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To the Members of
ISO/TC 176/SC 2 -
Quality Management and
Quality Assurance/
Quality Systems

Paper from NORMAPME: ISO 9001 standard, a fundamental regulatory instrument, in the Community legislation, for the determination of the "presumption of conformity" of many products

Please find a copy of the above paper attached. We are grateful to Mr Alberto Pasquali for submitting it to us.

Mr Pasquali has commented:

<< Finally, after a detailed and exhaustive work of my working group (composed by some organisation and production engineers, 2 lawyers, and 1 brigade general of the Italian Army, general manager of one of most advanced European manufacturing establishment in the ammunitions destruction), I have arrived to end the note, which redaction we have agreed in Saint Petersburg, regarding the strongly connection among the ISO 9001, the others European harmonized standards, and the mandatory prescriptions of the European Community legislation concerning the products.

These thematic is becoming more and more significant for the European manufacturing organizations and, consequently, we have establish to start 2 activities:

- To organize one or more national and European conferences on this argument, specially in aid of Small and Medium Enterprises, the first of which will be held before the end of this year.

- To open, in the website of FEDERMANAGER (the Italian Federation of the Managers of the industrial organisations), a realistic point of reference for its associates and for all the persons interested or involved in these arguments.

About this document and its technical and legislative contents, I think that it will be necessary to discuss together exhaustively, in our next meeting of March 2013 in Belo Horizonte, with the aim to define a solution able to help, as well as possible, the European Manufacturing organisations and the products' importers from the others world countries who, from the European legislation, have been legally identified as "producer".

Yours sincerely

Charles Corrie
for the BSI Secretariat of
ISO/TC 176/SC2

ISO 9001 standard, a fundamental regulatory instrument, in the Community legislation, for the determination of the "presumption of conformity" of many products

The aim of this note is to underline all the implications, both legal and productive, that European industrial organizations have to face with regard to the application of ISO 9001 and the others harmonised standards, as an explicit regulatory reference in the determination of product conformity, as bindingly prescribed by Community guidelines.

The above mentioned standard is indeed explicitly or implicitly referred to in the part of European legislation concerning:

- The compulsoriness, for the manufacturer, to exclusively place on the Community market *"safe"* products (i.e. free of faults which might cause harm to their users);
- the healthcare and preservation of the assets of all Community citizens damaged by products which, after their purchase, turn out to be faulty.

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The European legislation concerning “liability for defective products”

ISO 9001 standard, besides being a reference legislative element in the determination of the “presumption of conformity” of those products intended for circulation within the European Union, may also be effectively applied, in effective way, in the legal field (as in the debate for a “*liability for defective product*” cause). This type of legislation is very similar to the one existing in the U.S. legal system, since 1963.

This subject was regulated and developed, within the European Union, with the issuing of Council Directive n° 85/374/CEE of 25 July,1985 *(Official Journal of the European Union L 210 of 07-08-1985 page 29-33)*, concerning:

> *the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products*

which was integrated, in 1999, by Council Directive n° 1999/34/CEE of 10 May 1999 *(Official Journal of the European Union L 141 of 04-06-1999 page 20-21)*.

The basic element of such Council Directive may be underlined as follows:

- *Article 1*
  The producer shall be liable for damage caused by a defect in his product.

- *Article 4*
  The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.

- *Article 6*
  A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:
  a) the presentation of the product;
  b) the use to which it could reasonably be expected that the product would be put;
  c) the time when the product was put into circulation.

- *Article 7*
  The producer shall not be liable as a result of this Directive if he proves:
  ---
  b) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards;
  ---
  e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered;

One particular attention, in addition to the others, must be placed to 2 paragraphs of Article 3, concerning the meaning of the term “producer”:

1) “Producer” means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer.
2) Without prejudice to the liability of the producer, any person who imports into the Community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer within the meaning of this Directive and shall be responsible as a producer.

This Council Directive has already been integrated and implemented, in all national legislations of the different member states.

The basic juridical characteristic of Community legislation concerning the “*liability for defective product”* lies in the fact that, in the in-court domain, it must not be the damaged consumer to prove the producer’s responsibility for the damages caused by its faulty product, but it is the producer who must provide the necessary evidence to prove his objective strangeness in the events raised against him, namely that the product, when it was placed on the market, was reasonably “safe” and therefore free from (clear or hidden) non-conformity characteristics which may cause damages to its purchaser.

