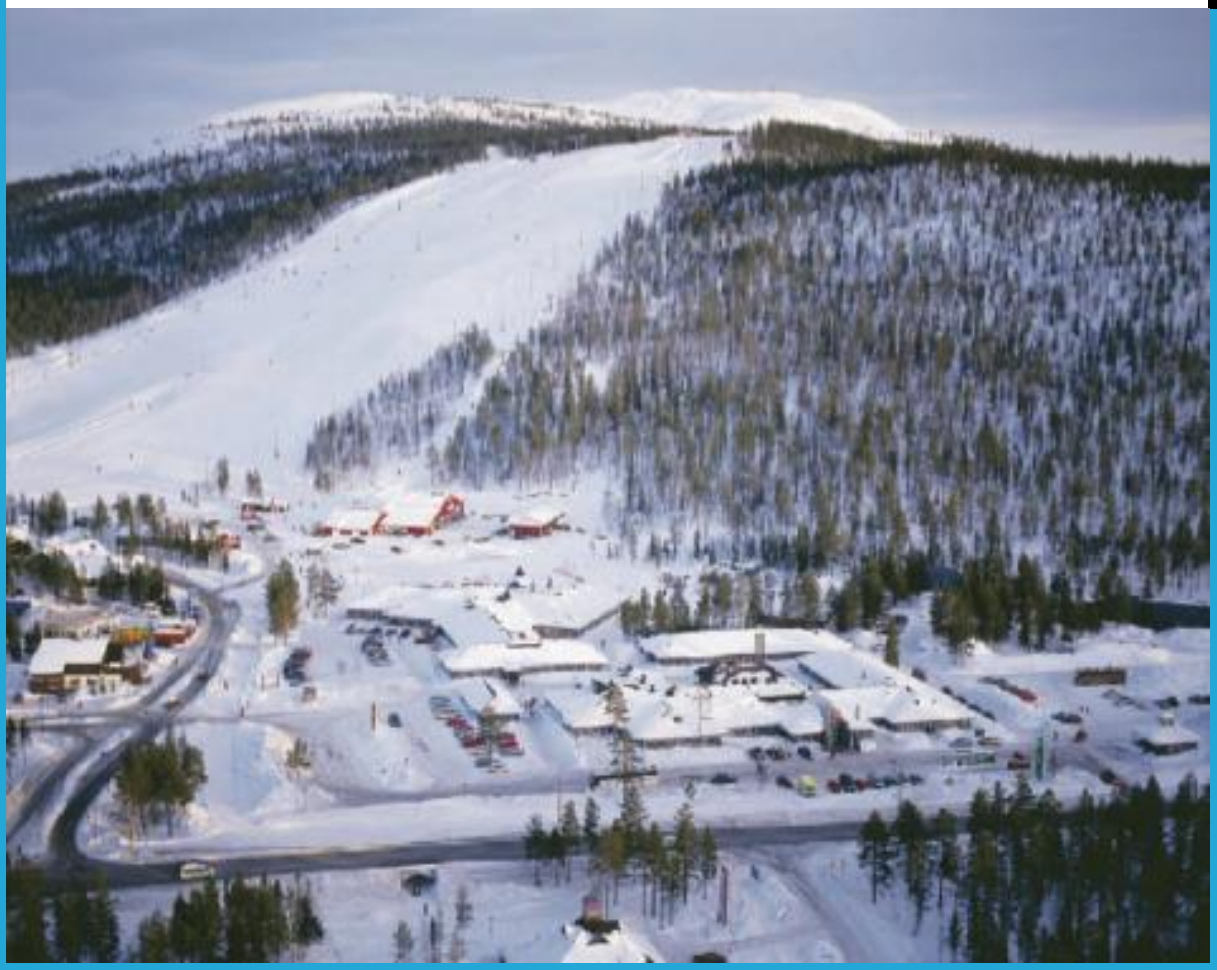
Finnish Institute of Occupational Health

9th EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT

29-31 January 2008
in SPA HOTEL LEVITUNTURI, LEVI, Kittilä, Finland

Seminar Report



WORK ENVIRONMENT RESEARCH REPORT SERIES 38
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SUMMARY

This seminar report publication contains papers presented at the ninth (9) EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT, held in Levi - Kittilä, Finland 29 - 31 January 2008.

The main aim of the PPE seminar was to give relevant information regarding the changes and recommendations for possible PPE solutions. The second aim of the seminar was to bring together European PPE experts dealing with standardization, testing, certification, research, manufacturing, and market surveillance. The seminar provided the opportunity for speakers and participants to exchange experiences and participate in debate.

The Seminar discussed the impact of new developments in European legislation (i.e. New Approach, REACH, noise, vibration, and optical radiation) on the PPE field. The emerging challenges were evaluated by different stakeholders. Practical exercises and demonstrations served to highlight problems related to the real efficiency of PPE. Presentations focused on examples from the field of protection against chemicals, and the role and importance of training, and the participation of all actors.

The seminar consisted of 51 registered participants from 13 countries; Health and Safety Institutes, Notified Bodies, Manufacturers and Consumer Associations. The attendees included research scientists, engineers, apparel manufacturers, and private consultants. In addition, representatives from the European Commission and market surveillance authorities attended the seminar.

The European Seminar on Personal Protective Equipment (PPE) was organized and financially sponsored by the Finnish Institute of Occupational Health and BG BAU Germany.

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Eero Korhonen and Helena Mäkinen, Finnish Institute of Occupational Health,
Alain Mayer, INRS, Rapporteur to CEN BT for PPE Sector
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Jukka Kallio, Safcon Oy

Helsinki, 30 January 2009

Susanna Mäki
Eero Korhonen
Finnish Institute of Occupational Health
Work Environment Development, Protection and Product Safety

CONTENTS

1. Revision of the new approach

Anja Liukko, Ministry of Employment and the Economy, Finland

1.1 A new legislative approach for EU legislation on technical harmonization

1) Commission proposal for a *Regulation*, setting out the requirements for accreditation and market surveillance relating to the marketing of products: COM(2007) 37 final
   - Complementary to existing EU legislation and proposed decision
   - Directly applicable legislation
   - Contents:
     - Organization and operation of accreditation of conformity assessment bodies
     - Framework for market surveillance of products subject to EU technical harmonization
     - Framework for control on products originating from third countries
     - Provisions on CE marking

2) Commission proposal for a *Decision* on a common framework for the marketing of products: COM(2007) 53 final
   - No direct impact on existing EU sectoral legislation
   - Provides a coherent basis for revision or recast of EU sectoral legislation
   - Repeals Decision 93/465/EEC
   - Framework for future and reference text for existing EU legislation on technical harmonization
   - Contents:
     - Definitions
     - Obligations of economic operators
     - CE marking
     - Notification of conformity assessment bodies
     - Safeguard clause procedure
     - Conformity assessment procedures
     - EC declaration of conformity

1.2 Aim and impact of proposals

- Role and legal basis for accreditation
- Legal basis and essential requirements for market surveillance
- Extension of RAPEX
- Member State co-operation and exchange of information
- Review of marking issues
- Criteria for notified bodies and notifying authorities
- Review of modules (ISO 9000)
- Coherence of future EU legislation on technical harmonization
- Old Approach & New Approach: New Legislative Approach

2. New Approach review and the Personal Protective Equipment Directive

Előd Ajtony DUDÁS – European Commission - DG Enterprise and Industry, Unit I4 - Mechanical, Electrical and Telecom Equipment

2.1 Introduction

The New Approach legislative framework continues to play a very important role in keeping the European market safe, by setting out common requirements for products that are intended to be placed on the market. Much experience has been gained since it was introduced in the 80s, but the framework could still be made more efficient by fine tuning its elements, providing a basis for some 25 New Approach Directives, e.g. the PPE Directive (89/686/EEC).

A major step towards achieving this was the adoption of two European Commission legislative proposals on 14 February 2007.

These proposals are subject to the so-called "co-decision procedure" based on Article 251 of the EC Treaty, which signals that the European Parliament and the Council legislate jointly.

Therefore it is hard to predict the outcome of the procedure, as these institutions need to examine the proposals thoroughly and suggest modifications if necessary.

2.2 Legislative tools

The two adopted proposals consist of a Regulation and a Decision. The Regulation sets out common criteria for accreditation and market surveillance, while the Decision deals with definitions for economic operators, conformity assessment procedures, and CE marking etc.

The legislation procedure – as referred to above – has not yet been finalized; therefore one cannot predict the outcome of the process in terms of impacts on the PPE Directive. However, with this caveat, one might make a preliminary assessment of future consequences for the field of personal protective equipment.

Regulation:

First and foremost it should be noted that this legal act contains elements that do not overlap with existing legislations, but on the contrary, complement them. The Regulation is directly applicable in the Member States, and no transposition is required.

Elements of the Regulation:

Accreditation: The accreditation i.e. the assessment of Notified Bodies (NBs) will have no immediate effect in the field of PPE, as the PPE Directive does not contain provisions on accreditation as a means of attesting the competence of NBs.

Market surveillance: The relevant provisions will result in the improvement of market surveillance that will require the Member States' Customs authorities, among others, to play a role in this process. Furthermore, it will extend the application of the Rapid Alert System for all dangerous consumer products (RAPEX system) to non-consumer PPE presenting serious risk. The RAPEX system is established by Directive 2001/95/EC on general product safety.

Decision:
The Decision is a sui generis decision that is addressed to the Legislator for future reference. Its provisions do not apply directly in the Member States, but represent a "toolbox", the elements of which the Commission can use in the case of an amendment/revision of a Directive or the creation of a new legal act. Prior to the application of this toolbox however, a proper assessment needs to be carried out in order to clearly see the impacts of the elements in the field concerned. (In our case, impacts in the field of PPE.)

Elements of the Decision:
Definitions/obligations of economic operators: The Decision defines the manufacturer, its authorized representative, the importer and the distributor, with obligations that depend on their role in the supply chain. Looking at the PPE Directive this might be a candidate for improving the text; the importer and distributor in particular, considering that the Directive deals with a large number of consumer products being distributed by such channels.

Requirements for Notifying Authorities and Notified Bodies: The relevant provisions of the Decision set out clear requirements for these two entities. The PPE Directive contains provisions on the NBs but does not have such requirements for the Notifying Authorities. Whether there is added value of using such provisions during the revision of the PPE Directive needs to be looked at carefully. Nevertheless, the NBs have some problematic areas that have already been recognized, such as their participation in European Co-ordination. The Decision takes a good step towards solving this issue.

Safeguard mechanisms (and market surveillance): Currently, the PPE Directive requires the European Commission to intervene in all safeguard clause notifications. (Please refer to Article 7 of the PPE Directive). The relevant provisions of the Decision, however, breaks down this procedure into two phases: Phase 1: information phase – if no objection is raised by other Member States or the Commission against any restrictive measure taken by a Member State against a CE marked product, then the measure is deemed justified. The Commission does not carry out a full inquiry as is required in Phase 2. Phase 2 is the safeguard clause procedure, as is the case in today's PPE Directive. The purpose of the breakdown of this procedure is to ease the heavy administrative burden on the European Commission and to speed up the process where possible.

CE marking: These provisions are rather similar to those already set out in the PPE Directive and therefore no major impact is envisaged in the field of PPE.

2.3 Conclusion – timeline

The legislative process has now been in place for almost a year. At this point it is impossible to give a definitive schedule as to when this process will be finalized. However, both the European Parliament and the Council are keen to adopt these legislations as soon as possible, as they feel the need for the reinforcement of the legislative framework of the New Approach. In order to underline their intentions, these institutions expressed their political will to finalize this legislative procedure during first reading. Thus we can estimate that the process may be concluded by the end of 2008.

The next issue that remains is how this can be taken into account when the revision of the PPE Directive begins. It is important to emphasize that a substantial analysis is required in order to determine which elements of the Decision bear added value for the PPE Community, and would help better functioning of the system in the field. This is an issue that needs to be addressed in the future, as soon as the other revision has produced two adopted legislative acts.

References

1. COM, 2007, 37 final of 14.2.2007 – 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.
2. COM, 2007, 53 final of 14.2.2007 – Proposal for a Decision of European Parliament and of the Council on a common framework for marketing products.
3. Council Directive of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (89/686/EEC).
4. Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.
5. http://ec.europa.eu/enterprise/mechan_equipment/ppe/index.htm
6. http://ec.europa.eu/enterprise/newapproach/review_en.htm

3. Impact of REACH Regulation on selection and use of PPE

Dr N Vaughan, Health and Safety Laboratory, Buxton, UK

3.1 Introduction

Regulation No. 1907/2006 (1) of the European Parliament concerns the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). It complements but does not replace existing European Directives concerning use and protection against hazardous substances in the workplace, nevertheless it subsumes the Safety Data Sheet Directive (2). The main aim of REACH is to maintain and promote the competitiveness of industry while improving the protection of human health and the environment. It sets out to achieve this by rationalizing the current EU regulatory system for chemicals, and significantly increasing the information available on hazards and risks of substances up and down the supply chain.

Responsibility for the risk management of substances belongs to those who place them on market, manufacture, import, or use them. All available and relevant information should be collected to identify hazards associated with the substances, and recommendations on Risk Management Methods (RMMs) should be systematically conveyed through the supply chain. Ultimately, it will not be possible to market substances for which there is insufficient information available on their safe use.

The introduction of the REACH provisions is phased, beginning with substances which are produced in large quantities (>100 tonnes/yr) or are carcinogenic, mutagenic, reprotoxic or highly environmentally damaging (registration by December 2008), moving on to cover lower volume substances (10 – 100 tonnes/yr and then 1-10 tonnes/yr). By 2018, all substances within the scope of REACH which are manufactured or imported at >1 tonne/yr will be covered.

3.2 Key provisions of REACH

Assuring the safe use of the substance in question is fundamental to the principles of REACH. The information which the manufacturer/importer will be required to provide along with the substances they supply, must include sufficient information on the RMMs that must be applied to ensure that the exposure of users to the substance is below the relevant Derived No-Effect Level (DNEL). As these DNEL values are to be generated and justified by industry, and independently evaluated by Member States, they are likely to be somewhat conservative.

The RMMs necessary to ensure that the DNEL is not exceeded must follow the accepted hierarchy of control – elimination, substitution, containment, engineering controls and lastly PPE. To specify RMMs effectively, manufacturers/importers will need to know and understand how the substances are actually used by industry, and two-way dialogue between these parties will be essential. Users are required to inform their suppliers of how they make use of the substances provided, so that this information can

be built into "exposure scenarios" for which RMMs will be developed. Any information on the effectiveness of the control measures applied by users, including PPE, should also be provided – arguably, this information should be readily available from PPE manufacturers under their PPE Directive responsibilities. All this information will be included in the Technical Dossier for the substance. (Technical Dossiers may be regarded as an enhanced and improved form of safety data sheet. "Dangerous" substances and those produced in amounts of >10 tonnes/yr will need more information on chemical safety related to human health, physicochemical aspects, and the environment).

Existing safety data sheets for substances may include basic information on what control measures to use, including PPE. Currently, this is typically of the form "use gloves and eye protection". Under REACH, this level of information will be deemed unacceptable. Sufficient information on the design, materials and use of the PPE necessary to adequately control exposure to below the DNEL will be required. The PPE specified will need to be described in significantly more detail. There will also have to be an implicit assumption of the level of protection that typical use of this equipment will provide in real work situations.

3.3 Information needs

Much of the information needed by REACH either does not yet exist, or has not been collated sufficiently for use. *Figure 1* shows the situation as it relates to the high volume substances included in the first tranche of those being considered in REACH.

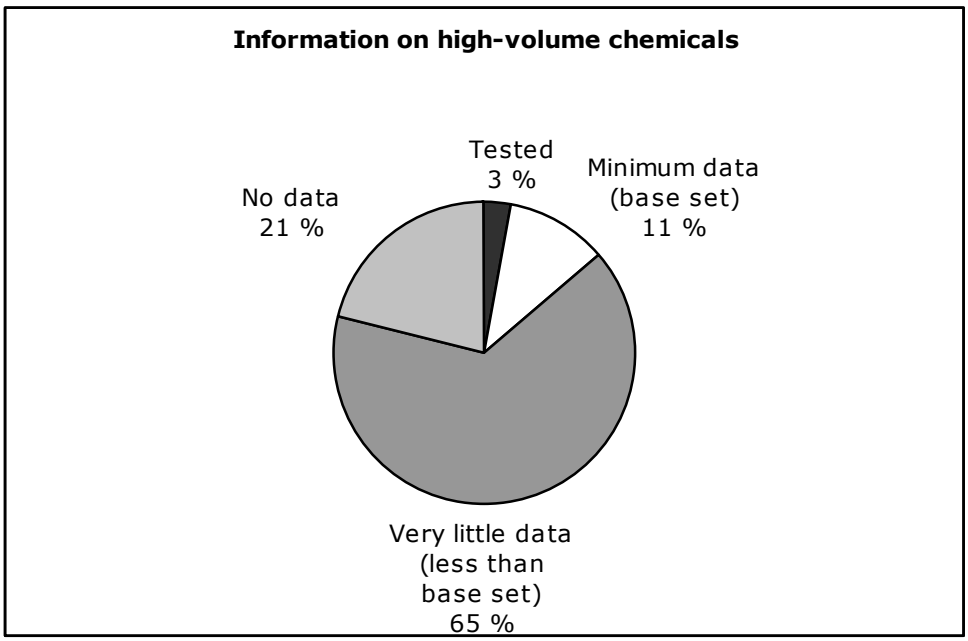


Figure 1. Availability of information needed for REACH for substances made in amounts of >100 Tonnes/yr (3)

Chemical substance manufacturers/importers need to know how their products are used in practice. This includes knowledge of what control

measures (including PPE) are being applied by users, and how effective they are. In many cases, the levels of protection actually achieved in practice by PPE have never been formally assessed. REACH makes provisions for the dissemination and sharing of information (and the associated costs of generating it) in order to avoid unnecessary duplication of effort.

It may be apparent whether the PPE used qualitatively prevents harmful exposures, but the actual level of protection is unknown. Quantified protection factors are likely to be essential in assessing control measures against DNELs. Note that these protection factors will not be the same as the levels measured in standard laboratory tests for the purpose of product certification.

The DNELs themselves have yet to be defined for many substances. The difficulty here is that different levels may apply for the same substance, depending on the route of exposure. Ingestion and inhalation are generally well understood in terms of exposure/dose relationships. However, exposure to substances which are hazardous or toxic by skin absorption has received less attention. Skin exposure by direct contact with contaminated surfaces is likely to produce a different response from exposure to an equivalent deposited mass of airborne material. Similarly, relating environmental surface contamination levels or airborne concentrations to skin deposition, and further to skin absorption, is highly problematic. For those substances which may be harmful by any combination of inhalation, ingestion or skin absorption, these uncertainties will lead to difficulties in defining the DNEL.

Clearly, there is a need for definitive information on the performance of PPE against chemical hazards, and this can be fed into the Technical Dossiers required by REACH. Where such information on the performance of RMMs already exists, accepted protection factor values can be published. An example of what this guidance may look like is contained in a draft guidance document (4). For PPE, this calls up existing published data on measured protection factors for coveralls (5) and respirators (6). Both of these data sets are based on limited information from specific use scenarios, and are cautious in the levels of protection they claim. Extrapolating this information to markedly different operations or non-identical items of equipment may be unsound, and possibly unsafe.

Whether or not a PPE-based RMM is effective can be established in a number of different ways, some of which will be expanded in a separate paper at this conference. Essentially, PPE performance can be assessed either directly or indirectly.

Direct assessment

The success or failure of the PPE selection and use regime is assessed by observing the outcome – are the users unaffected by the chemical? This approach avoids the need to quantify and sum the different aspects of the control regime, taking an integrated holistic approach to the problem. It relies on there being an observable effect of the exposure to the substance, which can be established by medical examination or biological monitoring.

The difficulties with this approach are:

- *If a health effect is observed, it is too late for the individual concerned – they have already been over-exposed;*
- *Health effects with long latency (e.g. development of cancer some years after exposure, as with asbestos) would not be apparent in the short-term;*
- *The RMMs applied in order to prevent health effects may be significantly more onerous than necessary, imposing unnecessary physiological and/or financial burdens on the user.*

Indirect assessment

Key aspects of the protective performance of PPE are quantified by measurement, and their overall performance in preventing or controlling exposure is calculated. This approach aims to prevent significant exposures from occurring, and not to rely on detecting the effects which result if they do. In this way, imposing excessive forms of PPE is avoided, striking a balance between protection and usability. The difficulties with this approach are:

- Challenge concentrations in the work environment must be known;
- DNELs must be known and relevant;
- Measurement of protection factors is difficult;
- Large quantities of data are needed for confidence in results;
- Intangible aspects of the PPE regime may defy quantification.

There is no simple solution to the shortcomings of these two approaches. In practice, it may be necessary to adopt both approaches to some degree – quantification of the aspects of performance which can be measured without too much difficulty, backed up by medical/biological monitoring to confirm that exposures are under control for those substances with which latent effects do not occur.

3.4 Conclusion

REACH continues industry's push towards self-regulation, which has been developing in European legislation throughout recent years. It seeks to improve occupational health and safety through ensuring wider and more effective communication of information throughout the chemical supply and use chain. To achieve this, all parties involved in the process, including the manufacturers of control measures such as PPE, will need to generate and exchange necessary information, and share it effectively if they are to avoid unnecessary duplication of effort and expense.

The ten years running up to the planned full implementation of REACH will be challenging. More than 30 000 substances and a multitude of uses will need to be addressed. At the end of the process, we should know vastly more about how to effectively control exposures, and be able to reap the benefits of reduced work-related illness and occupational disease.

References

1. Official Journal L396/1.
2. Directive 91/155/EEC (Official Journal L76/91) as amended by Commission Directive 93/112/EC of 10 December 1993 (Official Journal L314/93).
3. Environment fact sheet: REACH — a new chemicals policy for the EU © European Commission 2006.
4. Technical Guidance Documents in support of the New EU Chemicals Legislation (REACH) – V: Development of a Technical Guidance Document for preparing the Chemical Safety Assessment (REACH Implementation Project 3.2-2). Service Contract Number CCR.IHCP.C432365.X0. Chapter R.13 (Draft).
5. Gerritsen-Ebben R, Brouwer D, van Hemmen JJ. Effective personal protective equipment (PPE). Discussion document on the use of PPE in registration purposes for handling of agrochemicals, microbiological and biocidal pesticides. TNO Report, Zeist, 2006.
6. BS 4275: BSI, BS 4275. Guide to implementing an effective respiratory protective device programme. British Standards Institution, London 1997.

4. Impact of Noise Directive (2003/10/EC) on selection and use of PPE

Martin Liedtke, BGIA - Institute for Occupational Safety and Health of Deutsche Gesetzliche Unfallversicherung, Sankt Augustin, Germany

Abstract

The requirements of the new Noise Directive *(3)* change the conditions of design and testing for some types of hearing protectors, and the conditions for the selection and use of all types of hearing protectors. Thus we present details and approaches for considering "real world attenuation". For custom-moulded ear plugs, we give a further example of the direct effect of PPE production and testing. A selection tool for musicians' hearing protectors is also presented, as musicians require special selection.

4.1 Introduction

4.1.1 History of European Noise Control

On 12 May 1986, the Council Directive on the protection of workers from risks related to noise exposure at work *(1)* was published in the Official Journal of the European Communities. Article 13 specified that Member States had to bring into force the laws, regulations and administrative provisions necessary for compliance with the Directive by 1 January 1990.

4.1.2 Initial Council Proposal on 'Physical Agents Directive'

On 18 March 1993, the European Commission published a proposal on "minimum standards for health and safety of workers exposed to risks from certain specific physical agents" *(2)*. The combination of several risks (noise, mechanical vibration, optical radiation, electromagnetic fields and waves) as proposed, failed to achieve consensus in the European Parliament in 1994 (1st reading at European Parliament).

4.1.3 Developments prior to publication of Directive 2003/10/EG

In the period from January to June 2001, national consultations on a changed proposal of the directive were carried out by the Member States. The Council came to an agreement on 29 October 2001. However, although the European Parliament took a decision during its second reading on 13 March 2002, in the course of consultations, the positions of the Parliament and the Council could not be harmonized. A final agreement was only achieved when the Conciliation Committee joined in the discussions, and a joint text for the Directive was prepared on 8 March 2002.

4.1.4 The new European Directive on protection against noise

Finally the new European Directive on Noise Exposure (3) was published on 15 February 2003. Member States had to bring into force the laws, regulations and administrative provisions necessary to comply with the Directive before 15 February 2006.

Two exemptions were specified:

- Personnel on board seagoing vessels: if necessary, Member States may have an additional period of five years from 15 February 2006 to implement the provisions of Article 7 of the directive.
- Music and entertainment sectors: In order to allow the drawing up of a code of conduct providing practical guidelines for the implementation of the provisions of the directive, Member States shall be entitled to make use of a maximum transitional period of two years from February 2006.

In cases where hearing protectors must be used to achieve the worker's appropriate protection against noise, the old and the new directives differ in their consideration of the protectors' attenuation within risk assessment.

4.2 Old and new Noise Directive and PPE Directive

4.2.1 Approach of the old Noise Directive (1)

- *Assessment:* Article 3 of the Directive *(1)* specified that the employer should assess noise experienced at work and, when necessary, measure it. For the assessment of noise exposure, the attenuation of hearing protection was not taken into account as stated in Article 2 of the Directive *(1)*:
  - *Daily personal noise exposure does not take account of the effect of any personal ear protector used.*
- *Measures*: In a case where assessment shows that exposure action values are exceeded, the employer shall take appropriate measures to reduce the noise exposure (Article 4, 5, 6, and 7 of *(1)*).
- *Use of hearing protectors* (*(1)*, Article 6): If neither technical nor organizational measures can reduce the noise exposure of workers sufficiently, and
  - Where exposure is likely to exceed 85 dB (A), personal hearing protectors must be made available to workers.
  - Where the daily personal noise exposure of a worker exceeds 90 dB (A) or the maximum value of the unweighted instantaneous sound pressure is greater than 200 Pa, personal hearing protectors must be used.

Hearing protectors are deemed suitable and adequate if, when properly worn, the risk to hearing can reasonably be *expected* to be kept below the risk arising from exposure exceeding a daily noise exposure of 90 dB (A) (*(1)*, article 6). That is, when assessing the efficiency of the hearing protection used, the "expectation" of not exceeding 90 dB (A) was sufficient. Therefore in practice, the selection and use of PPE against noise was separated from the risk assessment:

- The protection level determined within the risk assessment was used to select PPE,
- However the level effective to the user's hearing (under the protector) was not assessed within the risk assessment.

4.2.2 Approach of the PPE Directive *(4)*

The PPE Directive (4) specifies in Annex II, clause 3.5: "PPE designed to prevent the harmful effects of noise must be capable of attenuating the latter to such an extent that the equivalent *sound levels perceived by the user do not* under any circumstances *exceed the daily limit values* laid down by Council Directive 86/188/EEC *(1)* of 12 May 1986 on the protection of workers from the risks related to exposure to noise at work."

This Directive is addressed to manufactures of PPE, the Notified Bodies responsible for testing and certification under the PPE Directive *(4)*, and Member States. Therefore in the past, only manufacturers and Notified Bodies (and sometimes the market surveillance of the Member States) had to assess the performance of hearing protectors by testing. The employer only used laboratory data to select PPE as guided by e.g. *(5)*, but did not assess the level effective to the user's hearing.

4.2.3 Approach of the new Noise Directive *(3)*

An excerpt of the "reasons of consideration" found in the new Noise Directive *(3)* shows interesting background information, and a new approach compared to that of the old Noise Directive *(1)*:

- Current scientific knowledge of the effects… is *not sufficient* to enable precise exposure levels covering all risks to health and safety,
- *Exposure limit values* are needed to avoid irreversible damage to workers' hearing; the *noise reaching the ear* should be kept below the exposure limit values.
- The particular characteristics of the *music and entertainment sectors* require practical guidance; Member States should be entitled to make use of a transitional period for the development of a code of conduct.

The old Noise Directive *(1)* did not provide any exposure limit value. *Table 1* shows a comparison of exposure action values and exposure limit values of the old and the new Noise Directive. The lower and upper action values were lowered by 5 dB(A) by the new Noise Directive *(3)*.

