EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks

SANCO.C2 - D/370080

COMMISSION NON-FOOD SCIENTIFIC COMMITTEES

(under the responsibility of the Health and Consumer Protection Directorate General)

SUMMARY OF THE OBJECTIVES AND ACTIVITIES FOR RISK ASSESSMENT IN THE MAIN AREAS OF ACTIVITY AND EVALUATION OF FUTURE NEEDS

(MAY 2003)

TABLE OF CONTENTS

INTRODUCTION

Nine independent scientific committees were established by Decisions 97/404/EC and 97/579/EC which provided respectively for a Scientific Steering Committee (SSC) and eight specific committees. The responsibilities for risk assessment previously carried out by the SSC and the five scientific committees in the field of food and feed safety and animal health and welfare, were transferred to the European Food Safety Authority (EFSA) in May 2003.

The following three scientific committees address questions in the "non-food" areas remained under Commission responsibility within the Directorate General for Health and Consumer Protection (DG SANCO) :

- the Scientific Committee on Toxicology, Ecotoxicity and the Environment (SCTEE); questions on the toxicity and ecotoxicity of chemicals, biochemical and biological compounds whose use may have harmful consequences for human health and the environment;

- the Scientific Committee on Cosmetics and Non-Food Products intended for Consumers (SCCNFP); questions on consumer health in the area of cosmetic and non-food products intended for consumers;

- the Scientific Committee on Medicinal Products and Medical Devices (SCMPMD); questions on Community legislation on medicinal products for human and animal use[1] and on medical devices and equipment.

It is opportune to review the work of these three Committees over the past 6 years and to assess the future needs of the Commission services and particularly with the Directorate Generals for Enterprise (ENTR), Environment (ENV), for Health and Consumer Protection (SANCO) which are the primary source of requests for independent scientific advice in support of their Community responsibilities.

This document summarises the results of this review which was carried out in co-operation with the services concerned. It presents

- background to requests for scientific advice in each of the primary areas of concern;

- estimations of the future number of annual requests (range) in each primary area;

- a summary of the number of opinions of the three scientific committees by year and area.

[1] Without prejudice to the specific responsibilities of the EMEA (European Medicines Evaluation Agency) and in particular of its Scientific Committees for Proprietary Medicinal Products and for Veterinary Medicinal Products.

BACKGROUND

TO

REQUESTS

AREA: CHEMICALS UNDER REGULATION 793/93.

Scientific Committee: SCTEE

Legislative basis:

Existing Substances Regulation 793/93 (European Inventory of Existing Commercial Chemical Substances Directive 67/548 amended by Directive 79/831) aims at the protection of man from exposure to dangerous substances via all possible routes and of the compartments of the environment. "Man" comprises in this context "worker, consumer and man indirectly exposed via the environment". The Regulation introduced a consistent and coherent system for evaluating the risks related to chemical substances. The control on hazardous chemicals should be based on an assessment of the actual risks to human health and the environment, rather than the hazardous properties of the substance only. Therefore it ensures that a Member State cannot ban a substance without carrying out a risk assessment according to principles agreed by all Members States.

Substances on priority lists must undergo an in-depth Risk Assessment, following the framework set out in Commission Regulation (EC) 1488/94 and implemented in the detailed Technical Guidance Documents (TGDs) on Risk Assessment for New and Existing Substances.

Responsible Commission Services: DG ENV (DG ENTR/JRC)

Objective of the consultation:

On the basis of the examination of each Risk Assessment Report provided, the SCTEE is asked whether it agrees with the conclusions of these reports on the risks posed to man and/or the environment, and to elaborate on any reasons why, in case it would disagree.

Summary of the process which leads to involvement of the SC:

The drafts of the Risk Assessment Reports (RARs) are written by the Member States, which act as "Rapporteurs". The Commission mediates the Technical Meetings that are aimed to reach consensus on the conclusions of the RAR, which later go to the SCTEE for peer review (Requests received from DG ENV or JRC).

The comprehensive reports (and summaries thereof) are published after adoption by the Member States, taking into account the opinion of the SCTEE. The results of the risk assessments are published as Commission Recommendations along with proposals for where risk reduction strategies are needed, such as a proposal for a restriction under the Marketing and Use Directive. In this case DG ENTR then takes the responsibility to start the process for making an amendment to Directive 76/769.

