EVALUATION AND FITNESS CHECK (FC) ROADMAP			
TITLE OF THE EVALUATION/FC	Second intermediate evaluation of the functioning of the SANTE non-food Scientific Committees (SCs)		
LEAD DG – RESPONSIBLE UNIT	DG SANTE C2	**DATE OF THIS ROADMAP**	11/2015
TYPE OF EVALUATION	Evaluation Interim Mixed	**PLANNED START DATE** **PLANNED COMPLETION DATE**	06/05/2015 05/04/2016
		PLANNING CALENDAR	http://ec.europa.eu/smart-regulation/evaluation/index_en.htm
This indicative roadmap is provided for information purposes only and is subject to change.			

A. Purpose

(A.1) Purpose

The objective of this evaluation is to assess the functioning of the SANTE non-food Scientific Committees (SC). To this end it will assess the relevance, the effectiveness and efficiency of its procedures as well as the coherence with other scientific bodies within and outside the EU. The results will inform the Commission about existing shortcomings of the system in place, also in view of its scope and long term sustainability.
On the basis of experience with the current system modifications in the current structure and working procedures of the SCs have already been introduced in a new Decision 2015/5383/EC establishing the Scientific Risk Assessment Advisory Structure adopted by the Commission on 7 August 2015. However, in order to have a sound evidence base for any changes in the system and to guide the Commission Services in establishing the rules of procedure of the Scientific Committees for the term 2016-2021 this formal evaluation is now undertaken according to the 5 evaluation criteria of relevance, effectiveness, efficiency, EU added value and coherence.

(A.2) Justification

The SCs that are established to provide the Commission with an independent scientific advice and risk assessment in relation to public health, consumer safety, and environmental risks are set up on the basis of Commission Decisions with a mandate that is limited in time and scope. The members of the Scientific Committees are appointed for a term of three years. The current term ends in April 2016 therefore it is timely to assess the functioning of the Scientific Committees in view of the renewal of its mandate.

B. Content and subject of the evaluation

(B.1) Subject area

The mission of the Scientific Committees is to provide the Commission, when preparing its policy and proposals, with scientific advice and risk assessment in the areas of public health, consumer safety, and environmental risks.
The SCs date back from 1960s when the cosmetic regulation[1] was adopted and they were established as an integral part of the European Commission. In 1997 the system of scientific advice within the European Commission was restructured following the BSE crisis. At this time the scientific advice on food was separated through the creation of the European Food Safety Authority (EFSA) while leaving the non-food scientific Committees within the responsibility of SANTE.

Even though the management of the SCs remains with the European Commission services also the structure of the SCs is based on the principles of separation between risk assessment and risk management as well as independence, excellence and transparency

Three independent Scientific Committees are established via Decision 2008/721/EC: The Scientific Committee on Consumer Safety (SCCS), The Scientific Committee on Health and Environmental Risks (SCHER) and The Scientific Committee on Emerging or Newly Identified Health Risks (SCENIHR).

[1] EU Regulation 1223/2009 - OJ L 342, 22.12.2009, p.59

Mandatory consultation of a scientific committee at EU level is foreseen by Cosmetics Directives[2], Toys Directive[3], and General Product Safety Directive[4].

Committees are always consulted on the basis of mandates provided by European Commission services, such as SANTE, GROW, JUST, ENV, ENER, RTD, JRC.

Each SC consists of a maximum of 15 members. The members of the SCs are appointed for a term of three years. Each Scientific Committee elects a Chair and two Vice-Chairs from among their members. Each Scientific Committee adopts scientific opinions by a majority of their members. Their members are from academia, research or other scientific bodies, appointed by the Commission in their own personal capacity, following open call. The criteria include excellence, independence, and as far as possible, geographical and gender balance. Based on transparency principle; all information is public available on SC website (http://ec.europa.eu/health/scientific_committees/index_en.htm): list of members and their CVs and declarations, mandates, minutes, opinions, calls for information, for expression of interest for experts, and public consultations.

