Impact of the European Product Directives on the Italian Legislation concerning Technical Safety

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The evolution of the european standardisation activities, following the implementation of a number of EU directives concerning products, had an increasingly impact on the legislation of the Member States, mainly in technical fields like fire safety, where national rules and provisions had previously been established since long. CPD, ATEX, PED, Machinery are all examples of directives that have changed the engineering and procurement practices adopted by the contracting firms for projects concerning process plants or civil works to be established in the EU. The conformity assessment procedures, aiming at demonstrating that the requirements concerning a product, a service or a system have been met, usually require third party involvement. In particular cases, notified bodies are involved also to ascertain and verify that the design of a specific item (i.e. a pressure equipments) meets the provision of the directives which apply to it. The paper describes the modification introduced in the Italian legislation concerning the technical safety to perform the assessments of a product, a service, a system and to evaluate the fitness for the intended use.

1. Introduction

While the new approach was developed to remove technical barriers to trade ensuring the free movement of goods between Member States, the provisions concerning the works and the permitting procedures remain legally, in compliance with the EC Treaty, in the national regulatory domain. However, as a consequence of the strong commitment by the EC Commission to reduce the administrative burdens on business activities and to promote the effective implementation of the principle of mutual recognition, it has been necessary in the last ten years to revise the national legislation concerning the inspection and putting into service in order to coordinate to the required conformity assessment procedure, as reported in Table 1 for the CPD, ATEX, PED, Machinery directives. Transposition of EU product directives into national law and competent national authorities responsible for market surveillance are reported for each directive together with the main administrative acts concerning the inspection and putting into service. It is worthnoting that the provisions of these EU Directives shall not affect Member States entitlement to lay down, with due regard to the provisions of the EC Treaty, requirements that may deem necessary to ensure safe use of the product, provided that this does not mean modifications to the product itself in a way not specified in the Directives, as shown in the last column in Table 1.

Table 1. Transposition of EU product directives into national law and main administrative provisions concerning the inspection and putting into service

EU product directive	*Field of application*	*Transposition of the Directive into national law*	*National authorities responsible for market surveillance*	*National provisions regarding inspection and putting into service*
PED 97/23/EC	Pressure equipment (PS>0,5 barg) and assemblies	D.Lgs. 25/02/00, n. 93	Ministry of the Industry	-Decree Ministry of the industry 01/12/04, n.329 - Circ. ISPESL 07/02/05, n. 3 - Circ. Ministry of the industry 23/05/05
CPD 89/106/EEC	Construction products	D.P.R. 21/04/93, n. 246 modified by D.P.R. 10/12/97, n.499	Ministry for the Infrastructures; Ministry of the Interior; Ministry of the Industry	- Nine Decrees dated 05/03/07 and three decrees dated 11/04/07 concerning various product families
ATEX 94/9/EC	Equipment and protective systems in potentially explosive atmospheres	D.P.R. 23/03/98 n. 126.	Ministry of the industry	- D.P.R. 22/10/01, n. 462 - Decree Ministry of the Interior dated 27/01/2006
MACHINERY 89/392/EEC, 98/37/EC 2006/42/EC	Machinery	D.P.R. 24/07/96, n. 459	Ministry of the Industry; Ministry of the Employment	- Circ. Ministry of the Industry 25/06/97, n. 162054 - Circ. ISPESL 22/11/97, n. 99 - Circ. ISPESL 21/01/03, n. 3

2. PED

The national authority competent to control the *design and manufacture* of pressure equipments before the PED entering into force was ISPESL, a public organization that that was also responsible for issuing the national regulations for pressure vessel mechanical design (known as VSR, VSG, M, S codes). Various tasks were assigned in the national codes to the ISPESL personnel in order to assess the conformity of the equipment produced. After PED entering into force, the responsibility for these controls has moved to the manufacturer and to the entities foreseen in the PED framework (notified bodies, recognized third party organizations), as reported in Table 2.

Table 2. PED entities responsible for controls in compliance with the national VSR,VSG,M,S codes (previously performed by ISPESL) during construction phase.

