



Department  
of Health

# Triennial Review of the Committee on Mutagenicity of Chemicals in Food, Consumer Products, and the Environment (COM)

Review Report

April 2017

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# Executive summary

The Triennial Review of the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) was conducted to provide assurance to the Department of Health (DH) and the public that COM's functions are required and the body is operating efficiently.

Stage one of the review examined the functions and form of COM. COM provides advice across government on the validity and methodology for genotoxic testing, and also on potential health risks from mutagenic compounds. COM provides advice to Government Departments/Agencies when requested, publishes its own guidance in relevant areas, and feeds into the development of international guidance through appropriate channels. The review concludes that there remains a demand for these functions and that COM plays a valuable role in providing expert and independent advice across government that is highly respected both nationally and internationally.

The report also concludes that COM should remain in its current form as an Advisory Non-Departmental Public Body (ANDPB). The body meets the Cabinet Office's tests for an ANDPB through performing a technical function that requires external expertise and by undertaking activities that need to be delivered with absolute political impartiality. The report considers possible mergers of COM with other bodies, in particular the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC), but concludes from the evidence that this would be likely to lead to inefficiencies and a loss of expertise. Nevertheless the report recommends an annual planning exercise to encourage a more flexible and coordinated approach when deciding how to allocate work between the two committees, given their overlapping interests.

Stage two of the review examines the performance, efficiency and governance of COM. Noting that the committee only meets three times a year, the evidence suggests that COM operates relatively efficiently but has come under pressure from a loss of resource in the secretariat. The report makes a number of performance recommendations covering committee papers and stakeholder engagement, and a number of governance recommendations covering the committee's website, appraisal and induction processes.

All recommendations are summarised on the following page.

## Stage One Recommendations

**Recommendation 1:** The COM Chair, COC Chair and joint secretariat should conduct an annual formal planning exercise to ensure flexible and coordinated approaches are adopted to work with intersecting interest.

**Recommendation 2:** The functions of COM should continue to be delivered in the current form of an ANDPB.

## Stage Two Recommendations

**Recommendation 3:** That secretariat staff are encouraged, and provided with opportunities, to develop their knowledge and expertise to produce material for the Committee. Additionally, that the COM Chair should consult members to maximise use of members' expertise when producing material for committee discussion.

**Recommendation 4:** COM should maintain effective communications with sponsoring departments and other relevant government bodies to ensure that knowledge is shared and work is coordinated.

**Recommendation 5:** The COM secretariat should review the website and explore options to ensure that it is easy to navigate, working with the sponsor team, DH digital team and the Government Digital Service.

**Recommendation 6:** The Department of Health, COM Chair and COM secretariat should establish a light-touch appraisals process.

**Recommendation 7:** The Department of Health, COM Chair and COM secretariat should establish a light touch induction process.

**Recommendation 8:** COM should maintain good communication links with professional bodies, academic institutions and research communities to promote awareness of the committee, and encourage future applications to the committee.

# 1. Introduction and background

## a) Aims of the Review

- 1.1. To support the Department of Health's (DH) stewardship function of the health and care system, the Department is undertaking a Triennial Review programme of its Non-Departmental Public Bodies (NDPBs), Executive Agencies, and Special Authorities. This reflects the current position of the Cabinet Office whereby all NDPBs should undergo one substantive review in a three-year cycle.
- 1.2. COM, an Advisory NDPB, was scheduled for a 'light touch' review.
- 1.3. Triennial Reviews have two principal stages:
  - to provide a robust challenge of the continuing need for individual NDPBs – both their functions and their form; and
  - where it is agreed that a body remain as an NDPB, to review:
    - a) its performance and opportunities for efficiencies;
    - b) its governance arrangements to ensure that the public body and its sponsoring department are complying with recognised principles of good corporate governance.

## b) About COM

- 1.4. COM is a non-statutory body established in its present form in 1978. It is an ANDPB sponsored by the DH with no regulatory role or executive powers. However it may provide advice to any government body where relevant including, for example, DH, the Food Standards Agency (FSA), and the Health and Safety Executive (HSE).
- 1.5. COM provides independent advice to UK government departments and agencies on the human mutagenic<sup>1</sup> risk of specific chemicals (the risk that these chemicals might cause mutations or damage to genetic material). COM also advises on important general

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<sup>1</sup> In accordance with COM's terms of reference this report refers to COM's advice on mutagenic risk rather than genotoxic risk although it is understood that the guidance that COM provides often also incorporates the latter. The distinction between mutagenicity and genotoxicity can be found in COM's 'Guidance on the Significance of Chemical-Induced Mutation for Human Health' which defines genotoxicity as 'the process by which chemicals interact with or damage DNA and/or the cellular apparatus which regulates the accuracy and efficiency of the DNA replication and repair process. Mutation is defined as permanent change in the amount or structure of the genetic material of an organism.' Further information on this can be found at:

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/315825/humanhealthsignificancefinal.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/315825/humanhealthsignificancefinal.pdf)

## Introduction and background

principles and new scientific discoveries associated with the assessment of genotoxic risk, and makes recommendations on mutagenicity testing. COM's full terms of reference can be found on its website<sup>2</sup>.

