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Marcin Pigłowski

Akademia Morska w Gdyni
Wydział Przedsiębiorczości i Towaroznawstwa
e-mail: m.piglowski@wpit.am.gdynia.pl

The legislations and countries operating in the new approach to technical harmonization and standards as an aspect of consumer safety

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Summary. In 1985, the Council issued the Resolution on a new approach to technical harmonization and standards. On the basis of the Resolution, legislations were issued, which are in force mainly in the countries of the European Union (EU) and the wider European Economic Area (EEA). They contain essential requirements for products placed on the EU market. The notified bodies are involved in the conformity assessment with those requirements. The goal of the article was to examine whether and which notifications (of notified bodies) related to legislations and countries (or groups of legislations and countries) had a dominant influence on shaping of ensuring of consumer safety. The calculations were made in Statistica 10 using the cluster analysis. It was found out that the division into clusters within the legislations and countries depended on the number of notifications (and in the case of legislation – additionally on similar types of products / risks). The legislations and countries with a big number of notifications created separate (or even single) clusters. Amending the former or issuing the new legislations should be linked to the development of a possibility of products assessment by the notified bodies from the smaller EU countries. In this process attention should be also paid to the products often notified in the RAPEX (Rapid Alert System for non-food dangerous products).

Introduction

In 1985 the Council issued the Resolution on a new approach to technical harmonization and standards. On the basis of this Resolution the legislative harmonization was limited to essential safety requirements (or other requirements in the general interest) for products (or risks in products) introduced into the market and therefore they could enjoy free movement in the European Union (EU) (Council, 1985).

The estimated share of intra-EU trade of new approach products accounted for 20% – see (Young, 2004). However, the old approach (detailing products or components) is still used in high-risk areas, such as pharmaceuticals, foodstuff, chemicals or motor vehicles – see (Egan, 2002).

The Resolution on a new approach to technical harmonization and standards indicated also private bodies: CEN (Comité Européen de Normalisation) and CENELEC (Comité Européen de Normalisation Electrotechnique) (currently also ETSI – European Telecommunications Standards Institute) as competent bodies to adopt the voluntary harmonized standards (within the scope of the appropriate legislation) covering technical specifications (Council, 1985).

The bodies, which carry out the conformity assessment according to the legislation are notified (or designated) by a country operating in the new approach (Council, 1985; European Commission, 2016). In 1989 the Council issued also the Resolution on a global approach to conformity assessment, which was the basis for: devising modules of the conformity assessment procedures, the designation and notification of bodies and the use of EC mark (currently CE marking) (Council, 1989).

Nowadays, the legislation within the new approach concerns 39 legislations (see tab. 1). There are mainly directives, but also two regulations and one decision. 37 countries operate within the new approach (see tab. 2). These are mainly 28 EU countries, together with 3 countries within the European Economic Area. These are also the countries, with which the EU has signed the mutual recognition agreement – MRA (bilateral agreements beneficial for industry by providing easier access to conformity assessment) (5 countries) and Turkey (European Commission, 2016; see also Pigłowski, 2015).

The number of legislations and countries is comparable but the number of notifications within the particular legislations and countries varies. Therefore, the goal of the studies was to examine whether and which notifications (of notified bodies) related to legislations and countries (or groups of legislations and countries) had a dominant influence on shaping of ensuring of consumer safety. The cluster analysis was applied.

Data and methods

The basic data are presented in table 1 (number of notifications within the particular legislation linked to the notified bodies according to the issue date and number) and table 2 (the number of notifications within the new approach from the particular countries linked to the notified bodies in the alphabetical order).

