

To: **Daniel Calleja Crespo,**  
**Director General, DG Enterprise and Industry, European Commission**

To: **Elena Santiago Cid**  
**Director General, CEN-CENELEC**

Milan, 19 April 2013

**Ref : 'SMEs and Standardization' European Conference – 28 May 2013**

Dear Ms Santiago Cid,  
Dear Mr Calleja Crespo,

My name is Alberto Spasciani. My company, Spasciani S.p.a., is an SME founded by my grandfather in 1892 as a manufacturer of Respiratory Protective Devices (RPD). Since November 2012, I am also the President of a newly established European association "SME Safety a.i.s.b.l." that represents the interests of European SME RPD manufacturers.

Besides being an entrepreneur, I am also an engineer and since at least three decades I am actively involved in standardisation at my National Standards Body UNI, as well as at CEN and at ISO.

In this respect, I am a good example of an SME that has voluntarily contributed to standards that have created great advantages to SMEs by setting a well functioning European internal market. The CEN standards on RPD, which give presumption of conformity with the PPE Directive, have harmonized the rules in the different Member States and, thus, contributed to the growth and competitiveness of many SMEs, like mine.

Having said this, my company and many other SMEs have lately experienced a very dangerous situation due to a misuse of standardisation. Despite the success of EN standards, since some years a couple of large global companies have championed the development of new ISO standards with the objective of replacing the existing European standards and allegedly creating a globally harmonized market for the supposed benefit of all manufacturers and consumers. It may be worth underlining that those companies are both non-European. I have followed very closely this project at ISO and, despite the high costs, I travelled to many meetings around the world in order to give my contributions. However, despite the declared good intentions, the draft ISO standards that are about to be published create huge troubles to SMEs and totally unfair advantages to larger companies.

In fact the new ISO standards differ dramatically from the CEN standards, and they increase the required performance levels to such an extent that the certification costs are expected to be at least 300 % higher than at present. Such increase in testing costs is not at all granted to correspond to a safer workplace and even though, such supposedly high safety levels are completely unjustified with respect to the accidents' rates registered under the CEN standards. This can be easily demonstrated by checking the enclosed tables that show how accidents have decreased over the years all over Europe. On the contrary it is widely accepted that most accidents happen for non-use or misuse of the Personal Protective Equipment. The tables are an excerpt from a presentation that I have repeatedly shown during the meetings of CEN Technical Committee 79 and ISRP (International Society for Respiratory Protection).

What is worse is that, despite clear signals of doubtful adoption of the new ISO standards in other regions of the world (e.g. USA, China, Brazil, etc.), the proponents of the ISO standards have heavily campaigned for the adoption in Europe and, thus, the replacement of the existing harmonised European standards with new EN ISO standards.

To make it simple, should that happen the raise in certification costs would make it impossible for my company and for the large majority of European SMEs to keep manufacturing these products. Not only this would damage European SMEs and consequently employment in the EU, but the dramatic reduction of competing manufacturers would certainly also create a damage to consumers.

I have devoted time and efforts to try to redress this dangerous situation in the last years. I particular, together with other SME representatives I have repeatedly tried to raise the problem within the technical groups at UNI, as well as at CEN and ISO. Despite this I realised that I was unable to change the course of the ISO project, nor to prevent its adoption in Europe. I then asked for help to my Industry Associations, firstly at Italian level and then at European level. I was answered that they could do little for me. I soon realised that those organisations do not only represent SMEs, but also those two large companies that had championed the ISO standards plus some other global players obviously less concerned about the risks that such an event implies.



When I got a refuse from my European Industry Association, I was also told that the only organisation that could perhaps do something on this case was called NORMAPME. I had never before heard about such body but, nevertheless, I decided to contact them at the beginning of 2012 via their website and I asked for help.

The answer I got was positive and, to make the story short, since then NORMAPME decided to help me. With the advice and support of NORMAPME, we convinced other SMEs from Germany, France, Spain, Hungary, Czech Republic and Italy to join our forces. We constituted SME Safety, the new European association of which I am now the President and that cares about the interests of SMEs of my sector in particular with regard to standardisation. Few weeks later in 2012, in view of the upcoming meeting of CEN TC79 where the adoption of ISO standards as EN harmonized norms was to be decided, we were able to mobilize SMEs in different National Standards Bodies. So, we participated in the meeting not being isolated, but being a stronger alliance among different national delegations. In addition to our SMEs, a staff member of NORMAPME was present at the meeting and supported our arguments referring to the recently adopted Standardisation Regulation ((EU) No 1025/2012) and, thus, calling for the conformity to CEN Guide 17 on SME needs. The result of such action was a success. Despite a long and difficult discussion at the meeting, we obtained that the adoption of the ISO standards was postponed by at least 10 years and that they will be checked against the expectations of Guide 17. Obviously this decision has to be supported all along this time period, the risk being a counter-decision that voids all our efforts.

Now, coming back to the SME Conference in ref, as an SME owner and as a standards expert, I am aware of several initiatives in favour of SMEs that have been undertaken by the EC, by CEN and by the NSBs. Firstly, I would like to mention the Standardisation Regulation that insists on the need to ensure the participation of SMEs. Then, I am aware some important initiatives of CEN, like SMEST2 and the SME Toolbox.

