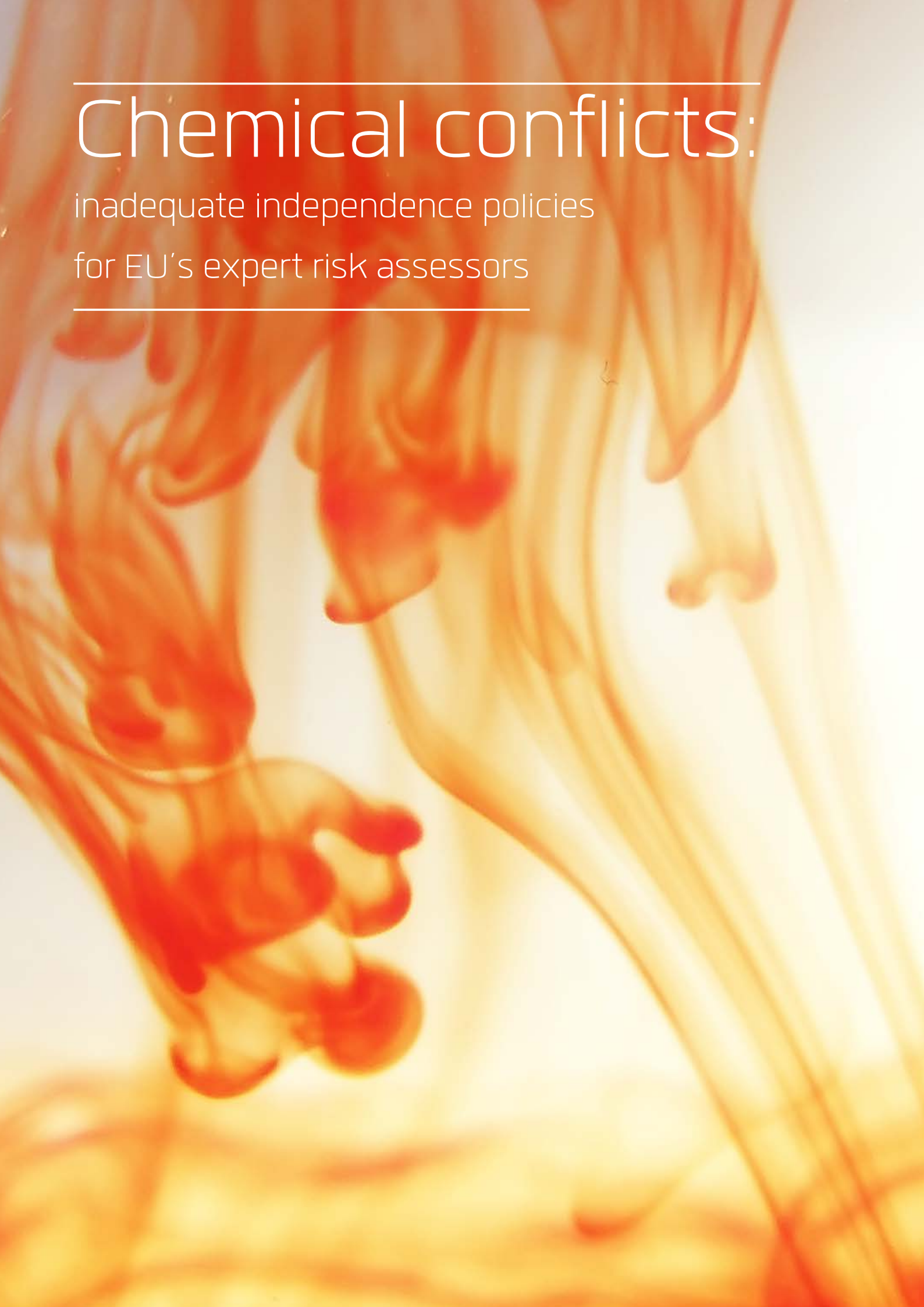

Chemical conflicts:

inadequate independence policies for EU's expert risk assessors

Contents

Disclaimer

The bulk of this report aims to review the independence policy of Directorate-General for Health and Consumers' DG SANCO Scientific Committees, and particularly its handling of conflicts of interest among their members. It is therefore important to point out that what is being assessed here is DG SANCO's decision-making process in whether to accept or reject given experts for its panels because of potential conflicts of interest. Having a conflict of interest due to connections with the commercial sector does not mean that an expert is criticised for his/her ethics or intellectual honesty, but simply that he/she cannot be considered independent from industry's influence. Therefore, we think the expert cannot legitimately participate in the work of a scientific body whose workload consists primarily in assessing the risk of industrial products which are already or will be commercialised on the EU market. All unreferenced interests mentioned in the report come from the experts' declarations of interests, downloaded from DG SANCO's website on 28 February 2014.

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Summary

The Scientific Committees of the European Commission assess the risk to humans and the environment of chemicals found in a huge range of everyday items, from shampoo to baby bottles. These opinions guide European Commission regulators, who decide what chemicals are safe for market and at what levels – as well as which should be banned. Not correctly regulating such chemicals could potentially cause great harm to human health and the environment; yet there is also a lot of money at stake, as such decisions may have a huge impact on the bottom line of businesses that make and sell products that contain them. That's why it is particularly concerning that civil society has questioned whether some opinions have shown a pro-industry bias, throwing open how the Committees implement their three guiding principles: independence, excellence, and transparency.

Looking at four recent case studies to assess the processes behind the principles, CEO discovered that two thirds (67%) of the scientists who drafted opinions on substances as controversial as endocrine disrupting parabens and dental mercury had at least one conflict of interest – and some as many as 20 – due to their direct and indirect links with affected industries. Yet they were given the green light. Interviews with DG SANCO, scientists working in the Committees and public interest groups also revealed worrying flaws in the processes to ensure excellence and transparency, including: perceived failure to attract a diverse and relevant range of scientific disciplines by not allowing minority opinions at the drafting stage; shutting down of disagreement and divergence of opinions; huge variation between Committees and working groups in the level and quality of stakeholder dialogues; inconsistent and non-transparent ways of collecting and using evidence. A recurring reason given was the institutional culture within DG SANCO and the Scientific Committees, reinforced by inadequate processes.

Recommendations on how the Committees can better meet their three principles were formulated during a roundtable with public interest groups. Key points include:

Independence:

- Create a broader definition and accompanying guidelines for conflicts of interest that covers the entire remit of the SCs, while outsourcing their screening to an independent body;

Excellence and Transparency:

- Develop a strategy with member state governments and universities to increase the disciplinary diversity of members, as well as improving strategic outreach in the short-term;
- Fully review all stakeholder engagement processes to produce clear criteria, with regular reviews; a public consultation should be held at the beginning of every new mandate as standard to comment on its focus and the necessary expertise required;
- Allow minority opinions at the drafting stage, and ensure clear, consistent terminology to express concern and risk in final opinions via error margins, also incorporating areas with insufficient or unsatisfactory data (not assuming no data equals no harm);
- Ensure clear criteria for what forms of evidence should (not) be used, including stakeholder contributions; that they are fully adhered to by all SCs; all draft and final opinion should detail what was (not) included and why;

In the Long Term

Coordinate other Commission bodies and agencies in devising a way to remove industry-linked scientists from the risk assessment of products all together to ensure independence and public research excellence;

Introduction

Showering, washing our hair, brushing our teeth, shaving, putting on make-up, applying body lotion, spraying deodorant, taking a run in the park, cooking dinner: from the time we get up to the moment our heads hit the pillow, we are exposed to a cocktail of man-made chemicals, some of them potentially hazardous. They're in cosmetic products like sun-screen, in the fibres of our clothes, the packaging of the food we eat, and even in the toys infants play with. These chemicals get into our bodies and can get passed onto our babies while the're still in the womb.

So what's the impact on public health of this daily chemical cocktail? Judging the potential risk to humans and the environment by deciding on the safe levels of exposure to substances like asbestos can avoid serious and chronic illness, and in extreme cases even death. Therefore the role of the expert assessors is incredibly important and influential; not just in terms of the impact on public health, but also on the financial fortunes of companies involved in producing and using the substances in question. A negative opinion on a certain chemical could lead to a Commission / EU ban, costing industry millions. But powerful interests are working to avoid such scenarios. Therefore the ability of the risk assessors to act independently and in the public interest is paramount.

In the European Commission, decisions regarding how to regulate a certain chemical or substance are informed by expert advice from the EU's myriad of risk assessment bodies, which include the three Scientific Committees under DG Health and Consumers (DG SANCO).[1] These three committees (see box 1 for more details) assess risk to humans and the environment of consumer items such as cosmetics or medical devices, as well as the safety of new technologies like nanomaterials or contaminants in the air and water. However, public interest groups have raised serious concerns with some of the committees' opinions, claiming their conclusions threaten human health and the environment while favouring industry. Are these claims founded, and if so why? The tobacco industry's tactics have demonstrated that corporate influence over science is nothing new, and CEO & Horel's October 2013 report on conflicts of interest within the European Food Safety Authority (EFSA), a European Commission agency, reveals the existence of financial links between scientists sitting on their committees and the industries they regulate.[2] However, DG SANCO is supposed to have processes and procedures in place to ensure its opinions are of the highest possible quality – above suspicion and commercial influence. Yet are these sufficient to ensure its Scientific Committee (SC) opinions adhere to its three overarching principles of independence, excellence, and transparency?[3]

By looking at the processes behind four specific opinions on controversial substances,[4] this report aims to shine a light

1 The responsibilities are divided between the Commission's own in-house Scientific Committees in DG SANCO (see box 1) and DG Employment (Scientific Committee on Occupational Exposure Limits), as well as scientific committees within the European Community agencies: the European Food Safety Authority; European Medicines Agency; European Environment Agency; European Centre for Disease Prevention and Control; European Chemicals Agency. The remits can be overlapping but are not supposed to undermine each other.

2 Similar questions were asked of EFSA's experts, and the resulting research produced by CEO and Stéphane Horel showed that over half of their experts deciding on the regulation of food-related products had ties to the very same industries they were supposed to be regulating. See CEO & Horel (2013) **Unhappy Meal**, **http://corporateeurope.org/sites/default/files/attachments/unhappy_meal_report_23_10_2013.pdf**

3 "[T]he scientific advice on matters relating to consumer safety, public health and the environment must be based on the principles of excellence, independence and impartiality, and transparency." Commission Decision 2008/721/EC, p. 1 **http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:241:0021:0030:EN:PDF**

4 There is wide divergence between industry and public health groups regarding the risk of the substances covered by the four

Box 1

The three Scientific Committees

The Scientific Committees (SCs) were created in 2004 and restructured in 2008 as "sound and timely scientific advice is an essential requirement for Commission proposals, decisions and policy relating to consumer safety, public health and the environment"[1] The decision to form an opinion can be a legal obligation (eg under the Cosmetics Directive), at the suggestion from the Committees themselves, from a third party (eg industry or civil society) or from the Commission itself (eg DG SANCO or another department, which is the most common when not legally mandated).

The three European Commission's committees are:

- **Scientific Committee on Consumer Safety (SCCS)** (15 members)
  SCCS assesses the health and safety risks of "non-food consumer products... and services", such as the ingredients of cosmetics, toys, tattoo inks, or artificial sun-tanning products[2] It also has a legal obligation under the Cosmetics Directive and the Toys Safety Directive to assess which ingredients are safe and which should be banned or limited under those directives, as well as authorise new products.

- **Scientific Committee on Health and Environmental Risks (SCHER)** (11 members)
  SCHER assesses the risks relating to pollutants and other substances which may impact health and the environment – for example air, water, and soil contaminants. It may also be invited by the Commission to address "health and safety issues related to the toxicity and eco-toxicity of biocides", eg weed killers or pesticides, which are covered by other Committees (EFSA and ECHA), but these opinions are not supposed to undermine the authority of other EU agencies and should often be done in collaboration with them.[3]

- **Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)** (15 members)
  SCENIHR's remit is more complex than the other two SCs, dealing with broad or multidisciplinary issues that require a "comprehensive assessment of risks to consumer safety or public health"[4] not covered by other risk assessment bodies. This can include the potential risks of emerging technologies such as nanotechnologies, tissue engineering, or electromagnetic fields from mobile phones and transmitters, or topics such as combination effects from multiple chemical exposures. Each year SCENIHR produces a list of 'emerging issues' which is given to DG SANCO and can lead to mandates for new opinions.[5]

After the Commission makes a request for advice (mandates an opinion), a working group is formed to make a draft based on a review of the existing evidence. This is then approved or amended during a plenary of the SC. Working groups can be ad hoc or permanent, and are originally formed by relevant committee members who then invite members from other SCs, external experts from the official 'Pool of Scientific Advisors' (formed following a call for applications) or failing that, from the 'Database of Experts' (which has an open door policy). If the SC feels this is still not enough, a call is put out for external experts.

