



Scientific Committee on Emerging and Newly-Identified Health Risks

SCENIHR

Position Statement on emerging and newly identified health risks to be drawn to the attention of the European Commission



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1. INTRODUCTION

The primary purpose of this position paper is to draw the attention of the EU Commission Services to emerging issues in the non-food area that have been identified by the SCENIHR members as having the potential to significantly impact human health and /or on the environment in the future.

Early identification of emerging issues is of great potential value in order to ensure a high level of public safety and environmental protection. However, inevitably the data available to inform the correct identification of emerging issues and their impacts is likely to be very limited. It is therefore important that each issue that is identified is regularly reviewed. It is the aim of the SCENIHR, therefore, to regularly review any relevant new developments and to produce an updated position paper at least every term of the Scientific Committees (this term 2013-2016). In considering emerging issues, the SCENIHR wishes to work closely with other EU scientific advisory committees that also have emerging issues as part of their mandate.

The SCENIHR recognised the need to establish a very flexible framework to aid the correct identification of emerging issues and their potential impacts.

Two parallel and complementary approaches have been indicated to identify emerging issues:

- A proactive approach by the SCENIHR. This requires 'brain storming' sessions to identify the emerging issues of principal concern followed by the introduction of procedures to detect and characterise their development.
- A more reactive approach based on the identification of indicators of change and the monitoring of these to detect emerging issues.

SCENIHR members have been asked during 2014 plenary meetings, in dedicated 'brainstorming sessions', to identify emerging/relevant issues that they think should be flagged for the Commission Services.

The criteria used to identify an emerging issue were as follows:

- Novelty of the stressor or process
- Scale of possible impacts on man and /or the environment
- Severity of impacts for particular organisms (priority for life threatening)
- Urgency i.e. the temporal nature of the likely changes (priority for rapid increases)
- Not investigated in depth recently by a reputable scientific body
- Anticipated to be increasingly important over time

To aid this, a standardised format has been used and issues have been placed in particular categories. It is acknowledged that further consideration of some of the issues that have been identified should be led by other scientific committees.

2. FORMAT FOR DESCRIBING AN EMERGING ISSUE

A common format was proposed to describe emerging issues. This was in the format of table (see fig. 1) in which the committee members have been asked to fill in the following:

- the topic proposed
- the author (your name)
- exposure categories (one or more selected items from the ones mentioned under point 1 between 1-9)
- Suggested hazard categories (indicating the choice e.g. A1, B2 etc.)
- Preliminary estimation (e.g.... very urgent , large impact, of media interest, etc ...)
- Description / background

1) Exposure categories

Risks associated with:

- 1) Agriculture and food, drinking water (chemicals, pesticides, nanomaterials, microorganisms)
- 2) Consumer products (chemicals, pesticides, nanomaterials, microorganisms)
- 3) Energy and energy transmission
- 4) Environmental changes
- 5) Evolution of diseases and microbial pathogens
- 6) Medical technology
- 7) Pharmaceuticals (excluding drugs: vaccines, DNA & synthetic biology , blood)
- 8) Social and lifestyle activities
- 9) Urban engineering

2) Suggested hazard categories:

A. New origin of risk

- 1) Development and implementation of new technologies
- 2) Newly identified pathogens

B. 'New modifier with pre-existing Origin'

- 1) Emerging issue related to a change in collective human behaviour
- 2) Emerging issue related to changing environmental factors

C. Change in 'scientific knowledge'

D. Risk perception by the Society

3. NEXT STEPS

The list will be used by the Secretariat for discussion of potential new mandates with relevant Commission departments.

4. TOPICS

4.1. 3D video

Topic	3D video
Author	Ana Proykova
Exposure categories	1.8 (need for extra category)
Suggested hazard categories	A.1)
Preliminary estimation	Moderate impact
Description/background:	
<p>The modern digital 3D effect using glasses makes this same effect effortless. Your eyes are invited or <i>forced</i> not to properly focus in order to get the full effect of eye-popping 3D.</p> <p>Some people report being temporarily disoriented when walking out of a 3D movie. Walking into the light while your vision shifts back to active binocular depth perception can indeed be disorienting for anyone.</p> <p>During that lag period where you're re-learning binocular vision, your depth perception is compromised and you may lack the visual acuity required to perform tasks, such as driving.</p> <p>So far, the only real research we have on the effect of prolonged exposure to 3D virtual environments has concluded that the health risks are real.</p>	
Ref: (forum page; 2010)	
http://www.audioholics.com/editorials/warning-3d-video-hazardous-to-your-health	