Table 1

The legislations and notifications within the new approach

Legislation	Number
89/686/EEC Personal protective equipment	120
90/385/EEC Active implantable medical devices	16
92/42/EEC Hot-water boilers	44
93/15/EEC Explosives for civil uses	13
93/42/EEC Medical devices	61
94/9/EC Equipment and protective systems intended for use in potentially explosive atmospheres	73
94/25/EC Recreational craft	37
95/16/EC Lifts	237
96/98/EC Marine equipment	43
97/23/EC Pressure equipment	291
98/79/EC In vitro diagnostic medical devices	23
99/5/EC Radio and telecommunications terminal equipment	80
2000/9/EC Cableway installations designed to carry persons	24
2000/14/EC Noise emission in the environment by equipment for use outdoors	64
2004/22/EC Measuring instruments	138
2004/108/EC Electromagnetic compatibility	167
2006/42/EC Machinery	189
(EC) No 552/2004 Interoperability of the European Air Traffic Management network *	2
2006/95/EC (ex-73/23/EEC) Low voltage	162
2008/57/EC Interoperability of the rail system (Recast)	61
2009/23/EC (ex-90/384/EEC) Non-automatic weighing instruments	181
2009/48/EC Safety of toys	53
2009/105/EC (ex-87/404/EEC) Simple pressure vessels	94
2009/142/EC (ex-90/396/EEC) Appliances burning gaseous fuels	53
2009/750/EC Interoperability of Electronic Road Toll Systems **	3
2010/35/EU Transportable pressure equipment	155
(EU) No 305/2011 Construction products *	667
2013/29/EU Pyrotechnic articles	11
2013/53/EU Recreational craft and personal watercraft	6
2014/28/EU Explosives for civil uses	2
2014/29/EU Simple pressure vessels	7
2014/30/EU Electromagnetic compatibility	2
2014/31/EU Non-automatic weighing instruments	1
2014/32/EU Measuring instruments	2
2014/33/EU Lifts and safety components for lifts	10
2014/34/EU Equipment and protective systems intended for use in potentially explosive atmospheres (Recast)	3
2014/53/EU Radio equipment	0
2014/68/EU Pressure equipment	22
2014/90/EU Marine equipment	0
Total:	3117

Notes: * Regulation, ** Decision implementing Directive 2004/52/EC.

Source: based on: European Commission, 2016.

Table 2

The countries and notifications within the new approach

Country	Number	Country	Number
Australia (MRA) *	6	Latvia	48
Austria	88	Liechtenstein (EEA) **	1
Belgium	76	Lithuania	30
Bulgaria	72	Luxembourg	13
Canada (MRA) *	1	Malta	2
Croatia	48	Netherlands	86
Cyprus	8	Norway (EEA) **	44
Czech Republic	105	Poland	186
Denmark	69	Portugal	54
Estonia	21	Romania	45
Finland	55	Slovakia	79
France	171	Slovenia	44
Germany	392	Spain	164
Greece	80	Sweden	65
Hungary	61	Switzerland (MRA) *	57
Iceland (EEA) **	2	Turkey ***	91
Ireland	13	United Kingdom	389
Italy	408	United States (MRA) *	41
Japan (MRA) *	2	Total:	3117

Notes: * MRA – Mutual Recognition Agreement, ** EEA – European Economic Area, *** Turkey is listed by virtue of Decision 2006/654/EC.

Source: based on: European Commission, 2016.

The largest number of notifications within the legislations has been notified for construction products (667), then: pressure equipment (291), lifts (237), machinery (189), non-automatic weighing instruments (181), electromagnetic compatibility (167), low voltage (161), transportable pressure equipment (155) and the smallest number of notifications has been notified within the legislations newly issued or replacing the previous ones (in 2014).

On the other hand, within the countries, the largest number of notifications has been notified by the large and medium-sized EU countries, i.e. Italy (408), Germany (392), United Kingdom (389), Poland (189), France (171), Spain (164) and the smallest number of notifications has been notified mainly from the EEA and MRA countries.

The data for the studies are collected in the cross table (not presented) in the following way: the legislations in columns and the countries in rows. The empty fields were filled in with the value 0. In order to examine how the notifications are clustered within the particular legislations and countries the cluster analysis was applied using Statistica 10. The following settings was adopted: analysis method: joining (tree clustering), linkage rule: complete linkage (that is the greatest distance between any two objects belonging to different clusters, used if the

objects form a separate, compact clusters), distance measure: Euclidean distance (the most frequently chosen metrics as the most "natural") – (see: Stanisz, 2007). There was also k-means clustering as another cluster analysis method applied in order to compare the results of using both methods. Aggregation was carried out according to columns (legislations) and rows (countries).

Results and discussion

In the case of joining, tree diagrams were obtained – see figure 1 (for legislations) and figure 2 (for countries). In the case of k-means clustering, the same result as presented in figure 1 was obtained for 5 clusters (see the legislations in tab. 3), whereas the similar result as presented in figure 2 was obtained for 9 clusters (see the countries in tab. 4). If more clusters were accepted, it led only to their greater fragmentation. The particular clusters and their elements were presented in table 3 and table 4 in the order of, respectively, figure 1 and figure 2. In table 4 it can be noticed that only two countries (enclosed in brackets) are in the other clusters in comparison with the tree diagram (fig. 2) and besides, some countries created single clusters.