1 Commission Decision 2004/210/EC, p. 2

2 Annex I of Commission Decision 2008/721/EC

3 Annex I of Commission Decision 2008/721/EC

4 Annex I of Commission Decision 2008/721/EC

5 The potential risks of nanosilver, one of the opinions looked at in this study, were originally flagged by SCENIHR and passed on to DG SANCO via such a report eight years ago.

on how – and if – the Committees meet their principles of independence, excellence, and transparency. Given the enormous commercial interests at stake, the main focus of the report will look at the independence of scientists assessing the controversial chemicals. All of their annual declarations (see box 5) – publicly available on DG SANCO's website – will be screened for links with industries with an interest in the work carried out by all three Committees (as scientists may serve in working groups across all three during their terms). To decide what is and isn't a conflict of interest, we've adapted the methodology used by CEO & Horel (2013) when assessing the interests of scientific panel members within within European Food Safety Authority (EFSA).[5] Analysis will be based on interviews with the Scientific Committees Secretariat in DG SANCO, scientists directly involved in the Committees (anonymised) and public interest groups who have engaged with the process of developing particular opinions, supplemented by desk research. The information from interviews also allows us to evaluate what DG SANCO has put in place to meet its goals of excellence and transparency, for example the gathering and using evidence or ensuring conclusions and rationale are transparent. Research and preliminary findings are then presented to a roundtable of public health experts who have been following the Committees,[6] in order to collectively come up with recommendations. While the four opinions chosen as case studies are in no way an exhaustive overview of the SCs, the processes that led to them do provide an insight into how the Scientific Committees function when assessing highly controversial chemicals. The report concludes with recommendations for DG SANCO to better meet all three principles.

opinions: titanium dioxide (nano form); parabens; mercury in dental amalgam; nanosilver.

5 CEO & Horel, (2013), *Unhappy Meal*, **http://corporateeurope.org/sites/default/files/attachments/unhappy_meal_report_23_10_2013.pdf**

6 Organisations involved in the workshop, its preparation and/or its conclusions were Baby Milk Action, CEO, CHEM Trust, ClientEarth, ECOS, EEB, HEAL, Health Care Without Harm, R.I.S.K.

Under the microscope: the four suspect substances

The four chemicals examined in this report may not appear to be household names – **parabens**, **nano titanium-dioxide**, **nanosilver**, and **mercury** – but they appear in everyday products from shampoo to toothpaste, paint to tooth fillings, skin lotions to deodorant. Even baby bottles. All four have been on the market for many years, widely used by many companies in hundreds of products that create considerable revenue. Yet all these chemical ingredients have come under increasing criticism as new research has alerted public health and environmental groups to the potential risks from their use. The cost of tougher regulation – or even a ban – would of course have consequences for industry. However, the EU has a responsibility to ensure that such concerns do not take precedent over protection of human health and the environment, particularly when one of its its guiding regulatory principles is precaution when addressing potentially harmful chemicals. Yet doing so requires the best possible assessment of the state of scientific knowledge surrounding the human and environmental health impacts of these four compounds.

However, this report does not intend to pass judgement on the opinions themselves, but rather the processes behind them, in order to provide greater insight into how the Committees try to and whether they achieve independence, excellence and transparency. The four opinions were chosen because all have been completed since the renewal of the Scientific Committee mandates (March 2013),[7] and all concern highly controversial chemicals that have been the subject of public campaigning and industry lobbying.

7 The final opinions were approved by the newly formed Scientific Committees (SCs), but the members of the working groups responsible for the draft opinions are in fact scientists from the previous mandate. However all have continued to serve within the SC system, either as SC members, members of the pool or as external experts. The two exceptions are two members who resigned in 2013.

Box 2

Endocrine disruptors

These chemicals are widespread in our food and environment, and interfere with our hormonal systems.[1] So far more than 870 potential endocrine disrupting chemicals (EDCs) have been identified, including widely used products such as the herbicide glyphosate (Monsanto's 'Roundup') and chemicals such as bisphenol-A (BPA, used to make plastics found in many consumer products). Both the EU's 2009 pesticide regulation and the 2006 industrial chemicals law (REACH) demanded the EU take action to better regulate EDCs. However, industry – particularly in the US – is already scaremongering about the consequences, with major US pesticide lobbyist Doug Nelson claiming: "The proposed policies for endocrine disruptors... could block more than $4 billion, or 40 per cent, of US agricultural exports to the EU in addition to exports of crop protection active ingredients."[2]

The report "State of the Science on Endocrine Disrupting Chemicals" jointly published in 2013 by the World Health Organisation (WHO) and the United Nations Environmental Programme (UNEP)[3] highlights that the vast majority of chemicals in products already on the market have never been tested for potential endocrine disrupting effects, while international test methods capture only some of the known endocrine disrupting effects. It also states that the exposure of both humans and wildlife to such chemicals is coming from an increasing number of sources. The WHO/UNEP study also stresses that the risk to humans and wildlife from mixtures of endocrine disrupting chemicals is severely underestimated. Scientists and risk assessors have traditionally studied the links between one endocrine disrupting chemical and a particular disease, when in fact people are exposed to many of these dangerous types of chemicals at the same time, ie the 'cocktail effect', which may occur below established safety levels for individual chemicals due to unexpected synergistic effects.

1 HEAL (2014), *Health Costs in the European Union: How much related to EDCs?*, available at **http://www.env-health.org/IMG/pdf/18062014_final_health_costs_in_the_european_union_how_much_is_realted_to_edcs.pdf**

2 **http://www.ecpa.eu/news-item/regulatory-affairs/03-14-2014/1312/crop-protection-industry-urges-stronger-regulatory-fram**

3 **http://www.who.int/iris/bitstream/10665/78101/1/9789241505031_eng.pdf?ua=1**

- **Substance: Parabens (propyl- and butylparaben)**
- **Scientific Committee: Scientific Committee on Consumer Safety (SCCS)**
- **Date opinion adopted: 3 May 2013**[8]

Parabens are a preservative that have been used – or still are – by almost all major cosmetic brands: from Nivea's sunscreen and body lotion, to Chanel's makeup, L'Oreal's shampoo, and Gillette's shaving cream. Even some foods, drinks, and pharmaceuticals contain parabens. This means that most people are exposed to them multiple times a day, which may be even more dangerous when combined with exposures to other potentially harmful chemicals in what is known as the 'cocktail effect' (see box 2).

In recent years parabens have increasingly come to people's attention, with the label 'paraben-free' becoming *en vogue* as a way to sell more products (many of the cosmetic products listed above now do 'organic' or paraben-free versions). This is because some parabens are now widely accepted to have endocrine disrupting effects,[9] which means they interfere with the body's hormonal systems (see box 2). Imbalances in hormones may lead to diseases and disorders such as male genital malformations, neurological problems, diabetes, and endocrine-related cancers (breast, prostate, testicular etc.), all of which have been rapidly increasingly.[10]

The heightened risk from exposure to a 'cocktail' of several endocrine disrupting chemicals (see box 2) led the Danish Government in 2011 to ban the same two parabens being assessed by the SCCS (propyl- and butylparaben) from care products for children under three,[11] based on evidence produced in 2009 by the its own Environmental Protection Agency.[12] Denmark's ban led to the European Commission to mandate the SCCS to review its opinion, which had to be done again after the findings were challenged by a study carried out by French authorities.[13]

8 **http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_132.pdf**

9 Health and Environment, July 2013, Parabens: endocrine disruptors in cosmetics and food?, *Health and Environment Online*, available at **http://healthandenvironmentonline.com/2013/06/17/parabens-endocrine-disruptors-in-cosmetics-and-food/**

10 World Health Organisation and the United Nations Environment Programme, (2013) *State of the Science of Endocrine Disrupting Chemicals – 2012*, available at **http://www.who.int/iris/bitstream/10665/78101/1/9789241505031_eng.pdf?ua=1**

11 See **http://eng.mst.dk/topics/chemicals/legislation-on-chemicals/danish-legislation-on-specific-substances/parabens-%E2%80%93-special-danish-legislation-for-child-products/**

12 The report assessed the health risks from the average daily exposure to endocrine disrupting chemicals experienced by a two-year-old. **http://eng.mst.dk/topics/chemicals/endocrine-disruptors/combined-effects-on-two-year-old-children/**

13 European Commission, (2014), 'COMMISSION Regulation (EU) No 358/2014, 9 April 2014', *Official Journal of the European Union*, available at **http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0358&from=EN**

- **Substance: Titanium Dioxide (nano form)**
- **Scientific Committee: Scientific Committee on Consumer Safety (SCCS)**
- **Date opinion adopted: 22 April 2014[14]**

Titanium dioxide (TiO_2) has been found in products like Colgate-Palmolive's toothpaste, Olay's anti-ageing creams (made by Proctor & Gamble) and other cosmetics, as well as in paints, plastics, inks, and papers – not to mention confectionary products like Trident chewing gum and Mars' M&Ms. Its main use is to provide whiteness and opacity to products, and is present in a number of sun blocking creams as a UV filter. However, because titanium dioxide leaves a white residue on the skin, manufacturers are increasingly opting for the nano form, as the smaller particles make them appear more transparent. However, this also means they penetrate the skin more easily (see box 4).

Controversially, research has shown that titanium dioxide can damage DNA and lead to mutations and cancer, as well as be poisonous to living cells, nerves and the reproductive system. In 2006, the International Agency for Research on Cancer (IARC) declared titanium dioxide a "possible carcinogen for humans" after animal tests showed it caused cancer – with even stronger effects from nano form titanium dioxide.[15] The US National Institute for Occupational Safety and Health (NIOSH) also found the nano scale to pose a higher risk, and recommended in 2011 that occupational exposure (by inhalation) to nano scale titanium dioxide particles should be considered a potential occupational carcinogen.[16]

Scientific research on the impacts of nano ingredients in sunscreens, particularly titanium dioxide, is leading to growing concern. When exposed to UV rays (inevitable in a sunscreen) it produces 'free radicals', which can damage the

14 **http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf**

15 See **http://monographs.iarc.fr/ENG/Monographs/PDFs/93-titaniumdioxide.pdf**

16 See **www.osha.gov/Publications/OSHA_FS-3634.pdf**

Box 3

Nanomaterials – falling through the regulatory gap

Nanomaterials are existing substances rendered into incredibly tiny particles: one nanometre is one *billionth* of a metre. The very small size of nanoparticles means they can more readily penetrate the skin (and even some protective equipment) than non-nano forms of the same chemical. Once in the body, nanoparticles have been found to rapidly migrate to the organs, get deep into the lungs, and cross the blood-brain barrier and placenta. The role of certain nanoparticles in some forms of environmental degradation is already well known, eg atmospheric nanoparticles play a central role in ozone depletion. Therefore nanomaterials may have a far greater negative impact on the environment and public health than the same substances in non-nano form. However, there is a severe knowledge gap on nano chemicals, as adequate testing has not been done – by industry or otherwise – despite knowledge of the heightened risk potential. Most risk assessment is done by manufacturers of products, ie industry, but for every €200 spent in the world on nanotechnology research and development, only €1 is spent on risk assessment.[1]

Europe's main law to regulate chemicals, REACH – the Registration, Evaluation, Authorisation and Restriction of Chemicals – does not cover nano forms appropriately. It requires manufacturers and importers to register their chemical substances to assure safety, but they do not need to indicate if the substances are nano or not (there is a box that can be ticked voluntarily). This means that neither regulators nor the public know whether chemicals regulated under REACH contain nanoparticles or not. Today, only nine substances have been registered as nano under REACH. This poses yet more questions about the EU's commitment to the precautionary principle (which requires evidence that a product is shown as safe before approving it for market), given the widespread availability of these materials on European markets already.

