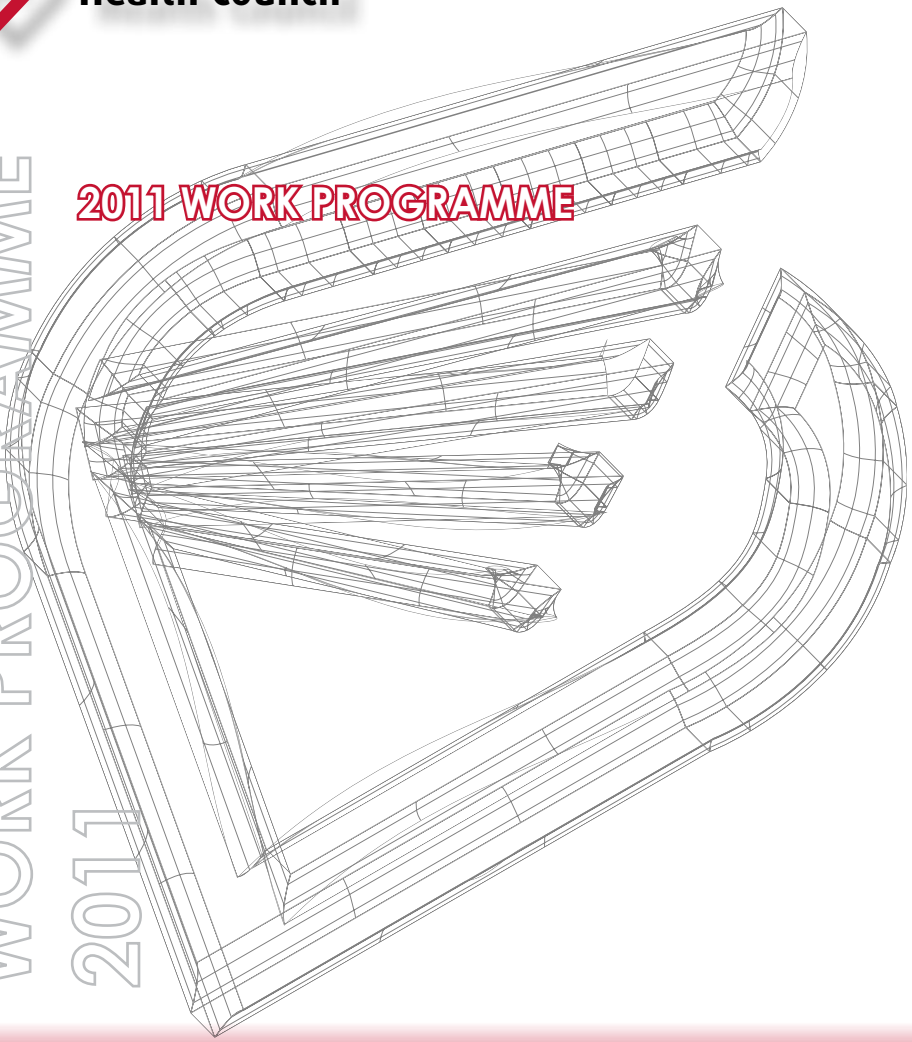
Superior
Health Council

2011 WORK PROGRAMME



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Federal Public Service Health, Food Chain Safety and Environment

Superior Health Council
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INTRODUCTORY

The 2011 work programme offers a survey of the activities that will be undertaken by the Superior Health Council (SHC) over the period extending from 1 January to 31 December 2011. The first ten chapters focus on the various dossiers for each of the specific fields of activity of the SHC, viz.

1. mental health and psychosocial factors;
2. physical environmental factors (ionising radiation, non-ionising radiation);
3. chemical agents;
4. nutrition and health, including food safety (NHFS) and food microbiology;
5. blood and blood products;
6. cells, tissues and organs of human and animal origin;
7. vaccination, infectiology and infection control during care;
8. cosmetology and cosmetic devices, including cosmetic surgery;
9. Public Health Genomics (PHG);
10. miscellanea and multidisciplinary groups.

Chapter 11 will be devoted to taking stock of the ongoing co-operation at the national and international level.

11. national and international co-operation (EUSANH, EFSA, etc).

Finally, chapter 12 will provide, for each field of activity, the main contact information of the internal scientific staff in charge of the requests for advice or projects that are carried out on the SHC's own initiative.

12. national and international co-operation (EUSANH, EFSA, etc).

The activities mentioned in these ten fields of activity can be subdivided into three categories, viz.

- "**Ongoing activities**": projects which are expected to be finalised in 2011 or 2012;
- "**Ongoing permanent activities**": recurring activities of the SHC;
- "**Planned projects**": new projects that the SHC is planning on its own initiative;
- "**Ideas in the pipeline**": project ideas to assess.

The "ongoing activities" concern dossiers which are already being treated and will continue to be dealt with or will be finalised during 2011. This concerns both requested advisory reports (select or confidential advisory reports) and advisory reports issued on the SHC's own initiative (projects) which were initiated before January 1st, 2011. It will be possible to finalise several of these activities before the end of the programme period. As a result, there will be time created for the

"**planned projects**". However, it is not always possible to foresee when the SHC can start working on the projects which it carries out on its own initiative, as it may have to deal with other priorities first or it may receive new requests for advice which are both unexpected and urgent. There may, therefore, be some changes in the priorities and deadlines for publication during this period, in close consultation with the competent authorities. The "**ongoing permanent activities**" describe the recurring activities of the SHC. They sometimes result in an advisory report within the period under discussion, but this is not systematically the case. What is meant here are a number of requests or recurring activities such as "Novel Foods", requests for substantial equivalence, second-line biocide dossiers, food supplements, vaccination programmes, etc. In addition, there is, for each field of activity, a think-tank whose purpose it is to concentrate now and again on the public health issues that we have (or will have) to deal with. The activities of these think-tanks also belong to this category. The chapter entitled "**ideas in the pipeline**" contains proposals for projects that have either not been assessed yet in terms of their feasibility and relevance or which do not constitute a priority for the time being.

1. MENTAL HEALTH AND PSYCHOSOCIAL FACTORS

In the field of mental health, the working groups issue advisory reports, recommendations or reports on health issues that are, wholly or partially, related to the behaviour of individuals, groups or the organisation of life in society (psychosocial factors).
The working groups especially focus on:

- high-risk behaviour related to addictions caused by substance abuse (alcohol, tobacco and drugs) and addictions linked to specific behaviours (pathological gambling);
- psychosocial factors which cause, prolong or worsen health problems;
- the quality of human relations, especially in healthcare;
- the training of health professionals in these matters.

"Ongoing activities": confidential and/or select advisory reports - projects

SHC 8155* – *Project concerning the prescription of psychotropic medicines for stress, anxiety, sleeping disorders and depression
This project aims at analysing the use of psychotropic medicines in Belgium, drawing scientifically founded conclusions and making relevant recommendations. Two publications are planned, one dealing with the treatment of depressions and the other with how to tackle anxiety disorders.

➤ Start 01/2006 – End 03/2011 - Contact: Sylvie GERARD

SHC 8570* – *Project regarding the prescription and use of Rilatine and related medication and on monitoring the patients concerned
Over the last few years, there has been a marked increase in the sale of Rilatine pills in Belgium. This dramatic increase raises questions about the dangers of this medicine. This advisory report will inform the public about such harmful effects as the risk of cardiovascular diseases and brain damage. Also, it will proffer new recommendations on prescribing these pills, and above all, on long-term follow-up (consequences for the psychomotor development of young people, etc.). The advisory report will also try to specify what diagnoses require the use of Rilatine.

➤ Start 06/2009 – End 03/2011 – Contact: Sylvie GERARD

SHC 8571* – *Project concerning the impact of benzodiazepines on health in general, with a particular focus on dementia
The short term effects of benzodiazepines are relatively well-documented, but little is known about the influence of such prescriptions on health. This is all the more

important as benzodiazepines are sometimes prescribed outside well-defined pathologies. More precisely, the emphasis should be on the cognitive and physical functioning of the elderly and on the prevalence of dementia in this consumer target group. As a matter of fact, there is scientific evidence that this medicine has a harmful effect on psychomotor abilities. The GPs' attention needs to be drawn to the possibly rather hasty lumping together of dementia with the effects of benzodiazepines. The interactions with neuroleptics and antidepressants are a frequent phenomenon and worsen the problems related to Alzheimer's disease.

➤ Start 06/2009 – End 02/2011 - Contact: Anne-Madeleine PIRONNET

SHC 8581* – *Project on pathologies that become chronic

It is now becoming clear in both mental healthcare as well as in somatic medicine that certain pathologies (depressions, addictions, etc.) become chronic, which process, after some time, results in the therapeutic means available being extremely limited. This advisory report will attempt to issue recommendations aimed at identifying symptoms of the chronification process that are either more closely related to the pathology or, on the contrary, that result from the lack of early psychosocial interventions. This should help as a guideline to measures taken in the area of public health.

➤ Start 01/2011 – End 2012- Contact: Sylvie GERARD

"Ongoing permanent activities": confidential and/or select advisory reports

As this work programme is being drawn up, it is difficult to predict what requests we may expect in the area of mental health and psychosocial factors in 2011. Still, there has been a standing think-tank set up to follow-up on this issue.

"Planned projects": new planned projects

Antipsychotics and the elderly

The work on this project is to start as soon as that on project No. 8571 on benzodiazepines in public health has been completed.