- 1.6. COM consists of a panel of independent doctors and scientists drawing relevant expertise from universities, research institutes and industry. Currently, the committee is made up of 13 individuals<sup>3</sup>: 5 (including the Chair) work at UK Universities, 6 work in the private sector, and 2 are lay members. One of the academics is ex officio as COC Chair. Of those in the private sector, 3 currently work for private companies and 3 now describe themselves as consultants (having previously worked for companies in the sector). The two lay members bring the observations of the wider scientific community and public views.
- 1.7. Members are supported by a joint secretariat provided by Public Health England (PHE) and the FSA. The secretariat provides members with comprehensive background information and briefing papers upon which reasoned decisions can be made.
- 1.8. Closely associated with COM are two further advisory committees: The COC and The Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment (COT).
- 1.9. COT's Triennial Review was undertaken by the FSA - their lead sponsoring body. There was regular communication between officials in order to ensure alignment between the two reviews. COC is an internal DH expert advisory committee and is therefore not subject to the Triennial Review process. However COC has been considered within this review where appropriate (such as when considering the relationship between the three committees).

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<sup>2</sup> <https://www.gov.uk/government/organisations/committee-on-mutagenicity-of-chemicals-in-food-consumer-products-and-the-environment/about/terms-of-reference>

<sup>3</sup> <https://www.gov.uk/government/organisations/committee-on-mutagenicity-of-chemicals-in-food-consumer-products-and-the-environment/about/membership>

## 2. Stage One Report

### a) Function

- 2.1. COM meets three times annually, and provides advice across government (and subsequently internationally) on the validity of methods for testing genotoxicity, best practice for such testing, and potential public health risks from mutagenic compounds.
- 2.2. The committee provides advice to all UK government bodies when requested, and over the period of 2009-14 has responded to requests from DH, FSA, PHE, HSE, COT, COC, the Veterinary Medicines Directorate, and the Advisory Committee on Pesticides (now the Expert Committee on Pesticides).
- 2.3. In accordance with the Code of Practice for Scientific Advisory Committees<sup>4</sup> (CoPSAC), the committee also plays a role in setting its own agenda through pro-actively monitoring developments in the areas of genotoxicity and mutagenicity - publishing statements and guidance when appropriate.
- 2.4. Over the same period (2009-15), COM has provided 14 guidance statements on testing methods and mutagenic compounds, contributed to joint statements on the mutagenicity of tobacco products and alcohol, and provided advice and conclusions on 8 further assays/compounds (alongside further discussions and presentations on relevant topics). Evidence suggests that COM's statements and guidance are widely respected and used across government and indeed internationally.
- 2.5. The committee is able to function through support from PHE, which provides a joint secretariat for both COM and COC, with further support from COT's FSA secretariat when appropriate. The PHE secretariat also maintains an annual contract with Imperial College to receive support from toxicologists in helping to write papers for the committees.
- 2.6. There clearly remains a demand for the functions of COM, as is evidenced through continuing requests from government agencies for its advice, and the work that it conducts is considered important. Its advice is highly respected both nationally and internationally, and the committee plays an important role in providing independent expert advice on public health risks and testing methods. This advice is particularly important in assuring the validity and quality of testing methods within industry. Such testing can have major commercial implications, and the work of the committee ensures

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<sup>4</sup> <https://www.gov.uk/government/publications/scientific-advisory-committees-code-of-practice>



an independent and balanced approach is taken to the appropriate protection of public health without unduly burdening industry.

## Reduction in number of compounds being presented to COM

- 2.7. Compounds are still presented to the committee for advice, including a request from the Advisory Committee on Novel Foods and Processes (via the FSA and COC) for COM to consider a novel food product in June 2015 and a current consideration of the mutagenicity of ethanol (and its metabolite acetaldehyde). However, there has recently been a notable reduction in the number of requests for COM's advice on chemical compounds. This appears primarily to be a consequence of regulatory controls for many compounds (such as pesticides) moving to the European Union level. Furthermore, rapid timescales make it more difficult for government agencies to ask COM for advice due to the frequency of their meetings; though issues can be dealt with through correspondence if necessary.
- 2.8. Whilst the committee nevertheless retains value in its capability to independently and expertly consider new genotoxic assays, it is worth emphasising the value the committee's expertise can have in providing advice on specific compounds. Both government agencies and the committee should ensure that, when appropriate, consideration is given as to when COM can help inform the UK's position on compounds to feed into international channels.
- 2.9. It is also worth highlighting that, when appropriate, committee members have previously responded to urgent requests between meetings (such as providing advice on the UK's input into OECD genotoxic test guidelines). Although the nature of the work presented to the committee does not usually allow rapid conclusions to be reached, committee members are potentially able to provide advice on urgent requests between meetings. The secretariat and COM Chair are best placed to make decisions as to whether an urgent request is suitable.

## b) Form

- 2.10. Cabinet Office guidance has a checklist of delivery options for government functions reproduced in Table 1. As seen in the table, this review primarily considered whether the functions are still needed (above), whether COM should be merged with another body, whether COM should be brought in-house, and finally whether the functions of COM should continue to be delivered in its current model as an Advisory Non-Departmental Public Body (ANDPB).

Table 1 - Assessment of Potential Delivery Models for COM

Delivery Option	Assessment
Abolish	Consider – are the functions required? (considered above).
Movement out of central government	Rejected – mutagenicity is not a localised issue, should not be delivered by the private sector due to conflicts of interest, and relevant expertise is not available in the voluntary sector.
Commercial model	Rejected – a commercial model is not suitable for COM.
Bring in-house	Consider – whether COM become an expert advisory committee of DH.
Merger with another body	Consider – whether COM, COC and/or COT should be merged.
Less formal structure	Rejected – COM has an annual cycle of work where a standing committee is most appropriate.
Delivery by a new Executive Agency	Rejected – COM has no executive powers
Continued delivery by an NDPB	Consider – does it meet one or more of the three tests: <ol style="list-style-type: none"> <li>1. Does it perform a technical function which needs external expertise to be delivered?</li> <li>2. Do its activities need to be, and be seen to be, delivered with absolute political impartiality?</li> <li>3. Does it need to act independently of Ministers to establish facts and/or figures with integrity?</li> </ol>

## Merger with COC and/or COT

2.11. COM, COC and COT are sister committees, which consider the oft overlapping scientific fields of mutagenicity, carcinogenicity and toxicity. It was therefore appropriate for the review to consider whether a merger of two or all three of the bodies would be appropriate and beneficial.

