
**The Committee on Toxicity of Chemicals in Food,
Consumer Products and the Environment (COT)**

A Report of the 2011 Quinquennial Review

March 2011

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Summary and Recommendations

Summary

There is a continuing need for COT, with value to the FSA and other Government Departments. The process for determining the work programme should be improved to ensure that the potential value contributed is maximised. Completed work should be summarised in terms of outcomes and impact achieved over time.

Objectives and roles

- There is a continuing need for COT, with value to the FSA and other Government Departments.
- The role and remit of the Committee is clearly defined and appropriate to where the Committee should have most impact, value and relevance.
- The work undertaken by the Committee reflects the scope of that remit, encompassing food and non-food issues.
- It is important that the Chair and the Secretariat continue to ensure that the full scope of the remit is considered in the planning of future work.

Work Programme

- COT publishes an annual report of its activities which is an example of good practice.
- It is recommended that the Horizon Scanning process and the process for determining the work programme are improved and a forward work plan published with proposed timescales for the work.
- Completed work should be summarised in terms of outcomes and impact achieved. This should be updated to track outcomes and impacts over time.

Research and Scientific Rigour

- Consistent and appropriate scientific support is in general provided by the Secretariat and it is important for that level of support to be continued.
- It is however recommended that the Committee takes greater steps to show evidence of scientific rigour by using the FSA's Good Practice Guidelines and Science Checklist more explicitly and also routinely considering whether peer reviews are appropriate for work on which the Committee's decisions are based.

Seeking and Using the Committee's Advice

- The Committee's advice is sought and used by a number of Government Departments in addition to the FSA and HPA.
- In general COT follows good practice in formulating and presenting its advice.
- COT has provided, and intends to continue to provide where appropriate, non technical lay summaries of its technical statements which is an example of Good Practice.
- The Secretariat provides an annual update on actions taken subsequent to COT advice which is an example of good practice but which could be of greater benefit if more comprehensive.

Working with other Committees

- At each meeting The COT Secretariat provides an update on the work of other FSA advisory committees in an information paper, which is an example of good practice.

- COT has worked and continues to work with other FSA committees as and when appropriate.
- COT should explore whether there might be mutual benefits from developing links with other non-FSA bodies in the toxicology arena.
- The FSA Secretariat should continue to keep abreast of toxicology issues being addressed by the European Food Safety Authority (EFSA).

Secretariat

- There is a lack of knowledge among members and assessors of who the members of the Secretariat are and what their roles on the COT Secretariat are.
- The FSA should consider having a core Secretariat team in attendance at each meeting with other members of its Secretariat attending on an “as required” basis.
- The administrative support provided by the Secretariat is of a consistently high standard.
- The Chair and Secretariat should consider Secretariat resources in terms of scientific expertise and amount of resource available in the planning of COT’s work plan and identify and address any gaps as appropriate.

Members and Assessors

- The number of members and the range of expertise represented by the membership are generally considered to be appropriate. However the Chair and Secretariat should consider whether any actions are required following the review of the balance of expertise undertaken in February.
- It is recommended that new members have an induction meeting with the Secretariat.
- There is a need to clarify who the assessors on the Committee are and the role and responsibilities of assessors and officials.

Meetings

- COT’s meetings are open and meeting agendas, papers and minutes are available on COT’s website, providing a high level of openness and transparency.
- COT should continue to consider the possibility of additional working groups when considering the most appropriate approach to addressing issues in its work plan.

Good Practice and Recommendations

	Paragraph reference
Examples of good practice	
1. The role and remit of the Committee is clearly defined and appropriate to where the Committee should have most impact, value and relevance.	12
2. The work undertaken by the committee reflects the scope of that remit, encompassing food and non-food issues.	13
3. COT publishes an annual report of its activities	24
4. COT has provided, and intends to continue to provide where appropriate, non technical lay summaries of its technical statements.	36
5. The Secretariat provides an annual update on actions taken subsequent to COT advice	37
6. At each meeting the COT Secretariat provides an update on the work of other FSA advisory committees in an information paper.	38
7. The administrative support provided by the Secretariat is of a consistently high standard.	56
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9. COT's meetings are open and meeting agendas, papers and minutes are available on COT's website, providing a high level of openness and transparency.	65
Recommendations	
1. The Horizon Scanning process and the process for determining the work programme should be improved and a forward work plan published with proposed timescales for the work. It is important that the Chair and the Secretariat continue to ensure that the full scope of the remit, including food and non food issues, is considered in the planning of future work.	16, 19 & 20
2. Completed work should be summarised in terms of outcomes and impact achieved. This should be updated to track outcomes and impacts over time.	25 & 37
3. It is recommended that the Committee takes greater steps to show evidence of scientific rigour by using the FSA's Good Practice Guidelines and Science Checklist more explicitly and also routinely considering whether peer reviews are appropriate for work on which the Committee's decisions are based.	30
4. COT should explore whether there might be mutual benefits from developing links with other non-FSA bodies in the toxicology arena.	43
5. The Secretariat should prepare a brief information paper for members outlining the roles and responsibilities on the COT Secretariat of each of the members of the COT Secretariat.	49
6. The FSA should consider having a core Secretariat team in attendance at each meeting with other members of its Secretariat attending on an "as required" basis.	54
7. The Chair and Secretariat should consider Secretariat resources in terms of scientific expertise and amount of resource available when planning COT's work	58

programme and identify and address any gaps as appropriate.