Such juridical principle, which substantially modifies the in-court position of both the parties involved, is universally known as:

reversal of the burden of proof

and it is not an insignificant element for the product producer in the trial stage.

With this principle, indeed, the European legislation define that, with regards to evidence, it pertains to the damaged customer to prove:

- that the fault in the product, emerged after its purchase, was already existing when it was put in the market,
- the amount of damage suffered,
- the causality between the faulty product and the damage suffered,

while the producer has the burden of proving objectively, i.e. in an adequately documented and plausible way, his *non-responsibility* for damages suffered by the product's user.

Notwithstanding the presence of the above mentioned legislation, the number of legal proceedings for compensation against producers has been negligible in the last 20 years because the most difficult element for the damaged Community citizen was to prove, during the trial, that the fault which had caused the damage was already existing in the product at the time of its purchase.

While on the one hand, this preliminary condition has turned out to be extremely difficult to overcome for the customer in order to start a legal action for compensation, on the other hand it has allowed the producer to avoid heavy pecuniary fines, and in many cases even penal ones.

This kind of legal constraint (which is extremely advantageous for the producer), has however been definitely superseded on 10 October 2007 with the issuing, by the 3rd Civil Section of Italian Supreme Court of Appeal, of the ruling n°20985, in which it is clearly stated that:

The product's unusual performance becomes sufficient to act as legally binding evidence that the product was already objectively faulty when it was launched on the market

(see specifically page 11 of the judgment, line 16 et seq.)

Considering that the Council Directive n° 85/374/CEE of 25 July 1985 concerning the "*liability for defective product"* has been integrated in the Italian legislation by the Decree of the President of the Italian Republic n°224 of 24 May 1988, the case law deriving from this ruling may be expressed as follows :

With regards to the protection of consumers' interests, with reference to the damages suffered because of faulty products, the first clause of article 8 "Test" of the Decree n°224 of 24 May 1988, i.e.:

the damaged party must prove the damage suffered, the fault and the causal connection between fault and damage

needs to be interpreted in the meaning that the causal connection, between fault and damage, the damaged party must prove that

the product has highlighted unusual performance, different from normal usage expectations, and that is an adequate legal evidence to prove an objective existence of a defect
(according to Art. 5 "Faulty product" of Decree n. 224/1988)

while it is entirely the producer's responsibility to prove that, considering the circumstances, it is likely that the fault did not exist when the product was placed on the market.

(according to Art. 6 "Exclusion of responsibility "
and Art. 8 "Test" of Decree n. 224/1988)

The above mentioned case law highlight, in a clear and incontrovertible way, not only the onus of proof lying with each of the parties in court, but it also points out the simplicity of the judicial course which is now at the consumer's disposal to request, and obtain, a verdict of guilty for the producer of the faulty product.

In such judicial context, the only legal element that is still certainly favorable for the producer summonsed for trial, is the one for which:

> a ***technical specification*** is a valid and incontestable element, in the determination of the "presumption of conformity" of a product.

As defined above becomes a very essential and indispensable element in the case where, during the legal debate between damaged consumer and producer, the latter will get to prove their "unaccountability" not in reference to article 7, paragraph b), of the Council Directive n° 85/374/CEE in which it is stated that:

> *having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards;*

but he wants to pursue a defensive line, in combination with or as an alternative to the one shown above, according to which:

> *the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered;*

In both these cases the technical norms (and particularly the EN ISO 9001 and the others European harmonized standards) become the basic element of the entire procedural system, and this for both the prosecution and the defence.

The European legislation regarding the "product conformity"

Several Community Directives have been adopted and implemented within the European Union, each of them aims at defining the parameters, both technical and judicial, according to which certain types of products may be considered sufficiently "safe" and therefore, as such, may circulate freely within the European Union.

Such parameters may be found in the appropriate attachments but also in specific lists of technical norms (issued by ISO, CEN or CENELEC) whose actual implementation, in the manufacturing of a specific type of products, allows applying to them the ***presumption of conformity*** to what is decreed as legally binding.