2.12. The evidence suggests that COM and COC have a greater alignment of work and interact more often than with COT. This is reflected in the fact that both COM and COC are committees of DH with a joint secretariat in PHE, while COT and its secretariat sit within FSA. Also, COT mainly considers the toxicity of chemicals in food, whereas COM and COC have a broader focus.

- 2.13. Consideration was therefore primarily given to the option of a merger between COM and COC. This is a question that has been raised before, with conflicting outcomes. The committees have, on occasions, considered the same topics (e.g., hormesis and epigenetics) and both are currently developing guidance statements on the carcinogenicity and mutagenicity of ethanol. In cases such as these, a joint committee would provide synergies and potentially improve the quality of the guidance produced.
- 2.14. However, the majority of the work undertaken by the committees, such as their respective considerations of genotoxicity testing methods (COM) and epidemiological studies (COC), has little or no overlap and its consideration by a single merged committee would lead to inefficient meetings (with only a proportion of members being involved in consideration of many issues), and conclusions either being reached more slowly or more meetings being required. Further, any merger of the two committees would lead either to a larger committee of 26 members or to some loss of relevant expertise. There was no evidence to suggest there was unnecessary or overlapping expertise on or between the committees.
- 2.15. On balance, a merger of the two committees is therefore not recommended. This is because the overlap of interests is insufficient to generate significant synergies and improve performance. There would quite probably instead be an overall loss of efficiency.
- 2.16. Nevertheless, there is greater scope for a more flexible and coordinated approach to be taken by COM and COC. Both COM and COC Chairs sit on each other's committees as ex-officio members and this, combined with the joint secretariat, should help to facilitate more flexible approaches to dealing with workloads.
- 2.17. It would be beneficial for both chairs and the joint secretariat to engage in a formal annual planning exercise where consideration was given to coordinating work that required input from both committees. For example, in some cases it might be best to set up a joint working group with suitable members from the two committees. This planning exercise should be transparent and make clear why particular approaches have been taken. The exercise should also factor in other bodies, such as COT, when appropriate. Although it is recognised that the committees and secretariat do already work cooperatively, it is felt that this process could be formalised to the extent necessary to ensure that best use is made of both committees' expertise and resources.

**Recommendation 1:** The COM Chair, COC Chair, joint secretariat and officials from relevant government agencies should conduct an annual formal planning exercise to ensure flexible and coordinated approaches are adopted to work with intersecting interest.

## Brought in-house or continued delivery as an ANDPB

- 2.18. COM meets the three tests to be considered appropriate for ANDPB status. It performs a technical function requiring expertise, requires political impartiality and should be independent from Ministers in establishing facts and figures. When COC became an expert committee of DH, COM remained an ANDPB due to the higher proportion of individuals from the private sector within its membership.
- 2.19. This membership composition is of benefit to COM and is not a cause for concern provided that good corporate governance practices are followed in maintaining and updating the recording of members' declarations of interest. Having a diverse range of experts on the committee, including from industry, is vital in ensuring that the committee is able to perform its functions, bring relevant and valuable experience to meetings, and maintain a close observation of developments in its field.
- 2.20. It is worth acknowledging that the review's evidence demonstrated clearly that COC has seen no noticeable difference in the way it operates or is perceived, since becoming an expert advisory committee of the Department. Whether an ANDPB or an expert committee, it is expected that all scientific committees maintain clear independence in accordance with CoPSAC's Principles of Scientific Advice to Government.
- 2.21. Nevertheless, as this membership ratio is still present and COM meets the three tests, there is no reason currently to change the status of COM from an ANDPB. However, the Review Team is aware of recent Cabinet Office guidance on the classification of public bodies, which encourages all departments to consider re-classification of ANDPBs across government to become expert committees of the department. The future classification of COM, as either an ANDPB or as an expert committee of DH, will need to be considered alongside the other ANDPBs in the Department to ensure that the approach is consistent. Consequently ANDPB status for COM remains appropriate for the present but DH plans to review the status of all ANDPBs during 2017-18.

**Recommendation 2:** The functions of COM should continue to be delivered in the current form of an ANDPB.

## 3. Stage Two Report

### a) Performance and Efficiency

- 3.1. COM meets three times annually and does not employ any individuals directly (with members paid fees and expenses). Therefore opportunities for efficiency savings are limited.
- 3.2. COM's secretariat do not work on committee matters full time, also having other roles within PHE, and their contract with Imperial College is negotiated on an annual basis with support from commercial officials within PHE. It is important that, moving forward, commercial officials continue to be consulted during negotiation of this contract to ensure best value for money.
- 3.3. The report also recognises that this relationship and contract with Imperial College is invaluable in facilitating the functioning of COM. It is clear that the relationship of drafting papers between the secretariat and scientists within Imperial College is vital in allowing members to devote time to discussing rather than drafting papers.
- 3.4. Nevertheless this report makes a number of minor recommendations for potential improvements in the performance of COM.