Table 1. Comparison of new and old European Noise Directives

EXPOSURE LIMIT VALUES AND EXPOSURE ACTION VALUES	*DIRECTIVE 2003/10/EG (06/02/2003)*	*DIRECTIVE86/188/EEC (12/05/1986)*
Lower exposure action values	$L_{EX,8h}$ = 80 dB(A) or p_{peak} = 112 Pa (135 dB(C))	L_r = 85 dB(A) or L_{peak} = 140 dB (200 Pa)
Upper exposure action values	$L_{EX,8h}$ = 85 dB(A) or p_{peak} = 140 Pa (137 dB(C))	L_r = 90 dB(A) or L_{peak} = 140 dB (200 Pa)
Exposure limit values (attenuation provided by ind. hearing protection shall be taken into account)	$L_{EX,8h}$ = 87 dB(A) or p_{peak} = 200 Pa (140 dB(C))	not existing

4.3 Two basic types of hearing protectors

4.3.1 Conventional hearing protectors

Conventional hearing protectors attenuate external sound in such a way that the external sound perceived by the user is reduced by the attenuation provided by the protector.

4.3.2 Hearing protectors with sound restoration

Sound restoration inside hearing protectors is used for e.g.

- communication (wireless or wired),
- level-dependent transmission of external sound to workers' hearing via an electro-acoustic transmission path at the user's workplace or
- entertainment via a built-in broadcast receiver.

Assessing the sound perceived by the user we have to consider two components for this type of protector:

- External sound reduced by the conventional attenuation of the hearing protector and
- The component produced by the in-built loudspeakers of the hearing protector.

An example may demonstrate the conditions when using hearing protectors with sound restoration: The sound exposure of a helicopter pilot was measured, and it was found that the in-flight sound pressure level at the pilot's workplace was 96 dB (A). The attenuation provided by the communication headset used was 15 dB (A). The remaining cabin sound level perceived by the pilot was therefore 81 dB (A). The sound level generated by the loud speakers in order to feed in necessary communications was determined to be 86 dB (A). The exposure level of the total sound perceived by the pilot through these two components resulted in 87 dB (A), which is much higher than the 81 dB (A) resulting from the sound inside the cabin transmitted through the cups alone.

4.3.3 Requirements for selection and use of hearing protectors

As already mentioned, the PPE Directive *(4)* specifies in Annex II, clause 3.5, referring to the old Noise Directive *(1)*, that the maximum level perceived by the user shall not exceed the daily limit value of 90 dB(A). The New Noise Directive *(3)* requires that the maximum level perceived by the user shall not exceed 87 dB (A). The reduction of 3 dB (A) by the new Noise Directive *(3)* can be acheived with conventional protectors by selecting those that offer higher attenuation values. But for sound restoration protectors, the sound level at the user's ear cannot be reduced by selection of other protectors because the remaining sound level inside the protector is pre-determined only by the settings made by the manufacturer while designing the hearing protector. This means the new Noise Directive affects the production and testing of these hearing protectors, and that manufacturers must adapt to the new situation.

For some forward-thinking Member States, this problem was already solved several years ago: in 1989 they reduced the upper action level from 90 dB (A) to 85 dB (A) by transposing the old Noise Directive *(1)* to their national law. From then on the maximum level allowed for the free movement of sound restoration protectors on the European market was reduced to 85 dB(A) in the relevant European harmonized testing standards for hearing

protectors *(6)*. These Member States do thus not need to adapt to the new situation created by the new Noise Directive *(3)*.

4.4 Attenuation performance of hearing protectors

As the attenuation performance of ear plugs in working conditions is most critical, the focus here is only on these types of hearing protectors – similar to a worst case scenario. In a German study *(7)* the "real-world" attenuation of hearing protectors was determined at plants for three types of ear plugs in use by 132 workers. Use of the data calculation (following *(5)*, HML Check Method) for HM-noise of 100 dB (A) yields the following: 14% of users would be exposed to levels effective to the ear above 87 dB (A), 47% above 80 dB (A), and 1% below 65 dB (A). The mean attenuation of the ear plugs found in "real-world" conditions was 20 dB showing a standard deviation of 7 dB. However, using the laboratory data of the corresponding ear plugs (mean 31 dB and standard deviation 5 dB; obtained according to procedures described in EN 352-2), calculations result in 0,01% users being exposed to over 87 dB(A), 1% over 80 dB (A), and 18% below 65 dB(A). In the worst case conditions, i.e. when the ear plug was selected so that the level effective to the ear would be 80 dB (A) (using laboratory data and following *(5)*, HML Check Method), calculation adds up to 42% of users exposed to over 87 dB (A). The selection of hearing protectors based on attenuation as specified in *(5)* aims for an A-weighted sound pressure level under the hearing protector equal to or less than the predicted level of 84%. For the "real-world" scenario mentioned above (external level of 100 dB (A)) this 84% level is 87 dB (A).

4.5 Approaches to considering "real world" attenuation

To consider "real world" attenuation, specified figures must be subtracted from the attenuation figures provided by the manufacturers. In Germany, fixed reductions of 3 dB for custom-moulded ear plugs, 5 dB for ear muffs and 9 dB for other types of ear plugs, are recommended. In cases where special measures are applied to ensure effective protection - e.g. special training, motivation and exercise provided to the users, and usage check - the subtraction may be omitted. In the United Kingdom, it is recommended that 4 dB be subtracted for all kinds of hearing protection devices. In Italy it was more specific: in the case of a risk octave band calculation, a "statistical range enlargement" of 3 σ should be used.

All Member States' approaches use data obtained by EC-type examination. Therefore only an indirect effect on PPE production and testing occurs.

During the various discussions on the transposition of the new Noise Directive *(3)* another possibility was considered: the measurement of levels under the protectors. The corresponding suitable measurement technique is known as the MIRE (microphone in real ear) technique and specified by *(8)*. However, this is a laboratory technique and can only be used by specialists. Because of its risks – damage of the ear drum – it is not of practical use for the application of the new Noise Directive *(3)*.

4.6 Example of direct effect on PPE production and testing

Vertical Group 4 ("Hearing Protection" of the Horizontal Committee of Notified Bodies – PPE) specified on 19 March 2007 an additional check of custom-moulded ear plug attenuations before taking them into use, through its "Recommendation for Use" sheet CNB/P/04.045. This additional check is to be carried out by the manufacturer in order to avoid leakage which causes a lack of, or decrease in protective function. Relevant leakages have been observed in brand-new products by both manufacturers and health and safety experts. The leakages occur frequently and can only be avoided by a final check of the product's protective function when placed in the user's ear canal.

4.7 PPE selection for the music and entertainment sector

Hearing is a musician's capital. Their total exposure is frequently not known by employers, as musicians often have additional engagements (giving lectures, etc.). Hearing protector selection is difficult, because the individual requirements are so diverse. Therefore, a simple selection tool was developed to be used by the musicians themselves; they do not have to be experts in acoustics (e.g. sound levels) in order to use it. This selection is available at: http://www.dguv.de/bgia/de/pra/softwa/musiker/index.jsp

References

1. Council Directive 86/188/EEC of 12 May 1986 on the protection of workers from the risks related to exposure to noise at work, Official Journal L 137, 24/05/1986 p. 0028 – 0034.
2. Proposal for a Council Directive on minimum standards for health and safety of workers exposed to risks from certain specific physical agents (93/C 77/02), Official Journal of the European Communities No. C 77, 18-03-1993, p. 12-29.
3. Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise), Official Journal of the European Union L 42, 15/02/2003, p. 38 – 44.
4. Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment, Official Journal L 399, 30/12/1989, p. 18.
5. EN 458:2004 - Hearing protectors - Recommendations for selection, use, care and maintenance - Guidance document.
6. EN 352 part 4, 5, 6, 7 - Hearing Protectors – General requirements.
7. Ref.: BIA-Report 5/89: Sound attenuation of hearing protectors in working practice, 1989 (in German).
8. ISO 11904-1:2002, "Acoustics - Determination of sound immissions from sound sources placed close to the ears - Part 1: Technique using microphones in real ears (MIRE-technique).

5. Impact of Vibration Directive (2002/44/EC) on selection and use of PPE

Dr. Eberhard Christ, Institut für Arbeitsschutz – BGIA, der Deutschen Gesetzlichen Unfallversicherung (DGUV)

Abstract

Unlike the three other individual directives for protection from risks to safety and health arising from physical agents at work, the individual Vibration Directive 2002/44/EC does not give any direct guidance on the use of personal protective equipment (PPE). This is because there is still a lack of suitable PPE for protection from vibration. Nevertheless, all individual directives are fundamentally subject to Framework Directive 89/391/EEC for the use of PPE when the respective limit values are exceeded. The possibility mentioned in the Directive's appendix, of including PPE in the programme of measures for preventing or reducing exposure to hand-arm vibration, refers to anti-vibration gloves. This PPE has only limited effectiveness and has not so far permitted any reliable assessment of achievable risk reduction. Effective personal protection from whole-body vibration is achievable with driver's seats whose spring damping system has been optimally adapted to the frequency characteristics of the mobile machine or vehicle. The effective elimination of health risks with tested driver's seats for agricultural and forestry tractors are an example worthy of imitation. Driver's seats provide reliable personal protection and should therefore qualify as PPE, even if they fail to satisfy the requirements of Article 1(2) of PPE Directive 89/686/EEC.

5.1 Protection from vibration at work – Directive 2002/44/EC

Directive 2002/44/EC *(1)* represents the first uniform regulation within the European Union for the protection of employees exposed to risks to health and safety arising from vibration at work. The preventive measures are targeted particularly at damage to the muscular/bone structure of the spine by whole-body vibration, and neurological and vascular disorders in the hand-arm system due to hand-arm vibration.

Unlike the three other individual Directives for protection from risks to safety and health from physical agents at work, the Vibration Directive fails to refer directly to personal protective equipment (PPE) in the catalogue of measures for avoiding or reducing exposure (Article 5). Personal protective equipment is merely mentioned in Annex A "Hand-arm vibration" as a possible aspect of a programme of measures once the exposure action value is exceeded. This means that the principle of the priority of technical and/or organizational protective measures over the use of PPE from Article 6 (2) of Framework Directive 89/391/EEC *(2)* is disregarded. In complete contrast, Noise Directive 2003/10/EC for instance, devotes a separate, detailed Article to the choice and use of hearing protectors.

The omission of PPE in the programme of measures for dealing with risks to safety and health due to vibration is the inevitable consequence of the lack of suitable PPE due to deliberations on the directive in the European Council. The fact that the so-called anti-vibration gloves so far available do not

satisfactorily comply with vibration protection requirements has also been confirmed by a study of the BGIA and BG BAU (statutory accident insurance institution for the construction industry), which was reported on at the 8th PPE Seminar in Saariselkä in 2007 *(3)*.

However, even without the direct mention of PPE in the Vibration Directive, the fundamental provisions of the Framework Directive (Article 1(3)) still apply. Because of the differences in the risks caused by vibration at work, hand-arm and whole-body vibration are treated separately below.

5.2 PPE for protection from hand-arm vibration

During work with hand-held and hand-guided tools, protection from the risks of vascular and neurological disorders and damaged bones and joints in the hand-arm region (Directive 2002/44/EC, recital point 3) can only be achieved by reducing or eliminating the transmission of vibration to the hands. Since the risk of vascular disorders is greater if the hands are cold, suitable protection is provided by gloves that not only keep the hands warm, but also include an effective vibration-absorbing insert on the palm (anti-vibration gloves). This is where the problem has not yet been satisfactorily solved, as the effect of vibration-absorbing elastic inserts is strongly frequency-dependent. Below 150 Hz (equivalent to a tool speed of 9000 rpm), no appreciable reduction in vibration transmission to the hands is achievable. However it is precisely in the vibration frequency range below 150 Hz that the hand-arm system is at its most sensitive. If high-speed tools are employed, a certain reduction in vibration transmissibility can be achieved with currently available anti-vibration gloves. Since it is not possible to quantitatively assess this reduction in the risk, targeted application within the programme of measures of the Vibration Guideline has not so far been possible.

Anti-vibration gloves are tested by notified bodies under PPE Directive 89/686/EEC *(4)* in accordance with DIN EN ISO 10819 *(5)*. If the gloves keep within the vibration transmissibility factors specified for medium test frequencies (31.5 to 200 Hz) TR_M = 1.0 *and* for high test frequencies (200 – 1250 Hz) TR_H = 0,6, they are certified as anti-vibration gloves and can be given the CE mark by the manufacturer. Because the vibration absorption effect differs even within the tested frequency ranges and cannot be expressed by these two generalised factors, it is not possible to reliably assess the protective effect in relation to tools with different vibration characteristics. What is required is a standardized test method with which the gloves' vibration absorption effect is given separately for the octave or one-third octave bandwidths of the test frequencies (comparable to the ear protectors' noise reduction values for the octave bands of the spectrum of audible sound). Only then will it be possible for users to reliably determine the protective effect of selected anti-vibration gloves for the particular vibration spectrum of individual tools. With such frequency-dependent values, it would also be possible for tool manufacturers to recommend specific anti-vibration gloves for specific tools, suitable for their particular application. This is part of their obligation to provide guidance for protection from risks to safety and health under the Machinery Directive 98/37/EC *(6)*. A current review of the market has shown that certain manufacturers are already making such recommendations, in an attempt to "embellish" the unfavourable obligatory details of the vibration emitted by their tools. Such recommendations are not currently based on reliable test results for anti-

vibration gloves. The responsible ISO/TC 108/SC 4 "Human exposure to mechanical vibration and shock" has included the revision of test standard ISO 10819 in its current work programme, so that in the future it will be possible, thanks to improved vibration absorption inserts in gloves, to choose and use suitable PPE for protection from hand-arm vibration. In this respect, the Vibration Directive has lent effective worldwide impetus to the further development of testing techniques and to an improvement in the effectiveness of anti-vibration gloves.

In accordance with Directive 89/656/EEC governing the use of PPE *(7)*, the choice and use of any PPE must take account not only of the desired protective effect, but also of new risks that may arise in connection with its use. For anti-vibration gloves, this means that the relatively thick vibration absorption layers on the palm may impede controlled tool use. They force the user to apply a firmer grip, resulting in faster fatigue combined with reduced precision in tool handling.

5.3 PPE for protection from whole-body vibration

The health risks mentioned in the Vibration Directive, arising from the effects of vibration on the body as a whole (whole-body vibration) relate to damage to muscular/bone structure (recitals point 3). This is primarily intervertebral disc damage in the lumbar part of the spine after many years of mainly vertical vibration acting on seated drivers of mobile machines and vehicles mainly operated on uneven or unsurfaced terrain (e.g. construction sites). The Directive also covers horizontal vibration if it affects the spine with sufficient force and frequency.

Under current laws, there is no PPE for protection from whole-body vibration. The seats installed on mobile machines and vehicles that affect the transmission of vibration from the vehicle chassis to the human body do not satisfy the definition of PPE in Article 1 of the PPE Directive 89/686/EEC. They have a dual function. They serve firstly as a positioning device for the driver in relation to the machine or vehicle to ensure reliable operation with hand or foot operated controls. At the same time, they also protect the driver individually from the damaging effect of vibration. To this end, they are personally adapted to each driver's body measurements and weight, and are thus "personal protective equipment" in the literal sense of the term. And as such, when optimally adapted to the specific vibration characteristics of the mobile machine or vehicle, they constitute the only means to keep away from the driver's body the damaging vibration that cannot be eliminated with technical and/or organizational measures. Suitable seats make it possible – much like the use of hearing protectors in noisy areas – to work safely at workplaces where damaging vibration cannot currently be eliminated.

In the design of vibration-reducing seats, like that of anti-vibration gloves, the frequency dependence of the spring damping systems employed is a decisive factor for the achievable reduction in vibration transmitted to the human body. But unlike the so far unsatisfactory vibration-absorbing inserts in the gloves, suitable technical solutions for seats are feasible. The current problem is their general application in the multitude of different mobile machines and vehicles. Despite excellent results from the application of specially adapted spring damping systems in vehicle seats for tractors, the situation in virtually all other mobile machines and vehicles is still unsatisfactory. A BGIA study on the state of vibration protection provided by

vehicle seats in currently used mobile machines and vehicles has ascertained excessively low damping values, and in some cases amplification of the vibration as a result of resonance effects.

In response to the sharp increase in vibration-related disorders of the spinal column observed in the 1960s, driver's seats with effective damping were developed for employees in agriculture and forestry. At the same time, practical test methods were developed, involving the exposure of test persons of different weights to simulated tractor vibrations in the laboratory in order to determine whether the seats envisaged for installation on agricultural and forestry tractors achieved the required decrease in vibration. This successful preventive procedure was bindingly introduced by the European Community in all Member States in the form of the Driver's Seat Directive for wheeled agricultural and forestry tractors 78/764/EEC *(8)* in 1978. This meant that the national admission authorities for these vehicles were in a position to check whether driver's seats achieved the minimum specified vibration reduction value. The Directive was brought into line with technical progress in 1999. However, this success story still awaits a sequel. For all other mobile machines and vehicles, vibration reduction requirements relating to seats have been included in the Machinery Directive 98/37/EC. Specific vibration reduction values, like those for tractors, have not yet been specified. In connection with the European standardization projects mandated by the European Commission, individual seat test methods have so far only been standardized for earth-moving machinery *(9)* and industrial trucks *(10)*.

References

1. Directive 2002/44/EC of the European Parliament and of the Council of 25 June 2002 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration) (sixteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). OJ L 177, 6.7.2002, p. 13.
2. Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work OJ L 183, 29.6.1989, p. 1.
3. *Christ, E.:* Protective Function of Anti-Vibration Gloves – Review of the German Market. 8th European Seminar on Personal Protective Equipment, 27–29 March 2007, Saariselkä, Finland, Seminar Report. Work Environment Research Report Series 27. In: Mäki S. (Ed.) Finnish Institute of Occupational Health, 2007, p. 110-116.
4. Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment. OJ L 399, 30.12.1989, p. 18.
5. EN ISO 10819:1996: Mechanical vibration and shock; Hand-arm vibration; Method for the measurement and evaluation of the vibration transmissibility of gloves at the palm of the hand.
6. Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery. OJ L 207, 23.7.1998, p. 1. Revised version (comes into force 29.12.2009): Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast). OJ L 157, 9.6.2006, p. 24.
7. Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal

protective equipment at the workplace (third individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC). OJ L 393, 30.12.1989, p. 18.
8. Council Directive 78/764/EEC of 25 July 1978 on the approximation of the laws of the Member States relating to the driver's seat on wheeled agricultural or forestry tractors. OJ L 255, 18.9.1978, p. 1. Adapted to technical progress by: Commission Directive 1999/57/EC of 7 June 1999 adapting to technical progress Council Directive 78/764/EEC relating to the driver's seat on wheeled agricultural or forestry tractors (Text with EEA relevance). OJ L 148, 15.6.1999, p. 35.
9. EN ISO 7096:2000: Earth-moving machinery; Laboratory evaluation of operator seat vibration.
10. EN 13490:2001: Mechanical vibration; Industrial trucks; Laboratory evaluation and specification of operator seat vibration.

6. The impact of the Optical Radiation Directive on PPE

Maila Hietanen, Finnish Institute of Occupational Health, Work Environment Development

6.1 Introduction

Optical radiation is any electromagnetic radiation in the wavelength range of between 100 nm and 1 mm. Optical radiation belongs to the part of electromagnetic radiation that is not capable of producing ionisation, hence called non-ionising radiation (NIR). The spectrum of optical radiation is divided into ultraviolet radiation, visible radiation and infrared radiation *(Table 1)*.

Table 1. Wavelength ranges of optical radiation

BAND	WAVELENGTH RANGE
UV-C	100 - 280 nm
UV-B	280 - 315 nm
UV-A	315 - 400 nm
Light	400 - 800 nm
IR-A	800 - 1400 nm
IR-B	1.4 - 3 µm
IR-C	3 µm - 1 mm

6.2 Scope of the EU Directive on Optical Radiation

The Directive (2006/25/EC) lays down the minimum requirements for the prevention and early diagnosis of damage to the eyes and skin from optical radiation. It sets exposure limit values and requires employers to carry out risk assessments. It also includes provisions on workers' rights to information, training, consultation and health surveillance.

Agreement was reached on most aspects of the Directive at an early stage, but there was one major hurdle: unlike the Council, Members of the Parliament believed that national authorities - rather than the EU - should lay down the rules on whether and how employers should assess dangers to the eyes and the skin of natural radiation from the sun, and how they must respond to such risks. The Council, on the other hand, wanted employers to

not only assess the risks, but also to set up an action plan if a risk is identified.

The EU directive was given by the Parliament and the Council in February 2006. The deal approved excludes any reference to natural optical radiation from the Directive and thus limits its scope to artificial optical radiation. The Council accepted the Parliament's demand that the legislation should not cover natural optical radiation sources, i.e. the sun.

Figure 1. Eye and face protection against strong optical radiation is required by the Directive

6.3 Employers' obligations

The aim of the Optical Directive is the timely detection of adverse health effects resulting from exposure to optical radiation. Therefore, the employer shall assess and, if necessary, measure and/or calculate the levels of exposure to optical radiation to which workers are likely to be exposed, so that the measures needed to restrict exposure to the applicable limits can be identified and put into effect. The methodology applied in assessment, measurement and/or calculations shall follow the standards of the International Electrotechnical Commission (IEC) in respect of laser radiation, and the recommendations of the International Commission on Illumination (CIE) and the European Committee for Standardisation (CEN) in respect of non-coherent optical radiation.

Where the risk assessment indicates any possibility that the exposure limit values may be exceeded, the employer shall devise and implement an action plan comprising technical and/or organizational measures designed to prevent this exposure.

As to the typical sources of artificial radiation, such as welding arcs, lasers and infrared sources, the Directive details the measures which the employer must consider in order to protect employees. These include adapting working methods to reduce the risks from optical radiation; limiting the duration and level of any exposure; adapting the design and layout of workplaces and workstations; and using appropriate PPE.

6.4 Worker information and training

The employer shall ensure that workers who are exposed to risks from artificial optical radiation at work receive information and training relating to the outcome of the risk assessment, e.g. the exposure limit values and the associated potential risks, the results of the assessment, measurement and/or calculations of the levels of exposure, an explanation of their significance and potential risks, how to detect adverse health effects of exposure, how to report them, the circumstances under which workers are entitled to health surveillance, safe working practices to minimize risks from exposure, and advice on the correct use of appropriate PPE.

6.5 Impact on PPE standards work

The Directive includes the exposure limit values both for laser and non-coherent radiation from 100 nm until 3000 nm. The present EN standards for eye protectors apply only to wavelengths lower than 2000 nm. Therefore they do not comply with the requirements of the Directive, and thus revision of the standards for eye protection against infrared radiation seems necessary in the near future.

References

1. DIRECTIVE 2006/25/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation). Official Journal of the European Union, L 114/38-59, 2006.
2. EN 169:2003 Personal eye-protection. Filters for welding and related techniques. Transmittance requirements and recommended use. CEN, Brussels.
3. EN 171:2002 Personal eye-protection. Infrared filters. Transmittance requirements and recommended use. CEN, Brussels.

7. The PPE Directive - improvement of market surveillance efficiency

Wolfgang Lentsch, Federal Ministry for Economy and Labour, Austria

7.1 Market surveillance

Improvement of efficiency - items to be discussed

- Improvement of MS officers training,
- Complexity of PPE Directive is and how it covers a range of different products,
- Key issues - co-operation and simplification of follow-ups for MS officers,
  - Follow-up of Commission opinions in safeguard procedures,
  - Follow-up of checklists for market surveillance officers.

Duties of Member States

- Each individual Member State is responsible,
- ADCO group: To discuss and provide guidelines for co-operation,
- PPE Directive: Only vague sentence,
- *Article 2:* 1. Member States shall take all appropriate measures to ensure that the PPE referred to in Article 1 may be placed on the market and brought into service only if it preserves the health and ensures the safety of users without prejudice to the health or safety of other individuals, domestic animals or goods, when properly maintained and used for its intended purpose.

Proposals for improvement

- Single market calls for an upgrading of market surveillance regulations,
- Closer co-operation between Member States, logistical and financial support for organizing meetings,
- More efficient safeguard clause procedure,
- Using findings of safeguard clause for similar products,
- Including actions of European Commission to speed up banning of unsafe products.

Revision of New Approach

- Commission proposal on market surveillance in regulation (stand-alone horizontal instrument),
- Commission proposal on safeguard clause procedure in Decision (toolbox for future revision of individual New Approach Directives).

Regulation:

- Impact on existing regulations of New Approach Directives not (yet) clear,
- PPE Directive regulations on market surveillance issues are poor,
- Recent solution in Machinery Directive 2006/42/EC,
- Suitable for PPE, but most likely not for horizontal regulation.

7.2 Machinery Directive 2006/42/EC

Article 4: Market surveillance

1. Member States shall take all appropriate measures to ensure that machinery may be placed on the market and/or put into service only if it satisfies the relevant provisions of this Directive and does not endanger the health and safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen.
2. Member States shall take all appropriate measures to ensure that partly completed machinery can be placed on the market only if it satisfies the relevant provisions of this Directive.
3. Member States shall institute or appoint the competent authorities to monitor the conformity of machinery and partly completed machinery with the provisions set out in paragraphs 1 and 2.
4. Member States shall define the tasks, organisation and powers of the competent authorities referred to in paragraph 3 and shall notify the Commission and other Member States thereof and also of any subsequent amendment.

Article 9: Specific measures to deal with potentially hazardous machinery

1. When, in accordance with the procedure referred to in Article 10 (i.e. Procedure for disputing a harmonised standard), the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery with technical characteristics presenting risks due to the shortcomings in the standard or to make such machinery subject to special conditions.

Article 9: Specific measures to deal with potentially hazardous machinery (cont.)

When, in accordance with the procedure referred to in Article 11 (i.e. safeguard clause against a product), the Commission considers that a measure taken by a Member State is justified, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery presenting the same risk by virtue of its technical characteristics or to make such machinery subject to special conditions.
2. Any Member State may request the Commission to examine the need for the adoption of the measures referred to in paragraph 1.
3. In the cases referred to in paragraph 1, the Commission shall consult the Member States and other interested parties indicating the measures it intends to take, in order to ensure, at Community level, a high level of protection of the health and safety of persons.

7.3 Commission opinion 03/05/2007 on filtering half-mask

Commission opinion of 03/V/2007: in application of Article 7 of Council Directive 89/686/EEC as regards a prohibition measure adopted by the French authorities in respect of a filtering half-mask.

The Commission considers that the evidence produced by the French authorities demonstrates that the type DM 0401 filtering half-mask subject

to the prohibition measure does not comply with the basic health and safety requirements mentioned above. These non-conformities constitute a threat to the health and safety of users.

Commission opinion of 03/V/2007: in application of Article 7 of Council Directive 89/686/EEC as regards a prohibition measure adopted by the French authorities in respect of a filtering half-mask (cont.)

Furthermore, the Commission draws the attention of the Member States to the fact that several types of masks bearing the DM 0401 reference and the identification number of the 0121 Notified Body which are different from the product certified by the BGIA may have been placed on the Community market, and that such products may constitute a threat to the health and safety of users.

7.4 Check lists for market surveillance officers

Austria proposed to use check list. PPE ADCO considered these to be useful, as common instrument. Other member states like Belgium have already checklist. In Belgium, these checklists were used in particular Market Surveillance campaigns. These are now available on CIRCA PPE ADCO:

- Helmets for pedal cyclist and for users of skateboards and roller skates (EN 1078)
- Personal protective equipment. Footwear (EN 345/346/347)
- Protective gloves. General requirements and test methods (EN 420)
- Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking (EN 149)
- Protective clothing. Wrist, palm, knee and elbow protectors for users of roller sports equipment. Requirements and test methods (EN 14120)
- High-visibility warning clothing for professional use. Test methods and requirements (EN 471)
- Protective clothing. Visibility accessories for non-professional use (EN 1150)
- Visibility accessories for non-professional use (EN 13356)
- Personal floating devices (ISO 12402-4)
- Personal eye-protectors
- Personal eye-protection, Sunglasses and sunglare filters for general use and filters for direct observation of the sun

7.5 How to proceed to effectiveness

- We cannot continue to work in isolation (single Member State),
- We need co-operation without legal or practical limits,
- Safeguard clause follow-up:
  - Commission must take initiative to support Member States Market surveillance,
  - Minimum: provision of distribution lists,
  - To be achieved: procedure according to Machinery Directive 2006/42/EC.
- Checklist follow-up:
  - To be established with consultancy of standardizers and Notified bodies,
  - Product sectors to be identified: PPE ADCO,
  - To be examined and elaborated for future strategy: PPE ADCO,
- PPE ADCO: Regular invitation to CEN/CENELEC, Standards consultants, NB-PPE group.