In 2009 the European Parliament called on the Commission to ensure REACH addressed nanomaterials properly. Civil society has made similar demands,[2] and some countries (France, Denmark, the Netherlands) have started implementing their own traceability systems[3] in light of the European Commission's failure to take action at a European level. However, the Nanotechnology Industries Association (NIA) has lobbied aggressively against extra regulation on nanomaterials, calling it "not warranted" and warning that doing so would cause "all investments in nanotechnologies [to be] driven out of Europe due to excessive administrative burdens."[4]

1 WECF, (2013), *Non-Communicable Diseases and Environmental Determinants*, available at **http://www.sustainlabour.org/documentos/NDCfinallight_2082013.pdf**

2 HEAL, June 2011, *Parliament backs NGOs' calls for tighter controls on nanotechnology*, available at **http://www.env-health.org/news/latest-news/article/parliament-backs-ngos-calls-for**

3 **http://www.etui.org/content/download/2646/29689/file/Policy_Brief_Social_Policy-Issue2-2011_EN.pdf**

4 **http://newsletter.echa.europa.eu/documents/6362380/8854846/newsletter_2013_issue_5_october_en.pdf**

Box 4: Industry vs. Public Health on Titanium Dioxide

What industry association TDMA says:	What public health organisations and scientists say:
✻ "There have been no identified health concerns associated with its exposure among consumers or the general population."[1]	✻ IARC classify TiO_2 as a possible carcinogen due to experiments on animals and inadequate evidence in humans. ✻ TiO_2 produces an inflammatory response in the lungs similar to asbestos[2] and can induce effects in cells such as oxidative stress, cytotoxicity and genotoxicity[3]
✻ The science shows TiO_2 nano is safe and there is "no association with an increased risk of cancer or with any other adverse lung effects."[4]	✻ In accordance with the European Chemicals Agency regulations, six TiO_2 manufacturers have classified TiO_2 in the nano/ultrafine form as a possible carcinogen; ✻ NIOSH has declared nano/ultrafine particles should be considered a potential occupational carcinogen.
✻ Only a small fraction of TiO_2 products on the market contain nanoparticles.	✻ Nano-TiO_2 is on the market with a very high fraction of (primary) particles in the nanosize range.[5]
✻ "It has been conclusively demonstrated that TiO_2 is safe for use in sunscreen products to protect skin from harmful effects of solar UV radiation. Even if the skin is sunburned the penetration of TiO_2 nanoparticles from representative sunscreen formulations is not enhanced."[6]	✻ The leader of CSIRO's (Commonwealth Scientific and Industrial Research Organisation) nanosafety group warned in 2008 that, as a worst case scenario, nano-ingredients in sunscreens could potentially cause skin cancer.[7] ✻ A number of studies suggest that skin penetration of nanoparticles can occur[8]

1 TDMA, 2012, *About Titanium Dioxide*, available at **http://www.cefic.org/Documents/Industry%20sectors/TDMA/About-TiO2-full-version-July-2013.pdf**

2 Nanoparticles activate the NLR pyrin domain containing 3 (Nlrp3) inflammasome and cause pulmonary inflammation through release of IL-1α and IL-1β. See **Amir S. Yazdi et al. http://www.pnas.org/content/107/45/19449.abstract?sid=425c8084-08f5-4e2b-aa03-cdbc7172b1e7**

3 Enpra (Risk Assessment of Engineered Nanoparticles) EU project coordinated by the Institute of Occupational Medicine (IOM) in Edinburgh. Available at: **http://www.enpra.eu/** ; Oxidative stress-induced cytotoxic and genotoxic effects of nano-sized titanium dioxide particles in human HaCaT keratinocytes. Alexandra Jaeger et al. Available at: **http://www.sciencedirect.com/science/article/pii/S0300483X12000704** ; Braydiche-Stolle et al (2009) Crystal structure mediates mode of cell death in TiO2 nanotoxicity, available at **http://link.springer.com/article/10.1007/s11051-008-9523-8**; Titanium Dioxide Nanoparticles Induce DNA Damage and Genetic Instability *In vivo* in Mice. Benedicte Trouiller et al. **http://cancerres.aacrjournals.org/content/early/2009/11/03/0008-5472.CAN-09-2496.abstract**; Nanoparticles can cause DNA damage across a cellular barrier. Gevdeep Bhabra et al. **http://www.nature.com/nnano/journal/v4/n12/abs/nnano.2009.313.html**; Roller M (2009). Carcinogenicity of inhaled nanoparticles. Inhalation Toxicology. 21(S1): 144-157.; Bourdon, JA (2012) et al. Carbon black nanoparticle instillation induces sustained inflammation and genotoxicity in mouse lung and liver. **http://www.particleandfibretoxicology.com/content/9/1/5**; Ghosh et al. (2010) *Genotoxicity of Titanium Dioxide* (TiO2) nanoparticles at two trophic levels: Plant and human lymphocytes.

4 TDMA, 2012, *About Titanium Dioxide*, available at **http://www.cefic.org/Documents/Industry%20sectors/TDMA/About-TiO2-full-version-July-2013.pdf**

5 Paper produced by EEB for TDMA. Original concentrations available at **nanonetwerk.com**

6 TDMA, 2012, *About Titanium Dioxide*, available at **http://www.cefic.org/Documents/Industry%20sectors/TDMA/About-TiO2-full-version-July-2013.pdf**

7 Australian Broadcasting Corporation, 17 December 2008, *'Safety concerns over high-tech sunscreens'*, available at **http://www.abc.net.au/7.30/content/2008/s2449409.htm**

8 Friends of the Earth, 2012, **Nano ingredients in sunscreen: the need for regulation**, available at **http://nano.foe.org.au/sites/default/files/Nano-ingredients%20in%20sunscreen%202012.pdf**; Bennet et al, 2012, **Photoinduced Disaggregation of TiO2 Nanoparticles Enables Transdermal Penetration, http://www.bren.ucsb.edu/news/nano_light_bennett.htm**

skin and DNA.[17] One study found this effect was so aggressive that applying commercially-available nano sunscreens (which contain titanium dioxide) to pre-painted roofs led to the paint breaking down 100 times faster than without the sunscreen.[18] In Australia, the leader of the Commonwealth Scientific and Industrial Research Organisation's (CSIRO) Nanosafety group warned in 2008 that nano ingredients in sunscreens could in fact cause skin cancer due to this effect.[19]

Despite many European manufacturers themselves classifying titanium dioxide as carcinogenic,[20] the Titanium Dioxide Manufacturers Association (TDMA), a sector group of the notorious European chemical industry lobby Cefic, continues to dispute the label. It claims that industry-conducted studies show no clear link,[21] while evidence that the nano form poses an even greater risk when inhaled is invalid because "the rat is uniquely sensitive" to the impacts from inhalation.[22] Unsurprisingly, the TDMA's claims are hotly disputed by public interest groups, who question the independence of the industry studies and call for thorough safety assessments before the green light is given for commercial use (see box 4). Unfortunately the chemical has already been on the market for years, potentially in very large quantities.

- **Substance: Mercury from Dental Amalgam**
- **Scientific Committee: Scientific Committee on Health and Environmental Risks (SCHER)**
- **Date opinion adopted: 10 March 2014[23]**

Making up 50% of an average tooth filling,[24] mercury has been used in dental amalgams for over 150 years due to its durability, strength, relative cheapness, and ease of application. However, increasing knowledge over the last few decades about the dangers of mercury amalgams to human health and the environment have seen more and more dentists move towards using alternative materials. Yet some controversial industry associations like the American Dental Association – a former patent-holder of amalgam – continue to promote it and minimise the risks,[25] as does the industry association FDI World Dental Federation, who partners with the corporate amalgam manufacturers and distributors Dentsply, Henry Schein Inc., and Ivoclar Vivadent.[26]

Mercury and its compounds are highly toxic to the environment and humans – especially to the developing nervous

17 Rampaul et al., (2007) Damaging and protective properties of inorganic components of sunscreens applied to cultured human skin cells, *Journal of Photochemistry and Photobiology A: Chemistry*, 191:2–3, p. 138–148

18 Note: this study did not examine the effect on skin, but demonstrated a potential toxicity mechanism of great concern to the scientific community. Barker P. and Branch A., (2008) 'The interaction of modern sunscreen formulations with surface coatings', *Prog Org Coatings*, 62: 313–320

19 Australian Broadcasting Corporation, 17 December 2008, 'Safety concerns over high-tech sunscreens', available at **http://www.abc.net.au/7.30/content/2008/s2449409.htm**

20 This information is submitted to the EU as part of the official classification, labelling, and packaging (CLP) regulation. See **http://www.beuc.org/publications/2013-00617-01-e.pdf**

21 TDMA, (2012), *About Titanium Dioxide*, available at **http://www.cefic.org/Documents/Industry%20sectors/TDMA/About-TiO2-full-version-July-2013.pdf**

22 TDMA, (2012), *About Titanium Dioxide*, available at **http://www.cefic.org/Documents/Industry%20sectors/TDMA/About-TiO2-full-version-July-2013.pdf**

23 **http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_165.pdf**

24 Amalgams to restore teeth typically consist of 50 per cent mercury and a mix of silver, tin, copper and zinc; the liquid mercury binds all elements together to make a solid filing.

25 ADA Statement on new APHA policy regarding dental amalgam, available at **http://www.dentistryiq.com/articles/2012/11/ada-statement-on-new-apha-policy-regarding-dental-amalgam.html**

26 Dentsply is an official sponsor of the FDI Continuing Education programme (see http://www.fdiworldental.org/events/ce-programme/2013-2014-ce-programme.aspx); Henry Schein is listed as an official partner by FDI (see http://www.fdiworldental.org/media/news/news/world-oral-health-day-opens-nasdaq.aspx) and Ivoclar Vivadent is an official supporter of the FDI Vision 2020 (see http://www.fdiworldental.org/oral-health/vision-2020/shaping-the-future-of-oral-health.aspx)

systems of the foetus. Reacting with bacteria, mercury forms methylmercury, which can contaminate ground water, air and surface water, accumulating within the food-chain, particularly in fish and shell fish. Methylmercury is a well documented neurotoxicant, in particular having adverse effects on the developing brain. It readily passes both the placental barrier and the blood-brain barrier and according to the WHO, even in small amounts, mercury exposure "may cause serious health problems and is a threat to the development of the child *in utero* and in early life."[27] In birds, fish and other forms of wildlife, mercury can cause deformities and changes in behaviour. According to DG Environment's 2012 *Study on the Potential for Reducing Mercury Pollution from Dental Amalgams and Batteries*, "more than 70% of the European ecosystem area is estimated to be at risk today due to mercury",[28] with the greatest threat to humans coming through fish and shell fish.

Furthermore, inhalation of elemental mercury vapour – which can come from dental amalgams – includes symptoms such as tremors, insomnia, memory loss, neuromuscular changes, and headaches.[29] Research commissioned by DG Environment shows dental amalgams account for more than half of the total environmental releases of mercury entering the water system via the sewers and the atmosphere via cremations, and called on mercury to be banned from dental amalgams.[30]

In 2008, Norway, Denmark, and Sweden banned the use of mercury in dental amalgam due to the environmental and indirect human impacts, with the Norwegian government going as far as banning all products containing mercury, claiming "mercury is among the most hazardous environmental pollutants".[31] In recent years, its use in amalgams has also been significantly reduced in the Netherlands, Italy, and Finland, while Germany, Spain, and Austria have imposed restrictions to its use or guidelines for safer application and recovery. The Scientific Committee on Emerging and Newly Identified Health Risks (SCHENIHR) has also been asked to reassess the safety of mercury in dental amalgams following new evidence, having first found them to be safe in 2008[32] (a result heavily criticised by the International Academy of Oral Medicine and Toxicology, a professional association of scientists[33]).

27 WHO, September 2013, Mercury and Health, Factsheet N0361, available at **http://www.who.int/mediacentre/factsheets/fs361/en/**

28 European Commission, (2012), *Study on the Potential for Reducing Mercury Pollution from Dental Amalgams and Batteries*, **available at http://ec.europa.eu/environment/chemicals/mercury/pdf/final_report_110712.pdf**

29 US Food and Drug Administration, *Fact Sheet: About Dental Amalgam Fillings*, available at **http://www.fda.gov/medicaldevices/productsandmedicalprocedures/dentalproducts/dentalamalgam/ucm171094.htm**

30 European Commission, (2012), *Study on the Potential for Reducing Mercury Pollution from Dental Amalgams and Batteries*, **available at http://ec.europa.eu/environment/chemicals/mercury/pdf/final_report_110712.pdf**

31 **http://www.regjeringen.no/nb/dokumentarkiv/stoltenberg-ii/md/Nyheter-og-pressemeldinger/pressemeldinger/2007/for-byr-kvikksolv-i-produkter.html?id=495138**

32 See the full report here **http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_016.pdf**

33 See the full 43-page critique here **http://www.akut.lu/downloads/critique_scenihr_iaomt.pdf**

- **Substance: Nanosilver**
- **Scientific Committee: Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)**
- **Date opinion adopted: 11 June 2014**[34]

Silver has long been used in hospitals for its antimicrobial characteristics to reduce the risk of infections. Its ability to tackle unpleasant odours means it has appeared in all sorts of common products like Nike's football shirts, washing powders, popular deodorants like AXE/Lynx (made by Unilever), as well as baby bottles, handrails in public transport and disinfectants.

