New possibilities for legal protection currently available for all European consumers damaged by a product considered by law as being defective

This document identifies and takes under examination various legislative, standard, productive and judicial aspects that currently conform to that prescribed by the European Community Directive on

Liability for Defective Products

General Product Safety

and are at the disposition of all European consumers damaged by a legislatively defective product (does not conform to Community harmonization legislation) in the ten years following its introduction to the market and who wish to obtain from the producer equitable damages for the damage incurred.
The consequences of such judicial action usually leads to the manufacturer being found guilty.

The extreme gravity of the financial and commercial consequences of such a judicial action are the subject of this document.

The efectiveeffective and complete knowledge of such infomationinformation thus becomes fundamental both for the consumer who intends to take legal action against a manufacturer for "liability for defective products", and for all European manufacturers.
This will give the opportunity to plan and put into effect all organizational, managerial and production activity that permits not only to avoid as much as possible to be pursued under law but also, whenever the case, to have sufficient legislative, informative and productive arguments to obtain a judgment of "not liable" for the occurrence of damaging events."

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Summary

a) Members of Technical-Scientific Committee

This section lists the names of experts that make up the Technical-Scientific Committee and by pooling their personal knowledge and experience in the professional field, they have contributed to the determination, drafting and ratification of this document.

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Member of FEDERMANAGER Directive Council of Bologna County
Member of FEDERMANAGER National Commission for new digital technologies "Industry 4.0"

Brigadier General Eng. Gennaro DI LAURO
Manager (up to December 2014) of the Military Factory "Re-establishment and Recuperation of Ammunitions", of the Defence Industry Agency, industrial organisation of the DEFENCE MINISTRY

b) The liability for defective products and its impact at social level

PRELIMINARY NOTE

In order to more easily comprehend this document, "Section C", not only contains references to legislative documents significant for "liability for defective products", but also the most important legislative requirements that characterize such documents.
In order to facilitate as much as possible their availability, each requirement has been appropriately coded.

b1) Initial considerations of the problem

Obtaining more efficient and efficacious protection for the life, health and property of every European Union citizen has been one of the primary objectives of the European legislation, determining specific legislative requirements both in favour of a party injured by a defective product as well as that concerning the technological characteristics that must be fulfilled for a product to be considered *"safe"* [see the legislative point c3.02)] and thus eligible to be placed on the community market.

In regard to consumer protection, the following law is still in force in all European states:

Council Directive n° 85/374/CEE of 25 July, 1985
(Official Journal of the European Communities L 210 of 07-08-1985)

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

Until a short time ago, the legislative requirements were, for years, a matter of discussion normally confined to a limited group of people.
In order to have an overall and exhaustive picture, the following are necessary:

- To have mastery of not only this part of European legislation but also of the technical, scientific and standard knowledge that contribute to define and complete it.
- To know how to optimally apply such knowledge inside production organizations, taking into account all relative interactions and reciprocal conditions among these in their operative application.

Furthermore, it must be taken into consideration that the determining manufacturing event that causes damage to the consumer, is considered by Italian jurisprudence, as well as that of other European states such as France, Belgium and Spain, to be a "legislatively" sufficient motive for such a product, and can to all effects be considered as:

already objectively faulty when it was launched on the market
[see the legislative point c9.01)]

Such jurisprudential conditions, highly favourably to the injured party, become extremely onerous for the producer. In Italian legislation, this legal concept is expressed as follows:

the rights of contribution or recourse conferred to the injured person shall be extinguished after a period of 10 years from the date on which the producer put into circulation that particular product
[see the legislative point c1.10)]

A guilty verdict highlights not only the obligation to pay damages, but also a lack of respect (by the product that created the damage) in that the product must be legislatively required to be considered *"safe"* [see the legislative point c3.02)].
This puts the manufacturer in a very critical commercial and financial situation. It cannot be excluded that the manufacturer will be forced to take drastic action in its entrepreneurial activity.

b2) Activity to be undertaken to reduce negative consequences to a minimum

In order to put the manufacturer in conditions to be able to comply with jurisprudential requirements and standards regarding

"liability for defective products"

it being naturally understood the just and incontestable right of every citizen to receive fair payment for damages incurred due to a defective product, the Technical–Scientific Committee that drew up this document has decided to first carry out a complete and detailed analysis of the problems involved, identifying legislative and standard requirements as well as their interconnections at an operative level.

The injured party has at its disposition in court the possibility to obtain a conviction of the manufacturer.

If the knowledge of such information is indispensible for the law firm representing the injured party, it is also fundamental for the manufacturer in that, with such knowledge, it is able to plan and carry out adjustments to improve the system of production so as to:

- significantly reduce the possibility of being sued for damage caused by a defective product,
- have available, when such an event occurs, all the elements necessary to demonstrate its

  "non-responsibility"

  for what happened to the injured party and thus obtain a verdict of

  "non-culpability"

Information gained from such analyses could be put at the disposition of experts in the various sectors that contribute to determining *"liability for defective products,"* in such a way as to realize a

"total model of company conduction"

that in addition to considering the requirements for handling such problems, can also be:

- generally valid for all industrial structures, above all if small or medium sized industries,
- already operatively applicable in a productive organization,
- structured in such a way as to permit the possibility of making any adjustments deemed opportune or necessary.

Evaluating the work load necessary to obtain this, such an objective can be reached only by a specific research project at a national or eventually community level.

b3) Recipients of this document

In examining the theme of *"liability for defective products" "* it becomes necessary to take into consideration other legislative requirements that significantly effect it operative application :

- The European Union has recently issued a series of legislative documents finalized not only to protect the health, life and property of EU citizens, but also to render the

  Community harmonisation legislation

  [see the legislative point c5.01) and following]

  more efficient and efficacious.

- The objective of the *"Community harmonisation legislation"* is the abolishment of regulatory, technical and fiscal barriers that can hinder the free circulation of goods and services throughout the European Union.

- The Common legislation, that establishes *"essential safety requirements" or "other requirements in the general interest"* refers to products to be put on the market, and foresees that the manufacturing process is carried out in compliance with such requirements. It must vigorously respect the *"harmonized standards"* relative to that product which express the legislative requirements in technical terms, that alone or with other requirements, determines its *"presumption of conformity."*

- The array of legislative provisions concerning the *"essential safety requirements"* and the *"other requirements in the general interest"*, as well as technical requirements contained in the *"harmonized standards"*, constitute the *"Community harmonization legislation."*

- In order to continually improve of the *"Community harmonization legislation"*, European Union legislators considered it opportune to entrust:
  - to Council Directives the definition of the *"essential safety requirements"* and *"other requirements in the general interest", as the objectives concerning the environmental protection and the taxation,*
  - to European and National organizations, competent in the standardization, the task of drawing up the technical specifications of the *"harmonized standards"* (namely those technical norms mutually recognized valid in all European Countries) witch are, as legislative reference, for the design and production of a wide products typology in many manufacturing sectors,

- Only the products that respect all the requirements of the *"Community harmonization legislation"*, and considered *"legislatively safe"* have the possibility to be put on the market and thus freely circulate throughout the European Union.

- Every manufacturer is civilly and criminally responsible for damages incurred due to a defective product (i.e. *legislatively "non-safe" or "dangerous"*), for a period of ten years starting from the date that it is put on the market [see the legislative point c1.10)] .

- The injured party, once the damaging event has been verified, has at its disposition a period of three years to identify the manufacturer and to initiate legal action in order to obtain just compensation for damages incurred [see the legislative point c1.11)].

- Also in the report of the International Technical Committee ISO TC 176/SC2, pupublished on February 25, 2013 with protocol n° 1143, also includes the conditions for which, following current community legislation, European manufacturers find themselves with the concrete possibility of being sued and liable for damages due to a defective product.
  This occurs when a manufacturer is not able to demonstrate that, during the realization of the product, all the *"legislative prescriptions and compulsory standards"* were not effectively respected, including the harmonized standard ISO EN 9001.

In consideration of this, it was considered opportune to make the results of the current investigation available not only to European industrial organizations but also to their various associations, banks, insurance companies and above all, to government structures, both national and EU.

It is foreseeable that soon an increasing number of manufacturers, particularly small and medium sized enterprises, will suddenly find themselves:

- on trial,
- judged *"responsible"* for damages caused to an injured party by the use of their product because it was *"already" objectively faulty when it was launched on the market"* [see the legislative point c9.01)],
- obliged to pay compensation for damages due to a defective product,

with all the inevitable economic, financial and social consequences brought about by such a situation.

b4) Current approach of manufacturers to binding requirements of European legislation

If, as stated previously, the only way for a manufacturer to avoid this is to demonstrate, in a sufficiently objective and documented way, that the product causing the damage

> was made in a *"safe"* way, in full respect to all the *"harmonized standards"*, fulfilling *"all fundamental requirements essential for safety"* as required by community legislation [see legislative point c5.06)]

it is true that to objectively document this, above all if the industrial structure is small or medium sized, proves to be very difficult to demonstrate.

Until a short time ago, and in many cases even up to now:

- The primary objective of almost all manufacturers has always normally been to "*make and sell a functioning product*".
- All supplementary activity undertaken to demonstrate having introduced to the market only products manufactured "*legislatively safe*" proved to the manufacturer to be only "*overabundant and expensive bureaucracy"* and therefore to effectively adapt if explicitly forced by the market or demanded (and paid for) by the client.
- Only a small number of manufacturers already carry out "*filing and conservation*" in their organizations.
  This means keeping (for a minimum of 13 years) all data that can demonstrate that a specific product, manufactured and introduced to the market in the preceding ten years, was made fully respecting that required by
  "Community harmonization legislation"

This "*demonstration"* of compliance with legislation and standards can be requested from the organization in many official circumstances, among which:

- For possible verification of conformity and control by community governments on one or more products made by the manufacturer.
  A negative result would be extremely serious for the company in that it would impede putting on the market products considered non-conforming and oblige manufacturers to recall those already delivered. Relatively large fines would be levied and may even result in civil or criminal conviction.
- When a manufacturer becomes involved in a court case for "*product liability"* in that this is the only element of proof to demonstrate its "*non-responsibility*".
- Upon request by the client, who wishes to have before buying, the reasonable certainty that such products are *"legislatively safe."*

b5) Time presumably available before recourse action is initiated

At present, as required by some industrial structures outside Europe, to make forecasts on a possible time period at the disposition of community manufacturing organizations to adapt, if necessary, their industrial structure to

"Community harmonisationharmonization legislation."