### Support to the Committee

- 3.5. COM's secretariat recently lost two scientists, including their principal scientific secretary. Both individuals had extensive experience and expertise in the fields of genotoxicity and mutagenicity, and their departures also reduced the overall resource capacity within the secretariat. Further resource restrictions within PHE also led to the loss of an individual who previously provided administrative support to the committee.
- 3.6. Attempts to recruit scientific replacements with similar expertise have proved unsuccessful, due to a shrinking pool of genotoxicity experts and the greater salaries on offer within the private sector. This is particularly challenging for COM as the committee functions through the secretariat drafting and providing the committee's papers, as opposed to the model used commonly across Europe whereby committee members draft either sections or all of a committee's papers for consideration.
- 3.7. A movement to the European model to address this problem is not suitable for COM, as members are not remunerated for this type of work and already face time pressures when committing to COM in addition to their full-time careers. Nevertheless, at a time

when specific expertise in genotoxicity is missing from the secretariat, it is important that a strategy is devised to ensure that papers arriving at the committee are of the highest possible standard.

- 3.8. Firstly, due to unsuccessful attempts to recruit from outside, it is vital that the COM Chair and the head of the PHE Secretariat establish a clear strategy for developing expertise within the secretariat. Ideally this should identify at least two suitable members of the secretariat for development of relevant expertise, such as familiarity with genotoxicity testing methods, to support the efficient functioning of COM in the future. It is important to recognise this is a long-term option, will likely involve significant 'on-the-job' learning, and should be implemented as soon as possible.
- 3.9. Recognising that this is a long-term option, there is also greater scope for utilisation of the expertise of members' to help maintain the standards of papers. It is vital that a balance is maintained and that committee members do not become overburdened. However greater use of members in scoping papers, (e.g. identifying the specific areas that papers should address and the right questions to be asking), should help assist the secretariat in their task. Members, if willing, could also be used to facilitate learning within the secretariat on how to scope papers themselves.
- 3.10. In both aspects of the strategy, it is important members are consulted for their views over the best and most efficient way to proceed. These two suggestions are by no means exhaustive and there may be other opportunities to help ensure the efficient functioning of COM. It is also worth acknowledging that there was no suggestion in the evidence that the quality of COM's final outputs or advice had diminished.

<p><b>Recommendation 3:</b> That secretariat staff are encouraged, and provided with opportunities, to develop their knowledge and expertise to produce material for the Committee. Additionally, that the COM Chair should consult members to maximise use of members' expertise when producing material for committee discussion.</p>
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## Communication with other Government Bodies

- 3.11. In accordance with the CoPSAC principle that openness of communication and engagement is expected between public bodies and the scientific committee providing advice, there is scope for improvements in the communication channels between COM and relevant government bodies.
- 3.12. It is vital that COM and relevant government bodies communicate in a timely and clear manner. When requests are made for COM's advice, there must be clear messaging from the government organisation as to the request being made, and from the COM

secretariat as to whether advice can be given and, if not, it should be made clear why the request is not appropriate or cannot be fulfilled (for example if timescales do not allow or it is outside COM's remit). Similarly, clear feedback should be given to government organisations in COM's annual horizon scanning exercise as to why certain issues were given priority and why others were not.

- 3.13. Finally, it is important that both COM and relevant government bodies maintain good communication channels to provide awareness of each other's work in order to ensure alignment across government. Whilst COM (and the government bodies) should maintain the independence to provide their own advice, it is vital there is an awareness of where similar work is being undertaken so that discussion can be facilitated and conflicting advice is not given without necessary explanation. As a minimum, the annual horizon scanning exercise offers a good opportunity for all parties to inform each other of on-going work and areas of common concern where alignment would be beneficial.

**Recommendation 4:** COM should maintain regular, targeted and concise communications with sponsoring departments and other relevant government bodies to ensure that knowledge is shared and work is coordinated.

## Website

- 3.14. There are clear problems for users of COM's website, which is an issue of concern as there are difficulties accessing and finding COM's valued guidance statements. User feedback suggests it is hard to navigate, difficult to find desired documents, is missing key governance documents, and also has duplicate sections for identical information (e.g. the committee's minutes appear on two different pages).
- 3.15. As a minimum, an update of the website should seek to ensure that all meeting documents (including agendas, minutes, papers and open meeting applications), published expenses of the committee, and the most recent joint annual reports of COM/COC/COT are present on the website. The publications page should also contain all recent guidance statements made by COM and a clear URL to its archived website, with an explanation that guidelines/publications previous to 2013 can be found there. All similar and related documents (such as governance documents and transparency documents) should also be moved to a single place, rather than appearing across different pages.
- 3.16. In order to take this forward it is further recommended that officials from COM, DH (sponsor and digital teams) and the Government Digital Service discuss whether reformatting COM's website to reflect a similar layout to COC's website would be

appropriate. This simplified format allows easier navigation to guidance and governance documents, and appeals more to those who use such committees' websites.

**Recommendation 5:** The COM secretariat should review the website and explore options to ensure that it is easy to navigate, working with the sponsor team, DH digital team and the Government Digital Service.

## b) Governance

- 3.17. Detailed analysis of COM's governance processes can be found in Annex F, which considers their compliance with principles of good corporate governance. COM has several matters of transparency to address, including the absence of published minutes from 2014, the committee's annual reports and members' expenses. These issues should be addressed as part of Recommendation 5.

## Appraisal

- 3.18. Currently there is no regular appraisal process within the committee. As the committee meets three times annually and is composed of prominent experts in their fields anything burdensome would be inappropriate.
- 3.19. Therefore a light touch annual appraisals process should be introduced which allows members to propose opportunities for improved performance of themselves, the Chair or the secretariat. Similarly the Chair should propose any opportunities for improved performance of members, himself as Chair, and the secretariat. The process should be done in the spirit of looking for opportunities to improve performance, rather than an assessment of the members' capabilities. Nevertheless this process should provide sufficient feedback loops for concerns to be raised if necessary.
- 3.20. COM's performance is not currently considered at DH board level (as per the principles of good corporate governance) as this would be inappropriate for a committee of COM's size. The Environmental Hazards Board in PHE should represent the first port of call for any substantial concerns regarding the policy and work of COM. Any concerns over governance and resource should be reported to the responsible SCS1 in DH for Infectious Disease and Environmental Hazards.

