Committee: Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

13 scientists were appointed as members. Three scientists resigned from the Committee during the term of office.

Background of members in general

One member was employed by a national health institute, 7 members were associated with universities/research institutes, of which one was also working as a clinician, and 2 members had retired from research institutions. Expertise covered included Epidemiology, Toxicology, Public Health, Physics, Microbiology, Medicine (Transfusion Medicine, Immunology), Biomaterials, Tissue Engineering, and Cell Biology.

Areas covered

According to its general mandate, the SCENIHR provided opinions on questions concerning emerging or newly identified risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk assessment bodies.

Examples of potential areas of activity included potential risks associated with interaction of risk factors, synergic effects, cumulative effects, antimicrobial resistance, new technologies such as nanotechnologies, medical devices including those incorporating substances of animal and/or human origin, tissue engineering, blood products, fertility reduction, cancer of endocrine organs, physical hazards such as noise and electromagnetic fields (from mobile phones, transmitters and electronically controlled home environments), and methodologies for assessing new risks.

Furthermore, in line with Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment, "the Scientific Committees shall draw the Commission's attention to a specific or emerging problem falling within their remit, which they consider may pose an actual or potential risk to consumer safety, public health or the environment…." (Article 2.4)

Number of opinions

During its mandate from September 2004 to January 2009, the SCENIHR adopted 18 opinions, and one position paper.

The focus of the work of SCENIHR was on Nanotechnologies (4 opinions), biological hazards (3 opinions – human-derived products and variant Creutzfeldt Jacob disease, human blood/organs and West Nile Virus, BSE risks from cosmetic ingredients), Antimicrobial resistance (2, one of which was developed and adopted jointly with SCHER), physical hazards (4 opinions - EMF (2), personal music players, energy-efficient light bulbs) and Medical Devices (2 opinions - dental restoration materials (1), plasticizers (1)). Further work was carried out on smokeless tobacco products.

Two opinions were jointly adopted with SCCP and SCHER: One concerned the Threshold of Toxicological Concern (TTC) and the other was on the methodologies for genotoxic and carcinogenic substances.

Finally, the SCENIHR wrote a position paper on emerging issues.

Members of the SCENIHR were also involved in the WG of the SCHER and SCCP and in work carried out jointly with other institutions (e.g. EFSA - Assessment of the possible effect of the four antimicrobial treatment substances on the emergence of antimicrobial resistance, Scientific Opinion of the Panel on Biological Hazards (Question No EFSA-Q-2007-203), adopted on 6 March 2008, The EFSA Journal (2008) 659, 1-26).

Number of meetings

In 2004: 5
In 2005: 22
In 2006: 42
In 2007: 49
In 2008: 52
In 2009: 5

Total: 175 meetings

Clients in the European Commission

The SCENIHR developed its opinions upon request of Commission services.

Biocides:
1 mandate was issued by DG ENV B3 (Biotechnology, Pesticides and Health) after consultation with various services in ENTR, SANCO and the JRC

Medical Devices (Dental Amalgam, DEHP, BSE in cosmetics):
3 mandates were issued by DG ENTR, Unit F3 (Cosmetics and Medical Devices)

Light sensitivity:
1 mandate was issued by DG TREN, Unit D3 (Energy efficiency of products & Intelligent Energy – Europe)

Personal Music Players:
1 mandate was issued jointly by DG ENTR I4 (Mechanical, Electrical and Telecom Equipment) and DG SANCO, Unit B3 (Product and Service Safety)

Nanotechnology, EMF:
2 mandates were issued by DG SANCO C7 (Risk Assessment)

Poultry carcasses
1 mandate was issued by DG SANCO, Unit E2 (Food Hygiene, Alert System and Training)

Smokeless tobacco, West Nile Virus, variant Creutzfeldt Jacob disease

3 mandates were issued by DG SANCO, Unit C6 (Health Law and International)

EMF (first mandate):
1 mandate was issued by DG SANCO, Unit C2 (Health Information)

Nanotechnology:
1 mandate was issued jointly by ENTR G2 and ENV D1 (4th mandate)
1 mandate was issued by ENV D1 (2nd mandate)
1 mandate was issued jointly by SANCO C7 and other services (ENTR, RTD, ENV and EMPL) (1st mandate)

The two joint mandates with SCHER and SCCP were issued by SANCO C7.