DG ENV is responsible for the Regulation 793/03 but with the European Chemical Bureau (ECB), JRC through a Memorandum of Understanding for all technical and scientific support work required under this regulation. JRC also holds the database of information submitted by Industry.

Outputs:

69 opinions, (46 relating to human health and 47 relating to environment) in 1998-2002

May lead to the identification of risk reduction measures to control the risks posed by certain substances if necessary.

Operational aspects: -- --

Co-ordination with other risk assessment bodies:

ECB (JRC)

Problems/Comments: -- --

Forecast for growth in the area:

Regulation has led to a programme designed to identify and control the risks posed by some of the 100 000 chemical substances in the EINECS.

The role of the SCTEE in risk assessment of chemicals will need to be clarified in the light of the future chemicals Regulation and the creation of the future Chemicals Agency.

SANCO interest:

SANCO interest is high on the aspects of the risk assessment for consumers (directly or via the environment) and the subsequent risk reduction measures that need to be considered within the framework of other legislative instruments, for example legislation relating to the marketing and use of certain dangerous substances and preparations, or worker and consumer protection legislation.

AREA: CONSUMER PRODUCTS

Scientific Committee: SCTEE and SCCNFP

Legislative basis:

The revised General Products Safety Directive (2001/95/EC) that relates to the general safety requirement on products including effects of chemicals that may be released from products/articles. A rapid system of information exchange (RAPEX) among Member States allows for the immediate notification of instances where products or chemicals in products pose serious health risks.

Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations

Directive 88/378/EEC amended by Council Directive 93/68/EEC safety requirements for toys – "must be so designed and constructed that, when used as intended or in a foreseeable way bearing in mind the normal behaviour of children, they do not present health hazards or risks of physical injury by ingestion, inhalation or contact with the skin, mucous tissues or eyes".

Directive 67/548/ EEC on the classification, packaging and labelling of dangerous substances and Directive 88/379/EEC in amounts that may harm the health of children using them - "it is strictly forbidden to include, in a toy, dangerous substances or preparations if they are intended to be used as such while the toy is being used.

Legislation on phthalate (test migration of plasticisers to be included) Directives 2003/113/EC, 98/485/EC, 99/815/EC

Harmonization of legislation for use of azodyes in textile and leather Directive 2002/61/EC Amendment of existing Detergent legislation – Directives 73/404/EEC, 73/405/EEC covering specific surfactants and prohibiting marketing where average level of biodegradability is below a specified percentage of biodegradability; Directive 82/243/ EEC on testing methods. Directive 82/242/EEC. European Union chemical legislation covers Directive 67/548/EEC on substances used in detergents, Directive 76/769/EEC amended by Directive 94/60/EC includes safety aspects of detergents

Responsible Commission Services:

DG SANCO, DG ENTR and sometime DG ENV (risks to the environment), DG JRC (exposure assessment of chemicals in articles, validation of methods) and DG MARKT (request for restrictive national legislation).

Objective of the consultation:

Overall objective: Safety assessment related to specific hazards in consumer products.

To peer-review scientific reports on chemicals or for use of alternatives (e.g. phthalate substitutes or plasticisers), validity of methods, e.g. surfactant biodegradability tests, methods to measure release of phthalates from toys and child care articles, review of European Standards proposed by CEN (e.g. on organic chemicals in toys). To investigate and support risk assessment activities in the context of notifications under the General Product Safety Directive (GPSD).

Summary of the process which leads to involvement of the SC:

Commission services (DG SANCO or DG ENTR) needing peer review of scientific reports and other pertinent information in support of legislative proposals. In the case of GPSD notifications, DG SANCO submits the available information from the notifying MS and from the public domain to the SC for advice.

Outputs:

17 opinions in this area in 1998-2002. Possible ban of certain phthalates and lead in candlewicks, possible mandatory use of tests, MSs asking for creosote restrictions succeeded following SCTEE opinion. Consumers products considered were toys, child-care articles, candles, textiles, leather goods, writing inks, paper products, wood, detergents, medicinal products.

Operational aspects:

Exposure data often lacking.

Co-ordination with other risk assessment bodies:

In specific cases JRC (migration tests) and EMEA (risks of medicinal products to the environment) highly involved (In future, EFSA).

Problems/Comments: -- --

Forecast for growth in the area:

Continuing and substantial increase interest in the safety of consumer products in particular in light of the provisions of the revised GPSD and the EIS-CHEMIRISKS and EIS-CHEMITESTS projects undertaken by the JRC at the request of DG SANCO to investigate the issue of consumer exposure to chemicals released from articles and to develop methodologies that will help identify and measure release. Expertise in migration method development and exposure assessment will be needed.