This turns out to be extremely difficult to define in that it depends only on the rapidity with which European consumers understand that they have at their disposition all judicial and regulatory frameworks to request and quickly obtain just compensation from the manufacturer for damage incurred.

It is also true however that once the initial consumers have understood and positively experienced this new legal recourse, such information will be rapidly diffused (by the internet and social networks) to all other community consumers. Therefore, the time period at the disposition of manufacturers to effectively adapt to standards and binding regulations can be definitively established.

This time period could be drastically reduced when law firms, and above all "personal injury law firms" realize that, thanks to an innovative way of operating at a judicial level discovered by our Technical-Scientific Committee, lawsuits regarding "*product liability"* can be an excellent source of business.

Law firms operating in Italy must adhere to a precise and professional code of forensic ethics defined by

Law n° 247 of 31 December 2012
Published in the *Official Journal Of Italian Republic* the 18 January 2013

Among other things, this regards the method of searching for clients and invoicing for professional services.

Personal injury law firms", without such restraints, have the possibility to make known this new sector of their professional activity by means of appropriate technical publications (both classic and on-line) and to highlight this, particularly in hospital Emergency Rooms or other areas furnishing health care.

That is to say, it is more likely to find parties injured by a defective product (this is already happening in the United States) and to quickly obtain the desired result.
In fact, the time necessary for a "personal injury firm" to initiate and become operative in this new field of activity does not exceed 30-60 days.

An extremely important factor in its favour is the possibility of reaching an agreement with a future client regarding conditions (given the high probability of obtaining a positive result), thus:

- *If the sentence is negative, all (or almost all) legal expenses sustained due to the trial are the responsibility of the "personal injury firm" that initiated legal proceedings.*
- *If the verdict is positive, damages obtained are shared between the injured party and the "personal injury firm" on an agreed upon case to case percentage basis.*

With these presumptions, only a few injured parties would refuse a similar offer in that they would have little or nothing to lose.

Considering the current social context, the evident tight economic circumstances are due to the difficult and uncertain recovery of the European economy.
Manufacturers are beginning to be sued and convicted (verified in many cases).

This is a parameter that should be taken into serious consideration, given that an unexpected financial windfall, even if only a modest sum, would be a great help in managing the family budget.

Injured parties should pursue this goal with the greatest determination.

c) Most useful legislative provisions for injured parties

This part of the document lists the principal legislative and regulatory information currently in force throughout the European Union.
Every product produced in the EU, naturally in relation to its specific characteristics, must conform to these provisions and regulations in order to be placed on the market.

The legislative provisions and/or regulations outlined in this present investigation are of fundamental use not only for manufacturers but also for consumers damaged by a product deemed to be *"legislatively defective"* in the 10 years following its introduction to the market.

In fact, such measures determine the judicial basis to obtain a conviction of a manufacturer and consequently attainment of requested damages.

Given their importance, it was decided that in order to facilitate their traceability when explicitly referred to in this document, a code system of identification was created:

- *the letter " c "* (the section of the document containing legislative provisions)
- *a number* (that identifies the specific community document being referenced)
- *a separation point*
- *a 2 digit number* (that determines the progression of each provision of a specific document)

The complete text of Community legislation expressly cited in the present consulting analysis, is available in all European Union languages at the web site below:

http://eur-lex.europa.eu/oj/direct-access.html

The initial page of the web site can also be found below.

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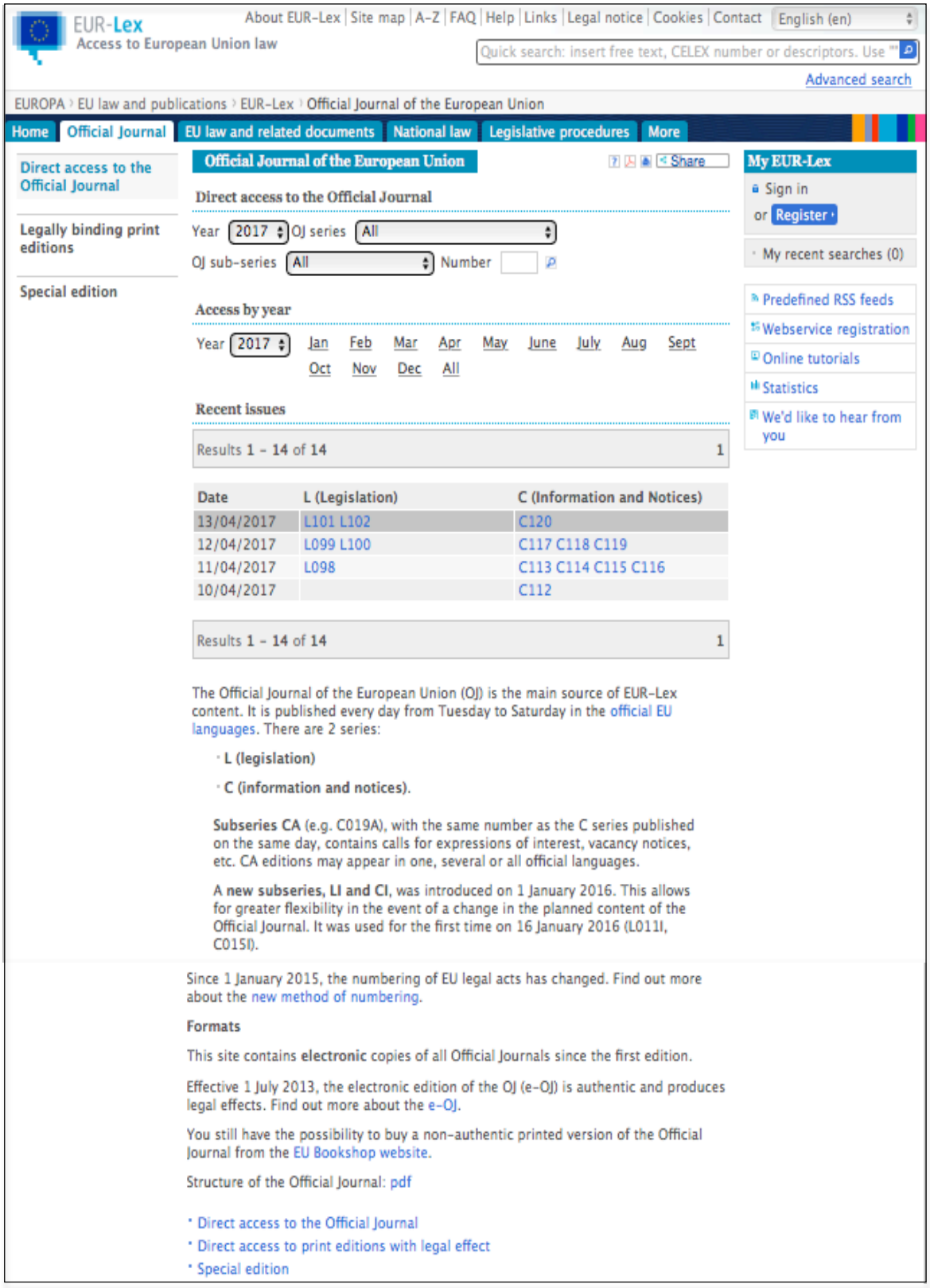
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c1) Council Directive n° 85/374/EEC of 25 July, 1985

(Official Journal of the European Communities L 210 of 7 august, 1985)

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

The fundamental elements of this Council Directive can be so summarized:

c1.01) *The producer shall be liable for damage caused by a defect in his product.*

c1.02) *'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.*

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.

Where the producer of the product cannot be identified, each supplier of the product (i.e. each link of the commercial chain witch has allowed to get it to the consumer) *shall be treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product.*

The same shall apply, in the case of an imported product, if this product does not indicate the identity of the importer referred to in paragraph 2, even if the name of the producer is indicated.

c1.03) *For the purpose of this Directive 'product' means all movables, with the exception of primary agricultural products and game, even though incorporated into another movable or into an immovable.*
'Primary agricultural products' means the products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing.
'Product' includes electricity.

NOTE WELL
The exception of "primary agricultural products" in the Council Directive on "liability for defective products", has been completely abrogated with the article n°1 of the Directive n° 1999/34/EC of the European Parliament and of the Council of 10 May 1999 amending Council Directive 85/374/EEC, promulgated on the Official Journal of the European Communities L, n° 141, of 4 June 1999.

c1.04) *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.

c1.05) *A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.*

c1.06) *Where, as a result of the provisions of this Directive, two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse.*

c1.07) *For the purpose of Article n°1, "damage" means :*

- *damage caused by death or by personal injuries,*
- *damage to, or destruction of, any item of property other than the defective product itself, with a lower threshold of 500 ECU* (actually 500 euros)*, provided that the item of property :*
  - *is of a type ordinarily intended for private use or consumption,*
  - *was used by the injured person mainly for his own private use or consumption.*

This Article shall be without prejudice to national provisions relating to non-material damage.

c1.08) *The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage*

c1.09) *The producer shall not be liable, as a result of this Directive, if he proves :*

- *that he did not put the product into circulation,*
- *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,*
- *that the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business,*
- *that the defect is due to compliance of the product with mandatory regulations issued by the public authorities,*
- *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,*
- *in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.*

c1.10) *The rights of contribution or recourse conferred from this Directive to the injured person, shall be extinguished upon the expiry of a period of 10 years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has in the meantime instituted proceedings against the producer.*

c1.11) *The recovery of damages, as provided in this Directive, is limited to a period of three years starting from the day on which the plaintiff became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.*

c1.12) *The liability of the producer arising from this Directive may not, in relation to the injured person, be limited or excluded by a provision limiting his liability or exempting him from liability.*

c1.13) *Without prejudice to the provisions of national law concerning the right of contribution or recourse, the liability of the producer shall not be reduced when the damage is caused both by a defect in product and by the act or omission of a third party.*

c1.14) *The liability of the producer may be reduced or disallowed when, having regard to all the circumstances, the damage is caused both by a defect in the product and by the fault of the injured person or any person for whom the injured person is responsible.*

c2) Council Resolution n° 85/C 136/01 of 7 May 1985

(Official Journal of the European Communities C n° 136, of 4 June 1985)

on a new approach to technical harmonization and standards

The fundamental elements of this Resolution can be so summarized:

c2.01) *Within the European law, the aim of the "Community harmonisation legislation" is to abolish the technical and fiscal barriers, able to obstruct the free circulation of goods and services in the European Union.*

The Council believes that standardization goes a long way towards ensuring that industrial products can be marketed freely and also towards creating a standard technical environment for undertakings in all countries, which improves competitiveness not only on the Community market but also on external markets, especially in new technology.