The position paper was developed upon the own initiative of the SCENIHR.

Budget [1]

SCENIHR	**Special indemnities**	**Travel + per-diem**	**TOTAL**
2004	12.900 €	26.874 €	
2005	69.800 €	106.351 €	
2006	105.150 €	174.940 €	
2007	106.800 €	186.823 €	
2008	86.250 €	202.311 €	
2009	11.400 €	11.302 €	
Total :	***392.300 €***	***708.601 €***	**1.100.901 €**

ICCG	**Special indemnities**	**Travel + per-diem**	**TOTAL**
2004	3.600 €	5.604 €	
2005	11.800 €	34.060 €	
2006	11.700 €	24.907 €	
2007	17.400 €	29.287 €	
2008	27.900 €	57.202 €	
2009	3.900 €	13.958 €	
Total :	***76.300 €***	***165.018 €***	**241.318 €**

[1] The figures for 2009 cover the first two months only

Layman versions

Layman versions were produced of the SCENIHR opinions on 'The safety of dental amalgam and alternative dental restoration materials for patients and users', 'The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies', 'Potential health risks of exposure to noise from personal music players and mobile phones including a music playing function' and on 'Possible effects of Electromagnetic Fields (EMF) on Human Health'.

Furthermore, additional layman versions are currently in process for the following opinions: 'Health Effects of Exposure to EMF', 'Light Sensitivity' and 'Assessment of the Antibiotic Resistance Effects of Biocides'.

Policy follow-up of opinions (examples)

Dental Amalgam
After considering the SCENIHR opinion on the safety of dental amalgam and alternatives, the Commission decided to maintain the use of dental amalgam for the time being. A meeting with stakeholders was organised by C7 to discuss and clarify scientific issues in relation to the two opinions delivered by SCENIHR and SCHER (see below).

di(2-ethylhexyl)phthalate (DEHP)
The opinion was very important in helping the Commission to take appropriate measures to ensure the safety of patients, such as the labelling requirement for products containing such materials.

Light Sensitivity
The Commission services requesting the opinion presented a detailed explanation on the current and foreseen regulatory steps that the Commission plans to take regarding the phase-out of incandescent lamps on the European market to SCENIHR. These measures were to take the recommendations of SCENIHR into account.

Personal Music Players
The Commission took note of the concerns that the opinion raises. In this context the opinion was presented to the Member States and a conference took place on 27 January 2009. In this meeting, including Member States, industry, consumer organisations, Members of the European Parliament and other stakeholders, examined the way forward and evaluated various policy options. A member of the working group presented the opinion. Furthermore, there was wide media coverage of the opinion which helped to alert both industry and consumers to the issue.

Biocides
The conclusions of the opinion were to be considered in the revision of the Biocides Directive (98/8/EC).

Smokeless Tobacco Products
The opinion was presented to the Tobacco Products Regulatory Committee on 16 April 2008.

Nanotechnology

- International collaboration on risk assessment and guidelines: SCENIHR opinions helped launch the Working Party on Nanomaterials (WPNM) under the OECD. Specifically, the conclusions of the first SCENIHR opinion on nanotechnology provided elements critical to taking the decision to establish the WPNM at the historical OECD workshop on the Safety of Manufactured Nanomaterials in Silver Springs, MD, on 7-9 December 2005. SCENIHR is unique in the world in producing periodic scientific opinions on the assessments of the risk of nanomaterials.
- Community research priorities: SCENIHR opinions contributed to identifying Framework Program priorities.
- EU legislation: the SCENIHR opinions on risk assessment methods, on definitions, and on products of nanotechnology had a significant impact in informing current discussions on regulation and policy.

EMF

The outcome of the two opinions delivered was considered in the discussions on the need to revise the Council Recommendation 1999/519/EC. Furthermore, research needs identified were to be discussed with relevant services in RTD, ensuring appropriate consideration and funding in the framework programme.

