



20 January 2009

RESPONSE TO THE REQUEST FOR INFORMATION BY THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION CONCERNING SUPPLIER'S DECLARATION OF CONFORMITY

INTRODUCTION

BUSINESSEUROPE, the Confederation of European Business, represents more than 20 million small, medium and large companies. It has as its members 40 central industrial and employers' federations from 34 countries, working together to achieve growth and competitiveness in Europe.

The EU-US trade and investment relationship is the largest in the world. EU investment stocks in the US stand at €934 billion. Investment from the US is worth €953 billion to the European economy. Combined trade flows are worth almost €350 billion annually. This unprecedented level of engagement means that EU and US companies are deeply impacted, not only by governmental measures taken at the border – tariffs, customs procedures etc. – but also by regulations, standards and conformity assessment procedures that are focused on the domestic market.

Companies believe in the need for regulators to be vigilant to fight health, safety and environmental risks to their citizens. They are themselves also committed to the highest standards in this regard. Regulation can achieve these objectives without creating barriers to trade, however. To do so it must adhere to better regulation principles of proportionality, transparency and prior impact assessment. It is in this light that BUSINESSEUROPE strongly supports the work of the Transatlantic Economic Council (TEC), which seeks to ensure that regulatory measures on either side of the Atlantic facilitate trade and investment, while achieving their objectives.

BUSINESSEUROPE is very pleased that the work of the TEC has resulted in a request for information (RFI) regarding supplier's declaration of conformity (SDoC) for electrical equipment by the Occupational Safety and Health Administration (OSHA). European companies have long expressed concern about the burdensome and restrictive nature of conformity assessment procedures in the United States for these products and this step forward is an example of how the TEC is delivering progress on issues of concern to companies. This should be applauded.

For this step to have a measurable positive impact on companies' business, however, it is important that OSHA take the next step. BUSINESSEUROPE believes that this consultation should result in concrete moves to reform the third-party testing regime for electrical equipment by moving to a system that is more efficient and open, while guaranteeing the same level of safety for workers and citizens. BUSINESSEUROPE believes that an SDoC approach such as that in place in the European Union for the same electrical products offers such a system.

1. THE EUROPEAN SYSTEM

Product conformity is a number one concern for companies. Manufacturers want to stay in business on a long-term basis and want to produce safe products. Placing unsafe or non-compliant products on the market spells disaster for companies' brand values.

It must be noted however, that there are 'willing' market players and market players who are 'unwilling' and evade the rules. In order to fight rogue market players and counterfeited goods, governments, independent of the conformity assessment rules they put into place, need to have a system to detect non-compliant products and take appropriate action against those who deliberately choose to bypass the rules. As explained in more detail in point four, we consider it of paramount importance to have a robust market surveillance infrastructure in place.

BUSINESSEUROPE has always been supportive of the EU's New Approach method of product legislation, which was developed in 1985. The New Approach restricts product legislation to essential requirements and gives manufacturers the flexibility to meet these, often through the application of voluntary harmonised European standards. These standards are frequently based on international standards, thereby facilitating trade across the world. BUSINESSEUROPE believes that the New Approach is the most efficient and effective way to ensure a common, high level of safety, health and environmental protection together with a level playing field for industrial and consumer products. Most products covered by this legislation have to show the CE marking, which represents a declaration by the manufacturer that the product is in conformity with the requirements of the relevant European directives and is thus, by implication, safe.

In addition to standards, reliable conformity assessment is part of the New Approach. Depending on the risk level, the conformity assessment regime under EU legislation is based on manufacturers' internal design and production control activities and/or third-party examinations by conformity assessment bodies, which are appointed by the authorities on the basis of harmonised criteria.

BUSINESSEUROPE believes that the New Approach has been instrumental in opening up the Single Market and continues to enable quick and safe introductions of new products.