To achieve this objective, the Council Directives are limited to the adoption of the essential safety requirements (or other requirements in the general interest) and to attain the objectives of principle concerning the environmental protection and the taxation, whereas to the European and National organizations competent in the standardization it has been entrusted the task of drawing up the technical specifications needed for the design, the production, and the placing on the market of products conforming to the essential requirements established by the Directives.

c2.02) *Legislative harmonization is limited to the adoption, by provided Directives, of the essential safety requirements (or other requirements in the general interest) with which products put on the market must conform, and which should therefore enjoy free movement throughout the Community,*

c2.03) *The task of drawing up the technical specifications needed for the production and placing on the market of products conforming to the essential requirements established by the Directives, while taking into account the current stage of technology, is entrusted to organizations competent in the standardization area,*

c2.04) *The Council adopts the principle, in matters of technical harmonization, to entrust the task of defining the technical characteristics of products to standards, preferably European but if necessary national, where the conditions necessary for this purpose, particularly as regards health protection and safety, are fulfilled.*

c2.05) *The technical specifications, defined by the standards organizations, are not mandatory and maintain their status of voluntary standards.*

c2.06) *The national authorities, at the same time, are however obliged to recognize that products manufactured in conformity with harmonized standards (or, provisionally, with national standards) are presumed to conform to the "essential requirements" established by the Directive.*
This signifies that the producer has the choice of not manufacturing in conformity with the standards but that in this event he has an obligation to prove that his products conform to the essential requirements of the Directive.

c2.07) *The quality of harmonized standards must be ensured by standardization mandates, conferred by the Commission, the execution of which must conform to the general guidelines which have been the subject of agreement between the Commission and the European standardization organizations.*

c2.08) *Concerning the national standards, their quality must be verified by a procedure at Community level managed by the Commission, assisted by a standing committee composed of officials from national administrations.*

c2.09) *CEN and CENELEC (one or the other, or both according to the products covered by the Directive) are the competent bodies to adopt European harmonized standards within the scope of the Directive, in accordance with the guidelines which the Commission.*

For specific sectors of industrial activity, other competent European bodies for the drawing up of technical specifications could be involved.

c2.10) *The Directives would provide for total harmonization as a general rule consequently, any product placed on the market falling within the scope of the Directive, must be in conformity with the requirements of the Directive.*
In certain specific conditions, optional harmonization for certain products may prove to be opportune however, the outline Directive, is drawn up with a view to total harmonization.

c2.11) *The products covered by the Directive may be placed on the market only if they do not endanger the safety of persons, domestic animals or goods when properly installed and maintained and used for the purposes for which they are intended.*

c2.12) *The essential safety requirements which must be met in the case of products which can be put on the market shall be worded precisely enough in order to create, on transposition into national law, legally binding obligations which can be enforced.*
They should be so formulated as to enable the certification bodies straight away to certify products as being in conformity, having regard to those requirements in the absence of standards. The degree of detail of the wording will depend on the subject matter.
If the basic requirements for safety are observed, the general clause in point c2.11) can be applied.

c2.13) *In order to respect the general principle on which the outline Directive is based, which is to leave to the trade the choice of the means of attestation of conformity and thus to prohibit Member States from setting up any system of control prior to placing on the market (except, of course, in cases where prior control is required by specific Directives for special sectors), it is obvious that the national authorities in order to acquit themselves of their responsibilities set out in this clause, must be allowed to exercise control on the market by way of spot checks.*

c2.14) *Free movement will be ensured in the case of products declared to conform to the protection requirements laid down in the Directive, without recourse as a general rule to prior verification of compliance with these requirements.*
Also In this case it is agreed that the national authorities can to exercise a control on the market, by way of spot checks.

c3) Directive n°2001/95/EC of the European Parliament and the Council of 3 December 2001

(Official Journal of the European Communities L n° 11, of 15 January 2002)

on general product safety

The fundamental elements of this Resolution can be so summarized:

c3.01) *Producers shall be obliged to place only safe products on the market.*

c3.02) *A product shall be presumed "safe"* (i.e. "non dangerous") *when, under normal or reasonably foreseeable conditions of use, 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, taking into account the following points:*

a) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance,

b) the effect on other products, where it is reasonably foreseeable that it will be used with other products,

c) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;

d) the categories of consumers at risk when using the product, in particular children and the elderly.

c3.03) *A product, as a technical point of view, shall be deemed "safe" :*

- *when it conforms the specific Community provisions governing its safety, and these references are issued from Commission on the Official Journal of the European Communities,*
- *when, in the absence of specific Community provisions issued from Commission on the Official Journal of the European Communities, the conformity of a product to the general safety requirement shall be assessed by taking into account the following elements in particular, where they exist:*

  a) voluntary national standards transposing relevant European standards, other than those issued on the "Official Journal",

  b) the standards drawn up in the Member State in which the product is marketed,

  c) Commission recommendations setting guidelines on product safety assessment,

  d) product safety codes of good practice in force in the sector concerned,

  e) reasonable consumer expectations concerning safety.

c3.04) *The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be "dangerous".*

c3.05) *Distributors shall be required to act with due care to help to ensure compliance with the applicable safety requirements, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with those requirements.*
Moreover, within the limits of their respective activities, they shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks, keeping and providing the documentation necessary for tracing the origin of products, and cooperating in the action taken by producers and competent authorities to avoid the risks. Within the limits of their respective activities they shall take measures enabling them to cooperate efficiently.

c3.06) *The Commission shall promote and take part in the operation in a European network of the authorities of the Member States competent for product safety, in particular in the form of administrative cooperation.*

c3.07) *This network operation shall develop in a coordinated manner with the other existing Community procedures, particularly RAPEX. Its objective shall be, in particular, to facilitate:*

- *the exchange of information on risk assessment, dangerous products, test methods and results, recent scientific developments as well as other aspects relevant for control activities;*
- *the establishment and execution of joint surveillance and testing projects;*
- *the exchange of expertise and best practices and cooperation in training activities;*
- *) improved cooperation at Community level with regard to the tracing, withdrawal and recall of dangerous products.*

c3.08) *Where a Member State adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, measures or actions to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of products by reason of a serious risk, it shall immediately notify the Commission thereof through RAPEX.*
It shall also inform the Commission without delay of modification or withdrawal of any such measure or action.

c3.09) *In particular, the competent authorities shall have the power to take the necessary action to apply with due dispatch appropriate precautionary measures in the case of products posing a serious risk* [and such as to consider "dangerous" products"] *including :*

a) For any dangerous product to ban its marketing and introduce the accompanying measures required to ensure the ban is complied.

b) For any dangerous product already on the market:

- *to order or organise its actual and immediate withdrawal, and alert consumers to the risks it presents;*
- *to order or coordinate or, if appropriate, to organise together with producers and distributors its recall from consumers and its destruction in suitable conditions.*

c3.10) *The existence of a serious risk is defined, from the member states, assessing each individual case on its merits and taking into account the guidelines concerning the management of RAPEX by the Commission and the Member States, witch are prepared and regularly updated in accordance with the procedure laid down from the Commission.*

c4) Regulation n° 765/2008/EC of the European Parliament and of the Council of 9 July 2008

(Official Journal of the European Union L n° 218, of 13 August 2008)

setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) n. 339/93

The fundamental elements of this Resolution can be so summarized:

c4.01) *"Community harmonisation legislation" shall mean any Community legislation harmonising the conditions for the marketing of products.*

c4.02) *"Accreditation" shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectorial schemes, to carry out a specific conformity assessment activity.*

c4.03) *"National accreditation body" shall mean the sole body in a Member State that performs accreditation with authority derived from the State;*

c4.04) *Where accreditation is not operated directly by the public authorities themselves, a Member State shall entrust its national accreditation body with the operation of accreditation as a public authority activity and grant it formal recognition.*

c4.05) *A national accreditation body shall, when requested by a conformity assessment body, evaluate whether that conformity assessment body is competent to carry out a specific conformity assessment activity.*
Where it is found to be competent, the national accreditation body shall issue an accreditation certificate to that effect.

c4.06) *Member States shall ensure that products which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on their market is prohibited, and that the Commission is informed without delay thereof, in accordance with Article 22* [Exchange of information - Community Rapid Information System] *of the present Regulation.*

c4.07) *The decision whether or not a product represents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence.*
The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering that a product presents a serious risk.