8. It is recommended that new members have an induction meeting with the Secretariat. 62
9. There is a need to clarify who the Committee's assessors are and the role and responsibilities of assessors and officials. 64
10. COT should continue to consider whether additional working groups would be appropriate when considering the most appropriate approach to addressing items in its work plan. 70

Background

Terms of Reference of Review

1. The 2002 Food Standards Agency (FSA) Report of the Review of Scientific Committees¹ recommended that all Scientific Advisory Committees should be reviewed at least once every five years to determine 'whether each committee fulfils its intended function and whether all the current committees are still needed'.
2. The main objectives of this review are to assess:
 - The need for the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT);
 - Whether the role and remit of the Committee is clearly defined and appropriate to where the Committee should have most impact, value and relevance;
 - The methods of operation and effectiveness, including the Committee's terms of reference and composition and the openness and transparency of its procedures (including with reference to the standards set out in the Code Of Practice for Scientific Advisory Committees² and the Good Practice Guidelines³);
 - The relationships between the Committee, the commissioning department and other bodies with related responsibilities (in particular the other scientific advisory committees that advise the Agency); and
 - The implementation of the 2002 review recommendations, the Code of Practice for Scientific Advisory Committees and the current governance structures.

Methodology

3. The work involved in undertaking this review included:
 - A review of COT's website⁴ and COT documentation including minutes, meeting papers and publications published on its website;
 - Attending the COT open meetings on 14th December 2010 and 1st February 2011;
 - Interviews with 34 internal and external stakeholders (as listed in the Appendix of this report).

¹ <http://www.food.gov.uk/science/researchpolicy/commswork/scicomrev>

² <http://www.bis.gov.uk/assets/bispartners/goscience/docs/c/cop-scientific-advisory-committees.pdf> (At the time of this review a consultation on an updated Code of Practice had closed, and a revised Code was due to be published imminently.)

³ <http://www.food.gov.uk/multimedia/pdfs/goodpracguide.pdf>

⁴ <http://cot.food.gov.uk/>

4. The review was undertaken with specific reference to:
 - The FSA's 2002 Report of the Review of Scientific Committees⁵;
 - The Government Office for Science Code of Practice for Scientific Advisory Committees, December 2007⁶;
 - The FSA's Good Practice Guidelines for the Independent Scientific Advisory Committees, December 2006⁷;
 - The FSA's Science Checklist⁸.

Background to COT

5. COT is an independent scientific committee that provides advice to the Food Standards Agency, the Department of Health and other Government Departments and Agencies on matters concerning the toxicity of chemicals.
6. The Committee's terms of reference as stated on its website⁹ is:
 - To advise at the request of:
 - Department of Health
 - Food Standards Agency
 - Department for Business, Enterprise and Regulatory Reform¹⁰
 - Department for the Environment, Food and Rural Affairs
 - Department of Transport, Local Government and the Regions¹¹
 - Health and Safety Executive
 - Health Protection Agency
 - Chemicals Regulation Directorate
 - Veterinary Medicines Directorate
 - Medicine and Healthcare Products Regulatory Agency

⁵ <http://www.food.gov.uk/science/researchpolicy/commswork/scicomrev>

⁶ <http://www.bis.gov.uk/assets/bispartners/goscience/docs/c/cop-scientific-advisory-committees.pdf>

⁷ <http://www.food.gov.uk/science/researchpolicy/commswork/good>

⁸ <http://www.food.gov.uk/science/researchpolicy/commswork/scienceschecklist/>

⁹ <http://cot.food.gov.uk/moreinfo/cotterms>

¹⁰ Now Department for Business, Innovation and Skills

¹¹ Now Department for Transport

Home Office

Scottish Executive

National Assembly for Wales

Northern Ireland Executive

Other Government Departments and Agencies.

- To assess and advise on the toxic risk to man of substances which are:
 - (a) used or proposed to be used as food additives, or used in such a way that they might contaminate food through their use or natural occurrence in agriculture, including horticulture and veterinary practice or in the distribution, storage, preparation, processing or packaging of food;
 - (b) used or proposed to be used or manufactured or produced in industry, agriculture, food storage or any other workplace;
 - (c) used or proposed to be used as household goods or toilet goods and preparations;
 - (d) used or proposed to be used as drugs, when advice is requested by the Medicines and Healthcare products Regulatory Agency;
 - (e) used or proposed to be used or disposed of in such a way as to result in pollution of the environment.
 - To advise on important general principles of new scientific discoveries in connection with toxic risks, to co-ordinate with other bodies concerned with the assessment of toxic risks and to present recommendations to toxicity testing.
7. Members are appointed for their individual expertise and experience and are not representative of any sector or organisation. There are currently 16 members and a Chair. Member biographies are provided on COT's website¹² and further details provided in the annual report.
 8. The Committee currently meets seven times a year. The agenda, papers and minutes of each meeting are provided on COT's website¹³.
 9. The COT is supported in its work by a Secretariat provided from the Food Standards Agency (FSA) and the Health Protection Agency (HPA). The FSA Secretariat is responsible for issues specifically related to chemicals in food, while the HPA Secretariat leads on issues related to consumer products and the environment. Members of the Secretariat are listed on COT's website¹⁴.

¹² <http://cot.food.gov.uk/membership/>

¹³ <http://cot.food.gov.uk/cotmtgs/cotmeets/>

¹⁴ <http://cot.food.gov.uk/membership/cotsecr>

10. COT has no independent budget or expenditure. The FSA covers the costs for the operation of the Committee.
11. COT has two sister committees, the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM)¹⁵ and the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC)¹⁶.

