

Conformity Assessment

a layman's ten-point guide

This Layman's Guide, in the form of simple questions with simple answers (on a subject where nothing is simple), is intended for the reader who has heard a bit about Conformity Assessment and would just like to have an elementary introduction to its concepts. This person is aware, no doubt, that this is not the last that he or she is going to hear of a subject whose interest, relevance and importance in today's world is growing by leaps and bounds as international trade increases. Readers wishing to go further could usefully consult ISO Development Manual 2, Conformity Assessment, that not only introduces interested parties to the basic concepts but also indicates which detailed international guides and technical documents should be referred to for full information on each concept.

- 1 What is Conformity Assessment?** Conformity assessment is a process whereby a product, process, service, or system is evaluated against a standard.
- 2 Why is it important?** Conformity assessment is important to suppliers, consumers, and regulators. It enables conscientious producers to distinguish their products from those made by disreputable ones. It provides consumers with a means on which to rely in selecting products in the marketplace. And it permits governments to enforce the regulations for which they are responsible, which protect the public health and safety.
- 3 Why is its importance increasing?** Nations in the Asia-Pacific, the Americas, and Europe are entering into regional trade Pacts to implement practices that facilitate trade. The World Trade Organization (WTO) fosters international trade based on, among others, conformity assessment practices that balance regulated public protection and heightened industrial competition.
- 4 What activities are included?** Conformity assessment may consist of any one of, some of, or all of the following: sample testing, item inspection, process evaluation, management system registration, and product certification: accreditation of the competence of the organizations conducting these activities may also be a complementary activity.
- 5 That are third party programmes and why rely on them?** When carried out by a party other than the supplier (the first party), or the purchaser (the second party), the conformity assessment is said to be provided by a third party, an entity which is independent of buyer or seller. Reliance on a third party may be required by a government regulator or specified by the customer; the supplier may seek it as a means of market differentiation for its product or to obtain independent feedback. Absent from these considerations, supplier may choose to self-declare conformity.
- 6 Why accreditation?** If there are a number of conformity assessment organizations, some may want to distinguish themselves from their competitors by having an impartial evaluation of their competence based upon international recognized criteria. Accredited

conformity assessment organizations can be expected to achieve at least a minimal level of performance with greater consistency in the services they offer and uniformity in the results they produce. Hence, accreditation allows for the recognition of the equivalence of services provided by competing organizations.

7 How is ISO involved? ISO studies methods used by national programmes in carrying out conformity assessment activities, reports its findings in requirements documents and informative guides, and promotes their understanding and use to promote international trade through reliance on globally harmonized procedures.

8 Who is involved at ISO? The Conformity Assessment Committee of ISO, CASCO, is comprised of representatives from 83 member bodies, from ISO technical committees, and other international organizations such as the International Electrotechnical Commission (IEC), the International Laboratory Accreditation Cooperation (ILAC), and the International Accreditation Forum (IAF).

9 What documents are available? CASCO has produced standards and guides that pertain to conformity assessment organizations and accreditation bodies and their diverse activities. They are available singly or in a set, 15 in number, in the ISO, IEC Compendium (of) Conformity Assessment published in 1999.

10 What does the future hold? Regionalism will encourage harmonization of diverse national requirements and procedures, with regionalism gradually giving way to increased global harmonization. Global product acceptance based on one-time-only product approvals will result from accreditation-based multinational agreements recognizing equivalence of national conformity assessment results.

Additional Information

For more information on ANSI's Conformity Assessment programs, please visit ANSI Online (www.ansi.org – see link for Conformity Assessment) or contact John Donaldson, vice President of conformity assessment (tel: 202-331-3603; e-mail: jdonalds@ansi.org) or Richard James, director of conformity assessment (tel: 202-331-3614; e-mail: rjames@ansi.org)

CONFORMITY™

Volume 4 No. 4

April 1999

Lax Product Safety Compliance May Mean Greater Exposure

Manufacturers concerned about compliance with product safety requirements in the European Union (EU) may worry most about possible sanctions by trade officials and others empowered to enforce technical requirements. But one EU-based legal expert is arguing that manufacturers of non-compliant equipment may have more to fear from litigious consumers than from official sanctions.

