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SCENIHR - Opinions

2013-2016

Medical devices

- Final Opinion on the safety of surgical meshes used in urogynaecological surgery (/health/scientific_committees/emerging/docs/scenihr_o_049.pdf)
  3 December 2015

Abstract

Final Opinion on the safety of surgical meshes used in urogynaecological surgery

Link to opinion (/health/scientific_committees/emerging/docs/scenihr_o_049.pdf)

SCENIHR WG on Surgical meshes
SCENIHR members: Philippe Hartemann (chair), Theodoros Samaras (co-rapporteur), Luis Martínez Martínez, Norbert Leitgeb
External experts: Christopher Chapple (rapporteur), Fred Milani, Xavier Deffieux, Jorge Garcia, Catherine Brogan
Contact: SANCO-C2-SCENIHR@ec.europa.eu
On request from: European Commission
Doi:
Adopted on: 3 December 2015

Content of the opinion:

Surgical meshes have been used since the 1990's for the treatment of male and female stress urinary incontinence (SUI), female pelvic organ prolapse (POP) and colorectal functional disorders (CFD). More recently the use of synthetic mesh and biological materials has become common requiring new surgical insertion tools and tissue fixation anchors.

The use of meshes in surgery has been shown to be associated with various adverse effects such as infection, tissue extrusion, separation of vaginal epithelium leading to mesh exposure, mesh shrinkage and adverse side effects including pain and sexual dysfunction. The European Commission has thus requested the SCENIHR to assess the health risks of meshes used in urogynaecological surgery.

The various options for the treatment of pelvic floor dysfunctions were reviewed based on the scientific literature and the guidelines from scientific societies and health authorities. Included were both non-surgical and surgical treatment methods.

In assessing the risk associated with mesh application, the SCENIHR calls attention to consider the overall surface area of material used, the product design and the properties of the material used. The available evidence suggests a higher morbidity in treating POP, which uses a much larger amount of mesh compared to SUI.

The implantation of any mesh for the treatment of POP via the vaginal route should be only considered in complex cases in particular after failed primary repair surgery. The use of autologous graft material is not feasible for POP because of the large mesh area required and the resulting donor morbidity. The use of absorbable mesh inserted either via a transabdominal or transvaginal route is associated with a high failure rate. Transvaginal surgery using non-absorbable synthetic mesh for POP involves a much greater surface area of mesh and is associated with a higher risk of mesh-related morbidity than seen with trans-abdominal insertion of this mesh. Sacrocolpopexy is associated with greater surgical morbidity.

Based on the available scientific evidence, SCENIHR's recommendations include:

- Material properties, product design, overall mesh size, route of implantation, patient characteristics, associated procedures (e.g. hysterectomy) and surgeon's experience are aspects to consider when choosing appropriate therapy.

- For all procedures, the amount of mesh should be limited where possible.

- The implantation of any mesh for the treatment of POP via the vaginal route should be only considered in complex cases in particular after failed primary repair surgery.

- A certification system for surgeons should be introduced based on existing international guidelines and established in cooperation with the relevant European Surgical Associations.

- Appropriate patient selection and counselling, which is of paramount importance for the optimal outcome for all surgical procedures. Patient selection and counselling should be based on the results of further clinical evidence, which should be collected in a systematic fashion for all of these devices.

Keywords:

SCENIHR, scientific opinion, risk assessment, surgical meshes

Opinion to be cited as:

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), The safety of surgical meshes used in urogynecological surgery, 3 December 2015.

- Final Opinion on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk (2015 update) (/health/scientific_committees/emerging/docs/scenihr_o_047.pdf)
  25 June 2015 - Revision February 2016

Abstract

Final Opinion on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk (2015 update)

Link to opinion (/health/scientific_committees/emerging/docs/scenihr_o_047.pdf)

SCENIHR WG on DEHP
SCENIHR members: Philippe Hartemann, Eduard Rodríguez-Farré, Emanuela Testai (Rapporteur)
SCCS members: Suresh Rastogi, Ulrike Bernauer
External experts: Wim De Jong, Hans Gulliksson, Aldert H. Piersma, G. Latini, Richard Sharpe, Dirk Schubert
Contact: SANCO-C2-SCENIHR@ec.europa.eu
On request from: European Commission
Doi: 10.2772/45179
Adopted on: 25 June 2015

Content of the opinion:

The main focus of this Opinion, which is an update of the 2008 SCENIHR Opinion, is on the potential risk for patients exposed to DEHP or similar plasticising compounds leaching from medical devices. Exposure of the general population to plasticizers has also been addressed. The assessment also includes information on currently available plasticizers as well as some proposed alternatives to DEHP in medical devices for neonates and for other patient groups.