Workshops, conferences, public hearings, other important meetings outside the committee meetings, Major EC-meetings on SCENIHR-issues, involving SCENIHR-members

Dental amalgam - Meeting with stakeholders, Brussels, 20 January 2009

Following a request from stakeholders, certain concerns regarding the scientific opinions on Dental Amalgam were discussed in a meeting including members of SCENIHR and SCHER. An invitation to this meeting was sent out after the expression of interest from stakeholders. No public announcement was made. The outcome of the meeting was compiled in a short report that will be presented to the new Scientific Committees. In particular, the issue of better communication of the work and structure of the Committees should be further elaborated, in order to avoid misunderstandings in the future. Finally, it was pointed out that collaboration with ENTR and ENV would always be / was always possible in case these services would like to investigate this issue further.

Major EC-meetings on SCENIHR-issues and involvement of SCENIHR-members:

Nanotechnologies
Safety for Success Dialogue Meetings in 2007 and 2008
http://ec.europa.eu/health/ph_risk/ev_20081002_en.htm
http://ec.europa.eu/health/ph_risk/ev_20071025_en.htm

Workshop on EMF and Health: Science and Policy to address public concerns,
Brussels, 11-12 February 2009
http://ec.europa.eu/health/ph_risk/ev_20090211_en.htm

Global Risk Assessment Dialogue, Brussels, 13-14 November 2008
http://ec.europa.eu/health/ph_risk/ev_20081113_en.htm
(included a Discussion Group on Emerging Issues)

Annual Meetings of the Chairs and Secretariats of Commission and Agency Scientific Committees and Panels involved in risk assessment (4 meetings since 2005)
http://ec.europa.eu/health/ph_risk/ev_20081104_en.htm
http://ec.europa.eu/health/ph_risk/ev_20071106_en.htm
http://ec.europa.eu/health/ph_risk/committees/ev_20061024_en.htm
http://ec.europa.eu/health/ph_risk/committees/ev_20051207_en.htm
(including discussion on nanotechnologies and emerging issues)
Establishment of a Discussion Group on Emerging Issues as related activity of these meetings

Risk Assessment Days in 2007 and 2008:
http://ec.europa.eu/health/ph_risk/ev_20080624_en.htm
http://ec.europa.eu/health/ph_risk/risk_days_en.htm

For a link to all events see:
http://ec.europa.eu/health/ph_risk/events_risk_en.htm

Committee: Scientific Committee on Consumer Products (SCCP)

19 scientists were appointed as a member of the SCCP. Three experts resigned from the Committee during the term of office.

Background of members in general

8 Members are employed by national health institutes, 6 members are associated with universities and 1 member works as an independent consultant.

Areas covered

According to its general mandate, the SCCP provides opinions on questions concerning the safety of consumer products (non-food products intended for the consumer). In particular, it shall address questions in relation to the safety and allergenic properties of cosmetic products and ingredients with respect to their impact on consumer health, toys, textiles, clothing, personal care products, and domestic products such as detergents and consumer services such as tattooing.

In practice, as a result of the legal requirement to consult the SCCP before updating the Annexes of the Cosmetics Directive 76/768/EEC to technical progress, the large majority of requests to the SCCP concerned the safety of chemicals used as ingredients in cosmetic products.

Number of opinions

During its mandate from September 2004 to January 2009, the SCCP adopted **180 opinions**, guidance documents, memoranda and position statements.

Out of these 180 documents, 178 were related to cosmetic products. Only 2 opinions concerned other consumer products (sun beds and nitrosamines in rubber balloons).

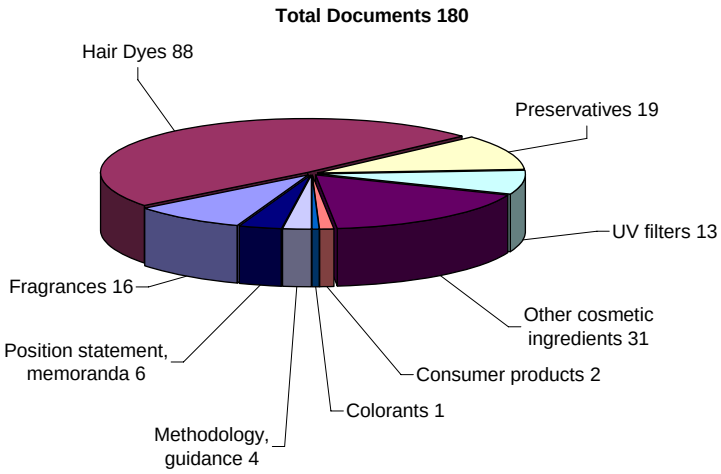
In addition to opinions and technical advice which were developed on request from other services, the SCCP issued two guidance documents, most notably a major update of the Notes of Guidance for applicants, as well as six memoranda and position statements.