SANCO interest:

Consumer safety policy and public health (various sources of exposure to chemicals and use of chemicals, subgroups of population at higher risks)

AREA: INDUSTRIAL/PROFESSIONAL USE PRODUCTS

Scientific Committee: SCTEE

Legislative basis:

Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations

Placing on the market of dangerous substances and preparations must aim at protecting the public, and particular persons using such substances and preparations, should contribute to the protection of the environment from all substances and preparations which have characteristics of ecotoxicity or which could pollute the environment, should also aim to restore, preserve and improve the quality of human life.

Directive 99/77/EC (adapting to technical progress for the 6th time Annex I of Directive 76/769/EEC) relating to asbestos restrictions.

Responsible Commission Services:

DG ENTR (Chef de file) but DG SANCO and DG ENV associated in most questions.

Objective of the consultation:

Overall objective: Assess the risk to health and the environment posed by specific substances in identified products.

To peer review risk assessment reports prepared under contract, including methodology, assumptions, health risks to consumers and workers, exposure and trends from non-food products or environmental sources (emission, releases), quantitative contribution of various sources, risks to the environment (accumulation).

Substances of concern include lead, arsenic, cadmium, copper, asbestos, preservatives, stabilizers and colorants. Products include fertilisers, cement, wood, antifouling paints, and textiles.

Summary of the process which leads to involvement of the SC:

Commission services (DG ENTR) needing peer review of scientific reports and other relevant material in support legislative proposals.

Outputs:

22 opinions in this area in 1998-2002 (among them 17 relating to the environment, 24 to public health and 16 to consumer products)

Measures for restrictions of current levels or product use or ban (e.g. asbestos). Proposal of alternative (e.g. workers using gloves to avoid skin allergies from cadmium)

Operational aspects:

Exposure data often lacking

Co-ordination with other risk assessment bodies: future co-ordination with EFSA

Problems/Comments: -- --

Forecast for growth in the area:

Increased interest in the risks posed by biocides (Directive 98/8/EC). Increase need of integrated risk assessment approach (air, soil, food, products)

SANCO interest:

Consumer safety policy use and Public health: various sources of exposure to substances, e.g. environmental sources, emission by industrial plants, specific risks at workplace, substances present in consumer products, e.g. textiles, industrial asbestos

AREA: AIR QUALITY

Scientific Committee: SCTEE

Legislative basis:

Directive 96/62/EC on the Ambient Air Quality Assessment and Management (close Framework Directive on Air Quality)

Responsible Commission Services: DG ENV

Objective of the consultation:

Revision of legislation on air quality; Commission proposal for setting limit values on Ni, Cd, As, PAHs and O_3

Summary of the process:

Directive 96/62/EC foresees Commission proposals on a number of air pollutants. SCTEE has been consulted on the position paper for ozone (resulting in directive 2002/3) and on position papers on Ni, Cd, As and PAHs, for which a proposal for a directive is currently in inter-service consultation. The position papers were developed by working groups composed as national and other experts, organised by DG ENV.

Output:

5 opinions (1999 - 2001)

Operational aspects: -- --

Co-ordination with other risk assessment bodies: -- --

Forecast for growth in the area:

Commission health and environment strategy (DG SANCO, DG ENV, DG RTD). The SCTEE may be involved in providing scientific advice to the Consultative Group on Environment and Health, which will identify risk management measures and review relevant policies in this area.

The Commission is committed to drawing up a thematic strategy on air pollution by mid-2005. A technical programme "Clean Air for Europe" is currently underway to gather the necessary scientific and technological information. SCTEE could play a useful role in complementing other sources of scientific information in this area.

As far as air quality is concerned the primary sources of independent scientific information concerning the effects of air pollution used by DG ENV in preparing its proposals are WHO (for effects on human health) and scientific centres under the UN/ECE Convention on Long-Range Transboundary Air Pollution. These sources are complemented by further information from JRC, EEA, DG Research, and the SCTEE. DG ENV would like to see the SCTEE play a more substantial and useful role in the future, but stresses that consultation of this committee should not be mandatory or automatic for each and every proposal, given that other legitimate sources of independent scientific information exist.

SANCO interest: public health (European Environment and Health Strategy).