The scientific opinions produced by the SCs are used for:

Policy and legislation
- Adoption of new or adapting existing legislation (e.g. cosmetics, toys, fertilizers, EMF)
- Policy options (e.g. Commission recommendation on nano-definition)
- Setting standards (e.g. water framework directive)

Presentation/discussion of opinions and possible follow-up
- Member States' committees (e.g. cosmetic and medical devices, consumer products, fertilizers)
- Debate at EU-level and international (convention on biodiversity and synthetic biology definition)

Organisation of dedicated events and activities
- EMF workshop, organised in March 2014 in Athens
- Fragrance allergens IDEA workshops organised annually

Research Agenda (synthetic biology, biomonitoring)

(B.2) Original objectives of the intervention

The general objective of setting up the scientific committees was to provide independent, high quality, up to date scientific advice on products intended to consumers, in particular on cosmetics, medical devices and toys. This advice is made available to EU policy makers to allow them to take science based policy decisions.

(B.3) How the objectives were to be achieved

See the intervention logic in the Annex.

C. Scope of the evaluation

(C.1) Topics covered

The evaluation covers the time period from March 2009, when Scientific Committees set up by Commission Decision 2008/721 /EC have become operational, to first quarter 2015; with a special focus on activities carried out between March 2013 and March 2015, when the new round of experts was appointed.

(C.2) Issues to be examined

1. Relevance:
The evaluation will limit itself to assessing the relevance of the opinions/scientific advice in relation to the needs for scientific advice on human health, the environment and consumer safety for products intended for the consumer in particular cosmetics, medical devices and toys and other products.

[2] http://ec.europa.eu/growth/sectors/cosmetics/legislation/index_en.htm

[3] Directive 2009/48/EC - OJ L 170, 30.6.2009, p. 1–37

[4] Directive 2001/95/EC - OJ L 11, 15.1.2002, p. 4–17

2. Effectiveness:
The evaluation will assess the effectiveness of structure and procedures set up to deliver opinions/scientific advice. It will analyse resource and task allocations within the scientific committees and the secretariat and assess its adequateness in relation to the results achieved.

The evaluation will assess the impact of the opinions/scientific advice in achieving the objectives of independent high quality advice. The evaluation will assess in how far the objective of transparency was achieved. It will analyse what influenced the achievements.

The evaluation will assess if the opinions/scientific advice were delivered with a quality and within a timeframe to allow for timely and appropriate action at EU policy level.

3. Efficiency:
The evaluation will assess the procedures and structures in relation to the scientific committees and the secretariat put in place allowed for delivering scientific advice in the most cost effective way.

4. Coherence:
The evaluation will assess internal coherence of procedures and methodologies between the different scientific committees and over time.
The evaluation will assess external coherence of procedures and methodologies and the separation of tasks with other EU risk assessment bodies.

5. EU added value
The scientific committees are a technical part allowing the achievements of wider EU interventions. Their assessment is rather limited to a performance audit, i.e. to the EU added value of the scientific advice provided by the Scientific Committees' to the Commission decision-making process.

(C.3) Other tasks

None

D. Evidence base

(D.1) Evidence from monitoring

The following evidence is available: budget, statistics on participation of members, number of meetings organised, number of opinions and other scientific advices produced, fact-sheets and web summaries produced, number of public consultations and hearings organised, workshops and conferences, participation in public consultations, web statistics, bibliometrics, and publications on scientific journals,

(D.2) Previous evaluations and other reports

A 1st intermediate evaluation has been performed by RAND in 2006 covering 2004 to 2009 (see http://ec.europa.eu/health/ph_risk/documents/risk_eval_frep_en.pdf).

(D.3) Evidence from assessing the implementation and application of legislation (complaints, infringement procedures)

NA

(D.4) Consultation

The Survey of stakeholders will be used to collect structured evidence on the stakeholders' perceptions, appreciations and awareness of specific aspects of SC's functioning and outputs.

In-depth interviews with key informants, namely the Secretariat, the Client services (within DG SANTE, DG GROW, DG ENV etc.), the Chairs / vice-Chairs of SC, other relevant EU level bodies such as ECHA, EFSA, EMA will cover both general aspects related to the organisational set-up and the efficiency, as well as specific opinion- related aspects (in the framework of case-studies).

Part of the desk review and in-depth interviews for Case-studies will be carried out in the framework of 'case-study' analyses of a sample of opinions to be essentially used for the quality of opinions and the use by policymakers and overall impact.