Violence against children

With this advisory report, the SHC intends to find out what are the effects of ill-treatment during childhood on teenagers.

The work on this project is expected to start as soon as that on project No. 8570 on Rilatine has been completed.

"Ideas in the pipeline": project ideas to assess

- What are the protective and disturbing factors (including contextual factors) that allow for the creation of long-term well-being (from childhood to old age)?

- Treatment programmes in mental healthcare: Bipolar disorders, eating disorders, addictions, schizophrenia, etc.

- Project "time spent in front of screens"

2. PHYSICAL ENVIRONMENTAL FACTORS

The task of the working groups in the physical agents area consists in issuing advisory reports and recommendations aimed at assessing the health risks associated with various physical agents and their applications. They also evaluate those measures which aim at maximally restricting the exposure of Man and the environment to radiation. The area is subdivided in two important sub-areas: ionising radiation and non-ionising radiation.

2A. Ionising radiation

"Ongoing activities": confidential and/or select advisory reports - projects

SHC 8277* – *Project aimed at informing and protecting the general public and staff directly or indirectly involved in nuclear medicine against radiation
This project aims at providing relevant information in order to make certain aspects of nuclear medicine less awesome and to draw attention to such important issues as its justification and the protection of individuals. It is targeted at non-nuclear medicine specialists as well as the nursing staff and patients.

➤ Start 11/2006 – End 06/2011 – Contact: Katty CAUWERTS

SHC 8322* – *Project concerning Intensity Modulated Radiation Therapy (IMRT)
Present-day radiation therapy technology makes use of highly technological radiation equipment that attempts to increase considerably the radiation dose applied to a limited target volume. In some IMRT technologies, as well as in flat beam technology, there is the problem of secondary patient doses which may spread to the whole body and need to be assessed. Other technologies result in the dose limits being concentrated outside the target volume (cf. some IMRT technologies for lung tumours). It is possible to start from a comparison of IMRT technologies with other technologies which still have to be validated. They include hadron therapy, modern photon therapies (stereotactic radiotherapy, 4D radiotherapy, etc.). Especially worth mentioning are the results of the workshop organised by the Belgian association for radiation protection in late 2006 – 2007, which dealt with the patient dose outside the target volume. The impact of tomographic imaging plays a key role in this.

➤ Start 03/2007 – End 2012 – Contact: Katty CAUWERTS

SHC 8650* – *Inquiry into the justification for the use of body scanners
Security body scanners are increasingly being used throughout the world in order to ensure air travel safety. The Federal Agency for Nuclear Control (FANC) therefore requests the advice of the SHC on the use of this technology as well as the risks

involved, not only in the area of air travel safety, but also in other areas of security, e.g. the entrances to buildings, admittance to events, etc.

➤ Start 02/2010 – End 2012 – Contact: Katty CAUWERTS

SHC 8683 – Inquiry into discharge lamps

Last year, the European Lamp Companies Federation (ELCF) and its individual members (e.g. Philips and Osram) sent a dossier to the FANC regarding the issue of gas-discharge lamps. Though the individual gas-discharge lamps are below the exemption level (EL), they can exceed the latter during transportation, storage, distribution, retail trade, etc. They can also do so after having been installed (government buildings, football stadiums, public roads, etc.). The inquiry therefore aims at obtaining an exceptional measure for these lamps that would exempt them from the license obligation. This request was not only submitted in Belgium, but also in the other European countries, given the lack of general regulations. It would therefore be advisable for there to be a European policy and regulations in this subject.

➤ Start 08/2010 – End 2012 – Contact: Katty CAUWERTS

SHC 8685 – Inquiry concerning a draft Royal Decree setting safety regulations for nuclear installations

Request for advice on a Draft Royal Decree modifying the Royal Decree of 20 July 2001 establishing the general regulations aimed at protecting the population, workers and environment against the danger of ionising radiation (abbreviated RGPRI) regarding the safety of nuclear installations. Adaptation of the European directive 2009/71/EURATOM of 25 June 2009 to Belgian law in co-operation with the *Western European Nuclear Regulator Association* (WENRA).

➤ Start 08/2010 – End 2012 – Contact: Katty CAUWERTS

SHC 8705 – Inquiry concerning dental cone beam CT (CBCT).

1. How safe is this technology in terms of the ionising radiation burden, compared to other medical imaging techniques used for the maxillofacial area, including the teeth and prosthesises, especially but not only with regard to traditional panoramic radiographs?
2. What are the aspects in which this technology differs from conventional radiographic CT-scanning with an electronic, computerised counting system?
3. What are the indications for and what is the place of this technology compared to other imaging techniques of the dentomaxillofacial parts of the body?
4. Does the use of such a device require specific training and particular precautionary measures in terms of need assessment, operation, supervision and interpreting the images?
5. What are the requirements that such training should meet?
6. What are the basic qualifications that the healthcare professional concerned must possess?

➤ Start 12/2010 – End 2011 – Contact: Katty CAUWERTS

SHC 8708* – *Inquiry regarding a draft Royal Decree concerning the protection against ionising radiation in veterinary practice

This request for advice fits within the framework of the general revision of the Royal Decree of 20 July 2001, which establishes the general regulations aimed at protecting the population, workers and environment against the danger of ionising radiation (RGPRI).

➤ Start 12/2010 – End 04/2011 – Contact: Katty CAUWERTS

"Ongoing permanent activities": confidential and/or select advisory reports

The SHC does not know beforehand what inquiries will be submitted by the Minister of Public Health or the competent authority. However, it is likely to receive requests for advisory reports on draft Royal Decrees (RD) modifying the RD of 20 July 2001 (General regulations regarding the protection of the population, workers and environment against the danger of ionising radiation, RGPRI). As a matter of fact, the Federal Agency for Nuclear Control (FANC) is currently revising the RGPRI and each modification will be submitted to the SHC for advice.

"Planned projects": new planned projects

Evaluation of the increasing patient exposure to radiation due to the use of tomodensitometry (CT)

This project aims at issuing recommendations on optimising the "patient dose" based on perceived dose indicators in the current CT-fleet according to the guidelines of the vademecum, as well as on the results of and the experience gained during the multicentric study in interventional radiology and in paediatric CT (including the aspects to do with giving information to the patient / the general public). These new recommendations will have to be adapted to CTs which use mAs modulation technology: encouraging the development of a method to evaluate the "patient dose" (adapting the dose indicators, actual doses, etc.) and adapting the acceptability criteria of the equipment (RP91). These recommendations are also valid for the restrictions on the use of low-dose technology.

To start in 2011-2012, as soon as the questions that have priority and ongoing projects are about to be finalised.

The issue of solid radioactive waste
The increasing use of technology that produces solid radioactive waste (nuclear medicine, power stations, etc.) raises problems related to its removal, which should guarantee as small as possible a risk to the population and the environment. The SHC intends to examine this issue and to find out what are the possible solutions.

To start in 2011-2012, as soon as the questions that have priority and ongoing projects are about to be finalised.

"Ideas in the pipeline": project ideas to assess

None

2B. Non-ionising radiation

"Ongoing activities": confidential and/or select advisory reports - projects

SHC 8560* – *Project on sunbathing wisely
This project will look at the current state of knowledge about the influence of exposure to UV radiation from the sun on health. Also, it will focus on the extent to which exposure to the sun can have a positive or negative influence on the occurrence of melanoma of the skin, the occurrence of forms of cancer other than skin cancer, the occurrence of infectious diseases, etc. Moreover, it will examine whether the positive health effects of exposure to the sun (vitamin D) can also be achieved in some other way and what are the advantages and disadvantages of the different alternatives.

➤ Start 01/2010 – End 2012 – Contact: Eric JADOUL

SHC 8635* – *Project on 3D Ultrasounds
Three-dimensional ultrasounds (called four-dimensional when moving pictures are involved) were developed at the end of the eighties. There is no doubt that this technique has numerous advantages, but there are also a number of conditions that have to be fulfilled. Thus, the gynaecologist carrying out such an ultrasound should have sufficient experience in traditional ultrasound examinations. However, 3D ultrasounds are also being carried out on a commercial basis, a practice referred to as "boutique ultrasounds". They are performed by commercial scanners who do not have the necessary skills. The aim of this project is to find out what are the potential problems posed by commercial 3D ultrasounds and what conditions should be imposed on carrying them out.

➤ Start 11/2010 – End 2012 – Contact: Eric JADOUL

"Ongoing permanent activities": confidential and/or select advisory reports

At the moment, the working group in charge of non-ionising radiation does not have any recurring permanent activities, except for the meetings of the think-tank.

"Planned projects": new planned projects

General project on the evaluation of non-ionising radiation (GSM, micro-waves, WIFI, RFID, metal detectors, etc.)

The Council announces that it will re-examine the scientific knowledge on the consequences of exposure to radiofrequency radiation. This will result in an advisory report that will contain public health recommendations regarding the use of wireless communication systems (not only for radio masts) and other technologies that make use of radiofrequency radiation.

➤ Start 01/2010 – End 2012 – Contact: Eric JADOUL

Health effects of various types of light bulbs

It has recently been shown in a number of publications that low-energy bulbs may have adverse health effects. This issue was brought to the media's attention by a French Action Group (called CRIEM). On the one hand, these bulbs are said to emit UV radiation, on the other, they contain mercury. This mercury is released when, for instance, the bulb is dropped. In addition to assessing the possible risks linked to low-energy bulbs, we will also discuss a number of other means of lighting in greater detail.