The New Approach has recently been modernised to further improve its effectiveness. In this context, BUSINESSEUROPE welcomed the EU's New Legal Framework, adopted on 23 June 2008, which consists of a regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products and a decision on a common framework for the marketing of products. BUSINESSEUROPE supports the EU's efforts to enhance the confidence in and quality of conformity assessment of products through reinforced and clearer rules on the requirements for notification of conformity assessment bodies. This includes the increased use of accreditation, which ensures that these bodies provide the high quality services that manufacturers, consumers and public authorities need.

With regard to the Low Voltage Directive (LVD), BUSINESSEUROPE supports the EU's view that a type approval regime for products falling under its scope (implying mandatory third-party testing as is the case in OSHA's Nationally Recognised Testing Laboratories programme) is not necessary to manage the risk that non-compliant and potentially dangerous electrical products enter the market. A type approval regime would not increase user safety for these products. The application of SDoC in this case is proportionate to the risk involved and builds on the responsibilities of manufacturers, their liability and consumer protection legislation. Rather than burdening well-intentioned manufacturers with unnecessary third-party certification requirements, attention should focus on tackling the 'unwilling' players on the market through effective market surveillance.

2. ECONOMIC BENEFITS OF SDoC

Although BUSINESSEUROPE has access only to limited formal documentation on the economic benefits of the supplier's declaration of conformity, anecdotal information from companies, reports from international organisations such as the OECD and ongoing in-depth discussions at the WTO suggest that there is widespread interest in SDoC and strong arguments for its use.

In response to questions VI.29, VI.30, VI.35, VI.36 and VI.37 in OSHA's RFI, BUSINESSEUROPE believes that the use of SDoC has two key economic benefits:

1) Lower approval costs

If manufacturers do not have to use third-party certification, they do not need to pay for third-party testing. Depending on the products, this can cost a considerable amount of money. One example, provided by a BUSINESSEUROPE member company, showed that for a new model of a high-end TV set, costs can reach up to €25,000 per tested model. In highly competitive markets, this adds markedly to the total design cost.

2) Faster time to market

With the SDoC system, where testing happens in-house, manufacturers can start the testing earlier in the design process than is possible when third-party testing is obligatory. Testing can be performed in parallel with the design of the product, saving valuable time and allowing for a timely introduction of the product onto the market.

Time to market is vital for consumer-oriented businesses and can make or break the company's ability to make a profit on or even recoup its investment in a given product. This is partly to do with consumer sales being highly seasonal. For instance, conformity assessors operating under mandatory procedures may not be sensitive to obvious business needs such as having a particular new technology on the market in time for a specific event. It also relates to the fact that some goods, such as electronics for instance, have a short life cycle.

It is important to note that businesses do occasionally opt voluntarily for third-party testing in certain cases. Smaller businesses may not have the necessary in-house

testing facilities and therefore rely on the certification to assess compliance. Larger companies have a tendency to do more in-house certification, even though they may also get third-party certification in certain circumstances. However, it is our firm belief that this should remain voluntary. Experience shows that, once third-party testing becomes mandatory, long red-tape-related delays may result. For example, companies have noted that the conformity assessor may feel less competitive pressure resulting in reduced quality of customer service.

3. SAFETY IS NOT COMPROMISED WITH SDoC

BUSINESSEUROPE believes that the European system guarantees a high level of safety for its citizens. The LVD, which has been comprehensively discussed by EU legislators, obliges EU Member States to ensure that only safe electrical equipment is placed on the market. The system has been further improved by the New Legal Framework, as outlined in section one.

Questions IV.1 to IV.4 of the RFI seek details and data related to the safety of an SDoC system. BUSINESSEUROPE is a horizontal organisation representing a broad spectrum of business interests. We are therefore not in a position to collect detailed statistical data of the type requested relating to a specific sector. Furthermore, having extensively consulted the European Commission and member companies on this issue, it would seem that statistical data correlating incidents with non-compliance do not, in fact, exist at this time.