8. Personal Protective Equipment – wanted, a feedback system.

Roland Gauthy, ETUI, Health & Safety Dept - Brussels, Belgium

8.1 Introduction

Their nature and the work situations that require them to be used mean that PPE is always critical from the workers' viewpoint and often extremely sensitive in terms of prevention. This article looks at how a dynamic and proactive approach can be taken to PPE from the two angles of prevention and the worker's situation.

8.2 A critical process

Allocating PPE is a critical process because of the reason why they are being allocated – namely that there is a risk situation in which hazards cannot be avoided by traditional prevention. The golden rule in prevention is risk elimination, so prescribing PPE is always a sign of failure – i.e., a situation that does not or cannot comply with the golden rule. The situation therefore remains hazardous for the exposed workers, which in turn requires management to look at the remaining hazards in order to limit their impact, find substitutes, inform and train the exposed population of workers. A typical strategy to replace unsuccessful risk elimination is to set up a risk reduction policy coupled with the knock-on prescription of PPE.

8.3 A problematic process

The use of PPE in such a situation is extremely problematic as it will corrupt the initial analysis of the work situation: it will modify the hazards and exposures (possibly adding new ones to those already existing), alter the wearer's perception, comfort and control, modify the person-system interfaces and add new stresses (constraints). These alterations will obviously require the entire work situation to be re-assessed. This dynamic process is a cornerstone of modern prevention: it is based not on "risk management" (which has a connotation of "hazard administration" where the hazard remains but is monitored on "score sheets", but rather on an ongoing endeavour to eliminate hazards through eradication, substitution, re-design and generally mainstreaming risk alleviation and well-being policies. Do SMEs – who make up the majority of European employers - have the capacity, competences or skill to do so? Do bigger firms always do so, including in more exceptional situations like limited runs, after incidents, etc.?

The variety of work situations is huge; but at the same time, competences and skills are often outsourced, and so not necessarily available where and when needed. The mainstreaming of risk alleviation and well-being at work mentioned above therefore needs to be based on a quite unique system – that of participation in the assessment, design and choice of equipment, including PPE. This article describes a model based on the use of workers' experience.

The choice and allocation of appropriate PPE is also critical as it is often the last thing that protects workers against physical harm. The wide range of hazards (e.g., chemicals, dust, electromagnetic waves and so on) mean that PPE suppliers worldwide are placing on the market more - if not more appropriate - competing products that leave buyers and end-users/operators confused. And even if the PPE are "CE-marked" – which not all are - questions remain about their suitability, effectiveness, use and dangers of misuse in specific situations. This is why the work situation has to be assessed and re-assessed on an ongoing basis as described above.

Another thing to bear in mind is that some classes of PPE have to fulfil a dual function of protecting production (e.g. food processing, pharmaceutical industry) from the risk of contamination by workers while at the same time protecting workers from hazardous processes (e.g., heat, UV, chemical hazards): which part of this dual role will get priority from job design engineers if workers' input and prevention practitioners' views are not integrated into the risk elimination or reduction process?

8.4 The need for an integrated approach

The need for such an integrated approach is obvious: it is a basic, repeated demand by workers and prevention practitioners as a minimum contribution to promoting healthier workplaces. In other words, work and successive changes in work situations over the entire working life*, should never lead to any form of harm to individual health – whether physical, social, mental, sensory or emotional Seen in the bigger picture, PPE need to be looked at as part of a systemic approach in which a least three subsystems interact: human factors, risk factors in the working situation and PPE-related factors. At the centre of these interactions lie well-being at work and the safety of workers.

We have seen that the most appropriate solution***(2)* when hazard alleviation is not a viable option is risk reduction combined with allocation of appropriate PPE and a set of administrative measures (re-assessment, information, training, etc.). From this angle, the choice of appropriate PPE means integrating data from different sources, like the wearer's characteristics (e.g., body shape and size), the "risk situation" comprised of hazards – like products, dusts, processes, etc. – the way they are dealt with, the human interactions, the artefacts (machinery), the availability of protective equipment, the commercial strategies used to promote their use, users' *** real willingness to use them properly. The complexity of the situation impacts directly on the decision-making procedure: standardized situations are normally modelled so as to facilitate decision-making, and so avoiding the iterative approach of assessment – re-assessment via participatory measures.

**The cumulative effects of different and successive exposures are generally ignored when a worker moves from one workplace to another, apart from in the case of radiation exposures.*

***This is even the basic requirement of EU Framework Directive 89/391/EEC on the safety and health of workers*

****Two different end-users have to be considered: buyers of equipment who bear entrepreneurial responsibility, and operators who use it to perform the tasks and missions assigned to them by the equipment buyer.*

This generalized short-cut strategy, combined with the fact that engineers and work systems designers design systems or tools that are sold by others who are "not aware of the inbuilt hazards", create complex situations once in operation, including failure, pace changes, etc., that are anticipated and corrected as they go by experienced workers. In fact, they pay a price for poor production system design that is usually due to ignorance of these failings. That ignorance usually stems from lack of communication and a lack of time at any stage of work system or machinery design: the engineers and designers do not work on shop floor, and the workers are not consulted or not used to communicating their difficulties to them: they are not normally trained in conceptualizing difficulties, and even where they can do so, no forums are provided to enable or stimulate such an exchange of views and practical experiences.

8.5 A need for structured communication: an experience feedback mechanism

This woeful lack of communication makes a platform to facilitate the exchange of information essential. Taking the Machinery Directive and the standardisation work done under it at European level as their framework, therefore, a team of researchers *(European system to improve machinery safety by drawing on users ' experience (2))* developed an "experience feedback system" that was tested out on one of the most dangerous machines - the forklift truck (*see figure 1*). The similarities between the Machinery Directive *(3)* and the PPE Directive are compelling.

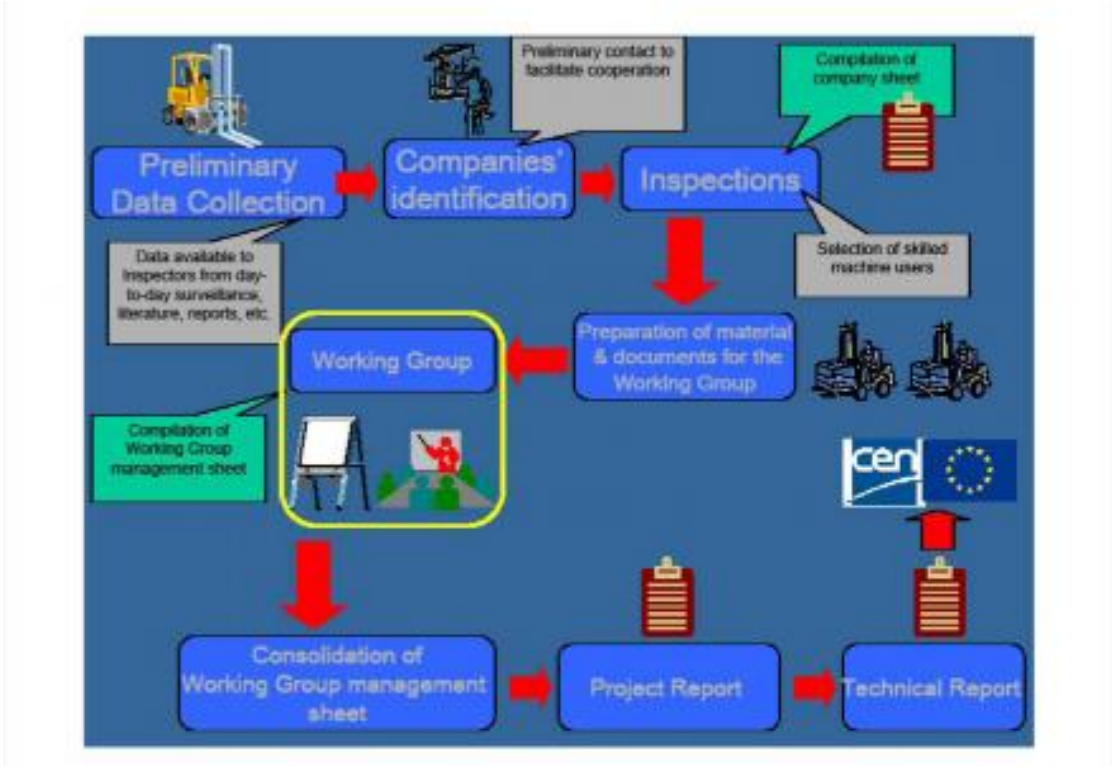


Figure 1. Developed "experience feedback system", tested on the most dangerous machine, namely the forklift truck

8.6 Reach

The specific context of REACH, where manufacturers must provide the so called DNEL (derived no effect level), and substances and products are manufactured all over the world, makes the choice of appropriate PPE more critical still. To achieve the DNEL, the manufacturer must propose risk reduction measures that incorporate appropriate PPE where necessary. Looking at manufacturers' values and measures from a workplace perspective where OELs (occupational exposure limits) are also in play, the question arises whether SMEs, other organisations, workers and their representatives, the authorities or occupational and environmental advisers really have the situation in grip?

8.7 Conclusion

The issues raised by PPE and others underpinning preventative mechanisms are vital to workers, their reps and the prevention practitioners who are helping them to frame well-being at work strategies. The complexity, diversity and flexibility of work situations in a globalized world where occupational health and safety strategies are not properly accommodated pose a real challenge. The flexibility and suitability needed in a globalized and changing world where small and medium-sized firms have to battle on international markets mean that efficient and relevant mechanisms, especially in the choice and allocation of protective equipment, are needed to integrate the invaluable practical knowledge developed by operators and workers.

References

1. Directive 89/391/EEC on the safety and health of workers.
2. Stefano Boy, ETUI-REHS Research Officer (2006), http://hesa.etui-rehs.org/uk/publications/pub39.htm
3. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery.

9. Implementation of (new) legislation: supplier's viewpoint

Henk Vanhoutte, European Safety Federation (ESF), Belgium

9.1 Introduction

PPE suppliers are confronted with an abundance of legislation. This is legislation either directly related to their products (e.g. manufacturing, marketing), or related to the use of their products (e.g. occupational health and safety legislation). Most of this legislation is European, but in some cases, there are differences between the Member States. What are the consequences for PPE suppliers of this great amount of legislation? How should they cope with it and what should be done to make it more transparent for all stakeholders?

9.2 Set of legislation

The *New Approach legislation* is the first important set of legislation. The PPE Directive (89/686) is of course the basis for the CE marking of PPE. However the revision of the "global approach" legislation will influence the daily life of PPE suppliers, and other specific directives may have an impact on specific PPE products. Next we should look at medical devices (MDD), pressure equipment (PED), equipment for use in potentially explosive atmospheres (ATEX), construction products (CPD) and so on.

General aspects are covered by a set of legislation that also needs to be taken into account in the design and production of PPE. Some of this legislation is recent (for instance REACH), others have existed for longer, but all are constantly evolving. Here we have to look at specific legislation on innocuousness (e.g. nickel content, azo-colorants) but also very general aspects such as environmental issues (e.g. waste removal) or legislation on products that come into contact with food and so on. The General Product Safety Directive also needs to be taken into account.

On the other hand, there is also a set of legislation for the "use" side of PPE -*the Occupational Health and Safety* framework Directive 89/391 with specific directives in the application of the framework. The PPE Directive 89/656 is well-known and applied, but the other directives (ATEX, Noise, Vibrations, Optical radiation, Chemical agents) also have an impact on the use and selection of PPE for specific situations, and thus need to be considered by PPE suppliers.

For those living in the EU, it is somewhat easier, as there is one set of legislation for the whole EU market. Or is this really the case? Certain aspects contain differences in the *national legislation* of separate EU Member States. A clear example is the limit values for chemical agents that differ from country to country. And of course, even with the same legislation, differences in interpretation by different authorities are not uncommon.

Nevertheless, here we first look at occupational environments, where PPE is increasingly used in private situations. This means that for the "use" side,

we are not only confronted with worker protection legislation, but also increasingly with *consumer protection.* This sometimes demands a specific approach by the PPE supplier, even if the product itself is the same.

The result of this *multitude of applicable legislation* is that it is not always easy for PPE suppliers to find their way in all these rules. Finding out what is really applicable for a specific product for a specific use can be difficult. However, this does not only pertain to the PPE supplier; all the other stakeholders also have similar problems. These results in a day-to-day reality: it is often only the PPE Production Directive (89/686) that is properly considered during design, production and marketing.

9.3 Implementation of the legislation

Even if a PPE supplier would like to take all applicable legislation into account, properly implementing this is made very difficult. What about the *harmonization* of the legislation? Having different definitions for the same notion certainly does not help (see definition of PPE in 89/656 and 89/686) and makes it hard for the average European citizen to understand. In certain directives, some product groups are excluded, which can also lead to problems. However, taking away these exclusions can lead to even bigger problems if all elements are not taken into account when making these revisions.

As an example, we can take the Medical Devices Directive and the PPE Directive. Until now, there has been an exclusion in the directives, so that a product cannot be a PPE and an MD at the same time. In reality however, there are products that protect both the patient (MDs) and the medical staff (PPEs). In a revision of the MDD, this exclusion is lifted, without, however taking full account of the provisions of the PPE Directive. Indeed, products that are to be classified as PPE category III and as MD class 1, will have to follow the conformity assessment of the MDD, resulting in auto-certification without any involvement of a notified body or third party. This means that in reality, the manufacturer of a mask who claims that his product can also be used as a surgical mask, will also be able to autocertify this mask for the protective properties that are typically subject not only to type examination but also to quality control by a notified body. We can only hope that those responsible for this legislation are fully aware of the possible consequences and have thus fully taken the health and safety of PPE users into account.

Manufacturers designing products that need to fulfil different "new approach" directives, with *CE marking* as a consequence of the conformity assessment, face extra difficulties. Indeed, the conformity assessment procedures for different directives are not usually the same. This means that for the same product there are different procedures to follow, which is of course confusing, and a possible source of mistakes. At the same time, bodies are very often notified of only one directive. So if the conformity assessment demands CE-type examination or more from a notified body, the manufacturer has to work with several notified bodies for the same product. The worst case scenario is that there are contradictions between the notified bodies involved. Which notified body has the final responsibility for the total product? A clear procedure for this type of products would certainly be helpful, preferably with one leading notified body. Thus certain parts can be "subcontracted" to another notified body, which would greatly help work towards the transparency of the system.

In the OHS Directives, reference to PPE is hardly made, apart from "the appropriate PPE needs to be used". For several of these directives, *guides for practical implementation* have been published by the EU Commission. Unfortunately when it comes to practical information for the PPE user, there is no more information than in the Directive itself. In practice, suppliers of PPE feel that there are many questions in the industry concerning appropriate PPE for specific situations (for instance ATEX). This is an issue certainly worth the attention of the authors of these guides, either for future revisions or for new guidance documents.

One of the issues receiving much attention recently is the *innocuousness* of PPE. This is certainly a very important issue and consumer awareness has been increasing due to some unfortunate cases with other products. It is clear that it makes sense to protect the user of PPE on the one hand and harm his health on the other by the use of certain dangerous substances. At this moment however, there are many open questions about the appropriate test methods for demonstrating the absence of harmful substances, the costs involved in these tests, and even about what substances need to be tested. The fact that the presence of a substance does not necessarily mean that the substance will be released and thus cause harm for the user, does not help in determining the test method. Common sense is required of all stakeholders if we are to find answers to these questions, and be able to reassure the consumer about the safety of PPE. As for all other aspects of PPE, it has to be made clear that these rules concern all manufacturers, also those from third world countries. This means that strong market surveillance is also necessary for these aspects. In fact, the question of innocuousness could be addressed to other aspects such as environmental issues, social responsible production and so on. In other words, "fair trade".

9.4 Conclusion

Given the wide scope of legislation applicable to PPE, all PPE stakeholders clearly need to look outside the PPE box. Co-operation and communication amongst them is needed more than ever. In addition, co-operation and communication with stakeholders in the general OHS or consumer safety field are clearly needed in order to achieve the goal of safe and healthy products for all EU citizens, supplied in a market that is open for all fair players.

10. New regulations – Views of Notified Bodies

Karl-Heinz Noetel, BG BAU, Germany

10.1 Introduction

This seminar is intended as a forum to discuss the impact of new EU-regulations on the PPE field. Looking at the new regulations and normative texts from the view point of the Notified Bodies (NBs), some have a larger impact on their work than others. In this presentation, I will focus on the regulations – especially the New Approach – that may have a major impact on the work of the NBs and address some issues that, from their viewpoint, will need further discussion.

10.2 Reach

The impact of REACH and the implementation of its decisions in all European countries are not likely to have a direct impact on the testing and certification of PPE. PPE is primarily affected by the use of relevant protection equipment when handling chemical substances. REACH requires the chemicals manufacturer to draw up exposure scenarios (inhalation, oral, dermal) and provide information on protective measures, i.e. including information on PPE, as relevant. This may also entail a need for more detailed specifications in the user information provided with PPE. In addition, it could eventually increase the general demand for PPE, and possibly require the development of new PPE for specific chemicals or scenarios.

10.3 Medical Devices Directive

The amendment of the Medical Devices Directive is a significant matter of concern, not only for the NBs, but also for manufacturers and Market Surveillance.

The amendment was to bring about a solution to the long-standing issue that a product could not be covered by both the Medical Devices and the PPE Directive at the same time. However, the situation has not really been solved by the current text and related interpretation. According to the amendment, a product can now in fact be covered by both Directives. This may sound a good achievement, but the interpretation effectively seems to be that the product will then be CE marked under the Medical Devices Directive, taking into account the requirements of the PPE Directive. It has to be noted that the certification procedures defined in the two directives are not identical. Products that would be category III PPE and thus require an EC type examination as well as quality control procedures could be covered by self-certification under the MDD. Thus, if a PPE can also be defined as a medical device, third-party testing will no longer be involved. Not only will there be confusion on the market, when the same type of product may be placed on the market as CE marked as 'pure' PPE or as a 'dual use' product. In addition, there is concern that manufacturers may declare their products dual-use products, and apply the certification rules of the Medical Devices Directive, avoiding the more demanding certification requirements of the PPE Directive, to reduce their costs. The situation urgently needs to be reconsidered by the stakeholders involved in medical devices and the PPE

field. The NBs hope that a solution can be agreed before the amendment to the Medical Devices Directive comes into force in March 2010.

10.4 New Approach

During the last few years, the EU Commission evaluated the experiences of the implementation of the New Approach Directives and started a revision of the New Approach. Although this process has not been fully completed, the discussions in the European Commission and the European Parliament are fairly advanced, and an initial evaluation of the coming regulations can be made.

Regulation

The draft for a Council Regulation mainly covers the issues of accreditation and Market Surveillance. The effects on NBs are rather indirect, but can still be important for the work of the NBs:

- A harmonized accreditation system may help to harmonize the basis for notification which is still different in the Member States. Currently, the requirements that national authorities set out as a basis for assessing the competence of a certification body are more stringent in some countries than in others, e.g. with regard to reporting, and fields of competence etc.. A harmonized approach may help reduce issues of competition between NBs.
- With the strengthening of market surveillance in general, and the involvement of customs authorities, the number of product checks that are carried out in Market Surveillance activities is expected to increase. Stronger co-operation among the authorities involved in Market Surveillance may also contribute to levelling out differences in the decisions taken by Market Surveillance authorities regarding product deficiencies. This is welcomed by the NBs, who often are the first point of contact for manufacturers when they complain about a lack of market control or unexpected burdens placed on them.
- Even if NBs are not directly involved in Market Surveillance activities, there may be a growing demand for testing to be carried out as subcontractors for the authorities. If Market Surveillance authorities choose or build up their own test institutes, they should become involved in inter-laboratory tests, in order to ensure the uniformity of the test results reached by NBs and by independent laboratories.
- When Market Surveillance authorities identify a problem with a product, it may be useful to systematically contact the notified body that was involved with the certification in the first place, in order to find out the reasons for the problem. Market Surveillance authorities should also be aware of agreements that NBs make regarding their testing and certification activities (e.g. Recommendation for Use sheets).

The NBs expect the Regulation to contribute to harmonizing notification requirements and strengthening Market Surveillance activities, and are looking forward to the practical implementation of the Regulation.

Decision

Whereas the Regulation will come into effect directly, the "Decision of the European Parliament and the Council on a common framework for the marketing of products" is intended to merely define the framework for the New Approach Directives. It will offer a "toolbox" for the individual sectors to take into account when they start reviewing or revising individual directives.

With regard to the PPE Directive, the Commission does not seem too keen to start the revision process soon; it has been mentioned that there may be a period of observation with regard to the New Approach documents and also possibly the PPE Guidelines before the official revision process can begin. Therefore, there may be those who say that it is too soon to look at the impact the Decision document may have on the PPE sector, and that it would be useful to define points for future discussions. On the other hand, there have been quite a few discussions in recent years about the interpretation of the PPE Directive and the need for changes, and the draft version of the Decision document seems to offer "tools" that may be used to address some of the long-standing issues surrounding the PPE Directive.

As the NBs are directly affected by some of the issues, I will take up some points that are of specific interest and offer them for future discussion.

- In the past, the definitions of the "manufacturer" and in particular the "authorized representative" (inside or outside of the EU) was repeatedly questioned. The definitions of the roles and tasks not only of these two categories, but of a whole range of "economic operators" may help to clarify the lines of responsibility. In this context, the Decision also offers a clearer specification of "own-brand certificates", which seems to support the approach taken by the PPE NBs.
- Together with the Regulation, the Decision offers the chance for stricter control of NBs by the notifying authorities/Member States, reaching as far as the withdrawal of notification if necessary. Clarifications can be introduced to notification procedures, for example sub-contracting by NBs, which has not always been handled uniformly.
- For the NBs, it is a very positive step forward that the Decision requires the obligation of NBs to follow standardization activities and the activities of the Coordination of Notified Bodies. Past experience has shown that a limited number of NBs spend time and money on activities that are needed to ensure their competence and harmonized working methods, for example through their participation in meetings and in inter-laboratory tests, and through the recognition of the Recommendation for Use sheets. The new possibilities offered by the Decision can help to improve the competence of NBs and reduce unfair competition by those who do not care to be involved in these activities.
- The draft Decision seems to aim at making it clear that a harmonized standard must not be assumed as fulfilling all basic health and safety requirements. Clarification is needed here, as some consider standards a sufficient basis for the presumption of conformity once their reference has been published in the Official Journal. However, it is acknowledged that the lack of specifications in a harmonized standard may mean that manufacturers, NBs and Market Surveillance authorities take different views as to what has to be required and tested in addition to the standard. Therefore, it would be of benefit if standards could actually cover the relevant basic health and safety requirements as completely as possible.
- An issue that has been discussed at length, but with no real solution is the tasks and obligations of various parties following the revision of a standard. The main issues in this context are points such as the

assessment of the significance of changes, the decision when a product has to undergo a new EC type examination or the mutual responsibilities of manufacturers and NBs. The NBs take the view that the assessment of the changes would best be left to the standardization bodies, where all stakeholders are involved. A revised PPE Directive would offer the opportunity to clarify responsibilities so that a product on the market would not be judged differently by the various authorities.

- With regard to the conformity assessment procedures, the draft document intends to offer manufacturers the widest possible choice of conformity assessment modules. Burdensome procedures are to be avoided, and the modules should be based on the Modules Decision. Although this is generally accepted, there are two major concerns in the field of PPE that will need careful consideration:
  - The Modules Decision does not offer any module that reflects Article 11 A of the current PPE Directive. Many PPE manufacturers follow Article 11A, and the change to another quality control route may be burdensome and costly, especially for small and medium-sized companies.
  - The NBs do not consider module H an appropriate choice for PPE. A third-party type test is generally seen as the necessary basis for PPE certification.
- Another important issue for the revision of the PPE Directive remains the question of time limits for certificates. In the past, the view was that there cannot be such limitations, but this approach was recently changed to the view that it is down to a contractual agreement between the manufacturer and the NB. As experience shows, manufacturers often inadvertently change their products in the course of time. Product changes would only come to light when a product has to be reviewed after a certain period of time, which NBs consider important for continuous safety.

10.5 Conclusions

New regulations and directives bear a more or less direct impact on the work of NBs. The latest developments (especially with regard to the New Approach) can generally be seen as positive, although there are still a few points of concern. The next stage will be the review of the PPE Directive, which was already discussed a few years ago, but was stopped and delayed until the New Approach revision was available.

The process should now be taken up again. A revision of the PPE Directive in the light of the New Approach Decision will offer the opportunity to solve issues that have been a matter of concern for some time.

Even if there is no clear plan for a revision yet, discussions should under way in preparation of a future review of the PPE Directive. It is important to assess the impact that any major changes will have for manufacturers, NBs and the authorities (Market Surveillance). Therefore it will be necessary to address these issues at an early stage and take into account the experience that the stakeholders have gained over the last 20 years.

11. Respiratory Protective Devices (RPD) within ISO TC94 SC15 – a progress report

Wolfgang Drews, Dräger Safety AG & Co KGaA, Germany, Chairman of ISO /Technical Committee 94/ Sub Committee 15

11.1 Introduction

The existing worldwide standards for respiratory protective devices (RPDs) are product or design-orientated. Sub Committee 15 (SC 15) within ISO TC 94 was founded in 2002 to start performance-orientated standardization based on the demands of wearers in their work environments. Human factors are the drivers for deriving the performance characteristics of future RPD.

11.2 Organization

SC 15 has structured its task by installing 3 working groups *(Figure 1).* WG2 and WG3, with their Project Groups, are responsible for writing the two main standards for filtering devices and supplied breathable gas devices. WG1 handles general topics such as human factors and the classification of RPDs. It was and still is essential that this WG is ahead of the standard writers work and supports the definition of the performance criteria of RPDs. The core of these criteria is the documents prepared by PG5. The first of a series of 5 titles related to Human Factors was published in 2007 as ISO 16976-Part 1-metabolic rates.

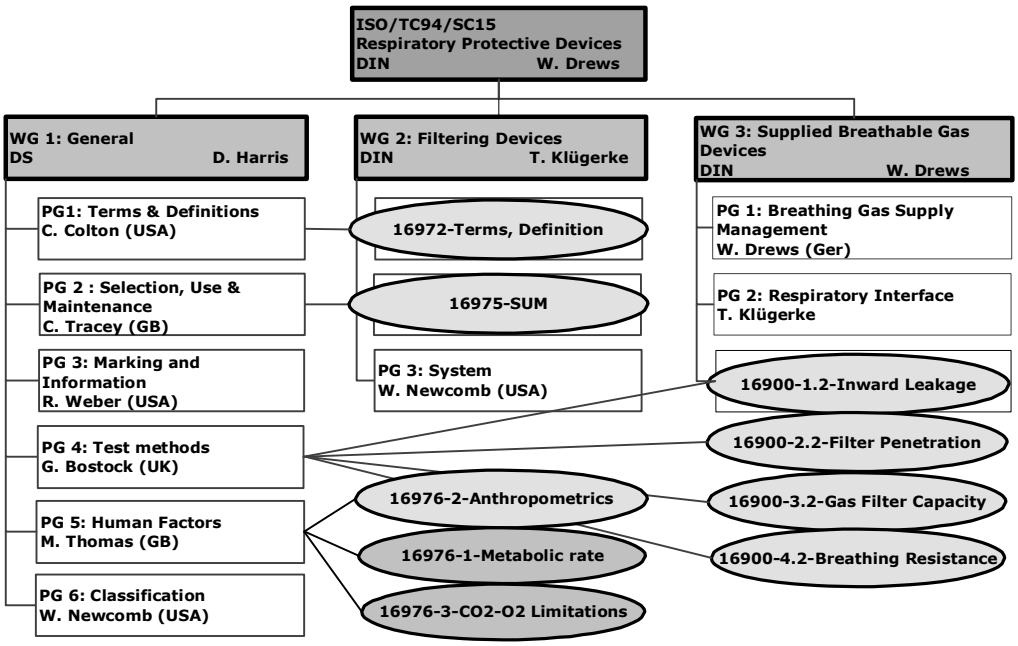


Figure 1. Working group ISO/TC95/SC15, Progress report, ISO-SC 15 Structure

Part 2 and 3, Anthropometrics and CO2- and O2- limitations will follow soon. Topics such breathing resistance, work of breathing and ergonomic characteristics will be considered in the near future. All performance criteria will be tested according to methods which will be listed separately under the ISO 16900 series of standards. The first 4 test method standards are in the voting routine. The "Terms and Definitions" standard is on page 2 in the final consideration, and the selection process, documented in the ”Selection, Use and Maintenance” standard follows the new classification scheme.