The nano form has become even more popular with manufacturers, being more effective in killing micro-organisms (both beneficial and harmful ones), far better at penetrating tissues and organs, and far easier to combine with consumer products. Its widespread use also means it is now found extensively within the natural environment and ecosystems.

However, there may be serious risks attached to the huge increase in the use of nanosilver. As it is used as an anti-bacterial, over-use can lead to bacterial resistance like we've seen with antibiotics, helping the spread of highly-resistant 'superbugs'.[35] On the other side of the coin, the build-up in soil can also have a disastrous effect on beneficial bacteria in the environment and the food chain, as it kills the bacterial microbes that are of crucial importance to healthy soils. These bacteria are also important to the human immune system, which is built up during childhood through repeated exposure. As a result, the widespread use of nanosilver could lead to an even greater allergy epidemic[36] – something already being experienced in industrialised countries.

There is a concern surrounding nanosilver, along with all nanomaterials, because of the lack of rigorous studies and assessment conducted into the effects from exposure,[37] despite evidence on the heightened risks from nanoparticles. This is particularly worrying as we don't know how much nanosilver currently circulates in the environment and the degree to which humans are exposed due to the lack of transparency and regulatory measures with regard to nanomaterials, such as registration, classification and labelling or dissemination of information (see box 4).

To give an indication of risk, a US court ruled in November 2013 that exposure to nanosilver coatings on clothes, carpets, and blankets posed a health risk to toddlers.[38] It threw out an approval given by the US Environmental Protection Agency (EPA) for unrestricted use of nanosilver coatings, which appeared to be based on the idea that something is safe until proven otherwise – 'no data, no harm', unlike the EU's precautionary principle that underpins the chemicals regulation, REACH. The German Federal Institute for Risk Assessment, BfR, said as early as 2009 that, "Until we are in a position to reliably rule out potential health risks, we recommend that manufacturers refrain from using nanosilver in consumer products".[39] However, given the widespread presence of nanosilver – and other nanomaterials – on the market in the EU despite the lack of evidence of its safety, the precautionary principle is apparently not being applied by the European Commission.

34 **http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_039.pdf**

35 FOE Australia (2011) *Nano-Silver – Policy Failure Puts Public Health at Risk*, available at **http://nano.foe.org.au/sites/default/files/Nano-silver-2011-v2.pdf**

36 FOE Australia (2011) *Nano-Silver – Policy Failure Puts Public Health at Risk*, available at **http://nano.foe.org.au/sites/default/files/Nano-silver-2011-v2.pdf**

37 The SCENIHR opinion on nanosilver (June 2014) warned of a "serious gap in knowledge" surrounding the impacts of nanosilver on antibacterial resistance, with shortcomings in other key areas of knowledge (toxicity on humans, release into environment, and impact on bacterial flora), available at **http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_039.pdf**

38 **http://cdn.ca9.uscourts.gov/datastore/opinions/2013/11/07/12-70268.pdf**

39 BfR, (2010), Press release: BfR recommends that nano-silver is not used in foods and everyday products, available at **http://www.bfr.bund.de/cm/349/bfr_recommends_that_nano_silver_is_not_used_in_foods_and_everyday_products.pdf** ; based on BfR Opinion Nr. 024/2010, 28 December 2009 (only in German)

How does the DG SANCO independence policy stand up?

Given the substantial commercial interests at stake, the pressure to lower trade barriers and expand EU global markets, and the important public role the opinions play through informing regulators, the independence of the scientists within the Scientific Committees (SC) must be above all suspicion of industry influence (whether real or perceived). The full power of the chemical industry was on display in the early 2000s, as a gargantuan effort led by German chemical giant BASF successfully watered down a major reform of over 40 EU chemicals laws to regulate harmful chemicals, known as the REACH Regulation.[40] Ensuring such powerful industries are not seen to be influencing the SCs is no easy feat, but one taken up by DG SANCO and the policies and processes it has put in place.

At a glance, DG SANCO's independence policy (see box 5) looks robust: not only do the rules state that scientists should be independent, but they should also be free from all forms of bias, including intellectual – in fact, it goes beyond the focus of this report, which sticks to assessing economic interests only. It also includes a cooling-off period of five years between working for industry and working for a Committee on that topic, which is commendable.

However, deciding what is and isn't a conflict on interest is surely the crucial first step, and when it comes to defining this, SANCO's policy is overly narrow: interests, ie ties to industry, are only judged to be a conflict if directly related to the experts' role for the SC or working group. For example, if an expert wrote a report for industry claiming a controversial chemical was completely safe, working on that chemical for the SCs would be considered a conflict; but the expert **would** be able to assess another chemical which the report didn't cover, but which was still produced by the same company. This is because DG SANCO assumes that, unless the expert is in a position to actively exploit the conflict eg consciously skew findings in favour of industry because they have a financial interest to do so (ie ensure the SC findings match the report), then the conflict can be managed.[41] However, research shows that the majority of cases whereby a scientist has acted in the interest of industry happen in more subtle ways, as a result of an unintentional bias. The bias may not even be linked to the specific work they have carried out for industry, but in fact a deeper (unconscious) sense of 'double loyalty' (see box 6).

The World Health Organisation (WHO) employs a far broader definition of conflict of interest for its Roll Back Malaria Partnership:

> "A conflict of interest can occur when a Partner's ability to exercise judgment in one role is impaired by his or her obligations in another role or by the existence of competing interests. Such situations create a risk of a tendency towards bias in favour of one interest over another or that the individual would not fulfil his or her duties impartially and in the best interest of the RBM Partnership. A conflict of interest may exist even if no unethical or improper act results from it. It can create an appearance of impropriety that can undermine confidence in the individual, his/her constituency or organization. Both actual and perceived conflicts of interest can undermine the reputation and work of the Partnership.[42]

This appearance of impropriety is not taken into account by DG SANCO but can be incredibly damaging to its reputation and the integrity of its opinions, particularly in light of the evidence regarding industry's influence over science. That's why in this investigation we've taken any financial links to a company that has a direct commercial interest in the risk assessment and resulting regulation of that chemical as a conflict of interest. Adapting the methodology first developed by CEO & Horel (2013) when assessing the independence of experts within the European Food

40 Greenpeace, (2006) *Toxic Lobby: How the chemicals industry is trying to kill REACH*, available at **http://www.greenpeace.org/international/Global/international/planet-2/report/2006/5/toxic-lobby-how-the-chemical.pdf**

41 "Conflict of Interest (CoI) meaning a situation when an individual is in a position to exploit his or her own professional or official capacity in some way for personal or corporate benefit with regard to that person's function in the context of his or her cooperation with Scientific Committees." Rules of Procedure, 2013, footnote p. 12.

42 **http://www.rollbackmalaria.org/partnership/secretariat/docs/RBMconflictOfInterestPolicy.pdf**

Box 5

DG SANCO's Conflict of Interest Policy

Independence is a key principle for DG SANCO, and it clearly states in the official 'Rules of Procedure' for the Committees that:

> " The scientific advice delivered by the Committees must not be influenced by any consideration other than the scientific assessment of the risks in question.... This principle implies in particular, independence from any external economic or political interests, but also from bias related to political, economic, social, philosophical, ethical or any other non-scientific considerations.

To ensure this happens, scientists involved in drafting opinions have to sign a declaration of confidentiality, a declaration of commitment to their independence,[1] fill in a detailed declaration of any interests (DOIs) over the past five years[2] (updated annually), as well as orally declare at each meeting any other potential conflict of interest related to the agenda. The definition of a conflict of interest used by SANCO (hidden away in a footnote of the 'Rules of Procedure'), is:

> " A situation when an individual is in a position to exploit his or her own professional or official capacity in some way for personal or corporate benefit with regard to that person's function in the context of his or her cooperation with Scientific Committees.[3]

The original DOI form is checked by a minimum of two evaluators during the selection process,[4] and the annual declarations are checked by the three-person SC Secretariat (with help in case of uncertainty from other SC members) against the remit of the particular SC for permanent members (extended if they work under other SCs), while for Pool members the conflict of interest definition applies to their specific working group. It is the Group chairs and Group peers who assess the oral declarations, but only against the specific agenda point of the meeting. Assessments are down to individual judgement, rather than set guidelines, but consequences of being in breach of the conflict of interest policy are decided by the Commission and the Secretariat.

1 "I undertake to act independently in the public interest and to make complete declarations of any direct or indirect interests that might be considered prejudicial to my independence."

2 The ten categories assessed by the declaration of interest are: ownership of shares or other investments; membership in a management body or equivalent structure; membership in another scientific advisory body; employment; consultancy/advice; research funding; the holding of intellectual property rights; other membership or affiliation; other; and interests of close family members. There is a cooling-off period of five years, meaning any activity before then does not have to be listed.

3 Rules of Procedure, 2013, footnote p. 12 **http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_2013_en.pdf**

4 All applicants are screened by a selection board, consisting of experts from DG Health and Consumers, the Secretariat General, DG Enterprise and Industry, DG Research and Development and DG Environment, as well as invited external experts, such as the President of the International Agency for Research on Cancer (IARC) who took part last time. Criteria are agreed before hand and each applicant has two evaluators, and if they don't agree a third person is brought in. The board then meets and makes a proposal for a Commission Decision to establish a new mandate.

Safety Authority (EFSA), CEO has used this definition to screen for conflicts across the official declaration of interest form's ten categories against the remit of all three Scientific Committees (given SC members and external experts serve in in multiple working groups – see box 1). For the full methodology of what we consider to constitute a conflict, see Annex I.

Again: the aim of this report is not to assess whether individual scientists are corrupt in any way, exploiting their links to industry for personal gain, but rather to see how effectively SANCO is protecting the independence of its risk assessment processes from commercial interests.

Box 6: When is a conflict of interest a problem?

An increasing number of studies have revealed a strong correlation between financial ties with industry and problems with research outcomes. Industry funding – which does not have to be related to the particular area of work in question – leads to an increased probability of the production of pro-industry conclusions, biased interpretations of data, and even obstruction of the publication of negative outcomes.[1] Social scientists have also found that a 'sense of indebtedness' towards the financial interest can cause further bias, known as double loyalty. But this may not be a conscious move: most studies conclude that a conflict of interest often rather results from an unintentional bias than from intended dishonesty.[2]

This 'soft' way of industry gaining the loyalty of regulators or assessors is a far more common source of regulatory capture, and was successfully pioneered by the tobacco industry.[3] For a concise overview of regulatory capture by industry, see the CEO & Horel (2013) report on conflicts of interest within EFSA.[4] DG SANCO has not taken this form of industry influence into consideration and designs its independence policy around the possibility of corrupt individuals intentionally distorting science for personal gain.

1 Babor T., and Miller, P. (2014) McCarthyism, conflict of interest and *Addiction*'s new transparency declaration procedures, *Addiction*, 109, 341–344, available at **http://onlinelibrary.wiley.com/doi/10.1111/add.12384/pdf**

2 Babor T., and Miller, P. (2014) McCarthyism, conflict of interest and *Addiction*'s new transparency declaration procedures, *Addiction*, 109, 341–344, available at **http://onlinelibrary.wiley.com/doi/10.1111/add.12384/pdf**

3 Brandt AM, (2012), Inventing conflicts of interest: a history of tobacco industry tactics, *American Journal of Public Health*, Jan; 102(1):63–71, available at **http://www.ncbi.nlm.nih.gov/pubmed/22095331**

4 CEO & Horel, (2013), *Unhappy Meal*, **http://corporateeurope.org/sites/default/files/attachments/unhappy_meal_report_23_10_2013.pdf**

Assessing conflicts of interest

Having gone through the annual declarations of the interests of all 57 members involved in the Scientific Committees' opinions on the four substances (checked by the three SC secretariat members and presumably judged to be free of conflicts),[43] it is worrying to see two thirds (67%) of the scientists have links with industries with a direct or indirect interest in the assessed chemicals. Declarations include links to well-known corporations such as pharmaceutical giant GlaxoSmithKline – which has been accused by respected medical journals such as the Lancet of distorting the results of scientific research for commercial profits;[44] chemical behemoth DuPont – notorious for its lobbying against stronger regulation of greenhouse gases, among other things;[45] and Unilever – a global producer of cosmetics (assessed by SCCS) and processed foods, and keenly interested in biocides (assessed by SCHER) with a track record of pro-free-trade lobbying and against regulation globally.[46]

The percentage of scientists with industry ties is relatively consistent across all four opinions, with no group lower than 62% but Mercury from Dental Amalgam reaching 75% (see table 1). It may be higher, but one member didn't fill out a form (see box 7). SCENIHR had the lowest number of conflicts while both SCCS groups were consistent, reaching around 70%.