➤ Start 2011 – End 2012 – Contact: Eric JADOUL

"Ideas in the pipeline": project ideas to assess

Protection in case of low-frequency magnetic fields such as those associated with magnetic resonance (including MRI).

3. CHEMICAL AGENTS

The questions concerning the risks of exposure to chemical agents are assessed within the working group. In addition, the latter also deals with other health issues which have to do with the presence of substances in the workplace and in the environment. Finally, the working group itself can take the initiative of examining the main aspects of this issue.

The responsibility for evaluating the risk of pesticides and biocides has been partially moved to the European level. As a result, the SHC has been given a second-line role and acts as an appeal panel in the event of a firm not agreeing with an advisory report of the Advisory Committee on Biocides (CAB), which belongs to the Administration.

"Ongoing activities": confidential and/or select advisory reports - projects

SHC 8603* – *Project concerning the effects of mobility on Man and the environment
Although there are fragmented regulations (per pollutant) regarding the effects of mobility on health and the environment, there are no general and standardised regulations available. The impact of mobility on health and the environment is related to various factors:

- the effect of particle emissions (NOx, PM10, PM 2.5, ozone, benzene, biofuels) into the atmosphere, etc.) as well as immission;
- psychological effects (light, noise, etc.);
- effects on the endocrine system;
- accidents.

Furthermore, the substances (both pollutants and non-pollutants) are not independent of each other (synergistic, antagonistic, additive effects) and new fuels are being marketed (biofuels), etc. Therefore, it was suggested during the June 2009 meeting of the SHC Board that it is desirable to investigate to what extent more inclusive and standardised regulations are required.

➤ Start 09/2009 – End 03/2011 – Contact: Muriel BALTES

SHC 8614* – *Inquiry into the issue of chlorine in swimming pools
Following a new publication that draws a connection between the use of chlorine in swimming pools and respiratory problems in children, new data will be examined at the Minister's request. The potential causal link between chlorine in swimming pools and health problems in children will be re-analyzed.

➤ Start 10/2009 – End 03/2011 – Contact: Muriel BALTES

SHC 8686* – *Inquiry into the risk involved in children and pregnant women being exposed to domestic biocides

On 2 September 2010, the SHC was questioned by Minister Laurette Onkelinx and Minister Paul Magnette about the potential need to provide biocide products that may be used by the general public with a warning aimed at pregnant women and young children. More precisely, the ministers concerned ask the SHC what could be mentioned in this warning and according to which criteria biocide products would have to be labelled with it. The SHC will also have to express an opinion on the scientific arguments in support of the idea that the general public should be protected against the risks involved in the use of certain biocides in the family circle of unborn children.

➤ Start 09/2010 – End 06/2011 – Contact: Muriel BALTES

"Ongoing permanent activities": confidential and/or select advisory reports

SHC "Appeal procedures for biocides"

As regards the authorisation procedure for the marketing of biocidal products (RD of 22.05.2003), firms can lodge an appeal with the Minister and the Administration against the decisions of the Advisory Committee on Biocides (CAB). The SHC is then requested to examine this appeal within a given period of time and according to a procedure determined by law. As each year, the SHC expects to be consulted on such matters. During the period 2009 – 2010, 2 such dossiers were dealt with. All biocide dossiers came to an end in 2010 and we will deal with new requests as we receive them.

"Planned projects": new planned projects

None

"Ideas in the pipeline": project ideas to assess

- Indoor air pollution (school, home, etc.)
- Frameworks/boundaries for authorisations
- Assessment of combined effects (3/4 products)
- Identifying "dangerous" chemical substances (e.g. DMF at the international level vs. the national level)
- Prospective analysis of nanomaterials, especially in clothing
- Bottom-up co-operation with REACH

4. NUTRITION AND HEALTH, INCLUDING FOOD SAFETY (NHFS) AND FOOD MICROBIOLOGY

As part of the normative policy of the FPS Public Health, Food Chain Safety and Environment (http://www.health.belgium.be/eportal), the standing working group NHFS carries out risk assessments for additives, chemical or microbiological contaminants, new ingredients (NI) or foodstuffs (NF "Novel foods"), etc.

As part of the nutritional policy of the FPS, the working group not only issues nutritional recommendations which form the foundation of such projects as the NFHP – B (National Food and Health Plan for Belgium) http://www.health.belgium.be/eportal/Myhealth/Healthylife/Food/FoodandHealthPlan/index.htm, but also provides advisory reports on food supplements, labelling, special diets and so on.

The NHFS working group is part of the European Food Safety Authority (EFSA,- http://www.efsa.europa.eu/) network and one of its members also represents the group within the ESCO (European Scientific Co-Operation) http://www.efsa.europa.eu/en/esco/escofolicacid.htm, a working group that analyses the risks and benefits of folic acid enriched foods.

"Ongoing activities": confidential and/or select advisory reports - projects

***SHC 8311* – Project aimed at assessing the exposure to risks linked to the natural presence of certain contaminants in natural mineral waters**

As a result of the revision of the European legislation and the Codex Alimentarius norms for natural mineral water, which determine the limit values for chemical contaminants that may be present in natural mineral water, there appears to be a tendency to bring these limit values simply in agreement with those of tap water. One of the consequences of this is that natural mineral water will also undergo a series of treatments, which, in the long run, will result in the loss of its natural character. It is important to preserve the characteristics of natural mineral water and, at the same time, protect the consumers' health against certain risks. Therefore, the Administration wishes to be informed about the current state of our knowledge about the toxicology of fluorine (and possibly that of such other substances as barium and boron) and about the health risks caused by their presence in natural mineral water, so that it may be determined whether the present-day norms are justified or whether they need to be revised.

Note: There has already been a scientific paper published on the basis of the ongoing activities: Vandevijvere S, Horion B, Fondu M, Mozin MJ, Ulens M, Huybrechts I et al. Fluoride intake through consumption of tap water and bottled water in Belgium. *Int J Environ Res Public Health* 2009 ; 6:1676-1690.

There is a tendency to align higher levels of fluoride in natural mineral water with the existing higher levels in tap water. Treating natural mineral waters could be detrimental to the preservation of their natural character. This study assessed the intake of fluoride via the consumption of bottled and tap water in the Belgian adult population, taking into account regional differences. A deterministic approach was used, in which the quantities of tap water and different brands of bottled water consumed were linked with their respective fluoride concentrations. This study drew on data from the national food consumption survey (2004) and applied the Nusser methodology to obtain usual intake estimates. The mean fluoride intake through total water consumption in Flanders was 1.4+/-0.7 mg/day (97.5(th) percentile: 3.1 mg/day), whilst in the Walloon region it was on average 0.9+/-0.6 mg/day (97.5(th) percentile: 2.4 mg/day). The probability of exceeding the UL of 7 mg per day with a normal diet was estimated to be low. Consequently, there is no need to revise the existing norms, but higher fluoride concentrations should be more clearly indicated on the labels. Reliable data are needed on the total dietary fluoride intake in children, including the intake of fluoride via tooth paste and food supplements.

➤ Start 02/2007 – End 2011 – Contact: Michèle ULENS

SHC 8464* – *Project on palm oil

Palm oil is well on its way to becoming the most commonly used vegetable oil worldwide (and probably also the most commonly used source of fats). Various factors can account for this fact, which mainly leads to what may be feared to be a negative influence on the health of the public, who, often unconsciously, use large amounts of saturated fatty acids.

➤ Start 10/2008 – End 02/2011 – Contact: Michèle ULENS

SHC 8666* – *Project on trans fatty acids

The SHC takes the view that it is necessary to draw up a full statement about a subject to which there turns out to be more than meets the eye and to issue recommendations that could be useful both to specialists interested in nutrition and human health, but also to the Legislator. This advisory report will be grounded in the analysis of the latest nutritional recommendations on this subject, especially on those issued by the Council in 2009.

➤ Start 05/2010 – End 02/2011 – Contact: Michèle ULENS

SHC 8671* – *Re-examination of the advisory reports on fluorine (6103 – 8309 – 8520)

The French Agency for the Sanitary Safety of Health Products (*Agence française de sécurité sanitaire des produits de santé*, AFSSAPS) published a statement on the use of fluorine in preventing dental decay before the age of 18 (AFSSAPS, 2008). In its advisory report No. 8520, the SHC did not question the position taken in its previous advisory reports SHC 6103 and 8309, yet it did find it useful to update its position on fluorine.

➤ Start 2010 – End 2011 – Contact: Anne-Madeleine PIRONNET
(in co-operation with Michèle ULENS)

SHC 8689* – *Inquiry concerning caffeine in foodstuffs
In the light of SHC advisory report No. 8622 on "energy drinks", the Administration requests the SHC to issue a general advisory report on the use of caffeine in foodstuffs and on the risks involved.

➤ Start 09/2010 – End 2011 – Contact: Michèle ULENS

"Ongoing permanent activities": confidential and/or select advisory reports

SHC "Novel foods"* – *Confidential advisory reports on "Novel Foods"(first-line, second-line, substantial equivalence)
The SHC has been requested to issue advice on new ingredients or foodstuffs for several years now. We can therefore predict that a series of requests for advice of this kind will be submitted to us in 2011 as well, before this routine competency is permanently transferred to the European Food Safety Authority (EFSA – http://www.efsa.europa.eu/). The SHC is currently examining 17 "novel food" dossiers.

➤ This activity is expected to come to an end in the course of 2011
Contact: Michèle ULENS

SHC "Food supplements"* – *Confidential advisory reports on food supplements
There are currently 5 "food supplement" dossiers under examination.