Use of PVC medical devices may lead to a higher exposure to DEHP compared to everyday sources affecting the general population. Examples of medical procedures with a potential for high exposure to DEHP are multiple procedures in preterm neonates, haemodialysis, heart transplantation or coronary artery bypass graft surgery, massive blood transfusion of red blood cells and plasma or peritoneal dialysis. The Opinion also focuses on these sorts of clinical procedures that result in high DEHP exposure.

Based on the available scientific evidence, SCENIHR considers that adult patients undergoing haemodialysis have the highest exposure, due to the chronic nature of the treatment. Children are potentially at higher risk, particularly neonates and infants due to their low body weight are particularly prone to high level of exposure on a body weight basis. There is evidence suggesting that DEHP causes the most severe reproductive toxicity in animal studies, when compared to other alternative plasticizers. There is therefore a strong need to develop and collect data on exposure of alternative materials in the actual conditions of use in order to refine the knowledge on their toxicological profile. The possibility of replacing DEHP with these products could then be considered, taking account the efficacy of the treatment as well as the toxicological profile and leaching properties of the alternative materials.

Keywords:

SCENIHR, scientific opinion, DEHP, phthalates, medical devices, neonates, alternative plasticizers, health risks

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Opinion to be cited as:

SCENIHR (Scientific Committee on Emerging and Newly-Identified Health Risks), Scientific Opinion on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk. 2015.

- Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users (/health/scientific_committees/emerging/docs/scenihr_o_046.pdf)
29 April 2015

Abstract

Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users

Link to opinion (/health/scientific_committees/emerging/docs/scenihr_o_046.pdf)

SCENIHR WG Dental amalgam
SCENIHR members: Eduard Rodríguez-Farré, Emanuela Testai
External experts: Ellen Bruzell, Wim De Jong, Arne Hensten, Gottfried Schmalz, Mogens Thomsen
Aknowledgements: Wolfgang Dekant, Philippe Grandjean, Jan van Dijken
Contact: SANCO-C2-SCENIHR@ec.europa.eu
On request from: European Commission
Doi: 10.2772/42641
Adopted on: 29 April 2015

Content of the opinion:

The Opinion, which updates SCENIHR's previous Opinion of 2008, evaluates the scientific evidence on the potential association between amalgam and its alternatives, and allergies, neurological disorders or other adverse health effects.

The SCENIHR recognises that dental amalgam is an effective restorative material and is a material of choice for specific restorations for the general population, with low risk of adverse health effects. However, the choice of material should be based on patient characteristics such as primary or permanent teeth, pregnancy, the presence of allergies to mercury or other components of restorative materials, and the presence of impaired renal clearance.

Placement and removal results in short-time exposure to the patients compared to leaving the amalgam intact. Therefore there is no general justification for unnecessarily removing clinically satisfactory amalgam restorations, except in those patients diagnosed as having allergic reactions to one of the amalgam constituents.

Recent studies do not indicate that dental personnel, despite somewhat higher exposures than general population, suffer from adverse effects that could be attributed to mercury exposure due to dental amalgam. However, exposure of both patients and dental personnel could be minimised by the use of appropriate clinical techniques.

The SCENIHR concludes that amalgam alternatives have certain clinical limitations and toxicological risks. More experimental, clinical and epidemiological research is required to ensure patient safety in the future.

Currently in the EU, there is a shift away from the use of dental amalgam in oral health care towards an increased use of alternative materials. This change is not only for technical and aesthetic reasons, but also reflects the increasing concern about the use of mercury – a major component in dental amalgam - and the general aim to reduce mercury use within the EU.

To reduce the use of mercury-added products in line with the intentions of the Minamata Convention (reduction of mercury in the environment) the Opinion recommends that for primary teeth, and in pregnant patients, alternative materials to amalgam should be the first choice. The SCENIHR recognises that there is a need for further research, particularly relating to (i) evaluation of the potential neurotoxicity of mercury from dental amalgam and the effect of genetic polymorphisms on mercury toxicity and (ii) to expand knowledge of the toxicity profile of alternative dental restorative materials. Furthermore, there is a need for the development of new alternative materials with a high degree of biocompatibility.