Box 7

Questionable declarations part 1 – cutting corners

Dr. 'See my CV' [SCHER opinion on Mercury in Dental Amalgams / 0 DOIs; 0 COIs]

One member of the SCHER opinion on Mercury in Dental Amalgams did not fill out a declaration of interest form, but wrote, "please see the section of professional activity of my attached CV". One would have assumed such a declaration would be deemed unacceptable by DG SANCO's screening process, but they allowed it to pass. Even if the secretariat checking all DOIs did go as far as checking the CV, the relevant sections do not make it clear which private interests have been worked for and if they pose a conflict or not. Under the category of consultancy, it states "private companies" and under academic activity it states they have "coordinated over 50 research projects for... Governments and private sectors." By not following the declaration of interest procedure in a transparent way, DG SANCO leads the public to question its ability to meet the three principles of independence, excellence, and transparency, regardless of whether Dr 'See my CV' had any conflicts of interest or not.

While 30% of scientists had no links with industry at all, over half (54%) had more than one link. Particularly worrying is the number of individuals with five or more conflicts (18%), with two in every working group having at least six conflicts – although some had as many as 19 and 20 conflicts within their declarations (see boxes 8-10: Questionable Declarations). This is a serious concern for the integrity and independence of DG SANCO and its Scientific Committees.

Even if one assumes all the self-declarations of interest are reliable, they highlight serious flaws in the DG SANCO conflict of interest process. The variation in the number of declarations made (some scientists making more than 40, with others leaving the form blank and simply writing "see my CV" – see box 7 above) points to a weak and erratic procedure. But that so many scientists with conflicts were then picked to take part in highly sensitive risk assessment points to a systematic failure in screening policy – almost every fourth interest declared represented a conflict (24%), yet was judged to be fine by DG SANCO.

43 Scientists involved in drafting opinions have to sign a declaration of confidentiality, a declaration of commitment and fill in a detailed declaration of interest (updated annually).

44 Richard Horton, editor of the Lancet, testifying to UK Parliamentary Select Committee on Health in 2005, see **http://www.europeanhealthjournalism.com/pdf/conflict-RH.pdf**

45 CEO, (2013), *F-gas lobby saga – how the industry lobby got in the way of climate policy*, available at **http://corporateeurope.org/climate-and-energy/2013/12/f-gas-lobby-saga-how-industry-lobby-got-way-climate-policy**

46 Unilever donated $467.000 to the corporate campaign against GM labelling in California, The Guardian, 8 May 2014, *Vermont takes on genetically modified foods with new labeling law,* available at **http://www.theguardian.com/sustainable-business/vermont-gmo-labeling-law-genetically-modified-foods-lawsuits**

Table 1

Overview of conflicts of interest assessment[1]

Scientific Committee	SCCS	SCCS	SCHER	SCENIHR	Total
	Parabens	Titanium Dioxide (nano form)	Mercury from Dental Amalgam	Nanosilver	
Total number of scientists in working group	16	20	8	13	57
Scientists assessed to have a conflict of interest	10 (62.5%)	14 (70%)	6 (75%)	8 (62%)	38 (67%)
Scientists assessed to have no conflict of interest	6 (37.5%)	6 (30%)	1 (12.5%)	5 (38%)	18 (32%)
Scientists not assessed[1]	0	0	1 (12.5%)	0	1 (2%)
Number of screened declared interests of working group members	161	219	90	203	673
Number of screened declared interests assessed to be in conflict with Committees' remit	38 (24%)	46 (21%)	38 (42%)	40 (20%)	162 (24%)
Number of screened declared interests not assessed for lack of information	4 (2.5%)	11 (5%)	7 (8%)	9 (4%)	31 (5%)

1 Due to insufficient declared information – see Box 7

Box 8

Questionable declarations part 2 – lenient definitions?

Dr. Industry-funded Research Department [SCENIHR opinion on Nanosilver / 36 DOIs; 20 COIs]

One member of the SCENIHR opinion on Nanosilver works at a respected university, but their research funding and consultancy contracts are in conflict with the remit of the three Committees (and SCENIHR in particular). Since 2010, they have signed ten consultancy contracts, all of them with private companies, including L'Oréal, Procter&Gamble, GAMA Healthcare, Tristel, and 3M. Each one was related to anti-septic, anti-bacterial or anti-microbial activities, meaning all of the companies are actively involved in the infection control and/or health care area, a sector where (nano)silver is commonly used for its antimicrobial properties. Dr. Industry-funded Research Department was brought in as an external expert for the nanosilver opinion.

One of these companies, 3M has already patented numerous nanosilver antimicrobial 'inventions',[1] giving it a clear interest in the outcome of the SC opinion, while Proctor & Gamble already has numerous antibacterial baby products on the market such as its 'baby pacifier' (a 'dummy' in UK English). To emphasise the potential problem of the industry links, P&G has also been involved in previous academic scandals, accused of attempting to influence and manipulate scientific research,[2] and last year spent over $4 million lobbying in the US and between €4m-€4.5m lobbying in the EU.[3]

Furthermore, the scientist in question received industry research funding for seven projects, including from Unilever, Steris, and GAMA Healthcare – again, companies with an active interest in nanosilver and any risk assessments which may impact regulation, the exact topic this scientist was asked by SCENIHR permanent members to be involved in.

The difference with this case compared with some others highlighted is that the money (research grant or consultancy fee) went to the scientist's employer, the well-respected university. While no less problematic – as the work itself was done directly for industry, creating the possibility of unconscious ties referred to in box 6 – it highlights the growing problem of universities demanding that researchers look for corporate funding, as well as engaging in private activities to raise funds. Despite this caveat, Dr. Industry-funded Research Department's declaration of interest should still have deemed them unsuitable to serve as an external SCENIHR expert – which they did on more than one occasion.[4]

1 See **http://www.google.com/patents/US20020051823**

2 Jennifer Washburn, December 2005, Rent-a-Researcher: Did a British university sell out to Procter & Gamble, Slate, available at **http://www.slate.com/articles/health_and_science/medical_examiner/2005/12/rentaresearcher.html**

3 See Procter & Gamble's entry in the EU Lobbying Transparency Register **http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=5519077766-10**

4 They also served in the SCENIHR working group on 'AMR – Zoonotic Infections'.

Where are conflicts most likely to occur?

Among the ten various categories in which conflicts can be declared, some appear more frequently and can be considered more serious conflicts of interest. By far the most common conflict within the declarations forms was working in a consultative/advisory role for industry (more than half of all declarations were conflicted), meaning direct payment to the expert – or in some cases their research institution – for services to those companies whose products were regulated as a result of Scientific Committee opinions.

Another statistic to point out is research funding: while our study found only 28% of the declarations in this category in conflict, the sheer quantity of conflicts (49) is significant. This points at the problem highlighted by many of our interviewees: that scientists find it increasingly difficult to attract dwindling public funding, while universities often expect public funds to be matched by corporate research money, a practice encouraged by the EU's research policy. 'Membership in a management body' of a journal or

Table 2

Most common types of declared interest (and conflicts of interest)

Declaration category	**Parabens (SCCS)** # declarations (# conflicts) %	**Titanium dioxide (nano form) (SCCS)** # declarations (# conflicts) %	**Mercury from dental amalgam (SCHER)** # declarations (# conflicts) %	**Nanosilver (SCENIHR)** # declarations (# conflicts) %	**Total** # declarations (# conflicts) %
1. Ownership of shares or other investments	31 (4) 13%	21 (6) 29%	3 (2) 67%	3 (0) 0%	58 (12) 21%
2. Membership in a private management body or equivalent structure	4 (1) 25%	7 (2) 29%	5 (4) 80%	10 (3) 30%	26 (10) 39%
3. Membership in another scientific advisory body	34 (3) 9%	51 (5) 10%	26 (5) 19%	36 (4) 11%	147 (17) 12%
4. Employment	19 (2) 11%	22 (5) 23%	9 (4) 44%	21 (2) 10%	71 (13) 18%
5. Consultancy/ advisory	16 (9) 56%	21 (5) 24%	17 (13) 77%	17 (11) 65%	71 (38) 54%
6. Research funding	23 (8) 35%	56 (16) 29%	16 (6) 38%	79 (19) 24%	174 (49) 28%
7. Intellectual property rights	9 (4) 44%	3 (0) 0%	0 (0) N/A	1 (0) 0%	13 (4) 31%
8. Other membership or affiliation	21 (5) 24%	37 (7) 19%	6 (1) 17%	34 (1) 3%	98 (14) 14%
9. Other	4 (2) 50%	1 (0) 0%	8 (3) 38%	2 (0) 0%	15 (5) 33%

For full methodological classifications of what does and does not constitute a conflict of interest see Annex I.

Box 9

Questionable declarations part 3 – Slipped through the net?

Dr. Vague Industry Declarations [SCHER opinion on Mercury in Dental Amalgams / 42 DOIs; 19 COIs]

One member of the SCHER working group on Mercury in Dental Amalgam, who has served within the DG SANCO Scientific Committee system for over a decade across all three committees, lists their official occupation as a professor at a university. However, their declaration of interests form reveals multiple alternative sources of income. Dr. Vague Industry Declarations has acted as a private consultant/advisor 16 times between 2008 and 2012, but worryingly, on their declaration of interest the employer is rarely listed ("pharmaceutical company", "chemical company", or simply "private company"). This alone should have rung alarm bells – particularly when they listed activities like assessing "contaminants in cosmetic products" – and asks serious questions of the Scientific Committees' screening procedures.

Equally, three entries which we have not labelled as conflicts – due to insufficient information – state "more than 100 meetings" and "more than 200 publications" without giving any detail on who they were with or for. Potentially, these could represent another 300 conflicts of interest.

One instance where the member in questions did disclose the name of the organisation was the membership of REXPAN since 2011. REXPAN is the scientific advisory panel of the Research Institute for Fragrance Materials (RIFM), a private research institute for the fragrance and cosmetics industry, with members such as BASF, who produces mercury-based products. RIFM members also include Chanel, SC Johnson, Colgate-Palmolive, Procter&Gamble, and L'Oréal, who all have an interest in decisions made by the Scientific Committee Consumer Safety (SCCS), where this scientist was a permanent member from 2009-2013, before moving to SCHER. Furthermore, since 2006, they have received research funding from Honeywell, a multinational company that produces systems for cars, energy generation, chemicals, and plastics.

The Scientific Committees were in fact well aware of this scientist's industry links, banning them from a SCENIHR plenary discussion on endocrine disrupting chemicals in June 2013 for that reason. They received money in 2008 from manufacturers of endocrine disruptor BPA to write a review which claimed there was no health risk to the general public from exposure to the chemical (not declared in the DOI, but potentially one of the hundreds of unnamed publications).[1]

This scientist's independence was questioned even further in 2013 when they co-authored a pro-industry open letter attacking DG Environment's attempts to tighten regulations on endocrine disruptors, written with numerous other industry-funded scientists.[2] This resulted in their resignation from SCENIHR, but they remain listed on the website.[3]

When interviewed by Environmental Health News on industry funding, Dr. Vague Industry Declarations claimed they didn't "consider conflict of interest as [a] measure tool to judge scientific debate" and that getting money from a mix of sources (including industry) was "the normal way" to do research nowadays.[4]

1 Human exposure to bisphenol A by biomonitoring. *Toxicology and Applied Pharmacology*. April 1 2008; 228 (1)

2 **http://www.environmentalhealthnews.org/ehs/news/2013/scientist-resigns**

3 Last checked 17 August 2014 **http://ec.europa.eu/health/scientific_committees/environmental_risks/scher_04-09/scher_members_en.htm**

4 **http://www.environmentalhealthnews.org/ehs/news/2013/scientist-resigns**

scientific committee also stands out, as corporate membership and sponsorship is increasingly seen as a way to raise revenue. While industry involvement can be desirable for product development, it raises grave concerns as far as the risk assessment of commercial products is concerned. These trends are particularly worrying for all public institutions who are trying to gather the highest quality and independent science to ensure they can regulate in the public interest without the interference – directly or indirectly – of commercial interests.

This study also extends beyond the four opinions in question: the experts who serve in the working groups being examined also serve on other opinions. In particular, out of 41 permanent members across all three Scientific Committees, these four case studies covered 28 of them. Among them, more than 70% had a conflict of interest. This is particularly worrying, as they don't just give input on these four chemicals, but on the whole remit of the Scientific Committees: discussing, voting and finally approving all final opinions within the Committee.