Writing in *Approval Magazine*, Dai Davis, a solicitor with Nabarro Nathanson in London, suggests that consumers have available to them a virtual arsenal of options with which they can punish manufacturers whose products fail to meet the highest standards of safety. According to Dai, those options, combined with increased consumer awareness of the legal liability assumed through the casual application of the CE mark, mean that consumers actually pose a far greater risk

to manufacturers than the legal enforcers of standards conformity.

According to Dai, there are at least four different ways that a consumer can bring a civil action against a manufacturer of an unsafe product. First, consumers can bring under contract law a claim against a manufacturer whose products causes injury, arguing that the manufacturer has a contractual obligation to supply products of "satisfactory quality." Second, consumers can bring suit against a manufacturer for negligence, based on the argument that the manufacturer did not fulfill his duty to protect end-users and innocent bystanders from unsafe products.

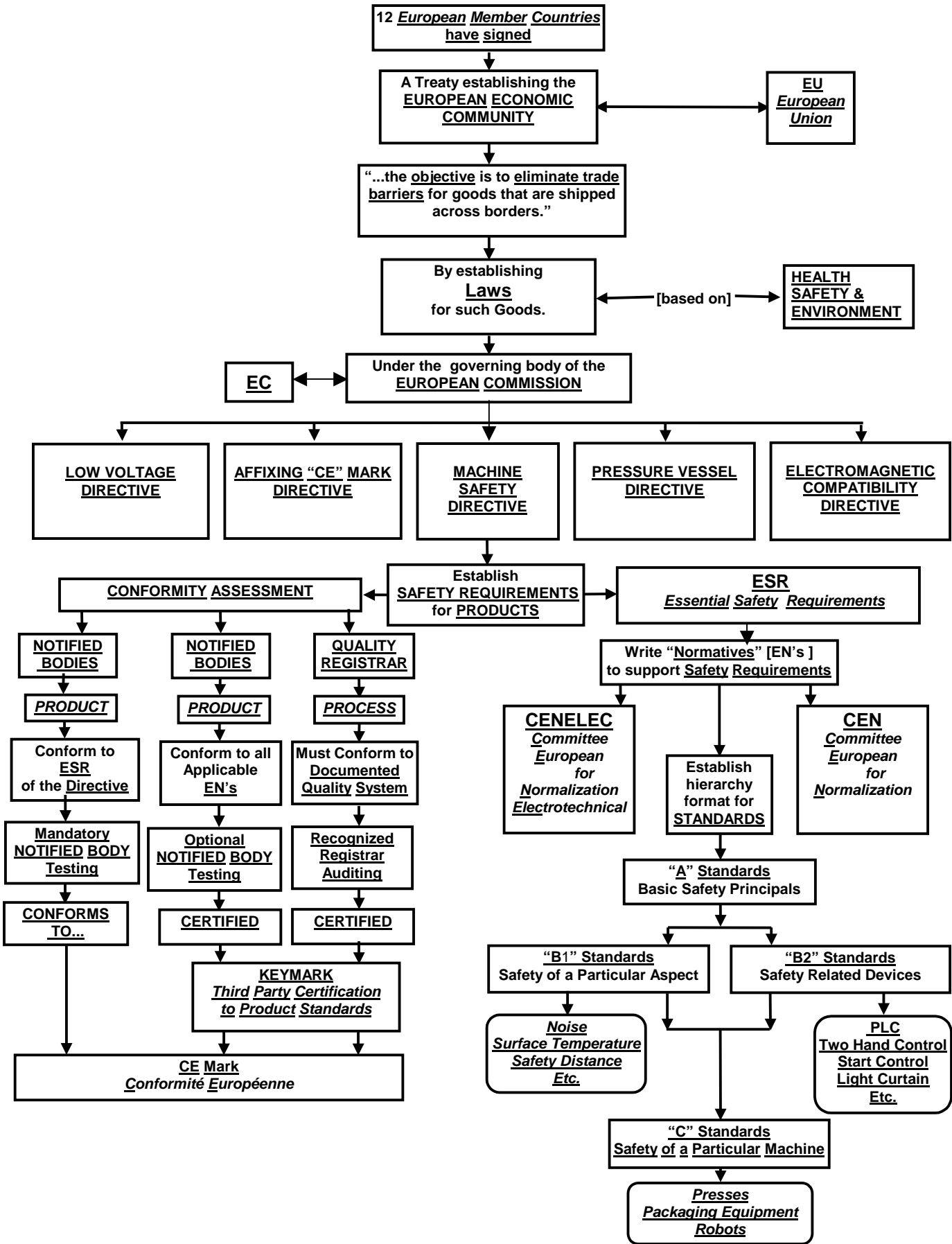
The third type of consumer action, according to Dai, is a suit based on product liability law, that requires all manufacturers to use the best available scientific and technical knowledge to ensure against product defects. The burden of product liability law falls heaviest on those manufacturers who cannot demonstrate that they adhered to the highest technical standards in the design and manufacture of their products.