AREA: WATER QUALITY

Scientific Committee: SCTEE

Legislative basis:

Water Framework Directive (2000/60/EC); Directive 76/160/EEC (Bathing Water Directive), Drinking Water Directive 98/83/EC.

Responsible Commission Services: DG ENV; DG SANCO

Objective of the consultation:

Revision of Bathing Water Directive taking account of new scientific information and the Water Framework Directive. Assessment of safety of drinking water in the EU.

Summary of the process:

In the context of the Bathing Water Directive revision, the Commission intended to propose two new microbiological indicators for coastal and fresh waters. The Commission asked the SCTEE on the appropriateness of these two indicators and limit values to ensure acceptable protection of human health.

In 1999 DG SANCO commissioned a study with the aim to assess the safety and quality of drinking water (tap and bottled), when received by the consumers in selected European cities. The SCTEE was asked to review the overall scientific quality of 2 large studies and to make recommendations for future similar studies.

The SCTEE was also invited to comment on studies which were commissioned in the preparation of the Water Framework Directive and the identification of priority substances in order to support the preparation of Commission proposals.

Output:

6 opinions (1998-2002)

Operational aspects:

Possible need to take account of related exposure throughout the food chain

Co-ordination with other risk assessment bodies: Possible future co-ordination with EFSA and European Centre for Diseases prevention and Control and bodies responible for risk assessment of chemicals (currently: JRC – European Chemicals Bureau, future: Chemicals Agency).

Forecast for growth in the area:

The implementation of the Water Framework Directive is at early stages. The next phase is the preparation of "daughter directives" in accordance to Article 16 (priority substances) and Article 17 (groundwater). In particular, as regards environmental quality standards for priority substances, DG ENV will request an opinion of the SCTEE, presumably in the second half 2003. In addition to this aspect, there may be particular scientific issues which may arise in the context of the Article 21 Committee of the Directive. Since the technical work of the Committee will start by the end of 2003,

it is estimated that a maximum of 1 – 3 requests for opinions will emerge from this process until the end of 2006.

On the Drinking Water Directive it is currently not possible to predict the future need for consultation of the SCTEE. Any potential need for SCTEE opinions are likely in 2004 and beyond in case the Commission decides that a revision of the Drinking Water Directive is necessary.

No involvement of the SCTEE is forecasted in relation to the Bathing Water Directive since it is currently under the review. Relevant consultation has already taken place (see above).

In conclusion, no growth but rather a decrease is expected in the area of water quality in comparison to the period 1998-2002.

SANCO interest: Public health and consumer protection

AREA: ELECTROMAGNETIC FIELDS, RADIO FREQUENCY FIELDS, MICROWAVE RADIATION

Scientific Committee: SCTEE

Legislative basis:

Council recommendation 5 July 1999 on the limitation of exposure of the general public to EMF.

Responsible Commission Services: DG SANCO

Objective of the consultation:

In the light of new knowledge and developments in technology and applications of sources and practises giving the exposure to electromagnetic fields, review health effects of exposure to EMF: epidemiological, biophysical and biological evidence (genetic, carcinogenic effects, effects on the immune, circulatory and nervous system, general behaviour). Appropriateness of ICNIRP guidelines and recommendation for exposure limits.

Summary of the process which leads to involvement of the SC:

Broad Community concern related to the safety of EMF.

Outputs:

3 opinions issued in 2001, 2002

No grounds at present for revision of exposure limits recommended by Council (OJ L199/59 – 30/07/99), but the SCTEE made recommendations for research priorities.

Operational aspects:

Exposure data inadequate.

Co-ordination with other risk assessment bodies:

Future co-ordination with the International Commission on Non Ionising Radiation Protection (ICNIRP) and the WHO

Problems/Comments:

EMF and related issues was at limits of expertise of the SCTEE.

Forecast for growth in the area:

Likely to require continuous updating of risk assessments as new data becomes available (very sensitive area).

Reviewing process of the Council Recommendation in 2004.

Increasing exposure to EMF consequent to the further growth in the use of electricity from the continuous development of the telecommunications industry and to a rapid increase in the installation of transmitter mass used as radiotelephone base stations.

SANCO interest:

Consumer safety and public health: Increasing proportion of public chronically exposed to ELF/EMF and RF (houses, business premises, schools).