The standards included in these lists are called **harmonised standards** and they have a particular judicial status, within the European Union, as they are a reference point for the

Community harmonisation legislation

i.e. the whole spectrum of standards which the producers must compulsorily adhere to in order to place, on the EC market, only those products which can be considered reasonably "safe" (i.e. free from those faults which may cause damages to their purchasers).

Among all harmonized standards, **EN ISO 9001** is the one which best shows the activities at organizational, productive and control level, (and generally identified as "circumstances" by the legislator) that a producer must execute if he wants to produce items which are "reasonably safe" such as, for instance:

- the planning of the activities which are necessary to the production of the item, free from faults both evident and hidden,
- the coordination and documentation of any activity aimed at carrying out and supervising one's own manufacturing process,
- the accurate identification and implementation of all the actions of prevention and/or preventive monitoring aiming to reduce, as much as possible, the chance of finding defective products during the various stages of the manufacturing process and able to cause damage to its purchaser.

Amongst other things, this standard is explicitly referred to in the list of harmonized standards concerning :

- Regulation n° 765/2008 of the European Parliament and of the Council of 9 July 2008 *(Official Journal of the European Union L 218 of 13-08-2008, page 30-47)*, on:

  setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) N° 339/93 [Text with EEA (Economic European Area) relevance]

- Decision of the European Parliament and of Council n° 768/2008/CE of July,9 2008 *(Official Journal of the European Union L 218 of 13-08-2008, page 82-128)* on:

  on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC [Text with EEA (Economic European Area) relevance]

  The purpose of this Decision of the European Parliament and of Council is the determination of general principles and reference provisions for the development of the conditions concerning the marketing of products (the "*Community harmonisation legislation*"), as well as the use of CE marking.

  Moreover it must also be remembered that, in recital 24° of this Decision of the European Parliament and of the Council, it is articulated a regulatory principle very useful, in the legal area, for consumers who were damaged by a product they purchased, **even when the product wasn't "defective" when the harmful event occurred to the consumer.**

  Such legal provision is expressed, by the European legislator, as follows:

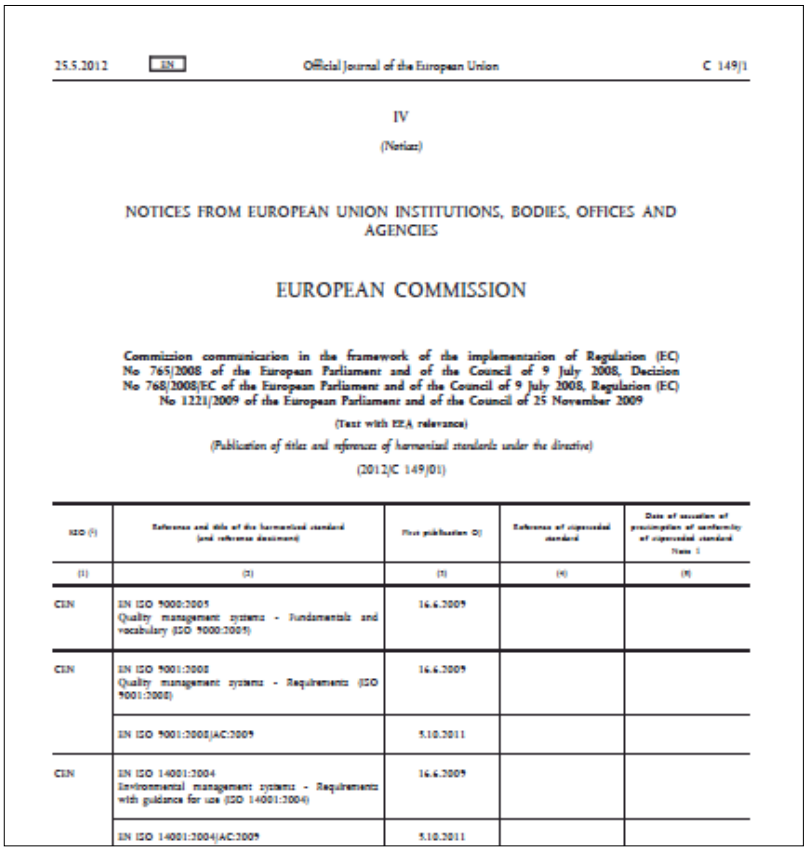
  Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning "liability for defective products" applies, inter alia, to products not in conformity with

  Community harmonisation legislation

  Manufacturers and importers who have placed noncompliant products on the Community market, are liable for damages under that Directive.