c4.08) *Member States shall ensure that any measure taken, pursuant to the relevant Community harmonisation legislation, to prohibit or restrict the product's being made available on the market, to withdraw it from the market or to recall it, is proportionate and states the exact grounds on which it is based.*

c4.09) *Any measure referred to in paragraph 1 shall be promptly withdrawn or amended upon the economic operator's demonstrating that he has taken effective action.*

c4.10) *With the term "CE marking" it is identified a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing;*

c4.11) *The Member States shall lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented.*

c4.12) *The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of the provisions of this Regulation*

c4.13) *The Member States shall notify the Commission of those provisions by 1 January 2010 and shall notify it without delay of any subsequent amendment affecting them.*

c4.14) *Without prejudice to Article 41* [see the preceding points c4.11) - c4.12) - c4.13)], *Member States shall ensure the correct implementation of the regime governing the CE marking and take appropriate action in the event of improper use of the marking.*

c4.15) *Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements.*
Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

c4.16) *The general principles of the CE marking can be so defined :*

- *The CE marking shall be affixed only by the manufacturer or his authorised representative.*
- *The CE marking as presented in Annex II shall be affixed only to products to which its affixing is provided for by specific Community harmonisation legislation, and shall not be affixed to any other product.*
- *By affixing or having affixed the CE marking, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable requirements set out in the relevant Community harmonisation legislation providing for its affixing.*
- *The CE marking shall be the only marking which attests the conformity of the product with the applicable requirements of the relevant Community harmonisation legislation providing for its affixing.*

c5) Decision n° 768/2008/EC of the European Parliament and of the Council of 9 July 2008

(Official Journal of the European Union L n° 218, of 13 August 2008)

on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

The fundamental elements of this Resolution can be so summarized:

c5.01) *The rules and the legislative agreements (valid on all Common area), that jointly definent the "Community harmonisation legislation", has been defined and constantly updated and integrated from European Union because, their objective, is to reach the repeal the fiscal and technical barriers, able to thwart the free circulation of goods and services in the Member States.*

c5.02) *Products placed on the Community market shall comply with all applicable legislation.*

c5.03) *When placing products on the Community market, economic operators shall, in relation to their respective roles in the supply chain, be responsible for the compliance of their products with all applicable legislation.*

c5.04) *Economic operators shall be responsible for ensuring that all information they provide with regard to their products is accurate, complete and in compliance with Community rules applicable.*

c5.05) *Community harmonisation legislation shall restrict itself to setting out the essential requirements determining the level of such protection and shall express those requirements in terms of the results to be achieved.*

c5.06) *Where Community harmonisation legislation sets out essential requirements to witch a product must refer for to be placed on the market, it shall provide for recourse to be had to harmonised standards, which shall express those requirements in technical terms and which shall, alone or in conjunction with other harmonised standards, provide for the presumption of conformity with those requirements.*

c5.07) *When placing their products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in … [reference to the relevant part of the legislation].*

c5.08) *Council Directive 85/374/EEC of 25 July 1985 concerning liability for defective products is applied, 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.*

c5.09) *The "presumption of conformity" to a legal provision conferred by conformity to a harmonised standard, should enhance recourse to compliance with harmonised standards.*

c5.10) *The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure.*

Conformity assessment should therefore remain the obligation of the manufacturer alone.

c5.11) *The successful accomplishment of the required conformity assessment procedure enables economic operators to demonstrate and the competent authorities to ensure that products made available on the market conform to the requirements applicable.*

c5.12) *It is necessary to ensure that products from third countries entering the Community market comply with all applicable Community requirements, and in particular that appropriate assessment procedures have been carried out by manufacturers with regard to those products.*

Provision should therefore be made for importers to make sure that the products they place on the market comply with the applicable requirements and that they do not place on the market products which do not comply with such requirements or present a risk.

For the same reason, provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that product marking and documentation drawn up by manufacturers are available for inspection by the supervisory authorities.

c5.13) *The distributor makes a product available on the market after it has been placed on the market by the manufacturer or the importer and must act with due care to ensure that its handling of the product does not adversely affect the compliance of the product.*

Both importers and distributors are expected to act with due care in relation to the requirements applicable when placing or making products available on the market.

c5.14) *Any economic operator that either places a product on the market under his own name or trademark or modifies a product in such a way that compliance with applicable requirements may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.*

c5.15) *When placing a product on the market, every importer should indicate on the product his name and the address at which he can be contacted.*

Exceptions should be provided for in cases where the size or nature of the product does not allow it.
This includes cases where the importer would have to open the packaging to put his name and address on the product.

c5.16) *The CE marking should be the only marking of conformity indicating that a product is in conformity with Community harmonisation legislation.*

However, other markings may be used as long as they contribute to the improvement of consumer protection and are not covered by Community harmonisation legislation.

c5.17) *It is crucial to make clear to both manufacturers and users that by affixing the CE marking to a product the manufacturer declares that the product is in conformity with all applicable requirements and that he takes full responsibility therefor.*

c5.18) *Community legislation should take account of the specific situation of small and medium-sized enterprises as regards administrative burdens.*

However, rather than providing for general exceptions and derogations for such enterprises, which might imply that they or their products are second rate or sub-quality and which might result in a complex legal situation for the national market surveillance authorities to supervise, Community legislation should provide for the situation of such enterprises to be taken into account in setting the rules for the selection and implementation of the most appropriate conformity assessment procedures and concerning the obligations placed on conformity assessment bodies to operate in a proportionate manner in relation to the size of undertakings and to the small serial or non-serial nature of the production concerned.

This Decision provides the legislator with the flexibility necessary to take account of such a situation, without creating unnecessary specific and inappropriate solutions for small and medium-sized enterprises, and without compromising the protection of public interests.

c5.19) *This Decision establishes provisions for conformity assessment bodies to perform their functions, while taking into consideration the specific situation of small and mediumsized enterprises and respecting the degree of rigour and level of protection required for products to comply with the legislative instruments applicable to them.*

c5.20) *Where Community harmonisation legislation requires conformity assessment to be performed in respect of a particular product, the procedures which are to be used shall be chosen from among the modules set out and specified in Annex II, in accordance with the following criteria:*

(a) whether the module concerned is appropriate to the type of product;

(b) the nature of the risks entailed by the product and theextent to which conformity assessment corresponds to the type and degree of risk;

(c) where third party involvement is mandatory, the need for the manufacturer to have a choice between quality assurance and product certification modules set out in Annex II;

(d) the need to avoid imposing modules which would be too burdensome in relation to the risks covered by the legislation concerned.

c5.21) *Where Community harmonisation legislation requires a statement by the manufacturer that fulfilment of the requirements relating to a product has been demonstrated (EC declaration of conformity), the legislation shall provide that a single declaration shall be drawn up in respect of all Community acts applicable to the product containing all information required for the identification of Community harmonisation legislation to which the declaration relates, and giving the publication references of the acts concerned.*

c5.22) *It is crucial to make clear to both manufacturers and users that by affixing the CE marking to a product the manufacturer declares that the product is in conformity with all applicable requirements and that he takes full responsibility therefor.*

c6) Type of products that require CE marking

Community legislators hold that the application of an ***CE Marking*** is of such importance, that for each of the various types of products on which this must be affixed, it is necessary to emit specific legislative documents further detailing the technical-legislative methods for its application.

This method of operating is a fundamental element for the involvement of both the manufacturer and the consumer in that affixing an *CE Marking* personally guarantees (and assumes full responsibility) that the product introduced to the market is *"legislatively safe"* and therefore conforms to the provisions of *"community standards of harmonization"* relative to that type of product.
The European Union has dedicated an entire section of its website to this theme in order to furnish all the useful and necessary information for everyone to comprehend its importance and usefulness for the protection of their safety.

The following is the website address of this section:

http://ec.europa.eu/growth/single-market/ce-marking_en

The following is a graphic representation of this section:

In this page, at first, it is evidenced the 6 types of information proposed from the system and in the paragraph **Product Groups** the twenty-five different types of products that the EU prescribes as needing the *CE Marking*):

01) Active implantable medical devices
02) Appliances burning gaseous fuels
03) Cableway installations designed to carry persons
04) Construction product
05) Eco-design of energy related products
06) Electromagnetic compatibility
07) Equipment and protective systems intended for use potentially explosive atmospheres
08) Explosives for civil uses
09) Hot-water boilers
10) In vitro diagnostic medical devices
11) Lifts
12) Low voltage
13) Machinery
14) Measuring Instruments
15) Medical devices
16) Noise emission in the environment
17) Non-automatic weighing instruments
18) Personal protective equipment
19) Pressure equipment
20) Pyrotechnics
21) Radio equipment
22) Recreational craft
23) Restriction of Hazardous Substances in Electrical and Electronic Equipment
24) Safety of toys
25) Simple pressure vessels

Once a specific type of desired product has been determined, it can be acquired based on the knowledge of certain information, among which:

- a specific legislative reference document currently in force,
- the latest list of harmonizing standards issued relative to that type of product,
- all other information and reference documents necessary or opportune for the manufacturer.

The European Commission, maintaining that the *"safety"* of a product is a fundamental element for protecting the life, health and property of its citizens, in addition to making as much information as possible available to facilitate manufacturers in assuring that their products fully conform to the provisions of the *"Community harmonization legislation*" it is also addressed to consumers with the following warning:

Notwithstanding that many producers, importers and European distributors respect the rules and regulations, consumers also have an important role to play in improving product safety, for which:

- Always buy in trusted shops and online markets. In fact, if an offer seems too good to be true, it probably is. Trusted stores pay particular attention to the products they sell and will usually accept returns. Conversely, dishonest shopkeepers tend to ignore the regulations regarding health and safety and they may also sell counterfeit products.
- Read all warnings and instructions, paying particular attention to age and safety recommendations, especially in regard to toys.
- Always inform the manufacturers or retailers where you purchased the product that has problems with safety. In addition to this, it is also necessary to contact the appropriate public authorities. This assures that necessary action will be undertaken to guarantee product safety.