AREA : ENVIRONMENTAL ISSUES

Scientific Committee: SCTEE or other SC as appropriate

Legislative basis:

Decision n° 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the sixth Community Environment Action Programme

+ Thematic legislative framework

Responsible Commission Services: DG ENV

Objective of the consultation:

Peer review of background documents, projects and studies, position paper…

Assessment of the potential hazards due to, and risk evaluation of, environmental factors on human health and ecosystems.

Assessment of environmental risks in an integrated system.

Summary of the process:

The global process can be summarised as follows : review of the available knowledge ; elaboration of legislative proposals or position papers, consultation carried with Member States ; environmental NGOs, industries and other stakeholders ; where appropriate development of scientific studies and request for peer review by the SCTEE on the final report and/or postion paper ; final drafting of legislation

This process shall in particular be adapted to the area concerned and the level of knowledge available.

Output: 2 opinions (2000-2001)

Operational aspects: -- --

Co-ordination with other risk assessment bodies:

Future co-ordination with EFSA, EEA, WHO, UNEP, UNECE …..

Forecast for growth in the area:

Revision of existing Directives and elaboration of new legislation on topics identified in the 6 EAP. Increased interest on the impact on human health through the environment (proposed European Environmental and Health Strategy)

SANCO interest:

Public health (Environment and public health strategy)

AREA : ENVIRONMENTAL ISSUES
SUB AREA : WASTE MANAGEMENT

Scientific committee : SCTEE

Legal basis : Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture.

Responsible Commission Services: DG ENV

Objective of the consultation:

Peer review of background documents on the use of sludge in agriculture prepared to support a proposal for extending the scope of the Directive

Prediction and assessment of the potential danger and effects of chemical substances on terrestrial ecosystems.

Summary of the process:

Consultation carried out by DG ENV with Member States, environmental NGOs, industries and other stakeholders; request for peer review by the SCTEE on the final report on the hygienic aspects relative to the use of sludge in agriculture

Output:

2 opinions (2000-2001)

Operational aspects: -- --

Co-ordination with other risk assessment bodies:

Possible future collaboration with EFSA and EEA

Forecast for growth in the area:

Revision of Directive 86/278/EEC foreseen for 2003; adoption of a Proposal for a Directive on the biological treatment of biodegradable waste foreseen for 2004. Due to this legislative development, it is probable that the SCTEE will be asked for further opinions to evaluate the scientific basis of reports carried out by external consultant. Main areas of interest are likely to be hygienic aspects, heavy metals, organic compounds, food chain, animal uptake of pollutants, protection of groundwater, biological risks in general. The strengthening of expertise in waste management and soil protection in the SCTEE would be an advantage.

AREA : ENDOCRINE DISRUPTION

Scientific Committee: SCTEE

Legislative basis:

Communication from Commission to the Council and the European Parliament on a Community Strategy for Endocrine Disrupters (COM (99) 706) on the necessity of the establishment of a priority list of substances to further evaluate their role in endocrine disruption

Responsible Commission Services: DG ENV (chef de file); SANCO and DG ENTR

Objective of the consultation:

Establishment of a priority list of substances for further evaluation of their role in endocrine disruption. Human and wildlife health effects of endocrine disrupting chemicals.

Summary of the process:

Study "towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption" carried out by The Netherlands: Request of an opinion of the SCTEE on the report.

Output:

2 opinions (1999-2000)

Operational aspects:

Horizontal issue affecting safety assessment of chemicals in many consumer and industrial products.

Co-ordination with other risk assessment bodies:

Possible future co-ordination with the proposed European Environment and Health Strategy which include endocrine disrupters among the priority pollutants; EFSA.

Forecast for growth in the area:

Commission health and environment programme (DG SANCO, DG ENV, DG RTD). Test and risk assessment of the substances included in the "list of substances with potential evidence of endocrine disruption".

SANCO interest:

Public health (various sources of exposure) and consumer protection (professional or consumer use)

AREA: INGREDIENTS/SUBSTANCES. COSMETICS UNDER COUNCIL DIRECTIVE 76/768/EEC.

Scientific Committee: SCCNFP

Legislative basis:

The prior consultation of the SCCNFP (former SCC) is mandatory. Directive 76/768/EEC on cosmetic products stipulates in its Article 8, paragraph 2 "…and after consultation of the Scientific Committee on Cosmetology (Former SCC, now SCCNFP), the amendments necessary for the adaptation to technical progress of the Annexes…". The Annexes refer to products/substances placed in the market.

