Position Paper

ANEC position on EC proposal to align nine directives with New Legislative Framework (NLF)

March 2012

ANEC-SC-2012-G-008

European Association for the Co-ordination of Consumer Representation in Standardisation
Av. de Tervueren 32, box 27 – B-1040 Brussels, Belgium - phone +32-2-743 24 70 - fax +32-2-706 54 30, e-mail: anec@anec.eu - internet: www.anec.eu

List of contents

1. Executive Summary

Many consumers believe market surveillance in Europe will protect them from buying unsafe or dangerous products. But that is not true. Unfortunately, still too many unsafe products reach the European market, as can be seen from the RAPEX notifications to the European Commission[1].

Market surveillance also means different things in different countries. Product safety may not be defined by central government as a priority, as was the case in the United Kingdom only a few years ago. These differences are important as market surveillance is the responsibility of Member States in Europe. It does not operate in a regulatory European framework. The individual Member States are responsible for resourcing and managing their own market surveillance programme and enforcement authorities. That is the problem.

With proper implementation, ANEC believes that the New Legislative Framework (NLF)[2] provides the potential to achieve a real improvement for both the safety of consumers and the competitiveness of the European industry.

However, as demonstrated by the recent scandal of PIP breast implants, European safety legislation, based on the principles of the "New Approach" and CE Marking, still fails to provide consumers with the high safety levels they are entitled to expect. Even when CE Marking is underpinned by the independent assessment of a notified body, such as in the case of breast implants, it cannot be a guarantee of a legal product (let alone a safe product) due to the variations in the quality of notified bodies. Once more, ANEC must repeat its serious reservations about CE Marking, as CE Marking is often perceived as a safety mark. We encourage the European Institutions, now considering a strengthening of market surveillance in line with our calls for a European framework, to expedite their efforts to achieve a more effective system of surveillance and enforcement[3].

This is why we believe European legislators should take the opportunity provided by alignment of several New Approach Directives with the New Legislative Framework to ramp up the effectiveness of market surveillance.

Although we understand it has been decided to undertake only a "technical recast" of the Directives, in line with the Impact Assessment made by the Commission, we believe this "technical recast" is a missed opportunity, as more ambitious and effective changes are needed to achieve the intent of the legislative modifications.

[1] http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm
[2] Regulation (EC)765/2008 and Decision 2008/768/EC of 13 July 2008
[3] ANEC press release for International Consumer Day "Cashing in the consumer protection dividend", 15 March 2012 (ANEC-PR-2012-PRL-002)

2. General Comments

2.1 Improvements

ANEC acknowledges that the New Legislative Framework brings several positive provisions, such as the inclusion of distributors within the economic operators obliged to ensure the safety of the products sold. This is of particular importance for consumer products, such as domestic appliances, which are now almost entirely imported from outside the EU. The NLF attempts to put in place controls on product conformity throughout the whole supply and distribution chain.

We also welcome the clarification and harmonisation of terminology, and the more stringent rules on accreditation of Notified Bodies. The reliability and high quality of the conformity assessment activities carried out by notified bodies are elements that have been missing until now.

2.2. Suggestions for further improvement

If the aims of the Directives and New Legislative Framework is to ensure a high level of protection of public interests - in particular public health & safety and consumer protection - and reduce the number of non-compliant products – unsafe products above all - then providing market surveillance authorities with an effective cooperation mechanism to ensure a common approach to non-compliant products is simply not enough.

The concept of “intended use”

Among other issues, the concept of safe use of a product is a key element of any legislation aimed at ensuring the safety of consumers. From the point of view of a consumer, and especially vulnerable consumers, the concept of the “intended use” of a product does not correspond with real-life situations and neglects expectations of consumers in modern society. However, apart from the General Product Safety Directive[4] and the Toys Directive[5], the other consumer-relevant product safety pieces of legislation do refer to the concept of “intended use”.