The most recent list of harmonized standard (concerning both these legal provisions), issued by the European Union to establish the "presumption of conformity" of a product, is the document n° 2012/C149/01 *(Official Journal of the European Union C 149 of 25-05-2012, page 1-4).*

In this paper the legislator highlight, explicitly, the presence both the standard EN ISO 9001:2008 and EN ISO 9000:2005.



25.5.2012 EN Official Journal of the European Union C 149/1

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Commission communication in the framework of the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008, Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008, Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009

(Text with EEA relevance)

(Publication of titles and references of harmonised standards under the directive)

(2012/C 149/01)

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 9000:2005 Quality management systems - Fundamentals and vocabulary (ISO 9000:2005)	16.6.2009		
CEN	EN ISO 9001:2008 Quality management systems - Requirements (ISO 9001:2008)	16.6.2009		
	EN ISO 9001:2008/AC:2009	5.10.2011		
CEN	EN ISO 14001:2004 Environmental management systems - Requirements with guidance for use (ISO 14001:2004)	16.6.2009		
	EN ISO 14001:2004/AC:2009	5.10.2011		

The legislative documents n°765/2008 and 768/2008/CE of the European Parliament and of Council prove their extreme importance, in the community legislation, as they define the overall regulatory framework for all those products (i.e. almost all the ones what are launched on the Community market) to which, the "CE" marking must be compulsorily attributed.

The apposition of the above said marking on each single product points out the fact that, for its production, the manufacturer has worked in compliance to what is bindingly prescribed by the "Community harmonisation legislation".

Moreover, 2 recapitulative tables has been included in Decision n° 768/2008/CE, (reported below), in which are determined different procedures to which the manufacturer must attain for the apposition of "CE" marking on their products.

Some of these procedures give specifically reference, to define the "presumption of conformity" of a product, to EN ISO 9001:2000 standard *(i.e. the standard version extant at moment of the publication of the European Decision).*

TABLE: CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION

DESIGN

A. Internal production control	B. Type examination	C. Unit verification	H. Full quality assurance
Manufacturer — keeps technical documentation at the disposal of national authorities	Manufacturer submits to notified body — technical documentation — supporting evidence for the adequacy of the technical design solution — specimen(s), representative of the production envisaged, as required Notified body — ascertains conformity with essential requirements — examines technical documentation and supporting evidence to assess adequacy of the technical design — for specimen(s): carries out tests, if necessary — issues EC-type examination certificate	Manufacturer — submits technical documentation	EN ISO 9001: 2000 (*) Manufacturer — operates an approved quality system for design — submits technical documentation Notified body — carries out surveillance of the QS H1 Notified body — verifies conformity of design (†) — issues EC-design examination certificate (†)

PRODUCTION

A.	C. Conformity to type	D. Production quality assurance	E. Product quality assurance	F. Product verification		
Manufacturer — declares conformity with essential requirements — affixes required conformity marking	C. Manufacturer — declares conformity with approved type — affixes required conformity marking	EN ISO 9001:2000 (*) Manufacturer — operates an approved quality system for production, final inspection and testing — declares conformity with approved type — affixes required conformity marking	EN ISO 9001:2000 (*) Manufacturer — operates an approved quality system for final inspection and testing — declares conformity with approved type — affixes required conformity marking	Manufacturer — declares conformity with approved type — affixes required conformity marking	Manufacturer — submits product — declares conformity — affixes required conformity marking	Manufacturer — operates an approved QS for production, final inspection and testing — declares conformity — affixes required conformity marking
A1. Accredited in-house body or notified body — tests on specific aspects of the product (†)	C1. Accredited in-house body or notified body — tests on specific aspects of the product (†)	D1. declares conformity to essential requirements — affixes required conformity marking	E1. declares conformity to essential requirements — affixes required conformity marking	F1. declares conformity to essential requirements — affixes required conformity marking		
A2. — Product checks at random intervals (†)	C2. — Product checks at random intervals (†)	Notified body — approves the QS — carries out surveillance of the QS	Notified body — approves the QS — carries out surveillance of the QS	Notified body — verifies conformity to essential requirements — issues certificate of conformity	Notified body — verifies conformity to essential requirements — issues certificate of conformity	Notified body — carries out surveillance of the QS