11.3 Metabolic Rates

When writing the appropriate performance characteristics of an RPD, standard writers have to understand the relation of human breathing and the workload humans are faced with whilst wearing an RPD. The oxygen uptake of wearers is related to the ventilation rate of the lungs and directly linked to these metabolic rates. According to the physiological measures described in ISO 16976-part 1, the metabolic rate is defined in Watts per square metre of body surface. The higher the surface, the more oxygen is needed to support muscle activity. This relationship is shown in Figure 2 for a human with a small body surface in comparison to a human with a large body surface. Eight levels are defined from resting to the exhaustive rate of 600 W/m^2 which reflects, for example the metabolic rate of a fire fighter in the application of structural fire fighting running up stairways. The corresponding minute volume for this activity for a large wearer will be 116 l/min. To cover a wide range of wearer's individual ventilation profile, the second standards error value is also given, which leads to 150 l/min. It has been found that speaking during ventilation is associated with high peak flows which also have to be considered by the standard writers.

Small person, body surface 1,69 m2						
Class	**Average metabolic rate**	**Oxygen uptake**	**Minute volume**	**Minute vol+2SE**	**Peak flow rates**	**Peak flow rates Speech**
	W/m2	l/min (STPD)	l/min (BTPS)	l/min (BTPS)	l/sec (BTPS)	l/sec (BTPS)
1	65	0,315	10	13	0,79	2,10
2	100	0,485	15	20	1,14	2,64
3	165	0,800	25	33	1,72	3,43
4	230	1,115	36	46	2,27	4,08
5	290	1,406	45	58	2,76	4,61
6	400	1,939	62	80	3,60	5,46
7	475	2,302	73	95	4,16	5,98
8	*600*	*2,908*	*93*	*121*	*5,05*	*6,76*
Large person (acc. to ISO 8996), body surface 2,11 m2						
1	65	0,393	13	16	0,95	2,36
2	100	0,605	19	25	1,37	2,96
3	165	0,997	32	41	2,07	3,85
4	230	1,390	44	58	2,73	4,59
5	290	1,753	56	73	3,31	5,18
6	400	2,418	77	100	4,33	6,13
7	475	2,872	91	119	5,00	6,71
8	*600*	*3,627*	*116*	*150*	*6,07*	*7,59*

ISO standard man (ISO 8996), body surface 1,84 m2

Class 1= resting, Class 2 = low MR, Class 3 = moderate, Class 4 = high, Class 5 = very high, Class 6= very very high, Class 7= intensive work, Class 8= exhaustive

Figure 2. Metabolic rates (MR) Vs Body surface, ISO/TC95/SC15, Progress report

From these human factors, "classification" of the project group derived seven classes of work rates, of which "resting" was not one. Taking into account one standard error of the metabolic rate of the large wearer, the graph in *Figure 3* shows the relation between the metabolic rates and the work rates classes. This line covers a 95 percentile of the wearer population and derives classes from 20 l/min to 135 l/min with its relevant peak flow values.

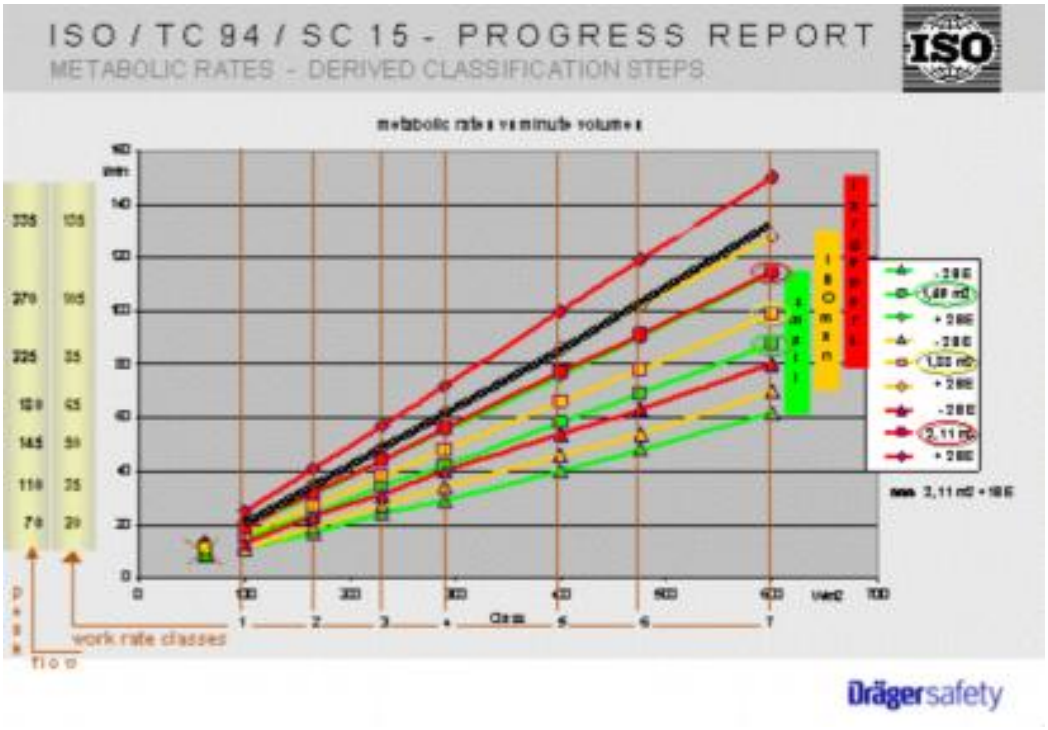


Figure 3. Metabolic rates - derived classifications steps

Compared with the existing requirements for testing RPDs, the maximum ventilation rate can be found in the NFPA Standard (USA) with a test level of 105 l/min. With the highest work rate of 135 l/min, the performance level of future RPDs will be roughly 30% higher once the RPD claims to fulfil the highest work rate class.

11.4 Flow Pattern

There is general discussion as to whether the setting of a laboratory breathing simulator should be based on the characteristics of human breathing cycles or whether a sinousoidal loop of inhalation and exhalation is close enough to represent human breath. *Figure 4* shows a typical sinousoidal breathing cycle with a tidal volume of two litres. A more realistic breathing cycle, the trapezoid breathing cycle, is shown on the right with the same tidal volume of two litres, where the inhalation follows the trapezoid contour whilst the exhalation differs. Furthermore, a human's inhalation cycle is shorter time-wise than exhalation, which is expressed as the ratio between the time of inhalation to the total breath cycle time in percent. The example of *Figure 5* visualises a typical ratio of 44%.

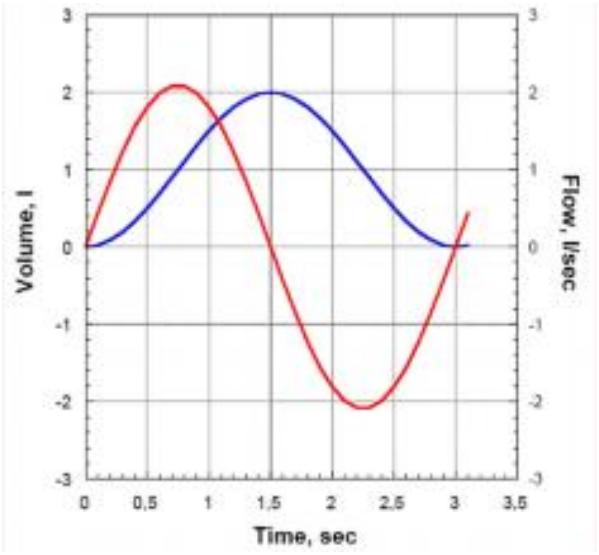


Figure 4. A typical sinousoidal breathing cycle

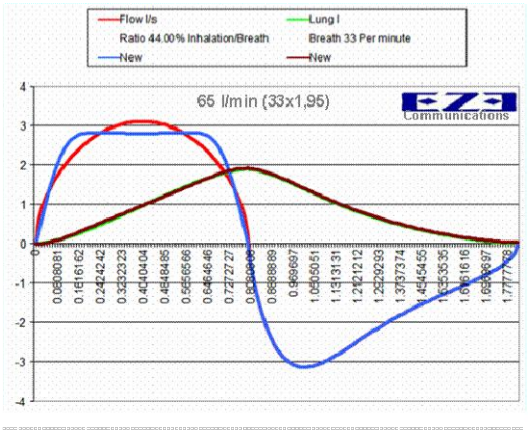


Figure 5. The trapezoid breathing cycle

Interestingly enough, humans respond to workload by the rational: the higher the work rate, the lower the ration is. How this will be transferred to test parameters for the seven work rate classes mentioned above is to be discussed within the Project Groups and has not yet been decided.

11.5 Anthropometrics

A very important area is the respiratory interface of human faces and the RPD. Based on the scope of this ISO-Subcommittee to derive performance characteristics of future RPD that fits a 5 to 95 percentile of the total wearer population, the face shape, geometry, and its anthopometric data have been analysed. The first approach follows the historical route. Two specific head contours, the face width and the face length, of more than 3000 US citizens were measured. It was the assumption, that within the US population all different head sizes, forms and contours were covered by the three main different ethnic groups: the negroid, the mongoloid and the caucasioid – see *Figure 6*.

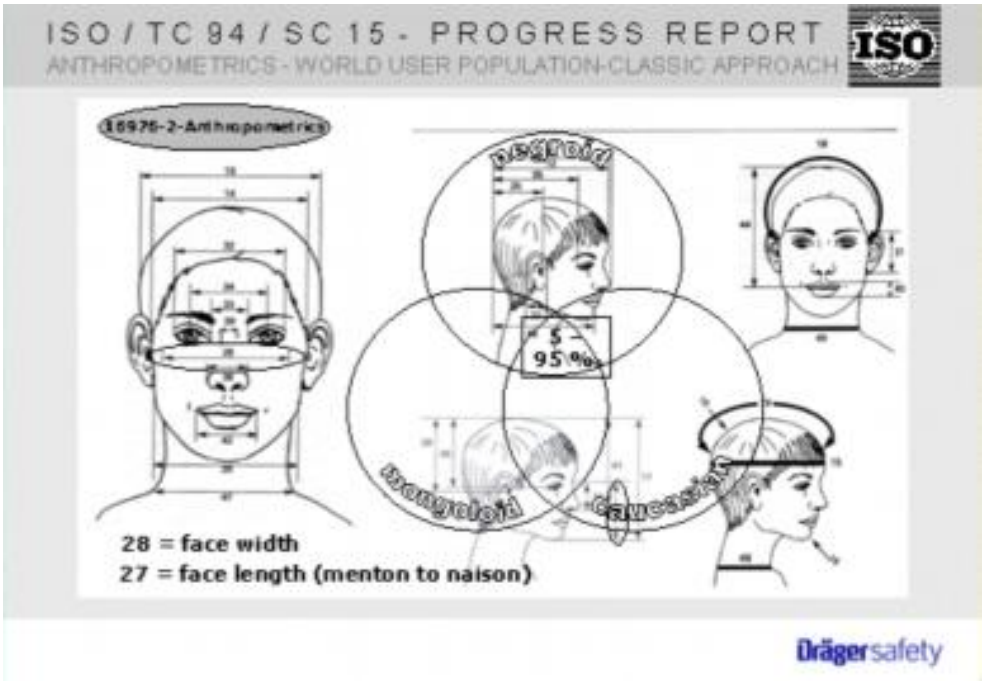


Figure 6. 16976-2 Anthopometric

By plotting these data in a bivariant distribution graph, 10 cells based on the well-known Los Alamos Panel could be generated to cover 5 and 95 percentiles of the wearer population - see *Figure 7*. If each of the ethnic group had covered its relevant cells, and the centre cells had been occupied by at least two groups, the solution would have been easy. However, the wearer population is much more inhomogeneous; globalisation has generated a mix of all face contours in almost all workplaces.

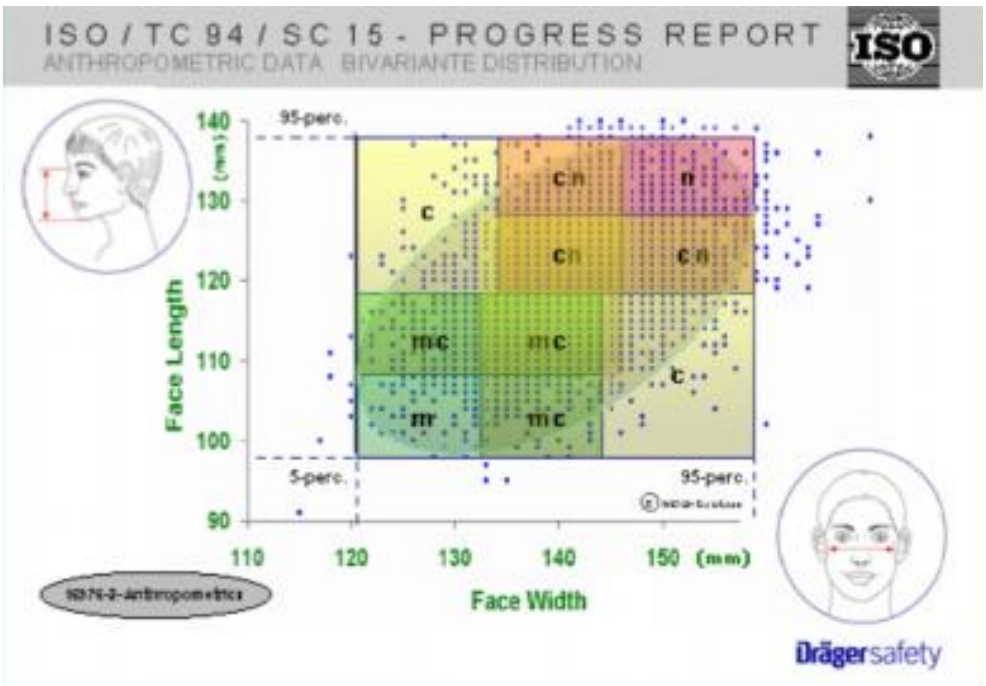


Figure 7. Anthropometric data, bivariante distribution

This approach was thus withdrawn and a new concept: the Principal Component Analysis, derived from 10 significant anthropometric measurements including face width and face length of wearer faces - see *Figure 8*- was developed. The PCA distribution panel was also generated. ll the 10 data points of the same 3000 test subjects taken for the Bivariant Analysis explained above were modelled by the PCA-analysis algorythm. The result of the two components of each person is shown in *Figure 9*.

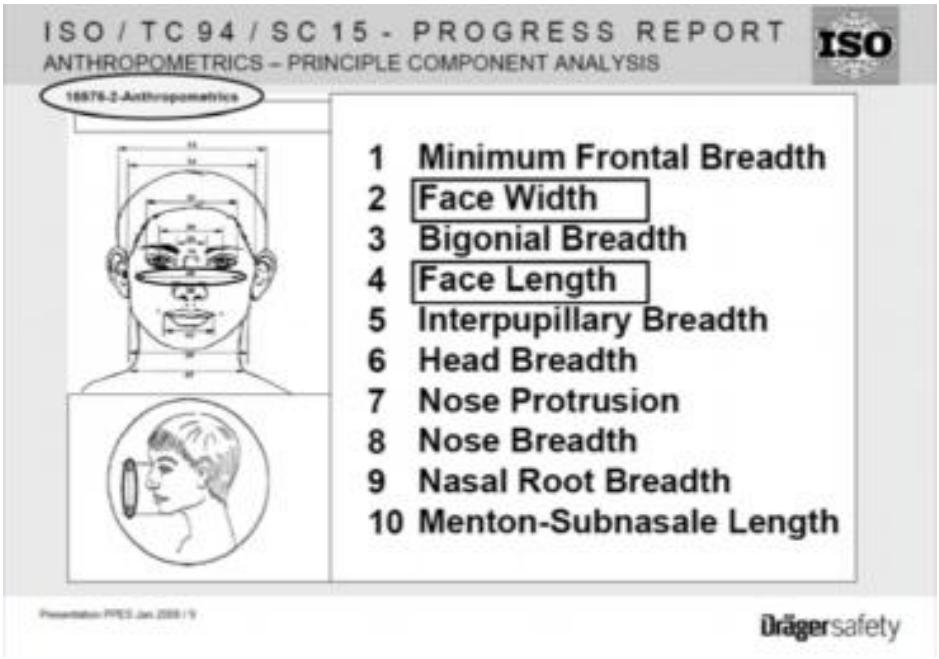


Figure 8. Anthropometric, the principle component analysis

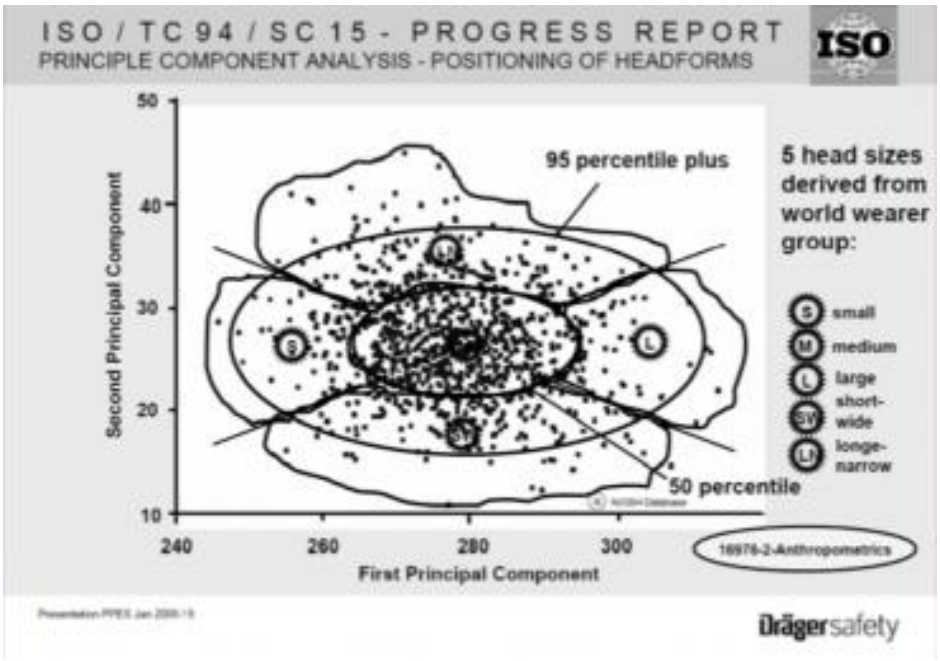


Figure 9. The principle component analysis

The 95 percentile of the wearer is outlined by an ellipse. The 50 percentile distribution is formed by the inner ellipse which represents medium size. Cutting the ellipses diagonally generates four additional segments, and the centre contours of each segment are calculated by the arithmetical means of all the data points within those segments. Five new head sizes were derived; in addition to small ”S”, medium ”M” and large ”L”, two additional head forms are defined - heads with short noses and wide head breadth: ”SW”, and the opposite, long noses and narrow face: ”LN”. These head forms were modelled by using five scans from person heads very close to the centre of the mathematical means. By an overlay of all five contours, a new, neutral size was created. A test head will no longer be a copy of one individual person.

11.6 Classification Scheme

Future RPDs will be classified according to their performance characteristics, which will result in a new scheme valid for both standards: the filtering device standard and the standard for supplied breathable gas devices.

The first column in this scheme – see *Figure 10* - represents the ”Mode of Operation” as a primary function, telling us whether the RPD filters hazardous substances or whether it supplies the wearer with breathable gas. The second column deals with the Total Inward Leakage (TIL), a value given in percent as a result of a laboratory test with test subjects wearing the RPD. Six levels from 20% to 0,001% were established. The third column reflects the appropriate work rate a wearer has to maintain and is described above.

These three columns will describe the basic system characteristic of an RPD. In the example, bottom left in *Figure 10*, the ”C5e” clearly identifies this device: ”supplied breathable gas device with a high TIL value 5 means 0.01% and with an extremely high work rate ”e” (85 l/min). Besides the basic characteristics, special application-driven characteristics, such as requirements from structural fire fighting, might exist. That RPD will be classified by adding SAF1 ”Special Application Fire fighting 1”, where 1 stands for structural fire fighting. If fire fighting activities present a chemical, biological, radioactive or nuclear threat, these specifics will be identified as CBRN. The total classification tells wearers about the overall characteristics of the RPD needed to protect them in their work environments. As concerns gas filtration, the various hazardous gases are clustered into four types - see column 4 in *Figure 10* - and one or more types can be selected. Associated to the type is the gas filter capacity, which will have four levels from 300 ppm up to 9000 ppm. These are comparable to the levels in European Standards today; the only new level is the lowest one, which reflects many user profiles, especially in the Asia Pacific region. The example chosen – see Figure 9, the lowest box in the centre - shows ”B3b” which means it is a gas/vapour filtering device (mode) with a level 3 of TIL, i.e. 1%, and a moderate work rate of 35 l/min. In this example, the type is a basic gas and the concentration is 3000 ppm. The box above shows the example of a typical particle filter, indicated by the first letter A from column 1, a 4 for the fourth TIL level and a ”d” for very heavy work rate (65 l/min). Another characteristic specifically for particle filters is the level of filter efficiency or penetration level. In the example given above, the Particle Filter Efficiency PFE is set to level 5, i.e. 99,99% efficient compared to a stored unbalanced backup. The concept follows the same principles for combination filters – see the third example in *Figure 10*.

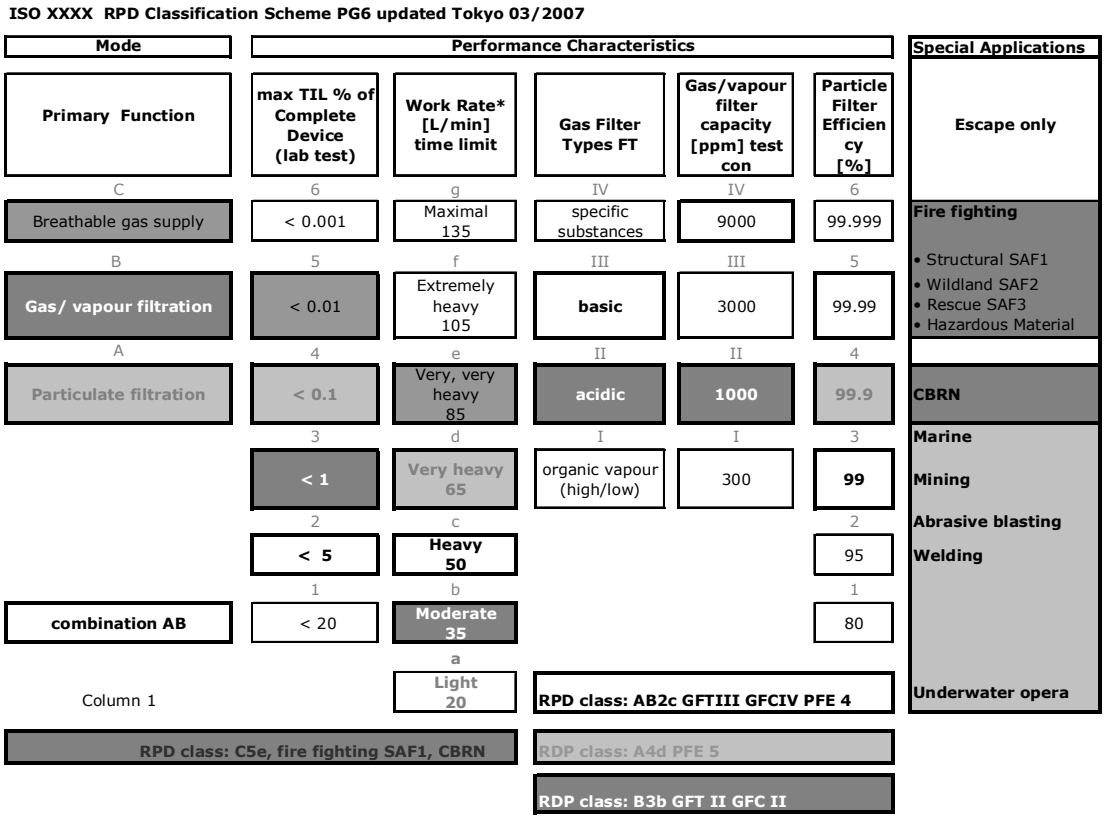


Figure 10. Classification scheme, ISO/TC 94/SC 15 RPD

11.7 Selection Process

One of the most important decisions regarding the occupational health and safety of workers is the selection of the right RPD prior to any exposures. Thus the committee should start its work prior to writing the requirements for the RPD itself. The selection process is based on the risk assessment users have to perform on each workplace in order to build the foundation for the right selection steps. This risk assessment has 3 major processes: the hazard assessment, the adequacy assessment and the suitability assessment- see *Figure 11*.

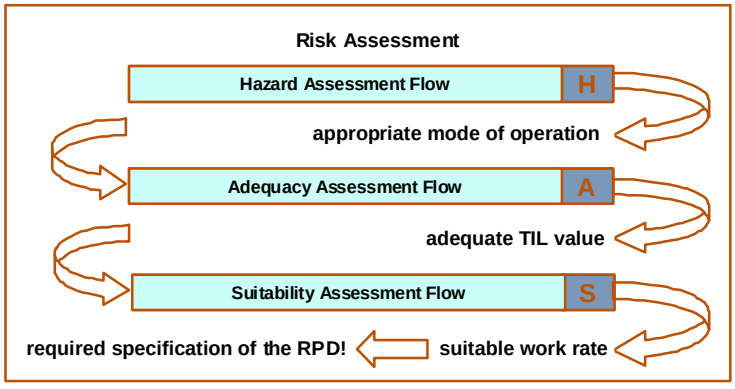


Figure 11. Risk assessment, How to select the classified RDD?

Each process results in key values for the selection, such as the appropriate mode of operation, the adequate protection factor derived from Total Inward Leakage, the suitable work rate and finally the alligned specification of an RPD correctly selected for the job in question. One key element in this process is to ask the right questions at the right time. The drafted guidance document ISO 16975 ”Selection, Use and Maintenance” provides these questions in the form of a flow chart for each of the assessment steps as shown in *Figure 12*.