**Recommendation 6:** The Department of Health, COM Chair and COM secretariat should establish a light-touch appraisals process.



## Induction

- 3.21. There is currently no regular induction process in place for members joining COM. Evidence suggests this would be beneficial and should be tailored to facilitate understanding of the committee's role, functions and remit.
- 3.22. This may be particularly helpful for lay members, and would offer a beneficial opportunity for the lay member and the COM Chair to discuss the exact role the lay member should play in the committee.
- 3.23. CoPSAC states that consideration should always be given to whether a separate 'lay summary' should be produced in order to ensure that all matters are accessible to interested parties regardless of specialist knowledge. As COM addresses a highly technical area of science this may not be appropriate in all cases. However, the role of the lay member could perhaps be developed to a greater extent, for example, in discussing when a 'lay summary' would be appropriate. It is important all members understand their role within the committee and the role of the committee itself.

**Recommendation 7:** The Department of Health, COM Chair and COM secretariat should establish a light touch induction process.

## Appointments

- 3.24. Interestingly, there was no evidence to suggest that COM has struggled to recruit members to the committee, as has been the case with a number of other expert scientific committees across government.
- 3.25. However, noting recent problems with recruitment to the secretariat and the fact that opportunities to start a career within the scientific field of genotoxicity are diminishing, it is important that COM ensure they pro-actively take action to ensure future interest in joining the committee.
- 3.26. In accordance with CoPSAC, COM members and the secretariat should remain in contact with professional bodies, academic institutions and research communities to promote the work of the committee, encourage interest in its functions and encourage either more immediate or longer-term applications for membership. Whilst the emphasis should always be on recruiting relevant experts and the best candidates, it is important that consideration is given to recruiting younger members to ensure the continuation of the committee.

**Recommendation 8:** COM should maintain good communication links with professional bodies, academic institutions and research communities to promote awareness of the committee, and encourage future applications to the committee.

## 4. Annexes

### Annex A - Review Process; Project Board Membership; Critical Friends Group Membership; Review Costs

#### Process

The start of the review was announced by Written Ministerial Statement to both Houses of Parliament on 25 June 2015. In accordance with Cabinet Office guidance that Triennial Reviews should be proportionate to the size of the body, the COM review followed a ‘light touch’ approach with evidence gathered simultaneously for both stages of the review.

The review was overseen by a DH deputy-director level Senior Review Sponsor (SRS). The SRS chaired a Project Board consisting of the COM Chair, a COM Secretariat representative, a DH Sponsor Team representative and two members of the Triennial Review Team. The Project Board was responsible for holding the review team to account and ensuring the final report’s conclusions were balanced and evidence-based.

A Critical Friends Group was also formed to provide further challenge to the review team’s conclusions and final report. The group was designed to provide constructive challenge to the work of the review team and not to represent all stakeholders with an interest in COM. Further details of both the Critical Friends Group and Project Board can be found in Annex A.

Evidence was gathered through desk-based research, interviews with key stakeholders and a public Call for Evidence. Further details can be found in Annexes C-E.

<b>Project Board Membership</b>	
Dr Hilary Walker (Chair)	Senior Review Sponsor
Dr David Lovell	COM Chair
Dr Ovnair Sepai	COM Secretariat Representative
Paul Holley	DH COM Sponsor Team
Will Karani	Lead Reviewer
David Dipple	Head of DH Triennial Review Programme
Dr Patrick Miller	COT Review Representative

<b>Critical Friends Group Membership*</b>
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## Triennial Review of the Committee on Mutagenicity of Chemicals in Food, Consumer Products, and the Environment (COM)

Dr Hilary Walker (Chair)	Senior Review Sponsor
Professor David Coggon	Professor of Occupational and Environmental Medicine (University of Southampton)
Dr Ian Dewhurst	Head of Mammalian Toxicology (HSE Chemical Regulation Directorate)
Dr Jan van Benthem	Head of the Department of Innovative Testing Strategies (Centre for Health Protection, National Institute for Public Health and the Environment - RIVM The Netherlands)

\* The group was designed to provide constructive challenge to the work of the review team and not to represent all stakeholders with an interest in COM.

### Review costs

The direct cost of the review is estimated to be £12,000. This comprises the DH resources (total salary costs for review team members).

No additional fees were paid to members of COM, the COM Secretariat, the SRS or the critical friends.

## Annex B - Initial Written Ministerial Statement of 25 June 2015

**Made by: Jane Ellison (The Parliamentary Under Secretary of State, Department of Health) HCWS57**

I am today announcing the start of the Triennial Reviews of the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment, the Human Fertilisation and Embryology Authority, the Human Tissue Authority, and NHS Blood and Transplant.

The Triennial Review programme ensures that all Government departments review their non-departmental public bodies on a regular basis. In order to ensure that the Department of Health is operating as an effective system steward and can be assured of all the bodies it is responsible for, it has extended the programme of reviews over the period 2014-17 to include all of its arm's length bodies.

The reviews are conducted in two stages. The first stage will examine the continuing need for the function and whether the organisation's form, including operating at arm's length from government, remains appropriate. If the outcome of this stage is that delivery should continue, the second stage of the review will assess whether the bodies are operating efficiently and in line with the recognised principles of good corporate governance.