Nevertheless, we feel it useful to highlight the following to support the case for OSHA to reform the current rules for electrical products and accept Europe's SDoC system:

As highlighted in BUSINESSEUROPE's previous submission to OSHA on the subject, some data are available regarding incident statistics featuring electrical fatal accidents in the USA vs. Germany from the 1970s to the mid 1990s. These data show that there has been a continuous decrease in the number of fatal accidents over this period (see Annex). Furthermore, this decrease has been sharper in Germany, where SDoC was applied, than in the USA, which demonstrates at the very least that third-party certification in this case did not lead to higher levels of safety.

Regarding the fatalities caused by non-compliance, we have been able to identify only one such case, relating to a steam iron used in Greece in 2005¹. This product had been certified by a third party, but later modified during production. This case further demonstrates that third-party certification is not a panacea for safety.

It is, furthermore, imperative to highlight that stricter legal and certification requirements do not solve the problem of rogue traders and counterfeit products but in fact put unnecessary burdens on well-intentioned manufacturers.

¹ The case is reported in the Commission's "Weekly overview of RAPEX Notifications, Week 17 – 2005" The reference number is 2, 203/05. Available online at: http://ec.europa.eu/consumers/dyna/rapex/create_rapex.cfm?rx_id=17.

In this context, a European Commission impact assessment contains some information on the nature of products that are notified under the safeguard clause provision of the LVD, under which Member States' authorities must notify their counterparts of any products removed from the market. The data shows that out of the 418 notifications received in 2005 under the LVD, approximately 50% of products bore a third-party certification mark but that, unfortunately all too often, these marks proved to be counterfeit.²

On the basis of this information it seems clear that third-party testing does not provide improved safety and so is therefore no better than the SDoC system.

4. MARKET SURVEILLANCE IS KEY

Efficient and effective conformity assessment procedures are only one part of ensuring product safety in any regime. Market surveillance - policing of this compliance by state authorities - is also vital.

OSHA has raised, in the RFI, some questions (VI.27, VI.28) about the potential cost challenges it would face in implementing a market surveillance system. BUSINESSEUROPE is not in a position to state what the costs to the US government would be of reaching an adequate level of market surveillance. It notes however that OSHA already carries out surveillance of workplace use of products. In addition the Consumer Product Safety Commission (CPSC) carries out market surveillance that includes product recalls on products which have a consumer use, including many items covered by the current Nationally Recognised Testing Laboratories (NRTL) system. Reliance on some of this work – and enhanced cooperation with CPSC in general - would certainly reduce potential costs in any new OSHA system. It should also be noted that a mechanism to allow consumer/user reporting of problems with products is a core element of any market surveillance system and does not require a large number of staff to maintain. Finally, the costs of a market surveillance system should be offset against the potential overall economic gains to society of a more efficient, less burdensome and more open regime.

OSHA also raises the issue of legal basis for taking market surveillance actions (questions VI.31 and VI.33). Again, it is difficult for BUSINESSEUROPE to make firm statements on matters of the US legal system. We nonetheless note that, as above, OSHA currently has the authority to carry out workplace inspections. This could also be construed to include inspection of products used in the workplace. In addition the CPSC has the authority to carry out product recalls on consumer goods. Given that the overlap between consumer and workplace products is likely very extensive, this could represent a serious approach to solving the problem under existing legal frameworks.

² The impact assessment is entitled: "Accompanying document to the Proposal for a Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and a Decision of the European Parliament and of the Council on a Common Framework for the Marketing of Products". See page 69. Available online at: http://ec.europa.eu/enterprise/regulation/internal_market_package/docs/impact_assessment_sec_2007_0173_en.pdf

As a final point, OSHA has made the assertion that the current US system already includes comprehensive post-market surveillance, carried out by the NRTLs as they seek to safeguard the value of their marks³. BUSINESSEUROPE believes that these activities do not absolve public authorities from their duty to undertake market surveillance themselves as they cannot tackle the most important problem – those actors who willingly seek to avoid compliance. Both NRTL and CE marks can be forged. Under the current US system, NRTLs carry out post-market surveillance on products they certify. However, rogue traders forging NRTL marks are implicitly excluded from this action as NRTLs are naturally unaware that their marks are being used by these actors.