4.2. 3-D printers

Topic	3-D printers
Author	Ana Proykova
Exposure categories	1.2) & ? 1.8)
Suggested hazard categories	A.1)
Preliminary estimation	Large impact
Description/background:	
<p>Most desktop 3-D printers work by extruding a string of plastic at high temperatures. There are two kinds of plastic used: acrylonitrile butadiene styrene (ABS), and polylactic acid (PLA), which is softer and used for medical devices, cups and plastic silverware.</p> <p>The researchers tested some popular brands of 3-D printers measuring how much particulate plastic is released by the machines. The particles themselves are tiny, a few nanometers across. Printers that use ABS plastic release about 190 billion particles per minute, while PLA machines release about 20 billion. That amount of particles classifies both types of machines as "high emitters."</p> <p>Breathing ABS plastic might have harmful effects. What's more, because the plastics are heated to high temps, they can change into other substances that might be toxic as well. The solution is relatively simple: use your 3-D printer in a room with good ventilation or at least open a window.</p>	
Ref. Atmospheric Environment, Volume 79, November 2013, Pages 334–339	

4.3. Cyanotoxins risk (haemodialysis and drinking water)

Topic	Cyanotoxins risk (haemodialysis and drinking water)
Author	Emanuela Testai
Exposure categories	1.1, 1.4 & 1.6
Suggested hazard categories	B.2
Preliminary estimation	Large impact
Description/background:	
<p>Cyanobacteria are a morphologically diverse group of photosynthetic prokaryotes that occupy a wide range of niches. Over the last decades, increased eutrophic conditions and climate changes (increased temperature, floods, droughts) have favoured cyanobacteria spreading and growing in water bodies up to elevated density, resulting in blooms and scum. As secondary metabolites they produce cyanotoxins, to which humans may be exposed through several routes: the oral one is by far the most frequent and quantitatively important, occurring by ingestion of contaminated drinking water, food (mainly aquatic organisms), dietary supplements or water during recreational activities. The parenteral route of exposure may also occur, when water from contaminated superficial water bodies is used for hemodialysis. This route of exposure is particularly dangerous and very likely underestimated, since most of the time hospitals/medical doctors are not aware of this risk. In Brazil, of a total of 131 exposed patients (treated with water contaminated with microcystins (MC), a family of potent hepatotoxins), 116 experienced symptoms, including visual disturbances, nausea, and vomiting; 110 developed acute liver failure and 60 died.</p> <p>This human exposure occurred mainly because of inefficient water treatment at the city's water treatment plant and inadequate water treatment at the renal dialysis clinics. The use of reverse-osmosis filters is considered to provide an efficient barrier to protect renal patients against MCs. However it has been shown that reverse osmosis also needs to be carefully monitored (also considering the operating conditions: i.e. the working temperature, since it does not always prevent MC contamination of water used in the treatment of dialysis patients, who might experience sub-lethal effects from the contamination (which might go undetected because these patients are already ill – their poor health condition might be blamed on their pre-existing disease rather than on being contaminated during treatment). Indeed, just as an example, the system is usually designed to work at room temperature (20°C ±5°C), but room temperature in the south of Europe in summertime can be much higher.</p>	
<p>Ref. Funari, E., and Testai, E. (2008) Human health risk assessment related to cyanotoxins exposure. <i>Crit. Rev. Toxicol.</i> 38, 97–125.</p>	
<p>Azevedo, S. M., Jochimsen, E. M., Rinehart, K. L., Lau, S., Shaw, G. R., and Eaglesham,</p>	

G. K. (2002) Human intoxication by microcystins during renal dialysis treatment in Caruaru-Brazil. *Toxicology* 181, 441–446.

Soares, R. M., Yuan, M., Servaites, J. C., Delgado, A., Magalhaes, V. F., Hilborn, E. D., Charmichael, W. W., and Azevedo, S. M. F. O. (2006) Sub-lethal exposure from microcystins to renal insufficiency patients in Rio de Janeiro - Brazil. *Environ. Toxicol.* 21, 95–103.

