for market surveillance, interpret the new approach directive criteria in the same manner.

Notified bodies are commercial organizations that enter into business agreements with manufacturers to test their products, they are also responsible to the public authority that notified them.

Questions raised: Does that mean that Notified Bodies have an obligation to make the test results available to enforcement agencies or should they be requested from the manufacturer? Opinions are varied, but in France, Notified Bodies are obliged to participate in meetings with enforcement authorities for information exchange purposes.

In the majority of CE Type examinations Notified Bodies and Conformity Assessment Bodies have been able to develop a common view. However, specific cases do exist where national

practices die hard. The problem of harmonization can exist in 1) procedures applicable to type examination testing and 2) in divergences of interpretation by national Authorities.

Networking of technical interpretations given by permanent committees and Notified Body Co-ordination Group could be considered a superior tool which will require substantial financing to implement.

This also raises the question of rights and obligations of the Notified Body which finds itself involved in a protection clause. If the authorities in charge of market surveillance find a product that they suspect to be in non-compliance, Notified Bodies have the duty to cooperate with the authorities, taking into account their general obligation of confidentiality.

A need exists for two clarifications:

- Authorities performing the surveillance do not systematically inform the Notified Body involved when they identify a possible problem. Notified Bodies are usually informed by the manufacturer who asks them to defend their position. Surveillance Authorities may request “Certificates and decisions” from the Notified Body.
- The meaning of “relevant information”.
Is it: answer to motivated questions related to specific issues? Or answers to any question related to the conformity assessment procedure? Or communication of the full conformity assessment report (based on testing, inspections and/or system certification?).

There is the additional question of market surveillance activities, which may or may not be implemented by Notified Bodies.

Notified Bodies can be involved in three types of surveillances, conflicts of interest should be avoided. Problem is that the main source of expertise is within Notified Bodies

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| Type I | Market Surveillance by a certification body is a relationship between a manufacturer and a Notified Body in purely commercial context. |
| Type II | Market Surveillance performed by a Notified Body within the context of a product conformity assessment for a manufacturer legally obliged to do so <u>before</u> the product is taken to market. This is also a contractual relationship between a manufacturer and a Notified Body. |
| Type III | Market surveillance performed by a Member State <u>after the product has been put on the market</u> and the Authorities ask the Notified Body to act as an expert. |

A proposed solution is to clearly define the manufacturer’s responsibility to have a post marketing surveillance system similar to the one defined in the Medical Device Directive. There is a view that if non-conformity is of serious nature not just one product but the entire production should be taken off the market.

Regional organizations involved in the Market Surveillance

Central and East European Countries - Trapex (CEEC-Trapex)

Trapex is a rapid information system about dangerous products in the EU Member States. Based on the experience of this system a similar system was formed in Bulgaria, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, and Slovakia in 1999. Only the non-food product network has been operating. One category stands out, electrical appliances: 28 notifications were sent out, also 3 textile products and 3 toys for a total of 43 notices.

The Low Voltage Directive was implemented December 1998, in the participating CEEC countries, which created a focus on electrical domestic appliances. The majority of dangerous products came from the Far East countries. These were not simply of poor quality but actually jeopardized lives, health and safety of consumers.

Measures taken included: sales ban, retailers to buy the goods back, fines and confiscation.

Major problem: prohibited products re-appear under a new brand name.

Swedish Board for Accreditation and Conformity Assessment SWEDAC

Created in 1998 responsible for the coordination of market surveillance cooperation between the Nordic Countries. They met 4 times between 1998-2000 and have issued a report highlighting market surveillance cooperation in different product sectors.

During a 1999 conference on market Surveillance with 170 participants from the Nordic Countries, EU member States and Central and East European countries it was concluded that:

- Continuing support for sectoral market surveillance cooperation will be vital.
- Contact points and forums identified on market surveillance must be used in communications between all attendees to build up and maintain more efficient networks.
- Need for in-depth dialogue between authorities, distributors and industry.
- Need for horizontal coordination of market surveillance.

The Machex Group

The senior Labour Inspectors Committee recognized the difficulties in applying the Machinery Directive consistently across the EU Community and formed an organization called MACHEx.

Machex operates on a voluntary basis and promotes consistency in the application of the Machinery Directive without duplicating work done by the standing committee established under Article 6.2 of the Directive.

- The network consists of 1 correspondent from each Member State.
- Information about unsafe machinery placed on the market is exchanged quickly.

- Action taken by one Member State may be followed by similar action in others.
- National laws on confidentiality to be respected.
- Technical file information is first requested directly from the manufacture, if this is unsuccessful it may then be requested through the Machex network.
- Requests for information to be restricted to just what is required for the purpose, instead of asking for the entire file, which could be very large.
- Information exchanged about actions to prohibit or restrict the placing on the market or putting into service of machinery will not replace the need for notifying the Commission under the safeguard clause procedure.

European Association for the coordination of Consumer Representation in Standardization - ANEC

Examples of dangerous products still circulating in Europe today:

Finland: 28.5% of 11,900 products failed to comply with the safety & marking regulations.

Sweden: soft toy animals, 50% were not CE-marked. The majority of those tested did not satisfy safety and marking requirements. Bicycle helmet models. 2/3rds were not CE-marked

Finland: 37.5% of sunglasses lacked the CE-mark. 34% of lifejackets & personal buoyancy aids checked for labeling and instructions for use violated regulations. 21% lacked CE Marking totally.

Sweden: 60 different models of baby rattles were tested, 30 did not pass the safety requirements, and 24 of these were not CE-marked.

UK: Consumers Association put 18 electric household appliances through basic safety check, 6 failed the essential requirements of the Low Voltage Directive. They also found blenders with lose-flying blades (if accidentally switched on), hair-curling tongs with separated and exposed live parts when the handle came apart.

Co-operation between Custom Agents and Surveillance Authorities

The removal of internal borders in 1993 does not mean diminished importance for European Customs. Their role has changed and now includes market surveillance. The scope of their surveillance is based on Council Regulation 339/93/EEC, focus is on products that are a serious and an immediate risk to health and safety and lack of compulsory marking, label or documentation. Since January 1996 the European Commission and the Member States have enabled customs administrations, through a well-funded program, to become efficient and perform as one single and unique administration. Implementation includes monitoring, studies, organization of seminars, working parties, exchange of officials, publications of manuals, information and communication actions, IT systems and training actions.

The five main areas of the Customs 2002 program, the name of the partnership between Member States customs administrations and the Commission, are:

- the improvement of the controls effectiveness based on good legislation and on modern management techniques such as risk analysis and audit; in addition exchange of expertise has also an important role to play.
- setting standards and measuring results
- the relation with trade
- training
- new developments, particularly in the fields of computerization and equipment.

Surveillance is producing a lot of insight into manufacturers willingness to comply with the requirements. As a result, quite a few Directives are being amended including the Machinery and the General Product Safety Directives. The draft of these amendments show a tendency towards the addition of an ISO 9000 Quality Assurance System Certification and product recall capabilities by the manufacturer.