The final weapon that consumers can levy on a manufacturer, writes Dai, is a civil action based on a manufacturer's false or misleading representation that their product complies with the appropriate technical requirements through the application of the CE Mark. According to Dai, this kind of consumer claim can also be brought against testing laboratories who have evaluated a specific product for compliance.

In the final analysis, it is the users of products that may prove a more formidable legal threat to manufacturers than government officials. Because consumer rights regulations in the EU give claimants considerable firepower against manufacturers of unsafe products, the best advice for manufacturers is to ensure compliance with all applicable regulations before their products reach the consumer, says Dai.

CONFORMITY™

THE NEW EUROPEAN REGULATIONS FOR MACHINE SAFETY
 [Enforced under the new EUROPEAN UNION LAWS, (EU)]



THE NEW GLOBAL REGULATIONS FOR MACHINE SAFETY
 [Enforced under the new WORLD TRADE ORGANIZATION, (WTO)]

169 Signatory Countries
have signed

A Treaty establishing the
GENERAL AGREEMENT
on TARIFF and TRADE

GATT

“...the objective is to eliminate trade
barriers for goods that are shipped
across borders.”

By establishing
Laws
for such Goods

HEALTH
SAFETY &
ENVIRONMENT

WTO

Under the governing body of the
WORLD TRADE ORGANIZATION

Government Bodies of
Signatory Countries
are obligated to enforce the
INTERNATIONAL
STANDARD

Signatory Countries are not
allowed to reduce the
requirements applicable to
to HEALTH, SAFETY and
the ENVIRONMENT

All trade disputes shall be
settled based on
INTERNATIONAL
STANDARDS

All Signatory Countries
are obligated to adopt
INTERNATIONAL
STANDARDS
as their National Standards

CONFORMITY ASSESSMENT

Establish
SAFETY REQUIREMENTS
for PRODUCTS

ESR
Essential Safety Requirements

IAF
International
Accreditation
Forum

QSAR
Quality
System
Assessment
Recognition

Adopt Safety Standards as
INTERNATIONAL STANDARDS

IEC
International
Electrotechnical
Commission

Establish hierarchy
format for
STANDARDS

ISO
International
Standards
Organization

PRODUCT
Must Conform to
Safety
Requirements

PROCESS
Must Conform to
Documented

“A” Standards
Basic Safety Principals

Establish GLOBAL
uniform
Testing Procedures

Establish GLOBAL
uniform
Auditing Process

“B1” Standards
Safety of a Particular Aspect

“B2” Standards
Safety Related Devices

CERTIFIED

CERTIFIED

Noise
Surface Temperature
Safety Distance
Etc.

PLC
Two Hand Control
Start Control
Light Curtain
Etc.

KEYMARK*
*Third Party Certification to
PRODUCT STANDARDS

“C” Standards
Safety of a Particular Machine

Presses
Packaging Equipment
Robots