4.4. The use of nanomaterials for medical imaging and drug delivery

Topic	The use of nanomaterials for medical imaging and drug delivery
Author	Michelle Epstein
Exposure categories	Medical technology, Pharmaceuticals
Suggested hazard categories	A
Preliminary estimation	Very urgent, large impact

Description/background:

The use of nano-technology in drug delivery and for medical imaging is a newly emerging identified risk. Although nanomaterials used for drug delivery and imaging aim to reduce toxicity and side effects of drugs and imaging compounds, the carrier systems may impose risks to patients. It is necessary to focus on nanoparticle (NP) /nanocage toxicity alone and combined with drugs and substances as administered by inhalation, oral intake and injection. NPs combined with drugs and imaging substances may affect exposure levels of the NPs, the drugs and substances in specific tissues, e.g. lung, liver, brain, etc. This is an important area of innovation with potential risk.

Close collaboration between EMA and SCENIHR will be necessary.

4.5. Electromagnetic fields, EC Recommendation 1999/519/EC

Topic	Electromagnetic fields, EC Recommendation 1999/519/EC
Author	Norbert Leitgeb
Exposure categories	3
Suggested hazard categories	B2, C, D
Preliminary estimation	Risk communication and coordination issue
<p>Description/background:</p> <p>Following the 1998 ICNIRP guideline on limiting electromagnetic fields and based on it, the EU Council issued a recommendation in 1999 to limit public exposure to electromagnetic fields (0Hz-300GHz) with reference levels derived from basic limits of EMF-induced intracorporal quantities.</p> <p>Meanwhile, in 2000, the Commission issued a paper on the precautionary principle COM(2000)1.</p> <p>In 2010 ICNIRP issued a revised guideline for the frequency range up to 10MHz with considerable changes such as increasing reference values for 50Hz magnetic fields by a factor of 2 and by more than 10fold in the intermediate frequency range. The IF range became increasingly important due to new and emerging technologies such as RFID and compact fluorescent lamps applying such frequencies.</p> <p>By now, some member states such as Germany have already - partly - adopted ICNIRP's new values. For instance, Germany stayed with the initial 100µT in the sensitive 50Hz range in spite of the proposed doubling.</p> <p>With regard to the 14-year-old EC paper and the obvious differences compared to the more recently issued guidelines, there is a need to either reinforce 1999/519/CE or to revise it in the light of newer accumulated experience both in science and in risk communication.</p> <p>The envisaged opinion on EMF could be a valuable starting point for a related action.</p>	
<p>Recommendation 1999/519/CE on limiting the general public's exposure to electromagnetic fields (0z to 300GHz)</p> <p>ICNIRP (2010): Guidelines for limiting exposure to time-varying electric and magnetic fields (1Hz-100kHz). Health Physics 99(6):818-836</p>	

4.6. Direct Current Ultra High Voltage Power lines (UHVDC-PL)

Topic	Direct Current Ultra High Voltage Power lines (UHVDC-PL)
Author	Norbert Leitgeb
Exposure categories	3, 4
Suggested hazard categories	A1, B2
Preliminary estimation	Urgent
Description/background:	
<p>As a consequence of the directive 2009/28/EC and its objective to increasingly use energy from renewable sources, such as wind from northern offshore plants or solar energy from North Africa (project DESERTEC), there is an urgent need for long-distance energy transfer facilities. For several physical reasons, (Ultra-) High-Voltage Direct Current overhead power lines are planned, which for the first time (in Europe) will emit substantial DC electric fields along thousands of kilometres.</p> <p>While DC magnetic field emissions are no major issue, it is still important that UHVDC-PL be designed so as to avoid excessive DC electric emissions.</p> <p>However, DC electric fields are now excluded from EMF regulations on a national and international level including 1999/519/CE and ICNIRP, in spite of existing risks from these fields which may become unacceptable without proper limitation. To protect the general population and to save utility companies from adapting already erected lines at additional costs, timely guidance on this issue would be urgently needed.</p>	
<p>Directive 2009/28/EC on promotion of the use of energy from renewable sources</p> <p>Recommendation 1999/519/CE on limiting the general public's exposure to electromagnetic fields (0z to 300GHz)</p> <p>ICNIRP (2010): Guidelines for limiting exposure to time-varying electric and magnetic fields (1Hz-100kHz). Health Physics 99(6):818-836</p>	