Interestingly, while external members can come from the pool of experts and the external database, they can also be picked from other SCs. For example, one external expert on the SCCS opinion on titanium dioxide is also a member of SCENIHR, while also being the Director of the Executive Committee of the industry-funded International Union of Toxicology.

A failure of conflict of interest policy?

The high frequency of conflicts of interest among experts is worrying (two thirds have ties with industries that are potentially affected by SC opinions), but the situation may in fact be worst, with almost five per cent of declarations not containing enough information to make a judgement; equally, under-reporting by experts wasn't further investigated (despite some instances being found while researching the disclosed declarations). Research has shown people to be very bad at honestly assessing their influences and own behaviour,[47] and worryingly it appears SANCO relies on these types of self-assessments without further investigation.

When attempting to answer why the number of conflicts was so high, it's worth looking at the Scientific Committee conflict of interest policy and how it is implemented. The lack of firm guidelines and diversity of assessors creates uncertainty: the original declarations of interest are checked by two evaluators, assessing the suitability of the candidate; oral declarations are assessed by the working groups themselves; and annually-updated declarations of interest are checked by a team of only three (the SC secretariat). This can lead to very differing approaches in applying the policy. Not only is this a huge amount of work for such a small team, it also leaves a great deal to individual judgement. DG SANCO intends to compile guidelines based on existing conflict of interest documents, which should hopefully go some way towards clarifying how the rules should be applied, but the narrowness of the definition is also problematic.

The SC working definition of a conflict – limited to whether a scientist is in a position to directly exploit their conflict – explains the difference between the findings in this report and SANCO's own assessments. A meeting with the Scientific Committees secretariat demonstrated they are keenly aware of avoiding industry influence and highly value SANCO's independence, but the narrowness of definition means they are picking experts with commercial links to industries directly affected by the work of the Committees (and in many cases, as this study shows, the specific opinions). It also means more work for the three-person secretariat, as they must re-assess Scientific Committee members as they join working groups under another Committee, as well as Pool members each time they join a different Group.

The DG SANCO definition puts too much emphasis on stopping individuals being able to expressly exploit a conflict, ie weeding out the feared 'industry mole', rather dealing with the wider regulatory capture at work through industry collaboration. This is clearly shown by the declaration of interest form, which states "having an interest does not necessarily mean having a conflict of interest,"[48] and assuming that this can be managed endangers independent risk assessment.

The oral declarations provide a good example of this approach: of the five oral declarations of interest made last year during working group plenary meetings, two experts were asked to not partake in meetings on a particular substance, yet others were allowed to take part who were involved in projects with industrial partnerships.[49] The decision was taken by the working group chair and its members in good faith, but against the specific agenda point rather than a wider remit, and again based on their own judgement rather than according to guidelines. DG SANCO has since confirmed that no further investigations were made into the cases. Ironically, the only instance where a conflict of interest was investigated further led to one of the most conflicted experts (see box 9) being deemed not to be in conflict.[50]

47 Steinman M.A., Shlipak M.G., McPhee S.J., (2001), Of principles and pens: attitudes and practices of medicine housestaff toward pharmaceutical industry promotions, *Am J Med*. May;110(7):551-7, available at **http://www.amjmed.com/article/S0002-9343%2801%2900660-X/abstract**

48 See **http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/doi_sccs_rogiers_en.pdf**

49 No details of names or industries are provided in the minutes, but four declarations were made in SCENIHR, with 'Dr Vague Industry Declarations' (see box 9) sitting out, while one was made in a working group meeting of SCCS (identity unknown) that led to an exclusion.

50 The incident was regarding a meeting attended by then-SCCS chair alongside 'Dr. Vague Industry Declarations' (see box 9), where they

At the heart of the problem is the increasing issue of trying to find independent scientists, and this was stressed in many of the interviews with scientists themselves: reductions in public funding, pressure from universities on researchers to attract private funding (and match public funds) as well as a lack of prestige attached to serving on such committees (which involves conducting literature reviews rather than producing new research), mean experts either increasingly have links to industry or are not interested. Interviews reveal that for those scientists without industry ties who do work in the Scientific Committees, serving on the SC meant they have had to forego grants and funding. This has led to serious pressure from their public institution, particularly in the absence of public grants to replace them, and in some cases had a detrimental impact on careers.

The problem extends beyond risk assessment into the wider world of science, particularly with regards to research priorities and funding patterns. But DG SANCO and other public institutions have a responsibility to protect the integrity, prestige, and funding involved in public research if they want to continue to be able to count on researchers whose independence cannot be publicly questioned. The cruel irony is that the European Commission, under strong pressure from business lobby groups, has been proactively working against this principle by spending its own research funding on public-private partnerships and encouraging public institutions to partner with industry.[51] Among the

defended endocrine disrupting chemicals on behalf of a chemical industry association. Access to document requests reveal that after submitting a written account of events to the SC secretariat and hearing no news, the SCCS chair resigned from the Committee of their own accord. SANCO subsequently published a recommendation that they should stand down from only the working group, and that the involvement of 'Dr Vague Industry Declarations' posed no conflict as they were not currently assessing any endocrine disrupting chemicals. For the full correspondence, see **http://www.asktheeu.org/en/request/conflict_of_interest_within_scie#incoming-4344**

51 For example, FP7, the European Commission's 7th Framework Programme (which ran from 2007-2013), is the EU's "chief instrument for the public funding of research", but has made collaborative research projects "the backbone of the framework programmes". See **http://cordis.europa.eu/fp7/sme_en.html**

Box 10

Questionable declarations part 4 – so what does constitute a conflict?

Dr. Industry Jobs on the Side [SCCS opinion on Parabens / 12 DOIs; 10 COIs]

One member who worked on the SCCS opinion on Parabens has a full time job at a respected university but has several other research and consultancy activities that generate income – the majority of them with private companies.

Half of all conflicts of interest identified involve research funding by industry, including pharmaceutical giants Basilea Pharmaceutica and Schering Plough, as well as the corporate Research Institute for Fragrance Materials, as with Dr. Vague Industry Declarations (see box 9). This particular scientists has also accepted research funding from a consortium of hair dye manufactures represented by L'Oréal. Despite this they were still deemed to be sufficiently free of conflicts to work on an opinion assessing the safety of parabens – a chemical the SCCS previously found as safe but has been re-examined after a ban by the Danish government and new research from French authorities. While some manufacturers have removed endocrine disrupting parabens from their cosmetics formulas, L'Oréal has opted not to, giving it a clear commercial interest in a positive risk assessment for parabens.[1]

This scientist's declared industry consultancy contracts should also have rung alarm bells, including Procter&Gamble, GlaxoSmithKline (GSK), and Astellas Pharma. GSK products also contain parabens – from their aspirins to their skin lotion. And the paid work for them relates specifically to hand cream containing parabens.

A Scientific Committee responsible for assessing ingredients in cosmetics should have seriously questioned this member's suitability to serve on the Committee, as well as this particular working group, given the numerous research and consultancy contracts. But their inclusion means that in addition to parabens they have also assessed the safety of aluminium and of boron compounds in cosmetics, as well as helping draft the EU rules for industry-testing of cosmetics. This is not to say that Dr. Industry Jobs on the Side has knowingly or purposefully acted in the interests of the cosmetics industry, but rather that their inclusion undermines the perceived independence of all institutions involved and is worrying given the evidence showing the influence industry ties have, conscious or not, on scientific research.

1 Some products do, but many still do not, leading the Environmental Working Group to label L'Oreal's cosmetics a "high hazard". **http://www.ewg.org/skindeep/brand/L'Or%C3%A9al/**

declarations, there were more than 50 instances of consultancy or research funding coming from the EU's Framework Programmes for Research, with 19 being flagged as representing a conflict due to the prominent role of industry and the relevance to the work of the Committees. A further nine declarations were not specific enough to evaluate. The EU is making the job of its own departments increasingly difficult, as well as having a very destructive effect on the overall funding landscape. With half of all research and development in the EU already privately funded[52] and the trend continuing, this will not only mean fewer and fewer eligible scientists, but allow private funding priorities to further guide public ones and undermine public safety, health and the environment as commercial interests are prioritised.

A strong argument can be made that the amount of work involved in sitting on a SC – especially for chairs – and the lack of remuneration (only for travel and board, but not for the work) are also off-putting, particularly (as some scientists have pointed out) without the support of one's employer. There have since been internal discussions on the remuneration of chairs,[53] but when interviewing the Scientific Committee secretariat, they expressed fear that excluding members with industry ties would lead to no members at all, and that conflicts can be managed. The view that it's near-impossible to find interesting and diverse scientists free of conflicts of interest has also been repeated by some interviewees, but accepting this will only lead to greater industry influence, rather than attempting to make reforms that challenge the situation. This is not an inevitable trend: almost one in three experts screened (32%) were completely free of industry ties. The more seriously the EU and other governments take the issue of conflicts of interest, the more scientists will be able to work independently from the economic sectors whose products they are assessing (which is actually good for innovation). DG SANCO's Scientific Committees should play an important role in this.

52 Grandjean P., Science for precautionary decision making, *Late lessons from early warnings: science, precaution, innovation,* European Environment Agency report No 1/2013. **http://www.eea.europa.eu/publications/late-lessons-2**

53 In the minutes of the February 2014 meeting of the Inter-Committee Coordinating Group (which appears to meet sporadically – the previous meeting was June 2013) a "A proposal to remunerate Chairs of the SCs and Chairs of the WGs was discussed", but no further information was given, see **http://ec.europa.eu/health/scientific_committees/inter_committee/docs/coor_mi_005.pdf**

Assessing Excellence and Transparency – scientists and public interest groups

To gauge how the Committees meet their principles of excellence and transparency, CEO interviewed DG SANCO; scientists directly involved in the Committees; scientists who follow the Committees' work; and public interest groups who have engaged with the process. This is in no way exhaustive but is intended to provide some crucial insights. The findings were then presented to a round table of civil society public health experts engaged with the Committees[54] to collectively put forward recommendations.

According to the Scientific Committees' Rules of Procedure,[55] adhering to the principles of excellence and transparency means:

* **Consulting the most qualified experts while ensuring independence to achieve a pluralistic and multidisciplinary group.**
* **Openness, dialogue, and collaboration with other bodies and third parties.**
* **Scientific Committee conclusions and their limitations/uncertainties must be clear and understandable for all stakeholders, including the public, as should the processes and rationale behind them.**

However, how do these principles play out in reality?

"Consulting the most qualified experts while ensuring independence to achieve a pluralistic and multidisciplinary group."

Process: a widely-published call is made for experts, while SANCO aims to renew at least 30% of the Committee membership each time.

Reality: Despite the processes, some scientists interviewed as well as public interest groups point to a lack of diversity among disciplines and philosophies of science and epistemic schools, which they claim translates into insufficient relevant expertise and a narrower and less informed perspective. Reportedly this isn't just within the core members, but also the Pool, which provides expertise for working groups.

Analysis: on first impression, the processes themselves appear robust: according to the head of unit responsible within SANCO, last time the Scientific Committees renewed their mandate (2013), the call was published on their website, public health websites, with scientific agencies, universities, member-states' public health institutions, among those who had previously participated, as well as going to their 20,000 newsletter subscribers. They received 450 applications, with a rigorous selection process including internal and external experts,[56] leading to 41 appointments, which saw just over 45% new membership in SCCS (7/15), 65% in SCHER and just under 55% in SCENIHR (8/15). One scientist interviewed even commended them for rejecting the applications of some existing members in order to bring in changes. Yet the underlying feeling from those interviewed is that the current policies are not effective in attracting the right sorts of experts.

The oft-mentioned lack of diverse expertise is particularly pronounced within SCENIHR, which deals with new and emerging threats so has a need for experts working on cutting edge issues. However, the lack can also be seen across the board: three of the four opinions looked at issued an external call for expertise. This means neither the Pool nor the Database of Experts had sufficient diversity. And while advertising for new Scientific Committee members involves extensive outreach, one long-serving scientist did not think that such extensive outreach happened when trying to attract experts at working group stage. However, it was also pointed out that many of those who do express interest are connected to industry while many of those with the right expertise are in fact outside the EU.

54 Organisations involved in the workshop, its preparation and/or its conclusions were Baby Milk Action, CEO, CHEM Trust, ClientEarth, ECOS, EEB, HEAL, Health Care Without Harm, R.I.S.K.

55 This is a synthesis of principles taken from the DG SANCO Rules of Procedure 2013, Annex V, p. 47, available at **http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_2013_en.pdf**

56 The President of the renowned International Agency for Research on Cancer (IARC) was one of the screeners. For a full account of the selection process, see Box 5.