Keywords:

Dental amalgam, mercury, toxicology, exposure, resin-based composites, glass ionomer cements, allergy, systemic health effects, SCENIHR

Opinion to be cited as:

SCENIHR (Scientific Committee on Emerging and Newly-Identified Health Risks), Scientific opinion on the Safety of Dental Amalgam and Alternative Dental Restoration Materials for Patients and Users (update), 29 April 2015.

- Final opinion on the safety of the use of bisphenol A in medical devices (/health/scientific_committees/emerging/docs/scenihr_o_040.pdf)
  18 February 2015

Abstract

Final opinion on the safety of the use of bisphenol A in medical devices

Link to opinion (/health/scientific_committees/emerging/docs/scenihr_o_040.pdf)

SCENIHR WG BPA in medical devices
SCENIHR members: Emanuela Testai, Philippe Hartemann, Eduardo Rodriguez-Farré
SCCS member: Suresh Chandra Rastogi
External experts: Wim De Jong, Juana Bustos, Laurence Castle, Ursula Gundert-Remy, Arne Hensten, Hilde Molvig Kopperud, Nicolás Olea, Aldert Piersma
Contact: SANCO-C2-SCENIHR@ec.europa.eu
On request from: European Commission
Doi: 10.2772/75546
Adopted on: 18 February 2015

Content of the opinion:

This opinion assesses whether the use of bisphenol A in medical devices such as implants, catheters, and dental devices could give reasons for safety concerns, to provide indications on limit values for BPA release from medical devices and to identify any patient group, e.g. infants, pregnant and breastfeeding women who would be particularly at risk.

Several exposure scenarios have been evaluated taking into account the material used, information related to BPA leaching, the duration of a single treatment and the frequency of treatments, giving rise to toxicologically relevant acute, short and long term exposure.

The SCENIHR concludes that risk for adverse effects of BPA may exist when the BPA is directly available for systemic exposure after non-oral exposure routes, especially for neonates in intensive care units, infants undergoing prolonged medical procedures and for dialysis patients. Although the benefit of medical devices has also to be considered, the SCENIHR recommends that, where practicable, medical devices that do not leach BPA should be used. The possibility of replacing BPA in these products should be considered against their efficiency in the treatment, as well as the toxicological profile of the alternative materials.

However, better data on exposure would be beneficial for the refinement of the present risk assessment, to be carried out when new data on exposure via medical devices will be available.

Keywords:

Bisphenol A, risk assessment, safety, medical devices, SCENIHR

Opinion to be cited as:

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Safety of the use of bisphenol A in medical devices, 18 February 2015.

- Final opinion on the safety of Metal-on-Metal joint replacements with a particular focus on hip implants (/health/scientific_committees/emerging/docs/scenihr_o_042.pdf)
  25 September 2014

Abstract

Final opinion on the safety of Metal-on-Metal joint replacements with a particular focus on hip implants

Link to opinion (/health/scientific_committees/emerging/docs/scenihr_o_042.pdf)

SCENIHR WG on metal-on-metal hip implants
SCENIHR members: Igor Emri, Peter Hoet
External experts: Charles Patrick Case, Wolfgang Dekant, Wim De Jong, Klaus-Peter Günther, Arne Hensten, Habil. Michael Morlock, Susanna Stea, Catherine Van der straiten, Cees Verheyen, Luigi Zagra
Acknowledgement: Special acknowledgement goes to Prof Dr Michael MORLOCK and Prof Klaus-Peter GÜNTHER for the use of the photographs in this opinion.
Contact: SANCO-C2-SCENIHR@ec.europa.eu
On request from: European Commission
Doi: 10.2772/76284
Adopted on: 25 September 2014

Content of the opinion:

The opinion aims to assess whether there are any health concerns linked to the use of MoM implants in arthroplasty. It also seeks, where possible, to provide indications on design of the devices, on patient groups and to identify needs for further research. This should inform related medical decisions and identify needs for further research.
The SCENIHR concludes that all types of MoM hip arthroplasties release metals. These, once in a person's body fluids and tissues, may lead to local and/or systemic adverse health effects. MoM implants with large diameters (large-head) show the highest incidence of local reactions. In addition, this type of implant should be avoided in total hip arthroplasty on the basis of their high failure risk. Due to the higher health risk when compared with alternative implants, the application of MoM hip arthroplasty should carefully be considered on a case-by case basis.
The SCENIHR endorses the strategy as outlined in the European Consensus Statement which recommends systematic follow-up for all patients and all implants, including clinical and radiographic investigation at intervals depending on local protocols. In particular, metal ion determination is recommended for large-head MoM total hip arthroplasty on a routine basis and for hip resurfacing arthroplasty patients at least in the first postoperative years.