ANEC thinks that consumers can be effectively protected only if their (foreseeable) behaviour is duly taken into account by manufacturers when designing products. If manufacturers are allowed to rely on the concept of “intended use” of the product as laid down in the instructions for use, consumers who are too young to read or cannot read, are at a higher risk of being exposed to harm or injury.

Hence, as far as consumer products are concerned, we call for the safety concepts of the Lifts Directive[6] and Low Voltage Directive[7] to be aligned with those of the

[4] Directive 2001/95/EC
[5] Directive 2009/048
[6] Directive 95/16/EC
[7] Directive 2006/95/EC

General Product Safety Directive ("foreseeable use"). For more details, see below under specific comments.

"Formal objection" to a harmonized standard

ANEC also wonders about the European Commission choice not to align the relevant directives with the NLF provisions on "formal objection' to a harmonised standard[8]. We take note of the Commission's explanation about the reference to the provisions on harmonised standards, and objection to harmonised standards, contained in the Commission proposal for a Regulation on European Standardisation published on 1 June 2011 and currently being discussed by the European Parliament and Council[9]. Nevertheless, we find it curious, and of a little concern, that reference is made to the provisions of future legislation still under discussion when there is an identical provision in another legal text.

Resourcing of market surveillance activities

Although the New Legislative Framework addresses the resourcing of surveillance activities for the first time, it still leaves responsibility to the Member States. ANEC fears such obligations will not achieve a consistent approach in all European countries. Nor will the funding needed be ensured as it is issues such as health, education and the economy that win national elections, especially in current times of economic and financial crisis. Not a commitment to better market surveillance[10].

In the face of the increasing complexity of enforcing EU legislation, ANEC calls on Member States and the European Commission to allocate significant resources to market surveillance and to increase their co-ordination efforts, so as to ensure that the *acquis communautaire* of the Single Market is preserved and strengthened to the benefit of consumers and responsible manufacturers. We believe this key in the year that sees the 20th anniversary of the Single Market.

Need for a pan-European market surveillance framework

Europe can have the best legislation. Europe can have the best standards. But without enforcement, both become worthless. Market surveillance is too important to be left to national governments to fund and manage. It is why ANEC calls on the institutions to create a framework to ensure that surveillance activities across Europe are both coherent and adequately funded. And we ask that the market

[8] Art. 9 of Decision 768/2008 on a common framework for the marketing of products

[9] Proposal for a Regulation of the European Parliament and of the Council on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council. COM(2011) 315 final

[10] ICPHSO – 18 November 2008 , Stakeholder Perspectives on Emerging Issues , Intervention by Stephen Russell, ANEC Secretary General

enforcement authorities be granted the powers to ensure the importers of illegal and dangerous products into the Single Market are stopped and punished[11].

Other changes

Finally, we also propose other changes, as explained in the following sections of this paper, for two directives in particular: the Lifts Directive and the Low Voltage Directive. These cover many products consumers use every day, such as ovens, lamps and lifts. Our position is based on our contributions to the public consultation held by the European Commission in 2010 on the alignment exercise[12].

[11] Joint ANEC/ORGALIME position paper "Call for an effective pan-European market surveillance system", (ANEC-SC-2009-G-014)

[12] ANEC response to the public consultation of the European Commission on the New Legislative Framework for the marketing of products: proposal to align 10 product harmonisation directives to Decision 768/2008: Low Voltage Directive – 2006/95/EEC (ANEC-DOMAP-2010-G-031); ANEC response to EC public consultation on NLF alignment of Lifts Directive (95/16/EC), July 2010 (ANEC-DFA-2010-G-044)

3. Specific comments on the alignment of the Lifts Directive with the NLF[13]

Concept of safe use

The concept of safe use of a product is a key element of any legislation aiming at ensuring the safety of consumers. From the point of view of a consumer, and especially vulnerable consumers, the concept of “intended use” of a product does not correspond with real-life situations and neglects the expectations of consumers in modern society. However, apart from the General Product Safety Directive and the Toys Directive, the other consumer relevant product safety pieces of legislation do refer to the concept of “intended use”.