(*) Supplementary requirements which may be used in sectoral legislation.
(†) Except for subclause 7.3 and requirements relating to customer satisfaction and continual improvement.
(‡) Except for subclauses 7.1, 7.2.3, 7.3, 7.4, 7.5.1, 7.5.2, 7.5.3 and requirements relating to customer satisfaction and continual improvement.
(§) Except for requirements relating to customer satisfaction and continual improvement.

The consequences of a sentence for "product conformity"

When a producer is sentenced for *"liability for defective products"*, i.e. when their product has caused damage to its purchaser and the manufacturer, before the judge, cannot to prove that it wasn't produced in a "reasonably safe way", it immediately becomes obvious to assume that, its bad production methodology, can also applied to the fabrication of all other "similar" items which, with the one considered "guilty", had been manufactured in the same production batch (generically referred to as "product" by the legislator).

Considering the aforesaid, it can be plausibly assumed that all the items belonging to the above said batch, or in any case a part of them, will be considered constructively "defective", i.e. **not safe**, independently from the fact that in those products the supposed defect has already revealed itself and has caused damages.

The absence of the requirement concerning the "reasonably safe" production of a certain number of items, creates all the judicial presuppositions for the application, to producer, also the statutory provisions of the Directive of European Parliament and of Council n°2001/95/CE of 3 December, 2001 *(Official Journal of the European Union L 011 of 15-01-2002, page 04-17)*, concerning:

general product safety

The basic elements of such Directive are pointed out as follows:

- *Article 1*
  The purpose of this Directive is to ensure that products placed on the market are safe.
- *Article 2, comma b)*
  "Safe product" shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons.
- *Article 3*
  Producers shall be obliged to place only safe products on the market.

Among the different restrictions that, under this circumstance, may be enforced against the producer or the importer, there is the arrangement, within a peremptory term, of the adequation of the marketed product to the safety requirements provided for the Directive (unless it is imminent risks for health safety and/or for public security), or the compulsory prescription to withdraw their product from the market (or in any case to be provided at his expenses) and, where necessary, to provide for its destruction.

If the manufacturer, for the damage caused by his faulty product, is object in court of a conviction for *Liability for Defective Product* (and eventually also for the *general product safety*) due to actual lack of compliancy of their manufacturing system to the provisions of standard EN ISO 9001, having **certified** such system to the above said standard from an external body, it is almost certain that the **aggravating circumstance** of "gross negligence" will be recognized in the court debate.

This will obviously have a very negative outcome on the determination of the guilt and consequently, almost certainly, also in that of the indemnity.

Following both the conviction for "*Liability for Defective Product*" and the consequences (almost certainly negative) caused by such writ to the business and financial relationships of the producer with their customers, there are all legal assumptions, for the producer, to take legal action towards:

- the certification body as well as
- the consultant, or consultancy firm, involved in the development of their own internal quality system,

by suing them, either separately or jointly, for

contract breach

with the possibility to include, in the total amount of claim for damages due to the poor quality of service received, also the total amount (or share) of expenses incurred due to past conviction/s.

Recent community legal provisions, as well as several sentences delivered by European courts (such as the juridical principle of the Italian Supreme Court of Appeal concerning the interpretation of juridical provisions about "*Liability for Defective Product*"), are quickly becoming, in the legal environment, basic reference elements in favour of damaged customers.

In consequence of that, an ever-growing number of legal actions for damage compensation have started, both by single users and by their associations or their behalf.
These actions, almost invariably, end up with a guilty verdict for the producer.