Keywords:

Total hip arthroplasty, hip resurfacing, metal-on-metal, metal ions, metal debris, health effects, adverse reaction, pseudotumours, ALVAL, ARMD

Opinion to be cited as:

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), the safety of Metal-on-Metal joint replacements with a particular focus on hip implants, 25 September 2014.

- Final opinion on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants (2013 update) (/health/scientific_committees/emerging/docs/scenihr_o_043.pdf)
12 May 2014

Abstract

Final opinion on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants (2013 update)

Link to opinion (/health/scientific_committees/emerging/docs/scenihr_o_043.pdf)

SCENIHR WG on PIP2 (Breast implants)
SCENIHR members: Hartemann
External experts: Jim Bridges, Wim De Jong, Marita Eisenmann-Klein, Jorge Garcia, Ian Kimber, Lisbet Rosenkrantz Hölmich, Dirk W . Schubert, Carlos Vázquez Albaladejo
Acknowledgement: Members of the Working Group are acknowledged for their valuable contribution to this opinion.
Contact: SANCO-C2-SCENIHR@ec.europa.eu
On request from: European Commission
Doi: 10.2772/66097
Adopted on: 12 May 2014

Content of the opinion:

The silicone Poly Implant Prothèse (PIP), which has been produced in France since 2001, had been found to contain non-medical grade silicone and had thus not been produced according to legal requirements to achieve CE marking. PIP breast implants are reported to have a higher prevalence and incidence of implant ruptures than other silicone breast implants, and that ruptures also tend to occur earlier in the implant life than is the case with other implants. Since the previous SCENIHR opinion on PIP breast implants in February 2012 several cyclic siloxanes (known as D4, D5 and D6) have been identified in PIP devices at higher concentrations than in other silicone breast implants. This has led to investigate the possible toxicological consequences of cyclic siloxanes release from damaged PIP implants. It became apparent that these chemicals are commonly present in the bodies of women even without breast implants. This is a consequence of the widespread use of siloxanes in many domestic products. Cyclic siloxanes D4, D5 and D6 are non-toxic and not irritant in standard tests. In some cases, implant gel-bleed or rupture has been associated with an inflammatory reaction either locally or in regional lymph nodes. In other cases, ruptures were free of symptoms. Neither implant rupture, nor local inflammation, has been found to be associated

with breast cancer or anaplastic large cell lymphoma. While there are differences in rupture rates, there is no reliable evidence that ruptured PIP implants create a greater health risk than a ruptured silicone breast implant from another manufacturer. The SCENIHR confirms that PIP silicone breast implants have far higher rupture rates than breast implants by other manufacturers. However, to date, no increased health risk has been associated with exposure to silicone gel emanating from a ruptured PIP implant, as compared with a conventional implant from another manufacturer. The SCENIHR concluded that explantation is advised in the case of implant rupture; however, there are no convincing medical, toxicological or other data to justify routine removal of intact PIP implants. However, the decision to remove an intact PIP implant for this reason should be based on an individual assessment of the woman's condition by her surgeon or other treating physician after consultation.

Keywords:

SCENIHR, PIP breast implants, implant failure, safety evaluation, toxicity, silicone

Opinion to be cited as:

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Scientific opinion on the Safety of Poly Implant Prothèse (PIP) Silicone Breast Implants (2013 update), 12 May 2014.