SANCO has also been forced to remind Committee chairs and vice-chairs that the possibility of attracting external expertise exists,[57] which could suggest some members are far happier than others to accept a lack of diversity. It is the chairs and the core Committee members who draw up a list of possible members and identify gaps, but while one scientist has expressed a desire to always push for a balanced group when in that role, they also admitted that it is down to individual chairs, vice-chairs and members to decide if extra expertise is necessary. Another long-serving scientists confirmed that it was very much a case-by-case basis, but tried to dismiss the short-comings by claiming that of course, "it can always be better". However, while the three Committees are very different, according to another scientist an "old school" institutional culture still pervades in some groups and among some scientists, making them less likely to look more widely for diverse expertise and also less welcoming of other approaches when they are brought in. The definition of diversity is undeniably important, and clearly varies, but this is why public interest groups have called for mandate and a list of proposed disciplines needed for the particular opinion to be put out to public consultation, to ensure as broad a definition as possible is reached.

A public health group interviewed also warned of the same thing, describing the SCCS (previously the Scientific Committee for Consumer Products) as an old-boys network, and found that suggestions for additional experts to join the group were hard-fought battles. In addition, the suggestion by a number of groups to pro-actively reach out to specific institutions in order to increase disciplines (eg university departments working on nanotechnology) appears to have not been taken on board when the previous mandate was renewed in 2009.[58] Instead, another public health group has suggested that epistemic silos exist (i.e. certain schools of scientific thinking) which lead to a "path-dependency" when it comes to who's picked: long-serving scientists pick others with whom they agree and feel comfortable with. Such an environment is not particularly inviting for outsiders. One scientist who recently served in the working groups said there was a fear within groups of newer scientists who would challenge the status-quo, with a preference for "old hands" who could be trusted to 'not rock the boat' and were loyal to SANCO.[59] They even went as far as admitting they were reluctant to attend meetings as the group was so closed and insular, describing the experience as "unpleasant" and "depressing".

The perception held by some of a closed group resistant to change is reinforced by the way opinions themselves are formed: every time an opinion is revised, such as the parabens opinion, the new one must build on top of the old one. Only new evidence can be accepted and anything that was previously dismissed cannot be looked at again. When the suggestion was made by one interviewee to start from scratch, it was immediately dismissed by other working group members. For new scientists who come from different backgrounds, this can appear as another way to exclude their perspectives and keep the same dominant culture alive. Another scientist who had served for many years in the Committees did not share this view, and saw debate taking place across "the whole spectrum", but if this is the reputation on DG SANCO's Scientific Committees among cutting-edge, actively publishing scientists not currently engaged, it's not going to encourage them to apply. If this is true, the result will be a lack of relevant expertise on important topics – which according to one scientist is already happening.

When viewed together with the structural issues highlighted in the independence section (lack of remuneration for the high work-load; lack of interest from public institutions chasing funding; lack of attractiveness for scientists who want to publish new research not conduct literature reviews), it begins to explain why – despite most interviewed agreeing that processes have been improving – there is still a lack of cutting edge scientists who can provide the latest expertise on emerging issues. From what interviewees have said, the situation within the Scientific Committees is far from the 'pluralistic and multidisciplinary group' that DG SANCO is aiming for.

"Openness, dialogue and collaboration with other bodies and third parties."

Process: stakeholder dialogues (call for evidence, public consultation, comments period for drafts, public hearings) are permitted and take place. However, there is no fixed rules or guidelines, and according to DG SANCO, they will take place if there are "wider health implications".

Reality: There are huge difference between the Committees and working groups in how far they go in engaging the public. Going by the four opinions in this study, SCCS put its draft opinions out for comment, which it does as standard; SCHER had a call for information, a public consultation

57 See the minutes of the February 2014 meeting of the Inter-Committee Coordinating Group **http://ec.europa.eu/health/scientific_committees/inter_committee/docs/coor_mi_005.pdf**

58 HEAL/HCWH, (2008), Response to DG SANCO Consultation Document on the Revision of the Scientific Committees

59 It was suggested in one of the interviews – and this has also been expressed by public interest groups – that SANCO uses the opinions for political purposes to ensure the success of the European Commission's project, which is based creating the right conditions for business through innovation, market expansion and global competitiveness

and a public hearing; while SCENIHR had a call for information and a public consultation. According to one scientist, in general SCENIHR uses the stakeholder dialogue system the most due to the nature of its opinions – which are very broad. Another scientist who has served for many years commented that the Scientific Committees' engagement with other bodies and the public has decreased.

Public interest groups have also complained on multiple occasions about the consultation process itself when it does take place – both in taking part but also transparency around how submissions are used (see next section).

Analysis: One key reason mentioned by scientists was a cut to budgets, which has seen a reduction in public engagement. Hearings with the European Parliament also used to be common, which greatly increased trust between the two institutions and made for better opinions, but this no longer takes place and trust levels have suffered as a consequence. Public interest groups also commented that consultations used to take place on the questions of an opinion and the mandate itself (was the opinion focusing on the right questions?) but this has also stopped, meaning input can only happen at a much later stage, when some might argue it is already too late.

As one Committee member pointed out, the difference in engagement also comes from the difference in Committee remits. While SANCO suggested it was down to the extent of "wider health impacts" this scientist believes it's to do with levels of controversy – how much public scrutiny and demand is there? One would assume SCENIHR, which deals with new and emerging risks in a very cross-cutting way, would engage more with the public, but this is no excuse for other Committees to do any less.

Another scientist puts higher levels of engagement from SCENIHR down to its internal culture: it is a newer Committee and therefore doesn't have the same institutional culture. An interviewee admitted that it was the chairs and vice chairs who decided the levels of engagement, with certain chairs pushing for it and others not, mirroring comments on reaching out for diverse scientific disciplines. However, even if outreach through public consultations does take place, many public interest groups spoken to complain that questions are overly leading and don't allow groups to fully express their arguments or submit extra supportive evidence to back-up their claim. This can only serve to limit the excellence of opinions.

Given the reductions in engagement from the SCs in general, as well as differing levels and forms in what practices remain, it is not surprising that a perception exists among many public interest groups that the SCs are not open to dialogue – whether this is true or not. DG SANCO needs to address this if it is to ensure it not only meets its stated goal of "Openness, dialogue and collaboration with other bodies and third parties," but also if, as one scientist highlighted, it is to restore trust in the opinions and the processes behind them.

"SC conclusions and their limitations/ uncertainties must be clear and understandable for all stakeholders – including the public – as should the processes and rationale behind them."

Three key issues have come out of the research and interviews to illustrate how well – or not – DG SANCO is meeting this principle: the ability to express disagreement over science; the way findings are presented; the transparency over the use of evidence.

Minority opinions

Process: "A working group shall endeavour to reach a consensus. In the absence of consensus, a position of the working group shall be approved by a simple majority of its members. Nevertheless, the chair of the working group and the rapporteur shall inform the committee of all the opinions expressed."[60]

Reality: Minority opinions are not able to be expressed at the working group level, which is where the experts on the topic are supposed to be reviewing and debating the evidence available. Minority opinions are very rarely taken up at the Committee level, with not one of the four opinions on controversial substances studied in this report registering one, nor in any of the 33 opinions published between March 2013 and June 2014 – 30 within SCCS. One scientist claimed that divergent views were buried at working group level as cases where no common position could be found on evidence led to it being excluded.

Analysis: The task of finding consensus falls on the individual working group chair, which according to one scientist is very difficult, and the lack of minority opinions at that level is "problematic". Public interest groups point out that when combining multiple scientific disciplines around such controversial substances and topics, a difference of opinion is inevitable and even in the public interest (as different

60 Rules of Procedure, point 73

perspectives on risk allow a better assessment). It was suggested the lack of minority opinions could be more than a sign of forced compromise (by excluding evidence), but highlight a lack of diversity within the working groups and Committees. Chairs are supposed to inform the SC plenary of major disagreements at working group level, which can lead to a minority opinion, but much depends on the chair.

The importance of personality and institutional culture is also highlighted by another scientist. They remark how difficult it is to get new ideas and practices into the Committees when they are full of scientists who have been there a long time and have worked extensively with each other, sharing the same scientific approaches. A further scientist also commented on the difficulty of breaking the institutional culture. One even goes as far as saying many of the more established scientists explicitly want the Committee opinion to disprove negative allegations, which suggests a clear intellectual bias – and maybe even more – and if true, certainly a threat to independence and excellence. However, group dynamics linked to the collective culture means such attitudes are unlikely to be reported.

Scientists and public interest groups alike echo the view that a lack of ability to express minority opinions at working group level can lead to the intellectual capture of the Committees and may also put off new scientists from diverse disciplines engaging with the Committees, as they feel unable to fully participate. To reach the high standards DG SANCO has set for itself, this needs to be addressed.

Expressing uncertainty:

Process: "The meaning of the scientific advice... the limits of their validity and the relevant uncertainties must be clear and understandable for users, relevant stakeholders and the public."[61]

Reality: Public interest groups feel that the question of uncertainty and what that can mean for people and the environment is often not expressed clearly enough for stakeholders and the public to understand, while one scientist sees the treatment of evidence contributing to the lack of clarity around risk, and even its dismissal.

Analysis: During interviews, public interest groups highlighted the lack of consistent terminology within opinions when expressing concern or uncertainty, which made it very difficult to know what the real-world risks being presented were. This can also be seen in the 'layperson' translations completed by GreenFacts, which do not make clear – or even downplay – the levels of risk and concern (although their interpretation can only ever be as good as the original opinion).[62] One scientist pointed out that in their experience, a lack of data or data that didn't meet the agreed standards (see the next section) saw the potential risk in that areas being downplayed or ignored – even if there was a potential reason for concern. If true and more widespread than simply anecdotal, this goes against the EU's principle of precaution, which means highlighting potential dangers in light of absence of definitive data, not ignoring them. While DG SANCO claims the principle is only for risk management rather than assessment, ie when making regulation, managers are not able to manage risk if they are not made fully aware of it by assessors. This could endanger public health, the environment as well as the integrity of the Scientific Committees.

Transparent use of evidence:

Process: Numerous memoranda exist to provide the SCs with guidance, and particularly relevant is the SCENIHR-produced *Memorandum on the use of the scientific literature for human health risk assessment purposes – weighing of evidence and expression of uncertainty*, which provides instructions on the identification and selection of relevant publications as well as how to weight the data appropriately.[63] According to DG SANCO, implementation is done by the working group members, but if evidence gathered later during a public consultation or call for evidence changes an opinion, that should also be documented.

Reality: Despite the guidelines, public interest groups interviewed complain of lack of transparency on how evidence is discussed and/or dismissed, while the treatment of additional stakeholder evidence varies greatly between SCs. Taking the four opinions studied as an example, SCCS does not publish feedback for any of its opinions, while SCHER and SCENIHR both provided detailed feedback for theirs (although not always satisfactory, according to some interviewees). This means in some cases stakeholders are left with little clue as to what evidence has been dismissed and why, as well as how evidence they submitted may have influenced an opinion or not. The parabens opinion remained the same after comments periods, while the titanium dioxide one changed nine months later with little indication as to how or why (both SCCS); the dental mercury

61 Rules of Procedure, point 14, p.5

62 Green Facts is a not-for-profit (although founded and funded by the Belgian chemical giant, Solvay, with continuing corporate funding) that is contracted by DG SANCO to translate the opinions, see **http://about.greenfacts.org**

63 SCHENIR, (2012), *Memorandum on the use of the scientific literature for human health risk assessment purposes – weighing of evidence and expression of uncertainty*, available at **http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_s_001.pdf**

and nanosilver investigations held stakeholder dialogues, and wrote up all contributions and their impacts (SCHER and SCENIHR respectively).

Analysis: Despite one scientist pointing out that the processes around transparency and access to documents have improved since 2008, the perceived lack of transparency from engaged public interest groups shows a disconnect between some within the Committees and those trying to engage with them. There is also an important distinction between superficial transparency, such as putting minutes online, and transparency which gives an indication of processes and the workings of the Scientific Committees, such as the selection and use of evidence – or the content of discussions in meetings, which are entirely absent from the minutes.

While clear criteria and rules exist around the collection and interpretation of evidence exist, the differing practices among Committees and individuals within them point once more to the importance of personalities and institutional cultures within the SCs. Regarding the collection and use of evidence, some scientists claim all peer-reviewed work is accepted (as does DG SANCO), while others say there are far stricter methodological standards (decided by the individual Committee). A weighting system for classifying evidence does in fact exist, but it is not made public. The guidelines also advise all evidence dismissed to still be included in the bibliography (marked as 'not judged to be necessary'),[64] but no opinion looked at for this study did so. Both of these increase the lack of transparency and therefore trust in the process.