For further information that may be useful or necessary for consumers regarding EU labeling, please contact:

ANEC, the European consumer voice in standardization
Avenue de Tervueren 32, Box 27
B-1040 Brussels, Belgium
E-mail: anec@anec.eu
www.anec.eu

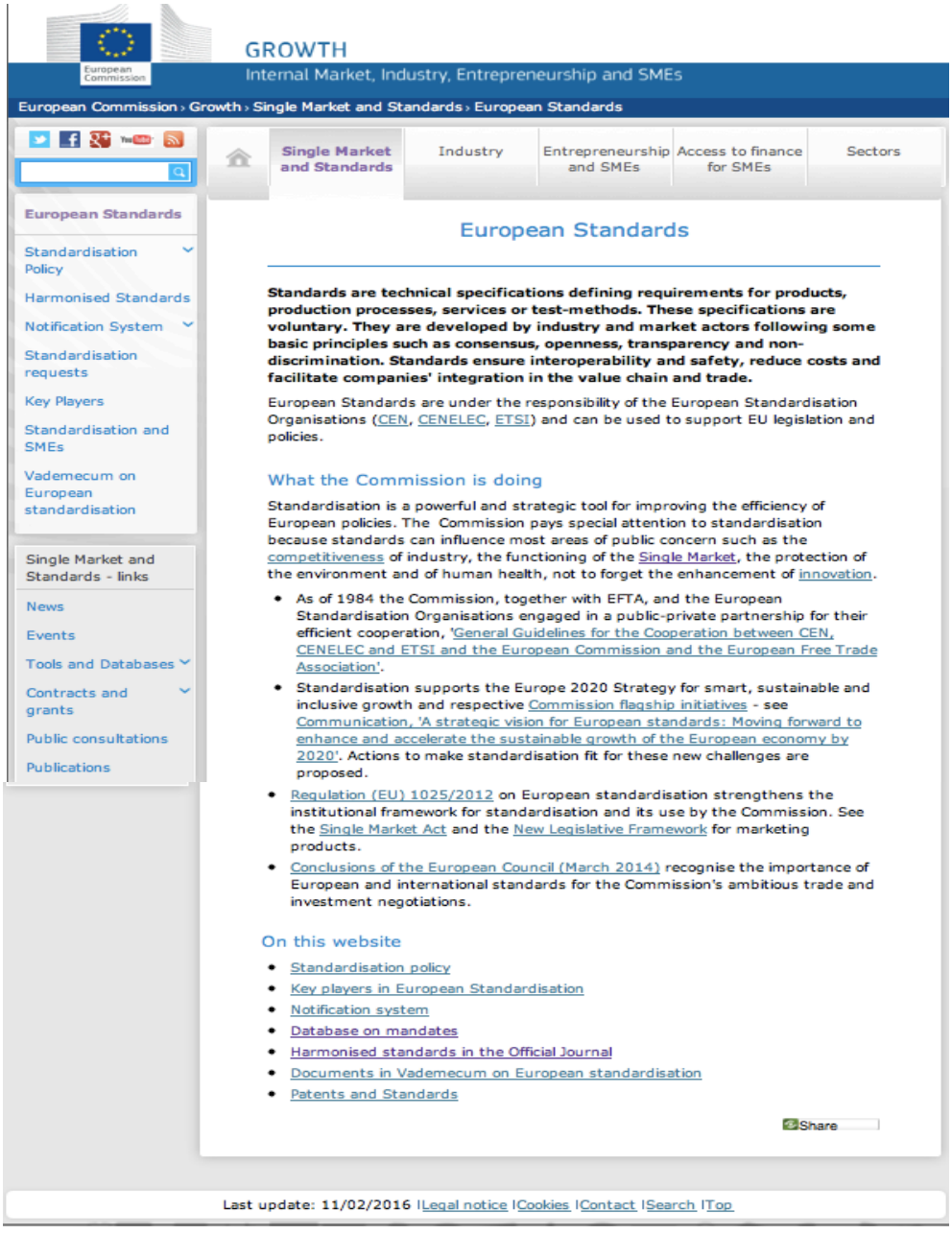
c7) Standardization and European "harmonized standards"

Since one of the fundamental aspects for European manufacturers is to respect all provisions regarding *"community standards of harmonization"*, this is synonymous with "harmonized standards." Based on this, the European Union has dedicated another section of its website to this aspect.

The website address can be found below:

https://ec.europa.eu/growth/single-market/european-standards_en

The following is a graphic representation of the first page of this section:



Selecting the heading

Harmonized standards in the Official Journal (at the bottom of the screen)

one can find all the information necessary to determine if, from the point of view of standards, the *"CE Marking*", affixed to the products by their producer, effectively validates the "*presumption of conformity"* of the product.

If not, the manufacturer is personally responsible and assumes the burden of all consequences deriving from such non-conformity.

c8) Judicial references to harmonized standard ISO EN 9001

c8.01) *Official Journal of the European Communities C 136, of 16 June 2009*

Commission communication in the framework of the implementation of the Regulation (EC) No 765/2008 of the European Parliament and of the Council, Decision 768/2008/EC of the European Parliament and of the Council, Regulation (EC) No 761/2001 of the European Parliament and of the Council

(2009/C 136/ 06)

(Publication of titles and references of harmonised standards)

References to standards are specifically indicated in this list:
ISO EN 9000:2005 – *Quality management systems Fundamentals and vocabulary (ISO 9000:2005)*
ISO EN 9001:2008 - *Quality management systems - Requirements (ISO 9001:2008)*

In all effects, these are considered to be *"harmonized standards"* and as such, are reference points for determining the *"presumption of conformity"*.

c8.02) The membership of both the standard *ISO EN 9000:2005* and *ISO EN 9001:2008* in the group of harmonized standards was further confirmed in the

Official Journal of the European Communities C 74, of 13 March 2013

(2013/C 258/ 05)

(Publications of titles and references of harmonized standards)

On 15 September 2015, the ISO TC 176 (International Organization for Standardization) issued the new edition of both the standard ISO 9000 and the standard ISO 9001.These will substitute the two standards in force up to that moment.

The transition time period, officially available to organizations for the definitive adaptation of their structures to the provisions of the new standards, has been set at 3 years.

c8.03) References to the new edition of the 2 quality standards recognized by the *European Committee for Standardization (C.E.N.)* immediately after their emission by ISO, were then published in

Official Journal of the European Communities C 412, of 11 December 2015

(2015/C 412/ 01)

(Publications of titles and references of harmonized standards)

With the designation:
ISO EN 9000 : 2015 – *Quality management systems - Fundamentals and vocabulary (ISO 9000:2015)*
ISO EN 9001 : 2015 - *Quality management systems - Requirements (ISO 9001:2015)*

These two new standards become, to all effects, "harmonized standards."
In regard to their preceding versions (ISO EN 9000:2005 and ISO EN 9001:2008), it has been officially set that for these, there is still the possibility until 15 September 2018, to continue to be taken as a reference point for the determination of "presumption of conformity" of a product (notwithstanding that these are currently officially outdated) as an alternative to those currently in force.

c9) Sentence of the Italian Cassation Court, fundamental for the injured party

If the European economic system sooner or later finds itself having to face the consequences derived from an efficient and efficacious application of the Community Directive regarding the *"liability for defective products",* experts have been aware of this since the middle 70s, when the editing of the said Directive was initiated.
They also noted the relevant economic impact in the United States of a similar law,

Consumer Protection Act

and its effect at both an industrial and social level.

The extreme relevance that such a type of legislation would have had on the entire entrepreneurial community, once adopted in Europe, perfectly explains why the Commission took 12 years (1973-1985) to put this Directive into effect.

Notwithstanding that its emission radically changed the relationship between producers and consumers, in the 20 years following its enactment, a large part of the community industrial world (especially small and medium sized enterprises) have always demonstrated a total lack of interest, both for the eventual possibility of being sued by injured parties for its defective products, and the consequences deriving from such a conviction.

This singular position assumed by European producers in regard to legislation on *"liability for defective products"* was due to the verification that this Directive, at the moment of its emission, contained many judicial requirements essential for safeguarding the life, health and property of community citizens, but no reference whatsoever was made regarding evaluation parameters that might be cited in court to determine, sufficiently and objectively, if the producer must be held *"responsible" or" not responsible"* for damage caused by its defective product.

Editor's Explanatory Note

Considerations on the inoperability of the law, wholeheartedly supported by European entrepreneurs, were mistaken in that, even if not particularly evident, the evaluation method to adopt, in order to express a reliable judgment in court, was present in the following provision:

> *a product is defective when it does not offer the safety that one can legitimately expect taking into account all circumstances……*
>
> [see legislative point c1.04)]

by means of the words *"….does not offer the safety…."*, passing completely unobserved in that it is not immediately referable to the concept of *"defective product".*

The subject matter of *"safety*" is in fact the fundamental reference point for all European legislation regarding product conformity and their commercialization, starting from legislative provisions for which:

> *Manufacturers are required to place on the community market only those products that are deemed safe*
>
> [see legislative point c3.01)]

both from a determination of a "legislatively safe product" and in conformance with specific community standards,

> *This is to say that a product conforms to specific community standards that regulate safety and whose reference points have been published by the Commission in the Official Journal of the European Communities.*
>
> [see legislative point c3.03)]

the legislative obligations establish in advance that

> *products considered by the Directive can be introduced to the market only if they do not compromise the safety of persons, domestic animals or property.*
>
> [see legislative point c2.11)]

The effective *"safety"* of products is therefore the restraint that influences the possibility of both their "*introduction to the market"* and their *"free circulation on community territory".*
Judicial concept that European legislators have developed and rendered operatively applicable by means of

"Community harmonisation legislation" [see legislative point c2.01)]

in which they have specifically underlined that:

> *To reach such a goal, community directives are limited to determining the fundamental necessities and principal objectives to attain, in matters of safety, environmental protection and fiscal obligations. Domestic and community standardization authorities are referred to when formulating or defining technical reference standards for the design and production of a wide range of products in many manufacturing sections.*
>
> [see legislative point c2.01)]

With what has been stated previously, one can therefore affirm that *"essential safety requirements for "Community harmonization legislation" (*determined at a legislative level for a certain product*)* become operative by the use of "*harmonized standards" (*regarding the same product*)* which express the legislative provisions in technical terms and that alone or together with other harmonizing standards, determine the "*presumption of conformity"* of that product to legal provisions.