Table 1 lists all opinions split up per category and per year.

Year	Colorants	Fragrances	Hair Dyes	Preservatives	UV filters	Other substances	Consumer products	Methodology, guidance	Total opinions	position statements, memoranda etc	Total documents
2004	-	2	2	1	-	3	-	-	**8**	-	**8**
2005	1	5	11	7	1	9	-	-	**34**	1	**35**
2006	-	6	28	5	6	4	1	3	**53**	2	**55**
2007	-	1	22	1	1	6	1	-	**32**	2	**34**
2008	-	2	23	2	3	8	-	-	**38**	-	**38**
2009	-	-	2	3	2	1	-	1	**9**	1	**10**
Total	**1**	**16**	**88**	**19**	**13**	**31**	**2**	**4**	**174**	**6**	**180**

Table 1: overview of opinions

The chart below gives an overview of the number of SCCP opinions on different categories of cosmetic ingredients and other consumer products.



Hair Dye evaluations under the European Hair Dye Strategy

Following reports that hinted to a link between the use of hair dyes and certain cancer types (bladder cancer, leukaemia), and a recommendation of the SCCNFP, the Commission developed a strategy to review and regulate all hair dye substances on the European market. This involved submission of updated safety information for these substances and evaluation by the Scientific Committee. After the submission deadlines data for 117 hair dyes had been submitted.

The SCCP started the review of the submitted safety files in 2004 and delivered a total of 88 opinions on hair dye substances in its term of office. These include full evaluations, assessments of additional data provided and opinions on reaction products of oxidative hair dyes.

At the end of term of the SCCP in January 2009, 50 hair dye ingredients have been finally assessed as safe, 5 were considered to pose a risk to the consumer. Of the initial evaluations, 25 could not be finalised since the SCCP considered the data submitted insufficient and requested additional information or studies. For 7 of the ingredients concerned, the requested data has been already provided and awaits further assessment, while for 18, a further submission is pending. Including some new submission that were made on hair dyes developed since the start of the hair dye strategy, altogether 40 hair dyes remain to be assessed.

Number of meetings

In 2004: 8
In 2005: 30
In 2006: 34
In 2007: 41
In 2008: 33
In 2009: 3

Total: 149 meetings

Clients in the European Commission:

The SCCP develops its opinions upon a mandate from other Commission services.

170 mandates were issued by DG ENTR, Unit F3 – Cosmetics and Medical Devices
1 mandate was issued by DG ENTR, Unit I4 - Mechanical, Electrical and Telecom Equipment
1 mandate was issued by DG SANCO, Unit B3 – Product and Service Safety

Six position statements and Memoranda as well as two guidance documents were adopted upon the own initiative of the SCCP.

Budget[2]

SCCP	Special indemnities	Travel + per-diem	TOTAL
2004	29.700 €	54.471 €	
2005	85.950 €	150.317 €	
2006	104.550 €	154.588 €	
2007	109.950 €	181.914 €	
2008	105.000 €	180.920 €	
2009	9.600 €	15.794 €	
Total :	***444.750 €***	***738.004 €***	**1.182.754 €**

[2] The figures for 2009 cover the first two months only

Layman versions

Layman versions were produced of two SCCP opinions:

- Biological effects of ultraviolet radiation relevant to health with particular reference to sun beds for cosmetic purposes
http://ec.europa.eu/health/opinions2/en/sunbeds/index.htm

-Hydrogen peroxide, in its free form or when released, in oral hygiene products and tooth whitening products
http://ec.europa.eu/health/opinions/en/tooth-whiteners/index.htm

Policy follow-up of opinions (examples)

Sun beds

The Low Voltage Directive (LVD) 73/23/EEC which is applicable to sun beds, follows the New Approach to technical harmonisation, meaning that European standards bodies draw up technical specifications which offer manufacturers a mean to comply with essential requirements for their products. Following the SCCP opinion, the European Commission initiated a revision of the harmonised standards for sun beds, which should take the SCCP recommendation into account. To already protect consumers during this ongoing process, Member States have agreed to already introduce the irradiance limit recommended by SCCP at the national level.