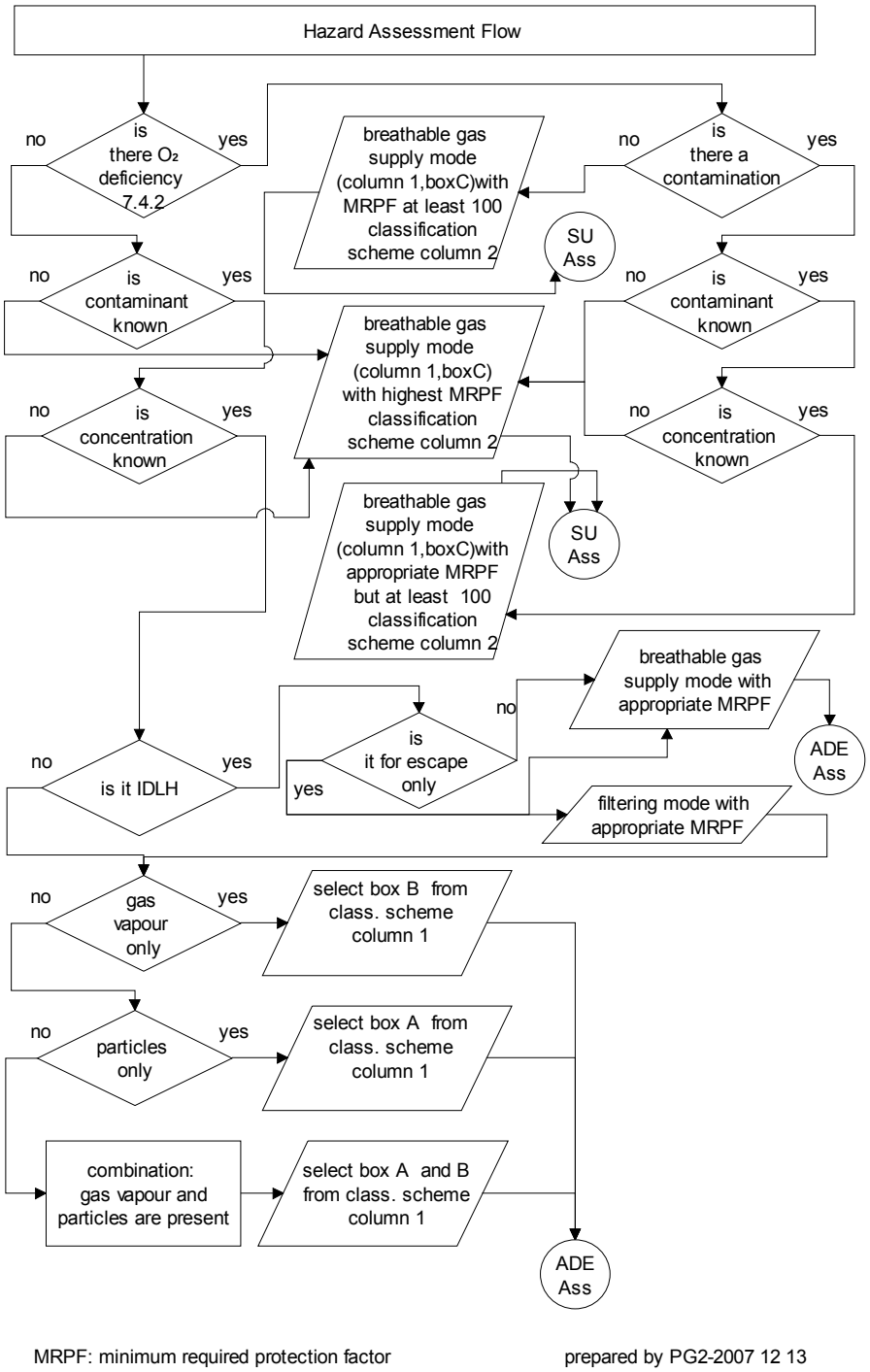


Figure 12. Hazard assessment flow, ISO/TC 94/SC 15

The first question of the Hazard Assessment Flow will always be: is there oxygen deficiency? If the answer is "no", the next question is: is the contaminant known? If there is no knowledge of the hazard, the user has to select an RPD with the supply mode of operation. Here the link to the classification scheme comes into the picture, the flow path leads to column 1; the primary function or mode of operation. In this column, box C has to be chosen when writing down the classification of the RPD. If the answer to the last question is "yes", the flow path follows the line to the next question: is the concentration known? If the answer is "yes" again, and if there is no IDLH, and if gas/vapour is the only hazard, then box B must be selected from column 1. After having selected the appropriate mode of operation, this flow chart automatically links to the next flow chart, the Adequacy Assessment Flow followed by the Suitability Assessment Flow Chart. This is not illustrated here, but is shown in the drafted ISO document.

Finally, all resulting answers form a detailed specification with the relevant designation of the classification. *Figure 13* illustrates this processes flow. With the RPD classification "C5e fire fighting SAF1 CBRN", users are able to ask the manufacturer for a quotation without asking for a specific type of RPD or technology used. This classification is not related to any type of RPD. The performance criterion is the driver, and the best technology will be selected according to which best fulfils his/her needs - another new approach for future RPD standardization.

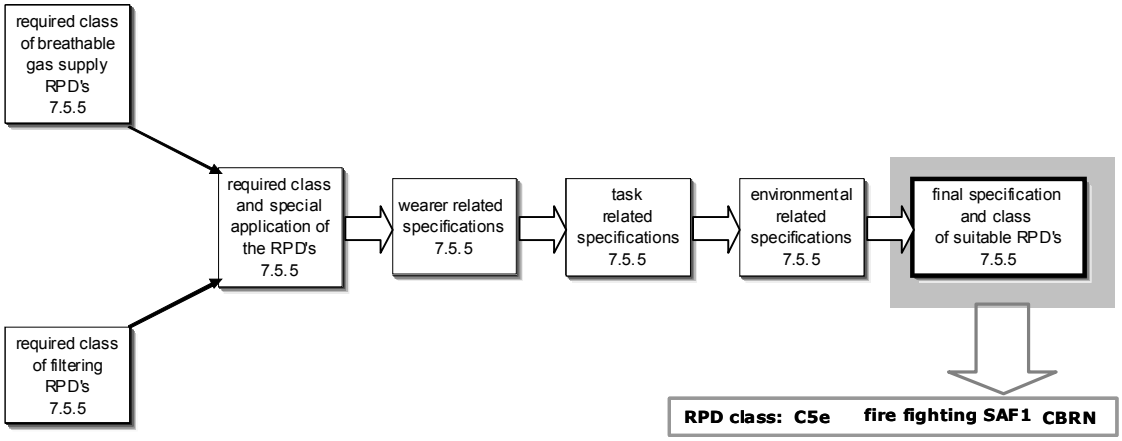


Figure 13. Hazard assessment, ISO/TC 94/SC 15

The project plan – see *Figure 14* - illustrates this near future. Parallel to finalizing the baseline documents, such as human factors, the work items for the two main performance standards will be envisioned in the autumn of this year, with a running time of four to five years. Thus the future of RPD has already started. It is time to take a chance and generate a globally accepted new standard, based on wearers' demands and their right to wear appropriate RPD, fit for its purpose.

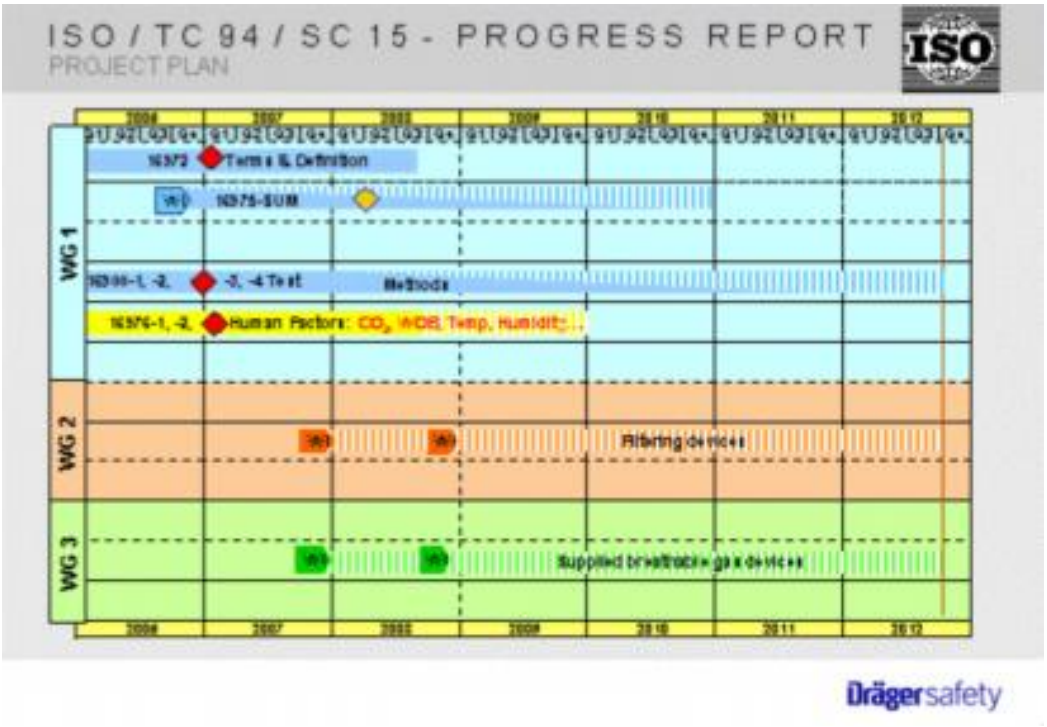


Figure 14. Project plan of working group

12. Real risks and workplace conditions as a basis for standardization

Helena Mäkinen, Finnish Institute of Occupational Health, Finland

12.1 Introduction

Basic health and safety requirements in Annex II of EU Directive 89/686/EEC define the basis for personal protective equipment (PPE) standards. All standards that have been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association must be examined to ensure that they support the essential requirements of the Directive. A general requirement applicable to all PPE is that it must provide adequate protection against all risks encountered, and the basic design principle is that PPE must be designed for foreseeable conditions of use. These provide a comprehensive starting point to standardization. In this presentation I will try to determine the length of time for which it is possible to take into account the real risks in foreseeable use situations when preparing requirement standards, and what additional measures are needed for proper protection by PPE in workplaces. I also will give examples of standard preparation work for some use areas, and how their real risks have been evaluated and applied to the standards.

12.2 Needs for using PPE

According to the occupational hygiene hierarchy, personal protective equipment is the last measure to be introduced. Thus PPE is used to protect against residual risks after technical and organizational measures. In reality, PPE is often the easiest and fastest "first hand" measure to increase safety at work sites.

Hazards against which the PPE is intended to protect are diverse: falls, from height, electrical shock, falling objects, chemical exposure, flames, radiant heat, contact heat, cold etc. The level of hazard can vary from very low to very high, and many different types of hazards can be present at the same time. For example a risk analysis in a shipyard revealed over 1000 different risks, the most serious consisting of physical hazards and accident risks. For adequate protection, workers need a helmet, face shield, respiratory protection, protective clothing, gloves and footwear, and sometimes equipment to protect against falls from height. The fact that different hazards differently harm various organs and parts of the body makes the need for protection very complex. The high number of harmonized European standards (over 250) also shows this complexity.

12.3 Risks and performance level(s) in standards

To be functional, PPE for the foreseeable conditions of use should provide the best possible compromise between a high level of protection and the lowest possible level of constraint. In many standards, lower classes of protection may be applied in order to provide more comfort, rather than the

PPE having an unnecessarily high level of protection. The selection of a suitable level of protection is then based on risk analysis. To make the selection easier, the standardization groups for different types of PPE have guidelines for their selection, use, care and maintenance, and provide relevant practical information regarding the link between the levels/classes of protection/performance and the corresponding risks.

12.4 Problems in most current standards

At the beginning of 1990, large numbers of European standards were created in quite a short time. In many cases, the standards were written based on existing products or national standards. Therefore, these standards do not take into account actual real risks and workplace conditions. They also overlook the ergonomic function. Thus the work has started at the wrong end. Now during revision work, the aim is to improve the content and consistency of the standards to better meet the needs for efficiency and comfort in actual use situations. But are we still too tied to the existing product standards?

One reason for the deficiency in user-friendly standards is the lack of participation of end users in the standardization process. Their representation is missing from most groups.

If we are able to set the performance classes as related to different levels of risks in foreseeable conditions, a second question is raised: how can testing in a laboratory simulate real use conditions? In the workplace, many other variables fit; maintenance, storage etc. affect the level of protection achieved with the used PPE.

12.5 Importance of user information

In all requirement standards the content of user information is given. In user information the different classes and other standard requirements are linked to certain products and use situations. To make the preparation of user information easier, a guide has been drafted: "How manufacturers can supply information to the users". This gives practical examples of e.g. the use area of PPE.

Examples:
Chemical suit model CHE-H is a type 6 suit that protects the whole body, except face, hands and feet against contact with small splashes of liquid products of low volatility and low toxicity. It has been designed for single use only. Do not re-use. Always wear this suit over normal working garments. After use, discard the suit in a safe container.

These overalls protect the body, except hands, feet and head, against the effects of radiant heat up to 20 KW/m^2 (approximately equivalent to the radiation received standing at 5 m from a fire in a building). For full protection, other items (gloves, boots and/or head and face protectors) may be necessary.

12.6 Examples of preparation of standards

The standardization of *diving suits* started in 1998. Many representatives of users participated in this work. It began with risk analysis, where different

dangers to the body were analysed, and required measures were listed. During this work we noticed that all risks cannot be covered by testing and performance requirements; in many cases the information of the manufacturer is also important for the proper selection and use of PPE.

Standardization of the performance of personal *protective equipment intended to safeguard fire fighters* against hazards encountered in the performance of their duties started in 2003 in ISO/TC 94/SC 14. End users are also represented in this work. One of the main objectives of the work was to ensure the health, safety and effectiveness of fire fighters through the establishment of minimum standards on fire fighters' personal protective equipment (PPE) for the various functions or duties they perform.

The performance standards will cover all PPE intended to provide the fire fighter with protection in the relevant function. The work programme consisted of five working groups covering:

- General requirements for personal protective equipment used by fire fighters.
- Personal protective equipment used by fire fighters during fire fighting (excluding wildland fire fighting).
- Personal protective equipment used by fire fighters during wildland fire fighting.
- Personal protective equipment used by fire fighters during hazardous materials incidents.
- Personal protective equipment used by fire fighters during non-fire related rescue incidents.

In all groups, the aim is to harmonize existing standards, develop new standards, and assist groups in defining general requirements in the development of the selection, use, care and maintenance guidelines of PPE used by fire fighters in different activities.

Today, draft standards from some above listed groups have been circulated for DIS voting. But do they meet the original aim if their content is a mixture of existing EN, ISO or NFPA standards or draft standards of different types of PPE with very different performance levels and test methods?

12.7 Summary

It is difficult, and in most cases impossible, to prepare a PPE standard which is unambiguously based on real risks and workplace conditions. The way to link real work conditions and performance levels of PPE is to create standards with performance levels (low, medium, high) for mandatory, essential and voluntary additional requirements; to require and instruct manufacturers to provide good user information; and to provide users with guidelines for selection and use.

References

1. Brouwer D H, Marquart H, van Hemmen J J, Proposal for an approach with default values for the protection offered by PPE, under European new or existing substance regulations. An.Occup. Hyg., 45 (2001) 7, pp 543-553.
2. Falk Roger, International standards and risk handling in workplaces. In Skiöld Lena editor, A look into modern working life. National Institute of working life 2000.

3. Mayer A, Bahima J, Guide for the drafting or the revision of EN standards on PPE. CEN PPE Forum, version 4.1 of 2006.
4. Personal protective equipment (PPE) - Guide for drafting the Information to be supplied by the manufacturers to the users in compliance with Directive 89/686/EEC, CEN PPE FORUM, PPE N 108, Rev 3, 25.10.2006.
5. PPE Guidelines, Guidelines on the application of Council Directive 89/686/EEC of December 1989 on the approximation of the laws of the member states relating to personal protective equipment, 17 July 2006.

13. NEW REGULATIONS - New opportunities for better harmonized standards

Alain Mayer, Institut National de Recherche et de Sécurité (INRS), France, Rapporteur to CEN/BT for the PPE sector

13.1 Background

European product legislation was revolutionised by the "New Approach" introduced in 1985. Its aim is to improve the free movement of goods in the EU which was already one of the bases of the Treaty of Rome in 1957 (Art36). The simple condition is that a manufacturer guarantees that products put on the EU market are in compliance with the corresponding EU regulations and provide a high level of protection to EU citizens (Art 95.3). This fundamental objective, social in nature and targeting the needs of social partners and consumers in particular, is often forgotten or ignored by standardizers.

According to mechanisms of the "New approach", the application of European harmonized standards remains voluntary, and the manufacturer may always apply other technical specifications to meet the requirements e.g. in absence of standards or where completely new technology is used to meet the essential requirements.

Nevertheless, using the technical references of EN/CLC Standards is the most comfortable way to assess the conformity of products to EU directives. In fact, products manufactured in compliance with harmonized standards benefit from a great advantage: a presumption of conformity with the corresponding essential health and safety requirements (EHSRs).

Presumption of conformity is a legal concept surrounding Harmonized Standards that denotes the relationship between the legislative and standardization processes. The European Commission and the European Standards Bodies collaborate to produce Harmonized Standards. The contract (or mandate) stipulates that the Body will produce a standard that will provide a technical solution to, or a technical interpretation of an essential health and safety requirement. When the standard is completed and the conditions of the Commission's mandate are met, the Commission publishes the notice of its completion in the *Official Journal of the European Communities.* Once a notice is published, the standard takes on the presumption of a conformity mantle. Therefore, a manufacturer using a Harmonized Standard in the design and/or production of the product is presumed to conform to the essential legal requirements.

The presumption of conformity is granted to a product that conforms to an EN harmonized standard *only for the essential requirements actually covered by this standard*. If the existing European harmonized standards do not cover all applicable EHSRs, then, in addition to applying these standards, conformity to the EHSRs not covered through other relevant technical specifications and test methods must be assessed. This could lead to

disparities in judgement on the conformity of the machinery, and worse still, to litigations.

From a technical point of view, standardized test methods and specifications must also be reliable and credible to technical experts such as OHS experts, consumer associations, and testing laboratories. They shall correspond in particular to the highest level of safety and ergonomics that can reasonably be expected from PPE and shall also allow assessment of the real comfort and protective performances of the PPE, to give reproducible, repeatable results.

In this respect, EN harmonized standards must be legally and technically robust and as complete as possible, in order to minimize the risks of disputes and possible lawsuits, and to give a high level of confidence not only to market actors but also to *all stakeholders* (*European and national authorities, social partners, consumers, actors of OHS prevention, manufacturers, notified bodies).*

13.2 Evolution of regulations and impact on EN standardization

As already discussed in the first part of this seminar, one should consider two complementary issues: the revision of the New Approach which should be adopted in the next few weeks and new social directives adopted in the final years.

13.2.1 The revision of the New Approach

The main benefits of the New Approach are a high level of protection as well as free circulation within the EU of a large number of products. This regulatory approach has considerable international impact. Many non-EU countries have adopted similar approaches (Russia, Japan, China, developing countries…).

However one can recognize that the New Approach does not always assure a sufficient, perceptible level of confidence in the CE marked products manufactured in the EU or imported from third world countries. Consumers do not always feel that they are effectively and correctly protected.

As previous lecturers already explained, the objective of the revision of the New Approach was not merely to add a new layer of requirements, but to ensure improved and more equal functioning of what already exists, in order to reinforce the credibility of CE marking in particular, and to bring coherence to the overall system.

The proposals likely to be adopted at the plenary session of the EU parliament in the coming weeks consist of:

- A regulation laying down rules regarding the organization and operation of notified bodies' accreditation. This new regulation put forward reinforced Community Policies on market surveillance *(e.g. obligations of Member States, type of checks and controls, safeguard mechanisms)* and accreditation *(e.g. mode of operation, cross-frontier accreditation, peer evaluation)*. The aim is to ensure that products respect a high level of protection of public interests such as general health and safety, health and safety at the workplace, and the protection of consumers, the environment, and security.

- A Decision; a sort of tool box setting out the common framework of general principles and reference provisions for the revision or recast of existing directives such as the PPE Directive 89/686/EEC. It contains rules related to conformity assessment procedures, the EC declaration of conformity, obligations of economic operators, CE marking, and safeguarding procedures. It also reinforces and clarifies the operational obligations of the notified bodies *(mechanisms for their designation, challenge of competence, subcontracting, participation in European co-ordination)* and their information obligations to the national authorities *(in case of e.g. refusal, restriction, suspension or withdrawal of certificates, or requests from market surveillance authorities).*

No part of these proposals deals specifically with either the standardization process or with the content of harmonized standards.

Although it is not new, there is a clear, important statement in Article 13 of the Decision Proposal concerning the coverage of the presumption of conformity *(Table 1)*. This clarification already exists in e.g. the Machinery Directive 42/2006/EC *(Art 7, 12)* and in the implementation guide of the PPE Directive 89/686/EEC *(foreword to Annex II comments)*. However, it is still subject to some disagreement or misunderstanding.

Table 1. Article 13

PRESUMPTION OF CONFORMITY
Products which are in conformity with harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in … [reference to the relevant part of the legislation]. *(1, 2)*
Add: "Harmonised standards and technical specifications shall contain a table of correspondence indicating which regulatory provision they relate to."
Alternative addition: "The correspondence between the essential requirements of legislation and the relevant provisions of the harmonised standards or of the other appropriate technical specifications shall be established."

This could be a good basis for the development of more complete and robust EN harmonized standards, covering all essential health and safety requirements (EHSRs) applicable to the PPE concerned, and when relevant, referring to other existing harmonized standards.

The proposed footnote to this article is intended to give a more legal character to Annex ZA attached to the existing EN harmonized standards but does not clearly identify the requirements not covered or partly covered by these standards.

To manufacturers and notified bodies this is a difficult task. This necessary preliminary step for the proper CE conformity assessment of the products is

not always identified by them. In practice, nobody really wants to rush into taking this responsibility, even as a voluntary exercise, as it entails questioning the validity of the EC type examination certificates already issued.

Most actors only apply incomplete EN Harmonized standards to certify PPE or machinery to the Directives. This situation is unsatisfactory, both legally and from an OHS perspective. Should a manufacturer incorrectly assume, after applying an incomplete standard, that his product satisfies all the relevant requirements of the Directive? The consequences of this could be serious in terms of risks of accidents and litigations.

In fact, standards which do not cover all applicable EHSRs may lead to discrepancies in conformity judgment and thus in the effective safety of CE certified products. This may contribute, through competition among notified bodies and manufacturers, to a downward spiral in quality and safety.

13.2.2 Entry into force of new social directives

Social directives are not related to the design and free circulation of products. They are aimed specifically at encouraging improvements to the safety and health of workers at their place of work, and prescribe only minimum requirements. Contrary to the "New approach" Directives, Member States remain free to keep or to adopt more stringent national measures. However national measures must not have the effect of introducing requirements beyond those of the Single Market Directives for products.

The only link between the two PPE Directives rests on the fact that according to Directive 89/656/EEC on the use of PPE by workers at the workplace *(3)*, the employer must provide workers with PPE which complies with Directive 89/686/EEC on PPE design. The employer shall also make sure that the PPE is appropriate for the risks involved without itself leading to any increased risk, that it takes account of ergonomic requirements, and is compatible with the use of other PPE. After having carried out a suitable analysis of the risks, the only real way the employer can select an appropriate PPE which satisfies the provisions of this Directive, is to trust the quality of the CE-certified PPEs available on the market, the information given by manufacturers, and in this respect rely on the quality of the reference standards and the practices of the notified bodies involved in the CE certification process.

The three new social directives recently adopted regarding the exposure of workers to the risks arising from physical agents of noise, vibrations and artificial optical radiations *(4, 5, 6)*, contain daily limit exposure values and requirements related to the corresponding PPE to be used. These requirements must be carefully considered by the standardizers when defining performance requirements for PPE standards, in order to facilitate the proper selection of adequate PPE by employers.

Directive 2003/10/EC on the exposure of workers to noise states that *"When applying the exposure limit values, the determination of the worker's effective exposure shall take account of the attenuation provided by the individual hearing protectors worn by the worker".* This will oblige TC 159 and 211 to reconsider the content of corresponding standards on hearing protectors, so as to generate more realistic reference attenuation data for the proper selection of HPD, and provide users with reliable information. *(9)*

Directive 2006/25/EC on optical radiation and Directive 2002/47/EC also set out exposure limit values. The reference values used by standardizers as a reference for the evaluation of the performances and the definition of protection classes of optical filters and gloves against vibration should be in adherence with those of the social directives. These aspects are being checked by the CEN/ TC 85 on eye and face protection.

13.2.3 Opportunity for progress in quality of standards

In a very competitive context, respect of the law often becomes a competitive disadvantage. Responsible manufacturers who respect the law could lose deals against unlawful competitors offering cheaper PPE, by saving compliance costs or having recourse to the less demanding notified bodies. The revision of the new approach is a real opportunity to improve this situation.

The reinforcement and clarification of the rules for market surveillance, of the co-operation between Member States, and of the duties of notified bodies as well as the use of the RAPEX procedure for accelerating the exchange of information in the case of serious risks, is likely to put more pressure on all stakeholders (market actors, notified bodies, national authorities).

This will help market actors and notified bodies in their efforts to fully apply the rules. One can only hope that it will encourage them to follow a methodical and rigorous approach to EC conformity assessment, rather than simply applying incomplete standards.

At the same time, this could help manufacturers, notified bodies and authorities to recognize the great benefit of setting irreproachable EN harmonized standards with a high level of legal security and push them to determine the real extent of the presumption of conformity given by each existing product standard.

The publication of new social directives on the exposure of workers to the risks arising from different physical agents has rehighlighted the importance of social partners' needs. They shall always be carefully considered by standardizers even though these actors are often not represented in the standardization process.

It is necessary to underline:

- The need on the market for effectively safe and ergonomic PPE of which standardized performances and protection classes are compatible with the exposure limit values laid down in these Directives.
- The need of purchasers and employers to have reliable information at their disposal on the real protective characteristics of the PPE. It is crucial to have reliable test methods representative of the real risks that the PPE is intended to protect the user against, and to identify foreseeable conditions of use.

13.3 Conclusion

The current CEN standardization and CE certification processes have proved their usefulness and have significantly enhanced the safety level of the PPE

placed on the EU market. Nevertheless, there is still a need to rebuild the confidence of stakeholders, consumers, industry and Member States in internal market legislation.

Improving the rules of the new approach and strengthening the market surveillance policy in particular will reinforce the responsibilities of all actors and will require them to more rigorously make the necessary efforts.

Even if these changes do not deal with this particular issue, they will no doubt have an impact on the standardization process and in particular on the quality of the content of the EN harmonized standards. In fact, the intensification of controls and the rigour by which national authorities prosecute cases of non-compliant or unsafe products will encourage market actors and notified bodies to watch over the unimpeachable character of their practices, their effective safety, and compliance with the CE approved PPE. In consequence, they will increasingly feel the need to be sure of the technical and legal robustness of the standards, which they often use as a unique reference for the evaluation of PPE conformity.

The assessment of the reliability of the product standards should be made on a consensus basis, notably between standardizers and certifiers. The checklist which is recommended in the CEN BOSS can be used to assess legal robustness. The assessment of the technical robustness (i.e. consistency, representativeness, repeatability, reproducibility of the test methods, uncertainty of measurements, and information to users) can be made by reference to the recommendations laid down in two guides issued by the CEN PPE Forum. *(7, 8)*

The important CEN work in progress for the implementation of the 2010 CEN strategy's ambitious action plan is another great opportunity. Several other key actions are related to making the New Approach more efficient:

- Review of the existing CEN processes (role of consultants, maintenance of EN harmonized standards, to make Annex Z a separate document)
- Consideration of the needs of users (presumption of conformity)
- Analysis of the experiences gained from revision of the machinery directive and a dialogue with EC and EFTA on improved processes.

Organizations working in the field of health and safety at work such as FIOH, BG BAU, INSHT, INRS and the EUROSHNET network, and also the European co-ordination of notified bodies, have a key role to play in the definition and promotion of this improvement process of EN harmonized standards.

It is a question of a revolution of mentalities, which should be accompanied by the visible political support of the EU Commission and CEN incentives to the TCs.

References

1. Proposal for a Decision of the European Parliament and of the Council setting on a common framework for the marketing of products, COM (2007) 53 final, Commission of the European Communities, 14.02.2007.
2. Proposal for a regulation of the European parliament and of the council setting out the requirements for accreditation and market surveillance relating to marketing of products, COM (2007) 37 final, Commission of the European Communities, 14.02.2007.

3. Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace.
4. European Parliament and Council Directive 2002/44/EC of the of 25 June 2002 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration).
5. European Parliament and Council Directive 2003/10/EC of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise).
6. European Parliament and Council Directive 2006/25/EC of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (artificial optical radiation).
7. Personal Protective Equipment - Guide for the drafting or the revision of EN standards on PPE (PPE N 122 version 1.5).
8. Personal Protective Equipment - Guide for drafting Information to be supplied by the manufacturers to the users (PPE N108 Rev.2).
9. The assessment of the real protective properties of personal protective equipment and representativeness of the test methods: The typical case of hearing protectors. A. Mayer, Elblag, 2007.

14. Information requirements for chemical products

Martine Reynier, National Research and Safety Institute for the prevention of occupational accidents and diseases (INRS), France

Users of chemicals need information on hazards and risks in order to implement the appropriate risk reduction measures, in particular when selecting the appropriate Personal Protective Equipment (PPE). It is the legal duty of the suppliers of chemicals to provide their customers with this information through the *Safety Labels* (SL) and the *Safety Data Sheets* (SDS), which are the main communication tools for providing the information laid down by the EU regulation for workplaces.

14.1 Safety Labels

EU legislation determines the standardized indications the supplier must put on the packaging of dangerous substances and mixtures. Adaptation of this legislation to the UN *Globally Harmonised System (GHS)* will provide the same level of information. Labelling will continue to provide the following basic elements:

- Name of some dangerous components,
- Hazard Symbol,
- Hazard indications and safety phrases.

