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Comparative review of risk terminology

A COMPARATIVE REVIEW OF TERMINOLOGY AND EXPRESSIONS USED BY THE THREE NON-FOOD SCIENTIFIC COMMITTEES ESTABLISHED BY COMMISSION DECISION 2004/210/EC AND BY THEIR PREDECESSORS ESTABLISHED BY COMMISSION DECISION 97/579/EC (REPEALED BY COMMISSION DECISION 2004/210/EC)

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SUMMARY

Clarity of scientific advice is vital if public authorities are to make the best risk management decisions and if these are to be understood and widely supported by stakeholders, consumers and industry alike. It is therefore essential that the opinions of scientific committees explain clearly the nature of the risks, their possible impact on humans and the environment and the uncertainty in available scientific information.

The former EC Scientific Steering Committee highlighted the wide variety of terms and phrases that were used to express risk and uncertainty, and recommended development of a harmonised terminology.

The purpose of the present project was to undertake a comparative review of the terminology used in concluding sections of 100 opinions issued by the European Community's former and current non-food scientific committees, and make recommendations for improved approaches to expressing risk and uncertainty.

Examination of the opinions revealed a large variety of terms and phrases that could be interpreted as expressions of risk, including: the word "risk" combined with a qualifier such as high or low; expression of risk in terms of effects or exposure; phrases that use the term "margin of safety"; expression of risk in terms of level of evidence; and expressions in terms of concern, or of safety.

Fewer opinions included quantitative expressions of risk in their concluding sections: most of these were ratios of toxicity and exposure (e.g. margin of safety). Very few included quantitative estimates of adverse effects.

An even larger variety of terms and phrases were found that could be interpreted as expressions of uncertainty, of which the most common was "may". The word "uncertain" or "uncertainty" was included in the concluding sections of 20 of the 100 opinions. Very few included quantitative expressions of uncertainty.

The detailed findings and recommendations of the review are listed in Section 6 of this report. The principal conclusions on the expression of risk and uncertainty are as follows:

1. Although attractive in theory, defining harmonised verbal terms to express risk would not improve risk communication. Different definitions would be required for different areas of risk. If the definitions were quantitative, then expressing the risk quantitatively would be more transparent and less liable to misinterpretation than using the verbal expressions. If the definitions were qualitative, variable interpretation by different people would cause inconsistencies in both the expression and understanding of risks, which would impair decision-making. Furthermore, it would be difficult to define qualitative terms in such a way that they could be used by assessors without making or implying risk management judgements.
2. In cases where quantitative measures of risk are an important part of the assessment, it is better to include the quantitative measure in concluding sections and summaries and not replace it with qualitative verbal expressions of risk. However, uncertainties affecting the quantitative expression should always be described, and should be included together with any relevant qualitative considerations as part of a balanced overall characterisation of the risk.

3. Even when an assessment is entirely qualitative, scientists should try to provide a quantitative expression of risk that reflects the degree of uncertainty, e.g. an upper bound or a subjective estimate of the probability of outcomes of interest to the decision-maker. In cases where assessors feel that the science will not support a quantitative expression, they should consider whether it really supports a qualitative expression, and ensure the uncertainty is fully understood by decision-makers.
4. Consideration should be given to adopting a systematic tabular approach for summarising and characterising uncertainties. This would be practical for expert committees to use and help them to evaluate the combined impact of multiple sources of uncertainty.
5. Consideration should also be given to exploring whether scientific committees could make more use of quantitative expressions of uncertainty, including subjective probabilities, and whether this would be useful to decision-makers. One option for doing this would be to carry out case studies with representative scientists and decision-makers, with assistance from experts in this type of analysis.

Further work involving the European scientific bodies involved in risk assessment would be required to harmonise approaches to expressing risk and uncertainty.

CONTENTS

1 INTRODUCTION

The Directorate General for Health and Consumer Protection (SANCO) is responsible for the management of three scientific committees composed of external scientists who give the Commission independent scientific advice in the field of consumer safety, public health and the environment.

Clarity of scientific advice is vital if the public authority is to make the best risk management decisions and if these are to be understood and widely supported by stakeholders, consumers and industry alike. It is therefore essential that the opinions of the scientific committees explain clearly the nature of the risks, their possible impact on humans and the environment and the uncertainty in available scientific information.

The need for a harmonisation of terms and expressions used in scientific opinions use of harmonised terminology to describe similar risks has been recognised as a key element in the achievement of clear scientific advice. The subject was addressed as part of a wide ranging review made by the Scientific Steering Committee (SSC) and published in its opinions on the Harmonisation of Risk Assessment Procedures (26-27 October 2000) (SSC 2000) and on The Future of Risk Assessment in the European Union (10-11 April 2003) (SSC 2003). In its opinion of October 2000, the SSC provided a glossary of terms for use in risk assessment. The need to provide greater harmonisation in other terms and expression used in the opinions of Community Risk Assessment bodies was more recently recognised at the meeting of Chairs of Community Scientific Committees and Panels responsible for risk assessment (Brussels 7/8 December 2005).

The objective of this project is to make a comparative review of the terms and expressions that are not included in the Glossary of Terms recommended by the SSC in its opinion on the Harmonisation of Risk Assessment Procedures (Appendix 1 of SSC 2000). The review is based on a sample of the scientific opinions of the following scientific committees:

- The current three non-food scientific committees established by Commission Decision 2004/210/EC:
    - The Scientific Committee On Consumer Products (SCCP)
    - The Scientific Committee on Health and Environmental Risks (SCHER)
    - The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)
- The former three scientific committees established by Commission Decision 97/579/EC:
    - The Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers (SCCNFP)
    - The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE)
    - The Scientific Committee on Medicinal Products and Medical Devices (SCMPMD).

The purpose of the comparative review is to assist the current non-food scientific committees to identify best practices in the expression of complex ideas used in risk assessment.

2 SCOPE OF REVIEW

2.1 Opinions examined

The project examined a total of 100 opinions. The selected opinions were suggested by the Commission following an initial meeting at the beginning of the project and are distributed between the Committees and over time as shown in Table 1.

Table 1. Opinions examined in this project, by Committee and year of publication.

	1998	1999	2000	2001	2002	2003	2004	2005	2006	Total sample	Total published
CSTEE	3	3	3	2	6	4	3			24	176
SCCNFP		4	1	1	5	2	7			20	257
SCCP							1	12	8	21	109
SCENIHR								1	4	5	11
SCHER								12	7	19	53
SCMPMD	2	1	3	2	2	1				11	26
Total	5	8	7	5	13	7	11	25	19	100	632

Of the 100 opinions examined, 10 addressed risks to both human health and the environment, 10 addressed only risks to the environment and the remaining 80 only human health.

In this report, references to individual opinions are made using the committee acronym and a reference number, e.g. SCCP01, CSTEE20. The reference numbers were assigned in chronological order for each committee. These identifiers can be used to locate the title, year of publication and page-count of each opinion, which are listed in listed in Appendix 1.

The remit for this report was to focus on the concluding sections of the opinions and not to undertake detailed analysis of the other sections of the opinions, although these were consulted when necessary to clarify phraseology used in the concluding sections.

2.2 Types of expressions and terminology considered

The project focussed on expressions and phrases used to characterise risk and uncertainty that are not covered by the SSC's Glossary of Terms, Appendix 1 of SSC (2000). The key terms defined by the SSC are reproduced in Appendix 2 of this report.

The remit for the project was to examine, for each opinion, the terms and phrases used to describe at least the following:

- the nature of the hazards identified
- the hazard considered to be the most significant for determining the risk to the public or the environment
- the expression of risk:
  - o qualitative expressions
  - o quantitative expressions including the basis for arithmetic calculations
  - o expression of « de minimis » risk
- the expression of uncertainties
- the identification of missing information
- overall conclusions

In addition, on the basis of its experience of participating in scientific committees, the contractor suggested to take the following as secondary points for comparison:

- phrases that (intentionally or unintentionally) imply a view on the importance or urgency of recommendations for action
- terms used to describe special sectors of the population (e.g. sensitive, vulnerable, at risk, infants, etc.).

Inclusion of these additional terms suggested by the contractor was approved by the Commission at the initial meeting. It was also agreed to add the terms 'safety factor' and 'uncertainty factor', even though they are included in the SCC's existing glossary of terms, and also terms used to describe risk assessment approaches. However in practice it was found that these terms very rarely appeared in the concluding sections of the opinions examined, therefore they are not considered further in this report.

In an interim report the contractor proposed to add terms used to describe worst case or conservative assumptions/assessments, and a brief account of this is included below.

3 METHODS

The Commission supplied to the Contractor a list of suggested opinions for review, and electronic copies of all the opinions on CD.

A database was constructed using Microsoft Access® to record and organise all the information extracted from the opinions, and facilitate comparisons across the large number of opinions involved.

The database was used to:

- Store a copy of the whole of the concluding section from each opinion examined.
- Record any of the reviewed terms or phrases that were found in each concluding section, together with the sentence or phrase in which they occur.
- Record other relevant information from the opinions including definitions of terms (although these were very rare), and also comments by the evaluator to assist with the subsequent analysis.

It was not always clear which section of an opinion to consider as the "concluding section". Often the opinion contained a final section with the heading "conclusion" or "opinion", or some other heading implying it represented the main conclusions of the opinion. Where such a section existed, it was selected for analysis. In all of the remaining cases, where there was no concluding section at the end of the document, we identified an equivalent section earlier in the document (with similar headings) and used that for the analysis.

Each concluding section was examined systematically to identify terms and phrases falling under the headings agreed for the review: hazards, qualitative expression of risks, quantitative expression of risks, expression of uncertainties, identification of missing information, overall conclusions and the additional terms agreed with the Commission (see above).

While every effort was made to be systematic and comprehensive, it is possible that a small proportion of relevant terms or phrases was overlooked. Furthermore, identification of relevant terms (e.g. different words used to express a hazard or risk, or to express uncertainties) is inevitably subjective and dependent on the interpretation placed on terms and phrases by the evaluator. Therefore, a broad view was taken of the interpretation of

terms so as to reduce the chance of missing potentially relevant terms. For the same reason, if a term or phrase appeared potentially relevant under more than one heading, it was recorded under both.

After examining all the opinions, the database was used to produce reports listing the information recorded for the terms and phrases found under each heading. These reports were then analysed to produce summarising table for each heading, grouping synonymous or related terms and phrases and separating groups of terms that have different meanings. These summarising tables are presented in the following sections.

4 RESULTS AND DISCUSSION

The results of the analysis are organised according to the main headings agreed for the review, after first listing for information the risk sources addressed in the opinions. As mentioned above, our identification and classification of relevant terms and phrases is inevitably subjective and reflects the interpretation placed on them by the evaluator. This may not be precisely the same as the interpretation intended by the opinion authors. This is a critical aspect of risk communication because the interpretation of other potential readers of the opinions would also vary, dependent in part on their perspective, expertise and experience (e.g. other scientists, risk managers, and stakeholders including industry and the general public). Therefore the tables below are designed to enable readers of this report to form their own view, by listing the specific phrases grouped in each category, by giving examples of their use, and by including references to the opinions in which they were found.

- Conclusions and recommendations emerging from the results are highlighted in text boxes, and summarised together in Section 6.

4.1 Risk sources

To provide an overview of the topics addressed by the opinions included in the review, Table 2 summarises terms the risk sources that were mentioned in the concluding sections. “Risk source” is defined in the SSC glossary as “Agent, medium, commercial/industrial process, procedure or site with the potential to cause an adverse effect(s)/event(s)” (SSC 2000). Note that in opinions on diseases, the concluding sections typically used the name of the disease (e.g. vCJD) rather than that of the causative agent.

Table 2. Summary of risk sources considered in the concluding sections of opinions examined for this report, listed alphabetically (continues on next page).

Risk sources	Opinions	Risk sources	Opinions
2,4-diaminophenoxyethanol HCL	SCCP16	free nanoparticles	SCENIHR03
2,4-diaminophenoxyethanol sulphate	SCCP16	furfural	SCCNFP19, SCHER01
4-MBC	SCCP14	furocoumarin	SCCP04
acetaldehyde	SCCNFP17	glyoxal	SCCP05
AIDS	SCMPMD01	hair dyes	SCCNFP16, SCCP11
arboviruses	SCMPMD12	HBV	SCMPMD01
arthropod-borne viruses	SCMPMD12	HCV	SCMPMD01
atranol	SCCP01	Henna Rot	SCCNFP10, SCCP07
azo colourants in toys	CSTEE10	hepatitis A	SCMPMD01
azo dyes in textiles and leather goods	CSTEE06	HHCB	SCCNFP07
BaP	CSTEE05	HIV	SCMPMD01
benzalkonium methosulphate	SCCP18	hydrogen peroxide	SCCNFP01, SCCNFP02, SCCNFP04, SCCNFP08, SCCP06
benzene	SCHER17	hydroxybenzomorpholine	SCCP19
benzoic acid	SCCP03	iatrogenic CJD	SCMPMD01
Benzyl butyl phthalate	SCHER07, SCHER15	impurities	CSTEE10
Bis(pentabromophenyl)ether	CSTEE15, CSTEE16	inorganic sulfites and bisulfites	SCCNFP12
bisphenol A	CSTEE17	Intermediate frequency fields	SCENIHR04
BSE	SCENIHR02	ketoconazole	SCCNFP03
cadmium	CSTEE22	Lawsonia inermis	SCCNFP10
cadmium accumulation in soil	CSTEE13	Lead	CSTEE08, CSTEE22
cadmium metal	CSTEE24	Lead-contaminated soil	CSTEE08
calcium oxide	CSTEE24	methyldibromo glutaronitrile	SCCP08, SCCP20
camphor	SCCNFP14	mobile phone use by children	SCENIHR04
cellulose fibres	CSTEE14	Musk ketone	SCCNFP20, SCHER14
chloroatranol	SCCP01	Musk xylene	SCCNFP20
chrysotile asbestos	CSTEE14	N,N-bis(2-hydroxyethyl)-p-phenylenediamine sulfate	SCCP21
CJD	SCMPMD01, SCMPMD07	nickel	CSTEE21
creosote	CSTEE05	non biodegradable detergent surfactants	SCHER05
Curry Red	SCCNFP18	nonylphenol	CSTEE07
Cytomegalo8 virus (CMV)	SCMPMD01	nvCJD	SCMPMD01
DeBDE	SCHER02	Octamethylcyclotetrasiloxane	SCCP09
Decabromodiphenyl ether	CSTEE09	organostannic compounds	CSTEE19
DEHP	CSTEE23	organotin compounds	SCHER18
Dengue	SCMPMD12	parabens	SCCP02, SCCP10
Dialkyl- and dialkanolamines and their salts	SCCNFP06	p-aramid fibres	CSTEE14
dichloromethane	SCHER04	particulate matter	SCHER06
d-Limonene	SCHER17	Parvovirus B19	SCMPMD01
Electromagnetic Fields	CSTEE12, SCENIHR04	PBDD/Fs	CSTEE15
existing substances	CSTEE11	perfluorooctane sulphonates	SCHER11
Extremely low frequency fields	SCENIHR04	phenol	SCHER08
fluoride	SCCP13	phosphate fertilizers containing cadmium	SCHER13
formaldehyde	SCHER17	phosphate-based detergent	CSTEE20

Risk sources	Opinions	Risk sources	Opinions
phthalate release	CSTEE01	Static fields	SCENIHR04
phthalates	CSTEE01, CSTEE02, CSTEE03	styrene	SCHER17
P-phenylenediamine	SCCP15	sunbeds	SCCP17
presence of nanoparticles in air	SCENIHR03	tagetes extracts and oils	SCCP12
presence of vCJD infected individuals	SCENIHR05	TAME	SCHER12
process additives	SCMPMD08	TBE virus	SCMPMD12
process errors	SCMPMD08	tetrabromobisphenol-A	SCHER10
product failure	SCMPMD08	toluene	SCHER17
Propan-1-ol	SCHER09	Tris (2-chloroethyl) phosphate (TCEP)	SCHER16
PVA fibres	CSTEE14	underarm cosmetics	SCCP10
R43	SCCP08	UVA radiation	SCCP17
Radio frequency fields	SCENIHR04	UVB radiation	SCCP17
salicylic acid	SCCNFP11	variant CJD	SCENIHR05
silver	SCMPMD06	West Nile Virus	SCENIHR01, SCMPMD12
size	CSTEE14	wood tar	SCCNFP13
sodium benzoate	SCCP03	xenotransplantation	SCMPMD09
sodium hydroxide	SCHER19	zeolite	CSTEE20
sporadic CJD	SCMPMD01		

4.2 Hazards

Hazard is defined in the SSC glossary as “The potential of a risk source to cause an adverse effect (s)/event(s)” (SSC 2000). Table 3 lists terms we identified as referring to hazards in the concluding sections of the opinions.

The majority of the hazards listed relate to effects on human health, as this was considered in 90% of the opinions, whereas 20% of opinions addressed risks to the environment.

The SSC definition for hazard (“The potential of a risk source to cause an adverse effect (s)/event(s)”) is described in their report as the “agreed definition” of the Working Party on Risk Assessment Procedures” (SSC 2000). They also provide a second definition of hazard from a WHO survey on risk assessment terminology (Lewalle 1999). This second definition is: “Inherent property of an agent or situation capable of having adverse effects on something. Hence, the substance, agent, source of energy or situation having that property.” The second sentence of this definition implies that the word “hazard” can also refer to the risk source (agent etc.) itself, as well as to its potential for causing adverse effects. In some cases, the risk source terms listed in Table 2 were being used in this way.

It can be seen from Table 3 that many of the terms we identified as referring to hazards in the opinions do strictly describe “potential” or “capability” or the “inherent property” of having that potential or capability. In some cases, several similar terms describe the same hazard, e.g. carcinogenic, carcinogenicity, carcinogenic hazard and cancer potency. Some other terms in Table 3 express hazard by using nouns such as “carcinogen”, which identify the risk source as a member of the class of risk sources presenting that hazard (e.g. X is a carcinogen).

Many terms in Table 3 strictly refer to the adverse effect itself (e.g. “cancer”), or in some cases the process affected by the hazard (e.g. development, behaviour). This is because the concluding sections of opinions sometimes express hazards by using phrases that express the potential for effects (e.g. can cause cancer, can affect development). In many cases, the concluding section does not contain any phrases that express the hazard directly, but instead includes phrases about the associated effect or risk (e.g. there is a risk of cancer), from which the reader could infer which hazards are involved.

Thus it is possible to express a hazard of cancer explicitly either by referring directly to the hazard (carcinogenicity), or by describing risk source as carcinogenic, or by stating that the risk source is a carcinogen, or by stating that it could cause cancer. It is also possible to express the hazard implicitly by referring to the associated effects or risk. It is our impression that these variations in choice of specific term do not form an obstacle to communication. It is more important that:

- Phrases describing hazard and risk should be carefully constructed so as to distinguish appropriately between the potential for effects (hazard) and the risk or prevalence of those effects actually occurring (e.g. can cause cancer vs. causes cancer).

Table 3. Summary of terms we identified as referring to hazards in the concluding sections of the opinions, listed alphabetically (continues on next pages).

Hazards	Opinions	Hazards	Opinions
accelerate development of transplanted tumours	SCENIHR04	carcinogenicity	CSTEE17, CSTEE24, SCCNFP05, SCCP15, SCENIHR04, SCMPMD08, SCMPMD10
accumulation in soils	CSTEE13	cardiovascular disease	SCENIHR04
acoustic neuroma	SCENIHR04	cataract formation	SCCP17
acute irritation	SCHER17	category I or II carcinogens	CSTEE06
acute leukaemia	SCCP11	cell death	SCHER18
acute toxic effect	SCHER19	cell modification	SCMPMD08
adverse health effects	SCHER06	cellular proliferation	CSTEE14
affect neonatal neurological development	CSTEE04	changed sexual behaviour	CSTEE04
allergens	SCCP01	childhood leukemia	SCENIHR04
allergic contact dermatitis	SCMPMD05	chronic inflammatory	SCHER01
allergy	SCMPMD05, SCMPMD08	chronic lymphoid leukaemia	SCCP11
altered immune function	CSTEE04	chronic/subchronic toxicity	SCCNFP02
anaphylactic shock	SCMPMD05	clastogenic	SCCNFP09, SCCP07
anaphylaxis	SCMPMD05	cognition	SCENIHR04
anti-androgen	SCMPMD10	contact allergies	SCCNFP15
anti-androgenic	CSTEE04	contact dermatitis	SCHER17
asthma	SCHER17, SCMPMD05	contamination	SCMPMD08
basal cell carcinoma	SCCP17	corrosivity	SCCNFP02, SCHER19
behaviour	CSTEE04	craniofacial abnormalities	SCHER18
benign skin tumours	SCCNFP13	cryptorchidism	CSTEE04
bioaccumulable	SCHER16	cytotoxicity	SCHER01
bioaccumulating	SCHER02	damage maintenance of homeostasis	CSTEE04
bioaccumulation	CSTEE07	deadly	SCMPMD01
bioavailability	CSTEE09	decline in sex ratio	CSTEE04
bioavailability of certain elements in toys	CSTEE22	decrease in semen volume volume	CSTEE04
biomagnify	CSTEE04	decrease in sperm concentration	CSTEE04
biopersistence	CSTEE14	degradation	CSTEE09
bladder cancer	SCCNFP16, SCCP11	degradation of nanocomposites	SCENIHR03
bone repeated dose toxicity	CSTEE24	delays in physical and mental development	CSTEE04
brain tumour	SCENIHR04	development	CSTEE04
breast cancer	CSTEE04, SCCP10, SCENIHR04	developmental effects	SCENIHR04
breathing difficulties	SCHER17	developmental neurotoxicity	SCHER18
cancer	CSTEE05, CSTEE06, SCCP11, SCENIHR04, SCHER17	developmental toxicity	CSTEE23, SCCP02, SCHER07, SCMPMD10
cancer potency	CSTEE05	died	SCCNFP02
carcinogen	SCENIHR04, SCHER14	Distorted sex organ development and function	CSTEE04
carcinogenic	CSTEE10, CSTEE14, SCHER01, SCHER07	disturbed sex differentiation	CSTEE04
carcinogenic hazard	CSTEE05	effects on body weight	SCHER18

Hazards	Opinions	Hazards	Opinions
effects on organ weight	SCHER18	immunotoxicity	SCHER18
effects on reproductive organs	CSTEE24	imposex	CSTEE04, CSTEE19, SCHER18, SCHER18
effects on the endocrine system	SCCNFP15	incompatibility reactions	SCMPMD01
effects on the immune system	CSTEE19	increase in sedimentation	CSTEE20
effects on the liver	SCHER18	increase of phosphorus load in surface water	CSTEE20
effects on the male reproductive system	SCCP02	increased amount of sludge	CSTEE20
egg-shell thinning	CSTEE04	induction of ovotestis	CSTEE04
electrical hypersensitivity	SCENIHR04	induction of reactive oxygen species	SCENIHR03
electromagnetic hypersensitivity	SCENIHR04	infection	SCMPMD09
embryo viability	SCCP02	infectivity of blood components	SCMPMD01
embryonic growth	SCCP02	inflammation	CSTEE14
embryo-toxicity	SCHER18	interference with drug therapies	SCMPMD09
emissions of suspended solids in surface waters	CSTEE20	intersex	SCHER18
endocrine disruption	CSTEE04, CSTEE18, CSTEE18	intersexuality	CSTEE04
endocrine effects	CSTEE19	intracranial tumours	SCENIHR04
endometriosis	CSTEE04	irritation	SCCNFP02, SCCP03, SCHER17, SCHER19
enhance effects of known carcinogens	SCENIHR04	kidney repeated dose toxicity	CSTEE24
erythema (sunburn)	SCCP17	kidney toxicity	SCMPMD10
erythrosin	SCMPMD02	latex allergic disease	SCMPMD05
estrogenic effects	SCCP02	latex sensitisation	SCMPMD05
estrogenic potential	SCCP10	leaching	SCMPMD10
estrogenicity	SCCP02	leukaemia	SCCP11, SCENIHR04
eutrophication	CSTEE20	lipophilic	CSTEE09
extreme corrosive properties	SCHER08	liver and kidney damage	CSTEE02
eye irritation	SCCP03	liver cancer	CSTEE02
feminized	CSTEE04	liver toxicity	CSTEE17, SCMPMD10
fertility	CSTEE17, CSTEE24, SCHER07	liver tumours	SCHER01
fertility patterns	SCMPMD10	local effects	SCHER08
fragmentability	CSTEE14	lung toxicity	CSTEE24
general long-term toxicity	CSTEE02	maintenance of pregnancy	SCCP02
genotoxic	SCCP15	male reproductive system	SCCP02
genotoxic carcinogen	SCCNFP13	malignant melanoma	SCCP17
genotoxicity	CSTEE05, CSTEE10, CSTEE17, CSTEE24, SCCNFP05, SCCNFP10, SCCP07, SCCP16, SCCP19, SCCP21, SCENIHR04, SCHER01	malignant skin tumours	SCCNFP13
gross pathology	SCHER01	masculinization of fish	CSTEE19
high surface to volume ratio	SCENIHR03	masculinized	CSTEE04
human carcinogen	SCHER17	microbiological contamination	SCMPMD08
hypospadias	CSTEE04	mitogenic action	SCCP10
hypothyroidism	CSTEE04	musculoskeletal abnormalities	SCHER18
immune function	CSTEE04	mutagenicity	CSTEE17, SCCNFP09, SCCP16, SCCP19, SCCP21, SCMPMD08
immunosuppressive	SCCP17	nanoparticle size, shape & composition	SCENIHR03

Hazards	Opinions	Hazards	Opinions
nanoscale characteristics	SCENIHR03	reproductive and developmental effects	CSTEE04
nanoscale features	SCENIHR03	reproductive and developmental toxicity	SCCP02
nanotopographical features	SCENIHR03	reproductive effects	SCENIHR04
neurobehavioral changes	SCHER04	reproductive toxicity	CSTEE18, SCHER07, SCHER18
neurobehavioral effects	SCENIHR04	resistance to infectious disease	CSTEE19
neurodegenerative diseases	SCENIHR04	respirability	CSTEE14
neurological effects	SCENIHR04	respiratory irritation	CSTEE24, SCHER19
neurotoxicity	CSTEE24, SCHER02, SCHER18	respiratory tract sensitisation	SCHER19
neurovegetative symptoms	SCENIHR04	rhinoconjunctivitis	SCMPMD05
nitrosamines' formation	SCCNFP06	secondary poisoning	CSTEE09, SCHER15
nitrosation	SCCP19	sensitisation	CSTEE10, SCCP03
non-toxic	SCCP10	sensitiser	SCCP15
not carcinogenic	SCCP10	sensitising potential	SCCP16, SCCP21
not co-carcinogenic	SCCP10	sewage sludge of unacceptable quality	CSTEE20
not genotoxic	SCCP10	sexual disorder	SCHER18
not mutagenic	SCHER07	skin cancer	SCCP17
not teratogenic	SCCP10	skin sensitisation	SCHER19
ocular melanoma	SCCP17	skin sensitizer	SCCP08
oestrogenic	CSTEE04, CSTEE07, CSTEE18	sleep quality	SCENIHR04
ovotestis formation	CSTEE04	specific brain lesions	SCHER18
oxidative stress experienced by cells	SCENIHR03	squamous cell carcinoma	SCCP17
oxygen depletion in surface waters	CSTEE20	sub-acute toxicity	SCHER08
ozone effects on forests	SCHER06	suppression of immune function	CSTEE04
PBT	SCHER15	systemic effects	SCHER08
persistence	CSTEE09	systemic toxicity	CSTEE18, SCHER19
persistence in animals	CSTEE14	testicular cancer	CSTEE04
persistency	CSTEE18	testicular damage	CSTEE01
persistent	SCHER16	testicular toxicity	CSTEE23, SCMPMD10
photokeratitis (snow blindness)	SCCP17	thymus atrophy	CSTEE19, SCHER18
phototoxic	SCCP12	toxicity	SCMPMD08
photo-toxicity	SCCP04	toxicity to forestomach	SCCNFP09
placental function	SCCP02	toxicity to haemopoietic system	SCCNFP09
precocious female maturation	CSTEE04	toxicity to kidney	SCCNFP09
process effects	SCMPMD08	tumorigenicity	SCHER14
prone to nitrosation	SCCP21	tumour promoting activity	SCHER14
prostate cancer	CSTEE04	unknown risks	SCMPMD08
reactions	SCCP08	unwanted cells	SCMPMD08
reduced resistance to Trichinella spiralis	CSTEE19	urticaria	SCMPMD05
reproduction	CSTEE04	vCJD infectivity	SCMPMD11
reproduction effects in fish	CSTEE07	very persistent	SCHER02
reproduction toxicity	CSTEE18	vitellogenin induction	CSTEE04

4.3 Identification of important hazards

The remit for this project included identifying terms and phrases used to describe the hazard considered to be the most significant for determining the risk to the public or the environment. We found very few instances where concluding sections included phrases explicitly referring to the relative importance of different hazards: these are summarised in Table 4. This may be because concluding sections of opinions frequently only refer to the most important hazards, without explicitly expressing them as such. Note that although the critical effect (defined as that which occurs at the lowest dose in the most sensitive species, SSC 2000) will generally have the highest risk for a given exposure it may not be most significant in terms of public health, if there is sufficient risk of a more severe effect that occurs at higher doses. In some of the phrases quoted in Table 4 (e.g. for SCHER18) it is not explicit in which of these senses importance is being judged.