## Annex C - Organisations given written notification of Call for Evidence

Medicines and Healthcare Products Regulatory Agency	Pesticides Safety Directorate	European Environmental Mutagen Society	National Institute for Health Research
Health Research Authority	Veterinary Medicines Directorate	United Kingdom Environment Mutagen Society	Academy of Medical Sciences
Public Health England	Environment Agency	Nuffield Council on Bioethics	General Medical Council
Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment	Home Office	Royal College of Physicians	Association of Directors of Public Health
Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment	The Welsh Assembly	House of Commons Science and Technology Committee	Health Education England
NHS Digital	Wales Office	The Academy of Medical Sciences	Faculty of Public Health
Food Standards Agency	The Scottish Government	European Federation for Immunogenetics	British Toxicology Society
Department for Environment, Food and Rural Affairs	Scotland Office	National Institute for Biological Standards and Control	Food Environment Agency
Health and Safety Executive	Northern Ireland Executive	OECD	European Food Safety Authority
ISLI/HESI IVGT Group	Northern Ireland Office	Medical Research Council	Royal College of Pathologists
EGMS	Chief Pharmaceutical Officers for UK Countries	Royal Society of Biology	National Centre for the Replacement, Refine & Reduction of Animals in Research
IEGMS	Scottish Environment Protect Agency (SEPA)	University of Birmingham	FRAME
	Office for Life Science	University of Lancaster	ECVAM
	Government Office for Science		University of Surrey
	Genetics Society		Brunel University
	Cranfield University		

## Annex D - Public Call for Evidence Questions

**Question 1:** Is there a continuing need for the functions undertaken by COM?

**Question 2:** COM is currently an Advisory Non-Departmental Public Body (ANDPB) of the Department of Health. Do you think an alternative organisational structure would improve or be detrimental to delivery of any necessary functions? Which of the following organisational forms would you support:

- **Become an advisory expert committee of the Department:** could a function be more efficiently delivered if COM moved into the Department of Health as an expert advisory committee? COC currently has this status – if you have also interacted with COC has their status affected your perception/interaction with the committee?
- **Merge with COC and/or COT:** could a function be better delivered by COM if it were merged with COC and/or COT? In this scenario, should the merged body be in the form of an ANDPB or as an expert advisory committee?
- **Continued delivery as an ANDPB:** do its activities need to be seen to be delivered with absolute political impartiality? Does COM need to act independently of Ministers to establish facts and/or figures with integrity?
- Other
- Don't know

Please give reasons for your answer:

**Question 3:** How well is COM currently performing and delivering its functions?

Very well/Well/Average/Poorly/Very poorly/Don't know

Please give reasons for your answer:

**Question 4:** How well do you think COM, COC and COT interact with each other?

Very well/Well/Average/Poorly/Very poorly/Don't know

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Please give reasons for your answer:

**Question 5:** Are there other organisations either nationally or internationally which could be used to benchmark COM's performance and outputs?

**Question 6:** Is COM's advice valued, respected and influential both nationally and internationally?

Yes/No/Don't know

Please give reasons for your answer:

**Question 7:** Do you think COM's expertise is utilised effectively? Do you feel that appropriate work is given priority when resources are limited?

Yes/No/Don't know

Please give reasons for your answer:

**Question 8:** How well do you think that COM interacts with organisations both within and outside of government?

Very well/Well/Average/Poorly/Very poorly/Don't know

Please give reasons for your answer:

**Question 9:** Do you think COM operates in an open, transparent, accountable and responsive way?

Yes/No/Don't know

Please give reasons for your answer:



## Annex E - Call for Evidence Engagement Summary

<b>Evidence base</b>	
<b>Call for Evidence Consultation Period:</b>	<p>Start: 06 July 2015</p> <p>Finish: 15 August 2015</p>
<b>Call for Evidence Responses Received:</b>	<p>1. Collated response from 5 individuals representing the following organisations:</p> <ul style="list-style-type: none"> <li>• Swansea University Medical School</li> <li>• The Genetic Toxicology Technical Committee (ISLI Health and Environment Sciences Institute)</li> <li>• Environmental Mutagen Society</li> <li>• Regulatory and Safety Evaluation Speciality Section (the Society of Toxicology)</li> <li>• Working Group on Quantitative Approaches to Genetic Toxicology Risk Assessment (International Workshops on Genetic Toxicology)</li> <li>• Genomics and Genetic Toxicology Laboratory Groups (Environmental Health Science and Research Bureau of Health Canada)</li> <li>• Environmental and Molecular Mutagenesis</li> <li>• The Office of Testing and Research (FDA Center for Drug Evaluation and Research, Rockville, MD)</li> <li>• Office of the National Center for Toxicological Research (Washington D.C.)</li> <li>• The SRI International Toxicology and Metabolism Laboratory (Menlo Park, CA)</li> </ul>
<b>Stakeholder bilateral:</b>	<ol style="list-style-type: none"> <li>1. Dr David Lovell (COM Chair)</li> <li>2. Dr Ovnair Sepai (COM Secretariat)</li> <li>3. Professor David Kirkland (COM Member)</li> <li>4. Professor David Phillips (COM Member and COC Chair)</li> <li>5. Philippa Hardwick (COM Lay Member)</li> <li>6. Professor Alan Boobis (COT Chair)</li> <li>7. Professor Peter Farmer (Previous COM Chair)</li> </ol>

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	<ol style="list-style-type: none"><li>8. Dr Henry Stemplewski (MHRA Assessor for COM)</li><li>9. Dr Lata Koshy (HSE Assessor for COM)</li><li>10. Ian Martin (EA Assessor for COM)</li><li>11. Sam Fletcher (VMD Assessor for COM)</li><li>12. Dr Michael Routledge (UKEMS)</li><li>13. Dr Anne Gourmelon (OECD)</li><li>14. Dr Nathalie Delrue (OECD)</li><li>15. Dr Penny Bramwell (FSA Deputy CSA)</li><li>16. Dr Diane Benford (COT Secretariat)</li></ol>
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## Annex F - COM Compliance with the Principles of Good Corporate Governance