Responsible Commission Services:

DG ENTR (chef de file), DG SANCO and JRC (validation of methods).

Objective of the consultation:

Risk assessment of substances used or to be used in cosmetic products (consumer safety) as basis for a Commission proposal to authorise or ban substances such as hair dyes, preservatives, UV filters, colorants and fragrances. Investigation of consumer and public health related issues associated with cosmetics. Most importantly the recent developments linking permanent hair dye use and bladder cancer have signalled the need for a more concerted strategy to address this issue.

Summary of the process which leads to involvement of the SC:

Requests from DG ENTR (mainly mandatory consultation).

Outputs:

162 opinions in period 1998-2002, including notes of guidance for the evaluation of the submitted dossiers.

Operational aspects:

Capacity of SCCNFP to handle workload (currently there is backlog of 65 requests for opinions), use of external experts, industry expertise, horizontal issues (e.g. harmonised risk assessment, replacement of animal testing, endocrine disruptors).

Co-ordination with other risk assessment bodies:

Future co-ordination with EMEA, EFSA, the future Chemical Agency.

Problems/Comments:

Need for better co-ordination/harmonisation risk assessments on same or related substances in other sectors.

Forecast for growth in the area:

Increased awareness of consumer exposure may lead to increased demand for regulation/risk assessment e.g. for hair dyes a single study in USA triggered the urgent revising of more than 100

ingredients which have been on the market in the EU without restrictions. Hair dye strategy will involve the re-evaluation of at least 80-90 hair dyes. In addition the planned DG SANCO sponsored activity to further elucidate the connection between permanent hair dyes and bladder cancer will require a strengthening of chemistry, metabolism, and cancer expertise.

SANCO interest: Consumer safety (typical “over the counter” frequent use consumer products)

AREA: ALTERNATIVE METHODS IN COSMETICS UNDER COUNCIL DIRECTIVE 76/768/EEC

Scientific Committee: SCCNFP

Legislative basis:

In the area of alternative methods to animal testing, Directive 76/768/EEC on cosmetic products requires the consultation of the SCCNFP (former SCC), and in particular: "Before submitting such measure, the Commission will consult the Scientific Committee on Cosmetology.

The 7th amendment sets deadlines (6 and 9 years) to ban cosmetic ingredients tested on animals. DG ENTR is obliged to set a timetable for reasonable action beginning in 2004. These measures will influence the SCCNFP work programme.

Once ECVAM validates an alternative method, the SCCNFP is requested to provide a scientific opinion on its relevance and applicability in the area of cosmetics.

Responsible Commission Services:

DG ENTR (chef de file), DG SANCO (Public Health) and JRC (validation of methods).

Objective of the consultation:

The overall objective is to verify if alternative methods, proposed by ECVAM or other scientific institutions, are relevant and applicable in the area of in vivo test for cosmetics.

Summary of the process which leads to involvement of the SC:

Requests from DG ENTR (mandatory consultation).

Outputs:

7 opinions in this area from 1998-2002. This includes notes of guidance. Only two endpoints have been validated from a total of 14 submitted for consideration.

Operational aspects:

There is a need for an examination of alternative methods taking account of the specificities of cosmetics.

Co-ordination with other risk assessment bodies: ECVAM

Problems/Comments: -- --

Forecast for growth in the area:

A need for increase is foreseen in 7th amendment and deadlines already agreed.

SANCO interest:

Indirect.

AREA: MEDICINAL PRODUCTS. DIR 65/65/EEC.

Scientific Committee: The SCMPMD.

Legislative basis:

Consultation is ad hoc and not associated with any specific legislation. The mandate is limited to subjects not fully covered by the mandate of EMEA which is responsible for marketing authorisation.

Responsible Commission Services: DG ENTR.

Objective of the consultation:

To provide a scientific basis to support Commission need in the area, e.g. to prepare new legislation such as "Orphan Medicinal Products".

Summary of the process which leads to involvement of the SC:

Requests put by DG ENTR.

Outputs:

10 opinions in period 1998 to 2000. No requests since.

Operational aspects:

The SCMPMD has the necessary expertise.

Co-ordination with other risk assessment bodies:

In principle EMEA, JRC (Ispra), IPTS

Problems/Comments: -- --

Forecast for growth in the area:

Little activity forecast.

SANCO interest: Public health aspects.

AREA: CJD/vCJD/BSE/OTHER DISEASES (BLOOD&TISSUE).