The legislations (see fig. 1 and tab. 3) with about 150 notifications were clustered in cluster 2. This cluster included: personal protective equipment – 89/686/EEC and machinery – 2006/42/EC, and also low-voltage products – 2006/95/EC and electromagnetic compatibility – 2004/108/EC (these two pairs products / issues are close).

The next cluster (number 5) is the most numerous, however, the particular legislations had usually only a few notifications. In this cluster there were all three medical products (active implantable medical devices – 90/385/EEC, medical devices – 93/15/EEC and in vitro diagnostic medical devices – 98/79/EC), pressure products (simple pressure vessels – 2014/29/EU and pressure equipment – 2014/68/EU), lifts and cableway installations (lifts and safety components for lifts – 2014/33/EU, cableway installations designed to carry persons – 2000/9/EC), pyrotechnic or explosives products (pyrotechnic articles – 2013/29/EU and explosives for civil use – 2014/28/EU). The majority of legislations clustered in this cluster were issued / amended in 2014 (the number of notifications among them is still very small). Some of these legislations occurred also in the next clusters (4 and 3) as yet not amended. However, in cluster 4 the legislations with a few dozen notifications were clustered. The similar products were: recreational craft – 94/25/EC and marine equipment – 96/98/EC and also appliances burning gaseous fuels – 2009/142/EC and equipment and protective systems intended for use in potentially explosive atmospheres – 94/9/EC.

The cluster 3 was created by the legislations with about or more than 200 notifications (lifts – 95/16/EC, pressure equipment – 97/23/EC and non automatic weighing instruments – 2009/23/EC) and the last cluster (1) consisted of only one

element (construction products – (EU) No 305/2011) with more than 600 notifications.

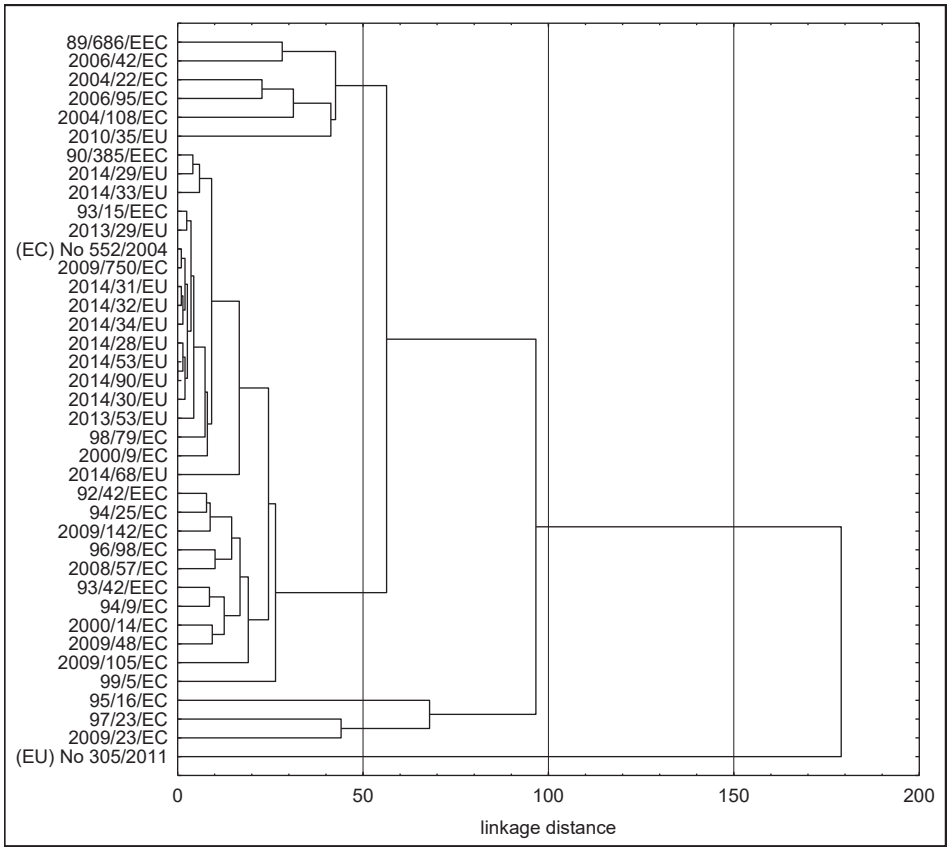

Figure 1. Tree diagram for legislations

Source: own study based on calculations in Statistica 10.