¹⁵ <http://www.iacom.org.uk/>

¹⁶ <http://www.iacoc.org.uk/>

Objectives and Roles

12. The objectives and roles of COT are summarised in the terms of reference (see paragraph 6 above). The scope of the Committee's role and remit covers the toxicity of chemicals in food, consumer products and the environment. The role and remit of the Committee is clearly defined and appropriate to where the Committee should have most impact, value and relevance.
13. The work of the Committee reflects the scope of that remit, encompassing food, consumer products and the environment. For example, recent issues addressed by the Committee include:
- Food related issues such as the Detection of Paralytic Shellfish Poisoning Biotoxins (TOX/2011/07)¹⁷ and Timing of Introduction of Gluten into the Infant Diet (TOX/2010/35)¹⁸;
 - Consumer product issues including Dibutyl Phthalate (DBP): Further Consideration of Danish EPA Review – DBP in Rubber Clogs (TOX/2010/36)¹⁹;
 - Environment issues including Definition of an Endocrine Disrupter for Regulatory Purposes (TOX/2011/07)²⁰ and Landfill Sites²¹.
14. The fairly regular presence at meetings of officials from the Health & Safety Executive (HSE) Chemicals Regulation Directorate (CRD), the Environment Agency (EA) and the Department for Environment, Food and Rural Affairs (Defra) as well as the presence of the FSA and HPA, means that those departments are aware of the work of COT and have the ability to benefit from the work undertaken by COT and the opportunity to raise issues for consideration by COT if appropriate. For example:
- The Definition of an Endocrine Disrupter for Regulatory Purposes (TOX/2011/07)²² resulted from a request to COT from the HSE. As a result of the COT recommendations, the HSE prepared a paper, for presentation to various EU stakeholders, which addressed the comments received from COT. This paper was subsequently amended to take into account the outcome of an impact assessment exercise undertaken by the HSE. The revised paper has been presented by HSE to a number of different platforms in the EU and has initiated bilateral discussions with the German authority, who have developed a similar proposal. Discussions to agree a final regulatory definition for an endocrine disruptor are still under way in the EU; comments resulting from the COT discussion are being used by the HSE to support the UK proposed definition.

¹⁷ <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2011/cotmeet1feb2011/cotagendapapers1feb2011>

¹⁸ <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2010/cotmeet14dec2010/cotagendapapers14dec2010>

¹⁹ <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2010/cotmeet14dec2010/cotagendapapers14dec2010>

²⁰ <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2011/cotmeet1feb2011/cotagendapapers1feb2011>

²¹ <http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2010/cot201001>

²² <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2011/cotmeet1feb2011/cotagendapapers1feb2011>

- The second statement on Landfill Sites²³, resulted from COT's view being sought on work commissioned by the Environment Agency which measured concentrations of chemicals around the boundaries of municipal waste landfill sites, and on new epidemiology studies.
- COT appraised a report entitled "State of the Art Report on Mixture Toxicity" which had been commissioned by the European Commission (EC) Directorate General for the Environment. The Committee were asked for comments in order to inform the UK's representatives in later discussions of mixture toxicity with the EC (TOX/2010/23)²⁴. The request to COT for comments was agreed by Government Departments and Agencies (Defra, HSE, FSA and the Centre for Environment, Fisheries & Aquaculture Science (CEFAS)). Defra lead the policy area and have submitted COT's comments in response to a call for information on mixtures issued by the EC Directorate General for Health and Consumers²⁵. The comments will feed into ongoing discussions on mixtures by European Union Scientific Committees.

15. Other Government Departments also submit requests to COT. For example:

- COT was asked by the Department for Transport to undertake an independent scientific review of data submitted by the British Pilots Association (BAPLA) due to concerns about the possible effects on aircrew health of oil/hydraulic fluid smoke/fume contamination incidents in commercial aircraft²⁶.
- The Home Office asked COT to provide toxicological advice on a revised formulation of an incapacitant spray and whether there was any increased risk to those directly or indirectly exposed compared with the previous formulation²⁷.

16. Paragraphs 13 – 15 above illustrate the range of the Committee's work. It is important that the Chair and the Secretariat continue to ensure that the full scope of the remit is considered in the planning of future work (see the section in this review on Work Programme for further details).

²³ <http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2010/cot201001>

²⁴ <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2010/cotmeet14sept2010/cotagendapapers14sept2010>

²⁵ http://ec.europa.eu/health/scientific_committees/consultations/calls/call_info_03_en.htm

²⁶ <http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2007/cotstatementbalpa0706>

²⁷ <http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2007/pava>

Summary

- ❖ There is a continuing need for COT, with value to the FSA and other Government Departments.
- ❖ The role and remit of the Committee is clearly defined and appropriate to where the Committee should have most impact, value and relevance.
- ❖ The work undertaken by the Committee reflects the scope of that remit, encompassing food and non-food issues.
- ❖ It is important that the Chair and the Secretariat continue to ensure that the full scope of the remit is considered in the planning of future work.