ANEC calls for alignment of the safety concept of the Lifts Directive with the concept formulated in Article 2b) of the General Product Safety Directive (GPSD) 2001/95: "Safe product" shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

- The characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- The effect on other products, where it is reasonably foreseeable that it will be used with other products;
- 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;
- The categories of consumers at risk when using the product, in particular children and the elderly. 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".

ANEC thinks that consumers can be effectively protected only if their (foreseeable) behaviour is duly taken into account by manufacturers when designing products. If manufacturers are allowed to rely on the concept of “intended use” of the product as laid down in the instruction for use, consumers who are too young to read or cannot read, are at a higher risk of being exposed to harm or injury.

This is even recognized by Article 16.2 of Regulation 765/2008, where reference is made to “products covered by Community harmonisation legislation which, when

[13] 2011/0345(COD)

used in accordance to their intended purpose *or under the conditions which can be reasonably foreseen* and when properly installed and maintained". We propose this wording be used in the recast Lifts Directive[14].

Notified bodies

Notified bodies have a very important role in guaranteeing the safety of products on the market and thus ensuring the protection of consumers. It is essential that they work in a competent and independent manner. However, the way their competence is assessed varies among Member States. For the lifts sector, for example, five complaints were introduced against Notified Bodies between 2009 and 2010[15].

Due to national differences, it is not clear how the competence of notified bodies is assessed. ANEC welcomes the introduction by the NLF Regulation of European-wide rules on the operation of accreditation and a peer-evaluation system. However, it does not make accreditation mandatory, which we regret as it will not create a true level playing-field for Notified Bodies.

Instructions for use

ANEC believes that having sufficient and adequate knowledge about the safety of products is a vital consumer need. Information must be reliable, understandable and transparent.

Hence we think that instructions for the use of lifts need to be articulated in the official language of the country, as well as a popular language[16]. This is of utmost importance for instructions about the use of lifts in case of fire or other emergency situations.

Implementation of Harmonised Standards

According to the present version of Articles 1.2 and 1.6.1 of Annex 1 (EHSRs) of Lifts Directive[17], lifts cars "must be designed and constructed in such a way that its structural features do not obstruct or impede access and use by disabled persons and so as to allow any appropriate adjustments intended to facilitate its use by them" and "the controls of lifts intended for use by unaccompanied disabled persons must be designed and located accordingly".

EN 81-70 "Accessibility to lifts for persons including persons with disability", a harmonised standard under the Lifts Directive, states that "This European Standard specifies the minimum requirements for the safe and independent access and use of

[14] Art. 4 EC proposal for recast Directive 95/16/EC
[15] 68% of notified bodies replying to the public consultation on the alignment package stated that there are problems with the quality of services of notified bodies. This view was shared by 84% of economic operators which use the services of notified bodies and 53% of public authorities.
[16] Annex 1, art. 6 EC proposal for recast Directive 95/16/EC
[17] Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts

lifts by persons, including persons with the disabilities mentioned in annex B, Table B.1." According to Clause 0.2, National Building regulations may supersede the requirements of EN81-70.

ANEC must express concern as it seems the application of EN 81-70 varies across Europe, despite it being a harmonised standard. This results in different conditions of safe access for people with disabilities. ANEC already expressed its concerns to CEN/TC 10 "Lifts" which decided to start the revision of the standards. However, we believe the alignment of the Lifts Directive with the NLF should provide an occasion for the strengthening of the provisions on the application of harmonized standards. Considering that one of the aims of the NLF is to strengthen market surveillance in the EU, we call for the implementation of Article R31 of Decision 768/2008 (on a common framework for the marketing of products) to tackle the implementation of harmonized standards and their relationship with (national) building codes and regulations as far as accessibility is concerned.