4.7. High-focused Ultrasound for cosmetic use

Topic	High-focused Ultrasound for cosmetic use
Author	Norbert Leitgeb
Exposure categories	Risk of misuse high-risk technologies with disputed benefit
Suggested hazard categories	A1
Preliminary estimation	Emerging wide-spread use
Description/background:	
<p>Cosmetic application of high-risk devices delivering high intensities to the body such as laser light, radio frequency electric currents and in particular high-intensity focused ultrasound HIF-US become increasingly common. Since those devices are not covered by the medical devices directive, particular risk arises from use by lay persons who are not aware of particular methodical risks and anatomical restrictions and by the fact that such devices are not approved or tested by anyone, nor are they subjected to regular safety tests as considered necessary by similar devices for medical use. Since there is also no requirement on vigilance reporting, quantitative data are lacking, but anecdotic reports are alarming. A first attempt to include high-risk cosmetic devices into medical device legislation is included in the draft proposal COM(2010)542, Annex XV, in terms of a short explicit list of devices, without, however, including HIF-US.</p> <p>In addition, the benefits of HIF-US for body shaping by lipolysis are disputed and independent scientific positions are lacking.</p>	
Proposal COM(2010)542 on medical devices, Annex XV of 2012-09-26	
Empfehlung der SSK: Ultraschallanwendung am Menschen. BAnz AT 22.04.2013 B4	

4.8. E-cigarette as consumer product

Topic	E-cigarette as consumer product
Author	Philippe Hartemann
Exposure categories	Consumer product
Suggested hazard categories	Emerging issue related to the change in collective behavior
Preliminary estimation	Large impact and a hot media topic. The EP proposed to regulate E-cigarettes like a drug
Description/Background:	
<p>Electronic smoking devices ("e-cigarettes") have penetrated the smoking market in a few years. The number e-cigarette users is increasing continuously. Their popularity is based on their perceived harm reduction and their possible function as smoking cessation aids. The e-cigarette has been described as a possible form of harm reduction [1-3] compared to 'classic' cigarettes, since exposure to most hazardous substances resulting from combustion of tobacco in 'classic' cigarettes is reduced substantially (9 to 450 fold). When the filling of an e-cigarette is heated, a temperature of 50 to 120°C is obtained. However, intensive use can lead to temperatures up to 250°C [4]. Traces of acrolein, formed from glycerine at 275°C, have been found [5].</p> <p>Electronic smoking devices are used to vaporize nicotine (also known as "vaping") to deliver nicotine without the combustion of tobacco; fillings containing (natural) flavours without nicotine are also used. The nicotine content of e-cigarettes varies from no nicotine (0 to 0.03 mg nicotine / filling) to low (1.4 to 4.1 mg) and medium (2.5 to 5.9 mg) to high (3.9 to 7.4 mg). High/heavy fillings containing more than 16 mg nicotine have been reported [6-7].</p> <p>Surveys indicate that many people will use the e-cigarette over long periods [8]. Surprisingly, very few safety studies of the compounds inhaled by vaping can be found. Chronic nicotine exposure in the mixture of tobacco smoke has been studied in numerous studies but not in vaping devices. Nicotine is not a mutagen but it may play a role in cell growth promotion and it has been identified as an immune-modulator.</p> <p>Data regarding vaping of non-nicotine-containing substances is extremely limited. These devices (e.g. Shisha-pens) vaporize "natural" substances with a typical flavour (aroma); some flavours (such as menthol and liquorice) are similar to those used as additives to increase the attractiveness of tobacco cigarettes, but others are often poorly defined chemically. These natural flavours are often considered as "GRAS" (Generally Regarded As Safe), but this assumption of safety only applies to their use in foods, and their toxicological profile upon inhalation (of the original substance or after heating) is often unknown.</p> <p>Between 01 June 2010 and 30 September 2013, 1,700 exposures were reported to</p>	

Poison Centers (USA) of e-cigarette devices and components, including nicotine-refill cartridges. The most frequent age group concerned was that of children age 5 and below, with 717 (42.2%) exposures. These incidence clearly show the acute health risk emerging from, mainly, the refill cartridges[9].

In conclusion, 4 associated hazards linked to e-cigarettes have been recognized:

1. Content in nicotine, including acute poisoning due to exposure to filling liquids;
2. Temperature of the instrument, which may induce the formation of combustion products like acrolein, formaldehyde, etc.;
3. Composition of the liquid with a total absence of control for a lot of producers;
4. Non-nicotine containing devices.

Ref.