Table 4. Summary of phrases found in the concluding sections of the opinions, which refer to the relative importance of different hazards.

Quotation from opinion, with key phrase underlined	**Interpretation**	**Opinion**
Limonene concentrations obtained from natural products, gel fresheners and sprays exceed the upper value suggested for repeated exposure but not a limit based on the NOAEC found in the critical effect study (reflecting acute irritation).	Acute irritation is the most important hazard.	SCHER17
Methyldibromo glutaronitrile causes contact allergies and has possibly effects on the endocrine system. Its mode of action is hitherto unknown. More scientifically based information is needed.	Contact allergy is more important than endocrine effects, in the sense of being more definite.	SCCNFP15
Risk characterization for consumers uses the NOAEL for developmental toxicity as a starting point and the MOS-values derived are >> 1 000	Developmental toxicity is the most important hazard.	SCHER07
critical effects for TBT are on the immune system and are used to set up TDI	Immunotoxicity is the most important hazard.	CSTEE19
none of these studies investigates endpoints related to the major health effects of tributyl tins (immunotoxicity) in detail	Immunotoxicity is the most important hazard.	SCHER18
The major adverse effects of concern caused by propyl paraben involve the male reproductive system	Reproductive toxicity is the most important hazard.	SCCP02
The toxicological effects of the dialkanolamine salts, and, in particular their readiness for nitrosamines' formation are similar to the respective properties of the dialkanolamines since there is a pH-dependent equilibrium between the salt and the respective free base.	Nitrosamine formation is the most important hazard.	SCCNFP06
The SCCP is of the opinion that the use of 2,4-diaminophenoxyethanol HCL itself as an oxidative hair dye at a maximum concentration of 2.0 % in the finished cosmetic product (after mixing with hydrogen peroxide) does not pose a risk to the health of the consumer, apart from its sensitising potential.	The only important hazard is sensitising potential.	SCCP16
Newer data on the toxicity of DEHP have led the CSTEE to change its previous NOAEL designation to 3.7 mg/kg/day with testicular damage as the critical effect.	Testicular toxicity is the most important hazard.	CSTEE01
The main target organs for DEHP toxicity are the liver, kidney and testes, with most attention being paid to testicular toxicity. This is of concern since, in animal models, exposure has been shown to be more significant in neonates or very young animals compared to any other age, with the testes as the most susceptible organs.	Testicular toxicity is the most important hazard.	SCMPMD10
CSTEE reiterates its previous conclusion that the evidence for harmful potential is more extensive for chrysotile than for its organic substitutes.	The hazard from chrysotile is higher than that from the alternatives	CSTEE14
it is not considered that these nanoscale features of larger objects (for example nanotopographical features on medical devices) pose any additional human health and environmental risks. The situation with free nanoparticles, including agglomerates, is quite different. It is the generation, application, distribution, persistence and toxicological characteristics of free nanoparticles that give rise to concerns over possible human health and environmental risks.	The hazard from free nanoparticles is higher than that from nanoscale features of larger objects	SCENIHR03
UVB is the most harmful part of the solar UVR spectrum for both acute and long term term-effects	The hazard from uvb is higher than that from other parts of the spectrum	SCCP17

4.4 Qualitative expressions of risk

The SSC glossary defines risk as "the probability and severity of an adverse effect /event occurring to man or the environment following exposure, under defined conditions, to a risk source(s)". This is very similar to the IPCS (2004) definition: "The probability of an adverse effect in an organism, system, or (sub)population caused under specified circumstances by exposure to an agent." Note that the SSC definition explicitly states that risk is "probability and severity" whereas in the IPCS definition, only probability is mentioned.

Part of the remit for this project was to identify terms used for qualitative expressions of risk. Risk characterisation as defined by both SSC and IPCS may be qualitative, quantitative or comprise elements of both (e.g. a quantitative estimate accompanied by qualitative expression of additional uncertainties). Qualitative expressions of risk use words, rather than numbers, to characterise risk.

Examination of the concluding sections of the opinions revealed a large variety of terms and phrases that could be interpreted as expressions of risk. Analysis of these suggested the following main categories:

- Phrases that express risk by using the word "**risk**" combined with a qualifier, such as high, low, etc.
- Phrases that express risk in terms of **effects**, by combining a term for a type of adverse effect with terms expressing its magnitude or probability of occurring
- Phrases that express risk in terms of **exposure**, by expressing the frequency or likelihood of exposures exceeding critical levels (e.g. the tolerable daily intake, TDI).
- Phrases that express risk by using the term "**margin of safety**" combined with a qualifier, such as high, low, etc.
- Phrases that express risk in terms of **evidence**, by combining a term for a type of adverse effect or situation with terms expressing the level of evidence that it does or will occur
- Phrases that express risk in terms of **concern**, by combining the word "concern" with with a qualifier such as high, low, etc.
- Phrases that express risk in terms of **safety**, by using the terms "safe" or "safe use" together with qualifiers to express the degree of confidence that a specified use or practice is "safe".

The following sections discuss these 7 categories in turn, and are followed by an eighth section summarising other **miscellaneous** forms of expression that were found less frequently in the concluding sections of the opinions examined.

4.4.1 Qualitative expressions using the term 'risk'

Qualitative expressions found in the concluding sections of the opinions and using the word "risk" are summarised in Table 5.

Each expression or phrase combines the word "risk" with some qualifying terms. For the purpose of discussion we have divided the phrases into 8 groups, shown in the left hand column of Table 5. Five of these groups relate to qualifying terms expressing different degrees of risk: none, possible, low, some, high. The other three groups express a difference or change in risk: less, more, or no change. The specific phrases are listed in the second column of Table 5. The type of effect that the risk refers to (or in some cases type of exposure, see next paragraph) is listed in the third column, and the reference

number of the opinion the phrase came from is listed in the fourth column: these lists are all in the same order so that the reader can identify which phrase and effect derive from which opinion. The final column quotes larger extracts of text to illustrate the use of selected example phrases in more detail.

In some places where the word risk is used, it appears to refer to something other than an adverse effect on health or the environment. Examples of this can be seen in the third column of Table 5, which contains entries for transmission of CJD, transmission of WNV (West Nile Virus), microbiological contamination and exposure. In these cases it is possible that the authors of the opinions intended the word risk to refer to the probability of transmission, contamination or exposure, rather than to their potential health consequences, although the wording of some the phrases is ambiguous[1]. Although such uses of "risk" would conflict with the SSC (2000) glossary definitions (the probability and magnitude of adverse effects of exposure), they would not be surprising because definitions of risk in other technical fields are sometimes broader (e.g. "the combination of a consequence and the probability of its occurrence", chemical accident risks, OECD 1992), and it is also used more broadly in non-technical language. However, these semantic issues about the usage of "risk" do not affect the major point here, which concerns the ambiguity of qualitative terms for the degree of risk.

Table 5 illustrates two important ambiguities of qualitative expressions. The first is thatqualitative expressions are inevitably relative, unless their relation to a quantitative measure of risk is defined. The examples quoted in Table 5 often do not specify what quantitative level of risk is meant by the qualitative terms "low", "high" etc., nor what magnitude of difference is meant by "less" or "higher" risk. In some cases, it is stated simply that a risk exists. An example of this is SCCNFP13, where the concluding section states: "wood tar and wood tar preparations do pose a health risk when used in cosmetic products… The products may represent risk of skin cancer." No indication is given of the magnitude of the risk. Another example is SCCP11, which concludes "there is an indication of excess risk of bladder cancer for women in USA using permanent hair dyes frequently and for long time." It is not indicated how large the excess risk is, nor are "frequently" or "for a long time" defined, all of which might be of interest to decision-makers. Quantitative information on this is discussed elsewhere in the Opinion, so it might be helpful if it could be summarised within the concluding section[2]. Otherwise, it is left to decision-makers (who are unlikely to be specialists in the field) to form their own interpretations.

The second important ambiguity of qualitative expressions is that they are liable to variable interpretation by different people. For example, it is unlikely that different people would rank the phrases in Table 5 in the same way. The use of the phrase "potential risk" is an interesting example. It might be interpreted by some people as indicating a low level of risk, but usually seems intended to describe a possibility that the risk is high enough to raise concern. This is illustrated for example by SCHER05 where "potential risk" refers to PEC/PNEC values above 1 for "hypothetical (worst) case conditions".

[1] For example: "There is also a risk for PBDD/F exposure, both for man and the environment, at the end-of-life of products containing DBDE" (CSTEE15); "Process-related microbiological contamination is considered to be much lower risk than with the source material and any such contamination should be relatively easily detected" (SCMPMD08); "In the European Union, where WNV is not endemic, the vast majority of individual donors could be considered to pose no risk of WNV transmission" (SCENIHR01).

[2] It might be objected that including numerical values in the concluding section would give a false sense of precision. However, this could be avoided by giving ranges to indicate the uncertainty (see later).

We conclude that:

- Qualitative expressions provide only a relative indication of the level of risk, unless their relation to a quantitative measure of risk is defined, and they are liable to variable interpretation by different people.

These ambiguities have important implications for risk communication because (a) risk managers, stakeholders and consumers may misinterpret the level of risk that risk assessors intended to convey, and (b) individual risk managers may vary in their interpretation. This could have an impact on risk management decisions and also damage the understanding and acceptance of those decisions by stakeholders. We discuss later whether these difficulties might be resolved either by adopting harmonised definitions for qualitative expressions, or by making more use of quantitative expressions.

Table 5. Summary of phrases including the term 'risk' found in the concluding sections of opinions, grouped into 8 categories for the purpose of discussion (note that these groupings are not proposals for standardised terminology).

Group	Specific phrases[3]	Effect/exposure term[4]	Opinion reference nos.	Examples
None	do not pose a health risk, does not pose a risk, negligible risk, no evidence of demonstrable risk, does not pose a risk, does not pose a risk, does not pose a risk, does not pose a risk…apart from its sensitising potential, do not appear to pose a relevant risk, a real risk is not recognisable	health risk, health, risk, risk, health risk, risk to health, health risk, health risk, risk, transmission of CJD	SCCNFP12, SCCNFP18, SCCP05, SCCP10, SCCP16, SCCP18, SCCP19, SCCP21, SCHER11, SCMPMD01	The SCCNFP is of the opinion that the use of Curry Red as a hair colouring agent ('direct' dye) in semi-permanent hair dye formulas at a maximum concentration of 0.4% in the finished cosmetic product does not pose a risk to the health of the consumer (SCCNFP18)
Low	the vast majority of individual donors could be considered to pose no risk, low risk for most applications, risk not measurable, risk not quantifiable	transmission of viruses, risk, transmission of CJD, transmission of CJD	SCENIHR01, SCHER05, SCMPMD01, SCMPMD01	Considering the overall values a generic estimation of low risk for most applications of aerobic sludge and anaerobic sludge submitted to aerobic processes and a potential risk for some applications of anaerobic sludge can be expected. (SCHER05)
Less	does not carry the same level of risk, less risk, much lower risk	not specified, not specified, microbiological contamination	SCMPMD08, SCMPMD08, SCMPMD08	tissue engineering could be associated with less risk than is seen with conventional medical devices or medicinal products (SCMPMD08)
No change	not considered to pose any additional risks, does not pose any increased risk, no substantial modifications in the risk	human & environmental risks, brain tumour or acoustic neuroma, risk	SCENIHR03, SCENIHR04, SCHER05	The balance of epidemiologic evidence indicates that mobile phone use of less than 10 years does not pose any increased risk of brain tumour or acoustic neuroma. (SCENIHR04)
Possible	potential risk cannot be excluded, cannot be excluded, potential risk for some applications, potential risk, potential future risk cannot be excluded, potential risk for high consumers, theoretical risk , theoretical risk, hypothetical risk	risk, health risks, risk, risk, risk, risk, transmission of CJD, transmission of CJD, transmission of CJD	CSTEE09, CSTEE24, SCHER05, SCHER11, SCHER16, SCHER18, SCMPMD01, SCMPMD01, SCMPMD11	On the basis of the few data available, a potential risk for the environment cannot be excluded. (CSTEE09)
Some	there is a risk, there is a risk, do pose a health risk, risk of allergy should be realised, there is a risk	cancer, exposure, health risk, risk of allergy, transmission of CJD	CSTEE05, CSTEE15, SCCNFP13, SCCP15, SCENIHR05	SCCNFP is of the opinion that wood tar and wood tar preparations do pose a health risk when used in cosmetic products. (SCCNFP13)
More	the report probably underestimates the risks, higher, indication of excess risk, some studies indicate excess risks, risk may be even larger	risk, risks, bladder cancer, leukemia, risk	CSTEE19, CSTEE21, SCCP11, SCCP11, SCHER18	It is concluded that there is an indication of excess risk of bladder cancer for women in USA using permanent hair dyes frequently and for long time. (SCCP11)
High	very high risk	not specified	SCMPMD08	some applications carry very high risk (for example when associated with the functional performance of a tissue engineered artery, the failure of which is likely to be fatal) but which address immensely important clinical conditions (SCMPMD08)

[3] The phrases, effect/exposure terms and opinion reference numbers are listed in the same order so that the reader can locate the source of each phrase.
[4] See discussion on previous page concerning use of "risk" in relation to exposure.

4.4.2 Risk expressed in terms of effect

Qualitative expressions found in the concluding sections of the opinions that express risk in terms of effects are summarised in Table 6.

Each expression or phrase in Table 6 combines a term for a type of adverse effect (or in some cases a hazard) with terms expressing its magnitude or probability. For the purpose of discussion we have used the same 8 terms to group the phrases as in Table 5, plus a ninth group named “acceptable”. The format of the other columns is the same as in Table 5.

Table 6 illustrates the same two ambiguities of qualitative expressions as Table 5, i.e. that they are relative and liable to variable interpretation by different people. Table 6 also contains examples that raise another issue affecting qualitative expressions:

- The same qualitative term might be interpreted differently for different types of effect, or for effects on different populations or systems.

For example, because they were described without qualifying terms, we have placed in the group “some” the phrases “population declines” (referring to seals in the Baltic and Wadden Sea), “causes” (referring to contact allergies), and “a 16-month-old boy has died” (after ingestion of a 3% solution of hydrogen peroxide). However, it is likely that people would attach differing weights to these effects, and that this might affect the qualitative expressions of risk (low, high etc) they would choose to describe them. As another (hypothetical) example, ecologists might describe 1% mortality of birds as a low risk (if it was considered unlikely to affect population stability) whereas an agent causing a 1% cancer risk in humans would probably be described as a high risk; describing both these risks with the same qualitative term would probably lead to misinterpretation.

These examples suggest that, if it was decided to adopt harmonised qualitative terms for expression of risks, it might be desirable to use different terms, or different definitions for the same terms, in different areas of risk assessment. An alternative would be to make more use of quantitative expressions. These options are considered further in Section 5.

Table 6. Summary of phrases found in the concluding sections of opinions, expressing risk in terms of effects.

Group	Specific phrases	Types of effect	Opinion reference nos.	Examples
Acceptable	not unacceptable	quality of sewage sludge	CSTEE20	the use of Zeolites in detergent products should not increase the amount (volume) of sewage sludge produced, or lead to a sewage sludge of unacceptable quality for agricultural use (CSTEE20)
None	not mutagenic in vivo, no health effect has been consistently demonstrated, no proven instances, not bioaccumulable	mutagenic, health effect, transmission of CJD, bioaccumulation	CSTEE17, SCENIHR04, SCENIHR05, SCHER16	There are no proven instances of vertical transmission of any human prion disease. However, the available animal and human data are inadequate to allow firm conclusions concerning vertical transmission to be drawn (SCENIHR05)
Low	suggestion did not have a strong estrogenic potential, very low, general low number of cases, low frequency, effects, if any, will be local and rapidly reversible	estrogenic potential, estrogenic potential, clinical vCJD, transmission of CJD, effects	SCCP02, SCCP10, SCENIHR05, SCENIHR05, SCHER05	the estrogenic potential of parabens has been found to be very low (SCCP10)
Less	less harmful, contribution to damage would be minor, lower, clearly lower, continuing decline, decline, decreasing	long-term toxicity, surface water environment, sludge quality, potency, BSE, clinical vCJD, incidence	CSTEE14, CSTEE20, CSTEE20, SCCP02, SCENIHR02, SCENIHR05, SCENIHR05	The incidence of vCJD in the UK is decreasing but there remain considerable uncertainties and concerns over future numbers of cases (SCENIHR05)
No change	should not increase, will not increase	volume of sewage sludge produced, volume of sewage sludge produced	CSTEE20, CSTEE20	use of phosphates in detergent products will not increase sludge volume (CSTEE20)
Possible	not ruled out, the possibility for transmission... seems likely, remains a possibility, a hazard cannot be excluded	phototoxicity, transmission of CJD, transmission of CJD, transmission of CJD	SCCP04, SCENIHR05, SCENIHR05, SCMPMD01	The data provided so far has not ruled out the photo-toxicity of any furocoumarin. (SCCP04)
Some	population declines, demonstrated oestrogenic effect, can occur in some soils, a 16-month-old boy has died, causes, has been observed, persistent, measurable	population size, oestrogenic effect, cadmium accumulation in soil, mortality, contact allergies, transmission of CJD, persistence, transmission of viruses	CSTEE04, CSTEE07, CSTEE13, SCCNFP02, SCCNFP15, SCENIHR05, SCHER16, SCMPMD01	Surgical iatrogenic transmission of CJD has been observed after dura mater transplantation, neurosurgery and ophthalmic surgery (SCENIHR05)
More	evidence for harmful potential is more extensive, increased, may increase, may be present at higher levels than the present numbers of identified clinical cases suggest	harmful potential, volume of sewage sludge produced, sludge quality, presence of vCJD infected individuals	CSTEE14, CSTEE20, CSTEE20, SCENIHR05	chemical phosphate removal (the most effective and extensively used procedure for phosphate removal in Europe) will lead to an increased amount of sludge, at a lower sludge quality (CSTEE20)
High	mass mortalities, severe population declines, decline or extinction of local populations worldwide, severe damages, significant number	mortality, population size, local populations, surface water environment, deaths	CSTEE04, CSTEE04, CSTEE04, CSTEE20, SCMPMD01	non treated effluents produce severe damages to the surface water environment due to many other pollution factors (e.g. organic matter and oxygen depletion) (CSTEE20)

4.4.3 Risk expressed in terms of exposure

Qualitative expressions found in the concluding sections of the opinions that express risk in terms of exposure are summarised in Table 7. For the purpose of discussion we have used the same 8 terms to group the phrases as in Tables 5 and 6, plus an additional group named “variable”. The format of the other columns is the same as in Tables 5 and 6.

Each expression or phrase in Table 7 contains terms expressing the magnitude, frequency or likelihood of exposures. While at first sight this might not seem to express risk in the sense of the SSC definition, in fact nearly all of them do because they refer explicitly or implicitly to the likelihood of exposures exceeding critical levels (e.g. the tolerable daily intake, TDI). This is explicit in those terms that mention the TDI or NOAEC directly, and implicit in those that use words that describe the importance of the exposure (e.g. of no importance, absolutely negligible, not negligible, significant increase).

Table 7 illustrates the same two ambiguities of qualitative expressions as Tables 5 and 6, i.e. that they are relative and liable to variable interpretation by different people. Table 7 also contains examples that raise another issue affecting qualitative expressions:

- Relative terms, especially strong ones such as “absolutely negligible”, “massive” and “extreme”, tend to imply a sense of the importance of the risk being described, and hence of the need for action and its urgency.

This is true to varying extents for all relative terms, e.g. “low” tends to imply no need for concern or action, whereas “high” tends to the opposite. This tendency for qualitative terms to be interpreted as simultaneously expressing both risk and importance may create difficulties if it is desired to separate assessment of the level of risk (risk assessment) from consideration of whether action is justified (risk management). Establishing harmonised definitions in terms only of risk would reduce this difficulty by making the meaning clear to the risk manager, but it seems unlikely this would avoid inferences on importance by stakeholders and the public. This could interfere with the making and communication of decisions. For example, a risk manager might consider on the basis of other legitimate factors (e.g. cost, benefit, legal issues) that a risk described by risk assessors as high did not require action, but may find it difficult to explain this adequately to stakeholders and the public and might even feel that this constrained their decision options. We discuss later whether this problem might be reduced by making more use of quantitative expressions of risk.

Table 7. Summary of phrases found in the concluding sections of opinions, expressing risk in terms of exposure (continues next page).

Group	Specific phrases	Exposure terms	Opinion refs.	Examples
Low	very low, of no importance, very small probability, absolutely negligible	exposure, contribution to risk, exposure, levels	SCHER10, SCHER18, SCHER18, SCMPMD02	In the developed scenarios, a potential for high exposure to tetrabromobisphenol A is only present during the addition of tetrabromobisphenol A to batches of polymer; exposures during the other scenarios is estimated to be very low. (SCHER10)
Less	several orders of magnitude lower, declined, decreasing, no longer a substantial contributor, will not increase…over those values accepted, below WHO guidance values	levels in serum, concentrations, exposure, contribution to total phosphorus load, emissions of suspended solids, concentrations	CSTEE04, CSTEE08, CSTEE08, CSTEE20, CSTEE20, SCHER17	For formaldehyde, styrene and toluene the highest values found in the BEUC study are below the WHO guidance values (SCHER17)
No change	rather stable	concentrations	CSTEE08	Levels of lead in food have declined in Denmark over the past decade, with levels in milk remaining rather stable. (CSTEE08)
Possible	cannot be excluded	presence of infectivity	SCMPMD11	The presence of vCJD infectivity in human blood can still not be excluded. (SCMPMD11)
Some	not negligible	contribution to total phosphorus load	CSTEE20	very variable (roughly speaking from 10 to 40%) as a function of different human activities and land use; even at the lower end of the interval, this contribution is not negligible especially in areas that can be subject to eutrophication processes (CSTEE20)
Variable	very variable	contribution to total phosphorus load	CSTEE20	the contribution of this phosphorus source to the total phosphorus load in surface water can be very variable (roughly speaking from 10 to 40%) as a function of different human activities and land use (CSTEE20)

Group	Specific phrases	Exposure terms	Opinion refs.	Examples
More	significant increase, additional exposure, increasing, exceeded levels at which effects have been reported, exceed the limit values adopted in several countries, exceed the upper value suggested for repeated exposure but not a limit based on the NOAEC found in the critical effect study, it can be assumed that some children's dietary intake exceeds the TDI, some people much higher than the TDI, several of the developed occupational exposure scenarios give exposures above this NOEL, doses of this dye that have been perfectly tolerated by various animal species are much higher than those that can reasonably be expected to be ingested in pharmaceutical product	contribution to total phosphorus load, additional exposure, use of hair dyes, effect concentration, concentrations, concentrations, exceedance of TDI, dose, occupational exposure, dose	CSTEE20, SCCP15, SCCP15, SCHER04, SCHER17, SCHER17, SCHER18, SCHER18, SCHER19, SCMPMD02	NOEL of 1 mg sodium hydroxide per m3 regarding respiratory irritation is derived and several of the developed occupational exposure scenarios give exposures above this NOEL. (SCHER19)
High	extreme, potential for high exposure, probability to exceed the TDI is high, massive doses	irradiance, exposure, dose, dose	SCCP17, SCHER10, SCHER18, SCHER18	a potential for high exposure to tetrabromobisphenol A is only present during the addition of tetrabromobisphenol A to batches of polymer (SCHER10)

4.4.4 Risk expressed in terms of margins of safety

Table 8 summarises qualitative expressions found in the concluding sections of the opinions that express risk by using the term "margin of safety" combined with a qualifier, such as high, low, etc. The phrases referred to in this table describe the margin of safety (MoS) qualitatively: in 3 cases (SCCP15, SCHER01, CSTEE03) a quantitative estimate was given either in other parts of the concluding section or in other sections of the opinion, but the other 4 opinions in Table 8 gave only a qualitative description of the MoS.

Table 8 again illustrates the same two ambiguities of qualitative expressions as Tables 5-7, i.e. that they are relative and liable to variable interpretation by different people. It also illustrates again the point raised by Table 7, that qualitative terms (e.g. very small, very) tend to convey a sense of importance and urgency as well as risk. This is especially true in the case of "not sufficient" and "not sufficiently large", which clearly convey concern or a need for action[5], and in the quotation from SCCNFP14 which directly links "very low MoS" with an explicit request for data to be provided as a matter of urgency.