Table 3

Clusters within legislations

Number	Legislations
2	89/686/EEC, 2006/42/EC, 2004/22/EC, 2006/95/EC, 2004/108/EC, 2010/35/EU (6 elements)
5	90/385/EEC, 2014/29/EU, 2014/33/EU, 93/15/EEC, 2013/29/EU, (EC) No 552/2004, 2009/750/EC, 2014/31/EU, 2014/32/EU, 2014/34/EC, 2014/28/EU, 2014/53/EU, 2014/90/EU, 2014/30/EU, 2013/53/EU, 98/79/EC, 2000/9/EC, 2014/68/EU (18 elements)
4	92/42/EEC, 94/25/EC, 2009/142/EC, 96/98/EC, 2008/57/EC, 93/42/EEC, 94/9/EC, 2000/14/EC, 2009/48/EC, 2009/105/EC, 99/5/EC (11 elements)
3	95/16/EC, 97/23/EC, 2009/23/EC (3 elements)
1	(EU) No 305/2011 (1 element)

Source: own study based on calculations in Statistica 10.

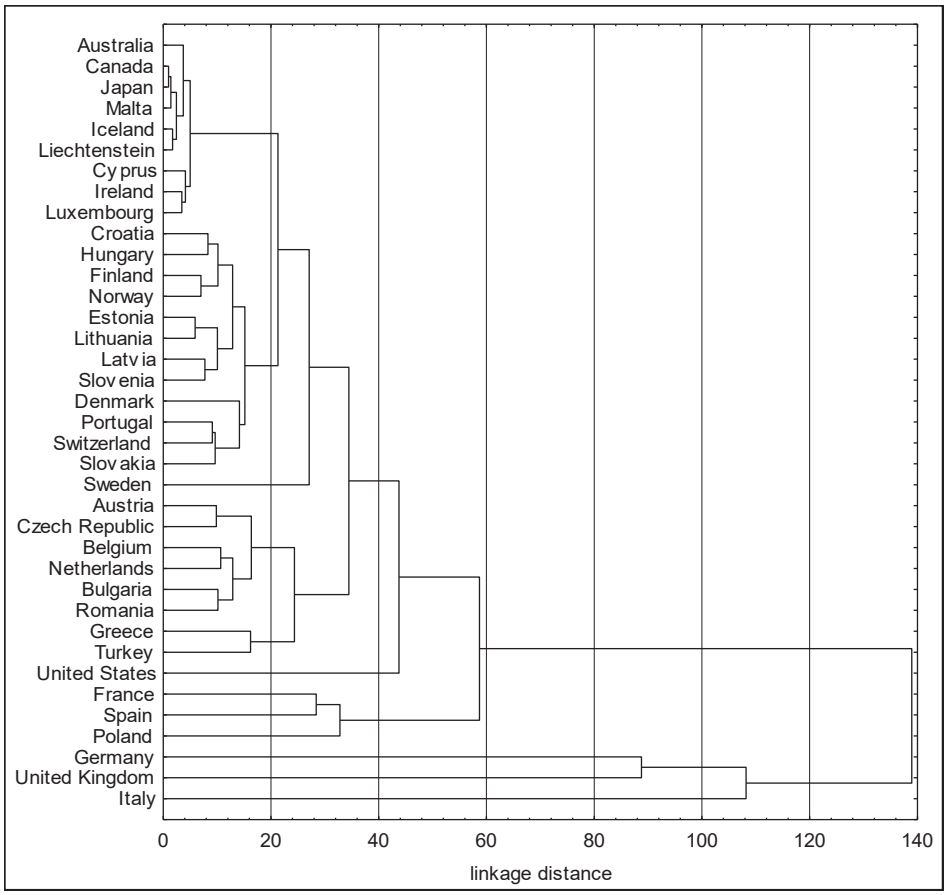

Figure 2. Tree diagram for countries

Source: own study based on calculations in Statistica 10.