(D.5) Further evidence to be gathered

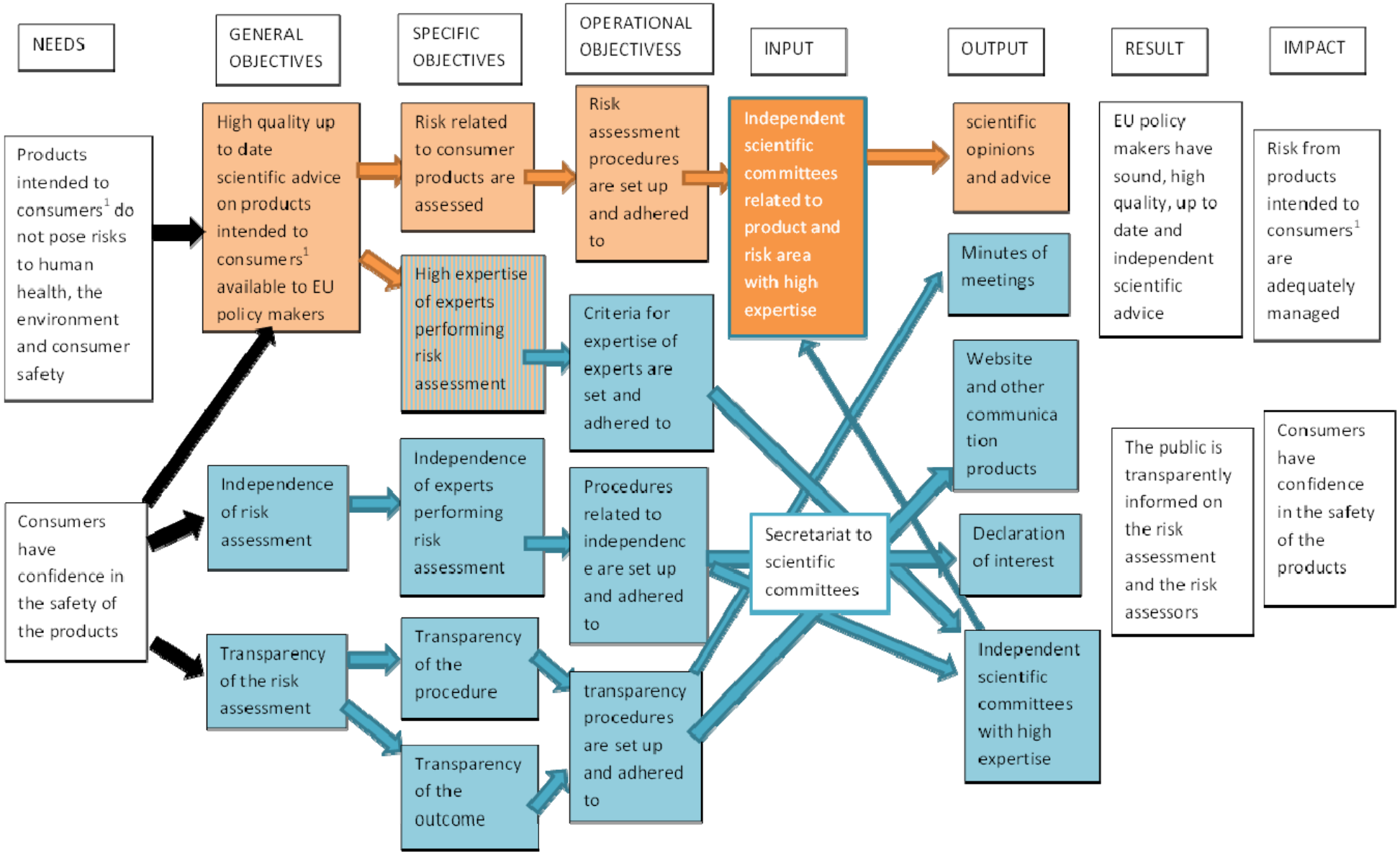
Bibliometrics /media impact. In a sample of cases, the broader impact of the opinion (i.e. beyond the Client

service that requested it) will be investigated through database-mining techniques. The method includes a citation analysis of the opinion through the SCOPUS database and its possible echo on media (as measured by the JRC's EMM system).

E. Other relevant information/ remarks

This evaluation could help also to provide information on the Commission scientific advice mechanism. EU legislation already laid down specific obligation to cooperate between scientific bodies undertaking risk assessment but evaluating the coherence/cooperation between scientific bodies remains an important aspect.

ANNEX – INTERVENTION LOGIC



1 cosmetics, medical devices, toys, and other consumer products