Given that a qualitative description of the MoS will generally have been based on a calculated value, it would clearly be possible to quote it. In some cases a committee might see reasons not to give a quantitative value, e.g. due to concern that it might convey too strong an impression of precision in cases where data are below the normal standard[6]. However, not stating the calculated figure lacks transparency and limits the ability of the risk manager to judge for themselves the urgency of obtaining better data.

More examples where MoS values were stated explicitly are presented in the section below on quantitative expressions of risk. The CSTEE have defined, in one of their opinions (CSTEE11), criteria for using MoS values to select standardised phrases to describe "conclusions" and the level of "concern": these are discussed in the corresponding sections below.

Table 8. Summary of phrases found in the concluding sections of opinions, expressing risk in terms of margins of safety (n.b. the margin of safety is an inverse measure of risk, e.g. a low margin of safety implies a high risk).

Group	Specific phrase	Opinion refs.	Examples
Low	low, very low, very small	CSTEE17, SCCNFP14, SCHER01	Because of the very low MOS which can be derived from currently available information, it is requested that the above data should be provided as a matter of urgency. (SCCNFP14)
Insufficient	not sufficiently large, not sufficient	SCCNFP02, SCCP15	The margin of safety for chronic/subchronic toxicity and for irritation and corrosivity are not sufficiently large for an oral hygiene product (SCCNFP02)
More	substantially higher	CSTEE03	For the 2 phthalates DINP and DEHP, the estimated margin of safety were below 100, namely 8.8 and 67, respectively. For DNOP, DIDP, BBP and DBP, the margin of safety were substantially higher (190, 710, 45 000 and 13 000, respectively). (CSTEE03)
High	very large	SCHER10	the Margin of Safety (MOS) are very large (SCHER10)

[5] "If one regards the exposure as being too high it is obvious that there is a need for limiting the risks" (p. 4 in CSTEE11).

[6] It seems likely this was true for SCCNFP14, where the word "can" (in "can be derived from currently available data") tends to imply some hesitancy about whether to actually derive an MoS, and the opinion also contains a bold heading "Margin of Safety" followed only by the words "Not applicable").

4.4.5 Terms expressing degree of evidence

Table 9 summarises qualitative expressions found in the concluding sections of the opinions that express risk in terms of evidence, by combining a term for a type of adverse effect or situation with terms expressing the level of evidence that it does or will occur.

Table 9 again illustrates the same two ambiguities of qualitative expressions as Tables 5-8, i.e. that they are relative and liable to variable interpretation by different people.

Phrases expressing level of evidence convey information about the degree of certainty or uncertainty, i.e. they relate particularly to probability[7], one of the two components of risk specified in the SSC (2000) definition. This contrasts with expressions that use the word "risk" (Table 5), which do not distinguish between the probability and magnitude of effects. The same is true of some other terms found in the opinions (e.g. concern, problem; see later). This raises another issue affecting qualitative expressions:

- Some qualitative terms used to express risk (e.g. risk, concern) do not distinguish between probability and magnitude.

This is potentially important because it fails to distinguish whether a high risk or concern is driven primarily by high probability or high magnitude, or a combination of both. This could lead to inappropriate risk management decisions, if for example the need for action, might differ between a high probability of a small impact and a low probability of a large impact. This is particularly relevant to criteria for invoking the precautionary principle, which require scientists to express the degree of uncertainty so that decision-makers can consider whether a precautionary approach is appropriate (EC 2000).

Qualitative expressions of the level of evidence provide one possibility for distinguishing between probability and magnitude. Other possibilities for expressing probability and uncertainty both qualitatively and quantitatively are discussed in later sections.

[7] Probability may be used to express variability or frequency as well as uncertainty. The SSC (2000) definition of risk does not specify which of these are intended, but the SSC definition of risk characterisation refers to (risk) estimates as including uncertainty.

Table 9. Summary of phrases found in the concluding sections of opinions, expressing risk in terms of evidence.

Group	Specific phrases	Types of effect	Opinion reference nos.	Examples
No	no evidence, no evidence, no evidence, no evidence, evidence is lacking	carcinogenic, microbial degradation, cancer, develop vCJD, toxicity	CSTEE14, CSTEE15, SCCP11, SCENIHR05, SCMPMD10	There is no evidence that individuals working in hospitals have developed vCJD by virtue of their occupation. (SCENIHR05)
No convincing	no convincing evidence	carcinogenic	CSTEE17	there is no convincing evidence that bisphenol A is carcinogenic (CSTEE17)
Little or no	little or no evidence	transmission of CJD	SCMPMD01	there is little or no evidence to date that CJD/nvCJD is spread by blood transfusion (SCMPMD01)
Sufficient	Sufficient evidence	carcinogenic	CSTEE14	there is sufficient evidence that all forms of asbestos, including chrysotile, are carcinogenic to humans (CSTEE14)

4.4.6 Risk expressed in terms of concern

Table 10 summarises qualitative expressions found in the concluding sections of the opinions that express risk in terms of concern, by combining the word “concern” with a qualifier such as high, low, etc.

Table 10 again illustrates the same two ambiguities of qualitative expressions as Tables 5-9, i.e. that they are relative and liable to variable interpretation by different people. Also, expressions describing the degree of concern, like those using the word “risk”, do not distinguish between the probability and magnitude of effects.

The term “concern” raises issues of particular interest with regard to the harmonisation of risk terminology, because it already has a formal meaning under at least one risk assessment regulation. This is Commission Directive 93/67/EEC, which lists four possible conclusions of the risk assessment for new notified substances: (i) The substance is of no immediate concern and need not be considered again until further information is made available… (ii) The substance is of concern and the competent authority shall decide what further information is required for revision of the assessment, but shall defer a request for that information until the quantity placed on the market reaches the next tonnage threshold… (iii) The substance is of concern and further information should be requested immediately. (iv) The substance is of concern and the competent authority should immediately make recommendations for risk reduction.

With these statements, Directive 93/67 defines a direct link between the concepts “of concern” and “no immediate concern” and different requirements for action. Each of the four conclusions implies a risk management judgement: (i) implies the risk is sufficiently low that no action of any type is required, (ii) implies that the potential risk is sufficiently high that additional information will be required when the substance passes the next tonnage threshold, (iii) implies the potential risk is sufficiently high that additional information is required immediately to decide whether risk reduction is required, and (iv) implies that risk reduction is implied immediately. Thus although the Directive does not directly define “concern”, it is indirectly given a risk management meaning. This raises the

possibility that use of the term "concern" in assessments under Directive 93/67 could be inferred as representing a risk management judgement. This is a relevant consideration in the context of this review, because of the importance attached by the Commission to ensuring a functional separation of risk assessment and risk management (e.g. Madelin, 2004).

The CSTEE recognised this same issue[8] with regard to their role in determining the 3 risk assessment conclusions defined for existing substances in the Technical Guidance Document for risk assessment of new and existing substances under Directive 93/67 and Regulation 793/93. As a solution the CSTEE proposed in their position paper on Margins of Safety (opinion CSTEE11) that their opinions "should be described in terms of 'cause for concern', meaning 'scientific concern'". However, in common language "of concern" means "of importance", "of interest" and also "anxiety" (OED Online[9]). Therefore describing something as being of "scientific concern" implies that it is of importance or of interest to science (i.e. to the development of scientific knowledge), whereas it is clear that within the context of these regulations, a scientific fact is "of concern" if it has importance for deciding between the specified conclusions.

Nevertheless, use of the term "concern" for assessments under Directive 93/67 need not imply a risk management judgement if there was an established "risk assessment policy" as defined in the field of food safety by the Codex Working Principles on Risk Analysis (Codex, 2007). Codex defines risk assessment policy as "Documented guidelines on the choice of options and associated judgements for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained". Codex also states that risk assessment policy "should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties". Thus if a risk assessment policy existed which specified scientific criteria for "concern", and if these criteria were established or endorsed by risk managers as a suitable basis for deciding between the conclusions for action, then the use of "concern" in a risk assessment could be determined on science alone without implying a new risk management judgement. Although Codex deals with food safety, the same logic is equally relevant to SANCO's non-food committees. The basic principle is that:

- If a term describing risk has been previously defined, in purely scientific terms, then its use in a risk assessment can be determined by purely scientific considerations even if the term also has a risk management meaning.

Note that Codex specifies that risk assessment policy should be established *in advance* of risk assessment. This is desirable from the point of view of efficiency and also, perhaps, to ensure that policy is decided on principle and not overly influenced by individual cases.

Scientific criteria for "concern" are provided by the Technical Guidance Document for risk assessment of new and existing substances under Directive 93/67 and Regulation 793/93. For the human health assessment, "where the exposure estimate is higher than or equal to the N(L)OAEL, this indicates that the substance is 'of concern'" (EC, 2003a, page 179). For the environmental risk assessment, "if the PEC/PNEC ratio is greater than one the

[8] "The main question has been on how far the responsibility of the CSTEE goes in relation to the conclusions in the risk assessment reports. The CSTEE should clearly concentrate on scientific issues, and be less concerned with risk management. The wording of the conclusions, especially iii), can be interpreted as being close to a risk management issue." (CSTEE11).

[9] Oxford English Dictionary Online, accessed August 2007.

substance is 'of concern' and further action has to be taken" (EC, 2003b, page 173). Criteria are also given for "high concern" with respect to human health[10].

However, these criteria do not completely determine the use of the term "concern", for two reasons. First, the basis for determination of the N(L)OAEL, human exposure estimate, PEC and PNEC is not rigidly defined but requires judgement at a number of points, e.g. on the level of confidence provided by data (e.g. toxicity studies) and on the conservatism of assumptions (e.g. in exposure assessment). Although assessing the levels of confidence and conservatism are scientific judgements, deciding what level of confidence or conservatism is sufficient involves a risk management judgement (what level of certainty does society require?)[11].

Second, the Technical Guidance Document contains additional criteria for deciding on concern, which provide further room for judgement. For example, when assessing risk to the aquatic environment for new substances, "where the PEC/PNEC ratio is between 10 and 100, the decision whether to request further testing immediately or at the 10 tonnes per annum production level will be made on the basis of a number of factors including: 1. indications of bioaccumulation potential; 2. the shape of the toxicity/time curve in ecotoxicity testing; 3. data on structurally analogous substances." (EC, 2003b, page 176). Similarly, where the human exposure estimate is less than the N(L)OAEL, "the risk assessor will need to decide which of the possible results applies. For this step, the magnitude by which the N(L)OAEL exceeds the estimated exposure (i.e. the 'margin of safety') needs to be considered taking account of the following parameters…Expert judgement is required to weigh these individual parameters on a case-by-case basis" (EC, 2003a, page 179-180).

A CSTEE position paper (CSTEE11) recognises that the latter quotation implies a need for judgement about the magnitude of the margin of safety, and poses the question "How large should the MoS be, then, in order not to 'raise concern'?". The paper states "It is agreed that a MoS of at least 100 should be used as a starting point, taking into account factors such as…" and goes on to list 6 "examples" of factors that would require a higher MoS than 100, and 6 examples of factors that would justify a lower MoS than 100. These factors include the reliability of data and the conservatism of exposure scenarios, which are likely to require risk management judgements (see above). Furthermore, since the listed factors are described as examples, they leave additional room for judgement regarding other factors.

These examples show that the principle expressed in the bulleted statement earlier in this statement is subject to a caveat:

- In practice, it is difficult to define a term describing risk in purely scientific terms such that it can be used without requiring any element of risk management judgement.

Possibilities for overcoming this are considered later, in Section 5.

Consideration of the use of "concern" in relation to new and existing substances raises a practical point about standardisation of risk terminology. As indicated by the examples

[10] "There will be a high level of concern if: the substance is classified "Toxic" with a risk phrase "R48"; or the substance is classified as a carcinogen or mutagen (of any category); or the substance is classified as toxic to reproduction (category 1 or 2)." (EC 2003a, page 79).

[11] For example, it is sometimes considered that greater conservatism is appropriate when assessing risks for children than for the general population. This is clearly a value judgement.

above, the Technical Guidance Document (EC, 2003a and b) contains a variety of statements on different ways of identifying substances of concern, but these are scattered through the document amongst a total of 195 instances of the word “concern”. There is no single place where all the criteria for determining concern are listed together, so it is difficult for the reader to get a full understanding of the way it is used. This lack of a single comprehensive definition also means that, when the term “concern” is used in the concluding section of an opinion, it is often difficult for the reader to know which of the various possible scientific grounds this is based on (this can be seen in some, but not all, of the examples quoted in the right hand column of Table 10).

- We recommend that, in guidance documents where a standardised or harmonised risk term is used, a complete definition of the term that lists all relevant criteria in one place should be provided. If a glossary is provided, it should include all standardised risk terms used in the document.
- When a standardised risk term that is defined by multiple scientific criteria is used in the concluding section of an opinion, it would aid transparency if it were accompanied by a phrase indicating which of the criteria applies in that case (e.g. there is concern because…).

Finally, we note from Table 10 that although the term “concern” was found most frequently in opinions of CSTEE and SCHER, addressing questions within the scope of the new and existing substances regulations, it is also used by the other committees in other areas of risk assessment. Furthermore, the word “concern” appears in definitions of terms used under other risk assessment legislation, e.g. “Substances classified into category 2 should be regarded as if they are carcinogenic, mutagenic or reproduction toxic to man, while category 3 substances are defined as causing concern for man, but for which the available information is not adequate for making a satisfactory assessment” (Directive 2001/59/EC on dangerous substances). This suggests that:

- Confusion could arise if the same term has different formal definitions in different areas of risk assessment, or if a term given a formal definition in one area is used informally with its common language meaning in another area.

Table 10. Summary of phrases found in the concluding sections of opinions, expressing risk in terms of concern.

Group	Specific phrases	Opinion refs.	Effect/exposure/risk term	Examples
None	does not pose a safety concern, not considered to be of concern, no concerns	SCCP13, SCHER10, SCMPMD10	safety, bioaccumulation, carcinogenicity	There are no concerns over carcinogenicity in humans on the basis of animal studies.The general view of DEHP toxicity is therefore that mechanisms for adverse effects do exist in rodents, but that these do not appear to be of great significance in non-human primates and that the evidence that such mechanisms could be operative in humans is lacking. (SCMPMD10)
Possible	potential concern for some combination of worst case environmental conditions	SCHER05	risk	There is a potential concern however, for some combination of worst case environmental conditions (PEC/PNEC values slightly above 1) but the SCHER cannot evaluate the realism of these combinations, i.e. do these occur under standard sludge application practices (SCHER05)
Low	minimal concern, do not seem to be of high concern	SCCP13, SCHER18	fluorosis, emissions	Thus emissions due to cleaning of cooling-water pipes do not seem to be of high concern. (SCHER18)
Some	some concern, concerns, reason for concern, concern, cause for concern, cause of concern, raised issues of concern, will be of concern, give rise to concerns, of concern, concerned, cause for concern, situations of concern were present	CSTEE01, CSTEE02, CSTEE03, CSTEE04, CSTEE14, CSTEE19, SCCNFP14, SCCP04, SCENIHR03, SCHER04, SCHER05, SCHER15, SCHER18	margin of safety, long-term toxicity, margin of safety, detection of ecological effects, harm, total exposure, safety, concentrations, human & environmental risks, exposure, levels, not stated, concentrations	The in vitro ability of cellulose to induce certain inflammation-related changes and its relatively long persistence in animals gives cause for concern. (CSTEE14)
High	clear concern, even a refinement of the information will not remove the concern, high concern, serious concern	CSTEE01, SCHER12, SCHER18, SCMPMD12	margin of safety, PEC/PNEC ratio, concentrations, introduction of viruses	A French survey, performed in 1999 along the coasts of Corsica, demonstrates concentrations of high concern for TBT and DBT (SCHER18)
Less	less concerned	CSTEE03	margin of safety	Although the margin of safety for DEHP was below 100, the CSTEE is less concerned with the estimated level of DEHP exposure, since humans appear to be less sensitive towards the critical effect of DEHP (hepatic peroxisome proliferation) identified in rats. (CSTEE03)
More	increase the concern	CSTEE01	margin of safety	The revised margin of safety (MOS) values are 75 for DINP and 19 for DEHP, respectively. The MOS for DINP raises some concern as it is less than the previously recommended safety margin of at least 100. The MOS for DEHP raises clear concern. Exposure to DINP and DEHP from other sources than soft PVC toys will increase the concern, but the magnitude of such exposures is uncertain. (CSTEE01)

4.4.7 Risk expressed in terms of safety

The term “safe” is not used with the same diversity of qualifiers as the terms discussed above, as can be seen from the specific phrases quoted in Table 11. In 10 cases, the use of a product is simply described as “safe”; in two cases use was described as safe under specified conditions; and in five cases the committee states that it cannot determine whether the use is safe.

It is notable that we found phrases including the term “safe” only in opinions of the SCCNFP and SCCP. This probably reflects the formal mandate of these committees, e.g. Commission Decision 2004/210/EC specifies that the SCCP shall provide opinions on “questions concerning the safety of consumer products (non-food products intended for the consumer)”.

The term “safe” is linked to a scientific criterion in the 2003 edition of the SCCNFP Notes of Guidance[12] and in the 2006 revision by the SCCP[13], which both state: “It is generally accepted that the MoS should at least be 100 to declare a substance safe for use”, where MoS is the Margin of Safety which they define as the ratio of the NOAEL to the SED (Systematic Exposure Dosage).

However, the Notes of Guidance also make clear that the MoS is not the only criterion for determining safety. They state that risk characterisation should only be based on MoS in the case of threshold effects. For non-threshold effects (e.g. non-threshold carcinogenic effects) the lifetime cancer risk is calculated, i.e. an estimate of the proportion of individuals in a population that will develop cancer (e.g. 1×10^{-5}).

The Notes for Guidance specify a criterion for safety based on the MoS (100, see above), but they do not contain a corresponding criterion for cancer risk. Nevertheless, the SCCNFP and SCCP opinions we reviewed contain examples of judgements of “safety” based on quantitative estimates of cancer risk, although these are not presented in the concluding sections. In SCCNFP17, a conclusion of safe use follows an estimated lifetime cancer risk of 7×10^{-7}. In SCCNFP19, a conclusion of safe use follows an estimated lifetime cancer risk of 1.7×10^{-5}, with the comment that “exposure should not be increased”, which suggests that this is close to the maximum cancer risk the SCCNFP would have found acceptable. In SCCNFP20, a conclusion of safe use follows estimated cancer risks of $3\text{-}4 \times 10^{-4}$, which is justified as follows: "Taken into consideration that only one animal carcinogenicity study in one species is available, that it is likely that the tumours are induced by a non-genotoxic mechanism and that a threshold may be present, the calculated risk is considered tolerable." Similarly, in SCCP05, a product with an estimated cancer risk higher than 10^{-5} is ultimately considered safe, because the conservatism of the exposure estimate, uncertainties in the toxicity data and some toxicokinetic considerations lead the committee to expect the true risk to be lower.

It can be seen from these examples that, as for “concern”, the Committees use more than one scientific criterion for determining safety, and some of the factors considered require judgements which are not purely scientific (because they relate to the conservatism of assumptions and the degree of uncertainty). Furthermore, and again as for “concern”, the

[12] SCCNFP/0690/03, Final : Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation, adopted by the SCCNFP during the 25th plenary meeting of 20 October 2003;
[13] The SCCP’s Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation, 6th revision. Adopted by the SCCP during the 10th plenary meeting of 19 December 2006.

scientific basis for the conclusion of safety is not always stated explicitly in the concluding section of an opinion. Finally, the term "safe use" clearly carries risk management implications. Therefore, consideration of the way "safe" is used by the SCCNFP and SCCP raises some of the same issues as the discussion of "concern" in the previous section: it is difficult to define a term describing risk in purely scientific terms; it would be helpful if guidance documents provided a complete definition of the term that lists all relevant criteria in one place; and it would aid transparency if the specific scientific justification for using the term could be included when it is used in the concluding sections of opinions.

Finally, in common language, "safe" means "free from danger" or "free from risk" (OED Online). But it is clear, from the definition of safe in terms of the MoS and the examples of its use in relation to cancer risk, that in SCCNFP and SCCP opinions "safe" refers not to an absence of risk but to some acceptable level of risk. Therefore,

- Consideration should be given to whether terms such as "safe", which may be interpreted by the public as implying no risk, are suitably transparent or require qualification, given the recognition by scientists and risk managers that there is "no such thing as zero risk"[14].

Table 11. Summary of phrases found in the concluding sections of opinions, expressing risk in terms of safety.

Group	Specific phrase	Opinion reference nos.	Examples
Safe	can be safely used, can be used safely, can be safely used, safe, can be safely used, can be safely used, can be safely used, can be safely used, safe for use, safe	SCCNFP01, SCCNFP03, SCCNFP07, SCCNFP11, SCCNFP17, SCCNFP19, SCCNFP20, SCCP02, SCCP03, SCCP06	The use of tooth whitening products up to 0.1% hydrogen peroxide is safe (SCCP06)
Safe under specified conditions	safe if used under the supervision of a dentist, safe after consultation with and approval of the consumer's dentist	SCCNFP08, SCCP06	Overall evidence indicates that the proper use of tooth bleaching agents containing 0.1 to 6.0 % hydrogen peroxide (or equivalent for hydrogen peroxide releasing substances) is safe if used under the supervision of a dentist. (SCCNFP08)
Safety uncertain	available data do not enable a decisive response, No safe use-level has been established, no safe limit of use in cosmetic products has been demonstrated, safe use cannot be established, no safe use-level has been established	SCCP02, SCCP08, SCCP12, SCCP14, SCCP20	No safe use-level for MDBGN in cosmetic leave-on or rinse-off products has been established. (SCCP08)

[14] E.g. speech by David Byrne, European Commissioner for Health and Consumer Protection, "Irrational fears or legitimate concerns", Brussels, 4 December 2003.

4.4.8 Other qualitative expressions of risk

Table 12 summarises other phrases found in the concluding sections of opinions, which express risk in miscellaneous terms not falling into directly in the categories described in Tables 5-11.

Two of the terms in Table 12 are close analogues to the more commonly-found terms in earlier tables. “PEC/PNEC ratio” is the environmental risk analogue of “Margin of Safety” (although the former is a ratio of exposure to toxicity, while the latter is a ratio of toxicity to exposure), and “indication” is used in a similar way to “evidence”.

Interestingly, although the SSC definition of risk includes “probability”, we found this word only once in an expression of risk in the concluding sections of the opinions we reviewed (SCHER18). “Probably” was used more frequently (see section on uncertainty, below).

Table 12. Summary of other phrases found in the concluding sections of opinions, expressing risk in miscellaneous terms not falling into directly in the categories described in Tables 5-11.

Form of expression	Magnitude	Measure	Quote	Ref. no.
Association	some indications of an association	acoustic neuroma	From the available data, however, it does appear that there is no increased risk for brain tumours in long-term users, with the exception of acoustic neuroma for which there are some indications of an association.	SCENIHR04
Indication	no indication	transmission of CJD	As cord blood is entirely fetal in origin, and as there are no proven instances of vertical transmission, there is no indication that prion infectivity is transmitted by cord blood cells. However, contamination with maternal blood during collection remains a possibility.	SCENIHR05
	no indications	fertility patterns	there are no indications that neonates of high DEHP exposure have any altered long-term fertility patterns	SCMPMD10
PEC/PNEC ratio	PEC/PNEC ratio higher than 1 in some sites	PEC/PNEC ratio	In some industrial sites a PEC/PNEC ratio higher than 1 has been calculated for the freshwater environment	SCHER12
	still lower	PEC/PNEC ratio	The PEC/PNEC ratios were all below 1 in the previous risk assessment, and with the lower emissions anticipated in this report they are still lower	SCHER02
Probability	high probability	exceedance of TDI	SCHER concludes that the probability for an individual of the general population, especially a child, to exceed the TDI for OTs is high, and that some people may be exposed to doses much higher than the TDI.	SCHER18
Problem	may be a problem	exposure	Regarding dermal exposure for workers it is not clear from the report how the body burden is calculated from the exposure predictions given in Table 4.1. The exposure for the PBDD/F may be a problem	CSTEE16
	no problems	toxicological,ecotoxicological & environmental	there are no toxicological or ecotoxicological problems related with the use of Zeolites in detergents, and no environmental problems have been documented in those areas where the use of Zeolites is already common, although monitoring programmes downstream of wastewater discharges are relatively common	CSTEE20
Relevant	health-relevant	health effect	The SCHER acknowledges the evidence for PM2.5 as health-relevant.	SCHER06

4.5 Quantitative expressions of risk

We found two main types of quantitative expression of risk in the concluding sections of opinions: those involving a ratio of toxicity and exposure, and those expressing risk as the percentage, fraction or rate of adverse effects or outcomes.

Quantitative expressions of risk as ratios of toxicity and exposure are summarised in Table 13, divided into two sub-types: ratios of effect level to exposure, and ratios of exposure to effect level. Ratios of effect level to exposure were found only in human health assessments (Table 13). They are often referred to as margins of safety, especially when used for assessments under the regulations on new and existing substances. The margin of safety is an inverse measure of risk: large margins of safety represent low risk. The most commonly found form of exposure to effect level ratio was the PEC/PNEC ratio used in environmental risk assessments, but exposure to effect ratios were also found in a number of human health assessments (Table 13). Exposure to effect ratios are positively related to risk, i.e. high ratios represent high risk.

Quantitative expressions of risk as the percentage, fraction or rate of adverse effects or outcomes were found in the concluding sections of 5 of the 100 opinions we examined, and are summarised in Table 14. In most cases they were absolute estimates, but one example was relative (the relative risk of effects in sunbed users compared to the general population, SCCP17).

The measures in Table 14 are divided into three types: percentage or fraction of population affected, percentage or fraction of occasions or events affected, and number of occurrences per unit of time. Note that many of these measures involve both a population and time element, and it is important to make these explicit: e.g. 7 deaths per year in France (SCMPMD01). Note that although this issue is more obvious for quantitative risk measures, it can also apply to qualitative expressions of risk.

- When an expression of risk refers to a particular population and/or time period, it is important to ensure that these are identified and understood by the reader.

Both types of quantitative measures of risk (ratios and effect estimates) are often calculated for conservative scenarios or using conservative assumptions. It is obviously essential to communicate this clearly to avoid misinterpretation of the result.

- Expressions of risk should be accompanied by information on how conservative they are, i.e. whether they are considered to over- or underestimate the true values, and to what degree.

An important characteristic of quantitative expressions of risk of all types is their reduced ambiguity compared to qualitative expressions. When a number is presented to express the level of risk, at least the number will be communicated without ambiguity. There is still potential for ambiguity if the measure the number represents is not clearly explained (e.g. the effect, population and time period it relates to, see above), or if the units are missing or incorrect, but this can be avoided by careful drafting.