5. CONCLUSION

In response to question VI.20 of the Request for Information, BUSINESSEUROPE believes that the US Occupational Safety and Health Administration should seriously consider adopting supplier's declaration of conformity as an alternative to its current third-party approval requirements as the current US regime for electrical products is not proportionate to the risks that it is managing. The use of Nationally Recognised Testing Laboratories should therefore not be mandatory.

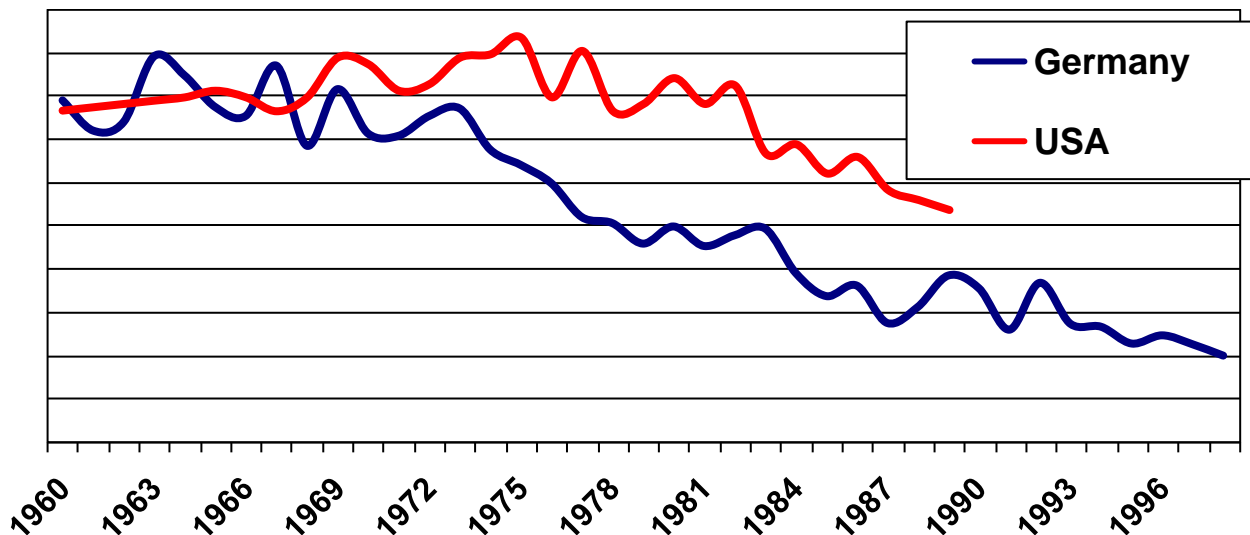
As illustrated in this report, the use of supplier's declaration of conformity would help to reduce unnecessary red tape for business and would by no means compromise today's high level of safety.

BUSINESSEUROPE remains at the Occupational Safety and Health Administration's disposal to clarify any of the statements made in the text or furnish any more detailed documentation requested.

³ Meeting Between OSHA and BUSINESSEUROPE on Supplier's Declaration of Conformity, 24 November 2008, Brussels, Belgium

Annex 1: Improvement of electrical safety since the 1970s

Fatal electrical accidents in the USA (1960-1989) vs. Germany (1960-1998)



Source: Biegelmeier, Dr. Gottfried, *Liber Amicorum – Liber Inimicis*, Stiftung Electroschutz, Vienna, 2000. Quoted in: Nowak, Kurt, "81 tödliche Stromunfälle" (81 fatal incidents in 1998), *Der Elektrotechniker*, 8/2000. Dr. Biegelmeier's work can be obtained at the following web address: <http://www.esf-vienna.at/publikationen.htm>. The graph above shows the relative change in the US and Germany where both start at 100% in 1960.