➤ End 2011 – Contact: Anne-Madeleine PIRONNET

SHC "Waters"* – *Confidential advisory reports on natural mineral water (NMW) and spring water (SW)
The authorisation for spring water to be labelled as "natural mineral water" as well as that for using the claim "suitable for the preparation of infant food" are submitted to the SHC for advice. A single "natural mineral water" dossier is still under examination and we are expecting additional requests on this subject.

➤ Start 2011 – Contact: Anne-Madeleine PIRONNET

SHC "Claims"* – *Confidential advisory reports on claims
In 2010, all "claims" dossiers came to a close and we will deal with new requests as we receive them.

➤ Start 2011 – Contact: Michèle ULENS

SHC "PET"* – *Confidential PET (Polyethylene terephtalate) advisory reports
For several years now, the SHC has been requested to issue confidential advisory reports on materials that come into contact with foodstuffs (PET). We can therefore foresee that we will receive a series of requests for advice of this kind in 2011 as

well, before this routine competency is permanently transferred to the European Food Safety Authority (EFSA – http://www.efsa.europa.eu/). Five "PET" dossiers are currently being examined by the SHC.

➤ This activity is expected to come to an end in the course of 2011
Contact: Anne-Madeleine PIRONNET

"Planned projects": new planned projects

***SHC 8623* – Project on the maximum intake of folic acid**
Following the drawing-up of two confidential advisory reports on folic acid, the NHFS group thought it useful to issue a public advisory report on the basis of these 2 confidential advisory reports, which have already been finalised. Following requests concerning the notification of food supplements and ingredients containing folic acid, this advisory report will focus on the maximum supplementary intake of folic acid.

➤ Start 02/2011 – 2012- Contact: Michèle ULENS

***SHC 8651* – Project on the efficacy and innocuousness of probiotic flora**
This project aims at taking stock of the methodologies intended for validating the efficacy and the innocuousness of probiotic flora in foodstuffs / food supplements.

➤ Start 02/2010 – End 2012 – Contact: Jean-Jacques DUBOIS

***SHC 8663* – Project on assessing the food safety risk entailed in salt reduction**
The SHC cooperates with the Scientific Committee (ref: SciCom 2010/09) of the Federal Agency for the Safety of the Food Chain (FASFC) to assess the food safety risk involved in the event of food reformulation: the case of salt reduction.

➤ Start 01/2011 – End 2012- Contact: Michèle ULENS

Project "updating the recommendations on essential fatty acids (omega 3)"- SHC 7945 (Michèle ULENS)
This project aims at providing a critical analysis of the recent literature on the basis of which rational conduct rules will be formulated for the various fields involved and the recommendations will be revised or clarified. More particularly, it will determine which of the various n-3 fatty acids in food have any protective (or harmful) effects as well as the circumstances under which they do.

➤ The work on this project will begin once that on the "safety of oils and fats" (8310) has come to a close (January 2011).

Project on transposing the nutritional recommendations (nutrients) into dietary recommendations "Food-Based Dietary Guidelines for Belgium" (Michèle ULENS)
The SHC has recently begun to focus on the "nutritional recommendations" (expressed in terms of nutrients), which have a very broad scientific basis. In order to enable the population to optimally implement them, the aim is now to transpose these recommendations into "food" or "dietary" recommendations (expressed in terms of foodstuffs) so as to inform and educate the consumer and to promote health through the acquisition of healthy food habits. Such recommendations must be appropriate for the region or country concerned, culturally acceptable and easy to implement.

The project under consideration is by no means easy to carry out, requiring as it does extensive consultation of the main parties involved as well as searching for a scientifically acceptable compromise. Yet the fact that this project is carried out as part of the SHC's activities is a guarantee in terms of procedure and scientific quality. It will allow for all considerations or interests that are liable to significantly impair the scientific quality of such recommendations to be set aside. However, it can by no means be ruled out that various sensitive aspects (cultural, societal, environmental or other) will be taken into account.

➤ The work on this project will begin once that on the "safety of oils and fats" (8310) has come to a close (January 2011).

"Ideas in the pipeline": project ideas to assess

- Assessment of nutritional aspects in the prevention of different types of cancer (project being reflected on within the NHFS working group) (Michèle ULENS)
- The issue of biogenic amines (with histamine-like effect) in vegetables (Jean-Jacques DUBOIS)
- The issue of the transmission of pathogenic bacteria via foodstuffs (Jean-Jacques DUBOIS)
- Mycobacterium paratuberculosis project (Jean-Jacques DUBOIS)

5. BLOOD AND BLOOD PRODUCTS

In this area, the general mission of the SHC is to draw up and standardise good transfusion practices. This working group is unabatedly intent on reducing the risk of known or unknown infectious diseases being transmitted through blood transfusions to an absolute minimum. All aspects of transfusion are covered: thus, this group examines such issues as the eligibility criteria for donations, the screening for communicable diseases and the clinical indications for the various blood components. Within this framework, the working group also devotes special and continuous attention to the impact of its risk analysis on the efficient management of the limited resource that is donated blood.

"Ongoing activities": confidential and/or select advisory reports - projects

***SHC 8382* – Project concerning the evolution of techniques for the screening for and reduction of pathogens in blood transfusion**

The safety of blood component transfusion is currently being increased by the (genomic) screening for and/or the reduction of pathogens in all blood donations. In contrast to serological screening methods, which are always applied to single "units", such Nucleic Acid Amplification Techniques (NAT) as are specific for viruses require a "pool" format in order to achieve economies of scale. Nevertheless, these technologies are not cost efficient because only a rather small reduction of the residual risk is observed as a result of the rejected donations. Moreover, new pathogen reduction techniques (which can eliminate certain unknown pathogens) are rapidly being developed. This in turn leads to expect individual unit donations to be made safe at an increased speed. In the light of new indications and risks (e.g. the transmission of recently identified pathogens), it is advisable to reconsider the progress made in newly acquired knowledge on the screening for and reduction of pathogens in transfusion medicine.

➤ Start 2010 – End 2012 – Contact: Roland HÜBNER

***SHC 8420* – Inquiry into the shelf life of red cell concentrates intended for patients who are to undergo cardiac surgery**

An article by Koch et al. entitled "Duration of red cell storage and complications after cardiac surgery" was published in the New England Journal of Medicine in 2008. In this retrospective study, the authors compared the outcome of administering preserved red cell concentrates to two groups of patients who had undergone cardiac surgery. The first group received only such red cell concentrates as had been preserved for less than two weeks, the other received only such red cell concentrates as had been stored for more than two weeks. The authors found out that administering red cell concentrates that had been preserved for over two weeks was associated not only with a significantly increased risk of post-operative

complications but also with a diminished short and long-term survival. These are important findings that may affect public health in this country as well.

Start 06/2008 – End 03/2011 – Contact: Roland HÜBNER

SHC 8669* – *Project regarding the recommendations in case of suspected TRALI
Transfusion Related Acute Lung Injury (TRALI) is a disorder with a potentially serious evolution and which arises during or shortly after the administering of blood components. The differential diagnosis with other lung disorders is not an easy one to make. It is therefore likely that its incidence, which varies greatly from one country to another, is under-estimated. The aim of this project is to draw up an advisory report on its clinical diagnosis and on the laboratory investigations that can support it.

Start 06/2010 – 03/2011 – Contact: Roland HÜBNER

SHC 8670* – *Inquiry into the screening for bacterial contamination in platelet concentrates
There is a test available that is being presented as a unique diagnostic test for detecting bacterial contamination in both pooled and single donor platelet concentrates. The Minister of Social Affairs and Public Health requests the SHC to issue advice on the screening for bacterial contamination and this new technology.

Start 06/2010 –02/ 2011 – Contact: Roland HÜBNER

SHC 8672* – *Project on allowing carriers of a haemochromatosis gene to give blood
At present, people with haemochromatosis are rejected by the blood establishments as donors of full blood and blood components. One the one hand, this is done on the basis of the legal provision (Royal Decree of 08/02/2005) according to which donor-candidates with specific diseases (which may include haemochromatosis) are to be permanently excluded as allogeneic donors. On the other, this follows from the fact that the requirement that blood donations should be voluntary and disinterested is not met as a result of the intended therapeutic effect of collecting blood from haemochromatosis patients. This entails the risk that information will be withheld in order to be able to give blood in spite of specific complaints. Conversely, excluding people with haemochromatosis results in the loss of a group of very willing, regular and loyal blood donors. This project aims at drawing up an advisory report based on rational arguments on the exclusion/eligibility of people with haemochromatosis as donors.

The following questions need to be addressed:
1. Are there any real risks involved in giving blood for the haemochromatosis patients themselves?
2. Are there any real risks involved in haemochromatosis patients giving blood for the safety of the blood products?
3. The answers to the two questions above need to be differentiated in terms of haemochromatosis patients and carriers.

4. In the event of people with haemochromatosis being authorised to give blood: do they need to meet specific requirements?

➤ Start 06/2010 – 2011 – Contact: Roland HÜBNER

Confidential advisory report on the efficiency of pathogen reduction in platelets

➤ Start 10/2010 –01/2011 – Contact: Roland HÜBNER

Confidential advisory report on implementing pathogen reduction in platelets

➤ Start 01/2011 – 04/2011 – Contact: Roland HÜBNER

"Ongoing permanent activities": confidential and/or select advisory reports

As this programme is being drawn up, it is difficult to predict what requests will be submitted to the SHC in 2011 in the area of blood and blood products.