In some opinions, quantitative measures of risk were presented in the body of the document but not included in the concluding section. For example, several opinions contained estimates of cancer risk, but none of them quoted the numerical result in the concluding section: instead, the outcome of the assessment was expressed qualitatively

by describing the product as “safe” (SCCNFP17, 19, 20 and SCCP05). Someone who reads only the concluding section will be unaware of the number actually calculated. Their impression of the level of risk will be influenced by their personal interpretation of the words used in the qualitative expression, and might be very different from what it would have been had they seen the number. In effect, expressing the risk qualitatively introduces additional uncertainty in communication of the risk to the risk manager and others, because of the ambiguous meaning of qualitative terms.

- Where a quantitative measure of risk is an important part of the assessment, presenting it in the concluding section of the opinion is less ambiguous than converting it to a qualitative expression, and avoids introducing additional uncertainty when communicating the risk. It also avoids the possibility of a value judgement being implied or inferred through the use of qualitative terms such as low, high etc.

A common objection to presenting numerical estimates of risk is that they may create a false sense of precision. This is an important problem, but can be avoided by taking care to ensure that the degree of uncertainty associated with the estimate is understood.

- It is essential to communicate clearly the degree of uncertainty associated with quantitative estimates, to avoid creating a false sense of precision.

Some of the examples in Table 14 include an indication of uncertainty, either qualitatively (e.g. “about 12%”, CSTEE08) or quantitatively (e.g. 1:1,000 to 1:10,000, SCMPMD01). Expression of uncertainty is of course important for both quantitative and qualitative assessments, and is considered in more detail in Section 4.7 and Section 5.

Finally, a quantitative estimate is often only one part of an overall characterisation of risk, in which other considerations are also important. This was illustrated by the examples of cancer risk in the preceding section, where consideration of additional factors led to the conclusion that the true level of risk would be lower than the quantitative estimate (SCCP05).

- When a quantitative estimate is only one part of the overall characterisation of a risk, it is important to present it together with the other considerations in a balanced way.

Table 13. Summary of quantitative expressions of risk as ratios of toxicity and exposure, found in the concluding sections of opinions.

Group	Type of ratio	How expressed	Opinion	Examples
Ratio of effect level to exposure level	margin of safety	75 for DINP and 19 for DEHP	CSTEE01	The revised margin of safety (MOS) values are 75 for DINP and 19 for DEHP, respectively. (CSTEE01) the ADI might be reached with a daily dose of 5-7 pills, capsules or tablets containing erythrosin, or 5-7 ml of a liquid preparation / day. (SCMPMD02)
		8.8 and 67	CSTEE03	
		77	SCCP15	
		> 1000	SCHER01	
		< 100 (for some scenarios)	SCHER07	
		> 100 for most scenarios	SCHER07	
	ratio of ADI to dose	single pharmaceutical dose is 7.6 times lower than ADI	SCMPMD02	
	number of doses to reach ADI	5-7 pills/day	SCMPMD02	
	ratio of tolerated dose in rats to pharmaceutical dose	~ 12,000	SCMPMD02	
Ratio of exposure level to effect level	PEC/PNEC ratio	higher than 1…over 10	CSTEE19	For all environmental compartments PEC/PNEC ratios are <0.01, except for the aquatic environment for which the uses 'formulation of paints' and 'processing of solvents' resulted in PEC/PNEC ratios of 0.03 and 0.02 (SCHER09) For a 70 kg person this gives an exposure exceeding the ADI more than 50 times. (CSTEE15)
		all below 1	SCHER02	
		values slightly above 1	SCHER05	
		<0.01	SCHER09	
		0.03 and 0.02	SCHER09	
		higher than 1 in some sites	SCHER12	
		over 1	SCHER15	
		below 1 in all cases, but mostly above 0.1	SCHER16	
	Intake relative to PTWI (permitted tolerable weekly intake)	95th percentile dietary intake 26-34%% of WHO PTWI	CSTEE08	
		average dietary intake is 19-22% of WHO PTWI	CSTEE08	
		worst case dietary intake did not exceed 33% of WHO PTWI	CSTEE08	
	exceedance of ADI	more than 50 times	CSTEE15	
	dose relative to RfD	> 200 µg/day relative to RFD of approx 350	SCMPMD06	
	amount absorbed	less than half the accepted adequate intake of 0.7 mg/day	SCCP13	
	CJD infectivity	4500 infectious units per therapeutic unit of blood	SCENIHR05	
	ratio to permitted level	nitrosamine content is 10-50 times higher than permitted	SCCP19	

Table 14. Summary of quantitative expressions of risk as the percentage, fraction or rate of adverse effects or outcomes, found in the concluding sections of opinions.

Type of measure	Type of effect or outcome	Specific measure	Opinion
Percentage or fraction of population affected	blood levels	an increase of about 12% in the percentage of children with a blood level exceeding 100 ug/L	CSTEE08
	childhood leukemia	less than 1% excess incidence of childhood leukemia	SCENIHR04
	plasma donations at CJD risk	30 per million donors	SCMPMD01
	melanoma	the risk for developing melanoma in relation to the use of sunbeds is around 1.5 (relative to non-users of sunbeds)	SCCP17
Percentage or fraction of occasions or events affected	transmission of viruses	in the range of 1:1.000.000 blood transfusions for HIV; 1:500.000 for HBV and 1:120.000 for HCV	SCMPMD01
	incompatibility reactions	1:1,000 to 1:10,000 blood transfusions in industrialised countries	SCMPMD01
Number of occurrences per unit of time	infected blood donations	up to 1250 infected donations per year	SCENIHR05
	infections	9 infections per year	SCENIHR05
	develop vCJD	1875 new individuals per year	SCENIHR05
	deaths	average 7 per year in France	SCMPMD01

4.6 Expression of *'de minimis'* risk

In their first report of the harmonisation of risk assessment procedures, the SSC stated that 18 different terms have been identified in the EU to describe *de minimis* risk, and it was part of the remit for the present project to identify terms of this type.

It is worth mentioning first that we did not find any case where the term *de minimis* was itself used in the concluding section of an opinion. However, it seems obvious that many of the terms listed in Tables 5, 6, 7, 9 and 12 were intended to communicate that the risk was minimal or negligible (especially those we have listed under the heading "none", but also some of those listed under the headings low, less and no change). This is consistent with the observation previously made by the SSC.

We consider in Section 5 the possibility of defining more harmonised terms to express *de minimis* and other levels of risk.

4.7 The expression of uncertainties

Expression of uncertainty is increasingly recognised as a vital component of risk assessment and of particular value to the risk manager (e.g. SSC 2000, 2003, Madelin 2004).

There are many definitions of "uncertainty" in the technical literature. In their second report on the harmonisation of risk assessment procedures, the SSC (2003, p.78) stated that "for the purpose of risk assessment 'uncertainty' is defined as the gap between scientific valid knowledge and the complete ultimate scientific evidence", and that "it includes data gaps and measurement errors as well as conceptional/modelling missing aspects or unknowns" although this definition was not included in their glossary (SSC, 2000). The IPCS (2004) definition of uncertainty is "imperfect knowledge concerning the present or future state of

an organism, system, or (sub)population under consideration". Taken together these definitions make clear that uncertainty exists at all stages of risk assessment: in the inputs of the risk assessment, in the way these inputs are combined (model uncertainty), and in the output of the assessment. We found terms expressing uncertainty in each of these three areas in the concluding sections of opinions, as summarised in Tables 15-18 below.

4.7.1 Uncertainties of assessment scope and procedures

Table 15 summarises phrases found in the concluding sections of opinions, expressing uncertainties relating to the scope of the risk assessment scope and the models or other procedures used in it. These are grouped into 5 contrasting categories.

The first two categories in Table 15 comprise examples that express difficulty or inability to make an assessment, either of the risk as a whole or of some factor affecting it. Expressing inability to make an assessment at all would be a very strong statement, and most of the examples are clearly not this extreme; for example, they express inability to make a firm or a quantitative assessment. In principle, a scientific committee should be capable of providing at least an uncertain assessment of most questions that are within its expert domain. This raises an interesting and important question: at what point does uncertainty on an issue become so great that a committee should decline to express an opinion? Scientists vary in their response to this but many prefer not to give an opinion when uncertainty is high. However, although it is clearly appropriate for the degree of scientific uncertainty to be assessed by scientists, the level of certainty required for decision-making is a societal question (how sure do we want to be?) and therefore a risk management judgement. This is recognised in the area of food safety by the Codex Working Principles for Risk Analysis, which state "The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors" (Codex, 2007). This implies that scientists should not take it upon themselves to decide when their opinion is too uncertain to be expressed, rather they should express the opinion and its uncertainty so that the risk manager can take them into account. If the uncertainty on a question is so great that the experts consider the risk to be unknown, this should be expressed. However, reaching this conclusion requires scientific expertise, because it requires an analysis of the evidence, so it will still be appropriate to issue an opinion that expresses the conclusion and explains how it was reached. These considerations suggest that:

- Questions outside the expertise of a committee should be declined. In all other cases an opinion should be given, even if it is very uncertain, but the uncertainty should be clearly expressed. If the uncertainty on a question is so great that the experts consider the risk to be unknown, this should be clearly stated and the nature and magnitude of the uncertainties explained.

The third category in Table 15 comprises examples where the committee expressed a limitation in the scope of their assessment, or of the factors considered. Common examples include geographical limitations (e.g. exposure assessment for a particular region or country, such as in SCENIHR05), limitation of the routes or sources considered in exposure assessment (e.g. CSTEE03, SCCP13), or limitation of the types of toxicity assessed (e.g. SCCNFP05). In some cases, the limitation derived from the question or mandate given to the committee (e.g. SCCP13); in others, the committee introduces the limitation in order to facilitate assessment (e.g. if key data are available for only one country as in SCENIHR15; or due to limitations on time or resources for the assessment). As was evidently recognised by the committees responsible for these examples, it is

essential to communicate such limitations. This should be accompanied, where possible, by an evaluation of the uncertainty introduced by the limitations, e.g. whether the limited assessment is considered to provide a conservative or unconservative answer to the question posed. This may usefully be done as part of a systematic consideration of all the uncertainties affecting the assessment (see later).

- It is important to communicate any limitations on the scope of the assessment or on the factors considered, and to take account of these in the overall evaluation of uncertainties affecting the assessment.

The fourth category in Table 15 comprises examples where the committee expresses limitations on the reliability or appropriateness of an assessment, or part of an assessment. Most of these examples derive from opinions where CSTEE and SCHER were tasked to review assessment reports produced by others, e.g. by Member State authorities or industry.

The final category in Table 15 comprises examples where committees expressed, in the concluding sections of opinions, assumptions on which their assessments were based. Assumptions are very often needed in assessments and the need to express them is well-recognised. However, it is essential to evaluate the uncertainty associated with assumptions. This may sometimes be overlooked but in risk assessment, it is essential to consider how closely the assumptions might relate to reality, and the impact of this on the assessment outcome, (e.g. whether the effect of the assumptions is conservative or unconservative). Again, this may usefully be done as part of an overall evaluation of uncertainties.

- It is important to express any important assumptions, and to take account of their effect in the overall evaluation of uncertainties affecting the assessment.

Table 15. Summary of phrases found in the concluding sections of opinions, expressing uncertainty of assessment scope and procedures.

Group	Specific phrases	Opinion ref. nos.	Examples
cannot determine/assess	cannot be assessed, cannot be definitely proven, cannot be established, cannot be used to assess, cannot evaluate, cannot quantify, firm conclusions cannot be drawn, impossible to evaluate, impossible to trace, not possible to estimate, not possible to evaluate, precludes any thorough evaluation	SCHER17, SCENIHR05, SCCP14, SCHER18, SCHER05, SCCP06, SCMPMD01, SCMPMD04, SCCP01, SCCP17, SCHER18, SCMPMD04	SCCP cannot quantify the risk of potential serious adverse effects in relation to the use of tooth whitening products (SCCP06) experience with nvCJD is just emerging and, therefore, very limited. As with CJD firm conclusions cannot be drawn. (SCMPMD01) as no data are reported for the past it is not possible to evaluate the temporal trend. (SCHER18)
difficult to assess or determine	difficult to compare, difficult to compare, difficult to extrapolate, difficult to judge, difficult to predict, difficult to quantify, difficult to quantify, difficult to quantify, difficult to scrutinise, difficult to translate, problem, problematic, very difficult to estimate	CSTEE04, SCCP17, SCHER02, SCHER04, CSTEE09, CSTEE19, SCENIHR01, SCMPMD06, CSTEE15, SCHER04, CSTEE18, CSTEE18, SCHER18	The SCHER agrees that it must be difficult to extrapolate the neurotoxicity effects seen in mice to birds' eggs (SCHER02) DeBDE is an extremely lipophilic substance, which makes it difficult to predict its environmental distribution. (CSTEE09) It is difficult to quantify the impact that this would have on the availability of blood from donors (SCENIHR01)
limitations in scope or factors considered	additional exposure, additional questions of broader relevance, applicable only, has not been assessed, has not made full use of the data, incomplete analysis of risks, limited notice, no effort made to assess, not accounted for, not addressed, not addressed in detail, not adequately addressed, not adequately taken into account, not assessed, not cover all eventualities, not developed in sufficient detail, not included, not sufficiently covered, not take into account, not take into account, not take into account, not taken into account, not taken into account, only considered, only performed for, other sources, other sources, real risk would also depend on…, should have been addressed	SCCP15, SCMPMD04, SCENIHR05, SCCP07, SCHER13, SCMPMD10, CSTEE18, CSTEE10, SCHER04, CSTEE10, SCCP13, CSTEE07, SCHER18, CSTEE19, SCMPMD05, SCHER13, CSTEE18, CSTEE18, CSTEE03, CSTEE18, CSTEE19, SCHER13, SCHER18, SCCNFP05, SCHER10, SCCNFP07, SCCP13, SCHER05, CSTEE19	The risk assessment is directly applicable only to the UK situation (SCENIHR05) it is the opinion of the SCHER that recent literature has not been adequately taken into account (SCHER18) the present assessment process has not taken into account that more than one phthalate may occur in children's toys or that there may be additional exposures through food, air and by dermal contacts to these phthalates (CSTEE03) The Opinion has only considered the genotoxicity and carcinogenicity of methyleugenol. (SCCNFP05) Although it is beyond the scope of the mandate, there is exposure to fluoride from other sources. (SCCP13)

Group	Specific phrases	Opinion ref. nos.	Examples
limitations in reliability or appropriateness	adequacy, bias, cannot be reliably estimated, confounding, crude, disputable, do not allow for a proper comparison, does not provide necessary reassurance, extrapolation, inconsistencies, lack of confirmation, lack of validation, lack of validation, lack of validation, limitations, low reliability, more robust, not appropriate, not consistently demonstrated, not extensively peer-reviewed, not fully applicable, not necessarily appropriate, not properly determined, not scientifically justified, not standardised, not sufficiently justified, not suitable, not suitable, not valid, not validated, poor predictor, poorly predictable, preliminary data from one model, provisional, questionable, questioned, rough calculation, scientific quality rather poor, shortcomings, should be interpreted with great care, small pilot experiment, some deficiencies, suitability of test species, too weak, unclear, unreliable, variable limit of quantification, weak, weak or non-existing, without presenting the motivation	SCENIHR04, CSTEE04, SCENIHR05, CSTEE04, CSTEE19, SCHER18, CSTEE14, SCCP06, SCCP13, SCMPMD12, SCMPMD11, SCMPMD05, SCMPMD07, SCMPMD11, CSTEE14, CSTEE10, CSTEE23, SCHER18, SCENIHR04, SCHER13, SCHER18, SCENIHR03, SCHER04, CSTEE10, CSTEE03, CSTEE10, CSTEE09, SCHER12, CSTEE18, CSTEE03, SCHER17, SCHER17, SCENIHR05, CSTEE09, SCHER08, SCHER19, SCHER18, SCHER05, SCHER18, SCHER18, SCHER10, SCHER13, CSTEE04, SCHER01, SCHER18, SCHER18, SCHER10, CSTEE04, CSTEE04, SCHER18	Amino acid analysis can technically be used for all rubber products, but has not yet been clinically validated for other products besides gloves. (SCMPMD05) the model EUSES2 is not fully applicable as the log Kow is outside the valid range (SCHER18) The existing methods used for environmental exposure assessment are not necessarily appropriate for determing the distribution, partitioning and persistence of nanoparticles in the various environmental compartments. (SCENIHR03) The reported degree of risk is not sufficiently justified (CSTEE10) It is not valid and even misleading to relate the endocrine disrupter effect of non-oestrogenic compounds with the endocrine disrupter effect induced by the natural ligand 17b-oestradiol in vivo in rats (4.2, pages 17 and 18; 6.1, page 34). (CSTEE18) these models differ considerably and have not been standardised and validated (CSTEE03) The appropriateness for using N(L)OAEC for human risk is questionable. (SCHER08)
subject to assumptions	assumed, assumed, assumed, assuming, assuming, assuming, assuming, assumptions, even if the calculation is correct, generally assumed, if it exists at all, if the sole source is toothpaste, if there are 1250 infected donations per year, must be assumed, presumably	SCHER18, SCHER18, SCHER18, CSTEE15, CSTEE19, SCENIHR04, SCENIHR05, SCHER18, CSTEE08, CSTEE15, SCMPMD01, SCCP13, SCENIHR05, SCENIHR05, SCCP15	Regarding recycling of PVC the information available to the SCHER is limited, but it is assumed that the processing of the recycled material is similar to that of new PVC. (SCHER18) Assuming zero exposure from food (CSTEE19) If there are 1250 infected donations per year they will result in 3750 new infections each year in the UK assuming that donations are typically split between 3 recipients. (SCENIHR05)

4.7.2 Qualitative expression of uncertainties in assessment inputs and outputs

Table 16 summarises qualitative terms and phrases found in the concluding sections of opinions, expressing uncertainty of individual elements of a risk assessment, e.g. specific inputs and outputs. Quantitative expressions of uncertainty are addressed in the following section.

It is not possible to know whether all of the terms listed in Table 16 were intended by the opinion authors to imply uncertainty. In some cases it can be inferred from other parts of text that the committee intended to communicate uncertainty (e.g. if adjacent parts of the text refer explicitly to uncertainty, or to specific data issues such as measurements below the limit of detection). However, ultimately what matters is what the reader infers, because this will influence both risk management and the perceptions of stakeholders and the public. One way to assess what may be inferred is to delete the term in question or replace it with others. For example, it might be thought that “estimated” means only that a calculation was made, but if “it was estimated that the risk will be X” is compared with “the risk will be X”, it seems likely that many readers will interpret the latter phrase as more certain, i.e. including the word “estimated” is inferred as indicating uncertainty. This reflects common language definitions of “estimate”, which include “to form an approximate notion of” (OED Online). Of course, interpretation will vary between readers, therefore we have included extensive examples and references to the source opinions in Table 16, so that the reader can make their own assessment if desired.

The first and most obvious conclusion from Table 16 is that a huge variety of phrases are used to express uncertainty: 43 different types of expression were found, and some of these contained many variations.

- The concluding sections of the opinions we reviewed contained a huge variety of phrases that express uncertainty, or could be interpreted as doing so.

The words “uncertain” or “uncertainty” were found in 46 of the 100 opinions when the full text of each opinion was searched, and in the concluding sections of 20 of them. These words were used quite frequently by SCTEE and SCHER, and in 4 of 5 SCENIHR opinions, but much less often by SCCNFP and SCCP (Table 17). There was no clear trend in their use over time (Table 18). Although “uncertain” and “uncertainty” were found in only 20% of concluding sections, when all phrases listed in Table 16 were considered together, they appeared in 57% of the concluding sections (Table 17).

Table 16 lists the phrases in groups, each group containing a particular word or close variants of it (e.g. possible and possibly). The most commonly encountered form of expression was phrases including the word “may”. This word exemplifies an important problem that applies to all the terms in Table 16 to varying extents: ambiguity regarding the degree of uncertainty. “May” has many meanings in common language (its entry in OED Online lists 29 different senses), but when used in a risk assessment context it can usually be understood as expressing possibility. For example, “the exposure for the PBDD/F may be a problem” (CSTEE16) implies it is possible there is a problem, but also possible that there is not. When used in this way, the word “may” implies that the following statement may be true, but communicates nothing about the degree of certainty (or uncertainty) that it is true. This presents a problem for risk managers, who need to understand the degree of uncertainty so that they can take account of it in decision-making.

Detailed examination of Table 16 suggests that it is very difficult to rank the groups of phrases with regard to the degree of uncertainty or uncertainty they convey. In addition, within some groups, some phrases include additional words which modify the strength of the uncertainty expressed, e.g. likely, highly likely, most likely. It seems likely that, in many cases, the precise form of words was chosen carefully to match the degree of uncertainty felt by the opinion authors. However, it is obvious that different readers would vary in their interpretation of the degree of uncertainty implied by the phrases, especially when considering readers with different first languages. We conclude that:

- All of the qualitative phrases we identified as expressing uncertainty were ambiguous about the degree of uncertainty. Many, such as “may”, express the presence of uncertainty but convey no information at all about the degree of uncertainty. This makes it very difficult to interpret the degree of uncertainty that opinion authors intended to communicate, and presents a serious problem for risk managers, who need to understand the degree of uncertainty so that they can take account of it in decision-making.

The variation and subtlety of phrasing is such that readers may not detect at all that a term was intended to imply uncertainty, or may infer uncertainty when none was intended. Again this problem may be increased for readers whose first language is not English, or if opinions or their summaries are translated into different languages. To reduce these problems,

- We suggest that to clearly identify phrases that are intended to express uncertainties, they should all contain the word “uncertainty” (or a close variant like “uncertain” or “not certain”), or they should be presented in a separate section of text with the word “uncertainty” in the section title.

This suggestion seems likely to be effective because it would establish a single, generally-recognised term to unambiguously identify phrases or sections in opinions that deal with uncertainty. This could be reinforced by including a suitable definition of uncertainty in relevant glossaries. Consideration could also be given to developing a limited number of harmonised terms to express different degrees of uncertainty. This is discussed further in Section 5.

Some of the phrases in Table 16 express, in qualitative terms, uncertainty about a numerical quantity (e.g. “around 50%”, SCENIHR05). Again, the qualitative expressions make the degree of uncertainty ambiguous.

- Qualitative expressions of uncertainty communicate that the true outcome or risk may be different from the estimate, but not by how much or with what likelihood, which is what the risk manager really needs to know.

Uncertainty about quantitative estimates can be communicated much more effectively by presenting upper and lower bounds, or a sensitivity analysis, to show the range of possible outcomes (see next section).

Table 16. Summary of qualitative terms and phrases found in the concluding sections of opinions, expressing uncertainty of assessment inputs and outputs.

Group	Specific phrases	Opinion reference nos.	Examples
ambivalent	ambivalent	SCMPMD07	So far, the available scientific data is ambivalent. (SCMPMD07)
appear	appear, appear, appeared, appears, appears, do not appear	CSTEE03, SCENIHR04, SCCP10, CSTEE04, SCENIHR05, SCHER11	Hydroxybenzoic acid, the common metabolite of all parabens, appeared to be inactive in the in vitro assays (SCCP10)
approximately	about, about, approximately, around, in the order of, in the range of, not accurate, rather stable, roughly	CSTEE08, SCHER18, SCENIHR05, SCENIHR04, SCHER18, CSTEE18, SCMPMD05, CSTEE08, SCENIHR04	Of these 3750 new infections the subgroup living long enough after the transfusion to develop vCJD is approximately 50 %, (SCENIHR05) Daily OTs emissions from painted ships are initially in the order of some µg/cm2. A large ship (hull area 6900 m2) would then release around 2-300 g TBT per day (SCHER18)
arbitrary	arbitrary	SCCP17	SCC is a stochastic effect for which there is no assumed threshold dose. Any annual dose limits given are arbitrary (SCCP17)
believe	believed, believes	SCENIHR05, SCHER18	SCHER believes that the most important exposure pathways are food, indoor air, household dust and via dermal contact with different polymer materials. (SCHER18)
borderline	borderline, borderline	SCCP18, SCHER14	Because of its borderline Margin of Safety, its use in other types of cosmetic products is not recommended (SCCP18)
cannot be assumed	cannot be assumed	SCENIHR03	it cannot be assumed that current scientific knowledge has elucidated all the potential adverse effects of nanoparticles (SCENIHR03)
cannot be excluded	cannot be excluded, cannot be excluded	CSTEE24, SCHER16	a potential future risk cannot be excluded if the production/use volumes rise in the future as a consequence of actions on other flame retardants (SCHER16)
considered	considered, widely considered	CSTEE08, SCENIHR05	reduction in airborne lead… is considered to be a primary reason for the general lowering in lead blood levels in children and adults in Member States (CSTEE08) pathogenesis of prion-related diseases is widely considered to be related to defective protein folding resulting in abnormal protein conformation (SCENIHR05)
could	could, could be, could be even higher, could be significant	SCENIHR05, SCMPMD01, SCHER18, CSTEE19	air concentrations could be a significant exposure route (CSTEE19)
disagreement	conflict, conflicting, conflicting results, controversial, differing conclusions, does not fit, failed to provide consistent support, no agreement	SCENIHR04, SCCP11, SCCP10, SCHER18, CSTEE04, SCENIHR05, SCENIHR04, SCMPMD05	the published data are conflicting (SCCP11) Conflicting results have been reported for p-hydroxybenzoic acid tested in vivo. (SCCP10) The degradation rate and pathways in sediments is still controversial. (SCHER18) this worst case scenario does not fit the current data on vCJD case trends in the UK (SCENIHR05)
estimated	estimated, estimated, estimated, estimated	CSTEE01, CSTEE03, CSTEE08, SCHER10	It is estimated that children with average body weights of 8 kg being exposed for 3 hrs to PVC toys containing DINP and DEHP will have maximal daily intakes of 200 m g/kg for both substances. (CSTEE01)
expected	anticipated, expected, expected, not expected, not expected	CSTEE08, SCCP10, SCHER05, CSTEE08, SCCP10	The poor biodegradability under anaerobic conditions for detergent surfactants is expected to increase the potential for exposure of soil organisms (SCHER05) Parabens are not expected to accumulate in tissues (SCCP10)
few/most	a few, almost all	SCHER18, SCMPMD02	This should indicate that, if emissions will be reduced and stopped in a relatively short time, sediment cleaning will occur in a few years (SCHER18)