Hair dye assessments

So far, 176 hair dye substances have been included in Annex II of the Cosmetics Directive (including the 20 banned before the start of the strategy). 25 substances with hair dyeing properties without updated safety file have not been banned yet since they are also used as colorants in cosmetics or in food.
Of the hair dyes already assessed by the SCCP, 17 that have received a positive evaluation were proposed for regulation in Annex III, part 1. The respective directive was published in the OJ on 16 April 2009.

Cosmetic ingredients

Numerous evaluations of cosmetic ingredients made by SCCS have been implemented as technical adaptations of the Annexes of the Cosmetics Directive 76/768/EEC.

Hearings

Hearing on Parabens

Different parabens (methyl-, ethyl-, butyl-, propylparabene) are widely used as preservatives in cosmetic products. While the SCCP had evaluated methyl- and ethylparabene as safe, some study results on butyl- and propylparabene had been a matter of extensive discussion during the evaluation process. To identify a way forward and a strategy to come a final assessment of these substances, the Commission and the SCCP organised a hearing on 23 October 2007. Three parties expressed interest after the publication of the announcement and were invited to the meeting. The available scientific data, their shortcomings and additional research that could support the safe use of the substances were discussed during the meeting.

This meeting, together with material submitted subsequently, formed the basis of the SCCP opinion on parabens of 24 June 2008, discussing the Industry proposal for further research and giving additional recommendations.

Committee: Scientific Committee on Health and Environmental Risks (SCHER)

Background of members in general

17 scientists were appointed as members. Seven members are employed by a national health institutes, 9 members are associated with universities/research institutes, and 1 member has retired from research institutions. Current expertise covered includes Epidemiology, Toxicology, Public Health, Ecology, Ecotoxicology, Chemistry, Biochemistry, Modelling, and *in vitro* and *in vivo* Testing.

Areas covered

Chemical risk assessment, public health, waste, environmental contaminants, drinking water, indoor and ambient air quality, animal testing and alternative methods, detergents, methodologies in risk assessment

According to its general mandate, SCHER provided opinions on questions concerning the toxicity and ecotoxicity of chemicals, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. In particular, the Committee addressed questions in relation to chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, drinking water, and air quality.

Furthermore, in line with Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment, "the Scientific Committees shall draw the Commission's attention to a specific or emerging problem falling within their remit, which they consider may pose an actual or potential risk to consumer safety, public health or the environment…." (Article 2.4)

In practice, the focus of the work of SCHER was on Risk Assessment Reports on existing chemicals under Regulation 793/93/EC (86 opinions), risk assessment (10 opinions – Detergents (4), cadmium in fertilizers, organotin compounds, mercury in dental amalgam, organic chemicals in toys, antifouling paints used on boats, and phthalates in school supplies), chemicals in products (dichloromethane in paint strippers), specific environmental issues (perfluoroctane sulfonate), ISO standard (ISO 10708), air quality (3 opinions – indoor air quality, air pollution, and air fresheners), non-animal testing (2 opinions – endocrine disruptors and non animal testing, and use on non-human primates in research), biological risks (antimicrobial resistance). Further work was carried out on research priorities for the 7th Framework Program (1 opinion).

Moreover, two opinions were jointly adopted with SCCP and SCENIHR. One opinion was on the Threshold of Toxicological Concern (TTC) and one on the methodologies for genotoxic and carcinogenic substances.

Number of opinions: During its mandate from September 2004 to January 2009, SCHER adopted 108 opinions

Number of meetings:

In 2004: 6
In 2005: 23
In 2006: 30
In 2007: 34
In 2008: 38
In 2009: 6

Total: 137 meetings

Clients in the European Commission: DG SANCO, DG ENTR, DG ENV, DG RTD

SCHER developed its opinions upon request of Commission services.