However, we do expect to receive new requests regarding haemochromatosis, haemovigilance and/or the revising of the advisory reports on photochemical methods for pathogen reduction in platelet concentrates.

A standing think-tank has been set up to follow-up on these issues and to determine which of the topics that will be tackled in 2011 will receive priority.

"Planned projects": new planned projects

In 2011, the numerous inquiries received at the end of 2010 will receive priority, as well as the finalising of the ongoing projects.

"Ideas in the pipeline": project ideas to assess

None

6. CELLS, TISSUES AND ORGANS (COT) OF HUMAN AND ANIMAL ORIGIN

The task of the working group in charge of this area is to rely on scientific developments to suggest and to monitor measures aimed at preventing the transmission of diseases as a result of the transplantation of organs, tissues and cells of human or animal origin or through the use of medical devices with cellular components.

This group is also tasked with revising and amending the quality standards according to the new national and European regulations.

Finally, this group issues advisory reports on technical issues or procedures that provide the Administration with assistance in carrying out its regulatory function.

"Ongoing activities": confidential and/or select advisory reports - projects

SHC 8630* – *Inquiry into the criteria for the preservation of reproductive cells and tissues by vitrification

The SHC quality standards No. 8292 for reproductive cells and tissues of 5 August 2009 do not contain any criteria regarding the preservation of tissues and cells by vitrification. This advisory report aims at suggesting criteria regarding this technique in order to objectivise this choice of procedure during inspections for the accreditation of banks for human body material that are linked to the programmes for assisted human reproduction. The specific issue of using an "open" system for the vitrification of embryos or gametes with ordinary non-sterile liquid nitrogen will also be broached in this advisory report.

➤ Start 12/2009 – End 03/2011 – Contact: Muriel BALTES

SHC 8677* – *Project regarding the banks for autologous cord blood

The clinical use of Human Leucocyte Antigen (HLA) matched related and unrelated cord blood (CB) in patients suffering from diseases that can be treated with a haematopoietic stem cell transplant (HSCT) is well documented. At present, there are over 100 cord blood banks worldwide that aim at making these products more easily available. In contrast, the evidence for the banking and indeed the clinical use of autologous cord blood is still scarce.

At present, it is difficult to find evidence in support of the need for and clinical applications of autologous cord blood. The applications that are often put forward concern the treatment of diseases and tissue regeneration (through the differentiation potential of stem cells).

The group takes the view that the issue of autologous cord blood banking cannot be separated from that of its clinical/medical use and therefore 3 main questions are addressed:

1. What is the scientific evidence in support of autologous cord blood banking?
2. What is the current or potential clinical application of autologous cord blood?
3. What are the quality, ethical and regulatory issues surrounding autologous cord blood banking and transplantation?

➤ Start 08/2010 – End 03/2011 – Contact: Muriel BALTES

SHC 8684* – *Project regarding HBV screening: Relevance of NAT testing

There are three European directives that regulate human body material. Since 2009, these directives have been partially adapted into national legislation, resulting in the Act of 19 December 2008 and several implementing Royal Decrees (AR). The RD of 28 September 2009 setting the quality and safety norms for cells and tissues requires that the following biological tests be carried out on live donors: Anti-HIV 1–2 ; HBsAg, anti-HBc; anti-HCV and the syphilis screening test. These same tests are to be repeated after 6 months, unless there was an HIV, HBV and HCV PCR carried out on the first sample beforehand or there was an inactivation step that was validated for the viruses concerned. For all deceased donors, the following tests need to be performed in addition to the biological tests mentioned above, unless the treatment includes an inactivation step that was validated for the viruses concerned: HIV 1 NAT, HCV NAT, HBV NAT A. As regards live donors, the RD is in keeping with the dictates of the directive 2006/17/EC and the SHC recommendations, except as regards HBV PCR. With respect to deceased donors, however, the requirements of the RD are more stringent than those of directive 2006/17/EC as well as the recommendations of the SHC. Indeed, the RD requires an HIV, HCV PCR as well as an HBV PCR.

Since 1 December 2009, the RDs apply. All human body material that is currently in quarantine or in storage and needs to be released must abide by this new requirement.

Faced with this regulatory discrepancy, the experts of the SHC standing working group "Cells, tissues and organs of human and animal origin" wished to look into this issue by raising the following questions:

1. Does screening for HBV by means of PCR increase tissue safety?
2. Under which conditions should human body material that was imported from Europe be accepted?

➤ Start 08/2010 – End 2011 – Contact: Muriel BALTES

SHC 8695* – *Inquiry into hepatocytes and the Act on human body material
The FAMHP has been called upon to set a price for hepatocytes within the framework of the Act of 19 December 2008 on human body material. The Minister has submitted questions on the following issues to the SHC:

- the clinical indications for administering hepatocytes;
- the potential therapeutic value for each indication;
- their position compared to liver transplantation;
- the specific norms concerning quality and vigilance.

➤ Start 10/2010 – End 04/2011 – Contact: Muriel BALTES

SHC 8698* – *Project on the microbiological aspects relating to the practice of banks for human body material
The working group "Cells, tissues and organs of human and animal origin", which is tasked with drawing up the quality and safety norms (Act of 19 December 2008) for human body material, finds it necessary to re-examine the microbiological aspects (testing, safety), especially those that concern the harvesting and testing of human body material. These considerations will be looked into in a comprehensive manner, as some of these aspects are common to all cells and tissues, but also in a way that is fine-tuned to the different cells and tissues.
These recommendations will, among other things, be based on SHC advisory report No. 8143 (inactivation and safety of cells and tissues with regard to prions, bacteria and viruses), current practice and the requirements of the new national regulations.

➤ Start 10/2010 – End 2012 – Contact: Muriel BALTES

SHC 8699* – *Project concerning the monitoring and controlling of the environment within the framework of the practice of banks for human body material
The hospital environment can constitute a potential source for the transmission of micro-organisms. Recommendations on monitoring and controlling the environment within banks for human body material prove to be useful to prevent such transmission. These recommendations would complement the SHC advisory report No. 8364 on controlling the surfaces and the water (used in a broad sense), as well as the air. The sampling, the methodology and practical norms were examined for the healthcare facilities, except for those that pertain to the clean rooms, the tissue and cell banks, etc. The aim would therefore be to adapt these recommendations to the practice of banks for human body material.

➤ Start 10/2010 – End 2012 – Contact: Muriel BALTES

"Ongoing permanent activities": confidential and/or select advisory reports

The SHC expects to be consulted by the Federal Agency for Medicines and Health Products (FAMHP) on all technical problems that arise during the inspection of banks for human body material. Since October 2009, it is no longer the task of the SHC to issue advisory reports on the re-accreditation of banks for human body material, for which the FAMHP is now competent. Considering the expertise of the SHC's experts in this field, it is to be expected that the SHC will, on numerous occasions, be requested to issue advice in connection with more general problems of a technical nature.

As this work programme is being drawn up, it is not yet clear what requests can be expected in 2011 in this area. Nevertheless, there has been a standing think-tank established to follow up on this issue.

The working group will also continue working on revising the quality standards for human body material, taking into account the new legislation that has recently come into force.

"Planned projects": new planned projects

As this work programme is being drawn up, it is not yet possible to say when these projects regarding the gradual revision of the quality standards will begin.

"Ideas in the pipeline": project ideas to assess

None

7. VACCINATION, INFECTIOLOGY AND INFECTION CONTROL DURING CARE

As regards the area of vaccination, infectiology (emerging diseases) and infection control during care, the SHC has ad hoc working groups operative in the sub-areas of infectiology and infection control during care. Furthermore, there is a standing working group on vaccination, which is tasked with issuing advisory reports and recommendations on vaccines, vaccination and vaccinology.

7A. Vaccination

The advisory reports and recommendations issued by the standing working group on vaccination have to do either with the practice of vaccination in general (e.g. the updating of the basic vaccination schedule) or with one particular vaccine that is required for public health.

"Ongoing activities": confidential and/or select advisory reports - projects

SHC 8384* – *Project regarding the vaccination against chicken pox (children)
In this advisory report, the SHC proffers recommendations on replacing the combined Measles – Mumps – Rubella vaccine by a combined Measles – Mumps– Rubella – Chicken pox vaccine, which would lead to across the board vaccination against chicken pox in Belgium.

····➤ Start 12/2007 –End 06/2011 – Contact: Katty CAUWERTS

SHC 8385* – *Project regarding the vaccination against zoster (adults)
In this advisory report, the SHC issues recommendations concerning the vaccination against herpes zoster, which aims at preventing herpes zoster and postherpetic neuralgia in adults.

····➤ Start 12/2007 –End 06/2011 – Contact: Katty CAUWERTS

SHC 8517* – *Inquiry concerning the vaccination against Measles – Mumps – Rubella
Following the objective of the Regional Office for Europe of the World Health Organization (WHO), which aims at eliminating measles and rubella from Europe by 2010, the SHC was requested to provide an advisory report on the following issues:

1. Is it advisable to administer the second dose of the Measles – Mumps – Rubella (MMR) vaccine at an earlier age than is the case at present? Indeed, this increases the guarantee of reaching the 95% vaccination coverage that is being aimed at.

2. Is it advisable to recommend two MMR doses for adults or for certain target groups?

➤ Start 12/2008 –End 02/2011 – Contact: Katty CAUWERTS

SHC 8561* – *Project concerning the vaccination of high-risk patients
This guide on complementary vaccination was drawn up in response to numerous questions from vaccinators. There is need for a condensed version of the guidelines for the vaccination of high-risk patients. A guide, intended for specialists, will be drafted for the following high-risk patient groups: premature babies, pregnant women, chronically ill patients and patients suffering from immunosuppressive disorders.