Phases foreseen in the national codes →	*Design Examination (1)*	*Materials Certification (2)*	*Welding qualification (3)*	*Proof test and final inspection (5)*
Module A (internal production control)	Manufacturer (technical dept.)	Certificate of compliance (2.2)	Manufacturer (inspection and testing dept.)	
Module A1 (internal manufacturing checks with monitoring of the final assessment)		Material manufacturer with quality assurance (3.1.B) or by point 3.1.C or 3.2 with manufacturer (insp./testing dept.)		Manufacturer (insp./testing dept.) and Notified body (4)
Module B (EC type-examination)	Notified body	N/A		Notified body (on "type")
Module B1 (EC design-examination)				N/A
Module C1 (conformity to type)	N/A	Material manufacturer with quality assurance (3.1.B) or by point 3.1.C or 3.2 with manufacturer (insp./testing dept.)	Notified body or Recognized third-party organizations	Manufacturer (insp./testing dept.) and Notified body (4)
Modules D and E (production/product quality assurance)				
Modules D1 and E1 (production/product quality assurance)	Manufacturer (technical dept.)			
Module F (product verification)	N/A			Notified body
Module G (EC unit verification)	Notified body			
Module H (full quality assurance)	Manufacturer (technical dept.)			Manufacturer (insp./testing dept.) and Notified body (4)
Module H1 (full quality assurance with design examination and special surveillance of the final assessment)	Notified body			

(1) In the PED framework it includes design and technical file examination.
(2) Refer to PED Guideline 7/5 and 7/16 for details.
(3) In the PED framework it is intended the notified body or third-party organization approval of operating procedures and personnel utilized for permanent joining of components which contribute to the pressure resistance of equipment in categories II, III and IV.
(4) Final assessment is controlled by means of unexpected visits of a notified body chosen by the manufacturer.
(5) In the PED framework it is intended the final inspection carried out internally and externally on every part of the equipment; the examination of the accompanying documents for demonstrate PED compliance; hydrostatic pressure test; inspection of safety devices.

Concerning the *putting into service, use and maintenance procedures*, subject to the national regulatory domain, the Ministry of the industry has issued the Decree dated 1 December 2004, n. 319, entered into force 12 February 2005, and a subsequent interpretative document dated 23 May 2005. It applies to the pressure equipments specified in art. 1 including also, but not limited to, those subject to PED, with the exemption listed in art. 2 (Table 3). It is still to be issued the decree concerning the technical specification concerning the use, as foreseen in art. 3, and a clear qualification of the subjects entitled to perform the compulsory checks on maintenance and repair.

Table 3. National administrative provisions concerning pressure equipments putting into service, use and maintenance contained in the Decree 1 dec. 2004, n. 319

Activity	*Field of application*	*Exclusions*	*Third party involved*	*Result*	*Surveillance authorities*
Putting into service	For all equipments subject to the regulation as listed in art. 1, prior to use (including those listed in art. 5)	Equipment exempted as per art. 2	--	As per art. 6: *Declaration* with technical documentation prepared by the user and sent to ASL and ISPESL	ASL and ISPESL (health and safety dept. established on municipal basis)
First installation check	As per art. 4: only for the assembly of pressure equipment on the site and under the responsibility of the user	As per art. 5: - portable fire extinguishers and compressed gas cylinders used in breathing apparatus; - simple pressure vessels with PS<12 bar and PS*V<8000 bar*l; - assemblies already verified by a notified body or user inspect.	Notified body or User inspectorate upon user request	The competent body must issue an attestation to the applicant.	--
Periodic checks	As above, only for workplace	As above	-- (ASL/ARPA)	Inspection / test report	ASL/ARPA (as above)
Periodic qualification (integrity & functioning control)	As above, with frequency established in the Annexes A and B to the decree or in the operating instructions set up by the manufacturer, if less	As per art. 11: - category II pressure equipment (except water) with PS<12 bar and PS*V< 8000 bar*l and no corrosion; - vessel with V< 1000 l and PS<30 bar in refrigerating sys.; - steam boiler with PS<10 bar and PS*V< 300 bar*l; - steam vessel with PS<10 bar and PS*V< 400 bar*l - acetylene generator; - vapour or gas traps and desuperheater; - vessels containing Group 2 liquids; - piping with Group 2 fluid classified I and II category; - portable fire extinguishers with powder, foam or water with propellant cartridge with PS<18 bar	Notified body or User inspectorate upon user request	The competent body must issue an *attestation* to the applicant.	--
Repairs and modifications	To be performed according to the procedures detailed in art. 14				

3. CPD

The national authorities competent for market surveillance of construction products in Italy are the Ministry for the Infrastructures for the mechanical resistance related aspects (essential requirement n. 1 in the CPD); the Ministry of the Interior for the fire safety issues (essential requirement n. 2 in the CPD) and the Ministry of the Industry for the other requirements: dangerous substances; safety in use; noise protection; heat retention (essential requirements n. 3,4,5,6 in the CPD).