[see legislative point c5.06)]

If all the "*harmonizing standards"* relative to a particular product are fully respected during its realization, the manufacturer can:

- attest to its "*presumption of conformity"* with that prescribed by such standards,
- consider its production as *"legislatively safe"* at the moment it is introduced to the market and as such, is sufficiently certain to be *"defect free*" [see legislative point c3.03)] **,**
- have the possibility, by means of specific audits, to furnish to third parties (clients, courts, government structures etc.) all the objective elements of proof capable of demonstrating with "*reasonable certainty*" that during the manufacturing process, all that prescribed by *"harmonized standards"* has been fully respected.
  When a product is introduced to the market, it is considered to be "*legislatively safe*" and "*defect free*."
  This will permit a judge to reach a ruling that the manufacturer is "*not responsible*" for damage caused by its defective product.

At the moment of the publication of the Directive on *"liability for defective products"* however, the strict relationship between the "*defectiveness*" of a product and its *"lack of safety"*, if comprehensible by judicial and standardization experts, is in no way perceived (not being specifically experts in the field) by:

- members of the judiciary,
- members of consumer associations,
- lawyers from law firms that could have been called to defend, in court, the divergent interests of the two parties in the case
- the same consumers who lack the information that there exists a European law that protects them whenever damaged by a defective product.

This lack of knowledge, effectively prescribed by the Directive, determines two extremely negative consequences that, in the time period 1985-2005, significantly influenced its application. That is to say:

- The conviction that this is a law in its own right, of grand ethical principles but of very difficult practical application in court
- The fundamental incorrect interpretation and consequent mistaken application of a specific legislative requirement by those in the judicial field.

The second element indicated is derived from the fact that normally, the judiciary accepted, as the only element of evaluation for the application of the law, that indicated in a literal sense in the prescription:

The injured party must prove the damage, the defect, and the causal connection between defect and damage.

[see legislative point c1.08)]

The procedural debate began with the injured party that had to furnish sufficient objective proof that the product was already defective when introduced to the market.

The request for such a demonstration, in almost all cases, concluded also the procedural debate in that, for the consumer, it was extremely difficult, if not impossible, to identify the manufacturing causes that determined the non-conformity of the product.

With such preliminary conditions to overcome by the injured party, the probability for the manufacturer to be convicted is truly minimal.
For this reason, many law firms advised their clients against undertaking legal action against the manufacturer.

As a consequence of this, between 1985 ÷ 2000 only very few producers were brought to trial, many of whom, as predicted, received a verdict of *"non-responsibility"* on the part of the manufacturer.

This way of interpreting the law, extremely disadvantageous for consumers, became completely subverted by the

Sentence of III Civil Section of Cassation Court
on *"liability for defective products"*
Sentence N° 20985 - Sentence Date 8 October 2007

which established that the legislative text must be interpreted and applied differently by the judiciary in that the overall context of the law prescribes that the manufacturer must demonstrate that the product was not defective when introduced to the market, rather than the consumer having to prove that it was.

The highest law derived from such a sentence establishes therefore that:

c9.01) *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.)

This innovative interpretation of the law radically changes the procedural path in that in demonstrating the "*product defect*" by the injured party, it is completely irrelevant to take under consideration the manufacturing process used by the producer to make the product but establishes that its "*defectiveness from the moment of being introduced to the market"* is legislatively ascertained by *its "unusual performance"*.

From this it follows that the product already *"lacked safety from the moment of being introduced to the market",* in that by law:

- only "*safe products*" can be put on the market [see legislative point c3.01)] ,
- only products that "*do not compromise the safety of persons, domestic animals and property"* can be introduced to the market. [see legislative point c2.11)] .

With this sentence, the Cassation Court has demonstrated that the definitive legislative connection between the "*defect*" and "*lack of safety*" was essential for the correct application of the law.

In order to avoid conviction, the manufacturer must demonstrate that all provisions of the *Community harmonisation legislation* have been respected for manufacturing the product.

The legislative connection between "*defect*" and "*lack of safety*" is fundamental and essential and furthermore, was specifically evidenced by the Community legislator in the

Decision of the European Parliament n° 768/2008/CE of 9 July 2008

This established that

Council Directive 85/374/EEC of 25 July 1985 concerning liability for defective products is applied, 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.

[see legislative point c5.08)]

d) The "ISO 9001 Certification" and its consequences in the judicial field

In 1998, the Accreditation Committee of SINCERT (at present ACCREDIA), the Italian Organism officially referred to in order to attest and subsequently verify periodically the conformity of the Certification Organizations, in issuing the *"conformity certification to ISO 9001 standard"* to domestic industrial organizations, it released the following official document:

Respect of legal requirements and regulations by companies
with a quality system certified by Accredited Bodies

Document protocol n° 98STE035T - Date 2 December,1998

With this, Authorities were solicited to pay particular attention to the fact that as part of the audits carried out in companies for the release of "*ISO 9001 Certification,*" checks were also made to determine if the method adopted to plan and produce their products conforms to the binding legislative requirements regarding that type of manufacturing. In other words, such companies effectively respected the provisions outlined in the *"Community harmonisation legislation"*.

The following has been specified in this document:

- *This application of the Accreditation Committee was further reinforced by the simultaneous verification of punctual episodes of intervention by Control Authorities of companies that have publicized the certification of their quality systems while putting on the market products that do not satisfy the legal requirements.*

- *The objective of this newsletter is to clarify the position of SINCERT based on the fact that:*

  1. *Certification Bodies, during audits carried out in companies, must verify that said companies identify and control the specified requirements, particularly those that are legally binding (ISO standard 9001 point 4.4.4 and ISO standard 9002 point 4.9).*
  2. *The lack of respect for binding requirements must be considered a valid motive for revocation of the ISO 9000 certification.*
  3. *A clause that sanctions this obligation must be immediately included in contracts undersigned by Certification Bodies and Organizations.*

- *In coherence with that stated above, SINCERT will include the evaluation of the proper management of these aspects when carrying out the verification and surveillance of Certification Bodies.*

In reality however, up to now, the provisions in this document have been rather ignored by *Certification Bodies* in their internal audits, above all in small and medium sized industries, in that:

- They are the same manufacturers that select and pay the certification authorities both for obtaining such certification and subsequent internal audits necessary to maintain the validity of certification.

- It is completely at the discretion of manufacturers to maintain or change, normally after a three year cycle, the Certification Board chosen initially.

- Well known is the intolerance of manufactures in regard to all the additional industrial activity necessary to document, objectively and completely, so as to introduce to the market only products considered

"legislatively safe"

If this "negligence" is useful for both Certification Bodies that do not wish to lose a client, and manufacturers desiring to obtain and keep their ISO 9001 certification, it is absolutely fundamental for injured parties, in that it is an extremely important factor in determining the culpability of producers and thus the awarding of damages for a defective product.

In fact, in all editions of the ISO 9001 Standard, among the provisions to be respected, it is specifically indicated to implement and constantly respect the *"applicable binding requirements,"* that is to say:

Legislative and regulatory mandatory requirements
eventually expressed as legally binding requirements

Given the provisions contained in the Standard, it follows that with the release of a "certification document" as prescribed by ISO 9001, the Certification Body issuing it officially attests that the producer:

- is perfectly aware that there are legislative dispositions (*"essential safety provisions"*) and standards (*"harmonizing standards"*) to be respected in the realization of its products in order that the *"presumption of conformity"* indicated by the *"Community harmonisation legislation"* is valid.
- knows the contents of such provisions and effectively applies them in its manufacturing processes.

The lack of respect for such provisions indicated above imposes the Certification Authorities to not only not issue a certification of conformity to ISO 9001 Standards but also to immediately revoke any certification issued previously (as prescribed by the SINCERT document) since this signifies that the producer is not operating in accordance with legal provisions by introducing products to the market without the "safety" requirements indispensible for the free circulation of such products in the EU territory.

One must also specify to having received the *"ISO 9001 certification"* without effectively conforming to all its provisions (especially legislative provisions), for the manufacturer this surely represents a judicially aggravating element since such an official confirmation leads clients, government organizations and the market to believe that it is acting in full respect to all standards and binding legal requirements, in the realization of its products.
In reality this is untrue and it represents a plain violation off the law in that the manufacturer should not have placed *"legislatively dangerous"* products on the market.

This fraudulent comportment by the manufacturer in regard to the market can be considered, from a judicial point of view, as a *"crime of fraud"* in that article no. 640 of the Italian Criminal Code establishes that:

> *The crime of fraud is committed by someone who induces another person by means of artifice or trickery, to procure for oneself or others an unjust profit.*
>
> *Such a crime is punishable by a prison sentence from 6 months to 3 years, and a fine from 51.00 to 1,032.00 euros.*

A guilty verdict against a manufacturer in a *"liability for defective products"* case, leads to an "aggravation of guilt" which normally determines an increase in sanctions for the manufacturer.

Products already produced will not be introduced to the market and those already on the market will be recalled because they were deemed

"*legislatively dangerous.*"

Upon conviction, and after conducting a complete inventory of moral and material expenses that were directly or indirectly sustained, a "*certified "ISO 9001*" manufacturer, convicted for *"liability for defective products",* can take legal action against the following to try to obtain a partial or total reimbursement of expenses incurred:

- The Certification Body that awarded the certificate, in that the producer can reasonably affirm that if the certification had been denied, with an explanation of the motive for such action, (which was its duty to do), then everything that followed would not have taken place because in the meantime, the producer would have taken steps to adequately respect the legal provisions.
- The consultant that supervised the finalization of the "ISO 9001 quality system" in the company.
  The manufacturer was led to believe that the system was totally and operatively in compliance with standard provisions when in reality this was not true.