Group	Specific phrases	Opinion reference nos.	Examples
in general	in general	CSTEE06	The CSTEE considers that the LGC report … conclusions are in general acceptable (CSTEE06)
incorrect	erroneous, false negative, false positive, misleading, not correct, not correct	CSTEE10, CSTEE04, CSTEE04, CSTEE18, SCHER18, SCHER18	An acceptable acute dose for humans is erroneously derived using animal acute lethal dose (LD50) data. (CSTEE10) in vitro assays for predicting in vivo endocrine disrupter effects may generate false-negative as well as false-positive results (CSTEE04)
increasing evidence	increasing evidence	SCHER06	The SCHER agrees, that there is increasing epidemiological evidence that acute PM2.5 exposure is related to adverse health effects (SCHER06)
indicate	an indication, indicate, indicate, indicate, indicate, indicates, indicates…possible, indication, indication, indications	SCCP11, CSTEE13, CSTEE15, SCENIHR05, SCMPMD01, SCENIHR04, SCMPMD04, SCHER17, SCMPMD01, CSTEE04	Animal experiments and neurosurgery-related iatrogenic cases of CJD indicate that a single exposure to TSE agent is sufficient to induce disease (SCMPMD01) There are indications that lower exposures to organochlorine compounds may affect neonatal neurological development (CSTEE04)
likelihood	balance of evidence, highly likely, likely, likely, likely, likely, most likely, most likely, not likely, suggest it is unlikely, unlikely, unlikely	SCENIHR04, SCENIHR05, CSTEE04, SCCP17, SCCP17, SCENIHR05, SCENIHR05, SCHER10, SCHER18, SCENIHR05, SCCNFP01, SCENIHR04	The balance of epidemiologic evidence indicates that mobile phone use of less than 10 years does not pose any increased risk of brain tumour or acoustic neuroma. (SCENIHR04) use of UVR tanning devices to achieve and maintain cosmetic tanning, whether by UVB and/or UVA, is likely to increase the risk of malignant melanoma of the skin and possibly ocular melanoma. (SCCP17) Blood transfusion appears the most likely route for inter-human transmission of vCJD, although other routes of transmission also should be considered (SCENIHR05)
may	may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may, may be modified, may be revised, may even, may largely overestimate, may not, may not, may not, may not be appropriate, may not be the most appropriate, may occur, may or may not	CSTEE03, CSTEE08, CSTEE09, CSTEE14, CSTEE15, CSTEE16, CSTEE18, CSTEE19, CSTEE20, CSTEE21, CSTEE23, CSTEE23, SCCNFP08, SCCNFP13, SCCP06, SCCP17, SCENIHR04, SCENIHR05, SCENIHR05, SCENIHR05, SCENIHR05, SCHER04, SCHER06, SCHER17, SCHER17, SCHER17, SCHER18, SCHER18, SCHER18, SCMPMD01, SCMPMD01, SCMPMD01, SCMPMD05, SCMPMD07, CSTEE03, CSTEE03, CSTEE15, SCENIHR05, SCENIHR03, SCENIHR05, SCENIHR05, SCHER19, SCHER13, SCHER19, SCCP18	The exposure for the PBDD/F may be a problem (CSTEE16) For example, the effects of natural and synthetic oestrogens may be additive (CSTEE18) The safety margin with respect to testicular toxicity in infants exposed to DEHP from breast milk may be adequate (CSTEE23) pre-existing oral tissue injury or concurrent use of tobacco and/or alcohol may exacerbate the toxic effects of hydrogen peroxide (SCCP06) vCJD infectivity may be present in the UK population at higher levels than the present numbers of identified clinical cases suggest. (SCENIHR05) the concentration of DCM may be higher at floor level. (SCHER04) SCHER recalls that even higher concentrations than measured may be formed from air fresheners under different conditions (SCHER17) several of the primary emitted compounds may undergo reactions (e.g. with ozone, hydroxyl or nitrate radicals) to form new compounds with other effects (SCHER17) the risk may be even larger than that described in the RPA report (SCHER18) The present evaluation of the CSTEE may be modified when the results of such studies become available. (CSTEE03) this figure does include the outlier which may or may not be relevant. (SCCP18)
might	might, might, might, might, might be a possible explanation	CSTEE08, SCCP10, SCHER11, SCMPMD07, SCHER18	A further reduction in both food and blood levels might be anticipated because the full impacts of the lead in petrol ban has yet to be realised (CSTEE08) estrogens might have a role through their mitogenic action to further stimulate the malignant transformation of premalignant cells (SCCP10)

Group	Specific phrases	Opinion reference nos.	Examples
not detected/ detectable	cannot detect all, no documented problems, not detected, not measurable, not quantifiable, below the limit of detection, below the limit of detection, detection limits, limit of quantification	CSTEE04, CSTEE20, SCMPMD01, SCMPMD01, SCMPMD01, SCENIHR03, SCHER10, CSTEE18, SCMPMD05	present regulatory toxicology test guidelines, in particular the guidelines for ecotoxicity testing, cannot detect all endocrine disrupting effects (CSTEE04) Epidemiological studies … did not detect a link between CJD and the administration of blood and blood products. (SCMPMD01) the detection limits for these compounds were in the range of, or above concentrations at which (oestrogenic) effects have been shown on fish (CSTEE18)
not established	not been established, not established, not established, not established, not established, not established	CSTEE04, SCCP08, SCCP13, SCCP20, SCHER18, SCMPMD01	Any causative role for endocrine disrupting chemicals in development of prostate cancer has not been established (CSTEE04) No safe use-level for MDBGN in cosmetic leave-on or rinse-off products has been established. (SCCP08) sources of airborne organotin compounds have not been established (SCHER18)
open questions	open questions	SCENIHR04	The open questions include adequacy of the experimental models used and scarcity of data at high exposure levels. (SCENIHR04)
outlier	outlier	SCCP18	this figure does include the outlier which may or may not be relevant. (SCCP18)
perhaps	perhaps	SCMPMD01	significant infectivity may remain in the plasma perhaps as cell debris (SCMPMD01)
possible	not ruled out, possibility, possibility, possibility, possibility, possible, possible, possible, possible, possible, possible, possible, possibly, possibly, possibly, possibly very important	SCCP04, CSTEE19, SCENIHR05, SCENIHR05, SCMPMD05, SCCP06, SCENIHR04, SCENIHR04, SCHER18, SCHER18, SCHER18, CSTEE04, CSTEE15, SCCNFP15, SCHER18	The data provided so far has not ruled out the photo-toxicity of any furocoumarin. (SCCP04) In most cases it is possible that the estimated exposure does not represent a worst case as it is stated in the report (SCHER18) The degradation products we know so far are lower brominated diphenyl ethers and, possibly, brominated dioxins and furans (CSTEE15) Methyldibromo glutaronitrile causes contact allergies and has possibly effects on the endocrine system. (SCCNFP15)
potential	potential, potential, potential, potential, potential, potential, potentially important	SCENIHR05, SCHER05, SCHER05, SCHER11, SCHER16, SCHER18, CSTEE19	a potential future risk cannot be excluded if the production/use volumes rise in the future (SCHER16) Maximum concentrations may indicate a potential risk for high consumers, (SCHER18)
probably	probable, probably, probably, probably, probably not, probably underestimates	SCENIHR03, CSTEE15, SCHER18, SCMPMD05, CSTEE09, CSTEE19	The compound is probably not dissolved in the polymer matrix were it is used (CSTEE09) due to too low exposure data and because additivity is not taken into account, the report probably underestimates the risks. (CSTEE19)
prone to	prone to	SCCP21	N,N-bis(2-hydroxyethyl)-p-phenylenediamine sulfate is a tertiary amine, and thus it is prone to nitrosation. (SCCP21)
reasonable	reasonable, reasonably assumed	SCHER18, SCCP17	A reasonable conclusion would be that adults are exposed to less than 10% of the ADI via dust (SCHER18)
seem	do not seem, seem, seem, seems, seems, seems, seems, seems reasonable, seems to indicate	SCHER18, CSTEE19, SCHER04, CSTEE15, SCHER17, SCHER18, SCMPMD01, SCHER18, SCHER18	Thus emissions due to cleaning of cooling-water pipes do not seem to be of high concern. (SCHER18) the temperature seems to be in the optimal range for formation of these types of compounds. (SCHER17) Experimental evidence seems to indicate that control measures before the total ban have been effective in reducing OTs concentrations in the marine environment (SCHER18)

Group	Specific phrases	Opinion reference nos.	Examples
should not	should not	CSTEE20	the use of Zeolites in detergent products should not increase the amount (volume) of sewage sludge produced (CSTEE20)
some	some, some evidence, some studies indicate	SCHER18, SCCP17, SCCP11	it can be assumed that some children's dietary intake exceeds the TDI. (SCHER18) There is some evidence that sunbed use is associated with ocular melanoma (SCCP17) some studies indicate excess risks for acute leukaemia and chronic lymphoid leukaemia for users of hair dyes (SCCP11)
suggest	strongly suggested, suggest, suggest, suggested, suggested, suggestion, suggestion, suggests, suggests, suggests, suggests…may	SCCP10, SCMPMD01, SCMPMD01, SCCP02, SCHER05, SCCP02, SCCP10, SCCP17, SCHER05, SCHER06, SCHER17	This leads to the suggestion that butyl paraben did not have a strong estrogenic potential during the developmental study. (SCCP02) The risk assessment of LAS included in this opinion suggests that most sludge applications have low risk for soil organisms (SCHER05) The evidence together suggests that some types of air fresheners may cause or aggravate symptoms in highly sensitive persons. (SCHER17)
suspected	suspected	SCMPMD01	White blood cells are suspected to be involved in the transport of the CJD and nvCJD agent via blood. (SCMPMD01)
theoretically	theoretically	SCMPMD05	The risk can theoretically be reduced by substitution of the most potent sensitisers with less sensitising chemicals (SCMPMD05)
uncertain	big uncertainty, considerable uncertainties, considerable uncertainty, considerable uncertainty, epistemological uncertainties, high uncertainty, high uncertainty, lack of ascertainment, non-quantified uncertainty, uncertain, uncertain, uncertain, uncertain, uncertain, uncertain, uncertain, uncertain, uncertainties, uncertainties, uncertainties, uncertainties, uncertainties, uncertainties, uncertainty, uncertainty, uncertainty, uncertainty, uncertainty, uncertainty	CSTEE19, SCHER18, CSTEE05, CSTEE23, CSTEE04, SCHER18, SCHER18, CSTEE04, SCHER13, CSTEE01, CSTEE24, SCENIHR03, SCENIHR04, SCENIHR04, SCHER17, SCHER18, SCMPMD12, CSTEE03, CSTEE12, CSTEE24, SCENIHR05, SCHER06, SCHER06, CSTEE02, SCENIHR01, SCHER04, SCHER17, SCHER18, SCMPMD10	considerable uncertainty exists in the database, both with respect to DEHP levels in milk and to combined exposures in children aged 0-3 years, especially from indoor air. (CSTEE23) The uncertainty of this estimate is high due to both the limited information on dust intakes and the bioavailability of the OTs. (SCHER18) Exposure to DINP and DEHP from other sources than soft PVC toys will increase the concern, but the magnitude of such exposures is uncertain (CSTEE01) the proposed LOAEL (Cd-U) of 2 µg/g creatinine is uncertain and not sufficiently conservative (CSTEE24) It is uncertain whether nanoparticles can reach the foetus. (SCENIHR03) For neurodegenerative diseases and brain tumours, the link to ELF fields remains uncertain. (SCENIHR04) The incidence of vCJD in the UK is decreasing but there remain considerable uncertainties and concerns over future numbers of cases (SCENIHR05) there is still uncertainty over mechanisms of DEHP toxicity in animals and their extrapolation to humans (SCMPMD10)
unclear	failed to indicate a clear NOAEL, lack of a clear NOAEL, less clear, not always clear, not clear, not clear, not clear, unclear, unclear, very unclear	SCCP02, SCCP02, SCMPMD10, CSTEE24, CSTEE16, CSTEE18, SCMPMD01, SCENIHR03, SCHER01, CSTEE08	The developmental rat study provided for propyl paraben failed to indicate a clear NOAEL value, (SCCP02) It is not yet clear what proportion of the blood-borne infectivity is distributed into white blood cells and which subtype classes of white blood cells … carry infectivity (SCMPMD01) It is also very unclear whether this lead would have a significant bioavailability. (CSTEE08)

Group	Specific phrases	Opinion reference nos.	Examples
under- or overestimate	overestimated, overestimates, serious underestimates, too high estimate, underestimation	SCHER18, SCENIHR05, CSTEE19, CSTEE23, CSTEE19	the intake via locally produced food may be overestimated (SCHER18) The actual volatility for the organotin compounds is much higher and the exposures may thus be serious underestimates (CSTEE19)
unexplained	unexplained, unexplained anomaly	CSTEE04, SCMPMD01	this decline in sex ratio remains unexplained (CSTEE04)
unknown	not always known, not known, not known, not known, not known, not yet known, relevance not known, unknown, unknown, unknown, unknown, unknown, unknown, unknown, unknown, unknown, unknown	SCMPMD01, CSTEE08, CSTEE15, SCHER18, SCMPMD01, SCCP17, SCENIHR05, CSTEE04, SCCNFP15, SCCP17, SCENIHR05, SCENIHR05, SCHER17, SCHER17, SCHER17, SCMPMD07, SCMPMD08	The fate and effect of these substances are not known to the SCHER. (SCHER18) Even in haemophiliacs treated with high amounts of factor VIII cases with CJD are not known (SCMPMD01) UVR tanning devices were not in widespread use before the 1990-s and the full health effects of their use are not yet known (SCCP17) Methyldibromo glutaronitrile … mode of action is hitherto unknown. (SCCNFP15) The uncertainty in those results is unknown (SCHER17) Unknown risks associated with the interaction between cells and scaffolds. (SCMPMD08)
variable	large variation, low and variable, variable quality	CSTEE03, CSTEE18, CSTEE02	there are uncertainties…assessing the actual exposures…because the measured amounts show large variation throughout the various reported studies. (CSTEE03)

Table 17. Occurrence of “uncertain”, “uncertainty” and terms expressing uncertainty in the opinions reviewed for this study, broken down by committee.

Committee	Total number of opinions reviewed	“Uncertain” or “uncertainty”				Any term from Table 16	
		Anywhere in opinion		In concluding section		In concluding section	
		Number	%	Number	%	Number	%
SCCNFP	20	1	5%	0	0%	4	20%
SCCP	21	6	29%	0	0%	11	52%
SCENIHR	5	4	80%	4	80%	4	80%
SCHER	19	10	53%	5	26%	12	63%
SCMPMD	11	6	55%	2	18%	8	73%
SCTEE	24	19	79%	9	38%	20	83%
Totals	100	46	46%	20	20%	59	59%

Table 18. Occurrence of “uncertain” and “uncertainty” in the opinions reviewed for this study, broken down by year of publication.

Year	Total opinions	Anywhere in opinion		In concluding section	
		Number	%	Number	%
1998	5	4	80%	3	60%
1999	8	3	38%	2	25%
2000	7	2	29%	0	0%
2001	5	2	40%	0	0%
2002	13	8	62%	2	15%
2003	7	4	57%	2	29%
2004	11	3	27%	2	18%
2005	25	10	40%	3	12%
2006	19	10	53%	6	32%
Totals	100	46	46%	20	20%

4.7.3 Quantitative expression of uncertainty

We found only a small number of quantitative expressions of uncertainty in the concluding sections of opinions. Table 19 shows examples of five important types: upper and lower bounds, ranges, alternative values representing different assumptions, and statements regarding statistical significance. Further examples of all except the latter can be found in Tables 13 and 14.

Putting bounds on the possible range of values – upper, lower, or both – can be very useful to risk managers, if it shows that the maximum risk or effect is acceptable (this is the principle of the conservative or “worst case” assessment used in many areas of risk assessment).

Showing results for a range of scenarios (“what if” calculations, scenario analysis) based on alternative assumptions is a form of sensitivity analysis. Scenario analysis can be very helpful if it is not possible to identify a worst case with confidence, or if the range of possible outcomes includes some unacceptable values. This is because it helps to identify the circumstances under which unacceptable consequences could occur. It will often be possible for the risk assessor to also give some indication about the relative likelihood of the different scenarios, thus providing the risk manager with approximate information about the likelihood of unacceptable effects. An example of this is provided by CSTEE08,

where average, 95th percentile and "worst case" dietary intakes were compared to the PTWI (permissible tolerable weekly intake) (see Table 13). In some cases, scenario analysis might enable identification of practical risk management measures that would reduce the likelihood of scenarios with unacceptable outcomes. An example of this is provided by a series of SCCNFP and SCCP opinions considering the risk from tooth whitening products with differing concentrations of hydrogen peroxide, leading to advice on a maximum concentration and on precautions to be taken at lower concentrations, e.g. "The use of tooth whitening products up to 0.1% hydrogen peroxide is safe…(and) proper use of tooth whitening products containing > 0.1 to 6.0 % hydrogen peroxide (or equivalent for hydrogen peroxide releasing substances) is considered safe after consultation with and approval of the consumer's dentist" (SCCP06).

- Ranges or bounds (including worst case assessments) and scenario or sensitivity analysis ("what if" calculations) are a simple way of providing useful information about the uncertainty of a quantitative measure of risk, including the range of possible values and some indication of their relative likelihood.

Statements of statistical significance provide probabilistic information about risk. The two examples in Table 19 relate to the probability that the slope of a trend over time differs from zero. In epidemiological studies, a statistical probability may be given for the difference in incidence of effects between different population groups, e.g. consumers and non-consumers of a particular product. Although statistical significance is most commonly tested at the 5% level, other levels may be used, so for transparency it is essential to state which level was used (this was not done in the examples in Table 19).

- When making statements about statistical significance, it is essential to state the significance or probability level that was used.

It is often overlooked that choosing the probability level to use is itself a risk management judgement, because it implies a judgement about how much certainty is required about the level of risk. In principle, this applies not only to statistical statements about the final output of the risk assessment, but also to each assessment input including, for example, tests of significance used to determine no-effect levels or detect dose-response relationships in toxicity studies. This is because probability propagates through the assessment, so the certainty of the output is a function of the certainty of each input. Although the 5% significance level is widely used, we are not aware that its appropriateness for risk assessment has ever been considered from a risk management standpoint[15]. Furthermore, it is possible that, from a risk management standpoint, a single level might not be equally appropriate for all purposes (e.g. risk managers and society might want more certainty for some types of effects, or some sectors of the population, than for others).

- Consideration should be given to the general issue of whether the statistical significance levels commonly used in the biological sciences provide appropriate levels of certainty for environmental and human health risks, and whether different levels of certainty might be required for different risks. This is ultimately a risk management question, but also requires analysis of the way different uncertainties combine.

[15] Note that choosing a significance level relates to uncertainty (how sure do we want to be), and is different from choosing percentiles of exposure distributions, which has received some debate but relates to variability (what proportion of the population do we want to protect). Both may be of interest to risk managers (what proportion of the population do we want to protect, and with what level of certainty).

Risk assessors could avoid making a risk management judgement for individual components of the assessment by presenting results for a range of significance levels (e.g. 1%, 5%, 10%). However, this will generally not determine the overall level of certainty of the risk assessment output, as this will depend on the uncertainty of multiple assessment inputs, only some of which may be quantified, and on the way they are combined in the assessment. A complete solution would require probabilistic analysis of all the uncertainties affecting an assessment, which may rarely or never be practical. Fortunately, in the majority of cases a simpler analysis of uncertainty, such as a basic worst-case assessment, is sufficient to enable a risk management decision to be reached. We consider later, in Section 5, some possible options for addressing these problems in cases where a basic worst-case assessment is insufficient.

Table 19. Summary of quantitative expressions of uncertainty, found in the concluding sections of opinions.

Form of quantitative expression	Quotation	Opinion ref. no.	Year
Lower bound	at least half of the low level infectivity associated with blood is recovered in white blood cells	SCMPMD01	1998
Lower bound for effect level	The effect, if any, seems to be limited to exposures above 0.4 µT.	SCENIHR04	2006
Upper bounds for exposure and incidence	In European countries, the proportion of children exposed to such levels is less than 1%…this would roughly correspond to an excess incidence of less than 1% childhood leukaemia.	SCENIHR04	2006
Upper bound for risk reduction	In view of the distribution of vCJD infectivity over the various blood compartments, leucodepletion may produce no more than a 25% reduction in infectivity.	SCENIHR05	2006
Upper bound	up to 1250 infected donations may occur, per year, in the UK.	SCENIHR05	2006
Range	A cubic meter of waste gives about 240 m3 gas emissions, containing some 10 to 100 mg of volatile OTs.	SCHER18	2006
Alternative risk estimates based on alternative assumptions	Taking the lower limit of the confidence interval of the prevalence from the UK appendix study and if it were assumed that only ten percent of infectious donations actually transmit the infectious agent, the number of infections resulting would be 9 per year in contrast to the 1250 predicted by the worst case scenario	SCENIHR05	2006
Statistical significance	The Norwegian study is less extensive but more systematic, covering 9 stations from 1997 to 2003, but does not show a statistically significant trend	SCHER18	2006
Statistical significance	In the Danish study a statistically significant decrease from 1998 to 2003 was observed in a few sampling stations (3 of 25). All studies were performed before the total TBT ban	SCHER18	2006

4.8 The identification of missing information

Table 20 summarises phrases found in the concluding sections of opinions, which identify missing information. The phrases are grouped in Table 20 by the term used to express that the information was missing or limited: absence, few, gaps, inadequate, insufficient, lack, limited, little, missing, no, not available, not demonstrated, not given, not provided, scarce, sparse, and a number of miscellaneous terms appearing less often.

All of these terms are effective in indicating that information is limited. Two of them – inadequate and insufficient – imply that the information is too limited for the risk to be

assessed with adequate certainty. Some of the other terms are in some cases accompanied by qualifiers that have the same effect, e.g. “do not enable a decisive response”, “too limited”. This implies a judgement on what level of certainty is required, which is strictly speaking a risk management judgement. The exception to this is where a minimum dataset has been defined in advance either by or in consultation with risk managers (e.g. in regulations). Such a specification of minimum data is a form of “risk assessment policy” as defined by Codex (2007). Where such a definition of minimum data exists, it is sufficient to express that it is lacking. In other cases, it could be argued that it is unnecessary to express that data are limited, since in principle this is always true – it would always be possible to have more information. The risk manager’s primary need is to understand the degree of uncertainty associated with the risk estimate (Madelin 2004, Codex 2007). In addition, because one of the options for risk management is to request further information[16] to reduce uncertainty, risk managers also need to know which types of additional information would contribute most to reducing uncertainty. They may also need to be advised how much time would be required to obtain the new information, in order to decide whether precautionary action is required to limit risk while the data is being generated (EC 2000). Therefore, if it is desired that scientific committees should avoid implying risk management judgements, we conclude:

- When the available data fall short of a minimum specified by regulations or other policy as being necessary for risk assessment, this should be stated explicitly. If literally nothing is known about the risk, this should also be stated explicitly. In all other cases, scientists should use whatever information is available to assess the risk (even when it is very uncertain), express the impact of data limitations by expressing the degree of uncertainty, and identify which types of additional information would contribute most effectively to reducing the uncertainty.

Table 20. Summary of phrases found in the concluding sections of opinions, identifying missing information (continued on next page).

Group	Specific phrases	Opinion reference nos.
absence	absence of data, absence of good data	SCHER18, SCCP06
few	few data, few data, few is known, few measured data, few studies, very few, very few studies	SCHER18, SCCP17, SCMPMD01, SCHER15, SCHER18, CSTEE19, SCENIHR03
gaps	gaps in knowledge, gaps in the scientific literature, important gaps in knowledge, major gaps in knowledge	SCHER06, CSTEE12, SCENIHR04, SCENIHR03
inadequate	adequate data not provided, data is inadequate, inadequate, inadequate data, inadequate data, inadequate data, inadequate to allow firm conclusions, not adequate scientific evidence	SCCP03, SCENIHR04, CSTEE24, SCMPMD12, SCCNFP10, CSTEE08, SCENIHR05, CSTEE10
insufficient	insufficient data, insufficient data, insufficient data, insufficient data, insufficient data, insufficient for an overall risk evaluation, insufficient information, insufficient information, insufficient knowledge, not sufficient, not sufficient evidence	SCENIHR04, SCCP07, SCCP10, SCENIHR03, SCENIHR03, SCHER17, SCMPMD04, SCCP15, SCENIHR03, SCHER05, SCHER06

[16] Deciding on whether to request further information is part of risk management, because it involves weighing the nature and level of risk and its uncertainty against (a) the cost and time required to reduce uncertainty through data collection (one risk management option) and (b) the urgency, cost and effectiveness of risk reduction measures (another risk management option).

Group	Specific phrases	Opinion reference nos.
lack	almost total lack of data, lack data, lack mammalian data, lack of data, lack of data, lack of evidence, lack of experience, lack of experimental proof, lack of good quality data, lack of human dose-response data, lack of information, lack of knowledge, lack of knowledge, lack of knowledge, lack of knowledge, lack of support, lack of systematic data, lacked meaningful information/data	CSTEE18, SCCP17, SCCP17, SCMPMD10, CSTEE04, SCMPMD10, SCMPMD12, SCMPMD07, SCENIHR04, SCCP17, SCHER05, SCMPMD07, SCMPMD11, SCHER06, CSTEE04, SCENIHR04, SCHER18, SCCP09
limited	limited, limited, limited, limited data, limited knowledge, limits the evaluation, seriously limited, too limited, very limited, very limited, very limited, very limited knowledge	SCHER18, SCHER18, CSTEE19, SCHER10, SCHER17, SCHER17, SCENIHR04, SCHER18, SCENIHR04, SCHER18, SCMPMD01, SCHER17
little	little or no evidence, little published data, very little data	SCMPMD01, SCENIHR03, SCENIHR04
missing	missing, missing data, missing data	SCMPMD12, SCHER18, CSTEE18
no	no consistent indication, no convincing evidence, no data, no detailed studies, no evidence, no evidence, no evidence, no evidence, no information, no information, no known mechanism, no new data, no quantitative human data, no recent data, no reliable information, no scientific proof, no support	SCENIHR04, CSTEE04, SCHER18, SCHER18, SCMPMD10, SCMPMD01, SCCP17, SCCP10, SCHER04, SCHER10, SCENIHR04, SCCP04, SCCP17, SCHER18, SCHER01, SCMPMD11, SCHER18
not available	available data do not allow adequate assessment, available data do not enable a decisive response, few data available, no studies available, not available, not available, not available, not available, not available, not yet available, original reports not available	CSTEE10, SCCP02, CSTEE09, SCCNFP02, SCMPMD12, SCMPMD01, SCHER14, SCMPMD05, SCENIHR04, SCHER15, CSTEE15
not demonstrated	not conclusively demonstrated, not demonstrated, not demonstrated, not demonstrated	CSTEE08, SCENIHR04, SCMPMD05, SCMPMD11
not given	not given, not given	SCHER04, SCHER10
not provided	not possible with information provided, not provided, On the basis of provided data, the SCCP is unable to assess	CSTEE20, SCCP03, SCCP09
scarce	scarce, scarcity of data, scarcity of data, very scarce	SCHER18, SCENIHR04, SCENIHR05, CSTEE09
sparse	sparse, sparse, very sparse	SCENIHR04, SCENIHR03, SCENIHR04
miscellaneous	ambiguous, aware of emerging evidence, do not enable a decisive response, does not have information, does not include enough information, does not say anything, greater confidence will be achieved by broadening the database, important omissions in cited literature, inconclusive, less substantial, more detailed support should be given, no data were submitted, not addressed, not aware, not been identified, not been verified, not considered, not established, not fully resolved, not investigated, not meaningful, not mentioned, not proven, not replicated, not reproducible, not stated, not substantiated, not sufficiently supported, not taken into account, not used, not yet examined, required for a better evaluation, should have been added, too scant, very limited knowledge, very meagre	CSTEE11, SCHER06, SCCP02, SCHER05, SCHER05, SCHER18, CSTEE23, CSTEE24, SCHER02, CSTEE08, SCHER07, SCCP16, CSTEE19, SCHER18, CSTEE04, CSTEE04, CSTEE19, SCMPMD05, SCHER06, SCMPMD01, SCCP09, CSTEE19, SCHER18, SCENIHR04, SCMPMD11, SCCP03, SCMPMD01, SCHER12, CSTEE19, CSTEE19, CSTEE19, SCCNFP14, CSTEE19, SCHER13, CSTEE18, CSTEE14

4.9 Expression of overall conclusions

Part of the remit for this project was to identify terms and phrases used within the concluding sections of opinions to describe overall conclusions. We found two types of material fitting this description: references in opinions of CSTEE and SCHER to conclusions i), ii) or iii) in relation to the assessment of existing substances, and sections of text within the concluding section of an opinion, identified in some way as an overall

conclusion. Our findings on these two types of conclusions are summarised in the following two subsections.