Nanotechnologies

- Final opinion on Guidance on the Determination of Potential Health Effects of Nanomaterials Used in Medical Devices (/health/scientific_committees/emerging/docs/scenihr_o_045.pdf)
  06 January 2015

Abstract

Final opinion on Guidance on the Determination of Potential Health Effects of Nanomaterials Used in Medical Devices

Link to opinion (/health/scientific_committees/emerging/docs/scenihr_o_045.pdf)

WG on Nano in medical devices
SCENIHR members: Igor Emri, Philippe Hartemann, Ana Proykova, Konrad Rydzynski
External experts: Jim Bridges, Lars Bjursten, Wim De Jong, Robert Geertsma, Arne Hensten, Nils Gjerdet
Acknowledgement: The members of the working group are acknowledged for their valuable contribution to this Opinion.
Contact: SANCO-C2-SCENIHR@ec.europa.eu
On request from: European Commission
Doi: 10.2772/41391
Adopted on: 06 January 2015

Content of the opinion:

This Guidance addresses the use of nanomaterials in medical devices and provides information for risk assessors regarding specific aspects that need to be considered in the safety evaluation of nanomaterials. According to the EU Recommendation for the definition of a nanomaterial (Commission Recommendation 2011/969/EU, EC 2011) any particulate substance with at least one dimension in the size range between 1 and 100 nm is considered a nanomaterial. These particles (nanoparticles) exhibit specific characteristics that differ from the characteristics of larger sized particles with the same chemical composition.

The use of nanomaterials in medical devices poses a challenge for the safety evaluation and risk assessment of these medical devices as the specific character of the nanomaterial used should be taken into consideration. The various aspects of safety evaluation and risk assessment of medical devices containing nanomaterials are addressed in this Guidance. The use of nanomaterials in medical devices can vary considerably. Examples are the use of free nanomaterials being a medical device and administered to the patient as such (e.g. iron oxide or gold nanomaterials for heat therapy against cancer), free nanomaterials in a paste-like formulation (e.g. dental filling composites), free nanomaterials added to a medical device (e.g. nanosilver as antibacterial agent in wound dressings), fixed nanomaterials forming a coating on implants to increase biocompatibility (e.g. nano-hydroxyapatite) or to prevent infection (e.g. nano-silver), or embedded nanomaterials to strengthen biomaterials (e.g.

carbon nanotubes in a catheter wall). In all these cases the potential exposure to the nanomaterials should be considered. It is additionally recognised that wear-and-tear of medical devices may result in the generation of nanosized particles even when the medical device itself does not contain nanomaterials.

Keywords:

Medical devices, nanomaterials, risk evaluation, SCENIHR, Scientific Committee on Emerging and Newly Identified Health Risks

Opinion to be cited as:

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Final Opinion on the Guidance on the Determination of Potential Health Effects of Nanomaterials Used in Medical Devices, January 2015.

- Final opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance (/health/scientific_committees/emerging/docs/scenihr_o_039.pdf)
  11 June 2014

Abstract

Final opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance

Link to opinion (/health/scientific_committees/emerging/docs/scenihr_o_039.pdf)

WG on Nanosilver
SCENIHR members: Philippe Hartemann, Peter Hoet, Ana Proykova
SCHER member: Teresa Fernandes
External experts: Anders Baun, Wim De Jong, Juliane Filser, Arne Hensten, Carsten Kneuer, Jean-Yves Maillard, Hannu Norppa, Martin Scheringer, Susan Wijnhoven
Acknowledgement: Martin Hoppe and Carsten Schlich who kindly provided up-to-date literature lists for silver nanoparticles in soils. Natalie von Goetz who provided recent literature on silver in food contact materials. Lutz Mädler and Jorg Thöming who contributed with important insights for Life-cycle assessment (LCA)
Contact: SANCO-C2-SCENIHR@ec.europa.eu
On request from: European Commission
Doi: 10.2772/76851
Adopted on: 11 June 2014

Content of the opinion:

The opinion assesses whether the use of nanosilver, in particular in medical care and in consumer products, could result in additional risks compared to more traditional uses of silver and whether the use of nanosilver to control bacterial growth could result in resistance of micro-organisms. The SCENIHR concluded that the widespread and increasing use of silver containing products implicates that both consumers and the environment are exposed to new sources of silver. Human exposure is direct (food, hand-to-mouth contact, skin) and may be lifelong; while in the environment silver nanoparticles may be a particularly effective delivery system for silver to organisms in soil, water and sediment and may act as sources of ionic silver over extended periods of time. Therefore, additional effects caused by widespread and long term use of silver nanoparticles cannot be ruled out. Regarding the hazard associated with the dissemination of the resistance mechanism following the use of silver nanoparticles, no studies are available at this moment, representing a serious gap of knowledge. Since other nanoparticles have been shown to substantially increase the horizontal gene transfer between bacteria – which is extremely relevant for developing resistance – the potential of silver nanoparticles to induce similar effects should be given particular attention. More data are needed to better understand bacterial response to ionic silver and silver nanoparticles exposure. Since the mechanisms resulting in silver nanoparticles resistance are not well understood, it is not possible to estimate at this time whether or not resistance of microorganisms will increase and spread in view of a more widespread use of silver nanoparticles in products.