Paragraph reference

Examples of good practice

The role and remit of the Committee is clearly defined and appropriate to where the Committee should have most impact, value and relevance.	12
The work undertaken by the Committee reflects the scope of that remit, encompassing food and non-food issues.	13

Work Programme

17. The primary role of each of the FSA's Scientific Committees is to advise on the specific issues that are referred to it by the Agency and the other Departments to which it responds. Issues are referred to COT by the Secretariat, including issues originating from Departments other than FSA and HPA.
18. Members of the Committees should also be free to propose additional items for consideration and the final decision on whether such issues should be included on the agenda should lie with the individual committee Chair, taking account of competing priorities. COT members are specifically invited to put forward suggestions for additional items for consideration. This is undertaken by a Horizon Scanning paper and meeting agenda item annually where proposed future work is presented by the Chair and Secretariat and members invited to put forward additional suggestions. Members are also able to draw particular issues to the attention of the Secretariat at any time. The Horizon Scanning paper for 2011 (TOX/2011/03 and TOX/2011/03 addendum)²⁸ was discussed at the February 2011 meeting.
19. It is recommended that this process be improved by considering the following:
- Presenting the information in an executive summary format with summary details of each item presented in a consistent format with further details provided in appendices to that summary.
 - Categorising the items into food, consumer products and environment and generic items that cover all three areas.
 - Ensuring that the Horizon Scanning process includes a method for identifying non-food items as well as food items.
 - Prioritising the issues in an appropriate way, for example in terms of importance, urgency, and impact.
 - Encouraging members to be proactive in suggesting items for consideration drawing on their specific areas of expertise and if necessary providing them with guidance on this.
20. It is recommended that the results of the Horizon Scanning process be developed into an agreed forward work plan for COT. The work plan should include:
- A proposed timescale for addressing each item. This should feed into to an overall time-plan for the Committee's work, drawing on the prioritisation identified in the Horizon Scanning process and allowing time for high priority items to be addressed at short notice as they arise.

²⁸ <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2011/cotmeet1feb2011/cotagendapapers1feb2011>

- Identification of the resources required to address each item within the proposed timescale including member and Secretariat resources as well as the need to co-opt additional expertise and involve other committees as required.
 - Identification of the most appropriate approach to address each issue in the context of the proposed timescale and resource availability, for example, whether the most appropriate approach is to address the item in full committee discussions or whether to set up a working group.
21. Once agreed by the members, the forward work plan for each year should be published on the Committee's website so as to meet the publication requirement of the Code of Practice for Scientific Advisory Committees²⁹.
22. The work undertaken for this review has suggested that the agenda for a number of recent meetings has been "heavy" in terms of content. For example, the meeting held on 1st February 2011 over-ran and there was not sufficient time to discuss item 10 on the agenda³⁰. A more tightly defined work programme will enable the Chair and Secretariat to ensure that:
- The items on the work programme for the year are well defined in terms of what they are, why they are required, the work that will be done and when, and the anticipated impact of the work;
 - The work and meetings are planned and scheduled in advance to avoid overly "heavy" agendas at meetings.
23. The COT website³¹ states that "statements" published by COT are the main way in which COT presents its advice. Only one statement was published in 2010. That compares with six statements in 2009 and nine statements in 2008. That appears to suggest a "light" workload, which conflicts with the "heavy" meeting agendas. The work undertaken for this review suggests that the reason for only one statement this year is not a light workload but partly because a number of issues were addressed in the minutes only as the nature of those issues did not warrant a separate statement, and partly because a number of issues being addressed were not concluded in 2010. Scheduling work in a forward work plan will provide visibility of the schedule of work and when statements are due to be published.
24. As well as publishing statements, COT publishes an annual report³² of its activities which is an example of good practice. The report is joint with COT's sister committees COC and COM, and includes a description of the Committee's work during the year. The draft 2010 Annual Report was due to be discussed at the meeting on 1st February 2011 but due to the rest of the agenda over-running, it was decided to review it remotely by email

²⁹ <http://www.bis.gov.uk/assets/bispartners/goscience/docs/c/cop-scientific-advisory-committees.pdf>

³⁰ <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2011/cotmeet1feb2011/cotagendapapers1feb2011>

³¹ http://cot.food.gov.uk/cotstatements/cotstatementsyrs/#id_554676

³² http://cot.food.gov.uk/cotreports/#id_436229

and telephone correspondence. The Chair and Secretariat should ensure that this does not lead to a delay in publishing the report.

25. It is recommended that in addition to the annual report, when work is completed by COT, a brief bullet point summary of the work undertaken, the outcomes of the work and its impact is produced. This should be added to over-time, so that the impact of the work can be tracked. For example, it could record the risk management options that have been considered, the risk management option adopted, results of the implementation of the risk management option; or alternatively, research recommended, progress with the research recommendation and whether the research is to be funded etc. This should be a brief bullet point document with references to the documents where the detail is provided.
26. Such an approach to determining the work programme and reporting on the work achieved will enable the Chair and Secretariat to ensure that the potential value contributed by COT is maximised and to provide both internal and external stakeholders with a clear statement of the work to be undertaken and the anticipated impact of the work as well as the outcome of that work and impact achieved.

Summary

- ❖ COT publishes an annual report of its activities which is an example of good practice.
- ❖ It is recommended that the Horizon Scanning process and the process for determining the work programme are improved and a forward work plan published with proposed timescales for the work.
- ❖ Completed work should be summarised in terms of outcomes and impact achieved. This should be updated to track outcomes and impacts over time.