- Mandates issued by DG ENV:
Unit D1 – Chemicals: 86 mandates on Regulation 793/93 (existing substances), and 2 on non animal testing
Unit C4 – Industrial emission & protection of ozone layer: 1 mandate on air pollution
Unit G2 – Environment and industry: 1 mandate on mercury in dental amalgam

- Mandates issued by DG SANCO:
Unit C4 – Health determinants: 1 mandate on indoor air quality
Unit B3 – Products and services safety: 1 mandate on air fresheners, 1 on phthalates in school supplies
Unit E3 - Chemicals, contaminants, pesticides: 1 mandate on organotins
Unit C7 – Risk assessment: 1 mandate on threshold of toxicological concern and 1 on genotoxic and carcinogenic substances
Unit E2 - Food hygiene, alert system and training: 1 mandate on antimicrobial resistance

- Mandates issued by DG ENTR:
Unit G2 – Chemicals: 4 mandates on detergents, 1 on antifouling, 1 on paint strippers, 1 on perfluoroctane sulfonate, 1 on cadmium in fertilizers, and 1 on ISO standards
Unit I/2 - International regulatory agreements, toys safety, CSR: 1 mandate on organic chemicals in toys

- Mandates issued by DG RTD
Unit I5 - Climate change and environmental risks 1 mandate on Research priorities for the 7th Framework Program

Budget:[3]

SCHER	Special indemnities	Travel + per-diem	TOTAL
2004	17.700 €	43.639 €	
2005	54.750 €	113.074 €	
2006	76.800 €	157.433 €	
2007	75.150 €	113.487 €	
2008	100.950 €	182.349 €	
2009	16.350 €	29.360 €	
Total :	***341.700 €***	***639.342 €***	**981.042 €**

Layman versions

Layman versions were produced of the SCHER opinions on dental amalgam and on indoor air quality.

Policy follow-up of opinions (examples)

Existing Substances
Risk reduction measures or restrictions on the marketing and use of several substances were decided on the basis of the outcome of several SCHER opinions on the Risk Assessment Reports under Regulation 793/93-existing substances

Perfluorooctane sulfonates (PFOS)
After considering the SCHER opinion on the risk reduction strategy and analysis of advantages and drawbacks of PFOS, the Commission decided to apply restrictions on the marketing and use of PFOS (Directive 2006/122)

Dichloromethane (DCM) in paint strippers
The opinion was used by the Commission to propose appropriate measures for restrictions on the marketing and use of DMC in paint strippers (COM(2008) 80)

Organostannic compounds
Following the outcome of the SCHER opinion on Organostannic compound the Commission has made a proposal for a decision on restrictions on the marketing and use of these compounds. The proposal is at present under discussion in the European Parliament.

Public Hearing on the use of non human primates on 6 November 2008

The Commission and SCHER organised a hearing on the draft opinion on the use of non human primates in biomedical research, production and testing of products and devices. Forty-eight representatives of various stakeholders, including academia, NGOs, industry, and governmental institutions participated in the meeting. The outcome of the discussion together with material submitted subsequently, were considered in the final opinion.

[3] The figures for 2009 cover the first two months only

Dental amalgam - Meeting with stakeholders, Brussels, 20 January 2009 (see SCENIR report)

EC meetings and involvement of SCHER members:

Global Risk Assessment Dialogue, Brussels, 13-14 November 2008
http://ec.europa.eu/health/ph_risk/ev_20081113_en.htm

Annual Meetings of the Chairs and Secretariats of Commission and Agency Scientific Committees and Panels involved in risk assessment (4 meetings since 2005)
http://ec.europa.eu/health/ph_risk/ev_20081104_en.htm
http://ec.europa.eu/health/ph_risk/ev_20071106_en.htm
http://ec.europa.eu/health/ph_risk/committees/ev_20061024_en.htm
http://ec.europa.eu/health/ph_risk/committees/ev_20051207_en.htm

Risk Assessment Days in 2007 and 2008:
http://ec.europa.eu/health/ph_risk/ev_20080624_en.htm
http://ec.europa.eu/health/ph_risk/risk_days_en.htm

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In general:

Payments: All payments to the members were made for the period 2004-2009. The average number of days from meeting to payment was e.g. 27 days for the period October-December 2008.