Keywords:

Nanosilver, risk assessment, antibacterial activity, medical care products, antimicrobial resistance

Opinion to be cited as:

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Nanosilver: safety, health and environmental effects and role in antimicrobial resistance, 11 June 2014.

Public Health

- Final Opinion on Additives used in tobacco products (Opinion 1) (/health/scientific_committees/emerging/docs/scenihr_o_051.pdf)
  25 January 2016

Abstract

Final Opinion on Additives used in tobacco products (Opinion 1)

Link to opinion (/health/scientific_committees/emerging/docs/scenihr_o_051.pdf)

SCENIHR WG on Tobacco additives
SCENIHR members: Emanuela Testai (Chair and Rapporteur), Peter Hoet (Rapporteur), Konrad Rydzynski, Theo Vermeire
External experts: Urmila Nair, Reinskje Talhout
Contact: SANCO-C2-SCENIHR@ec.europa.eu
On request from: European Commission
Doi:
Adopted on: 25 January 2016

Content of the opinion:

The main purpose of this scientific Opinion was to assist the Commission in identifying the additives that should be put on the priority list as foreseen by Article 6 of the Tobacco Products Directive 2014/40/EU (TPD), thus triggering additional reporting obligations by tobacco companies and even a potential ban.

The SCENIHR identified 48 single chemicals to be placed on this priority list. These compounds, including menthol, liquorice and caramel colours, were selected because they have or are suspected to have one or more of the following properties:

• toxicity in unburned form (including carcinogenic, mutagenic or toxic for reproduction)

• facilitating inhalation or increasing nicotine uptake, which may contribute to addictiveness

• characterising flavour, one of the factors potentially contributing to attractiveness

• formation of any kind of toxic chemicals after combustion

Six of the chemicals should be at the top of the list, according to the Scientific Committee: Titanium dioxide, maltol, diacetyl, geraniol, guaiacol and 2-furfural.

Keywords:

tobacco, addictiveness, additives, cigarettes, cigars, Roll-your-own, tobacco, smoking, toxicity, characterising flavour, facilitated inhalation, combustion products

Opinion to be cited as:

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Additives used in tobacco products, 25 January 2016.

Physical risks

- Final opinion on potential health effects of exposure to electromagnetic fields (EMF) (/health/scientific_committees/emerging/docs/scenihr_o_041.pdf)
  27 January 2015

Abstract

Final opinion on potential health effects of exposure to electromagnetic fields (EMF)

Link to opinion (/health/scientific_committees/emerging/docs/scenihr_o_041.pdf)

SCENIHR WG on EMF
SCENIHR members: Theodoros Samaras, Norbert Leitgeb
External experts: Anssi Auvinen, Heidi Danker-Hopfe, Kjell Hansson Mild, Mats-Olof Mattsson, Hannu Norppa, G. James Rubin, Maria Rosaria Scarfí, Joachim Schüz, Zenon Sienkiewicz, Olga Zeni
Contact: SANCO-C2-SCENIHR@ec.europa.eu
On request from: European Commission
Doi: 10.2772/75635
Adopted on: 27 January 2015

Content of the opinion:

As part of its mandate, the SCENIHR is asked to continuously monitor new scientific evidence that may influence the assessment of risks to human health in the area of electromagnetic fields (EMF) and to provide regular updates to the Commission.

This Opinion updates the SCENIHR Opinions of 2009 in light of newly available information and gives special consideration to areas where important knowledge gaps were identified. In addition, biophysical interaction mechanisms and the potential role of co-exposures to environmental stressors have been addressed.

The results of current scientific research show that there are no evident adverse health effects if exposure remains below the levels recommended by the EU legislation. Overall, the epidemiological studies on radiofrequency EMF exposure do not show an increased risk of brain tumours. Furthermore, they do not indicate an increased risk for other cancers of the head and neck region.

Previous studies also suggested an association of EMF with an increased risk of Alzheimer’s disease. New studies on that subject did not confirm this link.