4.9.1 Conclusions of assessments relating to existing substances

Instances where the concluding sections of opinions referred to “conclusion i), ii) or iii)” are summarised in Table 21. Some but not all of those opinions included a footnote defining these conclusions and identifying their source as follows:

“Terms defined by the Technical Guidance Document on Risk Assessment (EC 2003):

- conclusion i): There is a need for further information and/or testing;
- conclusion ii): There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already;
- conclusion iii): There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.”

There is some potential for confusion about the definition of numbered conclusions, because the same Technical Guidance Document (TGD) also lists 4 types of conclusions for the assessment of new substances, and the numbering and content of these is different.

The issues arising in relation to the use of these numbered conclusions in scientific committee opinions are similar to those discussed above in relation to the term “concern”. Deciding between the different conclusions involves a risk management judgement, unless specific scientific criteria for each conclusion have been established in advance by or in consultation with risk managers. As discussed in relation to “concern”, the TGD does contain scientific criteria but these leave some room for judgement and do not completely determine which conclusion applies.

In many of the CSTEE and SCHER opinions, the terms of reference explicitly asked whether the committee agreed with the conclusions of risk assessment reports prepared by other parties. The CSTEE recognised the potential for implying a risk management judgement when evaluating conclusions i) – iii) and issued a position paper (CSTEE11) attempting to establish scientific criteria for this purpose. The paper states “It is agreed that a MoS of at least 100 should be used as a starting point, taking into account factors such as…” and goes on to list 6 examples of factors that would require a higher MoS than 100, and 6 examples of factors that would justify a lower MoS than 100. These factors include the reliability of data and the conservatism of exposure scenarios, which are likely to require risk management judgements (see earlier sections). Furthermore, since the listed factors are described as “examples”, they leave additional room for judgement regarding other factors. Finally, the criteria suggested by CSTEE only relate to deciding on whether there is “concern” and their position paper does not specify how this determines the conclusion to be reached. It might be regarded as implicit that “no concern” would lead to conclusion ii), but there is no indication on how the CSTEE will decide between conclusions i) and iii) in cases where they judge that there is concern, which clearly involves a risk management judgement about the degree of the risk and uncertainty and the urgency of action (EC 2000).

It might be argued that a scientific committee’s opinion on conclusions i)-iii) could be regarded as a recommendation and that they are not actually “doing” risk management, because the final decision is taken by others. However, a committee cannot reach such a conclusion without making a judgement about risk management questions, such as what

levels of risk and uncertainty are acceptable and how to weigh this against other factors including economic, legal, social and economic factors, which will usually be outside both the remit and the expertise of the committee.

The observations in this section confirm the earlier conclusion that it is difficult to define purely scientific criteria for risk management decisions such that they can be used without requiring any element of risk management judgement. In addition:

- Committees whose remit and expertise is purely scientific may assess the risk for alternative risk management options but should not express a preference between them, unless purely scientific criteria for this have been established in consultation with risk managers.

Table 21. Summary of phrases found in the concluding sections of opinions, expressing risk in terms of the standard conclusions of the Technical Guidance Document for Risk Assessment (EC 2003).

Group	Specific phrases	Standard conclusions	Sector	Opinion reference nos.	Example
Agree	agrees with, will not change, supported, agrees with, agrees with, agrees with, is supported, adequately justifies, agrees, agrees with, supports, supports, , acceptable, supported, is acceptable	Conclusion ii), Conclusion ii), Conclusion iii), Conclusion i), Conclusion ii), Conclusion iii), Conclusion iii), Conclusion ii), Conclusion ii), Conclusion iii), Conclusion ii), Conclusion ii), Conclusion iii), Conclusion ii), Conclusion ii), Conclusion iii)	consumers and workers, consumers, workers, workers, consumers, workers, workers, workers, workers and consumers, workers and consumers, all compartments, humans, freshwater environment, environment, consumers, workers	CSTEE16, CSTEE17, CSTEE17, CSTEE24, CSTEE24, CSTEE24, SCHER01, SCHER07, SCHER08, SCHER08, SCHER09, SCHER10, SCHER12, SCHER15, SCHER19, SCHER19	The CSTEE agrees with conclusion i) concerning neurotoxic effects of low doses of cadmium. (CSTEE24)
Disagree	has difficulties to agree with, cannot accept, imply at least	Conclusion ii), Conclusion ii), Conclusion i)	worker, plants and animals, marine environment	CSTEE15, SCHER12, SCHER15	For a 70 kg person this gives an exposure exceeding the ADI more than 50 times. The CSTEE has therefore difficulties to agree with the conclusion ii) for occupational exposure. (CSTEE15)
Recommends	recommends, suggests	Conclusion i), Conclusion i)	humans, humans	CSTEE23, SCHER01	the CSTEE recommends the conclusion i) in order to gain more confidence in the exposure estimates (CSTEE23)

4.9.2 Subsections or text statements expressing overall conclusions

An overall conclusion might be a whole section of text, or a piece of summarising text within (probably at the end of) a section. As mentioned at the start of this report, it was not always clear which section of an opinion to consider as the “concluding section”. Often the final section of the document is headed “conclusion” or “opinion”, in which case we took that. Generally, this section appears before the list of references, but in a few cases (e.g. SCCNFP08, see below) it comes after the references at the very end of the document. In all of the remaining cases, where there is no such section at the end of the document, we identified an equivalent section earlier in the document and used that for the analysis. In no case is there a summary or abstract at the start, although in a few cases there is a section titled “executive summary” within the body of the document (e.g. SCMPMD05). Quite often, the concluding sections thus identified contain not only conclusions but also summaries of the evidence and/or argumentation.

Within the concluding sections, text that we interpreted as an “overall conclusion” was found in only 4 of the opinions reviewed. These 4 cases are presented below, together with details of what identified them as overall conclusions.

SCMPMD05. This went much further in highlighting overall conclusions than any other opinion we reviewed. The remit contained 16 questions, and the document contains 16 sections giving a separate opinion on each question. Fourteen of the 16 opinion sections end with an overall conclusion, clearly identified as a sentence or paragraph beginning with the words “In conclusion…”. In addition, the document contains an executive summary, which also ends with an overall conclusion paragraph, identified in the same way: “In conclusion, risk groups for latex allergy are atopics, and subjects frequently in contact with latex medical gloves, such as the medical profession and patients needing multiple surgery. … In general, ingredient information on rubber products may prevent allergic responses in those subjects allergic to latex proteins and/or chemicals.”

SCCNFP08. This is one of the cases where the concluding section is located after the reference list at the very end of the document. This short summarising section is headed “Opinion of the SCCNFP” and contains only two short summarising paragraphs, the second of which is the following single sentence: “Overall evidence indicates that the proper use of tooth bleaching agents containing 0.1 to 6.0 % hydrogen peroxide (or equivalent for hydrogen peroxide releasing substances) is safe if used under the supervision of a dentist.” The word “overall” together with the location of this sentence at the end of the concluding section identify it as the overall conclusion of the opinion.

SCMPMD02 and SCMPMD06. These 2 opinions on colourants both start with a statement of the question to the committee followed immediately by a section headed “Answer”. This section starts with one or two sentences of text, followed by a subheading, “Main elements of the scientific justification of the answer”. This structure implies that the one or two sentences immediately below the heading “Answer” can be interpreted as the overall conclusion of the opinion. For example, the conclusion for SCMPMD02 is “Given the quantities of the colourant allowed in certain foods, which can be consumed without any restriction whatsoever, it seems paradoxical to prohibit its use at levels that are absolutely

negligible in pharmaceutical products, the sale and consumption of which is regulated by law or in any case limited." [17]

We conclude that, although nearly every opinion contains a section that is identifiable as the conclusion or summary of the opinion, (a) none of the opinions start with an abstract or executive summary, and (b) within the concluding sections, very few contain text that is clearly identifiable as "overall conclusions". If well-constructed, summaries can facilitate communication of key conclusions to risk managers and stakeholders, and serve as a useful starting point for development of other risk communications such as press releases. On the other hand, in most opinions, the key conclusions require more context and qualification (e.g. to express uncertainties) than is feasible in a single sentence without it becoming unreadable. Therefore, we recommend that:

- Consideration should be given to including a summary as a standard component of scientific committee opinions.

4.10 Terms and phrases used to express recommendations

Phrases expressing recommendations that we found in the concluding sections of opinions consisted of two parts: a term or phrase identifying a possible action, and a term or phrase expressing the committee's opinion about whether the action should be considered or done. Both these aspects are summarised together in Table 22, and more detail on the latter is provided in Table 23.

All of the recommendations we found related to one of six types of action, shown in the first column of Table 22 : collection of data, further evaluation of risk, development of scientific methods, research needs, risk reduction measures, and screening or surveillance activities. It is not always recognised that a decision on any one of these six types of action, or deciding to do none of them, requires a risk management judgement. This is because deciding on any one of these actions implies a judgement that the level of risk and uncertainty justifies the investment of time and resources required to implement the action. It may also require consideration of legal, social, cultural and ethical issues. All of these issues except for the assessment of risk and uncertainty are outside the remit and expertise of the existing scientific committees, and balancing these issues is clearly a risk management judgement. This is stated clearly in the Food Regulation[18], but less so in other risk assessment legislation.

Deciding between the six types of action also involves a judgement about the acceptability of delay: recommending risk reduction implies a perceived need to reduce risk without delay, whereas all the other actions involve some degree of delay while action is taken that in one way or another provide further information, which may lead to risk reduction at a later date. Again, weighing the need for immediate risk reduction against options for

[17] In this example the overall conclusion is a comment on the consistency of regulation, but the scientific justification that follows it summarises an assessment of risk.

[18] Definitions from Article 3 of the Food Regulation, EC 178/2002: "'risk assessment' means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation; 'risk management' means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options." "Other legitimate factors" are identified in point 24 of the preamble to the same Regulation: "other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls."

reducing uncertainty involves a risk management judgement. There is also the need to decide whether to take precautionary action to limit the possible but uncertain risk during the delay before new information is available, and this too is a risk management judgement (EC 2000).

It might be argued that in expressing a recommendation for action, a scientific committee is not actually "doing" risk management, because the final decision is taken by others. However, it is clear from the preceding paragraphs that a committee cannot arrive at recommendations for action without making a judgement about risk management issues. Put simply, it would not be logical to recommend action without considering all the relevant factors, and some of those factors (societal, economic, traditional, and ethical factors and the feasibility of controls) are outside the remit and expertise of scientific committees.

It is also pertinent to examine the way in which the recommendations are expressed, as summarised in the third column of Table 22 and in more detail in Table 23. Most of the terms used express some level of importance or urgency, ranging from relatively mild terms such as "agrees", "consider", "propose", "recommend", "request", "suggest" and "support" through stronger terms such as "urgent", "priority", "necessary", "need", "important", "require" and "should", to imperatives such as "essential" and "must". The stronger terms imply, or may appear to readers to imply, an expectation on the part of the committee that the recommended action will be implemented. Even if this was not the committee's intention, it may be perceived this way by the public and could create an expectation of action that may constrain the risk managers' freedom to decide.

All of these issues can be avoided by recognising that the responsibility for decisions lies with risk managers, and formulating opinions so that they present the scientific information needed to support decision-making without implying a judgement or preference. The key principle is to focus on scientific assessment of the consequence of each option for action: assessment of the change in risk that could be achieved by different risk reduction measures (including the uncertainty of the change), and assessment of the extent to which uncertainty might be reduced by different options for data collection, research etc. At simplest, for example, "further toxicity studies should be conducted" could be replaced by "further toxicity studies would contribute to reducing uncertainty". In practice it will be difficult to estimate the potential for reducing uncertainty quantitatively, but it should be possible for a committee to make a qualitative assessment of the relative uncertainty in different parts of the assessment, and thus the potential of different types of additional information to reduce uncertainty (see Section 5). This information can be communicated without using any of the terms in Table 23, including the word "recommendation", and would be sufficient to enable the risk manager to weigh the risk and uncertainty against other considerations.

We conclude that:

- Recommendations for actions, such as risk reduction or data collection, imply risk management judgements. This can be avoided by limiting opinions to a scientific assessment of the consequences of different options for action, e.g. by assessing the change in risk that could be achieved by different risk reduction measures, and the relative contribution that different types of data collection could make to reducing uncertainty.

In some of the Opinions we reviewed, the questions posed to the committee explicitly requested recommendations on actions. Many of the questions put to the SCCNFP and SCCP ask whether the committee recommends any restrictions on the use of a substance

in cosmetic products. Recommendations for action are also sometimes requested in questions to other committees, e.g. “consider whether further studies are necessary to adequately assess the potential health risks from air fresheners” (SCHER17) and “should leucoreduction be recommended…?” (SCMPMD11). Such questions imply a need for the committee to make risk management judgements. This can be avoided by posing questions which ask committees to assess the risk consequences of particular actions (e.g. what would be the effect of leucoreduction?), or to identify possible options for reducing risk and assess their potential impact, thus leaving the risk management judgement to decision-makers. These issues require consideration at the beginning of the process, when agreeing on the remit or mandate for new opinions.

- Care is needed to ensure that questions put to and accepted by committees whose remit is purely scientific do not imply a need for risk management judgements.

Table 22. Summary of types of action suggested in the concluding sections of opinions, together with frequencies of different terms expressing their importance or urgency.

Type of action	No.	Form of recommendation	Selected examples
data requirements	56	agrees (1) consider (1) important (1) miscellaneous (9) need (13) propose (1) recommend (6) request (2) require (8) should (11) support (1) urgent (2)	Measurements of actual concentrations in the environment are needed (CSTEE19) Further quantification of emissions from and consumers use pattern of air fresheners is needed (SCHER17) To exclude a clastogenic potential of Henna Rot (Lawsonia inermis), additional testing with batch 1271 is required. (SCCP07)
further evaluation	22	consider (1) important (1) must (1) necessary (2) need (2) recommend (2) require (1) should (8) suggest (4)	The issue should also be reconsidered in the human health risk assessment. (SCHER12) The CSTEE considers that the risk related to uses in pesticide formulations should be refined. (CSTEE07) It is suggested that realistic scenario's are developed and assessed (SCHER13)
method development	23	essential (2) miscellaneous (6) must (2) need (3) priority (1) recommend (3) require (1) should (4) support (1)	The assays may need to be supplemented by additional tests, or replaced by modified tests (SCENIHR03) for fish, it is recommended to enhance the early life-stage test and to further development the partial life-cycle test (CSTEE04) The CSTEE should be proactive in the area of probabilistic methods in human and environmental risk assessment. (CSTEE11)
research needs	26	consider (1) miscellaneous (6) must (1) need (4) priority (4) recommend (6) require (1) should (3)	Accelerate investigation of the pathogenesis of model TSE diseases in readily accessible laboratory rodents. (SCMPMD01) Further research is recommended in order to assess the effect under 1000 ppm fluoride. (SCCP13) there are several aspects of the fundamental properties of nanoparticles that require elucidation (SCENIHR03)
risk reduction	111	agrees (7) consider (4) essential (1) important (1) miscellaneous (30) must (5) necessary (4) need (5) propose (3) recommend (13) should (29) suggest (2) support (7)	Information on the package of medical devices on the presence of natural rubber latex is therefore essential. (SCMPMD05) An increase of hydrogen peroxide (and equivalent) in toothpastes and mouth-rinses to 3.6% is not permissible. (SCCNFP02) it is the Committee's opinion that use of this metal as a colorant be prohibited in medicinal products (SCMPMD06) For clinical vCJD patients potentially contaminated instruments must be destroyed (SCENIHR05)
screening and surveillance	18	consider (3) essential (2) miscellaneous (2) recommend (6) should (5)	It is recommended that there is a follow-up for children that are born to mothers who had or developed clinical vCJD. (SCENIHR05) Use of tonsils from tonsillectomies is also recommended (SCMPMD01)

Table 23. Summary of phrases found in the concluding sections of opinions, expressing importance or urgency of action.

Form of recommendation	No. of cases	Specific forms (duplicates removed)
agrees	8	agrees, has difficulties to agree
consider	10	can be considered, considers, could be considered, does not consider, has to be considered, has to consider, might be considered, recommends a careful consideration, worth consideration
essential	5	could be essential, essential
important	3	important, more important, would be an important contribution
must	9	agrees...must not, agrees…must, must, must not exceed
necessary	6	deemed necessary, may be necessary in specific cases, might be necessary, necessary, necessity
need	27	fully support the need, is needed, need, need attention, need to be confirmed, need to be replicated, needed, needs, needs to be considered, no need, obvious need, SCCPs opinion that more information is needed
priority	5	a priority, high priority, important priority, priority
propose	4	agrees with the proposed restrictions, proposed, proposes, strongly proposed
recommend	36	cannot make clear-cut recommendation, does not recommend, does not recommend any further restrictions, no recommendation can be made, not recommended, recommendations, recommended, recommended should not, recommends, recommends…should, strongly recommends, supports recommendation
request	2	requested, requested to provide
require	11	is indeed required, is required, require, required, would be required, would be required before any further consideration
should	60	consideration should be given, efforts should be made, should, should be addressed, should be assessed, should be avoided, should be carried out, should be conducted, should be considered, should be implemented, should be investigated in more detail, should be performed, should be refined, should be restricted, should be supplied by, should be undertaken, should be used under supervision, should contain warning, should not, should not be intentionally added, should not be interpreted, should not be present, should not be used, should not exceed
suggest	6	suggested, suggested...can be improved, suggested...can be considerably improved, suggested…should, suggests, suggests…should
support	9	does not support, full support, may be supported, supported, supports
urgent	2	a matter of urgency, urgent need
miscellaneous	53	accelerate, acceptable, alternatives, attention is drawn, can be safely used, can only be answered, clearly has implications, encouraged, encourages, endorses present policy, especially, have to be, in order to, inadequate submission, mandatory, may, may be, may be useful, might be advisable, monitoring, no justification, no new grounds, not by itself regarded as an effective measure, not permissible, not restricted, not suitable for use, points out, possible approaches, preferred, prohibit, promotes, raises the issue, realizes, remain unchanged, safe for use, seems paradoxical, the appropriate measure, the most effective, the only possibility, warranted, well-balanced measure, will be enhanced, will facilitate, without any restriction, wll not change, would be in line with, would be relevant, would be useful, would provide

4.11 Terms used to identify special sectors of the population

Table 24 lists terms found in the concluding sections of opinions, identifying particular sectors of the population. In general, these terms were used either to indicate the scope of the assessment or to identify a sub-population at higher risk. However, there were many instances where the population considered was not specified explicitly in the concluding section. Furthermore, when sectors at increased risk were identified, their description was usually imprecise as can be seen in Table 24, e.g. “children” does not specify the age range concerned, and the difference between alcohol use, habitual alcohol use and alcohol abuse is ambiguous. Expressions of risk should be accompanied by specification of the population (human or ecological) concerned. In particular:

- Sub-populations at increased risk should be identified clearly, so that risk reduction or advisory information can be targeted appropriately.

Table 24. List of terms found in the concluding sections of opinions, identifying particular sectors of the population.

alcohol abuse
atopics
atypical and/or multiple moles
certain occupations
children
concurrent use of tobacco and/or alcohol
consumers
critically ill neonates
especially susceptible populations
family history of breast cancer
family history of melanoma
females
genetically susceptible
habitual alcohol users
habitual tobacco users
heavily contaminated areas
high consumers
high exposure
immunosuppressed recipients of transplants
individuals under the age of 18 years
low socioeconomic groups
malignant melanoma
medical profession
most sensitive persons
nursing mothers
patients
people having asthma
people with predisposing disease
persons reacting exceptionally sensitively
persons with gingivitis (and other conditions)
predisposing disease
pre-existing oral tissue injury
pre-existing tissue injury
presence of freckles
skin phototypes I and II
susceptible and vulnerable groups
susceptible sub-groups
tobacco users
USA women using hair dyes frequently & long
use of alcohol
use of tobacco
users of hair dyes
vulnerable groups
workers
young children
young people

4.12 Terms used to identify worst case or conservative assumptions or assessments

We found few examples of terms of this type in the concluding sections of opinions, and did not analyse them in detail. Those we noted were: clear overestimation, combination of worst case conditions, conservative, not sufficiently conservative, rather conservative, real worst case, realistic scenarios, realistic worst case, reasonable worst case and worst case.

The concept of conservatism is a very important tool for coping with variability and uncertainty in risk assessment and risk management, because it enables risk management decisions to be reached with limited information. In principle, this requires that the degree

of conservatism is appropriate to achieve the desired degree of protection. In practice, the degree of conservatism in standard risk assessment procedures and assumptions is often poorly understood, and very difficult to quantify (e.g. EFSA 2007).

It is essential to evaluate and communicate the degree of conservatism associated with expressions of risk, so that account can be taken of this in risk management. Some practical suggestions for this are included in the next section (5).

5 OPTIONS FOR IMPROVING THE EXPRESSION OF RISK AND UNCERTAINTY

A key part of the remit for this project was to develop recommendations for best practices for promoting harmonised approaches to expressing risk and uncertainty. This is addressed in the following sections, after first considering the definition of risk itself.

5.1 Definition of risk

The SSC glossary defines risk as "the probability and severity of an adverse effect /event occurring to man or the environment following exposure, under defined conditions, to a risk source(s)" (SSC 2000). We start by considering this definition of risk itself, noting that the SSC (2000) stated that "The list and the definitions suggested should not be considered a definitive work..." but should be open to revision.

First, we note that the SSC definition of risk refers to "probability and severity" of adverse effects, whereas the IPCS (2004) definition[19] refers only to probability. Clearly both probability and severity are of interest for risk management, which favours the SSC definition.

On the other hand, the SSC definition implies a quantity with more than one dimension, since probability and severity would be measured on different scales, and causes ambiguity when "risk" is used in qualitative expressions, e.g. "high risk" does not distinguish whether probability, severity or both are "high".

Third, probability and severity are not the only dimensions of interest for risk management. Other dimensions are also important, but are not explicitly included in the current definitions: e.g. magnitude, frequency in time, and the proportion of a population that is affected. Note that severity, magnitude, frequency and proportion affected are different dimensions of the degree of effect, whereas probability is a measure of the likelihood or certainty that a specified degree of effect will occur.

Therefore:

- We propose that the definition of risk should include both probability and the degree of effect, including its severity, but in a way that keeps them distinct and gives risk a single dimension. This could be achieved by adopting a modified version of either the SSC or IPCS definition, e.g. "*the probability of a specified type and degree of adverse effect /event occurring to man or the environment following exposure, under defined conditions, to a risk source(s)*", or "*the probability of a specified type and degree of adverse effect in an organism, system or (sub)population caused under specified circumstances by exposure to an agent*".

5.2 Expression of risk

The multi-dimensionality of risk has implications for the expression of risk as well as its definition. For example, a high probability (certainty) of a minor effect may be more or less

[19] "The probability of an adverse effect in an organism, system or (sub)population caused under specified circumstances by exposure to an agent".

acceptable than a low probability of a major effect, depending on the nature of the effect and the risk management context. Therefore, expressions of risk will often need to comprise at least two elements: one expressing the degree of effect and the other expressing its probability. In some cases more elements may be required to express multiple dimensions of the degree of effect where these are relevant for decision-making: e.g. where the prevalence of the effect in a population is of interest as well as its severity.

Note that the ratios of toxicity and exposure (e.g. Margin of Safety and PEC/PNEC ratio) used in many areas of risk assessment do not distinguish between the degree of effect and its probability, although they are positively related to both. For example, a high ratio of exposure to a no-effect level indicates that some degree of effect is likely but does not estimate the probability of any particular degree of effect. Nevertheless, ratios of toxicity and exposure are simple to calculate and, in many assessments, they are sufficient to conclude that the probability of adverse outcome is acceptably low. Consequently, they are suitable for screening purposes (first tier assessment). However, risk expressions that separate probability and degree of effect are more likely to be necessary for higher tier assessments.

The assessment and expression of probability and degree of effect can be either qualitative or quantitative; both are discussed in the following sections.

5.3 Harmonisation of terms for expressing risk

In its first report on the harmonisation of risk assessment procedures, the SSC highlighted the large variety of terms used to express apparently similar risks and recommended that the Community's scientific committees should adopt a common language to describe different levels of risk. In the SSC's second report, they recommend "Selection of a short list of descriptive terms for the expression of levels and likelihood of risk" (SSC 2003, p. 93). Here we discuss how such terms might be defined and, in particular, whether those definitions should be qualitative or quantitative.

There is a substantial body of scientific literature showing that people differ widely in how they interpret verbal representations of probability. Based on a meta-analysis of ten such studies, Theil (2002) concludes "there is no consensus about probability translations". Therefore, qualitative terms that have no quantitative definition will be interpreted differently by different people. This implies that (a) the same term will be used by different assessors to express different levels of risk, (b) the same term will be interpreted in different ways by different decision-makers, leading to inconsistencies in decision-making, and (c) the same term will be interpreted in different ways by different stakeholders and members of the public. Therefore, creating a set of terms with qualitative definitions would limit the variety of terms used but would not achieve consistency in the expression and understanding of risks.