Both the Certification Body (control structure) and the consultant (responsible for implementation of the system), for the type of work undertaken and the in-depth knowledge of the ISO 9001 system, were surely aware that in order to produce *"legislatively safe"* products, there were legislative provisions and binding standards to be respected.
Their comportment however has led the manufacturer to believe, in good faith, that the products it manufactured were in full compliance with legal provisions when this was operatively untrue, thus committing an illicit action considered to be "fraudulent".

e) Particular technical characteristics of the ISO 9001 Standard

Among all the *"harmonized standards",* the ISO 9001 is absolutely considered to be the most important, in that its provisions are not only a fundamental reference point for manufacturers to produce goods free of manufacturing defects, but are also relevant for the injured party since the lack of respect for such provisions is evident proof of the "*responsibility*" of the manufacturer in making *"legislatively dangerous"* products that do not respect judicial provisions for the *"presumption of conformity"* and thus cannot be introduced to the market.

The essential elements that characterize this standard can therefore be identified:

1) *Its fundamental difference in respect to all other technical harmonized standards is represented by the fact that this is not a "product standard" but rather a "system standard" that decisively limits the manufacturer in determining the procedures to adopt when planning and carrying out its entire productive process for each of its products.*

2) In the new edition of the ISO 9001 Standard, published in September, 2015, the following was also evidenced:

- *Conformity to standards is achieved if, during the entire process of design and realization of the product, requirements are respected by an organization that:*
  - *a) Must demonstrate the ability to regularly furnish products or services that satisfy clients' requests as well as "applicable binding requirements."*
    The diction "binding requirements" signifies compulsory, regulatory and legislative obligations, eventually expressed as legal requirements.
  - *b) Aims to increase client satisfaction by means of the efficient application of a quality system, including its improvement processes, in such a way so as to guarantee conformity to both client requests and "applicable binding requirements."*
    All standard requirements are of a general nature and are therefore foreseen as being applicable for all organizations, regardless of type or size.

- The necessity to respect *"applicable binding requirements"* by a manufacturer in the production of its products was deemed so important by the authors of the Standards, that this concept, already included in the preceding edition which came out in November, 2008, was explicitly underlined more than ten times throughout the text.

- In order to market a product that, with a high probability, is not only defect free but also does not cause any damage to its utilizers, a new provision was inserted that requires the planning and drafting of efficacious and efficient risk analysis documents in order to preventively avoid that during the execution of the various productive processes:
  - *a) Non-conforming products that, following their introduction to the market, demonstrate defects or an anomalous comportment so as to create damage to its utilizer.*
  - *b) Legislative provisions and reference standards, completely or in part, are not respected for a certain type of product. This would prohibit their subsequent marketing in that they are not judged to be legislatively "safe."*

- To confirm what is stated in the previous point, it is explicitly evidenced that in order to attain an efficacious and efficient system of quality management, *"risk-based thinking"* is an essential instrument.

- Been evident that utilization of risk analysis was a provision already implicit in preceding editions of standards, it follows that such managerial activity should have been carried out, especially in planning, re-examining and improving the company management system. This permitted the following:
  - the adoption of opportune preventive action in order to eliminate potential non-conformity,
  - analysis of every verified instance of non-conformity,
  - the defining and use of preventive action capable of impeding (or limiting as much as possible) the appearance of non-conformity.
- Current international standard specify provisions that require an organization to identify and comprehend its own industrial context, in order to determine risks as a basis for planning industrial processes that an organization will put into place for manufacturing its products.

f) Current level of implementation of ISO 9001 in organizations

Since the first emission of the Standard ISO 9001 in 1987, its effective implementation in companies has generally been rather scarce, if not almost casual, above all in small to medium sized enterprises.

It was important for many industrial organizations, especially small and medium sized enterprises, to obtain a *"certification of conformity"* for their company quality systems.
This was accomplished in such a way that the company structure, its organization and its production processes remained unchanged as much as possible.

The main objective of *the "certificate"* therefore was not to reach an important improvement in the internal production system in order to significantly increase the probability of producing only *"safe products",* but rather to enhance its commercial image in the eyes of the client.
This also offered the possibility to take part in many contract tenders of public administrations.

The International Technical Committee ISO TC 176 has been perfectly aware since the early 2000s of such improper comportment, both on the part of companies as well as the certification bodies. This committee was officially requested to supervise and maintain the ISO 9001 Standard.

The misuse of such standards by industrial organizations throughout the world, as well as the emission of official certificates of conformity to their provisions, when in reality management did not respect all or in part such requirements, was officially demonstrated (without obtaining any practical results in improvement) by the Secretary General of ISO in the following publications:

- document issued on 22 July 1999, with protocol "Council 99".
- document issued on 14 August 2000, with protocol "Council 2000",
- a special edition of ISO JOURNAL of May/June 2000, entitled:
  " A walk on the dark side of the 'ISO 9000 industry "

In 2012, The Secretary General of the International Technical Committee ISO TC 176 / SC2, in anticipation of the fact that the Standard ISO 9001 would soon become in Europe and in the judicial field as well, a fundamental reference element, decided to draw up a detailed internal report on the subject in order to inform the other members of the Committee.

Such a document, as was predictable, highlighted a rather serious situation due to the widespread *"non-conformity"* of European industrial organizations to provisions in ISO 9001, in addition to those imposed by Community Legislation (*applicable binding requirements*).
This demonstrated a rather high probability that many Community producers would, sooner or later, find themselves involved at a judicial level with a serious possibility of being convicted.

This internal report, considered to be extremely useful for industrial organizations operating in the EU, was made official on February 25, 2013, with protocol no. 1143.

g) The legal path to be taken by an injured party

At the moment a consumer acquires a product, it is good to remember that:

- If a product is among those sold by weight, size, volume or in any case without specific labelling to uniquely identify the producer, as are products such as fruit , vegetables, bread, small, metallic hardware material etc., it is opportune to keep the receipt issued by the seller (its usefulness will be explained later) at least for those products, that by nature, have a higher probability than others of causing damage to the user.
  For example, products that are possibly toxic such as mushrooms or small metallic hardware material (tubes, screws, wires etc.) whose structural failure could be the source of grave problems.
  For such products it is opportune to hold on to receipts until one can be sufficiently sure that the product can no longer create any type of danger.

- If a product is acquired in sealed packaging containing a label with the name of the producer and/or importer, (products coming from a country outside the European Union,) it is in the interest of the consumer to hold on to the following for a period of time congruent with the type of product:
  - the label with the name of the producer and importer,
  - the purchasing receipt issued by the seller,
  - all documentation accompanying the product, with particular attention to the instruction booklet, in that this is an important instrument for the injured party in legal proceedings, especially in cases where the documentation in Italian is not included. [see legislative point c3.02)]

- In sealed packaging, when it is not clear or does not contain the name of the producer and/or importer, it is advantageous for the consumer to record such information, validated by the seller before the definitive purchase of the product.

One must always request and obtain a "receipt" from the retailer, if not a "purchase invoice", as both of these documents surely contain the name and address of the producer and/or importer.

- Also in cases of purchasing a product where there is only the minimum possibility of causing damage over time (e.g. home appliances, gas equipment, pressurized vessels etc.) it is fundamental to request and obtain a "receipt" or "purchase invoice" from the seller.

Whenever a purchased product causes damage to its user in the 10 year period following its acquisition, [see legislative point c1.10)] or before its expiration date (food products, medicine etc.), an injured party may obtain damages from a producer for a defective product by enacting the following legal pathway:

(01) Verify that the product or its labelling contains the name and address of the producer and/or importer.

In fact, Community Legislation considers the "importer" to be, in all effects, the "producer," and as such, is accountable before the law [see legislative point c1.02)].

Whenever the names of the producer and/or importer are unknown, the consumer must contact, in writing, the retailer where the product was purchased.
The presentation of a receipt would help to avoid any eventual misunderstandings.

The consumer must explain what happened and request that this information be supplied within a reasonable time (i.e. 3 months), the name of the producer and/or importer or the person who supplied the product.

[see legislative point c1.02)].

In cases where the retailer does not respond with the requested information within a reasonable time or such information is incomplete, the retailer becomes, to all effects and purposes the "producer" and as such, must respond before the law [see legislative point c1.02)].

In this case, furnishing evident proof that the purchase was made at its place of business is an extremely important factor in reducing protests to a minimum.

This specific part of the problem is examined in more detail in point **(05).**

In order to initiate judicial proceedings against the "producer" for damages, once the producer has been identified by the consumer (producer, importer or supplier when unable to identify who furnished the defective product) the injured party still has three months at its disposition.

[see legislative point c1.11)].

(02) Once a "*producer*" has been sued and a trial has begun, the injured party has only to demonstrate, in front of a judge, the defect in a product by means of its *"anomalous comportment."*

[see legislative point 9a)]

(03) After such a demonstration, the burden of proof falls completely on the producer who, in order not to be held responsible for damages caused to the consumer by its product, must furnish sufficiently objective proof that, at the moment of its realization, all productive processes utilized for it finalization (from design to packaging) completely conformed to all the binding provisions contained in the *"Community harmonization legislation"* in regard to that specific type of product.