1. Britton J, et al. Tobacco control efforts in Europe. *Lancet* 2013;381:1588.
2. McNeill A, et al. Reducing harm from tobacco use. *J Psychopharmacol* 2013;27:13.
3. Hastings G, et al. Tobacco harm reduction: the devil is in the deployment. *BMJ* 2012;345:e8412.
4. OFT - Office Français de Prévention du Tabagisme. Rapport et avis d'experts sur l'e-cigarette. Press release 2013.
5. German Cancer Research Center. Electronic cigarettes - An overview. *Red Series* 2013;19.
6. Bullen C, et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet* 2013;382:1629.
7. Goniewicz ML, et al. Nicotine levels in electronic cigarettes. *Nicotine Tob Res* 2013;15:158.
8. Bullen C, et al. Study protocol for a randomised controlled trial of electronic cigarettes versus nicotine patch for smoking cessation. *BMC Public Health* 2013;13:210
9. Vakkalanka JP et al Epidemiological trends in electronic cigarette exposures reported to U.S. Poison Centers. *Clin Toxicol (Phila)*. 2014; 52(5):542-8.

4.9. Health effects from different composition of exhaust resulting from biobased fuels

Topic	Health effects from different composition of exhaust resulting from biobased fuels
Author	Theo Vermeire
Exposure categories	3
Suggested hazard categories	A1
Preliminary estimation	May have large impact
Description/background:	
<p>The influence of new emission control technologies and fuel types on both PM emissions and health effects has been less well investigated. The use of biofuels will not necessarily decrease the hazard of engine emissions. There is a need for a harmonised protocol to test various conditions and technologies on a range of relevant health endpoints in combination with a solid exposure assessment strategy.</p>	
<p>Ref. Gerlofs-Nijland, M.E., Totlandsdal, A.I., Tzamkiozis, T., Leseman, D.L.A.C., Samaras, Z., Lağ, M., Schwarze, P., Ntziachristos, L., Cassee, F.R. Cell Toxicity and Oxidative Potential of Engine Exhaust Particles: Impact of Using Particulate Filter or Biodiesel Fuel Blend. Environ. Sci. Technol. 2013, 47, 5931–5938.</p>	

4.10. Graphene nanomaterials

Topic	Graphene nanomaterials
Author	Theo Vermeire
Exposure categories	Potentially all
Suggested hazard categories	A1
Preliminary estimation	Urgent
Description/background:	
<p>Reviews suggest that graphene nanomaterials could exert a considerable toxicity and that considerable emission of graphene from electronic devices and composites are possible in the future. It is also suggested that graphene is both persistent and hydrophobic. Although these results indicate that graphene may cause adverse environmental and health effects, the results foremost show that there are many risk-related knowledge gaps to be filled.</p>	
<p>Ref. Bianco, A. Graphene: Safe or Toxic? The Two Faces of the Medal. <i>Angew. Chem. Int. Ed.</i> 2013, 52, 4986 – 4997.</p> <p>Arvidsson, R., Molander, S., Sandén B.A. Review of Potential Environmental and Health Risks of the Nanomaterial Graphene. <i>Human and Ecological Risk Assessment</i>, 19: 873–887, 2013.</p>	

4.11. Faecal Transplantation

Topic	Faecal Transplantation
Author	Philippe Hartemann
Exposure categories	Medical device or drug?
Suggested hazard categories	Emerging issue related to the change of treatments for severe diarrhea or prevention of infectious complications in immunosuppressed patients
Preliminary estimation	Mediatic issue, proposal of one Member State to regulate as a drug
Description/background:	
<p>The incidence of severe diarrhea episodes is increasing with the age of the population, especially due to <i>Clostridium difficile</i>, and antibiotics are selecting resistant microorganisms. The use of faecal transplantation (by oral administration) is now reported as giving excellent results, better than antibiotherapy, and is expanded to immunosuppressed patients for the prevention of nosocomial infections and refractory Crohn's disease with results which could be globally considered as positive.</p> <p>But the transplanted faeces have to be "safe": this requires preliminary controls for the absence of some pathogenic microorganisms. Thus it could be considered that transplanted faeces are a drug or a medical device. For regulatory purposes this question is very important and we need to regulate it now.</p> <p>This could be also considered as synthetic biology.</p>	
<p>Ref. Sa1922, Pilot study on the safety and efficacy of faecal microbiota transplantation in refractory Crohn's disease: Vermeire S., Joossens M., Verbeke K. &Hildebrand F. 2012 Wb Sanders.</p> <p>Systematic review: faecal transplantation for the treatment of Clostridium difficile - associated disease: Guo B. Harstall C. & Louie T. Alimentary 2012 (Wiley on-line library).</p> <p>Fame and future of faecal transplantation: developing next generation therapies with synthetic microbiomes: Vos V.M. Microbiol. Technology 2013 (Wiley on-line library).</p>	