Uncertainty regarding classifications should eventually be reduced through the classification and labelling inventory, which is one of the REACH provisions. Labelling is a simple tool to alert users about the hazards of chemicals, and as such, it gives a certain amount of information on the selection of adequate PPE.

14.2 Safety Data Sheets

SDSs are the most important source of information regarding dangerous chemicals. The EU regulation (REACH Article 31 replacing former SDS Directives) prescribes 16 obligatory headings. Heading 8 relates to Exposure controls/personal protection and contains adequate information on PPE, when necessary. There is no obligatory information that has to be provided under the headings, although there is a performance standard that must be met: the legal requirement is accompanied by guidance on content (Directive 2001/58, now replaced by Annex II of REACH).

The recommendation of the guidance with respect to the PPE is:

- *Where PPE is needed, specify in detail which equipment will provide adequate and suitable protection. Take into account Council Directive 89/686 of 21 December 1989 and make reference to the appropriate CEN standards:*

Respiratory protection
Specify the *type of protective equipment* to be used, such as:

- Self contained breathing apparatus, adequate masks and filters

Hand protection
Specify clearly *the type of gloves* to be worn, including:
- The type of material,
- The breakthrough time of the glove material, with regard to amount and duration of dermal exposure

Eye protection
Specify *the type of eye protection equipment* such as:
- Safety glasses, safety goggles, face shield

Skin protection
Specify *the type and quality of protection equipment* required, such as:
- Apron, boots and full protective equipment

Most experts agree that the quality of SDSs has improved steadily since their introduction. However, quality surveys in different countries show that there are still serious problems of inaccuracy, and insufficient or incorrect information. With regard to heading 8, the use of PPE is generally mentioned (often with no consideration to engineering and collective measures) but details on the type of material are often absent. Many SDSs use vague generalizations such as "wear gloves" without specifying what type of gloves should be worn.

Substance SDSs elaborated by manufacturers are of better quality than mixture SDSs. However, they may give long, albeit accurate information, which are in conflict with the user's experience (for instance if the product is to be used in small amounts, but the SDS is designed for bulk use processes).

The main causes for bad quality of SDSs are the lack of skills and expertise of their drafters: the level of expertise decreases down the supply chain and the use of SDS software favours inaccurate standard phrases. Other causes are:
- The lack of information on intrinsic properties of existing substances, on the suitable material for PPE (gloves) and on the ways chemicals are used in the workplace,
- The recommendations provided in most of the SDsS are based more on hazards than on actual risks,
- Most chemicals are mixtures: formulators have difficulties in merging information on the components (substances and mixtures) into an SDS for their mixtures.

Under REACH, users will continue to receive information on SDSs as previously. However REACH aims to increase the availability of relevant information. It introduces the new concept of Exposure Scenario and new information requirements along the supply chain (from producers to end-users and the opposite).

14.3 Exposure scenarios

The *Exposure Scenario* (ES) is a new concept introduced by REACH as a part of the Chemical Safety Assessment requested for dangerous substances produced or imported in quantities of ≥ 10 t/year.

An Exposure Scenario means "a set of conditions, including operational conditions and risk management measures, that describes how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment". It may cover one specific process or use, or several, as appropriate, and includes:

- Processes and tasks,
- Operational conditions,
- *The risk management measures* (RMM) required.

The detailed content of an ES is not in the Regulation, but Guidance Documents have been developed in the REACH Implementation Projects (RIP) to facilitate a better understanding of the requirements:

- Technical Guidance Document for preparing the Chemical Safety Assessment (RIP 3.2-2), in particular part D (how to develop an ES) and part G (how to integrate ES in SDS),
- Guidance Document on Downstream Users' requirements (RIP 3.5-2).

As regards PPE (respiration, skin, eyes), the type of information which can in principle be included in the ES is similar to that of an SDS. According to the hierarchy of the Chemical Agents Directive, PPE may be considered to reduce risk, as a last resort if collective measures are insufficient or not possible. Whether PPE is required or not usually depends on the operational conditions of use, which may differ from one ES to another. Therefore, the determination of appropriate PPE, including evaluation of their effectiveness, is part of the ES generation process. The guidance recommends listing the type of PPE and the conditions for when to apply it in each of the ESs. Furthermore, in order to facilitate effective, accurate communication in the supply chain across the European market, suppliers are advised to use a standard system of RMM phrasing (the RMM library).

REACH information requirements:

The manufacturers/importers (M/I) of dangerous substances produced or imported in quantities of ≥ 10 t/year, are responsible for:

- carrying out a Chemical Safety Assessment covering the whole supply chain,
- determining what is good control practice through exposure scenarios (ES),
- submitting the Chemical Safety Report to the Chemical Agency,
- communicating ES as an appendix to the SDsS (extended SDSs or eSDS).

REACH assumes that downstream users (DU) will also play an active role by providing feedback to suppliers. Before registration, they may provide their suppliers with information on the use of and the conditions under which they are using the substances, including the RMM (this is not mandatory). After registration, they have the following obligations:

- To check whether their use fits one of the ESs annexed to the eSDS of the supplier
- If the use is outside the conditions described in the ES, they have two options:
  1. To inform the supplier so that it can modify the ES, or
  2. Develop a new chemical safety assessment, or elaborate their own with their particular ES (use in quantity ≥ 10 t/year). This could happen when the use raises confidentiality concerns for the DU. Only a brief description of the use has to be submitted to the Agency.

If the down stream users (DU) place dangerous mixtures on the market (formulators), they must communicate to their customers the information available in the SDSs of the supplier in their own SDSs. This could be done directly in the SDS, by forwarding the received ES, or by developing a new ES for use in a mixture.

RMM in the ES should be consistent with the appropriate sections of the SDS. Examples of ES to be annexed to SDS are provided in Part G of the Technical Guidance Document for preparing the Chemical Safety Assessment (how to integrate an ES into the SDS). Some examples of PPE elements are:

Example 1: Hydrocarbon solvent for industrial uses

- When combating spills and during maintenance: use PPE as specified in chapter 8 of the SDS.

Example 2: Additive in compounding of polymers

If prolonged or frequently repeated contact and exposure may occur:

- Wear suitable protective gloves which are chemical resistant, with a breakthrough time of >480 min, nitrile rubber/nitrile latex/NBR (≥0.3mm), polyvinyl chloride/PVC (≥0.3mm), or polychloroprene/CR (≥0.3 mm).
- Wear goggles - not specified, or face shield.
- Use dust filter half-mask PI (efficiency 75%).

Example 3: Solvent for wide dispersed use

In case ventilation is not feasible use the following PPE:

- Air purifying half-mask (with gas/vapour cartridge that can be combined with a particulate filter); assumed effectiveness: 90%.
- Chemical resistant protective gloves.

Examples of preferred glove barrier materials are butyl rubber, or ethyl vinyl alcohol laminate (EVAL). Acceptable glove barrier materials are natural rubber (latex), neoprene, nitrile or NBR, PVC or vinyl, or Viton. When prolonged or frequently repeated contact may occur, a glove with a protection class 4 or higher (breakthrough time greater than 120 min according to EN 374) is recommended.

- Wear goggles if there is a risk of splashing.

14.4 Conclusion

REACH will generate more information on both hazards and exposure, so that uncertainty in workplace risk assessment is substantially reduced. The SDSs will remain largely the same for substances supplied under 10t/year. For substances supplied at over 10 t/year, it is assumed that the quality of the information in the extended SDSs supplied by the M/I to the immediate DU will improve.

It is possible that the increasing exchange of information between M/I and DU will improve the specific information on PPE. However, some problems and uncertainties still remain:

- PPE needs to fit the specific working conditions of the users. Most ES will be generic and substance-related, not of great help for users further down the supply chain (mostly users of mixtures) or end users.

- Although DU has obligations, any benefit will probably be limited in practice by the complexity of the regulation, the complexity of the supply chain, and the lack of expertise needed to fulfil this obligation.
- The challenge still remains of how to improve communication between users of chemicals and PPE manufacturers.

Furthermore, in addition to the issue of communicating appropriate information to the users of chemicals, other problems can be anticipated at the registration stage of REACH: e.g. How will the producers integrate the use of PPE in their risk assessment, taking into account the uncertainties and the lack of knowledge regarding their effectiveness?

15. Relevant Information on chemicals for proper selection of PPE

Norbert Kluger, BG BAU - GISBAU, Germany

Abstract

In many workplaces, e.g. in the construction industry, the application of technical or organizational protection measures is often not possible. This is why in the "hierarchy of prevention measures" the lowest risk control method, the proper selection of personal protective equipment (PPE), is so important. The selection of PPE is generally required as a result of an employer's risk assessment. The problem, however, is identifying which information is necessary for proper selection and how this information can be accessed. This is the focus of this paper.

15.1 Information on PPE from suppliers of chemical substances

The most important instrument of communication along the supply chain is the safety data sheet (SDS). The supplier of a dangerous substance or preparation must provide the recipient of the substance or the preparation with a SDS compiled in accordance with Annex II of the REACH Regulation. Apart from the labelling, in most cases, the SDSs for these dangerous preparations are the only available sources of information for employers. Even in 2007, statements in SDSs concerning protective measures were not as detailed as they should have been in order to support small firms sufficiently. Up until now, the information on PPE in SDSs has been inadequate. We eagerly await the influence of the REACH Regulation on this matter.

15.2 Information on PPE from manufacturers

It seems obvious, that the manufacturers of the PPE themselves should provide information on the proper selection of PPE. The leading PPE manufacturers normally offer a wide range of types for most personal protection products. On their websites and in their brochures they give extensive support for selecting the proper equipment. One can find a great deal of guidance for the selection and use of PPE.

However, the disadvantage is that he manufacturers - as well as many other sources of information (e.g. databases) - only provide information on pure chemicals. We have learned from research projects in the last years that suitable protection gloves, for instance, cannot be found simply by comparing the individual ingredients of the suitable materials.

15.3 Information on PPE in databases

Today, numerous databases provide data on single dangerous substances. GESTIS, the Substance Database of the BGs, is an excellently supported database on chemical pure substances. However, we have to bear in mind

that knowledge is required for obtaining information from data. For example, not everybody in the practice understands the meaning of physical data such as the flash point or the statement of certain R-phrases.
Even if sufficiently comprehensible information was available for chemically pure substances, this would provide only limited help in practice. We must always take into account the fact that only very few small and medium-sized enterprises use chemicals as pure substances in their activities. The majority of all companies nearly exclusively use chemical products which are usually sold by the manufacturers as mixed preparations, more or less ready for use.

15.4 GISBAU – a practical approach

The construction industry is an economic sector dominated by small and medium-sized enterprises. We know that these companies only have very restricted knowledge of the dangers of working with hazardous materials. In order to enable the companies to comply with their duties, and therefore to protect employees' health, the statutory accident insurance institution of the construction industry (BG BAU) created GISBAU, the hazardous materials information system, in 1989.
GISBAU, as an out-of-house support, strives to be a service facility for the companies in hazardous materials management, at the same time primarily promoting the safe handling of hazardous materials. The specifically new feature in this procedure is that the information regarding the preparation is available under its trade name, also, at present, in companies. Comprehensible, simply formulated instructions for safety at work and the protection of health are given for all hazardous materials in about 20 information chapters. The PC software WINGIS, as well as the internet database WINGIS-*Online*, also provide information on chemically pure substances, but primarily concern hazardous preparations used at workplaces. The product group information, booklets and much more is available at **www.GISBAU.de**.
As PPE, hand protection in particular, is very important for many job tasks with construction chemicals, the WINGIS-Information attaches great importance to choosing the correct gloves. For several product groups, the correct gloves have been determined in co-operation with the suppliers of the chemicals and the manufacturers of the gloves (e.g. epoxy resins, bitumen products). In one large project, GISBAU asked the glove manufacturers for recommendations concerning the wear duration of a certain glove for work with a product of a certain product group. Until recently, data for about 200 gloves have been compiled for more than 120 product groups in the areas of wood preservation, paints & varnishes, and cleaning agents. The GISBAU glove database provides easy access to these recommended wearing durations, which are distinguished between permanent contact or splash contact of concentrated cleaners or diluted products respectively.

15.5 Conclusion

The proper selection of PPE to minimize chemical risk is a demanding task. As in most other industrial sectors in which small and medium-size enterprises dominate, this task is difficult for the construction industry. Without out-of-house support, these companies are not able to effectively implement health and safety standards at work in this area.

16. Risk assessment and the relevance of harmonized approaches to PPE effectiveness: skin protection

Derk H Brouwer, Rianda MG Gerritsen-Ebben and Joop J van Hemmen, TNO Quality of Life, The Netherlands

Regulatory authorities in North America, Europe and Australia use different approaches to estimate the effectiveness of the exposure reduction of personal protective equipment (PPE) in risk assessment when registering (agro) a chemical. For dermal exposure in particular this might result in different outcomes of the risk assessment process and its impact on registration. Harmonizing the approaches to effectiveness would support unambiguous risk assessment.

In the recent past, the feasibility of deriving assigned protection factors for skin protective equipment (SPE) has been explored, similarly to approaches for respiratory equipment (1). Based on concepts of skin exposure, exposure reduction and experimental studies, it was concluded that the overall SPE performance in workplace practice will depend on three sets of relationships:

1) Between workplace contaminants and performance of SPE material and assembly,
2) Between workplace exposure and the performance of SPE design,
3) Between workplace exposure scenarios and user interaction, and performance of the SPE ensemble.

Different kinds of tests and standards are relevant, varying from SPE material integrity tests to laboratory simulated work activities, but should be completed with workplace protection performance tests. Generic protection factors for types of SPE, to be used for initial risk evaluations for example, could be potentially derived from simulated workplace protection studies. Therefore, studies according to standard protocols for establishing more of such generic data are recommended.

Since relatively few data have been published that meet these conditions and enable the assignment of sound protection factors for SPE, the next best option would be to harmonize approaches and set defaults for teh reduction of exposure afforded by PPE. Recently, a project to achieve an internationally harmonized set of PPE protection factors for regulatory use in the area of pesticides and biocides was concluded (2). A literature study was conducted and current approaches of regulatory authorities, industrial organizations and academia were listed and summarized in a consultation document. The document was reviewed and commented on and eventually a set of default protection factors was proposed.

References

1. Derk H. Brouwer, Robert J. Aitken, Reinhard Oppl (2005) Skin Protection Strategies: Evaluation of Real and Theoretical Effectiveness of Skin Protective Equipment in Industrial Exposure Scenarios. Summary of Project Results. TNO-CEFIC report.
2. Rianda M.G. Gerritsen-Ebben, Derk H. Brouwer, Joop J. van Hemmen (2007) Effective Personal Protective Equipment. Default setting of PPE for registration purposes of agrochemical and biocidal pesticides. TNO report.

17. Input from ergotoxicology for assessing effectiveness of personal protective equipment (PPE) against plant pest risk: from contamination analysis to collective readiness process

Alain Garrigou*, Isabelle Baldi, Patricia Le Frious***, *HSE Dpt., UIT, Bordeaux 1 University, **Work Health Environment Laboratory, Bordeaux 2 University, ***French National Labour Agency, Ministry of Labour Affairs, France**

17.1 Introduction

Through focusing on chemical risk, and more specifically plant pest risk, prevention management institutions have developed global prevention approaches that have now been deployed for a number of years. However, it is clear that the most widely implemented protection measures are centred on personal protective equipment rather than on initiatives designed to reduce risk at the source or to promote collective protection systems. Although it is the effectiveness of this final line of defence that has become determinant in terms of occupational health, it is precisely failures in PPEs that were highlighted in a study on French wine-growers.

17.2 An ergotoxicology driven approach to plant pest risk in viticulture

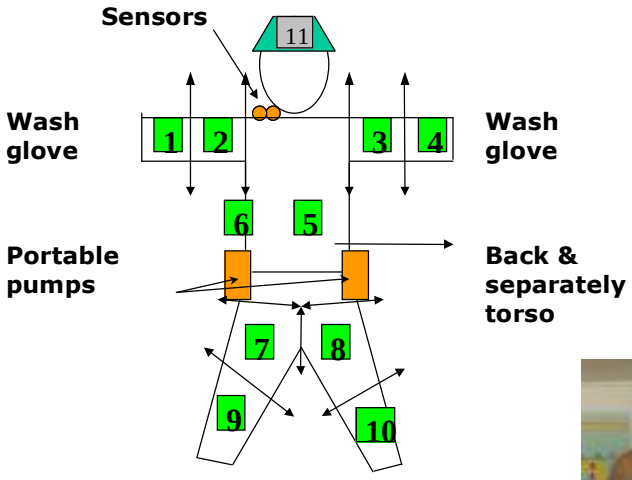
The ergotoxicological approach *(5,11,12,14)* seeks to identify situations where workers are exposed to chemical hazards and thus constitute a risk, based on occupational analysis of the activity. The approach then goes on to characterize the forms of *contamination*, i.e. where the product comes into contact with the skin or enters the body, in relation to the physicochemical and toxicological properties of the product and the occupational activity being performed. This makes it possible to pinpoint the technical, human or indeed organizational determinants driving these exposure situations, and build prevention solutions designed to transform them *(4)*.

Among the issues addressed in ergotoxicology, the utilization and effectiveness of protective equipment pose a great challenge for occupational health. Focusing on plant pest risk in agricultural work, researchers like Packham (2006) have raised doubts as to whether protective gloves are genuinely effective. We will take this argument further, drawing on external contamination results among wine-growers generated by the 'Pestexpo' study performed in the Bordeaux region by Isabelle Baldi *(2)* and Baldi et al. *(1)*. This study, which deployed an ergotoxicological approach, attempted to characterize the exposure levels and actual contamination of wine-growers due to plant protection agents (dithiocarbamates) in 2001 and 2002, in order to pinpoint the determinants of the contamination.

17.3 Contamination measurements

The study measured actual contamination among wine-growers from plant protection agents. For the treatment tasks, field observations carried out over 72 days (67 involving treatment applied by tractor-mounted sprayers and 5 involving backpack sprayers) generated various different datasets for each phase of the work (preparation of the spray mixture, treatment or application of the treatment, and cleaning down the equipment used). It should be stressed that contamination studies use the term "*actual contamination*" for contamination on the skin of the operator, as opposed to "*potential contamination*" which refers to substance deposits on the coveralls worn.

Contamination measurements were performed by analysing the quantity of plant protection agents deposited onto 10 cm² patches of surgical gauze. These patches were attached directly onto different body areas of the wine-growers, nd were changed after each phase of work (*see figure 1*). The study protocol followed the Organization for Economic Co-operation and Development (OECD) guidelines for this type of field study. The patches were placed directly onto the skin, i.e. underneath clothing, and underneath any protective coveralls.



Patches
- o 10 x 10 cm, surgical gauze, alu

Hand washing
- o 750 ml water

Filter, porable pump
- o at the airways

Urine collection
- o before treatment
- o at 4 hrs, 12 hrs, 48 hrs

Figure 1. Mesurements of cutaneous contamination Dithiocarbamates (2001-2002), Folpel 2003

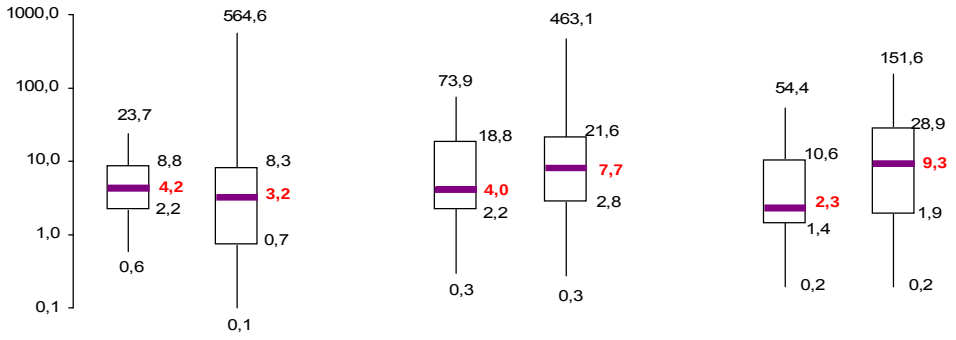
It should be emphasized that the wine-growers were allowed to continue their work as usual during the operations. Some wore protective gear,

others did not. Some of those using protective gear were appropriately equipped, others were not. During the preparation phases, around 2/3 of the workers wore protective gear, a little over half of them wearing it during treatment and over half of them wearing it while cleaning. However, the simple fact that the wine-growers wore coveralls does not mean that they were fully protected, i.e. the protective gear did not prevent all contamination.

The data from the 67 observations on treatment applied via tractor-mounted sprayers can be analysed to detail the frequency at which the PPE was worn:

- 50% of the wine-growers did not wear gloves, 40% wore gloves during either the preparation phase or 2% application phase, and only 10% wore gloves for both these phases;
- 58% wore no coveralls*, 24% wore them for one of the two phases (of which only 4% wore them for treatment application) and 18% for both
- 61% wore no mask, 36% wore a mask for one of the two phases (of which only 4% wore one for treatment application) and 3% for both phases.

The results were expressed in mg of active substance deposited on the farmer's skin (after extrapolating patch size to the surface area of the body zone). *Figure 2* shows median contamination level (horizontal bar) and distribution (from bottom-to-top: minimum, 25th percentile, median, 75th percentile, maximum).



** Shorts and/or t-shirt versus protective 'clothing*

Figure 2. External contamination (mg of active substance) in relation to whether or not coveralls are worn PESTEXPO Gironde (dithiocarbamates 2001-2002, (2))*

** The term coveralls refers here to coveralls which, although full-body, did not necessarily contain all the characteristics of the protective coveralls recommended by the prevention management bodies for protecting against the risks involved in using plant protection agents, such as type-4 coveralls designed to protect against aerosol chemicals*;

The most striking observation is the wide-spanning contamination distribution values. There are cases where people wearing protective clothing had higher contamination values than people not wearing protective clothing.
This leads to several conclusions:

- Wearing protective clothing *does not totally prevent* contamination;
- During the preparation phase, wearing coveralls *partially protects against contamination* but does not afford a total barrier;
- During the treatment and cleaning phases, those who wore coveralls *generally experienced higher contamination* than those who did not.

These results have caused disarray among the various protection management institutions, since one of the core guidelines of current prevention policy is to wear personal protective equipment, and in particular class-4 coveralls designed to protect against liquid aerosols.

17.3.1 Explanatory contamination hypotheses

Following discussions held with various key experts and prevention management bodies*, we formulated the following hypotheses for the contamination patterns observed:

- *Individual and collective precautionary know-how,* developed and consolidated through experience (such as the amount of care taken when opening and pouring from sack-packed forms of powdered plant protection agents), is a major driver of lower contamination levels. It follows that nurturing conditions for developing and communicating this kind of know-how industry-wide is a key challenge for prevention management;
- There is a lack of *guidelines on choosing, using, looking after and cleaning PPE;*
- *Precontamination* of PPE, stemming from re-use without prior cleaning or from storage in premises that are already contaminated;
- *Perceived overprotection:* wearing coveralls can exaggerate workers' perceptions of *"feeling protected"*, thus engendering a degree of laxity *vis à vis* certain precautionary measures;
- *False ideas among wine-growers on the contamination pathways:* ideas are centred on respiratory pathways while strongly underestimating the cutaneous route;
- *Contaminations stem from natural movements*: scratching head, or wiping face with gloves, or with hands that have been exposed to the product;
- *Sprayer hardware designers fail to engineer their equipment* for the requirements of wine-growers. E.g. workers may have to hold close onto the wall of tractored sprayer vats to keep them upright at the same time as having to empty powder into the vats. The outer surface of the vat is often caked in deposits of plant protection agents left over from previous treatments, or spillage when filling the vats;

**The medical benefits fund governing the agricultural-sector, the INRS (French national institute of health and safety research, the UIPP (French federation of plant protection agent producers), the ECPA (European federation of plant protection agent producers), the ministries of labour and agricultural affairs.*

- *Performance of the protective gear itself is non-effective*. Since autumn 2006, we have formulated a new hypothesis that challenges whether the coveralls recommended for use with plant protection agents are *actually effective*. While working with an industry producer of plant protection agents, we raised the issue of fabric permeation in certain coveralls. This industry partner, which has a prevention department as part of its sales mission that is aware of the hazards involved with using herbicides in conditions generating exposural risk (with a backpack sprayer), commissioned an approved test centre to run a series of lab-based permeation tests. These tests were run on class-4 coveralls recommended for use with herbicide treatments, and the tests followed the permeation testing protocol set out in standard EN 374-3: 2004.

Permeation *(Protective clothing – Terms and definitions FD CEN ISO/TR 11610)* was thus defined as the process whereby a chemical product crosses through a material at molecular level (see *figure 3*).

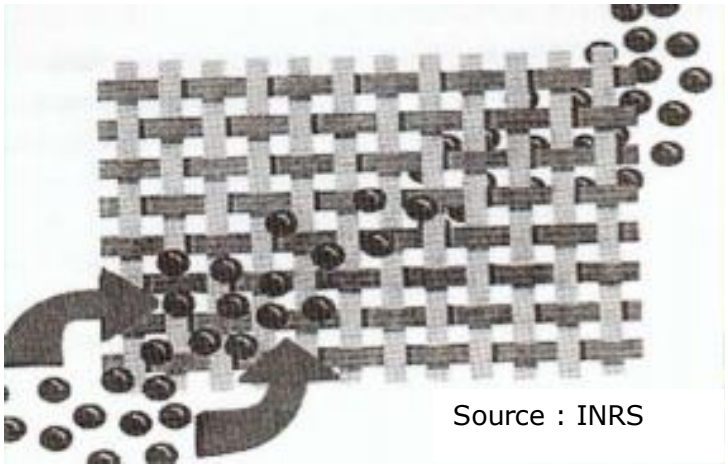


Figure 3: Permeation process

Permeation therefore involves:
- Absorption of the chemical product's molecules into the contact surface (outside) of a material;
- Diffusion of the absorbed molecules through the material;
- Desorption of the molecules from the opposite (inside) surface of the material interface.

Permeation is therefore a different process to penetration, which is the movement of chemicals through zippers, pores, seams or flaws in the gloves, at non-molecular level.

The tests produced *alarming* results, as they highlighted fast-action permeation effects occurring with a variety of widely-used agricultural herbicides, whereby pure products are able to migrate into the coveralls in less than sixty seconds while even diluted products get through in less than 10 minutes.

How is it that people who are *theoretically* protected in fact get contaminated? Discussions with coverall manufacturers revealed that the coveralls currently recommended for use in farming were primarily

developed for industry, with agriculture representing only a niche market, and indeed the effectiveness of the coveralls *has not been tested with the active substances contained in plant protection agents, including some of those most widely used*.

There is currently no evidence to deny that this permeation problem occurrs in industries such as pharmaceutical health, or more specifically the chemicals industry. Furthermore, it is highly likely that the sweat generated via physical activity and trapped within the coveralls actually promotes the penetration of plant protection agents into the coveralls. Focusing on the cleaning phase, the pressure of the water sprays together with run-off may well promote the migration of products building up on the outer shell of the coveralls.

Regarding prevention solutions, the initial response would be to recommend using class-3 or class-2 coveralls, which theoretically offer better protection. However, this would not necessarily resolve the permeation issue. One last point is that driving up the protection level would reduce thermal comfort among workers, as the coveralls would become "unwearable". This would also foster new risks related to working in hot environments by making it impossible to wipe away sweat, thus preventing the body's homeostatic mechanisms for controlling core body temperature from working. This is one of the reasons why PPE are not worn; it becomes impossible to work in these conditions.

17.4 Technical and organizational flaws in PPE design and certification

This survey highlights issues that can be qualified as technical and organizational flaws *(13)* in how the actual effectiveness of the coveralls is assessed, and thus in compliance with the requirements set out in the European standard governing PPE (design, certification and commercial sale). This issue has been raised previously by Mayer & Bahami *(9)* but received no response. Following on from Dubruc *(3)*, if we take an in-depth look at the manufacturer's instructions provided with each set of coveralls, it becomes clear that the information given in terms of coverall performance and limits of use is highly technical and sufficiently complex to deter a user from reading it.