	Paragraph reference
Examples of good practice	
COT publishes an annual report of its activities	24
Recommendations	
The Horizon Scanning process and the process for determining the work programme should be improved and a forward work plan published with proposed timescales for the work.	19 & 20
Completed work should be summarised in terms of outcomes and impact achieved. This should be updated to track outcomes and impacts over time.	25

Research and Scientific Rigour

27. A number of COT recommendations include recommendations for research to be undertaken by FSA or another Department. If the recommendation is accepted, then COT will be asked to review the research when it has been completed and to comment further. For example, the COT report on Risk Assessment of Mixtures of Pesticides and Similar Substances was published in 2002. In addition to drawing conclusions, this report made a number of recommendations requiring research to be funded and other actions. A paper discussed at the 1 February 2011 meeting (TOX/2011/01³³) provided the results of 17 research projects funded by the FSA in response to the recommendations and informed the Committee on what other actions have taken place or are in progress which address the other recommendations. The paper sought COT's advice on what conclusions can be drawn from the projects results, and the extent to which the report's recommendations have been addressed.
28. COT should continue to be kept informed of the progress of research it has recommended in terms of whether the research has been commissioned and the progress of the commissioned research in terms of its timescale for completion. If the research recommended by COT is not commissioned COT should be informed and have the opportunity to discuss that decision and the implications and update its statement if appropriate.
29. Much of COT's work is to review data put to them, for example data from the Total Diet Study (TDS). At the meeting in November 2010 COT considered data from an FSA survey looking at the occurrence on phthalates in the TDS. In December a draft statement summarising the data and provisional COT views was considered. An updated draft statement (TOX/2011/04³⁴) incorporating the Committee's discussions from their December meeting was included in the February 2011 meeting.
30. Consistent and appropriate scientific support is in general provided by the Secretariat and it is important for that level of support to be continued. It is however recommended that the Committee takes greater steps to show evidence of scientific rigour by using the FSA's Good Practice Guidelines³⁵ and Science Checklist³⁶ more explicitly and also explicitly considering whether in some cases peer reviews would be appropriate for work on which the Committee's decisions are based. The Committee should as a matter of course consider whether its draft findings could benefit from peer review by a wider range of experts than those on the Committee. That is particularly important where the Committee is reviewing scientific data that has not been subject to peer review and where only one or two members have a detailed knowledge of the area.

³³ <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2011/cotmeet1feb2011/cotagendapapers1feb2011>

³⁴ <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2011/cotmeet1feb2011/cotagendapapers1feb2011>

³⁵ <http://www.food.gov.uk/science/researchpolicy/commswork/good>

³⁶ <http://www.food.gov.uk/science/researchpolicy/commswork/scienc checklist/>

Summary

- ❖ Consistent and appropriate scientific support is in general provided by the Secretariat and it is important for that level of support to be continued.
- ❖ It is however recommended that the Committee takes greater steps to show evidence of scientific rigour by using the FSA's Good Practice Guidelines and Science Checklist more explicitly and also routinely considering whether peer reviews are appropriate for work on which the Committee's decisions are based.

**Paragraph
reference**

Recommendations

It is recommended that the Committee takes greater steps to show evidence of scientific rigour by using the FSA's Good Practice Guidelines and Science Checklist more explicitly and also routinely considering whether peer reviews are appropriate for work on which the Committee's decisions are based.

30

Seeking and Using the Committee's Advice

31. The Committee's advice is sought and used by a number of Government Departments in addition to the FSA and HPA. Examples are referred to in the section of this review on "Objectives and Roles".
32. There is no official presence on the Committee of representatives from Scotland, Wales or Northern Ireland. However, a representative from FSA Scotland keeps a watching brief on the work of the Committee on behalf of Scotland, Wales and Northern Ireland.
33. The range and type of recent issues addressed by COT has not led to a need for issues to be referred to the FSA Board. However, the FSA's Chief Scientist and Director of Food Safety are kept informed by the Secretariat of the issues being addressed by the Committee and the key outcomes. Advice is communicated within the other Government Departments via the assessors and officials.
34. The role of the FSA scientific committees is to advise on risk assessment. It is the FSA's responsibility to manage the risk based on their consideration of that risk assessment. Committees should not be asked to manage risks although they may be asked to provide scientific advice on risk management options. Evidence from the work undertaken for this review suggests that is understood and complied with by the Committee and that the Committee has a good understanding of the risk management context that their assessments will inform.
35. In general COT follows good practice in formulating and presenting its advice, including defining the issues, seeking input, validation, drawing conclusions and communicating its conclusions.
36. COT produced a non-technical lay summary for the statement on the review of the cabin air environment, ill-health in aircraft crews and the possible relationship to smoke/fume events in aircraft³⁷. The aim of that was to provide a concise non-technical summary of the issue and recommendations for lay people and is an example of good practice. COT intends to do that for its future statements and two lay summaries have recently been drafted for the COT statements on "The effects of chronic dietary exposure to methanol" and "Occurrence of mixed halogenated dioxins and biphenyls in UK food".
37. The Secretariat prepares an annual information paper on update on actions taken subsequent to COT advice. A paper was tabled for information on the agenda of the February 2011 meeting (TOX/2011/07³⁸) and provided an update on three issues – Endocrine disrupting chemicals, Mixtures – an appraisal of a report on "State of the Art on Mixture Toxicity" and Paralytic Shellfish Poisoning Biotoxins. This is an example of Good Practice and helps to inform members and other stakeholders of progress with

³⁷ <http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2007/cotstatementbalpa0706>

³⁸ <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2010/cotmeet2feb2010/cotagendapapers2feb2010>

issues following COT advice. However, it is recommended that this should be more comprehensive as outlined in paragraph 25 of this review.

Summary

- ❖ The Committee's advice is sought and used by a number of Government Departments in addition to the FSA and HPA.
- ❖ In general COT follows good practice in formulating and presenting its advice.
- ❖ COT has provided, and intends to continue to provide where appropriate, non technical lay summaries of its technical statements.
- ❖ The Secretariat provides an annual update on actions taken subsequent to COT advice which is an example of good practice but which could be of greater benefit if more comprehensive.