Table 4

Clusters within countries

Number	Countries
8	Australia, Canada, Japan, Malta, Iceland, Liechtenstein, Cyprus, Ireland, Luxemburg, (Estonia) (10 elements)
7	Croatia, Hungary, Finland, Norway, Lithuania, Latvia, Slovenia, Denmark, Portugal, Switzerland, Slovakia, (Greece) (12 elements)
2	Sweden (1 element)
6	Austria, Czech Republic, Belgium, Netherlands, Bulgaria, Romania, Turkey (7 elements)
9	United States (1 element)
3	France, Spain, Poland (3 elements)
1	Germany (1 element)
4	United Kingdom (1 element)
5	Italy (1 element)

Source: own study based on calculations in Statistica 10.

Non-EU and small EU countries (see fig. 2 and tab. 4) created one cluster (number 8) and mostly middle EU countries created two clusters (7 and 6). Three EU countries, i.e. France, Spain and Poland formed one cluster (3). Thus, in each of these four clusters the similar legislations and their numbers have been notified. There were also five single clusters, created by the EU countries with the largest number of notifications (see tab. 2), i.e. Germany (1), United Kingdom (4) and Italy (5), but also by other countries, i.e. Sweden (2) and United States (9). The creation of single clusters indicated that the notifications within the legislations from these five countries must have been varied.

Conclusions

The division into clusters within the legislations and countries depended on the number of notifications (and in the case of the legislations – additionally on similar types of products / risks). The legislation or country, which is in the middle of a particular cluster was generally more characteristic for it. The greater number of clusters in the case of the countries indicated that diversification of notifications from the countries was much higher than within legislations.

The legislation related to construction products – (EU) No 305/2011 and the countries: Germany, United Kingdom and Italy with a big number of notifications have created the single clusters. The separate cluster has been also created by other three EU countries (France, Spain and Poland). It leads indirectly to intensification of differences in the economic development (within technical harmonization) of the smaller and middle/big EU countries. The smaller countries are that way made dependent on the bigger ones within free movement of goods.

However, amending the former or issuing the new legislations (particularly in 2014) must be linked with globalization and importing of goods. In the last years in the RAPEX (Rapid Alert System for dangerous non-food products) the number of dangerous products for consumers, particularly originated from China indeed has been still increasing. In order to limit this problem there is a need not only for cooperation among the EU countries but also a need to support the smaller EU countries in developing the bodies, which assess the conformity with the new approach legislations. Particular attention should be paid to those products (covering by the new approach), which are frequently notified in the RAPEX: toys, electrical appliances and equipment (and also lighting equipment), protective equipment and pyrotechnic articles – see (European Commission, 2015).

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Akty prawne i kraje funkcjonujące w ramach nowego podejścia do harmonizacji technicznej i normalizacji jako aspekt bezpieczeństwa konsumenta

Słowa kluczowe: Unia Europejska, nowe podejście, akty prawne, analiza skupień

Streszczenie. W 1985 roku wydano Rezolucję Rady w sprawie nowego podejścia do harmonizacji technicznej i normalizacji. Na podstawie Rezolucji wydawane są akty prawne, obowiązujące głównie w krajach Unii Europejskiej (UE) i szerzej Europejskiego Obszaru Gospodarczego (EOG). Zawierają one wymaganie zasadnicze dla produktów wprowadzanych na rynek unijny. Jednostki notyfikowane zajmują się oceną zgodności z tymi wymaganiami. Celem artykułu było zbadanie, czy i które notyfikacje (jednostek notyfikowanych) związane z aktami prawnym i krajami (lub grupami aktów prawnych i krajów) miały dominujący wpływ na kształtowanie zapewnienia bezpieczeństwa konsumenta. Obliczeń dokonano w programie Statistica 10 z wykorzystaniem analizy skupień. Stwierdzono, że podział na skupienia w ramach aktów prawnych i krajów zależy od liczby notyfikacji (a w przypadku aktów prawnych – dodatkowo od podobnych typów produktów/ryzyk). Akty prawne i kraje z dużą liczbą notyfikacji utworzyły oddzielne (lub nawet pojedyncze) skupienia. Nowelizowanie wcześniejszych lub wydawanie nowych aktów prawnych powinno być powiązane z rozwijaniem możliwości oceny produktów przez jednostki notyfikowane z mniejszych krajów UE. W procesie tym powinno się także zwracać uwagę na produkty często zgłaszane w systemie RAPEX (Systemie szybkiego powiadamiania o niebezpiecznych produktach nieżywnościowych).

Translated by Marcin Pigłowski

Cytowanie

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