Concerning the *design* and *construction* rules, the "Technical Standards for Construction" (TCS) has been recently been revised by Decree of the Minister for Infrastructures dated 14 January 2008 and will enter into force 5 march 2008. The text, which is intended to clearly identify the levels of safety and the performance of buildings, unifies both standards on the behaviour and resistance of materials and structures, and those on the definition of actions and their effects on structures. It is consistent with the Eurocodes and Community provisions relating to construction products, specifically with CPD and the Recommendation of the European Commission of 11 December 2003 on the application and use of Eurocodes for construction works.

It is essential to note that, unlike the "new approach" directives, CE marking of the construction products is *only* possible when it is available an harmonized european standard (hEN) or via the European Technical Approval (ETA) issued by an Approval Body member of EOTA (only for innovative products or in case of deviation from an available hEN). When CE marking is possible, Member States can only establish the mandated characteristics to be assessed by the user or the installer/designer to demonstrate the *fitness for the intended use* of the specific product, with the only constraint to choose between those listed in the annex ZA.1 of the hEN or in the ETA (i.e. no further requirement/test is possible on national level). Having clarified that, the acceptance of a construction product to be incorporated in a work, in Italy is subject to the administrative provisions contained in:

- Chapter 11 of the TCS, concerning *structural* construction products, lays down standards on the qualification, certification and acceptance of materials and products for structural use. It applies both to structural products in CE marking regime and products outside CE marking (subject to national approval qualification procedure).
- 12 decrees issued by the three competent ministries concerning products in CE marking regime for which were available hENs.

  Nine decrees dated 5 March 2007 concerned mainly products of interest of fire safety: "Insulation products", "Building hardware", "Components for gas extinguishing systems", "Components for sprinkler and water spray systems", "Powder systems", "Fire detection and fire alarm systems", "Smoke and heat control systems", "Hose systems". Three decrees dated 11 April 2007 concerned mainly products for which is relevant the essential requirement 1: "Aggregates", "Structural bearings", "Geotextiles".

  In these decrees, Annex 3 lays down the product mandated characteristics for installation in conformity to the national legislation concerning the works. As the CPD does not contain provisions concerning the *putting into service/installation*, the article 3 defines, for each product family, the duration of the transitional period (ranging form 6 to 24 months), extending beyond the ending of the coexistence

period, after which it is possible *to install only CE marked products with the declared characteristics* indicated in the above mentioned decrees (representing a subset of all circulating CE marked products).

4. ATEX

The national authority competent for market surveillance of ATEX products in Italy is the Ministry of Industry, while the Ministry of Interior has to be involved in some technical activities. As usual the directive does not regulate the process of installation. Installing such equipment will generally be subject to legal requirements either workplace directives or the national legislation of the Member States.
The procedures regarding *putting into service, use and maintenance* have been established in Italy with the Presidential Decree n. 462, dated 22 October 2001, entered into force 23 January 2002. It applies to all electrical installation in workplace intended for use in potentially explosive atmospheres (ATEX), as specified in Table 4.

Table 4. National provisions concerning electrical installation in ATEX workplace putting into service, use and maintenance contained in D.P.R. n. 462/01.

Activity	*Field of application*	*Third party involved*	*Result*	*Surveillance authorities*
Putting into service	All electrical installations in workplace intended for use in potentially explosive atmospheres	--	As per art.5: *Declaration of conformity* (according to Law n. 46 of 5 March 1990) issued by the *installer*. The employer must sent it to ASL/ARPA before 30 days from the date of issue, *prior to use.*	ASL/ ARPA (health and safety dept. established on territorial basis)
First installation check	As above	Reserved only to ASL/ARPA	ASL/ARPA must issue a first installation *attestation* to the applicant ("*omologazione*").	
Periodic checks	As above, every two years	- Notified body - ASL/ARPA	The competent body must issue an *attestation* to the applicant.	
Extraordinary checks	As per art. 7: - negative periodic check; - substantial modification of the installation; - on user request.			
Modifications	As per art. 8: In case of substantial modification, transferring or stopping of the installation	--	The employer must inform the ASL/ARPA *and* ISPESL	

The national standardisation body for electrical installation (CEI) has issued in 2005 a voluntary Guide (CEI 0-14) in order to facilitate an uniform implementation of the assessment performed by third parties inspection bodies and by ASL/ARPA, to be used together with the Guide CEI-ISPESL 64-14 detailing the technical aspects of the control to be performed. When subject to fire regulation (mainly for petrol stations and vapour recovery system), the user/employer of ATEX equipments has also to respect the administrative provisions contained in the decree dated 27 January 2006 subject to the local fire brigade control. For products concerning fire safety issues, the Ministry of the interior has also issued a guideline (dated 22 August, 2006, n. 6651)