Epidemiological studies associate exposure to Extremely Low Frequency (ELF) fields, from long-term living in close proximity to power lines to a higher rate of childhood leukaemia. No mechanisms have been identified and no support from experimental studies could explain these findings, which, together with shortcomings of the epidemiological studies prevent a causal interpretation.

Concerning EMF hypersensitivity (idiopathic environmental intolerance attributed to EMF), research consistently shows that there is no causal link between self-reported symptoms and EMF exposure.

Keywords:

Electromagnetic fields, EMF, RF, IF, ELF, static fields, millimetre wave, THz, health effects

Opinion to be cited as:

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Potential health effects of exposure to electromagnetic fields (EMF), 27 January 2015.

Others

- Final opinion on Synthetic Biology III - Risks to the environment and biodiversity related to synthetic biology and research priorities in the field of synthetic biology (/health/scientific_committees/emerging/docs/scenihr_o_050.pdf)
3 December 2015

Abstract

Final opinion on Synthetic Biology III - Risks to the environment and biodiversity related to synthetic biology and research priorities in the field of synthetic biology

Link to opinion (/health/scientific_committees/emerging/docs/scenihr_o_050.pdf)

WG on Synthetic Biology
SCENIHR members: Theo Vermeire, Michelle Epstein, Philippe Hartemann, Ana Prokovya, Luis Martinez Martinez
SCHER member: Teresa Fernandes
SCCS members: Qasim Chaudhry, Suresh Chandra Rastog
External experts: Rainer Breitling, Camille Delebecque, Timothy Gardner, Katia Pauwels, James Philp, Markus Schmidt, Eriko Takano
Acknowledgement: Members of the Working Group are acknowledged for their valuable contribution to this Opinion.
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On request from: European Commission
Doi:
Adopted on: 3 December 2015

Content of the opinion:

In Opinion I on Synthetic Biology (SynBio), the three Scientific Committees SCHER, SCENIHR and SCCS answered three questions from the European Commission on the scope, definition and identification of the relationship between SynBio and genetic engineering and the possibility of distinguishing the two. The definition reads: Synthetic Biology is the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms. In Opinion II, the three Scientific Committees addressed five questions focused on the implications of likely developments in SynBio for humans, animals and the environment and on determining whether existing health and environmental risk assessment practices of the European Union for Genetically Modified Organisms are adequate for SynBio. Additionally, the Scientific Committees were asked to provide suggestions for revised risk assessment methods and risk mitigation procedures including safety locks.

The current Opinion addresses specific risks to the environment from SynBio organisms, processes and products, partly in the context of Decision XI/11 of the Convention of Biodiversity (CBD) (CBD)(CBD)(CBD), identifies major gaps in knowledge to be considered for performing a reliable risk assessment and provides research recommendations resulting from gaps identified. The Scientific Committees confined the scope of their analysis to the foreseeable future, acknowledging that its findings should be reviewed and updated again after several years, depending on the development of the SynBio technology. Outside the scope of the current mandates are specific, thorough analyses of social, governance, ethical and security implications as well as human embryonic research..

Keywords:

Synthetic biology; biotechnology; bioengineering; genetic engineering; microbiology; molecular biology; regulatory framework; genetically modified organisms (GMO); risk assessment; risk assessment methodology; risk mitigation; genetic part libraries; minimal cells; designer chassis; protocells and artificial cells; xenobiology; DNA synthesis and genome editing; citizen science; Do-It-Yourself biology

Opinion to be cited as:

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), SCHER (Scientific Committee on Health and Environmental Risks), SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), SCCS (Scientific Committee on Consumer Safety), Synthetic Biology III – Research priorities, Opinion, December 2015.

- Final opinion on Synthetic Biology II - Risk assessment methodologies and safety aspects (/health/scientific_committees/emerging/docs/scenihr_o_048.pdf)
4 May 2015

Abstract

Final opinion on Synthetic Biology II - Risk assessment methodologies and safety aspects

Link to opinion (/health/scientific_committees/emerging/docs/scenihr_o_048.pdf)

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On request from: European Commission
Doi: 10.2772/63529
Adopted on: 4 May 2015

Content of the opinion:

In Opinion I on synthetic biology (SynBio), the three non-food Committees of the European Union SCHER, SCENIHR, and SCCS answered the first 3 out of 11 questions from the European Commission on scope, definition and identification of the relationship between SynBio and genetic engineering, and the possibility of distinguishing the two.