Several studies have shown that people, including experts and decision-makers, prefer to use verbal phrases rather than numerical probabilities when communicating uncertainty, but prefer to receive information on uncertainty numerically (e.g. Erev and Cohen 1990, Fillenbaum et al. 1991, Wallsten et al. 1993). This suggests that the decision-makers who commission scientific opinions might prefer to receive numerical information. This is consistent with remarks made by Mrs Husu-Kallio, then the Deputy Director General and Head of Science at SANCO, at the first meeting of the Chairs of the Scientific Committees: "general terms such as 'negligible risk' and 'low risk' did not help the decision-making

process, making it difficult for the risk manager to estimate the risk"[20]. This remark also implies that, if risk expressions are defined in qualitative terms, risk managers will form their own quantitative interpretations, which might be quite different from what the scientists intended.

To avoid these problems, each term for expressing risk would require an unambiguous definition, to ensure it could be used in a consistent way by different assessors, and interpreted correctly by decision-makers. These definitions would have to be quantitative, as defining a qualitative term using other qualitative terms does not remove the intrinsic ambiguity of qualitative terms. For example, in one scheme "unlikely" is defined as "could occur at some time" and "possible" as "might occur at some time" (AS/NZS 2004). This simply replaces ambiguity about the difference between "unlikely" and "possible" with ambiguity about the difference between "could" and "might".

Schemes equating qualitative terms with different numerical levels of probability or likelihood have been developed in other domains of risk assessment and management, e.g. climate change (IPCC 2005) and project management (ICE/FIA 1998). Tavana et al. (1997) showed that within a restricted group in the same profession (30 financial analysts in a single company) it was possible to develop and use an agreed set of verbal probability terms. This suggests that it might be possible establish harmonised risk terminologies, at least within other restricted groups such as assessors and decision-makers in a particular area of risk regulation.

- If harmonised terms are established for expressing risk, then the definitions of those terms should be quantitative, in order to ensure that they can be used in a consistent way by different assessors and interpreted correctly by decision-makers.

5.4 Disadvantages of harmonising risk terms

The principal advantages of harmonising risk terms envisaged by the SSC (2000, 2003) were a reduction of confusion caused by the current variety of phrases used to express risk, improved clarity of risk communication and, perhaps, easier comparison of different risks. However, it is also important to consider potential difficulties of harmonising risk terms, and whether it would actually deliver the expected benefits.

1. The SSC's recommendation envisaged "a short list of descriptive terms for the expression of levels and likelihood of risk" (SSC 2003, p. 93). In fact, it is likely that multiple lists would be required. This is already implied by the SSC when they refer to "levels and likelihood" of risk, i.e. the degree and probability of effects, which need to be expressed separately. As discussed in sections 5.1 and 5.2, it may also be necessary to distinguish different dimensions of degree of effect, such as magnitude of effect, frequency in time and proportion of population affected. Different types of effect are likely to require different scales. In the domain of the EC's non-food committees, different scales would clearly be required for lifetime cancer risk, Margins of Safety, and PEC/PNEC ratios. Even if the same term (e.g. "low") occurred on each scale, its numerical definition would differ, so a general harmonisation on a single scale is not achievable. Furthermore, a single scale for probability or likelihood may not be considered equally appropriate for all types of risk. For example, "very unlikely" is defined as "<10% probability" on the IPCC (2005) scale for climate change assessments, but as "<1%" on the ICE/FIA (1998) scale for assessing project risks.

[20] Report of the First Meeting of the Chairs of Scientific Committees of Community bodies involved in Risk Assessment (7 and 8 December 2005). C7/MM D(2006) 370004. Brussels, 28 February 2006.

Therefore, it seems likely that not one or two but many different lists of terms would be required. This could actually lead to more confusion that the current unharmonised situation, especially if the same phrase had different definitions in different areas of regulation.

2. If quantitative definitions were established for risk phrases in a particular area of regulation, it could be expected that scientific experts and decision-makers working in that area would become familiar with them. It is less likely that the public or experts and decision-makers in other areas would be familiar with them, especially if different areas of regulation used different definitions. Therefore, outside the small group most closely involved, the general problem of variable interpretation (Theil 2002) would still occur, unless the phrases were always accompanied by their quantitative definitions – in which case, the phrases themselves would be unnecessary.

3. When numerical measures of risk are available, translating them into verbal expressions with quantitative definitions will almost always result in loss or distortion of information.
   - If the estimated range of the numerical measure (taking account of uncertainty) is narrower than the range defined for the verbal expression (e.g. 25-50 vs. 10-100), translation will result in loss of information.
   - If the estimated range bridges two verbal expressions, translation into one of them will be misleading (e.g. if the estimate is 5-25 and has to be expressed as either 1-10 or 10-100).
   - If the estimated range of the numerical measure is wider than the range of the verbal expression (e.g. 5-500 vs. 10-100), translation will result in exaggerated precision.

   Such a loss or distortion of risk assessment information will lead to impaired decision-making. This is because risk management may involve weighing the estimated risk against other legitimate risk management considerations such as societal, economic, traditional, and ethical factors and the feasibility of controls[21]. It may also involve balancing health risks and environmental risks, weighing health risks against health benefits, or weighing the risks and benefits of alternative products[22]. Translating the risk estimate to a verbal expression will always change its contribution to the balance, except for rare cases where the estimate has a range exactly equal to the definition of the verbal expression. Sometimes, the change in contribution will lead to a different – and presumably inappropriate – risk management decision. If the decision is a borderline one, even a small translation effect could change it[23]. These would be logical reasons for decision-makers to prefer receiving numerical information, as was found in some studies (see above).

[21] E.g. “decisions of importance for public safety … may also have major economic implications that need to be taken into account by the risk manager” (Madelin 2004).
[22] E.g. “In any consideration of restrictions on the use of PVC materials in medical devices, and especially DEHP-PVC materials, full account must be taken of the actual benefits of these materials and the balance between these benefits and risks.” (SCMPMD10).
[23] Quite small differences in margins of safety can have an impact on decision-making. For example, in an opinion on a hair dye (SCCP15), an MoS of 25 would have been acceptable, due to the availability of toxicokinetic studies, but the actual MoS of 16.3 was considered insufficient.

4. Another important consideration is that, even when quantitative definitions are provided, readers are likely to interpret qualitative terms as implying a risk management judgement about the need for action. This is especially true for terms like “safe” and “concern” but may also occur with expressions such negligible, unlikely and likely (see Sections 4.4.1-8). This could interfere with the making and communication of decisions. For example, a risk manager might consider on the basis of other legitimate factors (e.g. cost, benefit, legal issues) that a risk meeting the definition for “high” did not require action, but may find it difficult to explain this adequately to stakeholders and the public and might even feel that this constrained their decision options.

5. Perhaps the most compelling reason not to use verbal expressions is simple logic:
   - If a qualitative term has a quantitative definition then using that term implies that the risk corresponds to the definition, even if no quantitative assessment has been done.
   - In such a case, using the implied quantitative estimate would be more transparent and less liable to misinterpretation than using the verbal term, and would also avoid the possibility of implying a risk management judgement. Every such statement should of course be accompanied by a clear statement of its uncertainty.
   - If the assessor does not mean to imply a quantitative estimate, or if they consider that the available science will not support quantification, then they should not use a verbal term with a quantitative definition.

- We conclude that, although attractive in theory, defining harmonised verbal terms to express risk would not improve risk communication. Different definitions would be required for different areas of risk. If the definitions were quantitative, then expressing the risk quantitatively would be more transparent and less liable to misinterpretation than using the verbal expressions. If the definitions were qualitative, variable interpretation by different people would cause inconsistencies in both the expression and understanding of risks, which would impair decision-making. Furthermore, it would be difficult to define qualitative terms in such a way that they could be used by assessors without making or implying risk management judgements.

5.5 Alternatives to harmonised risk terms

5.5.1 When quantitative estimates are available, use them

In many of the opinions we reviewed, numerical measures of risk make a significant contribution to the overall characterisation of risk, including margins of safety, PEC/PNEC ratios, lifetime cancer risk and other measures. Often, the results of these calculations were not included in the concluding section of the opinion. For example, there were verbal references to margins of safety (MoS) in 31 of the 100 opinions we reviewed, but numerical values were given in only 21 of the opinions, and in only 6 of their concluding sections. The arguments in the preceding section imply that when these or other types of quantitative estimate are available from an assessment, it would be better to use them as quantitative expressions of risk rather than convert them into verbal phrases.

Some research suggests that people’s willingness to use quantitative terms depends on the precision of the available data (Wallsten et al. 1993), and it is often argued that quantitative expressions should not be used because they give an exaggerated impression of precision. However, this argument should not apply if the uncertainty of quantitative

expressions is clearly communicated. The SSC (2003) and the Commission (e.g. Madelin 2004) have both emphasised that risk assessments should include clear expression of uncertainty. Practical methods for doing this are available (see later). Therefore this objection to using quantitative expressions should be removed.

Another concern about communicating quantitative risk estimates is that they can be difficult to understand. For example, Lipkus et al. (2001) showed that 16-20% of a group of highly-educated people incorrectly answered basic questions relating to risk magnitudes (e.g. which represents the larger risk: 1%, 5% or 10%). One would expect that decision-makers who deal with risk assessments and interact with scientific committees on a regular basis should become proficient at interpreting the types of numerical information they encounter. However, this should be reinforced by providing suitable training, and by interaction between risk assessors and decision-makers to identify which forms of numerical estimate are preferred (e.g. probabilities expressed as percentages, proportions or odds)[24]. Communication of quantitative risk expressions to the public is more challenging. However, using a scale of verbal expressions with quantitative definitions will not help, because it will still be necessary to communicate the quantitative definitions. Therefore the only solution is to find effective ways of communicating quantitative risk information.

Of course, even in assessments where quantitative risk measures are used, they are rarely the only basis for risk characterisation. Usually, quantitative estimates need to be weighed against other scientific considerations, which may be of a qualitative nature. In such cases, the quantitative and qualitative considerations should be presented together as part of a balanced expression of risk. An example of this is provided in opinion SCCP05 (although not in its concluding section), where the committee estimate a lifetime cancer risk of above 10^{-5} but conclude that the true risk may be considerably less, due to the conservatism of the exposure estimate, uncertainties in the toxicity data and some toxicokinetic considerations.

- We conclude that, in cases where quantitative measures of risk are an important part of the assessment, it is better to include the quantitative measure in concluding sections and summaries and not replace it with qualitative verbal expressions of risk. However, uncertainties affecting the quantitative expression should always be described, and should be included together with any relevant qualitative considerations as part of a balanced overall characterisation of the risk.

5.5.2 Quantitative estimates from qualitative assessments

Many assessments are based wholly, or almost wholly, on qualitative considerations, without any significant quantitative component. Currently in such cases the conclusions are expressed in purely qualitatitive terms, and are therefore subject to the problems of variable interpretation (Theil 2004) and implied or inferred risk management judgement, as discussed for harmonised terms in section 5.4. Therefore there is a need to look for alternative approaches.

[24] Another research finding is that people frequently make errors if asked to make conditional calculations with percentages, such as “5% of diagnostic tests are positive, and we expect that 3% of the tests yields a false positive, what is the chance that you are positive if you are tested positive?” (Gigerenzer 2002). This problem can be avoided by ensuring that risk estimates address directly the question of interest to decision-makers, and do not require them to make conditional calculations or interpretations.

One possibility might be for scientific committees to summarise the qualitative evidence and leave the interpretation of risk to the decision-maker. However, this would transfer the job of risk assessment to the decision-maker. This breaches the principle of functional separation, and takes the assessment of risk away from the scientific experts who were selected for the purpose and are presumably best qualified to do it.

The alternative is for scientific committees to use their expert judgement to derive quantitative estimates of risk from qualitative evidence. The resulting expressions could take different forms, depending on whether the level of effect of interest to decision makers is known:

- If the effect level of interest is defined, the scientific committee weighs the qualitative evidence and provides a subjective estimate of the probability that this level will be exceeded (e.g. the probability that cancer risk < 10^{-5}).
- If the effect level of interest is undefined, the scientific committee provides a quantitative expression of risk that takes account of uncertainties, e.g. by estimating a range or an upper bound, or by estimating the probabilities of exceeding a number of different effect levels.

Subjective estimates will of course have high uncertainty, so they should always be accompanied by a clear expression of the uncertainties affecting the assessment (see next section).

We realise that many scientists will feel that making subjective estimates of quantitative measures of risk is unscientific, and would prefer to use a qualitative verbal expression. However, we suggest that when using a qualitative expression, they should consider, if they were a decision-maker or a member of the public, what quantitative interpretation would they put on their qualitative expression?[25]

- If they are able to provide a quantitative estimate, then using this for communication would be more transparent and less liable to misinterpretation than using the verbal expression.
- If they find that their quantitative interpretation of the verbal expression differs from what they intended, they should replace their verbal expression with a quantitative one that they feel is appropriate.
- If they feel totally unable to provide a quantitative interpretation of their qualitative estimate, they should consider what is the scientific reason for this. If it is because they feel the scientific evidence is too uncertain to support any quantitative estimate, then they should ensure that their qualitative expression reflects this and consider whether it might be over-interpreted by decision-makers.

As an illustration, suppose that an assessor expressed a cancer risk as “unquantifiable but probably low”. If 10^{-5} was generally regarded as an acceptable cancer risk, a decision-maker might interpret the assessor’s expression as meaning “unquantifiable but probably less than 10^{-5}”. If the assessor is comfortable with that, then using the quantitative version of the expression would be more transparent. If they feel that doing this would over- or underestimate the risk, it would be better to substitute “low” with a different number to

[25] Some will object that since they are not willing to express the risk quantitatively, their qualitative expression should not be interpreted quantitatively. However, it is not possible to prevent others from making a quantitative interpretation, so it is reasonable to consider what it might be. Indeed, it could be regarded as irresponsible not to consider it. The suggestion that decision-makers may make their own quantitative interpretation of qualitative expressions is consistent with the remarks made by Mrs Husu-Kallio, Deputy Director General and former Head of Science at SANCO, quoted earlier in this section: “general terms such as ‘negligible risk’ and ‘low risk’ did not help the decision-making process, making it difficult for the risk manager to estimate the risk”.

avoid misinterpretation of the verbal expression. If the science is too uncertain to support any number, then it is doubtful whether the word "low" is justifiable either, and using it could lead to an inappropriate decision being taken.

We conclude that the problem of variable interpretation applies to all forms of qualitative risk expression. Therefore:

- We recommend that even when an assessment is entirely qualitative, scientists should try to provide a quantitative expression of risk that clearly reflects the degree of uncertainty, e.g. an upper bound or a subjective estimate of the probability of outcomes of interest to the decision-maker. In cases where the science will not support this, they should consider whether it really supports a qualitative expression and ensure the uncertainty is fully understood by decision-makers.

5.6 Expressing uncertainty

In his address to the Inaugural Joint Meeting of the members of the Non-Food Scientific Committees in 2004, the Director General of SANCO said "Even though it is not a subject that lends itself easily to quantification, I would urge you to take account of the risk manager's need to understand the level of uncertainty in your advice and to work towards a systematic approach to this problem" (Madelin 2004). This suggests a preference for quantification, which is perhaps echoed in the subsequent remarks of Mrs Husu-Kallio, but also recognises its difficulty.

In its second report on the harmonisation of risk assessment procedures, the SSC's recommendations included "Agree a format for the presentation of uncertainties in each risk assessment (see chapter 9 of the Second Report)" (SSC 2003, page 93). The relevant section of chapter 9 states "the requested common format for expressing uncertainties under the harmonisation point of view cannot be a set of terms for the range of 'quantitative' uncertainties but should include nomination of the types of uncertainties considered with their weights (where possible also values) and contributions to the final judgement" (SSC 2003, page 77).

We agree with the SSC that a format for identifying the types of uncertainties and evaluating their contribution to the assessment outcome would be highly desirable. We outline below a practical example of such a format, which we believe could be useful for the Community's non-food committees. However, we disagree with the SSC's rejection of "quantitative uncertainties". The SSC's justification for their statement is "the uncertainties in a weight of evidence for a risk to be assessed including all levels of information from hypothesis/theory via different levels of experiments and possibly field observations can not be treated mathematically - e. g. as a 'uncertainty propagation' like error propagation. The results would be of no use – and not reflecting the true total uncertainty" (SSC 2003, page 77). We disagree with two of these assertions. First, it is possible to treat such uncertainties mathematically using Bayesian methods[26]. Second, the results of such analyses are of practical use, as has been demonstrated in various areas of science and risk assessment including the nuclear industry, medicine, veterinary science and meteorology (O'Hagan et al. 2006). We agree that quantitative analysis of uncertainties is

[26] The SSC statement reflects the perspective of classical or frequentist statistics. Both the frequentist and Bayesian schools are long-established and each has an extensive body of theory and practice. The disagreements between them are deep-seated, but this has not prevented successful application of both approaches in various fields of risk assessment.

unlikely to capture the total uncertainty, but we do not agree that this makes quantitative analysis inadmissible; what it does mean is that any quantitative analysis of uncertainty should be accompanied by a qualitative evaluation of the additional uncertainties that are not quantified. This important principle is incorporated in the approach outlined below.

A practical approach to characterising uncertainty in a risk assessment needs to comprise of three basic steps:

1. Identify sources of uncertainty. Systematically examine every part of the assessment, to maximise the chance that all important uncertainties are identified.
2. Evaluate each source of uncertainty. Evaluate each identified source of uncertainty, using appropriate methods, to characterise its potential influence on the assessment outcome.
3. Evaluate the uncertainty of the assessment outcome. Use appropriate methods to evaluate the combined effect of all the identified uncertainties on the overall uncertainty in the assessment outcome.

A variety of methods is available for the evaluations in Steps 2 and 3, ranging from qualitative methods through deterministic calculations to probabilistic modelling. Initially, all uncertainties may be analysed qualitatively. This may be sufficient, if the outcome is clear enough for risk managers to reach a decision. Otherwise, those uncertainties that appear most critical to the outcome may be analysed deterministically (e.g. scenario or sensitivity analysis) or probabilistically (e.g. frequentist or Bayesian approaches). This iterative (or tiered) analysis of the most significant uncertainties progressively refines the characterisation of uncertainty, and provides an increasingly clear picture of the probability that effects will exceed acceptable levels. As it will never be possible to quantify all uncertainties, every assessment should include a qualitative evaluation of the unquantified uncertainties.

An example of this type of approach is described in a recently-published guidance document on uncertainty in exposure assessment (EFSA, 2006). This includes a tabular approach for qualitative assessment of uncertainties. Three types of tables are suggested and illustrated in the document. The first two are for use in the initial identification of uncertainties, and are designed to help the user systematically identify different types of uncertainties in different parts of the assessment. The third table is designed to help users summarise the uncertainties and evaluate them qualitatively. This table has two columns: one column lists the uncertainties, and the second column gives an evaluation of the influence of each uncertainty on the assessment outcome. This is expressed as a qualitative score indicating the direction and magnitude of influence of each uncertainty: +, ++, +++ = uncertainty with potential to cause small, medium or large over-estimation of the exposure or risk considered; -, - -, - - - = uncertainty with potential to cause small, medium or large under-estimation. Thus for a particular source of uncertainty a score of - / ++ would indicate that its effect on the assessment outcome (other things being equal) would be in the range from a small under-estimation to a medium over-estimation. By summarising the uncertainties and their potential effects in this way, the table is intended to assist the user in forming a judgement about their overall combined effect on the assessment outcome: this conclusion may be shown at the foot of the table, or separately in accompanying text. It can also help to identify the most important uncertainties, which may then be subjected to quantitative analysis if required. Although described in the context of exposure assessment, this approach is applicable in principle to any type of risk assessment and appears to be practical for use by scientific committees.

- We recommend that consideration is given to adopting a systematic tabular approach for summarising and characterising uncertainties. This would be practical for expert committees to use and help them to evaluate the combined impact of multiple sources of uncertainty.

The tabular approach described by EFSA (2006) results in a qualitative expression of uncertainty, describing in words how conservative the exposure or risk assessment is. It could be useful when forming subjective quantitative expressions of uncertainty. For example, instead of expressing verbally how conservative an exposure estimate is, a tabular summary of uncertainties could be used to make a subjective estimate of the probability that the true exposure exceeds the estimate of exposure.

For an example from the reviewed opinions, consider SCCP05 where the committee calculates that the systemic exposure dose is 4 times the dose corresponding to a lifetime cancer risk of 10^{-5} but conclude that the true risk may be considerably less than anticipated from this calculation, due to the conservatism of the exposure estimate, uncertainties in the toxicity data and some toxicokinetic considerations. The phrase "may be considerably less" expresses a possibility that the true cancer risk is "considerably below" the level implied by the calculation but does not give any clear idea of the probability that it is below 10^{-5}, which may be what matters to decision-makers. A subjective estimate of this probability could be made by considering the committee's calculation together with the uncertainties they identified. A tabular approach might be helpful for weighing up the various uncertainties when developing such an estimate (e.g. "there is an X% chance that the true cancer risk is less than 10^{-5}"), and for communicating the basis of the conclusion. Of course it would be important to state clearly that the estimate was subjective. More formal methods for eliciting subjective judgements from experts exist (e.g. O'Hagan et al. 2006), and could also be considered.

As in the preceding section, we recognise that many assessors will feel that making subjective estimates of probabilities is unscientific, and would prefer to use a qualitative verbal expression. Nevertheless, the example above suggests that it may be possible to derive subjective quantitative estimates, which might be more useful to decision-makers. Furthermore, the way uncertainty has been accounted for should be more transparent than when the assessor provides an ambiguous verbal expression that is then interpreted by the decision-maker. However, given the novelty of the approach and the likely scepticism of assessors, it would be prudent to proceed cautiously. Therefore,

- We recommend that consideration be given to exploring whether scientific committees could make more use of quantitative expressions of uncertainty, including subjective probabilities, and whether this would be useful to decision-makers. One option for doing this would be to carry out some case studies with representative scientists and decision-makers, with assistance from experts in this type of analysis.

5.7 Risk assessment policy

We understand that it is the intent of the Commission that its scientific committees should restrict themselves to scientific considerations and should not make risk management judgements (e.g. Madelin 2004[27]). As noted at several points in this document, verbal

[27] "functional separation of administrative responsibility for risk assessment and risk management…is explicitly built in to the decisions setting up your committees… I would…ask you to be careful to ensure that your opinions do not go beyond the realms of objective scientific advice" (Madelin, 2004).

expressions of risk and uncertainty frequently imply – or could be interpreted as implying – a risk management judgement about what level of risk is acceptable, and what degree of certainty is required.

One way to maintain the functional separation desired by the Commission is to use quantitative rather than qualitative expressions, as suggested in preceding sections. However, some of the questions posed to the committees require a risk management judgement. The most obvious example of this are questions to SCCP which often take the form “Does the SCCP consider X safe for use” by consumers and “does the SCCP recommend any further restrictions on the use of X?”. These questions appear to conflict with the functional separation of risk assessment and risk management. This could be avoided by rewording the questions so that they ask for assessment of risk. Alternatively, it could be avoided by adopting the concept of “risk assessment policy” as discussed in section 4.4.6.

Risk assessment policy is defined for use in the area of food safety as “Documented guidelines on the choice of options and associated judgements for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained” (Codex 2007). The basic principle is that if criteria for a specific type of risk management decision (e.g. safety of cosmetics) can be defined in purely scientific terms, then the decision can be determined by purely scientific considerations without involving a new risk management judgement. This might be efficient if it avoided the need for risk managers to be consulted on routine cases. However, it requires that:

- the risk assessment policy “should be established by risk managers … in consultation with risk assessors and all other interested parties” (Codex, 2007),
- the scientific criteria for decisions must be defined very precisely and based on data from studies following standard guidelines, so that the user is not required to make judgements about whether the level of certainty is sufficient,
- there should be no scope for flexibility: cases that do not pass the standard criteria should be subjected to a full risk assessment leading to an expression of risk and uncertainty, so that the decision on safety or acceptability can be left to risk managers.

- If committees are to be asked questions that imply a risk management judgement (e.g. is the use of X safe for consumers), precise and purely scientific criteria for the decisions should be established in such a way that committees can give an answer without making a risk management judgement.

6. CONCLUSIONS AND RECOMMENDATIONS

Here we list all the conclusions and recommendations developed in the course of this review, grouped according to topic.

6.1 General

1. Consideration should be given to including a summary as a standard component of scientific committee opinions. (Section 4.9.2).
2. When an expression of risk refers to a particular population and/or time period, it is important to ensure that these are identified and understood by the reader. (Section 4.5).
3. Sub-populations at increased risk should be identified clearly, so that risk reduction or advisory information can be targeted appropriately. (Section 4.11).
4. Expressions of risk should be accompanied by information on how conservative they are, i.e. whether they are considered to over- or underestimate the true values, and to what degree. (Section 4.5).

6.2 Qualitative expressions of risk

5. Phrases describing hazard and risk should be carefully constructed so as to distinguish appropriately between the potential for effects (hazard) and the risk or prevalence of those effects actually occurring (e.g. can cause cancer vs. causes cancer). (Section 4.2).
6. Qualitative expressions provide only a relative indication of the level of risk, unless their relation to a quantitative measure of risk is defined, and they are liable to variable interpretation by different people. (Section 4.4.1).
7. The same qualitative term might be interpreted differently for different types of effect, or for effects on different populations or systems. (Section 4.4.2).
8. Some qualitative terms used to express risk (e.g. risk, concern) do not distinguish between probability and magnitude. (Section 4.4.5).
9. Relative terms, especially strong ones such as “absolutely negligible”, “massive” and “extreme”, tend to imply a sense of the importance of the risk being described, and hence of the need for action and its urgency. (Section 4.4.3).
10. Consideration should be given to whether terms such as “safe”, which may be interpreted by the public as implying no risk, are suitably transparent or require qualification, given the recognition by scientists and risk managers that there is “no such thing as zero risk”. (Section 4.4.8).
11. We recommend that, in guidance documents where a standardised or harmonised risk term is used, a complete definition of the term that lists all relevant criteria in one place should be provided. If a glossary is provided, it should include all standardised risk terms used in the document. (Section 4.4.6).
12. When a standardised risk term that is defined by multiple scientific criteria is used in the concluding section of an opinion, it would aid transparency if it were accompanied by a phrase indicating which of the criteria applies in that case (e.g. there is concern because…). (Section 4.4.6).

13. Confusion could arise if the same term has different formal definitions in different areas of risk assessment, or if a term given a formal definition in one area is used informally with its common language meaning in another area. (Section 4.4.6).