Principles of Good Corporate Governance		Findings of Review
Accountability	<p><b>Principle:</b></p> <p>The minister is ultimately accountable to Parliament and the public for the overall performance, and continued existence, of the advisory NDPB.</p>	
	<p><b>Provision 1</b></p> <p>The minister and sponsoring department should exercise appropriate scrutiny and oversight of the advisory NDPB. This includes oversight of any public monies spent by, or on behalf of, the body.</p>	<p>COM is fully compliant.</p> <p>COM is overseen by PHE (an executive agency of DH) and DH the sponsor Department.</p>
	<p><b>Provision 2</b></p> <p>Appointments to the advisory NDPB should be made in line with any statutory requirements and, where appropriate, with the Code of Practice issued by the Commissioner for Public Appointments.</p>	<p>COM is fully compliant.</p> <p>All DH public appointments follow the Code.</p>
	<p><b>Provision 3</b></p> <p>The minister will normally appoint the Chair and all board members of the advisory NDPB and be able to remove individuals whose performance or conduct is unsatisfactory.</p>	<p>COM is fully compliant.</p>
	<p><b>Provision 4</b></p> <p>The minister should meet the Chair on a regular basis.</p>	<p>COM is not compliant:</p> <p>The nature and size of COM does not require regular meetings with the relevant minister.</p>
	<p><b>Provision 5</b></p> <p>There should be a requirement to inform Parliament and the public of the work of the advisory NDPB in an annual report (or equivalent publication) proportionate to its role.</p>	<p>COM is partially compliant.</p> <p>An annual report is published with the annual report of COC and COT. However this is currently only present on the FSA website and not on COM's website. Recommendation 5 addresses this.</p>
	<p><b>Provision 6</b></p> <p>The advisory NDPB must be compliant with Data Protection legislation.</p>	<p>COM is fully compliant.</p> <p>The Secretariat is responsible for compliance.</p>

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	<p><b>Provision 7</b></p> <p>The advisory NDPB should be subject to the Public Records Acts 1958 and 1967.</p>	<p>COM is fully compliant.</p>
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<p><b>Role of the Sponsoring Department</b></p>	<p><b>Principle:</b></p> <p>The departmental board ensures that there are appropriate governance arrangements in place with the advisory NDPB.</p> <p>There is a sponsor team within the department that provides appropriate oversight and scrutiny of, and support and assistance to, the advisory NDPB.</p>	
	<p><b>Provision 1</b></p> <p>The departmental board’s agenda should include scrutiny of the performance of the advisory NDPB proportionate to its size and role.</p>	<p>COM is not compliant.</p> <p>The size and nature of COM does not require departmental board scrutiny. The Environmental Hazards Board in PHE should represent the first port of call for any substantial concerns and, following this, the responsible SCS1 in DH if further escalation is necessary.</p>
	<p><b>Provision 2</b></p> <p>There should be a document in place which sets out clearly the terms of reference of the advisory NDPB. It should be accessible and understood by the sponsoring department and by the Chair and members of the advisory NDPB. It should be regularly reviewed and updated.</p>	<p>COM is partially compliant.</p> <p>Terms of reference are derived and published in the annual report and on the Gov.uk. When updating the website as part of Recommendation 5, the Terms of Reference should be placed on the summary page.</p>
	<p><b>Provision 3</b></p> <p>There should be a dedicated sponsor team within the sponsor department. The role of the sponsor team should be clearly defined.</p>	<p>COM is fully compliant.</p>
	<p><b>Provision 4</b></p> <p>There should be regular and ongoing dialogue between the sponsoring department and the advisory NDPB.</p>	<p>COM is fully compliant.</p>
	<p><b>Provision 5</b></p> <p>There should be an annual evaluation of the performance of the advisory NDPB and any supporting committees – and of the Chair and individual members.</p>	<p>COM is not compliant.</p> <p>Recommendation 6 addresses this.</p>

<b>Role of the Chair</b>	<p><b>Principle:</b> The Chair is responsible for leadership of the advisory NDPB and for ensuring its overall effectiveness.</p>	
	<p><b>Provision 1</b></p> <p>The advisory NDPB should be led by a non-executive Chair.</p>	COM is fully compliant.
	<p><b>Provision 2</b></p> <p>There should be a formal, rigorous and transparent process for the appointment of the Chair. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments . The Chair should have a clearly defined role in the appointment of non-executive board members.</p>	COM is fully compliant.
	<p><b>Provision 3</b></p> <p>The duties, role and responsibilities, terms of office and remuneration (if only expenses) of the Chair should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements. The responsibilities of the Chair will normally include:</p> <ul style="list-style-type: none"> <li>• representing the advisory NDPB in any discussions with ministers;</li> <li>• advising the sponsoring department and ministers about member appointments and the performance of members;</li> <li>• ensuring that the members have a proper knowledge and understanding of their role and responsibilities. The Chair should ensure that new members undergo a proper induction process and is normally responsible for undertaking an annual assessment of non-executive board members' performance;</li> <li>• ensuring that the advisory NDPB, in reaching decisions, takes proper account of guidance provided by the sponsoring department or ministers;</li> <li>• ensuring that the advisory NDPB carries out its business efficiently and effectively; and</li> <li>• representing the views of the advisory NDPB to</li> </ul>	<p>COM is partially compliant:</p> <p>All public appointees have terms and conditions of appointment attached to their offer letter. These are cleared by lawyers and any statutory requirements would be set out. The responsibility to abide with the Cabinet Office's Code of Conduct is made clear.</p> <p>A lack of induction is addressed by Recommendation 7.</p>