According to one scientist, how evidence is treated is particularly contentious, not just between SCs but within them. The scientist made a distinction between the Committees, commenting on the 'old school' mentality within older groups, particularly the Scientific Committee for Consumer Safety (SCCS), something also brought up when discussing diversity of membership. There was a suggestion that this could also have serious implications for opinions themselves, as without transparency and the implementation of clear, consistent guidelines, it was claimed that working groups were able to cherry-pick evidence to show desired conclusions, a particular risk when many of the scientists come from similar disciplines and have worked together for a long time.[65] There was even a claim by one scientist that during a past revision of an opinion, evidence that contradicted the original finding was rejected. Such a culture could be one reason why a public interest group participating in the public consultation could find no trace of its evidence submitted to the titanium dioxide working group, despite being told the point raised had already been covered. A similar story was heard from groups working on dental amalgam. Yet this – as well as the frustration many public interest groups express at the responses they do get – points less to a failed policy and more to the domination of the SCs by a prevalent institutional culture, which chooses what is and isn't enforced and what evidence they should and shouldn't use.

Regarding what evidence is acceptable or not, the rule that all revised opinions must be based on new evidence doesn't just ensure the continuation of the current dominant culture within the SCs, (as mentioned under diversity), but it is a serious challenge for independence, excellence and transparency. It means there is no way to correct previous mistakes, or adjust for pro-industry bias that may have been held among previous members. Combined with comments by scientists on the big differences in how evidence is gathered, this could serve to undermine good scientific practice, as well as the integrity of SANCO and the Committees. Clearly rules do exist, and processes are in place, but the lack of transparency combined with a conservative institutional culture makes it difficult for public interest groups to trust the SCs' collection and use of evidence. Too much is left to individual scientists and Scientific Committees, which has meant that where best practice does exist, it has not been uniformly applied.

64 SCHENIR, (2012), *Memorandum on the use of the scientific literature for human health risk assessment purposes – weighing of evidence and expression of uncertainty*, available at **http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_s_001.pdf**

65 One interviewee serving within the committees commented on a dominant culture where group members were unwilling to accept some industrial chemicals as hazardous.

Conclusion

The four chemicals looked at in this report are highly controversial: they've been suspected of interfering with the body's hormonal system and cancer (parabens); causing damage to DNA and possibly cancer (nano titanium dioxide); affecting the nervous systems and brain development of the unborn child (dental mercury); and aiding the spread of 'super bugs' (nanosilver). Yet all four have been on the market for many years, widely used by some of the world's biggest corporations in hundreds of products, creating considerable revenues. Not correctly regulating them (what exposure levels are safe? Should they be banned?) could potentially cause great harm to human health and the environment; yet powerful commercial interests are at stake. So are the opinions behind the regulation of these potentially hazardous chemicals of the highest quality and free from industry influence? Many public interest groups have questioned this, while research by CEO and Horel (2013) on the European Commission's European Food Safety Authority (EFSA) has highlighted the close ties many members have with the industries they are supposed to be regulating.[66]

So how well does DG SANCO meet its own principle of independence? A narrow conflict of interest policy and insufficient resources allocated to screening and cross-checking have meant that two-thirds (67%) of the scientists looked at in this study were found to have financial ties to the same industries their risk assessments were helping to regulate. Scientists with links to Unilever, DuPont and GlaxoSmithKline were given the green light to serve on DG SANCO's Committees because it believes the risk of a conflict could be managed – despite a large body of academic research saying otherwise. The most common areas where conflicts of interest existed were advisory/consultancy roles, with more than half (54%) of all declared advisory/consultancy roles being linked to affected industries. Research funding was another area with a large number of conflicts.[67] Alongside the high number of industry advisory/consultancy roles, these findings point to the growing shift away from public- and towards privately-funded research, and seriously undermine the claims of independence within the Committees. However, that almost one third of scientists had no connection to relevant economic interests shows credible scientific advice is not a utopian ideal but a (threatened) reality – the 'management' of conflicts of interest, which DG SANCO's rules try and do, does not have to be the status quo.

How has SANCO lived up to the remaining two principles, excellence and transparency? Interviews with scientists (serving on the Committee and those following the issues), as well as public interest groups, complimented by desk research, have highlighted some worrying flaws in SANCO's processes. These include a perceived failure to attract a diverse and relevant range of scientific disciplines; shutting down of disagreement and divergence of opinions (by not allowing minority opinions when scientists draft opinions); a huge variation in the level and quality of stakeholder dialogues between the different Committees, as well as between working groups; inconsistent and non-transparent ways of collecting and using evidence. A recurring theme raised in the interviews was the dominant institutional culture within the Committees, which furthered the European Commission's pro-big business agenda. But by introducing the right processes and ensuring their implementation, DG SANCO could undoubtedly challenge this culture.

If DG SANCO's current policies around independence, excellence and transparency are to be credible, they are in serious need of review (see recommendations below). However, the question remains: do DG SANCO and the European Commission have the political will to do so?

66CEO & Horel (2013) *Unhappy Meal*, **http://corporateeurope.org/sites/default/files/attachments/unhappy_meal_report_23_10_2013.pdf**

67The percentage (28%) was relatively low, but the quantity (49 cases of research funding for a company linked to the remit of the Scientific Committees) was high.

Recommendations

These recommendations are the result of a civil society roundtable which took place in July 2014. After the original findings were presented to the group on the Scientific Committees' Independence, Excellence and Transparency principles, participants collectively formulated the proposals.

In the short-term, DG SANCO should:

Independence

* Create a broader definition of financial conflicts of interest which covers the remit of all three Scientific Committees, and a clear set of guidelines on how to apply them, effectively banning all conflicts of interest and not attempting to manage them;
* Outsource screening of all declarations to a suitable body to ensure independence and relieve the burden from the three-person secretariat;[68]
* Hold expert hearings within the working groups and committees to allow conflicted experts to still present their evidence, but not take part in drafting or decision making;

Excellence & Transparency

Expertise

* Publicise calls for expertise as widely and strategically as possible to scientists who are actively publishing peer-reviewed science.[69]
* Publicly consult on the relevant disciplines needed for each new mandate; if the necessary expertise cannot found within the scientific committees, the pool or the external database external experts should be sought;

Openness

* Publicly review all aspects of its stakeholder engagement processes to ensure it meets an agreed standard of excellence, with the aim of producing clear criteria and guidelines applied across all Scientific Committees; this should build on but not be limited to current best practices. A public consultation should be held as standard to gather feedback on the announcement of a new mandate and the questions that will guide the working group, alongside the proposed disciplines that will be sought.
* Ensure all SCs provide and publish responses to stakeholder comments, including rationale on inclusion/exclusion of provided evidence (implementation of best practice). To ensure stakeholders are aware of the progress of an opinion, a clear timeline should be detailed on the opinion website;

68 This could be carried out by the European Court of Auditors, but whoever took on the task would carry out proactive and random checks of declarations (for validity and omitted results). As this recommendation was also made to EFSA, this process could be centralised for all scientific bodies and agencies linked to the Commission.

69 For example in all relevant academic journals, contacting all relevant scientific institutions and announcing at all relevant conferences

Uncertainty

- Allow and publish minority opinions at working group level;
- Create a 'reader' and systematic terminology, in collaboration with the committees, to clearly and consistently describe levels of concern and uncertainty, including error margins, which allow the public to understand the risk of an opinion; this should also apply to areas where data is deemed inadequate or not suitable, rather than dismissing potential risks due to eg knowledge gaps/inconsistent methodology (using a precautionary approach to assessment, rather than no data equals no risk);
- Ensure minutes of meetings are descriptive enough to allow stakeholders and the public to understand what has been discussed in each meeting, including differences of opinion;

Evidence

- Publicly consult on the current criteria and practices of evidence collection, use and/or dismissal to ensure a shared understanding;[70] SANCO must then ensure that all SCs and working groups apply these criteria and guidelines, including disclosure and justification for why evidence is excluded;
- Allow working groups revising opinions to reconsider evidence that had been previously dismissed if they feel it is appropriate;

In the longer-term, DG SANCO should:

- Develop a strategy with national governments to increase the number of scientists from public universities and research institutions available for Scientific Committees;
- Develop and coordinate a strategy with other public bodies to fund conflict-free scientists to do risk assessments away from companies with commercial interests in the opinion at stake;
- Regularly review its processes and practices relating to stakeholder engagement to ensure continuous improvement and the uptake of best-practice not just in SANCO but across the Commission and its agencies.

70 As a minimum, only publicly published research should be considered as evidence by the committees.

Annex I: Declaration of Interest Methodology

The declared interests were assessed according to the overall remit of the Scientific Committees.

A cooling-off period of five years was set for all past activities, similar to DG SANCO's independence policy. We have considered that the Scientific Committees' policy to submit family members to the same rules as the scientists is excessive and therefore decided to not take those into account. When an interest was connected to the commercial sector (ie linked to industries under the Scientific Committee's remit), the following criteria were applied according to the interest type defined by DG SANCO:[71]

I. Economic interest

* Under Scientific Committee's remit: COI
* Investment funds: COI
* Shares in sectors not under Scientific Committee's remit: no COI

II. Member of a management body

* COI

Exceptions: consumer's associations, National or Royal academies, national or intergovernmental organisation with a public mandate.

III. Member of a scientific advisory body

* COI

Exceptions: consumer's associations, National or Royal academies, national or intergovernmental organisation with a public mandate.

IV. Employment

* Commercial entity with exclusively government, state or academic clients: no COI
* Commercial entity: COI
* Public agencies or institutions providing paid services to commercial entities and/or with substantial financial links with the commercial sector: COI

V. Consultancy

* Consultancy contract with a commercial entity, on a personal capacity or on behalf of employer: COI

Exceptions: consumer's associations, National or Royal academies, national or intergovernmental organisation with a public mandate.

VI. Research funding

* Research funding from the commercial sector
  - Research funding (personal or institutional, in the case of the employer) from the commercial sector: COI
  - Research funding (personal or institutional, in the case of the employer) from the commercial sector coming through a public body: COI
  - Research funding (personal or institutional, in the case of the employer) from non-profit entities financed by the commercial sector: COI

* European Framework Programme for Research (FP) projects
  - Consortium including minor commercial partners: no COI
  - Consortium including several commercial partners or at least one major commercial partner (multinational firm, trade association, lobby group, industry front group, industry-funded organisation, pseudo- institute of a multinational firm): COI

71 These criteria were based on the CEO & Horel (2013) report on the European Food Safety Authority, (EFSA), and adapted to fit the Scientific Committees as SANCO did not provide guidance on what did and did not constitute a conflict of interest.

Other elements were taken into account such as the topic and aim of the project, the role of the expert (coordinator, member of the advisory board etc), the relative number of commercial partners, the proportion of the EU's contribution on the total cost.

* PhDs financed by the commercial sector: COI

VII. Intellectual property rights relevant to Scientific Committee's remit

* COI

VIII and IX. Other membership, affiliation or relevant interests

We have introduced more specific categories within these 'miscellaneous' categories:

* Conferences, congresses, workshops etc.
  - Invited speaker at industry or industry-sponsored conferences: COI
  - Attending industry or industry-sponsored conferences, all expenses paid: COI
  - Attending industry or industry-sponsored conferences, no expenses paid: no COI

* Member of professional associations (order of ….): no COI

* Member of industry-funded non-profit organisations (not a scientific society): COI

* Scientific societies
  - Member of a society sponsored by industry and/or organising industry-sponsored conferences: no COI
  - Responsibilities in scientific societies sponsored by industry and/or organising industry-sponsored conferences: COI
  - Membership or responsibilities in a society with a majority of corporate members and/or a majority of industry employees in the management bodies: COI

* Scientific journals
  - Editor-in-chief or member of the Editorial Board of a journal owned by a society sponsored by industry and/or organising industry-sponsored conferences: COI
  - Editor-in-chief or member of the Editorial Board of a journal owned by a society with a majority of corporate members and/or a majority of industry employees in the management bodies: COI

CEO

Corporate Europe Observatory (CEO) is a research and campaign group working to expose and challenge the privileged access and influence enjoyed by corporations and their lobby groups in EU policy making.

This corporate capture of EU decision-making leads to policies that exacerbate social injustice and accelerate environmental destruction across the world. Rolling back corporate power and exposing greenwash are crucial in order to truly address global problems including poverty, climate change, social injustice, hunger and environmental degradation. Corporate Europe Observatory works in close alliance with public interest groups and social movements in and outside Europe to develop alternatives to the dominance of corporate power.