This is despite the fact that point 1.4 of Annex II under Directive 89/686/EEC states that the manufacturer's instructions must specify:
a) The performances recorded in technical tests designed to guarantee the levels or classes of protection afforded by the personal protective equipment;
b) The appropriate classes of protection for different levels of risk and the corresponding limits of use; and most importantly;
c) That they must be concise and easily understandable.

This is demonstrated by the set of manufacturer's instructions for their coveralls given in *table 1*:

Table 1. Manufacturer's instructions for their coveralls

RESISTANCE TO LIQUID PERMEATION, (EN ISO 6529, MIGRATION TIME AT 1 µG/CM²/MIN)					
Chemical	Migration time (min)	EN* class	Chemical	Migration time (min)	EN* class
Sulphuric acid (30%)	290	5 of 6	Sodium hydroxide (40%)	>480	6 of 6
Sulphuric acid (18%)	>480	5 of 6			
**In compliance with standard EN 14605/EN 14325*					
RESISTANCE TO LIQUID PENETRATION (EN ISO 6530)					
Chemical	Penetration index (%)	EN class	Repulsion index	EN class	
Sulphuric acid (30%)	0.0	3 of 3	96.5	3 of 3	
Sodium hydroxide (10%)	0.0	3 of 3	96.6	3 of 3	
o-xylene	6.2	1 of 3	83.7	1 of 3	
Butane-1-ol	3.1	2 of 3	88.4	1 of 3	

Firstly, users are expected to be familiar with the similar but very distinct notions of penetration and permeation, which in reality is rarely the case. Furthermore, although this is the class of coverall recommended by the prevention management institutions (Ministry of Agriculture and medical benefits fund, 2007), it is clear that the tests on resistance to permeation by liquids for these coveralls are not conducted using the active substances which feature in plant protection products, but using various sulphuric acid and sodium hydroxide-based solutions. Again, in the same vein as Dubuc *(3)*, it should be noted that this coverall manufacturer states limits of use that, while real, are nevertheless mostly incomprehensible to wine-growers *(see table 2)*.

Table 2. Manufacturer states limits of use

LIMITS OF USE
It is possible that exposure to certain fine-grain particles, to high-powered liquid sprays, and to splattering from hazardous substances may require coveralls to offer mechanical resistance and protective properties greater than those afforded by Tyvek® Classic Plus Model CHA5, Tyvek® Classic Plus

Studying this coverall, Dubuc *(3)* conducted an analysis of the tests that were performed according to standard *NF EN ISO 6529:* December 2001 *(Protective clothing – Protection against chemicals – determination of resistance of protective clothing materials to permeation by liquids and gases)*; Annex A lists the chemicals recommended for comparing the permeation resistance of protective clothing materials.

The list of recommended liquid chemicals includes a dozen substances which, although widely used in the chemical industry, are not representative of plant protection products. Thus operator contamination, despite wearing protective coveralls, is the result of choosing equipment that is not adapted to the risk being run. This poor choice is prompted by inadequate understanding of the manufacturer-drafted technical information. At this stage, it is at the very least surprising that neither the PPE manufacturers nor the notified bodies reacted when the French Ministry of Agriculture and medical benefits fund released a guide (2007) to indicate what they knew to be the limits of use of the coveralls recommended for use with plant protection agents.

Finally, it is unethical to expect plant protection product users to be responsible for making sure that the protective gear they are supplied with is effectively compatible with the plant protection products they use, based on the data information given in the manufacturer's data.

The notified bodies tasked with assessing conformity need to be more stringent on how well manufacturers' data is drafted, including regular reviews to coincide with the implementation of further PPE directive-related procedures (11A and B).

Finally, the governing standard itself contains ambiguity, both in its authorship and in the policy statements of certain experts, which is liable to be detrimental to user health and safety. The notified bodies, for their part, believe they are playing their role if they apply highly technical standards that are sophisticated to implement.

17.5 Input from ergotoxicology: from contamination and occupational analysis to the collective readiness process

At this stage in our analysis, it is important to recap on the various contextual factors which can explain the previously cited technical and/or organizational flaws. The first point is that the agricultural market is only – according to PPE manufacturers – a niche market, in which R&D investments are not deemed financially viable.

Second, the key players involved are effectively walled off. Plant protection product manufacturers are focused on developing new active ingredients that are effective, profitable, and as environmentally harmless as possible, not forgetting that they also need to think about gaining approval for their new active ingredients from the regulatory authorities as a prerequisite to any potential market launch.

On the other hand, PPE manufacturers are occupied with crossover applications for generic PPE initially developed for chemical or more conventional industry. As long as their models are certified as barriers against liquid aerosols (or spray-tight) as for class-4 coveralls, they will meet the health and safety requirements specified in the PPE Directive, even

if the permeation tests, rather than being carried out with plant protection products, were conducted as per standard, with a handful of classic acids and/or solvents.

Exchanges between these key actors (institution prevention management bodies, plant protection product manufacturers, and PPE manufacturers) remain few and far between. This investigation has highlighted how each of these actors remains in the field of competencies they consider their own, and it is very rare that mutual feedback is pooled. Nevertheless, over the last two years, the results published under the Pestexpo study have redefined some of the boundaries. An illustration of this is the example of one plant protection product manufacturer that opted to go beyond its core product development and marketing activity and address the issue of applicator safety. This strategic shift was prompted by government groups together with a media risk management initiative.

17.5.1 Whistleblower role

We have decided, at this global level, to act as a whistleblower *(15)*. For strategic reasons, a process was defined for drafting and releasing a warning notice in order to mobilize as many actors as possible. This process is an integral part of a fully-managed social constructivism approach fuelled by the results generated through the ergotoxicology approach. It is important not to lose sight of the fact that the permeation results were produced through a study led by a plant protection product manufacturer that we consider a partner. It was by cross-comparing this data with Pestexpo data that we were able to draw attention to the scale of the issue raised. This data nevertheless remains the property of the industry partner and as such, cannot be publicly released.

Hence the first step involved discussions with this partner, with a view to using these results, while keeping both the company's name and the name of the manufacturer anonymous. The second step was to test our analysis with the various actors involved. Once we had enriched the results, the decision was made to draft a warning notice in scientific article format. After informal talks with all the actors concerned, and notably those tasked with PPE project sponsorship roles at the various protection management institutions, this warning notice was sent by registered mail to the managers of the institutions concerned (6 in total), and then forwarded on to various agriculture and agribusiness trade associations and labour unions (5 in total).

The final stage in this whistleblowing process consisted of working together to draft a report *(8)* on farmer exposure to plant protection products for publication in a specialist review entitled "Santé&Travail", which enabled us to produce an in-depth, fully contextual study, while at the same time reaching a wider readership in touch with prevention issues, particularly farmers and/or agricultural labour associations. This report was then relayed via mass media channels such as radio and the press, which in turn have heightened general media pressure, particularly on the institutional actors. The final phase was to release the warning notice.

One issue revealed by this relatively painstaking process has been the importance of creating conditions whereby each actor is able to mobilize their competencies and mutualize them beyond the traditional boundaries.

17.6 Actions launched by institutions responsible for case report

When the Ministry of Labour (tasked with monitoring the implementation of Directive 89/686/EEC) received this alert on the ineffectiveness of the protective coveralls worn by personnel when working with plant protection products, they looked into several courses of action, all based on the principle that the findings revealed by the whistleblowers were due to different kinds of problems. It appeared necessary to review user practices (choice of coveralls, how they are stored, looked after and disposed of) and re-examine how the coveralls are actually engineered in relation to the content of the governing standards.

The first working hypothesis was to claim that the technical specifications set out in the standards and guiding coverall design make it impossible to design coveralls that provide users (paid hire and professionals alike) with genuinely effective protection. It is true that the coveralls are designed to protect against specific substances, whereas in real work situations the chemicals used are generally formulations, i.e. preparations containing a range of different substances. This is a glaring example of a misfit between how the standard is drafted, in terms of permeation testing, and workplace reality. Furthermore, the ministry opted to broaden its analysis to span protection against all chemical hazards, instead of focusing on exposure to plant protection products. However, there is as yet no detailed data on the actual effectiveness of these coveralls. To bridge this knowledge gap and check their first working hypothesis, the ministry tasked its government consultancy, the French national agency for occupational and environmental health (AFSSET), with producing a green paper on the objective effectiveness of these coveralls, as assessed by tests, in protecting against the chemicals actually used by workers in various business sectors. The results of this enquiry will make it possible to assess whether it makes sense to file a formal opposition to overturn the standards in place. The government agency acts as scientific advisory between the ministry and the independent testing body.

The tests will focus on coveralls intended to protect against liquid chemicals and liquid aerosols, i.e. class 3 and class 4 coveralls, as defined in Standard EN 14605. The tests will be conducted following standard-specified protocols, but with the *products actually used in real-world workplace situations* (i.e. exposure to biocides, disinfectants, insecticides, weed-killers, paints, solvents, etc.). The onus has been on deploying a professional use rather than the product family-based approach, such as soil disinfection, disease vector control, woodwork treatments, painting, herbicide treatments, etc.

The next step, spanning a panel of coverall manufacturers and based on the manufacturer's claims, will be to pair up the coveralls with the chemicals actually used in real-world workplace situations, in order to run permeation trials to test the effectiveness of the protection these coveralls afford. Taken together, the data generated should make it possible to pinpoint the level of protection workers are actually given when they use commercially available coveralls. These results will also provide useful groundwork for redesigning coveralls to specifications set out in the standards.

The second working hypothesis is focused on the difficulties experienced by users in choosing the right coveralls. There are two core strands to this issue:

1. Coveralls cover a very narrow protection spectrum, and do not afford protection against all chemical products, but only against three or four substances. Class 4 coveralls (spray-tight) are part of a coveralls category in which users choose the coveralls adapted to the specific chemical they need protection against.
2. The protective time-spans (resistance to permeation) vary widely between different sets of coveralls, which evidently have knock-on effects in terms of the protection actually afforded.

It is self-evident that choosing the right coveralls is a particularly tricky task, which explains why users end up being insufficiently protected against toxic chemical agents. Once again, standardization work could help take manufacturer's data forward by making the user-targeted instructions easier to understand.

The French Ministry of Labour aims to help people using hazardous chemicals in choosing coveralls adapted to their work by leading an initiative centred on safety data sheets. The safety data sheet, which is drafted by the hazardous chemical manufacturer, is required to include a detailed personal protection data section. It would appear that this section needs to be better drafted, since it often features insufficient statements such as "wear protective clothing and suitable gloves".

The Ministry of Agriculture, for its part, has launched a series of measures: a taskforce has been formed to develop a design standard governing coveralls specifically dedicated to plant protection treatments, coupled with an updated guide on choosing and using PPE for plant protection treatments, which states the specific limits of use for task-dedicated coveralls.

In addition, the French National Institute of Health and Safety Research (INRS) has authored a guide on "protective clothing: what to choose, where to use" *(10)*, which specifically states that protective clothing for work with chemicals does not provide protection against all chemical products, nor does it offer permanent protection.

17.7 Conclusion

These alarming observations may, over and above the agricultural sector, have a connection with the increasing incidence of occupational cancer. Indeed, in the majority of workplace situations, the only protection measures taken are to wear PPE, whereas the Pestexpo study has highlighted how PPE performance falls short in real-world situations. The issues and challenges involved mean that action is needed from qualified French and European institutions with expertise in risk prevention and the assessment of PPE conformity. The situation underlines the importance of re-engineering more reliable design standards and developing Europe-wide standardization for agriculture-dedicated PPE. This policy is under discussion in Germany (standard DIN 32781), The Netherlands *(7)*, Spain, Portugal and Greece. It may offer perspectives for resolving the technical and organizational flaws outlined above, provided that procedures are developed for assessing PPE effectiveness in farming-specific work situations.

References

1. Baldi, I., Lebailly, P., Jean, S., Rougetet, L., Dulaurent, S., Marquet, P. (2006). Pesticide contamination of workers in vineyards in France. *Journal of Exposure Analysis and Environmental Epidemiology.* 2006 Mar, 16(2):115-24.
2. Baldi, I., Rolland, P., Ducamp, S., Dulaurent, S., Marquet, P., Brochard, P. (2002). Assessment of pesticide exposure in vineyard workers. 12th Conference of the International Society of Exposure Analysis - 14th Conference of the International Society of Environmental Epidemiology, August 11-15 2002, Vancouver, BC, Canada. *Epidemiology*; 13 (July), abstract.
3. Dubuc, P. (2007). Rapport sur l'inefficacité de combinaisons devant protéger des risques liés à l'usage des produits phytosanitaires : aspects juridiques. Ministère du travail.
4. Garrigou, A., Peeters, S., Jackson, M., Sagory, P. & Carballeda, G. (2004). Ergonomie & prévention des risques professionnels. In P. Falzon (ed), *Traité d Ergonomie*. Paris, PUF.
5. Garrigou, A., Mohammed-Brahim, B. & Daniellou, F. (1998). *Etude ergonomique sur les chantiers de déflocage d àmiante.* Rapport final. OPPBTP/DRT.CT3. Bordeaux.
6. Garrigou, A., Baldi, I. (à paraître). Apports de l'ergotoxicologie à l'évaluation de l'efficacité réelle des équipements de protection individuelle (EPI) contre le risque phytosanitaire : de l'analyse de la contamination au processus collectif d'alerte. Revue électronique Piste (www.pistes.uqam.ca).
7. Gerritsen-Ebben, R., Brouwer, D., H., van Hemmen, J. (2007). *Effective Personal Protective Equipment.* TNO, Zeist, Netherland.
8. Mahiou, I. (2007). Pesticides : menace sur les agriculteurs. *Santé & Travail*, no 59, juillet 2007.
9. Mayer, A. & Bahima, J. (2006). *Guide for the drafting or revision of EN standards on PPE*. Rapport du CEN PPE Forum, PPE N122, version 1.4 du 10 mai 2006, 34 p.Mayer, A. & Garbowsky, C (2007). Les vêtements de protection, choix et utilisation. ED 995, éd. INRS.
10. Ministère de l'agriculture et CCMSA (2007). *Traitements phytosanitaires et protection des yeux, du corps, des mains et des pieds.*
11. Mohammed-Brahim, B. (1996). Du point de vue du travail ou comment sulfater la vigne autrement. Approche ergo-toxicologique des traitements phytosanitaires en viticulture. Mémoire de DESS d'ergonomie, Université Bordeaux 2.
12. Mohammed-Brahim, B., Garrigou, A., Pasquereau, P. (2003). Quelles formes d'analyse de l'activité de travail en ergotoxicologie ? In Actes du 38° congrès de la SELF. Paris, 24-26 septembre.
13. Reason, J. (2004). *Managing the risks of organizational accidents.* Ashgate, Hants.
14. Sznelwar, L. (1992). *Analyse ergonomique de l èxposition de travailleurs agricoles aux pesticides. Essai ergo-toxicologique* Thèse de doctorat en ergonomie. Laboratoire d'Ergonomie. Paris, CNAM.
15. Vaughan, D. (1996). *The Challenger Launch decision. Risky technology, culture, and deviance at NASA*, The Chicago University Press, Chicago, 1996.

18. Chemical protective clothing for pesticide applicators: the search for suitability and effectiveness

Eva Cohen , CNMP-INSHT, Spain

The use of suitable Personal Protective Equipment (PPE) for agricultural tasks in which exposure to pesticides cannot be prevented by other means, is obligatory. The level of risk involved must be identified in order to select the appropriate protective equipment so that plant protection products (PPP) can be used safely. Different regulations refer either directly or indirectly to the mandatory use of PPE. Among those regulations are the following EU legal texts:

- Directive 89/656/EEC, on the minimum health and safety requirements for the use of PPE by workers at the workplace, which obligates the employer to provide workers with suitable PPE for the risks involved, which in turn are in compliance with the relevant community safety and health provisions on design and manufacture.
- Directive 98/24/EC, on the protection of the health and safety of workers from the risks related to chemical agents at work , which refers to the use of PPE in situations where exposure cannot be prevented by other protection or prevention measures.
- Directive 91/414/EEC, concerning the placing of PPP on the market (see Annex VI), requires the use of personal protection when the level of the predicted operator exposure has to be reduced below the Accepted Exposure Operator Level (AOEL),
- Regulation (EC) 1907/2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), (see Annex II) requires that the content of Safety Data Sheets (SDS) supply specific information on adequate and suitable PPE when they are needed, taking into account the appropriate CEN standards.

Typical agricultural tasks which involve the handling of pesticides are:

1) Mixing/loading, i.e. transferring the pesticide formulation from its original container into a tank connected to either a hand-held sprayer, tractor-mounted sprayer or knapsack sprayer;
2) Spraying the diluted pesticide onto the plants either manually or via a vehicle and,
3) Re-entry tasks such as crop handling, fruit collecting, etc.

Among these tasks, the spraying of the liquid is that which can expose the operator to the highest dermal exposure. This exposure is more likely to affect the whole body than other tasks where exposure may be more restricted to the hands, torso or may only affect the inhalation route.

Therefore, in many cases, spraying of the liquid requires protection of the whole body. In this context, different scenarios can be found where the level of exposure can vary dramatically depending on e.g. outdoor or indoor applications (greenhouses), high or low targets, density of foliage, or spray equipment. Greenhouses may represent the worst case scenario due to manual applications and the narrow space between rows, which makes it difficult for operators, who are walking during the application, to avoid

continuously rubbing their bodies against wet and dense foliage. Moreover, high temperatures and humidity can worsen working conditions.

Over the past few years, CNMP-INSHT in Spain has been greatly concerned about the risk involved in this type of scenario, and many publications have been prepared regarding field exposure and personal protection. It is worth mentioning CNMP's participation in the SAFE USE INITIATIVE project, an initiative of the plant protection products industry through the European Crop Protection Association (ECPA). The project was first implemented and developed in the south of Spain between 2003 and 2005 and then continued in other countries in Southern Europe. CNMP has participated as an assessment body and testing laboratory in the search for specific protective clothing and gloves and other PPE. Field studies in greenhouses were also carried out to check the laboratory results when needed. Conclusions showed that Chemical Protective Clothing (CPC) of at least type 4 should be recommended. The chemical resistance to pesticides of the material used in CPC should also be addressed. Nevertheless, other scenarios may imply a lower risk, and the level of required protection defined may permit the selection of a more comfortable protective suit and allow a longer period of wear.

Furthermore, the registration process according to Directive 91/414/CEE, defines strict rules regarding the authorisation of a PPP which requires all the declared uses and risk assessments for health and environmental effects to be carried out before a preparation can be placed on the market. These risk assessments include the evaluation of operator exposure in realistic conditions to the important components of the PPP from a toxicological point of view. This evaluation may require consideration of the use of suitable chemical protective clothing to reduce the predicted exposure below the accepted operator exposure levels (AOEL). The protection associated with this type of clothing, in terms of percentage penetration considered for regulatory purposes, may differ from country to country and may be more easily harmonized once the protection needed for the operator is better defined at EU level. The TNO report on “Default setting of PPE for registration purposes of agrochemical and biocidal pesticides” attempts to deal with this issue.

Several proposals regarding the need for a standard for pesticide applicators' protective clothing are now under discussion on CEN and ISO levels. Meanwhile, different approaches are being taken at national levels.

Nevertheless, it is a fact that specific recommendations in the labelling of pesticides and Safety Data Sheets regarding gloves and protective clothing will help employers and workers; it will minimise exposure more efficiently and consequently minimise the resulting risk. Taking into account the hazard posed by the product itself, the properties which influence its ability to penetrate glove and clothing materials and the level of potential exposure depending on the scenario, it may be difficult to give a specific recommendation. In conclusion, the selection of appropriate PPE should be supported by relevant training in order to promote the safe use of pesticides.

19. Standard test methods for real PPE efficiency

Dr N Vaughan, Health and Safety Laboratory, Buxton, UK

19.1 Introduction

National Regulations and European Directives* *(1)* on health and safety at work have included the requirement for employers to make a suitable and sufficient assessment of the risks to their employees. Where the risk controls applied include PPE, this should include an assessment of the efficiency of the equipment being used. However, despite this requirement, there have been relatively few systematic studies into the actual levels of protection achieved in real work situations. Usually, the performance of the equipment during certification tests under laboratory conditions is extrapolated to the workplace; in many cases there is now growing evidence to suggest that this practice is neither safe nor sound.

The emergence of REACH, with its mandatory requirement that chemical substances be accompanied by sufficient information to ensure that they can be used safely in specific exposure scenarios, increases the need for more detailed information on the real protective performance of PPE. However, this need does not only apply to protection against chemicals. It is equally valid for any of the multiplicity of hazards against which PPE may be called into service.

19.2 Limitations of certification tests

Tests carried out for the purposes of PPE product certification are deliberately simplified in order to enhance reproducibility and repeatability. At best they only give a vague approximation to real-world operational environments and conditions. For example:

Chemical permeation tests - Tests conducted on static samples of material at 23 °C, with continuous contact between the material and the test chemical. Real use of clothing or gloves will invariably involve mechanical stressing of the protective material, possibly very different temperature ranges, and intermittent contact with one or more chemicals.

Inward leakage of respiratory protection – This is measured on a small number of subjects undertaking brief, minimally taxing, defined exercises at room temperature. Real use may involve markedly different work rates, postures, environmental conditions and wear durations.

Tests in isolation – Usually only a single item of PPE is tested for certification at a time. Real use will normally require the simultaneous use of several items of PPE, which may detrimentally interfere with each other.

**e.g. in the UK the PPE at Work Regulations (SI 1992/2966 as amended) enacting European Directive 89/656/EEC (Official Journal L393)*

Scope of performance tested – Certification testing concentrates on simple numerical protection measurement in response to a defined hazard e.g. force reduction on impact, time to breakthrough, reduction in levels of exposure, and does not consider other aspects of a PPE programme that can significantly influence performance, e.g. correct selection, user training in proper use, equipment servicing and maintenance.

However, for some certification tests, measurement techniques are well established and validated. These may be adaptable for use in the assessment of PPE performance in real work situations.

What is protection efficiency?

Put simply, protection efficiency is the ratio between the level of risk in the work environment and that experienced by PPE users, usually quoted as a Protection Factor (PF). In terms of exposure to chemicals it can be expressed as: PF = External concentration / In-PPE concentration

Why measure real PPE efficiency?

PPE efficiencies are needed as part of the selection process to ensure that the right level of protection (neither too low nor too high) is provided.

Where measurements or assessments of the efficiency of PPE in real work situations (Workplace Protection Factors, WPF) have been carried out, they often reveal levels of protection lower than those achieved for the purposes of certification (often referred to as Nominal Protection Factors, NPF). If the NPF is used as the basis for selecting adequate PPE, users may unknowingly be over-exposed to the hazard, leading to injury or ill health. For this reason, guidance documents on the selection of PPE tend not to recommend applying the NPF during selection, and suggest using somewhat lower levels of protection *(2, 3)* derived from measurement or experience. In the field of respiratory protection, the convention is to adopt the 5th percentile of measured WPF values as the Assigned Protection Factor (APF) for a given protective device.

At least part of the reason why there is not more WPF data available for consideration lies in the difficulty of making these measurements. Numerous hurdles must be overcome before meaningful WPF data can be collected:

- The protective property being assessed must be quantifiable – even for exposures to some chemical substances this is not always a simple matter. Extension to mechanical and physical hazards complicates things further;
- Measurement uncertainty and analytical detection limits must be known before the validity of measured protection values can be assessed – simple ratios between challenge and in-PPE concentrations can be misleading, and unreliable data needs to be identified and eliminated before drawing conclusions *(See 4. 89% of the data collected was rejected as unreliable)*;
- WPF studies must not put test subjects at risk – experimental ethics preclude some technically feasible avenues of study, such as using very high concentrations of harmful test agents to improve analytical accuracy, or even testing untried forms of PPE in real work situations;
- Making the measurement must not affect the protective performance of the equipment – this includes significantly altering the equipment to enable performance measurement, and the less tangible effects of behavioural alteration in the test subjects.

The net effect of these problems is that it may be impractical or impossible to measure protection efficiency in real work situations.

Because of these difficulties, and the need for significant quantities of data to ensure confidence in the results, WPF studies of any sort are expensive to conduct. Traditionally, national enforcement authorities with access to government funds have carried out this type of work for the purpose of generating guidance. For chemicals, REACH will shift the burden of proof onto industry, but makes provisions for spreading costs and sharing information. This should assist in avoiding duplication of effort and the associated costs. For this reason, if data from different studies are to be compared or accumulated to give broad consensus on the performance of a particular type of PPE control measure, there is an urgent need for standardized measurement protocols. Critically, results of such studies may depend on how measurements were made.

19.3 WPF protocols

The need for a standardized approach to the measurement of "real" protection has been recognized in the respiratory field for some time, and activity is already underway to develop an internationally agreed and accepted approach to WPF measurement (2. M Clayton, private communication. This activity is taking place within the membership of the International Society for Respiratory Protection). This has been prompted by the diversity in PF values adopted in guidance by different regional or national authorities, the development of International Standards for RPE, and the increasing globalization of the RPE market. While being specifically developed to address respiratory protection, many of the philosophies and principles included here will be equally applicable to other forms of PPE investigation.

Factors which have been identified as critical include:

- Whether the study is conducted in a real workplace (a WPF study), or if this is impractical, technically impossible or unethical, adopts an adequate simulation (a SWPF study);
- What approach to take in relation to correcting the behaviour of test subjects; is the study to be based on their pre-existing, possibly deficient, levels of knowledge and training in PPE use (an "as-is" study), or will additional training be provided and any observed bad practice corrected (a "good practice" study);
- Crucial information to be recorded for any study – e.g. the type of equipment being used; information on the supporting PPE programme; details of the test subjects; measurement and analytical techniques used and their uncertainty and detection limits; work environment, duration and activities undertaken during the trials;
- Data treatment and presentation techniques;

The validity of data generated by such studies can only be applied to situations which adequately conform to the equipment, use conditions and supporting PPE programme included in the investigation. Significant differences from the studied regime could render application of the derived PF levels invalid (either too high or too low, depending on the nature of the difference). This is likely to lead to testing of worst-case scenarios, and the adoption of fairly conservative protection levels based on the results, to minimise the need for repetition of studies.

Ultimately, the success or failure of a PPE programme will be judged by its ability to prevent harmful exposure of workers. For some risks, this will be apparent in the short-term. For others, only time will tell, whether exposure risks have been adequately controlled.

19.4 Conclusion

The availability of better information on the real levels of protection provided by PPE is long overdue. Changes in European legislation are increasing the profile of the need for this type of information.

Generating the necessary data will pose significant technical, ethical and economic challenges. To get the most out of any studies carried out in this area, there is an urgent need for harmonized approaches to the strategies and protocols used. This harmonization process is already underway internationally in the field of RPE. Although aspects of the protocols developed there will be applicable or adaptable for use in other PPE fields, there is still a very long way to go.

References

1. European Directive 89/656/EEC (Official Journal L393).
2. HSG53: Respiratory Protective Equipment at Work – A practical guide. HSE Books, 2005.
3. EN 529:2005 Respiratory protective devices – Recommendations for the selection, use, care and maintenance – Guidance document. CEN, Brussels.
4. Bolsover, J, Rajan-Sithamparanadarajah, B and Vaughan, N (2006) Workplace protection of air-fed visors used in paint spraying operations. Annals of Occupational Hygiene (2006) 50, 219-229.

20. Motivation

Jorma Saari, Finnish Institute of Occupational Health

Historically, the attitudes towards PPE are not too positive in Finland. This goes back to the seventies when there was a great need for technical improvements at workplaces. Many employees, even trade unions, suspected the use of PPE slows down the technical improvement of machinery. Even if things have much changed, too many people still carry these suspicions.

A problem is that people perceive the risk of injury as a remote one. The use of PPE may cause unpleasant feelings, such as, sweating, weight, irritation, etc. The use of PPE is, therefore, not inherently desired. A way to motivate the use is to introduce regulations and rules which then are enforced by sanctions. The negative thing is that you have to spend resources for enforcement and it is impossible to monitor everybody in every situation and moment. Therefore, motivation should come from inside, from a person's desire to use PPE and to behave safely.

A requirement for the successful implementation of rules is that people have good reasons to meet the rules. A strategy we have applied recently in Finland is the introduction of Zero Accident Philosophy (ZAP). According to the philosophy, all accidents are preventable. If a company adopts the philosophy, it commits to the use of a wide range of prevention strategies. It will use both technical and behavioural means. Using a behavioural (PPE) strategy does not mean neglecting necessary technical measures.