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	the general public, when required.	
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<b>Role of other members</b>	<p><b>Principle:</b> The members should provide independent, expert advice.</p>	
	<p><b>Provision 1</b></p> <p>There should be a formal, rigorous and transparent process for the appointment of members to the advisory NDPB. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments.</p>	<p>COM is fully compliant.</p> <p>All DH public appointments follow the Code.</p>
	<p><b>Provision 2</b></p> <p>Members should be properly independent of the department and of any vested interest (unless serving in an ex-officio or representative capacity).</p>	<p>COM is fully compliant.</p> <p>The Chairman and members declare all personal and non-personal interests and these are also recorded in the minutes and annual reports.</p>
	<p><b>Provision 3</b></p> <p>Members should be drawn from a wide range of diverse backgrounds, but should have knowledge and expertise in the field within which the body has been set up to advise ministers. The advisory NDPBs as a whole should have an appropriate balance of skills, experience, independence and knowledge.</p>	<p>COM is fully compliant.</p> <p>COM draws on relevant expertise from universities, research and industry. There are two lay members of the COM.</p>
	<p><b>Provision 4</b></p> <p>The duties, role and responsibilities, terms of office and remuneration of members should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements.</p>	<p>COM is fully compliant:</p> <p>All public appointees have terms and conditions of appointment attached to their offer letter. These are cleared by lawyers and any statutory requirements are set out. The responsibility to abide with the Cabinet Office's Code of Conduct is made clear.</p>
	<p><b>Provision 5</b></p> <p>All members must allocate sufficient time to the advisory NDPBs to discharge their responsibilities effectively.</p>	<p>COM is fully compliant.</p>
	<p><b>Provision 6</b></p> <p>There should be a proper induction process for new members. This should be led by the Chair. There should be regular reviews by the Chair of individual members' training and development needs.</p>	<p>COM is not compliant.</p> <p>Appraisal and induction processes should be introduced as part of Recommendations 6 &amp; 7.</p>

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<b>Communications</b>	<p><b>Principle:</b> The advisory NDPB should be open, transparent, accountable and responsive.</p>	
	<p><b>Provision 1</b></p> <p>The advisory NDPB should operate in line with the statutory requirements and spirit of the Freedom of Information Act 2000.</p>	<p>COM is fully compliant:</p> <p>The Secretariat is responsible for ensuring compliance.</p>
	<p><b>Provision 2</b></p> <p>The advisory NDPB should make an explicit commitment to openness in all its activities. Where appropriate, it should establish clear and effective channels of communication with key stakeholders. It should engage and consult with the public on issues of real public interest or concern. This might include holding open meetings or annual public meetings. The results of reviews or inquiries should be published.</p>	<p>COM is fully compliant.</p> <p>The COM website is the main form of outward communication. COM does not consult the public – but any member of the public can attend meetings as an observer. COM also has two lay members on the committee. The makeup of the committee is published.</p> <p>Any issues of transparency should be addressed as part of Recommendation 5.</p>
	<p><b>Provision 3</b></p> <p>The advisory NDPB should proactively publish agendas and minutes of its meetings.</p>	<p>COM is partially compliant.</p> <p>Minutes from 2014 are absent. This should be addressed as part of Recommendation 5.</p>
	<p><b>Provision 4</b></p> <p>There should be robust and effective systems in place to ensure that the advisory NDPB is not, and is not perceived to be, engaging in political lobbying. There should also be restrictions on members attending Party Conferences in a professional capacity.</p>	<p>COM is fully compliant.</p> <p>COM is not, and is not perceived to be engaging in political lobbying.</p>

<b>Conduct and Behaviour</b>	<p><b>Principle:</b> Members should work to the highest personal and professional standards. They should promote the values of the advisory NDPB and of good governance through their conduct and behaviour.</p>	
	<p><b>Provision 1</b></p> <p>A Code of Conduct must be in place setting out the standards of personal and professional behaviour expected of all members. This should follow the Cabinet Office Code. All members should be aware of the Code. The Code should form part of the terms and conditions of appointment.</p>	<p>COM is fully compliant.</p> <p>All public appointees have terms and conditions of appointment attached to their offer letter. The responsibility to abide with the Cabinet Office’s Code of Conduct is set out.</p>
	<p><b>Provision 2</b></p> <p>There are clear rules and procedures in place for managing conflicts of interest. There is a publicly available Register of</p>	<p>COM is fully compliant.</p> <p>The rules and procedures are set out in the Code of Practice.</p>



Interests for members. This is regularly updated.	The Code of Practice and the Register of Interests are both published in the publically available Annual Report.
<p><b>Provision 3</b></p> <p>There must be clear rules in place governing the claiming of expenses. These should be published. Effective systems should be in place to ensure compliance with these rules.</p>	<p>COM is partially compliant.</p> <p>There is a formal expenses policy in place. Claims are checked by the Secretariat and PHE's Finance staff. However these are not published on COM's website. This should be addressed as part of Recommendation 5.</p>
<p><b>Provision 4</b></p> <p>There are clear rules and guidelines in place on political activity for members and that there are effective systems in place to ensure compliance with any restrictions.</p>	<p>COM is partially compliant:</p> <p>Members are required to adhere to the Cabinet Office Code of Conduct for Board Members of Public Bodies as a condition of appointment.</p> <p>Members are asked to declare any activity. This should be addressed as part of the appraisal process moving forward.</p>
<p><b>Provision 5</b></p> <p>There are rules in place for members on the acceptance of appointments or employment after resignation or retirement. These are enforced effectively.</p>	<p>COM is compliant within the Terms of Reference of the committee.</p> <p>There is no restriction in place. The Rules Governing Proceedings make clear the confidential nature of proceedings.</p>