Scientific Committee: The SCMPMD

Legislative basis:

The consultation is ad hoc and not associated with any specific legislation. The Committee directly, or indirectly through the SSC, has been involved in questions related to the safety of blood and tissue for transfusion or transplantation. The EMEA has competence for blood derivatives used in medicinal products.

Responsible Commission Services: DG SANCO.

Objective of the consultation:

To provide a scientific basis in support of proposals for legislation.

Summary of the process which leads to involvement of the SC:

Requests have been made by DG SANCO.

Outputs:

The main application of the opinions was to support the drafting of EP and Council Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.

Operational aspects:

The SCMPMD has the necessary expertise.

Co-ordination with other risk assessment bodies:

In principle EMEA, JRC (Ispra), IPTS.

Problems/Comments: -- --

Forecast for growth in the area:

Potential activity.

SANCO interest: Public health aspects.

AREA: MEDICAL DEVICES.

Scientific Committee: The SCMPMD.

Legislative basis:

Council Directive 93/42/EEC on medical devices. The consultation of the Committee on these subjects is not mandatory. It was only consulted for certain products employed in the fabrication of medical devices and the possible health problems if these products were used

Responsible Commission Services:

DG ENTR (chef de file), DG SANCO interest through Public Health programmes.

Objective of the consultation:

To provide the Commission with independent scientific advice related to risks associated with Medical Devices.

Summary of the process which leads to involvement of the SC:

Questions put by DG ENTR.

N.B. Since the Directive dealing with Medical Devices is a new approach Directive, the Member States (through their Notified Body) have the authority to work independently in accordance with Guidelines established by the Commission through the CEN.

Outputs:

5 opinions in the period 1998-2000. No request since.

Operational aspects:

The SCMPMD has the necessary expertise to deal with the questions.

Co-ordination with other risk assessment bodies:

In principle JRC (Ispra), IPTS, CEN.

Problems/Comments: -- --

Forecast for growth in the area:

Potentially, very important activity.

SANCO interest: Public health aspects.

AREA: NEW TECHNOLOGIES (TISSUE ENGINEERING, XENOTRANSPLANTATION, ETC)

Scientific Committee: SCMPMD.

Legislative basis:

Questions arise on an ad hoc basis and are not associated with any specific legislation.

Responsible Commission Services: DG SANCO.

Objective of the consultation:

To provide an overview of scientific issues in this area.

Summary of the process which led to involvement of the SC:

Own initiative review.

Outputs:

The opinions contributed to drafting of the Commission proposal for an EP and Council Directive setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells.

Operational aspects:

The SCMPMD has the necessary expertise.

Co-ordination with other risk assessment bodies:

In principle EMEA, JRC (Ispra), IPTS

Problems/Comments: -- --

Forecast for growth in the area:

There is a potential importance.

SANCO interest: Public health aspects.

FUTURE NEEDS – ESTIMATED NUMBER OF OPINIONS PER YEAR (RANGE) FOR THE PRIMARY AREA OF CONCERN

	Reg or policy	Nature of risk	Opinions pa - Min	Opinions pa - Max	Current Committee	Competent DG -Unit	SANCO
Existing Substances Reg	793/93	Human health, Environment	6	10	SCTEE	ENV C3	B3 , G2
Dangerous substances and preparations	76/769	Human health, Environment	6	10	SCTEE	ENTR E3	B3
Detergents	73/404/EC; 73/405; 82/243; 82/242	Human health Environment	0	5	SCTEE	ENTR E3	B3
Fertilizers	76/116	Human health, Environment	0	5	SCTEE	ENTR E3	B3
Azo dyes in textiles and leather	2002/61/EC	Human health,	0	0	SCTEE		B3
Toys	88/378/; 93/68/EC	Human health,	1	2	SCTEE	ENTR D5/E3	
Phthalate (migration from toys)	2003/113/EC; 98/485/EC; 99/815	Human health,	0	0		ENTR D5/E3	B3, G2
Biocides	98/8/EC	Human health, Environment	25	40	SCTEE	ENV C4	G2
Environment /Public health Issues	EAP 6, Env and Health Strategy,	Human health, Environment	10	20		ENV B4	G2
Waste management and soil protection	86/278/EEC	Human health, Environment	0	5	SCTEE	ENV A2	D2
Air quality	96/62/EC, 2002/3	Human health, Environment	5	5	SCTEE	ENV B4	G2
Water safety (construction material)	89/106/EEC	Human health	6	10	SCTEE	ENTR G5	B3