To promote the philosophy, the Finnish Institute of Occupational Health launched a Zero Accident Forum (ZAF) five years ago. ZAF has now more than 160 member organizations employing over 200 000 people. These organizations promote the use of PPE, among other things, by convincing their employees that the use of PPE is part of professional, high quality work. The member organizations and their employees share the ambitious vision of zero accidents at some point in the future. They want to be forerunners and models for others.

21. Compatibility and systems

Petra Jackisch, BG BAU, Germany

21.1 Introduction

When looking at the practical use of PPE, the products are hardly ever used as "stand-alone items": in most cases, workers have to combine several PPE to ensure proper protection. In standardization, testing and certification, PPE products often seem to exist in isolation, and it is up to the user to select the right PPE. Compatibility and the right assembly and combination of the equipment need to be looked at more closely.

21.2 Combinations or systems of PPE

Various types of combinations or systems can be distinguished, and have their specific problems.

Integrated/standard PPE combinations

These include PPE such as helmet-mounted earmuffs which are covered by specific standards or standards that cover specific requirements relating to the interfaces. In practical use, this type of combination does not cause too many difficulties, since compatibility will be considered during the standardization process, and the relevant information for the user is available.

Combinations of various PPE components

The issue of compatibility gains importance when different PPE components must be combined in order to protect the user, as is the case in personal fall protection, respiratory protection, diving equipment etc. Often, the individual components are covered by separate standards. They usually include information on compatibility and interfaces with other components or products, but problems may still arise in the assembly and proper use of the resulting system. Users often require additional advice, on the specific items combined.

The revision of component standards causes additional problems. Since the publication of a revised standard hardly ever coincides with the revision of the other related standards, on-going compatibility may be compromised. Comprehensive information and training are a precondition for safe systems.

Different types of PPE for the same risk

Users often have to wear different types of PPE to protect them against the same risk, e.g. chemical protective clothing, footwear and gloves, or fire-fighters' equipment that may include clothing, gloves, footwear, respiratory protection and even fall protection equipment. The selection of the right equipment is often difficult due to deviations in the performance classes defined for the individual items of equipment. Information on criteria for compatibility is often lacking or insufficient, which makes it extremely difficult to combine the right equipment. Better user information and closer co-operation between standardization bodies is needed.

Users invariably ask for support relating to the selection of the right equipment, and the demand for standards or supporting documents offering advice relating to the selection and use of products is rising. This is not necessarily job-related advice (e.g. fire-fighting), but may also be specifically risk-related, as has recently been the case in the field of electrostatic risks.

Different types of PPE for different risks
Combining different types of PPE that are designed to protect against different risks is an issue that is often neglected. People tend to look at the individual PPE they are dealing with, without proper consideration of problems that may arise from interaction between the various pieces of equipment, due, for instance, to ergonomic reasons or the elimination of specific protective functions.

This should be an issue not only in the selection process and the use of the equipment, but also in standardization, testing and certification.

21.3 Combining fall arrest equipment with head protection and respiratory equipment

To investigate problems that may be caused by the simultaneous use of different types of PPE that protect against different risks, a study was carried out by the German Expert Committee on PPE in co-operation with the research institute of Berufsgenossenschaften (BGIA) in 2005. The objective was to test the effectiveness of fall arrest equipment when used in combination with head protection and respiratory protective equipment. This type of combination is commonly used by rescue services or may be required in various work environments, e.g. corrosion prevention, refractory construction, or building refurbishment work at a chemical plant.

In the study, drop tests were carried out with an articulated dummy that was equipped with an industrial safety helmet and a filtering half mask or breathing apparatus, as well as a full body harness attached to a lanyard and energy absorber.

These pictures illustrate the difficulties arising from the interaction of the various PPE items *(figures 1-4)*, or the consequences a fall may have on the protective properties of the PPE used:

Figure 1: displacement of mask, displacement of helmet / chin strap

Figure 2: displacement of helmet, loss of filter, chin strap exerts pressure on throat

Figure 3: disruption of air supply

Figure 4: displacement of straps, position of breathing apparatus, straps cutting into neck area

The study showed that there is a need to more carefully look into the possible negative effects of interaction between different PPE worn together.

It was also confirmed that for certain work environments, it may be difficult to find the appropriate equipment on the market, because the requirements would be too specific. In such cases, user companies may try to co-operate with manufacturers to develop special equipment that meets the expectations in practice. Following the study, discussions have evolved about using a combination of mountaineering helmets and industrial safety helmets, so that a different chin strap can be used, which will protect the user from being strangled when falling and suffering a displacement of the helmet. Other examples of developments considered a result of the study can be seen in *figures 5 and 6*.

Figure 5: new combinations between fall arrest equipment and breathing apparatus

Figure 6: chemical protective suit which allows the use of fall arrest equipment (with an integrated harness, energy absorber and connector)

21.4 More consideration of combinations and systems in standards and in use

Users are often insufficiently aware of the additional risks that may arise from the combination of equipment. Ideally, such risks should be taken into account as early as in the stages of product design and testing and certification. During the risk assessment the manufacturer has to carry out during product design, the specific use conditions for the tasks for which the equipment is intended need to be taken into account. The product requirements specified in the technical file should reflect the expected use, and also consider combinations with other products that are likely to occur in practice. Possible restrictions regarding the use of equipment in conjunction with other items need to be described more consistently in the information supplied by the manufacturer.

At a time when workplaces and working conditions are changing rapidly, product standards cannot be expected to cover the entire range of use that can be found in practice. Specific working conditions often call for specialized equipment and product requirements which may only become evident with the relevant experience. The information must come from the workplaces; a stronger involvement of users in standardization is thus called for. This may also lead to a stronger emphasis on ergonomic aspects.

Manufacturers are increasingly working together with users in order to develop equipment specifically designed for certain working conditions. It may be useful to carry out further studies to investigate the risks arising from combinations of equipment for specific working conditions.

Complex systems or new applications need particular attention. A field where this is apparent is the growing use of mountaineering techniques in the construction industry. Industrial fall protection equipment and mountaineering equipment cannot easily be combined, and the user must be aware of the specific characteristics and functions of items in the system. The restrictions of use are hard to define, and even differ among countries, depending on specific user regulations. Safety when using such techniques therefore requires not only detailed knowledge of the workplace for the correct selection of the relevant product characteristics, but also competence and training, in order to end up with a safe system of work.

Finally, appropriate user information is fundamental in order to allow workplaces to choose the correct equipment and ensure its correct use (i.e. to avoid misuse and related injury risks). Comprehensive information must be given about the right choice of equipment, the right assembly of the individual components, and the right use of the system. However, even if such information is available, misuse is often observed. The question remains as to what extent possible mistakes must be taken into account, or in fact in how far possible misuse can be taken into account in product standards. The gap between product standards and user regulations could be closed by stricter requirements for the instructions for use and possibly a larger number of relevant documents on the selection and use of equipment (SUCAMs).

21.5 Conclusions

The difficulties that arise in the context of PPE combinations and PPE systems show that there are various levels/possibilities for improvement.

Workers do not work in the standardized surroundings which standards sometimes assume, and cannot be forced to adapt their working methods to the needs of standardizers and regulators. Instead there must be a joint effort to ensure protection for workers by a systematic approach that combines standards, product development, information and training.

References

Ottersbach, H.J.: Combinations of personal protective equipment - falling safety, respiratory protection and protective headwear; in: Focus on BGIA's work, no. 0107, Edition 4/2005 Hrsg.: Berufsgenossenschaftliches Institut für Arbeitsschutz - BGIA, Sankt Augustin

22. Training of dealers and co-operation with SMEs

Eero Korhonen, Finnish Institute of Occupational Health, FIOH

Abstract

According to Directive 89/656/EEC, the employer shall specify the need of the use of PPE based on risk assessment. The specification of the PPE suitable for certain work situations requires detailed understanding and knowledge of personal protective devices. Many parameters shall be taken into account in the selection.

Normally, the work and risks of a workplace are known, but the selection of suitable PPE in many cases is difficult because of the lack of detailed knowledge of its properties. The dealers of safety products know their products well and normally have good knowledge of existing solutions in other similar work places.

In order to utilize the specific product knowledge, dealers should help workplaces in risk assessment and in the selection of suitable PPE. They could also provide training in correct use.

The dealers should be aware of OHS legislation and of the organization of OHS activities at work. Based on this knowledge, the prevention or control of risks can be planned and the role of PPE use can be made clearer. The use of PPE is only a small part of OHS activities at work.

The frame Directive requires that if such protective and preventive measures cannot be organized due to a lack of competent personnel in the undertaking and/or establishment, the employer shall enlist competent external services.

A training programme has been developed based on the initiative of the Association of Finnish Suppliers of Labour Safety Equipment. The programme consists of two compulsory modules on principles of OHS and OHS legislation, and risk assessment methods. A specific training module has been developed for each type of PPE. The total training programme requires 14 days. At the end of each module, participants must pass a test, after which they receive a certificate.

The system has proven to be very successful. Some companies no only buy from suppliers with competent and qualified sales personnel. The salesmen have reported that the training programme has had a positive impact on their daily work, and has helped create a more constant customer relationship.

22.1 The need for competent sales personnel

A study on the need for certified competence of PPE sales personnel was carried out in 1998. A questionnaire was sent to companies' heads of safety and safety representatives, occupational health care doctors and nurses, as well as some purchasers. Market control authorities were also interviewed.

The result of this study highlighted the need to improve the skills of sales personnel so that they are able to help workplaces in the selection and use of the correct PPE. There is a particular need to improve the flow of information, especially to small- and medium-sized workplaces.

An initial proposal for the content of a training programme was made on the basis of the information collected. The training programme and content requirements were drafted by a working group in which different stakeholders were represented.

In Finland, the amount of factory inspectors is limited and they very seldom have the opportunity to help workplaces in the selection and use of PPE. The study revealed that the amount of PPE sales personnel is about three times this, and it can be estimated that they make nearly 100 000 contacts to different workplaces, including small workplaces.

22.2 Training programme

It became obvious that sales personnel cannot be away from work for long periods. Therefore a modular system was created. Compulsory modules are Basics of occupational safety and health and labour protection and Risk assessment. One optional module is also included. (*Table 1*). After each module, participants must pass a test.

Table 1. Training modules

The courses are open, and people from different companies can attend. They can also be specifically arranged for the personnel of a certain company.

The certification of competence is made according to the standard describing the personnel certification scheme. The participants receive a card showing which PPE training they have completed *(Figure 1 and Figure 2)*.

Figure 1. Front of identification card

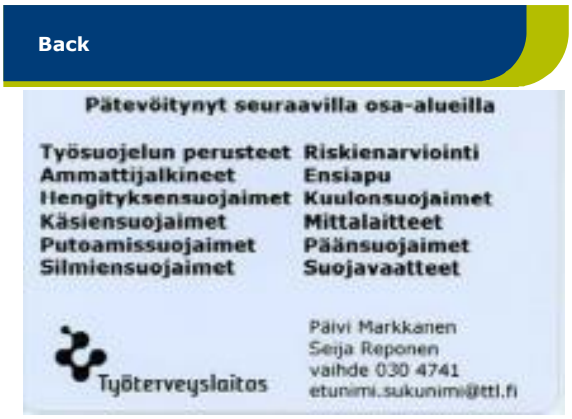


Figure 2. Back of identification card

The certificate is valid for five years, if the holder actively works in PPE sales and participates in meetings dealing with topical issues.

22.3 Further development

The sales personnel have accepted the training programme very well. Their competence now makes good, constant customer relations possible. Some workplaces have even announced that they will only buy PPE from companies with competent sales personnel.

A wish has been expressed for similar or joint training for those who are responsible for risk assessment, and the selection, maintenance and training of the use of PPE at workplaces. The first joint training course will be organized during the spring of 2009.

23. Developing a test method for in-situ workplace measurements of chemical protective glove breakthrough

Paszkiewicz P., Buchwald K. E. BGIA Institute for Occupational Health and Safety of GUV Germany

23.1 Problem definitions

Chemical protective gloves are personal protective equipment (PPE), worn in order to protect the hands and skin at the workplace during contact with aggressive chemical substances. In contrast to equipment for respiratory protection, in which penetration of the gas filter by chemicals can be detected by taste or smell, penetration by chemical substances of the glove material (elastomers) is detectable by the wearer of the glove only in exceptional cases.

A test method was developed, suitable for application in the field, for in-situ breakthrough measurement of chemicals through chemical protective gloves at the workplace. The basic principle is to take measurements from the test subject under the glove, so as to include all factors which may influence permeation by chemicals during wearing.

23.2 Methods

Two different methods were initially considered. In the first, a number of direct-reading gas detection instruments for continuous measurement (PID, semiconductor sensors, etc.) were tested with sampling from the void between the glove and the surface of the hand. In the second, discontinuous-mode enrichment systems such as activated carbon pads and detector tubes placed between skin and the glove were employed.

23.3 Findings

The direct reading method, involving a photo ionization detector (PID) with its own source of power and an integral sampling pump, proved to be the more suitable, owing to the near-instant detection of penetration and the concentration characteristics display facility as a function of wetting of the glove by the chemical.

Initial applications of the direct reading measurement arrangement in simulated work tasks have shown it to correlate with the standardized permeation test for glove materials, EN 374-3: "Protective gloves against chemicals and micro-organisms - Part 3: Determination of resistance to permeation by chemicals".

The first results of workplace measurements employing a small range of glove types and selected work processes are now available.

Posters

24. Permeation of antineoplastic drugs through four glove materials

Mäkelä EA, Tornaeus J, Nieminen K, Ilmarinen R, Hesso A, Rosenberg C, and Hämeilä M, Finnish Institute of Occupational Health, Finland

Health care personnel are exposed to antineoplastic drugs while preparing and administrating them to patients. Since skin is an important exposure route for these drugs, the gloves in use should provide efficient protection.

The aims of the study were:
1) To study the protection of gloves against antineoplastic drugs by measuring permeability;
2) To determine how alcohol wash during drug-handling affects the permeation of antineoplastic drugs;
3) To find out the relevant permeation test temperature; and
4) To provide knowledge for guidance and better glove choices for health care personnel.

The measure of permeation is breakthrough time, signifying the elapsed time between the initial application of a test chemical to the outside surface of the protective material and the detection of permeation through the material at a specified rate. The rate used in this study was 0.01 μg/min/cm^2, which is a hundred times lower than the limit stated in the current European standard for chemical permeation testing. Temperatures were measured for 30 min inside two different pairs of gloves worn by ten volunteers. On the basis of the registered temperatures, a test temperature of 35 °C was used. Permeation test time was 4 h. Of the tested compounds, 5-fluorouracil, etoposide, gemcitabine, and methotrexate did not permeate vinyl or nitrile rubber examination gloves or natural or chloroprene rubber surgical gloves. In addition, the nitrile and chloroprene rubber gloves were not permeable to cyclophosphamide. The breakthrough time of cyclophosphamide for the vinyl gloves was 28 min and for the natural rubber gloves 151 min. Cyclophosphamide permeation was not detected through a double layer of natural rubber gloves or through a double layer of vinyl and natural rubber gloves. The breakthrough times of carmustine through vinyl, nitrile rubber, natural rubber, and chloroprene gloves were 1.8 min, more than 177 min, 2.8 min, and 110 min, respectively. The breakthrough time of carmustine was 64–82 min for a double layer of natural rubber gloves and for a double layer of vinyl and natural rubber gloves. Carmustine permeation was not detected through a double layer of chloroprene gloves or a double layer of nitrile rubber and natural rubber gloves. A 5-minute alcohol wash did not increase the permeation of cyclophosphamide or carmustine.

The common practice of using double gloves and changing them every 30 minutes can be presumed safe when preparing large amounts of

antineoplastic drugs in hospitals. Special care should, however, be taken when handling carmustine.

When selecting gloves on the basis of breakthrough times, it is important to note that abrasion and flexing of the gloves, that is to say normal glove usage, increases permeation. Nitrile and chloroprene rubber are more effective as protective materials than vinyl and natural rubber.

In the European Union, permeation testing is not required for gloves meant for protection against antineoplastic drugs, which constitutes a serious deficiency.

References

Mäkelä E, Tornaeus J, Nieminen K, Ilmarinen R, Hesso A, Rosenberg C, Hämeilä M. Permeation of five antineoplastic drugs through four glove materials. In. Bowers AK, Bunge AL (eds.). Third International Conference on Occupational and Environmental Exposures of Skin to Chemicals; 2007 Jun 17-20; Golden, Colorado, USA. Golden: Colorado School of Mines, 2007:133-6.

25. Programme of the Seminar

9th EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT, 29-31.1.2008 **in SPA HOTEL LEVITUNTURI, LEVI, Finland**

Tuesday 29 January 2008

Introductory session, Chairman Karl-Heinz Noetel, BG BAU, Germany

14.30 - 15.00	Registration and coffee
15.00 - 15.10	Opening of the seminar FIOH, Finland
15.10 - 15.30	Revision of the New Approach Senior Government Secretary, Anja Liukko, Ministry of Trade and Industry, Finland
15.30 – 15.50	Impact of the revision of New Approach Mr. Elod Dudas, European Commission, Belgium
15.50 – 16.10	The impact of the REACH-Regulation on the selection and use of PPE, Dr. N.P. Vaughan, Health and Safety laboratory, UK
16.10 - 16.30	The impact of the Directive on noise (2003/10/EC) on the selection and use of PPE, Dr. Martin Liedtke, BGIA, Germany
16.30 – 17.00	Coffee break
17.00 – 17.20	The impact of Directive on vibration (2002/44/EC) on the selection and use of PPE, Dr. Christ, BGIA, Germany
17.20 - 17.40	The impact of Directive on optical radiation (2006/25/EC) on the selection and use of PPE Dr. Maila Hietanen, FIOH, Finland
17.40 -	Discussion Chairperson, Karl-Heinz Noetel, BG BAU, Germany
19.00	Get together party

9th EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT, 29-31.1.2008 **in SPA HOTEL LEVITUNTURI, LEVI, Finland**

Wednesday 30 January 2008

Implementation of the new regulations and the opinion of the PPE stakeholders, Chairman Alain Mayer, INRS, France

09.00 – 09.20	Improvement of the efficiency of M.S. Wolfgang Lentsch, Federal Ministry for Economy and Labour, Austria
09.20 – 09.40	PPE's from a worker's point of view Roland Gauthy, ETUI-REHS, Belgium
09.40 – 10.00	Manufacturers Secretary General, Henk Vanhoutte, European Safety Federation, Belgium
10.00 – 10.20	European Coordination of Notified Bodies Karl-Heinz Noetel, BG BAU, Germany
10.20 – 10.50	Coffee break

Challenges and practical solutions
Chairman Eero Korhonen, FIOH, Finland

10.50 – 11.10	ISO standardisation on Respiratory Protective Devices (RPD)- a status report Wolfgang Drews, ISO TC 94 SG 15
11.10 - 11.30	Real risks and workplace conditions as basis for standardisation Dr. Helena Mäkinen, FIOH, Finland
11.30 – 11.50	Stadardisation Alain Mayer, INRS, France
11.50 - 13.20	Lunch break

PPE against chemical risks

13.20 - 13.40	Information requirements regarding chemical products Martine Reynier, INRS, France
13.40 - 14.00	Relevant information on chemicals for proper selection of PPE Norbert Kluger, BG BAU - GISBAU
14.00 - 14.20	Risk assessment and selection / use to ensure efficiency of PPE Dr. Derk H. Brower, TNO, The Netherlands
14.20 – 14.50	Protective clothing against pesticides Patricia Le Frious, French Ministry of Labour and Alain Garrigou, University of Bordeaux, France

9th EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT, 29-31.1.2008 **in SPA HOTEL LEVITUNTURI, LEVI, Finland**

14.50 – 15.10	Chemical protective clothing for pesticides applicators: Search of suitability and effectiveness Eva Cohen, INSHT, Spain
15.10 – 15.30	Standard test methods and the real efficiency of PPE Dr N.P. Vaughan, HSL, UK
15.30 - 16.00	Coffee break
	Posters about the use of PPE

Training and information

16.20 - 16.40	Motivation Dr Jorma Saari, FIOH, Finland
16.40 - 17.00	Compatibility and systems Petra Jackisch, BG BAU, Germany
17.00 - 17.20	Training of dealers and cooperation with SMEs Eero Korhonen, FIOH, Finland (example with dealer/customer)
17.20 – 17.40	Discussion
	Free communications
17.40 - 18.00	Development of a test method for in situ-workplace measurements of the breakthrough of chemical protective gloves Dr. Peter Paszkiewicz, BGIA, Germany
20.00 -	Dinner

Thursday 31 January 2008

09.00 - 10.30 Panel discussion

10.30 - 11.00 Summing up of the seminar and closing

Work environment research series publications

1. Hongisto V, Helenius R, Lindgren M: Kaksinkertaisen seinärakenteen ääneneristävyys – laboratoriotutkimus. Helsinki 2002.
2. Hongisto V: Monikerroksisen seinärakenteen ilmaääneneristävyyden ennustemalli. Helsinki 2003.
3. Työhygienian koulutuspäivät 2003. (Imatra 20.–21.5.2003.) 2003.
4. Kaarlela A, Jokitulppo J, Keskinen E, Hongisto V: Toimistojen ääniympäristökysely menetelmän kehitys. 2003.
5. *Jurvelius Hannele (Ed.) European Seminar on Personal Equipment, Seminar Report. Work Environment Research Report Series 5, Finnish Institute of Occupational Health, Helsinki, Finland, 2003.*
6. Petra Larm, Jukka Keränen, Valtteri Hongisto: Avotoimistojen akustiikka. Helsinki 2004.
7. Työhygienian koulutuspäivät 2004. (Helsinki 25.-26.5.2004.) Toim. Mirja Kiilunen. Helsinki 2004.
8. Valkeapää A, Anttonen H, Niskanen J: Liike- ja palvelurakennuksien tuulikaappien vedontorjunta. Helsinki 2004.
9. Kaarlela A, Jokitulppo J, Helenius R, Keskinen E, Hongisto V: Meluhaitat toimistotyössä – pilottitutkimus. Helsinki 2004.
10. Toppila E, Laitinen H, Starck J, Pyykkö I: Klassinen musiikki ja kuulonsuojelu. pdf (www.ttl.fi/Aihesivut/Työhygenia/Melu/ Tiedonlähteet). 2004.
11. Hirvonen A, Kiilunen M, Valkonen S: Biologisen monitoroinnin palveluanalytiikan vuositilasto 2003. 2004.
12. Heikkilä P, Saalo A, Soosaar A: Työpaikkojen ilman epäpuhtausmittaukset 1994–2003. 2005.
13. Työhygienian koulutuspäivät 2005. (Tampere 15.–16.6.2005.) Toim. Starck J ja Laitinen R. 2005.
14. Maila Hietanen, Patrick von Nandelstadh, Tommi Alanko: Sähkömagneettiset kentät työympäristössä. Opaskirja työntekijöiden altistumisen arvioimiseksi. 2005.
15. Biologisen monitoroinnin palveluanalytiikan vuositilasto 2004. Helsinki 2005.
16. *Elo A-R, Korhonen E, Starck J (Eds.): 7th European Seminar on Personal Protective Equipment, Seminar report. Work Environment Research Report Series nro 16. Helsinki, Finland 2005.*
17. Puuntyöstöpölyn hallinnan kehittäminen (FineWood). Lappeenrannan aluetyöterveyslaitos, Fysiikan osasto ja VTT Tuotteet ja tuotanto. 2005.
18. Hautalampi T, Henriks-Eckerman M-L, Engström K, Koskela H, Saarinen P & Välimaa J: Kemikaalialtistumisen rajoittaminen automaalaa¬moissa. Työterveyslaitos, Turku 2006.
19. Alanko T, Hietanen M, von Nandelstadh P: Työntekijöiden altistuminen tukiasemien radiotaajuisille kentille. Työterveyslaitos, Helsinki 2006.
20. Niemelä R:Virtual 4D. Loppuraportti. Työterveyslaitos, Helsinki 2006.
21. Valkonen S: Biologisen monitoroinnin palveluanalytiikan vuositilasto 2005. Työterveyslaitos, Helsinki 2006.
22. Larm P, Hakala J, Hongisto V: Sound insulation of Finnish building boards. (Work Environment Research Report Series 22.) Finnish Institute of Occupational Health, Helsinki, Finland 2006.
23. Hongisto V, Keränen J, Larm P, Oliva D: Työtilan ääniympäristön havainnollistaminen, Virtual Space 4D ääniympäristöosion loppuraportti. Työterveyslaitos, Helsinki 2006.
24. Liesivuori J, Naumanen P, Aromaa E, Pääkkönen R, Starck J, Kauppinen T, Savolainen K: Muuttuva työympäristö – visio vuoteen 2015. Työterveyslaitos, Helsinki 2006.

25. Aitio A, Hakala E, Kiilunen M, Laitinen J, Mikkola J ja Valkonen S: Biologisen monitoroinnin palveluanalytiikan vuositilasto 2006, Helsinki 2007.
26. Romppanen V, Sulander J: Hyvintointi koulutyössä ja opiskelussa. Helsinki 2007.
27. *Mäki Susanna (Ed): 8th European seminar on Personal Protective Equipment. 27-29.3.2007 in Saariselkä, Lapland, Finland. Work Environment Research Report Series 27, Finnish Institute of Occupational Health, Helsinki, Finland 2007.*
28. Liesivuosi J, Naumanen P Visioita alueellisen työhyvinvoinnin ja työterveyden edistämisestä. Helsinki 2007.
29. Nurminen M, Norppa H Metallisen kromin ja kolmiarvoisten kromiyhdisteiden ammatillinen syöpävaara. Helsinki 2008.
30. Räikkönen, T Työelämä murtuvan aallon harjalla - mitä on tapahtumassa työhyvinvoinnin edellytyksille?, Helsinki 2008
31. Kasvio A, Nikkilä R, Moilanen L, Virtanen S Työ murroksessa -kyselyn aineistoraportti. Helsinki 2008.
32. Ahonen Ilpo & Liukkonen Tuula: Pellettivarastojen ilman epäpuhtaudet ja niiden aiheuttamien vaarojen ehkäiseminen. Työympäristötutkimuksen raporttisarja 32. Työterveyslaitos, Helsinki 2008.
33. Janhonen Minna, Laitinen Heikki, 3T-ratkaisut Oy: Pienyritysten kehittämishanke Mäntsälässä - hankearviointi. Työterveyslaitos, Helsinki 2008.
34. Alanko Tommi, Tolvanen Tuomas, Hietanen Maila: Mastotyöntekijöiden altistuminen radiotaajuuskentille. Työterveyslaitos, Helsinki 2008.
35. Hakala, Erkki, Kiilunen Mirja, Santonen Tiina, Mikkola Jouni: Biologinen monitorointi vuositilasto 2007.Työterveyslaitos, Helsinki 2008.
36. von Bonsdorff Monika, E., Janhonen Minna, Vanhala Sinikka, Husman Päivi, Ylöstalo Pekka, Seitsamo Jorma, Nykyri Erkki: Henkilöstön työkyky ja yrityksen menestyminen vuosina 1997 - 2007 - tutkimus metalliteollisuudessa ja vähittäiskaupan alalla. Työterveyslaitos, Helsinki 2009.
37. Hongisto Valtteri, Häggblom Henna: MAKSI hankkeen loppuraportti - Toimistojen mallinnettu ja koettu sisäympäristö. Työterveyslaitos, Helsinki 2009.
38. *Mäki Susanna (Ed): 9th European seminar on Personal Protective Equipment. 29-31.1.2008 in Spa Hotel Levitunturi, Levi, Finland. Work Environment Research Report Series 38, Finnish Institute of Occupational Health, Helsinki, Finland 2009.*

WORK ENVIRONMENT RESEARCH REPORT SERIES 38
Finnish Institute of Occupational Health, 2009

The WORK ENVIRONMENT RESEARCH REPORT SERIES 38, contains papers presented at the ninth (9) EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT held in Levi (Kittilä), Finland on 29-31 January 2008.

The seminar aimed at providing relevant information regarding the changes and recommendations for possible PPE solutions, and discussed the impact of new developments in European legislation (Revision on the New Approach, Impact of REACH regulation and impact of noise, vibration and optical radiation Directives, and the selection and use of PPE). The resulting challenges were evaluated by different stakeholders. Presentations focused on examples from the field of protection against chemicals, and the important role of training and information of all actors was emphasized.

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