5. MACHINERY

Before the Directive 89/392/EEC entering into force (21 September 1996), the machinery included in a list included in the Decree of 12 September 1959, to be used in a workplace, were subject to a national approval ("*omologazione*") by a public organization formerly known as ENPI (then ISPESL), before being put into the market.
Art. 11 of the Presidential Decree n. 459 of 24 July 1996, transposing the directive, established a three months transient (till 31/12/1996) only for the commercialization of this type of machinery provided that were previously been subdued to ISPESL examination. In the same article it was confirmed the obligation for the user/employer to inform ISPESL concerning putting into service of the machinery, to be used in a workplace, included in the list included in the Decree of 12 September 1959, whether CE marked or conform to previous national provisions. Regarding this subject ISPESL prepared an informative document n. 99 of 22 Octobre 1997, following the one issued by the Ministy of Industry n. 162054 of 25 June 1997and a subsequent ISPESL document n. 21 of 21 January n. 3. Table 5 summarize the regime applicable for CE marked products, listed in the Decree of 12 September 1959 and in the Law n. 359/99.

Table 5. National provisions concerning putting into service, use and maintenance of machinery listed in Decree of 12 September 1959 and Law n. 359/99.

Activity	*Field of application*	*Third party involved*	*Result*	*Surveillance authorities*
Putting into service	Machinery listed in Decree of 12 September 1959	--	*Declaration* with technical documentation prepared by the user/ employer for ISPESL, that issues an inspection log sent to the user and to the ASL/ARPA.	ASL/ ARPA (health and safety dept. established on territorial basis).
Periodic checks	- Machinery listed in Decree of 12 September 1959: every year - Machinery listed in Annex XIV of Law 359/99 (enlarged set)	- ASL/ARPA - Still needed a decree for Law 359/99 to define the inspection procedures	The competent body must issue an *attesta-tion* to the applicant (to be kept at list for five years for a machinery listed in Annex XIV of Law 359/99).	As above
Extraordinary checks	- negative periodic check - substantial modification	As above	As above	As above

t is worth noting that an installation (like a process unit) *is not usually* considered to be a machinery, which is characterized by the following figures:

- that it should be "for a specific application" (article 1(2));
- that it should be able to "function independently" (article 4(2)).

6. Conclusions

While the european product directives were developed to remove technical barriers to trade ensuring the free movement of goods between Member States, the national provisions concerning the works and the permitting procedures remain legally in the national regulatory domain. As a consequence, in Italy, as in other europeam countries, it has been necessary to modify the national provisions adopted to protect the workers, consumers or the environment in order to guarantee the compliance with the comunity legislation. This revision process has started in the early nineties and is still under develpment, causing a deep change in the administrative procedures esatblished by the competent national authorities.

7. References

PED

Directive 97/23/EC in O.J.E.C., L 181, July 09, 1997
Law D.Lgs. of 25 February 2000, n. 93 in O.J.I.R., 22 Apr. 2000, Suppl. Ord. n. 91
Decree of 11 December 2004, n. 319, in O.J.I.R., n. 22, Jan. 28, 2005

CPD

Directive 89/106/EEC in O.J.E.C., L 40, Feb. 11, 1989
Presidential Decree of 26 April 1993, n. 246 in O.J.I.R., n. 170, July. 22, 1993.
Decree of 14 January 2008, in O.J.I.R., n. 29, Feb. 4, 2008, Suppl. Ord. n. 30.
Decree of 5 March 2007, in O.J.I.R., n. 66, Mar. 20, 2007 and n. 67, Mar. 21, 2007.
Decree of 11 April 2007, in O.J.I.R., n. 91, Apr. 19, 2007.

ATEX

Directive 94/9/EC in O.J.E.C., L 100, Apr. 19, 1994
Presidential Decree of 23 March 1998, n. 126 in O.J.I.R., n. 101, May 4, 1998.
Presidential Decree of 22 October 2001, n. 462 in O.J.I.R., n. 6, Jan. 8, 2002.
Decree of 27 January 2006, in O.J.I.R., n. 32, Feb. 8, 2006.

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Directive 89/392/EEC in O.J.E.C., L 183, June 29, 1989.
Directive 98/37/EC in O.J.E.C., L 207, July 23, 1998.
Presidential Decree of 24 July 1996, n. 459 in O.J.I.R., 6 Sep. 1996, Suppl. Ord. n. 209.