➤ Start 05/2009 –End 2011 – Contact: Katty CAUWERTS

"Ongoing permanent activities": confidential and/or select advisory reports

SHC "vaccination programmes": Annual revision of the vaccination programmes
The standing working group on vaccination has as its task to clarify the vaccination schedule and to communicate it to the inter-ministerial conference of health ministers. It does this in close collaboration with the community and region officials. This annual revision is carried out in June.

The group is also tasked with approving the recommendations made about travel medicine on a yearly basis.

The group is also responsible for the periodic updating of the technical sheets dedicated to each recommended vaccination in the basic vaccination schedule for children, teenagers and adults as well as the sheets made for catch-up vaccinations or the rules for good vaccination practice. These sheets were compiled in the form of a vaccination guide in 2007 and are revised on a regular basis.

SHC "Influenza"
In close co-operation with the Interministerial Influenza Coordination Committee (http://www.influenza.be/fr/home_fr.asp), which is tasked with managing crisis situations, the SHC will issue advisory reports on seasonal influenza, avian influenza (A/H5N1), A/H1N1 influenza and pandemic influenza.

In particular, the group issues an advisory report each year on the recommendations concerning the vaccination against seasonal influenza.

SHC "new vaccines"
Whenever new vaccines are marketed, the SHC issues an advisory report on the need for and potential impact of these vaccines as well as the vaccination strategies that

will benefit public health the most. These dossiers are prepared by a sub-working group and are then submitted to the standing working group as a whole for discussion. The SHC also comments on the advice issued by the Belgian "health authorities" for each centrally registered vaccine (cf. the scientific leaflet of the vaccines).

"Planned projects": new planned projects

Project on the "anti-vaccine" movements
This project aims at examining the issue of vaccination refusal and the emergence of "anti-vaccine" pressure groups. The main issues that need to be looked into are the following:

1. Are the arguments on the basis of which vaccination is refused valid? If so, why? If not: how can patients be provided with accurate information?
2. What are the cultural differences and differences in approach between the different communities in Belgium?

Examining the phenomenon of "anti-vaccine" pressure groups requires expertise in sociology, psychology, communication, etc.

➤ Start 2011 –End 2012 – Contact: Katty CAUWERTS

"Ideas in the pipeline": project ideas to assess

None

7B. Infection control during care

In the area of infection control during care (formerly known as "Hygiene"), the SHC experts focus on infectious diseases that are liable to occur both in healthcare in general as well as in healthcare establishments in particular. The area "Infection Control during care" operates in close co-operation with the Belgian Infection Control Society (BICS - http://www.belgianinfectioncontrolsociety.be/).

"Ongoing activities": confidential and/or select advisory reports - projects

SHC 8363 – Project concerning the revision of the previous recommendations on «Hygiene in dental practice 5303-12» from March 1997
The previous SHC recommendations on hygiene in dental practice were drawn up in 1997 (SHC - 5303 -12). It follows that it is necessary to bring them up to date with current knowledge.

➤ Start 10/2007 – 2011 - Contact: Jean-Jacques DUBOIS

SHC 8383* – *Project concerning the revision of the booklet on Transmissible Spongiform Encephalopathies (No. 7276-2)

In 2006, a ministerial circular was addressed to the hospitals and, more particularly, to those in charge of hygiene, with the aim of implementing the recommendations of the SHC on the prevention of transmissible spongiform encephalopathies in hospitals. Among other things, these recommendations hold that the ophthalmology department has to destroy its instruments after a cornea transplant, as this is high-risk surgery. As regards these obligations, it is necessary to follow developments in decontamination techniques very closely, and to include them in a revised version of the booklet. The project will update the booklet in the light of new data on the decontamination of surgical instruments.

➤ Start 2010 – End 2012 - Contact: Roland HÜBNER

SHC 8429* – *Project concerning the directives on the prevention of needle stick injuries and the measures to be taken in the event of such an injury (in collaboration with the Scientific Institute of Public Health)

A catalogue of the safety equipment (needle containers, gloves, masks, blood sampling equipment, etc.) on the market (as well as an evaluation of its quality) already exists in France (www.geres.org). Indeed, the use of safety equipment is one of the mainstays of the prevention policy (http://www.nsih.be/surv_prik/inl_fr.asp) to prevent needle stick injuries (beside surveillance, training, inclusion of standard precaution measures, awareness raising campaigns, optimising the use of disposable equipment, etc.). Unlike its neighbouring countries, Belgium does not yet have any guidelines for the prevention of needle stick injuries and for the measures to be taken in the event of such an injury. This joint project of the IPH and the SHC therefore aims at filling this gap.

➤ Start 06/2008 - End 02/2011 - Contact: Jean-Jacques DUBOIS

SHC 8573* – *Inquiry on managing the OR

The Federal Platform for Hospital Hygiene has recently carried out an inquiry into the observance of hygiene prescriptions (based on foreign recommendations) in the operating room of Belgian hospitals. The analysis of the results shows that current practices vary greatly. Therefore, the SHC was asked to provide a list of standards and recommendations to remedy this.

➤ Start: 06/2009- End: 03/2011. Contact: Jean-Jacques DUBOIS

SHC 8579* – *Project concerning the revision of the recommendations on tuberculosis

The previous recommendations of the SHC on this subject go back to 1996. It follows that it is necessary to update them in the light of the evolution of knowledge about diagnostics, epidemiology and resistance surveillance.

➤ Start: 06/2009- End: 03/2011. Contact: Jean-Jacques DUBOIS

SHC 8580* – *Project concerning the management of risk factors for infection during the carrying out of works in hospitals

Building and renovation works as well as all technical activities undertaken in a healthcare establishment entail a series of infection risks for both patients and "staff" (e.g. Aspergillus and Legionella). Recommendations based on those already in existence at a national and international level are required and are expected by the healthcare sector.

➤ Start: 06/2009 - End: 03/2011 - Contact: Jean-Jacques DUBOIS

SHC 8582* – *Inquiry into Credé's method

The West Flanders regional platform has drawn up recommendations on preventing infections in the maternity ward. In Belgium, instilling eye-drops into newborns' eyes is mandatory. However, the West Flanders regional platform raises the question whether Credé's method is still essential. The practice of instilling silver nitrate eye-drops and antibiotics into a newborn's eyes (referred to as Credé's method) raises many questions about its relevance and use. It seems useful to make an assessment of the epidemiological situation (gonococcus) in Belgium. In order to proffer relevant recommendations, it is necessary to carry out an analysis of the present-day knowledge.

➤ Start 06/2009 - End 2011 - Contact: Jean-Jacques DUBOIS

SHC 8678* – *Inquiry concerning good hygiene practice in general practitioner and specialist waiting rooms

This advisory report will review the main recommendations on good hygiene practice published by the SHC and adapt them to the context of general practitioner and specialist waiting rooms.

➤ Start 07/2010 - End 2011 - Contact: Jean-Jacques DUBOIS

SHC 8692* – *Inquiry regarding the XMRV virus

The Minister of Social Affairs and Public Health requests the SHC to issue advice on the xenotropic murine leukaemia virus-related virus (XMRV). Request for advice on the significance of XMRV in terms of human health and its potential implications for transfusion medicine, organ transplantation or the preparation of advanced therapeutic medicinal products (ATMP).

➤ Start 09/2010 – 2011- Contact: Roland HÜBNER

Confidential advisory report on the assessment of alternative legionella control measures

➤ Start 12/2010 – 03/2011 - Contact: Jean-Jacques DUBOIS

"Ongoing permanent activities": confidential and/or select advisory reports

As this work programme is being drawn up, it is difficult to foresee what requests will be submitted in the area of "infection control during care" in 2011.

Still, there has been a standing think-tank set up to follow up on this issue. In the light of current events and the demand from the healthcare sector, this group of experts decided to give priority to the following topics in 2011: the issue of multiresistant bacteria (MRB) and the treatment and management of highly contagious diseases.

"Planned projects": new planned projects

***SHC 8704* – Project concerning the issue of multiresistant bacteria (MRB)**
The SHC has already issued several advisory reports on the issue of Methicillin-resistant Staphylococcus aureus (MRSA). This project aims at extending this examination to other multi-drug resistant organisms (MDRO). The think-tank "infection control during care" has therefore decided to issue specific, national recommendations on the prevention of and fight against these organisms.

The work on this project is expected to begin as soon as the ongoing activities involving urgent inquiries (8573 "OR" – 8582 – "Credé's method" - 8678 "Good hygiene practice in waiting rooms") as well as the work on the ongoing projects (priority 2011) have been completed.

The treatment and management of highly contagious diseases
The aim of this project is to update the state of knowledge on preventing and managing highly contagious diseases in hospitals.

The work on this project is expected to begin as soon as the ongoing activities involving urgent inquiries (8573 "OR" – 8582 – "Credé's method" -8678 "Good hygiene practice in waiting rooms") as well as the work on the ongoing projects (priority 2011) have been completed.

"Ideas in the pipeline": project ideas to assess

***SHC 8693* – Project concerning the revision of SHC advisory report No. 7721 on Group B streptococci (GBS)**
In 2003, the SHC published guidelines concerning the prevention of and fight against perinatal group B streptococcal infection (GBS). This project therefore aims at revising the 2003 recommendations in the light of new scientific data that have been published since.