Paragraph reference

Examples of good practice

COT has provided, and intends to continue to provide where appropriate, non technical lay summaries of its technical statements.	36
The Secretariat provides an annual update on actions taken subsequent to COT advice	37

Working with other Committees

38. At each of its meetings the COT Secretariat provides an update on the work of other FSA advisory committees in an information paper, for example, the paper TOX/2011/08³⁹ for the February 2011 meeting, which is an example of good practice.
39. Part of the role of the FSA's General Advisory Committee on Science (GACS) is to help improve the communication between the FSA's Scientific Advisory Committees and to identify and advise on issues that cut across, or fall between, the remits of individual committees. As part of its efforts to address that, regular updates are provided to GACS on issues identified by each of the individual committees that have a cross-cutting or strategic relevance. In the update presented to the GACS meeting in March 2011 (GACS7-2)⁴⁰ of the six areas identified that involve cross-SAC working, four involve COT:
- Timing of the introduction of gluten into the infant diet – Scientific Advisory Committee on Nutrition (SACN)⁴¹ and COT
 - Recommendations on vitamin D intake – SACN and COT
 - Review of complementary and young child feeding – SACN and COT
 - EFSA Guidance on risk assessment of nanomaterials – COT and The Advisory Committee on Novel Foods and Processes (ACNFP).
40. The evidence from the work undertaken for this review suggests that COT has worked and continues to work with other FSA committees as and when appropriate.
41. COT also has an appropriate working relationship with its two sister committees, COC and COM, although the need for cross working between COT with COC and COM is limited.
42. COT also works with the Advisory Committee on Pesticides (ACP) in a joint working group, the Bystander Risk Assessment Working Group (BRAWG), formed in 2009 to explore issues related to the assessment of risks to bystanders and residents from the application of pesticides.
43. It is recommended that COT explores whether there might be mutual benefits from developing links with other non-FSA bodies in the toxicology arena, for example, the British Toxicology Society and the Toxicology Specialty Advisory Committee of the Royal College of Pathologists.

³⁹ <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2011/cotmeet1feb2011/cotagendapapers1feb2011>

⁴⁰ <http://gacs.food.gov.uk/gacsmeets/gacs2011/3march11/gacsagenda110303>

⁴¹ SACN is now a Department of Health led committee rather than as FSA led committee. <http://www.sacn.gov.uk/>

44. The FSA Secretariat should continue to keep abreast of toxicology issues being addressed by the European Food Safety Authority (EFSA) via the Secretariat's presence on EFSA's Panel on Contaminants in the Food Chain, and ensure that work undertaken does not duplicate work being undertaken at a European level.

Summary

- ❖ At each meeting The COT Secretariat provides an update on the work of other advisory committees in an information paper, which is an example of good practice.
- ❖ COT has worked and continues to work with other FSA committees as and when appropriate.
- ❖ COT should explore whether there might be mutual benefits from developing links with other non-FSA bodies in the toxicology arena.
- ❖ The FSA Secretariat should continue to keep abreast of toxicology issues being addressed by the European Food Safety Authority (EFSA).

Paragraph reference

Examples of good practice

At each meeting the COT Secretariat provides an update on the work of other FSA advisory committees in an information paper.

38

Recommendations

COT should explore whether there might be mutual benefits from developing links with other non-FSA bodies in the toxicology arena.

43

Secretariat

45. The Secretariat of COT is staffed by ten officials from the FSA and one official from HPA. The FSA Secretariat is responsible for issues specifically related to chemicals in food, while the HPA Secretariat leads on issues related to consumer products and the environment. The Secretariat administrative support is provided by the FSA.
46. One of the ten FSA officials is currently on maternity leave and there are an additional three members of FSA staff (one covering the maternity leave) who joined recently and are in-training and act as additional minute takers for COT.
47. Of the FSA officials, only two of them spend 50% or more of their time on COT Secretariat work. The lead administrator spends approximately 60% of her time on COT work and is supported by an administrative officer who spends approximately 30% of her time on COT work. On the scientific side one member of the Secretariat team spends approximately 50% of her time on COT work, with the other members of the scientific Secretariat team all spending 30% or less of their time on COT Secretariat work. There is therefore a number of people collectively contributing the equivalent of around three full time equivalents (FTEs).
48. This distribution of Secretariat duties across such a wide number of staff enables COT to benefit from the range of experience provided by these individuals and also provides Secretariat experience to a large number of FSA staff.
49. However, there is a lack of knowledge among members and assessors of who the members of the Secretariat are and what their roles on the COT Secretariat are. It is recommended that the Secretariat prepares a brief information paper for members outlining the specific roles and responsibilities on the COT Secretariat of each of the members of the COT Secretariat.
50. The large number of members of the Secretariat also leads to a large number of non COT member attendees at the COT meetings. The number of COT members attending COT meetings are usually outweighed by the number of members of the Secretariat and other officials, although it is noted that not all members of the Secretariat sit at the main table.
51. For example at the meeting on 1st February 2010 the minutes (TOX/MIN/2011/01⁴²) show that in addition to the Chair the attendees at the meeting were:
- 11 COT members
 - 14 members of the FSA Secretariat
 - 1 member of the HPA Secretariat
 - 2 assessors

⁴² <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2011/cotmeet1feb2011/cotdraftmns1feb2011>