Formal objection to Harmonised Standards

ANEC wonders why Article R.9 of Decision 768/2008 (on a common framework for the marketing of products) has not been incorporated in the recast Lifts Directive. We take note of the European Commission's explanation about the reference to the provisions on harmonised standards, and objection to harmonised standards, cited in the Commission's proposal for a Regulation on European Standardisation, published on 1 June 2011 and now being discussed by the European Parliament and Council. We note that the reason behind this reference is one of legal certainty. Nevertheless we find curious, and a little worrying, that reference is made to the provisions of future legislation still under discussion when there is an identical provision in another legal text (Article R.9 of Decision 768/2008).

Review and reporting by Member States

We think an explicit provision obliging Member States to report on the effectiveness of market surveillance should be introduced.

According to Article 40 of Regulation (EC) No 765/2008, "By 2 September 2013, the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation, of Directive 2001/95/EC and of any other relevant Community instrument addressing market surveillance. That report shall, in particular, analyse the consistency of EU rules in the field of market surveillance (…)".

Of course, we agree this new provision is already directly applicable but we believe that it would be more practical to have also a "vertical" reporting obligation as the system of market surveillance differs across Member States.

4. Specific Comments on the alignment of the Low Voltage Directive (LVD) with the NLF[18]

Concept of safe use

The concept of safe use of a product is a key element of any legislation aiming at ensuring the safety of consumers. From the point of view of a consumer, and especially vulnerable consumers, the concept of “intended use” of a product does not correspond to real-life situations and neglects the expectations of consumers in modern society. However, apart from the General Product Safety Directive and the Toys Directive, the other consumer relevant product safety pieces of legislation do refer to the concept of “intended use”.

ANEC calls for the alignment of the safety concept of the LVD[19] with the concept formulated in Article 2b) of the General Product Safety Directive (GPSD) 2001/95: "Safe product" shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

- The characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- The effect on other products, where it is reasonably foreseeable that it will be used with other products;
- 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;
- The categories of consumers at risk when using the product, in particular children and the elderly. 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".

ANEC urges this alignment contributes to a single safety concept for all consumer products. We believe consumer products falling within the scope of the LVD should not follow a different safety philosophy from other consumer products. Why are consumers better protected when they use furniture than when they use electrical household equipment? In this respect, European product safety law has been incoherent to date. ANEC believes it is essential the LVD addresses this point.

[18] 2011/0347(COD)
[19] Art. 3 EC proposal revision Directive 2006/95/EC

This is now recognized by Article 16.2 of Regulation 765/2008, where reference is made to "products covered by Community harmonisation legislation which, when used in accordance to their intended purpose *or under the conditions which can be reasonably foreseen* and when properly installed and maintained". We suggest this wording be used in the recast LVD.

Formal objection to Harmonised Standards

ANEC wonders why Article R.9 of Decision 768/2008 (on a common framework for the marketing of products) has not been incorporated in the recast of the LVD. We take note of the European Commission's explanation about the reference to the provisions on harmonised standards, and objection to harmonised standards, contained in the Commission proposal for a Regulation on European Standardisation published on 1 June 2011 and now being discussed by the European Parliament and Council. W note the reason behind this reference is to achieve legal certainty. Nevertheless, we find it curious, and a little worrying, for reference to be made to the provisions of future legislation when there is an identical provision in another legal text (Article R.9 of Decision 768/2008).

This is particularly important for the LVD as, at present, it does not provide for a system of substantive pre-market control of harmonised standards with respect to their conformity to the essential safety requirements. The safeguard procedure[20] is product-oriented, not standards-oriented. Even if a product turns out to be unsafe due to a shortcoming in a harmonised standard, the safeguard procedure has consequences only for the product, which can be withdrawn from the market, not for the standard or the presumption of conformity that remains in place. ANEC is of the view the LVD should provide for a system to review and challenge harmonised standards.

Obligations of manufacturers and distributors

ANEC welcomes the inclusion of distributors in the economic operators obliged to ensure the safety of the products sold. This is of particular importance for consumer products, such as domestic electrical appliances, which are now almost entirely imported into the EU.