The work on this project has not begun yet and is not a priority.

Project of updating the list of hydro-alcoholic solutions in the context of the recommendations on "hand hygiene" (SHC 8349: 2007 project of revising the recommendations on hand hygiene). The work on this project has not begun yet and is not a priority.

Project of revising advisory report No. 5303-4 from 1998: Prophylactic use of antibiotics in surgery. The work on this project has not begun yet and is not a priority.

Project of revising certain sections of advisory report No. 5303-3: Nosocomial infections.

Project of providing an addendum to the transfusion manual (SHC 8381).
The work on this project has not begun yet and is not a priority.

Project concerning the issue of "Viral diarrhoea in hospitals" (norovirus).
The work on this project has not begun yet and is not a priority.

Project of issuing recommendations of the biosafety type for sample monitoring. From a legal point of view: P3 Lab safety, but not for clinical laboratories.
The work on this project has not begun yet and is not a priority.

Project 5303-4: Revising the recommendations on antibiotic prophylaxis prior to surgery.

Project 5303-3: Revising the recommendations on preventing urinary tract infections and pulmonary infections during care.

Project on the ageing population and infection control in retirement homes/ rest and nursing homes.

Project on Enterobacter in feeding bottles.

8. COSMETOLOGY AND COSMETIC DEVICES, INCLUDING COSMETIC SURGERY

The work on this project is expected to begin as soon as the ongoing activities involving urgent inquiries (8573 "OR" – 8582 – "Credé's method" - 8678 "Good hygiene practice in waiting rooms") as well as the work on the ongoing projects (priority 2011) have been completed.

"Ongoing activities": confidential and/or select advisory reports - projects

SHC 8587* – *Project on devices for cosmetic applications and related skin treatments
The SHC finds that there is need for an evaluation of quite a number of devices and new technologies which are being marketed for cosmetic applications. In the advisory report on thermodermie (SHC 8461), it was pointed out that, in view of the fact that the use of such devices is not completely without risk, it is important to urgently regulate a number of related fields that are concerned with skin treatment. The SHC concludes that it is necessary to draw a picture of the potential problems caused not only by the devices themselves and their operating mechanism, but also, and more importantly, by a faulty use and use on individuals with an underlying pathology. Moreover, it appears that there is no scientific foundation for the efficiency of these devices and that the advertising for them can often be referred to as misleading. With its advisory report, the SHC aims at providing more clarity about this practice. The SHC takes the view that collaboration on a European level is a plus in tackling this issue.

➤ Start: 08/2009 – End 01/2011 – Contact: Anne-Madeleine PIRONNET

SHC 8631* – *Inquiry into semi-permanent make-up
The SHC has been requested to issue an advisory report on the following specific questions regarding permanent and semi-permanent make-up:

1. What kind of training and skills, what sanitary conditions and precautions does the practice of semi-permanent make-up require?
2. What training and skills does the use of tattoo removal devices require?
3. Does the ink that is marketed for tattooing purposes or for semi-permanent make-up abide by the definition in the RD of 15/10/1997 on cosmetic products?
4. Insofar as this practice is not part of healthcare, which are the elements that could be subject to inspection by health services?

➤ Start: 12/2009 – End: 03/2011 – Contact: Anne-Madeleine PIRONNET

"Ongoing permanent activities": confidential and/or select advisory reports

As this work programme is being drawn up, it is difficult to predict what requests will be submitted to the SHC in 2011 in the field of cosmetology and cosmetic devices, including cosmetic surgery. Still, there has been a standing think-tank set up to follow up on this issue.

"Planned projects": new planned projects

Project regarding the sanitary requirements

➤ Planned to start 01/2011

"Ideas in the pipeline": project ideas to assess

None

9. PUBLIC HEALTH GENOMICS (PHG)

On 8 February 2010, the Belgian National Task Force (NTF) «Génomique et Santé Publique» (Public Health Genomics) organised a symposium on «How to correctly introduce genome-based knowledge in the Belgian health care services?». This working group was set up within the framework of the European project «PHGEN» (http://www.phgen.nrw.de/typo3/index.php), which looks at the prerequisites for a proper implementation of the achievements of public health genomics in the healthcare system.

This new area focuses on implementing the findings of human genomic research in clinical practice. The SHC therefore issues advisory reports on this subject. It then uses its networks to identify the different parties involved that are likely to play a significant part in this process, such as government scientific institutions, scientific councils, etc.

The structure of the SHC makes it the ideal environment to issue advisory reports. The latter can form the foundation for the formulation of various criteria, especially those that concern the carrying out of genetic testing in view of certain types of treatment. With these criteria, it should be possible to set up a framework with basic guidelines to which a detailed explanatory note would be added. These basic guidelines could then be transposed into legislation.

There are three mainstays to the SHC's role in public health genomics :

- The SHC takes into account the objectives of the Belgian national task force (national study group) when drawing up its advisory reports and uses the expertise available within its multidisciplinary network.
- The notion of personalised medicine is only one of the approaches to public health genomics. This is a very broad area that influences all sectors in medicine. The different working groups of the SHC seek to identify any common grounds between their own fields of activity and public health genomics and, if need be, look at how the issues concerned can be integrated into their work programme or how they can be handled.
- The SHC can rely on its network to identify all the stakeholders and reach a consensus on the practical way to tackle questions that are specific to the area of public health genomics.

"Ongoing activities": confidential and/or select advisory reports - projects

***SHC 8565* – Public Health Genomics in Belgium**
The SHC has been asked for its opinion on a national reflection in the field of Public Health Genomics. This advisory report was presented during a symposium in February 2010. It is currently being revised in the light of the comments received during this meeting, which aimed at coordinating the activities of the main Belgian parties involved.

➤ Start 05/2009 – End 01/2011 - Contact: Anne-Madeleine PIRONNET / Sylvie GERARD

"Ongoing permanent activities": confidential and/or select advisory reports

As this work programme comes into being, it is difficult to predict what requests we may expect in 2011 in the field of PHG. Nevertheless, there has been a standing think-tank set up to follow up on this issue and to provide transversal support to the other groups of the SHC that could require expertise in this field for their own area. In fact, a coordination meeting with the chairpersons of the other sections of the SHC was held in late 2010 in order to explore possible project avenues.

"Planned projects": new planned projects

Project direct-to-consumer genetic testing services
Over the last decades, the understanding of the genetic background of diseases has increased dramatically. More than 1600 genetic tests (http://www.ncbi.nlm.nih.gov/gtr/qa/) are currently available in clinical practice. These tests can be used to diagnose the presence of a specific disorder or to help determine a person's risk of developing or passing on a mainly single-gene disorder. Besides testing for specific and rare monogenic disorders, emerging technologies in genomics are bringing genetic tests that aim at predicting the risk of developing common diseases like diabetes, cancer, heart disease and other common complex disorders.

Genetic tests have always been approached carefully for various reasons. From a societal perspective, concerns have been raised that genetic testing may lead to misuse of the genetic information by third parties, including insurers, employers, adoption agencies or others, and/or might lead to stigmatisation or discrimination of individuals or groups. In addition, concerns were raised about the private and confidential character of genetic information. At a personal level, a person's genetic test results might have direct implications for relatives, including offspring. Moreover, genetic testing might provide information about the medical future of a healthy person, which is different from traditional medical

diagnosis, which says something about the current medical condition of a patient. Finally, it has been reported that a genetic test may also lead to psychological distress, including increased anxiety, depression, changed family relations, changes in self-image or health perceptions.

Because of these issues, genetic tests in most European countries are administered in a clinical genetics centre, where due emphasis is put on the individualised medical supervision of patients, the presence of pre- and post-test counselling, psychological follow-up and quality assurance of the tests performed.

In contrast to the approach taken in healthcare, private commercial companies have been advertising and selling genetic tests directly-to-consumers (DTC) for the past three years.

The goal of this proposal is (a) to provide an overview of the type of services provided, (b) to draw up a review considering the different issues at stake, (c) to issue good practice guidelines and (d) to describe the various regulatory actions that could be endorsed in Belgium.

➤ Planned to start 01/2011

Project on the use of prognostic genomic markers in breast cancer patients
The use of genetic markers for the identification of an increased risk for breast cancer is already well established in common practice. The use of prognostic markers is less well known.

➤ Planned to start 01/2011

Guideline project for the implementation of pharmacogenetics in Belgium
Guidelines are currently being developed within the European project PHgen II. The implementation of pharmacogenetic applications may need to follow a set of criteria for appropriate use, starting with the request for testing, the test and related test quality aspects, the treatment and the follow-up.

➤ Planned to start 01/2011

"Ideas in the pipeline": project ideas to assess

None

10. MISCELLANEA AND MULTIDISCIPLINARY GROUPS

Subsumed under the label "Miscellanea and multidisciplinary groups" are such topics as cannot be included in one of the previous fields, but for which the SHC is, however, required to issue advisory reports. They often concern a combination of several of our working areas or a very specific request.

"Ongoing activities": confidential and/or select advisory reports - projects

As this work programme is being drawn up, all 2010 "Miscellanea and multidisciplinary groups" dossiers have come to an end. We will handle the new requests for 2011 as we receive them.

11. NATIONAL AND INTERNATIONAL CO-OPERATION

This chapter reviews the ongoing initiatives and projects aimed at improving the coordination and integration of the SHC advisory reports at the national and international level.