6.3 Quantitative expressions of risk

14. Where a quantitative measure of risk is an important part of the assessment, presenting it in the concluding section of the opinion is less ambiguous than converting it to a qualitative expression, and avoids introducing additional uncertainty when communicating the risk. It also avoids the possibility of a value judgement being implied or inferred through the use of qualitative terms such as low, high etc. (Section 4.5).
15. It is essential to communicate clearly the degree of uncertainty associated with quantitative estimates, to avoid creating a false sense of precision. (Section 4.5).
16. When a quantitative estimate is only one part of the overall characterisation of a risk, it is important to present it together with the other considerations in a balanced way. (Section 4.5).

6.4 Uncertainty

17. The concluding sections of the opinions we reviewed contained a huge variety of phrases that express uncertainty, or could be interpreted as doing so. (Section 4.7.2).
18. All of the phrases we identified as expressing uncertainty were ambiguous about the degree of uncertainty. Many, such as “may”, express the presence of uncertainty but convey no information at all about the degree of uncertainty. This makes it very difficult to interpret the degree of uncertainty that opinion authors intended to communicate, and presents a serious problem for risk managers, who need to understand the degree of uncertainty so that they can take account of it in decision-making. (Section 4.7.2).
19. It is important to communicate any limitations on the scope of the assessment or on the factors considered, and to take account of these in the overall evaluation of uncertainties affecting the assessment. (Section 4.7.1).
20. It is important to express any important assumptions, and to take account of their effect in the overall evaluation of uncertainties affecting the assessment. (Section 4.7.1).
21. We suggest that to clearly identify phrases that are intended to express uncertainties they should all contain the word “uncertainty” (or a close variant like “uncertain” or “not certain”), or they should be presented in a separate section of text with the word “uncertainty” in the section title. (Section 4.7.2).
22. Qualitative expressions of uncertainty communicate that the true outcome or risk may be different from the estimate, but not by how much or with what likelihood, which is what the risk manager really needs to know. (Section 4.7.2).
23. Ranges or bounds (including worst case assessments) and scenario or sensitivity analysis (“what if” calculations) are a simple way of providing useful information about the uncertainty of a quantitative measure of risk, including the range of possible values and some indication of their relative likelihood. (Section 4.7.3).
24. Questions outside the expertise of a committee should be declined. In all other cases an opinion should be given, even if it is very uncertain, but the uncertainty should be clearly expressed. If the uncertainty on a question is so great that the experts consider the risk to be unknown, this should be clearly stated and the nature and magnitude of the uncertainties explained. (Section 4.7.1).

6.5 Statistical significance

25. When making statements about statistical significance, it is essential to state the significance or probability level that was used. (Section 4.7.3).
26. Consideration should be given to the general issue of whether the statistical significance levels commonly used in the biological sciences provide appropriate levels of certainty for environmental and human health risks, and whether different levels of certainty might be required for different risks. This is ultimately a risk management question, but also requires analysis of the way different uncertainties combine. (Section 4.7.3).

6.6 Missing information

27. When data required by regulations or other policy as being necessary for risk assessment are lacking, this should be stated explicitly. If literally nothing is known about the risk, this should also be stated explicitly. In all other cases, scientists should use whatever information is available to assess the risk (even when it is very uncertain), express the impact of data limitations by expressing the degree of uncertainty, and identify which types of additional information would contribute most to reducing the uncertainty. (Section 4.8).

6.7 Functional separation of risk assessment and risk management

28. Care is needed to ensure that questions put to and accepted by committees whose remit is purely scientific do not imply a need for risk management judgements. (Section 4.10).
29. If a term describing risk has been defined previously, in purely scientific terms, then its use in a risk assessment can be determined by purely scientific considerations even if the term also has a risk management meaning. (Section 4.4.6).
30. In practice, it is difficult to define a term describing risk in purely scientific terms such that it can be used without requiring any element of risk management judgement. (Section 4.4.6).
31. Committees whose remit and expertise is purely scientific may assess the risk for alternative risk management options but should not express a preference between them, unless purely scientific criteria for this have been established in consultation with risk managers. (Section 4.9.1).
32. Recommendations for actions, such as risk reduction or data collection, imply risk management judgements. This can be avoided by limiting opinions to a scientific assessment of the consequences of different options for action, e.g. by assessing the change in risk that could be achieved by different risk reduction measures, and the relative contribution that different types of data collection could make to reducing uncertainty. (Section 4.10).
33. If committees is to be asked questions that imply a risk management judgement (e.g. is the use of X safe for consumers), precise and purely scientific criteria for the decisions should be established in such a way that committees can give an answer without making a risk management judgement. (Section 5.7).

6.8 Definition of risk

34. We propose that the definition of risk should include both probability and the degree of effect, including its severity, but in a way that keeps them distinct and gives risk a single dimension. This could be achieved by adopting a modified version of either the SSC or IPCS definition, e.g. "*the probability of a specified type and degree of adverse effect /event occurring to man or the environment following exposure, under defined conditions, to a risk source(s)*", or "*the probability of a specified type and degree of adverse effect in an organism, system or (sub)population caused under specified circumstances by exposure to an agent*". (Section 5.1).

6.9 Recommendations for improving the expression of risk and uncertainty

35. If harmonised terms are established for expressing risk, then the definitions of those terms should be quantitative, in order to ensure that they can be used in a consistent way by different assessors and interpreted correctly by decision-makers. (Section 5.3)

36. We conclude that, although attractive in theory, defining harmonised verbal terms to express risk would not improve risk communication. Different definitions would be required for different areas of risk. If the definitions were quantitative, then expressing the risk quantitatively would be more transparent and less liable to misinterpretation than using the verbal expressions. If the definitions were qualitative, variable interpretation by different people would cause inconsistencies in both the expression and understanding of risks, which would impair decision-making. Furthermore, it would be difficult to define qualitative terms in such a way that they could be used by assessors without making or implying risk management judgements. (Section 5.4).

37. We conclude that, in cases where quantitative measures of risk are an important part of the assessment, it is better to include the quantitative measure in concluding sections and summaries and not replace it with qualitative verbal expressions of risk. However, uncertainties affecting the quantitative expression should always be described, and should be included together with any relevant qualitative considerations as part of a balanced overall characterisation of the risk. (Section 5.5.1).

38. We recommend that even when an assessment is entirely qualitative, scientists should try to provide a quantitative expression of risk that clearly reflects the degree of uncertainty, e.g. an upper bound or a subjective estimate of the probability of outcomes of interest to the decision-maker. In cases where the science will not support this, they should consider whether it really supports a qualitative expression and ensure the uncertainty is fully understood by decision-makers. (Section 5.5.2).

39. We recommend that consideration is given to adopting a systematic tabular approach for summarising and characterising uncertainties. This would be practical for expert committees to use and help them to evaluate the combined impact of multiple sources of uncertainty. (Section 5.6).

40. We recommend that consideration be given to exploring whether scientific committees could make more use of quantitative expressions of uncertainty, including subjective probabilities, and whether this would be useful to decision-makers. One option for doing this would be to carry out some case studies with representative scientists and decision-makers, with assistance from experts in this type of analysis. (Section 5.6).

6.10 Consultation with other relevant parties

41. Finally, we recommend that it will be relevant to consult other relevant parties when considering whether and how to implement the findings of this review.
42. Before implementing new approaches to the expression of risk and uncertainty, consideration should be given to seeking the views of risk assessors (including the members of scientific committees), risk managers, risk communication experts and press officers, and representative stakeholders including the general public.

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8. APPENDIX 1 – LIST OF OPINIONS EXAMINED IN THIS PROJECT

Identifier	Year	Title	Pages
CSTEE01	1998	Opinion On Phthalate Migration From Soft PVC Toys And Child-care Articles – Data Made Available Since The 16th Of June 1998	3
CSTEE02	1998	Opinion On Phthalate Migration From Soft PVC Toys And Child-care Articles (to Answer Four New Questions Put To The Scientific Committee On Toxicity, Ecotoxicity And The Environment (CSTEE) On The Subject)	1
CSTEE03	1998	Phthalate Migration From Soft PVC Toys And Child-care Articles	32
CSTEE04	1999	CSTEE Opinion On Human And Wildlife Health Effects Of Endocrine Disrupting Chemicals, With Emphasis On Wildlife And On Ecotoxicology Test Methods	96
CSTEE05	1999	Opinion (revised) On Cancer Risk To Consumers From Creosote Containing Less Than 50 ppm Benzo-[a]-pyrene And/or From Wood Treated With Such Creosote And Estimation Of Respective Magnitude	7
CSTEE06	1999	Opinion On Risk Of Cancer Caused By Textiles And Leather Goods Coloured With Azo-dyes	2
CSTEE07	2000	Opinion Of The Scientific Committee On Toxicity, Ecotoxicity And The Environment (CSTEE) On The Results Of The Environmental Risk Assessment Of Nonylphenol, Straight Chain [CAS N°8 4852-15-3] And Branched Cha In [CAS N°25154-52-3]	2
CSTEE08	2000	Opinion On Lead – Danish Notification 98/595/DK	31
CSTEE09	2000	Opinion On The Results Of The Environmental Risk Assessment Of : Decabromodiphenyl Ether	3
CSTEE10	2001	Opinion On: Report (final Draft) On Assessment Of The Risks To Human Health Posed By Azo Colorants In Toys, Writing Inks And Paper Products, And Analysis Of The Advantages And Drawbacks Of Restrictions On Their Marketing And Use.	3
CSTEE11	2001	Position Paper On Margins Of Safety (MOS) In Human Health Risk Assessment	4
CSTEE12	2002	Opinion Of The Cstee On “Effects Of Electromagnetic Fields On Health” Reply To Question B	4
CSTEE13	2002	Opinion On ‘Member State Assessments Of The Risk To Health And The Environment From Cadmium In Fertilizers’	9
CSTEE14	2002	Opinion On Risk To Human Health From Chrysotile Asbestos And Organic Substitutes	21
CSTEE15	2002	Opinion On The Results Of The Risk Assessment Of: Bis(pentabromophenyl)ether Environmental And Human Health Part	5
CSTEE16	2002	Opinion On The Results Of The Risk Assessment Of: Bis(pentabromophenyl)ether Human Health Part	4
CSTEE17	2002	Opinion On The Results Of The Risk Assessment Of: Bisphenol A Human Health Part	7
CSTEE18	2003	“Two Study Reports On Endocrine Disrupters By WRC-NSF And BKH Consulting Engineers”	20
CSTEE19	2003	Opinion On The Non-food Aspects Of “assessment Of The Risks To Health And The Environment Posed By The Use Of Organostannic Compounds (excluding Use As A Biocide In Antifouling Paints) And A Description Of The Economic Profile Of The Industry.”	14
CSTEE20	2003	The Environmental Impact (reduction In Eutrophication) That Would Result From Banning Sodium Tripolyphosphate (STPP) In Household Detergents	15
CSTEE21	2003	The LGC’S Report On “Risks Of Sensitisation Of Humans To Nickel By Piercing Post Assemblies” Final Report 31 March 2003 - Contract No. EDT/fif.2001592	7
CSTEE22	2004	Assessment Of The Bioavailability Of Certain Elements In Toys	5
CSTEE23	2004	Opinion On The Results Of A Second Risk Assessment Of: Bis(2-ethylhexyl) Phthalate [DEHP] Human Health Part	6
CSTEE24	2004	Opinion On The Results Of The Risk Assessment Of: Cadmium Metal Human Health	15
SCCNFP01	1999	Clarification Of The Opinion Concerning Hydrogen (carbamide) Peroxide In Tooth Whitening Products	2

SCCNFP02	1999	Opinion Concerning Hydrogen Peroxide And Hydrogen Peroxide Releasing Substances Used In Oral Care Products	2
SCCNFP03	1999	Opinion Concerning Ketoconazole Adopted By The Scientific Committee On Cosmetic Products And Non-food Products Intended For Consumers	2
SCCNFP04	1999	Opinion Of Concerning Hydrogen (carbamide) Peroxide In Tooth Whitening Products	2
SCCNFP05	2000	Opinion Concerning Methyleugenol	2
SCCNFP06	2001	Opinion Concerning Dialkyl- And Dialkanolamines And Their Salts In Cosmetic Products	5
SCCNFP07	2002	Opinion Of The Scientific Committee On Cosmetic Products And Non-food Products Intended For Consumers Concerning Hexahydro-hexamethyl-cyclopenta (γ)-2-benzopyran (HHCB)	8
SCCNFP08	2002	Opinion Of The Scientific Committee On Cosmetic Products And Non-food Products Intended For Consumers Concerning Hydrogen (carbamide, Zinc) Peroxide In Tooth Bleaching / Whitening Products	42
SCCNFP09	2002	Opinion Of The Scientific Committee On Cosmetic Products And Non-food Products Intended For Consumers Concerning Lawsone	23
SCCNFP10	2002	Opinion Of The Scientific Committee On Cosmetic Products And Non-food Products Intended For Consumers Concerning Lawsonia Inermis, Henna	16
SCCNFP11	2002	Opinion Of The Scientific Committee On Cosmetic Products And Non-food Products Intended For Consumers Concerning Salicylic Acid	36
SCCNFP12	2003	Opinion Concerning Inorganic Sulfites And Bisulfites	18
SCCNFP13	2003	Opinion Of The Scientific Committee On Cosmetic Products And Non-food Products Intended For Consumers Concerning Wood Tars And Wood Tar Preparations	12
SCCNFP14	2004	Opinion Concerning 4-methylbenzylidene Camphor	25
SCCNFP15	2004	Opinion Concerning Methyldibromo Glutaronitrile	5
SCCNFP16	2004	Opinion Concerning Use Of Permanent Hair Dyes And Bladder Cancer Updated 2004	12
SCCNFP17	2004	Opinion Of The Scientific Committee On Cosmetic Products And Non-food Products Intended For Consumers Concerning Acetaldehyde	17
SCCNFP18	2004	Opinion Of The Scientific Committee On Cosmetic Products And Non-food Products Intended For Consumers Concerning Curry Red	21
SCCNFP19	2004	Opinion Of The Scientific Committee On Cosmetic Products And Non-food Products Intended For Consumers Concerning Furfural	13
SCCNFP20	2004	Opinion Of The Scientific Committee On Cosmetic Products And Non-food Products Intended For Consumers Concerning Musk Xylene And Musk Ketone	22
SCCP01	2004	Opinion On Atranol And Chloroatranol Present In Natural Extracts (e.g. Oak Moss And Tree Moss Extract)	11
SCCP02	2005	Extended Opinion On The Safety Evaluation Of Parabens	11
SCCP03	2005	Opinion On Benzoic Acid And Sodium Benzoate	30
SCCP04	2005	Opinion on Furocoumarins in cosmetic products	9
SCCP05	2005	Opinion On Glyoxal	67
SCCP06	2005	Opinion On Hydrogen Peroxide In Tooth Whitening Products	50
SCCP07	2005	Opinion On Lawsonia Inermis (henna)	27
SCCP08	2005	Opinion On Methyldibromo Glutaronitrile (Sensitisation Only)	13
SCCP09	2005	Opinion On Octamethylcyclotetrasiloxane (D4)	69
SCCP10	2005	Opinion On Parabens, Underarm Cosmetics And Breast Cancer	8
SCCP11	2005	Opinion On Personal Use Of Hair Dyes And Cancer Risk	13
SCCP12	2005	Opinion On Tagetes erecta, T. minuta And T. patula Extracts And Oils (Phototoxicity Only)	20
SCCP13	2005	Opinion On The Safety Of Fluorine Compounds In Oral Hygiene Products For Children Under The Age Of 6 Years	12
SCCP14	2006	Draft Opinion On 4-methylbenzylidene Camphor	26
SCCP15	2006	Draft Opinion On P-phenylenediamine	62
SCCP16	2006	Opinion On 2,4-diaminophenoxyethanol And Its Salts	27
SCCP17	2006	Opinion On Biological Effects Of Ultraviolet Radiation Relevant To Health With Particular Reference To Sunbeds For Cosmetic Purposes	42
SCCP18	2006	Opinion On Camphor Benzalkonium Methosulfate	24
SCCP19	2006	Opinion On Hydroxybenzomorpholine	30
SCCP20	2006	Opinion On Methyldibromoglutaronitrile (Sensitisation Only)	11

SCCP21	2006	Opinion On N,n-bis(2-hydroxyethyl)-p-phenylenediamine Sulfate	34
SCENIHR01	2005	Updated Opinion On “the Safety Of Human Blood And Organs With Regard To West Nile Virus”	10
SCENIHR02	2006	Chinese Report On Possible Residual Bse Risks In Products Derived From Ruminant Materials And Used As Cosmetics Ingredients	10
SCENIHR03	2006	Modified Opinion (after Public Consultation) On The Appropriateness Of Existing Methodologies To Assess The Potential Risks Associated With Engineered And Adventitious Products Of Nanotechnologies	79
SCENIHR04	2006	Preliminary Opinion On Possible Effects Of Electromagnetic Fields (EMF) On Human Health	58
SCENIHR05	2006	The Safety Of Human-derived Products With Regard To Variant Creutzfeldt-jakob Disease	81
SCHER01	2005	Opinion On “Risk Assessment Report On Furfural Human Health Part”	4
SCHER02	2005	Opinion On “Update Of The Risk Assessment Of Bis(pentabromophenyl) Ether (decabromodiphenyl Ether)” Final Environmental Draft Of May 2004	6
SCHER03	2005	Opinion On “Compatibility Of The Iso Standard 10708 (biodegradability Test Method) With The Ultimate Biodegradability Requirements Imposed Through Annex III Of Regulation 648/2004 Of Parliament And Of The Council”	7
SCHER04	2005	Opinion On “effectiveness Of Vapour Retardants In Reducing Risks To Human Health From Paint Strippers Containing Dichloromethane” ETVREAD Final Report 01 April 2004	11
SCHER05	2005	Opinion On “Environmental Risk Assessment Of Non Biodegradable Detergent Surfactants Under Anaerobic Condition”	15
SCHER06	2005	Opinion On “New Evidence Of Air Pollution Effects On Human Health And The Environment”	15
SCHER07	2005	Opinion On “Risk Assessment Report On Benzyl Butyl Phthalate (BBP) Human Health Part”	5
SCHER08	2005	Opinion On “Risk Assessment Report On Phenol Human Health Part”	7
SCHER09	2005	Opinion On “Risk Assessment Report On Propan-1-ol Environmental Part”	5
SCHER10	2005	Opinion On “Risk Assessment Report On Tetrabromopbisphenol-a Human Health Part”	4
SCHER11	2005	Opinion On “RPA´s Report “Perfluorooctane Sulphonates Risk Reduction Strategy And Analysis Of Advantages And Drawbacks”	16
SCHER12	2005	Opinion On Risk Assessment Report On 2-methoxy-2-methylbutane (TAME: Tert-amyl-methyl Ether) Environmental Part	6
SCHER13	2006	Opinion On “Risk To The Environment And Human Health Resulting From The Use Of Phosphate Fertilizers Containing Cadmium” Report 285 - Czech Republic -november 2005	7
SCHER14	2006	Opinion On Classification Of Musk Ketone	6
SCHER15	2006	Opinion On Risk Assessment Report On Benzyl Butyl Phthalate Environmental Part	6
SCHER16	2006	Opinion On Risk Assessment Report On Tris (2-chloroethyl) Phosphate (TCEP) Environmental Part	5
SCHER17	2006	Opinion On The Report “emission Of Chemicals By Air Fresheners Tests On 74 Consumer Products Sold In Europe” (BEUC Report January 2005) Adopted By The SCHER During The 9th Plenary Of 27 January 2006	19
SCHER18	2006	Revised Assessment Of The Risks To Health And The Environment Associated With The Use Of The Four Organotin Compounds TBT, DBT, DOT and TPT	27
SCHER19	2006	Targeted Risk Assessment Report On Sodium Hydroxide (NaOH) Human Health Part	6
SCMPMD01	1998	Opinion On The Risk Quantification For CJD Transmission Via Substances Of Human Origin	46
SCMPMD02	1998	Opinion On Toxicological Data On Colouring Agents For Medicinal Products: Erythrosin	6
SCMPMD03		(This reference number not used)	
SCMPMD04	1999	Opinion On The Safety Of Boric Acid In Medicinal Products Adopted On 10 February 1999	2
SCMPMD05	2000	Opinion On Natural Rubber Latex Allergy	35
SCMPMD06	2000	Opinion On Toxicological Data On Colouring Agents For Medicinal Products: E 174 Silver	13

SCMPMD07	2000	Update Of The Opinion Given By The Scientific Committee On Medicinal Products And Medical Devices On The Risk Quantification For CJD Transmission Via Substances Of Human Origin	10
SCMPMD08	2001	Opinion On The State Of The Art Concerning Tissue Engineering	16
SCMPMD09	2001	Opinion On The State Of The Art Concerning Xenotransplantation	20
SCMPMD10	2002	Opinion On Medical Devices Containing DEHP Plasticised PVC; Neonates And Other Groups Possibly At Risk From DEHP Toxicity	34
SCMPMD11	2002	Opinion On The Safety Of Human-derived Products With Regard To TSE's	43
SCMPMD12	2003	The Impact Of Arthropod Borne Diseases (including WNV) On The Safety Of Blood Used For Transfusion As Well As Organs Used For Transplantation In The European Community	25

9. APPENDIX 2 – EXTRACTS FROM THE SSC GLOSSARY OF TERMS

This section quotes extracts from the Glossary of terms contained in Appendix 1 of the First Report on the Harmonisation of Risk Assessment procedures (SSC 2000).

Extracts from preamble by SSC:

"The Working Party identified a few key terms for which agreed definitions are provided in the following list, in bold italics. They are not listed alphabetically, but arranged in functional groups."

"A critical review has been conducted and published (P. Lewalle. Risk Assessment Terminology. Methodological considerations and provisional results. Report on a WHO experiment. Terminology Standardization and Harmonization, Volume II (1999), n°1- 4). This publication gives a snapshot picture of the terminology understanding that emerged from the survey. It is provisional in the sense that the corresponding definitions have not yet been subjected to an agreement. Nevertheless, the Working Party considered it useful to mention, for the key terms they have selected and where available, the outcome of this survey. In the text below, the survey definitions are presented as indents, between square brackets."

"The list and the definitions suggested should not be considered a definitive work. Rather, it is expected that it would provide to the EU Scientific Committees an opportunity to review the terms they currently use, clarify their definitions and, where appropriate, suggest the amendments necessary to ensure a greater compatibility of their nomenclatures."

KEY TERMS (reproduced from SSC glossary):

HAZARD
- *The potential of a risk source to cause an adverse effect (s)/event(s).*
[Inherent property of an agent or situation capable of having adverse effects on something. Hence, the substance, agent, source of energy or situation having that property]

RISK
- *The probability and severity of an adverse effect /event occurring to man or the environment following exposure, under defined conditions, to a risk source(s).*
[The probability of adverse effects caused under specified circumstances by an agent in an organism, a population or an ecological system]

RISK SOURCE
- *Agent, medium, commercial/industrial process, procedure or site with the potential to cause an adverse effect(s)/event(s)*

RISK ANALYSIS
- *A process consisting of three components: risk assessment, risk management and risk communication.*
[A process for controlling situations where populations or ecological systems could be exposed to a hazard. It usually comprises three steps, namely risk assessment, risk management and risk communication]

RISK ASSESSMENT

- A process of evaluation including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect (s) /event(s) occurring to man or the environment following exposure under defined conditions to a risk source(s). A risk assessment comprises hazard identification, hazard characterisation, exposure assessment and risk characterisation.

[A process intended to calculate or estimate the risk for a given target system following exposure to a particular substance, taking into account the inherent characteristics of a substance of concern as well as the characteristics of the specific target system. The process includes four steps: hazard identification, dose-response assessment, exposure assessment, risk characterisation]

HAZARD IDENTIFICATION

- The identification of a risk source(s) capable of causing adverse effect(s)/event(s) to humans or the environment species, together with a qualitative description of the nature of these effect(s)/event(s).

[The first stage of risk assessment consisting in the determination of particular hazards a given target system may be exposed to, including attendant toxicity data. (Depending on the context, another definition emerged: the determination of substances of concern, the adverse effects they may inherently have on target systems under certain conditions of exposure, taking into account toxicity data)]

HAZARD CHARACTERISATION

- The quantitative or semi-quantitative evaluation of the nature of the adverse health effects to humans and/or the environment following exposure to a risk source(s). This must, where possible, include a dose response assessment.

[The qualitative and, whenever possible, quantitative description of the nature of the hazard (alternative: of the nature of the possible adverse effects) associated with a biological, chemical or physical agent, based on one or more elements, such as mechanisms of action involved, biological extrapolations, dose-response and dose-effect relationships, and their respective attendant uncertainties]

DOSE-RESPONSE ASSESSMENT

- The determination of the relationship between the magnitude of exposure to risk source(s) [dose] and the magnitude or frequency and/or severity of associated adverse effect(s) [responses].

[The analysis of the relationship between the total amount of an agent absorbed by a group of organisms and the changes developed in it in reaction to the agent, and inferences derived from such an analysis with respect to the entire population]

EXPOSURE ASSESSMENT

- The quantitative or semi-quantitative evaluation of the likely exposure of man and/or the environment to risk sources from one or more media.

[The quantitative and qualitative analysis of the presence of an agent (including its derivative) which may be present in a given environment and the inference of the possible consequences it may have for a given population of particular concern]

RISK CHARACTERISATION

- The quantitative or semi-quantitative estimate, including attendant uncertainties, of the probability of occurrence and severity of adverse effect(s)/event(s) in a given population under defined exposure conditions based on hazard identification, hazard characterization and exposure assessment.

[Integration of evidence, reasoning and conclusions collected in hazard identification, dose response assessment and exposure assessment and the estimation of the probability, including attendant uncertainties, of occurrence of an adverse effect if an agent is administered, taken or absorbed by a particular organism or population.

Or

The qualitative and/or quantitative estimation, including attendant uncertainties, of the severity and probability of occurrence of known and potential adverse effects of a substance in a given population]

RISK MANAGEMENT

- The process of weighing policy alternatives in the light of the result of a risk assessment and other relevant evaluation and, if required, selecting and implementing appropriate control options (which should, where appropriate, include monitoring / surveillance).

[Decision-making process involving consideration of political, social, economic, and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyse, and compare regulatory and non-regulatory options and to select and implement the optimal decisions and actions for safety from that hazard]

(N.B. *Codex Alimentarius Commission*, ALINORM 99/37 (report of the 23rd session of the CAC): the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other relevant factors relevant for the health protection of consumers and for the promotion of fair practices, and, if needed, selecting appropriate prevention and control options)

RISK COMMUNICATION

- The interactive exchange of information and science based opinions concerning risk among risk assessors, risk managers, consumers and other actual or potential stakeholders.

[Interactive exchange of information about risks among risk assessors, managers, news media, interested groups and the general public]

(N.B. *Codex Alimentarius Commission*, ALINORM 99/37 (report of the 23rd session of the CAC): the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions).

NOTE: the SSC glossary also contains a list of additional terms used in their report, with definitions taken from other publications.