As consumers are buying more and more products over the Internet, we think that a new provision on Internet sales should be introduced. We must raise our concerns also about the protection of consumers when purchasing household appliances directly from manufacturers or importers using the Internet. Manufacturers and distributors should ensure all relevant information displayed on the package (e.g. instructions for use, warnings, voltage limits) is available to the buyer prior to the purchase, irrespective of the selling technique, including distance selling (eg: e-commerce).

[20] Art. 20 EC proposal revision Directive 2006/95/EC

In addition, we believe this would also benefit market surveillance authorities (so called "Desktop market surveillance").

We also suggest that instructions for use of household appliances need to be drawn up in the official language of the country, as well as another popular language. ANEC believes having sufficient and adequate knowledge about the safety of products is a vital consumer need. Information must be reliable, understandable and transparent[21].

Conformity assessment

ANEC is rather surprised, and a little bit worried, at the reading of Recitals 6 and 7 on conformity assessment as they seem to imply that manufacturers alone are technically competent enough and obliged to carry on the conformity assessment of the safety of their products.

While recital 7 mentions the possible role of "independent conformity assessment laboratory", it is far from clear to us what this means and to which specific module of conformity assessment it refers to, bearing in mind that Annex III of the EC proposal for the LVD recast only deals with Module A ("Manufacturer Declaration of Conformity"). ANEC calls the legislators to urgently clarify this point and consequently reword recitals 6 and 7.

General principles of the CE marking

In general, ANEC reiterates its concerns regarding CE Marking, which consumers often wrongly believe to be a safety label while it is not address to them but to market surveillance authorities.

Delegated acts and implementing acts

ANEC is wondering about the role of the present LVD Working Party within the new provisions on the European Commission delegated powers. We take note about those new provisions ("new Comitology under Lisbon treaty"[22]) as well as the relevant provisions of the Commission proposal for a Regulation on European Standardisation published on 1 June 2011 and now being discussed by the European Parliament and Council. Once more, as done for the issue of Formal Objection, we wonder how the above legal basis will interplay with the recast of the LVD. In particular, we wonder whether one of the aims of the alignment with the NLF is not to insert in all directives similar provisions on the exercise by the European Commission of its delegated powers and the corresponding role of Experts Groups[23].

[21] Art. 6 EC proposal revision Directive 2006/95/EC
[22] Art. 290, 291 of TFEU
[23] C(2010)7649 final

Review and reporting by Member States

We think explicit provision obliging Member States to reporting on the effectiveness of market surveillance should be introduced.

According to Article 40 of Regulation (EC) No 765/2008, "By 2 September 2013, the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation, of Directive 2001/95/EC and of any other relevant Community instrument addressing market surveillance. That report shall, in particular, analyse the consistency of Community rules in the field of market surveillance (…)".

Of course, we agree this new provision is already directly applicable but we believe that it would be more practical to have also a "vertical" reporting obligation as the system of market surveillance varies across Member States.

In addition, bearing in mind the alarming low level of compliance to the legislative requirements of the directive, including safety aspects, a monitoring and evaluation of the level of compliance with the new provisions seems more then justified.

Acknowledgements

This position paper has been prepared in consultation with the ANEC membership.

ANEC wishes to thank those who have actively contributed to the drafting of this position paper.

APPENDIX – About ANEC and other documentation

A.1 About ANEC

ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and conformity assessment as well as related legislation and public policies. ANEC was established in 1995 as an international non-profit association under Belgian law and represents consumer organisations from 31 European countries. ANEC is funded by the European Union and EFTA, with national consumer organisations contributing in kind. Its Secretariat is based in Brussels.

ANEC has signed the European Commission's Register of Interest Representatives and accepted its Code of Conduct: Identification Number 507800799-30.

A.2 Contact person at the ANEC Secretariat

Chiara Giovannini, Senior Manager, Policy & Innovation

More information about ANEC and its activities is available at www.anec.eu

Should you have any problems in accessing the documentation, please contact the ANEC Secretariat.

☎ +32/2-743 24 70
+32/2-706 54 30
anec@anec.eu
Avenue de Tervueren 32, box 27 – BE-1040 Brussels, Belgium