- 3 officials (2 from the FSA)
 - 2 invited experts and 1 external observer.
52. At the meeting on 14th December 2010 the minutes (TOX/MIN/2010/07⁴³) show that in addition to the Chair the attendees at the meeting were:
- 12 COT members
 - 11 members of the FSA Secretariat
 - 2 members of the HPA Secretariat
 - 3 assessors
 - 5 officials (3 from the FSA)
 - 1 invited expert and 1 external observer.
53. In terms of COT requirements, it should not be necessary to have all the members of the FSA Secretariat present throughout all of the meeting, and in fact not all of them were present throughout all of the above meetings.
54. The FSA should consider having a core FSA Secretariat team (for example, the FSA Secretariat lead with one or two scientific supports and one administration support) in attendance for all of the meeting (together with the HPA Secretariat), with the scientific and administration supports taking the minutes, and other members of the Secretariat attending when required to present papers or hear a discussion on a paper they have been involved in, or to sit in on the meeting for training purposes. The members of the Committee should be informed who the members of the Secretariat are who are present at the meeting and what their role at the meeting is.
55. This would also have the benefit of releasing a significant amount of time that could be redirected to other Secretariat work in support of COT, for example drafting of papers or supporting working groups. If, for example, four members of the FSA Secretariat were to attend each meeting rather than eleven, then over the course of seven meetings a year, that would equate to 49 person days a year that could be reallocated to other COT Secretariat tasks.
56. The administrative support provided by the Secretariat is of a consistently high standard. For example, meetings arrangements are managed efficiently and effectively, and the meeting minutes are comprehensive and clearly written. There is generally a large volume of documentation to be reviewed by members prior to each meeting for discussion at the meeting and it is therefore important that it is received by members in time for them to review prior to the meeting and the Secretariat should ensure that is the case. If there is a recurring problem with a significant amount of the paperwork not arriving with the Secretariat in time for it to be forwarded to members two weeks before

⁴³ <http://cot.food.gov.uk/cotmtgs/cotmeets/>

the meeting, then the Secretariat should consider introducing a cut off point for receipt of papers, where those not received by that time, will not be addressed at the meeting but will need to be deferred, unless there are exceptional circumstances e.g. an urgent short notice item. Where an agenda item requires members to review a particularly large amount of documentation, for example agenda item 4 at the February 2011 meeting on FSA-funded research and other progress on mixtures of pesticides and similar substances (TOX/2011/01⁴⁴) it is particularly important that the paperwork is provided to members well in advance of the meeting. The Secretariat should ensure that all members are aware that they have the option of receiving all documents electronically rather than by post if they prefer.

57. The HPA Secretariat spends between 15% - 20% of his time on COT Secretariat work and has a small amount of input from two other members of the HPA team. The HPA Secretariat leads on issues related to consumer products and the environment. That is a relatively wide scope of issues to be covered by a relatively small amount of Secretarial support and there is therefore a risk of resource issues in terms of areas of scientific expertise and resource availability.
58. The Chair and Secretariat should consider Secretariat resources in terms of scientific expertise and amount of resource available when planning COT's work programme (see the section in this review on "Work Programme" for further details), and identify and address any gaps as appropriate. This should apply to both the food and non-food items in the work plan.
59. The level of scientific support provided by the Secretariat is generally considered to be of a high standard and the FSA/HPA should continue to ensure that appropriate senior Secretariat level reviews of papers are undertaken before papers are submitted to the Committee.

Summary

- ❖ There is a lack of knowledge among members and assessors of who the members of the Secretariat are and what their roles on the COT Secretariat are.
- ❖ The FSA should consider having a core Secretariat team in attendance at each meeting with other members of its Secretariat attending on an "as required" basis.
- ❖ The administrative support provided by the Secretariat is of a consistently high standard.
- ❖ The Chair and Secretariat should consider Secretariat resources in terms of scientific expertise and amount of resource available in the planning of COT's work plan and identify and address any gaps as appropriate.

⁴⁴ <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2011/cotmeet1feb2011/cotagendapapers1feb2011>

	Paragraph reference
Examples of good practice	
The administrative support provided by the Secretariat is of a consistently high standard.	56
Recommendations	
The Secretariat should prepare a brief information paper for members outlining the roles and responsibilities on the COT Secretariat of each of the members of the COT Secretariat.	49
The FSA should consider having a core Secretariat team in attendance at each meeting with other members of its Secretariat attending on an “as required” basis.	54
The Chair and Secretariat should consider Secretariat resources in terms of scientific expertise and amount of resource available in the planning of COT’s work plan and identify and address any gaps as appropriate.	58

Members and Assessors

60. COT is a UK-wide Committee and is made up of independent experts appointed by the FSA Chair and the Chief Medical Officer. Members are appointed for their individual expertise and experience and are not representative of any sector or organisation. There are currently 16 members and a Chair. Member biographies are provided on COT's website⁴⁵ and further details provided in the annual report.
61. The number of members and the range of expertise represented by the membership are generally considered to be appropriate. Each year, as part of the Horizon Scanning exercise, the Committee routinely reviews the balance of expertise on the Committee, which is an example of good practice.
62. There is no formal induction process for new members, although new members are sent a comprehensive pack of information on appointment. It is recommended that new members have an induction meeting with the Secretariat.
63. At the time of this review the FSA was in the process of introducing a new assessment process for the Chairs and members of its advisory committees, and the assessment process had not yet been completed by COT so it was not possible to assess the effectiveness of the process within this review.
64. There is a lack of knowledge across the Committee's participants as to who the assessors are and the distinction between assessors and observers. The Secretariat should clarify who the assessors are, and remind the members, assessors and officials of the role and responsibilities of officials and assessors as there is evidence of uncertainty with regard to their exact roles and responsibilities. This should be undertaken at one of the meetings to allow for the opportunity for discussion to clarify any queries, and the meeting minutes will then also provide clarification for reference.