In this second Opinion (Opinion II), the Scientific Committees (SCs) addressed the five subsequent questions focused on the implications of likely developments in SynBio on human and animal health and the environment and on determining whether existing health and environmental risk assessment practices of the European Union for Genetically Modified Organisms (GMOs) are also adequate for SynBio. Additionally, the SCs were asked to provide suggestions for revised risk assessment methods and risk mitigation procedures, including safety locks.

Because SynBio is a rapidly evolving technology, the SCs suggest that risk assessment of and methodology for SynBio must be revisited at regular intervals. Although it is outside the scope of the current mandate, some background considerations about the social, governance, ethical and security implications of SynBio are also provided.

Keywords:

Synthetic biology; biotechnology; bioengineering; genetic engineering; microbiology; molecular biology; Regulatory framework; genetically modified organisms (GMO); risk assessment; risk assessment methodology; risk mitigation; Genetic part libraries; Minimal cells and designer chassis; Protocells and artificial cells; Xenobiology; DNA synthesis and genome editing; Citizen science; Do-It-Yourself biology

Opinion to be cited as:

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), SCHER (Scientific Committee on Health and Environmental Risks), SCCS (Scientific Committee on Consumer Safety), Synthetic Biology II - Risk assessment methodologies and safety aspects, Opinion, May 2015.

- Final opinion on Synthetic Biology I - Definition (/health/scientific_committees/emerging/docs/scenihr_o_044.pdf) Abstract
  25 September 2014

Final opinion on Synthetic Biology I - Definition

Link to opinion (/health/scientific_committees/emerging/docs/scenihr_o_044.pdf)

WG on Synthetic Biology
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On request from: European Commission
Doi: 10.2772/76553
Adopted on: 25 September 2014

Content of the opinion:

This Opinion is the first of a set of three Opinions addressing a mandate on Synthetic Biology (SynBio) from the European Commission to the three Scientific Committees (SCs). This first Opinion concentrates on the elements of an operational definition for SynBio. The two Opinions that follow focus on the methodology to determine what, if any, risks SynBio may potentially pose to public health and what type of further research in this field is required.
This first Opinion lays the foundation for the two other Opinions with an overview of the main scientific concepts, developments, tools and research areas in SynBio. Additionally, a summary of relevant regulatory aspects in the European Union (EU), in other countries such as the USA, Canada, South America, China, and at the United Nations is included.
The operational definition offered by the Scientific Committees addresses the need for a definition that enables risk assessment and is sufficiently broad to include new developments in the field. SynBio is the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms. This definition has the advantage that it does not exclude the relevant and large body of risk assessment and safety guidelines developed over the past 40 years for GM work and extensions of that work, if needed, to account for recent technological advances in SynBio. Additionally, it enables the rapidly advancing nature of GM technologies and adds an important nuance that supports the need for on-going updates of risk assessment methods, which will be addressed in Opinion II.
It is difficult to accurately define the relationship between genetic modification and SynBio on the basis of quantifiable and currently measurable inclusion and exclusion criteria. Thus, in addition to the definition, a list of specific criteria was considered reflecting that SynBio covers any organism, system, material, product, or application resulting from introduction, assembly, or alteration of the genetic material in a living organism. These criteria are helpful guiding principles that specify whether or not a certain process, tool or product belongs to SynBio, although none are quantifiable or measurable. Additional criteria, including the complexity of the genetic modification, the speed by which modification was achieved, the number of independent modifications, or the degree of computational design methods used, alone or in combination, are also unable to unambiguously differentiate SynBio processes or products from GM.

Keywords:

Synthetic biology, biotechnology, bioengineering, genetic engineering, microbiology, molecular biology, Regulatory framework, genetically modified organisms (GMO), definition

Opinion to be cited as:

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), SCCS (Scientific Committee on Consumer Safety), SCHER (Scientific Committee on Health and Environmental Risks), Synthetic Biology I Definition, Opinion, 25 September, 2014.

Statements

- Position Statement on emerging and newly identified health risks be drawn to the attention of the European Commission 20 November 2014

- Opinions SCENIHR (April 2009 - March 2013)

- Opinions SCENIHR (October 2004 - March 2009)

- Opinions SCMPMD (June 1997 - September 2004)

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