Indeed, this is all very important, but in my experience and in that of many other SMEs in my sector, there has been only one thing which is worth remembering. This thing is NORMAPME. Hereby, I can state that without the intervention of NORMAPME, my company and almost all SMEs in Europe would have disappeared or at least stopped manufacturing most of their RPDs.

Now, I am aware of the financial problems that caused the dissolution of NORMAPME. I am also informed that the Commission published a call for proposal and that it will finance a new organisation to do the job that NORMAPME remarkably did. With this letter, I would like to strongly encourage you, CEN and the Commission, to continue your support for an organisation of SMEs, like NORMAPME. I also would like to encourage you to take the opportunity of the SME Conference to inform the audience about the work that NORMAPME did and to encourage SMEs to unite forces and create a new organisation that can continue that important work.

My association SME Safety is highly interested and available to collaborate with you and with such new organisation for SMEs. I will attend the SME Conference on 28 May 2013 and I will be pleased to continue this discussion with you in that occasion.

Yours sincerely,



**Alberto Spasciani**

**President, SPASCIANI S.P.A.**  
**President, SME Safety a.i.s.b.l.**  
**Member of CEN TC 79 and ISO TC94 SC15**

3 annexes



# Improved Safety for Users

## In Europe

Member States	2003	2004	2005	2006	2007	Var, % 2007/ 2003
<b>Spain</b>	6,520	6,054	5,715	5,533	4,691	<b>-28.1</b>
<b>France</b>	4,689	4,434	4,448	4,022	3,975	<b>-15.2</b>
<b>Germany</b>	3,674	3,618	3,233	3,276	3,125	<b>-14.9</b>
<b>Belgium</b>	3,456	3,306	3,167	3,077	3,014	<b>-12.8</b>
<b>Finland</b>	2,847	2,864	3,031	3,008	2,758	<b>-3.1</b>
<b>Italy</b>	3,267	3,098	2,900	2,812	2,674	<b>-18.2</b>
<b>Austria</b>	2,629	2,731	2,564	2,394	2,160	<b>-17.8</b>
<b>UK</b>	1,614	1,336	1,271	1,135	1,085	<b>-32.8</b>
<b>Sweden</b>	1,252	1,148	1,130	1,088	997	<b>-20.4</b>

accidents/  
100,000 workers  
Data from INAIL

Alberto Spasciani



8

# Improved Safety for Users

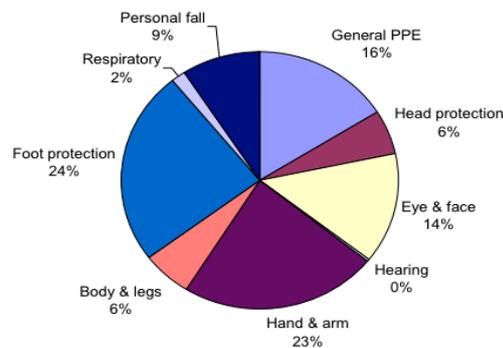


Figure 13 PPE-related accidents classified by PPE category

From "The Bomel Report for HSE UK 2006"

Alberto Spasciani



9



# Improved Safety for Users

## The Bomel Report :

***"In about 60 per cent of the accidents where PPE would have prevented or alleviated the accident, either PPE had been provided but not used or there had been a failure to consider that PPE should be worn for the job in hand. This indicates that people failings rather than equipment failings are the dominant contributor to PPE-related accidents."***

NIOSH web site:  
(Preventing Occupational Fatalities in Confined Spaces)

***"A 22-year-old worker died inside a toluene storage tank that was 10 feet in diameter and 20 feet high while attempting to clean the tank. The worker entered the tank through the 16 inch diameter top opening using a 1/2 inch rope for descent. Although a self-contained breathing apparatus was present, the worker was not wearing it when he entered the tank. The worker was overcome and collapsed onto the floor"***

Alberto Spasciani



10

# Improved Safety for Users

## The Bomel Report :

***"In about 60 per cent of the accidents where PPE would have prevented or alleviated the accident, either PPE had been provided but not used or there had been a failure to consider that PPE should be worn for the job in hand. This indicates that people failings rather than equipment failings are the dominant contributor to PPE-related accidents."***

NIOSH web site:  
(Preventing Occupational Fatalities in Confined Spaces)

***"A 22-year-old worker died inside a toluene storage tank that was 10 feet in diameter and 20 feet high while attempting to clean the tank. The worker entered the tank through the 16 inch diameter top opening using a 1/2 inch rope for descent. Although a self-contained breathing apparatus was present, the worker was not wearing it when he entered the tank. The worker was overcome and collapsed onto the floor"***

Alberto Spasciani



10



# Improved Safety for Users

FF Fatalities FEMA 2009, page 31

***“Both firefighters were equipped with full structural protective clothing and SCBA ... Both were found with their helmets in place, with SCBA regulator attached to the face piece, but the firefighters were not wearing face pieces.”***

Alberto Spasciani



12