Summary

- ❖ The number of members and the range of expertise represented by the membership are generally considered to be appropriate.
- ❖ It is recommended that new members have an induction meeting with the Secretariat.
- ❖ There is a need to clarify who the Committee's assessors are and the role and responsibilities of assessors and officials.

⁴⁵ <http://cot.food.gov.uk/membership/>

	Paragraph reference
Examples of good practice	
The Committee routinely reviews the balance of expertise on the Committee on an annual basis, which is an example of good practice	61
Recommendations	
It is recommended that new members have an induction meeting with the Secretariat.	62
There is a need to clarify who the Committee's assessors are and the role and responsibilities of assessors and officials.	64

Meetings

65. The Committee currently meets seven times a year. COT's meetings are open meetings which, together with the agenda, papers and minutes of each meeting available on COT's website, provide a high level of openness and transparency.
66. The meetings are open so that interested parties can attend and observe the Committee in operation and, although they cannot contribute to the meeting itself, they are invited to make statements or ask questions at the end of the meeting and those statements and comments and the Committee's response are included in the minutes subsequently published on the Committee's website. However, very few meetings are attended by external observers, the most notable exception being interested parties in the meetings including discussions on the cabin air review in 2007. By exploring whether there might be mutual benefits from developing links with other bodies in the toxicology arena such as the British Toxicology Society (see the section of this review on "Working with other Committees"), more stakeholders may become aware of the work of COT and its work programme.
67. Members are asked to declare any relevant changes to their interests in the Register of Members' Interests or any specific interest in items on the agenda. All declarations are recorded in the minutes.
68. The work undertaken for this review has suggested that the agenda for a number of recent meetings has been "heavy" in terms of content. For example, the meeting held on 1st February 2011 over-ran and there was not sufficient time to discuss item 10 on the agenda⁴⁶. A more tightly defined work programme (see the section of this review on "Work Programme" for further details) will enable the Chair and Secretariat to ensure that the work and meetings are planned and scheduled in advance to avoid overly "heavy" agendas at meetings.
69. COT currently has one active working group which is a joint working group with the Advisory Committee on Pesticides (ACP), the Bystander Risk Assessment Working Group (BRAWG), formed in 2009 to explore issues related to the assessment of risks to bystanders and residents from the application of pesticides.
70. It is recommended that COT continues to consider whether additional working groups would be appropriate when considering the most appropriate approach to addressing items in its work plan.

⁴⁶ <http://cot.food.gov.uk/cotmtgs/cotmeets/cotmeet2011/cotmeet1feb2011/cotagendapapers1feb2011>

Summary

- ❖ COT's meetings are open meetings which, together with the agenda, papers and minutes of each meeting available on COT's website, provide a high level of openness and transparency.
- ❖ COT should continue to consider the possibility of additional working groups when considering the most appropriate approach to addressing issues in its work plan.

Paragraph reference

Examples of good practice

COT's meetings are open and meeting agendas, papers and minutes are available on COT's website, providing a high level of openness and transparency. 65

Recommendations

COT should continue to consider the possibility of additional working groups when considering the most appropriate approach to addressing issues in its work plan. 70

Appendix: List of contributors to the review

COT Secretariat

Diane Benford (Scientific Secretary)	Food Standards Agency
Julie Shroff (Administrative Secretary)	Food Standards Agency
Jon Battershill (Scientific Secretary)	Health Protection Agency

COT members

David Coggon	COT Chair
Roger Brimblecombe	COT member
Derek Bodey	COT member
Alan Boobis	COT member
Anna Hansell	COT member
Nicholas Plant	COT member
John Foster	COT member

COT assessors

David Johnson	Health & Safety Executive, Chemicals Regulation Directorate
Camilla Pease	Environment Agency
Mike Roberts	Department for Environment Food and Rural Affairs
Paul Holley	Department of Health
Ovnair Sepai	Health Protection Agency

Other stakeholders

Claudia Heppner, Scientific Co-ordinator to the Panel on Contaminants in the Food Chain	European Food Safety Authority
Ruth Roberts, President	British Toxicology Society
Martin Rose, Contract Manager, Environmental Contaminants Team	Food and Environment Research Agency
Philip Carthew, Science and Technology Leader for Toxicology Risk Assessment	Unilever

Heather Wallace, Chair	Toxicology Specialty Advisory Committee, Royal College of Pathologists
Sandra Webber, Head of Aviation, Regulatory & Consumer Division	Department for Transport
Andrew Ashbourne, Branch Head, Regulatory & Consumer Division	Department for Transport
Peter Jackson, Acting Chair	FSA Social Science Research Committee
Anthony Williams, Chair	Maternal and Child Nutrition Sub Group of the Scientific Advisory Committee on Nutrition
Alison Tedstone, Observer, Scientific Advisory Committee on Nutrition	Department of Health
Geraldine Hoad, Secretariat	FSA Advisory Committee on the Microbiological Safety of Food
David Philips, Chair	Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment
Peter Farmer, Chair	Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment
Peter Aggett, Vice Chair	Scientific Advisory Committee on Nutrition
Frances Pollitt, HPA Secretariat	Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment and Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment
Andrew Wadge, Chief Scientist	Food Standards Agency
Alison Gleadle, Director of Food Safety	Food Standards Agency
Patrick Miller, Joint Head, Chief Scientist Team	Food Standards Agency
Anna Whyte, Head of Scientific Services	Food Standards Agency (Scotland)
Jacqui McElhiney, Foodborne Disease Strategy Senior Policy Advisor	Food Standards Agency (Scotland)