Water Quality	98/83/EC 2000/60/EC 76/160/EEC	Human health, Environment	0	6	SCTEE	ENV B1	G2
Endocrine disrupters	COM (99) 706	Human health, Environment	1	2	SCTEE	ENV	B3, G2
Hair dyes	76/768/EEC; 2003/15/EC	Human health	20	40	SCCNFP	ENTR F 3	B3
Preservatives	76/768/EEC; 2003/15/EC	Human health	6	10	SCCNFP	ENTR F 3	B3
UV filters	76/768/EEC; 2003/15/EC	Human health	6	10	SCCNFP	ENTR F 3	B3
Miscellaneous cosmetic ingredients	76/768/EEC; 2003/15/EC	Human health	10	20	SCCNFP	ENTR F 3	B3
Animal test alternatives	76/768/EEC; 2003/15/EC	Human health (Safety testing)	0	5	SCCNFP SCTEE	ENTR F 3 ENV C3	B3
Medical Devices Animal products	90/358/EC; 98/79/EC; 2000/70/EC	Human health	0	5	SCMDMP	ENTR G4	G
Medical Devices Human products	90/358/EC; 98/79/EC; 2000/70/EC	Human health	0	5	SCMDMP	ENTR G4	G
Dental amalgam, natural rubber, PVC, placticisers	90/358/EC; 98/79/EC; 2000/70/EC	Human health	0	0	SCMDMP	ENTR G4	G
Physical Risks e.g. EMF	Council Recommendation 5/7/99 OJ L199/59	Human health	1	2	SCTEE	SANCO G	G 2
General Product Safety e.g. Piercing, Tattooing, lead candlewick	2001/95/EC (Art 8)	Human health,	5	10	SCTEE	ENTR	B3
TOTALS			108	227			

NUMBER OF OPINIONS ADOPTED BY THE SCIENTIFIC COMMITTEES IN THE PERIOD 1998-2002

		1998	1999	2000	2001	2002	**Totals**
CSTEE	Chemicals under Regulation 793/93	4	-	15	24	26	**69**
	Consumer Products *(e.g. phthalate in toys, azo-dyes in textiles and leather goods)*	4	5	1	6	0	**16**
	Ind./Prof. Use Products *(e.g. asbestos, risks by cadmium used as colouring agent, stabiliser in polymers and for metal plating)*	5	3	5	1	7	**21**
	Air Quality *(e.g. air pollution by nickel compounds, standards and thresholds for tropospheric ozone, indoor air quality)*	-	1	-	4	-	**5**
	Water Quality *(e.g. list of priority substances, health standards for bathing water, safety of drinking water)*	1	1	1	1	1	**5**
	Electromagnetic Fields, Radio Frequency Fields, Microwave Radiations	-	-	-	1	2	**3**
	Specific Environmental Issues *(e.g. risk of chemical on terrestrial ecosystems, sludge treatment for pathogens reduction)*	-	-	1	1	-	**2**
	Endocrine Disruption	-	1	1	-	-	**2**
	TOTAL	**14**	**11**	**24**	**38**	**36**	**123**
SCCNFP	Hair Dyes	10	20	8	3	9	**50**
	Other ingredients *(e.g. CMRs, teeth bleaching)*	16	6	6	5	6	**39**
	Non Food (detergents)	0	0	0	0	2	**2**
	Notes of Guidance (cosmetic ingredients)	4	4	6	1	2	**17**
	Inventory of cosmetic ingredients	5	4	4	-	-	**13**
	Preservatives	1	3	-	-	9	**13**
	UV Filters	4	7	1	1	-	**13**
	Fragrance compounds	-	3	5	2	2	**12**
	Alternatives to animal tests	-	4	1	-	2	**7**
	Colorants	1		1	1	1	**4**
	TOTAL	**41**	**51**	**32**	**13**	**33**	**170**
SCMPMD	Medicinal Products	5	4	1	-	-	**10**
	CJD/vCJD/BSE (Blood & Tissue)	1	2	2	-	1	**6**
	Medical Devices	2	1	1	-	1	**5**
	New Technologies *(tissue engineering, xenotransplantation)*	-	-	-	2	-	**2**
	Other	-	1	-	-	1	**2**
	TOTAL	**8**	**8**	**4**	**2**	**3**	**25**