If, besides such legal instruments, we consider that:

- **The period of law decadence concerning the *Liability for Defective Product***
  i.e. the length of time during which every single product (since it is placed on the market) is subject to the provisions of the European Directive

  has been defined on 10 years

- **The prescription period of the same law**
  i.e. the length of time since the injurious event occurred, in which the injured party may take legal action against the producer for compensation

  is attested in 3 years

The only concrete chance, for the producer, to obtain a non-guilty verdict in a legal action concerning the *"Liability for Defective Product"*, is therefore:

- to effectively produce in an industrial "zero defect objective" environment as well as in full respect of what is prescribed by the Community harmonized standards,

- to be able to support, by documentary evidence, everything realized from the producer through a management system which can keep the traceability of all data concerning the whole manufacturing process, i.e. from the planning to the launch of the product on the market, for at least 13 years.

The aggregate of all data is indeed the only thing that allows the producer to prove in court that, *"having regard to the circumstances"*, the product was not faulty when it was placed on the market.

Moreover the data, in almost their entirety, is legally mandatory (for at least 10 years, as well) in the development of the technical file bindingly required by the

Machinery Directive

i.e. the Community Directive n° 2006/42/CE of 17 May 2006 (*Official Journal of the European Union L 157 of 09-06-2006, page 24-86).*

The most recent list of harmonized standards concerning the determination of ***presumption of conformity*** for this European Directive, has been identified by the n° 2012/C350/01 *(Official Journal of the European Union C 350 of 15-11-2012, page 01-50).*

Furthermore if we want to draw, in exhausting way, the chances for a manufacturer to be called to summons for damages caused to a user by one or more of their faulty products, we must statistically take into account (with some rare exceptions or particular industrial sectors, e.g. medical or aeronautical) the fact that

every year

a producer places on the market a number of defective products estimated as follows:

- **From a few units to some tens of units** (in the best case) if the manufacturing system is solely conditioned by factors that, in technical jargon, are called "casual mistakes" and consequently, as such, not only its turn out to be hardly predictable in advance, but also rather difficult to find these defective products in the generally limited period of time that is necessary to their realization.

- **Whole production batch,** if any "systematic error" happens within the production process.
  This kind of defectiveness become a lot easier to evidence by the operator, therefore the chance to place faulty products on the market diminishes considerably

- **The entirety of the production** manufactured in case the fault should be due to a "planning mistake" not evidenced or not effectively solved by the project managers.

If we finally consider that:

- on each of these faulty products, the Directive on *"Liability for Defective Product"* rests for 10 years after their launch on the market,
- a considerable number of these products, once placed on the market, might cause damage to things and/or people
- each of them may be subject to legal action against their producer or importer,

it may be easily understood how, the legislative problems evidenced in this document, is becoming a strongly conditioning for the European industrial fabric and, particularly, for the Small and Medium Enterprises

What happened to the manufacturing world in the USA with the introduction of the *Consumer Protection Act*,

i.e. the closure of a considerable number of small and medium enterprises due to legal controversies with consumers who were damaged by their faulty products

is an event that, unfortunately, is becoming more and more frequent in the Community context .

After all has been mentioned before, it can be claimed that both technical and legal provisions issued by the European Union concerning the *"presumption of conformity"* of the products, do not only involve the producers and consumers, but they also significantly condition all the economic Community system, which is largely made up by Small and Medium Enterprises.

Therefore, this complex issue directly and heavily involves all official institutions, such as:

government structures

industrial organizations

normalization bodies

which determine, through their decisions, the economic policy orientations to be followed .

Before the current European economic system becomes excessively conditioned by the sweepingly number of legal controversies between producers and consumers, it will therefore be their responsibility and task:

- To acknowledge the fact that the number of Community enterprises condemned for *"Liability for Defective Product"* and sentenced for damage compensation is rapidly increasing.
- To acknowledge the fact that in the judicial field, there is currently a legal path, which is extremely favorable to the consumers, which considerably increases the chances of a guilty sentence for the producer.
- To provide and implement, also considering the current prolonged economic crisis in all countries of European Union, all the actions that can support the productive fabric (above all concerning the part made up of small and medium enterprises) which might prove extremely useful to be able to face and solve, in an efficient and effective way, the complex technical-legislative issues concerning the marketing of products not only *"safe"* but also complying with the regulations of the *"Community harmonisation legislation".*

  In addition, such result would allow the above mentioned organizations, to obtain an extremely and positive double effect, i.e. to become more competitive on the markets and to drastically reduce the number of those who might end up in court with a sentence for placing not legislatively compliant products on the Community market , or for causing damages to their users.