11A. At the national level

For many years now, the SHC has been co-operating from time to time with the other Belgian scientific advisory bodies. At the moment, this co-operation is mainly linked to specific advisory reports. Nevertheless, some experts from the other institutions also take part in the SHC think-tanks on certain general fields of activity. They do so in a personal capacity and as specialists in the field under consideration. Moreover, given the Belgian context, many of the appointed experts of the SHC and members of the Board take part in the activities of other scientific groups of Belgian institutions. This in turn means that these activities are, to some extent at least, coordinated in this country. More detailed information on this subject can be found in the preceding chapters.

Still, the report from the Court of Auditors from January 2010 on the "scientific support to federal health policy" gives a mixed assessment of this coordination among the main Belgian parties involved.

"During its audit of scientific support to the federal healthcare policy, the Court of Audit found that there is no coherent system sustaining the healthcare policy. The process of acquiring knowledge is spread out throughout multiple organizations that, for lack of any central vision and strategy, carry out their missions according to their own views and means, without much mutual agreement or coordination. Although the audited organizations have tried to produce high standard reports and recommendations, there are still some areas – depending on the organization – that leave room for improvement, such as the planning, allocation of financial means, outsourcing, execution and following-up of the research activities. In the absence of feedback and owing to an untransparent decision-making process in the healthcare sector, it is often unclear whether the recommendations and research activities are used. The minister of Health agrees with most of the Court of Audit's conclusions and recommendations and will ask the administration to put forward a plan with suggestions for improvement.

New and emerging illnesses, increasing healthcare demand as well as technological progress put extra burden on the healthcare financial manageability. This social challenge requires a policy based on scientific knowledge in order to watch over the healthcare quality, evaluate the value of the new technologies and assess the efficiency of the healthcare system itself. The Court of Audit tried to determine

whether there is a coherent system providing scientific support to the federal healthcare policy and, if so, whether the said system meets the standards of the World Health Organization (WHO). The Court further examined the way the five most important knowledge institutes operate. Those are the following: the federal Health department, the Belgian Health Care Knowledge Centre (KCE), the Superior Health Council (CSS-HGR), the Scientific Institute of Public Health (ISP-WIV) and the National Institute for Health and Invalidity Insurance (INAMI-RIZIV).

Although the successive ministers have been aware of the importance of scientific research, a strategy allowing to acquire knowledge and make use of it has not been developed. Many organizations and councils write up scientific reports and recommendations. However, their missions and activities have not been clearly defined and there is no coordination on that matter. Budgeting could be improved too. As a result of various definitions and calculation methods, combined with expenses spread throughout several budget plans, there is no way to calculate the budget allocated to scientific support to the healthcare policy. Which amount of financial means is dedicated to which project or allocated to which organization? On what base have these choices been made? These questions are often left unanswered. These shortcomings prevent the optimal use of scientific knowledge to support the healthcare policy.

The Court of Audit recommends to better organise the knowledge landscape by mutual agreement between all the parties concerned, with the minister of Health acting as a coordinator. The Court also advises to see to it that the funding system allows to clearly calculate the cost of scientific research. In the long run, financing of separate organizations should be replaced by a system in which funds would be granted according to objectives and programs. Since there is no forum of consultation for bringing the various strategies in line, the five examined knowledge institutes mainly cooperate on project basis. This can result in poor consistency between the respective research activities. The coordination with the French-speaking and Flemish communities meets the same difficulties. The institutes endeavor to send high standard studies and recommendations to the minister and their other customers. Yet, the process of acquiring knowledge is not of the same level in every institute.

Some of the problems are listed below:

- *The data necessary to carry out high standard research are not always available in due time.*
- *The reason for choosing some research subjects and discarding others is often unclear.*
- *The planning is generally made on ad hoc basis and is limited in scope.*
- *The project management is not sufficiently rigorous. When it comes to outsourcing procedures, some of the knowledge institutes do not pay enough attention to the quality and usefulness of the research, the independence of the researchers and the transaction costs.*

- *Several knowledge institutes do not draw a detailed list of their scientific studies.*
- *The institutes could do better as regards publishing and distributing the research reports.*

The parties concerned, even the institutes themselves, have limited insight into the use that is made of research. The main cause of this problem resides in the lack of feedback from the beneficiaries of the reports and advices to the knowledge institutes. Furthermore, the advice and decision-making processes, which are not transparent in healthcare matters, are not conducive to an optimal use of the research results. The Court of Audit has made practical recommendations so as to help solve those shortcomings. The minister of Health has answered that she agrees with most of the Court of Audit's conclusions and recommendations. She will ask the different public services under her competence to put forward plans with suggestions for improvement."

The full report (82 p.), the summary (2 p.) and the press release can be found on the Court of Audit's website (www.rekenhof.be).

"Ongoing permanent activities": confidential and/or select advisory reports

In the light of this report, the SHC will take an active part in all initiatives aimed at improving the coordination between the main Belgian parties involved in 2011. The first action in response to this report will start in January 2011, viz. a project of creating a common database that should allow these different institutions to exchange their work programmes. Therefore, this database should first of all allow for a better follow-up of the ongoing and future activities and also promote their synchronisation. With this database, it should also be possible to define the competency of each more accurately and to promote close co-operation on related subjects whilst avoiding the issuing of overlapping advisory reports.

11B. At the international level

Certain groups and/or experts of the SHC are part of existing European and international networks, such as:

- the NHFS working group, which is part of the EFSA network (European Food Safety Authority – http://www.efsa.europa.eu/). One of its members also represents the group within the ESCO (European Scientific Cooperation – http://www.efsa.europa.eu/en/esco/escofolicacid.htm), a working group that analyses the risks and benefits of folic acid enriched foods;

- the PHG group, which works in close co-operation with the Belgian task force of the European PHGen network (http://www.phgen.eu/typo3/index.php);
- etc.

In February 2009, the EuSANH-ISA project (Improving science advice for health) was officially launched. It aims at working out the foundations for the functioning of the EuSANH[1] (European Science Advisory Network for Health – http://www.eusanh.eu/) network until February 2012. In this context, the SHC will increasingly take part in co-operation agreements with Spain, the Netherlands, Poland, Romania and Sweden, as well as with other European countries.

"Ongoing activities": confidential and/or select advisory reports - projects

SHC 8548* – *International co-operation project with the Dutch GezondheidsRaad (GR) "EuSANH WORKING GROUP ON CHILDHOOD LEUKAEMIA"

Leukaemia is the most frequent type of cancer in children in the developed countries. The increasing attention devoted to these disorders and the ever-improving treatments that are being developed have resulted in a significant increase in the survival rate of children with leukaemia in the last few decades. These days, attention is also paid to identifying potential causes.

The SHC and the Dutch GezondheidsRaad have therefore set up the first project of international co-operation of the EuSANH network in September 2010, viz. "**Childhood leukaemia: the role of environmental factors**". Some researchers have suggested that there is a correlation between childhood leukaemia and exposure to certain environmental factors. The main 'suspect' factors are ionising radiation (e.g. from nuclear power plants), non-ionising radiation (from high-voltage power lines) and chemical substances (such as pesticides). The EuSANH working group will assess the strength of the scientific evidence for causality in the reported relationships.

Start: 09/2010 – End 11/2011 – Contact: Katty CAUWERTS

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"Ongoing permanent activities": confidential and/or select advisory reports

The different 2011 work programmes of the organisations taking part in the network are currently being compared in order to explore potential avenues of cooperation for the setting up of new projects during the year.
In March 2011, there will also be the second annual meeting of the EuSANH network.

[1] *EuSANH is a network of scientific advisory bodies in Europe which are active in the field of health. The national scientific advisory bodies of 12 European countries have been taking part in the EuSANH network since October 2009. More advisory bodies are expected to join in the near future.*

Finally, the SHC will focus on continuing its search for new members and will pursue its reflection on the management, communication and co-operation structure of the network beyond the provisional framework of the EuSANH-ISA network (February 2012). The aim is to secure the existence of the EuSANH network. Also on the agenda for this year is working out communication tools as well as drawing up a community methodology handbook on issuing advisory reports on public health issues. This will be done in close cooperation with Spain.

"Planned projects": new planned projects

The 2011 programme includes the launching of the second joint EuSANH project on "implementing screening for certain types of cancers (cervical, colorectal, breast cancer) in Europe». This second pilot project is led by Sweden. The SHC will be actively involved in proofreading the report and will rely on its network of Belgian experts to do so.

Start 02/2011 – End 2012. In charge: Swedish Council on Health Technology Assessment – SBU

"Ideas in the pipeline": project ideas to assess

To be determined after having compared the 2011 work programmes within the framework of the EuSANH project.

12. SCIENTIFIC CONTACT INFORMATION PER FIELD OF ACTIVITY

The distribution of the tasks per field of activity reflects the current situation, which could change in the course of the year depending on the workload and/or arrival of additional scientific staff.

1. *Mental health and psychosocial factors in public health*

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Projects and new requests for advice

2. *Physical environmental factors (ionising radiation, non-ionising radiation)*

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Ionising radiation

3. *Chemical agents*

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4. *Nutrition and health, including food safety and food microbiology*

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5. *Blood and blood products*

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6. *Cells, tissues and organs of human and animal origin*

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7. *Vaccination, infectiology and infection control during care*

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Emerging infectious diseases

8. *Cosmetology and cosmetic devices, including cosmetic surgery*

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9. *Public Health Genomics (PHG)*

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10. *Miscellanea and multidisciplinary groups*

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11. *Internal, national and international coordination*

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Coordination of the SHC's scientific activities

Notes

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2011
WORK PROGRAMME

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