(04) The best way for a producer is to comply with this in order to furnish objective proof of its non-responsibility for what happened to the user of its product.
This can be determined by the following:

a) Check the document regarding the "analysis of risks on the functionality of the product" to verify if the defect that caused damage to the user had already been demonstrated.
If so, check which design features had been enacted in order to eliminate the hypothesis of such risks.

b) Furnish a list of *"harmonized standards"* that were reference points for the producer in the realization of that particular product.

c) Verify the "analysis of risks in design" to check if the requirements of the *"harmonized standards"* were respected.
These harmonized standards furnish specific references on how to plan and carry out the "design of a product" as well as their correct application at an operative level.

d) Verify the "analysis of risks in production" to check if the requirements of the *"harmonized standards"* were respected.
These harmonized standards furnish specific references on how to plan and carry out the "production of a product" as well as their correct application at an operative level.

e) Verify not only the efficiency of "control plans" adopted by the producer to impede the realization and sale of *"legislatively unsafe*" products but also to check that these were effectively carried out during the realization of the product which subsequently caused damage to the user.

f) Verify that all managerial and organizational provisions contained in the "*harmonized standards*" of reference for the *"Community harmonization legislation"* concerning that particular product, have been correctly implemented and rendered operative inside the organization.

g) The producer must furthermore keep in mind that for every single product introduced to the market:

- The EXPIRATION time of the law regarding the *"liability for defective products"* is 10 (ten) years [see legislative point c1.10)]
- For the plaintiff, the RECOVERY OF DAMAGES is limited to a period of 3 (three) years starting from the day on which he became aware of the identity of the producer.
[see legislative point c1.11)]

From these two legal provisions it follows that for the producer, to be able to demonstrate in court that it is not responsible for damage caused by one of its products, it must opportunely archive, for a period of 13 years from the date of its introduction to the market, all data regarding the production (from design to packaging) of each of its products such that it can be rapidly available during judicial proceedings.

A time period of 13 years archiving is considered necessary in that theoretically, a product defect could arise and cause damage on the day preceding the 10 year expiration period.

(05) In reference to what has been stated previously, among the industrial organizations that risk finding themselves more often involved with problems of *"liability for defective products"* there are surely the large "*commercial organizations"* that operate in the food sector and/or those industrial sectors whose products, in some way, have the possibility of causing damage to their end user, in that:

- Many of these structures put their brand name on a relevant number of products when they are surely not the effective "producer" but in fact present themselves as such.

  In these cases, each of these becomes the *"legal producer"* by law [see legislative point c1.02)], subsequently assuming all the relative judicial effects, both positive and negative.
  Among these is the obligation to furnish documented proof in court that, during the various phases of producing a particular product that demonstrated a defect after being sold, all the reference provisions of the *"harmonized standards"* were fully respected.

  This is practically impossible for "commercial organizations" given that, they are not the effective producers.

  To be excluded from judicial proceedings, the organization must demonstrate that in reality, it is only the "*supplier*" of the product with the obligation to respect the legislative reference provisions listed below.

- A *"commercial organization*" must pay particular attention when the same product is supplied by different producers but lacking the essential information.
  It becomes almost impossible to establish the effective origin of the product.

  Therefore, for this type of product (often seen in the food sector), the "*supplier*," except in particular cases when prescribed by law, cannot furnish the "effective name of its producer" to a party damaged by one of its products. [see legislative point c1.02)]

In reference to point 2) of paragraph **(05)**, in the Italian legislation this condition becomes a serious problem in that the only legislative provision that permits the *"supplier"* (a "*commercial organization"*) not to be considered the *"producer*" of the product, is reported in Article n. 116 of the

Italian Consumer Code
Legislative Decree n° 206 of 6 September 2005

which states the following:

1) *When the producer is not identified, it shares the same responsibility as the "supplier" that distributed the product, if it has neglected to furnish the name and address of the producer that furnished the product within three months of such a request.*

2) *The request must be in writing and must indicate the product that caused the damage, its location, and with reasonable approximation, the date of purchase. It must also contain a vision of the offered product if it still exists.*

3) *If the notification of the application initiating judicial proceedings was not preceded by the request foreseen in comma 2, the "supplier" can carry this out within the subsequent three months.*

4) *The "supplier" can be excluded from the judicial proceedings and therefore not considered to be the "producer" of the product if, within three months of the request by the injured party, it furnishes not only the name and address of the producer or persons who supplied the product, but also that the structures/persons indicated are present at the trial and do not contest being identified as the "producer" of a product causing the defect.*

5) *This article is applied to products imported into the European Union when the importer has not been identified, even if the producer is noted.*

Very interesting, for the damaged, the contents of the:

Sentence of III Civil Section of Cassation Court on
"Defective merchandise and damages: sharing of responsibility by the seller and producer"
Sentence N° 13432 - Sentence Date 1 June 2010

this also pointed out the following:

> *" the fact that, before the case, the damaged party failed to ask the retailer in writing for the data regarding the producer, does not prohibit the client from obtaining damages."*

Given the type of product that the commercial organization has sold, it is difficult that the identified "producer" would accept the obligation to qualify as the effective producer of the product, given that, except in particular cases, there is no objective element that permits the establishing the truthfulness of such an affirmation.

As a consequence of this, the "*supplier*" must appear in court as the "*producer*" of the product that caused damage to the client, with all the judicial consequences that such a decision may entail.

h) The involvement of sub-supply

Rapidly perusing this document in order to quickly focus on the fundamental elements of the most practical interest, the conclusion may be reached that the "*producer*" of the product that caused damage to its user must search among the various structures (normally the manufacturer but also the importer, wholesaler, marketer, retailer etc.) that, for various reasons, contributed to the commercialization of the product.

This hurried evaluation is however completely wrong in that in the Directive on the *"liability for defective products"*, there is already an explicit reference to the fact that:

> *The term "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.*
>
> [see legislative point c1.02)]

What has been stated previously demonstrates in an unequivocal manner that:

> whenever a product has caused damage to its user but the effective cause of its *"defectiveness"* is due to a component that the manufacturer did not personally make itself but rather "acquired" externally and inserted into its product, fully respecting the assembly provisions, and without making any technical modifications,

for that particular component, the "*manufacturer"* is considered to be a simple "*supplier"* and therefore with the only legislative obligation to furnish references to the "*real producer."*
[see an exhaustive treatment of this in section g) of this document].

In such an eventuality, the "manufacturer" can ask the judge to be excluded from the judicial action brought against him by the injured party.
The head of the production or commercial structure that sold the defective component must appear in his place, in that he must respond in court for the damage caused by his product.

Other fundamental elements legislatively binding on the activity of the "producer" in the realization of a really "safe" product are defined in the Directive on *"General Products Safety"*, that establishes the following:

> Among the various parameters that contribute to determining a "safe product other than the specific characteristics of the product itself (composition, packaging assembly mode) there are other parameters relative to its presentation such as labeling, eventual warnings and instructions for its use, the possible types of users (children and the elderly) in addition to both its method of installation and eventual maintenance over time .
>
> [see legislative point c3.02)]

Strict compliance with these legislative provisions is necessary not only for the producer, but also for all its external suppliers, given that this is expressly required by the

Decision of the European Parliament no. 768/2008/CE of 9 July 2008

which establishes that:

> *When placing products on the Community market, economic operators shall, in relation to their respective roles in the supply chain, be responsible for the compliance of their products with all applicable legislation.*
>
> [see legislative point c5.03)]

The Directive on "General Products Safety" furthermore imposes particular provisions in regard to the activity of distributors who commercialize products of the "producer", by means of affirmations for which:

> *Distributors shall be required to act with due care to help to ensure compliance with the applicable safety requirements, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with those requirements.*

> *Moreover, within the limits of their respective activities, they shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks, keeping and providing the documentation necessary for tracing the origin of products, and cooperating in the action taken by producers and competent authorities to avoid the risks. Within the limits of their respective activities they shall take measures enabling them to cooperate efficiently.*
>
> [see legislative point c3.05)]

In the legal field, another fundamental element of involvement of an external supplier and the producer to whom he sold the product, arises when the product put on the market by the producer causes injury to its user.
In reality, the effective cause of a harmful event is attributed to a joint failure of two or more components, in part made by the producer and in part by the external supplier.

In this case, the Community Directive on the *"liability for defective products"* prescribes that:

> *Where, as a result of the provisions of this Directive, two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse.*
>
> [see legislative point c1.06)]

In regard to this requirement, the Italian national legislation in article no. 12l of the

Italian Consumer Code
Legislative Decree no. 206, of September 6, 2005

prescribes the following:

Plurality of Responsibility

1) *If more persons are responsible for the same damage, joint liability for damages comes into effect.*
2) *One who has paid damages has recourse against the others in determining the size of the risk referable to each one, the gravity of eventual culpability and the consequences resulting from such a situation.*
3) *When in doubt, the allocation is carried out in equal parts.*

The conditions indicated in point 3) are practically the only ones applicable in cases in which the same component is acquired, by the producer, from more than one external supplier.

In cases in which, a specific component, is the cause (or a contributory cause) of damage incurred by the buyer of the product put on the market by the producer, part of the damages must be paid by those external suppliers who in reality, in this specific case, have no responsibility for the verified harmful event.

To avoid such a possibility, it is good practice for an external supplier to always identify its product with a brand, or some other particular marking, in such a way as to render the product uniquely identifiable.

For this reason it is advisable that the presence of a brand name, or some other recognizable marking, is also communicated to the buyer in that there is always the possibility (albeit minimal) that the same product, coming from different external suppliers, appears recognizable in the same manner.

i) Conclusions

It is the assessment that this document is sufficiently explanatory in regard to all problems of

liability for defective products

able to furnish:

- to all European consumers,
- to industrial organizations operating in the European market, both as producers and sub-suppliers,

an exhaustive picture both of the protections provided from European legislation for the Community citizens damaged by a product "legislatively defective", and the implications deriving for the European producers.

At this point, every entrepreneur must make a difficult decision in that its selection, in one way or another, will have significant consequences for the future of the organization. That is to say:

- Hope for good fortune because the organization can "never" be arraigned for a question of "*liability for defective products"*.

- Use the information present in this report as a first concrete support for the planning and accurate verification of its internal organization. This document illustrates how to have a clear idea of the type and entity of possible shortcomings or to confirm that it is already capable of demonstrating, also in court, that all its products are in strict compliance with all the provisions of the

Community harmonization legislation

seeing that this is the judicially binding condition to reach a verdict of *"guilty"* or *"not liable"* for the producer of a product that caused injury to its user.